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Customized porous implants by additive manufacturing for zygomatic reconstruction

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ABSTRACT

Background: Moderate to severe facial esthetic problems challenge the surgeons to discover alternate ways, to rehabilitate the patients using customized porous designs. Porous metal implants are available for over 30 years, but the pore architecture, is constantly changing to improve the stability and longevity of the implant.

Objective: To evaluate a customized porous implant produced from electron beam melting and to restore the zygomatic functionality.

Methods: Two customized zygomatic reconstruction implants-bulk and porous, are designed based on the bone contours and manufactured using state of art-electron beam melting technology. The two designed implants are evaluated based on strength, weight and porosity for the better osseointegration and rehabilitation of the patient.

Results: Porous structures due to their light weight, low volume and high surface area provided better specific strength and young's modulus closer to the bone. Microscopic and CT scanning confirmed that the EBM produced porous structures are highly regular and interconnected without any major internal defects.

Conclusions: The customized porous implants satisfies the need of lighter implants with an adequate mechanical strength, restoring better functionality and esthetic outcomes for the patients.

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²² **1. Introduction**

Every man and women in the current image conscious world 23 seek to possess perfect facial features, where looking good 24 25 makes all the difference [1]. The facial feature that is associated with youthful looking and charming case is the 26 27 cheek bone called zygoma [2]. Zygoma is a non-load bearing 28 bone with a small, quadrangular paired thick structure which 29 articulates with the maxilla, the temporal bone, the sphenoid bone and the frontal bone [3]. Zygoma plays an important role 30 31 in the facial contours with respect to functional and cosmetic 32 aspects. Any injury or trauma in the zygomatic region should 33 be adequately and properly diagnosed, and replaced with substitutes or reconstruction plates. Zygomatic bone due to its 34 position in the facial anatomy, represents 13% of all the 35 craniofacial injuries and bears the second most common mid-36 facial bone injury [4]. Zygomatic defects are due to congenital 37 38 maldevelopment, periodontal disease, bone loss, trauma or 39 surgical ablation. Zygomatic bone loss results in the restriction 40 of the mouth opening due to the coronoid impingement [5].

41 The reconstruction of zygoma is a challenging task for the 42 maxillofacial surgeons. The success of zygomatic bone reconstructive surgery depends on the preoperative evalua-43 44 tion of the defect, the implant material, design, fabrication and 45 finally the skills of the surgeon. Different surgical methods had been used in the zygomatic reconstruction, including autolo-46 47 gous and alloplastic grafts, free tissue transfer and osteotomy [6]. Microvascularized bone grafts (iliac, crest, mandible or rib) 48 49 are regarded as gold standard in facial reconstruction [7–9]. These autologous bone grafts have several disadvantages 50 51 which include the donor site morbidity, difficult to contour 52 accurately, bone resorption and multiple surgeries. The commercially available standard reconstruction plates are of 53 54 limited value in zygomatic reconstruction, due to its complex 55 anatomy and unusual bony defects. Moreover the standard 56 implants need manual bending prior to surgery and any 57 mismatch between the bone and implant interface results in 58 implant failure and leads to high revision rate [10,11]. In 59 contrast, to match the facial contours and provide better cosmetic results, it is essential to use the concept of 60 customized implant design using medical modeling software 61 and its fabrication using freeform additive manufacturing 62 (AM) technologies. Previous studies have explored the use of 63 computer assisted design surgeries in medical application 64 65 providing effective results [12]. AM, unlike traditional manufacturing, does not have any shape restrictions and 66 67 can produce complex structures in lesser amount of time with improved accuracy. 68

Titanium is widely used as a biomaterial since 1960 due to 69 70 its excellent biomechanical properties. One of the major 71 problems with the titanium bulk implant is its mismatch with 72 the surrounding bone, referred as stress shielding [13]. The 73 young's modulus of titanium alloy is about 114 GPa while that 74 of cancellous and cortical bone range from 0.5 GPa to a 75 maximum of 20 GPa [14]. Various studies indicate that 76 insufficient load transfer from the implant to the surrounding 77 bone may result in bone reabsorption and ultimately loosening of the prosthetic implant [15]. Hence, in order to reduce the 78 young's modulus, it is effective to make the implant porous. 79

The young's modulus can be easily controlled by changing the porosity.

Studies indicate that the interconnected pores with a size larger than 100 μ m were reported to be beneficial for osseointegration [16,17]. Open and interconnected porous networks are essential for cell nutrition, proliferation, tissue migration and vascularization and formation of new tissues [18]. Secondly, there should be good interconnections between struts without any cracks or defects. Thirdly, porous implant should be strong enough to withstand the desired load. In powder based AM processes, there is a common problem of the trapped powder particles within the lattice structure beyond reach [19].

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 [20,21]. However, all these process undergoes some kind of limitations such as non-uniform porosity, impurities, etc. Researchers have identified Electron Beam Melting (EBM) as one of the major breakthrough in the fabrication of customized porous titanium implants with controlled porosity [7]. EBM is a widely used technology for the fabrication of medical implants in both Europe and America with an FDA approval [22].

The objective of this study is to evaluate the porous implant fabricated using EBM technology and providing good functional and cosmetic results. This article gives an overview about the design process of customized porous implant for zygomatic reconstruction from the CT scan and its comparison with the bulk implant. The evaluation is based on the structural and mechanical characterization. These developments of customized porous implant in zygomatic reconstruction are unique as not many researchers attempted to design due to its complexity.

2. Materials and methods

2.1. Medical image processing

A patient suffering from a painful cheek swelling is considered 115 in this study. Standard CT scanning procedures were followed 116 to collect facial anatomical data. The resulting images were 117 stored in DICOM (Digital imagining and communication field 118 of medicine) format, which is an international standard. 119 Mimics 17.0[®] (Materialize NV, Belgium), a medical modeling 120 software, was used to convert the DICOM files into a typical 3D 121 model. In Mimics, Hounsfield unit in the range 390-2633 was 122 used for thresholding and region growing techniques to 123 segregate the hard and soft tissues. Fig. 1 shows the generated 124 3D model of the patient's tumor. The tumor was found to be on 125 the left side of the cheekbone, extending from the orbital flow 126 to the zygomatic arch. Subsequently, the produced 3D model 127 was saved in STL format for the next stage of implant design. 128

2.2. Customized implant design

The STL file was imported in 3-MATIC 9.0® (Materialize NV,130Belgium) software to design a customized zygomatic reconstruction implant. Mirror image reconstruction technique was131employed in designing the implant. In this technique, the133

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