

The Use of Orthoses in the Treatment of Medial Knee Osteoarthritis

Imagine walking 300 metres and not being able to carry on because of a painful joint. Or wanting to maintain a healthy and active lifestyle only to be told to do less so that any joint damage progresses slower. Well, the truth is osteoarthritis (OA) IS a pain.

It is the most common arthritis and it can limit physical function particularly in and around the knee joint to the extent that climbing up stairs or getting into and out of a car is challenging. The effect on an individual's quality of life and lifestyle can be severe. Published guidelines on the management of osteoarthritis recommend a series of conservative and non-invasive treatments ranging from lifestyle changes incorporating moderate, regular exercise through to modified footwear and orthoses (NICE 2008). While considerable research attention has been given to exercise therapy, the advice regarding orthoses and its effectiveness in treating osteoarthritis is often conflicting.

The use of orthoses therapy for the treatment of osteoarthritis is often based on anecdotal evidence or clinical preference rather than the evidence-base. Laterally wedged orthoses (LWO) are often recommended for the treatment of knee pain in medial knee osteoarthritis. The lateral wedge works on the premise of laterally tilting the heel of the foot, thus affecting the angle of the ankle and subsequent alignment of the knee joint. Figure 1 illustrates how an LWO would redirect pressures from the medial compartment of the knee to the lateral compartment.

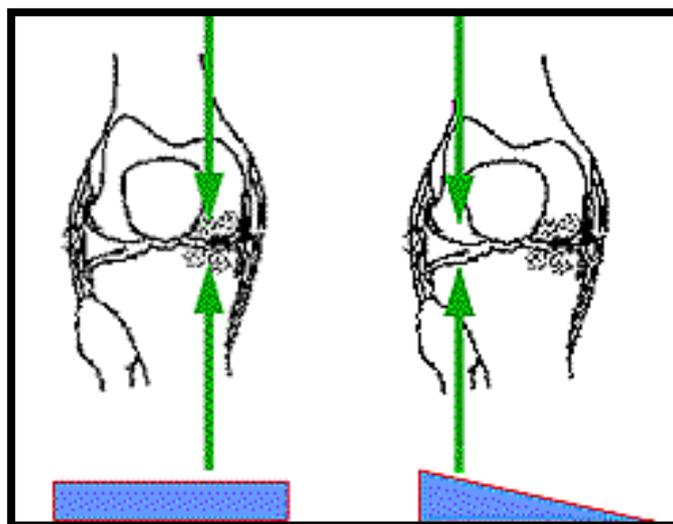


Figure 1. Illustration showing how pressure is re-directed from the medial aspect of the knee to the lateral aspect using a lateral wedge.

A Cochrane review highlighted that there was only ‘silver’ level evidence suggesting that laterally wedged orthoses had a small beneficial effect on pain and function (Brouwer *et al.*, 2007). The treatment costs and time were minimal compared to alternatives such as surgical procedures. The existing research was, however, inadequately designed, with small participant numbers, the inclusion of participants with varying disease severity and poorly described LWO designs. There was a need to develop well-designed trials to evaluate the effectiveness of LWO and account for these research factors as well as footwear choice, compliance with treatment and self-management in an OA population.

This served as the foundation for applying to the Welsh Assembly’s Research Capacity Building Collaboration’s PhD Fellowships in 2008 after receiving my BSc (hons) in Podiatry from the University of Wales (Cardiff). There was a definite gap in the literature with regards to the use of LWO in the treatment of medial knee OA, and factors such as the effect of lower limb alignment, foot posture and footwear were rarely considered. OA has always been a considerable health burden, not only in Wales but in the UK, with the total cost of OA valued at £3.2 billion as a conservative estimate (NICE 2008).

Firstly, there was a need to understand the biomechanical lower limb alignment profiles of patients with OA and how these differed from the general population with healthy knees. Subsequently, the effect of a LWO and footwear intervention on patient outcomes such as pain and quality of life in OA needed to be investigated. In addition, patient engagement and patient adherence to treatment, rightly regarded as the holy grail of health care, needed to be assessed, encouraged and maintained in an OA patient group.

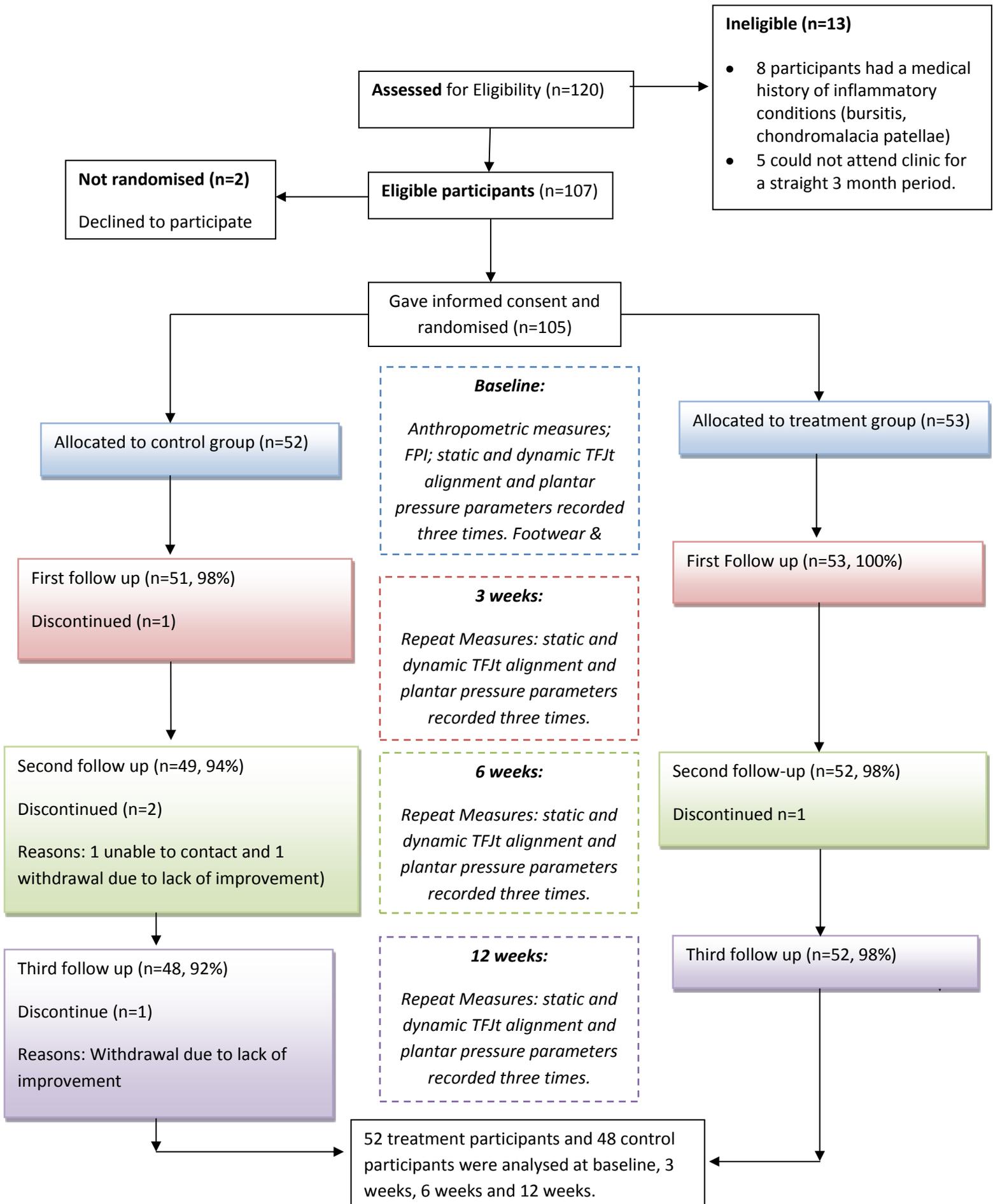
Design of the study:

Once I was awarded my RCBC PhD funding, I started my research degree in 2009. The research study, particularly the randomised controlled trial (RCT), was designed in the early stages of the project using the recommendations of the Cochrane review for further research and guidelines in the Consolidated Standards of Reporting Trials (CONSORT) statement. The CONSORT statement is a robust, evidence-based checklist for reporting RCTs.

The aim of the RCT was to evaluate the effectiveness of LWO compared with neutral inserts on patient centred outcome scores. It also included further sub-group analysis based on foot posture and footwear in an OA population. Participants were block randomised to two groups with one group receiving the LWO and the second receiving the neutral inserts. The LWO

were made using a Slimflex base with a three quarter length 5° wedge (extending to the base of the metatarsals) and a valgus arch support. The control orthoses were a plain Slimflex insole. Participants were followed-up at 3 weeks, 6 weeks and finally at 12 weeks. They were given a journal diary to document medication intake, footwear type and adherence to the orthoses (noted as hours worn per day) every week for 12 weeks of the study. Figure 2 demonstrates the flow of participants through the RCT.

Figure 2. Flow chart of participants through the RCT in the treatment arm and control arm respectively.



Results of the study:

The results of the study found a significant difference in pain scores in both the treatment group and the control group. Pain was evaluated as part of a patient centred outcome questionnaire (Knee Injury and Osteoarthritis Outcome Score or KOOS score). However, while the control group improved between 0 – 3 weeks, the treatment group with LWO had shown significantly improved pain scores that were maintained over the 12-week study period. This improvement was also clinically significant as there was an improvement of 14.9% in the treatment group as opposed to 7.5% in the control group alone. Figure 3 illustrates the changes in the treatment and control group over the course of the study.

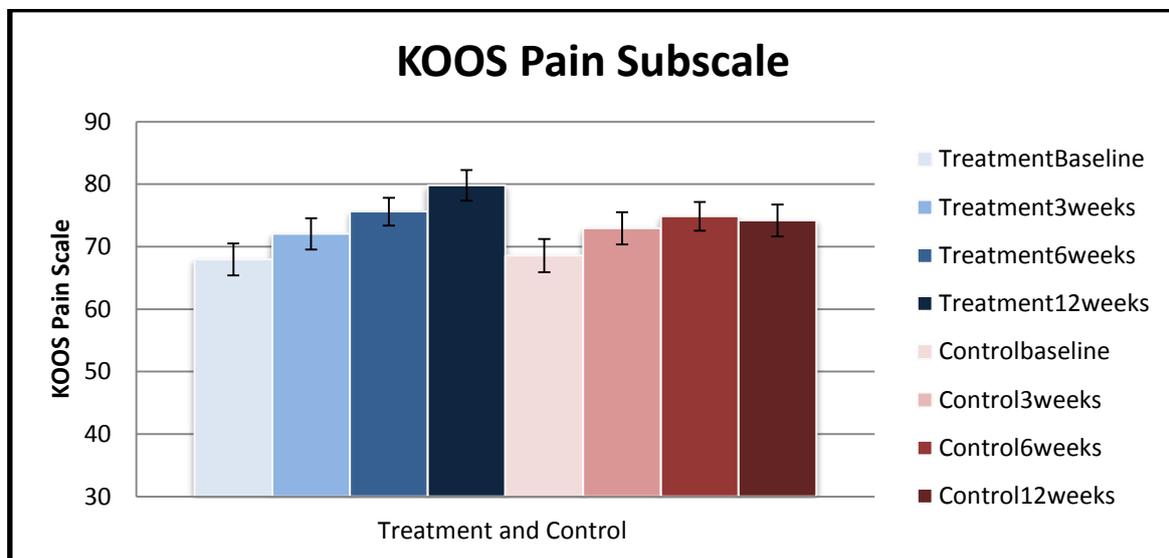


Figure 3. KOOS Pain scores in the treatment and control group at baseline, 3 weeks, 6 weeks and 12 weeks. The higher the score on the KOOS pain scale, the better the pain outcomes.

When overall quality of life (QoL) was measured, there was a greater improvement in the treatment group over 3 months of 26% compared with the control group (9.9%). Again, this difference was clinically significant only in the treatment group and not in the control group.

When adherence was assessed, both groups adhered to and complied with prescribed treatment similarly, wearing the orthoses every day for 5 hours a day on average. There was no significant difference between the two groups. Participants did anecdotally report that the footwear diary helped them keep track of their symptoms based on predominant footwear worn during a given week. For future studies, further qualitative research is warranted to assess the patient's perspective, attitudes and behaviour towards OA self-management.

The study also found that in the treatment group, the combined effect of LWO and footwear had an effect on loading in the midfoot region, suggesting footwear styles could influence in-shoe loading patterns and subsequent loading of the medial knee joint. An increase in midfoot loading suggests improved dynamic stability. This was particularly the case with athletic shoes and trainers in contrast to walking boots, oxford style shoes and court shoes. The results therefore indicate a case for a combined treatment intervention prescribing footwear alongside LWO as opposed to LWO or customised orthoses alone.

Limitations of the study included the lack of standardisation of footwear and the relatively short follow up period of 12 weeks. While footwear types were categorised in the study using a validated footwear questionnaire, standardisation using the same footwear type in all participants was unfeasible, may have increased non-compliance and was cost-prohibitive. Given the findings of an effect of LWO on outcome scores and the fact that OA is a progressive, chronic condition, a 12 week intervention period could be considered as limited in predicting the long-term effects of LWO on a patient's clinical outcomes. This could be remedied by a longer study follow up period.

Case Study 1:

Juli Phillips is a 65 year old retired Events Organiser at the Museum of Welsh Life. She signed up for the study after suffering from knee OA for 6 years. She found that after wearing the LWO for 12 weeks, there was a significant improvement of symptoms. 'The orthoses have helped my stance (and posture) so they have worked for me. I would recommend that others try them and I think that when combined with regular physical activity such as Pilates, it has had a positive effect. The mantra seems to be no pain, no gain and it is too easy to use arthritic joints as an excuse to eschew effort'.

Case Study 2:

Leo Paschalis is a 69 year old retired teacher. He signed up for the study after suffering with pain that had grown progressively worse over the past 10 years. 'The pain was becoming severe after walking just 300 metres or less.' Leo signed up to the study, as orthoses seemed such a simple solution that could be incorporated into his daily life. 'I have continued with the advice given as it has seemed to help me long term. On the occasions when I have not used them, my ability to walk unaided is noticeably reduced'. Leo has suggested that he

would like to see the orthoses made available readily on the NHS and fitted properly to different footwear for maximal benefit.

Case Study 3:

Alun Salisbury is 75 year old retired gas service manager. He first experienced the symptoms of osteoarthritis 20 years ago with noticeable pain and discomfort in the hands, feet and knees. He was informed about the study by his GP and signed up as he met the inclusion criteria of the study. The advice on footwear as well as the orthoses made a difference to Alun. 'The orthoses helped a great deal, but the advice on correctly fitting shoes was equally as good, and helped a great deal'. He would recommend patients attend their local Podiatry service to get the right advice on footwear and orthoses so that they can manage their condition successfully and will not need to access the health service so regularly.

Interpretation of the literature and findings

The results of the study conclude that while there was an improvement in pain and outcome scores in both the treatment and control group, the minimal important clinical difference (MIC) for pain, symptoms, activities of daily living (ADL) and overall quality of life was achieved in the treatment group alone. Copay *et al.*, (2007) stated that an MIC is conceptually important as it represents a change that would be considered '*meaningful and worthwhile by the patient*', so much so that they would consider receiving or maintaining the intervention when given the choice. This is relevant as the KOOS scores for 4 of the 5 'Quality of Life' outcomes fall within or exceeded the MIC thresholds as identified by Roos and Lohmander (2003).

Footwear:

A key finding of the trial is that the combination of footwear and LWO had an effect on in-shoe loading and could have influenced patient outcomes. There was no difference at all on the in-shoe loading in the group with the control orthoses. The study results suggest walking shoes and athletic trainers might offer optimal treatment when combined with LWO.

Clinical Implications:

OA of the medial tibiofemoral joint is a major source of physical disability and reduced quality of life in developed countries such as the United Kingdom (Hunter *et al.*, 2002). Due to an increased life expectancy and the obesity epidemic, our ageing populations are faced with the burgeoning public health problem that OA has inevitably become (Russell and Hamill 2010). Pain management strategies and individual holistic assessments have been recommended, and conservative interventions, such as LWO, can be used to address both these priorities (NICE 2008). Understanding the LWO mechanism of action and effect on the lower limb could provide further, focused evidence-based treatment strategies for pain management.

The results of the RCT demonstrated that there were clinically significant improvements in the treatment when using MIC thresholds despite the lack of statistically significant differences between the groups. Footwear has rarely been considered or standardised in similar RCT designs. Its combined effect with LWO could be understood, improved and finally implemented as an effective management to improve OA patient outcomes by reducing pain, managing symptoms and improving QoL. The findings support the use of LWO as a conservative, non-invasive, cost-effective and low-risk treatment strategy compared to pharmacological or surgical interventions (Pinto 2012). More importantly, the potential mediating effect of footwear should not be overlooked (Shakoor *et al.*, 2010) and varying footwear choice could explain some of the discrepancies in LWO effectiveness on patient outcomes.

Conclusion

The literature suggests that knee mechanics can be effectively altered in a knee OA population over a 12 month period with LWO compared to neutral orthoses (Barrios *et al.*, 2013). Skou and colleagues (2013) suggested further customisation of LWO by including arch supports and varying the angulation of the wedge as a factor in pain reduction and improvements of function. Interestingly, Penny *et al.*, (2013) conducted a systematic review in which pain and functional outcomes did not improve with LWO. However, the authors suggest that the variation in LWO angulation and non-standardised footwear could be

contributing factors. Therefore, while further research is needed on the long-term beneficial effects of LWO, it remains that OA should be conservatively treated using a combination of self-management, patient education and footwear advice with individualised orthoses prescription.

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