# Designing and Prototyping a Bespoke Spinal Implant Using Additive Technologies

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*Additive Manufacturing (AM) is rapidly becoming a common practice within the medical industry. Used for applications such as tools and devices, custom implants, scaffolds or even organ printing, AM technologies have already started to improve medical practice, patient care management and treatment outcomes. The authors developed a concept for a custom intervertebral fixing implant starting with the medical data of a specific patient. The proposed bespoke implant replicates identically the anatomical features and caters to particular conditions of the patient in cause. The implant was designed in correspondence with the cervical spine using specialised medical software. Several triangle based analyses were used in order to evaluate the adequacy of the *.STL files before 3D printing. Film Transfer Imaging technology was used to manufacture both the anatomical model of the cervical spine and the bespoke spinal implant concept. The parts were presented to surgical specialists for through fitting evaluation and testing. Feedback and recommendations were given in terms of additional support and fixing. Surgical procedure tests were recommended on an explanted animal cervical spine.*

*Keywords: bespoke spinal implant, medical data processing, *.STL evaluation, medical software simulations, additive manufacturing*

Additive Manufacturing (AM) is one of the potential game changers that, for some applications, has already reached a tipping point of maturity. These days, we are already witnessing the growing enthusiasm and an increased adoption of these technologies, especially in the medical applications. AM has a number of advantages, including un-rivalled geometric freedom of design, near 100% material utilisation, and short lead times, depending on the technology [1-3]. These advantages together with ongoing technology innovations are the main drivers that will possibly revolutionize entire industries.

A breakdown of the percentage of industrial sectors using AM technologies showed that the Medical/ Dental sector is on the fourth place, with 13.7% of the share market [1,3]. Medical applications are set apart amongst each other by bespoke concept models, innovative functionality and material choices. Within the medical industry materials need to comply with strict characteristics and specifications very closely related to the end purpose of the product. Often, materials need to be biocompatible, bioresorbable or biodegradable in order to follow precise regulations in the medical industry. The medical industry uses standardised biocompatible materials for a series of domains, such as: reconstructive surgery, tissue engineering, clinical engineering, dental, genetic and neural engineering etc. [3-5]. Some of the most common applications refer to custom implants, bespoke surgical guides, medical devices and surgical tools, prosthetics, scaffolds, tissue and organ printing [1,3]. Several types of spinal implants have been developed so far, which include: general surgery systems, access and minimally invasive access systems, anterior column plating, interbody and vertebral body replacement systems, spine augmentation systems [6-8].

The current research proposes the concept development of a bespoke spinal implant for a vertebral body replacement specific application. Apart from existing spine implant concepts, the novelty of the proposed model is the accurate materialization of the anatomical surfaces of the vertebral bodies. The implant supports the spine on exact replicas of the anatomical features of the patient. Moreover, the concept also incorporates special adjustments in accordance with other anatomical distortions of the patient. For fitting and validation purposes, the concept models were manufactured using a high detail photopolymer resin. The final bespoke spinal implant will be manufactured from a titanium biocompatible alloy, considering different AM technologies [1,2]. Issues like standardization, medical device approval, patent protection and liability, certification, commercialization and transportation will be dealt with in a specific stage, after the product development [1,4,9].

## Experimental part

### *Method: Evaluation and CT data processing*

The research was undertaken on a 59 year old male patient, who was under observation in an oncology department. He underwent several analyses, amongst which a Computer Tomography (CT) scan. The CT scan evaluation revealed that the patient had a cancerous growth formation which caused the fusion of vertebrae C3 and C 4. It was established that surgery is the most viable option and offers the best possibility of recovery. The surgical solution involves the removal of the tumour, implicitly the two vertebrae bodies [10]. The gap between C3 and C4 needs to be filled with a spinal fusion type implant and fixed with posterior supports [11,12]. It can be seen (fig. 1) that the patient has a cervical right side scoliosis, which impedes the usage of a spinal fusion implant without correcting the scoliosis. In this specific case the scoliosis treatment was not recommended, due to the type of cancerous formation. The optimum approach was to fit the patient with a custom made implant that could

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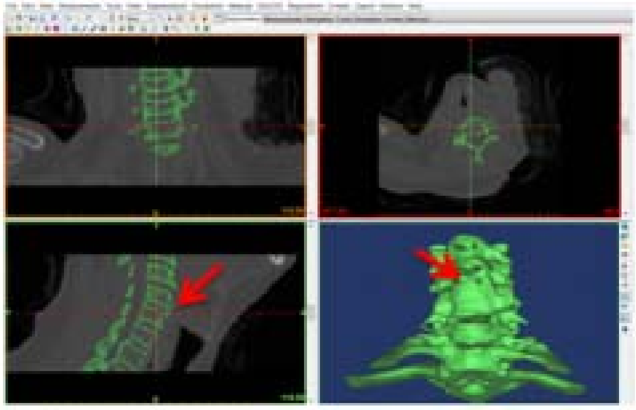


Fig. 1 CT data scan of the patients' anatomical data

reproduce the anatomical surfaces involved and sustain the patient, given the unique shape of the spine.

Considering the above-mentioned, a surgical planning management strategy is proposed by the authors together with a surgeon specialist. The main stages of the management strategy are as follow: 1. Bone density evaluation from the CT scan images using Mimics Research software; 2. Analysis of the optimum cutting line when resecting the bone tumour; 3. Creating the *.STL files for the spine anatomical model with the cut-out tumour and exporting it to 3-Matic Research software; 4. Designing the bespoke spinal implant using 3-Matic Research; 5. *.STL accuracy analyses; 6. Manufacturing of the anatomical model of the patients' spine; 7. Manufacturing of the bespoke spinal implant prototype; 8. Fitting and functional tests; 9. Surgical procedure planning; 10. Manufacturing of the final titanium implant; 11. Surgical procedure and post-op patient care. The current research paper deals with the first nine stages and proposes improvements for manufacturing the final titanium implant.

The bone density was evaluated using Mimics Research by defining new masks of the bone and soft tissue. The implicit values for the CT bone masks were used and an image gradient was added in order to enhance the visibility of the bone tissue and to eliminate noise [13]. The predefined threshold sets were between a minimum of 226 units and a maximum of 3.053 units. In order to visualise the 3D model of the spine a 3D object was defined from the mask. After identifying the mass of the tumour and the bone density by using the measurement tools, the optimum cutting line was created and the affected bone resected (fig. 2).

Further the *.STL file was obtained from the new 3D object. The *.STL file was prepared for the implant definition by smoothing the surfaces using three functions provided by Mimics: Meshing, Triangle Reduction and Smoothing (fig. 2).

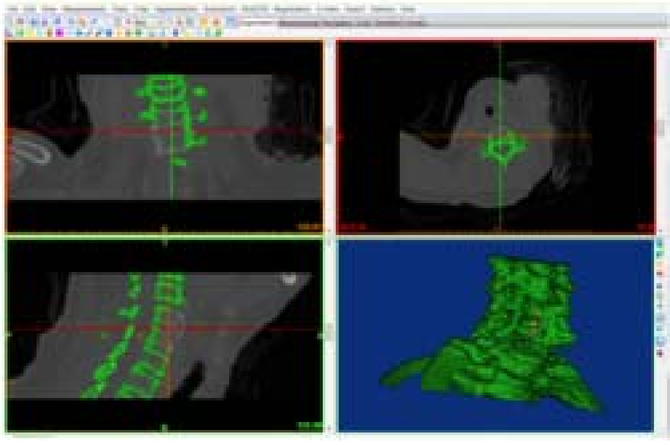


Fig. 2 Resection of the tumour from C3-C4 vertebrae bodies

## Results and discussions

*Spinal implant concept development*

For developing the bespoke spinal implant anatomical reverse engineering was necessary. The spine *.STL file generated using Mimics Research was imported in 3-Matic Research in order to manipulate the anatomical surfaces. The implant was designed to snap into place between vertebrae C2 and vertebrae C5. The custom implant was designed to be supported in the posterior region with a standardized metal fixing system [6,7,14], screwed in place from the transverse process of C2 up to the transverse process of C5.

The bespoke implant recreates identically the surfaces of the C2 and C5 spinal bodies, in order to provide a perfect fit for the patient [15,16]. Three steps were undertaken in order to create the implant. First, the surfaces of spinal bodies were marked and the contour line was smoothed out. The surfaces were then extruded into two custom plates. The second step was to identify the centre of mass for each custom plate and join them with an axis. The last main stage consisted of joining the two plates with a cylinder between the two centres of mass. Fillet was used to relieve the implant of stress in the union points of the cylinder with the plates. The final bespoke spinal implant concept was assembled together with the patients' spine, in order to validate orientation and custom fitting (fig. 3).

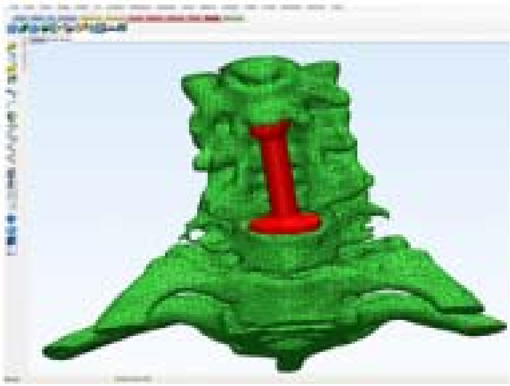


Fig. 3 Final concept of the bespoke spinal implant

Re-meshing of the implant and the spine was undertaken to prepare the *.STL files for further analyses.

*Spinal implant concept manufacturing*

The accuracy of the printed part is highly influenced by both the material and the quality of the *.STL files. Thus, a detailed set of triangle-based analyses was undertaken in order to validate the adequacy of the final models. For fitting and testing both the implant and the patients' spine were analysed.

Three main analyses were deployed using the *Analyze* add-on from 3-Matic Research: Curvature analysis (Gaussian and Maximum), Wall thickness analysis and Extrema analysis. The results obtained from the three analyses are presented in figure 4. This stage is extremely important both for the manufacturing stage and for the fitting stage. If there are any flaws in the *.STL files the parts may be printed incorrectly and may not replicate exactly the anatomical surfaces of the patients spine.

That could lead to manufacturing a final implant that doesn't completely fit the patient.

Figures 4a and 4b show the curvature analysis that calculated and assigned a specific curvature to each triangle of the*.STL. The mesh type was set to smooth with a fitting radius of 5 mm for both the spine anatomical

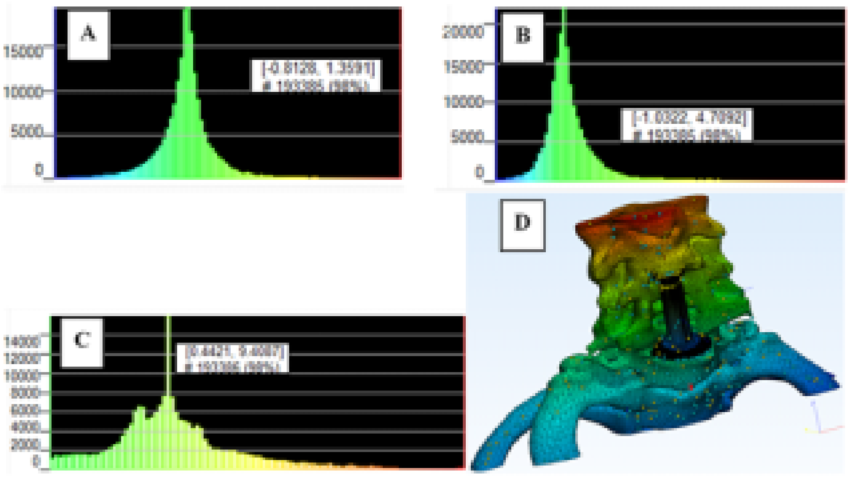


Fig. 4. *.STL analyses:
a) Gaussian Curvature analysis;
b) Maximum Curvature analysis; c)
Wall thickness analysis; d)
Extrema analysis.

model and the implant. The Gaussian curvature analysis (fig 4a) was used to calculate the curvature in each point based on the local minimum and maximum curvature. The Gaussian interpolation resulted in a histogram range between -0.8128 and 1.3591. In figure 4b the local maximum curvature was calculated for each point and the histogram range resulted between -1.0322 and 4.7092. Both ranges are in the recommended limits. The overlapping triangles were identified in the transverse processes of C5. The mesh was smoothed in those regions and triangles rearranged. The curvature analysis was not influenced by local peaks.

The Wall Thickness analysis is represented in figure 4c and was undertaken with a 10 mm maximum wall thickness. All triangles with a wall thickness above this maximum value were implicitly assigned with a 10 mm value. The thickness of the part was calculated with a histogram value range between 0.4421 and 9.4087. There were no abnormal triangles identified and the surface was considered continuous and proper for 3D printing.

For the extrema analysis (fig. 4d) an axis direction was defined alongside the inertia axis of the custom implant on the Z direction. The analysis was undertaken for both entities simultaneously. Maximum and minimum extrema points were represented in order to identify any stranded triangles from possible errors of the CT scan. The analysis showed that there was no CT noise encapsulated in the *.STL files and all the extrema points were within specified limits. After the corrections made on the *.STL files, the parts were ready to be 3D printed.

Due to the required precision of the study, manufacturing was done on a Projet 1500 3D printer. The equipment uses Film Transfer Imaging (FTI) technology that allows parts to be built much quicker than other methods of rapid prototyping. A film is coated in UV curable photopolymer. This resin is then transferred from the film to the built platform and is cured by a flash of light from a DLP projector. The process is repetitive, building layer over layer until the part is entirely built. By curing each layer with a single flash of projected light, instead of tracing each layer with a laser or ejecting material in specific locations, parts can be built quickly, accurately and with fine resolution.

The VisiJet® FTI-Ivory material was chosen for the final concept models, due to its specific material characteristics, which brought visible benefits. VisiJet® FTI materials created durable plastic concept models with excellent, high resolution detail that were tough enough for functional testing and snap-fit applications. The characteristics of the photopolymer composite material allowed an accurate representation of the two proposed medical parts.

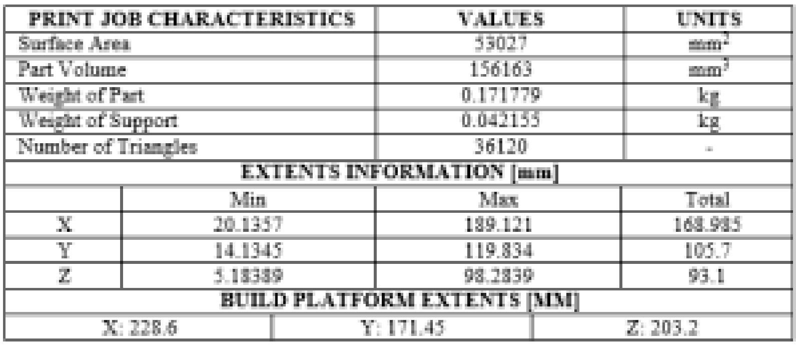
The material was delivered in liquid state in 2kg cartridges. The main components are: Isobornyl acrylate (15-25%), Tricyclodecane dimethanol diacrylate (34-50%), Urethane acrylate oligomers (30-40%). The material is usually stable under normal conditions but exposure to heat, sunlight and UV light was avoided when manipulated for 3D printing. Special care was taken when preparing the print and evacuating the part due to possible hazardous decomposition, as it could include $CO_2$, CO, $NO_x$ and smoke. In this regard, work safety measures were considered and implemented. The specific material characteristics are given in table 1.

The decision was taken to print the bespoke concept models at a 1:1 scale for validation reasons. Due to the size of the patients' cervical spine, two separate print jobs were designed with 3D Systems ProJet Accelerator software. The first print job was set to manufacture the

**Table 1**
VISIJET® FTI-IVORY MATERIAL CHARACTERISTICS

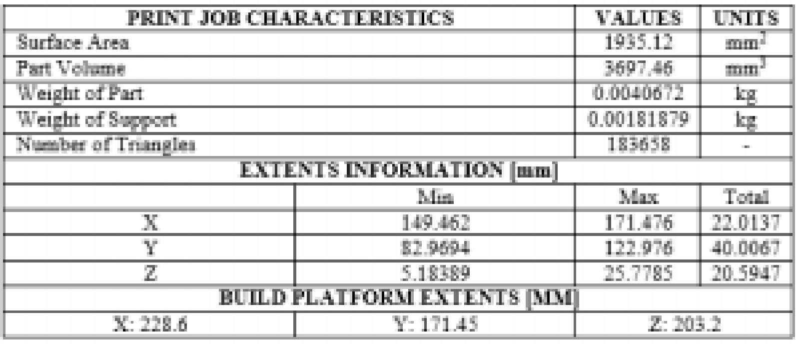
| MATERIAL CHARACTERISTICS | VALUES | TEST METHOD |
|---|---|---|
| Density (liquid) at $30^0$C | 1.08 [g/cm$^3$] | NA |
| Tensile Strength | 41630 [MPa] | ASTM D638 |
| Tensile Modulus | 800 – 1200 [MPa] | ASTM D638 |
| Elongation at Break | 41308 [%] | ASTM D638 |
| Flexural Strength | 23 – 34 [MPa] | ASTM D790 |
| Flexural Modulus | 750 – 1100 [MPa] | ASTM D790 |
| Impact Strength | 16 [J/m] | ASTM D256 |
| Heat Deflection Temperature | 52 [$^0$C] | ASTM D648 |
| Hardness, Shore D | 77 – 80 | NA |
| Glass Transition | 82 [$^0$C] | ASTM DMA, E'' |
| PH at 1:1 in Water | 6 – 7 | NA |
| Solubility (H2O) at $20^0$C (68F$^0$) | Insoluble | NA |
| Vapour Pressure at $20^0$C (68F$^0$) | < 2 [Pa] | NA |

**Table 2**
PRINT JOB CHARACTERISTICS
FOR THE PATIENTS' SPINE
ANATOMICAL MODEl



| PRINT JOB CHARACTERISTICS | | VALUES | UNITS |
|---|---|---|---|
| Surface Area | | 53027 | $mm^2$ |
| Part Volume | | 156163 | $mm^3$ |
| Weight of Part | | 0.171779 | kg |
| Weight of Support | | 0.042155 | kg |
| Number of Triangles | | 36120 | - |
| EXTENTS INFORMATION [mm] | | | |
| | Min | Max | Total |
| X | 20.1357 | 189.121 | 168.985 |
| Y | 14.1345 | 119.834 | 105.7 |
| Z | 5.18389 | 98.2839 | 93.1 |
| BUILD PLATFORM EXTENTS [MM] | | | |
| X: 228.6 | Y: 171.45 | Z: 203.2 | |

**Table 3**
PRINT JOB CHARACTERISTICS
FOR THE BESPOKE SPINAL
IMPLANT CONCEPT



| PRINT JOB CHARACTERISTICS | | VALUES | UNITS |
|---|---|---|---|
| Surface Area | | 1935.12 | $mm^2$ |
| Part Volume | | 3697.46 | $mm^3$ |
| Weight of Part | | 0.0040672 | kg |
| Weight of Support | | 0.00181879 | kg |
| Number of Triangles | | 183658 | - |
| EXTENTS INFORMATION [mm] | | | |
| | Min | Max | Total |
| X | 149.462 | 171.476 | 22.0137 |
| Y | 82.9694 | 122.976 | 40.0067 |
| Z | 5.18389 | 25.7785 | 20.5947 |
| BUILD PLATFORM EXTENTS [MM] | | | |
| X: 228.6 | Y: 171.45 | Z: 203.2 | |

spine in 8 hours and 40 min. The main characteristics are summarised in table 2.

For the implant, a second print job was designed, which contained three different concepts of the bespoke spinal implant. The bespoke implant was printed with different diameters of the central cylinder, of ø 8 mm, ø 10 mm and 12 mm respectively. Also, for two of the concepts an offset of 0.15 mm from the anatomical surfaces of the spinal bodies was provided. This was undertaken in order to compensate the machines' repeatability. The printing of the three concept models of the implant lasted for one hour and 20 min. The main characteristics of the second print job are summarised in table 3.

The parts come out of the printer with a viscous coating (fig. 5a) which requires cleaning. The parts are washed in an isopropyl alcohol recipient and left 10 to 15 min to degrease.

In order to obtain the above-mentioned mechanical characteristics, the degreased parts need to fully harden and dry in a UV Projet curing unit (fig. 5b). Due to its size, the cervical spine anatomical model was UV cured in two cycles of 30 minutes. The bespoke spinal implants concept models were UV cured in a single 30 min cycle. The UV post-processing was used to improve scratch and solvent resistance, and facilitate superior bonding of the material.

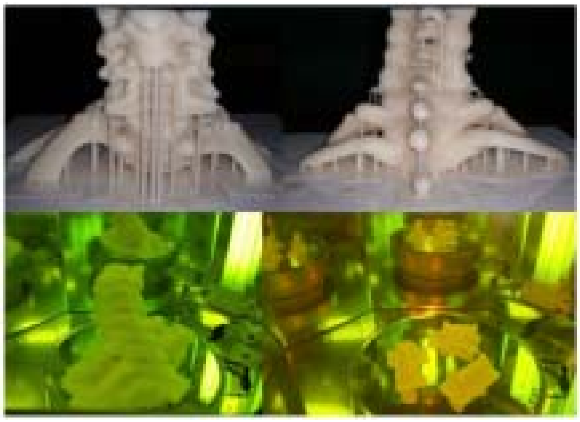


Fig. 5 a) Cervical spine of the patient printed in VisiJet® FTI-Ivory; b) Curing with UV light the cervical spine and bespoke spinal implant concept models

Fig. 6 Surface roughness measurement of custom spinal implant concept 1

Other post-processing steps include: removing the support structures, sanding down the contact points of the supports, sanding any rough edges of the models, painting/ silicone sprayed.

Surface finishing of the implant obtained with the VisiJet® FTI-Ivory was checked with Double Linnik-Schmalts microscope. Due to the irregular surface of the implant, the surface roughness was measured in three different sections of the cylindrical body (fig 6). The implants were printed at a 15 degree angle on the Z axis in order to show the staircase effect and allow the measuring of the roughness. The parts were measured before surface finishing and with the support structure still attached, in order to facilitate orientation on the microscope table. The summarized results are shown in table 4.

As is, the surface roughness is fairly good for the fitting and testing of the concepts. Nevertheless, sanding and painting of the models was undertaken.

### *Fitting and testing*

The bespoke spinal implant concept that was used for fitting had a ø10 mm diameter of the cylindrical body and an offset from the upper anatomical spinal body surface of 0.15 mm. The implant fitted perfectly when assembled with the cervical spine model (fig. 7). The anatomical models were presented to the surgical specialists for

**Table 4**
SURFACE ROUGHNESS FOR THE BESPOKE SPINAL IMPLANT CONCEPT

| | SOURFACE ROUGHNESS Ra [μm] | | |
|---|---|---|---|
| | Section 1 | Section 2 | Section 3 |
| **Concept 1** | 35.06 | 37.83 | 40.80 |
| **Concept 2** | 38.46 | 40.16 | 41.65 |
| **Concept 3** | 29.96 | 30.81 | 33.79 |

Fig. 7 Fitting of the bespoke spinal implant with the cervical spine anatomical model

feedback and improvement recommendations. The most important issues that require further investigation are as follows: proper fixation of the implant; surgery technique; deviations from the real anatomical model regarding the process – CT scan, *.STL processing, implant manufacturing.

The fixation of the implant will be done with external posterior guides from the transverse process of C2 up to the transverse process of C5. Additional elements are considered, such as: screws through the implant anatomical plates and the vertebral bodies; custom spikes on the contact surfaces of the implant; redesigning the implant as to be connected to the transverse processes of C3 and C4. Deviations will be considered for evaluation on the final titanium model, as process characteristics greatly influence the final dimensions and surface finish of the part.

It was recommended that the identified issues should be tested on an explanted animal spine using SLS prototypes, due to their mechanical characteristics [17].

## Conclusions

Reconstructive surgery can benefit a great deal from the proven advantages of additive manufacturing technologies. The zero cost of part complexity is a main driver in designing, manufacturing and using bespoke devices, implants, surgical guides, prosthetics and much more.

The present research paper proposed the usage of AM's possibility of materializing complex anatomical features, in a spine reconstructive surgery application. A novel concept of a bespoke spinal implant was proposed and designed using Mimics Research and 3-Matic Research software. The concept models were manufactured for functional fitting and testing on a 3D printer and given to surgeons for feedback. Future research includes surgical technique, proper fixation and deviations.

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