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# Additive Manufacturing of Custom Orthoses and Prostheses – A Review

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**Abstract**

Additive manufacturing (AM) of custom foot orthoses (FO), ankle-foot orthoses (AFO) and prosthetic socket is reviewed and compared to the traditional plaster molding fabrication techniques. A study was first conducted at the University of Michigan Orthotics and Prosthetics Center (UMOPC) to study the quantity and revenue of various types of orthoses and prostheses. FO and AFO were identified as the highest revenue orthoses. Together with the prosthetic socket, which is prevalent among amputees, the current fabrication procedure at UMOPC and a detailed review of the design and AM research of these three types of orthoses and prostheses in the past 25 years are investigated. The laborious steps and long fabrication time of the traditional manufacturing method and the progress and benefits of AM for custom orthoses and prostheses are evident. The study concludes that there are still clinical, financial and technological barriers for full-scale implementation of AM in a service system for custom orthoses and prostheses


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*Keywords:* Additive manufacturing; Prosthetic socket; Foot orthoses; Ankle-foot orthoses ;

## 1. Introduction

Orthoses and prostheses (O&P) are assistive devices to help people with disabilities. Orthoses, colloquially known as braces, support and modify the structural and functional characteristics of human neuromuscular and musculoskeletal systems. Orthoses apply force to the body for biomechanical needs of patients with impairments contributed to functional limitations. The amount of force, the site of application, and the means of controlling force all contribute to the efficacy of an orthosis. Orthoses increase users ability to function and improve their quality-of-life. Each orthosis has specific purposes to: 1) maintain or correct the alignment of a body segment, 2) assist or resist joint motion during key phases of patient's gait, 3) relieve or distribute distal weight-bearing forces, 4) protect from external stimuli, 5) restore mobility, and 6) minimize risk of deformities.

There is a growing need for O&P due to an aging population, veterans injured in recent conflicts and auto accidents. In the United States (U.S.), the American Academy of Orthotists and Prosthetists projects that the number of persons using orthoses is expected to increase from 5.6 million in 1995 to 7.3 million by 2020; and the number of persons using prosthesis is expected to increase from 1.6 million in 1995 to 2.4 million by the year 2020 [1].

In 2012, Medicare approved payment for nearly 2.4 million orthotic codes that accounted for more than $710 million in Medicare expenditures [2]. There are many types of O&P. O&P are named according to the joint and the limb involved. The nomenclature for most common O&P is listed in Table 1 [3]. Examples of foot orthoses (FO) and ankle-foot orthoses, (AFO), manufactured using conventional and additive manufacturing (AM) methods, are illustrated in Fig. 1.

There are two types of O&P: custom and off-the-shelf. Custom O&P can fit the patient's body and perform better than off-the-shelf O&P. A study of the prosthetic care of 581 veterans and service members with major traumatic limb loss from the Vietnam and Iraq war era [4] as well as in another study of long-term prosthesis use for patients with lower-limb amputation [5] have both reported that the fitness of O&P is


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the most important factor for O&P users' satisfaction. The AM has the potential for rapid and cost-effective fabrication and transformative service of the custom O&P.

Table 1. Orthotics and prosthetic nomenclature [3]

| | | | |
|---|---|---|---|
| **Upper Limb Orthoses** | | | |
| HO | Hand orthoses | WHO | Wrist-hand orthoses |
| WO | Wrist orthoses | EWHO | Elbow-wrist-hand orthoses |
| EO | Elbow orthoses | | |
| **Spinal Orthoses** | | | |
| CTLSO | Cervical-thoracic-lumbosacral orthoses | | |
| CO | Cervical orthoses | TLSO | Thoracic-lumbosacral orthoses |
| TO | Thoracic orthoses | LSO | Lumbosacral orthoses |
| LO | Lumbar orthoses | SIO | Sacroiliac orthoses |
| **Lower-Limb Orthoses** | | | |
| FO | Foot orthoses | AFO | Ankle-foot orthoses |
| KO | Knee orthoses | KAFO | Knee-ankle-foot orthoses |
| HpO | Hip orthoses | HKAFO | Hip-knee-ankle-foot orthoses |
| **Prostheses** | | | |
| AE | Above elbow | BE | Below elbow |
| AK | Above knee | BK | Below knee |

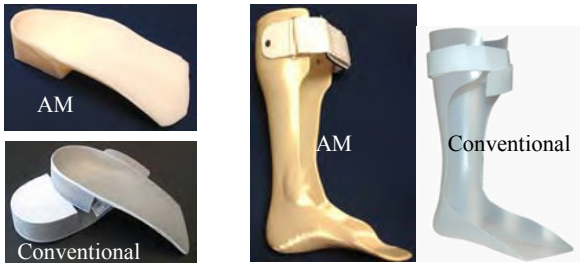



Fig. 1. Examples of orthosis and prosthesis fabricated using the convention and additive manufacturing, (a) foot orthosis and (b) ankle-foot orthosis

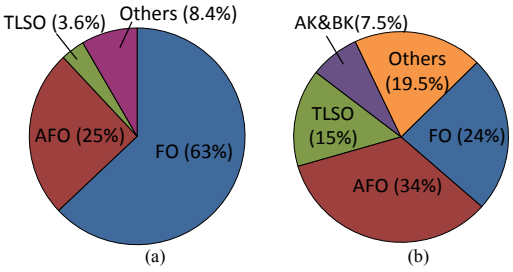



Fig. 2. O&P fabricated at UMOPC: (a) quantity and (b) revenue.

To investigate the business prospect of AM in O&P, we have conducted an in-depth study of the types of O&P manufactured and revenue generated based on either the Medicare reimbursement code or patient out-of-pocket expense at the University of Michigan Orthotics and Prosthetics Center (UMOPC) in academic year (AY) 2013 (July 1, 2012 to June 30, 2013). In AY2013, UMOPC had 36,315 patient visits and 12,438 prescriptions of new O&P. Results of this study are graphically shown in Fig. 2. Among O&P fabricated at UMOPC, about 63% are FO and 26% are AFO in quantity with 25% and 34% in revenue for FO and AFO, respectively – making FO and AFO the two most common as well as the highest revenue generating O&P.

Traditionally, custom O&P are manufactured using a labor intensive plaster molding technique. AM provides the opportunity to eliminate much of this labor, potentially providing an ideal fabrication method of custom O&P. The socket that fits the residual limb for AK and BK prostheses is critical for the fit and comfort of amputees. A review of traditional and AM for FO, AFO and socket will be presented in the following three sections.

## 2. Traditional and Additive Manufacturing of FO

FOs support and align the foot to prevent or correct foot deformities, provide an even distribution of the body weight, or to improve the functions of the foot. Depending on the range of movement in the joints allowed, orthotists can prescribe three types of FO: rigid, semi-rigid, and soft.

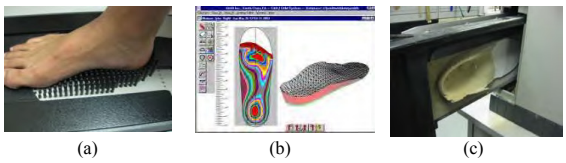



Fig. 3 The Amfit® system for manufacturing of soft FOs: (a) foot plantar surface profile measurement device based on elevating contact pins, (b) CAD software, and (c) CNC carving machine for 3-axis milling of FO.

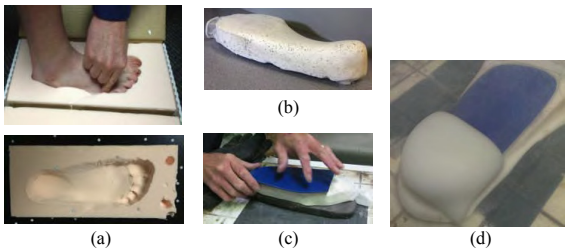



Fig. 4 Fabrication of rigid and semi-rigid FOs: (a) foam impression box, (b) plaster mold made out of the foam box, (c) laying the thermoplastic sheet over the mold, and (d) adding the heel block and vacuum forming.

For FO made of soft foam material, a system developed by Amfit® (Vancouver, WA) is the current market leader. Fig. 3 shows the UMOPC's Amfit® system, which consists of three key devices. One is the pin-based contact digitizer machine (Fig. 3(a)) to measure the plantar surface profile of the foot. Depth of the pins in contact with the foot is measured and converted by the computer-aided design (CAD) software (Fig. 3(b)) to the profile of the insole. This profile, after modification by the orthotist, is used in a 3-axis computer numerical control (CNC) carving machine (Fig. 3(c)) to fabricate the FO made of ethylene-vinyl acetate (EVA) material with about 35 Shore A hardness. Machining time of a standard size FO in the Amfit® CNC carver is about 30 to 60 min. The current practice for manufacturing rigid and semi-rigid FOs uses traditional plaster molding and vacuum forming processes. As shown in Fig. 4(a), the patient's foot is pressed into the foam box to create a negative impression of the plantar surface. This negative impression is used as a mold for plaster to create the positive model of the foot (Fig. 4(b)). The positive model is placed on a vacuum table and then draped with a sheet of thermoplastic (Fig. 4(c)) which has been heated to its molding temperature in an oven. Vacuum is then applied to mold the thermoplastic into the geometry of

the model. Heel posting or balancing of the orthoses is then achieved by molding a foam block onto the heel area (Fig. 4(d)). The extra materials of the edge are trimmed and smoothed to finish the final FO, as shown in Fig. 1(a).

Figure 5 shows the steps of fabricating the FO using AM. Firstly, a 3D laser scanner captures the 3D geometry by either scanning the impression of the foam box (Fig. 5(a)) or by directly scanning the patient's foot. The surface profile is processed using software; for example, the Tracer® CAD by Ohio Willow Wood. This surface profile is fitted to the 3D geometry of foot plantar surface, as shown in Fig. 5(b). Orthotists makes modifications to the geometry by using Tracer® CAD (Fig. 5(c)). The modified geometry is exported as a stereolithography (STL) file and transferred to another software Magics™ (Materialise, Leuven, Belgium). In Magics™, the "offset" function generates a given thickness of a surface representation to make a solid model. A heal block is generated in SolidWorks™ (Dassault System, Waltham, MA) and exported as another STL file. These two STL files were merged in Magics™ and a single STL file is created to fabricate the FO (Figs. 5(d) and (e)). Finally, as shown in Fig. 5(f), the FO is fabricated using the fused deposition modeling (FDM) method. It is estimated that, with the advanced FDM technique and sparse structure, the printing time can be reduced to less than 60 min. The time for AM of FO could further be feasible if material use is optimized with topology and sparse structure, and by implementing advanced FDM with higher material deposition rate.

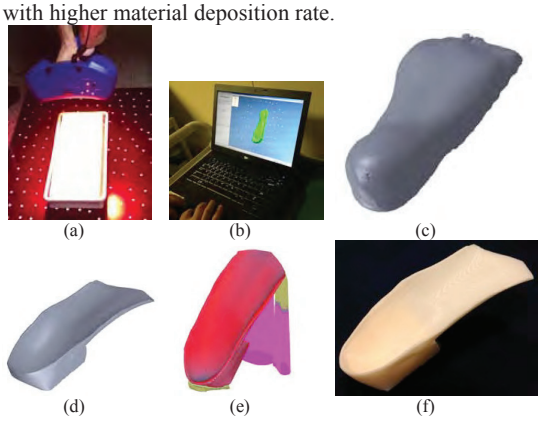



Fig. 5 Procedure of AM for FO: (a) 3D scanning of the foam box, (b) geometry modification in Tracer® CAD, (c) modified STL file of a positive foot model, (d) merged FO (insole and heel block), (e) FO setup for AM, and (f) FO made by FDM and ABS material.

The research of AM of FO has been carried out by Pallari et al. [6-9]. The selective laser sintering (SLS) of Nylon 12, as shown in Fig. 6(a), was utilized to fabricate FOs for a clinical evaluation of 7 patients, who worn the FOs fabricated using the traditional and AM methods and their walking gait is measured using pressure pad and analyzed. The study validated that FOs fabricated by AM have the same performance as the traditional FOs [8]. Another study by Pallari et al. [9], shown in Fig. 6(b), identified software needs for the design of FO. The business case for SLS and FDM of FOs has also been conducted [10]. Dombroski et al. [11] studied the scanning and ABS FDM of a low-cost custom FO and validated the feasibility and effectiveness in one user. FOs by AM have demonstrated to be cost competitive. A company, SOLS® has commercialized FOs fabricated using AM, as shown in Fig. 6(c). Clinically, the custom FO made by AM was also demonstrated for the clubfoot (Fig. 6(d)) [12], rheumatoid arthritis (Fig. 6(e)) [6] and reducing the peak pressure at the metatarsal heads using adjustable elements [13].

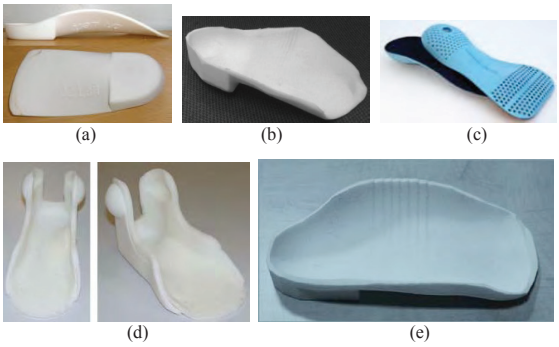



Fig. 6 FOs fabricated by AM (a) SLS [9] and (b) FDM [10], (c) FOs by SOLS®, FO for (d) clubfoot correction [12] and (e) rheumatoid arthritis [6].

## 3. Traditional and Additive Manufacturing of AFO

AFOs are used to support and align, suppress spastic and overpowering muscles, assist weak and paralyzed muscles, prevent or correct deformities, and improve the functions of the ankle and foot. The traditional plaster molding process to fabricate a custom AFO is shown in the left column of Fig. 7. Step 1 is the measurement including the length, successive circumferences, and mediolateral and anteroposterior dimensions of the ankle and foot. In Step 2, a negative impression is taken with a plaster of Paris bandage or a fiber resin tape. A layer of tubular stockinet is used to cover the ankle and foot to create a protective interface and control the position of soft tissue structures. Bony prominences or other important guiding landmarks are marked in this stockinet layer. A thin layer of plaster of Paris (or fiber resin tape) is applied. While the mold hardens, the clinician supports the ankle and foot in the desired position, sometimes applying a light corrective force. Once the cast is hardened sufficiently, it is carefully cut/sectioned and removed, preserving its shape and contours, and checked for alignment. This negative is then shipped in a package to a fabrication facility for the following steps if the clinic does not do in-house fabrication. In Step 3, a positive model is created by pouring liquid plaster of Paris into the sealed negative impression mould. A mandrel is embedded into the positive model and is used to hold the model for rectification as well as the rest of the production process. Although the positive plaster model is a 3D representation of the ankle and foot, it cannot relay information about the tissue that it will interface. In Step 4, additional plaster is added over bony prominences to relief pressure; while plaster is removed where additional forces are to be applied. The surface of the positive plaster model also needs to be sanded/polished to ensure the surface is smooth. In Step 5, a polypropylene (PP), polyethylene (PE), PP-PE copolymer, or other thermoplastic sheet is precut, heated in an oven until it reaches its plastic state, wrapped around the plaster model and then formed to the model via vacuum. Once the plastic has cooled and returned to its solid state,

trimlines are delineated on the formed plastic and the edges are then smoothed. In Step 6, The finished AFO is then fitted to the patient's body to observe and seek feeback from the patient on the fit and function of the orthoses. The time duration for the traditional manufacturing usually takes two weeks.

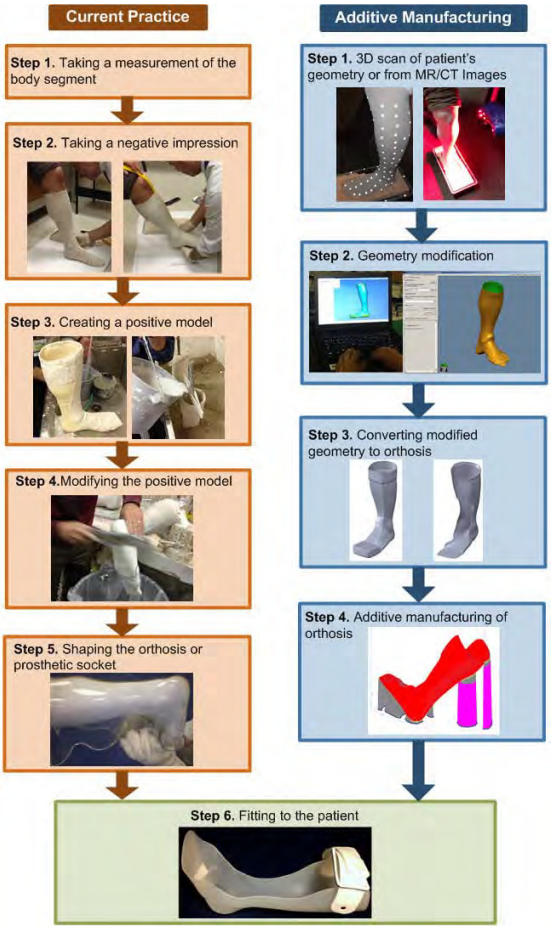



Fig. 7 Current plaster molding and AM of AFO.

For AM of AFO, as shown in the right column of Fig. 7, the Step 1 is the 3D scanning on the ankle and foot (including the plantar surface). The subject's foot plantar surface is also scanned, either using the foam impression box (Fig. 5(a) for FO fabrication) or by direct scanning. In Step 2, the scan data is processed using Tracer® CAD and Magics™. Two scans (one on ankle/foot and another on the foam impression box) could be stitched together by aligning three fixed dots placed on the edge of the foam box, which are scanned during both scans. The trimlines for AFO were created and smoothed manually. In Step 4, the FDM path for the AFO and support structure was designed and the AFOs were fabricated and evaluated on users.

The concept of using AM for the fabrication of AFO was published by Milusheva et al. [14] in 2005. Research has been conducted from the technical and clinical perspectives. From the technical perspective, Faustini et al. [15] fabricated the passive dynamic AFOs (Fig. 8(a)) using the SLS of Nylon 12, glass-fiber filled Nylon 12 and Nylon 11 and tested in three ways. Results were compared to a carbon fiber AFO and showed the SLS was ideal for fabrication of AFO with adequate stiffness and better damping. Nylon 11 was the SLS material that can withstand the whole range of destructive testing. Pallari et al. [9] applied the finite element modelling (FEM) and topology optimization for the design of AFOs fabricated by SLS. The concept of integrating sensors (e.g. temperature, pressure, and humidity) in 3D-printed AFO was proposed. Schrank and Stanhope [16] proposed a five-step customization and manufacturing framework on the subject characterization, alignment of the foot and leg segment using landmarks, and the effect of orientation in SLS on the dimensional accuracy. Results (Fig. 8(b)) showed the accuracy of SLS and the cost effectiveness of SLS vs. traditional AFO. Telfir et al. [13] has developed the AFO with adjustable stiffness levels in the sagittal plane (shown in Fig. 8(c)) to adjust the stiffness on ankle joint and showed the stiffness effect on ankle kinematics in a healthy subject. Schrank et al. [17] integrated the CAD model parameterization and FEM analysis to quantitatively tune and predict and experimentally validate the bending stiffness of the FDM AFO.

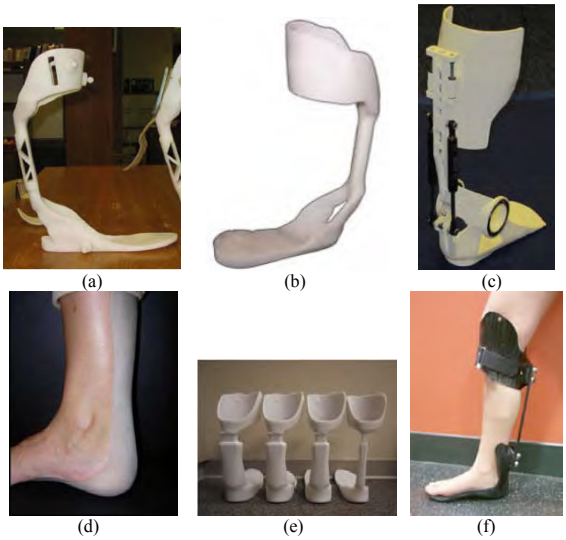



Fig. 8 Examples of AM AFOs, produced by (a) Faustini et al. [15], (b) Schrank et al. [16], (c) Telfer et al.[13], (d) Mavroidis et al. [18], (e) Schrank et al. [17] and (f) Harper et al. [20].

Clinically, Mavoridis et al. [18] tested two AFOs (flexible and rigid) using stereolithography (SLA) (shown in Fig. 8(d)) and showed the equivalent walking speed, step length and double support time in the comparison with standard AFO in gait parameter study. Creylman et al. [19] studied the SLS and regular PP AFOs on eight subjects with unilateral drop foot gait. The SLS and PP AFOs showed equivalent performances. Harper et al. [20] conducted a clinical evaluation on 10 subjects with unilateral lower-limb impairments and measured the gait subjects using regular carbon fiber and stiffness-matched SLS AFOs. Minimal differences in gait performance were observed. SLS AFOs can be applied to study the effects of altering designs on gait performance.

## 4. Review of AM of Prosthetic Sockets

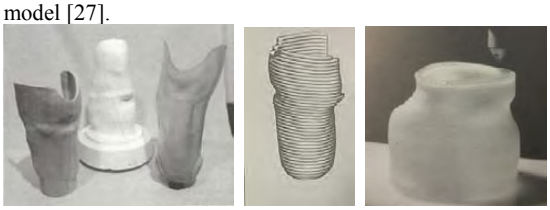
Nearly 2 million people are living with limb loss in the United State [21]. Every year, about 185,000 amputations occur in the US [22]. In 2009, hospital costs associated with amputation totalled more than $8.3 billion [23]. The prevalence of diabetes is expected to further increase this number. Most amputees need prostheses as assistive devices to help to enhance their mobility, activity and for independent living. The prostheses usually consist of socket, suspension mechanism, alignable components, joints such as knees or ankles and a foot. The socket is important for the comfort and proper function of the prosthetic.

All amputees suffer the discomfort from high contact pressure points in the socket. Volume change of a residual limb is another challenge. Associated with the volume change is the change of pressure and pressure points. Users typically require several sockets. In the first month after amputation, the volume of a residual limb is expected to change significantly and a preparatory prosthesis, or socket replacements may be used during this time to accommodate changes to the residual limb. The volume of a residual limb decreases gradually due to muscle atrophy, reduction in edema, with daily consistent use of a prosthesis. When the volume of residual limb decreases, the limb sinks further into the socket than when the prosthesis was initially done. As a result, the user feels discomfort at the distal end as a result of tibia pressure and/or at other bony prominences. Prosthetic socks of various thicknesses (ply) are commonly used inside the socket to compensate for the volume loss in the patient's limb. The volume of the limb may also increase due to sores, salt intake, medication, or trauma. Based on the Center of Medicare and Medicaid (CMS) code [24], socket replacements are considered reasonable and necessary if there is adequate documentation of functional and/or physiological needs, including volume changes in the residual limb, irreparable damage, or wear/tear due to excessive user weight or high activity levels.

The traditional approach to the design and fabrication of a prosthetic socket starts with the wrapping of the residual limb in plaster bandages in order to capture its geometry in a cast. As they wrap the residual limb, the prosthetist palpates for potential pressure points at bony prominences and takes note of their locations. The cast of the residual limb is then removed and filled with plaster slurry. Once the slurry is set, the plaster cast is destroyed, leaving a solid model (a positive mold) of the patient's residual limb. An alternative, and faster, way to make the positive mold uses optical scanning of the residual limb. The scan data is converted into surface geometry and imported into a CNC milling machine which then carves a model of the residual limb from a foam block. Whichever method is used to create the positive model, modifications are used to add volume to any bony prominences or sensitive areas and volume is removed from pressure tolerant areas as determined by the prosthetist's evaluation and experience. The positive socket mold is wrapped by a semi-molten PE, PP, or co-polymer (mix of both PE and PP) plastic sheet, which is vacuum-formed to match the shape of the mold. Alternatively, carbon fiber and other textiles infused with epoxy resin can be wrapped around the positive mold and cured in order to form stronger, lighter-weight (and more expensive) sockets often required by "active" amputees.

Like FO and AFO, the current socket fabrication process is labor intensive. The process is also wasteful of material, as the plaster molds and excess fabrication materials are destroyed during fabrication. Should another socket be required due to the inevitable changes in the residual limb, the entire process has to be repeated. The location and thickness of build-ups to modify the positive plaster or foam mold is based on the initial examination and experience of the prosthetist, and thus varies for each patient and prosthetist.

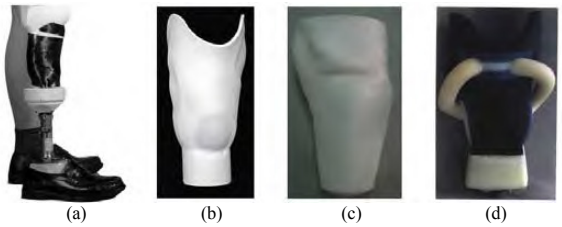
The AM of a prosthetic socket was conducted by Rovick in 1990 [25, 26] at Northwestern University. The SLA and its CAD and computer-aided manufacturing (CAM) software were just available for adoption in AM of custom O&P. The wooden CNC carved socket, plaster residual limb model, and SLA socket from this well-recognized pioneering application of AM in O&P is shown in Fig. 9(a). In the manuscript, the layer-to-layer fabrication concept (Fig. 9(b)) to build a socket (Fig. 9(c)) was illustrated. The mechanical digitizer was applied to obtain the 3D geometry of the plaster residual limb model [27].



(a) (b) (c)

Fig. 9 AM of socket (a) the wooden and SLA sockets and the plaster mold, (b) layer-by-layer deposition concept and (c) socket by AM [25, 26].

In the early 1990s and the following two decades, a group at University of Texas at Austin and Health Science Center at San Antonio have collaborated on SLS for prosthetic socket [28-33]. In 1991, the procedure of digitizing the residual limb using a 3D laser scanner, modifying the geometry using a CAD software, and using SLS to produce the socket was presented [28]. A scale-down transtibial socket was fabricated in 1991 and a full sized socket with a fitting for attaching the pylon was built in 1992 and an amputee in a supervised setting wore this socket briefly [33]. The SLS of the double-wall socket with compliance in selected region was studied and evaluated on a human subject for fit [30, 31]. The SLS of pylon adapter and selectively compliant socket was developed [32]. Rogers et al. [33] provided detailed reviews of the AM of prosthetic sockets before 2007 and had integrated the compliant socket technology in a test to measure contact pressure.



(a) (b) (c) (d)

Fig 10: Examples of AM prosthetic sockets, produced by (a) Herbert et al. [35], (b) Roger et al. [33], (c) Hsu et al. [36], and (d) Sengeh et al. [37].

Freeman et al. [34] investigated the cost build and tested a SLA socket and studied the cost for potential application. Herbert et al. [35] demonstrated the socket technology and provided a good review of AM technologies for prosthetic sockets. Hsu et al. [36] explored covering 3D-printed sockets with resin to improve the durability. The most recent research was the AM of a variable hardness socket using the Objet Connex capable of 3D-printing plastic with 10 levels of hardness polymer [37]. The socket was designed such that its hardness had an inverse relationship to the tissue compliance at each contact point (i.e. more compliant tissue rested against harder material, and vice versa).

## 5. Conclusions

This paper summarized the traditional and AM of custom FOs, AFOs and prosthetic sockets in the past 25 years. In limited clinical evaluations, the AM technology had demonstrated to be capable to fabricating custom FOs, AFOs and prosthetic sockets with good fit and adequate strength. However, some evidence also clearly shows that there are clinical, technological (on both design and manufacturing) and financial barriers to overcome before the AM technology can be adopted for full-scale implement in a service system for custom O&P.

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