A Review of Rapid Prototyping in Medical Implants

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ABSTRACT

The combination of two recent computer based technologies, rapid prototyping (RP) and reverse engineering (RE) have great potential towards important application in medical field. The replica of a fracture or defected bone with complex geometry is one of the applications to represent the present status and providing the state of the art as well as direction of the development for the use of additive manufacturing technique in medical field. This article reviews the current status and presents a methodology about the use of medical CT/MRI scanning, three-dimensional reconstruction, anatomical modeling, computer-aided design, RP and computer-aided implantation in treating a complex fracture of acetabulums, calcaneum, and medial condyle of femur (Hoffa's fracture). This paper reviews the suitability of RP technology and associated medical software solutions to transfer 2-D Digital Imaging and Communications in Medicine (DICOM) data into 3-D Standard Triangle Language (STL) data. This data is then utilized using medical software solutions to manufacture preoperative planning models and customized medical implants for the benefit of patients and surgical planning teams alike the project also gives an overview of relevant subject matter such as medical scanning,RP, preoperative planning models, customized implants/jigs and biocompatible materials. This paper reviews themethod of illustrating how the different technologies integrate and function to produce tangible successful outcomes that make a significant difference in medical interventions.

***Keywords:* Bio-Fabrication, Bio-Medical Devicesmedical Implants,Rapid Prototyping,Tissue Engineering,**

I INTRODUCTION

This Paper investigates the suitability of using RP technology and associated medical software solutions to transfer 2D Digital Imaging and Communications in Medicine (DICOM) data into 3D Standard Triangle Language (STL)

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data [32]. As per the requirements for Medical applications and individual patient data Additive Manufacturing (AM) provides extensive customization. This data is then utilized using medical software solutions to manufacture preoperative planning models and customized medical implants for the benefit of patients and surgical planning teams alike [33]. This paper also gives an overview of relevant subject matter such as medical scanning, RP, preoperative planning models, customized implants/jigs and biocompatible materials. Prior to RP the production of medical models of individual patients was very rare due to the difficulty and cost of generating (usually by CNC machining) complex geometry associated with anatomy [35]. Medical implants were manufactured using pressing, forging, machining and casting processes. Unfortunately, due to the limitations of the manufacturing processes this often resulted in bulky, poorly fitting and costly implants. With the introduction of RP technology, these types of problems were solved using the additive manufacturing (AM) or "layer by layer" process. Building intricate geometrical parts suddenly became less problematic and cheaper this helped RP technology gain acceptance by the medical profession [34].

II 3D DATA PROCESSING

1. Medical Scanning

Medical Imaging generates a representation of a patient's anatomy in order to facilitate medical diagnosis. Techniques include Computerized Tomography (CT), Magnetic Resonance Imaging (MRI) and Ultrasound. These tools increase diagnostic accuracy hence reducing both risk and the recovery time of the patient. Specific technologies are outlined below [1].

2. CT Scanning

A CT scan, also known as CAT (Computer Axial Tomography) is a non-invasive medical scanning technique. It uses x-ray technology to obtain geometric data of a body from different positions. A CT scan uses modified x-ray technology, selectively exposing sections of the patient to radiation. The data is then processed to generate a cross-section of the human body's tissues and organs [2]. In order to facilitate the tomography of certain organs, x-ray opaque material may be ingested or injected. Radiologists interpret tomographs, identifying trauma, diseases and determining the existence and impact of various pathologies.

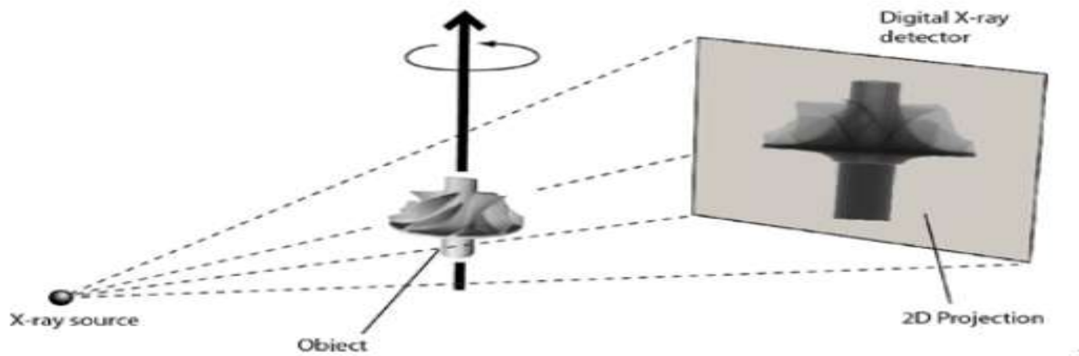

Fig.1: Working of CT Scanning [3]

Fig.2: CAT Machine [4]

Fig.3: 3D CT scan of Mandible Bone [5]

3. MRI Scanning

In 1993 the first functional MRI machine was developed which displayed an image of the brain [6]. The MRI scanning technique generates pulsed radio frequency (RF) EMR via magnetic coils. The realignment time of displaced hydrogen atoms contained in the tissues is determined and processed to produce an image of the tissue.

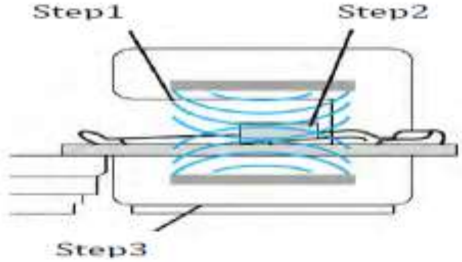

Fig.4:Working Principle of MRI Scanner [7]

4. Ultrasound

This technique uses the analysis of sound waves reflected within the human body to generate an image. In 1962 Joseph Holmes designed the first contact B-mode scanner [8].

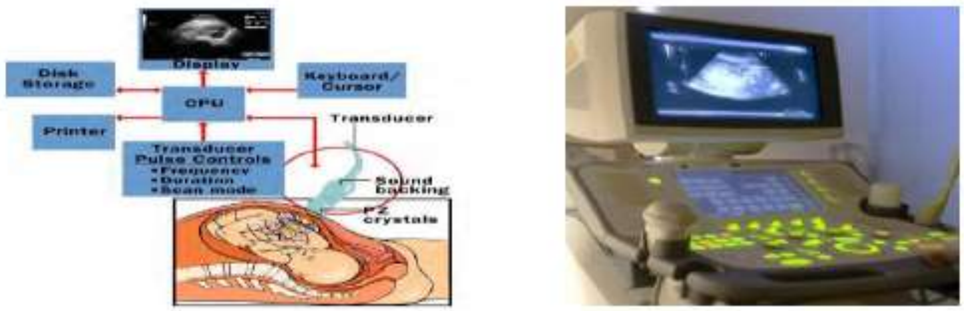

Fig.5: Ultra Sound Scanning Process & Modern Ultrasound Scanning Device [9,10]

5. Digital Imaging and Communications in Medicine (DICOM)

DICOM is a worldwide information technology standard established in 1993 [11]. The standard overs file format and transfer protocol, permitting exchange of data regardless of hardware origin. Devices that make up a DICOM system are:

a) Hardware modules, such as CT and MRI scanners

b) Picture Archiving and Communication Systems (PACS)

c) Reporting and post processing workstations

d) Printing services

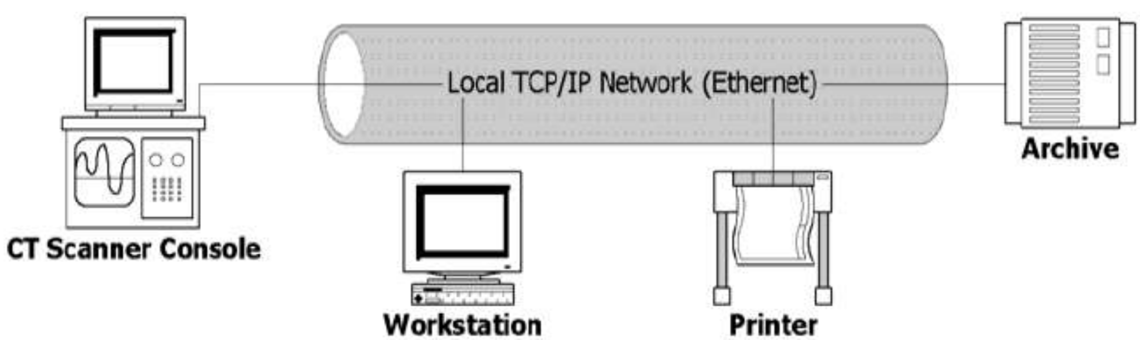

Fig.6:Standard DICOM Network [12]

III RAPID MANUFACTURING

1. Introduction to RP

The AM process generates physical models by depositing successive layers of material on top of each other. The profile of each layer is determined by processing CAD data, and the profiles of successive layers determine the overall geometry of the body. Materials include paper (LOM), photosensitive resins (SLA), polymers (SLS, 3D Printing) and powdered metals (SLS, SLM and EBM). Complex geometries can be formed, however part orientation, size and material are considerations. RP uses the above technologies to produce prototype models for analytical, marketing and investment decision purposes. One of the most significant breakthroughs in recent years has been the identification and potential use of RP technology within the medical field. In this sector RP is used for generating preoperative models of the human anatomy for the cranial and maxillofacial regions. This area has been further developed to design and build custom fit implants for both in vivo and in vitro applications. The intention here is to increase the quality of patient's lives who are burdened with a defect caused by trauma, genetic defect or disease. Although RP has many advantages, it does not solve all design problems. It does conversely simplify problems in areas that are very difficult to overcome using existing conventional design and manufacturing techniques.

2. Integration of Medical Modeling and RP

It was created to investigate the process and significance of constructing solid medical customized anatomical models. This was done in the context of preoperative planning, simulation and optimization of intricate surgical interventions. The models developed were based on high resolution images taken from CT and MRI scans and developed into physical models built using RP processes. One of the findings of this project identified that the accuracy of the models are influenced by the accuracy of the medical images and scanning equipment used. Subsequently project networks were established between 40 different partners across 11 European countries which formed a research network. The network was primarily involved with performing specific research and commercialization in the areas of medical modeling. This research became involved in all areas of medical modeling such as image generation and processing, clinical research and machine development.

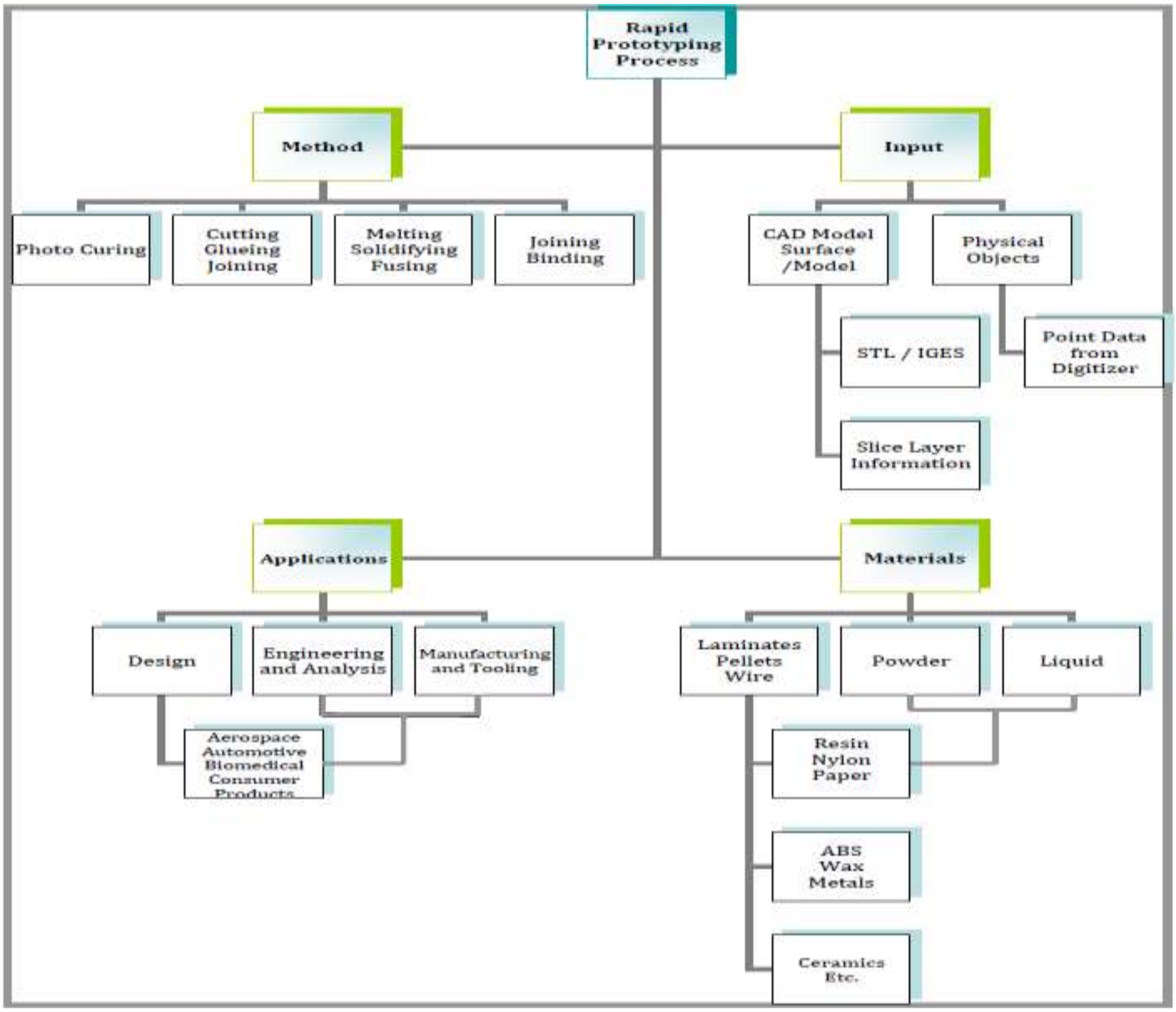

Fig.7:Overview of RP Process [13]

I. PREOPERATIVE PLANNING MODELS

1. Introduction

Due to the complex nature of the human anatomy good preparation and accurate patient data are fundamental in achieving precise and repeatable results. Preoperative planning models have been used since the early 1980's for maxillofacial, orthopedic and oral applications. Anatomical models were traditionally manufactured using a five axis CNC machines but had limitations in terms of undercuts and thin cross sections. These short comings were eliminated by RP technology and were subsequently identified as a suitable manufacturing method for preoperative planning models. The previously mentioned Phidias Project was initiated to develop and integrate RP technology into the medical sector. The project's recommendations led to developments in data acquisition technologies. This,

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combined with improved RP, has led to the availability of preoperative models that are fit for purpose. Preoperative planning models have become one of the preferred tools available to surgeons [14].

2. Physical Modeling

In complex medical cases it can be difficult for surgeons to ascertain a patient's medical condition. However this can be overcome at least in part by having a physical model of the patient's anatomy. This allows medical teams to intuitively understand complex anatomical details. Precise preoperative planning models also facilitate the accurate calculation of medical implant geometry and assist with proactive surgical planning and preoperative training. This helps to identify surgical risk and appropriate actions to reduce same. Overall surgical time and risk to the patient is therefore minimized. Review of medical research papers indicates that increasing use of preoperative planning models yields several advantages.

3. Benefits of Preoperative Planning Models

I. Improved patient confidence
II. Improved communication, leading to reduced ambiguity
III. Reduced operating times
IV. Decreased level of risk to patient
V. Faster recovery time
VI. Improved incision accuracy
VII. Reduced numbers of corrections
VIII. Physical models of dislocated elements facilitate predictable surgical outcomes
IX. Used as a reference during preoperative planning meetings
X. Benefits in terms of diagnosis, treatment planning, as a reference during surgery and in the fabrication of custom made implants and surgical jigs and fixtures [15]

Alternatives to preoperative planning models are virtual or augmented 3D models. Virtual and augmented 3D models have been used with the aid of head mounted displays and holograms which are a significant improvement over 2D images. One of the major benefits of using this technology is the ability to overlay images. Limitations associated with this technology, include:

I. Deformed anatomical geometry can be difficult to understand
II. 2D visual displays do not provide an intuitive interpretation of 3D geometry
III. Planning complex 3D interventions based on 2D data can be complicated and misleading [16]

Surgeons vary in systems preference, but it is always beneficial to have a physical model during medical interventions.SLA models of the cranium have proven in many cases to be very useful for preoperative planning models and surgery simulation. The material characteristics of SLA models allow various mechanical procedures to be performed such as removing burrs, drilling and the location and installation of fasteners. Another advantage of the process is its ability to produce enclosed voids. The fact that the model is transparent allows internal canals and structures to be visible. This permits the modeling of other medical conditions such as tumor expansion and reduction of arteries which lead to reduced blood flow.

4. RP Processes and Preoperative Planning Models

The processes mainly used for the generation of preoperative planning models are:SLA,FDM,3D Printing,SLM, although this process is mainly used for producing custom medical implants. The above model was built on a Connex 350 machine, by Objet. Constructed of transparent FullCure 720 material and FullCure Vero material and allows the generation of 3D translucent medical models. This model shows details such as nerves, arteries and tumors and displays the full versatility of preoperative planning models [20].The bone based on this model had to be reset 9 times due to the fact that the surgeons had poor radiological 2D data. Therefore bad alignment resulted in multiple surgeries.

Normally the recovery time for this fracture would take 6 weeks but took 54 weeks and extensive physical therapy. Successful alignment was eventually achieved using a CT scan from which a 3D RP model was made.

Fig.8: FDM 3D Human Skull Model Showing a Severe Cranial defect [17]

Fig.9: SLA Model of Mandible Bone fitted with customized implant [18]

Fig.10: FDM Partial Spine Model

Fig.11: 3D Printing Model Biomedical & Translucent Preoperative planning Model [19]

Fig.12:3D SLA model of a Pelvis & Femur [21]

Fig.13:Right forearm FDM Model with a Broken radius bone [22]

II. CUSTOMIZED MEDICAL IMPLANTS AND JIGS

1. Introduction

Applications for customized medical implants include maxillofacial, cranial, knee and hip implants. Implant profile determination is a limiting factor, leading to implant categorization as "standard" and "custom". The use of iterative design differentiates custom from standard implants. [60] In certain circumstances anatomical complexity indicates the use of a custom implant. AM technology is ideal for the production of complex geometries, and hence is the method of choice for implant and orthotic device manufacture. These geometrically accurate implants have become a proven technology and are preferred by surgeons to traditionally manufactured devices. Surgeons fit customized implants for the following reasons:

- Reduced operating time
- Reliable and relatively low cost

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- Reduction in time between diagnosis and surgery
- Reduced infection rates
- Minimal excision of good tissue [23]

2. Customized Implants

Customized implants are made for many parts of the human anatomy specifically for each individual patient to increase functionality, aesthetic appearance and reduce discomfort. Some examples are provided in this section.

2.1 Scaffolding and Tissue Engineering

Tissue engineering requires *inter alia* the implantation of customized permeable implants (scaffolds) to support tissue regeneration. One of the main characteristics of a scaffold is that it must contain micro channels with a high degree of porosity. This property allows the generation and diffusion of tissue cells and nutrients which facilitates the speedy generation of new cell tissue. In existence since the 1980s, original scaffold manufacturing processes yielded poor pore size and geometry repeatability. Contemporary AM technology obviates this problem.Knee implant procedures are performed on a regular basis due to the breakdown of thejoint induced by cyclical loading causing wear and degradation.

2.2 Knee Implant

Knee implant procedures are performed on a regular basis due to the breakdown of the joint induced by cyclical loading causing wear and degradation.

3. Mandibular Implant

A common maxillofacial trauma is mandibular bone fracture. Accurate design andpositioning of the implant facilitates aesthetic and functional recovery.

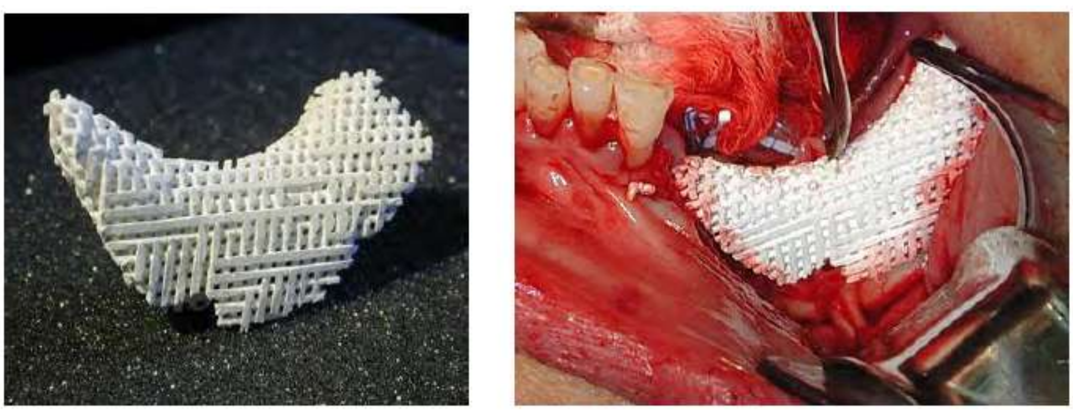


Fig.14: A post machined FDM hydroxyapatite manufactured scaffold used in the reconstruction of a mandibular implant [24]

(a) (b) (c)

Fig.15(a): SLA pattern of a hemi-knee joint

Fig.15(b): A master for the titanium joint

Fig.15(c): implant for the femur bone [25]

4. Implant Design

Medical CAD software has streamlined the design and manufacture of complex bonereplacement implants.Bone is a living connective tissue and is the main constituent of the human skeleton. It solidifies due to calcification, becoming hard and brittle, but with low density. Bone also changes over the course of a person's life, continually being produced as the body grows. Factors that affect the formation of bone growth include metabolic causes, endocrine changes, mechanical stimuli and exposure to drugs. [26]

Bone is considered to be a composite material; it has the capability of healing andremodeling itself. However, severe blunt force trauma, disease or congenital abnormalities prevents this. In these instances bone repair is achieved by grafting, using either a part of the patients own bone (autographs) or a donor's bone (allographs).Synthetic substitutes exist, comprised of materials such as ceramics, metals, polymers and composites used to help bridge this shortcoming. Bio-ceramic materials are one of the main groups of materials used as they have a chemical composition similar to that of human bone.

When designing an implant points that must be considered are:

a) Mechanical properties

b) Biocompatibility

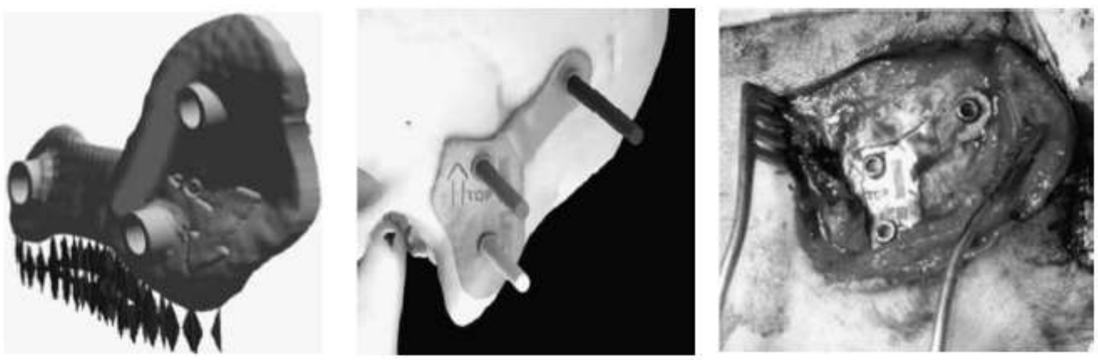
c) Cost effectiveness of manufacture

d) Geometric accuracy

The implant must exhibit the mechanical properties of the bone being replaced so as to facilitate function and perform satisfactorily at the point of substitution. The material chosen for the implant must be biocompatible, i.e. must not produce a toxic or chemical reaction which may lead to further medical complications. Accuracy of the part must be ensured, as this reduces the risk of infection, increases the functionality of the implant and minimizes healthy tissue excision [27].

5. Customized Medical Jigs

Customized jigs assist the surgeon with the accurate placement of medical implants.AM processes (e.g. SLA, SLS) produce accurate, robust parts that are sterilization tolerant. In certain circumstances AM produced implants may require reinforcement to become fit for purpose, leading to the use of reinforcing elements. However, new processes such as SLM and Electron Beam Melting (EBM) produce non porous metal parts, overcoming the limitations of other AM technologies. With the introduction of these new metals, surgical guides can be made smaller with a reduced cross sectional area and still retain sufficient stiffness. This reduction in size allows the surgeon greater visibility, permitting the surgeon to make smaller and more accurate incisions [28].



(a) (b) (c)

Fig.16(a):Surgical guide showing support structures for rapid manufacture

Fig.16(b): Surgical guide being used in preoperative planning showing drilling locations,orientation and patient's name

Fig.16(c): Surgical guide inuse [30]

5.1 Existing and previous practice

The positioning of Osseo-integrated implants for the retention of prosthesis is important in terms of aesthetics, function and comfort.Previous methodological steps include:

a) Patient brought to clinic for preoperative planning session
b) Planning performed on patient and the ideal prosthesis location marked on patients skin
c) The markings transferred to a transparent plastic template
d) The template is then used to transfer the location of the implant onto the patient's bone using a hypodermic needle and sterile ink.
e) The skin is then cut and folded back to show the ink marks for the implant locations. Although this procedure works, problems can occur with soft tissues movement when used as a reference surface leading to inaccurate positioning of the implant hence producing poor aesthetics. Since this procedure provides no diagnostic data on the quality or thickness of the bone at the point of implantation this

could increase the operating time if the bone quality is not sufficient and the fixing points have to be altered.

Existing methodological process steps for producing a SLM process surgical guide:

a) A CT scan made of the patients relevant anatomy. Includes software formatting and manipulation to produce STL files
b) Computer aided surgical planning and design. Includes using CAD software to perform functions such as mirroring and Boolean operations, assessing quality of bone at the location point. All soft tissue data is removed before the surgical guide is designed and then located onto the bone
c) Surgical guide manufactured by the SLM process
d) Finishing involves removing support material used in the construction of the guide to maintain dimensional accuracy and post surface finishing processes such as bead blasting which reduces the surface roughness (Ra value) caused by the layering process
e) Evaluation, comprising fitting the guide onto a preoperative planning model of the patients anatomy to guarantee a good fit. The location of the osteotomies and drilling locations are checked by surgeons and confirmed before the surgery takes place [29].

III. BIOCOMPATIBILITY

The biocompatibility of a long-term implantable medical device refers to the ability of the device to perform its intended function, with the desired degree of incorporation in the host, without eliciting any undesirable local or systemic effects in that host[31].

1. Biomaterial Applications

Examples are:Bone plates,Heart valves,Contact lenses,Skin repair devices,Blood vessel prostheses,Dental implants, Orthopedic replacements, Customized medical implants

2. Research Direction and Future scope

Methodology

i. Identification and selection of medical test cases
ii. Identification of relevant software solutions
iii. Identify a systematic approach for each case
iv. Evaluation of methodology and results

Software Solutions

To integrate DICOM data with the finished RP product, software solutions programs are necessary to make this link. These are: Materialise Mimics – used to convert 2D DICOM data from MRI/CT scans to 3D data Materialise, Magics and 3-matics – used for the manipulation of line geometry, editing and processing of files.

Evaluation of results

The results obtained overall were good in all cases but should be evaluated by consulting an expert in the area or a surgeon who performs interventions on a regular basis. Only then can the results be evaluated properly.

Conclusion

The above diagnostic techniques permit accurate analysis of patients' conditions and facilitate correct medical and surgical interventions. The technology is a critical link in the process of reducing patient morbidity and mortality rates.

Although there have been considerable advancements in medical reconstructive surgery certain fundamentals have not changed. Surgeons use their hands to control operating tools and rely on their eyes to provide closed loop feedback in relation to the movement and adjustment of their hands. Therefore the more data they have at their disposal before an intervention takes place the higher the success rate, preoperative planning models being a critical part of this data.

Additive Manufacturing technology is used to create 3D parts directly from CAD models and quickly fabricate complex-shapes. Additive Manufacturing application in the case of medical applications model is useful for surgical planning. This technology plays a significant role in reverse engineering applications, E-manufacturing Processes, Rapid Tooling, Product design and development, Medical Field, etc. Medical education and training, Designing and development of medical devices, designing of the customised implant, scaffolding and tissue engineering, prosthesis and orthotics, mechanical bone replica, forensics, various problems are solved in dentistry by implementing this Additive Manufacturing technology. AM system provide extensive support in medical applications, providing better accuracy and speed, product visualisation and customisation, customised tools, improved modelling and extensive assistance in decision making. Additive Manufacturing is opening up a new market to help the humanity.

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