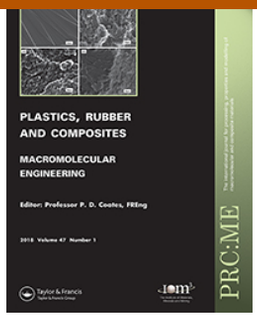

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Development and clinical evaluation of laser-sintered ankle foot orthoses

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ABSTRACT

Ankle foot orthoses (AFOs) are traditionally manufactured using vacuum thermoforming as shaping technology. Additive manufacturing has the potential to disruptively change the way these orthopaedic devices are produced. In this study, AFOs are developed which are virtually designed and produced with laser sintering as shaping technology. The mechanical and clinical performances of these laser-sintered AFOs are compared with traditionally manufactured AFO by asking seven patients (both children and adults) to walk with each type of AFO.

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Patient; gait; orthotics; ankle foot orthosis; additive manufacturing; selective laser sintering; polyamide 12; mechanical properties

Literature survey

An ankle foot orthosis (AFO) is a device that can be prescribed to individuals with movement impairments. The specific aim of an AFO depends on an individual: his/her medical condition, functional needs and activity level. In general an AFO can support weak muscles and/or restrain spastic muscles, ultimately leading to a smoother, more stable and more energy efficient locomotion. Today patients can choose between standard off the shelf AFO and custom-made AFO. Standard AFOs are cheaper but might offer less comfort to a patient than custom-made AFO. On the other hand, production of custom-made AFO is a labour-intensive task requiring highly skilled personnel [1]. Today plastic custom AFOs are typically produced from polypropylene (PP) sheets using the vacuum thermoforming technique.

Recent advances in medical imaging and in additive manufacturing (AM) technology might change the way custom AFOs are produced. The following AFO AM production scheme is suggested: (1) patient's anatomy is captured by laser scan, (2) captured data is used to recreate the patient's anatomy in three-dimensional (3D) space and (3) using 3D patient data a personalised AFO is designed, analysed (virtually) and prepared for AM [1]. Once AM technology matures, the production of custom AFO might become cheaper, faster, more controllable and more accurate than using current technology [2].

Different aspects of AM of custom AFO have already been researched. Some researchers carried proof of concept studies [3,4]; some investigated dimensional accuracy of AM AFO [2], while others investigated material characteristics and prototype AM AFO performance on a small sample of healthy or impaired subjects [4–7].

In 2007 Milusheva et al. [3] suggested an early concept of AFO production by AM using a modular design AFO with exchangeable elastic springs. Milusheva et al. used laser scanning and laser sintering (LS, SLS®) to produce the prototype conceptual AFO, not reporting on AFO fit or performance. In 2012, Telfer et al. [4] suggested a new concept of modular AFO with adjustable stiffness in sagittal plane. Telfer et al. produced a prototype AFO from PA 12 powder by LS and tested it on a healthy subject in a gait analysis laboratory. They found that by adjusting AFO, stiffness in the sagittal plane ankle kinematics could be varied. Thus, Telfer et al. suggested that in the future custom AFO with superior features to current AFO might be produced by AM.

Dimensional accuracy and fit of 3D printed AFO on two healthy subjects have been investigated by Schrank and Stanhope [2]. Four half scale AFO and two full scale AFO were printed for the purpose of the study. Schrank and Stanhope found that dimension discrepancies between actual LS AFO and their CAD models were below 2 mm and that LS build orientation and position did not have a significant influence on dimensional accuracy. Two full scale AFO that were designed for two healthy subjects, by subjective visual judgment, provided a good fit on those subjects.

Faustini et al. [5] investigated energy release and storage properties of three polyamide (PA)-based materials: DuraFormTM PA (glass-filled PA 12),

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DuraFormTM GF (PA 12), RilsanTM D80 (PA 11) and compared them to carbon fibre (CF), material that is also often used to produce traditional AFO. RilsanTM D80 (PA 11) proved to have the lowest mechanical damping characteristics out of the three LS materials tested; however mechanical damping in the RilsanTM D80 AFO was still appreciably greater (36%) than in CF-AFO. RilsanTM D80 was the only material out of three materials tested to withstand large deformations.

Mavroidis et al. [1] used 3D laser scanning and a stereolitography (SLA) process to produce custom AFO for a healthy subject. Two types of materials were used for SLA AFO production: (1) Accura 40 resin for the production of rigid SLA AFO and (2) Somos 9120 resin for the production of flexible SLA AFO. The performance of LS AFO was compared to a prefabricated plastic posterior leaf spring AFO in the gait analysis laboratory. Mavroidis et al. found that both rigid and flexible SLA AFO performed similar to prefabricated AFO. The minor differences in performance of different AFO were attributed to difference in their stiffness. However, stiffness of the AFO was not reported in this study.

Harper et al. [6] carried out a study to compare the performance of modular AFO with CF strut and LS produced PA 11 strut. The study involved 10 subjects with unilateral limb impairments. Harper et al. reported that the differences between gait performance while walking with LS PA 11 and CF struts were minimal. Thus, authors concluded that PA 11 is a material suitable for use in orthotics.

Creylman et al. [7] compared the performance of LS AFO to the performance of custom PP AFO in eight subjects with unilateral foot drop in the gait analysis laboratory. They did not find significant differences between performance of LS AFO and PP AFO, thus concluding that LS AFO can perform as well as custom-made PP AFO.

The results achieved to date support the use of AM technology in orthotics. However, more extensive clinical studies are still needed for AM technology acceptance.

Methodology

In this study, seven patients (both children and adults) are selected. The pathologies considered were trauma, neuro-muscular disorder and cerebral palsy. Before participation in the study, the patients are screened by a team of medical specialists. In order to participate in the study, the patients have to be able to walk without walking aids. Among others, exclusion criteria were: insufficient hip and knee power, severe obesity, stiff knee gait and muscle tone of Ashworth 3 or more in psoas, hamstrings, adductors, rectus femoris, gastrocnemius or soleus.

Before production, the team of medical specialists prescribed the stiffness of the AFO devices around the ankle joint, according to the pathology of the patients (Table 1). Further, some AFO were prescribed with leather boots to ensure adequate foot support and to ensure that heel contact with the AFO is maintained.

Table 1. AFO ankle stiffness prescriptions for patients of the clinical study.

	Left	Right
Patient 1, child	Rigid[a]	Rigid[a]
Patient 2, child	Semi-flexible	Semi-flexible
Patient 3, adult	Semi-flexible[a]	Flexible
Patient 4, child	Semi-flexible	Semi-flexible
Patient 5, adult		Flexible
Patient 6, adult		Flexible
Patient 7, adult		Flexible[a]

[a]These AFO include a leather boot to compensate for foot pathologies.

Owing to growing of the patients, normal wearing times for AFO in Belgium is 1 year for patients younger than 14 years, 2 years for patients between 14 and 21 years, and 5 years for patients older than 21 years. During the clinical study the patients were asked to wear the laser-sintered AFO for 6 weeks and the traditionally manufactured AFO for another 6 weeks (with order randomised). All patients wore the same semi-orthopaedic shoes for both types of AFO.

Manufacturing of orthotic devices

Figure 1 schematically depicts how both the traditionally manufactured and selective laser-sintered AFO were produced. The production process of both AFO started with 3D scanning of the leg of the patient, using Artec Studio® alongside standard physical measures (which are the height of the fibula, heel width, meta width, ankle width, foot length, heel to meta length). When the pathology of the patients was too severe, a plaster cast was also taken in addition to the 3D laser scan. In these cases, the plaster cast was also scanned. When comparing the physical measurements, it was found that the direct scan of the leg captured best the meta width and the scan of the plaster cast captured best the heel width.

As a second step, the scans were virtually corrected using specialised orthopaedic software (Rodin 4D®). The result of this correction (i.e. an .STL file) is used as a step in producing both the traditionally manufactured AFO and the laser-sintered AFO.

Traditionally manufactured AFO

The corrected positives were milled out of wood, using a five axes milling machine. These positives were used as a mould in a vacuum thermoforming process using 4 mm heated PP sheet to create a classic AFO.

The ankle trim lines (i.e. the way the polypropylene shell was cut around the ankle) were adjusted according to the clinical prescription for the flexibility of the AFO around the ankle. If the clinical prescription

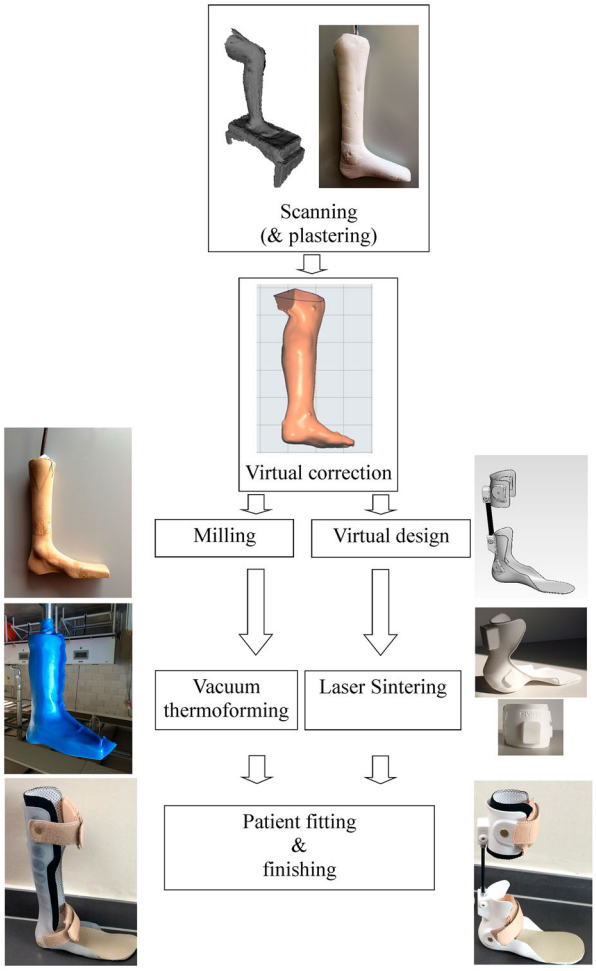

Figure 1. Production of traditionally manufactured (left) and laser-sintered (right) AFO.

was rigid, semi-rigid, flexible or very flexible, the trim lines were respectively anterior to (in front of), through, or posterior to (behind), or very posteriorly to the lateral malleolus (Table 2).

Selective laser-sintered AFO

The corrected scan files were used as a starting point in the computer-aided design of the AFO, which consisted of a calf part of 3.0 mm thickness, a foot part of 3.0 mm thickness and two carbon fibre rods connecting them. In order to design the AFO, a combination of the following design software programs was used: 3-Matic® (Materialise N.V.) and SolidWorks® (Dassault Systemes) & Rhinoceros® (Robert McNeel & Associates). The resulting calf and foot parts were laser sintered out of ther polyamide 12 (PA12) material (3D Systems and/or EOS LS machines).

The diameter of the two carbon fibre rods was adjusted according to the clinical prescription for the flexibility of the AFO around the ankle. Where the clinical prescription was 'rigid', a rod diameter of 10 mm for adults and 8 mm for children was selected. When the clinical prescription was 'semi-rigid or flexible', a rod diameter of 8 mm for adults and 6 mm for children was selected. The exception was one adult patient who was provided with a very flexible AFO, having rods of 6 mm diameter. For all laser-sintered AFO, the ankle trim lines were through the lateral malleolus (Table 2).

Patient fitting and finishing

In a next step, a Certified Prosthetist Orthotist adjusted the devices (e.g. adding foot support material where needed) according to their experience. Finally, the device was finished with the placement of padding, a thin insole, the attachment of hook and loop fasteners and the placement of leather boots (if prescribed, Table 1).

Results and discussion

All patients walked with both laser-sintered and traditionally manufactured AFO.

The time required for the patient fitting was less for the laser-sintered AFO (rough estimation of saved time: 10–20%). During the the virtual (CAD) design of the laser-sintered AFO, the trim lines were already defined. For the traditionally manufactured AFO, the

Table 2. Definitions of ankle stiffness of both traditionally manufactured and laser-sintered AFO.

	Traditionally manufactured	Laser sintered
Children		
Flexible	• Trim line behind lateral malleolus	• Trim line through lateral malleolus • 6 mm rods
Semi-flexible/semi-rigid	• Trim line through lateral malleolus	• Trim line through lateral malleolus • 6 mm rods
Rigid	• Trim line in front of lateral malleolus	• Trim line through lateral malleolus • 8 mm rods
Adults		
Very flexible	• Trim line a lot behind lateral malleolus	• Trim line through lateral malleolus • 6 mm rods
Flexible	• Trim line behind lateral malleolus	• Trim line through lateral malleolus • 8 mm rods
Semi-flexible/semi-rigid	• Trim line through lateral malleolus	• Trim line through lateral malleolus • 8 mm rods
Rigid	• Trim line in front of lateral malleolus	• Trim line through lateral malleolus • 10 mm rods

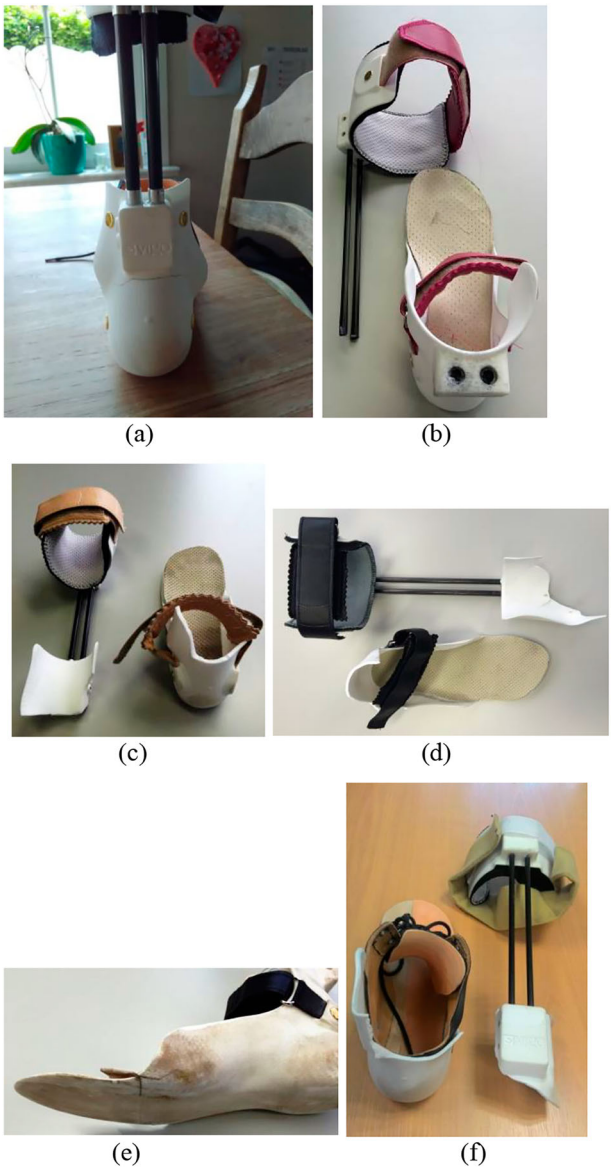

Figure 2. Breaking of right AFO of patient 1 ((a) breaking of plastic shell), right AFO of patient 3 ((b) breaking of rods), left AFO of patient 4 ((c) breaking of shell), right AFO of patient 5 ((d) breaking of shell), right AFO of patient 6 ((e) fatigue crack at location of metatarsal phalangeal joint) and right AFO of patient 7 ((f) breaking of shell).

trim lines are manually defined/refined during the patient fitting.

All traditionally manufactured AFO survived the 6 weeks of clinical trial without any failure or noticeable wear. Nevertheless, the strength of the laser-sintered AFO developed for the clinical study needs to be optimised:

(1) Patient 1: After 1 day, the plastic shell of the laser-sintered AFO broke when the patient (child) was running around and playing 'catch'. The strength of this AFO seemed to be insufficient (Figure 2(a)).
(2) Patient 2 wore the laser-sintered AFO for the 6 weeks trial period with no failure. In this case, the strength of the AFO was sufficient.
(3) Patient 3: The carbon rods of the right laser-sintered AFO broke at their lowest point after 3 days of use (Figure 2(b)). This was probably due to inaccurate cutting and grinding of the rods introducing a crack/notch at a critical point.
(4) Patient 4: After 4 weeks, the plastic shell of the left laser-sintered AFO broke (Figure 2(c)) during a sudden impact while the patient (child) was playing soccer. It seems that a combination of fatigue failure (4 weeks of walking) and high stresses during the sudden impact caused the AFO to fail.
(5) Patient 5: After 3 weeks, the plastic shell of the laser-sintered AFO broke while the patient walked up stairs. Probably this happened due to a fatigue failure (Figure 2(d)).
(6) Patient 6 wore the laser-sintered AFO for the 6 weeks trial period. Nevertheless, the AFO became dirty and a cracking began at the metatarsal phalangeal joint (Figure 2(e)). Further investigation of the fatigue behaviour of the PA12 material and investigating stain release post-processing methods are mandatory to solve these issues.
(7) Patient 7: After 5 weeks, the plastic shell of the laser-sintered AFO broke during hiking. Probably this happened due to fatigue failure (Figure 2(f)).

Conclusions

Compared to the traditionally manufactured AFO, the time needed for patient fitting is less for the laser-sintered AFO (rough estimation of saved time: 10–20%). However, long-term clinical studies are mandatory to test the behaviour of the laser-sintered AFO in daily use conditions. The clinical pilot study reported here to develop/evaluate the process of producing laser-sintered AFO, highlights the importance of more extensive mechanical characterisation tests (such as strength, fatigue, impact) both on coupon-level material samples and on the final product, processing of carbon material (if used) and stain release post-processing methods. As such, it also highlights the need to use finite element modelling and simulation, including appropriate material models, when producing a laser-sintered AFO for a patient.

Disclosure statement

No potential conflict of interest was reported by the authors.

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STREAM (STRuctural Engineering materials through Additive Manufacturing).

References

[1] Mavroidis C, Ranky RG, Sivak ML, et al. Patient specific ankle-foot orthoses using rapid prototyping. J Neureng Rehabil. 2011;8(1):1.

[2] Schrank ES, Stanhope SJ. Dimensional accuracy of ankle-foot orthoses constructed by rapid customization and manufacturing framework. J Rehabil Res Dev. 2011;48(1):31–42.

[3] Milusheva S, Tosheva E, Tochev D, et al. Personalized ankle foot orthosis with exchangeable elastic elements. J Biomech. 2007;25(6):90–95.

[4] Telfer S, Pallari J, Munguia J, et al. Embracing additive manufacture: implications for foot and ankle orthosis design. BMC Musculoskelet Disord. 2012;13(1):1287.

[5] Faustini MC, Neptune RR, Crawford RH, et al. Manufacture of passive dynamic ankle-foot orthoses using selective laser sintering. IEEE Trans Biomed Eng. 2008;55(2):784–790.

[6] Harper NG, Russell EM, Wilken JM, et al. Selective laser sintered versus carbon fiber passive-dynamic ankle-foot orthoses: a comparison of patient walking performance. J Biomech Eng. 2014;136(9):091001.

[7] Creylman V, Muraru L, Pallari J, et al. Gait assessment during the initial fitting of customized selective laser sintering ankle foot orthoses in subject with drop foot. Prosthet Orthet Int. 2013;37(2):132–138.