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.
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.
was saved as STL (Standard Tessellation Language) file for implant design process.

2.2. Customized implant design

The STL file of the 3D model (Fig. 2a) was imported in 3-Matic 9.0® (Materialise NV, Belgium) software to design a customized cranial reconstruction implant. The customized cranial implant was designed using mirror image reconstruction technique. In this technique, the skull was divided along the mid-plane by selecting two extreme endpoints (Fig. 2b). Afterward, the defective left side was cut and removed (Fig. 2c,d) and the contralateral side, the healthy bone was mirrored with reference to the mid-plane (Fig. 2e). Merging and wrapping operations were performed to overcome the gaps and discontinuous surfaces (Fig. 2f,g). Next, a Boolean operation (Fig. 2h) was performed between the newly developed skull model (Fig. 2g) and the old model that contains the tumor (Fig. 2a). This operation generates the customized cranial implant (Fig. 2i) with a thickness of ≃2.5 mm, the thickness of skull bone. An inward offset operation was performed on the implant design to reduce the thickness by half which is then used as a template, based on which the porous implant was built.

2.2.1. Porous implant design

The customized implant design obtained from the previous stage was a fully solid (bulk) design with a thickness of 1.25 mm. The four fixation lips with taper screw holes were designed for the firm attachment and fixation of the implant to the cranium as shown in Fig. 3b. The taper designed screw holes helps in the stability and rigidity with the complete sinking of the screws.

The bulk design file (Fig. 3a) was imported into Magics 18.03® structural module (Materialise NV, Belgium). Porous design cell type of body diagonals with nodes (Fig. 3d) from Magics® was patterned into the middle region (Fig. 3c). Fig. 3e illustrates the porous implant with the inner region as porous and the outer ends as bulk for fixing of screws. The virtual assembly and validation of the implant design were performed by placing the mesh implant onto the skull model with a perfect fit, with little dead spaces as shown in Fig. 3f. The screw hole slots were tapered as shown in Fig. 3g, so that the screw heads can completely sink inside the holes, enhancing the patient comfort during implant service. The designed cranial implant has a porosity level of 49.81% with the strut size of 800 μm and pore size diameter of 700 μm. Designed porosity was calculated according to the following equation, where the volume parameters were obtained from STL files using 3-Matic®.

\[
\text{Porosity} = \left( \frac{V_1 - V_2}{V_1} \right) \times 100
\]

where \( V_1 \) is the volume of the bulk implant and \( V_2 \) is the volume of the porous implant.

2.3. Fabrication of designed cubes

It’s important for the implants to be lighter in weight with good mechanical strength for better efficiency. The obtained cranial mesh design is lighter than the bulk implant by a porosity level of 49.81%. Cranial mesh implant due to its uneven and irregular structure cannot be subjected to any standard mechanical procedures. Hence, to study the mechanical strength of porous structure, a solid cube of 15 mm was designed and patterned with body diagonals node cell structure used in the cranial design as shown in Fig. 4. Few researchers have also performed similar work on porous titanium cubes with different structures, to study the mechanical properties and structural designs [26,27,28].

The STL model of the porous cube (Fig. 4b) was loaded into Arcam’s EBM machine for fabrication. EBM produces complex 3D parts directly from STL file. EBM selectively melts the metal powder in a layer building fashion. Titanium powder (Ti6Al4V ELI) with the particle size of 50–100 μm was used in this study. The chemical composition of

Fig. 2. Steps involved in the cranial reconstruction implant design using 3-Matic®.
Ti6Al4V ELI (Extra low interstitial) was made of 6.04% Al (Aluminum), 4.05% V (Vanadium), 0.013% C (carbon), 0.0107% Fe (Iron), and 0.13% O (Oxygen), with the rest as Ti (Titanium) in weight percent. The schematic working principle of an EBM machine is illustrated in Fig. 5a. The EBM process consists of three stages in general.

• Preheating the metal powder
• Scanning and melting the powder
• Lowering the build platform and raking the powder bed

**Stage 1:** The laid titanium powder in the powder bed was preheated by scanning the entire powder layer at high scan speed till the specified target temperature (730°C) was achieved. In preheating, the powder layer was preheated to 80% of the melting temperature, which fuses the powder particles. Preheating is done to reduce the residual stresses and to sinter the loose powder to hold the subsequent next layer of powder. Standard Arcam parameters—preheat I and preheat II were used in this stage. In preheat I, the entire powder bed was scanned and in Preheat II, the scanning was performed only in the build area.

**Stage 2:** In scanning and melting stage, the high-velocity beam of electrons scans the metal powder line by line, by means of a magnetic lens, as per the defined CAD geometry. Scanning and melting operation consist of two stages, contouring and infill hatching. First, the contours were melted as per the boundary cross-section of the 2D slices by multiple electron beams. In
hatching the beam current and the scan speed were increased when compared to contouring and was rastered in a snaking melt strategy in back and forth direction, to melt and fill the area between the contours. Only the contours and the hatching part, melts the metal powder and leave the rest of the powder untouched, which was recycled later.

**Stage 3:** After preheating and melting of each layer, the build platform was lowered by one-layer thickness (50 μm) and a new layer of powder was dispensed from hoppers and spread evenly onto the previously solidified layer using raking blades. These three stages were repeated in a cycle until the final three-dimensional physical parts were built.

The fabricated EBM porous cube as shown in Fig. 5b was then blasted in powder recovery system (PRS) with high-pressurized air mixed with Ti6Al4V ELI powder to remove the loosely trapped powder between the pores and the channels.

### 2.3.1. Structural characterization

In order to examine the structural integrity of the build porous cubes, they were subjected to micro-CT scans. Bruker Skycam 1173 scanner was used to detect any stochastic defects and to demonstrate the inner construction of the struts in the porous cube. A high resolution of the x-ray beam with a source voltage of 120 kV and a spot size of 5 μm was focused on the porous cube. Each 2D slice image in the form of 512 × 512 bitmap as output data was collected. The surface and elemental analysis of the EBM built porous cube was done by scanning electron microscope (SEM) using JOEL JSM-6610LV electron microscope along with the attached energy dispersive spectroscopy (EDS).

### 2.3.2. Mechanical characterization

The strength of the porous implant is dependent on the porosity of the part. The compressive strength reduces with increase in porosity. The EBM produced cubes (n = 3) were subjected to axial compression test to determine their mechanical strength. The compression test was carried out using an Instron universal testing machine (3385 H, United States) with a crosshead speed of 1 mm/min. The applied load and displacement data were continuously monitored and recorded in a computer during the test for further analysis. Average compressive strength and modulus of elasticity of the porous structure were determined from the stress–strain curves, derived from the load-displacement data recorded during the compression test. The surface mechanical properties of the porous cube were determined by Vickers micro-hardness test using Buehler Micromet 5100-unit machine on the polished cubes with a load of 200 mgf and dwell time of 10 s. Three random areas were selected from the top surface of three porous cubes and an average value of 9 measurements was reported for hardness.

### 3. Results and discussion

#### 3.1. Structural characterization results

The internal characterization results from the micro-CT scan of the EBM fabricated porous cube are illustrated in Fig. 6. They prove that the produced porous cubes are free from substantial internal defects such as cracks or voids and are interconnected with a series of network channels.

The EBM fabricated cube when subjected to Energy-dispersive X-ray (EDX) analysis, shows peaks corresponding to the various elements. As shown in Fig. 7, the titanium (Ti) peaks are more pronounced than the aluminum (Al) and vanadium (V) as expected.

The overall composition of the specimen is given in Table 1. Based on the composition results, it can be said that the chemical composition of the fabricated cubes did not differ much from the original composition of the feedstock powder.

The EBM fabricated porous cube subjected to SEM at low magnification after mechanical polishing. The SEM on the top surface of the cross-sectional porous cube (Fig. 8a) illustrates the microscopic image of one of the junctions as shown in Fig. 8b, where four struts meet. No major discontinuity and internal defects were found in struts or at their junctions.

#### 3.2. Mechanical characterization results

The stress–strain relationship of the porous cube (n = 3) was calculated and plotted as shown in Fig. 9. The compressive strength
and modulus of elasticity were derived from the stress–strain relationship curve. The maximum stress of 62.5 MPa in porous cube corresponds to the collapse of the individual layers with the thinnest struts collapsing first. The compressive strength of the porous cubes (62.5 MPa) is sufficient for the cranial reconstruction implants as these are non-load bearing implants. The porous cubes with modulus of elasticity of 1.20 GPa obtained from the stress–strain curve were closer and within the range of bone modulus of elasticity (1–20 GPa), thus providing a promising means of stiffness reduction and stress shielding effect.

The micro-hardness test was performed on the porous cube, to study the material’s resistance to deformation as shown in Fig. 10. The corresponding average hardness together with compression test results are displayed in Table 2.

The porous cubes resulted in higher average hardness of 343 HV in comparison to bulk part (310 HV [29]), a similar trend reported by other studies as well [30]. The higher hardness of porous structure is attributed to the high solidification rate of the porous struts when compared to the bulk cube.

4. Fabrication of cranial implants

The customized cranial mesh implant was initially fabricated through polymer based fused deposition modeling (FDM) for rehearsal and fabrication of the cranial mesh implant. The customized cranial mesh implant was designed using computer-aided design (CAD) software and then fabricated using FDM. The CAD design was imported into the FDM machine and the implant was printed using a thermoplastic polymer material. The implant was then removed from the FDM machine and cleaned with an ultrasonic cleaner. The implant was then sterilized using an autoclave and was ready for surgical implantation.

Table 1

<table>
<thead>
<tr>
<th>Element</th>
<th>Weight %</th>
<th>Atomic %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Al</td>
<td>6.24</td>
<td>10.59</td>
</tr>
<tr>
<td>Ti</td>
<td>89.87</td>
<td>85.91</td>
</tr>
<tr>
<td>V</td>
<td>3.89</td>
<td>3.50</td>
</tr>
</tbody>
</table>

Fig. 6. Micro-CT scan images of the porous cube representing different cross-sectional views along with a 3D view.

Fig. 7. (a) Scanning Electron microscopic image and (b) EDX Spectrum of EBM built Ti6Al4V ELI specimen.
Fig. 8. (a) Cross-section of the porous cube and (b) SEM observation and distribution of micro-pores.

Fig. 9. Compressive stress–strain relationship curve of porous cubes.

Fig. 10. (a) Vickers hardness test done on the porous cube and (b) indentation display on the cube.
fitting evaluation. If the polymer implant fails in fitting evaluation, due to the shrinkage effect and orientation of the build, the design process is repeated till the satisfactory results are achieved. Upon successful rehearsal and fitting evaluation, the final porous (Ti6Al4V ELI) implant was fabricated using EBM.

<table>
<thead>
<tr>
<th>Specimen</th>
<th>Average compressive strength (MPa)</th>
<th>Average modulus of elasticity (GPa)</th>
<th>Average hardness (HV)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Porous cube</td>
<td>62.5</td>
<td>1.20</td>
<td>343</td>
</tr>
</tbody>
</table>

Fig. 11. (a) Stratasys FDM machine with produced parts, (b) Skull framework with the cranial implant and (c) Fitting evaluation of the cranial implant.

Fig. 12. (a) The PRS unit used for blasting excess powder, (b) Cranial implant inside the PRS unit, (c) Implant with supports with attached teeth and (d) implant after support removal.
4.1. Polymer-based implant fabrication for rehearsal and fitting evaluation

The STL models of the customized implant design and the skull framework were imported into the Stratasys FDM machine for fabrication. FDM uses Acrylonitrile Butadiene styrene (ABS) plastic and polycarbonate material which provides strong, robust and functional parts for testing. The FDM produced skull framework and the implant were assembled for rehearsal and fitting evaluation as illustrated in Fig. 11. The polymer-based model(s), provides a comprehensive view of physical defects and the surgeon can plan accordingly based on pre-operative examination using both physical analysis and digital simulation. It helps the surgeons to make better-informed decisions during surgery, thus improving the surgical success and patient recovery. The polymer models also provide surgical guidelines and hands-on surgical rehearsal in precision drilling and best location of placement of screws, prior to surgery.

4.2. Fabrication of titanium implant using EBM process

After successful fitting evaluation of polymer models, the cranial implant design was fabricated using Ti6Al4V ELI through EBM technology. Support structures were added to the implant during the EBM built, for allowing the heat transfer to prevent deformation and to assist the overhanging parts. The supports attached to the implant are equipped with teeth at top and bottom for easy removal. The EBM produced cranial implant was passed through powder recovery system (PRS) to remove the excess powder particles (Fig. 12a,b). The blasted Ti powder was filtered and recycled for future use. Fig. 12c,d illustrates the cranial implant with support and after support removal.

The porous cranial implant after blasting was fitted with the polymer skull framework for a final rehearsal. The implant precisely fits inside the defective region with little dead spaces as shown in Fig. 13b,c,d. The porous structure is surrounded by a 10 mm bulk part, which provides strength to the implant while fixing screws. This new concept of customized cranial mesh design with design validations and fabrication using state of the art-AM technology reduces the waiting time and faster surgery, thus assisting the patients to resume their normal functionality more quickly.

5. Conclusion

Implant with porous structures plays a crucial role in long-term stability and bone ingrowth formation. In addition to porous structure, the implants should have adequate mechanical strength with patient-specific geometry to ensure proper connection to bone tissue without any need of handcrafting during surgery. In this study, a custom designed cranial implant with porous structure was developed from the CT scan and fabricated using AM. The EBM produced

Fig. 13. (a) EBM A2 machine used for the fabrication of Ti6Al4V ELI porous implant, (b) Top view of skull framework with porous cranial implant, (c) Front view of skull framework with porous cranial implant, and (d) Back view of skull framework with porous cranial implant.
titanium mesh implant satisfied structural characterization with adequate strength. Moreover, the implant displayed a regular pattern of interconnected channels without any defects and voids. The use of customized cranial mesh implant, enhances the esthetic and functional rehabilitation of craniofacial deformities with faster healing and bone ingrowth formation and achieving immediate and efficient reconstruction.

Conflict of interest statement

The authors have no conflict of interest to declare.

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