Functional Evaluation of a Custom-Molded Leather Ankle Lacer

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ABSTRACT

The purpose of this study was to evaluate the efficacy of a custom-molded leather ankle lacer for treating painful problems of the ankle and hindfoot. The evaluation involved patient self-assessment, clinical examination and radiographic determination of the effectiveness of the ankle lacer.

Overall, patients who used the lacer experienced moderate pain relief with significant but not complete restriction of motion. Based on this study and clinical experience, the authors concluded the leather ankle is a compliant and comfortable treatment strategy for patients who desire some retained motion of the ankle and hindfoot without intolerable pain.

Introduction

Arthritis frequently affects both the ankle and hindfoot. Studies show 17 to 20 percent of patients who have rheumatoid arthritis initially experience symptoms in the foot and ankle areas; in the later stages of the disease, foot and ankle complications affect 90 percent of patients (1).

Initial treatment of this condition typically involves activity modification and use of oral anti-inflammatory agents. If these measures fail, orthoses to reduce motion and unload the affected joints may be considered. Currently, the most popular approaches typically involve fabrication of a polypropylene ankle-foot orthosis (AFO). Although this method is generally well-tolerated, it sometimes causes difficulties such as excessive restriction of motion, skin irritation, or gradual loss of it due to leg atrophy or volume reduction.

At the University of Iowa, the custom-molded leather ankle lacer (see Figure la and Figure 1b) has been used for more than 50 years to treat selected patients who have had chronic ankle or hindfoot problems-since Jordan first described the application of leather racing to treat problems of the ankle (2). The leather ankle lacer remains a viable alternative to modern synthetic orthoses because of its apparent acceptance by patients.

The present study assesses the lacer's effectiveness in pain relief and restriction of motion. To the authors knowledge, no text concerning custom-molded leather ankle orthoses, other than Jordan's paper on the modification of a knee corset, exists.

Materials and Methods

Subjects

Five patients from the University of Iowa Hospital and Clinics participated in this study. Each patient wore one leather ankle lacer and was evaluated and/or treated in the contralateral lower-extremity area. Since each patient fit the profile being studied, a formal selection process was not necessary. All patients signed informed consent forms approved by the institution's Human Subjects Review and Radiation Protection committees.

The study group was comprised of three women and two men. The mean age of the group was 66 years, with ages ranging from 53 to 79 years. The average length of lacer wear was 5.5 years. Basic subject data are presented in Table 1 .

PATIENT HISTORY

Age	Sex	Weight	Length of Orthosis Wear (Years)	Medical Condition
1. 79	F	170	10	Subtalar Instability
2. 53	F	140	5	Rheumatoid Arthritis
3. 78	F	170	1	Ankle DJD
4. 62	M	194	5	Ankle Instability
5. 58	M	200	7	Ankle Instability

Table 1. Statistical data were recorded for each of the five subjects involved in the study.

Procedures: Subjective Evaluation

A written questionnaire (see Table 2) and personal interviews were the methods used to subjectively evaluate the orthosis. Patients were asked about:

SELECTED QUESTIONS

When do you wear the brace?
a. Always, including sleeping.
b. Throughout the day.
c. Only during activity.
d. Never.

Do you feel the brace adversely affects your appearance?
❑ Yes ❑ No

How comfortable is the brace?
a. Very comfortable.
b. Somewhat comfortable.
c. Not comfortable.

How satisfied are you with the leather ankle brace?
a. Extremely satisfied.
b. Moderately satisfied.
c. Not satisfied.

Table 2. Part of the subjective evaluation of the patients involved a written questionnaire that included the above questions as well as other queries.

- their ability to function both with and without the lacer,
- how many hours each day they wore the lacer,
- their daily activity levels,
- the lacer's appearance and comfort, and
- overall satisfaction with the custom-molded leather ankle lacer.

Procedures: Physical Examination

During the physical examination phase of evaluation, the condition of each patient's skin underneath the orthosis was examined; the presence of any calluses or ulcers was noted. Calf atrophy was determined by measuring the calf circumference 10 cm below the medial knee joint line and comparing that measurement with a congruous measurement of the contralateral lower leg. Range-of-motion (ROM) measures for the ankle and subtalar joints were taken with a goniometer.

Procedures: Three-Dimensional Electrogoniometry

A three-dimensional electrogoniometer constructed from mutually perpendicular potentiometers was used to measure motion (see Figure 2). Patients were instructed to maximally flex, extend and rotate their ankles. Motion was measured with and without use of the lacer in the sagittal and frontal planes.

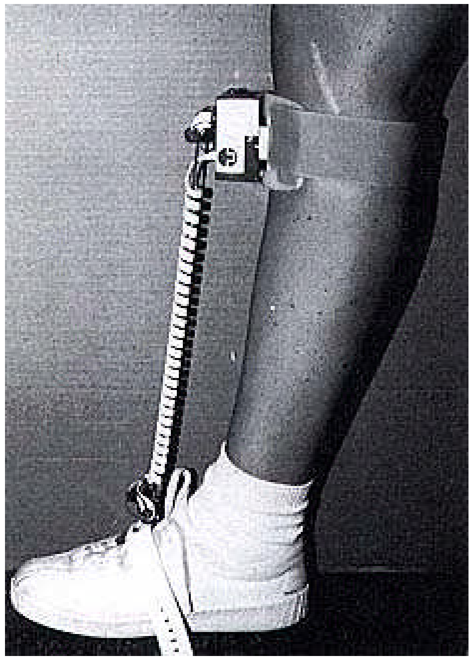

Figure 2. The three-dimensional electrogoniometer consists of two orthogonally mounted potentiometers.

The method's reliability was determined by comparing electrogoniometnc measurements to those made from radiographs. Comparisons were performed between free active ROM and measured ROM with the lacer in place in the weightbearing position.

Procedures: Radiographic Analysis

Sagittal plane motion also was determined radiographically. Four lateral X-rays of each foot and ankle were taken by a standard protocol (see Figure 3). Radiographs were taken in maximum flexion and maximum extension phases both in and out of the lacer. From these lateral X-rays, motion was measured in the ankle, hindfoot and midfoot.

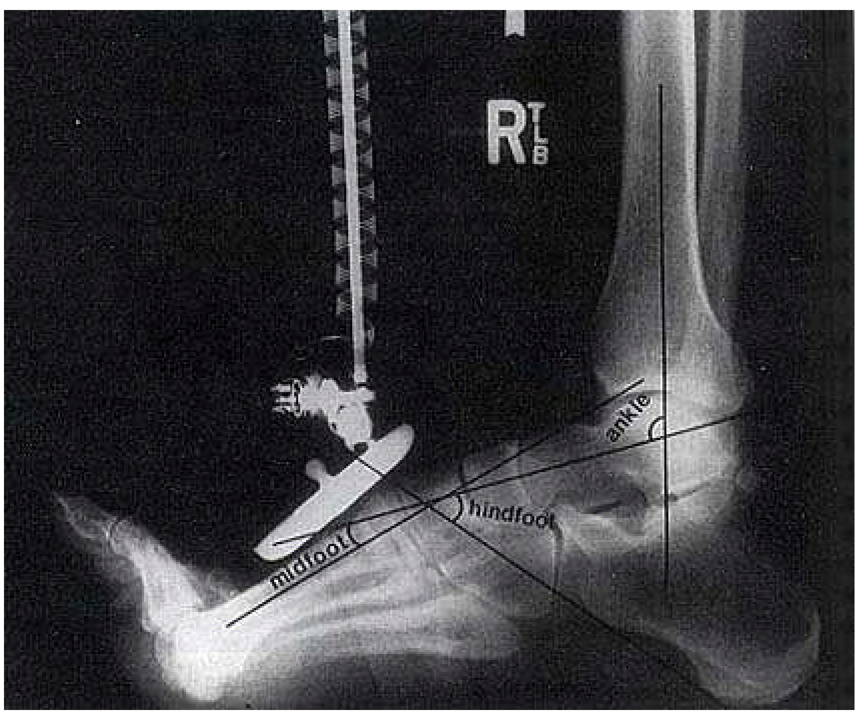

Figure 3. A lateral radiograph demonstrates 1) technique for making angular measurements of the ankle, hiudfoot and midfoot, and 2) simultaneous positioning of the electrogoniometer.

Ankle motion was determined by changes in the tibiotalar angle. The tibial axis was defined by a line drawn between the medial and lateral cortex parallel to the long axis of the bone. The talar axis was determined using the method of Digiovanni *et al.* (3).

Hindfoot motion was measured by changes in the talocalcaneal angle. The calcaneal axis was defined by a line drawn tangent to its interior surface.

Midfoot motion was determined by changes in the tab-first metatarsal angle. The first metatarsal axis was defined by a line longitudinally bisecting its shaft.

To reduce the error of measurement, lines were drawn on each X-ray three times by two examiners. The mean differences between flexion and extension values were used to indicate sagittal plane motion. These differences between angles, with and without the orthosis, represented the restriction of motion from the lacer. Data were analyzed using Systat statistical software.

Fabrication of the Custom-Molded Ankle Lacer

The custom-molded leather ankle lacer was fabricated for each patient using a standard methodology consistent with the axial resist AFO method taught at Northwestern University (4). The impression of the foot and ankle is taken carefully with consideration of the anticipated amount of necessary correction or accommodation. In this position, the ankle often rests in slight pronation with compensatory forefoot supination (5); complete correction of the deformities may not be possible and usually is not well-tolerated by patients. Following the negative impression, a positive model is made and modified with careful attention to overall cylindrical reduction in circumference to provide loading on the leg.

Smooth molding leather is soaked in water, secured to the model and allowed to dry completely. Soft lining leather is stretched under the molding leather and covered with a plastic wrap that acts as a barrier. Once dry, the leather is cut off the model anteriorly, making room for the tongue to be added later. Eyelets or Velcro(r) roller loops are applied. The metal stays, carefully contoured to produce the desired support, are added to the medial and lateral sides of the lacer. Leather stay covers are glued over the metal stays.

Trimlines generally resemble those of other AFOs: mid-metatarsal head, neck of the fibula, and slightly above the apex of the gastrocnemius muscle bellies posteriorly (5). Polyethylene or mesh wire may be substituted for the metal stays for more general support. Both materials are "sandwiched" between the two leather layers. The trim lines of the orthosis shown in Figure 1a appear proximal since a prosthetic foot was used in the photograph.

Results

Subjective Evaluation

The five patients involved in this study reported the lacer relieved pain in all cases (pain was reduced but not eliminated). Each patient's ability to function in various situations was difficult to assess due to the general low level of activity of the subjects involved.

Four of the five patients used the lacer throughout the day. One of the five reported the lacer was "very comfortable"; the remaining four found it "somewhat comfortable." Three of the live added their own padding to improve their comfort levels.

Only two of the five found the lacer cosmetically acceptable. Despite the cosmetic concerns, three of the subjects rated themselves as extremely satisfied, and two of the five rated themselves as moderately satisfied. No patient claimed to be dissatisfied.

Physical Examination

The lacers were well-tolerated by the skin in all cases. The authors found no areas of erythema or ulceration. Compared to the uninvolved side, there was an average 2.2 cm atrophy in the calf circumference of the involved leg (n = 3).

Three-Dimensional Electrogoniometry

The three-dimensional goniometric measurement of total sagittal plane motion was compared in each case to the radiographic measurement of that motion. The correlation between these measures was strong ($R^2 = 0.79$), suggesting the validity of the electrogoniometric technique and its potential clinical utility. All patients demonstrated decreased motion in both the frontal (axial) and sagittal planes resulting from use of the orthosis. A typical example of a patient's motion with and without the orthosis is shown in Figure 4 . The electrogoniometer was especially helpful in measuring motion in the frontal plane, which cannot be fully examined by conventional radiography. A 70-percent restriction in frontal plane motion was found in the subjects using the leather lacer ($p < .002$) (see Figure 5).

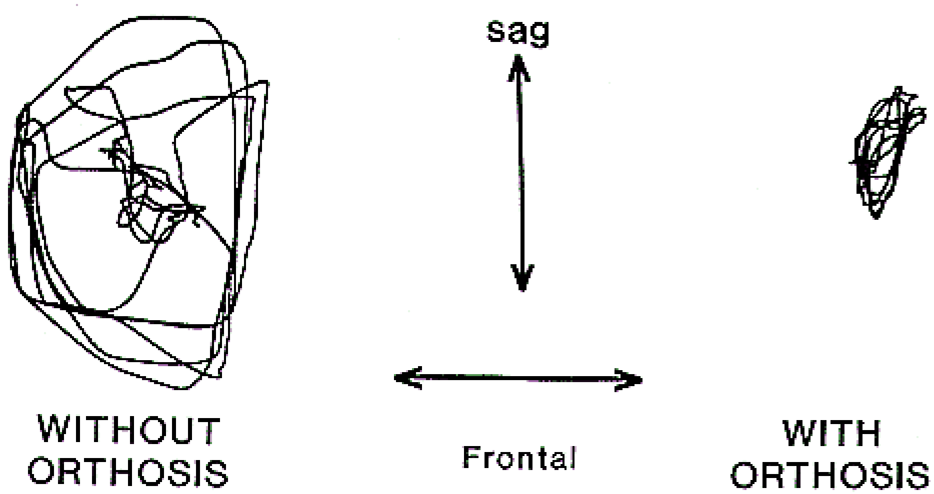

Figure 4. An example X- Y plot of electrogoniometrically measured frontal and sagittal plane motion indicates a marked decrease in global foot and ankle motion with use of the custom-molded leather ankle lacer.

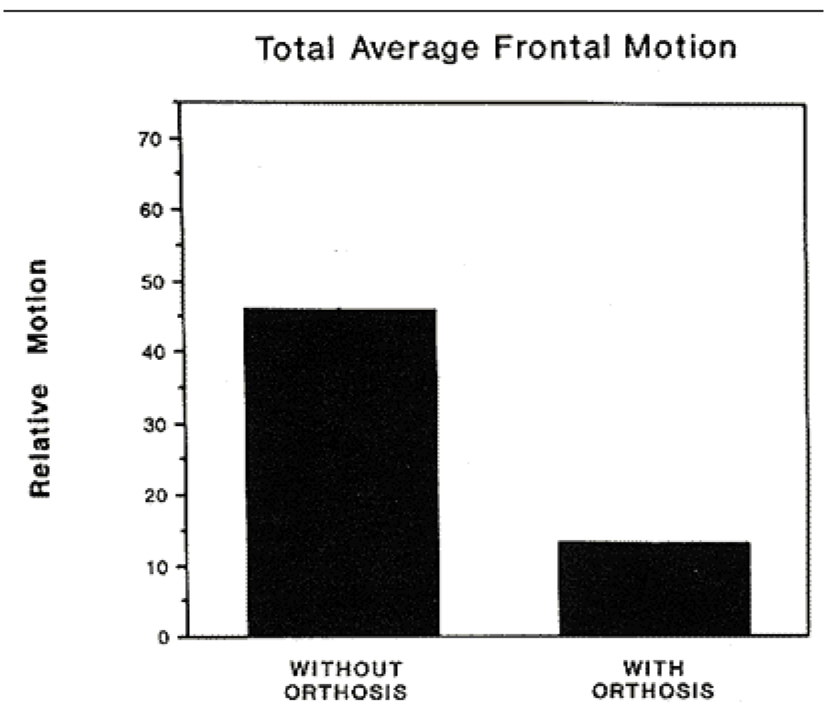

Figure 5. Frontal plane ankle and hindfoot motion was reduced an average of 70 percent with use of the lacer.

Radiographic Results

The radiographic results (see Table 3) showed a significant decrease in sagittal plane motion in the involved ankle and hindfoot resulting from use of the orthosis. The midfoot motion was not significantly reduced.

RADIOGRAPHIC RESULTS

	Mean Angle (deg)		Standard Deviation		Mean Angle	
Region Difference (deg)	Orthosis Without	Orthosis With	Orthosis Without	Orthosis With	Orthosis With	T-Test Result
Ankle	34.9	25.9	20.9	18.8	$p = 0.001$	8.9
Hindfoot	8.8	4.5	5.1	3.8	$p = 0.001$	4.4
Midfoot	8.4	7.7	4.2	4.4	$p = 0.64$	0.7

Table 3. The radiographic results indicate the greatest reduction in motion occurred at the tibiotalar joint in the ankle.

The largest reduction in motion occurred at the tibiotalar joint where motion was reduced an average of 8.9 degrees, representing a 26-percent reduction from the maximal amount of unrestricted ankle motion. The decrease in sagittal motion at the subtalar joint was 4.4 degrees, representing a 50-percent reduction.

Discussion

The findings of this study confirm the authors' clinical experience with use of the custom-molded leather ankle lacer. The lacer is generally well-tolerated and affords pain relief, motion restriction and functional improvement. Although the amount of pain relief was only moderate, it was consistent. The results may reflect a selection bias since the authors evaluated only long-term users of the lacer. Patients who were dissatisfied with its use probably would have discontinued use. No attempt was made to compare the leather lacer with other treatment orthoses such as rigid, polypropylene AFOs. Therefore, the subjective results are anecdotal.

The degree of motion restriction also was moderate. In the sagittal plane, the authors found an average 26-percent decrease in motion at the ankle joint, a 10-percent decrease in the subtalar joint and negligible change in the midfoot. The effect on frontal plane motion was more profound. With use of the electrogoniometer, the authors found an overall 70-percent decrease in motion (see Figure 5).

These data suggest that, in terms of motion restriction, the best indication for use of the custom-molded leather ankle lacer is the presence of ankle or hindfoot hypermobility in the frontal plane. Since all patients reported some degree of comfort while wearing the lacer, it can be presumed they were more uncomfortable without it; this explains the continued use.

Modification of existing orthoses, or new impressions and new orthoses, might have yielded different results. Rubin reported consistent loss of volume while wearing patellar-tendon-bearing (PTB) orthoses as well as concomitant loss in ability to off-load forces on the heel, secondary to the volume reduction (6). Perhaps a similar situation exists with the lacer.

In the authors' practice, the leather ankle lacer is primarily prescribed as an alternative to rigid polypropylene, solid ankle-foot orthoses. The lacer tends to provide sufficient stability while allowing some motion. Unlike more rigid AFOs, the lacer more easily allows for changes in calf volume and may help unload the hindfoot in stance phase (7).

Conclusion

The paucity of skin problems makes this device particularly helpful to patients on long-term corticosteroids with vasculitis or fragile skin. Although three of the five patients maintain they added padding for comfort, evaluation indicated these additions were made in an effort to deal with volume loss and increased pressure on the medial midfoot.

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