Chapter

Design and Fabrication of Prosthetic and Orthotic Product by 3D Printing

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Abstract

In the clinical field, 3D Printing producing is a progressive innovation for various applications, specifically on account of its capacity to customize. From bioprinting to the making of clinical items, for example, inserts, prostheses, or orthoses, it is having a significant effect. Given that there are many energizing activities and organizations in every one of these territories today we will present to you a positioning of the best 3D printed orthoses. Dissimilar to prostheses that supplant a non-existent piece of the body, orthoses are clinical gadgets that are made to settle, soothe, immobilize, control, or right a piece of the body. Since every patient is unique, 3D printing is especially appropriate for these kinds of items and gadgets. Requiring an orthotic or prosthetic item likely methods a work concentrated, tedious, and chaotic procedure. For makers, creating great fitting orthotic and prosthetic gadgets is costly and requires profoundly gifted staff. Patients can anticipate that to a lesser degree a hold up should get their gadget, fewer fittings, and improved sturdiness. Developing a comfortable, properly fitting prosthesis is not just a science, it is also an art. 3D printing has the power to take today's bespoke, artisanal manufacturing process and transform it into a highly repeatable and consistent process, which ultimately results in more effective clinics and better patient outcomes.

Keywords: additive manufacturing, mass customization, product development, prosthetic and orthotic

1. Introduction

The design of medical products is a huge industry worldwide, of which, a major interest has always been the design of orthotics and prosthetics. Orthotics are devices, which provide support or stabilize an affected part of the body. They are used in cases of reduced musculoskeletal functionality. In most of these cases, the orthotics are used as the external aid or body support [1]. However, these supports can be used internally in the form of rods and braces. The most widely used orthotics includes splints, braces, slings, compression sleeves, and insoles. There are some simple orthotic products that we use in daily life such as glasses or spectacles, but these have been transformed from simple disability products to a fashion icon [2]. The timeline of Additive Manufacturing process is shown in **Figure 1**.

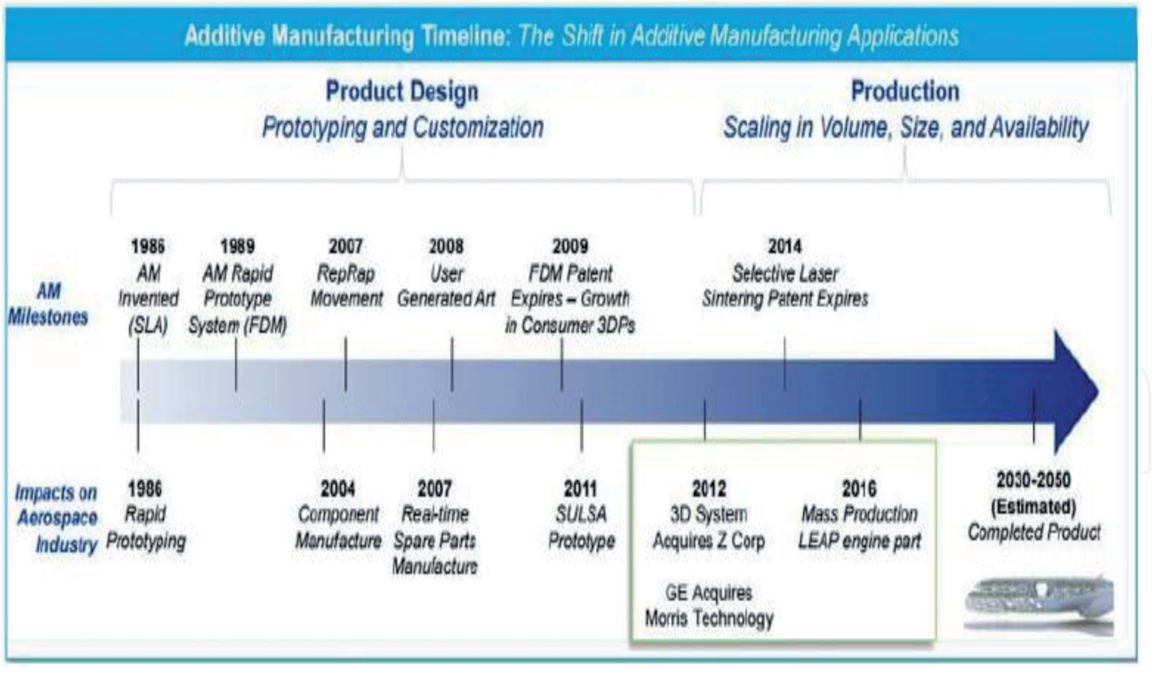

Figure 1.
Additive manufacturing process timeline.

Prosthetic devices replace or enhance the functionality of a body part [3]. They are used in cases of severe medical deformities or amputations. Other examples of prosthetic use include implants, artificial hearts and limbs. In previous studies, it is quite evident that the use of prosthetics not only aid the user by increasing mobility, but also helps in performing daily activities, thereby enhancing physical, social and emotional well-being [4]. The new science of "Prosthology" [5] deals with concept of the prosthetic part of the body being fully integrated as a new part of the body, as described by Gestalt's concept of totality [6].

Limb amputation has many disturbing and irritating impacts on patient psychology [7] often leading to stress and despair [8] Product design studies have suggested that the visual appearance of a product is one of the key elements affecting user choice and the product-user relationship. Visual esthetics also has the tendency to make products more acceptable and effectively usable in many cases [9]. However, this may differ across products and contexts. The overall appearance of a prosthetic limb is very important and may alter the level of the patient acceptance for the prosthesis [10]. However, in designing medical products, functionality is the designer's primary concern; with minimal attention given to product esthetics. This can affect user experience and satisfaction. Most of the available literature is focused on the technical and functional aspects of prosthetics, with only a few studies dedicated on esthetics, showing a lack of interest of designers and researchers in this area [11]. In the case of hand prosthesis, a previous study [12] also describes a prioritization of functional usage over esthetics. General steps of the 3D printing process as shown in **Figure 2**. While, another study by [13] suggests prosthetic appearance to be a factor that significantly influences the decision to wear or use a wearable prosthetics. The decision of whether or not to wear a prosthetic may be based on the user's life style and personal needs [14]. However, esthetics plays an important role in altering device adaptability. Additionally, if the prosthesis is purely functional but overly bulky, it can affect user acceptability and satisfaction. This can also have consequences which may affect the user's psychology state and social interactions skills [15]. In order to avoid such situations, it is important to focus on the esthetics of prosthetics.

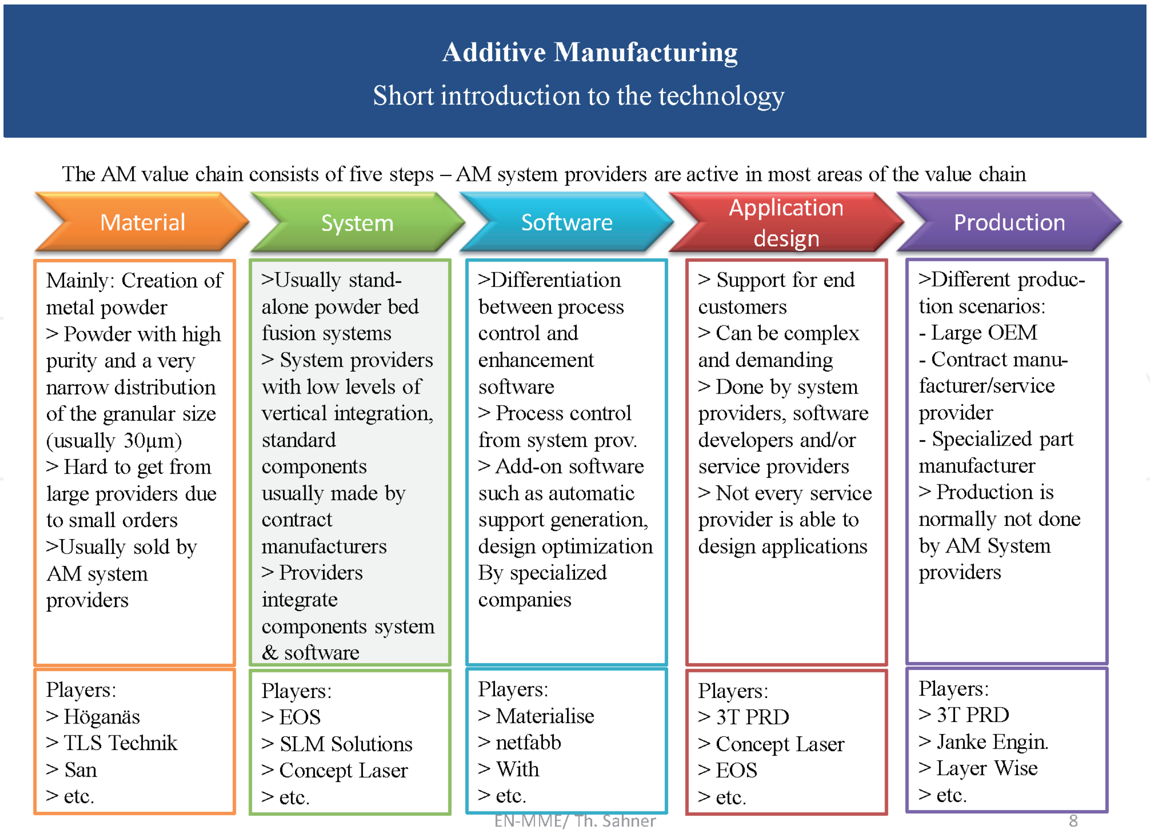

Figure 2.
General steps of the 3D printing/additive manufacturing process.

Several studies have shown that the acceptability of medical products can be improved significantly by addressing their esthetics [16]. However, a very limited number of studies have been conducted in the area of medical product design esthetics. The majority of these studies have mainly focused on improving the esthetics of upper and lower limb prosthetics [17]. There is still a wide range of possible medical products, whose designs can be optimized by improving their visual appearance and esthetic properties. In this paper, the authors explore the field of medical product esthetics. Some valuable suggestions and recommendations for medical product designers with the aim of improving user experience and satisfaction have also been discussed.

The joining of PC helped plan and assembling (CAD/CAM) has been around for fifty years. The innovation, which was initially evolved during the 1950s for use in the U.S. military, immediately spread to use by the car business. As the innovation filled in modernity, so did its applications. Today, CAD/CAM innovation is being utilized to produce everything from fine china and fly drive frameworks to-you got it-orthotic and prosthetic gadgets. Patients are as of now profiting by carefully planned and made cranial protective caps, AFOs, and numerous other orthotic applications, all or the majority of which have been made conceivable by the laser scanner, which has changed the manner in which shapes are caught and empowered massive advancement in the manners O&P professionals can think about their patients.

1.1 CAD/CAM technology in prosthetics and orthotics

The prosthetic and orthotic field has gone through huge changes with respect to innovative advances. PC supported plan (CAD) and PC helped fabricating (CAM), be that as it may, has increased just a moderate degree of acknowledgment in this field. Early programming programs were restricted in their capacity to exhibit to prosthetists that CAD-CAM was a successful device. As programming, equipment, and PC education increment, more specialists look to CAD-CAM to improve the effectiveness of their practices. New programming and equipment improvement ought to be embraced to advance acknowledgment of this innovation.

Computer Aided Design/Computer Aided Manufacturing is generally known as CAD/CAM, what's more, is an innovation that is used in prosthetics and orthotics. Foundation utilizes two strategies for CAD/CAM: one includes a fiberglass form which is then digitized into a PC for additional plan and assembling, while another strategy includes laser examining. The picture made is advanced and is three-dimensional. Foundation basically utilizes Biosculptor programming. Foundation utilizes CAD/CAM in prosthetics to catch the state of the leftover appendage, and in orthotics to catch the state of a patient's spine. With this exact picture, the specialist can change and address the shape electronically, and send the picture to our own profoundly qualified specialized staff for manufacture. The picture is then put away for future access.

For quite a long time, the manufacture of the prosthetic attachment has been a cautious and high quality workmanship endeavoring to make an agreeable, strong, and practical attachment for the remaining appendage. Through this attachment, the body's weight is moved to the rest of the prosthetic gadget and to the ground. It is the absolute most significant aspect of a prosthetic gadget, and the most individual and uniquely designed aspect of the prosthesis. As one would expect, there presently exists a huge scope of methods, styles, and ways of thinking on the best way to best make the attachment.

A careful form of the leftover appendage is certifiably not a decent attachment. The attachment must be precisely indented in territories that can all the more likely endure the exchange of powers, and the attachment must be soothed out away from the remaining appendage in zones that are less lenient towards power and weight. These uncommon regions of the attachment that require change are called locales.

Robotized innovation starts with getting an exact and reproducible advanced portrayal of the cut away appendage, and moving this computerized picture into a PC [11, 12]. Analysts actually banter the ideal method to "digitize" the remaining appendage, regardless of whether the appendage ought to be shaped with a cast or not, and whether the anatomic information ought to be acquired while weight bearing or not. Additionally, the level of exactness of the information keeps on being discussed. The primary effective frameworks utilized a hand-wrapped cast, which incorporated some conventional embellishment and alteration during the projecting cycle by the prosthetist. This prompts some variety in the beginning "computerized" map. In the event that a patient is casted multiple times, each cast and, in this way, each computerized guide will be marginally unique.

When the computerized portrayal of the remaining appendage is acquired, programming is utilized to include the alterations that change the advanced shape from a definite form of the cut off appendage, to the state of a working prosthetic attachment. This cycle is called amendment, and presents spaces on areas that can endure more weight, and help in districts that cannot endure weight also. Most programming bundles have layouts that will distinguish these locales and include these alterations likewise in any event, for various measured and formed appendages. There are in a real sense a great many varieties and speculations about the specific area and state of these areas, and on the best way to depict the inconspicuous subtleties of steady versus more sudden adjustment, and the area of the summit and the size of the change [13, 14]. Most programming bundles will permit an individual prosthetist to by and by refine the amendment cycle. Prosthetists can make their own layouts, so their top choice or best "corrections" can be imitated for different patients [15].

When the amendment cycle is finished, an altered model is cut, and an attachment manufactured over this model [14–16]. Once more, there exist an assortment of instruments for the manufacture of the attachment, and materials from which to create the attachment. While numerous prosthetists actually demand manufacturing every attachment inside their own office, the creation at this point do not should be done at the prosthetics office, and Central Fabrication locales exist to aid the various phases of the amendment and creation measure. When the attachment is conveyed, minor changes are frequently required, with the pounding or cushioning of little regions. The attachment then should be adjusted to ideally situate the leftover appendage according to the remainder of the prosthetic gadget, the weight bearing lines of power, and the ground.

The 1985 Special Issue of Prosthetics and Orthotics International- - CAD/CAM- - Computer Aided Design and Manufacturing catches and features huge numbers of the first ideas and thoughts from this time [11]. George Murdoch delineated the potential outcomes of making and fitting a few attachments surprisingly fast, and how this innovation will permit a professional and patient to investigate various ways of thinking of attachment plan or groundbreaking thoughts. He remarked on how this will build profitability of a prosthetist, and permit him to fit more patients in a given time. He additionally remarked on how this innovation will bring about improving the part of the handicapped in the creating scene: “there must be some reality in the fantasy that one prosthetist could quantify, manufacture, and fit many, numerous patients in about a solitary day.”

Bo Klasson, likewise writing in 1985, gave a fantastic early on audit of CAD/CAM, and featured a significant number of the applications and points of interest of mechanized frameworks. Computerized frameworks can dodge duplication of work, improve considering three-dimensional math evading physical models, disentangle contribution of information for investigations and show of results, streamline documentation of the item, and store insight and data from past plans. He brought up that reproducibility will be a significant angle later on, and that the handcrafting fitting cycle is not reproducible. He likewise brought up the expected effect on instruction by changing over quiet information, which is picked up by training and experience yet is difficult to report, into verbalized information, which is clarified and dissected.

Klasson additionally talked about Gunnar Holmgren’s high quality methodology and reasoning: that adjusting an attachment does not involve including or shaving endlessly a couple of millimeters anywhere, it is fairly a matter of changing the weight conveyances when making the cast. This discussion on projecting has proceeded. Klasson anticipated a Computer Aided Stump Measurement Technique, where the estimation procedure copies the embellishment cycle, effectively alters the shape, and reenacts the attachment before the estimation happens. This forecast has not yet become reality.

1.2 Current uses of cad/cam

So as to feature the wide scope of clinical employments of CAD/CAM in prosthetic practice, two offices were picked for in-house interviews. These two practices were picked in light of the fact that they speak to the closures of the range of CAD/CAM use. One is an enormous gathering practice that uses a full set-up of CAD/CAM gear to enhance in-house creation; the subsequent office is of an independent expert who limits overhead with an incredibly high utilization of focal manufacture.

The enormous private practice bunch has two workplaces, six suppliers, and two occupants. They possess and work a full in-house set-up of CAD/CAM gear, and accept the utilization of CAD to be their most effective model. The rule supplier initially bought a full in-house CAD framework in 1991. The next year, the gathering joined the utilization of another digitizer, beta test rendition of new programming, and another carver. This framework worked well until the finish of 1997, when the need to create spinal orthoses prompted the acquisition of an all-encompassing carver, digitizer, and redesign in programming. This update included changing over from a Macintosh framework to a PC framework. Tragically, the new overhauled framework was not completely utilitarian until mid 1999 when this gathering exchanged to an even fresher four-hub carver and a more current variant of programming. During this time of somewhat more than one year, the gathering returned exclusively to conventional manufacture strategies.

The current framework has been completely utilitarian for more than two years, and is utilized for creation of 95 percent of the TLSOs, 70% of the transtibial prostheses, and 40% of the transfemoral prostheses. Halfway foot, Syme, knee disarticulation, hip disarticulation, and all furthest point prostheses are finished by customary hand strategies. Transtibial prostheses start with a digitized hand cast, and every specialist has his/her own arrangement of layouts that function admirably for him/her. While the various experts all cast with marginally extraordinary method, their own inward consistency makes every specialist effective with his/her own arrangement of formats. For transfemoral prostheses, the ischial control attachments and elastomeric suspension attachments are made off CAD, while quadrilateral attachments and genuine attractions suspension attachments are made by hand.

This gathering creates around 30 TLSOs every month, and practically all are made utilizing the CAD framework. Strangely, essentially all TLSOs start with basic estimations, by-the-numbers method. Seven average/sidelong caliper estimations, seven circumferential estimations, and six length estimations are taken. The tourist spots are the navel (midsection), xyphoid, areola line, sternal score, ASIS line, pubis, and trochanteric line. This by-the-numbers approach has brought about a 95-to 98-percent effective first fitting, which is equivalent to the rate accomplished with the additional tedious inclined and recumbent projecting, and digitizing strategies. The specific, anatomic digitized detail is essentially not required for effective fitting of TLSOs in this predominately grown-up and injury populace. This gathering is as of now increasing some involvement in the new scoliosis conventions that depend on straightforward estimations, yet as of now digitize a hand cast for all scoliosis TLSOs.

2. Customary design attitude of ortho-prosthesis and need of esthetics

Conventionally, medical personnel such as doctors, physiotherapists and prosthetists are typically involved in the ortho-prosthetics' design process in order to ensure functionality. In the case of prosthetics and orthotics, functionality is important for enhancing mobility and fundamental in performing activities of daily living. However, the esthetic value of the product is generally neglected or only considered after the users functional requirements have been met [18]. Functionality is often considered as the cutoff requirement in process of designing medical products unless the product have some clear marketing value based on fashion and styling only. As the industry shifts towards user-centered designs, user experience has gained considerable importance and mainstream designers are increasingly aware of the impact. Hence, medical product designers now need to focus on product esthetics as well as functionality.

Today, we live in a world where bodily perfection and beauty are given a high priority. People who use medical products such as prosthetics encounter challenges related to esthetics such as social validation and acceptance [19]. Often unacceptance based on image and esthetics can cause feelings of social exclusion. Limb amputees face extreme difficulty in accepting new prosthetic modifications to their body [20], which can often lead to depression. Prosthetic users tend to avoid public exposure and are more prone to social isolation due to feelings of awkwardness and being self-conscious. These behaviors can affect psychological wellbeing, self-esteem and the ability to interact in social situations [21].

Design esthetics play a significant role in changing user behavior and product preference. A designer from Reebok theorized the value of good design by stating that "good design can make you fall in love with the product" [22]. Manufacturing process including Conventional and Additive processes as shown in **Figure 3**. By improvising upon esthetic features, users can have an opportunity to actively or to passively express themselves in their own unique way. Styling can enhance the acceptability of prosthetic usage among amputees by having positive psychological impacts. This can have positive effects on self-esteem and confidence. Hence, it is tremendously important to consider esthetics when designing medical products.

2.1 Parameters of esthetics affecting user experience

Incorporating natural elements in esthetic improves the user experience and acceptance. Many designers have used natural and organic elements in the product design process such as those found previously in Art Nouveau [23]. Organic elements not only mimic abstract human forms but can also be used as a stylistic element when designing prosthetics. Due to the level of craftsmanship and material handling involved, natural forms were considered to be difficult to manufacture. However, with emerging technology and ease of use of techniques like 3D scanning, modeling and printing, it has become possible to design and customize esthetically

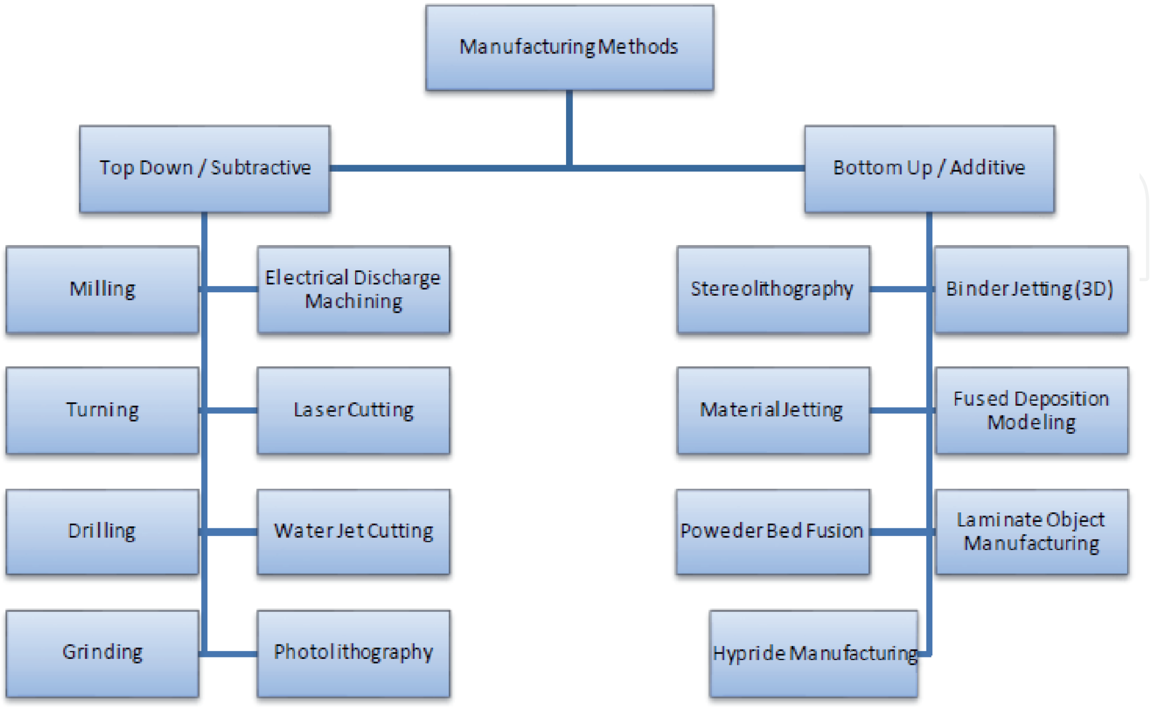

Figure 3.
Manufacturing process including conventional and additive processes.

pleasing medical orthotic and prosthetic devices based on personal preference. In the following sections, the authors attempt to explore the current esthetics issues of existing medical products and provide some possible suggestions and recommendations for improving these esthetic elements.

2.2 Shape and form

The shape and form of a medical device primarily defines its visual appearance. A study [22] attempted to investigate the factors affecting user satisfaction. They found that the most important factor suggested by the users was the shape of the device and how it matched the corresponding part of the body. For prosthetics, shape is an important element related to both functionality and esthetics. Another study [24] had similar findings. By exploring the relationship of Uncanny Valley and prosthetic devices. Uncanny valley is a hypothesized relationship between a prosthetic's human-likeliness and individual's emotional response to them. In the study, they selected 30 different designs with three different types of forms – artificial looking devices, devices with moderate human-likeness and devices with high human-likeness. Based on their results, the level of user attractiveness increased in proportion to the human-likeness of the device's form. This demonstrates the importance of designing devices with shapes that resemble or mimic real body parts. Conversely, other studies also suggest that this can generate negative moods instead of feelings of attraction [24]. Therefore, the impact of shape and form in the design process of ortho-prosthetics should be kept in considerate balance in order to promote user acceptability.

One of the key challenges in achieving an ideal product shape is the packaging and placement of functional elements (i.e., electro-mechanical components). For instance, some battery-powered medical devices, battery placement can be problematic if it is not considered during the design process. These elements can affect product esthetics and lead to user discomfort.

The workmanship and the development process also play a major roles in the form of the final product. With 3D scanning technology, it has now become possible to acquire accurate anthropometric data, which can be used to develop accurate digital human models [25]. It can also be used to develop highly customized medical products. With the continued improvement of 3D printing facilities, it becomes possible to produce such forms with a high level of precision and superior finishing.

Wearable art is one of the potential future trends in medical product manufacturing Wearables can be customized to fit a particular set of functional requirements and customary esthetic elements for every user. Existing orthotics and prosthetic devices could then be made to look like wearable art forms that blend with the users clothing. Esthetics and functions can fused together in this way to give psychological pleasure as well as the feeling of fashion and peculiar style sense. The esthetics of shape and form may differ based on gender. Previous studies have demonstrated differences in the choice of prosthetics that were based on gender perceptions.

In designing prosthetics for children, designers should make an attempt to stretch the boundaries of their imagination in order to make products interactive or in the form of wearable toys. Some research groups have also tried to develop Do It Yourself (DIY) types of prosthetics where the user is given the liberty to design their own device. A South African carpenter who lost his hand due to occupational hazards, sought a customized DIY prosthetic hand. He developed it using online resources and the help of a special effects artist. In addition to individual and laboratory-based applications, DIY prosthetics have also been developed as a manufacturing solution for amputees with the ubiquity and greater availability of more economical 3D printing facilities. The process of DIY ortho-prosthetic design and manufacturing can create new opportunities and facilitate in the design process of medical products.

2.3 Size and scale

The size of the product has a substantial impact on visual appearance. Size and material affect the weight of the device. If it is too large, it may cause discomfort and may be inconvenient for daily usage. Minimizing the size and visual prominence of prosthetics is important. Although reducing the size of a device may be more costly and technically challenging, it has a positive impact on patient's psychological well-being. Current braces have metallic parts, which are difficult to conceal under regular clothing. Smart textile materials can be used in place of metallic components to maintain product esthetics. However, if it is not possible to reduce size or to make a device more compact, then efforts should be allocated to make it unnoticeable and discrete in nature.

The size of a prosthetic should also conform to individual differences in body type to ensure that it maintains perfect symmetry with the contralateral part, side or limb. In order to develop products, which are generalizable and can be scaled according to a broader user base, it is important to understand individual variance in shape among the target audience. This can be accomplished by developing a database containing large anthropometric data samples based on country, location, ethnicity, age and gender of end users. Customization techniques like casting; last formation, which have been traditionally used, can be replaced by 3D scanning and modeling to achieve better results. In addition, modularity in ortho-prosthesis can be introduced at a grass root level to optimize device size and fitting. The concept of modular design can be implemented to achieve a "one size fits all" design methodology for mass production and may help to stabilize the user market.

2.4 Color

A lot of research has already been conducted on the relation between color, user perceptions and product selection. Although the range of color options for medical products is limited, still the color of the product contributes heavily in the product appearance.

In the case of orthotics, there is more flexibility to experiment with different colors compared to prosthetics. Depending on the application and user demands, products can be made transparent or incorporate color to stimulate concealing. The product design value for users changes when the product style or design parameters also change. For instance, traditional dental braces use metallic wiring to correct alignment issues. However, they are not esthetically pleasing and often make eating difficult for the user. Recently, several dental product manufacturers have started producing transparent dental braces without the slightest compromise on functionality. This example illustrates the influence of color preference in producing a positive user experience without sacrificing functionality.

With prosthetics, many users prefer the product to be similar to the tone of human skin. Due to the limited amount of color options for prosthetic devices, matching a user's skin color is challenging and may influence product acceptance. This could lead to a psychological unacceptance of the product as a part of their own body. Some users prefer their prosthetic devices to be more vibrant and colorful. Several new prosthetic limbs with printed artwork have been made available, which have been well received and successful among young users. Similarly researchers have tried introducing printed cartoon characters on orthotics designed for children which have been very effective. Body art's fashion trends such as tattooing are additional design possibilities whereby prosthetics can be perceived as more of a fashion statement rather than a reflection of personal limitation or disability. An intensive care must be taken to make the color of the device/product as natural and as iconic to meet the user's acceptability and psychological treat. The user should take certain cultural considerations into account when incorporating this type of device customization as it may not be appropriate for mass production. Interchangeable design skins may be a viable option in such circumstances. It is important to understand user needs and preferences when choosing the color of ortho-prosthetic devices.

2.5 Material and texture

Material selection is a key step in orthotic/prosthetic design. From the perspective of product design, material characteristics have a strong impact on the physical product. It is important to ensure the material selected has the necessary mechanical and physical properties required for the functional needs of the user. Concomitantly, careful consideration must be given when addressing more intangible characteristics like perceived values, personal associations and emotions. A study by, provides a detailed summary of key parameters to be considered by designers when selecting materials with a greater emphasis placed on the intangible characteristics of materials for improving the product design process. With advancements in material research and technology, it is possible, with new material options, to satisfy these intangible needs. Most medical prosthetic devices use metallic components to provide the necessary mechanical strength and polymers or plastics for the external encasing. Newly developed inert materials such as fiberglass, biopolymers and various metal alloys have been used to improve mechanical strength. The synchronization between user perception and product material should also be considered. Material texture preferences may be influenced by gender and various socio-cultural factors. Material, which mimics skin, may or may not be desirable depending upon the circumstances.

2.6 Adaptability to fashion and clothing

Just like physically fit human beings, people with special needs also have the desire to be perceived as attractive. An individual's appearance is highly affected by the style of clothing and fashion accessories being worn. However, the ability to use the prosthetic under fashionable clothing is an aspect often overlooked by medical practitioners when designing the device. Velcro straps can be used to affix bulky orthotic splints and braces which are often prominent, detract from personal esthetics and make it difficult to wear clothing over top. Due to bulkiness and prominent visibility of prosthetic devices, the range of clothing is limited Current design technologies have the ability to produce customized and sleek products which can be either hidden under clothes or can blend with an ensemble by matching the contour of an individual physique.

The majority of lower limb prosthetics are designed for wearing normal flat-soled footwear. This reduces the number of footwear options and may negatively alter the biomechanics of the prosthetics predisposing the user to postural imbalance and injury. Hence, there is a need for designing adjustable ankle prosthetics, which not only support body weight but can also adapt to different types of footwear. Following fashion and style trends are often important for the reasons of personal esthetic preferences. The aforementioned design considerations would help ortho-prosthetic users have greater autonomy and fewer limitations when it

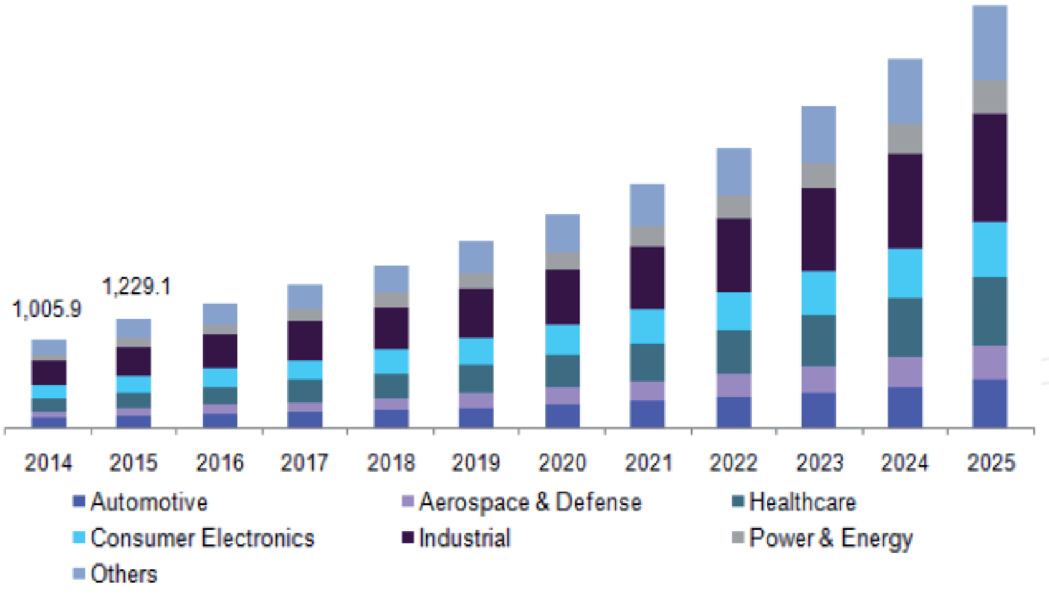

Figure 4.
Industrial growth in worldwide by 3D printing process.

comes to choice of clothing. This could have positive effects on social interactions psychological well-being and self-confidence.

2.7 Other factors

Factors like age, gender, cultural affiliations and personal attitude affect consumer esthetic tastes.Previous studies have shown that males prefer more masculine product patterns whereas females are more inclined towards products of beautiful and elegance. Regulatory and legal factors also affect material selection as products often needs to comply with standards approved by the Food and Drug Association (FDA). Industrial Growth in worldwide by 3D printing process as shown in **Figure 4**. Other factors, which also affect the design process, include the cost of manufacturing and affordability of the target users. However, esthetics should not be compromised based on manufacturing costs or material selection. Although traditional manufacturing processes help in producing more economical medical prosthetics in mass scale, 3D printing has proven to be highly cost effective concerning the customization of products. 3D printing can also avoid f material waste incurred during the casting and manufacturing process. In 100 addition, 3D printing techniques can be used to facilitate a modular development of ortho-prosthetic devices for individual customization.

3. Design approach – modular design

Modular designs are based on the concept of separating products into multiple parts, segments or modules that can be individually modified and customized. Recently, a large number of research contributions have been made in this particular area. A study done in 2014 proposed a similar approach, which they termed “Non-finito” product design. The products are intentionally unfinished giving users the option to customize and complete them based on their own personal choices and creativity. This kind of approach can help in achieving mass customization and facilitate product design flexibility based on individual preferences. Allowing users to be actively involved during the design process can help to initiate a better product-user relationship, which would better address the user’s needs. This can also make the potential problems encountered in the design phase more visible to the designers. However, this type of design approach is seldom adopted in the field of medical product design. Therefore, the team attempted to incorporate the concept of a modular design approach without compromising the primary function (i.e., locomotion and movement) of the prosthetic limb. As previously discussed in the introduction, for the construction of the orthosis two important points are necessary, firstly, the scanned arm, and secondly, the anthropometric measurements. The first step to make the model in 3D, is to open the file in which the image of the scanned arm is located as shown in **Figure 5**.

Once the file is opened, the sketch of the measurements is drawn. For the sketch, three drawings are drawn, corresponding to each small size (S) measurement, which are, the perimeter of the forearm (plane 1), the perimeter of the wrist (plane 2) and the hand's breadth (plane 3)as shown in **Figure 6**. This way, the orthosis construction will be easier, since, to start from correctly adjusted measurements, a stabilizing orthosis will be achieved.

The structure has been created by surfaces, where the tool "lofted surface" has been used, and the 3 edges corresponding to the measurements have been selected. Then, the previously created surface has been thickened and part of the structure has been cut to achieve the desired esthetics. Also, the whole piece has been rounded off for a better result. Finally, a sketch has been made on the top face, where holes of random size and position are created, thanks to which better ventilation and hygiene will be possible.

Figure 5.
3D scanning of human hand.

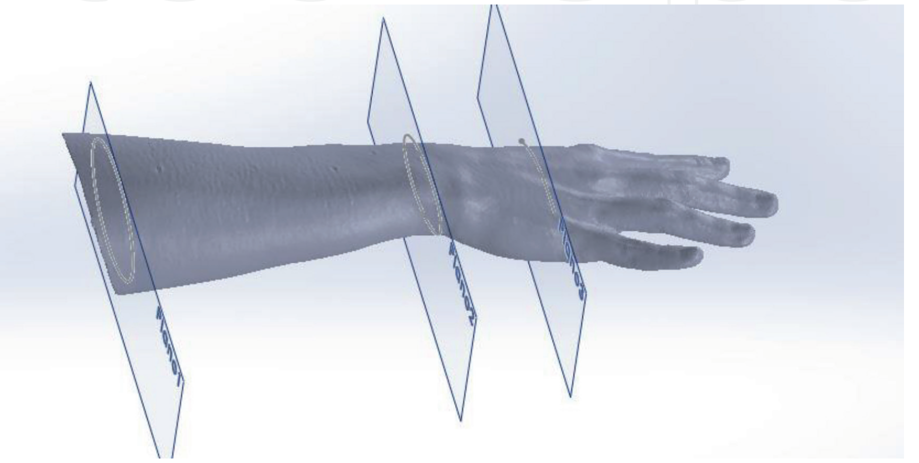

Figure 6.
Sectioning of 3D scanning file.

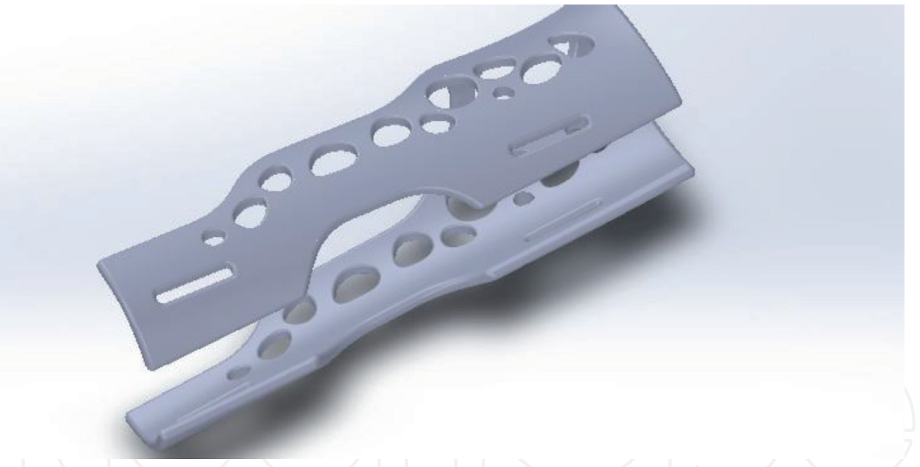

Figure 7.
Final 3D printed prototype for hand support.

Last but not least, the assembly is going to be made between the three components. The orthosis structure and the velcro bands are the parts of it, so a 3D model is going to be made. As final result it has been obtained a mass of 0,125 kg (125 g) as shown in **Figure 7**. A rather small value, so it can be said that the designed orthosis is a low weight orthosis, and that therefore it has been possible to satisfy the needs of a light and comfortable orthosis for the patient.

4. Result and discussion

Modular and DIY design approaches can help to address these issues by allowing the user to be more actively involved in the design process. With a modular design approach, it is possible to customize prosthetics based on the user's requirements. Users can also employ a DIY design approach by combining different prefabricated parts to manufacture their own product. This could facilitate the customization of such products on a mass scale. Additionally, designing ortho-prosthetic devices in the form of wearable art could revolutionize the field of medical product design and add an element of fashion to the customization process. Not only with this allow the user the option of incorporating their own sense of style or fashion into the development of their device but it can also create awareness for the inclusion of amputees across various social contexts. For ortho-prosthetic device users, better product esthetics are more than simply a means of flaunting or showing off, but means by which they can look and feel beautiful or be able to wear fashionable clothing like other people around them. Amputees have the same needs and desires as non-amputees. Meeting their needs is achievable when designers can give the opportunity to re-evaluate the ortho-prosthetic' design process with the objective of enhancing user acceptance in mind. It has been achieved a fairly simple esthetic, while innovative. This factor will make the product something attractive for sale, and therefore, it will stand out in the market. This esthetic has been chosen because the fact that it is a product for both genders as for all ages, so it is going to reach a greater number of people.

5. Conclusion

Allowing the end user to be more involved in the design process having user-oriented design (UOD) approach can improve upon conventional approaches to ortho-prosthetic device development. With the advent of modular design techniques, it is now possible to develop products, which are partially or entirely customized based on personal preference. Involving the user in the design process has positive psychological benefits and gives the user a platform for highlighting their creativity. Computer assisted design (CAD) systems have also been used to assist in creating the positive improving consistency and repeatability of this process, but the process remains slow and complex and it requires considerable input from experienced craftsmen. Furthermore, in these traditional processes the possibilities for innovation or product development are limited. With CAD systems it has been observed that orthoses rejection ratio has been reduced combined with time reduction up to 50% and cost saving up to 25% to 50%.

Maslow's hierarchy describes three different levels of user needs. These encompass basic, psychological and self-fulfillment needs. Traditional ortho-prosthetic devices address basic functional needs and allow the user to perform daily activities. Psychological well-being and self-fulfillment needs can also be met by addressing device esthetics. Ortho-prosthetic product design is a vast and constantly evolving field, which has undergone rapid growth. In past few decades, product designs for amputees have transformed from simple mechanical devices to highly sophisticated bionic devices. However, the esthetic features of these devices have received little consideration. Studies have shown that the absence of esthetics can have negative psychological and cognitive consequences for users. This study attempted to identify some of the key esthetic parameters, which influence the ortho-prosthetic design process. The authors have provided relevant suggestions and recommendations for addressing these issues with a modular design approach. A case study involving the design of a prosthetic limb socket was given to elucidate the benefits and implications of this user-centered approach. Developing a single product, which satisfies the needs of every individual user, is challenging. There are social, psychological, economic, cultural and personal preference factors, which influence user perception and experience.

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