Developing "Growing" Prosthetics for Growing Children

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Abstract:

From birth to old age, humans are constantly physically changing, these changes are more minimal from adulthood. The stage this project focuses on is when the human is in the stage of development where there's the most changes; childhood. In childhood, the human body is constantly growing and developing with sudden growth spurts as well, an amputee or a child born without a ligament would be constantly needing their prosthetic limbs to updated and changed, this can be expensive and very time consuming in manufacturing.

Therefore, what will be focus on this project is coming up with a solution to reduce the need to constantly needing to update the prosthetic, so instead of the child needing the prosthetic needing a new prosthetic every 3 to 6 months, for the prosthetic to last up a 1 year or longer if possible. Doing this will reduce the amount of expenses needed to manufacture the prosthetic, additionally making the "growing prosthetic" to develop alongside the child if added AI is integrated into the prosthetic.

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1. Introduction

As part of the Laidlaw research essay/project, this report looks into how a “growing” prosthetic could be manufactured and prototyped for it to be used on growing children in the future so they would have prosthetics that last longer than prosthetics that are currently on the market.

1.1. Motivation

The motivation behind this ambitious project is to come closer in how to make prosthetic that could last longer periods of time. This is due to the fact that the manufacturing and production of prosthetics and any sort of orthotics take time and by the time the child has their new prosthetic, it may not fit them well and comfortably. Alongside this, children will go through many prosthetics whilst they are in the development and growing stage of their life, this is due to growth spurts and hormonal changes and also the fact that the stump of the limb can change as the body goes through these changes.

The two different aspects that will be looked at within this project that could also be potentially combined with each other are;

- Firstly looking at materials that could be “growable” meaning the material has enough elasticity in the material to expand and grow - similar to how memory foam remembers and holds the shape of the user. One potential material that could be looked at is different polymers and different techniques used in 3d printing, e.g. how 3d printed fabric is made
- If the limb is a hand, have integrated AI within a prosthetic and to keep the hand size to fit to the size of the body, have different sized outer shell cases that can be changed to change the hand size and same with fingers. The same approach can be done for a foot, mainly focusing on the ankle and knee if the user has no upper leg.

2. Primary Investigation

Within this section of the report, initial research is conducted. With this research, concept designs can be prototypes as well as how and which materials can be used and fabricated to make the initial “growing” prosthetic.

2.1. Current prosthetics

What is a prosthetic? A prosthetic is a device that is designed to replicate the movement or function of a missing body part to enable the person to be able to perform at a better standard. [1] When the word prosthetic is thought of, what usually comes to mind are devices that are manufactured in position of a limb that the person may be missing, however, prosthetics also include internal organs, joints and bones that a person may need replacing. For example, a pace maker could be classified as a prosthesis or knee replacement implants. These internal prosthetic help widely within the field of medicine, saving and improving the quality of many people who have had complication to their body.

Whilst the research and fabrications of internal prosthetics and prosthesis is always changing and developing, it is a slower case for external prosthetics. The issue with external prosthetics are that the prosthetics that are widely available to people don't really aid and improve the quality of life compared to the internal prosthetics that are available in medicine. However, those with money are able to afford the more advanced prosthetics.

Current prosthetics component that are available to the public by the NHS or other providers are [1, 2]:

- Body powered – these types of prosthetics are controlled by the body by using a cable that is controlled by a muscle or part of a body. For example, the movement of an arm would be controlled by the users shoulder.
- Motor powered – these prosthetics would already have pre-registered coding and movements, which the user would be able to control by buttons to control the movement of the prosthetic.
- Myoelectric powered – these prosthetics are still very new, as technology advances, so do these types of prosthetics. They are controlled by electrodes that are connected onto the limb of the user, so the user is able to control the prosthetic with the use of electrical signals. This makes it feels as if the prosthetic limb is one with the user and the body.

In a perfect world, all prosthetics that are available to users who need them would have prosthetics similar the myoelectric prosthetics, therefore developing on a way for prosthetics that grow with a child will make this one step closer to this "ideal" world.

2.2. Materials and fabrication investigation

Ideally, it would be suitable for the prosthetic to be manufactured using materials and components that are widely accessible, this is to ensure that the price of the prosthetic is at a reasonable range allowing the market to afford the prosthetic. If the prosthetic has a highly high price range, this can be off putting and discourage the market to get this prosthetic. Furthermore, of the fabrication process of the materials to manufacture the prosthetic isn't complex as well as the overall manufacturing process of the prosthetic, then this will also make the price of the product in a reasonable range to the market.

One of the materials that this report will be looking at is polymers along side with the method of 3D printing. Currently, 3D printing within the biomedical industry represents 11% [3] of the market share and is a strong driver for new technologies within the field.

- The general 3D printing process

3D printing, which is also known as additive manufacturing (AM), is a method of manufacturing where three dimensional object is created layer by layer by the use of CAD (computer aided design).

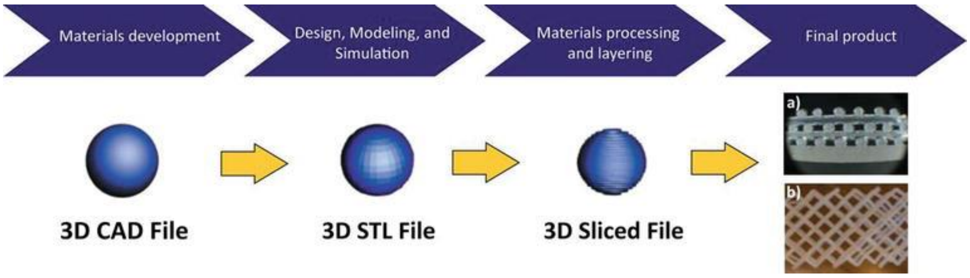

Fig 1. – the outline of the general process of 3D printing, all 3D printing methods follow this general process [3]

3D printing Technique	How it works	Materials	Cost	Advantages	Disadvantages
Inkjet 3D printing	With the use of thermal or acoustic force, the printer ejects small sizes of substrate	Natural polymers, such as collagen. Hydro gels	low	High printing res, low costs, fast printing speeds	Poor mechanical properties in printed objects
Fusion deposition Modelling (FDM)	Using liquid thermoplastics, the material is placed on the bed in a layered pattern	Thermoplastics	Medium	Low cost and large range of materials to work with	Only able to use thermoplastics
Extrusion Based 3D printing	Materials is extruded from one or more nozzles, under control, in a layered pattern	Most natural polymers, synthetic polymers	Low	Large range of materials to work with, flexible properties	Moderate resolutions in printed products
Stereolithography (SLA)	Free form technology is used on a photosensitive polymer under a formulation beam	Photopolymers	Low	High printing res, fasting printing speeds.	Cytotoxicity of the laser beam, difficult to work with
Digital Light processing (DLP)	Free form technology is used on a photosensitive polymer under a formulation beam	Photopolymers	low	High printing res, fasting printing speeds.	Cytotoxicity of the laser beam, difficult to work with
Laser – based 3D printing	High pressure is made from laser pulses which will bubble the material together	Natural polymers e.g. gelatine, polymers e.g. PCL and PLGA	High	High printing resolutions	High printing resolutions

Fig 2. - table of different 3D printing methods [4]

Using the table above, the two main types of 3D printing that could be looked at is Fused Deposition Modelling (FDM) or Extrusion-based 3D printing. Both of these types of printing is widely used in both in and out of the medical field of engineering, additionally, can be used with biomaterials, polymers and metals [4]. Looking at which material is best used for the prosthetic, it would be a mix of nylon and thermoplastic polyurethane (TPU). [5] Most 3D printed fabric are produced from TPU due to the flexible properties of the material, however, nylon is also a common material that is used in the manufacturing of prosthetics, it being light weight, durable and very wear resistant, hence making nylon suitable for prosthetics. Furthermore, Nylon also has some slight flexible properties.[5]

The idea of using the same geometrics as 3D printed fabric, for the casing of the limb, then in theory the casing should be able it have some elasticity to casing. For example, the main fabric of clothing has some give/elasticity to fit over our heads and limbs and it also stretches to how to the body moves around. To create this type of material via 3D printing, one method would be the infill method, instead of putting in a lot of the effort in the CAD process, it is more of taking advantage of infill patterns in the slicing programs of the 3D printer. [6] 3D printed objects aren't printed solid, as this would take up a lot of time of printing as well as a lot of material, hence the 3D printer will put the object through a slicing program, giving the object solid wall but a non-solid infill [6]. The infill of the object can be changed to look like fabric, but also having similar flexibility properties like fabric.

3. Secondary Investigation

Using the primary investigation research, the basics of how to prototype and design the initial "growing" prosthetic can be conducted.

3.1. Hardware

Within this section, what will be mentioned is the basic hardware that could be used to make the first prototype of the prosthetic.

Firstly to fit to the idea of the hand or feet that "grows" along with the child, there will need to be a microcontroller within the skeleton of the hand, foot or knee. From the microcontrollers that are currently easily accessible, Arduinos would be the best pick. The Arduino has a standard clock speed of 16MZ [7], looking at the Arduino Nano 33 BLE as a starting microcontroller, the device as a large amount of pre-existing libraries readily available to use when coding. Furthermore, if the prosthetic's AI part was made open source, this will allow the user to change up the coding to their liking. The size of the controller is 45mm x 18mm, making it ideal for it to fit into the skeleton. In addition to this, the Arduino Nano 33 BLE has features such as a 9 axis inertial measurement unit (IMU) which allows the micro controller to have accelerometer, gyroscope, and magnetometer functions. These functions make the Arduino Nano 33 BLE more suitable choice for the prototype of prosthetic. [8]

Sensors would be very important to the prosthetic. There are many types of sensors that could be used, such as infrared, ultra sound or time of flight (ToF). Out of these three sensors, infrared are readily available and inexpensive, however, they need to calibrate to the surrounding lighting and to angular conditions. Making the choice of sensors for prosthetics either ultrasonic or Time of Flight (ToF). Ultrasonic sensors measure distance with ultrasonic waves and ultrasonic sensors are similar to infrared sensors where the sensor releases an invisible light and emits it like the ultrasonic sensors.

3.2. Conceptual Designs

Using the research that was conducted within the initial research as well as the secondary research, concept designs can be made to have an idea of how the prototype would work or look like is a visual point of view. This can be seen from the figure below.

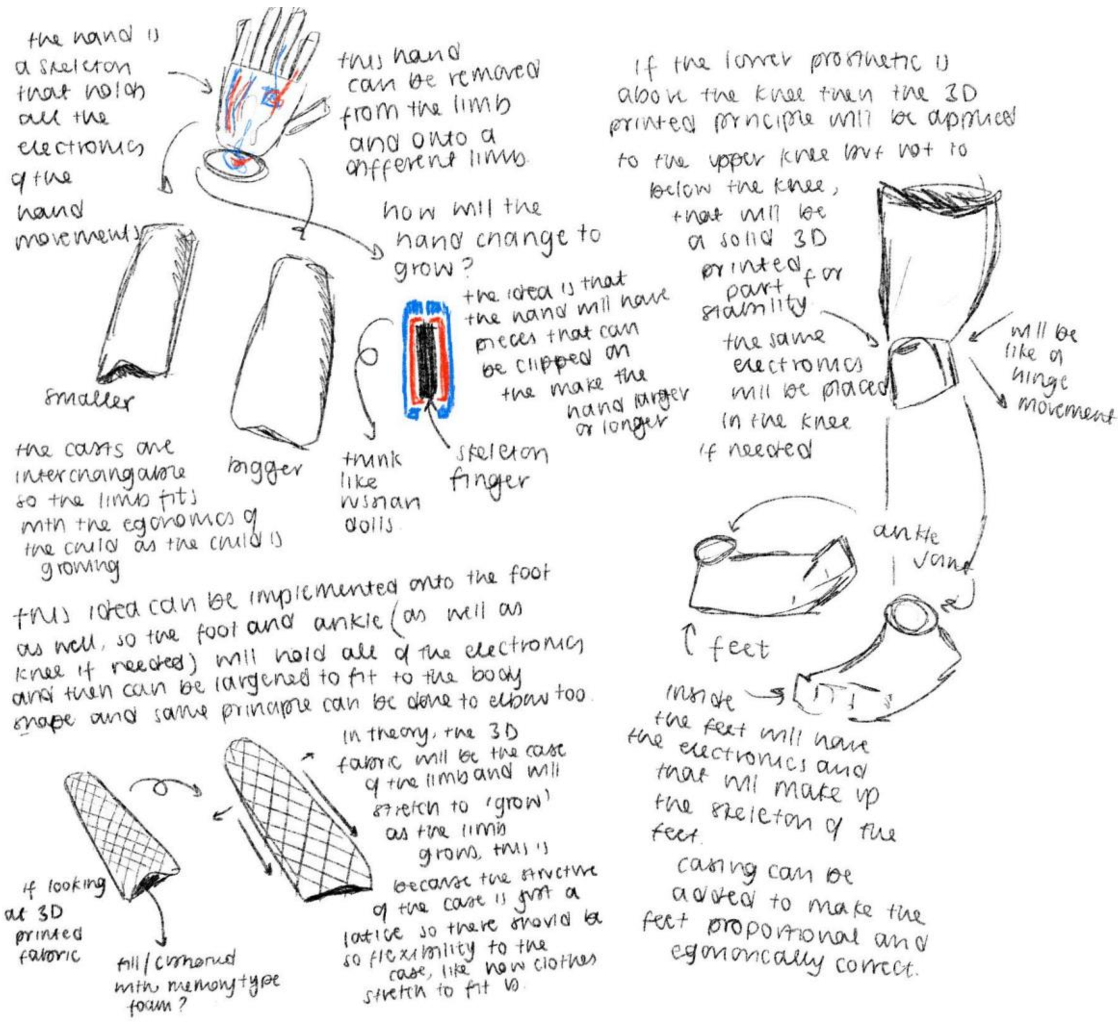

Fig 3. – Concept design of the idea of the growing prosthetic

4. Standards and legalisation

Before the prosthetic can be used by the market range, in this case, growing children, the prosthetic will need to go through compliance.[9]

The manufacturing process of the prosthetic will need to follow the specific requirements to ensure that the prosthetic meets the patient safety. The prosthetic would come under the category of part iv of the UK MDR 2002

It is also important that the prosthetic would need to be registered and comply with the MHRA. "The Medicines and Healthcare products Regulatory Agency (MHRA) is responsible for regulating the UK medical devices market." [10] Alongside this, the prosthetic would need to fit the specifications of the CE until 30th June 2023.

5. Ethics

There are a range of ethical considerations that need to be considered when manufacturing the prosthetic as well as when the prosthetic will be out for use by the market group.

Whilst the prosthetic goes under prototyping for improvements and development, the prototype will be tested by the market group, children, to ensure that the final product performs to the best of its abilities. When this testing happens it is important to;

- Ensure all data that is collected when manufacturing the prototype of the prosthetic is kept private and confidential for a certain period of time (e.g. if data was collected in 2022 then to be erased in 2025). This is as per the General Data Protection Regulation (GDPR). Security measures need to be put and taken into place to ensure that all personal information is safe. . Furthermore, stronger, legal protection is required for information on race, ethnic background, health etc. [11]
- All date that is collected to be kept anonymous, not leaving any links to the individual, as this applies to the "the Data Protection Act". [12]
- Respect all the volunteers and respect all the data we get from them.
- all volunteers need to give consent in taking part in the testing of the prosthetic. The consent has to be a written consent with a signature, however, an oral consent can be given too. But, the volunteer can at any point have the right to stop and back out at any given time. [13]

Other ethical considerations that needs to be taken account of;

- A risk assessment need to be carried out before the prosthetic is in the manufacturing process as well as when the prosthetic is in commercial use.
- Right to repair – the user has the right to repair at any given time, therefore, it needed to be made sure that the prosthetic is made up of components that are easily accessible as well as being low in cost with good working quality. Alongside this, we need to make sure that the prosthetic is easy to maintain for the patient.
- Environmental – the components and materials that make up the prosthetic should ideally be recyclable and during the production of manufacture of the prototype and final device, there should be minimal waste produced.

6. Conclusion

This project has been a very ambitious project from the very beginning, making it have some pros and cons in the research process, as there is some of the technologies that are needed to make the "growing" prosthetics that may not exist just yet, or there is the possibility that the entirety of the design of the prosthetic to be different depending on how the world of engineering and medicine will be as technology enhances and changes these fields. However, till then, this is a starting point on how the possibility of "growing" prosthetics could come onto the market, helping and easing the development of children. Using all the research that was conducted, ideally makes this report into a basic design specification and guide on prototyping the firsts of the "growing" prosthetic, on which can be changed as the prototype is developed.

7. References

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