A long term evaluation of permanent bonded retention after treatment with fixed orthodontic appliances

ROBERT CERNY BDS MDSc

A thesis submitted in the fulfilment of requirement for the degree of
Doctor of Philosophy
Discipline of Oral Health
School of Health Sciences
Faculty of Health
University of Newcastle, Australia

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Statement of Originality

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Date.
Disclosure

I do not have any financial or professional interest in any company, product or service mentioned in this PhD.

(Signed)...........................................
Robert Cerny. BDS. MDSc.
Publications from this study

This study has resulted in the following three publications in the Journal of Clinical Orthodontics:


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List of Abbreviations

ABI  Alveolar Bone Index
ADA  Australian Dental Association
APL  Arch perimeter length
BOP  Bleeding on probing
BSSMAORIF  Bilateral Sagittal Split Mandibular Advancement Osteotomy with Rigid Internal Fixation
CA  Comparative Analysis
CEJ  Cemento-enamel junction
CI  Calculus Index
CR  Chief researcher
D  Diameter
DHI  Dental Health Index
DI  Decay Index
EX1.O  Specialist orthodontic examiners
EX2.O  Specialist orthodontic examiners
EX3.P  Specialist periodontist examiners
EX4.P  Specialist periodontist examiners
F  Female
FMR  Fixed Metal Retainer
GRI  Gingival Recession Index
LII  Little’s Irregularity Index
M  Male
Mb  Mandible
MOD  Mandibular Osteogenic Distraction
MGI  Modified Gingival Index
MS  Multi stranded twist flex wire
Mx  Maxilla
N  Number
No  Number
NCG  Neots Control Group
NEOTS  Newcastle Effects of Orthodontic Treatment Study
NS  Nil Significance
NSG  Neots Study Group
NSW  New South Wales
OD  Osteogenic Distraction
OPG  Orthopantomograph (radiograph)
p  Level of significance
p a  per annum
<table>
<thead>
<tr>
<th>Abbreviation</th>
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<tr>
<td>P</td>
<td>Patient</td>
</tr>
<tr>
<td>PP</td>
<td>Potential Participant</td>
</tr>
<tr>
<td>PBR</td>
<td>Permanent Bonded Retention</td>
</tr>
<tr>
<td>PI</td>
<td>Plaque Index</td>
</tr>
<tr>
<td>PM</td>
<td>Periodontal Measures</td>
</tr>
<tr>
<td>PP</td>
<td>Potential participant</td>
</tr>
<tr>
<td>PSI</td>
<td>Periodontal Severity Index</td>
</tr>
<tr>
<td>RR</td>
<td>Removable Retention</td>
</tr>
<tr>
<td>S</td>
<td>Single strand wire</td>
</tr>
<tr>
<td>SCC</td>
<td>Spearman's rank Correlation Coefficient</td>
</tr>
<tr>
<td>TMD</td>
<td>Temporomandibular Joint Dysfunction</td>
</tr>
<tr>
<td>TMJ</td>
<td>Temporomandibular Joint</td>
</tr>
<tr>
<td>UR1</td>
<td>Upper Right Central Incisor</td>
</tr>
<tr>
<td>VFR</td>
<td>Vacuum Thermoformed Retainer</td>
</tr>
<tr>
<td>WHO</td>
<td>World Health Organisation</td>
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Abstract

In 2004 and again in 2009, the Cochrane collaboration reviewed orthodontic clinical practice on retention. The review found; “there are insufficient data on which to base our clinical practice on retention at present”. The Aims of this study were two; the first was to review the effectiveness, durability and dental health impacts of bonded retainers (BRs) that have been in place for more than 15 years. The second was to discover the opinions of dentists and patients on comparing BRs to removable retainers (RRs). Method This was a 15 year retrospective study which reviewed 61 patients who had undergone conventional fixed appliance treatment with the chief researcher (CR) prior to 1993. Study sample size calculations required 44 BR study group and 44 RR control group patients for a valid analysis. Overall, 46 patients had experience with 55 BRs and 43 had experience with 55 RRs; 28 patients had worn both a BR and a RR at the same time and were thereby included as paired observations in both groups. All 61 participants completed a specifically designed questionnaire relative to their orthodontic treatment experience. They also underwent a clinical examination, had a series of intra-oral and extra-oral digital images and an OPG radiograph taken. Seventy one dentists who had referred patients to the CR over the previous 25 years were sent a confidential questionnaire; to be completed anonymously for their opinions on RRs and BRs. Statistical analyses were carried out using SPSS V16 (2008) and statistical significance was set at the 0.05 level. A Newcastle University statistician worked with the CR in analysing the results and compared them with those of four independent specialist examiners using Bland-Altman plots and Spearman’s rank correlation coefficient (SCC) analyses. Results The CR’s measures were found to be reliable and valid. After 15 years, the BRs were 100% effective at maintaining acceptable alignment while 53% of the control group had unacceptable alignment. The BRs had a unit composite bond/wire fracture rate of 0.58% per annum. The BRs did not produce any clinically significant negative dental health impacts. The majority of patients and dentists rated BRs as superior to RRs. Conclusions After 15 years, BRs were found to be adequately durable, effective at stabilising the anterior dentition and they did not produce adverse dental health effects. The majority of patients felt BRs improved their quality of life.
Chapter 1 Introduction and Aims

1.1 Introduction

Orthodontics is a specialist discipline in dentistry involved with the movement of teeth through their supporting alveolar bone into more desirable locations for purported functional and aesthetic benefits.\(^1\)\(^,\)\(^2\) All that is required to move teeth is to apply a constant force of 35-60 grams (gf) for tipping, 70-120 gf for bodily movements and up to 800 gf for orthopaedic/orthodontic movements.\(^3\)\(^-\)\(^5\) The force needs to be applied for several weeks or more onto the crown of the tooth in the direction it needs to be moved. The orthodontic/orthopaedic movement of teeth is demonstrated in Figure 1.1.

![Before treatment](image1)
![After 5 months of treatment](image2)

Figure 1.1. Clinical photographs demonstrating the extent of tooth movement occurring over five months of orthodontic treatment

1.2 Reasons for undergoing orthodontic treatment

Opinions are divided as to why patients undergo orthodontic treatment; mindful that the time taken to complete treatment is usually two years and involves a great deal of discomfort, inconvenience and monetary cost.\(^6\)\(^,\)\(^7\) The main reasons cited by both patients and dentists can be classified as either functional benefits and/or psychosocial benefits.

1.2.1 Functional benefits

The dental profession has historically promoted orthodontic treatment for the stability and functional benefits provided by having an ideal Class I occlusion.\(^8\) However, these claims have little support from the evidence available in the literature.\(^9\)\(^-\)\(^16\) The long-term, post-treatment reviews of the ‘Seattle Studies’\(^17\) have found the establishment of an ideal occlusion rarely guarantees stability. Little\(^17\)\(^,\)\(^18\) warned orthodontists to expect that even their best treated cases would be unstable. Studies by Shaw et al and others\(^14\)\(^-\)\(^16\) found that even people with severe malocclusion rarely present with, or complain of, having functional problems with mastication and speech. Once orthodontic treatment is completed and their dentitions are ideally aligned, patients rarely comment that they notice any functional improvement. In addition, there are claims that unless the dentition is correctly aligned, temporomandibular joint dysfunction (TMD)
will probably occur in later life and result in painful arthritis in the temporomandibular joints (TMJs). These claims lack any credible support from the literature but they do provide plausible reasons for patients to consider undergoing orthodontic treatment. To avoid the uncomfortable stigma of vanity which has long been associated with cosmetic enhancement procedures, use of the term ‘functional benefits’ as a reason to straighten teeth has become an effective and universally acceptable reason for undergoing orthodontic treatment.

1.2.2 Psychosocial benefits

The Macquarie dictionary defines the following words as: **Psyche**: spirit, soul. **Social**: connecting to others, relationships, friendships.

Human beings are social creatures who thrive in groups. An individual’s happiness is enhanced by their popularity within their social group and in this regard, being attractive is far more helpful than being otherwise. Studies have shown that the majority of orthodontic patients are embarrassed by their unattractive dentition. They want their teeth to be white, well shaped and placed in an arrangement that enhances the attractiveness of their smile and face.

1.3 The importance of an aesthetically attractive dentition

From her studies on ‘Social and Psychological Implications of Dentofacial Disfigurement’, Macgregor emphasised that any disfigurement of the face is amongst the “most tragic handicaps” a person can have as it cannot be hidden or disguised:

“The area in and around the mouth is both emotionally charged and strongly connected to one's self-image. As an instrument of speech and eating, as well as a mirror of emotions, it also has unique social and psychological implications and symbolic meaning. Any abnormality in this area, therefore, is not only highly visible and obtrusive but, as research has shown, tends to evoke a type of aversion which is both aesthetic and sexual. During social contact, the eyes attend the face and any irregularities can be distracting and produce an uneasiness for the afflicted and the non-afflicted alike. Spontaneity is inhibited by the rule of ‘not noticing’ The closer the defect is to the communicating equipment upon which the listener must focus their attention, the smaller the defect needs to be to throw the listener off balance. This type of handicap is both social and psychological.”

Shaw and Jones found ugly teeth provide a focus for ridicule and teasing, especially for children at school. Baldwin and Barns, and Berry pointed out that facial appearance is a key element in social interaction and success. It impacts heavily upon our lives from preschool through to old age. The handicapping effect of an unattractive face is carried on into many aspects of our lives from social acceptance, education, romance, employment, medical care and daily judgements of the type of people we are. Astle makes the comment that “beauty is a signpost to health and (by implication) desirable genes”. Beauty is a primary source of attraction.
to other people, especially the opposite sex. In her book ‘Beauty Bias: Discrimination and Social Power’, Berry\textsuperscript{21} points out how beautiful people have social power and inequitable advantages over plain people; their beauty impact adds positive biases to how other people treat them.

Any accessible procedure which improves facial attractiveness and enhances the quality of life is generally sought out by people. Orthodontic treatment can have a dramatic positive and long lasting effect in this regard which explains why many parents seek out and undertake the monetary and time sacrifices required to provide this treatment for children who have an unattractive dentition.\textsuperscript{24} A survey by Linn\textsuperscript{32} found 80\% of parents felt that orthodontic care for a needy child was a more important investment for the family than buying a house. Examples of the aesthetic enhancement of orthodontic treatment are shown in Figure 1.2.

\begin{figure}[h]
\centering
\includegraphics[width=\textwidth]{before_after_photos}
\caption{Clinical photographs to show the impact of orthodontic treatment on the dentition and facial appearance}
\end{figure}

Photos reproduced with the kind permission of the patients (see Appendix F2).

1.4 Professional treatments and ‘Duty of care’ to patients

All medical and para-medical professionals including Orthodontists, have a ‘duty of care’ when treating patients.\textsuperscript{33, 34} They must inform patients of the treatment options available and provide the best treatment possible with regard to the patient’s expectations, while also being mindful of the circumstances presented (some treatment options may be beyond the patient’s finances). This means achieving an outcome which involves the least burden on the patient in terms of trauma, monetary cost and time taken to complete treatment.\textsuperscript{35} The resulting
dentition should satisfy the patient's aesthetic and functional expectations. It should be healthy, stable, require minimal maintenance and enhance the patient's quality of life.\textsuperscript{35}

1.5 Evidence based orthodontic treatment

The judicial system and many governing bodies of the health professions, including dentistry, are now insisting that any treatments performed on patients should be evidence-based.\textsuperscript{33}

Sackett,\textsuperscript{36} a pioneer of evidence-based medicine, has made significant contributions in the measurement of the presence of diseases in populations, and in particular, how we assess the effectiveness of various forms of treatment. He has emphasised the importance of randomised controlled clinical trials (RCTs) and other forms of evidence in evaluating the effectiveness of treatments and how treatments can be made more effective for the patient's benefit. In 1986, Sackett\textsuperscript{37} reviewed the speciality of orthodontics for its scientific validity and stated that “in terms of the number of published randomised trials, orthodontics was behind such treatment modalities as Acupuncture, Hypnosis, Homoeopathy and Orthomolecular Therapy, and on par with Scientology, Dianetics and Podiatry”. He went on to opine “This is, I submit, a sad state of affairs that will soon be set right as orthodontists replace rhetoric with randomisation”. Since that review by Sackett, orthodontic researchers have provided new evidence which has dispelled several of the myths involved with some orthodontic treatments. Included amongst these myths are two of particular interest:

- Temporomandibular joint dysfunction (TMD) and malocclusion. TMD is no longer considered to be caused by malocclusions or incorrect orthodontic treatment.\textsuperscript{12, 13, 38} In fact, it has now been acknowledged that TMD problems often have very little to do with the occlusion, TMD causes are multifactorial and poorly understood.\textsuperscript{39}
- Orthodontic orthopaedic treatments that are undertaken to enhance facial bone growth do not contribute significant growth changes.\textsuperscript{40-44} The Cochrane collaboration\textsuperscript{44} has acknowledged that orthodontic and orthopaedic treatments experience relapse and neither contribute significant beneficial growth changes to the skeletal bases. The positive changes that they appear to bring about are either due to natural growth, which would have occurred anyway, or are due to dentoalveolar changes that occur with routine orthodontic treatments.

1.6 Dental alignment deterioration due to relapse and ageing

A major concern following successful orthodontic treatment has been with maintaining the achieved alignment of the dentition. Of particular concern is retaining the alignment of the aesthetically important anterior teeth over the long term, that is, for the rest of the patient’s life.\textsuperscript{8, 17, 45-50}
Orthodontic treatments have proven abilities to move teeth effectively and efficiently into more desirable arrangements. However, once all of the orthodontic appliances are removed, the teeth will often slowly move out of alignment due to two processes; these are relapse, and natural physiological ageing. Both processes occur in an unpredictable manner for different individuals.

### 1.6.1 Relapse

Relapse is the movement of teeth back towards their original positions after orthodontic treatment is completed. An example is shown in Figure 1.3. This patient's retention protocol involved wearing removable Hawley retainers for six months full-time and then a further 18 months at night only. Note also that the relapse pattern is not identical to the original incisor mal-alignment.

![Before Treatment](before.png) ![After Treatment](after.png)

**Figure 1.3.** Photographs demonstrating the extent of relapse that occurred seven years after orthodontic treatment. Note, the relapse pattern is not identical to the original incisor mal-alignment.

The rate of relapse is variable and may not be apparent in the first five years post-treatment. However, according to a large long-term retrospective study, which was undertaken at the University of Washington, within 10 years, up to 2/3rds of treated patients will exhibit unacceptable relapse and this may increase to 90% within 10 years.

### 1.6.2 The natural physiological ageing process

A longitudinal study undertaken by Thilander (2009) reviewed ‘the dentoalveolar development in 436 subjects with normal occlusion between the ages of 5 and 31 years’. None of the subjects had undergone any form of orthodontic treatment. Thilander found that the
dental arch perimeter length (APL) reached a maximum, in females, at the age of seven years in the mandible and 10 years in the maxilla; and in males, the APL reached a maximum at the age of 10 years in both the mandible and the maxilla. From then on, the APLs gradually decreased and the dental arches also underwent a gradual constriction. Several researchers\textsuperscript{17, 51, 52} have reported that this natural physiological ageing shrinkage results in the dental arches squeezing the teeth out of alignment as time passes. APL shortening continues throughout life and is demonstrated in a young person in Figure 1.4 and in an older person in Figure 1.5.

![Figure 1.4](image1.png)

**Figure 1.4.** A mandibular dentition with no crowding at age 11 years (4a) and the crowding that developed in 8 years as the dental arch constricted and shortened (4b) at age 19 years.

![Figure 1.5](image2.png)

**Figure 1.5.** An adult mandibular dentition at age 46 years (5a) and viewed again 17 years later at age 63 years (5b) with a noticeable increase in dental crowding due to arch constriction and shortening.

The undesirable tooth movements that occur with relapse and ageing are disappointing for everyone involved, especially patients who undertake orthodontic treatment with the expectation that the treatment will provide them with straight teeth and an attractive smile for the rest of their lives.\textsuperscript{55}

In a guest editorial on ‘Relapse and Retention - professional and public attitudes’, Vanarsdall and White\textsuperscript{55} wrote: “Generally, patients and dentists have believed that if orthodontically aligned teeth do not remain straight after the appliances are removed, the treatment has failed”. Similar concerns were raised by Lockett\textsuperscript{56} in 1926. The problems of relapse and ageing alignment deterioration are well demonstrated in Figure 1.6.
The girl shown in Figure 1.6 underwent specialist orthodontic treatment involving the removal of four first premolar teeth, two years of fixed appliance treatment, followed by two years of retention with removable Hawley type retainers. Within 11 years of completing treatment, her five millimetre overjet had returned and her dental alignment had deteriorated to a degree which both she and her parents considered was unacceptable. She sought and underwent re-treatment.

The ‘Seattle studies’ found the changes shown in Figure 1.6 are prevalent in up to two thirds of patients within ten years of completing orthodontic treatment and this number increases to 90% within 20 years. The guest editorial comments by Vanarsdall and White on patients’ expectations from orthodontic treatment highlight the need for the orthodontic profession to address this problem and find an effective solution to prevent relapse and undesirable post-treatment tooth movements.
1.7 Other problems associated with orthodontic treatment

1.7.1 Aesthetic outcomes and relapse

The emphasis of achieving an optimum aesthetic outcome from orthodontic treatment has long been acknowledged and, as discussed previously, has been an important motivating force for patients to undergo treatment.\textsuperscript{32, 57}

1.7.1.1 Dental arch expansion, aesthetics and relapse

When dental arches are narrow and/or retruded, they are usually unattractive. Orthodontic arch expansion treatment often improves their appearance as is demonstrated in Figure 1.7.

![Before Treatment](image1)
![After treatment](image2)

Figure 1.7. The aesthetic benefits of non-extraction arch expansion treatment

*Photos reproduced with the kind permission of the patient.*

Arch expansion treatments were initially popular with dentists and patients because of the aesthetic improvements they brought about. However, these improvements were very unstable and the relapse that followed was disappointing for everyone involved.\textsuperscript{58, 59} To avoid relapse, many orthodontists would extract teeth rather than expand the dental arches.\textsuperscript{60} Studies have found that the extraction of teeth usually results in less severe relapse.\textsuperscript{61, 62}

Permanent retention provides orthodontists with a means of expanding narrow arches and preventing anterior relapse.
1.7.1.2 Rotation correction

The correction of rotations as shown in Figure 1.8 often produces aesthetically pleasing results. However, rotation corrections are known to be very unstable and will usually relapse unless fiberotomy and/or permanent retention is employed.\textsuperscript{63-65} The fitting of bonded retention (BR) in these circumstances prevents relapse and negates the need for unpleasant surgical fiberotomy procedures.

Figure 1.8. The aesthetic benefits of aligning rotated teeth and bonded retention

1.7.1.3 Dental arch constriction to close gaps

The constriction of dental arches to close unattractive inter-dental spaces (gaps) as shown in Figure 1.9 is a common treatment method for dealing with spacing problems. However, the resulting dentition is usually very unstable and long term retention is required to prevent spacing relapse.\textsuperscript{66, 67} Permanent bonded retention was used in this case.

Figure 1.9. The aesthetic benefits of arch constriction and anterior space closure

Photos reproduced with the kind permission of the patient.
The use of adjunct surgical procedures such as ‘fiberotomy’ to minimise the risk of rotational relapse, and ‘frenectomy’ to prevent the return of diastemas and gaps, are now known to be unreliable. They are also unpleasant surgical procedures for patients to endure and add additional costs to the treatment.

1.8 Additional findings from relapse studies

Additional information on relapse was presented at the AAO Congress in 2004 by Little and quoted here from the Seattle Studies lecture - Treatment outcomes/complications:

1. The idea that stability will eventually occur after treatment and retention, “that's not reality”.
2. The dentition continues to change over time; this appears to be a normal physiological process. “The arches diminish in lateral expansion and antero posteriorly they are constricting”. “The body seems to want to have these dental archers gets smaller and smaller with time, unfortunately ... and the only way to resist that I suppose is to use a long-term retainer”.
3. This arch constriction also happens to the untreated (malocclusion cases) and also to untreated normal ideal cases.
4. The claim that relapse means inappropriate treatment is not true, “what we are seeing is a return to normal physiology, not failure of treatment”.

Little concluded his lecture by saying, “I would like to leave you with the message that you should fix them as perfectly as you can and then freeze them in place with a fixed retainer”.

1.9 A Cochrane Collaboration review of relapse

Treatment for relapse was reviewed for the Cochrane collaboration by Littlewood et al in 2004, 2006 and again in 2009. Their selection criteria were to review “randomised controlled trials (RCTs) on children and adults who had had retainers fitted or adjunct procedures undertaken, following orthodontic treatment with braces to prevent relapse”. The outcomes measured were; “how well the teeth are stabilised, survival of retainers, adverse effects on oral health and quality of life”. The reviewers’ conclusions were: “There are insufficient data on which to base our clinical practice on retention at present. There is an urgent need for high quality randomised controlled trials (RCTs) in this crucial area of orthodontic practice”.

The concept of a hierarchy of Evidence Based Research to determine which treatment procedures are effective is established and accepted in the scientific world. However, Donovan and Heymann pointed out one aspect that has been left out or is not properly dealt with is “time”. This is well demonstrated in a study by Fredrikssen et al where 236 teeth that were restored with flexible post, composite resin core and crown were followed for mean time of 30 months. The failure rate was 2%. This was considered to be an outstanding success. However a follow-up examination of the same patients 6.7 years later showed the failure rate had risen to 35% which is “woefully failing” and unacceptable. ‘Time’ is especially important in evidentiary
research dealing with dental materials and techniques as is the case for orthodontic treatment outcomes. For how long do orthodontic patients expect the outcome of their treatment to endure? Is it for five years, 10 years or is it forever? Riedel pointed out that relapse often does not commence until five years after retention ceases.\textsuperscript{71} The studies of note on retention and relapse beyond five years have been retrospective reviews and although these are regarded as ‘low grade evidence’, they have shown relapse is minimal during the active retention stage while patients are wearing retainers. This applies to removable retainers, (Hawleys’ and Essix) or bonded retainers.\textsuperscript{72-74} However, according to Little\textsuperscript{17}, once retainers are dispensed with, relapse often commences. The Cochrane collaboration and any other researchers may need to include the time element when reviewing relapse and retention. The credibility of the effectiveness of different retention methods is questionable without due consideration of the time factor. Several ‘low evidence’ retrospective studies and observations have highlighted how relapse often does not impact upon the treatment outcome until 10 and 20 years later.\textsuperscript{75-77} The evidence of latent relapse has additional strong anecdotal support within the profession.\textsuperscript{50} Because of this, the need for permanent retention to prevent relapse has the support of a steadily increasing number orthodontists around the world.\textsuperscript{74, 76, 78} However, there is still no consensus regarding which form of permanent retention is the most suitable, is it with removable retainers or is it with bonded retainers?\textsuperscript{79-81}
1.10 Permanent Retention options

Permanent Retention options involve the use of either:

- Removable Retainers (RRs)
- Bonded Retainers (BRs)

1.10.1 Removable Retainers (RRs)

RRs as shown in Figure 1.80 need to be worn with strict compliance to the orthodontist’s instructions. They are usually worn on a full-time basis for the first six months after orthodontic appliances are removed and thereafter at night for an indefinite period, often for the rest of the patient’s life.\textsuperscript{74, 77} RRs have been used in orthodontics since the late 1800s and their effectiveness has always been unreliable. The introduction of clear (invisible) Essix/vacuum thermoformed retainers (VFRs) RRs in the 1980s has not increased patient compliance with wearing RRs; a study by Pratt et al.\textsuperscript{82} in 2011 found orthodontists “grossly overestimated patient compliance with (wearing) RRs at 5 years after debonding.” Patients find wearing RRs is a nuisance and impacts negatively upon their quality of life. If patient compliance wanes and they stop wearing RRs as instructed, relapse usually follows.\textsuperscript{49, 83} The evidence from the literature is unequivocal on the unreliability of both Hawley and Essix/VFR RRs. Dentists and orthodontists acknowledge the disappointing outcomes from wearing RRs for the majority of patients.\textsuperscript{73, 80, 83}
1.10.2 Bonded Retainers (BRs)

Figure 1.91. The current design of the BRs used in this study

In their endeavours to find a means of preventing relapse and dental arch alignment deterioration in a way that was acceptable to patients, several orthodontists experimented with different forms of lingually placed ‘invisible’ bonded retainers (BRs). Zachrisson, a pioneer in this field, demonstrated how dental composite resins could effectively bond fine and well adapted retention wires to the lingual surfaces of the anterior teeth to prevent relapse. The success of this new form of retention encouraged others to do likewise. However, the profession at large was initially reluctant to embrace BR because of concerns raised; who would be responsible for maintaining BRs over the long-term? Orthodontists may not want this as it could become an ongoing obligation. Were there any long-term health risks associated with leaving these retainers in the mouth for an indefinite period? How effective and durable were BRs? The answers to these questions were not known because BRs were new retention appliances, being introduced around the 1970s. Initial reports on BRs mentioned few problems with plaque and calculus accumulations around the wires. There has been a slow but steadily increasing acceptance of these retainers. In June 2007, acknowledgement of the need for permanent retention came with the following statement from the Australian Society of Orthodontists: “lifetime retention after orthodontic treatment is now a reality if the patient wishes to guarantee that the teeth remain in the position that they are in after active orthodontic treatment is completed”. Little believes the best form of permanent retention is permanent bonded retention.

The recommendations from the Cochrane Collaboration for prospective RCTs to resolve the question of which retention method is best have not as yet been undertaken, possibly because they would raise ethical objections. Melrose and Millett point out that assigning patients in prospective clinical trials on retention methods would be difficult and could ‘only be considered realistically when there is an intention to retreat, if necessary’. There is sufficient information available in the orthodontic literature from retrospective studies to strongly suggest that any prospective RCTs comparing the use of RRs to BRs would result in varying degrees of relapse for many patients assigned to the RR groups. The question then arises, who would be responsible for sanctioning such studies and for the retreatment of any relapsed cases? The present ad hoc methods of retention using BRs appear to be producing superior outcomes to those seen in the past with RRs. A review of retrospective research by Zachrisson, Durbin, Cerny, the Seattle Studies, Pandis et al, Booth et al and
Zachrisson\textsuperscript{102} again, has shown that where BRs are attached to teeth, they are effective in preventing relapse. BRs are also durable over the long term (20+years) and have minimal adverse effects on the oral health or quality of life of the patients who are wearing them.

An example of the effectiveness of BR over 20 years is shown in Figure 1.102.

![Figure 1.102. Orthodontic treatment (Class II Div. 2) and bonded retention for more than 20 years](image)

Photos reproduced with the kind permission of the patient.

In 2004, Ackerman\textsuperscript{103} made the following pertinent comment, “The challenge facing orthodontists in the 21st century is the need to integrate the accrued evidence into clinical orthodontic practice”. How can this be applied to dealing with relapse using permanent retention? There is as yet insufficient information available to draw unequivocal conclusions on the long term effectiveness, durability and impact on dental health of BR. The opinions’ of patients and dentists on the use of BRs also requires further investigation. The lingering concerns about possible harmful effects from the use of BRs infer that any shortcomings they have need to be exposed and addressed if BRs are to become a safe and acceptable form of orthodontic retention.
1.11 The Aims of this study

The Aims of this study were to undertake a long-term review of more than 15 years of bonded retainers (BRs) in orthodontics to assess:

1. The effectiveness and durability of BRs.
2. The long-term dental health impact of BRs on the teeth and their supporting periodontal tissues.
3. To discover the opinions’ of patients and dentists on the use of BRs and RRs.

The BR’s reviewed here were only those designed and fitted by the author.
Chapter 2 Relapse and Fixed Retention in Orthodontics

2.1 A review of the literature

In 1986, Sackett\textsuperscript{37} mentioned that orthodontics was sadly lacking in credible evidence. In October 2007, Keim,\textsuperscript{104} undertook a general electronics search of current evidence in orthodontics on Pub Med and found 33,249 orthodontic papers, of which only 31, fell into the best evidence category. Papadopoulos and Gkiaouris,\textsuperscript{105} in 2007, wrote a paper on “A critical evaluation of meta-analysis in orthodontics”. They found only 16 articles that presented adequately supported evidence. Keim pointed out that these 16 articles represented 0.048% of the papers in the orthodontic literature that could be relied upon as our “best evidence”. None of these 16 articles dealt with retention or relapse. The Cochrane collaboration (Review) of 2009’ by Littlewood et al\textsuperscript{68} on “Retention procedures” concluded that “There are insufficient research data on which to base our clinical practice on retention at present”.

Taking into account the need for a time frame of 10 years or more, and assuming a cohort of 30 or more patients and a similar number of controls would be required for a valid assessment of relapse,\textsuperscript{71} in July 2012, the author searched the electronic data bases of Medline (1946 to 31/07/2012) and Embase (1947 to 31/07/2012) using the following key words; Orthodontics/ or Orthodontics, Preventive/, retention, relapse, randomised controlled trial. pt., controlled clinical trial.pt.,randomized.ab., randomly.ab., trial.ab. Medline produced 9 papers and Embase produced 133 papers, however, none of the studies fulfilled the necessary criteria of an evidence based study on retention and relapse.

If the aim of orthodontic treatment is to produce a stable and well aligned dentition, then the best available evidence in the literature shows that the orthodontic profession has not yet achieved this goal. How to prevent relapse is still a major concern for orthodontists and their patients. The absence of evidence upon which to base treatment strategies for dealing with relapse leaves this important topic in a vacuum. However, the evidence gained from the many ‘low-grade evidence’ retrospective reviews that exist in the literature does provide valuable information regarding relapse and what is known about the outcomes of different treatment and retention strategies. This evidence is the “best available evidence” for dealing with relapse.\textsuperscript{104}

2.1.1 An historical review of relapse

Relapse has been known about since the late 1800s and many retrospective studies since have added threads to the tapestry of knowledge on this subject.

History has not recorded exactly who the first orthodontists were, however; these people were able to move crooked teeth into more aesthetically desirable positions; which is what their patients sought treatment for.\textsuperscript{106-108} The first dentists/orthodontists also saw this as a way of correcting malocclusions and probably improving the functioning capacity of the
dentition. With this knowledge, they developed effective and efficient mechanisms to move teeth and ‘orthodontic braces’ came into being. Unfortunately, there was a major problem that often manifested itself soon after tooth movements were completed and all of the bracing appliances were removed; in the majority of cases, the teeth would, slowly but surely, revert back towards their pre-treatment positions. This problem is called relapse; it has been, and still is, the most significant issue affecting almost all orthodontic treatments.

Adding confusion to the relapse problem was the fact that a small percentage of cases did not relapse. This relapse/no relapse dilemma was verified by the late 1900s from the long-term (beyond 50 years) ‘Seattle Studies’ on post orthodontic treatment and ageing changes. Little, from the ‘Seattle Studies’, pointed out that over the long term (20 years), only approximately 10% of orthodontically treated cases would remain acceptably well aligned. This 10% group who did not relapse would have confused the first orthodontists and made them wonder what they were missing in their diagnosis and treatment of the 90% of patients who did relapse.

In the 1750’s, a Frenchman, Etienne Bourdet, recommended the extraction of the first premolars to relieve severe crowding. He was not alone with this extraction philosophy as it was based on what appeared to be the obvious solution for severely crowded dentitions. As a consequence of the extractions, less severe relapse occurred. However, extraction treatments were never popular and the two opposing solutions of extraction versus non-extraction for the orthodontic treatment of crowded dentitions are still present today.

The pre-Angle period up to 1887 saw the development of more sophisticated dental arch expansion appliances that were very effective at gaining space to un-crowd and straighten mal-aligned teeth thereby enhancing the beauty of the dentition and smile. Orthodontists may have been seduced by the rewarding aesthetic outcomes of such treatments and the anticipation that the teeth would eventually stabilise if retained for a sufficient period of time. However, the profession also began to realise that although the teeth could be moved into more desirable arrangements, most would relapse back towards their original position unless some form of long-term retention was employed.

2.1.2 Relapse and Retention during the Angle period (1887-1930)

Relapse was such a problem for the first orthodontists that Angle commented, “It is far easier to lay down rules for the governing of tooth movements than for retention”. In 1919, Hawley wrote: “One of the great unsolved problems of orthodontia has been, and is today, RETENTION”. An anonymous colleague of Hawley’s had remarked to him about retention, “If anyone would take my cases when they are finished, retain them and be responsible for them afterward, I would gladly give him half the fee”. Another anonymous orthodontist said, “Any fool can move teeth, but it takes a wise man to make them stay”.

Angle stressed the need for retention. He wrote, “After malposed teeth had been moved into the desired position they must be mechanically supported until all the tissues involved in
their support and maintenance in their new positions shall have been thoroughly modified, both in structure and in function to meet the new requirements”. Angle would recommend the use of either removable or fixed retainers for an indefinite period if necessary.

To deal with intransigent relapse cases, Angle designed many fixed metal retainers (FMRs) made of metal bands and spurs soldered to arch bars and he sometimes deliberately placed spurs into teeth or restorations to prevent relapse. Examples are shown in Figure 2.1.

![Figure 2.1. Examples of Angle's fixed retention appliances. A; wire arch bars soldered to metal bands. B; metal spurs soldered to metal bands. C; metal spurs placed into dental restorations.](image)

Whenever Angle considered fixed metal retention (FMR) was necessary, he encouraged his patients to accept them by stressing that any aesthetic drawbacks from the visible metal bands of the FMRs were a minor annoyance compared to the benefits of having straight teeth and a well functioning and stable ‘normal occlusion’.

Case\textsuperscript{45} (1847-1923) supported Angle regarding the use of removable and permanent fixed retention. Case also used FMRs but his were usually made from gold castings and gold spurs as shown in Figure 2.2 A and B. Case used gold alloy where FMRs were visible because he thought that patients would be less likely to reject them on aesthetic grounds. He also used his dental prosthetic skills to fit invisible fixed palatal retainers with retention pins cemented into holes he purposefully drilled into the palatal enamel of the abutment teeth; examples are shown in Figure 2.2 C.
Figure 2.2. A, B, C. Examples of Case’s fixed metal retainers (FMRs) that were usually made from gold to increase patients’ acceptance of their use

Other orthodontists of the time including Lischer\textsuperscript{112} and Hawley\textsuperscript{113} also used FMRs whenever they thought it was necessary. Lischer recommended the use of entire arch embracing FMRs as shown in Figure 2.3. These were made up of an arch bar soldered to four or more metal bands attached to the first permanent molars, canines and any other teeth which threatened to relapse. Figure 2.3 demonstrates how Lischer’s metal retainers were sometimes fitted in both arches; elastics may also have been used to hold orthopaedic corrections as with Class II skeletal base malocclusions.

Figure 2.3. Lischer’s fixed metal retainers (FMRs)

2.1.3 Hawley’s objections to fixed metal retainers (FMRs)

In the early 1900s, FMR appeared to be the best solution for preventing relapse. However, FMRs had many detrimental weaknesses and Hawley\textsuperscript{113} listed the following five objections to their use:

1. FMRs often needed to be worn for up to three years (and more). During this time, inspection was less frequent than during treatment and if the cemented bands loosened and this was not noticed by the patient or operator, often decay or disintegration of the enamel would result.
2. The forces of mastication could bend the FMRs arch bars and displace the attached teeth.
3. Brushing and cleaning FMRs was difficult, with resulting injury to the enamel and soft tissues.
4. The rigidity of the FMRs restricted the individual movement of the teeth and often prevented their settling into perfect interdigitation and locking of the cusps.
5. The bands on the teeth were unsightly and wearing of them for so long a time decreased the desirability and the practicality of the whole operation.

It was these objectionable features of FMRs that made them unpopular with patients and the dental profession. This prompted Hawley to re-investigate the use of removable retainers (RRs).

2.1.4 McBride and Hawley removable retainers (RRs)

In 1906, Hawley\textsuperscript{113} went to Dresden in Germany and viewed McBride’s RR plates (Figure 2.4) that were successful in preventing rotational relapse. Rotational relapse was one of the main concerns for orthodontists, particularly when anterior teeth were involved. Hawley improved McBride’s RR appliances further (Figure 2.4) and the modified versions were well accepted by the profession. The Hawley retainers became the most commonly used RR appliances in orthodontics for the next century.\textsuperscript{74}

![McBride’s and Hawley’s RRs](image)

Figure 2.4. McBride’s and Hawley’s RRs

2.1.5 Angle’s arch expansion and relapse

During the Angle period, the influence that Angle had on orthodontics was immense due to the fact that many of the practicing orthodontists were initially his students and later his staunch disciples. Angle dictated which treatments were acceptable and he was so adamant that teeth were not to be extracted that almost all treatments involved dental arch expansion. It is well documented that expansion treatments are very unstable.\textsuperscript{17, 58, 59} Because of this, the advancement of the speciality of orthodontics was held back as it suffered greatly from the consequential problems of relapse. Figure 2.5 is of two contemporary cases (1990s) to demonstrate the degrees of relapse that commonly occur after two years of orthopaedic expansion treatment followed by two years of orthodontic expansion treatment; viewed four years after the completion of treatment.
2.1.6 The benefits of extractions for orthodontic treatment

During the Angle period (1887-1930) there were some orthodontists who defied Angle and would extract teeth to achieve alignment. It was not until 1940 that Angle's authority in this regard was seriously challenged. Tweed, an orthodontist who had been trained by Angle, presented a paper on 100 cases of consecutively treated patients, all of whom had four first premolar teeth extracted as a necessary part of their treatment. At the conclusion of his presentation, Tweed was verbally castigated by most of the orthodontists present. One exception was Strang, another orthodontist who had been trained by Angle. Strang was amazed at how “magnificently and beyond criticism” Tweed’s results were. Strang went on to become a Tweed disciple as he saw the benefits of extractions for attaining good occlusions and that extraction treatments resulted in fewer problems with relapse.

It was also at this time that Begg, an orthodontist from Australia, presented papers on his studies of primitive man's dentition. Begg reviewed the teeth in the skulls of 'stone age' primitive dentition's and concluded that the 'attrition occlusion, continuous eruption and mesial migration' he observed were all part of human dentitions' natural physiological maturation and ageing process. He proposed that 'modern' dentitions did not experience the abrasive diets and parafunctional use of primitive dentitions and therefore would become more crowded with ageing due to the absence of attrition and the persistence of the constant eruption and mesial migration of the teeth. For this reason, Begg considered extractions were necessary in modern dentitions, not only to relieve any crowding that may already be present, but also to prevent future crowding that would develop with the mesial migration of the teeth.

Both Tweed and Begg had a profound influence upon the teaching and practice of orthodontics. As a consequence of their extraction philosophies, the problems of relapse were far fewer (as verified later by Boley and) and extraction treatments were then adopted by most members of the profession. However, although relapse occurred less often and to a lesser degree with extractions, it still happened and remained a problem.
2.1.7 Extractions and ‘dishing–in’ the face

The extraction of teeth resulted in less relapse and the profession accepted it as the best method of dealing with crowding and moderate skeletal base discrepancies. However, extractions sometimes have unpleasant aesthetic consequences for many patients, especially those with minor crowding, Class II mandibular retrognathic malocclusions and those with narrow arches. The aesthetic damage alarmed some patients and dentists and resulted in a backlash against extractions from within the dental profession and by the general public. The orthodontic profession in turn attempted to explain this problem and justify the need for extractions by emphasising the importance of an attractive lip profile on the beauty of the face and also the importance of achieving an ideal Class I occlusion for optimum function and stability. This explanation was unsatisfactory as patients undergo orthodontic treatment to align their teeth and enhance the appearance of their face and smile. The relevance of lip profile in relation to dental profile and dentition appearance when speaking and smiling has never been clearly articulated by the orthodontic profession.

Studies have shown that the poor aesthetics of narrow dental arches can often be enhanced by orthodontic expansion with regulated protrusion of the anterior teeth and elimination of dark buccal corridors. While expansion treatments are known to be very unstable, relapse can be prevented by employing permanent retention.

During the post Angle period (1930-1970), the use of FMRs was restricted as the visibility of the metal bands resulted in these appliances being as unpopular as Hawley had commented earlier. According to Strang, the duration of retention may have been one or more years depending upon what patients would tolerate. FMRs were only used as temporary measures in favour of the more commonly used RRs such as Hawley and more recently in the 1990s, clear Essix VFRs retainers (Figure 1.80 page 13).

The use of RRs has suited the orthodontic profession as it places the responsibility for preventing relapse onto the patients. However, most patients find these retainers are inconvenient, unhygienic and unreliable. If patients do not wear their RRs as instructed and relapse occurs, the blame could be placed on the patient for their lack of compliance. As relapse became more noticed, the profession began to acknowledge that to maintain the alignment achieved by treatment, the retention needed to be permanent.

2.1.8 The ‘Seattle Studies’; a unique long-term study on relapse and ageing changes

In 1947, the problems of stability and relapse prompted two orthodontists, R.Riedel and A.Moore, from Seattle, Washington, USA to begin recalling their treated patients on a regular basis to see what changes occurred to their dentitions with the passing of time. These patients included both those who had undergone orthodontic treatment and those who had not. The orthodontic department at the University of Washington has continued their study and in 2009, it had over 900 sets of long-term records. This research project is referred to as the ‘Seattle Studies’.
From the results of their observations, Dr Riedel referred to the first three to five years after braces are removed as “the honeymoon period” because the occlusion often appeared to be stable and little relapse was seen. However, by ten years post-treatment, the relapse problems had begun to express themselves with one third of patients remaining stable, one third experiencing moderate relapse and the final third exhibiting severe relapse. The degree of relapse usually continued to increase slowly for the rest of the patient's life and within 20 years, up to 90% of treated cases had unacceptable mal-alignment. There were no known predictors for relapse, nor were there any special treatment recommendations that could be applied to guarantee the prevention of relapse. Untreated patients also experienced a gradual deterioration in alignment due to continual arch shrinkage and a mesial migration of the teeth what is now regarded as being a natural physiological ageing process. A longitudinal study of normal occlusions by Thilander found that the dental arches continue to constrict and shorten from the age of seven years in females and ten in males. Other similar studies by Bishara et al and Linklater and Fox reached the same conclusions. As a consequence of these findings, in 2009, Little recommended that if patients were to avoid dental arch alignment deterioration due to relapse and ageing changes, once active treatment was completed, they should have bonded retainers fitted and these should be left in place permanently.

The post-war economic boom brought with it new wealth that improved the quality of life for most people, especially in the western world. Along with water fluoridation, improved diets and better oral hygiene practices, there came less tooth decay. The incidence of dental extractions decreased and subsequently there was an increase in dental crowding and an increased demand for orthodontic services. Zachrisson mentioned that as patients became more discerning about the results of their orthodontic treatment, the aesthetic outcomes would be of paramount importance to them and even minor relapse could cause concern. Addressing the relapse problem in a satisfactory way was the next hurdle for the orthodontic profession.

### 2.2 The composite bonding period: beyond 1970

#### 2.2.1 Background

In 1955, Buonocore discovered that dental enamel could be roughened and its surface area dramatically increased by etching it with acid; such a surface could then be successfully bonded to with acrylic resins. This provided dentistry with a new and more conservative means of restoring teeth. In 1956, Bowen presented a paper on the ‘Use of Epoxy Resins in Restorative Materials’. He described how synthetic epoxy resins could be used as a binder for fine particles of fused silicon dioxide and porcelain to provided excellent properties for adhesive dental filling and bonding materials. They were called Bis GMA (Bisphenol A diglycidylether methacrylate) composite resins. Their thermal expansion coefficient is compatible with that of dental enamel, they have excellent adhesive properties, are colour stable and apparently stable and insoluble in the oral environment. Buonocore and Bowen’s discoveries heralded a new era in dentistry and orthodontics. It was not long before most
orthodontists discarded the ‘ugly’ metal bands and began directly bonding smaller and more aesthetically pleasing orthodontic brackets to teeth. The bonded brackets proved to be effective and reduced the incidence of hidden tooth decay that sometimes occurred beneath the metal bands they superseded. The aesthetic composites were also applied to the retention problem.

### 2.2.2 Bonded retention (BR) in orthodontics

By the 1970s, Zachrisson\(^8\) and others\(^9\) orthodontists began experimenting with bonded (lingual and palatal) retainers because they were “invisible” and had the potential to be effective at preventing relapse. Patients and parents were more receptive to the use of fixed invisible retainers over RRs as the appearance of the dentition was not compromised. Being fixed to the teeth, BRs were not a daily nuisance for patients; compliance with wearing them was not an issue. BRs could not be lost and did not require removal and reseating for meals and tooth brushing. BRs were adequately comfortable, convenient and showed no signs of being harmful to the patient or the dentition.\(^{81, 92, 98}\)

Zachrisson\(^12\) experimented with different types of BRs, fitting them in both the maxilla and mandible; examples of Zachrisson’s BRs are shown in Figure 2.6. Zachrisson became a leading advocate and promoter for the use of BR.

![Contemporary examples of the types of bonded retainers used by Zachrisson](image)

**Figure 2.6. A,B,C. Contemporary examples of the types of bonded retainers used by Zachrisson**

Figure 2.6 A, Mandibular (Mb BR) plain thick 0.025" round wire bonded to the canines only. This one has been uneventfully *in situ* for 16 years. Figure 2.6 B; Mandibular (Mb BR) twist flex 0.0215" wire bonded to all labial teeth. Figure 2.6 C; Maxillary (Mx BR) twist flex 0.032" wire bonded to all labial teeth. This one has been uneventfully *in situ* for 23 years.

#### 2.2.2.1 Experimentation with bonded retainers (BRs)

Orthodontists were able to experiment with BRs by using different composite materials, enamel bonding agents, wire types, shapes and thicknesses. They also developed a better understanding of the techniques required for preparing the teeth and placing the composite resin. However, to date, there has been no agreement reached among orthodontists on which materials, techniques or wire types or designs are the best.\(^8\) The literature contains several papers describing different methods of fitting BRs but there are few follow-up studies to verify their long-term effectiveness and reliability.\(^6, 84-86, 129-136\)

In 1995, ‘A review of Bonded orthodontic retainers’ by Bearn\(^9\) presented a summary of studies on different BRs and the composite materials used; the review highlighted the variety, success, short-comings and dental health impacts of BRs. Bearn concluded that there were no
findings of adverse dental health effects due to the presence of BRs. He noted the failure rate of BRs ranged between 10.3% and 47.0%. Maxillary BRs fractured at twice the rate of those in the mandible. The most common fracture site was the wire composite interphase and Bearn suggested that this was due to insufficient composite thickness or to the material thinning by wear abrasion. In 1997, Bearn\textsuperscript{137} completed a study on the BR composite thickness and recommended that for optimum comfort and strength the ideal thickness of composite over the wire was one millimetre.

There was a notable absence of credible reports in the literature discrediting the use of bonded retention in orthodontics.

### 2.2.2.2 A review of bonded retainers (BRs), 1997-2009

Since the Bearn review of 1995, an updated ‘in vivo’ studies summary on wire type, diameter and shape, composite used and failure rates from 1997 to 2009 is presented in Table 2.1.

#### Table 2.1. Reports on bonded retainers (BRs) wire types, diameter, shapes and sizes, composite and failure rates from 1997 to 2009

<table>
<thead>
<tr>
<th>Author</th>
<th>Year</th>
<th>Bonded Retainers No</th>
<th>Duration years</th>
<th>Wire Diameter</th>
<th>Wire Type</th>
<th>Wire Type</th>
<th>Sites</th>
<th>Sites</th>
<th>Composite</th>
<th>Failure Rate % per annum</th>
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<tr>
<td>Artun, J.; et al.\textsuperscript{97}</td>
<td>1997</td>
<td>11</td>
<td>3</td>
<td>0.032&quot; S</td>
<td>√</td>
<td></td>
<td>√</td>
<td>√</td>
<td>Concise</td>
<td>3.03</td>
</tr>
<tr>
<td>Artun, J.; et al.\textsuperscript{97}</td>
<td>1997</td>
<td>13</td>
<td>3</td>
<td>0.032&quot; M</td>
<td>√</td>
<td></td>
<td>√</td>
<td></td>
<td>Concise</td>
<td>10.3</td>
</tr>
<tr>
<td>Artun, J.; et al.\textsuperscript{97}</td>
<td>1997</td>
<td>11</td>
<td>3</td>
<td>0.0205&quot; M</td>
<td>√</td>
<td></td>
<td></td>
<td></td>
<td>Concise</td>
<td>9.1</td>
</tr>
<tr>
<td>Andre, A.; et al.\textsuperscript{138}</td>
<td>1998</td>
<td>119</td>
<td>5-14.5</td>
<td>0.015-0.0195&quot; M</td>
<td>√</td>
<td></td>
<td></td>
<td></td>
<td>Concise</td>
<td>7.2</td>
</tr>
<tr>
<td>Lumsden, K.W.; et al.\textsuperscript{139}</td>
<td>1999</td>
<td>140</td>
<td>5</td>
<td>0.018&quot; M</td>
<td>√</td>
<td></td>
<td></td>
<td></td>
<td>Relyabond</td>
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<td>√</td>
<td></td>
<td></td>
<td></td>
<td>Helioprogress</td>
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<td>1.78</td>
<td>0.0175&quot; M</td>
<td>√</td>
<td></td>
<td></td>
<td></td>
<td>Durafill flow</td>
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<tr>
<td>Stormann, L.; Ehmer, U.\textsuperscript{141}</td>
<td>2001</td>
<td>103</td>
<td>&lt;2</td>
<td>0.0195, 0.0215&quot; S</td>
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<td></td>
<td></td>
<td></td>
<td>Heliosit/Concise</td>
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<tr>
<td>Durbin, D.D.\textsuperscript{73}</td>
<td>2001</td>
<td>12 000</td>
<td>20</td>
<td>0.028&quot; S</td>
<td>√</td>
<td></td>
<td></td>
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<tr>
<td>Cerny, R.\textsuperscript{40}</td>
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<td>350</td>
<td>17</td>
<td>0.018&quot; S</td>
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<td></td>
<td>3MZ100</td>
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<tr>
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<td>10 000</td>
<td>30</td>
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2.2.2.3 Wire types used for bonded retainers (BRs)

Stainless steel orthodontic wires, either plain single strand (S) or multi-strand twist flex (MS), were the most popular wire frames used for BRs. The use of fibreglass strands has an unacceptably poor survival rate and is rarely reported.\(^{133, 143}\)

The wire types varied in diameter and texture. The most popular and effective wires used in the mandible, when attached to the canines only, were S - 0.025" diameter (D) to MS - 0.032" D. When the BRs were attached to all of the labial teeth in the mandible, the most popular wires were thinner S - 0.018" to MS - 0.0215". Zachrisson\(^{102}\) and Cerny\(^{101}\) preferred to bond to all of the labial teeth to minimise the risk of root torque and rotational relapse. The wires used for maxillary BRs were the thinner S - 0.018" to MS - 0.0215". The number of labial teeth attached to the BRs was variable. The need for BR in the maxilla was not universally popular being routinely used by Cerny\(^{101}\) and as deemed necessary by Zachrisson,\(^{102}\) Lumsden et al,\(^{139}\) Segner and Heinrici,\(^{140}\) Durbin\(^{73}\) and Andren et al.\(^{138}\)

2.2.2.4 Wire shapes used for bonded retainers (BRs)

The most popular wire shape used was relatively straight wire that followed the contours of the teeth involved; as is shown in Figure 2.6 A,B,C (page 25) The wire shapes that Cerny used (Figure 1.11. page 14) have loops between the abutment teeth wherever it was practical; loops were not placed between the lower incisors as the distances are too short and they create additional cleaning and tongue irritation problems. Loops were placed to allow easier access inter-proximally for flossing and restoration placement, if required. The loops also increase the flexibility between abutment teeth and thereby reduce the incidence of composite stress fractures. One additional benefit of the loops is that they counter root torque relapse.\(^{90}\)

2.2.2.5 Composites used for bonded retainers (BRs)

The most popular composite and bonding agents used were 3M Concise.\(^{8}\) Most of the other brands reported on since 2002 performed well with fracture rates below two percent. The Bis GMA composites performed better than the acrylic resins; the incompatible coefficients of

<table>
<thead>
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<th>Author</th>
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<th>Wire Type</th>
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<td>2007</td>
<td>381</td>
<td>1-10</td>
<td>0.030&quot; S</td>
<td>√</td>
<td>√</td>
<td></td>
<td></td>
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<td>Zachrisson, B.U.(^{102})</td>
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<td>700</td>
<td>1-10</td>
<td>0.0215&quot; M</td>
<td>√</td>
<td>√</td>
<td>√</td>
<td>√</td>
<td>Concise</td>
<td>1.32</td>
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<tr>
<td>Booth, F.A.; et al.(^{91})</td>
<td>2008</td>
<td>45</td>
<td>20</td>
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<td>√</td>
<td></td>
<td></td>
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<td>Al-Nimri, K.; et al.(^{142})</td>
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<td>31</td>
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<td>0.036&quot; S</td>
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<td></td>
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</table>
thermal expansion and contraction between acrylic resins and enamel would account for this. The majority of composites were light cured.

\^ 3M Unitek, 2724 S. Peck Road, Monrovia, CA 91016, USA.

### 2.2.2.6 Failure rates of bonded retainers (BRs)

Measurements of the failure rates of BRs have previously been assessed as total failures irrespective of the time factor. Such a method of assessment is confusing and inaccurate because it fails to take into account how long each retainer has been in situ and the fact that more breakages would be expected to occur over longer time periods. For this study, the failure rates were standardised to include the time factor and the measurements were assessed as fracture percentages per annum (pa); this method of assessment was applied to all of the studies presented in Table 2.1.

The failure rates of BRs have dropped from between 47% pa and 7.27% pa prior to 2001, to as low as 0.03% pa in 2008. This has been accompanied by an increasing popularity in BR use. In 1995, Bearn found that the maxillary BRs fractured twice as often as those in the mandible. In 2007, Cerny reported a fracture rate in the maxilla that was marginally higher at 60% when compared to that in the mandible at 40%. The reasons for this decrease in fracture rates could be due to improvements in the properties of composite bonding materials. There is also a better understanding of optimum wire diameter and BR design, improved techniques of fitting BRs and optimum thickness of composite materials.

The total elimination of BR fractures is unlikely as wear and tear, trauma, mishandling of materials and accidental breakages are unavoidable. The fracture rate of other dental adhesive treatments such as orthodontic bonded brackets, dental restorations and appliances, ranges between 5% to 11.8% pa. This suggests that the recently recorded BRs fracture rates of less than two percent are within an acceptable range.

### 2.2.2.7 The dental health concerns and impacts of bonded retainers (BRs)

A review of studies on the dental health and periodontal concerns and impacts of bonded retainers are summarised in Table 2.2; Chapter 3 has details of the indices used.
Table 2.2. Reports on bonded retainers (BRs) dental health and periodontal concerns and impacts, from 1977 to 2008

<table>
<thead>
<tr>
<th>Author</th>
<th>Year</th>
<th>Bonded Retainer No</th>
<th>Duration Months</th>
<th>Retainer Site</th>
<th>Oral Hygiene</th>
<th>Plaque Decay</th>
<th>Calculus Index</th>
<th>Gingival Index</th>
<th>Alveolar Bone Index</th>
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<td>Zachrisson B.U.¹⁸⁸</td>
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<td>43</td>
<td>12-30</td>
<td>-</td>
<td>43</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>N.R</td>
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<td>Artun J.⁹⁵</td>
<td>1984</td>
<td>63</td>
<td>7-91</td>
<td>14</td>
<td>49</td>
<td>1</td>
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<td>1</td>
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<tr>
<td>Dahl E.H., Zachrisson B.U.¹⁴⁶</td>
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<td>166</td>
<td>32-90</td>
<td>120</td>
<td>46</td>
<td>1</td>
<td>0</td>
<td>1</td>
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<td>1</td>
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<tr>
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<td>47 short 2 unit</td>
<td>27</td>
<td>N</td>
<td>R</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>NR</td>
<td>1</td>
</tr>
<tr>
<td>Heier E.E. et al.⁹⁶</td>
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<td>22</td>
<td>6</td>
<td>-</td>
<td>22</td>
<td>1</td>
<td>0</td>
<td>1</td>
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<tr>
<td>Artun J. et al.⁹⁷</td>
<td>1997</td>
<td>35</td>
<td>36</td>
<td>-</td>
<td>N R</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>1</td>
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<tr>
<td>Durbin D.D.⁷³</td>
<td>2001</td>
<td>12000</td>
<td>240</td>
<td>N R</td>
<td>11</td>
<td>1</td>
<td>0</td>
<td>N R</td>
<td>N R</td>
<td>N R</td>
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<tr>
<td>Cerny R.¹⁰⁰</td>
<td>2001</td>
<td>440</td>
<td>204</td>
<td>N R</td>
<td>N R</td>
<td>1</td>
<td>0</td>
<td>N R</td>
<td>N R</td>
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</tr>
<tr>
<td>Cerny R.¹⁰¹</td>
<td>2007</td>
<td>2300</td>
<td>60</td>
<td>1150</td>
<td>50</td>
<td>N R</td>
<td>0</td>
<td>N R</td>
<td>N R</td>
<td>N R</td>
</tr>
<tr>
<td>Pandis N. et al.¹⁰²</td>
<td>2007</td>
<td>32</td>
<td>115</td>
<td>-</td>
<td>N</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Zachrisson B.U.¹⁰²</td>
<td>2007</td>
<td>1081</td>
<td>50</td>
<td>509</td>
<td>2</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Booth F.A et al.⁹¹</td>
<td>2008</td>
<td>45</td>
<td>240</td>
<td>-</td>
<td>N R</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Levin L. et al.¹⁴⁸</td>
<td>2008</td>
<td>&gt;25&lt;50</td>
<td>55</td>
<td>N R</td>
<td>1</td>
<td>N.R</td>
<td>1</td>
<td>N R</td>
<td>N R</td>
<td>1</td>
</tr>
</tbody>
</table>

Rating scores: 0=Nil, 1=Minor, 2=Moderate, 3=Severe N.R = Not Recorded

The 13 studies reviewed for dental health and periodontal concerns and impacts of BRs between 1977 and 2008 are summarised in Table 2.2. They include BR numbers ranging from 22 to 12000 over periods from 6 months to 240 months. There were no mentions of patients being concerned about having BRs placed in their mouths. There were no reports of dental caries that could be attributed to the BRs. There were five studies where concerns were expressed with the dental health aspects of oral hygiene, the plaque index, the calculus index or the gingival health index, however, none were of clinical significance.⁹₅, ⁹⁶, ¹⁴₂, ¹⁴₆, ¹⁴₈ The only alveolar bone levels reported on were in the study of 32 mandibular BRs by Pandis et al.⁹₂ they found only minor alveolar bone loss and isolated instances of pocketing; it was unclear whether these pocketings were due to the BRs.

A study by Levin et al¹⁴⁸ in 2008 reported increased but not clinically significant levels of plaque, BOP and gingival recession associated with BRs.

Between 1977 and 2008, there were no reports in the literature of clinically significant harm to the dentition that could be directly attributed to the presence of BRs.

Brenchley¹⁴⁹ presented a paper of three case studies where the outcomes of BR use were considered failures, however, each case involved a two unit BR using fine braided wire (0.0175” and 0.01195”) attached to the maxillary central incisors; a thicker/firmer wire size and
design with circles or loops at each end of the wire to counter rotational and root torque forces would have been more appropriate. Katsaros et al.\textsuperscript{150} found during follow-up visits over three years, 21 patients had post treatment problems with six unit mandibular BRs and almost half of them required retreatment. However, this study was undertaken in a post graduate orthodontic clinic where neither the total number of patients reviewed nor the percentage of failures were mentioned.

The studies presented by Bearn\textsuperscript{98} and those in Table 2.1 and Table 2.2 indicate BRs overall are effective, durable and provide patients with the stable dental alignment outcomes they expect from treatment. There have not been any adverse reports from studies involving groups of patients using BRs. Many parents and patients have commented favourably about the use of BRs, particularly with respect to their effectiveness and convenience.\textsuperscript{73, 80}

### 2.2.2.8 Comparisons of bonded retainers (BRs) vs. removable retainers (RRs)

It has been difficult to compare BRs to RRs because few patients have had experience with both types. A survey by Wong and Free\textsuperscript{83} comparing BRs to RRs found both patients and dentists preferred the BRs; “Patients found fixed retainers more acceptable than removable retainers because of appearance and comfort”.

Collective anecdotal evidence supported the claim that parents were more in favour of BRs as they were rarely lost and parents did not have to repeatedly check that their children were wearing them. For patients and parents, BRs were more convenient and did not impact negatively on daily routines or quality of life.

The orthodontic profession was initially sceptical of BRs, mainly because BRs effectiveness, durability and impact on dental health were unknown and there were concerns about who would be responsible for these retainers in the future.\textsuperscript{93} Some orthodontists thought the responsibility of the retention process should be passed over to the patient.\textsuperscript{93} Other orthodontists were uncomfortable with these suggestions and continued experimenting with BRs. This review found some researchers suggested the long term use of BRs was not harmful to the dentition if patients maintain a sensible oral hygiene regime.\textsuperscript{91, 96, 102, 151} BRs appear to be effective and durable; and patients find them more comfortable and convenient than RRs.\textsuperscript{83, 122} All of these positive attributes have resulted in a steadily increasing use and acceptance of BR by both the dental profession and the general public.\textsuperscript{78}

### 2.3 Summary of the literature review

The published literature has shown many retrospective studies confirming the reality of relapse and arch alignment deterioration with ageing. These problems are time-dependent and as Riedel and Little\textsuperscript{17, 71} pointed out; unacceptable relapse is often not seen in the first five years post retention but after 10 years, relapse affects up to two thirds of patients and this number slowly increases to 90% of patients by 20 years.
Evidence based studies on retention and relapse would require RCT’s with 30 or more cases and 30 or more controls that have more than 10 years of post treatment experience. With this in mind, an electronic search of Medline and Embase from 2000 to 2012 was undertaken; the outcome of this search was that there were no studies that fulfil these requirements.

2.4 Conclusions

The electronic searches of the orthodontic literature found there were no RCTs studies on retention or relapse that extended beyond five years post de-band. There are many retrospective studies and these have encouraged the direction of change in dealing with retention to prevent relapse. There is repeated evidence that mechanically induced changes to the dentition have a very high probability of relapsing, be it by way of orthodontic, orthopaedic, or orthodontic/surgical means. Compounding this problem is the discovery that undesirable dental alignment deterioration due to ageing changes will also occur unpredictably as time passes. Currently, the most reliable form of permanent retention is achieved with correctly constructed and fitted permanently bonded retainers (RBRs). Long-term review studies of retention and relapse suggest that BRs are not a dental health hazard and they appear to be reliably effective and durable if they are designed and fitted correctly. There is an increasing acceptance of PBR by orthodontists, dentists, patients and their parents. However, the dental profession and patients must be aware of and accept that BRs need to be regularly maintained and reviewed.

This research project aims to further investigate BRs/RRs with a specific focus on the long-term (15 years) effectiveness and durability, dental health impacts, and the opinions of dentists and patients on the use of BRs.
Chapter 3  Materials and Methodology

3.1 Study setting

This study was undertaken in the chief researcher’s (CR’s) specialist orthodontic practice (one principle and two satellite practices) located in the port city of Newcastle in a region called the Hunter. Newcastle has a population of approximately 200,000 and is situated 160 kilometres north of Sydney in N.S.W. Australia. The Hunter region is comprised of three districts, Newcastle, Lake Macquarie and the Valley and has a combined population of about 0.75 million people. The region has primary, secondary and tertiary industries which service a long established and stable population. The dental practices here are modern and progressive, providing a comprehensive range of dental services either directly or by way of supporting specialist practices. The long standing nature of the dental practices has resulted in a continuity of dental care to many families in the Hunter and provides the dentists with opportunities to review the outcomes of the orthodontic treatments their patients have undergone.

This study was referred to as NEOTS (Newcastle Effects of Orthodontic Treatment Study). The CR has been using both removable retainers (RRs) and bonded retainers (BRs) in his specialist orthodontic practice in Newcastle since 1984.

3.2 Types of retainers reviewed

3.2.1 Removable retainers (RRs)

The RRs used by the CR were and are still commonly used by many orthodontists.\textsuperscript{77, 79} They are modified maxillary Hawley and mandibular Hawley spring-aligners as shown in Figure 1.80 (page 13).

3.2.2 Bonded retainers (BRs)

The bonded palatal and lingual retainers (BRs) under investigation in this study were only those fitted by the CR to the anterior teeth in the maxilla and mandible prior to 1993. Examples of these are shown in Figure 3.1 A-E.
Chapter 3 Materials and Methodology

Figure 3.1 A-E. Palatal maxillary and lingual mandibular bonded retainers (BRs) investigated in this study

Figure 3.1 A, B and C show examples of the BRs used in the maxilla with six, four and two labial adjacent teeth bonded to the wire. Figure 3.1 D and E are of the BR types used in the mandible with the wire bonded to the canines only in D, and to all six labial teeth in E.

All BRs investigated in this study were in situ for more than 15 years. The maxillary BR wire frames are 0.018” diameter Regular Plus Wilcock* (round stainless steel) Orthodontic wire. The mandibular BR wires are stainless steel round wire 0.018” Regular Plus Wilcock (round stainless steel). The composite was 3M Silux.**

* AJ Wilcock, Yea R’d, Whittlesea, VIC, 3757. Australia.
** 3M Unitek, 2724 S. Peck Road, Monrovia, CA 91016, USA.

3.3 Ethical considerations

Ethical approval for this research project was obtained from the University of Newcastle’s Human Research Ethics Committee; Ref No: H-216-0506. The initial application for ethics approval for research involving humans required a detailed explanation form to be completed for assessment (see Appendix D).

3.3.1 Safe-guards and protection for participants

Participation in this study was voluntary. It did not involve any painful or invasive procedures and there were no benefits or incentives offered to potential participants (PPs). An information package was posted to all PPs. The package contained an invitation to participate, comprehensive information about the Neots study, what their involvement would entail (see Appendix E) and an informed consent form (see Appendix F).

Participants’ privacy was of paramount importance; each participant was assigned and only identified by a unique coded number. All hard-copy records were kept in a secure location in a locked filing cabinet in a locked room. All electronic records were kept in a password controlled database.
All assistant researchers involved in the study signed declarations that they would treat information about participants as being strictly confidential. All clinical procedures performed on patients were non-invasive and painless. Only one OPG x-ray was taken of each participant and this involved a minimal radiation exposure dose equivalent to 1.3 days of background radiation. Prior to commencing this study, the competency of the X-Ray machine used was assessed and approved by a licensed inspector (see Appendix G).

This study was to cease immediately if any harm was detected due to the presence of the BRs. Such an event would be investigated thoroughly and then dealt with through the University of Newcastle’s Ethics Committee.

Participants were required to sign a consent form covering all aspects of the research involving them; they did this before being included in the study (see Appendix F1). Patients whose photographs were to be used in this Ph.D, if agreeable, were asked to sign a consent form for this purpose (see Appendix F2). Participants could withdraw from the study at any time without prejudice and they were provided with information regarding who to contact at the University of Newcastle for any concerns or grievances that may arise during the course of the study.

3.4 Sample size calculations

Sample size calculations were based on the following variables: the incidence of dental decay and periodontal disease in the general population. A review of the literature found Australian general population dental health surveys were less comprehensive than those done in the UK and the USA. Researchers have found that the dental health of people in the United States and Australia are remarkably similar. For this reason, the sample size calculations were based on UK and USA studies where the general populations were assumed to have similar dental health to those of Australia.

3.4.1 Sample size calculations based on dental decay measures

According to a census survey done in the United Kingdom in 1998, five percent of the British adult population had dental decay affecting their mandibular anterior teeth. For the NEOTS study, it was estimated that after 15 years of wearing a BR, up to 30% of patients in the study group may have a similar amount of decay due to the presence of a BR. This was deduced from studies which found that BRs attract larger accumulations of dental plaque. Using Dupont and Plumber’s ‘Power and Sample size program’ (See Appendix H), 43 patients were needed to provide a sample with a significance level of $p \leq 0.05$, and a power of 0.8.

3.4.2 Sample size calculations based on periodontal measures

Population studies on the incidence of periodontal disease within the general population in the USA found approximately 20% of adults have marginal periodontal inflammation.
was estimated that after 15 years of wearing a BR, up to 50% of patients with BRs may have similar inflammation due to the larger amounts of dental plaque that BRs attract.\textsuperscript{55, 96} Using Dupont and Plumber’s\textsuperscript{159} ‘Power and Sample size program’, (See Appendix H), 44 patients were needed to provide a sample with a significance level of \( p \leq 0.05 \), and a power of 0.8.

### 3.4.3 Sample size required

Therefore, the number of patients required was calculated to be:

- NEOTS Study group (NSG), patients with BRs = 44.
- NEOTS Control group (NCG), patients without BRs = 44.

The significance level would be set at \( p \leq 0.05 \) and a power set at 0.8.

All patients reviewed in this study had completed a comprehensive course of orthodontic treatment prior to 1993.

### 3.5 Study design

This study was a 15 year review of BR involving both retrospective elements and current opinions and perceptions dealing with three separate aspects of this form of orthodontic retention. They were:

1. The effectiveness and durability of BR.
2. The dental health impacts of BR on the teeth and the periodontal tissues.
3. The current opinions of patients and dentists on the use of BR.

A review of the literature found there were several retrospective studies on BR of a similar nature, however, most were either of shorter duration and/or involved fewer measurements (see Table 2.1 pages 26-27 and Table 2.2 page 29). There were two studies which extended beyond 10 years; the Pandis et al\textsuperscript{92} study (10 years) was mainly concerned with the long-term periodontal impacts of BRs; the Booth et al\textsuperscript{91} study (20 years) reviewed the reliability of BRs and some periodontal measures associated with BRs.

### 3.6 Dental sites and Indices reviewed

The dental sites reviewed in this study involved those palatal or lingual regions associated with the anterior teeth surfaces were BRs were attached in the NSG or the equivalent sites in the RRs NCG. Comparative analyses were also done of the labial surfaces.

#### 3.6.1 Effectiveness of bonded retainers (BRs)

Little’s Irregularity Index (LII)\textsuperscript{163} is the most commonly used method for reviewing the effectiveness of retention mechanism by measuring how much mal-alignment (relapse) occurs to the labial teeth supported by the retainer.\textsuperscript{62, 91, 164, 165} The LII is the gross sum of the five linear displacements of adjacent anatomical contact points of the six anterior teeth, (Figure 3.2), measured in millimetres (mm).
The LII can be applied to the anterior teeth in both the maxilla and the mandible. A study by Naidu et al\textsuperscript{166} in 2008 found the LII can be accurately measured from photographs. In this study, the LII was assessed by measuring the contact point displacements on paper copies of the occlusal view digital photographs using digital callipers; then by using comparative analysis of the size of the central incisor in the paper copy with the actual size of the patient's tooth measured during the clinical examination.

The LII ranks the incisor irregularities and displacement in ranges from 0 to 10+ mm using the following scale: 0 mm = ideal alignment; 1-3 mm = minimal irregularity; 4-6 mm = moderate irregularity; 7-9 mm = severe irregularity; ≥ 10 mm = very severe irregularity\textsuperscript{167}

For this study, the LII rankings were modified to include 100ths fractions of a millimetre to be more precise. The scale used was: 0 - 0.99 mm = ideal alignment; 1 - 2.99 mm = minimal irregularity; 3 - 5.99 mm = moderate irregularity; 6 - 8.99 mm = severe irregularity; ≥ 9.00 mm = very severe irregularity. Little suggested that an acceptable LII measure was one < 3 mm.

\subsection{3.6.2 Durability of bonded retainers (BRs)}

The durability of the BRs was measured by recording any composite and/or wire fractures that had occurred over the 15 years. The BRs were examined \textit{in situ} at the time of the clinical examination (see Figure 3.3) and additional information was gained by questioning the patients regarding, if, when, where and how their BR had been fractured or damaged and repaired in the past. The overall durability measure was calculated for all BRs to provide a fracture rate as a percentage of breakages (unit composite bond/wires) per annum (pa).

Figure 3.3. Damage to the BRs could be seen during a clinical examination and is demonstrated by the arrows showing composite fractures on both lateral incisors. Note the detached lateral incisors have only undergone minor movements
3.7 The long-term dental health impacts of bonded retainers (BRs): Dental Health Indices (DHIs) reviewed

Dental studies have always struggled with reaching agreement when assigning values to DHIs. This is because, as time passes, it is normal for dentitions to deteriorate and experience one or more of the following: periods of accumulations of plaque and/or calculus, gingival recession, gingivitis, periodontitis and alveolar bone loss. Ideally, all patients should be free of dental disease and any potential dental pathogens. However, in reality, this is never the case and researchers have to be practical and establish acceptable guidelines when assigning values to DHIs. A review of “Periodontal diseases in Europe” (2002) resulted in chief dental officers in Europe agreeing that acceptable levels of dental pathogens (such as plaque and calculus) and periodontal disease ‘are those that are compatible with maintaining a functionally and socially acceptable dentition for the patient’s lifetime’.  

Acceptable levels of the DHIs as deferred to by that review were set as the upper bounds in the statistical analyses for clinical significance in this study.

The DHIs reviewed included the following:

1. Decay Index (DI)
2. Plaque Index (PI)
3. Calculus Index (CI)
4. Modified Gingival Index (MGI)
5. Gingival Recession Index (GRI)
6. Alveolar Bone Index (ABI)

The regions of the dentition that were reviewed included the anterior teeth and periodontal tissues adjacent to where the bonded retainers were (NSG) and similar sites for the (NCG). A comparative analysis was also done of the labial sites.

3.7.1 Decay Index (DI)

The Decay Index (DI) is commonly used in dentistry to measure the amount of decay present in the dentition. It was measured by visually inspecting debris free enamel and recording any tooth decay and sub-surface de-calcification present.

3.7.2 Plaque Index (PI)

The Plaque Index (PI) (also known as the Oral Debris Index) has been commonly used in dental research and similar studies (see Table 2.2 page 29) to assess the amount of plaque present on the teeth and the gingival tissues.

Plaque disclosing tablets ( # ) were used to stain and highlight the amount of plaque present on the six anterior teeth and gingiva, as shown in Figure 3.4B.

# Discotab by Colgate, 195-203 Forster Road, Mt Waverly, Victoria. Australia. 3149.
Figure 3.4. The Plaque Index (PI) scores for the anterior teeth as demonstrated by the arrows are shown in Figure A; a clinical example is shown in Figure B

Figure 3.4A shows the plaque present (arrows) and the corresponding scores assigned to them. Figure 3.4B shows the diplaque stain (arrow) highlighting the sites and amounts of plaque present on the teeth and gingival tissues.

The PI as described by Greene and Vermillion\(^{170}\) was used in this study. The PI has also been used in other similar studies\(^{92, 96}\) (see Table 2.2 page 29). The scale shown below was used to measure the PI: 0 = an absence of plaque; 1 = plaque covering up to one third of the tooth surface; 2 = plaque covering up to two thirds of the tooth surface; 3 = plaque covering more than two thirds of the tooth surface.

The results of the plaque measures were averaged separately for both the buccal and the lingual surfaces of all six anterior teeth in each arch to obtain specific buccal and lingual PI measures.

### 3.7.3 Calculus Index (CI)

The Calculus Index (CI) as described by Greene and Vermillion\(^{170}\) has been commonly used to quantify the amount of calculus present on teeth in both similar and general dental health studies (see Table 2.2 page 29).\(^{27, 92, 97, 171}\) The Greene and Vermillion scale shown below in Figure 3.5 was used to measure the calculus accumulation levels: 0 = an absence of calculus; 1 = calculus covering up to one third of the tooth surface; 2 = calculus covering up to two thirds of the tooth surface and the presence of some sub-gingival calculus flecks; 3 = calculus covering more than two thirds of the tooth surface and the presence of a continuous band of sub-gingival calculus.

Figure 3.5. The Calculus Index (CI) scores for the anterior teeth are demonstrated by the arrows highlighting the amounts of calculus present and the corresponding scores assigned to them.
The results of the calculus measures were averaged separately for the buccal and lingual surfaces of all of the anterior teeth in each arch to obtain specific buccal and lingual CI measures. Figure 3.6 is an example of what was seen clinically; it demonstrates the amount of calculus seen in the maxilla (A) where there were no visible deposits of calculus, and (B) in the mandible where the calculus seen is highlighted by the arrows.

![Figure 3.6. The calculus present on each tooth is visually identified (arrow)](image)

3.7.4 Gingival Recession Index (GRI)

The Gingival Recession Index (GRI) was included in this study to assess if the presence of BRs were responsible for aggravating the rate of gingival recession. The GRI is an average measure of the distance from the cemento-enamel junction to the gingival margin, measured in millimetres (mm) for the six anterior teeth. It is commonly used in periodontal studies to measure the loss of gingival tissue. An example of gingival recession is shown by the arrow in Figure 3.7 A Maxillary labial. The amount of the GRI was averaged separately for both the buccal and lingual surfaces of all the anterior teeth in both arches to obtain specific buccal and lingual GRI measures.

![Figure 3.7. The Gingival Recession (GRI) measures as shown by the arrow (labial surface) in Figure 3.7A. No gingival recession was observed (palatal surface) in Figure 3.7B](image)

3.7.5 Modified Gingival Index (MGI)

The Modified Gingival Index (MGI) was chosen to assess the degree of inflammation of the gingival tissues because it does not involve an invasive and painful ‘bleeding on probing’ (BOP) component. A BOP measure has the potential to be painful as it requires the probing of six sensitive sub-gingival sites around each tooth measured. Participants in this study were informed that their clinical examination would not include any painful procedures. Support
for the case against the use of a BOP measure came in 1996 from the American Academy of Periodontology - World Workshop in Periodontics.\textsuperscript{178} The delegates at the workshop concluded “The presence of bleeding on mechanical stimulation is neither a good indicator of disease severity nor a good predictor for the progression of periodontitis”.

The MGI was reviewed and validated in 1989 by Lobene et al;\textsuperscript{179} they concluded that the MGI was “logistically simpler, has less variability (than other gingival indices) and is thereby more accurate in inter-examiner calibration. It affords greater sensitivity in detecting therapeutic efficacy”.

During the clinical examination, the CR used air blasts from a triplex syringe to inspect the gingival tissues of anterior teeth to identify potential pockets and sub gingival calculus.

The scale for the MGI as described by Lobene et al and use in this study was: 0 = normal (absence of inflammation); 1 = mild inflammation (slight change in colour, little change in texture) of any portion of the gingival unit; 2 = mild inflammation of the entire gingival unit; 3 = moderate inflammation (moderate glazing, redness, oedema, and/or hypertrophy) of the gingival unit; 4 = severe inflammation (marked redness and oedema/hypertrophy, spontaneous bleeding, or ulceration) of the gingival unit. The results of the MGI were averaged separately for both the buccal and lingual surfaces of all the anterior teeth in each arch to obtain specific buccal and lingual MGI measures. An example of a clinically assessment rated at two for the MGI on the labial and lingual surfaces is shown in Figure 3.8.

![Figure 3.8. The Modified Gingival Index (MGI) of the anterior teeth measures the degree of inflammation of the periodontal tissues as shown by the arrows](image)

### 3.7.6 Alveolar Bone Index (ABI): Periodontal Severity Index

The Alveolar Bone Index (ABI) was recorded to assess the amount of alveolar bone height loss that may be associated with the presence of BRs. The levels of bone loss were assessed by an averaged overview of the crestal alveolar bone heights as seen in the OPG radiographs. This method has been used in other dental studies.\textsuperscript{180-184}

For this study, the following scale of the Periodontal Severity Index (PSI), as described by Adams and Nystrom,\textsuperscript{180} were used to categorize the ABI by measuring the percentage of Alveolar Bone Loss from the cemento-enamel junction to the root apex: 0 = ideal bone levels; 1 = 1 - 9.9% bone loss; 2 = 10 - 19.9% bone loss; 3 = 20 - 29.9% bone loss; 4 = 30 - 39.9% bone loss; 5 = 40 - 49.9% bone loss; 6 = 50 - 59.9% bone loss; 7 = 60 - 69.9% bone loss; 8 = 70 - 79.9% bone loss; 9 = 80 - 89.9% bone loss; 10 = 90 - 100% bone loss.
For this study, 1mm of alveolar bone height loss represented approximately 10%. The ABI was rated at: 0 to 9.9% = very good; 10 to 19.9% = good; 20 to 39.9% = fair; 40 to 59.9% = poor and ≥ 60% = very poor.

One standard OPG was taken of each participant to provide an overall view of the alveolar bone supporting the entire dentition. OPGs were used as they involve only a small dose of radiation exposure, they are easy to standardize and convenient for both the patient and the operator. Several studies have promoted the merits of OPGs compared to periapical radiographs for assessing periodontal disease and the ABI. The use of a percentage of bone loss scale, measured from the CEJ to the root apex was regarded as being practical for this study and would involve less risk of introducing inter- and intra-examiner variability. The alveolar bone levels were assessed in two parts, one for the anterior teeth, and the other for the posterior teeth. This would enable the examiners to determine if the presence of BRs had a noticeable impact on ABIs. Figure 3.9 shows an example of OPGs of two female Caucasian patients of similar age. In Figure 3.9A, a NSG patient who has an ABI rated at two, which is good. In Figure 3.9B, a NCG patient who has an ABI rated at six, which is very poor. The very poor rating was thought to be due to her chronic smoking habit.

![Figure 3.9. A review of the ABI from the OPGs of two Caucasian female patients of similar age (mid 40s). Note the severe bone loss in patient B thought to be due to her chronic smoking habit.](image)

### 3.8 The opinions’ of patients on retention appliances

This is presented separately in Chapter 5.

### 3.9 The opinions’ of dentists on retention appliances

This is presented separately in Chapter 6.

### 3.10 Recruiting the study groups

The orthodontic records of 671 patients who completed a comprehensive course of orthodontic treatment with the CR prior to 1993 were eligible to participate in this study. From those records; 231 patients had BRs fitted and they formed the NEOTS Study Group (NSG); 440 had worn RRs and they formed the NEOTS Control Group (NCG).

The current telephone numbers of potential participants (PPs) were sourced from either their orthodontic records, local telephone directories, the on-line telephone directories or their
addresses in the electoral rolls. To avoid introducing additional bias to the study, the CR did not contact the PPs; this was done through a research assistant who was not familiar with the patients. Those patients whose telephone numbers were traced were phoned by the research assistant to confirm their postal address. Whenever phone contact was not made, if a phone message machine was present, a brief message explaining the reason for the call and a request for the call to be returned was made. Up to three follow-up phone calls were made for each PP and if contact was not successful by then, no more calls were made as badgering patients would breach ethics guidelines. From the groups of patients who were contacted and their addresses obtained, 100 NSG PPs were to be randomly selected using a simple randomisation device that can be accessed on the Internet (see Appendix I). These PPs were posted a package containing comprehensive details of the NEOTS study, what their participation would involve, an invitation to participate (see Appendix E), a Consent Form (see Appendix F1) and a request to respond to the research assistant within three weeks. Those who did not respond within three weeks were posted a second package with a request to respond within two weeks. PPs who did not respond were not contacted again as their participation was purely voluntary.

Limiting the initial group contacted to 100 was done to avoid recruiting too many patients. If the initial group of 100 did not achieve the required minimum number of 44 NSG participants, then more PPs would be randomly selected and contacted until 44 were recruited. Once the NSG quota was filled, the NCG would be randomly selected and where possible, matched to the NSG for age, gender and treatment type.

3.11 Methodology

3.11.1 Clinical assessment and self reporting

Consenting participants were given an appointment to attend the CR’s orthodontic clinic at a time that suited them. Upon arrival, they were greeted and asked to hand in their signed ‘consent to participate form’ (see Appendix F) as this was an obligatory requirement to participate. A consent form for the use of photographs in this Ph.D (see Appendix F2) was given to patients who agreed to have their photographs published in educational circumstances.

Participants then completed the patient questionnaire (see Appendix J) relating to general information, medical history, dental health care, dietary habits, smoking habits, orthodontic treatment and retention experiences. Once this was done, the CR reviewed the questionnaire with the patient to ensure that it had been completed and to clarify any queries from the patients. A standard OPG digital radiograph was taken. A series of 12 standardised digital photos were then taken of the patient’s face, teeth and dentition as shown in Figure 3.10
Figure 3.10. Examples of the 12 digital photographs taken of each participant before undergoing a clinical examination

Photos reproduced with the kind permission of the patient.

A clinical examination of the dentition and any BRs was then undertaken by the CR. Air blasts from a triplex syringe were used to clear and dry the sites to be examined and to expose any enamel decay or sub-surface de-calcification, periodontal lesions and sub-gingival calculus. Recordings were made of any tooth decay, plaque deposits, supra- and sub-gingival calculus...
deposits, gingival recession and of the health of the gingival tissues. The widths of the maxillary and mandibular right central incisors were recorded in millimetres (mm) to 1/100\textsuperscript{th} mm with digital callipers for later comparative analysis. Following the initial examination and record taking, each patient was given a plaque disclosing tablet to chew up and rinse out. Five photographs, as shown in Figure 3.11 were then taken to record the DHI measures such as where plaque was present. A digit record of the OPG was also taken. (Figure 3.11).

Figure 3.11. An example of the five digital photographs taken of the dentition after disclosing the teeth for dental plaque, and a copy of the OPG

Where necessary, the anterior teeth were scaled, cleaned and re-examined. Any previously missed dental pathologies such as caries, sub-surface enamel decalcification or periodontal disease were recorded. Following the clinical examinations, participants had the opportunity to discuss the findings and any of their concerns with the CR. A copy of the patient's OPG, a written report on the state of their dentition and recommendations for any necessary dental treatment were given to the patient by the CR (see Appendix K).

3.11.2 Data storage and collation for analysis

The digital images of the patients, their teeth and OPG were placed on individual CDs with the written information collected and these were stored in the patient's orthodontic files. All
of this information was also duplicated into a master data file on the CR’s password protected computer. The information obtained from the questionnaire was transferred to a master database spread sheet for analysis. All information obtained from the clinical examination was analysed, measured (where necessary) and also transferred to the master data file.

3.12 Statistical analysis

Statistical analyses were carried out using SPSS V16 (2008)\textsuperscript{186} and statistical significance was set at the $p < 0.05$ level.

The statistical methods used are presented under three major headings associated with the two research questions for which statistical assistance was provided.

1. The demographics and dental health practices of the patients: $N=61$, NSG=46, (all patients with a BR in situ) NCG=15 (only patients without a BR in situ).
2. Primary research question – Effect of BRs: NSG=46 (55 sites), NCG=43 (55 sites). (The 28 patients who had experience with both a BR and an RR at the same time were treated as paired observations and included in both the NSG and the NCG). These effects included the effectiveness of BRs for the purpose of retention, and the dental health impacts of BRs on the dental and periodontal tissues.

3.12.1 The demographics and dental health practices of the patients

The demographics included: ethnicity, malocclusion marital status, gender, age, education, general health, and smoking habits for the NSG and NCG. Dietary information was not essential and too complicated to be included. The dental health practices included: brushing frequency, inter-proximal cleaning with dental floss and toothpicks, and dental checkups with or without prophylactic scaling and cleaning for the NSG of 46 patients and the NCG of 15 patients. The statistical significance of the variations in the demographics between the NSG and the NCG were measured using Pearson chi-squared tests; level of significance set at $p < 0.05$.

3.12.2 Primary research questions – Effect of bonded retainers (BRs)

The primary research questions were concerned with whether the sites where BRs (NSG) were present had differences in effectiveness of retention and dental health compared to where RRs (NCG) were present. In the total study cohort of 61 patients, four sub-groups were identified with respect to the types of retainers worn: 3 sub-groups (NSG of 46 patients with 55 BR sites) representing those with BRs in the maxilla (32), the mandible (5), and both (9). The
fourth sub-group (NCG of 43 patients with 55 RR sites) consisting of those 28 who had worn a BR and a RR at the same time combined with the 15 who had only worn 27 RRs.

3.12.2.1 Effectiveness of bonded retainers (BRs): evaluated by Little’s Irregularity Index (LII)

The effectiveness of BRs was evaluated by measuring the Little’s Irregularity Index (LII) of all patients in the NSG and NCG. Due to the skewed nature of the distribution of results for some of the groups, the Kruskal-Wallis non-parametric test was used to assess the differences between the four groups. The acceptable level of incisor irregularity in orthodontics has been acknowledged as any LII < 3mm. With this in mind, for clinical significance, the statistical analysis in this study set the upper bound for the LII at < 3mm.

The statistical significance of the variations in the LII between the NSG and the NCG were measured using Fisher's exact test (2-tailed), level of significance set at p < 0.05.

3.12.2.2 Dental health impacts of bonded retainers (BRs): Dental Health Indices (DHIs)

The dental health impacts of BRs were evaluated by measuring the dental health indices (DHIs) of all patients in the study group. The scores for Dental Health Indices (DHIs) / periodontal measures were rated from five levels of assessment:

0 = Very Good, 1 = Good, 2 = Fair, 3 = Poor, 4 = Very Poor.

The sites reviewed in this regard were those six anterior teeth (palatal / lingual) sites adjacent to where BRs were present for the NSG and their equivalent for the NCG.

The association between group differences and the five periodontal indices of plaque, calculus, gingival recession, modified gingiva, and alveolar bone was evaluated using chi-squared tests with the Monte-Carlo exact option (2-tailed) used as a check on the reliability of the chi-squared $p$ values. The differences between the means of the two groups were tested using an independent samples $t$ test.

For clinical relevance, the DHIs had statistically relevant upper bounds set according to practical levels that were considered appropriate. The levels were based upon an epidemiological review paper ‘Periodontal disease in Europe’ by Shieham and Netuveli (2002). This paper mentioned that ‘what we call periodontal disease is contentious’, and the literature shows that how we measured periodontal disease is also contentious. A group of chief dental officers of Northern Europe concluded that the retention throughout life of a functional, aesthetic, natural dentition of not less than 20 teeth was a reasonable goal for periodontal disease control. They believed that what was necessary for this was for people... ‘to achieve a level of plaque which is compatible with a rate of periodontal destruction which will retain teeth essential for a socially and personally acceptable dentition for a lifetime and does not cause handicaps’. With ageing, ‘there was general agreement that some loss of periodontal attachment and alveolar bone height was acceptable’... ‘The rates of alveolar bone loss varied...
between 0.07 and 0.14 mm per year in persons aged between 25 and 65 years; older subjects had rates of 0.28 mm per year.\textsuperscript{189}

For this study, the majority of patients were over 30 years in age and the statistical upper bounds for the DHIs were set with this in mind.\textsuperscript{168} These upper bounds were: Plaque Index (PI) = 1.5, Calculus Index (CI) = 1.5, Gingival Recession Index (GRI) = 1.5mm, Modified Gingival Index (MGI) = 1.5 and Alveolar Bone Index (ABI) = 2mm or 20% alveolar bone height loss.

3.12.3 Secondary research question – Validation of measurements by the chief researcher (CR): Measurement agreement / comparative analysis (CA)

An assessment of the reliability and validity of the measurements recorded by the CR was carried out prior to the complete data analysis. This involved comparing the measurements the CR made on two groups of ten (stratified and randomly selected) patients on two occasions, six months apart (CR1 and CR2). These measurements were compared to those of four external independent (blind) specialist examiners (two orthodontists (EX1.O and EX2.O) and two periodontists (EX3.P and EX4.P)). One group of ten patients was used to assess the Orthodontic effectiveness of maintaining dental alignment using Little’s Irregularity Index (LII), and the other group was for assessing the Periodontal impacts using dental health indices (DHIs). Each group of ten patients was made up of a severity stratified random sample from the NSG (six patients) and the NCG (four patients). The two pairs of external examiners were selected from two groups of specialists (academics and private practice) nominated by the study supervisor. Potential examiners were approached in turn until the required number was achieved (see Appendix L).

A pilot analysis estimated the time required for each examiner to complete the assessments and measures on the group of ten patients would be approximately 60 minutes; the examiners were advised of this.

The ten patients records were sent by registered mail to the four external examiners in a package containing the following: a brief summary of the NEOTS study, a checklist of the orthodontic measures (see Appendix M) or periodontal measures (see Appendix N), paper copies of the ten patients relevant dentition images and OPG, reference articles on the parameters to be measured, the Little’s Irregularity Index,\textsuperscript{163} or the periodontal measures,\textsuperscript{170, 179, 184} a CD with only the relevant dentition and OPG images of the ten participants, prepared sheets for recording results, electronic metric callipers accurate to 1/100th of a millimetre (mm), a calculator, a records summary sheet for the ten participants and a return stamped and addressed postage satchel.

The purpose of comparing agreement between the CR’s two sets of measures six months apart (CR1 and CR2) was to establish how reliably the CR could accurately reproduce measurements. The purpose of comparing agreement between the CR’s two sets of measures
Chapter 3 Materials and Methodology

(CR1 and CR2) with the two pairs of independent examiners’ measures was to verify the validity of the CR's measures.

The comparative analysis was based on the paper by Bland and Altman (1986)\textsuperscript{190} for comparing agreement between two sets of clinical records. It was adapted by considering each pair of the four sets of records, two from the CR (CR1 and CR2) and the two pairs from the external examiners (EX1.O / EX2.O and EX3.P / EX4.P). Then all 6 pair-wise comparisons between practitioners were assessed for two features, the presence of bias, and precision.

3.12.3.1 Assessment of the presence of bias

Gao Smith and Smith\textsuperscript{191} defined bias as a systematic distortion of a result due to a factor not allowed for in the design of the study. The presence of bias was assessed by Bland-Altman plots of the difference between scores of two practitioners against the mean of the two scores. If there was a constant difference or the difference varied with the mean score then there was evidence of bias. The significance of the relationship between the different scores and the mean score was determined using Spearman's rank correlation coefficient (SCC),\textsuperscript{192} assessed by how close the SCC number was to zero; significance (2 tailed) set at $p < 0.05$. The clinical significance of the outcomes was determined by the upper bound as set for the measure being assessed.

3.12.3.2 Assessment of precision

The precision of the measurements was assessed by examining the range of differences between the examiners as seen in the Bland-Altman plots\textsuperscript{190}. In similar medical reviews, the clinical significance outcome is more important than the statistical significance outcome.\textsuperscript{191} Unacceptable precision would involve a range that was substantial enough to be clinically significant.

3.13 Conclusions

The patients reviewed in this study were only those who had undergone comprehensive orthodontic treatment with the CR prior to 1993. The treatment methods used and the retainers fitted, were all similar. The CR was the sole operator responsible for all of the treatments.

The study was designed to be ethically acceptable with safeguards in place to protect participants.

The statistical requirements for a valid study were researched and applied. External specialist examiners were used to determine if the CR's measures were unbiased and valid.

The nature of the investigations into BR effectiveness, durability and dental health impacts were the products of reviews of similar research. The results of these investigations and relevant discussions pertaining to the outcomes are presented in Chapter 4.
Chapter 4  Results and Discussions

4.1 The sample of patients

A flow chart of achieving the study groups is presented in Figure 4.1. NSG (NEOTS study group) and NCG (NEOTS control group).

![Flow chart of achieving the study groups](image)

The initial sample of patients consisted of 671 randomly selected potential participants; 231 NSG and 440 NCG; 236 (35.2%) had their phone numbers traced, 454 phone calls were made (up to three calls for some patients, see Appendices O and P). The 454 phone calls resulted in the following outcomes. There were 27 wrong numbers, 28 patients had moved away, four female patients were pregnant and could not participate as an OPG X-ray was required, 107 were not interested, 54 said they would participate and 16 said maybe. Seventy invitations to participate were sent out and a total of 61 patients agreed. This was a response rate of 9.1% of the initial sample and 25.8% of those whose telephone numbers were located. The positive response rate of the NSG was 46 patients (19.5%) and for the NCG it was 15 patients (3.6%). The recruitment period was over six months. The ability to randomise the selection of patients as was initially intended, was not possible because there were so few positive responses that all were included. This low number of patients was initially thought to be inadequate with only 15 NCG patients as 44 were needed for a valid study. However, a
breakdown of the groups found the NSG had 28 patients who had both one BR and one RR fitted; according to Pandis et al\textsuperscript{193}, these 28 could be used as paired observations in both the NSG and the NCG. A study by Hess\textsuperscript{194} showed this combination made the review a matched case controlled study.

4.1.1 The study group achieved

A flow chart of the retainer types is presented in Figure 4.2.

![Flow chart of the retainer types](image)

**Figure 4.2. Flow chart of the 61 participants’ retainer types**

Key: BR = Bonded Retainer.

RRs = Removable Retainer.

28 P: patients who had both 1 BR and 1 RR fitted; they were paired observations and thereby fitted into both the study and control groups.

The total study cohort consisted of 61 patients who were grouped as shown in the flow chart in Figure 4.2. There were 12 patients who had one arch treatment only and 49 who had two arch treatment. The study groups were made up of the following; 18 (15 females [F] + 3 males [M]) patients had only BRs fitted; 28 (20 F + 8 M) had one BR and one RR fitted and 15 (11 F + 4 M) had only RRs fitted. The 28 who had both a BR and a RR fitted are paired observations and were thereby included in both the study and control groups. This made the
study more efficient since 28 BR and 28 RR sites are more similar thus reducing variance and therefore number requirements.\textsuperscript{193} In summary:
The total study cohort = 61 patients (46 F and 15 M)

NSG = 46 (35 F + 11 M) with 55 BRs.

NCG = 43 (31 F + 12 M) with 55 RRs.

For the NSG, the duration since active treatment was completed and BRs were fitted ranged from 15 to 22 years (average = 17.3 years); for the NCG, the range was 16 to 28 years (average = 19.3 years).

### 4.1.2 Gender and bonded retainer (BR) types

Table 4.1. The gender of patients and their bonded retainer (BR) types

<table>
<thead>
<tr>
<th>Bonded Retainer (BR) type</th>
<th>No of bonds</th>
<th>Females</th>
<th>Males</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>BRs Bonds</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Maxilla;</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>a. 3-3</td>
<td>6 15 5</td>
<td>20</td>
<td>120</td>
<td></td>
</tr>
<tr>
<td>b. 2-2</td>
<td>4 13 3</td>
<td>16</td>
<td>64</td>
<td></td>
</tr>
<tr>
<td>c. 1-1</td>
<td>2 4 1</td>
<td>5</td>
<td>10</td>
<td></td>
</tr>
<tr>
<td>Mandible;</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>d. 3-3</td>
<td>6 3 2</td>
<td>5</td>
<td>30</td>
<td></td>
</tr>
<tr>
<td>e. 3-3</td>
<td>2 7 2</td>
<td>9</td>
<td>18</td>
<td></td>
</tr>
<tr>
<td>Totals</td>
<td>35 (7 x2 BRs)</td>
<td>11 (2x2 BRs)</td>
<td>55</td>
<td>242</td>
</tr>
</tbody>
</table>

Table 4.1 shows the gender of the BR patients. There were 35 female patients, 28 had one BR and seven had two BRs. There were 11 male patients, 9 had one BR and two had two BRs. The different types of BRs used consisted of the following: in the maxilla, there were 20 of the six unit retainers (3-3), 16 of the four unit retainers (2-2) and five of two units retainers (1-1). In the mandible, there were five of the six unit retainers (3-3), and nine of the two unit retainers (bonded only to the lower canines). The total number of bonded retainers was 55 and these were secured to the anterior teeth with 242 composite bonds.

### 4.1.3 Gender and removable retainer (RR) types

Table 4.2. The gender of patients and their removable retainer (RR) types

<table>
<thead>
<tr>
<th>Removable Retainer</th>
<th>Females</th>
<th>Males</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient number</td>
<td>30</td>
<td>13</td>
<td>43</td>
</tr>
<tr>
<td>Number with 1 RRs</td>
<td>21</td>
<td>10</td>
<td>31</td>
</tr>
<tr>
<td>Number with 2 RRs</td>
<td>9</td>
<td>3</td>
<td>12</td>
</tr>
<tr>
<td>Maxillary Hawley Retainer</td>
<td>12</td>
<td>6</td>
<td>18</td>
</tr>
<tr>
<td>Mandibular Spring aligner Ret</td>
<td>27</td>
<td>10</td>
<td>37</td>
</tr>
</tbody>
</table>

Table 4.2 shows the gender of the RR patients. There were 30 female patients, 21 had one RR and 9 had two RRs. There were 13 male patients, 10 had one RR and 3 had two RRs.

The types of RRs used were Hawley in the maxilla and Spring aligners in the mandible (see Figure 1.80 page13). The total number of removable retainers was 55 (18 Hawley and 37 Spring aligner).
4.1.4 A unique group: 30 patients who wore a RR that was replaced within six months with a BR

Prior to 1993, BRs were not routinely fitted to all patients by the CR when active treatment was completed. In the NSG group of 46 patients, 30 had experienced both a RR and later a BR in the same arch. This came about as a result of these 30 patients completing active treatment and initially having RRs fitted, however, within less than 6 months it became apparent that their treated occlusions were too unstable for the RRs to maintain alignment. It was then decided to retreat (where necessary) those patients where relapse was occurring and fit BRs to ensure that ideal alignment was achieved and maintained. This group of 30 patients was unique in that they had experienced wearing a RR and within six months, a BR in the same arch(s). These patients were therefore better able to assess the merits and shortcomings of both retainer types.

4.2 General patient information

4.2.1 Demographic information

All of the demographic information is presented as graphs and measured as percentages wherever possible. The patient groups were arranged as the following. The NSG was made up of 46 patients from three BR sub-groups; those with a BR in the maxilla, the mandible, or both. The NCG is presented as the control group of only those 15 patients who did not have BRs fitted. **The paired group of 28 patients was included only in the NSG for the demographic analysis. It was too complicated to assess in both groups and the demographic information was a peripheral issue to the BR theme.** The statistical analysis involved Pearson Chi-Squared tests and the level of significance was set at $p < 0.05$. The $p$ value representing the statistical significance between the two groups was attached to each graph.

4.2.1.1 Ethnicity of Patients

There were 60 Caucasians and one (NSG) female Asian patient.

4.2.1.2 Malocclusion types.

**Table 4.3. Malocclusion types found in the study groups**

<table>
<thead>
<tr>
<th>Patients</th>
<th>Number</th>
<th>Class I</th>
<th>Class II Div 1</th>
<th>Class II Div 2</th>
<th>Class III</th>
</tr>
</thead>
<tbody>
<tr>
<td>NSG</td>
<td>46 with 27 #</td>
<td>28</td>
<td>6</td>
<td>8</td>
<td>4</td>
</tr>
<tr>
<td>NCG</td>
<td>15 with 10 #</td>
<td>8</td>
<td>4</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Total</td>
<td>61 with 37 #</td>
<td>36 with 18 #</td>
<td>10 with 7 #</td>
<td>9 with 9 #</td>
<td>6 with 3 #</td>
</tr>
</tbody>
</table>

# Number of extraction cases

Table 4.3 shows the malocclusion types found in the total study group. There was a normal spread of malocclusion types in both the NSG and NCG.
### 4.2.1.3 Marital status

Overall, of the 61 patients, 67% were married, 16% were in de-facto relationships and 17% were single. In the female group 76% were married, 13% were in de facto relationships and 11% were single. In the male group, 40% were married, 27% were in de-facto relationships and 33% were single. Statistical analysis found there was no statistically significant difference between the NSG and the NCG in marital status \((p = 1.435)\).

### 4.2.1.4 Gender of the study groups

The majority of patients (74%) were females and 26% were male. Statistical analysis (Pearson Chi-Squared test) found there was a statistically significant difference between the NSG and the NCG for gender \((p = 0.046)\).
4.2.1.5 Ages of the study groups

The majority of the study group (65%) were younger than 40 years and there were more of the younger patients in the NSG than in the NCG. However, statistical analysis (Pearson Chi-Squared test) found there was no statistically significant difference in ages between the NSG and the NCG ($p = 0.539$).

4.2.1.6 Education levels

The Higher School certificate was achieved by 21% of patients, 34% achieved a certificate or diploma and 45% had achieved a university degree or higher. The NCG had more high school only graduates, fewer certificate or diploma graduates, no university graduates, but more graduates with higher university degrees. Statistical analysis (Pearson Chi-Squared test) found there were statistically significant differences in the education levels between the NSG and the NCG ($p = 0.010$). No comment is proposed as to why there is a difference.
4.2.1.7 Self-reported general health

Figure 4.7. Self-reported general health of the study groups (p = 0.439)

Ninety eight percent of patients reported they were in good, very good, or excellent health, while 2% reported being in poor health. Statistical analysis (Pearson Chi-Squared test) found there was no statistically significant difference in general health between the NSG and the NCG (p = 0.439).

4.2.1.8 Self-reported smoking history

Figure 4.8. Self-reported smoking history of the study groups (p = 0.849)

Fifty-four percent of patients reported that they had never smoked, 15% said they used to smoke and 31% smoked either occasionally or regularly. Statistical analysis (Pearson Chi-Squared test) found there was no statistically significant difference in smoking habits between the NSG and the NCG (p = 0.849).
4.3 Dental health practices

4.3.1 Patients’ self-reported frequency of brushing their teeth

Figure 4.9. Patients’ self-reported frequency of brushing their teeth (p = 0.052)

All patients reported brushing their teeth daily; 15% said they brushed once-a-day, 75% twice a day and 10% reported brushing three times a day. Statistical analysis (Pearson Chi-Squared test) found there was no statistically significant difference in the brushing frequencies between the NSG and the NCG (p = 0.052).

4.3.2 Patients’ self-reported frequency of using dental floss

Figure 4.10. Patients’ self-reported frequency of using dental floss (p = 0.922)

Daily flossing was done by 33% of patients with 5% flossing twice each day, 15% reported that they flossed weekly, 23% flossed monthly and 24% never used dental floss. Statistical analysis (Pearson Chi-Squared test) found there was no statistically significant difference in the flossing routines between the NSG and the NCG (p = 0.922).
4.3.3 Patients’ self-reported frequency of using toothpicks

![Graph showing toothpick frequency](image)

Figure 4.11. Patients’ self-reported frequency of using toothpicks (p = 0.130)

Toothpicks were used every day by 15% of patients, 10% reported that they used toothpicks weekly, 13% monthly and 62% reported they never used toothpicks. Statistical analysis (Pearson Chi-Squared test) found there was no statistically significant difference in the use of toothpicks between the NSG and the NCG (p = 0.130).

4.3.4 Patients’ self-reported frequency of dental check-up visits

![Graph showing check-up frequency](image)

Figure 4.12. Patients’ self-reported dental check-up frequency (p = 0.615)

Fifty nine percent of patients reported that they visited their dentist once or twice each year, 18% visited once every two years while 23% reported that they never visited a dentist; they may have visited a dentist only on ‘a need to go basis’. Statistical analysis (Pearson Chi-Squared test) found there was no statistically significant difference in the frequency of dental checkups between the NSG and the NCG (p = 0.615).
4.3.5 Patients’ self-reported frequency of professional prophylactic scaling and cleaning

The most frequent attendees (72%) who visited their dentist more often than every two years for checkups reported that they usually had prophylactic scaling and cleaning of their teeth, 12% who visited less often than every two years reported the same and 16% reported they never had professional cleaning of their teeth. Statistical analysis (Pearson Chi-Squared test) found there was no statistically significant difference in the frequency of professional scaling and cleaning between the NSG and the NCG (p = 0.333).

4.4 Discussion on general patient information

4.4.1 General demographic variables of patients

The Australian Institute of Health and Welfare (AIHW) released the ‘Australia’s Health No 11’, Report in June 2008\(^\text{195}\). This report provided relevant demographic information for comparisons with the sample in this orthodontic study.

The NEOTS study group is made up of a sample of adults, three quarters were women and two thirds were between 27 and 40 years of age. The gender ratio discrepancy was not unexpected as the orthodontic practice where this study was done has a recorded gender patient ratio of two thirds female to one third male.\(^\text{101}\)

The general health of the patients in this study was self-reported as being between good and excellent for 98% of participants. This is slightly above the figure of 95% from the AIHW report.\(^\text{195}\)

The educational levels of the study group were well above the community average with 79% having higher educational qualifications compared to the 51.4% in the AIHW report and 45% having a university degree or higher compared to the AIHW figure which is 20.6%.
The percentage of those who smoked either occasionally or regularly was 31% which is above the AIHW figure of 19.8%. The figures on smoking are unusual in that the expected trend is for people who are better educated will smoke less, 19.8% from the AIHW compared to 31% for this study group. The statistics on smoking as reported by the AIHW report are not consistent with those figures reported by Hill et al\textsuperscript{196} in 1995. The Hill et al\textsuperscript{196} study reported that for adults in a comparable age range (30 and 50 years) approximately 30% would be smokers; these figures are similar to those seen in this study (31%). Overall, there were few differences between the NSG and NCG in regards to their demographics.

4.4.2 Dental health practices of patients

A literature search revealed one large survey of people’s dental health practices that could be used for comparative analysis; this was an adult dental health survey carried out in the United Kingdom (UK) in 1998.\textsuperscript{197} The UK survey was used for comparison in this study because of the similarity in the two societies.

The UK survey reported that 59% of people between the ages of 35 and 45 years had regular dental check-ups and 30% only attended when they had trouble with their teeth. This study group had similar check-up rates, 59% of patients visited their dentist once or twice a year, 18% once every two years, and 23% attended less often than once every two years.

In this study group, 100% of patients brushed their teeth every day, 75% brushed twice a day, 15% once a day, and 10% three times a day. These figures are similar to the UK survey in which 96% of patients brushed their teeth every day; 74% cleaned their teeth at least twice a day, 22% once a day and 4% less than once a day.

Within this study group, 38% of patients reported using dental floss every day and 23% never used dental floss. This compared to the UK survey that found 28% of people were regular users of dental floss, the number who never used dental floss was not reported. In this survey, 15% of patients used toothpicks every day, 62% never used toothpicks and the remainder used them infrequently, either weekly (10%), or monthly (13%). The use of toothpicks was not reported in the UK survey.

With regards to having their teeth professionally prophylaxed and cleaned, 56% of respondents in this study did so yearly, 28% every two years or more and 16% reported that they never had professional cleaning of their teeth. The UK survey did not include professional prophylaxes and cleaning data in their report.

In conclusion, the patients in this study generally had similar attitudes to those of the general public in the UK towards visiting the dentist and cleaning their teeth. There was a lower than expected rate of both the use of adjunct inter-dental cleaning aids and professional prophylaxis and cleaning of teeth.

The dental health practices analysis found that within the study groups, there were no statistically significant differences between the NSG and the NCG for the following: brushing, p
= 0.052; for using dental floss, p = 0.922; for using toothpicks, p = 0.130; for dental checkups, p = 0.615 and for having professional prophylactic scaling and cleaning, p = 0.333.

Overall, there were only minor differences between the NSG and NCG in regards to their dental health practices.

### 4.5 Measurements of validity and reliability of the chief researchers (CR’s) measures / comparative analysis (CA)

The measures were of the same groups of patients done by four examiners, two were from External Examiners and two were from the CR done six months apart.

The measurements of bias and precision were determined using Bland Altman plots as shown in Figures 4.14 to 4.22. The differences in agreement between two examiners are plotted on the Y axis against the averages (mean) differences of the two examiners on the X-axis. Ideally, the differences should be 0.00. However, the differences or bias are presented by a line above or below the 0.00 line; a positive bias is a line above the 0.00 line and a negative bias is one below the 0.00 line. The height of the line determines the level of bias and the slope shows how the bias changes. The clinical significance of the bias is determined by the upper bound of the Index being measured; if the bias is within the upper bound limit, the bias is considered clinically insignificant. Precision was assessed by examining the range of the differences.

#### 4.5.1 Little’s Irregularity Index (LII) Bland-Altman plots

Significance determined by Spearman’s rank correlation coefficient ($r$) Significance (2-tailed) and p set at < 0.05. Upper bound was set at < 3.0 mm (minimal acceptable irregularity in Little’s Irregularity Index (LII)). Bland-Altman plots for comparing agreement between two examiners for the measures of incisor dental alignment irregularity are shown in Figure 4.14.
Examiners EX2.O and CR1

Examiners EX2.O and CR2

Examiners EX2.O and EX1.O1

Examiners CR.1 and CR2

Figure 4.14. The Bland Altman plots of comparing agreement for Little’s Irregularity Index (LII) as measured by the examiners EX1.O, EX2.O, CR1 and CR2

Table 4.4. Comparative analyses for the Little’s Irregularity Index (LII) between examiners EX1.O, EX2.O, CR1 and CR2. LII upper bound limit for clinical significance is < 3 mm

<table>
<thead>
<tr>
<th>Examiners</th>
<th>SCC* [r]</th>
<th>Variable bias present</th>
<th>Mean Range of differences</th>
<th>Clinical Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>EX1.O - CR1</td>
<td>0.086</td>
<td>No. p = 0.73</td>
<td>0.6 ~ 1.2</td>
<td>Nil</td>
</tr>
<tr>
<td>EX1.O - CR2</td>
<td>0.212</td>
<td>No. p = 0.21</td>
<td>0.3 ~ 1.5</td>
<td>Nil</td>
</tr>
<tr>
<td>EX2.O - CR1</td>
<td>0.092</td>
<td>No. p = 0.70</td>
<td>-0.3 ~ 0.2</td>
<td>Nil</td>
</tr>
<tr>
<td>EX2.O - CR2</td>
<td>0.086</td>
<td>No. p = 0.72</td>
<td>-0.2 ~ 0.4</td>
<td>Nil</td>
</tr>
<tr>
<td>CR1 - CR2</td>
<td>0.268</td>
<td>No. p = 0.25</td>
<td>-0.4 ~ 0.6</td>
<td>Nil</td>
</tr>
<tr>
<td>EX2.O - EX1.O</td>
<td>0.305</td>
<td>No. p = 0.20</td>
<td>-0.4 ~ 1.4</td>
<td>Nil</td>
</tr>
</tbody>
</table>

SCC* Spearman’s rank correlation coefficient [r]; (ideal outcome is 0.000)

4.5.2 Discussion for Little’s Irregularity Index (LII) comparative analysis (CA)

The LII is regarded within the orthodontic profession as being the gold standard for assessing the amount of relapse that occurs after treatment. Hence, it was adopted for this study to assess the effectiveness of BR for maintaining the alignment achieved by orthodontic
treatment of patients over the long term of 15 years. The LII measurements recorded for the
other groups of different patients by the examiners were over a range of about 0 to 10 mm.

Table 4.4. shows the difference in the Bland Altman plots between the examiners; these
were used to assess both the precision (variability) of measurements and the possible presence
of bias, that is, one examiner having systematically different results to the other. The Spearman
correlations were used to test if there were systematic differences that were increasing or
decreasing over the range of the measurements.

4.5.2.1 Precision

For the Little’s irregularity index (LII), the upper bound of acceptable irregularity is < 3
mm. In this study, at the lower levels, the differences between examiners were of the order of
about 0.5 mm or less. At the higher end of the range, the discrepancies were of the order of 1.0
to 1.5 mm. These differences were not substantial enough to change any conclusions about the
state of the alignment of the teeth. So the precision is considered satisfactory.

4.5.2.2 Bias

Systematic differences are of two types, a constant difference of the whole range of
measurement, or a variable difference where for example, the difference increases at larger
values. The Spearman correlations were used to statistically check on the second type of
systematic difference and as they were all not significant it could be concluded there is no
evidence of this kind of bias between the examiners. The Bland-Altman plots suggested a
possible bias in three of six cases and these all involved examiner EX1.0, but were judged to be
small and not significant from the clinical perspective. The conclusions drawn from this are there
was no evidence of significant bias.

4.5.3 Conclusions for Little’s Irregularity Index (LII)

comparative analysis (CA)

The acceptable range of incisor irregularity for the (LII) is < 3 mm. Agreement between
examiners for the LII was assessed to be accurate and valid with acceptable precision (0.5 to
1.5 mm). There was an absence of significant biases; this was true for both the inter- and intra-
examiner perspectives.

4.6 Comparative analysis (CA) results for Dental Health

Indices (DHIs)

Two external specialist periodontists (EX3.P and EX4.P), individually (blind) measured
the Dental Health Indices of a group of 10 randomly selected participants. Their results were
compared to those of CR1 and CR2 for inter- examiner comparative analysis using Bland
Altman plots and Spearman’s rank correlation coefficient [r] (SCC) analysis, Significance (2-tailed) and set at 0.05.
Dental Health Indices (DHIs)

1. Decay Index (DI)
2. Plaque Index (PI)
3. Calculus Index (CI)
4. Gingival Recession Index (GRI)
5. Modified Gingival Index (MGI)
6. Alveolar Bone Index (ABI)

The measures were rated as: very good, good, fair, poor and very poor.

4.6.1 Decay Index (DI) comparative analysis (CA)

There were no recordings of dental decay or sub-surface de-calcification associated with any of the BRs, nor were there any within the control group (RR) dentitions.

4.6.1.1 Discussion for the Decay Index (DI) comparative analysis (CA)

This study found there was no difference between the NSG and the NCG for the Decay Index on the lingual or palatal surfaces of the anterior teeth.

4.6.1.2 Conclusions on the Decay Index (DI) comparative analysis (CA)

The presence of BRs did not increase the risk of decay occurring on the lingual or palatal surfaces of the anterior teeth.

4.6.2 Plaque Index (PI) comparative analysis (CA)

Significance determined by Spearman's rank correlation coefficient (r). Significance (2-tailed) and p set at < 0.05. Upper bound set at ≤ 1.5. The Plaque Index Bland Altman plots of comparing agreement between Examiners EX3.P, EX4.P, CR1 and CR2 are shown in Figure 4.15.
Examiners EX4.P and CR1

Examiners EX3.P and EX4.P

Examiners CR1 and CR2

**Figure 4.15.** The Bland Altman plots of comparing agreement for the Plaque Index (PI) as measured by the examiners EX1.O, EX2.O, CR1 and CR2

<table>
<thead>
<tr>
<th>Examiners</th>
<th>SCC* [r]</th>
<th>Variable bias present</th>
<th>Mean Range of differences</th>
<th>Clinical Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>EX3.P-CR1</td>
<td>0.235</td>
<td>No. p = 0.24</td>
<td>-0.6 ~ 0.35</td>
<td>Nil</td>
</tr>
<tr>
<td>EX3.P-CR2</td>
<td>0.095</td>
<td>No. p = 0.64</td>
<td>0.1 ~ 0.02</td>
<td>Nil</td>
</tr>
<tr>
<td>EX4.P-CR1</td>
<td>0.494</td>
<td>Yes p = 0.002</td>
<td>-0.2 ~ 0.6</td>
<td>Nil</td>
</tr>
<tr>
<td>EX4.P-CR2</td>
<td>0.207</td>
<td>No. p = 0.22</td>
<td>0.0 ~ 0.5</td>
<td>Nil</td>
</tr>
<tr>
<td>CR1-CR2</td>
<td>0.262</td>
<td>No. p = 0.11</td>
<td>0.2 ~ 0.15</td>
<td>Nil</td>
</tr>
<tr>
<td>EX3.P-EX4.P</td>
<td>0.364</td>
<td>No. p = 0.07</td>
<td>0.1 ~ 0.6</td>
<td>Nil</td>
</tr>
</tbody>
</table>

SCC* Spearman’s rank correlation coefficient [r]; (ideal outcome is 0.000)

### 4.6.2.1 Discussion on Plaque Index (PI) comparative analysis (CA)

Table 4.5 shows the PI assessment; all of the examiners were in general agreement with the majority of their assessments being in the very good and good ranges. While there was one statistically significant different score from the six comparisons (EX4.P-CR1: p = 0.002), this was not of clinical significance as the mean range of difference of -0.2 to 0.6 was below the upper bound of ≤ 1.5.

### 4.6.2.2 Conclusions on Plaque Index (PI) comparative analysis (CA)

The upper bound for the PI was set at ≤ 1.5. There were three instances of variable bias between EX3.P and CR1 and CR2; and also between EX3.P and EX4.P. However, these
biases were not clinically significant. Overall, agreement between the examiners for the PI was assessed to be accurate and valid with acceptable precision (-0.2 to 0.6). There was an absence of clinically significant biases; this was true for both the inter- and intra-examiner perspectives.

### 4.6.3 Calculus Index (CI) comparative analysis (CA)

Significance determined by Spearman’s rank correlation coefficient (r). Significance (2-tailed) and p set at < 0.05. Upper bound was set at ≤ 1.5. The Calculus Index (CI) Bland-Altman plots of comparing agreement between Examiners EX3.P, EX4.P, CR1 and CR2 are shown in Figure 4.16.

![Bland-Altman plots](image)

**Figure 4.16.** The Bland Altman plots of comparing agreement for the Calculus Index (CI) as measured by the examiners EX1.O, EX2.O, CR1 and CR2
Table 4.6. Comparative analyses for the Calculus Index (CI) between examiners EX3.P, EX4.P, CR1 and CR2. CI upper bound limit for clinical significance was set at ≤ 1.5

<table>
<thead>
<tr>
<th>Examiners</th>
<th>SCC* [r]</th>
<th>Variable bias present</th>
<th>Mean Range of differences</th>
<th>Clinical Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>EX3.P-CR1</td>
<td>0.667</td>
<td>Yes. p = 0.000</td>
<td>0.0 ~ 0.7</td>
<td>Nil</td>
</tr>
<tr>
<td>EX3.P-CR2</td>
<td>0.554</td>
<td>Yes. p = 0.001</td>
<td>0.0 ~ 0.7</td>
<td>Nil</td>
</tr>
<tr>
<td>EX4.P-CR1</td>
<td>0.023</td>
<td>No. p = 0.87</td>
<td>-0.02 ~ 0.03</td>
<td>Nil</td>
</tr>
<tr>
<td>EX4.P-CR2</td>
<td>0.080</td>
<td>No. p = 0.84</td>
<td>-0.02 ~ 0.05</td>
<td>Nil</td>
</tr>
<tr>
<td>CR1-CR2</td>
<td>0.070</td>
<td>No. p = 0.67</td>
<td>0.0 ~ 0.0</td>
<td>Nil</td>
</tr>
<tr>
<td>EX3.P-EX4.P</td>
<td>0.590</td>
<td>Yes. p = 0.000</td>
<td>0.06 ~ 0.55</td>
<td>Nil</td>
</tr>
</tbody>
</table>

SCC* Spearman’s rank correlation coefficient [r]; (ideal outcome is 0.000)

Discussion on Calculus Index (CI) comparative analysis (CA)

Table 4.6 shows there were variable biases present between the examiners when measuring the CI. While CR1 was in good agreement with EX4.P and himself CR2, there were noticeable differences with EX3.P for both the CR1 and CR2 measures, and also between the two external specialist examiners EX3.P and EX4.P. However, the averaged amounts of calculus present were generally minor (Score of ≤ 1) and in amounts what are commonly seen in the general population. The measures made by EX3.P were consistently higher than the other two examiners inferring a bias of interpretation. To demonstrate this, Figure 4.17 shows a patient with calculus in the lingual anterior mandibular region and the measurements scored by EX3.P who rated it at two (two thirds enamel coverage with calculus), EX4.P, CR1 and CR2 all rated it at 1 (one third enamel coverage with calculus).

Figure 4.17. Demonstrating calculus deposits rated by one examiner at level 2 (67% enamel coverage) and the other two examiners at level 1 (< 33% enamel coverage)

4.6.3.1 Conclusions on Calculus Index (CI) comparative analysis (CA)

The acceptable range of the CI was set at ≤ 1.5. Agreement between examiners for the CI was assessed to be accurate and valid with acceptable precision (-0.02 to 0.7). There was an absence of clinically significant biases; this was true for both the inter- and intra-examiner perspectives.

4.6.4 Gingival Recession Index (GRI) comparative analysis (CA)

Significance determined by Spearman’s rank correlation coefficient (r). Significance (2-tailed) and p set at < 0.05. Upper bound set at ≤ 1.5mm. The Gingival Recession Index (GRI)
Bland Altman plots of comparing agreement between examiners EX3.P, EX4.P, CR1 and CR2 are shown in Figure 4.18.

Figure 4.18. The Bland Altman plots of comparing agreement for the Gingival Recession Index (GRI) as measured by the examiners EX1.O, EX2.O, CR1 and CR2
Table 4.7. Comparative analyses for the Gingival Recession Index (GRI) between examiners EX3.P, EX4.P, CR1 and CR2. GRI upper bound limit for clinical significance was a score of ≤ 1.5 mm

<table>
<thead>
<tr>
<th>Examiners</th>
<th>SCC* [r]</th>
<th>Variable bias present</th>
<th>Mean Range of differences</th>
<th>Clinical Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>EX3.P-CR1</td>
<td>0.695</td>
<td>Yes. ( p = 0.000 )</td>
<td>0.2 ~ 1.75</td>
<td>Minor</td>
</tr>
<tr>
<td>EX3.P-CR2</td>
<td>0.663</td>
<td>Yes. ( p = 0.000 )</td>
<td>0.2 ~ 1.6</td>
<td>Minor</td>
</tr>
<tr>
<td>EX4.P-CR1</td>
<td>0.137</td>
<td>No. ( p = 0.42 )</td>
<td>-0.1 ~ 0.7</td>
<td>Nil</td>
</tr>
<tr>
<td>EX4.P-CR2</td>
<td>0.062</td>
<td>No. ( p = 0.089 )</td>
<td>-0.1 ~ 0.5</td>
<td>Nil</td>
</tr>
<tr>
<td>CR1-CR2</td>
<td>0.279</td>
<td>No. ( p = 0.086 )</td>
<td>-0.02 ~ 0.22</td>
<td>Nil</td>
</tr>
<tr>
<td>EX3.P-EX4.P</td>
<td>0.590</td>
<td>Yes. ( p = 0.000 )</td>
<td>0.02 ~ 0.55</td>
<td>Nil</td>
</tr>
</tbody>
</table>

SCC* Spearman's rank correlation coefficient [r]; (ideal outcome is 0.000)

**4.6.4.1 Discussion on Gingival Recession Index (GRI) comparative analysis (CA)**

From Table 4.7, the GRI was assessed from both the labial and lingual/palatal surfaces of the anterior teeth. Gingival recession was often seen on the labial surface but this was more to do with excessive brushing rather than from periodontal disease. Gingival recession on the lingual surfaces was rarely seen.

There were biases present in assessing the GRI, particularly where examiner EX3.P was involved. EX3.P’s measures were generally higher and most different to those of CR1, CR2 and EX4.P. However, these biases were consistent and most were of minor clinical significance being within the upper bound of 1.5mm. An example of the difference between the examiners is demonstrated in Figure 4.19. For the GRI (average) in the mandibular anterior labial region, EX3.P rated the GRI value at 2, EX4.P rated the value at 0.33 and CR1 and CR2 rated the value at zero.

![Figure 4.19](image-url)

**Figure 4.19.** The average amount of gingival recession seen on the labial anterior teeth. The GRI was rated at level 2 0 mm by EX3.P, at levels 0.33 mm by EX4.P and 0 by CR1/CR2

All of the examiners found the incidence of GRI was minor (< 1.6 mm) and most often seen in patients as isolated occurrences or associated with patients who had enthusiastic tooth brushing methods.
4.6.4.2 Conclusions on Gingival Recession Index (GRI) comparative analysis (CA)

The acceptable range of for the GRI was set at \( \leq 1.5 \text{ mm} \). Agreement between examiners for the GRI was assessed to be valid with acceptable precision (0.0 to 1.6 mm). There were statistically significant biases but the majority of these were well below the upper bound set at \( \leq 1.5 \text{ mm} \) and these were generally not clinically significant; this was true for both the inter- and intra-examiner perspectives.

4.6.5 Modified Gingival Index (MGI) Comparative Analysis (CA)

Significance determined by Spearman's rank correlation coefficient (r) Significance (2-tailed) and \( p \) set at < 0.05. Upper bound was set at \( \leq 1.5 \). The Modified Gingival Index (MGI) Bland Altman plots of comparing agreement between EX3.P, EX4.P, CR1 and CR2 are shown in Figure 4.20.
Chapter 4 Results and Discussions

Figure 4.20. The Bland Altman plots of comparing agreement for the Modified Gingival Index (MGI) as measured by the examiners EX1.O, EX2.O, CR1 and CR2.

Table 4.8. Comparative analyses for the Modified Gingival Index (MGI) between examiners EX3.P, EX4.P, CR1 and CR2. MGI upper bound limit for clinical significance was a score of ≤ 1.5

<table>
<thead>
<tr>
<th>Examiners</th>
<th>SCC* [r]</th>
<th>Variable bias present</th>
<th>Mean Range of differences</th>
<th>Clinical Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>EX3.P-CR1</td>
<td>0.579</td>
<td>Yes. p = 0.000</td>
<td>0.2 ~ 1.6</td>
<td>Minor</td>
</tr>
<tr>
<td>EX3.P-CR2</td>
<td>0.740</td>
<td>Yes. p = 0.000</td>
<td>0.2 ~ 1.9</td>
<td>Minor</td>
</tr>
<tr>
<td>EX4.P-CR1</td>
<td>0.479</td>
<td>Yes. p = 0.004</td>
<td>0.1 ~ 0.7</td>
<td>Nil</td>
</tr>
<tr>
<td>EX4.P-CR2</td>
<td>0.568</td>
<td>Yes. p = 0.000</td>
<td>0.1 ~ 0.9</td>
<td>Nil</td>
</tr>
<tr>
<td>CR1-CR2</td>
<td>0.255</td>
<td>No. p = 0.117</td>
<td>0.0 ~ 0.25</td>
<td>Nil</td>
</tr>
<tr>
<td>EX3.P-EX4.P</td>
<td>0.294</td>
<td>No. p = 0.114</td>
<td>0.25 ~ 0.8</td>
<td>Nil</td>
</tr>
</tbody>
</table>

SCC* Spearman’s rank correlation coefficient [r]; (ideal outcome is 0.000)

4.6.5.1 Discussion on Modified Gingival Index (MGI) comparative analysis (CA)

Table 4.8 shows there were biases present in the assessment of MGI between the examiners EX3.P and EX4.P with CR1 and CR2. CR1 and CR2 were consistently less critical of the periodontal health measures in their assessments, particularly towards the more severe end of the scale. However, the overall periodontal health of the patients was most often within the upper bound set at 1.5 and the differences between the examiners were not of clinical significance.

An example of the different MGI ratings by the investigators can be seen in Figure 4.21, EX3.P rated the MGI at 0.60, EX4.P rated it at 0.40 and CR1 and CR2 rated it at 0.17.
4.6.5.2 Conclusions on Modified Gingival Index (MGI) comparative analysis (CA)

The acceptable range (upper bound) for the MGI was set at ≤ 1.5 mm. The external examiner EX3.P consistently recorded higher MGI readings than the other examiners and the CR was lower in his assessments. However, agreement between examiners for the MGI was assessed to be valid with acceptable precision (0.0 to 1.9 mm). There was an absence of clinically significant discrepancies; this was true for both the inter- and intra-examiner perspectives.

4.6.6 Alveolar Bone Index (ABI) comparative analysis (CA)

Significance determined by Spearman’s rank correlation coefficient (r) Significance (2-tailed) and p set at < 0.05. Upper bound set at ≤ 2mm or ≤ 20% of alveolar bone height loss. The Alveolar Bone Index (ABI) Bland Altman plots of comparing agreement between examiners EX3.P, EX4.P, CR1 and CR2 are shown in Figure 4.22.
Figure 4.22. The Bland Altman plots of comparing agreement for the Alveolar Bone Index (ABI) as measured by the examiners EX1.O, EX2.O, CR1 and CR2

Figure 4.22 shows the plots of comparison between the four examiners for the ABI. The scores for the alveolar bone measures are only 0, 1, 2, 3, and many of the dots are superimposed if examiners have the same values. The many superimpositions of values resulted in the few number of dots on each graph.
Table 4.9. Comparative analyses for the Alveolar Bone Index (ABI) between examiners EX3.P, EX4.P, CR1 and CR2. ABI upper bound limit for clinical significance was a score of ≤ 2mm / 20%

<table>
<thead>
<tr>
<th>Examiners</th>
<th>SCC* [r]</th>
<th>Variable bias present</th>
<th>Mean Range of differences</th>
<th>Clinical Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>EX3.P-CR1</td>
<td>0.320</td>
<td>No. p = 0.056</td>
<td>-0.6 ~ 0.1</td>
<td>Nil</td>
</tr>
<tr>
<td>EX3.P-CR2</td>
<td>0.362</td>
<td>Yes. p = 0.030</td>
<td>-0.9 ~ 0.4</td>
<td>Nil</td>
</tr>
<tr>
<td>EX4.P-CR1</td>
<td>0.450</td>
<td>Yes. p = 0.004</td>
<td>-0.4 ~ 0.2</td>
<td>Nil</td>
</tr>
<tr>
<td>EX4.P-CR2</td>
<td>0.780</td>
<td>Yes. p = 0.002</td>
<td>-0.7 ~ 0.1</td>
<td>Nil</td>
</tr>
<tr>
<td>CR1-CR2</td>
<td>0.039</td>
<td>No. p = 0.809</td>
<td>-0.4 ~ 0.2</td>
<td>Nil</td>
</tr>
<tr>
<td>EX3.P-EX4.P</td>
<td>0.590</td>
<td>No. p = 0.732</td>
<td>-0.2 ~ 0.4</td>
<td>Nil</td>
</tr>
</tbody>
</table>

SCC* Spearman’s rank correlation coefficient [r]; (ideal outcome is 0.000)

4.6.6.1 Discussion on Alveolar Bone Index (ABI) comparative analysis

Table 4.9. Shows the ABI’s were most often assessed to be very good (< 10%) or good (<20%) by all examiners. The independent examiners had varying minor but statistically significant degrees of differences of opinion with the CR1 and with each other. However, there were no concerns raised regarding the BRs presenting a health risk to the alveolar bone. The amount of bone height loss was consistent with what would be accepted as normal within this age group. An example of the different ABI ratings by the different investigators can be seen in Figure 4.23; EX3.P rated the ABI at 1mm / 10% loss, EX4.P at 2mm / 20%, CR1 at 2mm / 20% and CR2 at 1mm / 10%.

Note, if concerns arose about BRs causing alveolar bone loss, long cone periapical radiographs may have been considered as radiologists regard these to be the ‘gold standard’ in accurately measuring alveolar bone height.

Figure 4.23. The alveolar bone levels seen here were rated at level 2mm (20%) loss by two examiners and at levels of 1mm (10%) loss by two examiners

4.6.6.2 Conclusions on Alveolar Bone Index (ABI) comparative analysis

The acceptable range of for the ABI was set at ≤ 2 mm (20%) bone height loss based on the average age of the study groups. Bearing in mind, the clinical significance of the discrepancies between examiners, agreement between examiners for the ABI was assessed to be valid with acceptable precision (-0.9 to 0.2 mm). There was an absence of clinically significant biases; this was true for both the inter- and intra-examiner perspectives.
4.7 General discussion on the comparative analyses (CA)

The comparative analysis results showed the differences of opinion between the examiners were greater than was originally anticipated. The varying measurement sensitivities of the examiners to different indices values were consistently reflected in their differing assessments; these differences of opinion also occurred between the external examiners.

For the periodontal measures, the Bland-Altman analysis showed there were biases present when measuring the values of the different indices but the measurements were generally within the 'very good' and 'good' ranges of measures and therefore not of clinical significance. Other than mild accumulations of dental plaque and calculus, there were no periodontal health concerns seen by any of the examiners that could be attributed to the presence of the BRs. There were no differences of clinical significance between either the inter-examiner analyses or the intra-examiner analyses.

4.8 Conclusions on the comparative analyses (CA)

Overall, there was good agreement in the Little’s Irregularity Index measures; the precision measures were satisfactory and there were no significant biases.

The Plaque Index and Calculus Index measures had satisfactory precision and were generally free of bias. There were statistically significant differences in some of the other dental health indices, (GRI, MGI and ABI) however, the majority of these biases were seen in the very good and good scores of the measures and were not large enough to be of practical or clinical importance. The Dental Health Indices generally show the periodontal health of patients was not compromised by the presence of BRs.

The conclusions that can be drawn from the Dental Health Indices comparative analysis are that although there were occasional differences in the measures of the examiners, these differences were not substantial enough to alter any conclusions about the DHI’s, hence, the precision was regarded as satisfactory and the biases that were seen were not of clinical significance.

4.9 General results and discussion

4.9.1 Effectiveness of bonded retainers (BRs)

The LII was recorded for all patients in both the maxilla and mandible to determine the effectiveness of the BRs in maintaining the achieved dental alignment corrections and to assess the amount of relapse that occurred over 15 years. Additional assessments were made to determine the degree of displacement which was attributed to where the BR was no longer attached to all six anterior teeth due to fractures of the BR wire or composite.

For the NSG, when BRs remained intact and attached to all of the anterior teeth involved, the teeth remained straight and the LII was ideal at between 0 and 0.99 mm for all
patients. If a BR was broken and repairs were not done almost immediately, the teeth associated with the fracture would often move out of alignment. An example of this is demonstrated in Figure 4.24.

Figure 4.24. The BR wire fractured (arrow) from the lateral incisor and canine which allowed these teeth to separate and rotate mesio-labially

In this study, where a BR wire was not attached to all of the anterior teeth, as with two unit and four unit BRs or where a fracture had not been repaired, the amount of irregularity which was associated with the non attachment or fracture, was factored into the calculations as a discrepancy and subtracted from the total LII measure.

Summaries of the Little’s irregularity index for the NSG and NCG are presented in Table 4.10.

Table 4.10. The Neots study group (NSG) vs. Neots control group (NCG); variations in the Little’s Irregularity Index (LII).

<table>
<thead>
<tr>
<th>Little’s irregularity index (LII)</th>
<th>Maxilla</th>
<th>Mandible</th>
<th>Totals</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scales in mm</td>
<td>NSG</td>
<td>NCG</td>
<td>NSG</td>
</tr>
<tr>
<td>0 – 0.99 mm (Ideal)</td>
<td>92.7%</td>
<td>11%</td>
<td>78.6%</td>
</tr>
<tr>
<td>1 – 2.99 mm (Acceptable)</td>
<td>7.3%</td>
<td>45%</td>
<td>21.4%</td>
</tr>
<tr>
<td>3 – 5.99 mm (Unacceptable)</td>
<td>0%</td>
<td>33%</td>
<td>0%</td>
</tr>
<tr>
<td>&gt; 6 mm (Severe)</td>
<td>0%</td>
<td>11%</td>
<td>0%</td>
</tr>
<tr>
<td>Average</td>
<td>0.21mm</td>
<td>3.13 mm</td>
<td>0.4mm</td>
</tr>
</tbody>
</table>

Fisher’s exact test – (two tailed), level of significance set at \( p \leq 0.05 \)

There were no statistically significant differences between the NSG and NCG in the mandibular assessments for acceptable relapse (1-2.99 mm) and severe relapse > 6mm. The same also applied for severe relapse in the maxilla, and the maxilla and mandible combined. All other measures showed there were statistically significant differences between the NSG and the NCG. The NSG experienced very little relapse when the BR remained intact (LII < 0.99 mm for 89% of patients and < 3 mm for 100%). Acceptable relapse of< 3 mm occurred in the remaining 11% and was observed with mandibular BR where the lower incisors were not attached to the BR wire and/or where wire fractures had occurred.
The NCG patients were given Hawley and/or spring aligners RRs after completing their active treatment. Fifteen years later, approximately 7% experienced no relapse with LII < 0.99 mm, 40% experienced acceptable relapse movements between 1 - 2.99 mm, 42% experienced unacceptable relapse movements of between 3 - 5.99 mm and 11% experienced severe relapse of > 6 mm.

There were statistically significant differences in the LII seen between the NSG and the NCG for both acceptable alignment (LII 0 - 2.99 mm, p = 0.0001) and unacceptable alignment (LII > 2.99 mm, p = 0.0001). This highlighted both the effectiveness of BRs for maintaining dental alignment in the NSG and the relapse that occurs after patients in the NCG stopped wearing their RRs.

4.9.1.1 Discussion regarding the effectiveness of bonded retainers (BRs)

After 15 years, the effectiveness of the BRs used in this study was found to be excellent when no fractures occurred (p = 0.0001) and the rate of fracturing was low at 0.58% per unit bond/wire pa. If the wire or composite bonds did fracture, the teeth involved would usually move out of alignment. This is demonstrated in the Figure 4.24 where a patient’s maxillary wire fractured off a lateral incisor and canine and small spaces developed.

The images in Figure 4.25 demonstrate the relapse movement that occurred after a BR wire was removed from the palatal surface of four upper incisors approximately five years earlier. Since the removal of the BR, the central and lateral incisors had moved but not as yet to a degree that was of concern to the patient.

![Figure 4.25. Relapse tooth movement seen (arrows) five years after removal of a Mx BR](image)

If a mandibular BR was not attached to all of the anterior teeth, occasionally some of these teeth move out of alignment as is shown in Figure 4.26. This type of movement was observed in 24% of similar BR cases in this study.
4.9.1.2 Effectiveness of bonded retainers (BRs): conclusions

This study found that after 15 years, the BRs were effective at maintaining the achieved orthodontic alignment. When BR fractures did occur, if they were repaired soon thereafter, the dental alignment would be maintained, if not, a minor amount of relapse usually occurred as is shown in Figure 4.24.

4.9.2 Durability of bonded retainers (BRs)

Fifteen NSG patients reported breaking their BRs and three had broken their BRs on two occasions; this brought the total reported breakages to 18.

The clinical examination revealed five broken wires and three detached bonds in six patients. Most patients in this group were unaware of their breakages and had not noticed any tooth movement; the amount of tooth movement that had occurred was < 3mm (LII) in all cases. Overall, 21 patients out of the 46 in the NSG had experienced 26 fractures in 15 years.

4.9.2.1 Fracture rate of bonded retainers (BRs)

There were 55 BRs (55 wires) held in place by 242 composite bonds. The total number of units that could fracture was 297 (55+242). The total number of fractures recorded in 15 years was 26 made up of 21 bonds (81%) and five wires (19%). The total unit bond/wire fracture percentage in 15 years was 8.754%; this amounted to a net BR fracture rate of 3.15% pa and a net unit bond/wire fracture rate of 0.58% pa.

4.9.2.2 Reasons for fractures

The reasons patients gave for fractures occurring included the following: Nine (35%) said biting something hard, 12 (46%) said they didn't know, “it just broke”, and five patients (19%) experienced wire breakages but they were unaware of them.

4.9.2.3 Discussion regarding the durability of bonded retainers (BRs)

The long-term durability of BRs was acceptable as the net unit bond/wire fracture rate in this study was found to be 0.58% pa and the net BR fracture rate was 3.1% pa. This compares favourably with the recorded fracture rate of 5% pa for orthodontic appliances and of between two and 14.5% pa for the dental restorations. It also compares well with other reported fracture rates of BRs ranging from 0.08 to 23.3 as shown in Table 2.1 (page26-27). Whenever a fracture does occur, repairs can be completed effectively and efficiently with the readily
available composite materials and wires. Figure 4.27 and Figure 4.28 show repairs that were completed nine and eight years prior to this study. Cerny noted that the average clinical time required to achieve these repairs is approximately 15 minutes per unit bond.

![Figure 4.27. Repairing of BR wire fracture. The BR wire was repaired between the central and lateral incisors (arrow) nine years prior to this image being taken](image)

![Figure 4.28. Repairing of BR composite fracture. The lateral incisor bond (arrow) had been broken and a composite repair was done eight years prior to this image being taken](image)

4.9.2.4 Conclusions on the durability of bonded retainers (BRs)

This 15 year retrospective study found that BRs of the type described in Chapter 3 had a fracture rate of 0.58% unit bond/wire pa.

4.10 Results of Dental Health Impacts

This part of this study focused on the areas of the dentition that were adjacent to BRs in the NSG and equivalent areas in the NCG patients who had worn RRs. The results of the dental health impacts are shown in the following graphs. The graphs presented here measure four separate groups of patients (P) as determined by the location of the wire (BR) in the anterior regions of the dentition. The wire location was the most important feature of this study as it was expected to highlight any significant dental health impacts from wearing a BR.

- In the maxilla, BR on the palatal surface; No = 32.
- In the mandible, BR on the lingual surface; No = 5.
- BRs in both the maxilla (palatal) and the mandible (lingual); No = 9x2 =18.
- Where no BR (wire) was present, that is, the NCG (control group); No = 55.

The total number of NSG patients = 46 with 55 BR sites.

The total number of NCG patients = 43 with 55 RR sites.
Labial measurements were also done on the same teeth for comparative analysis. The values of the assessments were rated as either: Very Good; Good; Fair; Poor; Very Poor.

The statistical significance between the NSG group and the NCG group was assessed by the Fisher's exact test, (2 tailed), significance level set at $p \leq 0.05$.

4.10.1 The Decay Index (DI): anterior regions, maxilla and mandible

![Chart showing decay index] Location of BR
- NSG - Maxilla
- NSG - Mandible
- NSG - Both
- NCG - No BR
- NSG, N=55 sites
- NCG, N=55 sites

Figure 4.29. The percentage of patients with no decay or subsurface decalcification in the anterior regions of the maxilla and mandible (p could not be measured as all readings were 0)

Figure 4.29 demonstrates that 100% of patients had no observations of decay or subsurface decalcification seen affecting any of the anterior teeth associated with the BRs (NSG) or the RRs (NCG) in both the maxilla and the mandible.

4.10.1.1 Discussion regarding decay and bonded retainers (BRs)

The incidence of tooth decay in the incisor regions of the mouth on the palatal and lingual surfaces of the teeth for a similar age group is usually very low at $< 5\%$. The reason for this appears to be due to the self cleansing actions of the tongue and also the beneficial effects of saliva in providing acid buffering, antibodies and high concentrations of calcium and phosphate ions which helped re-mineralize any decalcified enamel surfaces. The patients reviewed in this study were generally in good health with none complaining of a dry mouth. Reports have shown that if the saliva flow becomes abnormally low and a dry mouth (xerostomia) results, the incidence of tooth decay in the incisor regions will increase. If patients can maintain a sensible and regular oral hygiene routine, the risk of tooth decay appears to be very low in these regions of the mouth, even when a BR is present.
4.10.1.2 Plaque Index (PI): maxillary anterior – palatal

Figure 4.30. Plaque levels seen on the palatal surfaces of the maxillary anterior dentition (p = 0.408)

Figure 4.30 shows the percentage of patients and their Plaque Index (PI) measurements on the palatal surfaces of their maxillary anterior teeth (MXP) as defined by the location of their wires (BRs). When BRs were present in the maxilla, the PI was very good and good for 100% of patients. When BRs were present in the mandible, the PI was very good and good for 100% of patients. When BRs were present in both the maxilla and mandible, the PI was very good and good for 90% of patients, and fair for 10%. In the control group, the PI was very good and good for 100% of patients. There were no observations of poor or very poor PIs in any of the groups.

There was no statistically significant difference in PI in the anterior maxilla palatal region between the NSG (see Figure 4.31) and the NCG, (see Figure 4.32) p = 0.408.

Figure 4.31. The average amount of plaque that was commonly seen associated with BRs in the maxilla, highlighted on the right with dipplaque
Figure 4.32. The average amount of plaque that was commonly seen on the palatal surface of maxillary anterior teeth in the control group, highlighted on the right with diplaque.

4.10.1.3 The Plaque Index (PI): mandibular anterior – lingual

Figure 4.33. Plaque levels seen on the lingual surfaces of the mandibular anterior dentition (p = 0.060)

Figure 4.33 shows the percentage of patients and their Plaque Index (PI) measurements on the lingual surfaces of their mandibular anterior teeth (MB-LI) as defined by the location of their wires (BRs).

When the BRs were present in the maxilla, the PI was very good and good for 90% of patients and fair for 10%. When the BRs were present in the mandible, the PI was very good and good for 40% of patients and fair for 60%. When the BRs were present in both the maxilla and mandible, the PI was very good and good for 55% of patients and fair for 45%. For the control group, their PI was very good and good for 80% of patients and fair for 20%. There were no observations of poor or very poor PIs in any of the groups.

There was no statistically significant difference in PI in the mandibular lingual region between the NSG (see Figure 4.34) and the NCG (see Figure 4.35) p = 0.060.
4.10.1.4 Discussion on the Plaque Index (PI) measures and bonded retainers (BRs)

There were mild but noticeable increases in the levels of plaque in the mandibular lingual regions seen associated with BRs. This did not appear to be a problem for the patients as, after 15 years, there were no signs of caries, sub-surface de-calcification or periodontal disease of concern seen in these regions and most patients were generally able to maintain an adequate level of oral hygiene care around their BRs. There may also be a reduced risk of caries and sub-surface de-calcification in these regions due to the constant presence of saliva which is super-saturated in calcium and phosphate ions that have a buffering effect on any acidy foods or drinks that are ingested.\textsuperscript{185, 202} The movements of the tongue also have a cleansing effect.
4.10.1.5 The Calculus Index (CI): maxillary anterior – palatal

Figure 4.36. Calculus levels seen on the palatal surfaces of the maxillary anterior dentition (p could not be measured as all readings were 0)

Figure 4.36 shows the percentage of patients and their Calculus Index (CI) measurements on the palatal surfaces of their maxillary anterior teeth (MXP) as defined by the location of their wires (BRs).

There were no observations of calculus deposits on the palatal surfaces of the maxillary anterior teeth in 100% of the NSG and the NCG patients (see Figure 4.37).

There was no statistically significant difference in CI in the anterior maxillary palatal region between the NSG and the NCG; the p value could not be assessed as all readings were zero.

Figure 4.37. There were no deposits of calculus seen on the palatal surfaces of the anterior teeth in either the BR or the control groups
4.10.1.6 The Calculus Index (CI): mandibular anterior – lingual

Figure 4.38. Calculus levels seen on the lingual surfaces of the mandibular anterior dentition (p = 0.288)

Figure 4.38 shows the percentage of patients and their Calculus Index (CI) measurements on the lingual surfaces of their mandibular anterior teeth (MB-LI) as defined by the location of their wires (BRs). When the BRs were present in the maxilla, the CI was very good and good for 98% of patients and fair for 2%. When the BRs were present in the mandible, the CI was very good and good for 80% of patients and fair for 20%. When the BRs were present in both the maxilla and mandible, the CI was very good and good for 78% of patients and fair for 22%. Overall, for the control group, their CI average was very good and good for 100% of patients. There were no observations of poor or very poor CI's in either the NSG or NCG. There was no statistically significant difference in CI in the anterior mandibular region between the NSG and the NCG, p = 0.288.

Figure 4.39. The average amount of calculus seen associated with BRs and the control patients on the lingual surface of the mandibular anterior teeth
4.10.1.7 Discussion on Calculus Index (CI) measures and bonded retainers (BRs)

Figure 4.39 and Figure 4.40 show for a small number of NSG and NCG patients, there were noticeable amounts of supra-gingival calculus around mandibular BRs and also noticeable amounts were seen in the control group. Generally, the levels of calculus were similar to what is seen in adults of this age group.162, 168

4.10.1.8 The Gingival Recession Index (GRI): maxillary anterior – palatal

Figure 4.41. Gingival recession levels seen on the palatal surfaces of the maxillary anterior teeth (p = 1.000)

Figure 4.41 shows the percentage of patients and their Gingival Recession Index (GRI) measurements on the palatal surfaces of their maxillary anterior teeth (MXP) as defined by the location of their wires (BRs). When the BRs were present in the maxilla, the GRI was very good for 97% of patients and good for 3%. The GRI was very good for 100% of all patients in all of the other groups. There were no observations a fair, poor or very poor GRI's in either the NSG or the NCG.

There was no statistically significant difference in GRI in the anterior maxillary palatal region between the NSG and the NCG, p = 1.000.
Figure 4.42. Gingival recession (arrow) was rarely seen on the palatal surfaces of both the BR in the top two images and RR patients in the bottom two images.

Gingival recession was rarely seen on the palatal surfaces of both the BR and control patients. However, it was seen in Figure 4.42 (arrows) on the labial surfaces of a few of their anterior teeth and this was usually attributed to their overzealous tooth brushing practices.

4.10.1.9 The Gingival Recession Index (GRI): mandibular anterior – lingual

![Gingival Recession Index Chart](chart.png)

**Figure 4.43.** Gingival recession levels seen on the lingual surfaces of the mandibular anterior dentition (p = 0.056)

Figure 4.43 shows the percentage of patients and their Gingival Recession Index (GRI) measurements on the lingual surfaces of their mandibular anterior teeth (MB-LI) as defined by the location of their wires (BRs). The GRI was very good and good for 100% of all patients in all of the groups.

There was no statistically significant difference in the GRI in the anterior mandibular lingual region between the NSG and the NCG, p = 0.056.
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4.10.1.10 Discussion on Gingival Recession Index (GRI) measures and bonded retainers (BRs)

The incidence of clinically significant gingival recession was rare, only affecting a few isolated single teeth in both the study group and the control group on the palatal and lingual surfaces of the anterior teeth. However, on the labial surfaces of some patients who were overzealous with their tooth brushing, (see Figures 4.44) there were noticeable incidents of gingival recession. Reports indicate this is commonly seen in the general population with people who brush their teeth excessively.\(^{172, 203, 204}\) In both groups, there were isolated instances of gingival recession usually affecting only one or two teeth. No explanation for why this happened is offered, however, the same is also commonly reported in the general population.\(^ {162, 172, 204}\)
4.10.1.11 The Modified Gingival Index (MGI): maxillary anterior palatal

Figure 4.45. The Modified Gingival Index (MGI) levels seen on the palatal surfaces of the maxillary anterior dentition (p = 0.129)

Figure 4.45 shows the percentage of patients and their Modified Gingival Index (MGI) measurements on the palatal surfaces of their maxillary anterior teeth (MXP) as defined by the location of their wires (BRs). When the BRs were present in the maxilla, the MGI was very good and good for 100% of all patients in all groups.

There was no statistically significant difference in the MGI in the anterior maxillary palatal region between the NSG and the NCG, p = 0.129 (see Figure 4.46 and Figure 4.47).
Figure 4.46. The worst example of chronic marginal gingivitis seen associated with BRs in this study, the effects of this inflammation on the alveolar bone levels was minor.

Figure 4.47. The worst case of chronic periodontal inflammation seen during this study was in a middle-aged control patient manifested by the gingival colour change with mild oedema and the loss of gingival tissue stippling. There was also mild gingival recession and alveolar bone loss (30%).
4.10.1.12 The Modified Gingival Index (MGI): mandibular anterior – lingual

Location of BR
- NSG - Maxilla
- NSG - Mandible
- NSG - Both
- NCG - No BR
- NSG, N=55 sites
- NCG, N=55 sites

Figure 4.48. The Modified Gingival Index (MGI) levels seen on the lingual surfaces of the mandibular anterior dentition (p = 0.129)

Figure 4.48 shows the percentage of patients and their Modified Gingival Index (MGI) measurements on the lingual surfaces of their mandibular anterior teeth (MB-LI) as defined by the location of their wires (BRs). When the BRs were present in the maxilla, the MGI was very good and good for 98% of patients and fair for 2%. When the BRs were present in the mandible, the MGI was very good for 80% of patients and fair for 20%. When the BRs were present in both the maxilla and mandible, the MGI was very good and good for 90% of patients and fair for 10%. For the control group, their MGI was very good and good for 95% of patients and fair for 5%. There were no observations of poor or very poor MGIs in either the NSG or the NCG. There was no statistically significant difference in the MGI in the anterior mandibular lingual region between the NSG and the NCG, p = 0.129.

Figure 4.49. The worst example of chronic marginal gingivitis seen associated with BRs in the mandible on both the lingual and labial gingiva

Figure 4.50. An average NCG patient’s mandibular incisor region showing the minor degree of gingival inflammation on the lingual surface and a very healthy gingiva on the labial surface
4.10.1.13 Discussion on Modified Gingival Index (MGI) measures and bonded retainers (BRs)

Overall, the MGI readings were either very good or good for most patients with a few exhibiting isolated areas of mild to moderate inflammation as is seen in Figures 4.32 and 4.33. The worst examples of the MGI were similar in the NSG and the NCG patients and are shown in Figure 4.49 and Figure 4.50.

4.10.1.14 The Alveolar Bone Index (ABI): maxillary anterior region

<table>
<thead>
<tr>
<th>Location of BR</th>
<th>NSG - Maxilla</th>
<th>NSG - Mandible</th>
<th>NSG - Both</th>
<th>NCG - No BR</th>
<th>NSG, N=55 sites</th>
<th>NCG, N=55 sites</th>
</tr>
</thead>
</table>

Figure 4.51. The Alveolar Bone Index (ABI) in the maxillary anterior region (p = 0.845)

Figure 4.51 shows the percentage of patients and their Alveolar Bone Index (ABI) measurements of their maxillary anterior teeth (MX) as defined by the location of their wires (BRs). When the BRs were present in the maxilla, the ABI was very good and good for 85% of patients, fair for 13% and poor for 2%. When the BRs were present in the mandible, the ABI was very good and good for 100% of patients. When the BRs were present in both the maxilla and the mandible, the ABI was very good and good for 78% of patients and fair for 22%. For the control group, their ABI was very good and good for 90% of patients and fair for 10%. There was no statistically significant difference in the ABI in the anterior maxillary palatal region between the NSG and NCG, p = 0.845.
4.10.1.15 The Alveolar Bone Index (ABI): mandibular anterior region

Figure 4.52. The Alveolar Bone Index (ABI) in the mandibular anterior region (p = 0.520)

Figure 4.52 shows the percentage of patients and their Alveolar Bone Index (ABI) measurements of their mandibular (MB) anterior teeth as defined by the location of their wires (BRs).

When the BRs were present in the maxilla, the ABI was very good and good for 83% of patients and fair for 17%. When the BRs were present in the mandible, the ABI was very good and good for 100% of patients. When the BRs were present in both the maxilla and mandible, the ABI was very good and good for 100% of patients. For the control group, their ABI was very good and good for 65% of patients and fair for 35%. There were no observations of poor or very poor ABI in either the NSG or the NCG.

There was no statistically significant difference in the ABI in the mandibular anterior lingual region between the NSG and the NCG, p = 0.520.

4.10.1.16 The Alveolar Bone Index (ABI): maxillary posterior regions

Figure 4.53. The Alveolar Bone Index (ABI) in the maxillary posterior regions (p = 0.837)
Figure 4.53 shows the percentage of patients and their Alveolar Bone Index (ABI) measurements of their maxillary (MX) posterior teeth as defined by the location of their wires (BRs). When the BRs were present in the maxilla, the ABI was very good and good for 81% of patients and fair for 19%. When the BRs were present in the mandible, the ABI was very good and good for 100% of patients. When the BRs were present in both the maxilla and mandible, the ABI was very good and good for 79% of patients and fair for 11%. For the control group, their ABI was very good and good for 68% of patients and fair for 32%. There were no observations of poor or very poor ABI in either the NSG or the NCG.

There was no statistically significant difference in the ABI in the maxillary palatal posterior regions between the NSG and the NCG, \( p = 0.837 \).

### 4.10.1.17 The Alveolar Bone Index (ABI): mandibular posterior regions

<table>
<thead>
<tr>
<th>Location of BR</th>
<th>NSG - Maxilla</th>
<th>NSG - Mandible</th>
<th>NSG - Both</th>
<th>NCG - No BR</th>
<th>NSG, N=55 sites</th>
<th>NCG, N=55 sites</th>
</tr>
</thead>
</table>

Figure 4.54. The Alveolar Bone Index (ABI) in the mandibular posterior regions \( p = 0.778 \)

Figure 4.54 shows the percentage of patients and their Alveolar Bone Index measurements of their mandibular posterior teeth as defined by the location of their wires (BRs). When the BRs were present in the maxilla, the ABI was very good and good for 87% of patients and fair for 13%. When the BRs were present in the mandible, the ABI was very good and good for 100% of patients. When the BRs were present in both the maxilla and mandible, the ABI was very good and good for 100% of patients. For the control group, their ABI was very good and good for 80% of patients and fair for 20%. There were no observations of poor or very poor ABI in either the NSG or the NCG.

There was no statistically significant difference in PI in the mandibular posterior regions between the NSG and the NCG, \( p = 0.778 \).
4.10.1.18 Discussion on Alveolar Bone Index (ABI) measures and bonded retainers (BRs)

The alveolar bone levels seen in this study were all well within the normal range of what would be expected in healthy individuals within a similar age group.\textsuperscript{162} This applied to both the NSG and NCG patients.

![Male BR patient, aged 29 years](image1)

![Male control patient, aged 28 years](image2)

Figure 4.55 shows similar good and very good alveolar bone levels in a 29 year old male BR patient and a 28 year old male control patient.

![Female BR patient, age 45 years](image3)

![Female control patient, age 44 years](image4)

Figure 4.56 shows the average alveolar bone levels seen in middle-age female BR and control patients. The condition of the alveolar bone for most patients was either very good or good with few exceptions. The worst-case of alveolar bone loss was seen in a female patient who was a smoker and 52 years old, shown in Figure 4.57. Smoking is a well-known cause of alveolar bone loss.\textsuperscript{205}

![This OPG is of a patient who is a smoker and 52 years old. She has noticeable alveolar bone loss in all regions of the dentition](image5)

Figure 4.57.
4.10.1.19 Conclusions on Alveolar Bone Index (ABI) measures and bonded retainers (BRs)

The presence of BRs did not produce any statistically or clinically significant adverse effects on the alveolar bone levels.

4.11 Comparative periodontal measures

In order to discover if BRs had an effect on the other periodontal tissues not adjacent to but on the (opposite) labial surface of the anterior teeth, the analysis was extended to investigate these areas.

The following graphs in Figure 4.58 are of the group’s periodontal measures on the anterior labial surfaces of their dentitions where BRs were not directly adjacent; the p values of differences between the NSG and NCG are attached to each graph. There were no measures of concern from the labial surfaces of the dentitions.
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[Graphs and images are not transcribed here.]

Figure 4.58. These graphs are of NEOTS group’s periodontal measures on the labial surface of their dentitions where BRs were not directly adjacent. There were no statistically significant differences between the NSG and NCG with all measurable p values $> 0.05$.

The periodontal measurement from nearby parts of the dentition that were not in direct contact with the BRs did not have the same degree of relevance for this study as the measures taken from sites adjacent to BRs. However, analyses done in this regard and presented in Figure 4.58 found there were no statistically relevant differences between the NSG and NCG with all measurable p values $> 0.05$.

4.12 Conclusions on dental health outcomes with bonded retainers (BRs)

The periodontal measures recorded in this study found there were no statistically or clinically significant differences between the NSG and the NCG. The presence of BRs did not have any different impacts upon the dental or periodontal health of the patients wearing them when compared to similar patients without BRs.
4.13 Research critique: concerns with bias

All investigations of this type have problems with bias; this study was no exception. Sackett\textsuperscript{206} mentioned up to 35 biases arise in sampling and measurement. Biases accompany all analytical research and contribute a distortion to the analysis and interpretation of the results. Avoiding bias is a foremost aim of scientific studies; difficulties arise with retrospective studies as some biases are pre-existing and cannot be circumvented. The original intention of having a large number of potential participants was to allow the selection of patients to be randomised and thereby reduce the bias. However, with only 61 patients agreeing to participate, they were all included to make up the numbers required and randomisation was not possible.

This study recognises that there were many forms of bias that could affect the validity of the results and conclusions drawn. These include: selection bias, response bias, volunteer bias, non-responder bias, survivor bias and others. There are biases associated with the fact that all patients were those of the CR and the CR was also the clinician responsible for fitting and monitoring all of the retainers. The CR was also responsible for all of the measurements in this study and was therefore not blind to the patients’ treatments thus introducing observer bias and expectation bias. Other biases come from the participants; these include recall bias, personal assessment and opinions biases and others. Patients truthfulness cannot be measured which introduces obsequiousness bias; however this may have been reduced by patients completing the questionnaire before the clinical consultation. The poor response rate of 25.8\% of the 236 contactable patients adds to the problem of bias as it decrease the power of the study and raise concerns of the non-responders being different in their treatment outcomes and opinions. However, initially, the participants were randomly selected and the final group was similar to the overall initial cohort in their gender ratio and orthodontic treatments. Many of the participants had experienced both RRs and BRs with a unique group of 30 having RRs fitted initially and within six months, these were replaced with BRs. There were 28 patients who had simultaneously experienced a BR in one arch and an RR in the other. These 28 were included in both the NSG and NCG as paired observations; thereby reducing potential confounders and increasing the precision of the comparisons.\textsuperscript{194} Overall, from the cohort of 61, there were 46 patients who had long-term experience with 55 BRs and 43 patients who had conventional experience with 55 RRs.

The CR provided all of the treatment and assessments thereby eliminating variability bias that would be associated with multiple operators and multiple assessors. The CR's contact and influence with patients in this study was restricted by the ethics guidelines and the 'Patient Questionnaire’ which was designed in conjunction with advice from an expert in Population Health studies (Dr. D Lloyd). The reader needs to bear in mind that the conclusions reached from this study may have been influenced by the many biases that impacted upon the results. However, all such studies have difficulties with avoiding bias. Wherever possible, the information gained in this study was compared to other similar studies to address the biases. In general, the majority of referring dentists positively support the use of BRs; this is examined in more detail in chapter 7; and has support from other studies.\textsuperscript{80, 83}
Although this study has a long list of biases, it is unique in that it involved the assessment of patients who were all treated by one operator, the CR. The BRs were all designed and fitted by the CR using the same materials and they are assessable as a group after more than 15 years. A similar type of study would be difficult to achieve as not many orthodontists have reported fitting BRs over a similar time-span. With regard to the history of orthodontics and the ad hoc evolution of bonded retention, there have not been any prospective randomised clinical trials (RCTs) published in the literature on this type of retention method. However, there is now increasing support within the profession to the claim that BRs are superior to RRs. This support has come from retrospective research. The need for prospective RCTs to assess the merits of BRs has been recommended by Littlewood et al from the Cochrane review committee and others.\(^{68, 105, 207}\) However, the literature review revealed the many shortcomings of RRs and how poor patient compliance is with wearing RRs beyond five years.\(^{82}\) While taking into account the problems of the many biases in this study and that being a retrospective study, it will be considered by some to have poor credibility in evidence-based science, there are many similar retrospective reviews that have provided orthodontists with much valuable information and orthodontic patients with many positive benefits.

### 4.14 Conclusions

This study reviewed and compared the effectiveness, durability and dental health impacts of 55 BRs in 46 patients with 55 RRs in 43 patients. All patients had completed a course of comprehensive orthodontic treatment at least 15 years earlier. The statistical requirements for a valid study of this type were to have 44 BR and 44 RRs cases. The study cohort of 61 patients included 28 patients who had simultaneously worn both a BR and a RR. These 28 were thereby included in both the NSG and NCG as paired observations. Pandis et al\(^{193}\) point out that paired observations reduce variance and therefore sample size requirements. The demographics and dental health practices of the 46 NSG patients were compared to those 15 patients of the NCG who had no experience with BRs. The few statistically significant differences between these two groups were not of clinical significance. Comparative analyses of the measures made by the CR were undertaken as two separate studies on 10 randomly selected patients and involved two pairs of (blind) external specialist examiners. The CR’s measurements were found to be valid and reliable, there were no constant biases observed and the precision discrepancies between the external examiners and the CR were not large enough to be of clinical or practical significance.

The effectiveness of BRs was very statistically significant when compared to that of RRs with a p value of 0.0001. The durability assessment found that the fracture rate for BRs was 0.58% per unit composite bond/wire per annum. None of the dental health impacts (DHI) of BR group, when compared to the control group, were statistically or clinically significant.

Other important matters to be considered are the opinions of the patients and dentists concerning the use of BRs and RRs. These are discussed in the following chapters.
Chapter 5 The Opinions’ of Patients on Orthodontic Retention Appliances

This chapter has been published as a paper titled “A Survey of Patient Opinions on Fixed vs. Removable Retainers” in the Journal of Clinical Orthodontics 2009;43:784-7.

5.1 Introduction

There is an increasing awareness among patients of the need for long-term orthodontic retention. This may be due to their parents and/or their own personal observations and experiences with the problems of relapse. The literature has established that the reason people undertake orthodontic treatment is primarily for its aesthetic benefits. Patients and their parents are justifiably upset if the ideal alignment that is achieved by their treatment deteriorates in any way as time passes. A survey in 2008 found that patients and their parents are becoming more accepting of the need for permanent retention to avoid any relapse and the disappointment it brings. Permanent retention has been a closeted feature of orthodontic treatment for over 100 years, the use of bonded retention (BR) has only been incorporated into a steadily increasing number of orthodontic practices since the late 1970s. The orthodontic profession has become more active in promoting the use of BR as its effectiveness and durability appear to be favourable. Concerns that BRs may impact negatively upon the patient’s dental health have not eventuated. However, there is little information in the literature on the subject of the opinions’ of patients on removable retention (RR) or bonded retention (BR). Which method of retention do patients prefer and what are patients prepared to accept? This part of the study endeavoured to discover the opinions’ of patients on the use of RRs and BRs.

5.2 Method

The 61 patients who participated in this study were asked to fill in a questionnaire (see Appendix J) on their experiences of both their orthodontic treatment and of the different retention appliances they wore. This was done at the time of their clinical visit and examination. The questionnaire included the following sections:

- Experiences with RRs regarding comfort, cleaning, impact upon quality of life, assessment of the outcome of treatment and straightness of their teeth, bite comfort and temporomandibular joint dysfunction (TMD).
- If and why they stopped wearing their RRs and awareness of any relapse occurring.
- Experiences with BRs regarding comfort, cleaning, impact upon quality of life, assessment of the outcome of treatment and straightness of their teeth, bite comfort and TMD.
Once patients had completed the questionnaire, the chief researcher (CR) reviewed it with them to ensure all sections were completed. The information was then transferred to a database for statistical analysis.

### 5.2.1 Statistical consideration

Patients wearing a BR would be expected to have increased oral hygiene needs as they would experience an increased risk of developing tooth decay, periodontal disease and maintenance requirements for their BRs.

Using statistical software with a Power to Sample Size programme, it was found that assuming 20% of patients would be disadvantaged by the presence of a BR compared to a RR, for a level of significance set at $p \leq 0.05$ with a Power of 0.8, a sample size of 44 BR patients was necessary with a control sample of 15.

### 5.3 Results

#### 5.3.1 General patient information

The cohort reviewed in this study is presented in detail in Chapter 4. The information gathered from the questionnaire (Appendix J) is presented in graphs. Not all sections of the questionnaire were completed by some patients due to uncertainty of their memory.

#### 5.3.2 A unique group of 30 patients who experienced both removable retainers (RRs) and bonded retainers (BRs)

In the NSG of 46 patients, 30 had experienced both RRs and BRs in the same arch. This came about as a result of these 30 patients completing active treatment and having RRs fitted before it became apparent that their treated occlusions were too unstable for the RRs to maintain alignment. It was then decided to retreat where necessary and fit BRs to ensure ideal alignment would be achieved and that relapse would not occur. The patients in this group were most qualified to judge the merits and shortcomings of both RRs and BRs; they also added nine patients to the NCG for this part of the study.

Overall, 46 patients had experienced wearing one or two BRs and 52 (43+9) had experienced wearing one or two RRs.
5.3.3 Patients’ experience with retainers

5.3.3.1 Patients’ opinions on removable retainers (RRs)

From Figure 5.1, regarding the comfort of their RRs, 54% of patients rated them as very good or good, 24% rated it as fair and 22% as poor. Regarding the cleaning of their RRs, 69% rated them as very good or good, 20% rated it as fair and 11% as poor. Regarding the impact of treatment upon their quality of life, 45% rated it as very good or good, 40% as fair and 15% as poor.

5.3.3.2 Patients’ opinions on bonded retainers (BRs)

From Figure 5.2, regarding the comfort of their BRs, 95% of patients rated them as very good or good, 5% as fair, and none as poor. Regarding the ease of cleaning, their BRs, 78% rated it as very good or good, 16% as fair, and 6% as poor. Regarding the impact of their BRs upon their quality of life, 95% rated it as very good or good, 5% rated it as fair, and none rated it as poor.
5.3.3.3 Reasons patients stopped wearing their removable retainers (RRs)

Figure 5.3. Reasons patients stopped wearing their RRs

From Figure 5.3, the reasons given by patients for ceasing to wear their RRs within two years were: 44% complained of discomfort, 15% were embarrassed by the presence of their RRs and 41% gave other assorted reasons including most often it was due to them ‘hearing’ that they could discontinue wearing their retainers after two years.

5.3.3.4 Removable retainers (RRs) patients' self-reported relapse noticed

Figure 5.4. Removable retainers (RRs) patients' self-reported notice of relapse occurring

From Figure 5.4, for patients who had worn RRs, 63% noticed relapse occurring after treatment was completed while 37% did not notice that any relapse had occurred.
5.3.3.5 Self-reported treatment outcomes with removable retainers (RRs)

![Figure 5.5](image1)

From Figure 5.5, in the group of patients who had worn RRs, 87% rated the overall straightness of the teeth as very good or good, 13% as fair and none as poor. With regard to how they felt about the outcome of their treatment, 93% rated it as very good or good, 7% felt the outcome was fair, and none thought it was poor. The bite comfort of their dentition after treatment was rated as very good or good by 100% of patients.

5.3.3.6 Self-reported treatment outcomes with bonded retainers (BRs)

![Figure 5.6](image2)

From Figure 5.6, for BR patients, 100% rated the straightness of their teeth as very good or good. For the overall outcome of treatment, 94% rated it as very good or good, 6% rated as its fair, and none rated it as poor. The bite comfort of their dentition after treatment was rated as very good or good by 100% of patients.

5.3.3.7 Temporomandibular joint dysfunction (TMD)

Both the NSG and the NCG reported similar TMD outcomes, 80% had no TMD, 16% reported clicking symptoms and 4% reported experiencing painful episodes.

5.3.3.8 Statistical analysis for the patients’ opinions on retention appliances

Chi-squared ($\chi^2$) analysis was used to analyse the differences between RRs and BRs and found the following levels of significance:
• Comfort: \( p = 0.339 \) (NS, Nil Significance).
• Oral Hygiene: \( p = 0.776 \) (NS).
• Quality of Life: \( p = 0.557 \) (NS).

This confirmed that the presence of BRs did not present inferior outcomes for the patients when compared with RRs for comfort, oral hygiene and quality of life.

5.3.3.9 The unique group of 30 patients who wore removable retainers (RRs) and later bonded retainers (BRs)

![Figure 5.7. Comparison of RRs and BRs by patients who experienced both types of retainers](image)

From the data presented in Figure 5.7, there were no patients who considered BRs were worse than RRs for comfort, 50% felt the comfort was the same and 50% felt BRs were more comfortable. With regard to oral hygiene, 27% of patients considered BRs were worse than RRs, 43% felt they were the same and 30% felt they were better. Regarding impact on quality of life, 7% of patients felt their quality of life was worse when BRs were fitted, 36% felt there was no change and 57% felt it improved.

Chi-squared \( (\chi^2) \) analysis found that patients who had experienced both RRs and BRs had levels of significance for:

• Comfort: \( p = 0.002 \) (significant).
• Oral Hygiene: \( p = 0.497 \) (NS).
• Quality of Life: \( p = 0.003 \) (significant).

These results highlighted that patients considered BRs were superior to RRs for comfort and impact on quality of life, and similar for oral hygiene.
5.4 Discussion

5.4.1 Patients’ experiences with removable retainers (RRs) and bonded retainers (BRs)

In this study of self-reported treatment outcomes, the overall opinions of patients on their experiences with RRs and BRs in regards to comfort, oral hygiene and impact upon quality of life demonstrates that BRs are regarded more favourably when compared to RRs.

In regards to relapse, 100% of BR patients did not think any relapse had occurred after 15 years, however, 63% of patients wearing RRs reported they noticed relapse occurring after treatment was completed. The other 37% of patients who claimed that they did not notice any relapse included ten (56% of this relapsed group) who had relapsed beyond 3 mm into the unacceptable relapse category on the Little’s Irregularity Index (LII) scale; these patients were unconcerned about this movement. Examples of relapse that some patients were unaware of are shown in Figure 5.8.

![Figure 5.8. Two patients with relapse greater than 3 mm on the Little's Irregularity Index (LII) scale; both felt no relapse had occurred](image)

The tolerance two patients demonstrated in Figure 5.8 of not being concerned about moderate relapse may account for why within the broader orthodontically treated community, more treated patients generally do not complain about relapse and seek retreatment. One hundred percent of patients in the RR and the BR groups rated the comfort of their bite as very good or good once treatment was completed.

The reporting of temporomandibular joint dysfunction (TMD) was the same for both groups; 80% had no TMD, 16% reported clicking and 4% reported having painful episodes with their temporomandibular joints (TMJs). These figures are similar to what is seen in the general population.211

The unique group of 30 patients who had experienced both RRs and later BRs had a statistically significant greater number of patients who were pleased when BRs were fitted. This was because they considered BRs were more comfortable and had a less negative impact on their quality of life. Regarding comfort, no patients thought BRs were more uncomfortable than RRs, 50% thought BRs and RRs were the same and 50% thought BRs were more comfortable \( (p = 0.002) \). With regards to oral hygiene, 27% of patients thought BRs were worse than RRs, 43% thought they were the same and 30% thought BRs were better \( (p = 0.497) \).
Regarding impact on quality of life, 7% thought BRs were worse than RRs, 36% thought they were the same and 57% thought BRs were better ($p = 0.003$). These findings corroborate similar findings by Wong and Freer.\textsuperscript{80, 83}

### 5.5 Conclusions

This study found statistically significant support for patients preferring BRs over RRs. Patients were of the opinion that compared to RRs, BRs were more positive in the categories of retainer comfort and impact upon quality of life. Patients considered BRs were marginally better for overall outcome of treatment and straightness of teeth and equal with RRs for oral hygiene, TMD, and bite comfort once treatment was completed.

The group of patients who had experienced both RRs and later BRs found the BRs were the more preferred method of dealing with retention.
Chapter 6 The Opinions’ of Dentists on Orthodontic Retention Appliances

This chapter has been published as a paper titled “Dentists’ Opinions on Orthodontic Retention Appliances” in the Journal of Clinical Orthodontics 2008;42:415-9.

6.1 Introduction

Surveys of orthodontists and orthodontic treatments have shown the relationship between orthodontist and patient usually lasts for approximately four years; this includes two years of active braces treatment followed by two years of supervised retention. Patients are then discharged back to the ongoing care of their dentist. According to Riedel’s observations from the Seattle studies, relapse may not begin to manifest itself until three to five years after active orthodontic treatment is completed. For this reason, orthodontists often do not view the relapse problem first hand; however, dentists do so because they continue to recall their patients in an ongoing manner once or twice each year for checkups. The poor long-term effectiveness of casual RR wear has resulted in acknowledgement from within the profession of the need for permanent retention if enduring dental alignment is to be maintained. How to best achieve permanent retention is in dispute and currently involves a choice between using either BRs or RRs. A search of the literature found no studies of dentists’ opinions comparing the suitability and effectiveness of BRs against RRs.

The aim of this part of the study was to discover the opinions of dentists in regard to the effectiveness, durability and other characteristics of BRs and RRs after active orthodontic treatment is completed.

6.2 Background

This study was done from the chief researcher’s (CR’s) specialist orthodontic practice located in the Hunter region of NSW, Australia. The long standing nature of the dental practices here has resulted in a continuity of dental care to many families in the Hunter region and provides the dentists with opportunities to review the outcomes of the orthodontic treatments their patients have undergone. The CR’s orthodontic practice has been in Newcastle for over 30 years. During this time, his referring dentists have had the opportunity to review and form opinions on the effectiveness, durability, benefits and shortcomings of both BRs and RRs.

6.3 Method

6.3.1 The sample of dentists

Seventy one dentists who had referred patients to the CR’s orthodontic practice over the previous 23 years were selected for the study. These dentists were familiar with the RRs
and BRs shown in Figures 1.11 and 1.12; they had opportunities to review patients with them. Dentists who were excluded from this study included those who had been retired for more than five years, had moved away from the area or who were on leave during the survey period.

6.3.2 The dentists’ questionnaire

The dentists’ questionnaire was self-complete (see Appendix R). It covered the following topics:

1. Demographic information about the dentists including age, gender and years in dental practice.
2. Approximate number of their patients treated by the CR.
3. Duration of observation of both BRs and RRs.
4. Ratings of both types of retainers for effectiveness, durability, oral hygiene in the maxilla and the mandible, patient satisfaction and their own personal rating. The ratings were based on a four point scale of poor, fair, good, very good.
5. Reasons for rating poor or fair on any issue.

The dentists were also invited to write comments they wished to include at the end of the questionnaire.

6.3.3 The survey procedures

A covering letter (invitation to participate) explaining the purpose of the study (see Appendix Q) and questionnaire (see Appendix R), (both of which had been approved by the University of Newcastle Ethics Committee), were posted to the 71 dentists. A return stamped addressed envelope was also enclosed. The dentists were informed that the questionnaire would take approximately 10 minutes to complete. The survey was designed to be anonymous; no individual data was to be reported and the questionnaires were sent out without any identification markings. This was done to reduce bias by allowing respondents to be honest in their answers without fear of professional consequences. The covering letter was an invitation for dentists to participate in this study; it explained the aims for the research and briefly summarized what was being asked of participants, time limits, privacy protection, data release and the ethics approval number. It also contained information regarding who could be contacted for any questions or concerns with this survey. Two weeks after the initial posting out date, all of the dentists who had been sent a survey were contacted with a follow-up phone call by a research assistant and asked to complete and return the survey as soon as possible unless they had already done so, or unless they did not want to participate. No further contact was made with the dentists. The closing date for returns was four weeks after the follow up phone call. All returned surveys were gathered, the data was entered into a computer and frequency tables were generated.
6.4 Results and discussion

6.4.1 The final sample of dentists
The participants and responders are shown in the flow chart in Figure 6.1.

Figure 6.1. The flow chart of the sample selection process and respondent dentists

6.4.2 The non-responders *
No explanation is offered for why the 13 (22%) of eligible dentists failed to respond as this was an anonymous survey and so there was no means of finding out who they were.

6.4.3 Response rate and respondents of the survey
The positive response rate was 78% (45 responders) which compared well to other dental survey studies where response rates varied between 51.8% and 65%. Some dentists did not complete all sections in the questionnaire.

The respondents included 22% females and 78% males which was a fair gender representation of dentists within the profession in NSW. A recent Australian Dental Association (ADA) survey (2009) of gender ratios of dentists in NSW found 29% were female and 71% were male (see Appendix S).

6.4.4 Years in practice of respondent dentists

Figure 6.2. The number of years in practice of respondent dentists
Figure 6.2 summarises the clinical experience of the respondent dentists. Four dentists did not complete this section. The majority of dentists, 76%, had more than 15 years experience, 69% had more than 20 years and 12% had less than 10 years.

6.4.5 Number of years of reviews of bonded retainers (BRs) and removable retainers (RRs)

Figure 6.3. The percentage of respondent dentists who had reviewed BRs and RRs for up to 5, 10, 15, 20 and more than 20 years

Figure 6.3 shows the percentages of dentists and their years of reviewing patients with both BRs and RRs. One dentist did not complete the section on BRs and six did not complete the section on RRs. Sixty three percent of dentists had reviewed patients with BRs for more than 15 years and 84% had reviewed patients with RRs for more than 15 years. Dentists with ten years or less experience with BRs were 37% compared to 16% for RRs.

6.4.6 Dentists’ ratings of bonded retainers (BRs)

Figure 6.4. Dentists’ ratings for bonded retainers (BRs)
Figure 6.4 summarises the rating of BRs by the dentists in six different categories, one dentist did not complete this section. The dentists combined ratings of very good and good for effectiveness were 100%, durability 95%, oral hygiene in the maxilla 82%, oral hygiene in the mandible 36%, patient satisfaction 86% and the dentists’ personal satisfaction ratings were 93%. No dentists rated the BRs as poor in the categories of effectiveness, durability or patient satisfaction and only 2% rated them as poor overall. Oral hygiene was considered to be the greatest concern with 13% rating BRs as fair and 5% as poor in the maxilla; and 45% rating them as fair and 19% as poor in the mandible.

6.4.7 Dentists’ ratings of removable retainers (RRs)

Figure 6.5 summarises the ratings of RRs by the dentists in six different categories. Six dentists did not complete this section. Their combined ratings of very good and good for effectiveness were 39%, durability 38%, oral hygiene in the maxilla 97%, oral hygiene in the mandible 91%, patient satisfaction 38% and dentists own ratings 29%. The dentists’ combined ratings of fair and poor for effectiveness were 61%, durability 62%, patient satisfaction 62% and dentists rating 71%. Their combined ratings of fair and poor for oral hygiene were 3% in the maxilla, and 9% in the mandible.

6.4.8 Comments by the dentists on bonded retention (BR)

Thirty-five respondent dentists wrote comments about their thoughts on BR. Of these, 83% had concerns regarding oral hygiene problems including 46% who were particularly concerned about oral hygiene difficulties in the mandible and 34% were concerned about calculus build ups in the mandible. The wire obstructing flossing between the lower incisors was raised by 23% of respondents. Concerns about breakages, how were they detected and who was responsible for repairing them, were raised by 17%. Nine per cent mentioned how some patients found the BRs irritating. A summary of comments and concerns included the following:

- “There is no ideal retention philosophy.”
- “A reasonable compromise.”
• “Without fixed retention, teeth drift out of alignment.”
• “BRs are the only effective mechanisms we have to stop tooth relapse.”
• “Well designed and with good patient education, they are very good.”
• “Zigzag wires that don’t impinge, (they) work well.”
• “The only way to go.”
• “BRs should be fitted straight after de-banding.”
• “Long-term, what happens?”
• “Who should repair and maintain them?”
• “Surely they can be removed after 10 years.”
• “Research needed into how long they should be worn for.”
• “Posterior cross-bite retention-doesn’t happen.”
• “Sometimes they break.”
• “Some patients ask to have them removed.”
• “Root Canal treatments, complications caused by the wire.”
• “Cleaning – can’t be cleaned!”
• “Oral hygiene education and patient education is poor.”
• “Generalised decrease in periodontal ligament width.”
• “Periodontal concerns for middle age patients, what will happen?”
• “Issues with allergy induced Nickel gingivitis.”
• “BRs are better.”
• “They are far from perfect but they are the best available.”
• “I am surprised at patient acceptance.”
• “The majority of parents prefer BRs.”

6.4.9 Comments by the dentists on removable retention (RR)

Thirty-four respondent dentists wrote comments about their thoughts on RR. Of these, 91% mentioned their concerns of patient non-compliance with wearing their RRs as instructed and 47% added their concerns about the subsequent relapse that followed. The problems of plaque and calculus accumulation on the RRs were mentioned by 12% of the group.

A summary of comments and concerns with RRs included the following:

• “Superior to BRs if worn.”
• “RRs are better at preventing posterior cross-bite relapse.”
• “Poor oral hygiene can be a problem.”
• “Poor oral hygiene – RR covered in calculus.”
• “Appliances get broken and lost.”
• “Compliance (with wearing RRs) drops off dramatically after 12 months.”
• “Compliance is the big issue.”
• “Tendency for relapse is extremely high.”
• “50% of cases I see relapse.”
“After years of orthodontic treatment, patients don’t want to think about this (wearing retainers) anymore and discard them.”

6.5 Discussion

There were no reports found in the orthodontic or dental literature on the opinions of dentists in regard to orthodontic retainers or retention. This study group of dentists contained a mix of both recent and long term graduates with the majority, 64 %, having more than 20 years of clinical experience and 54 % having more than 100 cases of BRs patients to draw on.

Evidence based scientific studies rate individual anecdotal evidence as the poorest form of evidence; however, collective anecdotal opinions from a large group of experienced dentists should be considered to have some credible scientific merit. The accumulated qualitative observational knowledge of any professional group is a largely untapped evidence resource. Not all knowledge comes from teaching institutions and/or quantitative research. The knowledge gained from experience is an important educator and the scientific merit of such knowledge increases when it is corroborating group knowledge involving a large number of professionals as was the case in this study involving 45 dentists. Many of the dentists in this survey were concerned by poor patient compliance with wearing their RRs as instructed. This concern has support from surveys by Keim et al,74 Wong and Freer,83 Mollov et al208 and Pratt et al.82

6.5.1 Review of responses

The dentists regarded BR as superior to RR in the categories of effectiveness 100% vs. 39%, durability 95% vs. 38%, patient satisfaction 86% vs. 38% and dentists’ satisfaction rating 93% vs. 29%. However, the oral hygiene components were opposite with RRs being regarded as more hygienic in the maxilla at 97% vs. 82% and RRs were rated as much more hygienic in the mandible at 91% vs. 36%.

The high patient satisfaction response of 86% supports the conclusions reached by Wong and Freer who reported ‘patients found fixed retainers more acceptable than removable retainers because of appearance and comfort.’

The positive acceptance was discovered from surveys of orthodontists on their views of BR; (97%) in the Netherlands and (93%) in Australia and New Zealand.80

6.5.2 Oral Hygiene concerns

The wire frames of the BRs reviewed in this study have a looped inter-dental design to allow flossing access for easy inter-proximal cleaning. The exceptions are that there are no loops between the lower incisors as the inter-proximal distances here are too short to comfortably accommodate them. The CR has found patients sometimes mention the mandibular loops between the canines and lateral incisors are irritating to the tongue. However, canines bear considerable occlusal loading during function and the loops are necessary to reduce the stress on the canine composite pads; their bond fracture rate was much higher if the loops were omitted.90 Careful fabrications of mandibular retainers can place the loops more
snugly into the embrasure between the canine and lateral incisor and thereby reduce the tongue irritation problem. The concerns by the dentists about the oral hygiene problems they encountered with BRs were primarily due to the difficulties in cleaning the mandibular BRs and the subsequent build up of plaque and the supragingival calculus deposits that occurred. The maxilla BRs rarely pose any oral hygiene problems or concerns as the inter-proximal loops allowed for easy flossing access and supragingival calculus was not seen. In the mandible, the absence of loops between the incisors makes interproximal cleaning difficult. A floss threader may be used to get through the embrasure and under the wire. Inter-dental brushes and tooth picks are of benefit here if they are used regularly, however, many patients do not use inter-dental aids routinely because it is awkward and time consuming. Unfortunately, anything that is an inconvenience gets less attention and while the oral hygiene of diligent patients is good, for the less diligent, there is often a subsequent build up of calculus around the lower incisors and wire. This is a concern for everyone involved, however, periodontal studies have found that calculus deposits are present on the teeth in over 90% of the general population, whether a BR is present or not.\textsuperscript{162, 215} For optimum oral hygiene, it may be necessary for the calculus to be professionally removed on a regular basis, usually, six or twelve monthly, and this can be done at the patient’s routine bi-annual and/or annual dental checkups and treatments.\textsuperscript{216}

A study on ‘Periodontal implications of bonded versus removable retainers’ by Heier et al\textsuperscript{96} concluded that within their evaluation period of 6 months, slightly more plaque and calculus were present on the lingual surfaces in the BR (mandibular) group. This did not result in more pronounced gingival inflammation.

Patient education on the need for a sensible and regular oral hygiene protocol is constantly reinforced by the dental profession. However, patient compliance in this regard is not always ideal; this problem is common in dentistry. Orthodontic patients with BRs do have an additional oral hygiene burden but with due diligence they can successfully attend to this problem.\textsuperscript{91} The ‘duty of care’ regarding oral hygiene requires that the patient’s dental service providers demonstrate how and why patients should clean their teeth, it is then up to the patient to act upon this advice.\textsuperscript{33}

### 6.6 Additional benefits of bonded retention (BR)

Some additional benefits of BR over RR include BRs cannot be misplaced, lost or not worn; this is convenient for both the patient and their parents. Parents are grateful for not having to police their children’s wearing of retainers and for avoiding the additional costs involved if the retainers are lost or broken and need to be replaced.

Parents and patients are also more accepting of BRs when told attaching them is a non-invasive procedure; BRs are only bonded to the teeth and in the future, if the need arises, they can be easily removed.
6.7 Issues and answers to some of the concerns raised by the respondent dentists regarding bonded retention (BR)

6.7.1 “There is no ideal retention philosophy”
This comment is very true and has the support of the Cochrane collaboration. From the beginning of orthodontics as a specialty, there has been a constant stream of articles published in the literature on the problems of retention and suggestions for dealing with it; but there is still no universally accepted solution.

6.7.2 “They (BRs) sometimes break”
The dental literature reports a failure rate of between 2 and 10% per annum for dental restorations and appliances. There is no known guaranteed way of preventing breakages, however, the breakage rate for the BRs evaluated in this study was 0.58% per unit bond/wire per annum.

6.7.3 “Who is responsible for repairing BRs?”
Some treatments have a guarantee period determined by the operator or the profession. For these BRs, the orthodontist provides patients with a 5 year written guarantee to cover any accidental breakages; after this period, the patients are told any repairs will involve an additional cost. There has been favourable acceptance of this by both patients and their parents. Repairs of BRs can be done by either the orthodontist or their dentist.

6.7.4 “Posterior cross-bite retention does not happen”
The BRs reviewed in this study are only fitted to the anterior teeth as maintaining alignment of these teeth “in the aesthetics zone” is what concerns patients most. Patients want orthodontic treatment to provide them with an aesthetically pleasing dentition that will endure indefinitely. Extending BRs to include the molars has been trialled by the CR and was abandoned because it introduced additional problems; these included higher fracture rates, food impaction between the wire and the teeth in the molar regions and additional discomfort and irritation for the patient. If it is necessary, preventing posterior cross-bite relapse can be achieved by using RRs that are worn permanently, however, patient compliance with wearing RRs over the very long-term is known to be poor. The need to prevent posterior cross-bite relapse has yet to be justified as the literature shows posterior cross-bites do not necessarily cause patients functional or aesthetic problems.

6.7.5 “Some patients ask to have them (BRs) removed”
If a patient wants to have their BRs removed, this can be easily done by their orthodontist or dentist. However, before removing a BR, the patient should be made aware of
the consequences of doing so and of the high risk of relapse occurring in the future unless another form of permanent retention is employed. A written acknowledgement of the possible consequences of removing a BR, signed by the patient and their parents when applicable, would be a prudent undertaking for the operator.

6.7.6 “Long-term, what happens?”

BRs using composite bonded wires have been in use since the 1970’s and the observational studies reported to-date, including this one, have found they do not appear to cause any harm to the dental or periodontal tissues. However, for some people, the periodontal tissues become more vulnerable to disease with age and this vulnerability may be exacerbated by the presence of BRs. Patients are being educated to realise the importance of good oral health practices for good dental health, general health and well being. The patients who have orthodontic treatment and BRs fitted should be aware of the benefits of having an aesthetically pleasing dentition and the need for regular dental care and maintenance. Ongoing studies are needed to determine exactly what does happen to the dentition of patients who wear BRs over the very long term between 20 and 80+ years. If harmful effects do arise, the use of BRs would need to be reviewed.

6.7.7 “Surely they can be removed after ten years?”

The Seattle Study group found that if BRs are removed after 10 years, relapse still occurs. They concluded BRs postpone relapse until they are removed.

6.7.8 “Issues with allergy induced nickel gingivitis”

The stainless steel in 0.018 regular plus Wilcock wire that is used for these BRs does not appear to generate a nickel allergy problem. This is supported by more than 50 years of use of this wire type in orthodontics and the absence of unfavourable reports in the literature. Kao et al’s study found nickel containing orthodontic metal bracket immersion medium appears to be biocompatible with oral gingival fibroblasts and human oestrogenic sarcoma cells.

6.8 Conclusions

The main concerns with RRs for 91% of the dentists were the patient’s non-compliance with wearing their RRs as instructed and the subsequent relapse that often followed. This observation supports Pratt et al survey of orthodontists who “grossly overestimated patient compliance with removable retainers at 5 years after debanding.”

The dentist’s main concerns with BRs were to do with perceived oral hygiene difficulties. Overall, the dentists rated BRs above RRs (93% vs. 29%) as the best solution available at present for dealing with the problems of relapse after active orthodontic treatment has been completed.
Chapter 7 General Discussion

7.1 Discussion introduction

Relapse and natural ageing changes make it difficult for orthodontists to satisfy the expectations patients have of long-term alignment stability once orthodontic treatment is completed. The time factor is a very important aspect of orthodontic treatment. All patients would like to know exactly how long their treatment outcome will last; they would hope that it would be forever. For the profession, this, durability element is an unknown entity and ideally, it needs to be constantly reviewed to discover how effectively treatments will endure over the very long-term beyond 80 years. This study was a 15 year review of long term stability and it posed many challenges. Recruiting the study group proved to be far more difficult than was first anticipated; from the initial cohort of 671 potential participants (100%), 231 NSG and 440 NCG; after 15 years, only 236 (35%) could have their addresses/phone numbers located. From the 236 locatable patients, only 61 agreed to participate, that is, 9.1% of the initial cohort. Because the final number of participants was so small (61), it was not possible to achieve randomisation of the groups and this reduced the overall credibility of the study. The number recruited was well below what was initially anticipated and on reflection, the following reasons for this are suggested: most patients were teenagers between the ages of 14 and 16 years old when they complete treatment and by the time 15 more years had passed, they would be approximately 30 years old. By then most would have completed their education, left home and relocated either somewhere locally or far removed, depending on their employment requirements or circumstances. Many of the girls may have married and change their names. The current privacy laws and ethics guidelines restrict how people can be located and contacted. From the group of 236 that could be located, they included 27, wrong numbers, 28 wrong addresses and 4 pregnant women, thereby reducing the potential participant number to 177. There were 107 from this final group who were not interested in participating for unknown reasons and again, because of ethics guideline restrictions, it was not possible to discover why. Possible reasons include, they were too busy, apathy, unpleasant memories of treatment, disappointment due to a poor treatment outcome, etc. All of these reasons are purely speculative and have no scientific merit, but they present confounding problems for the study; why would these patients not participate? What impact would their inclusion have had on the outcome of the study? The final result was that only 9.1% of the initial study cohort participated.

7.2 Orthodontic treatment objectives

The objectives of orthodontic treatment have always been to provide patients with a stable and ideal Class 1 “Normal” occlusion. This ideal was established by orthodontists, including Angle at the turn of the 18th century and still has strong support today. However, as Ackerman et al stated in their paper on ‘How ideal occlusion became the philosopher’s Stone
of orthodontics’, the concept of ideal occlusion is the last remaining Victorian idea of orthodontics. To the question "Is an ideal Class 1 occlusion really necessary?" The literature has many entrenched anecdotal presumptions of support, but no conclusive evidence. There is a growing body of evidence that contradicts the claimed inadequacies of malocclusions. It appears that the majority of malocclusions function as well as normal occlusions. Studies by Kayser found that dental arches which had been shortened by multiple molar extractions were not a serious or long-term handicap for those people. In fact, the World Health Organisation (WHO) suggests that it is only necessary to retain 20 (opposing) teeth for a functionally adequate dentition. To provide evidence-based treatments, the orthodontic profession needs to understand what is required for a dentition to function adequately and what orthodontic treatments are really capable of achieving. Orthodontists also need to factor into their treatment planning exactly what outcomes patients expect from treatment.

The literature shows that most malocclusions function adequately. Patients rarely undertake orthodontic treatment to improve function. It appears that what patients mainly seek from orthodontic treatment is to improve their dental and facial appearance. No studies could be found that have specifically asked patients themselves what they want from treatment and in this regard, the profession has been lacking. Ackerman et al (2006) mentioned that good communication with patients is paramount in orthodontic care. ‘A shift that has occurred in the last 15 years of dental practice is the evolution of patient autonomy and informed consent and the departure from paternalism in the decision-making process.’ More studies are required to discover what patients would like and expect from treatment.

7.3 What can orthodontic treatment achieve?

The orthodontic literature regularly shows excellent clinical outcomes. Orthodontists have the ability to move teeth efficiently and effectively into more desirable arrangements as shown in Figure 7.1. However, there is a bias in the literature and at orthodontic conferences towards avoiding the exposure of unfavourable (embarrassing) alignment deterioration that occurs due to relapse and ageing changes. Between 1995 and 2009, international orthodontic conferences have consistently devoted less than five percent of their conference time to the problems of relapse.
7.4 What are the shortcomings of orthodontic treatment?

Successful orthodontic treatment can be viewed as that which provides patients with the result they expect. The literature shows patients want treatment to provide them with an aesthetically pleasing dentition that functions adequately, requires minimal maintenance and is stable forever. It is the ‘stable forever’ part that is difficult for the orthodontist to achieve. This is because, over time, many variables can impact upon the alignment of the teeth and dental arches. The only way to guarantee alignment deterioration will occur less often is to use permanent retention.\(^{58, 59, 72, 124}\) Some reasons why permanent retention is necessary are presented in the following sections of this study.
7.4.1 Orthodontic relapse

The Seattle studies\textsuperscript{17} and others\textsuperscript{68, 224} have shown that orthodontists should expect that without permanent retention, up to 90\% of their treated cases, including their best treatment outcomes, may relapse unacceptably within 20 years and that the alignment of the dental arches will continue to deteriorate further with ageing.

7.4.2 Orthodontic orthopaedic relapse

Pancherz\textsuperscript{40} and others\textsuperscript{41-43} including the Cochrane collaboration\textsuperscript{44} reported that functional appliance and orthopaedic treatments, including rapid palatal expansion\textsuperscript{225} will relapse in time. The orthopaedic changes that are observed consist of two components, one is dento-alveolar and the other is pseudo-skeletal. In the long term, the orthopaedic skeletal changes caused by the treatment will revert. The overall relapse that follows over time results in insignificant permanent changes to the skeletal base. Permanent retention is required to guarantee maintenance of any favourable dentoalveolar changes.\textsuperscript{48, 72, 77}

7.4.3 Maxillofacial surgery / orthodontic relapse

Long-term reviews of maxillofacial surgical corrections have found the surgical procedures that involve lengthening or expanding the bones of the face have a high rate of relapse. These include bilateral sagittal split mandibular advancement osteotomies with rigid internal fixation (BSSMAORIF), and mandibular osteogenic distraction (MOD). Joss and Thuer\textsuperscript{152} found the relapse rate for BSSMAORIF procedures averaged out at 60\% of the initial advancement within 12.7 years; that is, 5\% per annum. Joss and Vassalli\textsuperscript{226} (2009) also found in a systematic review of BSSMAORIF cases that significant relapse occurred. Figure 7.2 shows the 17 years post treatment occlusion of a female who underwent a surgical bilateral sagittal split mandibular advancement procedure; she noticed how her surgical advancement gradually relapsed by 85\% over those 17 years.
Figure 7.2. A woman who underwent extensive orthodontic treatment coupled with a surgical bilateral sagittal split mandibular advancement at age 27 years, relapsed 10mm (85%) in 17 years

Photos reproduced with the kind permission of the patient.

The use of osteogenic distraction procedures to lengthen the mandible have a disturbingly high rate of relapse; a study by the Hooper et al. found an average relapse rate of 44.7% (range 25% to 80%) at one year post treatment. A 10 year follow-up study involving a patient with hemi facial microsomia treated with osteogenic distraction and fixed orthodontic appliances by Iseri et al. found that this case relapsed 100% within 10 years. Unfortunately, at present, there appears to be no guaranteed means available to prevent skeletal expansion or extension relapse.

7.4.4 Conclusions from the literature on relapse

The literature shows that almost all mechanically induced alterations to the dental arches will slowly relapse. This is especially true in cases that involve any expansion or alteration to the arch form, be it dento-alveolar or skeletal. The reason for the relapse may be due to the fact that although the tissues are altered en masse, the individual tissue cells are not
altered. Each cell has a unique genetic code which controls its growth and replacement that comes with ageing. It therefore follows that with further ageing after mechanically induced changes, the cellular replacement processes would re-establish the original (genetically determined) anatomy.\textsuperscript{228} This would explain why relapse usually occurs slowly.

### 7.5 What do patients want from orthodontic treatment?

The primary reason why patients undergo orthodontic treatment is to improve the appearance of their dentition and smile.\textsuperscript{25, 29, 30, 229} Patients rarely complain of having functional problems with their dentition either before during or after treatment. On the other hand, an unattractive dentition is known to be a psychological and social handicap with unpleasant consequences for the patient throughout their life time.\textsuperscript{21, 28, 230, 231}

#### 7.5.1 Patients’ long-term expectations from orthodontic treatment

In an editorial on patients’ expectations from orthodontic treatment, Vanarsdall and White\textsuperscript{55} mentioned patients expect that once active orthodontic treatment is completed, the teeth will remain aligned to the rest of their lives. Patients are disappointed if relapse occurs but they often accept the blame for any relapse because of their failure to strictly adhere to post-treatment retention instructions.\textsuperscript{73} These patients are also embarrassed by the relapse and often don’t complain about their result. These comments rely mostly upon anecdotal support because there are few studies in the literature to verify them. It is highly unlikely that patients would undergo orthodontic treatment if they were sure the treatment would fail and fortunately for the profession, almost all treatments result in some improvement to the dentition. Relapse discredits the credibility of both the patient’s orthodontist and the orthodontic profession and for this reason, preventing relapse is of paramount importance for everyone involved. Additional support for this claim comes from a study by Ren et al.\textsuperscript{232}(2009) on ‘Why do orthodontic patients seek retreatment’. The study found for the 100 adults patients involved (average age 27 years), the retreatment was to improve the smile and overall facial aesthetics. The relapse that occurred following their initial treatment provides further evidence of the need for permanent retention.

### 7.6 The need for orthodontists to educate dentists and patients about the problems of relapse and ageing changes

For orthodontic services to be improved, the orthodontic profession needs to educate both the dental profession and the general public about the problems of orthodontic, orthopaedic and surgical relapse; and also arch alignment deterioration that occurs with ageing. The profession and the public should to be made aware of the fact that ‘retention may be
forever’ if the outcomes achieved by orthodontic treatment are to be maintained indefinitely. They also need to be informed of the options available for achieving effective permanent retention.

7.7 Patients’ expectations from retention appliances

Ideally, patients would prefer retention appliances that are invisible, comfortable, convenient, not harmful, effective, durable, easy to clean and maintain and do not have a negative impact upon their quality of life.35 The best solutions available at present appear to be by using permanently bonded retainers (PBRs). The majority of dentists and patients surveyed on this topic were in agreement that BRs are the preferred option to RRs for preventing relapse.

7.8 Results of studies on the profession's acceptance of bonded retention (BR)

There has been a gradual increasing acceptance of the use of BRs within the dental and orthodontic professions. A survey of orthodontists in the USA in 200874 revealed that in 2002, 32% of orthodontists used mandibular BRs and by 2008 this percentage had increased to 41.4%. In 2002, 5.2% of orthodontists used maxillary BRs and this double to 10.6% by 2008. The opinions’ of orthodontists on the need for using PBR has increased from 27.2% of the profession in 2002 to 36.4% in 2008. Being conservative is a well demonstrated characteristic of orthodontists as is demonstrated by this slow uptake of new ideas on retention strategies.

7.9 Results from this 15 year retrospective (NEOTS) study

7.9.1 Effectiveness of bonded retainers (BRs)

The results of the effectiveness of the BRs reviewed in this study are presented in Tables 4.8. The conclusions drawn from these observations were that PBRs are effective at maintaining the alignment achieved by orthodontic treatment for beyond 15 years.

7.9.2 Durability of bonded retainers (BRs)

The durability of the BRs assessed in this study was excellent with a fracture rate of 0.58% of unit bonds/wires per annum. Some studies have shown similar low fracture rates89, 91, 101, 102 while others have been unacceptably high.98

The reasons given by patients for fractures occurring were: biting something too hard (35%), it just broke (46%) and the wire fractures (19%). De-laminations of the composite bond off the enamel surface occasionally occur within the first six months of BR fitting and these fractures probably happen due to contamination during the bonding process. The CR found that
the incidence of delamination decreases with increasing operator experience. To reduce the incidence of trauma related fractures, immediately after the BRs were fitted, patients were warned of the stress bearing limitations of BRs. The patients were asked to use their teeth sensibly; that included, to avoid biting hard foods or objects with their front teeth. They were advised to wear a mouthguard when playing any contact sports. They were also asked to report any breakages that occur as soon as possible so that repairs could be done expeditiously.

### 7.9.3 Long-term dental health impacts of bonded retainers (BRs)

These involved assessments of the following; Decay Index (DI); Plaque Index (PI); Calculus Index (CI); Gingival Recession Index (GRI); Modified Gingival Index (MGI); Alveolar Bone Index (ABI).

#### 7.9.3.1 Decay Index (DI)

There were no incidents of enamel decay or subsurface decalcification seen associated with any of the BRs or with any of the control group patients reviewed in this study. This supports the findings by other investigators who found likewise.\(^{91, 92, 95, 96, 100}\) The literature infers that the absence of enamel decay and subsurface decalcification may have been due more to the constant presence of saliva around the BRs rather than to good oral hygiene management. The protective buffering effect saliva has on bacterial acids is greatest in the anterior lingual regions of the mouth. The saliva also contains antibacterial agents and calcium, phosphate and other mineral ions which helped to re-calcify any enamel that is damaged by acid attack.\(^{202, 233}\)

#### 7.9.3.2 Plaque Index (PI)

Accumulations of plaque were observed in all NSG and NCG patients. Larger plaque accumulations were seen around and on the BRs. However, these were not excessive amounts and patients who manage their oral hygiene effectively had no problems because of this. There were no instances of tooth decay or subsurface decalcification observed. There were instances of gingivitis but these were seen in both the NSG and NCG patients.

The dental literature highlights how plaque is present in all mouths and it exists as a biofilm which requires regular (daily) mechanical removal to reduce the incidence of tooth decay and periodontal disease.\(^{185, 234, 235}\) The amount of plaque that accumulates is determined by many factors including the patient’s genetics, diet, eating habits and attention to oral hygiene.\(^{233, 236}\) The patients with BRs in place in this study did manage to keep their dental plaque under control by applying effective oral hygiene procedures.

#### 7.9.3.3 Calculus Index (CI)

Calculus was commonly seen associated with the BRs on the lingual surface in the mandible but not in the maxilla. The amounts of calculus were generally within the normal range that would be seen in any similar population group without BRs.\(^{27, 185, 215}\) The control group patients also had calculus accumulations in the same regions.
The periodontal literature highlights the fact that up to 90% of the adult population has calculus deposits on their dentition.\textsuperscript{27, 162} These deposits are particularly common adjacent to the saliva gland ducts in the lower lingual anterior regions and on the buccal surface of the maxillary first molars.\textsuperscript{215} The formation of calculus is constantly happening in mouths where there is a super saturation of mineral deposits in the saliva.\textsuperscript{202, 233} It is common for minerals to precipitate into any dental plaque matrix that is present in the immediate vicinity of saliva ducts. The presence of calculus itself is not a dental health risk, however, it provides a surface that plaque will readily accumulate on and thereby irritate the periodontium.\textsuperscript{237} The dental profession advises patients that the professional removal of calculus should be done on a regular six monthly or 12 monthly basis. Patients need to be aware of this if they wish to maintain an optimum level of oral hygiene and periodontal health.

7.9.3.4 Gingival Recession Index (GRI)

There were few instances of mild gingival recession seen associated with the BRs and none of these were attributed to the presence of the BRs. There were isolated instances of gingival recession involving a single tooth in several patients but these were not associated with any BRs. The most notable sites of gingival recession were not adjacent to the BRs; they sometimes occurred on the labial surfaces of the dentitions in both the NSG and NCG patients. Gingival recession occurred more often in mouths that were very well maintained; this was probably due to mechanical abrasion that accompanies over-enthusiastic tooth brushing.\textsuperscript{172, 204} There were no indications that the presence of BRs was responsible for gingival recession.

7.9.3.5 Modified Gingival Index (MGI)

Periodontal disease is a major concern in dentistry because of the potentially harmful implications it has for the general health and well-being of the patient.\textsuperscript{185, 238} The pathogenesis of the periodontal disease is complicated. There are up to 600 different types of microorganisms that may be present in the mouth and many establish themselves around the dentition in biofilms.\textsuperscript{234} These biofilms provide protection and nourishment for the microorganisms to the detriment of the host.\textsuperscript{239} A high standard of oral hygiene appears to be the best method of protection against oral biofilms.\textsuperscript{216} Approximately 15% of the population has a susceptibility to periodontal disease due to the following factors: the presence of specific bacteria, genetic factors, host responses, environmental factors, patient well-being, age, smoking habits and other factors not previously defined.\textsuperscript{185, 216, 233, 236}

The MGI was used in this study to gauge the periodontal health of the patients involved. This was done because it is a non-invasive procedure that is pain-free and has merit in its validity when combined with other periodontal assessments.\textsuperscript{179} The need to avoid potentially painful procedures such as periodontal pocket probing to obtain a bleeding on probing (BOP) measurement, was considered essential as this study may result in a need for ongoing reviews of the same patients in the future. If patients experienced pain in this study, it may discourage them from any future participation in similar studies.\textsuperscript{176}
From the observations of periodontal health in this study, it was concluded that patients did not have a higher risk of developing periodontal disease because of the presence of BRs.\textsuperscript{168}

### 7.9.3.6 Alveolar Bone Index (ABI)

Standardised OPG radiographs were taken to assess the alveolar bone height levels and determine if the BRs were responsible for any bone height loss. Many radiologists are aware that OPG views are poor for accurately assessing alveolar bone height. For this, long cone periapical radiographs are regarded as the gold standard. However, the use of OPGs for this purpose has support from many studies and was adopted for this study for the following reasons: the radiation exposure was minimal, the view of the bone levels were comprehensive and if there were any concerns arising from what was seen on the OPG radiograph, more in-depth long cone periapical radiographic investigations could be undertaken.\textsuperscript{181, 183, 240} An additional benefit was that OPGs are a time record of the patient's alveolar bone condition and can be used for comparative analysis in the future.

The levels of alveolar bone height seen in both the NSG and NCG patients were generally in the very good and good ranges with exceptions in patients who were elderly and/or who were smokers.

### 7.9.4 Opinions of Patients

This study found the majority of patients preferred having BRs fitted rather than wearing RR\text{Rs}. Patients were more appreciative of BRs when compared to RRs for reasons of convenience, effectiveness, durability, comfort, cleaning and impact upon their quality of life.

### 7.10 Opinions of Dentists

The majority of dentists, when surveyed for their opinions of the different retention methods, were in favour of the use of BRs rather than RRs. Most dentists were concerned by the non-compliance of patients when it came to wearing RRs and because of this; they saw that the BRs were more effective for preventing relapse. They also noticed that BRs were well accepted by patients. There were concerns amongst the dentists of poor oral hygiene problems with BRs in the mandible, however, the majority of dentists were in agreement that BRs were the best solution available at present to deal with the problems of relapse.

### 7.11 Conclusions

Upon the conclusion of active orthodontic treatment, this study strongly recommends that permanent bonded retention (PBR) is fitted to maintain the treatment outcome over the long term and thereby fulfil the expectations that patients have from orthodontic treatment.
Chapter 8  Conclusions and Future Recommendations

8.1 Introduction

The epidemiologist Sackett\textsuperscript{37} described how health professionals should assess the effectiveness of their treatment methods and develop strategies that will make treatments more efficient and effective over the long term for the benefit of all patients. Ackerman\textsuperscript{103} noted how ‘the challenge facing orthodontists in the 21st century is the need to integrate the accrued scientific evidence into clinical orthodontic practice’.

Until recently, the orthodontic profession asserted that the main benefits from correcting malocclusions were improved dental health and functioning of the dentition\textsuperscript{2}. However, the literature shows that dental health is more dependent upon the patient’s attitude and ability to maintain good oral hygiene than on the alignment of the teeth.\textsuperscript{216, 234} People with malocclusions very rarely seek orthodontic treatment to rectify functional problems with their dentition. This is because the majority of intending orthodontic patients do not have problems with mastication, swallowing, speech or with the general everyday functioning of their dentitions prior to commencing treatment.\textsuperscript{11, 14-16} Nor is this the case once treatment is completed. So why do patients undergo orthodontic treatment? Macgregor\textsuperscript{25} points out how a facial disfigurement such as an unattractive dentition, ‘is amongst the most debilitating handicaps a person can have’. The literature shows that the primary motivating force for people to undergo orthodontic treatment is to enhance the aesthetics of their dentition and smile.\textsuperscript{24, 229} Most pre-orthodontic treatment patients are embarrassed by the appearance of their crooked anterior teeth and see orthodontic treatment as a means to provide them with the solution to this problem.

This is where the philosophies of orthodontic treatment need to be revisited. As Sackett\textsuperscript{37} and Ackerman\textsuperscript{103} point out, it is the application of new knowledge that is necessary to advance orthodontics. However, achieving a consensus of opinions within the orthodontic profession regarding what treatment strategies should be adopted to prevent relapse, is very difficult as the profession is fractured by countries, faculties, interpretation of the evidence, bias and egos. Meanwhile, many patients are not receiving the benefits of this recently gained knowledge. Patients themselves may decide that they do not want PBR once active treatment is completed; however, the profession has a ‘duty of care’ to advise them of the post treatment relapse risks and of their retention options. Patients can then choose to accept or refuse PBR.

Acknowledging the need for permanent retention is the first step towards addressing the changes to orthodontic treatment protocols that are necessary. Once this is done, then a consensus on permanent retention strategies can be implemented. The orthodontic profession needed to ensure that permanent bonded retention was safe and effective before it was adopted; this has been done and recorded in the literature by Bearn\textsuperscript{98} and others; see Table 2.1 (page 26-27) and Table 2.2 (page 29).
At present, there is acknowledgement within the orthodontic profession that the best form of permanent retention is through the use of permanently bonded retainers (PBRs). However, PBRs have only been recently accepted for use (since the 1980’s) and there are still lingering concerns that they may not be safe or reliable enough for very long term use.

### 8.2 What this study found

This study confirmed the findings of others that BRs are effective, durable and safe for use over the longer term beyond 15 years. There were strong indications that BRs would endure well into the future. Figure 8.1 shows an example of a BR that has been in situ for more than 20 years; it has undergone only one composite repair (arrow) due to trauma and has shown no signs of fatigue or failure, or of causing dental health problems.

![Figure 8.1](image.png)

**Figure 8.1.** This maxillary BR has been in situ for 20 years and required only one composite repair (arrow) due to trauma

### 8.3 Benefits of bonded retention (BR)

The benefits of BR include an opportunity to reconsider the philosophy of orthodontics and how treatment options could be modified to improve treatment outcomes. The use of BRs would allow treatment plans to incorporate some degree of dental arch expansion and arch form modification in a way that would benefit the aesthetic outcome of treatment. Orthodontists could undertake treatments that would normally require extractions or have a high relapse potential with the knowledge that in the future, undesirable dental movements due to relapse and ageing would be prevented in the aesthetically important anterior regions. An example of this is demonstrated in Figure 8.2. Such treatment would require less time to complete and be less of a burden on the patient. The current unpleasant adjunct procedures such as fiberotomies and frenectomies involving the anterior teeth would not be necessary as the BRs are very effective at preventing rotational and spacing relapse.
Figure 8.2. A non-extraction orthodontic treatment that involved a mild degree of expansion in both arches and resulted in an aesthetically pleasing outcome. BRs were fitted in both arches.

Photos reproduced with the kind permission of the patient.

The patient in Figure 8.2 underwent (non extraction) orthodontic treatment because she was embarrassed by the appearance of her dentition. BRs were fitted to prevent the relapse that would otherwise have been anticipated because of the rotation corrections and expansion of the dental arches that occurred during treatment. No adjunct fiberotomy procedures were considered necessary.

The incorporation of BRs into treatment planning allows orthodontists more scope with their treatment options and also more confidence of providing a stable outcome.

The BR shown in Figure 8.3 was fitted to a corrected Class II Division 2 patient 23 years earlier; it demonstrates how durable composite resin can be after 23 years. This degree of durability adds long-term predictability to the outcome of treatment for both the patient and the orthodontist.
8.3.1 Future directions

BRs have been in use for approximately 30 years and now have proven effectiveness, reliability and dental health safety. The current intention of these retainers is that they remain in place permanently which may be for up to 80 years and more. With this in mind, there will be a need for ongoing reviews of BRs for over 80 years to monitor their reliability and dental health impacts. This will require ongoing up-dating of information gained both in private practice clinics and the University research fields. A dedicated world-wide web database could achieve this by allowing all dental personnel access to file reports on individual and group patients’ experiences with BRs, be they either positive or negative. The public and the dental profession could also be regularly updated on any new findings about the BRs.

The ultimate goal for the orthodontic profession is to provide patients with durable, comfortable and effective PBR which is not harmful to their dental health or quality of life. The cleaning and maintenance of BRs should not be a burden. The profession needs to reach agreement on the optimum design and fitting of these PBRs to ensure that all patients received the best current treatment outcome. This would require assessments of the current BRs and establishing optimum standards for the retainers that are fitted in the future.

8.3.2 Standardisation

BRs that are not properly designed or fitted are more likely to fail and bring their use and the reputation of individual orthodontist and the profession into disrepute. Standardising the requirements of ideal BRs would minimise the risks of failure and disappointment for both the patient and the orthodontist.
Consensus is required within the profession on the optimum design of BRs. with regards to the following:

1. **The wire frame**, its shape, length, thickness and the type of wire, should it be multi-stranded twist flex (MS) or single strand (S)? The use of non-wire frame materials could be investigated; at present, fibreglass materials have proven to be unreliable.
2. **The composite material and the bonding agent**.
3. **The fitting technique** with clarity of how the teeth should be cleaned, acid etched, rinsed and dried. The optimum shape, coverage and thickness of the composite over the wire needs to be determined.
4. **Techniques for repairing or replacing** fractured wires and composite material.
5. **Oral hygiene protocols**, daily cleaning and professional cleaning each year at dental checkups.

### 8.3.3 Education

There is a requirement to educate the dental profession and patients on the benefits of BRs. Who should make the judgement on which form of retention to use? The patient is often a child in their early teenage years without the maturity required to make a valued assessment of which retainers to fit. Should it be their parents or should it be the orthodontist who makes this judgement? If bonded retainers are fitted to a child, that child can have them removed when they come of age; removal of BRs is a non-invasive and straightforward process.

Patients need to be informed of the importance of maintaining an acceptable standard of oral hygiene if BRs have been fitted. The biofilms of dental plaque need to be removed effectively on a daily basis. All hard calculus deposits need to be removed by professional dental personnel at the least once each year depending upon the patient's rate of build-up. The BRs need to be inspected for damage once or twice each year; this could be done at the patient’s routine checkups.

Orthodontic schools may consider teaching students the procedures required for fabricating and fitting BRs and also for repairing them.

Both patients and professional dental personnel require ongoing education on the progressing developments of BRs and their oral hygiene requirements.
8.3.4 Ongoing research

In order to maintain the most up-to-date and effective means of preventing relapse and maintaining good oral health, there needs to be ongoing research and dissemination of information on the following:

- Oral hygiene protocols.
- Designs of BRs.
- Materials used for BRs.
- Fitting techniques for BRs.
- Education of both the dental profession and the general public.

8.4 Conclusions summary

There was no evidence found in the literature to provide credible support that even with long term use, removable retainers would guarantee the prevention of relapse. The current information gained from retrospective studies, including this one, demonstrated that bonded retainers are a far better solution for preventing relapse. What the literature did show was that the orthodontic profession generally dismissed patients from their care after the second year of retention and the profession grossly overestimated, or erroneously assumed, that patients would continue to wear their removable retainers indefinitely.\(^6, 74, 77, 208\)

The Cochrane Collaboration’s review of retention and relapse in 2009\(^68\) included a thorough search of the literature for randomised control trials on retention; none were found. A search of the literature by the author up until 2012 also failed to find any relevant RCTs on retention. The intention of the Cochrane Collaboration was to measure the following:

1. How well the teeth are stabilised.
2. Survival of retainers.
3. Adverse effects on oral health.
4. Adverse effects on quality of life.

This study was handicapped by being retrospective and without randomisation. However, it found that after 15 years, the bonded retainers as described in Chapter 3 produced the following outcomes.

1. The teeth were stabilised very well with 89% of bonded retention patients experiencing minor relapse of less than 1 mm on the Little’s Irregularity Index (LII) scale and for the remaining 11%, relapse was minor (acceptable) at less than 3mm. Whereas, over the same period, 53% of patients who were fitted with RRs experienced unacceptable relapse of > 3.0 mm.
2. The survival rate of the BRs in the 46 patients in the NSG was 100% with a fracture rate of 0.58% per annum. A few patients required and had successful repairs to their BRs.
3. There were no adverse effects on the oral health of patients wearing bonded retainers.

4. A statistically significant number of patients felt that their quality of life was better when bonded retainers were fitted, \( p = 0.003 \).

Although BR is not an ideal solution to relapse, the outcomes from this study were favourable for what the Cochrane Collaboration was intending to measure. These results support the use of BRs as a means of maintaining the outcome of orthodontic treatment over the long term. However, as the intended use of BR's is that they are left in place permanently, further monitoring over their expected lifetime of 80 years and more is necessary.

This study was unable to stratify the analysis into social (including dietary factors), professional and clinical factors. However, bonded retainers as described in this study were found to be very durable and effective at maintaining the alignment of the anterior teeth they were attached to. The study found that bonded retainers were not a risk to the health of the patients reviewed in this study. Equally, the patients and dentists survey to in this study preferred bonded retainers to removable retainers.
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Appendix A

Dentists’ Opinions on Orthodontic Retention Appliances

ROBERT CERNY, BDS, MDS
DEBORAH LLOYD, PHD, BA(Hons), Dip Ed

The need for permanent retention to prevent relapse is now widely acknowledged by orthodontists.1 Whether this is best achieved with permanent bonded retainers (PBRs) or removable retainers (RRs), however, is still a matter of debate. A review of the literature revealed no published studies comparing these two approaches to permanent retention.

Relapse is rare during the first five years after the end of active treatment, but within 10 years of debonding, fully one-third of orthodontic patients will have experienced severe relapse, with another third showing moderate relapse and the remaining third mild or no relapse.2,3 Because the relationship between patient and orthodontist typically lasts for only four years,4 relapse is seldom seen by the orthodontists themselves, but more often by the patients' general dentists. The present study was undertaken to determine the opinions of general dentists on the effectiveness, durability, and other features of PBRs and RRs.

Retainer Design

Although the participating dentists were instructed to rate any type of fixed retainers they had encountered, their primary experience was with the looped PBR used in Dr. Cerny's 30-year-old orthodontic practice in Newcastle, New South Wales, Australia (Fig. 1). The current PBR design is the product of many years of experimentation with different wire types and shapes to achieve optimal hygiene, comfort, effectiveness, and durability. A modification of Zachrisson's lingual wire retainer,5 it uses .018" round Regular Plus stainless

![Fig. 1 Loop-designed maxillary and mandibular permanent bonded retainers (PBRs).](image-url)
Appendix A

Dentists' Opinions on Orthodontic Retention Appliances

![Fig. 2 Respondents' ratings of permanent bonded retainers (PBRs).]

Steel wire, which has proved to be durable, flexible, comfortable, and easy to bend. The wire is bonded to the lingual and palatal surfaces of all anterior teeth with composite resin. Loops are added to the maxillary retainer to allow flossing and to avoid root-torque relapse. The longer span between abutment teeth increases the wire's flexibility and reduces loading stress on the composite resin, lowering the risk of composite fracture. Interincisal loops are not used in the mandibular design because of the shorter distance between the lower incisors, which makes the loops impractical and detrimental to patient comfort and oral hygiene. A five-year review of the reliability of these PBRs found that their fracture rate was less than 5%. Calculus deposits were common around the mandibular wires, but there were no cases of caries or periodontal disease.

The RRs reviewed in this study included conventional Begg and Hawley maxillary retainers, mandibular spring aligner retainers, and the increasingly popular thermoformed retainers, which were used in both arches.

Methodology

The initial study sample consisted of 71 dentists who had referred patients to Dr. Cerny's practice over the previous 23 years and were familiar with both conventional RRs and the looped-design PBRs. Dentists who had been retired for more than five years, had moved away from the area, or were on leave during the survey period were excluded.

The questionnaire covered the following topics:
- Demographic information, including age, sex, and number of years in dental practice.
- Approximate number of patients treated by the orthodontist.
- Duration of observation of both PBRs and RRs.
- Ratings of both retainer types for effectiveness, durability, oral hygiene in the maxilla and the mandible, patient satisfaction, and dentist satisfaction, with four rating options: poor, fair, good, and very good.
- Reasons for any rating of poor or fair.

The dentists were also invited to provide comments at the end of the questionnaire.

The questionnaire and a cover letter were sent to the 71 dentists along with a pre-addressed, stamped return envelope. Responses were kept anonymous to encourage the dentists to answer all questions.

*J. Wilcock, 45 Yea Road, Whitley, Victoria 3957, Australia.*
Appendix A

Cerny and Lloyd

![Graph showing respondents' ratings of removable retainers (RRs).](image)

Fig. 3 Respondents' ratings of removable retainers (RRs).

Questions honestly without fear of professional consequences. Two weeks after the mailing date, the dentists were telephoned by a research assistant and asked to return their completed questionnaires as soon as possible. The deadline was four weeks after the follow-up phone call.

**Results**

Of the 71 dentists who were mailed questionnaires, nine had moved away, three were on leave, and one had been retired for more than five years. This left 58 eligible dentists, 45 of whom returned the questionnaires, for a response rate of 78%. These respondents were 22% female and 78% male, roughly reflecting the ratio of dentists in New South Wales. About 64% of them had been in practice for more than 20 years, and 54% had encountered more than 100 patients with PBRs.

The combined percentages of dentists who rated the PBRs very good or good were 100% for effectiveness, 95% for durability, 82% for oral hygiene in the maxilla, and 36% for oral hygiene in the mandible (Fig. 2). For patient and dentist satisfaction, the combined ratings of very good or good were 86% and 93%, respectively. No dentists rated the PBRs poor in effectiveness, durability, or patient satisfaction, and only 2% rated them poor in dentist satisfaction. Oral hygiene was the greatest concern: 13% rated maxillary PBRs fair and 5% poor; 45% rated mandibular PBRs fair and 19% poor.

On the other hand, the percentages rating RRs very good or good were 39% for effectiveness, 38% for durability, 97% for oral hygiene in the maxilla, and 91% for oral hygiene in the mandible (Fig. 3). Patient and dentist satisfaction were rated very good or good by 38% and 29%, respectively. The percentages of dentists rating RRs fair or poor were 61% for effectiveness, 62% for durability, 62% for patient satisfaction, and 71% for dentist satisfaction. Oral hygiene was rated fair or poor in the maxilla by 3% and in the mandible by 9%.

Thirty-five respondents added comments on PBRs. Of these, 83% mentioned oral-hygiene problems, including 46% who noted the difficulty of cleaning in the mandible and 34% who were concerned about calculus buildup. Obstruction of flossing between the lower incisors was cited by 23% of the respondents. Concerns about detection and repair of broken retainer wires were raised by 17%. Nine percent noted that some patients found the PBRs irritating. Other concerns were uncertainty about how long PBRs should be worn, long-term effects and their potential contribution to
Appendix A

Dentists’ Opinions on Orthodontic Retention Appliances

periodontal problems, interference with root-canal treatment, and gingivitis caused by nickel allergies. Forty-six percent of the remarks were positive. Representative comments included:

- "Well designed, and with good patient education, they are very good."
- "PBRs are the only effective mechanisms we have to stop tooth relapse."
- "Without fixed retention, teeth drift out of alignment."
- "They are far from perfect, but they are the best available."
- "PBRs should be fitted straight after debanding."
- "Who should repair and maintain them?"
- "Some patients ask to have them removed."
- "The majority of parents prefer PBRs."
- "Zigzag wires that don't impinge work well."
- "Can't be cleaned!"
- "Oral-hygiene education and patient education are poor."
- "Generalized decrease in periodontal ligament width."
- "Periodontal concerns for middle-age patients—what will happen?"
- "Research needed into how long they should be worn."
- "Surely they can be removed after 10 years."
- "Issues with nickel-allergy-induced gingivitis."

Thirty-four respondents provided comments on RRs. Ninety-one percent were concerned about long-term compliance with retention. The problems of plaque and calculus accumulation on RRs were mentioned by 12%, and breakage and loss of retainers were also cited as problems. On the positive side, RRs were noted to be better than PBRs at preventing posterior crossbite relapse. Some of the responses were:

- "Superior to PBRs if worn."
- "Compliance drops off dramatically after 12 months."
- "Poor oral hygiene can be a problem."
- "In 50% of cases, I see relapse."
- "Appliances get broken and lost."
- "After years of orthodontic treatment, patients don’t want to think about this any more and discard them."

Discussion

These survey results showed that PBRs were regarded as superior to RRs in terms of effectiveness, durability, patient satisfaction, and dentist satisfaction. For oral hygiene, however, RRs were seen as somewhat better in the maxilla and much better in the mandible. The high patient satisfaction rate for PBRs (86%) supports the conclusions of Wong and Freer, who noted that “patients found fixed retainers more acceptable than removable retainers because of appearance and comfort.” The high dentist satisfaction rate (93%) supports the findings of Wong and Freer on the acceptance of fixed retention by orthodontists in Australia and New Zealand, where “most respondents preferred bonded retainers.”

The primary problem of the PBRs reviewed in this study was inadequate oral hygiene. Although the looped-wire design allows flossing between teeth, the impracticality of loops between the lower incisors makes cleaning in these areas difficult (Fig. 4). A floss threader can be used to guide the floss under the wire, and regular use of interdental

Fig. 4 Increased accumulation of plaque and calculus around mandibular retainer compared with maxillary retainer.
Appendix A

Cerny and Lloyd

brushes and toothpicks can help, but only the most diligent patients will succeed in avoiding calculus buildup around the lower incisors and retainer wire. Therefore, calculus should be professionally removed every six to 12 months, as in any patient. Moreover, dental-care providers need to stress the importance of oral hygiene and educate patients in how to achieve it. In a study on the periodontal implications of bonded and removable retainers, Heier and colleagues concluded: "Slightly more plaque and calculus were present on the lingual surfaces in the fixed retainer group. This did not result in more pronounced gingival inflammation than in the removable retainer group, within the evaluated period (six months)."

Some respondents commented that PBRs did not prevent crossbite relapse. PBRs that have been extended to incorporate the molars have experienced problems of durability and food impaction between the wires and the teeth. Even though RRs were considered better at preventing posterior crossbite, however, such relapse does not necessarily create functional or esthetic problems.

Questions remain about the long-term effects of PBR wear. Composite-bonded PBRs have been in use only since the early 1970s, but observational studies to date have found no apparent harm to the dental or periodontal tissues. Periodontal tissues seem to become more vulnerable to disease with increasing age, however, and this vulnerability may be exacerbated by PBRs. Further studies are needed to determine long-term outcomes of PBR wear.

Regarding gingivitis due to nickel allergies, the "018" Regular Plus stainless steel wire shown here has been used in orthodontics for more than 50 years without apparent problems. Moreover, Kao and colleagues found that nickel-containing orthodontic metal bracket immersion medium appears to be biocompatible with oral gingival fibroblasts and human osteogenic sarcoma cells.

The main concern about RRs was noncompliance and subsequent relapse. As one dentist wrote, "We are talking about teen-agers here; show me a 16-year-old teen-age boy who is going to wear a removable retainer for years." Such non-compliance is virtually impossible with PBRs, which cannot be misplaced or taken off.

Conclusion

This study found that permanent retainers were regarded as superior to removable retainers in terms of effectiveness, durability, patient satisfaction, and dentist satisfaction. The majority of respondents, however, expressed concern about oral-hygiene problems in the mandible, where cleaning is difficult and supragingival calculus buildup is common. When removable retainers, the respondents were concerned about noncompliance and subsequent relapse. Overall, the general dentists believed permanent bonded retainers to be the best currently available approach to the problem of relapse after orthodontic treatment.

REFERENCES

Appendix B

A Survey of Patient Opinions on Fixed vs. Removable Retainers

ROBERT CERNY, BDS, MDS
DEBORAH COCKRELL, PHD, BDS, FDS RCPS
DEBORAH LLOYD, PHD, BA(Hons), Dip Ed

As many as two-thirds of all patients will demonstrate moderate-to-severe relapse within 10 years after orthodontic treatment. As a result, patients are becoming both more aware and more accepting of the need for long-term retention. Although many orthodontists have promoted the need for permanent retention, few investigators have assessed the opinions and preferences of patients regarding the use of permanently bonded retainers (PBRs) as opposed to removable retainers (RRs). The present survey, part of a long-term retrospective study, solicited the views of post-retention patients on the relative merits of fixed vs. removable retainers.

Methodology

The University of Newcastle, Australia, granted approval for this study. All patients had completed comprehensive orthodontic treatment, including both extraction and nonextraction therapy, with Dr. Cerny before 1993. Of 671 randomly selected potential participants, we had valid telephone numbers for 236. Of these, 61 agreed to participate, for a response rate of 25.8% of the patients who could be located, or 9.1% of the initial sample.

The RRs prescribed were maxillary Hawley plates and mandibular spring aligners. The PBRs were typically fabricated from .018" round Wilcock* Regular Plus stainless steel wire bonded to all the anterior teeth; in nine cases, only the mandibular canines were attached to .025" stainless steel round wires. The adhesive used was Silux** composite.

Each patient who responded to the invitation was asked to complete a questionnaire that included the following items:
- Demographics: sex, age, and education
- General health, including smoking habits
- Dental health practices: brushing, flossing, toothpick use, and frequency of dental visits and cleanings
- Comfort, oral hygiene, and impact on quality of life of retainers
- Perceived results of retainer wear: straightness of teeth, overall outcome, bite comfort, and TMD
- Reasons for discontinuing use (if applicable)
- Any relapse noted

Dr. Cerny reviewed the questionnaire with each patient to ensure completion. Some sections were left blank because of uncertain patient recall. The data were then transferred to a spreadsheet for analysis.

We assumed that 20% more of the patients who had worn both PBRs and RRs would rate the PBRs as better in terms of comfort, oral hygiene, and impact on quality of life. Under that assumption, at least 44 treated patients (PBR and/or RR) and 15 control patients (RR only) would be needed to demonstrate a statistically significant difference (p < .05), as indicated by a power of .8 in chi-square testing.

After completing the questionnaire, each patient underwent clinical examination, facial and intraoral photography, and panoramic radiography. Based on this evaluation, Dr. Cerny rated each patient's relapse as minimal (1-3mm), moderate (4-6mm), or severe (7-9mm), according to the Little Irregularity Index scale.

Results

The study group consisted of 46 patients who had worn 55 PBRs (41 maxillary, 14 mandibular, nine in both arches; Table 1) and 28 RRs (four
Appendix B

Dr. Cerny is in the private practice of orthodontics at Hunter Valley Orthodontics, 199 Scott St., Newcastle, New South Wales 2300, Australia; email: rcerny48@gmail.com. Dr. Cockrell is an Associate Professor and Head of Discipline of Oral Health, and Dr. Lloyd is a Consultant in Medical Research and Medical Education and Conjoint Academic, School of Medicine and Population Health, Faculty of Health, School of Health Sciences, University of Newcastle. This research was part of Dr. Cerny’s doctoral study for the Discipline of Oral Health, University of Newcastle.

### TABLE 1
PERMANENTLY BONDED RETAINERS IN SAMPLE

<table>
<thead>
<tr>
<th>No. Bonds</th>
<th>No. Patients</th>
<th>Total Bonds</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maxilla</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3-3</td>
<td>6</td>
<td>20</td>
</tr>
<tr>
<td>2-2</td>
<td>4</td>
<td>16</td>
</tr>
<tr>
<td>1-1</td>
<td>2</td>
<td>5</td>
</tr>
<tr>
<td>Mandible</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3-3</td>
<td>6</td>
<td>5</td>
</tr>
<tr>
<td>3-3</td>
<td>2</td>
<td>9</td>
</tr>
<tr>
<td>Totals</td>
<td>55*</td>
<td>242</td>
</tr>
</tbody>
</table>

*9 patients had bonded retainers in both upper and lower arches.

maxillary, 24 mandibular). The control group included 15 patients who had worn 27 RRs (14 maxillary, 13 mandibular). Because Dr. Cerny did not routinely prescribe PBRs upon completion of active treatment before 1993, 30 of the 46 patients had been fitted with PBRs after initially wearing RRs in the same arches.

Overall, 75% of the patients were female, 65% were under age 40, 45% held a university degree or higher, 98% reported good or very good health, and 46% were current or former smokers. The time elapsed since active treatment ranged from 15 to 22 years, with a mean of 17.3, for the PBR group and from 16 to 28 years, with a mean of 19.3, for the RR group. All patients reported brushing their teeth daily, and 33% flossed daily. Although 72% of the patients visited a dentist more often than every two years, usually involving prophylactic scaling and cleaning, 16% reported that they had never had professional cleaning (Fig. 1).

The proportions of patients who rated the RR as good or very good were 54% for comfort, 69% for hygiene, and 45% for impact on quality of life (Fig. 2). Ratings of good or very good for the PBR totaled 95% for comfort, 78% for hygiene, and 95% for impact on quality of life (Fig. 3). The differences among the two groups were not statistically significant.
Among the 30 patients who had worn PBRs after initial RRs (Fig. 4), 100% rated the comfort of the PBR as the same or better than that of the RR, 73% rated their hygiene as the same or better, and 93% rated the impact on their quality of life as the same or better. Half of these patients thought the PBRs were more comfortable than the RRs, and 57% felt the impact on their quality of life was better with the PBRs. There was no significant difference between the retainer types in terms of oral hygiene.

Among the RR group, 87% rated the straightness of their teeth as good or very good, 93% rated their overall treatment outcomes as good or very good, and 100% rated their bite comfort as good or very good (Fig. 5). The corresponding ratings for the PBRs were 100% for tooth straightness, 94% for overall outcome, and 100% for bite comfort (Fig. 6). TMD experiences were similar for the two groups: 80% reported having no TMD, 16% reported clicking symptoms, and 4% reported painful episodes.

Patients stopped wearing their RRs because of discomfort (44%), embarrassment (15%), and other reasons (41%), which included “hearing” that they could stop wearing their retainers after two years. Sixty-three percent of the RR patients had noticed post-treatment relapse. Even among those who had noticed no relapse, however, 56% showed at least moderate relapse in their clinical evaluations (Fig. 7).

Discussion

In this limited study of self-reported treatment outcomes, patient opinions were more favorable overall for PBRs than for RRs with regard to comfort, hygiene, and impact on quality of life. These findings are nearly identical to those of our previous studies of a different sample of patients and a group of practicing dentists. The patients most qualified to judge the
merits of both retainer types were the 30 who wore PBRs after initial RR use. Most of these patients preferred the PBRs, especially for comfort and impact on quality of life. These findings corroborate those of our earlier study and another by Wong and Freer.

Signs of TMD occurred in similar proportions of both groups: 16% reported clicking and 4% reported having painful episodes with their joints, corresponding to observations of the general U.S. population.

The dental health practices of our study group were similar to those of an adult sample from the United Kingdom: more than half the patients in both studies visited the dentist at least once a year, more than 95% brushed their teeth at least daily, and about a third used dental floss regularly.

Limitations

Like other retrospective studies, the present survey displays several known types of bias: selection bias, response bias, volunteer bias, non-responder bias, and survivor bias, among others. Because Dr. Cerny had fitted all the retainers and supervised the patients' retention programs, he was aware of their treatment histories during the clinical reevaluations. This could have introduced observer and expectation bias, but it also removed the possibility of interobserver variability.

Self-reporting can result in recall, personal assessment, and opinion biases. We attempted to minimize some of these patient-related biases through random selection and by having patients complete the questionnaires before the clinical examinations. The final study group was similar to the overall patient cohort in terms of orthodontic treatments, consisting predominantly of adult women with above-average educational levels who were in good health, but were somewhat more likely to smoke than the general Australian population.

Conclusion

Maintenance of acceptable oral hygiene with permanently bonded retainers was not a concern for most of this sample of orthodontic patients. In general, they favored the PBRs over removable retainers for effectiveness, comfort, and impact on quality of life, and they appeared to accept the need to wear and maintain the PBRs indefinitely.

REFERENCES

Appendix C

Long-Term Results of Permanent Bonded Retention

ROBERT CERNY, BDS, MDS
DEBORAH COCKRELL, PHD, BDS, FDS RCPS
DEBORAH LLOYD, PHD, BA(Hons), Dip Ed

Relapse or age-related deterioration in arch alignment, or both, occurs in more than 90% of orthodontic patients after their appliances are removed.1,2 Permanent retention has been found to be the most reliable way to maintain alignment.3,4

Fixed retention has evolved considerably since the introduction of early devices,5,8 which were highly visible, unattractive, and labor-intensive.7 The development of reliable, esthetic bonded retainers5,9 and additional refinements have led some orthodontists to place these wires permanently—that is, as permanent bonded retainers (PBRs).10,11 Surveys have found that both dentists and patients prefer PBRs over removable retainers (RRs),12-14 and studies have also shown PBRs to be more effective and reliable for long-term retention.10,11,15-17

Although unfavorable reports about PBRs have been rare,18,19 the evidence regarding their long-term reliability and iatrogenic effects on the dentition has been inconclusive. We evaluated the effectiveness, durability, and dental-health impact of PBRs in both arches more than 15 years after treatment.

Methodology

This study involved patients participating in the Newcastle Effects of Orthodontic Treatment Study (NEOTS), for which the methodology has been previously published. Each patient had worn a PBR or RR, or both, over the past 15 years. Forty-six patients had worn PBRs for more than 15 years, and 43 patients had worn RRs for as long as two years. (Most RR patients stopped wearing their retainers before two years had elapsed.) The survey instruments for each patient included a panoramic radiograph, a questionnaire about the patient’s orthodontic treatment, and a clinical examination in three stages:
1. Four extraoral and seven intraoral digital imag-
Appendix C

**Long-Term Results of Permanent Bonded Retention**

### TABLE 1

<table>
<thead>
<tr>
<th>LII* Relapse Category</th>
<th>Maxilla</th>
<th></th>
<th>Mandible</th>
<th></th>
<th>Totals</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>PBR**</td>
<td>RR***</td>
<td>PBR</td>
<td>RR</td>
<td>PBR</td>
</tr>
<tr>
<td></td>
<td>(N = 41)</td>
<td>(N = 18)</td>
<td>(N = 14)</td>
<td>(N = 37)</td>
<td>(N = 55)</td>
</tr>
<tr>
<td>None (0-1mm)</td>
<td>92.7%</td>
<td>11.0%</td>
<td>78.6%</td>
<td>5.0%</td>
<td>89.0%</td>
</tr>
<tr>
<td></td>
<td>p &lt; 0.001</td>
<td>p &lt; 0.001</td>
<td>p = 0.334</td>
<td>p &lt; 0.001</td>
<td>p &lt; 0.001</td>
</tr>
<tr>
<td>Mild (1-3mm)</td>
<td>7.3%</td>
<td>45.0%</td>
<td>21.4%</td>
<td>38.0%</td>
<td>11.0%</td>
</tr>
<tr>
<td></td>
<td>p = 0.002</td>
<td>p = 0.001</td>
<td>p = 0.002</td>
<td>p &lt; 0.001</td>
<td>p &lt; 0.001</td>
</tr>
<tr>
<td>Moderate (3-6mm)</td>
<td>0.0%</td>
<td>33.0%</td>
<td>0.0%</td>
<td>46.0%</td>
<td>0.0%</td>
</tr>
<tr>
<td></td>
<td>p &lt; 0.001</td>
<td>p = 0.002</td>
<td>p = 0.002</td>
<td>p &lt; 0.001</td>
<td>p &lt; 0.001</td>
</tr>
<tr>
<td>Severe (&gt;6mm)</td>
<td>0.0%</td>
<td>11.0%</td>
<td>0.0%</td>
<td>11.0%</td>
<td>0.0%</td>
</tr>
<tr>
<td></td>
<td>p = 0.089</td>
<td>p = 0.565</td>
<td>p = 0.057</td>
<td>p = 0.057</td>
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</tr>
<tr>
<td>Mean</td>
<td>0.21mm</td>
<td>3.13mm</td>
<td>0.40mm</td>
<td>3.49mm</td>
<td>0.26mm</td>
</tr>
</tbody>
</table>

*Little’s Irregularity Index.
**Permanent bonded retainer.
***Removable retainer.

es were taken, the widths of the maxillary and mandibular right central incisors were measured to within .01 mm with digital calipers, and relevant pathologies involving the enamel or periodontium and PBR fractures were recorded.

2. Plaque-disclosing tablets (Discolat®) were used to indicate the presence of any dental plaque, and five intraoral digital images were taken.

3. Prophylactic scaling and cleaning of the anterior teeth and any PBRs preceded a thorough final examination and recording of any previously missed dental or periodontal pathology.

The effectiveness of the retainers was assessed according to Little’s Irregularity Index (LII),20 which categorizes the amount of misalignment (relapse) in the anterior teeth as none (0-1mm), mild (1-3mm), moderate (3-6mm), or severe (>6mm). LII measurements were made from paper copies of the occlusal digital images of the anterior teeth and compared with the actual widths of the right central incisors for reliability.21

The durability of the retainers was evaluated by the number of times the PBRs had broken (bond or wire fractures), as determined both in clinical examinations and from patient reports.

The impact on dental health was measured by the following Dental Health Indices (DHI), each of which was rated very good, good, fair, poor, or very poor:

- Decay index
- Plaque index22
- Calculus index22
- Gingival recession index23
- Modified gingival index24
- Alveolar bone index25

The reliability and validity of measurements made by the chief researcher (Dr. Cerny) were assessed by comparing them with measurements made by two pairs of blinded, independent examiners (two orthodontists and two periodontists). Records for two random sets of 10 patients each (six from the PBR group, four from the RR group), selected by stratified random sampling, were used for comparison—the first set for the LII measurements and the second for the DHI rankings. The chief researcher repeated his measurements on two occasions, six months apart, to establish their reproducibility. The two random sets were compared for agreement (validity) with those of the four independent examiners using Bland-Altman plots and Spearman’s rank correlation coefficient analysis.27 The measurements were verified as reliable and valid in consultation with an independent University statistician.

The statistical significance of differences between the PBR and RR groups was assessed by means of the chi-square Fisher’s exact test, with a two-tailed p value of ≤.05 considered significant.

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Results

Among the 61 NEOTS patients who participated in the study, 46 had worn 55 PBRs (41 maxillary, 14 mandibular), and 43 had worn 55 RRrs (18 maxillary, 37 mandibular). The 28 patients who had worn both PBRs and RRrs were included in both groups as appropriate.

The average LII after 15 years of retention was .26mm for patients who wore PBRs and 3.37mm for those who wore RRrs (Table 1). When the PBR had remained intact, 100% of the patients showed mild or no misalignment. Mild relapse in this group was associated with composite or wire fractures or with failure to bond the lower incisors to the retainer wires (Fig. 1). In contrast, more than half the RR group had experienced moderate or severe relapse. The differences between the groups were significant in all categories except severe relapse.

Three bond failures and five broken wires were detected in six patients in the PBR group upon clinical examination. Most of the patients were unaware of the breakages and had not noticed any tooth movement. Another 15 patients in the PBR group reported having broken their PBRs over the 15-year period, with three having done so on two occasions. Overall, 21 of the 242 composite bonds and five of the 55 retainer wires had fractured over the 15 years, for a total PBR fracture rate of 3.15% per year and a unit bond/wire fracture rate of .58% per year. Composite fractures accounted for 81% of the failures and wire fractures for 19%. Of the bond fractures, 43% were attributed by the patients to biting down on something hard, while the causes of the remaining 57% were unknown.

None of the DHI rankings differed significantly between the two groups. No incidents of decay or subsurface decalcification were seen in any of the patients.

The plaque index on the maxillary lingual tooth surfaces was consistently rated very good or good, except among the 10% of patients who wore PBRs in both the maxilla and the mandible, for whom the plaque index rating was fair ($p = .408$ compared with the RR group). On the mandibular
lingual surfaces (Fig. 2), the plaque index was very good or good for 40% of the PBR group and 80% of the RR group ($p = .060$).

No calculus was noted on the maxillary anterior lingual surfaces in any of the patients in either group. On the mandibular lingual surfaces, the calculus index was rated very good or good for 80% of the PBR group and 100% of the RR group ($p = .259$). Only a few patients in either group were rated as poor or very poor (Fig. 3).

Gingival recession ratings were very good or good for all patients in both groups. Isolated instances of gingival recession were not considered to be related to the retainers (Fig. 4).

The modified gingival index was rated very good or good in the maxillary arch for all patients. In the mandibular arch, it was rated very good or good for 80% of the PBR group and 95% of the RR group ($p = .129$). There were no ratings of poor

Fig. 3 Extreme example of calculus seen in PBR patient.

Fig. 4 Gingival recession seen on labial surfaces of anterior teeth, attributed to overzealous oral hygiene.

Fig. 5 Worst examples of chronic marginal gingivitis, in PBR patient (A), and chronic periodontal inflammation, in middle-aged control patient (B), affecting alveolar bone only minimally in each patient.
or very poor in either group (Fig. 5).

The maxillary alveolar bone index was very good or good for 85% of the PBR group and 90% of the RR group (p = .845). The mandibular index was very good or good for 100% of the PBR group and 90% of the RR group (p = .520). Overall, the alveolar bone levels in both groups were rated very good or good for more than 85% of the patients, excluding those who were older than 50 and those who smoked (Fig. 6). There were no indications that PBRs were responsible for alveolar bone loss.

Discussion

In this retrospective case-control study, PBRs effectively maintained the alignment achieved by treatment for as long as 15 years, with an LII of less than 1mm in 89% of the cases and less than 3mm in the other 11%. In contrast, only 7% of the patients who wore RRs showed less than 1mm of relapse, and 40% had less than 3mm. The degree of gingival recession, periodontal disease, and alveolar bone loss did not differ significantly between the two groups.

The annual fracture rate for the PBRs was .58% per unit bond/wire, which compares with findings in other studies.\textsuperscript{10,28,30} The time required to repair fractured PBRs was usually less than 15 minutes per unit bond/wire.

Although accumulation of dental plaque and calculus tended to be greater in the PBR patients, neither group showed tooth decay or subsurface decalcification of the enamel. This may be explained by the placement of the PBRs in areas constantly bathed with saliva, which contains remineralizing ions and has acid-buffering and antibacterial properties.\textsuperscript{31} Furthermore, considering that most of the PBR patients had routinely visited their dentists once or twice a year,\textsuperscript{14} any calculus deposits were likely to be removed, thus reducing the risk of periodontal disease.

Conclusion

Fifteen years or more after their placement (Fig. 7), permanent bonded retainers were found to be very effective at maintaining the alignment.
Appendix C

Long-Term Results of Permanent Bonded Retention

achieved by orthodontic treatment. We found no clinically significant differences in the dental health of patients who had worn permanent bonded retainers vs. those fitted with removable retainers.

REFERENCES


Appendix D

Human Research Ethics Committee
The University of Newcastle

Hunter Area Research Ethics Committee
Hunter Health

INITIAL APPLICATION FOR
ETHICS APPROVAL FOR RESEARCH INVOLVING HUMANS

NOTE: This form is to be used for applications to The University of Newcastle Human Research Ethics Committee (HREC), and/or the Hunter Area Research Ethics Committee (HAREC), Hunter Health.

Do not use this form to renew an existing approval or to apply for approval of additions or variations/amendments to an approved project – refer to Renewal and Variation application forms.

1 SHORT TITLE OF PROJECT (limit 150 characters – see Guidelines)

THE NEWCASTLE EFFECTS OF ORTHODONTIC TREATMENT STUDY (NECTS)
Permanent Fixed Lingual Retention in Orthodontics: long-term effectiveness and impact on periodontal health.

2 APPROVAL FROM ANOTHER ETHICS COMMITTEE

Has this project been submitted (or will be submitted) to another Ethics Committee for approval – this includes dual submission to HREC/HAREC? Yes ☐ No ☒

If YES, name the committee(s), and give the status of each application? (Attach 4 copies of correspondence with each Committee)

<table>
<thead>
<tr>
<th>Name of Ethics Committee and Institution</th>
<th>Application Reference No.</th>
<th>Approved/Pending/Rejected/To be submitted</th>
</tr>
</thead>
</table>

3 CHIEF INVESTIGATOR or PROJECT SUPERVISOR (Note: only one person to be named)

Deborah Cockrell PhD, BDS, FDSRCS
Head of Discipline of Oral Health Uni of Newcastle.
Qurimbah Campus, PO Box 127, Brush Rd. Kurimbah 2258

deborah.cockrell@newcastle.edu.au

4 CO-INVESTIGATORS and/or STUDENT RESEARCHER

Dr Deborah Lloyd
BA (Hons), Dip Ed, PhD
Consultant in Medical Research and Medical Education, and Conjoint Academic, School of Medical Practice and Population Health, Faculty of Health
PO Box 6952 Kiahba 2550

deborah.lloyd@newcastle.edu.au

Dr. Robert Cerny
BDS, MDSc: Specialist Orthodontist
139 Scott St. Newcastle 2300

cerny@bpeodont.net.au
Appendix D

5 STUDENT RESEARCH
Is the research the project of a student of The University of Newcastle?  Yes [x]  No [ ]
(Note: coursework students applying to the Hunter Area Research Ethics Committee (HAREC) must first obtain approval from the respective faculty based research ethics committee.)

If YES:  
Name of student:  Robert Carney  
Course of study:  PhD  
Principal supervisor:  Associate Professor D Cockrell

Student No:  3037689

6 ESTIMATED DURATION OF PROJECT (dd/mm/yyyy)
This is the period during which you anticipate contact with participants, their personal records, or human tissue samples.

From:  01/02/06  To:  31/12/07
Appendix D

7 FUNDING
Is the project the subject of an application for funding to an internal or external grants body, drug company, etc? Yes ☐ No ☒

If YES: (a) List the funding sources and give the status of each application. (Attach 4 copies of the primary application for funding)

<table>
<thead>
<tr>
<th>Funding Body</th>
<th>Approved/Pending/Rejected/To be submitted</th>
</tr>
</thead>
<tbody>
<tr>
<td>NA</td>
<td></td>
</tr>
</tbody>
</table>

(b) What is the exact project title on the funding application(s)?

8 PRIVACY LEGISLATION
Does the project involve access to personal information held by a Commonwealth department or agency, or a private sector organisation? Yes ☒ No ☐

If YES, will the access to personal information be without the consent of the individual(s) to whom the information relates? Yes ☐ No ☒

If YES to both of the above, specify the type of data to be accessed/collected, the departments/agencies holding the information, and the number of records involved.

This project involves access to a database containing the orthodontic clinical records held by Robert Cerny (student). All patients were aware at the outset of their treatment that clinical records were legally required to be maintained by this practitioner. The database will be used to identify patients who completed orthodontic treatment between January 1989 and December 1991 (see Item 14). Each record will be independently coded and these codes will be used throughout the study. It is estimated that a total of approximately 700 patients will be eligible for inclusion, from which a sample of 250 will be randomly selected.

9 AIMS AND VALUE OF PROJECT
Using plain English, provide a concise and simple description of your proposed research, which sets out the background, precise aims/hypotheses/research questions, why you consider the research is worth doing, and what its potential merit and significance might be. Include references from your literature review to support the description.

The aim of this study is to investigate the long-term dental alignment stability and periodontal health of patients who had orthodontic treatment completed between January 1989 and December 1991 and to compare the impact of fixed and removable retainers on these outcomes. During the period under investigation, Robert Cerny used both fixed retainers and removable retainers after orthodontic treatment.

Orthodontic (braces) treatments are used to align crooked teeth thereby improving the functioning of the dentition and self-esteem of the patient as it enhances the beauty of the face and smile (Graber 1972). One of the most significant problems associated with orthodontic treatment is the retention of the achieved final occlusion after treatment is completed. It is recognised that once the braces are removed, the teeth often relapse back towards their pre-treatment malalignment positions (Little 2002).

The use of Permanently Fixed Lingual Retainers (PFLR) involves a custom shaped stainless steel wire bonded to the back surface of the anterior (front) teeth as this appears to provide a solution for the problem of relapse (Wong and Freer 2005). Heier et al. (1997) reviewed the periodontal health of teeth that were attached to PFLR's for only 3 years or less and found no significant problems of concern. In view of the lack of long-term evaluation of outcomes, Littlewood et al (2004) have expressed an urgent need for good studies in this field of orthodontics. As more orthodontists around the world are now adopting this method of retention, its effectiveness and impact on oral health needs to be scientifically assessed to justify its continued use.

Robert Cerny has a database of all patients who received orthodontic treatment during the defined period and who were provided with either removable or fixed retainers. The database also contains demographic data and other treatment information for all patients. This data has been kept with the
Appendix D

patients consent and complies fully with professional privacy requirements. The recruitment of patients from this database will be completed by a Research Assistant and Robert Cerny will only communicate with the patients during the clinical examination and on completion of the study (please see later notes).

The information obtained from this research will be beneficial for both orthodontic patients and the orthodontic profession.

Further avenues of research that will be created by this project include:

1. Longitudinal evaluation of PFLR
2. Design analysis of PFLR
3. Materials used in fabricating PFLR
4. Techniques used when fitting PFLR


10 REPLICATION STUDIES

Has the same or a similar study been conducted in Australia or overseas? Yes [X] No

in Australia, the student researcher (Robert Cerny) completed and reported (Journal of Clinical Orthodontics 2001) a pilot study review of the long-term (up to 17 years) effectiveness and oral health impacts of PFLR. The pilot study indicated that the PFLR were effective in preventing relapse and that there were no detrimental effects on oral health status however the sample size was small and the scientific method used was inadequate for establishing valid conclusions. This pilot study has informed the development of this proposal.

There have been few other studies on this topic. Studies that have been done on the effectiveness and/or oral health impacts of PFLR include Artun (1984), Zachrisson (1995), (1997) and Heier et al (1997). However, these studies were limited by sample size and did not consider PFLR that had been in situ for any longer than 6 years. There were no reports of any significant harmful effects from any of these studies.


INITIAL APPLICATION FOR ETHICS APPROVAL FOR RESEARCH INVOLVING HUMANS – HE1.5/02  Checklist
Appendix D

11 SPECIFIC TYPES OF RESEARCH

<table>
<thead>
<tr>
<th>Research Category</th>
<th>Yes</th>
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</tr>
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<tr>
<td>Children or young people under 18 years of age? (NS 4)</td>
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</tr>
<tr>
<td>People with an intellectual or mental impairment, temporary or permanent? (NS 6)</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>People highly dependent on medical care, eg emergency care, intensive care, neonatal intensive care, terminally ill, or unconscious? (NS 8)</td>
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<tr>
<td>Aboriginal and Torres Strait Islander individuals, communities, or groups? (Guidelines and NS 9)</td>
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<tr>
<td>Other specific cultural, ethnic or indigenous groups? (NS 8~ Collectivities)</td>
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<td>Assisted reproductive technology? (NS 11)</td>
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<td>Epidemiology research? (NS 14)</td>
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<td>Human genetic research? (NS 16)</td>
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<tr>
<td>Deception of participants, concealment or covert observation? (NS 17)</td>
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<td>X</td>
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</tbody>
</table>

12 CLINICAL TRIALS

Does the project involve the use of drugs, alternative or complementary therapies, therapeutic devices, or departure from standard treatment/care? Yes [ ] No X

13 SAFETY IMPLICATIONS

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<td>Biologically hazardous materials</td>
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<tr>
<td>Chemically hazardous materials</td>
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<td>Radiotoxins</td>
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<td>Non-ionizing radiation</td>
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</tr>
<tr>
<td>Any other potential safety hazard for either participants or researchers?</td>
<td></td>
<td>X</td>
</tr>
</tbody>
</table>

One standard dental Orthopantomograph Radiograph (OPG) will be taken of each participant in this study. This will be done using a modern dental Planmeca (CC 2002) Proline Dental X-Ray machine in a lead lined radiographic room at Hunter Valley Orthodontics. 464 The Esplanade, Warners Bay, NSW 2282.

An accepted method of estimating the amount of radiation exposure for various medical and dental procedures is to compare them with natural background radiation that people are exposed to every day that is Background Equivalent Radiation Times (BERT). This method was adapted from Perkins study (Perkins 1995). Investigations BERT

<table>
<thead>
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<th>Duration</th>
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<tr>
<td>1 Standard chest x-ray</td>
<td>4 days</td>
</tr>
<tr>
<td>2 Bite-wing dental x-rays</td>
<td>32 hours</td>
</tr>
<tr>
<td>1 OPG dental x-ray</td>
<td>28 hours</td>
</tr>
</tbody>
</table>

The risk of induction of fatal cancer or a serious hereditary illness from radiation when taking an OPG X-ray has been calculated to be one in a million. The smoking of one cigarette has an equivalent risk (Abbott 2000).

The consent form for participation in this study will include the need to have an OPG x-ray taken. Patients will be told in writing the risks associated with an OPG x-ray. The x-ray machine to be used is serviced and recalibrated annually by an external licensed technician to ensure that it is safe for...
Appendix D

RESEARCH PLAN AND PROCEDURES

What is the research design/method?
This is a retrospective randomised cohort study on the long-term effectiveness and impact on periodontal health of using permanent fixed lingual retainers (PFLR) to maintain dental alignment after orthodontic treatment is completed. Subjects who had PFLR fitted between January 1989 and December 1991 will be compared with those who had removable retainers fitted during the same time period. The project will involve qualitative and quantitative analyses.

Selection of patients
The database records of all patients who completed orthodontic treatment during the specified time period will be coded by a research assistant. This coding will result in two separate databases being established; Database 1 will comprise all patients who were fitted with PFLR on completion of treatment and Database 2 will comprise all patients who had removable retainers fitted on completion of treatment. Each patient will be allocated a unique identifier and this identifier will be kept separately under password protection. The databases will contain details of treatment type (different treatments have different tendencies for relapse), date of birth (the incidence of periodontal conditions increases with age) and gender (there are different incidences of disease between males and females). Sampling frames will be established for each database. 100 patients will be randomly selected from Database 1 (those who had PFLR fitted) using a computer program of random numbers. These patients will then be matched to patients in Database 2 (those who had removable appliances fitted) according to gender and nearest birth date, thus generating a group of matched controls.

Number of patients
Statistical advice has been sought and obtained from the CCEB. In order to have completed data for at least 40% control patients and at least 40% treatment patients at the end of the study, 100 patients will be selected in each group. This number has been derived assuming a non-contactable rate of approximately 30%, a refusal rate of 20%, and an incomplete rate of 5%.

All participants will be required to:
1. Complete a brief open- and closed-response questionnaire containing questions relating to:
   - general information, general health, dental health, dietary habits, smoking habits and orthodontic treatment and retention experiences. A copy of the questionnaire is attached.
   - The questionnaire has been tested and validated in consultation with Dr Deborah Lloyd.
   - The questionnaire will be completed by all participants at the time of their visit to the orthodontic clinic just prior to their clinical examination. In testing, the questionnaire will take approximately 15 minutes to complete.
   - At the completion of the clinical examination the Research Assistant will check through the questionnaire with the patient to ensure that it has been completed and, if necessary, to clarify any issues arising.
2. Participate in a non-invasive clinical examination of their teeth which will involve:
   - clinical photographs of their teeth and face, a thorough cleaning of their anterior (front) teeth, a dental examination and charting and one orthopantomograph (OPG) dental x-ray.
   - Standardised clinical photographs and the OPG will allow independent analysis of findings by an independent examiner. Pre-study inter- and intra-investigator reliability will precede any clinical examination of study subjects.

Following this clinical examination, participants will have the opportunity to discuss the findings of the clinical examination with the student researcher. This discussion will result in a written report on their oral health status and a summary of any oral health needs identified during the clinical examination. The participant may take this report to their general dentist for further advice and/or dental treatments. Participants who have serious oral health problems will be referred directly by Robert Cerry to their General Dental Practitioner or a Specialist Dental Surgeon.

The digital records obtained will be stored on CD or DVD discs and in a secured computer program designed for this project. This will be password protected and not available on the desktop of a computer. All paper records will be kept in a locked filing cabinet in a secured room at Hunter Valley Orthodontics 464 The Esplanade, Warners Bay NSW 2282.

Where will the project be conducted?
As this research requires clinical and radiographical dental facilities, all participants will be examined in the Hunter Valley Orthodontics Clinic of Robert Cerry (and Dr. Robert Chapman) at 464 The Esplanade, Warners Bay NSW 2282. Ph: (02) 48 489 909.

What is the participant group(s) and why has it been selected?

INITIAL APPLICATION FOR ETHICS APPROVAL FOR RESEARCH INVOLVING HUMANS – H1:5/02 Checklist
Appendix D

This project aims to investigate outcomes for participants who had orthodontic treatment completed between January 1989 and December 1991. The participants of this study will be randomly selected as detailed above.

How many participants will be recruited and what is the rationale for that number?
The number of participants was determined from a comprehensive literature review relating to the prevalence and aetiology of periodontal disease in adults and in consultation with Dr R Gibbard, Biostatistician with the Faculty of Health, Newcastle University.

This study will comprise;
Group 1 (the study group): 100 patients who had orthodontic treatment completed between January 1989 and December 1991 will be randomly selected from Database 1 (containing de-identified records for approximately 250 patients)
Group 2 (the control group): Patients who had orthodontic treatment completed between January 1989 and December 1991 and removable retainers fitted will be matched by age, sex and treatment type with Group 1 using Database 2 (containing de-identified records for approximately 450 patients)
At least 42 participants from each of Groups 1 and 2 will be required for analysis based upon a level of significance of 5% and power of 80% (as recommended by CCEB). A total of 100 patients will be recruited to each group to ensure this number (see comments above).

How, by whom, and where, will potential participants be selected and approached to receive the invitation to participate?
Each of the randomly selected members of Group 1 will be sent a personal request to participate and an information sheet (attached). The Research Assistant will complete all elements of this process. A consent form will be sent and participants will return this using a supplied reply-paid envelope.

Consenting Group 1 participants will be contacted by the Research Assistant and will be given an appointment for the examination and completion of the questionnaire. Selected members of Group 1 who fail to respond within the given time will be sent identical information with a revised response date. Invited Group 1 participants who do not consent or who fail to respond will be deleted, without prejudice, from the Study Group 1 database.

Group 2 will comprise 100 participants matched (where possible) by sex, age and treatment type. Where multiple matches exist, the participants will be randomly selected from the eligible group. These participants will be sent identical letters, information sheets and consent forms (attached).

Consenting participants will be contacted by the Research Assistant and will be given an appointment for the examination and completion of the questionnaire. Selected members of Group 2 who fail to respond within the given time will be sent identical information with a revised response date. Invited Group 2 participants who do not consent or who fail to respond will be deleted, without prejudice, from the Study Group 2 database. In the case of non-participation of Group 2 members, additional matches will be identified where possible and an identical recruitment process followed.

How much time will potential participants have to consider the invitation to participate?
The initial invitation will request a response within three weeks. The second request (see above) will allow an additional two-week response period. At the end of this five-week period, non-respondents and those who do not consent will be deleted, without prejudice, from the Group 1 and 2 databases.

What is required of participants?
All participants will be required to:
1. Accept the invitation to participate and sign the consent form (attached)
2. Complete an open- and closed-response questionnaire (attached)
3. Participate in a clinical examination (see above)
4. Discuss the findings of the clinical examination with Robert Cerny.

Relevant experience of researchers
Supervisor and Chief Investigator: Dr Deborah Cockrell is Head of Discipline of Oral Health and obtained her PhD from the University of Sydney in 2003, having obtained a Graduate Certificate in Population Health Research Methods in 2003. She is a recipient of NH&MRC Commonwealth Department of Health and Ageing and Dental Board of NSW funding. She currently supervises two PhD students.

Supervisor and Co-Investigator: Dr. Deborah Lloyd obtained her PhD from the University of Newcastle in 1999 in Behavioural Science in relation to Medicine in the Faculty of Health. She is now a consultant in Medical Education and Medical Research and is also Conjoint Academic in the School of Medicine and Public Health in the Faculty of Health at the University of Newcastle.

PhD student: Dr. Robert Cerny has been a specialist orthodontist since 1977 (MDSc. Sydney University) and has been in private practice in Newcastle since 1978.
Appendix D

15 ANALYSIS

1. The questionnaire
This will be used to identify Group characteristics and assist in identification of, and allowance for possible confounders. All information will be entered into the Group 1 and 2 databases. SPSS software will be used to analyse the quantitative findings and grouped themes (using Excel spreadsheets) will be used to analyse and report on the qualitative findings. This information will also be analysed in conjunction with the findings from the clinical examinations to provide an in-depth appraisal and understanding of the effectiveness and impacts of the two different retainers used.

The questionnaire (attached) comprises six sections:

a) General characteristics – patients of different ages, genders, race, educational attainment, marital status and employment status have been described as having different incidence and severity of periodontal disease.

b) General health – certain medical conditions (e.g. diabetes and immunosuppression) are associated with increased incidence and severity of periodontal disease.

c) Dental health, dental hygiene habits and self-appraisal of their orthodontic treatment will establish how the participants care for and feel about their teeth and orthodontic treatment. Participants with high dental motivation are likely to have improved periodontal status.

d) Dietary habits – high soft drink and sucrose intake are associated with poor oral health.

e) Smoking habits – smokers have an increased incidence and severity of periodontal disease.

f) Control group – This will give information on patient compliance. Euro J of Orthod 2003:25:343-350. Therapy, the durability of PFLR, the effect of retainers on self-assessed quality of life indicators such as eating.

2. The clinical examination
The clinical examination will involve a series of digital images of the anterior teeth from the front, sides and occlusally (biting surface) with the aid of intra-oral mirrors. These images will be standardised and stored on CD’s or DVD’s for measuring and assessing later and for viewing and reviewing by other examiners. The images of the teeth and gingival tissues will show plaque (soft) and calculus (hard) deposits (to determine oral hygiene), gingival (gum) height levels (to determine extent, if any, of gingival recession), gingival colour (to determine the degree of tissue inflammation), the PFLRs and the alignment of anterior teeth (to determine relapse). The impact on periodontal health will be assessed using the plaque and calculus scoring procedures described by Rustogi (1992), the Gingivitis Index (GI) described by Silness and Loe (1964) and modified by Talbott, Mandel and Chilton (1977) and the Gingival Recession score as described by Alalas and Melsen (2003).

The OPG x-rays will show the bone height supporting the anterior teeth (as a marker of periodontal health). Each patient will have the width of their upper and lower right anterior incisors measured with dial calipers measuring to 0’ths of one millimetre. These measurements will be recorded and used during the analyses of image records for comparative assessments of linear measurements. Alveolar bone loss will be measured from the OPGs using Zeichner et al.’s recommendations.

The extent of relapse will be calculated by measuring the sum of incisor irregularity using Little’s “Irregularity Index” (1975). Readings are calibrated as:

0 = perfect alignment
1-3 = minimal irregularity
4-6 = moderate irregularity
7-9 = severe irregularity
>10 = very severe irregularity.

These measurements will be obtained from the vertical or occlusal images of the anterior teeth where the distances between the teeth contacts points from canine to canine is measured to within one tenth of a millimetre and totalled. These totals will be collated and graphed to determine the mean degrees of irregularity for the two groups. Accurate measurement readings will be obtained by comparative analysis using the patient’s actual incisor width compared to measured width on the image. To ensure the examiners measurements are accurate, three external examiners will be used to measure a sample group of patient images for comparison and to provide intra- and inter-examiner reliability.


Appendix D

16 PROPOSED REVIEW OF PROGRESS, PARTICIPANT CARE, WINDING UP PROCEDURES

Review of progress of the project.
This project will be reviewed monthly by the research team comprising Robert Cerny, Dominique Cook (Research Assistant), Deborah Cockrell and Deborah Lloyd.

Duty of care to participants and research staff.
All participants will be treated in accordance with the expected duty of care as established by the Dental Board of NSW. All participants will be informed of their right to cease participation at any time without prejudice. They will also have an independent channel through which they may communicate any grievances to the Newcastle University Research Ethics committee about this survey and full details will accompany all correspondence (attached). All participants will be de-identified by the Research Assistant and all records will be completely confidential. Data and other participant information will be strictly safe-guarded and protected with records kept on password controlled personal computers (not on desktops) and in locked filing cabinets. All research staff will be in accordance with University of Newcastle policy. All similar previous studies and pilot studies that have been reported in the literature have not reported any significant adverse findings. Consultation with professional associations and indemnifiers has confirmed that any adverse findings will not jeopardise any element of professional practice.

Procedures for reporting adverse events.
The literature review and pilot study have indicated that it is unlikely there will be any adverse events. However, if an adverse event or finding of a sufficiently serious nature occurs, the following procedures will be put into action:

The Chief Investigator, Dr D Cockrell will provide the following information to the Ethics Committee:
- Unique identifier for the event, eg participant study ID, report number
- Participant's date of birth
- Date of entry into the study
- Date of event
- Details of the event
- The investigator's opinion as to whether the event is related to the study
- Action taken in response to the event
- Advice re. continuation or discontinuation of the project
- Determination whether changes are required to the Information and Consent documents as a result of the event.

Premature cessation of project.
This project will cease immediately if any adverse findings of a sufficiently serious nature arise. This is considered unlikely. The relevant authorities will then be informed of the adverse findings and the necessary steps taken to rectify any problems arising from these findings.

Feedback of results to participants.
All participants will be informed of the completion of their clinical assessment, for a discussion of their oral health status at this time, and, if required, given a written summary that will include any recommendations for dental treatment which they may then discuss with their general dentist. Any serious findings will be followed up in writing by Robert Cerny and a referral to an appropriate General or Specialist Dental Surgeon will be arranged. This discussion will be of direct value to the patient and will recognise their contribution to the research.

Post study follow-up.
All participants will receive a written post-study summary of the outcomes of this study.

17 SUMMARY OF ETHICAL CONSIDERATIONS

How will voluntary participation be ensured?
Voluntary participation will be ensured by all contact being made in writing by an independent Research Assistant. The initial contact forms sent to the participants clearly state that participation is entirely voluntary, refusal to participate (or withdrawal) will be without prejudice and contact details in case of grievance.

Is active consent being sought from all participants for all aspects of the research involving them? If No, why not?
Active consent will be sought from all participants for all aspects of the research involving them. A comprehensive information sheet will be provided and a consent form will be signed (attached).

How will participants' privacy be protected during the recruitment process, or access to

INITIAL APPLICATION FOR ETHICS APPROVAL FOR RESEARCH INVOLVING HUMANS – HEI/5/02 Checklist:
Appendix D

**Tissue samples, or access to records?**

Participants’ privacy will be protected at all times by the assigning of a unique coded number that will be determined by the Research Assistant. These codes will be kept in a separate location in a locked filing cabinet. Patient names will not appear on any of the records used in this study. All records will be kept in secured locations in files in locked rooms. All electronic records will be kept in password controlled databases (not desktops).

**What are the benefits and risks to participants and how will risks be minimised?**

This study will involve no cost to the participants.

The benefits include:

1. A copy of their OPG
2. A professional cleaning of their anterior teeth
3. A clinical examination and written report of the findings
4. A discussion with the principal researcher about their oral health and any relevant findings
5. A written summary of the general findings of the study.

There are no perceived risks due to direct involvement in the research. The risks (in terms of adverse clinical outcomes as a consequence of PFLR placement) are considered to be low based on the literature review and pilot study. Indirect risks towards PFLRs do not appear to be harmful to the dental tissues or patients.

**Are there any potential conflicts of interest for the researchers?**

There are no sponsors or commercial interests involved with this study. The technique is non-patentable. Robert Cerny has been using the PFLR clinically since 1970 and the technique is now widely-used in orthodontic practice. This study aims to provide high-quality evidence to support future orthodontic practice for all practitioners.

**Will the research involve payments/rewards/inducements to participants?**

The research will not involve any payments, rewards or inducements other than a free clinical examination, cleaning and radiograph.

**How will confidentiality/anonymity of information received be ensured?**

Confidentiality and anonymity of information will be ensured by the following:

a) All participants will be identified by a coded number. Their names will not appear on any survey papers, photographs, x-rays or dental records that will be stored on the dedicated research computer or DVDs. All hard copies which do bear the patients’ names will be securely stored with their existing orthodontic records in a separate location.

b) The coded number master identification sheets will be kept by the Research Assistant in a locked filing cabinet.

c) Access to the coded number master identification sheets will be strictly limited to the Research Assistant who will not share this information with anyone outside of the University of Newcastle supervisory group associated with this study.

**Any other ethical issues specific to your research?**

There are no additional ethical issues identified.

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**STORAGE, ACCESS AND DISPOSAL OF DATA**

Storage of data from this study will be at Hunter Valley Orthodontics at 464 The Esplanade, Warners Bay NSW 2282. All files will be kept in a locked filing cabinet in a locked room in a secured building at the above address. All de-identified computer information will be kept in a secure computer. The coded number master identification sheets of the participants will be kept in a locked filing cabinet in a separate location. Access to data will be limited to the Research Assistant, student researcher, the co-investigators, the statistician and the nominated external examiners. The data will not be disposed of unless it is necessary to do so. It is anticipated that ongoing studies will be undertaken to monitor the longer-term impact of PFLR’s upon the maturing dentition.

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Initial Application for Ethics Approval for Research Involving Humans – HE11/502 Checklist
Appendix D

19 DECLARATION BY APPLICANTS

1. In signing this application, I declare that the research protocol conforms to the National Statement on Ethical Conduct in Research Involving Humans, 1999, which I have read.

2. Where I am the project supervisor for the research described herein which will be conducted by a student of The University of Newcastle, I declare that I have provided guidance to the student in the design, methodology and consideration of ethical issues of the proposed research.

3. I make this application on the basis that the information it contains is confidential and will be used by The University of Newcastle and/or Hunter Health for the purposes of ethical review and monitoring of the research project described herein, and to satisfy reporting requirements to regulatory bodies. The information will not be used for any other purpose without my prior consent.

All investigators named at Q3 and Q4 are to sign this declaration.

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<tr>
<th>Name</th>
<th>Signature</th>
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<tr>
<td>Chief investigator/project supervisor</td>
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<td>Investigator 2</td>
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<td>Investigator 6</td>
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</table>
Appendix D

Q20 and Q21 ARE TO BE COMPLETED ONLY FOR APPLICATIONS TO THE UNIVERSITY OF NEWCASTLE

20 UNIVERSITY INSURANCE

For cover under the University’s insurance, the insurer requires the following information.

Does the proposed research involve physically invasive procedures? Yes [ ] No [x]

If YES, briefly describe the invasive nature of the research and why it is necessary:

21 DECLARATION BY FACULTY NOMINEE

At the direction of the Research Portfolio Committee, all applications submitted to the Human Research Ethics Committee from 1 July 2002, must have the following declaration completed by the respective Pro Vice-Chancellor, Head of School or other faculty nominee.

1. I declare that the research protocol described herein has been peer reviewed:
   by: [name]
   on: [date]

2. This application is submitted to the Human Research Ethics Committee on the basis that it is methodologically sound and if the research is conducted according to this protocol it is expected to yield valid and useful data.

Faculty Nominee

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<th>Name</th>
<th>Position</th>
<th>Signature</th>
<th>Date</th>
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INITIAL APPLICATION FOR ETHICS APPROVAL FOR RESEARCH INVOLVING HUMANS – HE15/02 Checklist
# Appendix D

**INITIAL APPLICATION FOR ETHICS APPROVAL FOR RESEARCH INVOLVING HUMANS**

**CHECKLIST**
Complete and attach to your application as the FIRST page

**CHIEF INVESTIGATOR or PROJECT SUPERVISOR** (The person identified at Question 3 on the ‘Initial Application for Ethics Approval for Research Involving Humans’)

| Name: Title / first name / family name | Deborah Cockrell PhD, BDS, FDS RCPS Head of Discipline of Oral Health Ourimbah Campus, PO Box 127, Brush Rd. Ourimbah 2256  
deborah.cockrell@newcastle.edu.au |
|----------------------------------------|--------------------------------------------------------------------------------|

**SHORT TITLE OF PROJECT** (as per Question 1 of the Initial Application)

THE NEWCASTLE EFFECTS OF ORTHODONTIC TREATMENT STUDY (NEOTS)  
Permanent Fixed Lingual Retention in Orthodontics: its long-term effectiveness and impact on periodontal health.

<table>
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<th>Before lodging this application, please check that you have done the following: (N/A = not applicable)</th>
<th>Applicant</th>
<th>Committees use only</th>
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<tr>
<td>Yes</td>
<td>No</td>
<td>N/A</td>
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<tr>
<td>All questions have been answered</td>
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<td>All investigators have signed the Declaration (Q18)</td>
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<td>Faculty nominee declaration is completed (Q19) <em>(University only)</em></td>
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<td>Correspondence from other ethics committees is attached (Q2)</td>
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<td>Funding application is attached (Q7)</td>
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<td>Participant Information Sheets are attached</td>
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<td>Participant Consent Forms are attached</td>
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<td>All letters, advertisements, posters or other recruitment material to be used are attached</td>
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<td>All surveys, interview/focus group schedules, data sheets, etc, to be used in collecting data are attached</td>
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<td>Appendix A – Clinical Trials – has been completed</td>
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<td>Appendix A – full clinical protocol is attached</td>
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<td>Appendix A – Indemnification for Clinical Trials is attached</td>
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<td>Application has been collated <em>(see Preparation of your application)</em></td>
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INITIAL APPLICATION FOR ETHICS APPROVAL FOR RESEARCH INVOLVING HUMANS – HE175/02
Checklist
### CHECKLIST for Committee Use Only (N/A = not adequately)

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<td>The source of participants, tissue samples, or records is identified (Q14)</td>
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<td>The method by which participants will be recruited, samples obtained or records accessed is explained (Q14)</td>
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<td>• Signed by researcher(s) and student, if applicable</td>
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<td>• Specific consent statements, eg access to records, excerpts from transcripts, archiving data, etc</td>
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<td>Surveys: Identifies researchers and institution</td>
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Appendix E: Information sheet for participants

THE NEWCASTLE EFFECTS OF ORTHODONTIC TREATMENT STUDY (NEOTS)
Permanent Fixed Lingual Retention in Orthodontics: long-term effectiveness and impact on periodontal health

Information Sheet for Participants

We write to invite you to participate in the Newcastle Effects of Orthodontic Treatment Study (NEOTS). As you completed a course of Orthodontic treatment between January 1989 and December 1991, you have been randomly selected to participate in NEOTS, a study looking at the long-term effects of retention after orthodontic treatment. If you choose to be involved your participation in this study will be entirely voluntary. There is no cost for involvement and you can withdraw at any time without prejudicing your future orthodontic care. This information sheet provides you with details of the study and the methods of this research.

What will participation in the Newcastle Effects of Orthodontic Treatment Study (NEOTS) involve?

If you agree to participate in this study you will be required to complete two components:
1. Complete a short questionnaire; this should take about 15 minutes.
2. Attend a clinical examination with Robert Cerny (orthodontist – see contact details below); this is likely to take 30 minutes.

How long do I have to decide whether I want to take part or not?
We would like you to respond to this request by dd/mm/yy and we have enclosed a reply-paid envelope for you to use. If we do not hear from you by this date, we will re-send this information and a new Consent Statement. Please feel free to contact Dominique Cook (whose contact details are below) if you need any additional information.

I would like to participate in this research so what do I do next?
At the end of this Information Sheet you will find an Informed Consent Statement for Participants. You will need to sign this form and return it to our Research Assistant, Dominique Cook. We have enclosed a reply-paid envelope for you. If you have any questions or concerns about any element of this project, Dominique will be happy to discuss these with you before you sign the Consent Statement. A consent form must be signed before we can make any arrangements for your examination. Domnique’s contact details are:
Miss Dominique Cook, Research Assistant
Hunter Valley Orthodontics
464 The Esplanade, Warners Bay, NSW 2282.
Telephone: 1800 021 064

Will it affect my orthodontic care if I do not wish to participate?
No. Participation in NEOTS is entirely voluntary and you will not be affected in any way should you choose not to become involved.

What will completing the Questionnaire involve?
The questionnaire has been designed to assess several different elements. We would like to know a bit more about you, your general health and dental health. We are interested in your personal experiences of orthodontic treatment and the impact of this treatment on your daily life. The questionnaire will take about 15 minutes to complete and will be given to you when you attend your clinical examination. Dominique will help you if there any questions you do not understand and she will make sure that all sections of the questionnaire have been completed.

What will my clinical examination entail?
The clinical examination will begin with you having photographs taken of your face and teeth. You will then have your teeth disclosed (this is when you chew a pink tablet that shows where dental plaque is present on your teeth). You will then have photographs taken of your teeth. This will be followed by a professional scaling and cleaning of your front teeth before taking a final set of photographs of your cleaned teeth.
Appendix E

A dental OPG x-ray will be taken; this is a standard scan x-ray that shows all of your teeth and the bone supporting them. You will be given a digital copy of this x-ray. Following your clinical examination, you will have a discussion with the researcher (Robert Cerny) and you will be given a written summary of the results of the clinical examination that you may choose to discuss with your dentist. If there are any serious problems with your dental health, Robert Cerny will refer you to a dentist or dental specialist.

Who will be doing the research?
Rob Cerny is an enrolled PhD student at the University of Newcastle and is the student researcher for this project. He will complete your clinical examination and will discuss the findings with you. Deborah Cockrell (Head of Discipline of Oral Health, University of Newcastle) is the Chief Researcher and will be supervising. NEOTS, Deborah Lloyd (School of Medical Practice and Population Health, University of Newcastle) will be supervising analysis of the questionnaire. Our Research Assistant, Dominique Cook, will be the research team member that you will have most contact with. Another orthodontist will examine all of the photographs and x-rays so that we can make sure our results are accurate.

Are there any risks or costs involved with the study?
There are no costs associated with this study and the clinical examination will not involve any discomfort. As mentioned above, you will have one dental (OPG) x-ray taken and this is not considered to be a risk. The risk of induction of fatal cancer or a serious hereditary ill-health from radiation exposure has been calculated to be one in a million for an OPG x-ray. The smoking of one cigarette has an equivalent risk (Abbott 2000).

What are the benefits of taking part in the study?
In addition to supporting important research into this area of orthodontics you will be provided with a clinical examination and radiograph at no cost.

How will my privacy be protected?
Any information you provide for this Study will remain completely private and confidential. Your information will be entered on a computer and you will be identified by a study number only; your name will not be on the same file as your questionnaire or orthodontic assessment information. No individual information will be reported; results will only be reported for groups of participants. Your name and contact details will be stored separately in a locked filing cabinet, in a locked room, and will be used only to provide you with the results of this study and for future contact if you agree. At the end of the study, the file containing your survey and other health information will be securely stored in locked filing rooms with all personal identifiers removed.

Will I get a copy of the final study report?
It is expected that this study will take some time to complete and a summary report will be sent to you when the findings are known.

How will I arrange an appointment for the examination?
Once we have received your signed Consent Statement, Dominique will contact you to make an appointment for the clinical examination at your convenience. A letter confirming this appointment date, time and the location of the orthodontic clinic will be sent to you. You should expect to be at the clinic for approximately one hour to provide time to complete the questionnaire and clinical examination and then discuss the findings with Robert Cerny.

What if I consent and then change my mind?
Taking part in any part of the Newcastle Effects of Orthodontic Treatment Study (NEOTS) is entirely voluntary. You can withdraw from all or any part of the study at any time without prejudice. If you do change your mind about being involved, you will be in no way disadvantaged and this will not affect any element of your future orthodontic care. If you do decide to withdraw from the study, you have the option of withdrawing all data collected for this study relating to you. An unlikely exception to this is in the case of a serious adverse event, where the data needs to be retained for regulatory reporting.

Who do I contact if I have any concerns or complaints about this Study
This research has been reviewed and approved by the University of Newcastle Human Research Ethics Committee (Approval number: xxx). Should you have concerns about your rights as a participant in this research, or if you have a complaint about the manner in which the research is conducted, it may be given to the Chief Researcher (details above), or, if an independent person is preferred, to the Human Research Ethics Officer, Research Office, The Chancellery, The University of Newcastle, University Drive, Callaghan NSW 2308, telephone (02) 49 216 333, email Human-Ethics@newcastle.edu.au.
Appendix F1

Appendix F1: Informed Consent form for Participants

Informed Consent Statement for Participants

I agree to take part in The Newcastle, Effects of Orthodontic Treatment Study (NEOTS). In signing this consent form I acknowledge that I have read and understood the information about this Study and have had the opportunity to ask questions about any aspect of the Study and my own participation. I also understand that this will involve completion of a questionnaire, a clinical assessment involving photographs of my face and teeth and professional scaling, cleaning and polishing of my anterior teeth, an orthodontic examination of my teeth, a standard dental OPG x-ray and a discussion with the researchers.

I understand that participation in this study will not cost me anything.

I understand that my participation is purely voluntary and that I am able to withdraw from the NEOT Study at any time, and that my decision to do so will not disadvantage me in any way or cause detriment to my future dental health care. I also have the option of withdrawing all data collected for this study pertaining to me, unless it needs to be retained for regulatory reporting.

INFORMED CONSENT
I agree to participate in the NEOTS Study, as outlined in the participant information statement.

Name________________________________________
(Please print name)

Signed_______________________________________  __/__/__
Please give our completed questionnaire to our research team at the time of your clinical appointment.
Appendix F2: Consent form for use of patients photographs

Patient Name- ..........................................................
Address- ..........................................................
..........................................................
..........................................................
Hereby give Hunter Valley Orthodontics permission to use my orthodontic records for non-profit exposure in orthodontic educational circumstances, be it conferences, seminars, journalistic publications or such.

I would like my eyes to be COVERED/LEFT EXPOSED in any facial photographs

Signed ..........................................................
Witnessed ..........................................................
Date ..........................................................
Location ..........................................................

Appendix G
Appendix G: Radiographic machine license approval after validation

Radiation Dosimetry Report

Planmeca PM 2002 OPG Study – Robert Cerny

Dosimetry Information:

Source of Exposure: Planmeca PM 2002 OPG x-ray Unit
68 kVp, 5 mA exposure with slit x-ray source and digital detector.

Based on published data from a paper by S. Baechler et al. “Exposure in Dental Radiology: A comparison between Intra-Oral, Panoramic and Tomographic Examinations”.

<table>
<thead>
<tr>
<th>Dose Type</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Dose for Study</td>
<td></td>
</tr>
<tr>
<td>Effective dose</td>
<td>6 microSv</td>
</tr>
<tr>
<td></td>
<td>(0.006 mSv)</td>
</tr>
</tbody>
</table>

The effective dose received from this study, not including any exposures incurred as part of the normal clinical management of the participant, is not likely to exceed the relevant dose constraint in Table 1 of the ARPANSA Code of Practice “Exposure of Humans to Ionizing Radiation for Research Purposes”.

The recommended statement in the patient consent form for this study is as follows.

This research study involves exposure to a very small amount of radiation. As part of everyday living, everyone is exposed to naturally occurring background radiation and receives a dose of about 2 to 3 millisieverts (mSv) each year. The effective dose from this study is about 0.006 mSv. At this dose level, no harmful effects of radiation have been demonstrated and the risk is negligible.

Paul Cardew
9 April 2009
Appendix H

Appendix H: Statistical determination to calculate valid sample size

Decay Group Numbers
Appendix H

Periodontal Group Numbers

![Diagram of Power and Sample Size Program: Main Window]

- Studies that are analyzed by chi-square or Fisher's exact test
- Sample size
- Design
  - Matched or Independent: Independent
  - Case cohort? = Prospective
  - How is the alternative hypothesis expressed? = Two proportions
  - Uncorrected chi-square or Fisher's exact test? = Fisher's exact test

Input

- \( \alpha \): 0.05
- \( P_0 \): 2
- \( P_1 \): 5
- \( P_2 \): PERIODONTAL

Logging is enabled.
Appendix I: Randomised selection code

Source: www.randomizer.org
Appendix J: Questionnaire for patients regarding RRs and BRs

The Newcastle Effects of Orthodontic Treatment Study (NEOTS) Questionnaire

This research is being undertaken by Robert Cerny, PhD student at the University of Newcastle, who is supervised by Associate Professor Deborah Cockrell PhD, Head of Discipline of Oral Health, and Dr Deborah Lloyd, School of Medical Practice and Population Health, at the University of Newcastle.

This questionnaire has six short sections to complete. We have entered the date and your personal project code number at the top of each page of the questionnaire. Please do not write your name anywhere on this questionnaire. Our Research Assistant will help you if you have any questions and will check that all sections have been completed.

The questionnaire will take approximately 15 minutes to complete.

Thank you for assisting us with our research into orthodontic outcomes.

Please read the questions carefully. Circle the answer that applies to you best or, where applicable, write your answer in the space provided.

Newcastle Effects of Orthodontic Treatment Study (NEOTS)
Student Investigator: Robert Cerny
University of Newcastle Human Ethics Committee approval number: H-216-0506
Appendix J

Study ID Number: __________________________

Date survey completed: __________________________

Questionnaire

1. **General questions about you**

a) What is your date of birth and your age?

   Date of Birth
   
   Day ____________ Month ____________ Year ____________

   Age ____________

   Years

b) What is your gender?

   Female 1
   Male 2

c) Where were you born?

   Australia 1
   Other (please specify) 2

d) What is the highest qualification you have completed? (Circle one number only)

   No formal qualifications 1
   School or Intermediate Certificate (or equivalent) 2
   Higher School or Leaving Certificate (or equivalent) 3
   Trade or Apprenticeship 4
   Certificate (e.g. chef, hairdresser) 5
   Certificate or Diploma (e.g. child care, technician) 6
   University Degree 7
   Higher University Degree (e.g. Grad Dip, Masters, PhD) 8

Newcastle Effects of Orthodontic Treatment Study (NEOTS)
Student Investigator: Robert Cerny
University of Newcastle Human Ethics Committee approval number: H-216-0506
Appendix J

Study ID Number:

e) What is your marital status? (Circle one number only)

Married 1
Living with a partner / de facto 2
Widowed 3
Divorced 4
Separated 5
Never married 6
Don't know 7
Other (please specify)

f) Are you currently in paid employment?

Yes 1
No 2

If YES, please specify:

Full-time 1
Part-time or casual 2
2. **General Health**

   a) In general, would you say your health is:  
      (Circle one number only)

      | Health Level   | Number |
      |----------------|--------|
      | Excellent      | 1      |
      | Very Good      | 2      |
      | Good           | 3      |
      | Fair           | 4      |
      | Poor           | 5      |

   b) Have you been told by your doctor that you have any of the following illnesses? (Circle any that are applicable)

      | Illness             | Number |
      |---------------------|--------|
      | Asthma              | 1      |
      | Diabetes            | 2      |
      | Leukaemia           | 3      |
      | Crohn Disease       | 4      |
      | Cardiovascular Disease | 5     |
      | Head or Neck Cancer | 6      |
      | Other serious illness | 7     |

      (please specify)

   c) Have you had or are you taking any of these medications or treatments? (Circle any that are applicable)

      | Medication          | Number |
      |---------------------|--------|
      | Long term antibiotics | 1      |
      | Long term oral steroids | 2    |
      | Long term inhaled (asthma) steroids | 3 |
      | Chemotherapy        | 4      |
      | Radiotherapy        | 5      |
      | Other long-term medications or treatments (please specify) | 6 |
Appendix J

Study ID Number:

### 3. Dental Health

#### a) How often do you have a check-up at the dentist? (Circle one number only)

<table>
<thead>
<tr>
<th>Frequency</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 monthly</td>
<td>1</td>
</tr>
<tr>
<td>6 monthly</td>
<td>2</td>
</tr>
<tr>
<td>Yearly</td>
<td>3</td>
</tr>
<tr>
<td>Every 2 Years</td>
<td>4</td>
</tr>
<tr>
<td>Never</td>
<td>5</td>
</tr>
<tr>
<td>Other (Please specify)</td>
<td>6</td>
</tr>
</tbody>
</table>

#### b) How often do you have your teeth scaled and cleaned at the dentist? (Circle one number only)

<table>
<thead>
<tr>
<th>Frequency</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 monthly</td>
<td>1</td>
</tr>
<tr>
<td>6 monthly</td>
<td>2</td>
</tr>
<tr>
<td>Yearly</td>
<td>3</td>
</tr>
<tr>
<td>Every 2 Years</td>
<td>4</td>
</tr>
<tr>
<td>Never</td>
<td>5</td>
</tr>
<tr>
<td>Other (Please specify)</td>
<td>6</td>
</tr>
</tbody>
</table>

#### c) How often do you brush your teeth? (Circle one number only)

<table>
<thead>
<tr>
<th>Frequency</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 times a day</td>
<td>1</td>
</tr>
<tr>
<td>2 times a day</td>
<td>2</td>
</tr>
<tr>
<td>Once a day</td>
<td>3</td>
</tr>
<tr>
<td>Never</td>
<td>4</td>
</tr>
<tr>
<td>Other (Please specify)</td>
<td>5</td>
</tr>
</tbody>
</table>

Newcastle Effects of Orthodontic Treatment Study (NEOTS)
Student Investigator: Robert Cerny
University of Newcastle Human Ethics Committee approval number: H-216-0506
Study ID Number:

d) How often do you floss your teeth? (Circle one number only)

- 3 times a day: 1
- 2 times a day: 2
- Once a day: 3
- Never: 4
- Other (Please specify): 5

---

e) How often do you use toothpicks or interbrushes (circle one number only)

- 3 times a day: 1
- 2 times a day: 2
- Once a day: 3
- Never: 4
- Other (Please specify): 5

---

f) How easy is it for you to clean your teeth? (Circle one number only)

- Very difficult: 1
- Difficult: 2
- Easy: 3
- Very easy: 4

---

g) How would you rate the straightness of your front teeth now? (Circle one number only)

- Very straight: 1
- Straight: 2
- Crooked: 3
- Very crooked: 4
Appendix J

Study ID Number:

| h) How do you rate the outcome of your orthodontic treatment? (Circle one number only) |
|-------------------------------|-----------------|
| Poor                          | 1               |
| Fair                          | 2               |
| Good                          | 3               |
| Very good                     | 4               |

| i) How has your orthodontic treatment changed your quality of life? (Circle one number only) |
|---------------------------------------------|-----------------|
| Much Worse                                 | 1               |
| Worse                                       | 2               |
| No change                                   | 3               |
| Better                                      | 4               |
| Much better                                 | 5               |
| Please specify                              |                 |

<table>
<thead>
<tr>
<th>j) How comfortable is your bite now? (Circle one number only)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very comfortable</td>
</tr>
<tr>
<td>Comfortable</td>
</tr>
<tr>
<td>Uncomfortable</td>
</tr>
<tr>
<td>Very uncomfortable</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>k) Do you have any jaw joint problems?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
</tr>
<tr>
<td>No</td>
</tr>
</tbody>
</table>

If YES, please specify if it is:

| Pain                                  | 1               |
| Clicking                              | 2               |
| Both pain and clicking                | 3               |
| Other (Please specify)                | 4               |
Appendix J

Study ID Number:

4. Dietary Habits

a) How often do you snack on sweet foods (biscuits, lollies, chocolates etc) between meals? (Circle one number only)
   - Never: 1
   - Occasionally: 2
   - Often: 3
   - Very often: 4

b) How often do you have drinks with sugar in them each day? (e.g. soft drinks, cordials, fruit juice, tea, coffee, etc.) (Circle one number only)
   - Never: 1
   - Occasionally: 2
   - Often: 3
   - Very often: 4

c) How often do you have carbonated drinks (sports drinks, diet drinks, etc.)? (Circle one number only)
   - Never: 1
   - Occasionally: 2
   - Often: 3
   - Very often: 4

5. Smoking

a) Which of the following best describes your smoking status? (Circle one number only)
   - I have never smoked: 1
   - I have only smoked a few times: 2
   - I used to smoke: 3
   - I now smoke occasionally: 4
   - I now smoke regularly: 5

Newcastle Effects of Orthodontic Treatment Study (NEOTS)
Student Investigator: Robert Cerny
University of Newcastle Human Ethics Committee approval number: H-216-0506
Appendix J

Study ID Number:

6. **Removable Retainers** — these are the wire and plastic plates or hoops used after the braces were removed. Please ask our Research Assistant if you are unsure about this.

   a) Did you wear your removable retainers full-time for the first 6 months?

   |   |  
---|---
Yes | 1  
No  | 2  

If you answered **No**,

d) for how long did you wear them?  
(Circle one number only)

|   |  
---|---
Never | 1  
Less than 2 months | 2  
Less than 4 months | 3  
Less than 6 months | 4  

ii) Why did you stop wearing them?  
(Circle one number only)

|   |  
---|---
Kept forgetting them | 1  
Lost them | 2  
They were uncomfortable | 3  
They were socially embarrassing | 4  
Other (Please specify) | 5  

b) Did you wear the removable retainers at night for the first 6 months?

|   |  
---|---
Yes | 1  

Newcastle Effects of Orthodontic Treatment Study (NEOTS)  
Student Investigator: Robert Cerny  
University of Newcastle Human Ethics Committee approval number: H-216-0506
Appendix J

Study ID Number:

If you answered No,

1) How long did you wear them for?  
   (Circle one number only)
   - Less than 6 months: 1
   - Between 6-12 months: 2
   - Between 1-2 years: 3
   - More than 2 years: 4
   - Other (please specify): 5

ii) Why did you stop wearing them?
   - Kept forgetting them: 1
   - Lost them: 2
   - They were uncomfortable: 3
   - They were socially embarrassing: 4
   - Other (please specify): 5

c) Do you still wear your retainers?
   - Yes: 1
   - No: 2 (go to part f)

d) If YES, how often? (Circle one number only)
   - 7 days a week: 1
   - Up to 3 days a week: 2
   - Once a week: 3
   - Once every 2 weeks: 4
   - Other (Please specify): 5

Newcastle Effects of Orthodontic Treatment Study (NEOTS)
Student Investigator: Robert Cerny
University of Newcastle Human Ethics Committee approval number: H-216-0506
Appendix J

Study ID Number:

e) How do you rate your retainers for? (Circle one number only)

<table>
<thead>
<tr>
<th>Comfort</th>
<th>Poor</th>
<th>Fair</th>
<th>Good</th>
<th>Very good</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Cleaning</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Impact on quality of life</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

f) Why did you stop wearing them? (Circle one number only)

<table>
<thead>
<tr>
<th>Reason</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Told to do so by my orthodontist</td>
<td>1</td>
</tr>
<tr>
<td>Kept forgetting them</td>
<td>2</td>
</tr>
<tr>
<td>Lost them</td>
<td>3</td>
</tr>
<tr>
<td>They were too uncomfortable</td>
<td>4</td>
</tr>
<tr>
<td>They were socially embarrassing</td>
<td>5</td>
</tr>
<tr>
<td>Other (Please specify)</td>
<td>6</td>
</tr>
</tbody>
</table>

g) Do you think that your teeth moved out of alignment after you stopped wearing your retainers?

<table>
<thead>
<tr>
<th>Answer</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>1</td>
</tr>
<tr>
<td>No</td>
<td>2</td>
</tr>
</tbody>
</table>

h) If Yes, how soon after you stopped wearing them did you notice your teeth moving? (Circle one number only)

<table>
<thead>
<tr>
<th>Time Frame</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Within a few weeks</td>
<td>1</td>
</tr>
<tr>
<td>Within 6 months</td>
<td>2</td>
</tr>
<tr>
<td>Within 12 months</td>
<td>3</td>
</tr>
<tr>
<td>Within 2 years</td>
<td>4</td>
</tr>
<tr>
<td>Other (Please specify)</td>
<td>5</td>
</tr>
</tbody>
</table>
Appendix J

Study ID Number:

i) Do you have any problems/concerns with the retainers?
   Yes 1
   No 2

If Yes, please circle any that apply. Did your concerns relate to:

- Discomfort 1
- Nuisance 2
- Unhygienic 3
- Socially embarrassing 4
- Other (Please specify) 5

6. Permanent Fixed Lingual Retainers (PFLR) (wire retainers bonded to the back of the front teeth to keep these teeth straight permanently)

a) Are your PFLRs still in place?
   Yes 1
   No 2

b) If No:
   i) When were they removed? (Circle one number only)
      - Less than 5 years after fitting 1
      - 5-10 years after fitting 2
      - More than 10 years after fitting 3
      - Other (Please specify) 4

Newcastle Effects of Orthodontic Treatment Study (NEOTS)
Student Investigator: Robert Cerny
University of Newcastle Human Ethics Committee approval number: H-216-0506
Appendix J

Study ID Number:

ii) Why were they removed? (Circle one number only)

<table>
<thead>
<tr>
<th>Reason</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Uncomfortable</td>
<td>1</td>
</tr>
<tr>
<td>Unhygienic</td>
<td>2</td>
</tr>
<tr>
<td>They broke</td>
<td>3</td>
</tr>
<tr>
<td>Just wanted them off</td>
<td>4</td>
</tr>
<tr>
<td>Other (Please specify)</td>
<td>5</td>
</tr>
</tbody>
</table>

iii) How were they removed? (Circle one number only)

<table>
<thead>
<tr>
<th>Method</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Self removal</td>
<td>1</td>
</tr>
<tr>
<td>Dentist removed them</td>
<td>2</td>
</tr>
<tr>
<td>Orthodontist removed them</td>
<td>3</td>
</tr>
<tr>
<td>Other (Please specify)</td>
<td>4</td>
</tr>
</tbody>
</table>

c) Have your PFLR’s ever broken?

<table>
<thead>
<tr>
<th>Answer</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>1</td>
</tr>
<tr>
<td>No</td>
<td>2</td>
</tr>
</tbody>
</table>

If Yes:

i) How often have they broken? (Circle one number only)

<table>
<thead>
<tr>
<th>Frequency</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Once</td>
<td>1</td>
</tr>
<tr>
<td>Twice</td>
<td>2</td>
</tr>
<tr>
<td>Three times</td>
<td>3</td>
</tr>
<tr>
<td>Other (Please specify)</td>
<td>4</td>
</tr>
</tbody>
</table>

ii) How did they break? (Circle one number only)

<table>
<thead>
<tr>
<th>Reason</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>They just broke</td>
<td>1</td>
</tr>
<tr>
<td>Hit in the mouth</td>
<td>2</td>
</tr>
<tr>
<td>Biting something hard</td>
<td>3</td>
</tr>
<tr>
<td>Other (Please specify)</td>
<td>4</td>
</tr>
</tbody>
</table>
Appendix J

Study ID Number:

iii) Were they repaired?
   Yes  1
   No   2

iv) If yes, who repaired them? (Circle one number only)
   Dentist  1
   Orthodontist  2
   Other (Please specify)  3

e). How do you rate your PFLR's for

<table>
<thead>
<tr>
<th>Comfort</th>
<th>Poor</th>
<th>Fair</th>
<th>Good</th>
<th>Very good</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cleaning</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Impact on quality of life</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

f) Do you have any problems/concerns with your PFLR's now?

   Yes  1
   No   2

If Yes, please circle any or all that apply

   | Discomfort | 1 |
   | Nuisance   | 2 |
   | Unhygienic | 3 |
   | Socially embarrassing | 4 |
   | Other (Please specify) | 5 |

Thank you for completing this questionnaire.

Newcastle Effects of Orthodontic Treatment Study (NEOTS)
Student Investigator: Robert Cerny
University of Newcastle Human Ethics Committee approval number: H-216-0506
Appendix K: Patient's dental health report following clinical examination

**NEOTS Dental Report**

**Patient ID Number**

**GENERAL CONDITION**

<table>
<thead>
<tr>
<th></th>
<th>Very Good</th>
<th>Good</th>
<th>Average</th>
<th>Poor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Teeth</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gums</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Jaw Joints</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Wire</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**OPG X RAY SHOWS**

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Teeth</td>
<td></td>
</tr>
<tr>
<td>Bone</td>
<td></td>
</tr>
</tbody>
</table>

**SUMMARY**

**RECOMMENDATIONS**

Signed ROBERT CERNY – M.D.S
Appendix L

Appendix L: Request letter for specialist Orthodontist collaboration with measures and results

FACULTY OF HEALTH

Tuesday 4th March 2008

Dear

Re: Newcastle Effects of Orthodontic Treatment Study (NEOTS)
Student Research Project: Robert Cerny

Robert Cerny is enrolled in a Higher Research Degree program at this University. He is investigating the effects of Permanently Bonded Retainers (PBR) and one element of this research is to review the effectiveness of the retainers in maintaining the achieved alignment of the anterior teeth in the aesthetic zone.

Following consultation with a Statistician, it has been recommended that we seek external validation for Robert’s data. I therefore write in the hope that you can assist in this process. Your contribution will be acknowledged unless you indicate otherwise.

Within this package you will find clinical photographs for ten patients, selected randomly from the study group. Robert has included details and references for each of the measurements he has made.

The package also contains a summary record sheet and we estimate that this validation will take no longer than 30 minutes of your time.

We are most grateful for your support for Robert’s research project (Human Research Ethics Committee approval number H – 216-0508) and we thank you in advance for your help.

Very best wishes,

Deborah Cockrell
Head of Discipline of Oral Health
T +61 2 4349 4514
F +61 2 4349 4567
Deborah.cockrell@newcastle.edu.au

NEWCASTLE | CENTRAL COAST | PORT MACQUARIE | SINGAPORE
The University of Newcastle
Cnr John Street & Pacific Hwy, Callaghan NSW 2295 Australia
www.newcastle.edu.au

Appendix L

Appendix L: Request letter for specialist Periodontist collaboration with measures and results

Tuesday 4th March 2008

Dear

Re: Newcastle Effects of Orthodontic Treatment Study (NEOTS)
Student Research Project: Robert Cerny

Robert Cerny is enrolled in a Higher Research Degree program at this University. He is investigating the effects of Permanently Bonded Retainers (PBR) and one element of this research is to review the periodontal status of the study group.

Following consultation with a Statistician, it has been recommended that we seek external validation for Robert’s data. I therefore write in the hope that you can assist in this process. Your contribution will be acknowledged unless you indicate otherwise.

Within this package you will find clinical photographs for ten patients, selected randomly from the study group. For each patient, the following measurements have been recorded:

- Plaque index
- Calculus index
- Gingival recession
- Modified gingival index

Robert has included details and references for each of these measurements. In addition, a digital OPG has been provided for each patient from which mesial and distal alveolar bone levels can be measured.

The package contains summary record sheets for each patient and we estimate that this validation will take no longer than 60 minutes of your time.

We are most grateful for your support for Robert’s research project (Human Research Ethics Committee approval number H – 2105-0505) and we thank you in advance for your help.

Very best wishes,

Deborah Cockrell
Head of Discipline of Oral Health
T +61 2 4349 4514
F +61 2 4349 4567
Deborah.cockrell@newcastle.edu.au

THE UNIVERSITY OF NEWCASTLE
AUSTRALIA

- 197 -
Appendix M

Appendix M: Information letters and details for collaborating Orthodontist

Summary of NEOTS

NEOTS: Newcastle Effects of Orthodontic Treatment Study. 
Ethics approval No H-216-0506

This PhD study is a long term (15 years) review of the effects of permanently bonded retainers (PBRs) in orthodontics. The main areas of concern are:

a) The effectiveness of PBRs in maintaining the achieved alignment of the anterior teeth in the aesthetic zone.

b) The periodontal health impacts of PBRs.

To validate the clinical measures, 2 independent experts in each field of

a) Orthodontics,
b) Periodontics;

are being asked to measure the relevant indices for comparison with those of the PHD student’s.

Being a well respected expert in Orthodontics you have been approached to be an expert participant in this study. Your contribution will be acknowledged in the PhD reports unless you request otherwise.

The total time estimated for you to take to complete these measures is...<60.....minutes.

Would you please measure and record the indices listed for the following 10 patients. You can mark the images to make the measuring easier. Each patient has a sheet with measures to be filled in. Any comments would be welcomed.

A summary sheet to record all cases is also enclosed. Would you please retain a copy of this summary sheet in case the returned satchel is misplaced.

I greatly appreciate your invaluable contribution to this study.

Thank you
Best Regards

Robert Cerny.

University of Newcastle; NEOTS. Ethics No- H-216-050
Appendix M

CHECK LIST

NEOTS
Orthodontic Measures.

Contained here-in are;

- Summary explanation of the Research Objectives.
- Original article on:
The Irregularity Index:- by Professor Robert M Little,
  Known as Little’s Irregularity Index (LII).
- Score sheets for 10 patients.
- Coloured print out of occlusal images of the maxillary and
  mandibular anterior teeth of 10 patients.
- CD with dental images of 10 patients.
- Summary sheet for all 10 patients.
- Returned stamped and addressed satchel with funds for this
  to be sent back by REGISTERED MAIL.

Would you please retain a record of your results in case the
returned satchel is misplaced.

University of Newcastle; NEOTS.  Ethics No- H-216-050
Orthodontic Examiner Code: _____  Patient ID No: _____
Date of measuring: _____

<table>
<thead>
<tr>
<th>R</th>
<th>Maxilla</th>
<th>L</th>
<th>R</th>
<th>Mandible</th>
<th>L</th>
</tr>
</thead>
<tbody>
<tr>
<td>Real Width of UR1 (RWU) = _____</td>
<td>Real Width of LR1 (RWL) = _____</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Image Width UR1 (IWU) = _____</td>
<td>Image Width LR1 (IWL) = _____</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Image Measures (IM) in mm:</td>
<td>Image Measures (IM) in mm:</td>
<td></td>
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</tr>
<tr>
<td>R. 3-2 = _____ mm</td>
<td>R. 3-2 = _____ mm</td>
<td></td>
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<td></td>
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</tr>
<tr>
<td>2-1 = _____ mm</td>
<td>2-1 = _____ mm</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>1-1 = _____ mm</td>
<td>1-1 = _____ mm</td>
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<td></td>
<td></td>
<td></td>
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<tr>
<td>L. 1-2 = _____ mm</td>
<td>L. 1-2 = _____ mm</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2-3 = _____ mm</td>
<td>2-3 = _____ mm</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Total (TIM.Mx) = _____ mm</td>
<td>Total (TIM.Mb) = _____ mm</td>
<td></td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

L.I.I Mx

\[
\text{RWU} \times \text{TIM.Mx} = _____ \times _____ \\
\text{IWU} = _____
\]

L.I.I Mb

\[
\text{RWL} \times \text{TIM.Mb} = _____ \times _____ \\
\text{IWL} = _____
\]

University of Newcastle; NEOTS.  Ethics No- H-216-0506
NEOTS Summary Sheet

Orthodontist Examiner Code _____

Date _____

Littles Irregularity Index Measures:

<table>
<thead>
<tr>
<th>Patient ID No.</th>
<th>L.I.I Maxilla</th>
<th>L.I.I Mandible</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

Comments:

University of Newcastle; NEOTS. Ethics No- H-216-0506
Appendix N

Appendix N: Information letters and details for collaborating Periodontists

Summary of NEOTS

NEOTS: Newcastle Effects of Orthodontic Treatment Study
Ethics approval No H-216-0506.

Dear Date:

This PhD study is a long term (15 years) review of the effects of permanently bonded retainers (PBRs) in orthodontics. The main areas of concern are the effectiveness of PBRs in maintaining the achieved alignment of the anterior teeth in the aesthetic zones of the dentition and the long term impact of these retainers on the dental and periodontal tissues.

To validate the clinical measures, 2 independent experts in each field of
  a) Orthodontics,
  b) Periodontics;
are being asked to measure the relevant indices for comparison with those of the PhD student’s.

Being a well respected expert in Periodontics, you have been approached to be an expert participant in this study. Your contribution will be acknowledged in the PHD reports unless you request otherwise.

The total time estimated for you to take to complete these measures is estimated to be ……..< 60…..minutes.

Would you please measure and record the indices listed for the following 10 patients. Each patient has a sheet with measures to be filled in. Any comments would be welcomed.

A summary sheet to record all cases is also enclosed. Would you please retain a copy of this summary sheet in case the returned satchel is misplaced.

I greatly appreciate your invaluable contribution to this study.

Thank you
Best Regards

Robert Cerny

University of Newcastle; NEOTS. Ethics No- H-216-0506
CHECKLIST

NEOTS Periodontal Measures

- Summary explanation of Research Objectives.
- Original articles on:
  1. Plaque scores
  2. Calculus Scores.
  4. Modified Gingival Index.
  5. Alveolar Bone Loss.
- Score sheets for 10 patients.
- Print out of OPG’s of 10 patients.
- CD with dental images of 10 patients.
- Calipers (metric) x 1.
- Calculator x 1.
- Summary sheet for all 10 patients.
- Returned stamped and addressed satchel with funds for this. To be sent back by REGISTERED MAIL.

Would you please retain a record of your results in case the returned satchel is misplaced.
## Appendix N

**Reviewer No** | **Patient ID**
---|---

**Plaque Index (PI) – Rating code. 0, 1, 2, 3.**

### Maxillary (Mx) Dentition

<table>
<thead>
<tr>
<th>Tooth No</th>
<th>Labial</th>
<th>Lingual</th>
<th>Total(T)</th>
<th>PI</th>
</tr>
</thead>
<tbody>
<tr>
<td>23</td>
<td>22</td>
<td></td>
<td>21</td>
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<tr>
<td>11</td>
<td>12</td>
<td></td>
<td>13</td>
<td>13</td>
</tr>
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</table>

### Mandibular (Mb) Dentition

<table>
<thead>
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<th>Labial</th>
<th>Lingual</th>
<th>Total(T)</th>
<th>PI</th>
</tr>
</thead>
<tbody>
<tr>
<td>33</td>
<td>32</td>
<td>31</td>
<td>41</td>
<td>42</td>
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<tr>
<td>42</td>
<td>43</td>
<td></td>
<td></td>
<td>43</td>
</tr>
</tbody>
</table>

**Calculus Index (CI)– Rating code. 0, 1, 2, 3.**

### Maxillary (Mx) Dentition

<table>
<thead>
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<th>Labial</th>
<th>Lingual</th>
<th>Total(T)</th>
<th>CI</th>
</tr>
</thead>
<tbody>
<tr>
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<td>22</td>
<td>21</td>
<td>11</td>
<td>12</td>
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<tr>
<td>12</td>
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<td></td>
<td></td>
<td>13</td>
</tr>
</tbody>
</table>

### Mandibular (Mb) Dentition

<table>
<thead>
<tr>
<th>Tooth No</th>
<th>Labial</th>
<th>Lingual</th>
<th>Total(T)</th>
<th>CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>33</td>
<td>32</td>
<td>31</td>
<td>41</td>
<td>42</td>
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<tr>
<td>42</td>
<td>43</td>
<td></td>
<td></td>
<td>43</td>
</tr>
</tbody>
</table>

**Gingival Recession (GR) as measured on the image**

**Code:** 0 = Nil  1 = <1mm  2 = <2mm  3 = 2-4mm  4 = >4mm

### Maxillary Dentition

<table>
<thead>
<tr>
<th>Tooth No</th>
<th>Labial</th>
<th>Lingual</th>
<th>Total(T)</th>
<th>GR</th>
</tr>
</thead>
<tbody>
<tr>
<td>23</td>
<td>22</td>
<td>21</td>
<td>11</td>
<td>12</td>
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<tr>
<td>12</td>
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<td></td>
<td></td>
<td>13</td>
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</tbody>
</table>

### Mandibular Dentition

<table>
<thead>
<tr>
<th>Tooth No</th>
<th>Labial</th>
<th>Lingual</th>
<th>Total(T)</th>
<th>GR</th>
</tr>
</thead>
<tbody>
<tr>
<td>33</td>
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<td>31</td>
<td>41</td>
<td>42</td>
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<tr>
<td>42</td>
<td>43</td>
<td></td>
<td></td>
<td>43</td>
</tr>
</tbody>
</table>

**Modified Gingival Index (MGI)**

**Code:** 0 = Nil  1 = Minor  2 = Mild  3 = Mod  4 = Severe

### Maxillary Dentition

<table>
<thead>
<tr>
<th>Tooth No</th>
<th>Labial</th>
<th>Lingual</th>
<th>Total(T)</th>
<th>MGI</th>
</tr>
</thead>
<tbody>
<tr>
<td>23</td>
<td>22</td>
<td>21</td>
<td>11</td>
<td>12</td>
</tr>
<tr>
<td>12</td>
<td>13</td>
<td></td>
<td></td>
<td>13</td>
</tr>
</tbody>
</table>

### Mandibular Dentition

<table>
<thead>
<tr>
<th>Tooth No</th>
<th>Labial</th>
<th>Lingual</th>
<th>Total(T)</th>
<th>MGI</th>
</tr>
</thead>
<tbody>
<tr>
<td>33</td>
<td>32</td>
<td>31</td>
<td>41</td>
<td>42</td>
</tr>
<tr>
<td>42</td>
<td>43</td>
<td></td>
<td></td>
<td>43</td>
</tr>
</tbody>
</table>

University of Newcastle NEOTS

Ethics No-H-216-0506
Maxillary Dentition; Alveolar bone loss (ABL) : as reviewed on the screen and measured on the paper image, in mm.

Alveolar bone loss measured from CEJ to Alveolar bone crest on the distal (D) and mesial (M) surface (mm)

<table>
<thead>
<tr>
<th>Tooth No</th>
<th>D 13 M</th>
<th>D 12 M</th>
<th>D 11 M</th>
<th>M 21 D</th>
<th>M 22 D</th>
<th>M 23 D</th>
</tr>
</thead>
<tbody>
<tr>
<td>CEJ-Al B mm</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Mean Alveolar bone loss = \[ \frac{\text{Sum Total}}{12} \times \frac{\text{Real Width of ULI}}{\text{Image Width of ULI}} \]

= \[ \frac{\text{Sum Total}}{12} \times \frac{\text{Real Width of ULI}}{\text{Image Width of ULI}} \] = mm

Manibular dentition; Alveolar bone loss (ABL) : as reviewed on the screen and measured on the paper image, in mm.

Alveolar bone loss measured from CEJ to Alveolar bone crest on the distal (D) and mesial (M) surface (mm)

<table>
<thead>
<tr>
<th>Tooth No</th>
<th>D 43 M</th>
<th>D 42 M</th>
<th>D 41 M</th>
<th>M 31 D</th>
<th>M 32 D</th>
<th>M 33 D</th>
</tr>
</thead>
<tbody>
<tr>
<td>CEJ-Al B mm</td>
<td></td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

Mean Alveolar bone loss = \[ \frac{\text{Sum Total}}{12} \times \frac{\text{Real Width of LLI}}{\text{Image Width of LLI}} \]

= \[ \frac{\text{Sum Total}}{12} \times \frac{\text{Real Width of LLI}}{\text{Image Width of LLI}} \] = mm

Comments regarding the Al B levels supporting the;

a). Anterior teeth.

b). Posterior teeth.

University of Newcastle; NEOTS. Ethics No- H-216-0506
## Appendix N

<table>
<thead>
<tr>
<th>Reviewer No</th>
<th>Patient ID</th>
</tr>
</thead>
</table>

### Comments Generally:

General Periodontal Health in the:

a) Anterior region.

b) Posterior regions.

c) Overall.

### Other Comments
Appendix O

Appendix O: Contacting participants with phone calls, and follow up actions

**NEOTS:**

**Phone call; follow-up action on initial sample**

25/07/2006  (Dominique Cook)

<table>
<thead>
<tr>
<th>Initial Sample of 100 – study group patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>100 patients where selected from the total study group of 231 patients using a computer generated randomized code.</td>
</tr>
<tr>
<td>56 could not be contacted by using last known phone No. white pages, electoral rolls or patients records.</td>
</tr>
<tr>
<td>44 could be contacted by phone and were sent letters of invitation, of these:</td>
</tr>
</tbody>
</table>

**From Follow up phone calls:-**

12 made appointments.

6 refused (1 Pregnant, 1 moved too far away, 4 gave no reason).

1 lost FLR – and could not be included

6 willing (3 will phone back, 1 wants a specific appointment time, 2 will call when back in Newcastle).

3 wrong numbers.

16 were left messages
(6 no answer).

Patients address where sourced from:-

1. Initial orthodontic records
2. Electronic phone book
3. Electoral rolls
4. Google

The University of Newcastle Ethics guide lines for contacting patients where very strict and precise. Patients who where contactable by phone where contacted for there postal address details only.

The letter and information as stipulated by the Ethics committee where sent to those patients who’s address where found. This contained 4 full A4 pages of reading.
Appendix P: Overall phone calls summary

SUMMARY OF NEOTS – Patient gathering and participation.

Follow-up action on total sample

3/07/08

<table>
<thead>
<tr>
<th>Sample</th>
</tr>
</thead>
<tbody>
<tr>
<td>231 Study group</td>
</tr>
<tr>
<td>440 Control group</td>
</tr>
</tbody>
</table>

236 patients in all had their telephone numbers sourced and were included to participate.

454 phone calls were made to contact the patients. Answering machines were asked to return the call. Multiple calls, up to 3, were made to those left messages and failed to return their calls.

27 wrong numbers

51 made appointments

19 maybe – of these 10 made appointments

12 not interested

28 patients live out of town

Final outcome – 46 study group patients
15 control group
Appendix Q: Letter to Dentists - invitation to participate

Associate Professor Deborah Cockrell  
Head of Discipline of Oral Health Uni of Newcastle  
Ourimbah Campus, PO BOX 127, Bush Rd, Ourimbah  
NSW 2258.

DATE

Dear...  

I am writing to invite you to participate in NEOTS, a research project through the University of Newcastle. Patients of the orthodontic practice of Dr Robert Cerny who completed a course of treatment between January 1989 and December 1991, have also been invited to participate. It is hoped the research will contribute valuable information on the effects of permanent fixed lingual retainers (PFLRs) and to the science of orthodontics generally.

Apart from feedback from patients, we are also interested to hear what dentists like you think of PFLRs.

You have been chosen to be invited to participate because you have orthodontic patients who have been treated by Dr Cerny and you have had the opportunity to examine and assess these PFLRs. Your participation is entirely voluntary and the questionnaire is anonymous. All that is required of you is to complete the enclosed brief questionnaire and return it in the stamped addressed envelope.

What is the research about?  

Researchers in orthodontics have found that after braces treatment is completed, the teeth often slowly move out of alignment. This study will review what happens to dental alignment over the long term of 15 years after orthodontic treatment, and what benefits different forms of retention may offer to the treatment results.

It will also review if there are any adverse effects of PFLRs on the periodontal tissues and bone supporting the teeth.

Who is doing the research?  

The Principle Researcher is Dr. Robert Cerny (Orthodontist). This research is part of a PhD study through the University of Newcastle. The Project Supervisor is Associate Professor Deborah Cockrell (Head of Discipline of Oral Health, University of Newcastle). The Project Co-Supervisor is Dr Deborah Lloyd, (School Medicine and Public Health, University of Newcastle)

What will participation in the study involve?  

If you agree to participate in this study you will be asked to complete the enclosed questionnaire and return it via the enclosed stamped addressed envelope. The questionnaire should take less than 10 minutes to complete.

How long do I have to decide whether I want to take part or not?  

If you would like to participate we would like you to respond as soon as possible after receiving this letter. We will contact you after two weeks to remind you to complete the questionnaire if you haven’t already done so.

If you don’t want to participate in the research you are free to do so. You can withdraw from the study at any stage without penalty.

What are the benefits of taking part in this study?  

There are no direct benefits to you apart from contributing knowledge to important research in orthodontics that will be beneficial to your future patients.

How will my privacy be protected?  

Neither the questionnaire nor the return envelope have any identification markings on them so the survey is completely anonymous. No individual data, only group data will be recorded.

Will I get a copy of the final study report?  

It is expected that this study will take some time to complete (two years) and a summary report will be sent
to all of the dentists who have been invited to participate.

I would like to participate in this research, so what do I do next?
Please fill in the enclosed questionnaire and return it in the stamped addressed envelope.

How can I contact the researcher if I want more information?
Telephone Dr Robert Cerny or Mrs Michelle Murphy (research assistant) toll free on 1800 021 064 during working hours.

Who do I contact if I have any concerns?
This research has been reviewed and approved by the University of Newcastle Human Research Ethics Committee (Approval number: H-216-0506). Should you have any concerns about your rights as a participant in this research, or if you have a complaint about the manner in which the research is conducted, it may be given to the Project Supervisor (details above), or, if an independent person is preferred, to the Human Research Ethics Officer, Research Office, The Chancellery, The University of Newcastle, University Drive, Callaghan NSW 2308, telephone (02) 4921 6333, email Human-Ethics@newcastle.edu.au.

Signed Dr Robert Cerny...........................................
Principle Researcher

Signed Associate Professor Deborah Cockrell...........................................
Project Supervisor
Appendix R

Appendix R: Questionnaire for dentists
Questionnaire for dentists regarding RRs and BRs.

NEOTS QUESTIONNAIRE for DENTISTS;
RE-ORTHODONTIC RETAINERS.
Please fill in the answer you want to give or √ (tick) the appropriate box.

Personal Information  Age: ……. Sex: M / F  Years in Practice: ……….. 
If retired …….  year retired
Approximately how many of your patients have been treated by Dr R Cerny;
1—25, 26—50, 51—100, >100.

1. Do you have current or past orthodontic patients who have Permanent Fixed Lingual Retainers PFLRs?
   YES……   NO……

If you answered NO, please go to the next page (section #2).
If you answered YES, please continue:

For approximately how long have you been reviewing these patients with PFLRs?
1- 5yrs  6-10yrs  11-15yrs  16-20yrs  > 20yrs

Regarding the PFLRs, please fill in what percentage % you would fit into the following categories:

<table>
<thead>
<tr>
<th></th>
<th>Poor</th>
<th>Fair</th>
<th>Good</th>
<th>Very Good</th>
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<tbody>
<tr>
<td>1. Effectiveness</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>100%</td>
</tr>
<tr>
<td>2. Durability</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>100%</td>
</tr>
<tr>
<td>3. Hygiene of Maxilla PFLRs</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>100%</td>
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<tr>
<td>4. Hygiene of Mandible PFLRs</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>100%</td>
</tr>
<tr>
<td>5. Your impression of patient satisfaction with their: PFLRs</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>100%</td>
</tr>
<tr>
<td>6. Your overall rating of PFLRs initially</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>100%</td>
</tr>
<tr>
<td>7. Your overall rating of PFLRs now</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>100%</td>
</tr>
</tbody>
</table>

If you have marked poor or fair anywhere above, would you please expand on the reason for this.

____________________________________________________________
____________________________________________________________
____________________________________________________________
____________________________________________________________

Do you have any other comments regarding the PFLRs?

____________________________________________________________
____________________________________________________________
____________________________________________________________

P.T.O
Appendix R

Do you have current or past orthodontic patients who have or had Removable Retainers? (RRs)  

[YES]  [NO]  

If you answered NO, this section is complete. If you answered YES, please continue.

How long have you been reviewing patients with RRs?

1-5yrs  6-10yrs  11-15yrs  16-20yrs  >20yrs

Regarding RRs, please fill in What percentage % you would fit into the following categories:

<table>
<thead>
<tr>
<th></th>
<th>Poor</th>
<th>Fair</th>
<th>Good</th>
<th>Very Good</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Effectiveness</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>100%</td>
</tr>
<tr>
<td>2. Durability</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>100%</td>
</tr>
<tr>
<td>3. Hygiene of Maxilla RRs</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>100%</td>
</tr>
<tr>
<td>4. Hygiene of Mandible RRs</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>100%</td>
</tr>
<tr>
<td>5. Patient Satisfaction with the RRP</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>100%</td>
</tr>
<tr>
<td>6. Your overall rating re:RRs</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>100%</td>
</tr>
</tbody>
</table>

If you have marked “poor” or “fair” anywhere above, would you please expand on the reason for this.

________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________

Do you have any other comments regarding the RRs?

________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________

Thank you for participating
Please place the completed questionnaire in the stamped, addressed envelope and post it back to the researchers.
Appendix S

Appendix S: Gender ratios of ADA dentists in NSW in 2008-2009

As requested the breakdown of our membership between males and female as at today’s date (2008-9) is:

<table>
<thead>
<tr>
<th>Demographic</th>
<th>Total</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female</td>
<td>983</td>
<td>29%</td>
</tr>
<tr>
<td>Male</td>
<td>2398</td>
<td>71%</td>
</tr>
<tr>
<td>Grand Total</td>
<td>3381</td>
<td></td>
</tr>
</tbody>
</table>

Please don’t hesitate to contact me if I can be of any further assistance.

Regards

Bernard Rupasinghe
Policy Officer
Australian Dental Association (NSW Branch) Limited
71-73 Lithgow Street, St Leonards NSW 2065
Tel: +61 2 8436 9900Mob: +61 408 234 344
Fax: +61 2 8436 9905Email: bernardr@adansw.com.au Web: www.adansw.com.au