The Foot (1999) **9**, 128–133

ORIGINAL ARTICLE

The effect of custom moulded ethyl vinyl acetate foot orthoses on the gait of patients with rheumatoid arthritis

A. MacSween,* G. Brydson,* J. Hamilton†

**Department of Physiotherapy, Podiatry and Radiography, Faculty of Health, Glasgow Caledonian University, UK, † Medical Unit A, Southern General Hospital NHS Trust, Glasgow, UK*

SUMMARY. There is a high incidence of foot involvement in rheumatoid arthritis (RA) and an accepted practice of prescribing accommodative foot orthoses despite a lack of research evidence. This study evaluated the effect of custom moulded ethyl vinyl acetate (EVA) foot orthoses on walking ability in patients with RA. A prototype contact sensitive walkmat was used to assess the stable predictors of gait, namely velocity, stride length and cadence. Perception of comfort was examined using a Likert type scale. An intra session reliability study (n=22) was conducted on the walkmat, intraclass correlation coefficients (r) for all objective parameters measured were classed as 'high' (r>0.90). A sample of RA subjects (n=8) was recruited; all subjects having been prescribed custom made EVA orthoses in the previous 6 months. Results show a statistically significant (P<0.05) increase in average stride length with the orthoses in situ. Increases also occurred in velocity and cadence but not at statistically significant levels. All subjects reported improved comfort levels. © 1999 Harcourt Publishers Ltd

INTRODUCTION

Foot involvement in rheumatoid arthritis (RA) is extremely common[1] affecting 16% at diagnosis,[2] and 90–100% in patients with a 10 year history.[3]

Foot orthoses are often prescribed to relieve the resulting foot pain and normalize the gait pattern in patients with RA.[4] Despite an abundance of claims for the benefits of foot orthoses in this population there is little published research into their effectiveness.[5] Merrit described orthosis prescription as being based upon, 'empiricism, deduction and consensus', this 'consensus' extending only to the use of an orthotic device.[6] The type of orthosis, material used and the indication for prescription varies widely between practitioners.

The only published studies on the objective effects of foot orthoses on gait in subjects with RA[7] and degenerative joint disease,[8] have involved subjects walking with attached equipment and trailing wires. It has been reported that this type of instrumentation interferes with velocity at a statistically significant level.[9] Hence this methodology is far from ideal. Some subjective evaluation has been undertaken, but very few studies isolated effectiveness in RA subjects.[5,10,11]

Correspondence to **A. MacSween** Research Physiotherapist, Glasgow Caledonian University, Department of Physiotherapy, Podiatry and Radiography, Faculty of Health, City Campus, Cowcaddens Road, Glasgow G4 OBA, UK. Tel: +44 (0)141 331 8143; E-mail: A.Macsween@gcal.ac.uk

The published work on gait analysis shows there is no uniformly accepted parameter or parameters for measuring gait. Indeed it has been said that no one parameter can fully represent gait,[12] and the difficulties of quantifying such a complex activity must be acknowledged. There is, however, substantial evidence that it is velocity, stride and cadence which change in RA[13] and are the parameters of choice with which to measure the effectiveness of foot orthoses.[14]

On this basis, orthoses of this type and material which act only in an accomadative manner are best assessed by these fundamental measures of walking ability. This study aimed to investigate the response of subjects with RA to foot orthoses in terms of these parameters, employing instrumentation which does not affect walking ability and yields results which are easy to interpret by both clinician and patient.

METHODS

Instrumentation

Assessment of gait

Objective data was collected with a prototype contact sensitive walkmat system located in the Centre for Clinical Research, Southern General Hospital NHS Trust, Glasgow. The system operates by processing information from 4048 contact sensitive switches mounted beneath non slip matting. The switches are constructed from copper track covered

with conductive top material so an electrical circuit is completed on contact. The switch output is relayed and controlled thought a separate unit containing the switch encoding circuitry to an IBM compatible DAN 486 computer. All switches are sampled at a rate of 80 Hz, the output is then processed with software written in house. A central active section of 2.8 m length is flanked by visually identical inactive sections of 1.25 m eliminating the acceleration and deceleration phases of gait.[15] The interested reader is referred to Al Mijalli[16] for more detailed technical specifications.

A reliability study for the parameters under investigation was conducted prior to the patient study. Twenty-two subjects with no locomotor problems were recruited from the staff and students of Glasgow Caledonian University (11 male, 11 female, mean age 30.4 st/dev 9.2 years). The protocol used was identical to that of the patient study. Intraclass Correlation Coefficients (r) were calculated for Velocity (m/s) 0.91, Average stride (cm) 0.91 and Cadence (st/min) 0.97. r was calculated as advocated by Currier[17] where;

$$r = \frac{\text{ms between (subject)} - \text{ms within (trial)}}{\text{ms between (subject)}}$$

For all parameters reliability is excellent.[18]

The subjects had a mean age of 30 years, range 21–62, the best recent source for normative data is Whittle.[19] Matching the reliability study sample results with those from the closest published age band; the study subjects mean velocity was 1.38 m/s the normative value range is 0.94–1.82 m/s, central value of 1.38 m/s. The study subjects' mean stride was 150 cm (the normative value range is 106–185 cm, central value of 146 cm). The study subjects' mean cadence was 111 st/min (the normative value range is 91–138 st/min, central value 115 st/min).

Whittle published only normative ranges for all parameters with 95% limits and the full data sets collected were not published. Therefore, it is not possible to quote or calculate the mean and the central values of the published ranges are given here instead.

Absolute accuracy in the measure was not required in the present study as the value under scrutiny was the change in the parameters not their absolute values. On the basis of this, albeit limited, comparison there is a strong argument that the study has shown a high degree of absolute accuracy and hence validity in the instrument's measurement in addition to reliability.

Assessment of comfort

Subjective data was gathered using a Likert scale question designed to a model advocated by many authors and was piloted in the reliability study.[20] Five options were presented describing the difference between the first and second sets of five walks; 'much more' and 'more comfortable', 'unchanged', and 'much more' and 'more' uncomfortable.

Ethics

Ethical clearance for the study was granted by the Ethics committees of the Southern General Hospital (SGH) Trust and Glasgow Caledonian University.

Sample

Eight consecutive patients (five female and three male) who met the following inclusion criteria were recruited from the SGH Rheumatology Clinic.

Inclusion criteria

1. Diagnosed with classical or definite RA, American Rheumatology Association Criteria.[21]
2. Aged over 16.
3. Bilateral forefoot pain with or without swelling of metatarsal heads.
4. Prescribed bilateral custom moulded ethyl vinyl acetate (EVA) foot orthoses issued through the Department of Podiatric Medicine of the SGH Trust within the previous 6 months.
5. Able to walk without other aids.

Patients who were in a clinically defined state of flare, or who were not able to complete the required walking distance were excluded from the study. The mean age of the subjects was 61.4 years (range 41–77) with a mean disease duration of 11.1 years (range 5–23). The subjects self-report of pain in the hindfoot, lower limb and lower back was recorded. Pain from these sites has been reported as influencing gait in RA subjects.[1,22] Five subjects reported lower limb pain, four experienced hindfoot and three lower back pain. The sample is described in these terms in Table 1.

Orthotic Device

Custom moulded EVA orthoses were used by all subjects. The design is based on that of the UC-BL model and are moulded from rectified sub-talar neutral casts (non-weightbearing). All the orthoses were less than 6 months old.

Protocol

1. Orientation to the laboratory and the walkmat system.
2. Read information sheet and completion of consent form.
3. Foot length and height in chosen footwear measured.
4. Completion of five walks over the contact sensitive walkmat wearing self selected footwear, at self selected pace, with orthoses.

Table 1 Disease profile

Subject	L/Limb	L/Back	H/Foot	D/Duration
1	Yes	No	Yes	8
2	No	No	Yes	6
3	Yes	Yes	Yes	23
4	No	Yes	No	15
5	Yes	No	No	7
6	Yes	Yes	No	14
7	No	No	No	5
8	Yes	No	Yes	12

5. Subjects then removed their orthoses and rested for 5 min to negate any possible fatigue effect.
6. Completion of five walks at self selected speed, without orthoses.
7. Completion of subjective assessment question.

Analysis

Change in performance with/without orthoses was analysed using a balanced two-way ANOVA, being mathematically similar to but more powerful than a single sample *t*-test. This allowed the subject to be factored in as a source of variance increasing the isolation of the dependent variables' effect.[17] Post hoc tests were not required as the degree of freedom for the treatment is one.

RESULTS

Changes in all objectively measured parameters when the orthoses were fitted are shown in Table 2, the level of change is statistically significant only for stride ($P<0.05$).

Subjective parameters

Three (62.5%) subjects stated walking with their orthoses was more comfortable and five (37.5%) much more comfortable.

Disease profile

The effect of the orthoses on individual subjects can be seen in Figure 1–3. Relating this to Table 1, in very general terms, those subjects who experienced hindfoot and lower limb joint pain responded more favourably to the orthoses with improvements occurring in all parameters. One clear exception is subject three who responded with decreases in all parameters.

DISCUSSION

Instrumentation

The results of the reliability study establish the Walkmat System as an ideal instrument with which to assess the temporal and distance parameters of gait. Intra-session reliability is excellent ($r>0.9$) for all three parameters. The analysis of instrument reliability is not subject to universally accepted methods. The analysis performed here is more powerful than that often employed.

Simple correlative methods such as Pearsons Product Moment or Spearmans are common but are limited as they do not separate systematic sources of error from random. Systematic error may therefore, be mistakenly interpreted as reliability.[17] ANOVA analysis and the calculation of r examines multiple sources of variability including both between and within measures and hence isolates, as far as is possible, variance due to the instrument from other sources of variance.

This study demonstrated the Walkmat System as a non-intrusive instrument. Subjects are tested with no preparation other than being directed to walk over the walkmat, and no attachments or footwear modifications are required. Boonstra et al.[9] established that velocity is affected at statistically significant levels by instruments which employ trailing wires, this system therefore enjoys a considerable advantage over many others.

Effect of the orthoses

The results of this study show that some increase occurred in velocity, cadence, stride length and comfort with orthosis use. While this reflects a move away from the characteristic rheumatoid gait which has been described as, 'slow and shuffling',[13] the change was statistically significant ($P<0.05$) in average stride length only. Broadly speaking, those subjects with hindfoot and lower limb joint pain in addition to forefoot pain responded most favourably.

The present results can be interpreted as reflecting improvements in all objective parameters which are not statistically significant for velocity or cadence due to the low numbers in the sample. An alternative interpretation would be that the statistical significance of the change occurring in stride length is an anomaly, possibly explained by one or two exceptional subjects exerting a disproportionate effect in a

Table 2 Mean values +/– 1 S.D.

	With	Without	Increase
Velocity (m/s)	0.71 +/– 0.21	0.68 +/– 0.27	0.03 +/– 0.14
Average Stride (cm)	99.10 +/– 14.4	94.75 +/– 14.36	4.36 +/– 10.86*
Cadence (st/min)	85.5 +/– 21	84.22 +/– 26	1.28 +/– 14.13

*$P<0.05$.

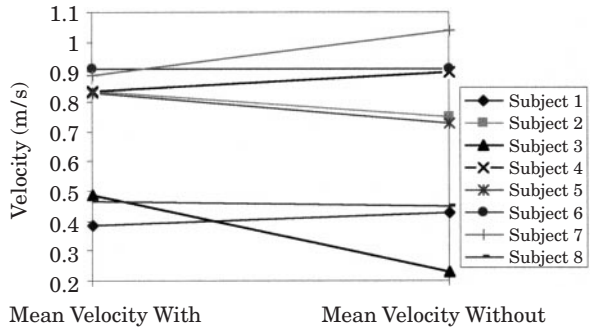

Fig. 1 Change in velocity with/without

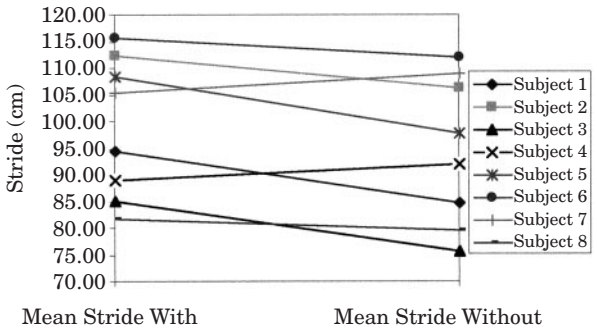

Fig. 2 Change in stride with/without

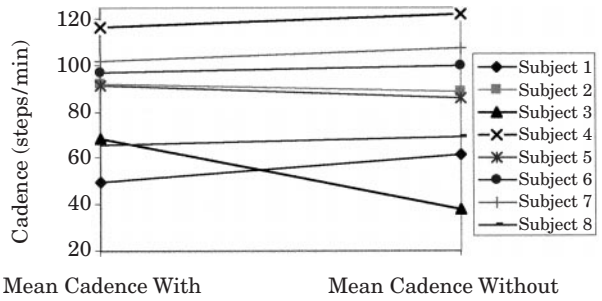

Fig. 3 Change in cadence, with/without

small sample. The analysis of the individual responses (Figs 1–3) demonstrate that this is not the case. There is no marked difference in individual subjects responses in stride length compared to the other parameters.

Another possible theory is that subjects are already achieving, or are close to their optimum gait, albeit with pain. What the orthoses may do is permit this optimum gait with reduced pain, this would explain the discrepancy between the changes in velocity and cadence which were not statistically significant and the overwhelming (100%) comfort improvements reported.

The present sample had a mean age of 61 years, range 41–77 and exhibited a mean velocity of 0.7 m/s, stride length of 96.9 cm and cadence of 85 st/min. From Whittle's normative data[19] the best age match is with the 50–64 years group, the central value being 57. These healthy elderly subjects velocities lay in the range 0.91–1.68 m/s, central value 1.3 m/s, stride is in the range 140–182 cm, central value 143 cm and cadence lies in the range 83–137 st/min, central value 110 st/min.

This is not an ideal comparison as the two groups are not perfectly age matched and Whittle's data is not published in a form where mean values are calculable. However, it is clear that the RA patients are significantly underperforming in comparison with their peers over all temporal and distance parameters of gait. Hence it is unlikely that the orthoses are primarily permitting optimum gait with improved subjective sensations. For that reasons further study with a larger sample is recommended.

The importance of the orthotic/shoe combination and fit is accepted and well documented.[23] Lockard[24] states that, 'shoe inserts are rarely successful without appropriate footwear'. The subjects for this study self selected their footwear under the advice of the dispensing podiatrist. However, no analysis was made of the patients' compliance with the podiatrists' advice. Neither does this methodology 'absolutely' standardize for this variable as testing all the patients in the same footwear would have. It does, however, provide data on the foot orthoses effectiveness in the circumstances in which they are actually being used, and hence provides a clinically relevant measure. However, to truly judge orthoses effectiveness, compliance and the dispensing podiatrists opinion of the shoe would be beneficial and is recommended in future studies. Time pressures prevented the dispensing podiatrist attending the testing sessions in the present study.

Only one previous study has objectively assessed the use of foot orthoses in RA. Locke et al.[7] tested the effectiveness of an extended UC-BL orthosis which is designed to include functional control of both foot and ankle. While the orthosis tested in the present study is based upon the UC-BL model, it acts in an accomadative and functional role at the foot alone. Both studies have shown reduced pain and a significantly improved stride length with a form of orthosis in place. Locke et al.[7] found significant increases in velocity with the orthoses in situ, a trend reproduced here, albeit not at a statistically significant level.

The subjective results from this study support the findings of Haworth et al.,[10] McCourt[5] and Fox et al.,[11] that patients find foot orthoses comfortable. However, in these studies, the number of patients prescribed foot orthoses who do not use them was also included; it is important to note that the reasons given for not using prescribed orthoses frequently relate to discomfort.[10,11] In the present study no analysis was made of the number of rheumatoid patients issued with orthoses who do not use them. This was beyond the remit of the study but is worthy of further investigation.

The effectiveness of orthoses in terms of either static[25–27] or dynamic[28–30] kinetic parameters has been

studied and shows reductions in pressure and ground reaction forces in non RA samples. The effectiveness of different types of materials in normal subjects[26,28–30] has also been examined. No studies on EVA orthoses alone have been published, nor do any of the published comparative works include EVA. The present results indicate that this lack should be remedied.

LIMITATIONS

The reliability study did not encompass assessment of intra session reliability for a pathological sample. To counter intra session variance in the pathological sample five measures were taken both with and without. This confounds the intra session variance of both the instrument's measurement and the actual performance but increases the likelihood of fatigue or learning effects becoming relevant.

To address the issue of fatigue, the time taken to remove the orthois was standardized to 5 min, providing a rest period between the taking of the with and without measurements. The protocol could also have been counterbalanced which would have helped to negate any learning or fatigue effects. Patients could have been randomly allocated to walk either with or without their orthosis first.

To make a logical judgment as to whether or not counterbalancing was appropriate, intra session reliability data for patients is required, i.e. evidence of a learning or fatigue effect in the patient's performance. Due to limitations on access to patients this and the other components of a full reliability study which required an RA sample could not be undertaken for this work. On that basis, the design was not counterbalanced and a standardized procedure was employed with acknowledgment of all sources of error. With this structure any learning effect would confound any fatigue effect. However, in a future study analysis of any learning or fatigue effect is recommended to inform the decision as to protocol counterbalancing.

CONCLUSIONS

Utilizing a sample which encompassed a wide range of disease durations and clinical profile, these results show improvements in both subjective assessment of comfort and objective improvement in stride length. Whilst the present results should be interpreted with caution it is recommended that large prospective comparative trials are undertaken to determine the most effective and economic form of material and orthosis design. The equipment and methodology applied in this study are both reliable and simple to use and could be employed with relative ease to answer some of these questions.

ACKNOWLEDGEMENTS

The authors would like to thank Daniel Rafferty, HD, T.Eng, Glasgow Caledonian University Centre for Clinical Research, Southern General Hospital NHS Trust, Judith Marsh, Department of Podiatry, Southern General Hospital NHS Trust and, William MacLaren PhD, Department of Mathematics, Glasgow Caledonian University.

REFERENCES

1. Michelson J, Easley M, Wigley F M, Hellman D. Foot and Ankle problems in rheumatoid arthritis. Foot Ankle Int 1994; 15: 608–613.
2. Geppert M J, Sobel M, Bohne W H. Rheumatoid Foot, part 1: Forefoot. Foot Ankle 1992; 13: 550–558.
3. Jacobs S R. Rehabilitation of the person with arthritis of the ankle and foot. Clin Podiatry 1984; 1: 373–399.
4. Arthritis and Rheumatism Council. Footwear and Orthoses. Newark; ARC Cards Ltd 1992.
5. McCourt F J. Report of a survey on in-shoe orthotic provision. JBPM 1994; 49: 73–76.
6. Merrit J L. Advances in orthotics for the patient with rheumatoid arthritis. J Rheumatol 1987; Supp 15, 14: 62–67.
7. Locke M, Perry J, Campbell J. Ankle and sub-talar joint motion during gait in arthritic patients. Phys Ther 1984; 63: 504–509.
8. Voloshin A, Wosk J. Influence of artificial shock absorbers on human gait. Clin Orthop 1981; 160: 52–56.
9. Boonstra A M, Fidler V and Eisma W H. Walking speed of normal subjects and amputees: aspects of the validity of gait analysis. Prosthet Orthot Int 1993; 17: 78–82.
10. Haworth R J, Hickling P, Hutton C W. Audit of lower limb orthoses in rheumatoid arthritis practice. Journal of Orthopaedic Rheumatology 1994; 7: 164–168.
11. Fox H J, Winson I G. Foot Orthoses: an audit of expenditure and efficacy. Foot 1994; 4: 79–82.
12. Gage J R. Gait analysis: principals and applications. J Bone Joint Surg 1995; Vol 77-A: 1607–1623.
13. Platto M J, O'Connell P G, Hicks J E, Gerber L H. The relationship of pain and deformity of the rheumatoid foot to gait and an index of functional ambulation. J Rheumatol 1991; 18: 38–43.
14. Gronley J K, Perry J. Gait analysis techniques Rancho Los Amigos Hospital Gait Laboratory. Phys Ther 1984; 64: 1831–1838.
15. Hirokawa S. Normal gait charactercistics under temporal and distance constraints. J Biomed Eng 1989; 11: 449–456.
16. AI Mijali M H, Solemonides S, Spence W, Rafferty D, Bell F. Design specifications of a walkmat system for the measurement of temporal and distance parameters of gait. Gait Posture 1993; 1: 119–20.
17. Currier D P. Elements of Research in Physical Therapy 2nd ed. Baltimore: Waverly Press Inc 1984; 145–175.
18. Blesh T E. Measurement in Physical Education, 2nd Ed. New York: The Ronald Press Co, 1974.
19. Whittle M H. Gait Analysis: an Introduction, 2nd Ed. Oxford: Butterworth Heinimann, 1996.
20. Bork O E. Research in Physical Therapy. Philadelphia: JB Lippencott Co 1993; 31–34.
21. ARA, (American Rheumatology Association) Arnett F C, Edworthy S M, Block D A et al. The American Rheumatology Association 1987 revised criteria for classification of rheumatoid arthritis. Arthritis Rheum 1988; Mar, 31: 315–324.
22. Dimonte P, Light H. Pathomechanics, gait deviations and treatment of the rheumatoid forefoot: a clinical report. Phys Ther 1982; 62: 1148–1156.
23. Tinley P. Appliances for the rheumatoid foot. Ballieres Clin Rheumat 1987; 1: 383–402.
24. Lockhard M A. Foot orthoses. Phys Ther 1988; 68: 1866–1873.
25. Bennet P, Miskewitch V, Duplock L. Effect of custom moulded foot orthotics on pressure distribution beneath the human foot: Abstract. Gait Posture 1994; 2: 248.
26. Barrow J, Hughes J, Clark P, Klenermann L. A study of the effect of wear on the pressure relieving properties of foot orthoses. Foot 1992; 1: 195–199.

27. Boulton A J M, Francks C I, Betts R P. Reduction of abnormal foot pressures in diabetic neuropathy using a new polymer insole material. Diabetes Care 1984; 1: 113.
28. Pratt D J. Long term comparison of some shock attenuating insoles. Prosthet Orthot Int 1990; 14: 59–62.
29. Johnson G R. The effectiveness of shock absorbing insoles during normal walking. Prosthet Orthot Int 1988; 12: 91–95.
30. Pratt D J, Rees P, Rodgers C. Assessment of some shock absorbing insoles. Prosthet Orthot Int 1986; 10: 43–45.