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Research article

Effect of a thin customized insole on pain and walking ability in rheumatoid arthritis, a randomized study

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Abstract

Objective: The aim of the study is to investigate the immediate effects of a thin, easily customizable insole on pain and walking ability in patients with rheumatoid arthritis (RA) who have forefoot pain, and to determine whether the insoles were in use one year afterwards.

Design: An experimental, assessor-blinded design was applied to compare the immediate outcomes when walking with or without insoles in random order. After one year a structured telephone interview was conducted.

Participants: Twenty-one subjects with RA and foot pain in at least one forefoot when walking and in response to the Gänslen test were recruited consecutively from the outpatient clinic and the inpatient ward at a hospital for people with rheumatic disease.

Intervention: Each subject was given a 4-mm thin individually customized insole of a malleable plastic material (CI-Core®) with synthetic textile material on the upper side.

Main Outcome Measures: The six-minute walk test (6MWT) was used to assess the ability to walk and a 10-cm visual analog scale (VAS) to measure the intensity of foot pain induced by walking with and without the insole. A standardized questionnaire with five items was used to determine the use of, and degree of satisfaction with, insoles after one year.

Results: The median (interquartile range) foot pain intensity was 19 (15) with and 36 (27) without insoles ($p<0.001$; effect size =0.6). No statistically significant differences in 6MWT were found between the presence or absence of insoles ($p=0.07$). After one year, 90 % of the participants were still using the insoles.

Conclusions: The use of thin, easily customizable insoles resulted in immediate clinically relevant relief in walking-induced forefoot pain. Most of the patients were still using the insoles after one year.

Keywords

Forefoot, insole, pain fheumatoid arthritis

1. INTRODUCTION

Rheumatoid arthritis (RA) is an autoimmune disease which affects about 1% of the population, most frequently women (Bal, Aydog, Aydog, & Cakci, 2006; Gabriel & Michaud, 2009). RA is characterized by inflammation and destruction of joints, particularly the extremity joints, and the feet are frequently involved at onset (Bal et al, 2006; Woodburn, Hennessy, Steultjens, McInnes, & Turner, 20010). Lasting and repeatded episodes of inflammation may lead to permanent changes in joint structure and functioning (Gabriel & Michaud, 2009). Healthcare professionals are attentive to problems of hand functioning but tend to overlook or pay little attention to problems involving the feet (Borman, Ayhan, Tuncay, & Sahin, 2012; Otter et al., 2011). This observation is reflected in the disease activity score 28 (DAS28), which includes assessments of all the extremity joints except those of the foot (Son, Song, Lim, Seo, & Kim, 2012).

Foot pain is reported in up to 90% of patients with RA (Brooks & Hariharan, 2013; Cho, Hwang, Chang, Koh, & Park, 2009), and the metatarsophalangeal (MTP) joints are most frequently afflicted (van der Leeden et al., 2008). Involvement of the MTP joints is still being observed, even in patients treated with the effective new disease-modifying drugs leading to remission of arthritis (Otter et al., 2011; van der Leeden et al, 2008; van der Leeded, Steultjens, van Schaardenburg, & Dekker, 2010). In general, arthritis is accompanied by pain, swelling and stiffness, and the increased pressure on the MTP joints due weight-bearing may aggravate forefoot pain and affect walking ability (Baan, Dubbeldam, Nene, & van de Laar, 2012; Carrol, Boocock, Dalbeth, Parmar, & Rome, 2015; Grondal, Tengstrand, Nordmark, Wretenberg, & Stark, 2008; Hodge, Bach, & Carter, 1999; van der Leeden, Dekker, Steultjens, Dekker, & Prins, 2006). Moreover, longstanding or recurrent episodes of arthritis, together with weight-bearing pressure, may weaken MTP joint capsules and ligaments, which in turn may flatten the longitudianl and transverse arches of the foot (Barn, Turner, Rafferty, Sturrock, & Woodburn, 2013). From a clinical point of view, pressure on the MTP joints needs to be minimized to obtain pain relief and support the arches of the feet. Additional insoles are used for these purposes (Hennessy, Steultjens, & Woodburn, 2012).

Previous studies have found that both insoles that are custom built to support the longitudinal and transverse arches (Hennessy et al., 2012; Mejjad et al., 2004; Moreira et al., 2016) as well as prefabricated, non-customizable insoles (Cameron-Fiddes & Santos, 2013) are effective in relieving pain but most studies on insoles have found no (Chalmers, Busby, Goyert, Porter, & Schulzer, 2000; Mejjad et al., 2004; Novak, Burger, Marincek, Tomsic, & Vidmar, 2009) or minor to moderate (van der Leeden et al., 2011) effects on walking. However, in our clinical experience both kinds of insoles have certain shortcomings. Custom-built insoles takes time to manufacture and are expensive, and many patients, especially women, do not wear them since they often do not fit the shoes they prefer to wear (Henddry, Barr, Brenton-Rule, & Rome, 2015; Naidoo et al., 2011; Williams & Graham, 2012). A drawback of prefabricated, non-customizable insoles is that, in our experience, they may not always support the patient's foot arches adequately. Authors of systematic reviews have pointed to the importance of studies on the effects of cost-effective, easily customizable insoles for patients with RA (Clark, Gray, O'Hare, Plant, & Rome, 2006; Conceição, Baptista, Gomes, Neto, Mendes, & Sá, 2015; Riskowski, Dufour, & Hannan, 2011). Accordingly, we wished to examine whether a thin, prefabricated, easily customizable insole fitting the patient's ordinary shoes would be appropriate for patients with RA. The primary aim of the present study was to examine whether this type of insole had any immediate effects on pain and walking ability in patients with RA who had forefoot pain, and secondly to examine whether the insoles were still being used 12 months later.

2. PATIENTS AND METHODS

2.1.Subjects

The study included 21 subjects recruited consecutively from the outpatient clinic and the inpatient ward of a hospital for rheumatic diseases during the period May 2011 to December 2012 (Figure 1). The inclusion criteria were: a definite diagnosis of RA (Britsemmer, Gerritsen, Usum, van Tuyl, & van Schaardenburg, 2011), ≥18 years of age, foot pain on walking, and pain in at least one forefoot when assessed for affliction

of the MTP joints with the Gänslen test (Wiesinger, Aletaha, Smolen, & Stamm, 2013). The Gänslen test was performed at the time of recruitment and immediately before the walking tests. Patients with walking problems due to pain in the ankle, knee or hip were excluded.

2.2.Design and ethics

An experimental design was used to compare the outcomes of walking with and without insoles for each individual. The two test rounds were performed in random order on the same day. Randomization was undertaken by drawing lots from 30 closed, opaque, sealed envelopes, one half of which included a note saying 'insoles first round' and the other half 'insoles second round'. The envelopes were opened after the insoles had been customized. The assessor was blinded to the use of insoles during the testing. A sample-size calculation to reach a statistical power that would detect a difference of 50 m on the six-minute walk test (6MWT) with a standard deviation of 32 m, 90% power and p value ≤ 5% showed that a minimum of five subjects was required. However, such a low sample size may have a low degree of external validity, and consequently we decided to include all eligible patients during the period of data collection.

The study was performed according to the principles of the Helsinki Declaration. The ethical and methodological quality of the study was appraised and approved by the Internal Appraisal Board at the Department of Health Sciences, University of Oslo.

2.3.Customization of the prefabricated, customizable insole

A 4-mm thin, flat insole of a malleable plastic material (CI-Core®) with synthetic textile material on the upper side was customized to provide support for the transverse and longitudinal arches of the foot. The insoles were heated in a portable electric heater for about 10 minutes to a temperature of 90° in order to make the plastic material suitable for moulding. To reduce the pressure on the MTP joints during weight-bearing, a metatarsal dome was formed to support the transverse arch of the foot by pressing the insole down over one of the prefabricated hard plastic domes. The size of the dome was

based on the size of the foot; the smallest dome had a height of 4 mm and the largest 7 mm. To support the transversal arch, the position of the dome on the insole was determined by palpating the MTP joints, and the highest point of the dome was placed posterior to the second to the fourth MTP joints. To support the patient's longitudinal arch, the insole was pressed for about 60 seconds towards the medial longitudinal arch of the patient's foot while they were seated in a non-weight-bearing position. The textile material on the upper side avoided the skin becoming burnt during the customizing procedure. The insole was then cooled down for 20 minutes to solidify the shape before it was ready for use. The patient then tried the insoles for few minutes to ensure that they were comfortable and fitted their own preferred shoes. If not, the insoles were reheated and readjusted. However, this was only necessary in one case. The same physical therapist performed the clinical examination of the feet and customized the insoles for all patients. The cost of each pair of insoles was approximately USD 50, which was covered by the hospital.

2.4. Test procedures

In accordance with the randomized order of the test rounds, the patients performed a walking test with and without insoles in their own preferred shoes. Pain, exertion and walking time were registered after both rounds. There was a 20-minute break between the two test rounds, in which the subject went into a separate room with a different physical therapist either to take the insoles out or put them into the shoes to maintain blinding of the assessor. The subjects were told not to reveal to the assessor whether or not the insoles were being used. After one year, a telephone interview was conducted to determine the patient's degree of satisfaction with the insoles. All the interviews were conducted by the physical therapist performing the study.

2.5. Patients' and disease characteristics

Demographic data, disease duration and duration of foot pain were registered. The patients' functional level was classified into functional classes I–IV according to the American College of Rheumatology (ACR) 1991 Classification of Functional Status

(Hochberg et al., 1992). The Foot Function Index (FFI) was used to determine foot pain and disability (Budiman-Mak, Conrad, & Roach, 1991). The FFI is a self-report questionnaire consisting of 23 items grouped into three domains: foot pain (9 items), disability (9 items) and activity limitation (5 items). All items are rated using a numeric rating scale from 0 (no problem) to 10 (worst problem).

2.6. Outcome measures

Walking distance was assessed by the 6MWT according to the American Thoracic Society guidelines (Brookes, Gibbons, & Solway, 2003). The subjects were told to walk as far as possible without running for 6 min back and forth along a 30m corridor. The walking distance is given in whole meters. The 6MWT has been found to have acceptable validity and reliability in several studies (Camarri, Cecins, Eastwood, Jenkins, & Thompson, 2006; Lelieveld et al., 2005).

The intensity of foot pain was assessed after walking with and without insoles by a 10-cm visual analog scale (VAS) where 0=no pain and 10=worst pain (Price, Buckingham, McGrath, & Rafii, 1983). Exertion was also assessed after each test using the Borg category ratio scale (Borg CR10) where 0=nothing at all and 10=maximum exertion (Borg, 1998).

The patients' experience of and degree of satisfaction with the insoles after one year were assessed by a standardized questionnaire with five items; whether the patient still had foot pain, whether the insoles were in use, whether pain relief was obtained, whether they could walk for a longer distance with insoles, and which types of shoes the insoles fitted into.

2.7.Statistical analysis

Data were analyzed using the SPPS for Windows, version 20 Clinical Innovation ApS, Hedehusene, Denmark. Descriptive statistics are presented as number (%), mean (standard deviation, [SD]) and median (interquartile range, [IQR]). To show the heterogeneity of our sample, the range of characteristics was given as min–max.

Differences between walking with and without insoles were examined by the paired samples t-test for normally distributed data and the Wilcoxon signed rank test for non-normally distributed continuous data and categorical data. Pearson's correlation was used to analyze the relationships between changes in outcome scores. The chi-squared test was used to analyze results from the one-year follow up. P values ≤0.05 were considered statistically significant. Evaluation of effect size was based on Cohen's index, where 0.10–0.29 was considered small, 0.30–0.49 moderate and >0.50 large effects (Cohen, 1988).

3. RESULTS

3.1.Patients' characteristics

The study included 21 patients with RA. There was a large variation in age, disease duration, duration of foot pain and functional status (Table 1).

3.2.Immediate effects of insoles

The median (IQR) in VAS pain was 19 (15) walking with insoles compared with 36 (27) walking without insoles ($p<0.001$), (Figure 2). The effect size was 0.6.

The mean (SD) walking distance in 6MWT without insoles was 588 (103) m compared with 612 (103) m with insoles ($p=0.07$). The mean Borg CR10 score was 2.7 (1.3) without insoles and 2.9 (1.1) with insoles ($p=0.31$). No statistically significant correlations were found between changes in pain scores, walking distance or perceived exertion scores.

3.3.Use of insoles at one-year follow-up

Most of the patients were still using the insoles one year after the initial test ($p<0.001$). (Table 2). They reported that the insoles could be used in all their shoes except sandals and pumps.

4. DISCUSSION

In the present experimental study, we found a statistically significant reduction in foot pain for the group using the insoles during the 6MWT, but no statistically significant effect on walking distance. Most patients were still using the insoles after one year.

The pain-relieving effect of the thin, prefabricated but customizable insole corresponds to the findings of other studies where custom-built insoles were used (Clark et al., 2006; Hennessy et al., 2012). The VAS was also used as an outcome measure in the studies of Mejjad et al. (2004), who used a crossover study design, Moreira et al. (2016) and Cho et al. (2009), who used a parallell group design. The degree of pain reduction demonstrated in our study is approximately similar to the difference in VAS in these studies when use of insoles was compared with non-use. In a review of 17 studies on different insoles, Hennessy et al. (2012) concluded that there is evidence that both custom-built and customized prefabricated insoles have an effect on foot pain, but that there does not appear to be a definite difference between the different types of insoles. The same findings are reported in the review by Clark et al (2006).

Hence, the pain-relieving effect of our thin, prefabricated but individually customized insoles seems to be similar to that of custom-built insoles. Accordingly, our insole might be an appropriate alternative to custom-built insoles since it takes less time to customize it than to build a customized insole. This should also make the prefabricated customizable insoles a cheaper alternative. This is supported by a study by Rome et al. (2017), in which the authors found that customized foot orthoses were far more expensive than semi-rigid customized insoles, partly because of the time spent for the therapist and travel expenses for the patient.

It is relevant to question whether the pain-relieving effect has any clinical relevance. The minimum clinically relevant difference is assessed in terms of how much change has to be achieved before the patient detects any difference (Pope, Khanna, Norrie, & Quimet, 2009). According to Pope et al., a change of 12 mm on VAS is the minimum clinically relevant difference in pain intensity in patients with RA. The pain-relieving effects in both our study and the above-mentioned studies using VAS are above this level. However, the mean effects in these studies range from about 15 to 25, which is

relatively moderate. On the other hand, the test only involved walking for 6 minutes, and it is likely that weight-bearing pressure on the feet would aggravate pain progressively as the patient continues walking. Thus, our finding that most of the patients still used their prefabricated customized insoles for pain relief after one year is a promising one.

In designing the study, we hypothesized that pain relief would lead to an immediate - improvement in walking. If insoles reduce pain in the forefoot while walking, we assumed that this would lead to a more efficient use of the forefoot, resulting in an ability to walk faster and increase the distance walked during 6 minutes. We found that the walking distance was longer when the patients used insoles than when they did not, but the difference was not statistically significant. As our study had a strong statistical power, even small differences should have been detected. The lack of improvement in walking ability in this and other studies indicates that no immediate improvement in walking distance can be expected assessed by 6MWT.

Although insoles provide some degree of pain relief, earlier studies have shown that they are often not used if they do not fit preferred shoes (Hendry et al., 2015, Naidoo et al., 2011; Williams & Graham, 2012). In the present study, the participants reported that the insoles could be used in most footwear, and 90% were still using their insoles after one year. However, they did not report that the customized insoles increased their ability to walk longer distances. Nevertheless, it seems reasonable to conclude that less foot pain during walking is likely to make walking more comfortable and that this helps to keep up the patient's motivation for being physically active. At the same time, if the patient should experience an increased walking ability because of reduced pain, we do not know the degree to which the joints are aligned. It is therefore important that the patient is aware of any visible changes in structure and informed about whom to contact.

As the participants served as their own controls, the results were not influenced by personal characteristics such as gender, age or body weight. Conducting both test rounds on the same day also limited any bias caused by fluctuations in pain and disease activity in the same individual (Gabrile 6 Michaud, 2009). On the other hand, performing the 6MWT test twice could have led to more pain and exertion after the

second trial, and is likely to have produced a learning effect, which has been shown to increase the walking distance between the first and second test rounds by 7–15% (Brooks et al., 2003; Enright & Sherill, 1998). However, this problem was minimized by randomizing the order of the test rounds. None of the participants revealed when the insoles were in use during testing, so the blinding of the assessor appears to have been successful.

4.1.Study limitations

The patients themselves knew whether the insoles were used or not, and this could have influenced the results, perhaps especially for the subjective scores of pain and exertion. However, we consider that it would have been difficult for them to remember their exact scores from one assessment to the other with a 20-minute break in between. It would have been preferable to test a customized insole against a placebo insole, but we believe that it would be difficult for the patients to be unaware of the placebo insole because the customization procedure would already have made them familiar with the customized insole. The fact that the results of the 6MWT were within the reference values for healthy adults (Enright & Sherrill, 1998) is also a limitation, and suggests the possibility of a ceiling effect. Thus, in future studies the use of a more challenging walking test than the 6MWT should be considered.

Nevertheless, we believe that the strict experimental design and well validated assessment instruments indicate that our findings of immediate pain relief when using insoles have a certain degree of validity.

The sample size in this study was fairly small, and the degree to which the findings can be generalized naturally depends on its representativeness. Our sample was heterogeneous with respect to gender, age, disease duration and duration of foot pain. However, the patients' ability to walk was relatively good and so were their FFI scores. Accordingly, the results cannot necessarily be generalized to RA patients with severe affliction of the feet.

5. CONCLUSION

The use of a thin, prefabricated, customizable insole resulted in immediate forefoot pain relief during walking. Most of the patients were still using the insoles after one year and considered that they had a pain-relieving effect. The findings show that these insoles can be recommended to relieve forefoot pain in patients not severely afflicted by RA and that the disease was well controlled in the lower extermities. The type of insole used here is simple to customize, ready for use on the same day, fits most footwear and is relatively cheap compared with bespoke models.

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Table 1. Characteristics of patients with rheumatoid arthritis (n=21)

Variables	n (%)	Mean (SD)	Median (min-max)
Age (years)		54 (11)	54 (27-72)
Gender (women)	17 (81)		
Body Mass Index		24.0 (4.1)	
Disease duration (months)			48 (3-300)
Duration of foot pain (months)			24 (4-300)
No. with forefoot pain[a]			
Unilateral	6 (29)		
Bilateral	15 (71)		
ACR funksjonsklasse I-IV			
Functional class I	4 (19)		
Functional class II	6 (29)		
Functional class III	10 (47)		
Functional class IV	1 (5)		
FFI			
Dissability			6.6 (0-32)
Difficulties			16.5 (3.3-52.2)
Pain		32 (16)	
Total			20 (4.7-51.3)

[a] A positive Gaenslen sign indicates a pain when giving a bilateral compresion of the metatarsophalangeal joints to detect musculoskeletal abnormalities and primary chronic inflammation.
ACR: American College of Rheumatology 1991 Classification of Functional Status
FFI: Foot Function Index
SD: standard deviation

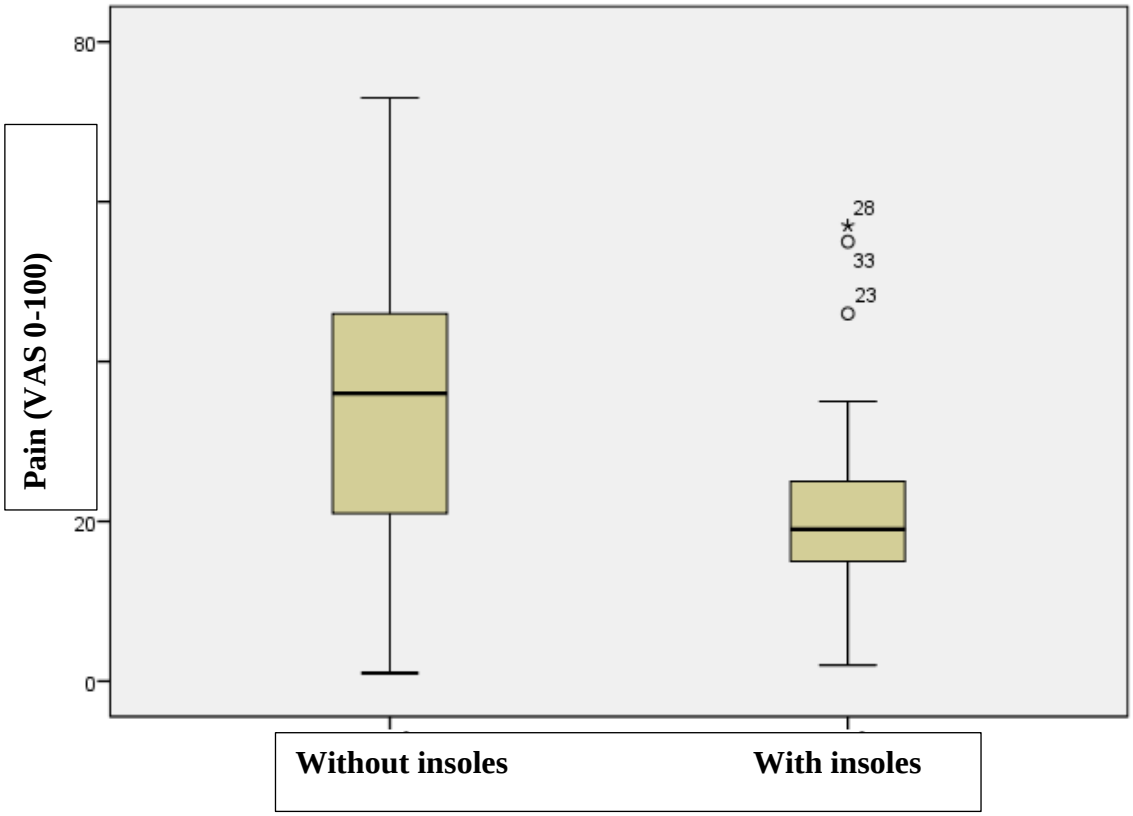

Figure 2. Foot pain reported after walking without and with insoles. The boxes represent the interquartile range (iqr) which contains 50% of the values, the horizontal lines within the boxes the median, and the horizontal lines crossing the vertical lines the min–max values.

Table 2. The use of insoles at one year follow-up (n=20)

Variables	**n(%)**		
	Yes	**No**	**p-value**
Have you had foot pain in the last year?	19 (95)	1 (5)	<0.001
Do you use the insoles?[a]	18 (90)	2 (10)	<0.001
When you have foot pain, do you use the insoles?[a]	17 (85)	3 (15)	0.002
When you have foot pain, do the insoles give you pain relief? [a]	15 (75)	5 (25)	0.03
Can you walk longer distances with insoles?[b]	12 (60)	8 (40)	0.25

[a] Yes: sometimes, often, always. No: Seldom, never

[b] Yes: significantly longer, little longer. No: No difference, little shorter, significantly shorter