

# Foot & Ankle Research Review™

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Issue 13 – 2012

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### Abbreviations used in this issue

**IQR** = interquartile range; **RA** = rheumatoid arthritis;  
**RR** = relative risk; **SMD** = standardised mean difference;  
**US** = ultrasound.

## Welcome to the thirteenth edition of Foot & Ankle Research Review.

I have included a number of articles that you will find interesting and perhaps controversial. Two articles relate to the non-surgical management of plantar fasciitis. A widely used treatment in clinical practice is local corticosteroid injection (McMillan et al: Ultrasound guided corticosteroid injection for plantar fasciitis: randomised controlled trial. *BMJ*. 2012;344:e3260: <http://tinyurl.com/86st3bc>). Another approach has recently been proposed for the management of plantar fasciitis: injection with botulinum toxin type A (Díaz-Llopis et al: Randomized controlled study of the efficacy of the injection of botulinum toxin type A versus corticosteroids in chronic plantar fasciitis: results at one and six months. *Clin Rehab*. 2012;26(7):594-606: <http://tinyurl.com/82968n9>). These two articles use identical injection techniques over 1 month and report similar findings. However, the use of corticosteroids over 6 months shows poor results. I recommend you read both articles as the methodology and interpretation of the results are different. A final comment is that I have included two foot and ankle related articles published in the British Medical Journal, both from Australia. It is a major achievement to see work related to the foot in this prestigious journal.

I hope you enjoy reading the latest edition of Foot and Ankle Research Review and welcome any feedback.

Kind regards,

**Professor Keith Rome**

[keithrome@researchreview.co.nz](mailto:keithrome@researchreview.co.nz)

## The Māori foot exhibits differences in plantar loading and midfoot morphology to the Caucasian foot

**Authors:** Gurney JK et al

**Summary:** Static and dynamic foot morphology and plantar loading were evaluated using Harris mat and pedobarographic analyses in order to assess whether Māori individuals with diabetes may be more or less prone to ulceration than New Zealand Caucasian individuals. A total of 40 Māori and New Zealand Caucasian diabetic and non-diabetic participants were included in the study. Māori subjects with diabetes exhibited significantly higher peak pressures at the central forefoot compared with diabetic New Zealand Caucasian subjects. Non-diabetic Māori subjects exhibited significantly higher static and dynamic arch index values and significantly higher sub-arch angle values compared with their New Zealand Caucasian peers, indicating that Māori may have a predisposition towards having a flatter foot than New Zealand Caucasian individuals.

**Comment:** This New Zealand study will be of interest to both clinicians and researchers evaluating foot types between ethnic groups. The authors discuss a number of hypothetical scenarios for their findings, which are logical and are relevant to clinical practice. The Māori diabetic group exhibited significantly higher peak pressures than the New Zealand control group at the central forefoot – a region prone to ulceration in diabetic populations largely due to high and repetitive loading, suggesting that they were more prone to ulceration at this region than their Caucasian peers. However, the authors noted that increased peak pressures are not the only cause of ulceration, but act in combination with other risk factors such as sensory neuropathy. The authors found that Māori participants exhibited a significantly flatter foot than their New Zealand control peers. Obtaining adequate footwear for Māori and Pacific Island people is an issue. The results from the current study add crucial information in understanding the foot characteristics of different ethnic groups.

**Reference:** *Gait Posture* 2012;36(1):157-9

[http://www.gaitposture.com/article/S0966-6362\(12\)00018-5/abstract](http://www.gaitposture.com/article/S0966-6362(12)00018-5/abstract)

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## Randomized controlled study of the efficacy of the injection of botulinum toxin type A versus corticosteroids in chronic plantar fasciitis: results at one and six months

**Authors:** Díaz-Llopis IV et al

**Summary:** Botulinum toxin type A was compared with local injection of a corticosteroid plus local anaesthetic for their efficacy in treating chronic plantar fasciitis in this randomised, single-blind study involving 56 patients (28 in each treatment group) who had the condition for  $\geq 6$  months. The Foot Health Square Questionnaire was employed to evaluate patients 1 month after treatment. Patients who did not exhibit a clinical response at that time point were subsequently treated with a second injection using the drug from the other arm of the study, and all patients were re-evaluated at 6 months. A clear clinical improvement was reported at 1 month in both treatment groups, with a significantly greater improvement reported in the botulinum type A toxin group for the pain item ( $p = 0.069$ ). A continued improvement in all items was seen at 6 months in patients treated with botulinum toxin type A, but at that time point corticosteroid-treated patients had lost part of the improvement seen at 1 month. Six-month results: botulinum toxin type A versus corticosteroid; pain 19.10/-6.84 ( $p=0.001$ ), function 16.00/-8.80 ( $p<0.001$ ), self-perceived foot health 25.44/-5.41 ( $p<0.001$ ), footwear 13.48/-7.95 ( $p=0.004$ ). The authors concluded that botulinum toxin type A should be considered for the treatment of chronic plantar fasciitis, but that further studies with larger samples are necessary to confirm their results.

**Comment:** This Spanish study looks at a different approach for treating chronic plantar fasciitis. The clinical trial found that botulinum toxin type A is better than corticosteroid injections over 6 months. At first glance, this looks interesting. However, careful inspection of the data reveals that the pain scores were not significant after 1 month. A p-value needs to be equal or below 0.05 to show statistical significance. In the current study it is shown to be 0.069. This maybe an error on the part of the publishers, but if it is a valid score then regardless of the intervention pain reduction is no different between the groups. The conclusions need to be carefully reviewed as we do not know if one intervention is better than the other. The authors reported in the discussion that ultrasound imaging was not used to assist in the injection site. This is a potential source of error. One final point is that a study of 56 patients does not necessarily provide sound evidence of its efficacy.

**Reference:** *Clin Rehabil.* 2012;26(7):594-606  
<http://cre.sagepub.com/content/26/7/594.abstract>

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## A pilot study of a crossover trial with randomized use of ankle-foot orthoses for people with Charcot–Marie–Tooth disease

**Authors:** Phillips MF et al

**Summary:** The effects of ankle-foot orthoses for individuals with Charcot-Marie-Tooth (CMT) disease were investigated in this pilot study. Eight adults with CMT disease type 1 or 2 were randomised to crossover treatment with Ligaflex™, custom-made polypropylene and silicone ankle-foot orthoses, each worn for 3 weeks with a 1-week washout period in between each of the three interventions. Participants then chose one of the interventions to wear until 28 weeks. Analysis of gait parameters, practical aspects of use and achievement of goals was undertaken. Gait velocity (the primary outcome measure) was significantly greater while wearing polypropylene orthoses with a median of 0.96 m/s (IQR 0.75-1.18 m/s) compared with a median of 0.88 m/s (IQR 0.71-1.12 m/s) with silicone orthoses and a median of 0.79 m/s (IQR 0.56-0.84 m/s) with no orthoses ( $p = 0.006$ ). With regard to pain and comfort, silicone orthoses met goals more successfully than the other orthoses, with scores of 5.5 ( $p = 0.015$ ) and 5 ( $p = 0.003$ ), respectively.

**Comment:** This Australian study of adults with CMT will be of interest to those clinicians who deal with neuromuscular conditions. Although, the study was only a feasibility study, a prelude to a larger clinical trial, the results illustrated significant differences in gait velocity, comfort and pain. Clinicians need to consider the use of ankle-foot orthoses in many instances when dealing with neuromuscular conditions. A cautionary note to the study is that only eight patients were assessed and it is difficult to generalise to all adult patients with CMT disease. However, the authors did report that 27 patients would be necessary to report any future studies that would be clinically meaningful.

**Reference:** *Clin Rehabil.* 2012;26(6):534-44  
<http://cre.sagepub.com/content/26/6/534.abstract>

## Intrinsic functional deficits associated with increased risk of ankle injuries: a systematic review with meta-analysis

**Authors:** Witchalls J et al

**Summary:** This systematic review and meta-analysis was undertaken to determine functional deficits that may be predictive of ankle injury. A total of 13 articles reporting adequate data on intrinsic functions in healthy ankles were sourced from electronic databases and included in the analysis. Results were pooled for measures of strength, postural control, proprioception, muscle reaction time in response to perturbation, range of movement and ligament stability. Factors found to be associated with an increased risk of ankle injury were: being in the lower postural stability group (RR 2.06, 95% CI 1.36-3.11,  $p = 0.001$ ); higher postural sway (SMD 0.69, 95% CI 0.15-1.23,  $p = 0.012$ ); lower inversion proprioception (RR 0.57, 95% CI 0.24-0.90,  $p < 0.001$ ); higher concentric plantar flexion strength at faster speeds (RR 0.37, 95% CI 0.09-0.65,  $p = 0.009$ ) and lower eccentric eversion strength at slower speeds (RR 0.33, 95% CI 0.12-0.56,  $p = 0.003$ ).

**Comment:** This Australian systematic review's results will be of interest to both clinicians and researchers with an interest in this common sports-related injury. The findings from the study suggest patients are more prone to injury if they have an increased postural sway, lower inversion proprioception, higher concentric plantar flexion strength at faster speeds and lower eccentric eversion strength at slower speeds. Biomechanical risk factors are important, but as with other soft-tissue injuries there are also external risk factors to be considered. The article will be of interest to read, but with any systematic review only randomised clinical trials are included and there may be a wealth of good evidence from other non-randomised clinical trials.

**Reference:** *Br J Sports Med.* 2012;46(7):515-23  
<http://bjsm.bmj.com/content/46/7/515.abstract>



Foot and Ankle Research Review

**Independent commentary by Professor Keith Rome,**  
 School of Podiatry, AUT University, Auckland.

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Research Review publications are intended for New Zealand health professionals.

## Custom-made orthosis and shoes in a structured follow-up program reduces the incidence of neuropathic ulcers in high-risk diabetic foot patients

**Authors:** Rizzo L et al

**Summary:** The impact of a structured follow-up program (custom-made orthoses and shoes) on the incidence of diabetic foot ulceration was assessed in this prospective trial involving 298 high-risk diabetic patients with an ulcerative risk score of  $\geq 2$  (subjects were selected, based on their risk score, from 1874 diabetic patients referred to the Diabetic Foot Unit of the University of Pisa). Subjects were randomised to receive standard treatment or custom-made orthoses and shoes. Among the patients, 46% had neuropathy and deformities, 25% had previous minor amputation, 20% had previous ulceration and 9% had neuro-osteoarthropathy. At 12-months follow-up, significantly fewer patients in the standard treatment group had experienced diabetic foot ulceration compared with those who had received custom-made orthoses and shoes (38.6% vs 11.5%;  $p < 0.0001$ ). In patients followed for 3 and 5 years, the cumulative incidence of ulcer was higher for those receiving standard care compared with those receiving custom-made orthoses and shoes; 61% vs 17.6% ( $p < .0001$ ) and 72% vs 23.5% ( $p < 0.0001$ ), respectively.

**Comment:** Diabetic foot ulceration is a major problem not only for clinicians, but also to key stakeholders within the health system. In this large Italian clinical trial, the results clearly demonstrated that custom-made foot orthoses and shoes reduced the incidence of diabetic foot ulceration by 26.1% after 12 months. Figures after 3 and 5 years were even more promising with the incidence reducing by 42.4% and 48.5% respectively. The study illustrates that custom foot orthoses are useful in reducing diabetic foot ulceration and are also a more cost-effective intervention than standard care. Many clinics continue to use methods that are known to be ineffective or that have not been proven to be effective, while ignoring methods that have demonstrated efficacy. Such an approach would improve the often poor current expectations for the incidence of diabetic foot ulceration. I would strongly recommend you read this article.

**Reference:** *Int J Low Extrem Wounds* 2012;11(1):59-64

<http://ijl.sagepub.com/content/11/1/59.abstract>

## The effect of textured insoles on gait in people with multiple sclerosis: an exploratory study

**Authors:** Dixon J et al

**Summary:** The ability of textured insoles to improve gait in individuals with multiple sclerosis was investigated in this study involving 46 patients (mean age 49 years) with the disease. All of the patients were able to walk 100m with or without resting with the use of one stick or crutch. Patients were randomised to one of two textured insole groups: texture A (Algeos UK Ltd, Liverpool, UK) or texture B, a commercial insole (Crocs™, Den Haag, The Netherlands). Baseline walking tests with patients walking at their preferred speed along an instrumented walkway (GAITrite) were undertaken and temporal-spatial parameters extracted. Patients repeated the testing after wearing the insoles for 2 weeks. An increase in stride length between baseline and follow-up in both legs in group A (left  $p=0.01$ , right  $p=0.02$ ) and group B (left  $p=0.02$ , right  $p=0.02$ ) was evident; however, velocity and cadence did not change significantly in either group.

**Comment:** This UK study used textured insoles to enhance postural stability and walking velocity in patients with multiple sclerosis. Previous studies have evaluated foot orthoses in enhancing postural stability. The use of textured insoles has been partially successful in older adults with and without a history of falls. The study results demonstrated a lower walking velocity and other gait parameters, but since the study was only over one session, the short or long-term effects need to be investigated. The concept of using foot orthoses rather than ankle-foot orthoses in multiple sclerosis is novel, but future work may investigate the differences from a clinical and cost-effectiveness perspective on the two different types of devices. I suggest you read this article and the one relating to Charcot Marie-Tooth disease.

**Reference:** *Physiother Res Int.* 2012;17(2):121-2

<http://onlinelibrary.wiley.com/doi/10.1002/pri.521/abstract>

## Ultrasound guided corticosteroid injection for plantar fasciitis: randomised controlled trial

**Authors:** McMillan AM et al

**Summary:** The efficacy of ultrasound-guided corticosteroid injection in the treatment of plantar fasciitis was investigated in this randomised, investigator- and participant-blinded, placebo controlled trial involving 82 patients with a clinical and ultrasound diagnosis of the condition, unrelated to systemic inflammatory disease. Following an ultrasound-guided posterior tibial nerve block with 2% lidocaine (lignocaine), patients underwent ultrasound-guided injection of the plantar fascia with either 1 mL of 4 mg/mL dexamethasone sodium phosphate or 1 mL of normal saline. Analysis of pain, a primary outcome (measured by the foot health status questionnaire 0-100 point scale), revealed a significant reduction at 4 weeks favouring the dexamethasone group by 10.9 points (95% CI 1.4-20.4,  $p = 0.03$ ); there were no statistically significant between-group differences in pain at weeks 8 and 12. The other primary outcome measure, plantar fascia thickness measured by ultrasound at 4, 8 and 12 weeks, favoured the dexamethasone group by -0.35 mm (95% CI -0.67 to -0.03,  $p = 0.03$ ), -0.39 mm (95% CI -0.73 to -0.05,  $p = 0.02$ ) and -0.43 mm (95% CI -0.85 to -0.01,  $p = 0.04$ ), respectively. At 4 weeks, the number needed to treat with dexamethasone for one successful outcome for pain was 2.93 (95% CI 2.76-3.12).

**Comment:** This Australian study demonstrates the short-term effects of corticosteroids. The single ultrasound-guided dexamethasone injection was shown to be safe and effective in the short-term treatment for plantar fasciitis, providing better pain relief than placebo at 4 weeks. The treatment also had a sustained biological effect on the plantar fascia tissue, leading to reduced fascial swelling, as observed by diagnostic ultrasound over a 3 month period. The design of this trial was scientifically rigorous, incorporating adequate statistical power, random treatment allocation, placebo control, and blinding of the investigator carrying out the injection, the assessor and the participant. The use of a standardised stretching programme was also undertaken to better represent normal clinical practice. This is an excellent article, which has been published in the prestigious British Medical Journal and should be used as an exemplar of a randomised clinical trial.

**Reference:** *BMJ.* 2012;344:e3260

<http://www.bmj.com/content/344/bmj.e3260.pdf%2Bhtml>



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## Effect of metatarsal pad on the forefoot during gait

**Authors:** Koenraadt KL et al

**Summary:** This study examined the effect of a metatarsal pad on the geometry of the forefoot in 16 primary metatarsalgia feet and 12 control feet to see if pain relief was related to foot widening and the provision of extra space between the metatarsal heads. Using a motion analysis system, a metatarsal pad was found to be associated with a significant mean increase of 0.60 mm in forefoot width during the stance phase and of 0.74 mm in midstance. Walking with a metatarsal pad also increased the height of the second metatarsal head by a mean of 0.62 mm. There were no differences between metatarsalgia and control feet. The combination of an increased forefoot width and height of the second metatarsal head increased space between the metatarsal heads.

**Comment:** I have included this Dutch study into the review, as metatarsal pads are commonly prescribed for patients with forefoot problems. Although the authors found the width of the forefoot increased during the stance phase of walking with a metatarsal pad, the increase was very small (0.60 mm) and if you consider the accuracy of the equipment was 0.50 mm you can see major issues with the interpretation of the data. If you also consider the very small number of subjects within the study, the conclusions reported by the authors that the increase in space between metatarsal heads may play a role in reduction is rather speculative. Overall, it is a disappointing article and I would like to see further work on the role of metatarsal pads undertaken, especially in high-risk patients such as those with rheumatic diseases.

**Reference:** *J Am Podiatr Med Assoc.* 2012;102(1):18-24  
<http://tinyurl.com/6msqfs4>

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## Identifying patient-reported outcomes in rheumatoid arthritis: the impact of foot symptoms on self-perceived quality of life

**Authors:** Otter SJ et al

**Summary:** To examine self-perceived quality of life in patients with RA, the authors of this study used a self-administered, 33-item postal questionnaire sent to all RA patients attending outpatient clinics over 1 month at one of three different hospitals (n = 390). Among 190 respondents, nearly all (n = 177; 93.2%) indicated their quality of life was adversely affected by their foot complaint; over half rated their quality of life as 'badly' or 'very badly' affected. Using a 10 cm visual analogue scale, the mean score for how severely foot complaints affected their quality of life was 5.36, suggesting a moderate-to-severe effect. The most significantly affected aspects were the ability to walk and wear a variety of shoes. People with RA focus on the choice of footwear and ability to walk as key negativities of living with RA in their feet.

**Comment:** This UK study relates to the development of an outcome measure related to RA. Within the current literature there already exists a number of specific RA foot-related tools. Although the study demonstrated rheumatoid patients suffer from foot pain and severe effects on quality of life, the sub-section about footwear was a key component. Footwear is a major problem with patients with rheumatic diseases and the negativity associated with poor footwear and choice of footwear has been highlighted in this article. However, the outcome has not been validated and the use of 33-questions is perhaps too long for any patient to answer. For those clinicians and researchers who have an interest in rheumatic diseases and the use of outcome measures, I recommend you read the article.

**Reference:** *Musculoskeletal Care* 2012;10(2):65-75  
<http://onlinelibrary.wiley.com/doi/10.1002/msc.1001/abstract>

## Reliability and predictive validity of Inlow's 60-Second Diabetic Foot Screen Tool

**Authors:** Murphy CA et al

**Summary:** To determine the consistency of risk recognition for development of ulceration when using Inlow's 60-Second Diabetic Foot Screen Tool, independent of specific assessor and practice setting, 69 patients with diabetes (26 from an acute care setting [dialysis] and 43 from long-term-care [LTC]) underwent screening by two independent assessors to determine inter-rater reliability, and a repeat screening by one of the assessors to determine intra-rater reliability. Intra-rater reliability for LTC patients based on the intra-class correlation coefficient was 0.96 (95% CI 0.93-0.98) right foot and 0.97 (95% CI 0.95-0.98) left foot. In dialysis patients it was 1.00 right and 1.00 left foot. The inter-rater reliability for LTC patients was 0.92 (95% CI 0.86-0.96) right foot and 0.93 (95% CI 0.87-0.96) left foot, while for dialysis patients it was 0.83 (95% CI 0.65-0.92) for both right foot and left foot. With respect to predictive validity, two subjects who had high Inlow's screening tool scores experienced events (1 ulcer and 1 amputation) 1 to 5 months after screening.

**Comment:** This study will be of interest to clinicians who deal with diabetics. The assessment tool gives a generic overview of aspects related to structure and function. The results from the current study are encouraging with high scores for both intra- and inter-tester reliability. However, the study lacks information about measurement error and should be read with some caution. The tool has the potential to be used in a busy clinical setting and rural settings. I will be interested to observe the number of articles that use this simple non-invasive tool over the next few years. Overall, the article should be read.

**Reference:** *Adv Skin Wound Care* 2012;25(6):261-6  
<http://tinyurl.com/7azes5f>

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