Mass Customization of Foot Orthoses for Rheumatoid Arthritis Using Selective Laser Sintering

Jari H. P. Pallari, Kenneth W. Dalgarno*, and James Woodburn

Abstract—Rheumatoid arthritis is an inflammatory joint disease that can lead to pain, stiffness, and deformity, often with marked involvement of the small joints of the foot and ankle. Orthotic devices are commonly prescribed for this condition to lessen symptoms and improve function and mobility, and customized devices are most effective. The work reported in this paper has examined the feasibility of using an additive manufacturing-based approach to manufacture customized orthoses. In order to test feasibility, orthoses have been manufactured using the additive manufacturing technology of selective laser sintering, and have been evaluated through a small-scale patient trial (n = 7). The trial indicated that these orthoses performed as well as the patients’ current prescribed customized devices in terms of the observed gait and subjective evaluation of fit and comfort. It is concluded that the feasibility of the additive manufacturing approach has been demonstrated, and further development of a mass customization system to deliver orthoses, together with exploitation of the design freedom offered by the manufacturing method, will give the overall approach significant clinical potential.

Index Terms—Additive layer manufacturing, mass customization, orthotics, rheumatoid arthritis (RA), selective laser sintering (SLS).

I. INTRODUCTION

RHEUMATOID arthritis (RA) is an inflammatory joint disease with an estimated prevalence between 0.3% and 1% [1]. Inflammation causes joint destruction, leading to painful and deformed foot joints and orthotics are commonly prescribed to redistribute load, restrict or alter motion, or compensate for a deformity or muscle weakness. Orthoses have been shown to reduce pain [2], delay the progress of deformity [3] and disability [2], and improve joint function in the foot [4]. Custom-made orthoses, tailored to the needs of a particular patient, have been shown to offer improved fit and comfort over mass-produced orthoses [2].

Custom orthoses have traditionally been made using craft techniques [5], often based on plaster casting an impression of the patients’ foot or lower leg, using this “negative” mold to create a “positive,” and then, casting or molding from that to create an orthosis. Current state of the art is moving toward computer-aided design and computer-aided manufacturing (CAD/CAM)-based systems [6] with various centralized and distributed models ranging from complete office-based solutions to factory-based manufacturing. These approaches are attempts to move from craft-based customization to mass customization—customization processes, which are systematic and aimed at large markets [7]. However, CAD/CAM is considered to raise significant training issues in its application in the industry [8], with additional concerns that the design software is often basic and the product range is limited by the geometries; it is possible to create using milling. The aim of this study was to evaluate the potential for an automated and entirely digital mass customization process based on geometry capture using a digital 3-D scanner and manufacture using the additive manufacturing process of selective laser sintering (SLS). Additive manufacturing processes have been available to produce low volumes of components with low lead times since the early 1980s [9], and have more recently been exploited in the production of medical devices, including the manufacture of customized in-the-ear hearing aid shells [10] and the creation of drill guides for dental surgery [11], and have also been evaluated for their potential in creating ankle–foot orthoses [12]. One significant advantage of additive manufacturing approaches over and above the low lead times they operate with is that they offer “design freedom” [13], with few manufacturing constraints on geometry. In order to evaluate the potential for a mass customization process based on 3-D scanning and SLS, we have developed a simple rule-based mass customization process. A key element of any mass customization system is that a customized specification can be quickly translated to create a customized product design. Typically, this will be based on some modular design principles: adding, combining, or adapting different elements of a design to create one-off functionality, and the development of the design rules to support the mass customization approach has been central to the research. This simple rule-based mass customization process has been then used to create orthoses, which were evaluated by a small sample of patients who have orthoses prescribed for them as a result of RA: with the goal of understanding whether or not these orthoses could match the performance of the patients’ existing orthoses. To our knowledge, this is the first time that a patient trial has been reported with...
foot orthoses manufactured using an additive manufacturing process.

II. METHODS

A. Design Rule Development

The approach taken in the development of the design rules has been to use a scan of the patients’ foot to define a “shell,” and then, to adapt that basic shell in light of the orthosis prescription. There were three main features to consider, which are as follows.

1) **Heel and arch supports.** These define a “cup” in which the heel will be positioned and the arch support, which normally prevents the foot arch from collapsing. Heel supports are used to deepen posterior support and increase the effectiveness of arch support, prevent the collapse of the heel fat pad, and increase the control during the early stages of the gait cycle and reduce pain. Arch supports can also realign the foot and increase the arch contact area in order to take pressure from other painful areas of the foot. Table I summarizes the rules developed for the development of heel and arch supports on a particular orthosis.

2) **Rearfoot wedges.** The function of a rearfoot wedge is to realign the foot during the gait cycle by rotating the rearfoot relative to the rest of the foot. Table I summarizes the rules developed for the development of rearfoot wedges on a particular orthosis.

3) **Metatarsal pads, bars, and cut outs.** These come in a variety of shapes and sizes and are used to redistribute the plantar pressure in the forefoot. Table II summarizes the rules developed for the development of metatarsal supports on a particular orthosis.

Tables I and II present the outcome of a large and systematic literature review in order to develop the rules. Full details of the process and logic applied can be found in [14].

B. Mass Customization Process

The simple mass customization process used as an exemplar in the study is outlined in Fig. 1. Clinical assessment of the patient (based on physical examination and gait analysis) was used to develop an orthosis specification. In parallel with this, a scan of the patients’ foot was taken to give the basic geometry, which an orthosis would be adapted to.

Weight and nonweight-bearing scans were taken using a hand-held Cobra 3-D scanner (Polhemus, Colchester, VT). Whether to use a weight or nonweight-bearing scan was determined by the podiatrist, on the basis of whether the arch

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### TABLE I

<table>
<thead>
<tr>
<th>Example Condition/ Symptoms to be Treated</th>
<th>Design Instructions</th>
<th>Features on standardised orthotic devices</th>
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<tbody>
<tr>
<td>Non-specific postural flat feet, valgus heel deformities, pes planus, and excessive pronation or instability</td>
<td>The basic shell is designed with the following features, illustrated opposite: 1. Uniform shell thickness. 2. The heel cup is formed medially and laterally and the height adjusted according to the desired motion control (higher wall height up to 20mm for maximum motion control). 3. The arch should be proximal to the metatarsals (MT), starting from the sustentaculum tali (ST) to the navicular tuberosity (NT). 4. The highest point of the arch should be at the navicular tuberosity (NT). The most crucial region for the stabilization is the triangle formed by the 1st metatarsal base / medial cuneiform (MB) and the talus (T) via the navicular and the calcaneus (C) medially. 5. Special modifications e.g., grooves, cut-outs, and flanges. 6. In-built or externally added ‘posting’ (rearfoot and/or forefoot) to control motion. The angle of the rearfoot posting is calculated as: if the standing angle is X, the posting angle should be (3X+5) degrees. The objective of the post or ‘wedge’ is to maintain an optimal angular relationship between the foot segments. The posts were placed so that the foot is in contact with the insole when the foot is in a neutral position. A medial rearfoot post is incorporated with the flat heel section whilst an external forefoot post is narrow and is positioned just behind the first metatarsal head.</td>
<td></td>
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<tr>
<td>Metatarsalgia or metatarsal head callouses</td>
<td>Metatarsal bars, pads and cushioning elements is designed with (illustrated opposite): 1. The orthotic shell/base extends to the distal metatarsal heads. The thickest part of the metatarsal pads and bars are placed posterior to the metatarsal heads to redistribute load to the metatarsal bone shafts. 2. The anterior border of the bar or pad should follow the convexity of the metatarsal heads to maximise pressure off-loading. The size of the bar/pad is based on the depth of the transverse metatarsal arch and the thickness of the plantar tissue. 3. Further cushioning material, with or without cut-outs for discrete lesions or painful areas over the metatarsal heads, can be extended forward of the metatarsal bar. Additional information MT pads are used for just one MT head and bars when pressure relief is needed below more than one MT head. These features should also be used only together with a &quot;total contact&quot; orthoses and a heel support. Patients with plantar heel pain received the addition of a soft local pad. Those with plantar callouses on other plantar sites or under bony prominences were given soft supports to reduce local overload. Finally, for patients with flexible hammer/claw toe, a bar was fitted to the inner surface of the vamp of the shoe, lying on the proximal phalanges of the feet.</td>
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needed to be preserved or supported—in all but one case of nonweight-bearing was chosen. Scans were taken with the patients seated, with their legs held out horizontally and supported on a cushioned table, with a Velcro strap holding the leg to be scanned in position on the table. The foot joints were passively manipulated into the subtalar joint neutral alignment while the scans were performed. This pose replicates the standard neutral casting techniques used in a high proportion of clinical practices. Two or three passes of the scanner along the foot were used to capture the geometry of the foot, with the scanner proprietary software combining data from the passes to produce a single surface model.

The foot scan was then exported in .stl format and manipulated within the Magics CAD software package (Materialise, Leuven, Belgium) in order to meet the specification, manually applying the design rules outlined in Section II-B. Once a design had been completed, the orthosis was produced in Nylon 12 (Duraform PA, 3D Systems Europe, Hemel Hempstead, U.K.) on a Vanguard SLS machine (3D Systems, Rock Hill, SC). This combination of material and manufacturing process was chosen as it allowed for the manufacture of robust orthoses in a material, which is United States Pharmacopeia (USP) class-IV certified (allowing parts to be used in biocompatible and skin contact situations [15]). After manufacturing, the parts were cleaned and finished (typically to smooth surfaces and remove sharp angles where that it had not been possible to remove digitally) before returning to the clinic for fitting to the patient for assessment, which will be next described in Section II-C.

C. Patient Trial

Seven patients with a definite diagnosis of RA and a current history of foot impairments were recruited from the Rheumatology Outpatient Clinic at Chapel Allerton Hospital (Leeds, U.K.). All patients were in receipt of customized foot orthotic treatment on one foot. National Research Ethics Service approval (Bradford Local Research Ethics Committee (LREC) Ref: 06/Q1202/36) and Leeds Teaching Hospitals, Research, and Development Department approval (Ref: RR06/7554) were obtained for the study.

The prototype laser-sintered orthoses were benchmarked against current customized orthotic devices by comparing 1) the impact on gait and 2) perceived comfort and fit.

The sample comprised three female and four males patients, with a mean age of 53.4 years (range 29–68 years), mean body mass of 74.9 kg (range 63.9–96.8 kg), and a mean body mass index of 26.2 (range 21.4–31.4). The patients have been diagnosed with RA for 11.3 years (range 1–25 years) on average.

From the patients’ perspective, the trial was completed in two stages. In the first stage, assessment of each patient underwent a normal clinical assessment of RA activity in the foot, carried out by Woodburn following the procedure described by Helliwell et al. [16], which includes examination of the skin, nail, foot, and footwear, together with consideration of patient history, tender and swollen joint counts, and a pain assessment. Patients’ self-rated pain and orthotic comfort and fit were assessed using 100-mm visual analog scales (VASs) [4]. This involved the patients making a mark on a simple linear scale, where the ends of the scale represented “bad” and “good” fit or comfort depending on the measure being assessed. A normalized indication of fit or comfort was then obtained by a measurement of where on the line the mark had been made, with 0 designated as “bad” and 100 as “good.” In addition to the normal clinical assessment, the patients had nonload bearings scans of their feet recorded using the Cobra 3-D Scanner with the foot passively manipulated into a neutral pose to align the joints.

Once this first stage had been completed, the process outlined in Section II-B was followed in order to create an orthosis, which would be fitted to and evaluated by the patient at stage two. The main aim was a comparison of the orthoses produced using the mass customization system in Fig. 1 with the patients’ current orthoses. Laser-sintered orthotics were fitted to the patient’s own footwear, through placing the orthosis inside the shoe and manually trimming any material from the orthosis, which prevented it from lying flat within the shoe— in practice, this meant trimming material from the metatarsal area forward, depending on the shoe design. The patient’s were requested to undergo free walking to evaluate initial fit and to acclimatize to the device. This typically took between 10 and 20 min. Patients were then asked to walk (at their normal speed) barefoot, with their current orthoses and with the orthoses produced, as shown in Fig. 1, along a Gaitrite instrumented walkway (CIR Systems, Havertown, PA.). This is a 48 × 288 array of pressure sensors encapsulated in a roll-up carpet, which allows the stride length, walking velocity, cadence (steps/min), and cycle time (time for a full gait cycle) to be measured. Each patient walked three times down the Gaitrite carpet for each condition, with the average of the three measurements used for analysis. Patients were then asked to report on comfort and fit of the SLS orthosis using the same VAS that had been used to assess their own orthoses.

For statistical analysis of results, two standard tests were used. To assess any differences in gait observed between patients, a one-way analysis of variance (ANOVA) test of variance was performed. This is relevant, where only one independent variable (variance between groups) is being investigated. In order to compare the results of the comfort and fit assessment, a simple paired t-test was used, as this test is appropriate, where the

Fig. 1. Mass customization process.
same subjects are being tested under two conditions. The level of statistical significance was set at $p < 0.05$.

III. RESULTS

A. Geometry Capture, Orthosis Design, and Manufacture

Fig. 2 shows a typical “raw” foot surface scan and shows that the scan data could be rather noisy. This was filtered and spurious data was removed. The scan was then imported into Magics where the surface was distally extruded to create a 5 mm thick solid model as shown in Fig. 3. The 5-mm wall thickness was chosen empirically, as it was found to offer a good combination of strength and stiffness for the application.

Where necessary material for heel support and forefoot extension could be added as a block of material, and then, trimmed to the required shape (shown in Fig. 4 prior to trimming). In practice, only heel supports were utilized in the SLS foot orthoses as the forefoot extensions, in a solid material construction were too stiff to allow necessary toe flexion. The heel support was trimmed from the top to match the 5-mm wall thickness around the heel shape. Sharp edges were cut off so that the orthoses would fit inside the shoe and not damage it.

Wedgeing was achieved through creating a series of small steps in the arch region in order to provide a graduated transition of the required angle, as shown in Fig. 5. To create the rearfoot wedge—the whole orthosis was rotated to match the wedging angle, as shown in Fig. 5(a). Next, the orthosis was “cut” to create small sections, as shown in Fig. 5(b). The “cuts” were 1-mm wide and the distance between the “cuts” was 4–5 mm. After these cuts were made, everything else, except the heel support part (which was to remain wedged) was rotated 1° back to the original position. Then, the section closest to the heel was kept in place, while the other sections were rotated another 1°. This was repeated as many times as necessary to get the forefoot segment back to its original position. The sections now blended the wedge to the heel segment while keeping the forefoot flat. The sections were then joined together to create a single solid, as shown in Fig. 5(c).

Metatarsal bars were created by elevating “islands” of material, as shown in Fig. 6, and metatarsal cut outs by removing material from the model to create recessed volumes. Fig. 7 shows a typical orthosis after manufacture on the SLS machine and finishing.
B. Patient Trial

Table III shows the results velocity, cadence, cycle time, and stride length measured (using the Gaitrite walkway) on the seven patients for both orthotic treatment conditions. Results showed only small numerical differences in spatial and temporal gait parameters between the orthotic treatment conditions. The mean [standard deviation (SD)] walking velocity for the standard customized (SC) foot orthoses was 115.1 (19.3) and 113.6 (16.7) cm/s for the SLS foot orthoses. Cadence was 103.7 (10.2) and 101.7 (9.4) steps per minute for the SC foot orthoses and the SLS foot orthoses, respectively. The left and right cycle times were 1.16 (0.12) and 1.17 (0.11) s, respectively, for the SC foot orthoses and 1.19 (0.11) s and 1.18 (0.11) s, respectively, for the SLS foot orthoses. The left and right stride lengths were 133.5 (17.5) and 134.4 (17.5) m, respectively, for the SC foot orthoses and 134.7 (14.3) and 134.5 (13.6), respectively, for the SLS foot orthoses. Table IV shows the results of a one-way ANOVA test, which indicates no difference in walking performance of the patients using the two orthoses [14].

Figs. 8 and 9 summarize the subjective responses of the patients regarding the fit and comfort of the two sets of orthoses, determined using VAS scales. While there is some variation in the ratings for a particular patient, the outcome overall in terms of the average response is very similar. The mean (SD) fit ratings for the SC foot orthoses were 79.4 (8.2) mm compared to 77.0 (11.1) mm for the SLS foot orthoses. The comfort ratings for the SC foot orthoses were 65.7 (19.7) mm compared to 60.6 (21.6) mm for the SLS foot orthoses. A simple paired t-test, shown in Table V, indicated no statistically significant difference between the two sets of results at the $p < 0.05$ significance level [14].

IV. DISCUSSION

A. Patient Trial Results

The main conclusion from the patient trials was that the process had shown that the SLS foot orthoses, manufactured using the process outlined in Fig. 1, had performed as well as the current clinical best practice, etc., while further work is required to develop the concept and approach further, the feasibility of an additive manufacturing-based mass customization process for
foot orthoses has been demonstrated. There were two other main findings from the patient trial. One was that the lack of cushioning on the SLS foot orthoses had a significant impact—the patients perceived the orthoses to be “hard,” and the podiatrist rejected designs incorporating metatarsal bars, as they were too stiff. It is common with orthoses to apply a layer of cushioning material onto the upper surface, and to have both soft and hard areas of the surface. We had hoped that the quality of the fit would remove the need for these, but that was not the case. It is possible that the perception of the SLS foot orthoses as “hard” adversely affected the patient trial results with these orthoses, but further work would be required to demonstrate this. The second point was that the amount of finishing of the orthoses was significant, and therefore, use of software, which would allow more of the “smoothing” to be carried out virtually, would be of significant value.

It was noted in Section II-B that all but one of the patients were scanned with their foot nonload-bearing. The patient who was scanned with the foot load-bearing was patient 3. Figs. 8 and 9 show that this patient thought the SC orthosis was a better fit and more comfortable than the SLS orthosis, and Table III shows that the patient showed a modest increase in walking speed with the SLS orthosis. Overall, these results are not so different from the others to suggest that the use of a load-bearing scan had any significant impact on the overall assessment. We remain of the view that the choice of scan type should be with the podiatrist.

### B. Mass Customization Process

The mass customization process used was commercially naïve. We have made no attempt to develop a valid “supply chain” as part of this feasibility study. While this has resulted in a simple system with which to evaluate feasibility, it also means that quality systems (management systems to ensure product safety, efficacy, and customer satisfaction) and the flow of product data (how digital information and knowledge from scans and designs would be communicated efficiently and securely from clinic to orthotic designer to manufacturer) have not been addressed to the depth required of any medical device.

### C. Design Rule Development

Tables I and II present a structured and systematic approach to the development of orthoses, something without which no mass customization process can function effectively. The initial set of design rules, based on current clinical practice, showed good face validity, especially for features related to orthotic shape and functional elements. The rules created close-fitting contoured surfaces at the heel and midfoot and wedging to meet the therapeutic objectives of load distribution, focal pressure relief, and motion control for feet affected by RA. Further work is required to refine the stiffness and flexibility features of the sintered material relative to the desired requirements on a patient-to-patient basis. Preliminary statistical analysis supported the observations of both the clinicians and the patients. We consider the set of design rules presented as a starting point—further work will be required to expand and refine the number of rules (in part through the application of biomechanical modeling) and to test them through more comprehensive clinical trials.

### D. Clinical Potential

The adoption of mass-customized orthoses using additive manufacturing approaches will only be widespread if they can be shown to offer high performance, value for money, and a good service model. The work presented in this paper has shown that orthoses made by SLS to a mass customization model can match the performance of SC foot orthoses, but this has not fully exploited the capability of layer manufacture systems to locally tailor the structure of an orthosis to provide different functional elements. For example, work by Rogers et al. [17] has shown within an prosthetic socket design that a device can be fabricated, which includes low and high stiffness areas, specifically engineered to give a particular mechanical response, and this effect could be exploited in foot orthoses in order to mix characteristics from hard and soft orthoses. Other possibilities include the generation of engineered tactile areas on an orthosis in order to enhance sensitivity in particular areas of the foot (for example, the arch regions of the foot are more sensitive than the heel, and patients with a high sensitivity in this area show a good ability to redistribute pressure [18], and therefore, a surface that magnified this effect could have clinical value [19]). Further work will examine the potential for enhanced orthotic performance through the use of compliant structures and tactile surfaces for function and comfort.
The patients who took part in our trial reported paying an average of £82 (approximately $140) for their existing orthoses (not including clinical costs) [14], and we estimate the design and manufacture costs for producing orthoses using SLS to be of the order of £50 (~$80) [20]; therefore, while cost remains a serious concern within healthcare systems, producing orthoses through this route is not inherently expensive compared to market norms. The quality of service, which such a system could provide, would depend on the nature of the commercially developed mass customization system. For current additive manufacturing machines, a central (factory based) manufacturing model would be most likely in order to most effectively use the physical machine capacity, and this would likely make the minimum lead time for an orthosis 24 h (the orthoses made in this study had a one day lead time). However, there is a trend toward smaller, cheaper, “desktop” machines, which would be better suited to a distributed, manufacture at point of prescription model [21]. These machines would not be SLS based, but would employ additive manufacturing principles and have the potential to bring the lead time down to a few hours. Whether or not such technologies can deliver the technical performance required is yet to be seen. However, experience with CAD/CAM machines [8] has shown that machines intended for distributed use must be designed with a nonexpert user in mind.

Taking the potential for enhanced performance, competitive pricing, and potential lead times together, we consider that a mass customization system for foot orthoses based on additive manufacturing does have significant potential.

V. CONCLUSION

Overall, we consider that the feasibility study has shown that the prototype mass-customized orthoses produced using additive manufacturing are as effective (within the constraints of the small-scale patient trial) as currently proscribed orthoses. Further work is required to refine the mass customization system, and to establish that an additive manufacturing-based system can deliver clinically effective, enhanced performance orthoses.

REFERENCES


Authors’ photographs and biographies not available at the time of publication.