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Research article

Structural and mechanical characterization of custom design cranial implant created using additive manufacturing

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A B S T R A C T

Background: Reconstruction of customized cranial implants with a mesh structure using computer-assisted design and additive manufacturing improves the implant design, surgical planning, defect evaluation, implant-tissue interaction and surgeon's accuracy. The objective of this study is to design, develop and fabricate cranial implant with mechanical properties closer to that of bone and drastically decreases the implant failure and to improve the esthetic outcome in cranial surgery with precision fitting for a better quality of life. A customized cranial mesh implant is designed digitally, based on the Digital Imaging and Communication in Medicine files and fabricated using state of the Art-Electron Beam Melting an Additive Manufacturing technology. The EBM produced titanium implant was evaluated based on their mechanical strength and structural characterization.

Results: The result shows, the produced mesh implants have a high permeability of bone ingrowth with its reduced weight and modulus of elasticity closer to that the natural bone thus reducing the stress shielding effect. Scanning electron microscope and micro-computed tomography (CT) scanning confirms, that the produced cranial implant has a highly regular pattern of the porous structure with interconnected channels without any internal defect and voids.

Conclusions: The study reveals that the use of mesh implants in cranial reconstruction satisfies the need of lighter implants with an adequate mechanical strength, thus restoring better functionality and esthetic outcomes for the patients.

1. Introduction

A cranial bone defect is caused by traumatic bone destruction, cranial tumor, congenital defects and result in functional and esthetic deficiencies. Craniofacial reconstruction is a complicated surgical process because it involves operating the body part which contains brain, eyes and other sensory organs, all within a confined space. The best way of treating cranial defects is by autogenous bone transplantation, as this will have fewer complications of infections when compared to implants from other materials [1]. However, their use is restricted due to the limited availability of suitable donor sites, especially for the large and complex defects, tissue harvesting problems, donor site morbidity and expensive surgeries. For this reason, implants from other materials are sought. Several biocompatible materials which are lightweight and non-carcinogenic such as polyethylmethacrylate (PMMA), hydroxyapatite (HA) and Polyethylene are tried but each has its own individual shortcomings, such as risk of infections and lesser strength [2,3,4]. Currently, titanium, as in porous implants of different sizes, is the commonly used material for cranial reconstruction due to its excellent biocompatibility, customization and mechanical performance [5]. When titanium implant gets in contact with the body tissues, complex reactions takes place at bioenvironmental/oxide interface and a passive film forms on the titanium surface which is dense, protective, and adhere strongly to a substrate [6].

The ultimate aim of cranial bone reconstruction is to protect the brain and alleviate psychological affliction caused by the bone defect and to restore the appearance and psychological stability of the patient. The success of cranial reconstruction depends on the preoperative defect evaluation; implant design, material, and fabrication; and skills of the surgeon. Implant with a porous surface is considered more effective than rough coating [7]. Porous implant provides interfacial adhesion with the bone, leading to effective fixation and shorter healing time [8]. It should have high porosity with sufficient space for cell adhesion

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and transportation of fluids. The ideal pore size for the bone ingrowth lies in the range of 500–1500 μm [9]. Various researchers have revealed that porous titanium with a porosity of 50% is ideal for bone tissue ingrowth [9,10]. A porous structure having good interconnected pores results in significant bone ingrowth formation and in better implant fixation [11]. Although high porosity and pore size favor bone formation, a substantial increase of the same can diminish the strength of the implant. Hence the ability to produce a porous structure with controlled porosity through design and fabrication is a critical factor in the future clinical success.

In the past, several kinds of techniques have been employed in fabricating porous titanium and its alloys which include casting, fiber deposition and powder sintering [12,13,14]. However, all these processes have some kind of limitations, such as non-uniform porosity, impurities, and loose interconnections. Nevertheless, the ability to quickly and efficiently produce a patient-specific mesh implant has always been appealing from the manufacturing standpoint. One of the major developments in the medical industry is the adoption of Computer-aided design and Computer-aided manufacturing (CAD/CAM), and more recently additive manufacturing (AM) [10].

AM revolutionized the fabrication process in the medical industry with its unique technique of metal deposition using layer upon layer fashion. The advances of AM techniques have significantly improved the ability to prepare parts with precise geometries, using data from medical imaging, which is difficult while using traditional methods. The traditional method of manufacturing implants has many drawbacks, which include a compromise in the design and increase in production cost and time. Moreover, the implant doesn't match the requirement of bone contours and it involves manual bending and shaping by hand forming techniques [15]. In contrast, to match the bone contours and provide better cosmetic results, it is essential to use the concept of customized implant design using medical modeling software and its fabrication using freeform AM technologies. AM's strength lies in the areas where traditional methods reach their limitations with respect to “Customization”. The AM technique can fabricate fully dense and graded structures with high precision and process flexibility. In recent years, cranial reconstruction implants are fabricated using AM and also these can be used as a template for producing the actual implant by the forming technique [16].

Electron Beam Melting (EBM) is one of the most recent and important technologies of AM. Researchers have identified EBM as one of the major breakthroughs in the fabrication of customized porous titanium implants with controlled porosity [17]. EBM is a widely used technology for fabrication of medical implants in both Europe and America with an FDA (Food and Drug administration) approval [18]. Previous studies have proved EBM as a valid option for custom designed implants using titanium alloy in orthopedic, craniofacial and maxillofacial surgeries [19,20,21]. Cranial defects have been repaired in earlier studies using bulk titanium implants with 1.6 times more weight than the portion of the bone removed [22]. This bulky titanium implant introduces stress shielding effects at the implant-bone interface, because of the wide differences in the Young's modulus [23]. Young's modulus is considered as an important criterion to judge the suitability of the implant in medical reports [24]. Some researchers have tried reducing the stress shielding effect, by introducing porous structure in the cranial implants, but with no clear evidence and investigation on the behavior of the porous structure, porosity and its strength [17,25]. One of the important criteria for the success of a porous implant is its open and interconnected network of channels without any internal defects and its mechanical strength to withstand the desired load. In the present study, we have designed and fabricated a customized cranial mesh implant from CT scan with design validation. The designed mesh implant was investigated and evaluated based on its porous structure and mechanical strength.

2. Materials and methods

2.1. Medical image processing

A 38-year-old patient was referred to a craniofacial surgeon with a large cranial defect in the left parieto-temporal area. The patient was subjected to CT scanning and the resulting images were saved in DICOM (Digital imagining and communication field of medicine) format. Mimics 17.0® (Materialise NV, Belgium) software specially developed for image processing was used to convert the DICOM files into a typical 3D model. The obtained 3D model contains information about the patient's bones, skin, and soft tissues. Segmentation and region growing techniques were applied with a Hounsfield unit in the range of 310–2850 for the segregation of hard and soft tissues. The generated 3D model of the patient facial anatomy using Mimics® is illustrated in Fig. 1. The 3D model with tumor located on the left side

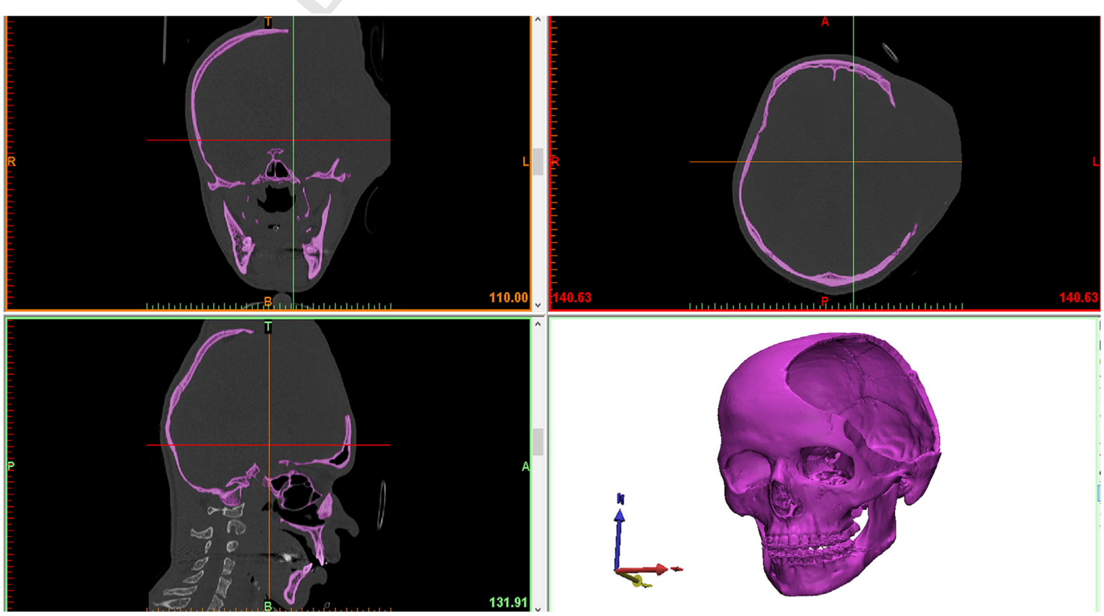

Fig. 1. 3D model of the patient's skull showing the tumor location on the left.