Journal of Advances in Science and Technology
Vol. 18, Issue No. 1, March-2021, ISSN 2230-9659

Analysis of Additive Manufacturing Methodology for Limb-Part Prosthetics

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Abstract - The concept of Additive manufacturing is deeply studied, observed, and measured as a means of makingprosthetic devices for custom-made lower limbs. With the help of custom-made prosthetic device Amputees seems to be largely beneficial. Moreover, in increasing reachability for custom-made hand prostheses, additive manufacturing yielded good outcomes successfully, however there persist a requirement for evaluation of additive manufacturing that can be deployed for making lower limb prostheses systems. Elaboratelythis technique will be studied as a potential fabrication schemes, their classifications, various materials which can be applied, and a sequence of examples focusing how it has previously been effective in health sector will be explained. Proposed techniques focusses on virtual modellingof residual limb of patients and virtual procedure is highly combined and flow of data is as in liquid state as possible. There exist identification of three main phases:validation, design, and production of socket. Primarily, technician utilizes Socket Modelling Assistant (SMA) tool for designing of socket shape. Later, for validation of socket shape and regulating pressure distributiona numerical simulation is executed. Lastly, for making socket a multi-material 3D printer is applied. Firstly outcomes are shown andresults are drawn taking into account challenge of multi-material 3D printing of sockets.

Keywords - Additive Manufacturing, Limb, Prosthetics and3D Printing.

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1. INTRODUCTION

This research work is to recognize significant opportunities and present technical issues for application of innovative manufacturing methods in healthcare products. The healthcare [1] engineering has brought environment in a stage, where development in life sciences are not only agreeable to, but requires energetic contribution of engineering manufacturing and design to attainresolutions for complicated biological issues.

Infrastructure of Healthcare [1] executes a significant part in a society andis prospering at a faster pace in western countries; its features varies from other more conservativebusiness places, and put up issues in both development of newly developedand deployment of recent technologies. Medical researchers currently are looking for new techniques for production to make medical productslike; synthetic limbs, implants, prosthetic, customized insoles or customized orthotic device, planning and foot models for surgical equipment of assembling in inside body parts rapidly as well asmore precisely [2]. Many podiatrist use conventional manufacturing technique [3] like; plaster cast mold, milling, computer controlled milling and CNC machining to fabricate insole, which involves higher lead time. Moreover, incorporating novelty in design is not possible/limited because of the manufacturing method.

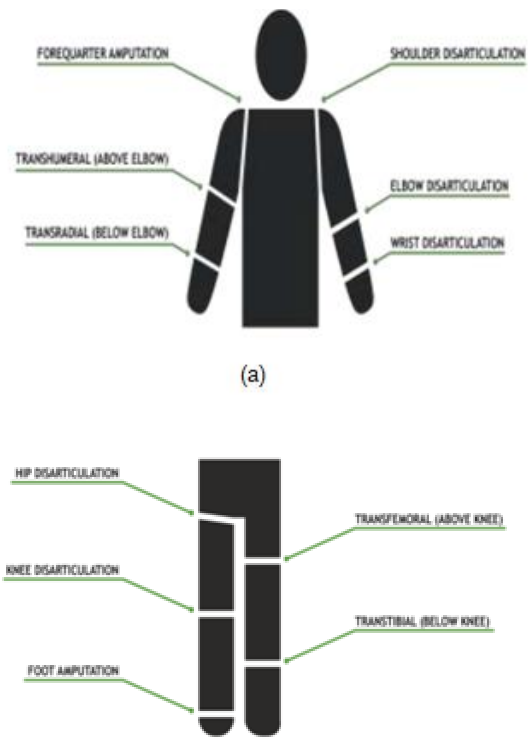
Additive manufacturing [4] exhibit significantpart forcustomized products production as it can produce parts with different shore values. For development of customized split insole, our studies emphasizes on discovering current technical issues and deliversexceptional solution by application of additive manufacturing method. By taking into account necessary anatomical observation on bio-mechanics, Custom foot insole is produced,plantar pressure, gait pattern and anthropometric information of human foot [5] – [8]. Aninnovativeproduct was createdafter considering differenthuman and mechanical parameters, and outcomes are explained along with probable enhancement that designed and developed insoles have catered [9], [10].

2. LITERATURE SURVEY

This literature review offers a structured review to aid the exploration in the research topic. The following sections provide a detailed outline of the health issues, healthcare product and the customized healthcare product manufacturing technique.

Both upper and lower extremity prosthesis are included in Limb prosthesis. At differentiating levels of amputationUpper-extremity prosthesis wereapplied as shown in fig 1 (a).: elbow disarticulation, wrist disarticulation, forequarter, trans-humeral prosthesis, shoulder disarticulation, trans-radial prosthesis, partial hand, full hand, full finger, partial finger. To replace missing arm missing lower to elbow, a prosthesis of trans-radial is used as man-made limb [11-12].

Lower-extremity prosthesis give substitutions at different levels of amputation as shown in fig 1 (b). These include trans-femoral prosthesis, hip disarticulation, knee disarticulation, Syme's amputation, trans-tibial prosthesis, partial foot, foot and toe. The lower extremity prosthetic devices are subcategories into two part; one is trans-femoral and another one is trans-tibial. Trans-femoral and trans-tibial are congenital anomaly resulting in a femoral deficiency and a tibial deficiency respectively [13-15].



(b)

Figure 1: (a) Levels of amputation for upper limb and (b) Levels of amputation for lower limb.

2.1. Development of Newly designed Product

It gets initiated with creation of idea and terminates ends with physical finished product, companies begins product developing pertaining to the market requirement [16]. Chidamber&Kon (1994) [6], mentioned that level of innovation was assessed by scientific approach and gets transformed application and technology. Corporates determining and identifying latest advancement in product as one of budding schemes which undergo this processes as a main activity inside any firm due to viable instability in product market . Such scenarios occurs because of the fact that, any products does not last long in the market hence corporates are bound to innovate and add upcoming products to design portfolio so as to substitute those product which will soon be outdated in a very near future (Grunert&Trijp 2014) [7].

Platform products is next product type that are taken from a product stagewhich should cater to need of different types of business positions (examples – Sony Walkman) (Simpson et al. 2006) [8]. Various corporates were applying product development that depends on platform to improve customization efforts in extremely competitive world market (Simpson 2004) [9]. As per (Simpson and Farrell 2003) [10], (Simpson 2004) [9], Platform product enhances the reaction to clients need, improvement in different range of product, decreases lead time, expenses of manufacturing and designing of goods. It was also realized that platform; high-risk and intensive process product cannot be included in scope of research, with perspective to this concept further, literature survey is based on narrowing down technology push with customized product in medicalhealthcare infrastructure . Insight to Current status of healthcare issues in India is given in following part.

2.2. Healthcare

Countries around the World are looking forward towards India, due to its high understanding and implementation regarding design and development in field of medical healthcare systems, socio-economic and political transformation (Patil et al. 2002) [11]. Need of sophisticated healthcare service has tremendously risen in India. Large proportion healthcare services are catered private practitioners and hospitals .Institutions like these increased by leaps and bound specifically in rural and urban portion of India (Bhat 1993) [12]. Unfortunately in a country like India, existence of entire spectrum of diseases is very high in countrysideregionscomparatively to urban zones, where people have adopted and evolved in accessing of healthcare services, however people from rural background still denies access to healthcare services mainly because of their disability to perceive its benefits (Patil et al. 2002) [11] (Murugesan et al. 2007) [13].

In terms of revenue and employment India has emerged as one of greatest sectors in healthcare. These facilities is quickly rapidly and is was found that its growth in 1990's documented to be whopping 16%, making around thirty four billion US dollars in today's market value (Hazarika 2010) [14].

From assistance of advanced technology applied in Healthcare industry has benefit by catering personalized medical aids or devices in treatment so as to produce more precise outcome (Chen et al. 2011) [15].

With respect to above literature, there arises explicit scope in development of innovative or new custom-made healthcare products wereto be mainly contributing in growthof this sector. Furthermore, literature survey unravels major research in an areas of (i) healthcare product (ii) Manufacturing methods and (iii) health issuesin design and development of customized healthcare goods.

It was found that there were many additive manufacturing processes that are accessible, however their basic principles of operation remains same. Primary phase involves constructing CAD model and later converting them to STL format. As soon as models are transformed to STL file format they must check and fix STL filesThereby generating support infrastructure, if required. Afterward, STL file is chopped into a different layer and generates physical product layer-by-layer, after the part is built, remove the support structure and post processes the product (Liou 2008) [16].

For enhancement of geometrically complex and custom-made products Conner et al. (2014) [17] suggested additive manufacturing processcomparatively to other preexisting manufacturing methods such asjoining, formative, subtractive procedures. To develop customized split insole there is a need of choosing suitable additive manufacturing process which is an aim of research to be developed.

Telfer et al. (2012) [18], suggest that additive manufacturing may allow innovative customized orthotic devices that is to be made with it, which is way far from current technological challenge. Salles&Gyi (2012), [19] conducted a study to explore the process of developing insoles for the personalized footwear using additive manufacturing. Additive manufacturing can produce anything which a designer think/imagines/design; part complexity and geometry were not influencing manufacturing capability of product (Diegel et al. 2010) [20].

Applications that are based on Medical additive manufacturing can be classified in different ways [21-22], however with respect to this research, different levels of uses are applied. Following groups could be utilized to classify additive manufacturing applications: education and planning,models for pre-operative training, tools, parts for medical devices and instruments, inert implants, medical aids, supportive guides, splints and bio-manufacturing and prostheses [23]. With reference to widergrouping, this could betaken into consideration with an intention ofgrafts are not needed to be unmotivated, prototypes for preparation of pre-operative, training& education, can alsocontainoperative and models used in postoperative conditions.

Supportive Guides, Prostheses, Medical Aids and Splints are prepared with additive manufacturing processes, suchthings could remain pooledthroughcustomaryuses inpermitting custom based designing. Fixators, motion guides, prosthesis sockets, external prostheses, orthopedic, personalized splints,Long-term and postoperative supports applications are some instances of uses in these areas [24–26]. Primary step isMedical imaging , which is thentrailed by segmentation, execution of 3-D scanning is done, or normally referred to as 3-D measurements, together which could give information that could be utilized in 3-D modelling procedures. As an substitute processing with additive manufacturing techniques CNC machine systems are widely applied. [27]. Based on various uses, different components may require variety of post-processing, likeheat treatments, removal of support, and painting or coating. Atypical proceedings of Additive Manufacturing phase in equipment of prostheses, splints, supporting manuals, and surgical aid. As an instance under consideration were customized,mobilizing reinforcement from outsideregarding fracture of pilon, where 3-D design is aimed atanalyzing activity of patient's ankle, replacing additive manufacturing parts for positioninghinge in such a way as if it administers displacements due to pressure near ankle's unrestrictedmeasure in body.

Diabetes Mellitus has become highest fatal ailments in entire world, and never stops in counting eventually growing exponentially; obesity enhancement and decreased physical exercise due to various machines agadgets is result of impact due to diabetes asan alterations in life-style at personal level [28].

Hindustan is growing to becomeas an epicenter of diabetes [29], comparatively a person having diabetes incur twice as medical expenditure than those individual‘s having nodiabetic conditions [30]. In accordance to this conditions, study and research is mainly narrowed in targeting on diabetic complications. Subsequent portion focusses regarding diabetic conditions and its problems.

In diabetic masses diabetic neuropathy is the greatest problem, affecting about50 % of diabetic populace [31], [32]. Weakening of intrinsic foot muscles and Loss of sensation is caused by Diabetic neuropathy, effecting in dysfunction biomechanically of foot by strange pressure flow in lower edge of feet [33]. Lower fringeproblems in diabetic masses initiates through neuropathy and consequently results in diabetic foot wounds, leading to contamination, gangrene and lower part of body amputation [32].

3. METHODOLOGY

Three main steps can be identified:

1. Socket modeling and Residual limb: From Magnetic Resonance Imaging (MRI) information 3D modelling of residual limb is created and shows initiating point for designing of socket. With assistance from an ad-hoc advancement in house CAD usesknown as Socket Modelling Assistant (SMA) Socket modeling is possible. Around 3D virtual prototype ofremaining limb SMA virtualizes entire stages of preexisting socket manufacturing procedures.

2. Analysis of Pressure: This platform combines a module particularly advanced to combine a numerical simulation tool and driveprostheticswhich is capable inrunning automatically with FE examination and authenticate socket functionality and design.

3. Manufacturing of additive Socket: As soon as perfect shape is produced as per outcome of previous steps, system autonomously produces3D print multi-material socket from geometric modelsby applying FDM methodology.

3.1. Socket modeling and residual Limb

Modeling processes were deployed autonomous or semiautonomous way and SMA dictates prosthetist step-by-step with a certain strings of protocols. SMA defines a set of design procedures and rules (example, how and where to change the shape of socket) and to design socket shape as per preexisting methods provides a collection of communicating tools virtually. Furthermore, for imitating hand-made procedures as age old tradition practiced by orthopedic technicians a software module make use of hand-tracking gadgets (i.e., Leap Motion device). Beyond technical issues of producing tools like ICT and application of handheld-tracking gadgets,significance ofsection in concern is majorly because of inner assembly it has with medical appliances. Prototype has been established using knowledge of orthopedics received by doctor'sdiscussions with finest case scenarios,embedded and coded in system. Recently, two types of communication mode is provided by the user interface of SMA. The first one depends on age old communication gadgets (i.e., keyboard & mouse) and secondary with handheld-tracking device that is low-cost. This is being done either for testing feasibility and potential with reference to a conditions where computer assisted tools are not generally deployed or in providing availability of modeling tools that allows to imitate highly handmade procedures. Primary stepsconstitutes providing patient's information and history, likemuscles tonicity, weight, residual limb and skin conditions stability that can be utilized in applying embedded protocols which proposes bettermethod for socket design. Residual limb's virtual model is produced from MRI images by assistance from softwares, designed and enhanced in housewhich autonomously result in reconstructions with no man made interaction, residuum 3D model.Three phases are constituted in reconstruction phase: 3D models generation, voxel segmentation and image pre-processing [3]. 3D geometric model is at an output, with neutral format (IGES) that allows CAD data interchange among modules composing platform of design. So as to model socket shape, residual limb and socket geometry are represented by triangular meshes. We embraced this representation as it enables us to emulate shape deformation with local changes implemented to mesh. Defining a preliminary socket shape is done in second step that can be refined as per morphology of residual limb in third phase.

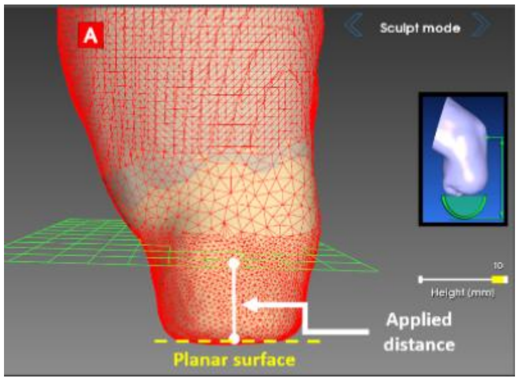


Figure 2: Socket pressure analysis of automatic definition of lowest zone

Taking into account various patient's characteristics socket shape can be furthermore optimizedresulting in socket shape approximately as expected. But, as fewfeatures could becomedifficult to be converted into models, such as mechanical properties of residual limb or theirdistortion whilegait donning.Figure 2, 3 showcases an instance of simulation outcome with respect to residual limb pressure distribution of a trans-femoral amputee in which perilousareas are coloured in red portion.

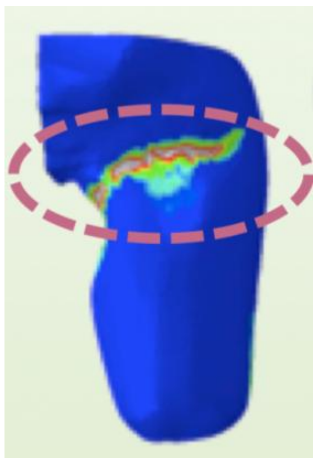


Figure 3: Mapdepicting pressure distribution on residual limb

3.2. Additive Manufacturing

Using additive manufacturing pattern various efforts and attempt have been carried out (in commercial perspective too) in making socket, however many of them depends on application of a mono-material for this purpose. We studied possibility and prospects to discussvarious mechanical performance with respect to specific socket zones by changing infill modes and combining two or more materials. We applied a 3D printer to manufacture socket that depends on famous FDM (Fused Decomposition Modelling) methodology. It allows in constructing product physical model protruding outside mixed or combined material for printing plane layer-after-layer [16]. Various kinds of plastic filaments can be used by us. Widely used are ABS (Acrylonitrile butadiene styrene), HPIS (High Impact Polystyrene) andPLA (Polylactic acid), but to confer great deformation we can identify few filaments which were calibrated through material of rubber for our goal in succeeding.

4. RESULTS

With an aim of initiating a validation procedure, tools and techniquesshowing till now is being used insome of cases improvingprospective mistakes and tuning system for more efficient use. With experimental information numerical simulation has been authenticated[14] and, presently, both simulation and modelling and tools are meanwhile in calculation to assess their performance and usability in association with professional orthopaedicexperts. In creation of socket's 3D models, Prosthetists have been involved extensivelyand numerical simulation have been executed prior to authentication of prototypes. Outcome of design phase has been understood with aid from additive manufacturing in applying extrusion techniques on material. In Fig5 a patient with socket is shown.

Figure 4: An LLP socket using printing

Figure 5: Patient demonstrates socket with latest digital process and AM

5. CONCLUSIONS

There exist UN ending requirement to deliver amputees with customised prosthetic devices is covered in conclusion. In most of third world countries due to unavailability of trained professional who can deliver amputees with quality custom-made prosthetic devices to relieve them from their everlasting pain. Such requirement of rise in accessibility to hand prostheses is recently being discussed with assistance from additively manufacturing methods. Hence, it becomes most significant part assess possibility of applying materials that are found in domestic 3D printer kit to produce an acceptable lower limb prosthesis for these patients. Moreover, benefit of applying additive manufacturing processes in producing medical devices previously done old-fashioned methods like casting, shows promising outcomes in thesespace of prosthetics. Advantages like these consists of improved regulations on manufacturing and material composition techniques. Withrespect to application of 3D printed lower limb prosthetics, there exist a need for further evaluation. We wish and hope that eliminating requirement for labor-intensive mold production for purpose of lower limb prostheses can be circumvented by use of 3D scanning and computer models combined with 3D printing schemes. Hence, by generating custom-made lower limb prosthetic devices and gadgets can be made available to a wider areas to needy patients.

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