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Association between ankle equinus and plantar pressures in people with diabetes. A systematic review and meta-analysis.

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ABSTRACT

Background. Diabetes is one of the most common chronic diseases in the world and is associated with a life-time risk of foot ulcer of 12-25%. Diabetes related restriction in ankle joint range of dorsiflexion is proposed to contribute to elevated plantar pressures implicated in the development of foot ulcers.

Methods. A systematic search of EBSCO Megafire Premier (containing MEDLINE, CINAHL, SPORTSdiscus and Academic Search Complete) and The Cochrane Library was conducted to 23rd November 2016. Two authors independently reviewed and selected relevant studies. Meta-analysis of study data were conducted where possible.

Findings. Fifteen studies met the inclusion criteria. Three studies were eligible to be included in the meta-analysis which found that equinus has a significant, but small, effect on increased plantar pressures (ES = 0.26, CI 95% 0.11 to 0.41, $p = 0.001$). Of the remaining studies, eight found evidence of an association between limited ankle dorsiflexion and increased plantar pressures while four studies found no relationship.

Interpretation. Limited ankle joint dorsiflexion may be an important factor in elevating plantar pressures, independent of neuropathy. Limited ankle dorsiflexion and increased plantar pressures were found in all the studies where the sample population had a history of neuropathic foot ulceration. In contrast, the same association was not found in those studies where the population had neuropathy and no history of foot ulcer. Routine screening for limited ankle dorsiflexion range of motion in the diabetic population would allow for early provision of conservative treatment options to reduce plantar pressures and lessen ulcer risk.

Key Words. Ankle, dorsiflexion, ulcer, pressure, equinus, diabetes

Highlights

- We found a significant association between equinus and increased plantar pressures
- Association present particularly in participants with a history of foot ulceration
- Potential for equinus to elevate plantar pressures independent of neuropathy

1. Introduction

Diabetes is one of the most common chronic diseases in the world, affecting 9% of the population in 2014,(1) and is associated with a life-time risk of foot ulcer of 12-25%.(2) Diabetic foot ulcers lead to high morbidity, increased associated healthcare costs and are estimated to precede lower extremity amputations in 75-85% of cases.(3) Foot ulcer development has been associated both prospectively and retrospectively with elevated plantar pressures in people with diabetes.(4, 5) It is well established that factors such as peripheral neuropathy(6), foot deformity(7) and limited joint mobility in the foot(8) contribute to elevated plantar pressures.

Ankle equinus has emerged as a possible contributory factor to increased plantar pressures,(9, 10) and may play a significant role in the development of pressure related foot ulcers.(11, 12) Limited ankle joint dorsiflexion, or equinus, acts to restrict the forward progression of the tibia over the foot during stance phase. This is proposed to result in gait compensations such as an early heel lift, excessive subtalar joint pronation and associated midtarsal joint pronation.(13) It is hypothesised that these changes lead to prolonged weight bearing at the forefoot and increased plantar pressures which subsequently contribute to the development of pressure ulceration.(14, 15)

Prevalence of equinus in the general population is not well documented, with most reports being observational or anecdotal.(16, 17) Prevalence of equinus in an urban population with diabetes is variable, ranging from 10.3% to 37.2%, a threefold increase in risk compared to a group without diabetes.(9, 18) The higher prevalence of equinus in people with diabetes is thought to be, in part, due to the non-enzymatic glycosylation of soft tissues resulting in structural abnormalities and thickening of the Achilles tendon leading to increased tendon stiffness and reduced joint mobility.(19, 20)

Given the increasing burden of diabetic foot complications, it is important that risk factors for foot ulcer development and subsequent amputation are identified and managed. If ankle equinus is found to contribute to high plantar pressures then it could present an opportunity for earlier clinical detection of patients at risk of pressure-related foot ulcer and, may also provide additional preventative treatment options for these patients.(12) Therefore, the aim of this review is to systematically evaluate the current literature to determine if, for people with diabetes, there is an association between equinus and high plantar pressures, and to evaluate study findings by meta-analysis where possible.

2. Methods

An electronic database search of EBSCO Megafire Premier (containing MEDLINE, CINAHL, SPORTSDiscus and Academic Search Complete), EMBASE, and The Cochrane Library was conducted from their inception to 23rd November 2016. The search strategy used for the EBSCO database used the following terms:

- #1 Diabet* and ((Pressure or loading or function) and (plantar or foot or forefoot or peak))
- #2 Ankle or dorsiflex* or DF
- #3 Equinus or contracture or LJM or 'joint mobility' or 'joint motion' or 'joint stiffness' or 'range of motion' or ROM or orthop* or flexibility
- #4 1&2&3

No language, publication date or publication status restrictions were used. Reference lists of included studies, clinical guidelines and review articles were also searched.

Published reports including prospective cohorts, case series and observational studies were eligible for this review. Included studies were required to investigate ankle dorsiflexion range of motion and plantar pressures in people with diabetes. Studies were excluded if the individuals had current plantar foot ulcers preventing foot pressure measurement or neurologically induced limited ankle joint range of motion (such as stroke or cerebral palsy). Studies were also excluded if they reported ground reaction forces or joint moments only, or if ankle joint range of motion was reported as a combination of plantarflexion and dorsiflexion only and data specific for dorsiflexion range of motion could not be provided. One reviewer conducted the electronic searches (AS). Titles and abstracts were independently assessed by two reviewers (AS and VC). Disagreements were resolved by consensus and a third reviewer where necessary (MS).

An assessment of the methodological quality of the included studies was conducted using the Observational Study Appraisal Checklist designed by Health Evidence Bulletins – Wales, which is designed for critical appraisal of observational studies.(21) This tool was selected as it allows use of one set of questions for all included studies, includes a small number of key domains, is a simple checklist rather than a scale and was developed using a variety of literature sources.(22) Methodological quality of the studies was assessed according to four key domains: domain A (aims and outcomes of study), domain B (population, bias and follow up), domain C (results, statistical methods and conclusions), and domain D (external validity).

Data from each trial were extracted from the available text. Meta-analysis was performed to compare plantar pressures in people with and without equinus where possible. Studies were included in the meta-analysis if data for equinus and non-equinus groups were reported separately. For the purpose of the meta-analysis equinus was defined as less than or equal to

zero degrees of ankle dorsiflexion.(9) Where the data provided was not reported in equinus and non-equinus groups, the corresponding author of the trial was contacted via email and the relevant data requested. All data analyses were performed using STATA version 12.1 software. A random effects model was used as it is considered more suitable for combining the results of studies that may not be functionally equivalent and allows for a more generalised inference of effect size.(23) Effect sizes were calculated as Cohen's d and then converted to Hedge's g(24) which provided a less biased estimate of the treatment effect.(25) An effect size of greater than or equal to 0.8 was considered to represent a large clinical effect, 0.5 a moderate effect and 0.2 a small effect.(26) Statistical heterogeneity between studies was assessed by use of the I^2 statistic and a value of >50% was considered to indicate significant heterogeneity.(27)

3. Results

The initial database search resulted in a total of 386 citations of which 47 were appropriate for full review (Figure 1). After review, 15 studies were included (Table 1) and 32 were rejected on the basis of exclusion criteria (Supplementary Table 1). The 15 studies, with sample sizes from 10 to 1666 people, included a total of 2544 participants with an age range of 45 to 80 years of age and duration of diabetes of between 1 and 31 years. Twelve of these studies measured ankle joint dorsiflexion with a goniometer, two with custom devices that allowed standardised torques to be applied at the ankle joint, and one described using a musculoskeletal exam to identify equinus. Five studies measured plantar pressures in shoe while the other ten used a barefoot pressure platform. Details of individual studies are included in Table 1.

Methodological quality of the studies is detailed in Supplementary Table 2. All of the studies provided detailed information for study population, aims, outcomes, study method and follow up. The least favourably ranked questions were those regarding whether the population studied was appropriate, the presence of selection bias and if the results could be applied more widely. With regard to the population studied, three studies did not randomly select case-controls,(10, 28, 29) one did not have matched case controls(30) and one did not provide details of the population.(31) None of the studies reported blinding the investigators. Seven(10, 30, 32-36) of the 15 studies reviewed specific populations that could make comparison to a wider population difficult. These populations included all Asian,(10) all high risk,(32) all older males,(33, 34) all American Indian,(30) all under 65 years of age(35) and all without motor deficit.(36) One study did not define the sample population.(31)

3.1 Meta-analysis results for the effect of ankle equinus on plantar pressures

Two of the studies reported ankle joint dorsiflexion and plantar pressure data separately by equinus and non-equinus groups(9, 33) and the authors of two other studies provided these data on request.(31, 34) This allowed for four studies to be included in the meta-analysis (Figure 2). However, due to a very small equinus sample size ($n=2$), the Orendurff et al. study (31) was excluded from the meta-analysis. Statistical analysis to assess the risk of publication bias was not used as fewer than 10 studies were included in the meta-analysis, in which case test power has been reported to be too low to distinguish chance from actual asymmetry.(37) The meta-analysis showed presence of an ankle equinus had a significant but small effect of increasing plantar pressures (Hedges $g = 0.26$, CI 95%: 0.11 to 0.41, $p = 0.001$) with no significant heterogeneity present ($I^2 = 0.0\%$, $p = 0.92$). However, it should be noted that the results are predominantly linked to the large Lavery et al. study,(9) that found participants

with an equinus had statistically significant higher peak plantar pressures than those without an equinus.

3.2 Other results for the effect of restricted ankle joint dorsiflexion on plantar pressures

An additional four studies(28-30, 32) investigating diabetes cohorts with neuropathy and a history of foot ulcers also found an association between increased plantar pressures and restricted ankle joint dorsiflexion. Bennett et al.(28) demonstrated increased plantar pressures and restricted ankle joint dorsiflexion co-existed in a diabetes cohort with previous history of neuropathic foot ulceration compared with a group without neuropathy or a history of foot ulceration. In the cohort with a previous history of neuropathic foot ulceration, mean plantar pressures were significantly elevated, (8.7 kg/cm² (SD 2.3) versus 6.0 kg/cm² (SD 2.1), $p<0.01$) and mean ankle dorsiflexion was significantly reduced (5.1° (SD 4.0) versus 11.0° (SD 5.3), $p<0.01$). Birke et al.(29) measured foot and ankle mobility and plantar pressures in four groups: with diabetes and a history of ulceration at the first metatarsal head; with diabetes and a history of other forefoot ulceration; with diabetes and no history of foot ulceration; and a group without diabetes. This study demonstrated a link between reduced ankle joint dorsiflexion and history of foot ulcers, where the group with a history of ulceration at the first metatarsal head had significantly smaller mean ankle dorsiflexion (2.2° (SD 4.2), $p<0.05$) and higher mean plantar pressure (87.1N/cm² (SD 25.8), $p<0.05$) than all other groups.

McPoil et al.(30) also compared foot and ankle mobility and plantar pressures between diabetes groups (participants without diabetes, participants with diabetes but without neuropathy, and participants with both diabetes and neuropathy). The diabetes with neuropathy group, of whom almost a third had a history of ulceration, had the smallest

amount of mean ankle dorsiflexion (5.7° (SD 4.6)), and higher mean central forefoot plantar pressures (616.4kPa (SD 21.8)). In contrast the diabetes without neuropathy group demonstrated larger mean ankle dorsiflexion (7.3° (SD 4.4)) and lower mean central forefoot plantar pressures (518.0kPa (SD 22)). These findings are consistent with those of Armstrong et al.(32) in their comparison of ankle dorsiflexion and plantar pressures in participants with a history of neuropathic plantar ulceration before and after surgery for percutaneous lengthening of the Achilles tendon. Prior to surgery the participants had an ankle dorsiflexion range of -5° to 5° , and at 8 weeks post operatively mean ankle dorsiflexion was significantly increased from 0° (SD 3.1) to 9° (SD 2.3) and mean peak forefoot pressure was significantly reduced, by approximately 27% from 86 Ncm² (SD 9.4) to 63 Ncm² (SD 13.2).

A further four studies,(10, 31, 35, 36) involving populations with no current ulceration, also found an association between increased plantar pressures and restricted ankle joint dorsiflexion. Sacco et al.(35) compared participants with diabetic neuropathy but no current ulcer and a non-diabetes group. This study found that the neuropathy group had significantly smaller mean active range of ankle dorsiflexion (control: 15.6° (SD 4.2) versus diabetes: 12.9° (SD 6.2)), reduced dynamic ankle dorsiflexion at heel strike, and higher peak pressures in the midfoot and forefoot at push-off. Consistent with these findings, Amemiya et al.(10) also compared a group of whom the majority had diabetic neuropathy but no current ulcer with a non-diabetes group, and examined the relationship between plantar pressures, gait features and participant characteristics. They found that elevated plantar pressures in people with diabetes in the stance and push-off phases of gait were related to specific gait parameters including small roll and yaw motions of the body and foot. These were in turn associated with both reduced ankle dorsiflexion range of motion and neuropathy. Similarly, Orendurff et al. (31) reported that participants with diabetes and equinus defined as less than 5° of

dorsiflexion, had a higher mean forefoot pressure than participants with diabetes and no equinus (63.9Ncm^2 (SD 13.3) versus 50.9Ncm^2 (SD 14.1)). However, while linear regression revealed a significant relationship between equinus and forefoot pressure, equinus only accounted for a small portion (15%) of the variance in forefoot pressure. Cerrahoglu et al.(36) conducted a randomised trial investigating the effects of a four week home exercise program on ankle range of motion and plantar pressures in people with diabetes both with and without neuropathy. At baseline, none of the participants had ankle equinus and there was no statistical difference in plantar pressures between the groups. Following the exercise program, the exercise group reported a significant increase in dynamic ankle dorsiflexion range of motion and decrease in plantar pressure at the lateral forefoot.

In contrast, four studies(38-41) investigating diabetes cohorts with neuropathy and without a history of ulceration did not find any an association between increased plantar pressures and restricted ankle joint dorsiflexion. Using regression analysis to examine clinical and radiological measures, both Payne et al.(38) and Guldemonnd et al.(39) demonstrated the presence of neuropathy was significantly associated with increased plantar pressures but there was no association for ankle joint dorsiflexion range of motion. Counter to those findings, Tang et al.(40) found no significant association between neuropathy and increased plantar pressures, which may have been related to a mild severity of neuropathy in the group studied. In addition they found no relationship between ankle range of motion and increased plantar pressures. Finally, Rao et al.(41) reported that while individuals with diabetes and neuropathy demonstrated reduced passive ankle dorsiflexion compared to a group without diabetes, neither this or peak dorsiflexion during gait was found to be related to peak plantar pressures.

4. Discussion

We found fifteen studies that allowed comparison of ankle joint dorsiflexion and plantar pressures. The three studies that were included in the meta-analysis showed a significant but small effect size of equinus on increased plantar pressures, although this is predominantly due to the findings of the large Lavery et al. study.(9) Of the remaining twelve studies, eight studies reported evidence of an association between limited ankle dorsiflexion and increased plantar pressures while four studies found no relationship.

This review demonstrates that a reduced range of ankle dorsiflexion in people with diabetes can potentially elevate plantar pressures, in addition to increases associated with neuropathy. In all the included studies, where the target sample population had a history of neuropathic foot ulceration, a relationship was found between limited ankle dorsiflexion and increased plantar pressures(9, 28-30, 32). The same association was not found in those studies where the sample population had neuropathy and no history of foot ulcer.(38-41) These findings are consistent with a number of studies that have shown an increased risk of ulceration in association with limited ankle joint mobility,(11, 12, 14, 18) with one study showing a fourfold risk in the equinus group,(18) and another that in 78.9% of cases the first ulcer occurred in the foot with lower ankle joint mobility.(12) Limited ankle joint dorsiflexion has also been clearly linked to delayed ulcer healing,(42, 43) and increased likelihood of diabetic foot ulcer recurrence.(43)

The findings of this review support an association between increased plantar pressures and ankle equinus in diabetes cohorts with a previous history of neuropathic foot ulcer. Although it is not known from these data if ankle equinus is an independent predictor for the development of foot ulcer, our analysis of existing literature suggest such a relationship may exist. This is supported by findings of a significantly higher prevalence of equinus in people

with elevated risk of diabetes related foot complications. In the general population with diabetes, the prevalence of an equinus is reported to be between 10.3% and 37.2%,(9, 18) while in high risk groups, including those with neuropathy or history of ulcer, rates of 72 to 91% have been recorded.(11, 44) Screening for restricted ankle joint dorsiflexion may therefore be a useful early clinical indicator of increased risk of foot ulcer in people with diabetes.

Routine screening would allow for the early provision of conservative treatment options to reduce plantar pressures and lessen ulcer risk, however the current conservative treatments have recognized issues. Pressure reducing devices such as insoles, therapeutic footwear and orthoses have been shown to be effective but have very low compliance which undermines their widespread use,(45) and this form of therapy does not address the underlying dysfunction. Musculoskeletal interventions aimed at increasing ankle joint dorsiflexion may reduce gait compensations associated with ankle equinus and subsequently reduce forefoot pressures. Cerrahoglu et al.(36) found a combined program of range of motion, stretching and strengthening exercises resulted in significant increases in total ankle range of motion as well as some associated decreases in forefoot pressures in both neuropathic and non-neuropathic diabetes cohorts. A simple calf stretching program has been shown to increase ankle range of motion in the older female population without diabetes.(46) As comparable non enzymatic glycosylation changes occur in tendons with both aging and diabetes,(47) it is possible that a similar stretching regime may also increase ankle range of motion and reduce plantar pressures in the diabetic population. The authors are conducting a randomised trial to investigate this further.

Three main factors appear to be contributing to the lack of a consistently clear association between equinus and increased plantar pressures in people with diabetes. Firstly, there is no standard definition regarding the degree of dorsiflexion that constitutes an ankle equinus. Studies included in this review variously defined equinus as less than 0°, 0° or less, less than 5° or less than 10° of dorsiflexion, making comparisons between these studies difficult. Secondly, there is no standardised method for assessment of an equinus.(17) A recent review identified as many as ten different techniques reported in the literature to measure ankle dorsiflexion, and while the majority of studies included in this review measured ankle dorsiflexion passively with a goniometer, concerns have been raised about the reliability of this method.(48) Issues raised include errors with placement of the arms of the goniometer, variable and undefined force used to dorsiflex the ankle, incorrect maintenance of subtalar joint neutral during measurement, and inconsistent participant and leg positioning.(48) Finally, the results of the different systems commonly used for measuring plantar pressures, either in-shoe devices or barefoot pressure platforms, are not always directly comparable.(49) Five studies in this review used an in-shoe device,(10, 33, 38, 40, 41) while the other ten used pressure platforms.(9, 28-32, 34-36, 39)

Although this review was designed to be comprehensive with a robust search on relevant databases, it is possible that not all studies were identified. Researchers in the field were not contacted for unpublished studies, authors were only contacted where information from included articles was missing. In addition only a small number of studies provided data that enabled meta-analysis, and the significantly larger sample in one study may have affected these results.

5. Conclusion

Our findings support the possibility that limited ankle joint dorsiflexion may be an important factor in elevating plantar pressures in people with diabetes. This relationship appears to be independent of neuropathy and it may also be related to whether people with diabetic neuropathy go on to develop a foot ulcer. All the included studies where the population had a history of neuropathic foot ulceration found a relationship between limited ankle dorsiflexion and increased plantar pressures. This association was not observed in the studies where the sample population had neuropathy and no history of foot ulcer. An equinus may be an early clinical indicator of increased ulcer risk, and it would be advisable for clinicians to assess for this movement restriction, especially in high risk groups such as those with neuropathy. This review has also demonstrated inconsistencies in the literature relating to the definition of equinus, reliability issues with methods of measuring ankle dorsiflexion, comparing varied plantar pressure measurement systems and plantar pressure variables which are likely to contribute to heterogeneity of results.

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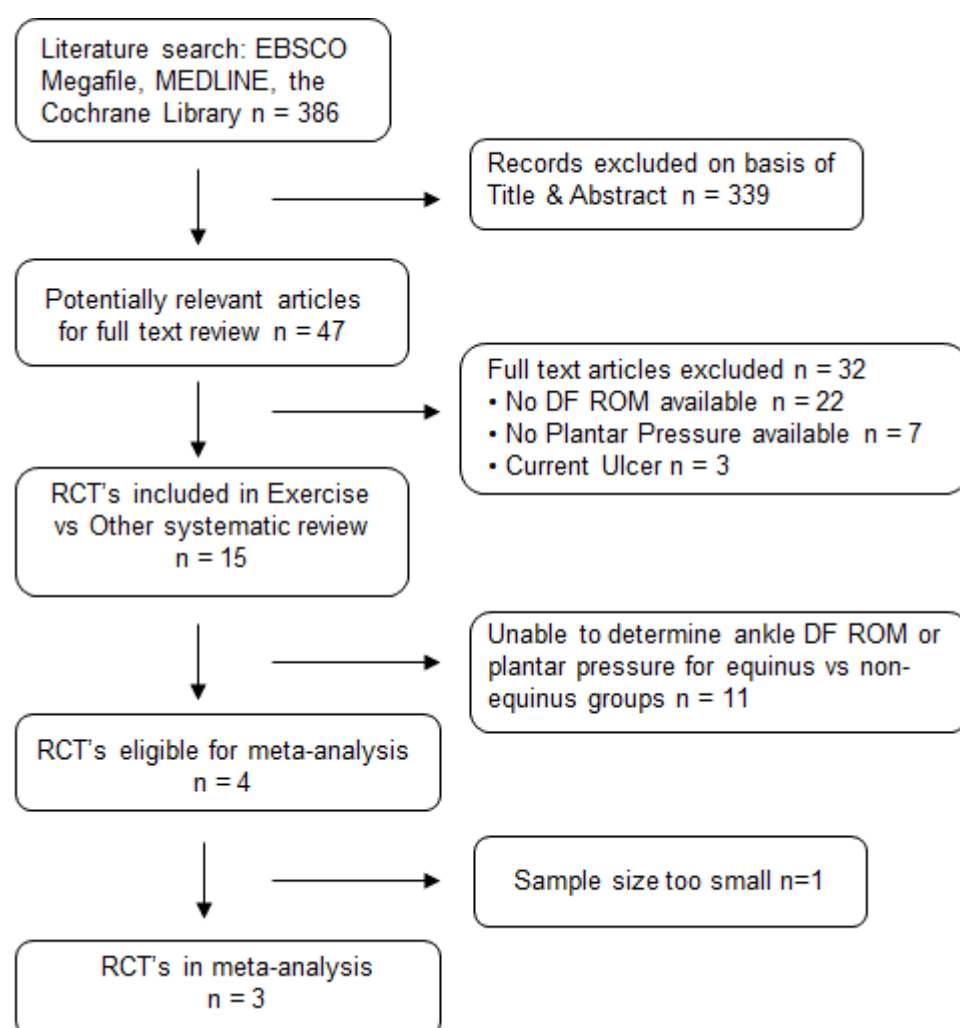


Fig 1. Flow diagram of systematic review inclusion or exclusion

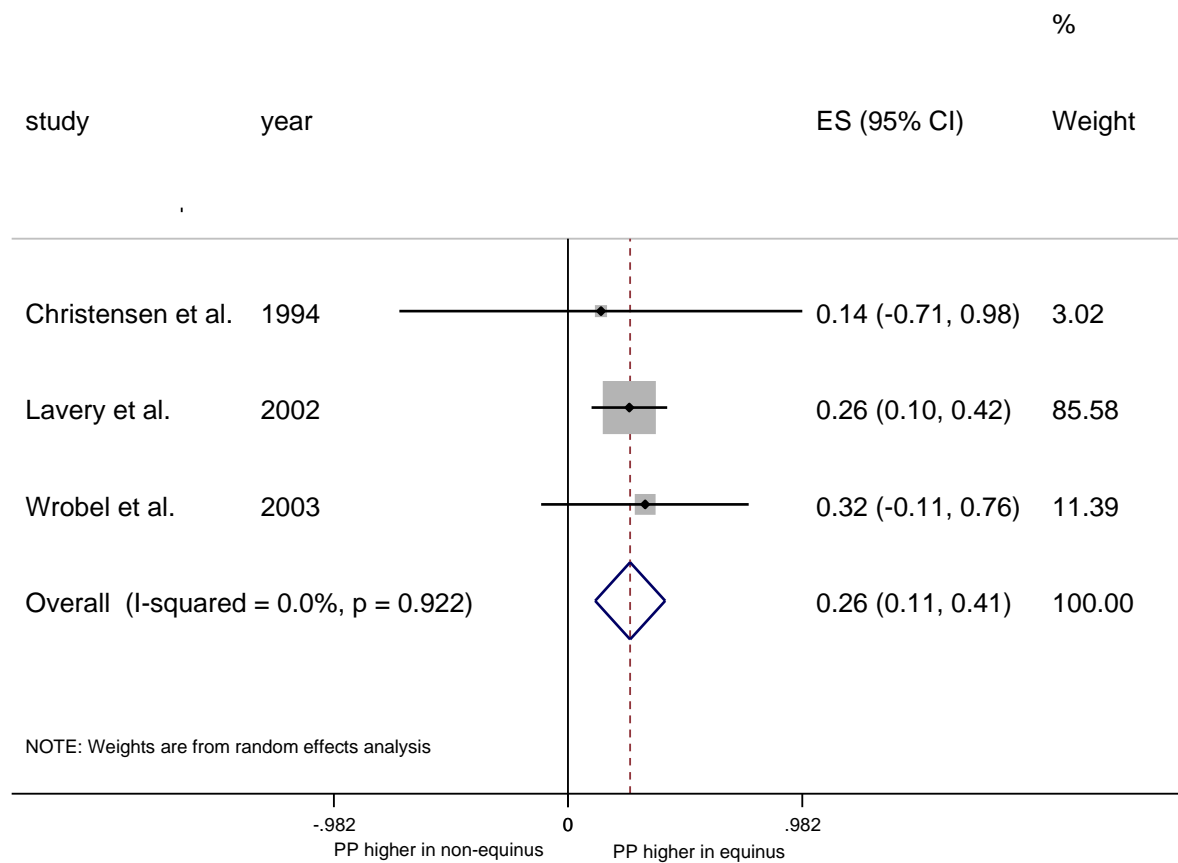


Fig 2. Forest Plot of the association between plantar pressures and equinus. PP=plantar pressure

Supplementary Table 1: Excluded studies.

Article	Reason for Rejection
Barn 2015 Predictors of barefoot plantar pressure during walking in patients with diabetes, peripheral neuropathy and a history of ulceration	No ankle DF ROM available from article
Bokan 2010 Risk Factors for Diabetic Foot Ulceration – Foot Deformity and Neuropathy	No ankle DF ROM available from article
Cerrahoglu 2013 Determination of the Effectiveness of Home Exercise program in patients with Diabetic Neuropathy	No ankle DF ROM available from article
Cheuy 2016 Metatarsophalangeal Hyperextension Movement Pattern Related to Diabetic Forefoot Deformity	No Plantar Pressure data available from article
Fernando 2016 Gait parameters of people with diabetes-related neuropathic plantar foot ulcers	No Plantar Pressure data available from article
Francia 2015 The role of joint mobility in evaluating and monitoring the risk of diabetic foot ulcer	No Plantar Pressure data available from article
Francia 2015 Postural Alterations and Limited Joint Mobility in Young Patients with Type 1 Diabetes Mellitus	No ankle DF ROM available from article
Giacommozzi 2006 Peak pressure curve: An effective parameter for early detection of foot functional impairments in diabetic patients	No ankle DF ROM available from article
Goldsmith 2002 The Effects of Range-of-Motion Therapy on the Plantar Pressures of Patients with Diabetes Mellitus	No ankle DF ROM available from article
Hamatani 2016 Factors Associated With Callus in Patients with Diabetes, Focused on Plantar Shear Stress During Gait	No ankle DF ROM available from article
Hastings 2000 Effects of a tendo-achilles lengthening procedure on muscle function and gait characteristics in a patient with diabetes mellitus	Current ulcer
Lavery 1998 Practical Criteria for Screening Patients at High Risk for Diabetic Foot Ulceration	No ankle DF ROM available from article
Maluf 2004 Tendon Achilles lengthening for the treatment of neuropathic ulcers causes a temporary reduction in forefoot pressure associated with changes in plantar flexor power rather than ankle motion during gait	Current ulcer
Melai 2013 Increased forefoot loading is associated with an increased	No ankle DF ROM available from article

plantar flexion moment	
Mueller 1994 Differences in the gait characteristics of patients with diabetes and peripheral neuropathy compared with age matched controls	No Plantar Pressure data available from article
Mueller 1995 Relationship of plantar-flexor torque and dorsiflexion range of motion to kinetic variables during walking	No Plantar Pressure data available from article
Mueller 2002 Effects of tendo achilles lengthening on forefoot plantar pressures, ankle motion and plantar flexor power during walking in subjects with diabetes and peripheral neuropathy: a prospective controlled clinical trial	Current ulcer
Mueller 2003 Forefoot structural predictors of plantar pressures during walking in people with diabetes and peripheral neuropathy	No ankle DF ROM available from article
Nobumasa 2016 Factors affecting the range of motion of the ankle and first metatarsophalangeal joints in patients undergoing hemodialysis who walk daily	No ankle DF ROM available from article
Peters 2001 Effectiveness of the diabetic foot risk classification system of the international working group on the diabetic foot	No ankle DF ROM available from article
Qiu 2013 Risk factors correlated with plantar pressure in Chinese patients with type 2 diabetes	No ankle DF ROM available from article
Raspovic 2013 Gait characteristics of people with diabetes-related peripheral neuropathy, with and without a history of ulceration	No Plantar Pressure data available from article
Salsich 2000 Relationships between plantar flexor muscle stiffness, strength, and range of motion in subjects with diabetes-peripheral neuropathy compared to age matched controls	No Plantar Pressure data available from article
Sartor 2011 Relationship between foot range of movement and plantar pressure distribution in diabetic neuropathic patients	No ankle DF ROM available from article
Sartor 2014 Effects of strengthening, stretching and functional training on foot function in patients with diabetic neuropathy: Results of an RCT	No ankle DF ROM available from article
Sauseng 1999 (german) Effect of limited joint mobility on plantar pressure in patients with type 1 diabetes mellitus	No ankle DF ROM available from article
Savelberg 2009 Redistribution of joint moments is associated with changed plantar pressure in diabetic polyneuropathy	No ankle DF ROM available from article
Sawacha 2012 Integrated kinematics-kinetics-plantar pressure data	No ankle DF ROM available from article

analysis. A useful tool for characterising diabetic foot biomechanics	
Turner 2007 The relationship between passive range of motion and range of motion during gait and plantar pressure measurements	No ankle DF ROM available from article
van Schie 2011 Foot pressures, peripheral neuropathy and joint mobility in Asian and European patients with diabetes	No ankle DF ROM available from article
Viswanathan 2003 Association of limited joint mobility and high plantar pressure in diabetic foot ulceration in Asian Indians	No ankle DF ROM available from article
Zimny 2004 The role of limited joint mobility in diabetic patients with an at risk foot	No ankle DF ROM available from article

Supplementary Table 2: Quality Assessment. A table showing the individual quality assessment for each included article.

Articles			Anemiya	Armstrong	Bennett	Birke	Cerrahoglu	Christensen	Guldemond	Lavery	McPoil	Orendurff	Payne	Rao	Sacco	Tang	Wrobel
	1. Is the study relevant to the needs of the project?		Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
	2. Does the paper address a clearly focussed issue in terms of:	The population studied?	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
		(Case-control only) Is the case definition explicit and confirmed?	Y	Na	Y	Y	Na	Na	Na	Na	Y	Na	Na	Y	Y	Na	Na
		The outcomes considered?	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
		Are the aims of the investigation clearly stated?	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
B. Do I trust it?	3. Is the choice of study method appropriate?		Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
	4. Is the population studied appropriate?	(Cohort study) Was an appropriate control group used – i.e. were the groups comparable (Case-control study) Were the controls randomly selected from the same population as the cases?	U ^a	Y	U ^a	U ^a	Y	Y	Y	Y	U ^e	U ^g	Y	Y	Y	Y	Y
	5. Is confounding and bias considered?	Have all possible explanations of the effects been considered?	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
		(Cohort study) Were the	U	N	U	U	U	N	N	N	N	N	N	U	N	U	N

did they find?	use of statistical methods, if employed?															
	9. What are the results of this piece of research? Are the author's conclusions adequately supported by information cited?	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
D. Are the results relevant locally?	10. Can the results be applied to the local situation?	U ^b	U ^c	Y	Y	Y	U ^d	Y	Y	U ^f	U ^g	Y	Y	U ^h	Y	U ^d
	Consider differences between the local and study populations which could affect the relevance of the study															
	11. Were all important outcomes/results considered?	Y	Y	Y	Y	Y ^j	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
	12. Is any cost information provided?	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	13. Accept for use as further Type IV evidence?	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y

From Weightman AL, Mann MK, Sander L, Turley RL: Health Evidence Bulletins - Wales. Questions to assist with the critical appraisal of an observational study eg cohort, case-control, cross-sectional. (Type IV evidence).

Abbreviations: Y (yes), N (no), U (unknown), Na (not applicable), ^a not random selection of case-controls, ^b Asian population, ^c all high risk patients, ^d all older male patients, ^e not matched case-controls, ^f all American Indian population, ^g population not specified, ^h all subjects under 65 years old, ⁱ not matching age group, ^j excluded if motor deficit found

Table 1: Summary of included studies

Study	Design	Population	Participants Age (yrs) mean(SD)	Diabetes Duration (yrs) mean(SD)	Ankle DF measure	Pressure measure	Results mean (SD)
Amemiya, 2014(10)	Case Control	Foot Outpatient clinic attendees at University of Tokyo Hospital, Japan	49 non DM 57 DM (29M, 20F) Age: 66.6 (10.8)	Duration: 14.4 (10.6) Type 1: 4(7.0%) Type 2: 50(87.7%) Other: 3(5.3%)	Passive Goniometer Knee extended	In-shoe F-scan, at 4 plantar segments	Roll and yaw motions of the body and foot are related to elevated pressures. These gait features are associated with diabetes duration, toe-gap force, ankle ROM, foot length & neuropathy.
Armstrong, 1999(32)	Clinical Trial	Surgical patients, San Antonio, USA	8M, 2F DM with forefoot ulcer history Age: 53 (5.1)	Duration: 11 (5.4) Type 1: NS Type 2: NS	Passive Tractograph	Barefoot EMED pressure platform at forefoot	Pre-operation PP: 86 (9.4) N/cm ² Pre-operation DF: 0 (3.1) degrees Post-operation PP: 63 (13.2) N/cm ² Post-operation DF: 9 (2.3) degrees
Bennett, 1996(28)	Case Control	Patients with history of foot ulceration attending diabetes units at hospitals in Queensland & Tasmania, Australia	50 DM no neuro 27 DM with ulcer history (18M, 9F) Age: 55 (13)	Duration: 17.5 (12.0) Type 1: 12(44.4%) Type 2: 15(55.5%)	Passive Goniometer Knee extended & prone	Barefoot Musgrave Footprint system at metatarsal heads, hallux & heel	DM ulcer PP: 8.7 (2.3) kg/cm ² DM ulcer DF: 5.1 (2.3) degrees DM PP: 6.0 (2.1) kg/cm ² DM DF: 11.0 (2.1)

							degrees
Birke, 1995(29)	Case Control	Patients with a history of foot ulceration at Medical Centres & recruits from newspaper adverts in Louisiana, USA	<p>19 non DM (7M, 12F) Age: 57.1 (12.3)</p> <p>19 DM no ulcer history (7M, 12 F) Age: 56.4 (13.20)</p> <p>20 DM with forefoot ulcer history (7M, 12F) Age: 54.5 (11.4)</p> <p>19 DM with 1st metatarsal ulcer history (11M, 9F) Age: 56.3 (13.4)</p>	<p>Duration DM: 10.9 (13.1)</p> <p>Duration DM forefoot ulcer: 20.3 (10.4)</p> <p>Duration DM 1st metatarsal ulcer: 20.7 (11.9)</p> <p>Type 1: 18 (31%) Type 2: 40 (69%)</p>	Passive Goniometer	Barefoot EMED pressure platform at 1 st metatarsal head	<p>Non DM PP: 40.7 (21.3) N/cm² Non DM DF: 5.9 (4.3) degrees</p> <p>DM PP: 39.2 (20.9) N/cm² DM DF: 5.9 (3.8) degrees</p> <p>DM forefoot ulcer PP: 49.5 (29.8) N/cm² DM forefoot ulcer DF: 3.6 (3.3) degrees</p> <p>DM 1st metatarsal ulcer PP: 87.1 (25.8) N/cm² DM 1st metatarsal DF: 2.2 (4.2) degrees</p>
Cerrahoglu, 2016(36)	Clinical Trial	Patients attending Physical Medicine centre, Celal Bayer University, Turkey	<p>38 DM neuro (14M, 24F) Age: 56.87 (9.42)</p> <p>38 DM no neuro (14M, 24F) Age: 53.66 (9.36)</p>	<p>Duration DM neuro: 11.18 (6.86) Duration DM: 9.58 (7.07)</p> <p>Type 1: none Type 2: 76(100%)</p>	Passive Goniometer Knee flexed & prone	Barefoot RSscan pressure platform at 6 plantar segments	<p>Pre-exercise right neuro forefoot PP: 50 (7.26) N/cm² Pre-exercise right neuro DF: 19.68 (5.67) degrees</p> <p>Post-exercise right neuro forefoot PP: 45 (7.990 N/cm²</p>

							Post-exercise right DF: 25.36 (6.60) degrees
Christensen, 1994(33)	Clinical Trial	Volunteers with peripheral neuropathy at Veterans Medical Centre, Colorado, USA	20 DM (20M) Age: 63 (6)	Duration: NS Type 1: NS Type 2: NS	Passive Goniometer Silfverskiold Test - Knee Extended & Flexed	In-shoe F-scan system at forefoot & sub-first metatarsal head	Peak plantar pressures for equinus vs non-equinus displayed non-significant results under the 1 st metatarsal head & forefoot.
Guldemon, 2008(39)	Case Series	Outpatient clinic attendees at University Hospital Maastricht, Netherlands	44 DM neuro (15M, 29F) Age: 58.8-64.9 49 DM no neuro (19M, 30F) Age: 50.9-56.3	DM neuro Duration: 16.3-18.1 Type 1: 9(20%) Type 2: 35(80%) DM no neuro Duration: 11.6-13.8 Type 1: 18(37%) Type 2: 31(63%)	Passive Goniometer Knee flexed & prone	Barefoot EMED pressure platform at 6 forefoot regions	DM neuro forefoot PP: 698 (279k) Pa DM neuro DF: 9 (6.9) degrees DM no neuro forefoot PP: 551 (226) kPa DM no neuro DF: 10 (6.4) degrees
Lavery, 2002(9)	Case Series	Patients attending outpatient clinic in Texas, USA	1666 DM (838M, 828F) Age: 69.1 (11.1)	Duration: 11.1 (9.5) Type 1: NS Type 2: NS	Musculoskeletal exam	Barefoot EMED pressure platform at entire foot	Equinus PP: 92.7 (23.1) N/cm ² Non-equinus PP: 85.7 (27.7) N/cm ²
McPoil, 2001(30)	Case Control	American Indian recruits living in Gila River Indian Community in Arizona, USA	20 no DM (4M, 16F) Age: 39.9 (8.5) 24 DM no neuro (7M, 17F)	Duration no neuro: 11.7 (6.5) Duration neuro: 20.6 (7.9) Type 1: NS	Passive/Active Goniometer Knee extended & prone	Barefoot EMED pressure platform at 8 regions	No DM PP: 533.0 (20.2) kPa No DM DF: 9.5 (3.7) degrees DM no neuro PP:

			Age: 44.9 (9.1) 21 DM neuro (8M, 13F) Age: 53.6 (9.9)	Type 2: NS			518.0 (22.1) kPa DM no neuro DF: 7.3 (4.4) degrees DM neuro PP: 616.4 (21.8) kPa DM neuro DF: 5.7 (4.6) degrees
Orendurff, 2006(31)	Case Series	University of Washington, Seattle, USA	27 DM unknown sex Age: 66.3 (7.4)	Duration: 13.4 (12.6) Type 1: NS Type 2: NS	Passive Custom device with torque of 10 Nm for 5 seconds (equinometer) Knee extended	Barefoot EMED pressure platform at forefoot	Non equinus forefoot PP: 50.9 (14.1) N/cm ² Non equinus DF: 8.1 (2.9) degrees Equinus forefoot PP: 67.8 (19.2) N/cm ² Equinus DF: 2.1 (2.0) degrees
Payne, 2002(38)	Case Series	Volunteers with diabetes from newspaper adverts & podiatry and medical clinics in Victoria, Australia	50 DM (28M, 22F) Age: 63.8 (13.7)	Duration: 8.4 (9.6) Type 1: 12(24%) Type 2: 38(76%)	Passive Tractograph	In-shoe Pedar system at hallux, 1 st metatarsal head, lateral forefoot & heel	1 st met PP: 230 (81.9) kPa DF: 4.0 (9.0) degrees
Rao 2006(41)	Case Control	Recruits from Diabetes Foot Clinic, Iowa, USA	10 non DM 10 DM (6M, 4F) Age: 56 (11)	Duration: 20 (11) Type 1: 2(20%) Type 2: 8(80%)	Passive Iowa Ankle ROM device with torque of 15, 20 & 25 Nm	In-shoe Pedar Insoles at metatarsal head region	No DM PP: 24.6 (1.5) N/cm ² No DM DF: 19.3 (3.9) degrees

					Knee extended & supine		DM PP: 27.2 (6.1) N/cm ² DM DF: 6.4 (6.9) degrees
Sacco, 2009(35)	Case Control	Recruits with diabetic neuropathy from Diabetes assistance group in Sao Paulo, Brazil	16 no DM Age: 46 (11) (5M, 11F) 15 DM neuro (9M, 6F) Age: 57 (6)	Duration: >5 Type 1: 0(0%) Type 2: 15(100%)	Active with manual goniometer Dynamic gait with electro-goniometer	Barefoot Pedar-X system at forefoot, midfoot & rearfoot	No DM forefoot PP: 218.9 (35.3) kPa No DM DF: 12.9 (6.2) degrees DM forefoot PP: 245.7 (56.3) kPa DM DF: 15.6 (4.2) degrees
Tang, 2015(40)	Cross Sectional	Patients referred to University Hospital in Gothenburg, Sweden	74 DM (37M, 37F) Age: 60 (15)	Duration: 15 (12) Type 1: 27(36.5%) Type 2: 47(63.5%)	Active Goniometer Standing with knee extended	In-shoe F-scan system at hallux, metatarsal heads, midfoot & heel	Right active DF: 27 (7) degrees Active DF did not have a high association with PP
Wrobel, 2003(34)	Case Series	Recruited through Veterans Affairs medical centre in Vermont, USA	152 DM (all M) Age high PP: 66.5 Age low PP: 67.5	Duration: 10 Type 1: NS Type 2: NS	Passive Goniometer Knee extended	Barefoot F-scan system at entire foot	High PP (> 4kg/cm ²) DF: 4.5 degrees Low PP (< 4kg/cm ²) DF: 5.9 degrees

F:female, M:male, PP: mean peak pressure, DF: dorsiflexion, NS: not stated, DM: diabetes mellitus, PP: plantar pressure, neuro: neuropathy, met: metatarsal