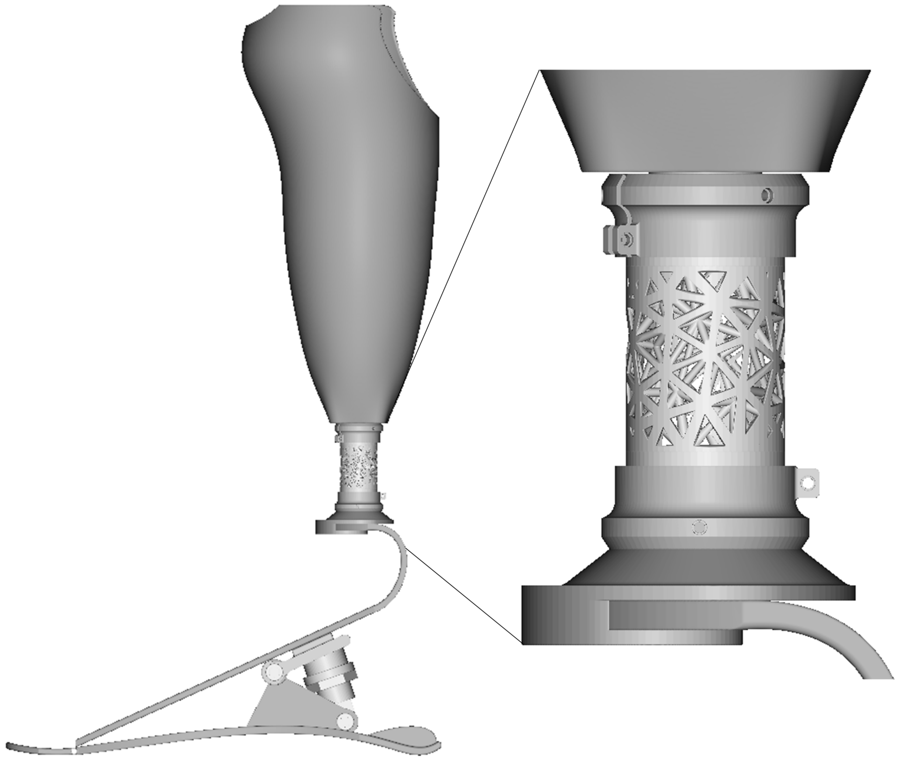

# Rapid deployment of patient-specific prosthesis assemblies in emergency medicine


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Amputation surgery is often necessary for severe musculoskeletal trauma following large natural disasters, military conflicts, and industry/infrastructure-related accidents. The inability to perform rapid triage due to logistical, socioeconomic, and safety reasons following a mass causality event, further increases the rate of limb amputation as blood loss and infection compromise the remaining tissue. Following limb amputation, individuals are often without a prosthesis and functional recovery support as the focus moves from human survival to rebuilding of infrastructure and more pressing societal needs [1]. However, it is imperative that those undergoing limb amputation receive a prosthesis almost immediately following surgery to allow for the maximum restoration of functionality [2].

The time and cost associated with obtaining a fitted prosthesis is often prohibitive in developing nations and difficult to support for private aid organizations due to the individualized nature of care required through the fitting process [3]. In addition, for infants and children, such prosthetic devices require periodic modifications to address growth spurts. Without proper fitting of prosthetic devices, individuals are unable to fulfill their potential, participate in society, or resume their activities of daily living. An example of this is following the 2010 earthquake in Haiti, where 96% of lower limb amputees has received a prosthesis at a two year follow up, with a mean time to device being 136 days [4]. However, the perceived function of the device at two years follow up was satisfied or very satisfied for only 22% of those receiving lower limb prostheses [4]. Therefore, it is imperative that individualized prosthetic design be re-evaluated with emergent digital manufacturing technologies in an aim to reduce cost, time to patients and functional recovery following events requiring a rapid medical response.

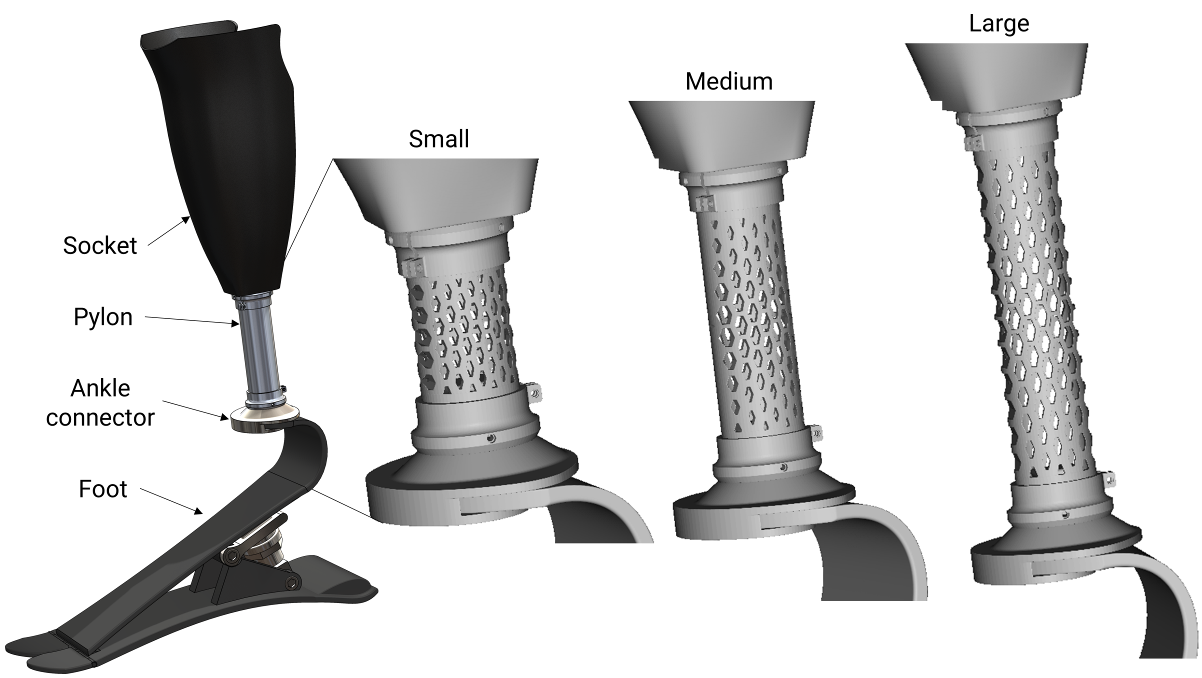


Figure 1: Prosthetic transtibial leg assembly (adapted from [5]) alongside gradient honeycomb inspired pylons with small, medium, and large variants.

# 1 Functionality and durability

Through the use of digital manufacturing, additional testing of functionality and durability can be simulated before deployment of the technology to ensure function in the field. Typically, individuals with prostheses would have an ongoing and lifelong relationship with their device provider to modify and exchange devices over time. In the instance of rapid response to catastrophic global events, it is more common that devices be rapidly provided with disregard for fit, customization, functionality, and longevity. By front-ending these design requirements, we can provide an improved final product to the user. Additionally, the use of loading field-driven design approaches enables possibilities of obtaining prosthetic CAD topologies that are functional, durable, and lightweight - as proposed in this report. The number one failure mode of existing prostheses is the poor fit of the socket (Figure 1) to the residual limb. By customizing socket design through the use of three-dimensional scanning and additive manufacturing (AM), this problem can be largely rectified without the costly and time-consuming practitioner visits. ISO 13028 is a technical standard geared towards goals of standardised durability and safety for lower-limb devices [6], which can be used to ensure the adequate performance of AM prostheses.

# 2 Utilization of digital manufacturing processes and materials

The necessity to provide remote care throughout the ongoing COVID-19 pandemic has revolutionized the ability to provide rapid response digital medical care. In combination with direct digital manufacturing, digital medicine provides an exciting new avenue for the rapid production of personalized prostheses. The most time consuming and costly aspect of individualized prosthesis design is the fitting of the socket to the residual limb (Figure 1). This often requires multiple visits to a specialized facility to cast the residual limb, generate a custom mould, and manufacture multiple iterations of the socket to ensure a perfect fit as to not further damage the remaining tissue.

Through the use of digital manufacturing this process can be markedly streamlined to allow socket fitting and design to happen offsite, and in the event of global disasters, outside of the zone of impact. Personal camera smartphones can now be used to obtain three-dimensional data of the residual limb. Contrasting markers will be placed on the skin of the residual limb and a series of video captures will be taken to capture and transfer limb geometry to manufacturing specialists. The three-dimensional reconstruction of the residual limb will be generated entirely in situ removing the need for in-person casting and fitting. Patient-specific socket designs can then be manufactured through multiple polymer AM techniques. There is also a possibility for the use of multi-material printing [7], or a combination of hard material printing and soft material overprinting (via volumetric AM [8]) to ensure comfort at the socket-residual limb interface.

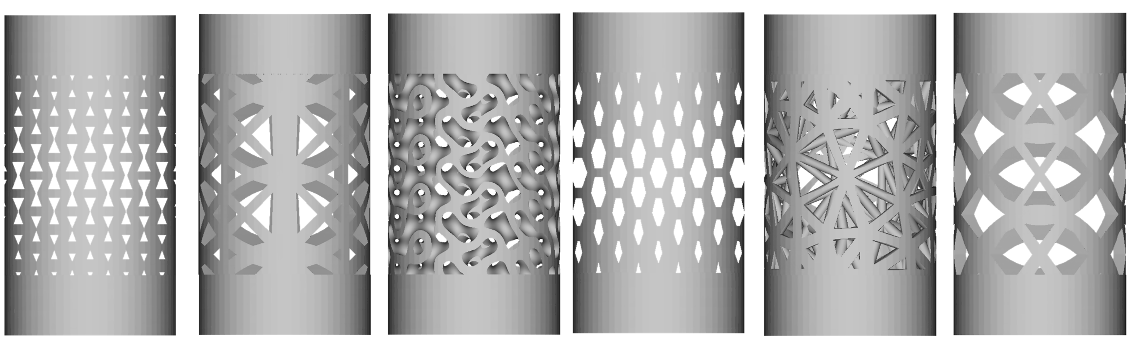

Figure 2: Gradient lattice options for the additively manufactured pylons.

From the prosthetic leg assembly shown in Figure 1, AM of the socket and pylon is proposed. Manufacturing of the socket will occur through fused deposition modeling (FDM) methods using polylactic acid (PLA), as this popular FDM material has been shown to have similar strength to conventional thermoplastic sockets using ISO 13028 testing [9]. Next, the pylon will be customized through nTopology to minimize part weight while accounting for individual body mass. Laser powder bed fusion (LPBF) manufacturing of the pylons using a lightweight aluminium alloy (AlSi10Mg) is proposed. LPBF (alongside electron beam melting) has emerged as the leading metal AM technology for industrial part production in aerospace, medical, and automotive applications [10]. The high industrial uptake of LPBF has lead to an increasing presence of affordable machines and reduction in overall manufacturing costs for batch production, useful for pylons [11, 12]. Additionally, LPBF enables a finer print resolution and best surface finish, compared to other metal AM technologies, thereby aiding the production of complex field-driven pylon designs [13]. The pylon will be ready-made in a suit of sizes - small (S), medium (M), and large (L) - as shown in Figure 1. Through rapid response enabled by direct digital manufacturing, prostheses can be custom designed, fitted, and manufactured in a matter of hours as opposed to the months required for traditional methods [14].

# 3 Design integration and innovation

The gradients of the pylon variants (Figure 2) were created in a way to avoid failures near the joining areas of the pylon with the socket and feet. Conventional pylons for this setup (left of Figure 1) would be hollow cylinders (inner and outer diameters - 18.5 mm and 20.5 mm respectively) with lengths of 40 mm (S), 70 mm (M), and 100 mm (L). AlSi10Mg built pylons would thereby conventionally lead to masses of 6.54 g (S), 11.45 g (M), and 16.36 g (L). The use of LPBF helps with weight savings of 25% (S), 28% (M), and 35% (L) compared to the conventional pylon designs. Conventional manufacturing of the dynamic response prosthetic foot (Figure 1) is proposed using spring moulded carbon-fiber infused PLA as customization is not necessary for this component for adequate performance [15]. Similarly, conventional metal forming and machining techniques can be used for the adapters required for the prosthetic leg assembly (Figure 1), as the three pylon size options would have the same diameter and only vary in length. Carbon fiber composite sockets exhibit better mechanical performance for sockets when compared to PLA and conventional thermoplastic sockets [9] but they: (a) cannot be manufactured by FDM, (b) are prohibitively expensive, and (c) the manufacturing technologies used for these sockets are not suited for rapid medical response [16]. Hence, the use of carbon-fiber infused PLA [17] or other industrial carbon-fiber infused FDM materials [18] will be provided as an option for the printing material for potentially improved mechanical performance (compared to PLA) with the caveat of a higher prosthesis cost.

# 4 Cost analysis, marketing, systems integration, and logistics

The cost of a traditional mechanical prosthesis can range from \$5,000 – \$50,000 with electro-mechanical models reaching >\$100,000 in some instances [19]. Therefore, existing high quality prostheses are prohibitively expensive when needed to address large scale disasters. FDM manufacturing of a prosthetic foot using PLA has already been explored academically with an estimated manufacturing cost of <\$15 [20], which has the potential of expanding rapid prosthesis deployment as a low-cost aid for developing countries.

The use of a popular material like PLA and an AM technology like FDM enables easy access to produce prostheis assemblies for small and large manufacturers, as well as hobbyist manufacturers as desktop FDM printers are currently available for <\$200. This allows aid organizations to maximize their prostheses distribution while minimizing cost.

Logistically, prostheses distribution following large-scale disasters is challenging due to the nature of medical aid provision [3]. By streamlining the prostheses distribution process through a direct digital manufacturing model people who have undergone limb amputation can receive custom prostheses faster and at less cost for aid organizations.

# 5 Social, environmental, health, safety, and regulatory compliance

The customized socket and pylon design enabled by the use of digital manufacturing can have lasting social implications by improving implant customization, alongside the functionality, durability, and lightweight features. The use of ISO 10328 [6] has already enabled positive results about the deployments of AM prostheses. Owen and DesJardins [9] report comparable strength of AM polylactic acid (PLA) transtibial sockets when compared to conventional polyethylene terephthalate glycol (PETG) thermoplastic sockets. Despite all of the advantages that digital manufacturing of prostheses for rapid medical response offers, further research is required on the durability of AM prostheses [21], relationships between socket fit and comfort [22], and standardization of upper-limb prostheses testing [23]. Lastly, digital manufacturing methods should be taught at prosthetic and orthotic centers to accelerate the adoption of AM prostheses [21].

## Acknowledgments

The authors would like Mark Fuchko for his invaluable insights to lower limb prostheses challenges and to thank nTopology, Inc. for supporting us with an educational license to their software for this project.

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