DESIGNED FOR ADDITIVE MANUFACTURING: UPPER LIMB PROSTHESES

Chris Baschuk, MPO, CPO, FAAOP(D)

Point Designs, LLC

ABSTRACT

To mitigate high levels of prosthesis abandonment for upper limb difference individuals, new manufacturing methods and techniques, including additive manufacturing (AM), and the principles of design for additive manufacturing (DfAM) can be employed to improve the weight, bulk, comfort, and heat dissipation of upper limb prostheses. This project demonstrates how the principles of DfAM can be applied to upper limb prostheses to address each one of these specific areas. This case study of the design, development, and production of a shoulder disarticulation prosthesis not only exemplifies the practical application of AM in creating more effective and user-friendly prosthetic devices but also highlights the importance of material innovation in solving complex challenges. As this technology continues to evolve, it holds the promise of further breakthroughs in prosthetic devices, offering hope and improved quality of life for individuals with amputations. The success of this prosthesis underscores the transformative potential of combining advanced materials like PA12 and TPU with the precision and flexibility of additive manufacturing, paving the way for the next generation of prosthetic development.

INTRODUCTION

Additive manufacturing (AM), commonly known as 3D printing, is revolutionizing the field of prosthetics and orthotics. Unlike traditional methods which often require molds, casts, and extensive manual labor, additive manufacturing provides a more streamlined, customizable, and cost-effective approach [1]. There are three distinct areas in which additive manufacturing offers additional advantages over traditional prosthetic fabrication processes such as laminations and vacuum forming (Table 1).

Table 1: Benefits of 3D printing in prosthetic design and fabrication

Category	Benefits
Materials	Expansive array of materials, from flexible thermoplastics to strong polymers. Ability to layer or combine materials for desired textures, flexibility, and strengths. Nuanced material choices tailored to user needs.
Design Flexibility	Precise tailoring to the user's anatomy using digital software. Incorporation of advanced features like lattice structures for weight reduction. User-driven designs with aesthetic and functional preferences.
Manufacturing Methods	Customizability inherent in layer-by-layer additive manufacturing. Ability to create complex structures unachievable with traditional methods. Precise control over prosthetic socket wall characteristics. Digital simulation and validation prior to physical production. Ease of adjusting designs.

The success of a prosthesis hinges on the proper integration of materials, design, and manufacturing methods by the prosthetist. When balanced, these components yield a prosthesis that harmoniously merges technology with the user's daily life.

BACKGROUND

There are multiple compounding factors that can result in a high rate of prosthesis abandonment for individuals with upper limb loss or differences. These factors may include any, or a combination, of the following: excessive weight of the prosthesis, excessive bulk of the prosthesis to accommodate prosthetic components, lack of adequate heat dissipation, improper fit, and inability to perform the desired functionality [2]. The more proximal the amputation is on the arm, the greater the likelihood that this abandonment will occur [3][4]. There have been advances in prosthetic socket design and trim lines over the course of the past 20 years that have been meant to address some of these issues however these designs have still relied on the traditional fabrication methods of thermoforming plastic, custom silicone fabrication, and performing composite laminations. These processes are well described and understood within the prosthetic and orthotic profession. An externally powered shoulder level prosthesis requires a significant amount of clinical time and technical labor to produce. The process to construct a definitive shoulder level prosthesis from the diagnostic phase requires the design and fabrication of a flexible interface, a rigid frame type socket, a shoulder bulkhead, a humeral section, and a forearm section. Special care needs to be undertaken to maintain the alignment of the modular components in 3D space with respect to the socket. This requires the creation of special jigs and fixtures to accomplish. Not all prosthetic clinics have the capacity to perform this level of involved fabrication in their own facilities and therefore often rely on outsourcing this process. The definitive fabrication process for a shoulder level prosthesis can take several days or more to complete depending on the requirements and complexity of the design. Once the definitive prosthesis is completed, any adjustments or changes to the overall design and function of the prosthesis are very limited without having to completely redo the fabrication process.

METHODS

To address the five above-described contributing factors to prosthesis abandonment, the principles of design for additive manufacturing (DfAM) were applied to the design and production of a revolutionary multi-material shoulder disarticulation prosthesis. Through the application of DfAM, a shoulder level prosthesis was able to be produced that relied on well-established socket design principles [5], but that utilized new methods and materials to further improve upon the design. Additionally, a digital semi-automated workflow was created in the process of the design and development of this shoulder disarticulation prosthesis that allows these same techniques and principles to be easily applied to all other levels of upper limb amputations. The production process is streamlined, reducing the time and labor traditionally required to create a prosthetic. This efficiency not only makes the prosthetic more accessible but also opens the door for iterative design improvements based on user feedback, ensuring that the prosthesis continually evolves to meet the needs of its users more effectively [6].

This innovative approach leveraged the distinctive capabilities of additive manufacturing to address and overcome the longstanding challenges associated with conventional prostheses, including bulkiness, weight, discomfort, and the complexity of fabrication. Designed for a patient in Canada aiming to return to work as a commercial truck driver, this prosthesis highlights the potential of using specific materials and modern manufacturing techniques to enhance user comfort, functionality, and acceptance.

To address the weight, bulk, comfort, and heat dissipation of the prosthesis it was determined that a combination of PA12 (Polyamide 12) and TPU (Thermoplastic Polyurethane) would be the most appropriate materials. PA12 is known for its exceptional strength, rigidity, and resistance to many chemicals and abrasion, making it an ideal choice for the structural components of the prosthesis. Its use ensures durability and longevity, critical for a prosthetic that must withstand daily wear and tear. TPU, on the other hand, offers flexibility and resilience, qualities essential for parts of the prosthesis that require movement or are in direct contact with the user's skin. The combination of PA12 and TPU, each selected for their specific material properties, enables the creation of a prosthesis that is both strong and comfortable.

The main socket and inner flexible portion of the prosthesis are comprised of lattice structures as much as possible. A honeycomb lattice structure was selected for its strength as well as the ability to reduce the overall material volume required for the prosthesis by 50%. This ultimately reduces the weight of the prosthesis by 50%, the material consumption needed for the prosthesis by 50%, and therefore the overall cost to print the components of the prosthesis by 50%. This choice in design and materials reduced the surface area of the body covered by the prosthesis by 50% because the perforations in the lattice on the inner flexible and the rigid outer frame are perfectly aligned.

Utilizing the principles of DfAM areas of the prosthesis that were meant to be rigid, such as the areas over the electrodes were able to be kept rigid while areas of the prosthesis that would benefit from having more flexibility were able to be designed to be more flexible through variable wall thickness. For example, the area around the shoulder girdle was kept more rigid whereas the area around the ribs was allowed to be more flexible. This allowed the prosthesis to better move with the user's body (Figure 1).

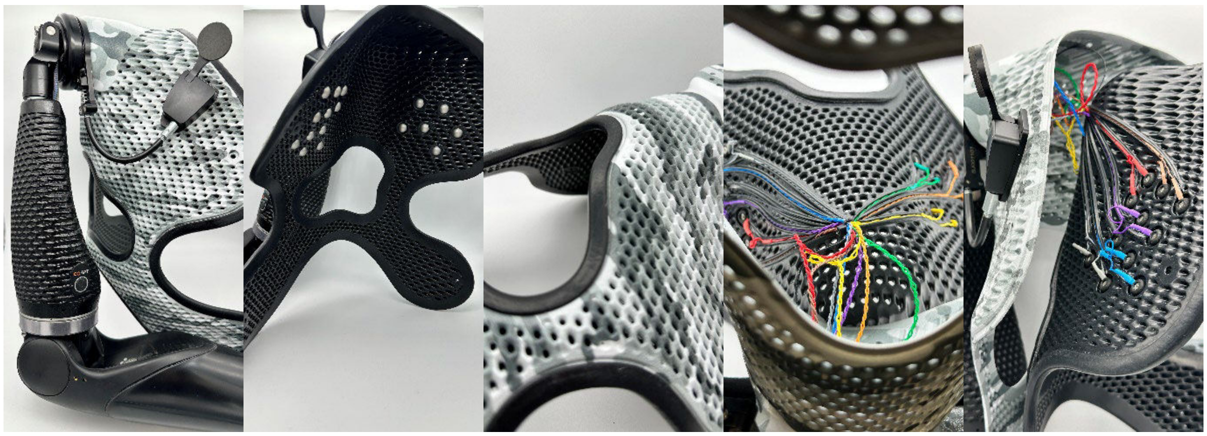

Figure 1: Images from left to right: outside of prosthesis; inside of prosthesis; close up of lattice structure and TPU overlap of rigid frame; wire organization of pattern recognition system; partially assembled prosthesis.

DISCUSSION

Utilizing AM, the prosthesis is custom fitted to the patient, ensuring a perfect match with their anatomical structure and functional needs. This technology allows for intricate designs that accommodate the electronic components necessary for advanced functionality, such as batteries, sensors, and wiring, without adding unnecessary bulk. Moreover, additive manufacturing significantly reduces the waste associated with traditional prosthetic fabrication methods, offering a more sustainable solution. This prosthesis utilized a pattern recognition system with 17 individual electrode domes. Because the inner flexible was printed from TPU it allowed for the electrodes and wires to be embossed into the material which significantly reduced the overall bulk and thickness of the prosthesis. Because the components of the prosthesis were all digitally laid out prior to the production of the prosthesis, clearances were able to be confirmed which allowed for the overall thickness and profile of the prosthesis to be kept as minimal as possible without sacrificing structural integrity. To significantly reduce the bulk along the trim lines the TPU inner flexible was designed to wrap around the edge of the rigid frame creating a seamless transition.

CONCLUSION

This project not only exemplifies the practical application of additive manufacturing in creating more effective and user-friendly prosthetic devices but also highlights the importance of material innovation in solving complex challenges. As this technology continues to evolve, it holds the promise of further breakthroughs in prosthetic devices, offering hope and improved quality of life for individuals with amputations. The success of this prosthesis underscores the transformative potential of combining advanced materials like PA12 and TPU with the precision and flexibility of additive manufacturing, paving the way for the next generation of prosthetic development.

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