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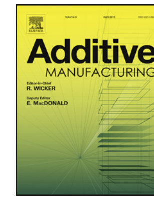

Review

Additive manufacturing of custom orthoses and prostheses—A review

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ABSTRACT

This study reviews the progress of using additive manufacturing (AM) for custom orthoses and prostheses (O&P) in the past 25 years. Foot orthoses (FOs), ankle-foot orthoses (AFOs), and prosthetic sockets are the most common types of O&P that are custom fabricated. A brief introduction to traditional plaster molding fabrication techniques for custom O&P are given for FO, AFO, and prosthetic sockets, followed by the AM process. Prior studies on AM of FOs, AFOs, and prosthetics sockets are reviewed. Applications of AM for other types of O&P are also presented. Lastly, future trends and challenges for adoption of AM for fabrication of O&P in clinical settings are discussed.

Contents

1. Introduction

Orthoses and prostheses (O&P) are assistive devices that help people with disabilities. Orthoses, colloquially known as braces, support and modify the structural and functional characteristics of human neuromuscular and musculoskeletal systems. For patients with impairments that contribute to functional limitations, orthoses are used to apply forces on the body for biomechanical needs. Prostheses are devices that replace missing body parts, such as a hand prosthesis. The portion remaining of the limb is referred to as the residual limb. The prosthetic socket is a cup-like structure that fits around the residual limb of amputees and transfers mechanical loading from the amputee to the prosthesis. The socket is critical for the comfort and function of prosthesis users.

O&P are named according to the joint and the limb involved. The nomenclature for most common O&P is listed in Table 1 [1]. Examples of foot orthoses (FO) and ankle-foot orthoses (AFO) are illustrated in Fig. 1. There is a growing need for O&P due to an aging population, veterans injured in recent conflicts, and auto accidents. In 2013, Medicare approved payment for nearly 2.4 million orthotic codes, 2.07 million prosthetic services, and 5.9 million pedorthic codes that accounted for more than $734 million, $664 million, and $255 million, respectively, in Medicare expenditures [2].

O&P can be either custom fabricated or prefabricated. Prefabricated O&P are less expensive and are readily available as off-the

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Table 1
Orthotic and prosthetic nomenclature [1].

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

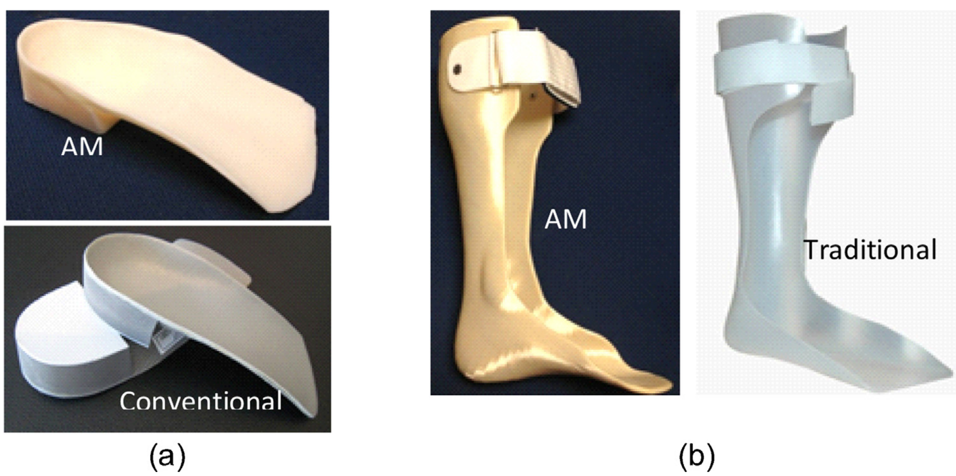

Fig. 1. Examples of orthosis and prosthesis fabricated using the traditional and additive manufacturing: (a) foot orthosis and (b) ankle-foot orthosis.

shelf products. However, custom O&P have better fit to the patient's body and perform better than the prefabricated 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 [3] as well as in a study of long-term prosthesis use of patients with lower-limb amputation [4] have both reported that the fitness of O&P is the most important factor for O&P users' satisfaction. Traditionally, custom O&P are manufactured using a labor intensive plaster molding technique. Additive manufacturing (AM) is an ideal technology for mass customization and provides the opportunity to eliminate much of this labor. The potential for AM has been demonstrated for rapid and cost-effective fabrication and transformative service of the custom O&P.

Figs. 2(a) and (b) show the quantity and Medicare expenditures of the most common types of O&P reported by the Centers for Medicare & Medicaid Services [5]. FO is the largest in terms of quantity (66.0%) and expenditures (20.9%). AFO has only 4.3% in quantity but costs 10.4% in overall expenditure. Similarly, AK and BK have 1.3% in quantity but cover 10.3% in overall expenditure. The percentages of LSO and KO in overall expenditure are 20.8% and 12.6%, respectively, but most of these two types of orthoses are prefabricated and fitted to the patients. In this paper, we focus on reviewing AM research on FO, AFO, and lower limb prosthetic sockets (AK and BK). In the next three sections, we first provide an introduction to the traditional manufacturing process for custom O&P and then review the AM research for FO, AFO, and lower limb prosthetic sockets, respectively. AM of other types of O&P are discussed in the following section. Lastly, future trends and challenges are summarized.

2. Traditional and additive manufacturing of the foot orthosis

FOs are used to 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 or activity levels, orthotists (or pedorthists) can prescribe three types of FO: rigid, semi-rigid, and soft.

For soft FOs made of soft foam material, Fig. 3 shows three key devices for fabrication. One is the pin-based contact digitizer machine (Fig. 3(a)) that measures the plantar surface profile of the foot. Depth of the pins in contact with the foot is measured and converted by the O&P 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 CNC carver (by Amfit®) takes 30–60 min.