THE APPLICATION OF ADDITIVE MANUFACTURING IN DEVELOPING 3D PRINTED PROSTHETICS AND ORTHOTIC DEVICES

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Abstract: This paper covers the advanced Additive Manufacturing (AM) techniques used to fabricate prosthetic and orthotic devices. It reviews the available literature and summarizes the advances in medicine, computing and engineering that have led to the development of currently available prostheses. Some of the open-source bionic hands and other available prosthesis are shown, as well as the technologies and materials which are used to manufacture the parts. Since prototyping, combined with the possibility for easy maintenance and repair, is very attractive for prosthetic design, as a conclusion we summarize and discuss some of the key areas that could lead to improvements in bionic limb functionality and use.

KEYWORDS: ARTIFICIAL LIMBS, ADDITIVE MANUFACTURING, 3D PRINTING, ORTHOTIC DEVICES

1. Introduction

Prosthetic and orthotic devices can help patients regain mobility and limb function post-stroke or amputation, but the process of creating custom devices takes time and labor. Additive manufacturing (AM) technologies can be utilized to create assistive devices that are better tailored to each individual in less than a day.

Prostheses are devices used to replace a lost limb, while orthoses are braces used to protect, align or improve function or stability to injured limbs. A research showed that more than two-thirds of stroke victims require long-term rehabilitation, and many of them can be helped with custom orthotics. The devices can also help children with cerebral palsy, myelomeningocele and other conditions gain stability and walk more easily.

3D scanning nowadays is also pretty common in reverse engineering lost limbs in order to speed up the orthopedic development and manufacturing. In the past, to make a custom brace for a patient, the patient would be covered in plaster and would have to lie motionless until the plaster hardened. It would then be cut off the patient and the mold would be sent to a brace manufacturer. There, all measurements would be done manually, and the brace would be sent back to the doctor for a final fitting. If it did not fit, the process restarted from the beginning. Digital technology speeds up the process of creating prosthetics and makes it a lot simpler and more efficient.

2. AM technologies used in developing 3D printed prosthetics

Using additive technologies such as fused deposition modeling (FDM), stereolithography (SLA), and selective laser sintering (SLS), allows designers and manufacturers to convert CAD data to three-dimensional products. Although these methods are still not suitable for bulk production volume, designing and building prosthetic devices is a customized process in which each model needs to match its user’s disability. This means the end product is unique for each patient. The design process for 3D printing a prosthetic device is similar to the traditional process—just more affordable and accessible. To summarize, the 3D-printed prosthetic process includes the following stages:

1) The stump and the rest of the arm are carefully measured so the prosthetic will fit the patient’s needs and ensure maximum functionality.

2) Either 3D scanning or creating a mold for the prosthetic will allow testing to ensure accurate measurements for the final design. 3D scanning allows the form and function of the prosthetic model to be tested on the computer CAD application before printing.

3) Once the prosthetic is scanned and converted to a 3D model, there are other factors to consider. Although the 3D prosthetic device can be computer-modeled based on the scanned arm using various CAD applications, many of these models are available for free download on the designers’ websites in separated documents for each part of the prosthetic. These free models can be downloaded in STL format, which is readable by all the available 3D printers. In most cases, customization should be applied in order to fit with the patient’s needs; this can be done using 3D modeling applications that support exporting the files in STL or OBJ format. In contrast with the traditional process, digital 3D-modeling of the prosthetic hand contributes significantly in reducing the production cost, time, and effort required to create the model.

4) The most used additive technologies for fabricating the prosthetic devices are FDM, SLA and SLS (Fig 1, 3 & 4). FDM is the cheapest of the three and it builds the model using thin layers of filament based on the STL digital model. And herein lies another advantage of the 3D-printed prosthetic: The materials used in...
traditional prosthetic production significantly increase the cost of the final product, but the plastic based filament used in 3D printing is cheap and can be modified easily, even after printing. SLA can be used more or less in the same devices as FDM, but offers better surface finish and potentially the use of special reins.

Fig.2.3. Stereolithography (SLA) – Schematic (Source: http://www.custompartnet.com)

Laser sintering or laser melting is used when there is a need for metal implants for a specific need. A Melbourne-based medical device company Anatomics 3D printed a sternum and rib cage implant by using high resolution CT scans. The sternum and rib cage features a complex geometry that means the flat and plate implants traditionally used for this part of the chest can come loose over time. For this reason, the surgical team thought a custom 3D-printed implant would be a better option. The implant was designed with pieces that went over the remaining bone and allowed them to be attached securely with screws (Fig. 2.5).

Fig.2.4 Selective Laser Melting (SLM) – Schematic (Source:cadimensions.com)

5) Assemblies are put together using cords, screws, and foam padding. In just a few hours, the entire prosthetic can be put together and ready to use.

Fig.2.5 3D-printed sternum and rib cage implant (Source: http://www.anatomics.com)

6) The prosthesis is then installed on the patient and evaluated for functionality. Specifically for devices meant for patients with amputated upper limbs, there is a practice period in which the patient has to learn how to move the device using the remaining muscles in his or her arm. This stage gives the designer some feedback for future prosthetics development and production processes. Many individuals, organizations, and universities are mounting initiatives to build 3D-printed prosthetics that match the efficiency of traditional prosthetics.

3. Upper limb prosthetics (bionic hand prostheses)

Upper limb prosthesis are (ULP), can be classified as follows [6]:

- Passive
  - Cosmetic Prostheses
- Active
  - Conventional (Body-Powered) Prostheses
  - Electrically Powered Prostheses
- Myoelectric Control
- Servo Control
- Push Button Control
- Harness Switch Control

Other hybrid types are also available. The authors in [6] also cover the human grip taxonomies. Feix et al. [8] summarizes 17 general grips from 33 types. The grips mostly used in the open-source projects are as follows:

- Grips
  - Pinch grip
  - Hook
  - Tripod grip
- Gestures
  - Full open / close
  - Thumbs up / down
  - Index finger point

There are a lot of commercially available types of artificial hands ranging from more hi-tech options to more affordable, open source prosthetics.

The open source options include projects like: eNable [9], Limbitless [10], NotImpossible [11], ROMP [12], Youbionic [13] and others. These prosthetics are based on more accessible 3D technologies and are meant to reduce their cost and use them in more remote regions of the world.
The inexpensive prosthetics are also very useful for children patients that are still growing. As stated in [2], only limited number of upper extremity prostheses are appropriate for young children. In these cases, most patients are fitted with either a passive prosthesis or a body powered voluntary closing terminal hook device given the durability and low cost of these options. More complex devices or myoelectric devices are rarely used in skeletally immature individuals due to both cost and weight. This makes the modularity of the design a paramount issue which can be solved by scaling the size of the hand and socket. This way users can easily print new prosthetics as they grow older.

However, the inexpensive design has a few limitations that include short battery life, noise from the motors, low grip strength of the terminal device and low durability of mechanical components.

A summarization of the characteristics of multiple upper limb prosthetics fabricated with 3D printing technologies is done by Vujaklija and Farina [3]. This review is shown in table 3.1 and covers the level of disability, the actuation and other features unique to each design.

<table>
<thead>
<tr>
<th></th>
<th>Level of disability</th>
<th>Printing material</th>
<th>Actuation</th>
<th>Control</th>
<th>Unique feature</th>
</tr>
</thead>
<tbody>
<tr>
<td>Origami Finger</td>
<td>Finger</td>
<td>Nylon 618</td>
<td>Passive</td>
<td>Body powered (finger phalanx)</td>
<td>Compliant</td>
</tr>
<tr>
<td>Cyborg Beast</td>
<td>Partial hand</td>
<td>PLA/ABS</td>
<td>Pre-tension /cable</td>
<td>Body powered (wrist)</td>
<td>Highly robust</td>
</tr>
<tr>
<td>Flexy Hand</td>
<td>Partial hand</td>
<td>Filla Flex</td>
<td>Pre-tension /cable</td>
<td>Body powered (wrist)</td>
<td>Compliant and biomimetic</td>
</tr>
<tr>
<td>Brunel Hand</td>
<td>Transradial / transcarpal</td>
<td>PLA</td>
<td>Electric linear actuators</td>
<td>EMG/IMU</td>
<td>CE certified</td>
</tr>
<tr>
<td>Etho Hand</td>
<td>Transradial / transcarpal</td>
<td>ABS</td>
<td>DC Motors</td>
<td>Not defined</td>
<td>Ball joint motorized thumb</td>
</tr>
<tr>
<td>Andriainesis’ hand</td>
<td>Transradial / transcarpal</td>
<td>Duraform HST</td>
<td>Shape memory alloy</td>
<td>EMG/FSR</td>
<td>SMA actuators and motorized wrist</td>
</tr>
<tr>
<td>Create arm</td>
<td>Transhumeral</td>
<td>Flexi fit</td>
<td>Pre-tension /cable</td>
<td>Body powered (shoulder)</td>
<td>Medical grade printing material</td>
</tr>
<tr>
<td>Robotic Arm</td>
<td>Transhumeral</td>
<td>PLA</td>
<td>Electric servo motors</td>
<td>Not defined</td>
<td>High level motorized device</td>
</tr>
</tbody>
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At the Wroclaw University of Technology a rehabilitation orthosis device was developed specifically for a patient with a partially-paralyzed hand. The wearable device needed to be light and comfortable, so as to avoid damaging the weakened appendage to which it’s attached, in this case the patient's hand.

The researchers set about tackling the problem by making a plaster cast of the patient’s right hand, and then using it to create a detailed 3D model. The model was then used as a guide when using CAD software to design a mechanical solution that would directly assess the patient’s needs.

The 3D printing-based CAD/CAM process often begins with a scanner to accurately capture the patient’s shape. With using a CAD software instead of modifying the shape to create a positive mold, the generated final device design can include sophisticated cellular wall structures of variable thickness and stiffness. The traditional CAD/CAM process involved carving a foam mold then thermoforming uniform thickness plastic sheets around the mold. 3D printers replace those steps by precisely depositing heated plastic beads or filaments to build up the final device directly.

Once the initial 3D model I developed it can be used for more than just fabrication. Because some fractures are frequently observed in certain regions it is helpful to study the mechanical behavior of these devices to determine the most likely areas of fracture, by analyzing the stress and strain distributions, using Finite Element (FE) analysis, on a simplified geometrical model. This is done in [14] in order to assess whether or not, personalization of the scanned model is contributing to increase fracture probability.
4. Conclusion

Thanks to the variable-thickness wall structures that can be generated by 3D printing, the stiffness and strength can be controlled at every point around the final device. That enables the fabrication of much lighter devices with greater stiffness in areas where support is required and greater flexibility in other areas for improved comfort. In many cases, 3D printing also allows you to create devices that are much thinner than is possible with solid, uniform-thickness plastic sheeting. Tailored stiffness, lighter weight, and greater comfort all lead to greater patient compliance and the potential for better treatment outcomes.

Additive manufacturing processes open up a lot more opportunities in fabricating prosthetic devices. The main benefit is that each prosthetic is unique and it’s possible to design and adapt individual devices very quickly with the help of CAD techniques. Another important issue is in the cost and availability of spare parts. In the case of failure it is easy to print the proper parts and implement them in the device. Unfortunately, the quality level of 3D printed prosthetics in some aspects still lags behind commercially available solutions, but the further development of materials and 3D technologies tends to close this gap at an increasing rate.

5. References