Comparative Evaluation of Optimum Additive Manufacturing Technology to Fabricate Bespoke Medical Prototypes of Composite Materials

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*The medical industry has greatly benefited from the aid of various additive manufacturing (AM) technologies, especially for applications that include the fabrication of bespoke implants and guides, devices and surgical instruments. Manufacturing functional prototypes that can behave as close as possible to the final product is a key factor in developing successful anatomically compliant medical products. The current research is intended to evaluate the optimum AM technology to fabricate medical prototypes with thin wall structures, destined for anatomical functional tests and surgical practitioner feedback. The main criteria of evaluation were: speed of fabrication from *.STL file to final prototype, mechanical characteristics and manufacturing costs.*

Keywords: bespoke medical prototype, optimum additive technology, functional simulations, anatomical thin structures

Additive manufacturing (AM) has established itself as a key technology in the development of bespoke medical products. An array of AM technologies is used for their specific benefits in conceptualising, prototyping, and creating finished medical devices [1-3]. Various medical fields have implemented AM technologies in their product development processes, mainly due to the unique characteristic, that design complexity is free of constraints. AM uses a number of materials and technologies, each with specific advantages to enable the development of improved end-use medical devices and prototypes for a wide variety of applications [1, 4-8].

In an annual report, Reeves estimates that $131.8-million was invested in 2013 in AM machines used within the medical sector for direct part production, casting patterns and vacuum forming tool manufacture [2]. This figure is expected to rise to $306-million within 5-years and to $555.7-million within 10-years [2]. According to Wohlers [1], the medical/dental sector is the third greatest 3D printing industrial sector using AM technologies, with a market share of 16.4%, whilst functional parts account for 28.1 % of the AM application market [1].

Orthopaedics, reconstructive surgery and dentistry are just a few of the medical specialities that benefit from custom-fit and patient compliant medical products [9-13]. According to Wohlers [1], there is a large range of AM medical applications, which include: custom orthotic splints, personalised prosthetics, surgical cutting guides, bespoke implants, hearing aids, optimised medical devices, topology optimised surgical instruments, bioengineered tissues and organs, anatomical models and more [2, 3, 7, 8, 14-16].

AM technologies have been adopted with such success by the medical sector due to their demonstrated major advantages: reduced number of instruments used in the surgical theatre; less surgery stages; reduced duration of the surgery; improved accuracy; reduced risk of complications and better outcome; reduced recovery and hospitalisation time for the patient and increased comfort for the patient during the surgical procedure and the recovery period; better surgery management and planning; reduced fatigue for the surgeon, improving personal performance [13, 17-19]. Ultimately, the development of medical products using AM will lead to improving current surgical techniques and will influence the development of completely new techniques [20, 21].

When compared to traditional prototyping technologies, AM drastically shortens the time from concept to prototype, or finished product. For specific applications and when using competent personnel, the development process for medical prototypes and products can be shortened from weeks to days or even hours [1, 2, 12, 14, 15, 21]. The costs involving traditional prototyping methods are also significantly reduced. Thus, it can be stated that AM is more adaptable and cost effective when it comes to bespoke, one-off and highly complex medical prototypes and products, especially when compared to traditional processes like injection moulding, mechanical processing or casting [1, 22].

Some medical device parts, components, and end-use products often can be designed to be manufactured in a single printing process, usually with increased functionality [9, 23, 24]. Thus, in order to create a prototype or an end-use medical product, the need to manufacture and assemble different parts is eliminated [1, 10].

For mass production purposes, AM could also facilitate the presentation of a fully functional concept to a manufacturer. In order to determine that an idea is feasible, a proof of concept is a key factor. AM can be considered as a bridge technology in empowering engineers and

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Fig.1. Proposed tracheostomy device concepts: Concept Model 1, 2 and 3 (left-to-right)

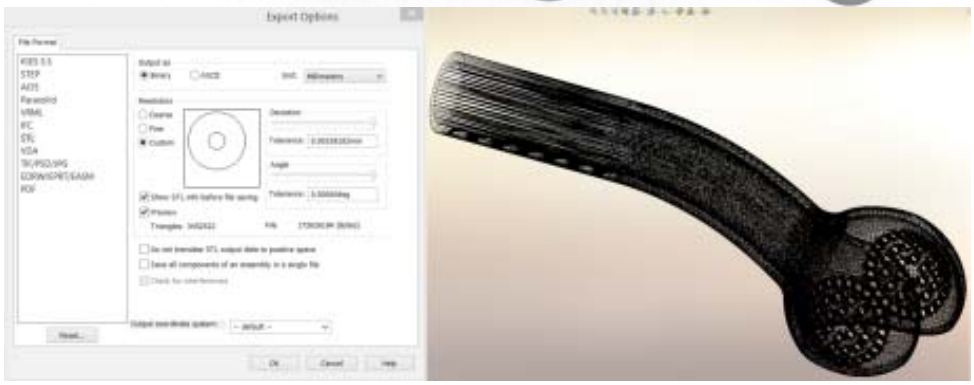

Fig. 2. Mesh parameter settings for *.STL generation of the Concept Model 2 body tube

physicians to actively engage in the design and development of bespoke medical devices [4, 20, 25]. A study by Smith et. al. [26] showed that the most useful scientific instrument innovations for medical devices originated from other physicians in approximately 80 percent of cases. Thus, the medical prototype must be manufactured so that to translate a need into a functional device, for the physician to accurately evaluate its potential added value.

The importance of appropriate and accurately designed prototypes led to the study of opportunity and optimum AM technologies in fabricating for specific medical applications. The current paper proposes the development and manufacture of a medical device prototype used in tracheostomy surgeries. Three concepts were proposed and manufactured with two different AM technologies. The tracheostomy device was designed to fulfil a well identified function, stated as follows: to ensure and maintain an access stoma (hole) through the trachea, allowing a constant airflow and pressure throughout the breathing and deglutition process. The goal was to asses through several criteria, which of the AM technologies used allowed the manufacture of a prototype that behaved as close as possible to the final desired product, allowing accurate functional anatomical testing. A secondary objective was the overall cost of the prototype.

Methodology

The design process for the tracheostomy concept prototypes were targeted at fulfilling specific functions identified using a Technical Functional Analysis (TFA) approach [27]. Technical solutions were proposed taking into consideration that the medical prototypes will be manufactured using AM technologies. The functions were addressed with innovative technological solutions considering the geometric complexity freedom that AM provides.

Two methodologies were considered for the current research: Scan, Spin and Selectively Photocure (3SP™) from EnvisionTEC and Three-Dimensional Printing (3DP™) from ZCorp.

CAD Concepts

Computer Aided Design (CAD) concepts were developed using TFA by identifying the main functions of the tracheostomy device [27, 28]. Level 2 functions were defined as: F1.1 - To ensure proper position during surgery; F1.2 - To maintain position subsequent to surgery; F1.3 - To maintain shape; F1.4 - To ensure safety in usage; F1.5 - To maintain comfort. After identification and rigorous definition of the products' functions, the customization of the proposed concept was initiated according to a male patients' anatomy. The patient was selected considering that he should fit into the average of the following criteria: tracheal width; gender frequency tracheostomy occurrence; average demographics (age – excluding infants and children under 16; height; weight); principal diagnosis (respiratory disease) [28, 29, 30].

The prototype device was split into three main components: 1. The body of the tube measured from the connector with the mechanical ventilators right up to the anterior wall of the trachea; 2. The tracheal fixing system; 3. The neck plate. The other two components, the obturator and the adapter, did not undergo any significant modifications.

The body of the tube followed the literature recommendations [28] using a curvature of 60^0 in all designed concepts. The body was provided with a cylindrical cut-out element on the bottom side, which ensures the orientation of the endotracheal tube during and after surgery. In connection with the neckplate, it also enables fixation and maintenance of the position during and after surgery. The internal diameter of the tube was set at 7 mm and the adaptor was designed with a 15 mm external diameter. The dimensions were chosen from a set of standardised values, so that the medical prototypes could connect with all general types of tubing from ventilators, humidifiers and speaking valves. The wall thickness of the body tube is 1.5 mm. The fixing system has a spherical/ toroidal surface with three variations in geometry: full lateral gripping elements; lateral gripping elements with model driven micro-perforations; and structural shaped lateral gripping elements (fig. 1). Three concepts of the neck plate were developed (fig.1), all of them having a common cylindrical gripping element that fits perfectly on the outer diameter of the body tube. Also, an embossed cylinder was provided in order to orient and fix the neck plate onto the tracheostomy tube. The shape of the neck plate indicates the orientation of the tube subsequent to surgery.

The mesh for *.STL conversion (fig. 2) had the same parameters for all of the concept model parts. The input

1. Prepare, orientation & position	Print job layout using ZPrint 7.6 software	Support generation using Mimics SG Module
		Print job layout using Perfactoy
2. 3D Printing	Machine preparation	Machine preparation
	3D printing	3D printing
	Component cooling	
3. Post-processing	Part removal	Part removal
	Part hardening at room temperature	Ethylic alcohol part cleaning
		Part UV Curing
	Part infiltration	Removal of support structures
		Sanding of support witness marks
	Part drying	Silicone based solution spraying
		Part drying

Table 1
SPECIFIC SUB-STAGES FOR THE 3SP™ AND 3DP™ TECHNOLOGIES

parameters for generating a high quality mesh were the following: deviation tolerance 3.382μm; angle tolerance 0.5 deg; output as binary; metric unit system.

Experimental part

Technology: 3SP™ and 3DP™

The first technology used to manufacture the tracheostomy device prototypes was 3SP™ (Scan, Spin and Selectively Photocure), on the Ultra 3SP™ 3D printer. E-Dent 3SP™ was the chosen material for this specific application, due to its characteristic benefits towards the manufacturing of the medical prototypes. The photopolymer was used strictly for test model manufacturing. The surface finish, the characteristics of the material together with the build capabilities of the machine, made the Ultra 3SP™ one of the best choices to undergo this research.

The second technology used to manufacture the medical prototypes was 3DP™ (Three-Dimensional Printing) using a ZPrinter 310 machine. Specifically for this technology and machine, the chosen material had the following components: ZP131 powder; ZB63 Black binder; Z-Max High Strength Epoxy Infiltration System.

In both cases, the parts were printed from *.STL files generated with SolidWorks *.sldprt files.

For both technologies, the main manufacturing stages of the medical prototypes were as follows (table 1): 1. Preparation, orientation and position of the *.STL files; 2. 3D printing; 3. Post-processing of the prototypes.

Results and discussions

Manufacturing of the medical prototypes

The first stage of the manufacturing process implies manipulation of the .STL files and their preparation for the printing job.

In the case of 3DP™, two sub-stages were required in order to obtain the proper *.STL files for printing, namely: generation of support structures using Mimics SG Module software and design of a print job layout using Perfactoy software (fig. 3a). Custom support structures were designed in order to accurately print the models. The structures for each individual part were developed and modified according to each surface. The bespoke supports of the prototypes were constructed in several steps, for each individual component, as follows: 1. Load the *.STL file with the component; 2. Check and verify the surface of the model – make changes if necessary; 3. Check and verify the orientation of the model – make changes if necessary; 4. Check and verify the position – make changes if necessary; 5. Generate the supports automatically; 6. Modify the support types and construction parameters in accordance with the unique characteristics of the component; 7. 2D and 3D editing of the supports in accordance with the unique surface shapes; 8. Save and export the custom supports; 9. Save and export the new *.STL file of the loaded component. By saving the component at the end of the support generation process, it was ensured that the supports and the part kept the same position and orientation in relation to each other and in relation to the coordinate system associated with the equipment build platform.

In order to print all the components, a build platform was set. The print job was designed with Perfactory software and loaded on the machines control computer. The build job was comprised of ten parts, as follows: three concepts of the tracheostomy tube with the different spherical surface tracheal fixing system; six parts of the neck plate (two of each concept); and one 15mm adaptor (fig. 3a). The neck plate concepts were printed as duplicates due to their thin features. There was concern that they would break when removing the support structures.

For the 3DP™ technology, ZPrint 7.6 software was used to orient and position the *.STL files within the build platform volume (fig. 3b). As the parts did not have the same coordinate system origin as that of the machines' coordinate system origin, several commands were used to position and orient the parts: "Rotate", "Justify Parts" and "Translate". The first part loaded on the build platform was Concept 1 of the tracheostomy device body tube, followed by the other two concepts. Concept 3 was printed twice in case of damage to the thin wall features. The same reasoning led to manufacturing of three copies of the neck plate. The neck plate concepts were positioned

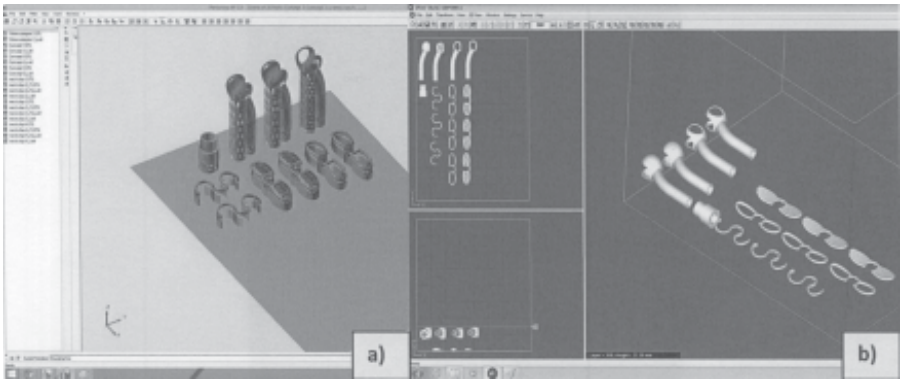

Fig. 3. Orientation and positioning of the medical prototypes on the build platform: a) the Ultra 3SP machine; b) the ZPrinter 310 equipment

	3DP™	3SP™
Printer Type	ZPrinter 310	Ultra 3SP™
Material Type	ZP 131	E-Dent 3SP™
Build Height	38.10 mm	68.15 mm
Layer Thickness	0.0889 mm	0.050 mm
Number of Layers	428	1363
Estimated Build Time	1 h 18 min	10h 35 min
Estimated Binder Usage	36.8 ml	-
Total Volume of Parts	11.98 cm^3	67.02 cm^3
Total Surface Area	248.36 cm^2	418.51 cm^2
Surface to Volume Ratio	52.68	15.86

Table 2
PRINT JOB CHARACTERISTICS FOR THE MEDICAL PROTOTYPES

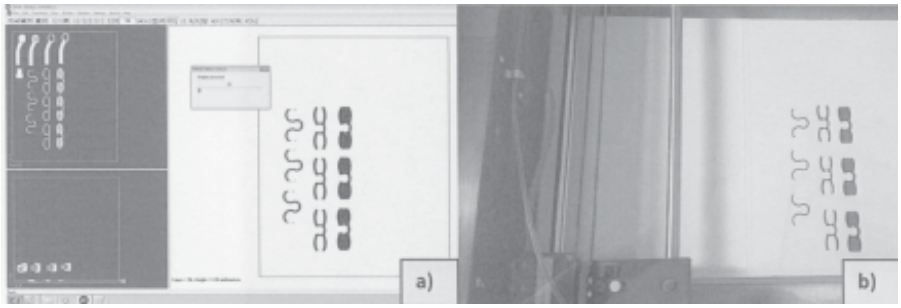

Fig. 4. 3DP™ technology on the Zprinter 310:
a) "Collision Detection" Function – Layer 20; b) 3D Printing – Layer 20

at the bottom of the build platform using the "Justify Part – to Bottom" command in the XOY plane. This action was needed to facilitate removal of the parts by separating the more rigid components from the more frail ones. Thus, the entire build was comprised of fourteen parts: four concepts of the tracheostomy tube; nine parts of the neck plate (three of each concept); and one 15mm adaptor.

Using the available software, the main construction parameters were established. For the ZPrinter 310, a ZP131 powder was used with a shell and core saturation level of 100%. The binder used was ZB63 Black with a shell binder/ volume ratio of 0.215 and a core binder/ volume ratio of 0.107. Layer thickness was set to 0.0875 mm, and with bleed compensation had a value of 0.889 mm. "Time estimation report" function was enabled and the final full report of the print job was saved. The characteristics are presented in table 2.

In the proposed configuration, the parts were verified for collision with the "Collision Detection" function. The function was deployed for a 2D representation, thus, as all the layers were checked successively, the screen showed a real time image of the current analysed layer (fig. 4a). The print job was collision free and the parts were printed in the defined configuration.

The second stage consisted of the 3D printing of the parts by successively deploying the intermediary sub-stages, as presented in table 1.

With the 3SP™ technology, the batch was fabricated in 10 hours and 35 min with a voxel size depth of 50 μm.

In the case of 3DP™, the ZPrinter 310 was prepared by levelling the feed and build platforms of the machine, using a succession of the following commands: "spread", "build" and "feed". Before giving the print command, the level of binder and powder are checked, as well as the network connectivity of the machine and of the ZPrinter software. The actual printing process lasted an hour and eighteen minutes (fig. 4b). The parts and the machine were left to cool down before opening the top cover and beginning the part removal process.

Post-processing is the final stage of prototype manufacturing for both technologies.

For the 3SP™ manufactured prototypes, the post-processing stage required: removal of parts from the build platform; degrease in ethylic alcohol bath; UV curing; removal of support structures; sanding of support connection points; spraying with degrease solution (50-50 water ethylic alcohol); and air-dry. The removal of the parts from the build platform table was undertaken using a special palette knife. Before removing the support structures, the parts were left in ethylic alcohol in order to remove the oils from the photopolymer. The parts were placed in a UV curing unit in order to fully harden. After curing, the supports were removed using special cutters and pliers. The supports were removed with minimum marks and residue on the connection surface due to their bespoke design in accordance with the type of surface. The desired surface finish was achieved by sanding down the support marks with different size emery paper. A silicone based solution was sprayed on all parts for a better surface finish and left for half a day to rest. Subsequent to the post-processing and treatment stages, the parts were air and paper dried and assembled in order to assess the functionality of the assembly.

The post-processing for the 3DP™ parts consisted of: part removal from the build platform; part hardening at room temperature; infiltration of parts; and air dry at room

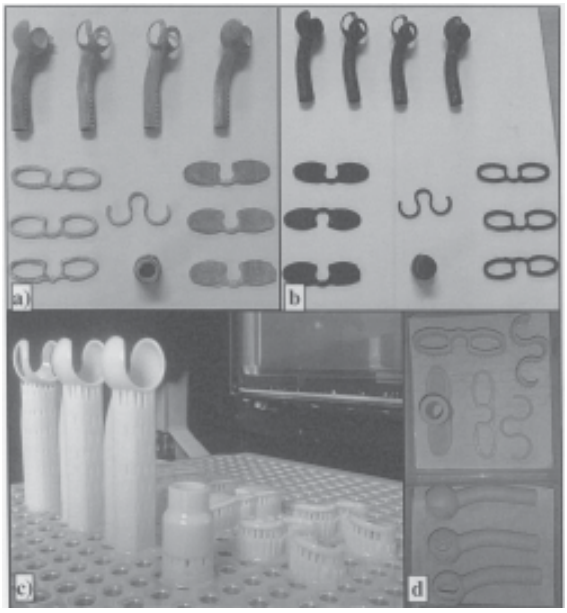

Fig. 5. Medical prototypes fabricated: with 3DP™: a) before post-processing, b) after the last stage of post processing; with 3SP™: c) before post-processing, d) after the last stage of post processing

	Mechanical properties [MU]	Value
3DP™, zp151, Z-Max 90	Tensile Strength [MPa]	26.4
	Elongation at Break, %	0.21
	Modulus of Elasticity [MPa]	12560
	Flexural Strength [MPa]	44.1
	Flexural Modulus [MPa]	10680
3SP™, E-Dent	Tensile Strength [MPa]	30
	Modulus of Elasticity [MPa]	> 4400
	Flexural Strength [MPa]	> 90
	Vickers hardness [HV]	25
	Compressive Strength [MPa]	> 250

Table 3
MECHANICAL PROPERTIES FOR ZP151 INFILTRATED WITH MAX 90 AND E-DENT

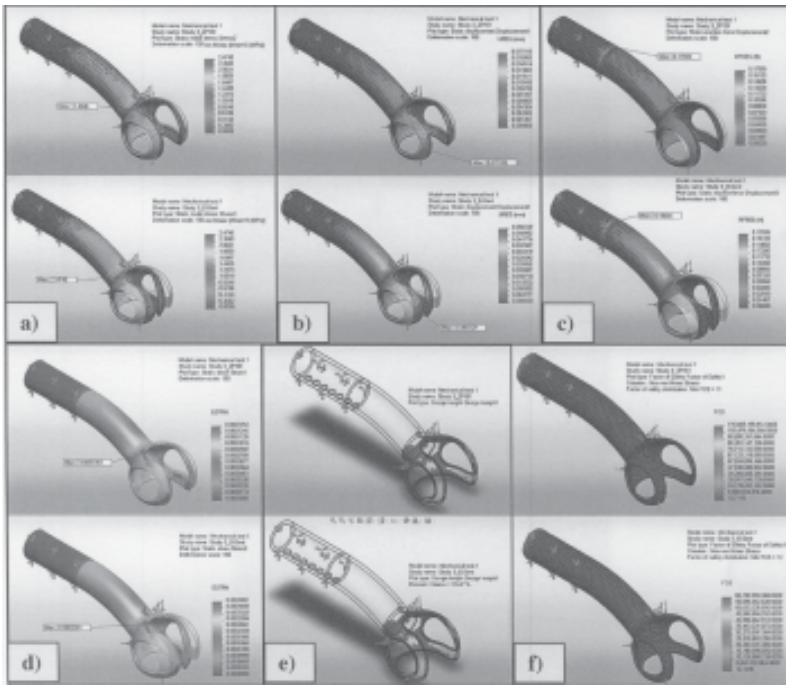

Fig. 6. Mechanical simulations for Concept Model 3: a) von Mises Stress; b) Resultant Displacement; c) Resultant Reaction Force; d) Equivalent Strain; e) Insight Design; f) Factor of Safety (materials: ZP151 – upper; E-Dent – lower)

temperature. The manufactured parts were removed from the build platform by successive lifting of the platform and continuous powder evacuation. The clean parts were left to dry at room temperature for approximately one hour. The infiltration system is used to improve the mechanical properties of the part. Thus, a mixture of 100 parts Z-Max resin to 41 parts Z-Max hardener by volume was used. For impregnation of the fourteen parts, 30.5 mL of infiltration mixture was required. Due to the dimension of the parts and the quantity of infiltration mixture, the prototypes were left to dry at room temperature for six hours. The prototypes obtained with the two selected technologies are presented in figure 5, before and after the post processing stage.

Mechanical characteristics and simulations

The prototypes obtained with 3SP™ and 3DP™ technology would eventually be destined for functional tests undertaken by medical specialists. Thus, the authors decided to evaluate the mechanical properties using FEA simulations. The mechanical simulations were defined in SolidWorks using the mechanical properties given by the materials suppliers and presented in table 3.

After the material definition stage, a fixture was defined around the cylindrical section of the body tube. This segment was considered to be held in place by the adaptor when the fitting of the prototype occurred. The neck plate is fitted tangentially to the cylindrical body tube and to the adaptor. Hence, the neck plate and the adaptor were regarded as static and isolated from the simulations. The next stage required the identification of external surface loads and values. Recommended literature values [28- 32] were used to define: the clamping force of the spherical fixing system during the insertion procedure; the force around the connection point of the spherical surface with the cylindrical body maintained by the stoma after the insertion and fixing; the pressure of the spherical fixing system on the tracheal wall. Thus, the loads are as follows: Force 1 - 5N; Force 2 - 2N; Pressure 1 - 2.942 kPa. In order to evaluate the mechanical characteristics of the prototypes, six simulations were undertaken for both materials, ZP161 and E-Dent: 1. The von Mises Stress; 2. URES - Resultant Displacement; 3. RFRES – Resultant Reaction Force; 4. ESTRN – Equivalent Strain; 5. Design Insight; 6. Factor of Safety with Maximum von Mises Stress criterion.

In figure 6, the results from all six simulations are presented, for Concept Model 3 in materials ZP161 and E-Dent. A deformation scale of 100 was used for all plots. Similar mechanical simulations were developed for all three concepts of the new tracheostomy device and the results are summarized in table 4.

The results obtained show that the geometry of the spherical fixing system influences the behaviour of the models under stress. The first concept model has the highest values for all mechanical parameters studied. Nevertheless, all concepts have a very good factor of safety. The stresses and deformations that involve the anatomical fitting tests will not affect any of the proposed concepts. The E-Dent materials obtained higher values for all simulations, than the ZP151. That is not necessarily a good result, as the prototypes need to be flexible enough to be fitted into the tracheal lumen and to snap into place.

Manufacturing costs

When choosing an AM technology, price is also considered, especially for prototype applications, which tend to be iterative. Complexity costs can be ignored, but the amount of material and the labour involved in the manufacturing of the part tend to dictate the overall price.

Material	Mechanical simulation	Concept Model 1	Concept Model 2	Concept Model 3
3DP™, zp151, Z-Max 90	von Mises Stress [MPa]	3.2263732	3.0010204	2.4646416
	URES [mm]	0.0195384	0.0193413	0.0174165
	RFRES [N]	0.2119656	0.2091173	0.1759941
	ESTRN	0.0001786	0.0001584	0.0001353
	Design Insight [%]	21.47	21.26	19.47
	FOS	8.18256	8.79701	10.71149
3SP™, E-Dent	von Mises Stress [MPa]	3.2276466	3.0047846	2.4745104
	URES [mm]	0.0559340	0.0552547	0.0501292
	RFRES [N]	0.2234910	0.2183614	0.1860382
	ESTRN	0.0005248	0.0004685	0.0003991
	Design Insight [%]	21.60	20.27	19.47
	FOS	9.29469	9.98408	12.12361

Table 4
SIMULATION RESULTS FOR THE PROPOSED TRACHEOSTOMY DEVICE CONCEPT MODELS USING ZP151 INFILTRATED WITH MAX 90 AND E-DENT

1	Print job layout	20 min	Support generation	3h
			Print job layout	15 min
2	Machine preparation	25 min	Machine preparation	30 min
	3D printing	1h 18 min	3D printing	10h 35min
	Component cooling	60 min		
3	Part removal	15 min	Part removal	10 min
	Part hardening at room temperature	60 min	Ethylic alcohol part cleaning	30 min
			Part UV Curing	5h
	Part infiltration	15 min	Removal of support structures	45 min
			Sanding of support marks	1h
	Part drying	6 h	Silicone based solution spraying	5 min
			Part drying	12 h
TOTAL		10h 33min		33h 50min

Table 5
MANUFACTURING TIME ESTIMATIONS FOR THE MEDICAL PROTOTYPES USING THE 3SP™ AND 3DP™ TECHNOLOGIES

Thus, there are three main cost drivers when using AM technologies to fabricate medical products: amount of material, time and skilled labour.

This pricing structure is completely different from traditional manufacturing methods, where mass manufacturing reduces the overall cost of one individual part. Traditional methods often produce relatively simple design parts in large quantities. For these traditional methods, the costs rise with the complexity of the shape and the number of operations needed. In this matter, AM can drastically reduce costs and accelerate product development in the early stages, this being the case for bespoke medical devices.

In the case of the tracheostomy prototypes, the manufacturing costs were evaluated considering the following criteria: material usage; energy usage; labour; and recycling characteristics.

As shown in table 2, the total volumes for both of the printed batches are: 11.98 cm^3 for the 3DP™ technology and 67.02 cm^3 for the 3SP™ technology. The difference in volume of material used is as a result of the need for support structures, which were customised for the thin wall structures of the medical prototypes.

Material costs were purchased from the manufacturers at different rates. For the 3DP™ there are three components of the material, each priced differently: ZP 131 powder at 769 euro/ 8KG bucket; ZB63 Black binder at 267 euro/ 1 litre cartridge; Z-Max High Strength Epoxy Infiltration System at 110 euro / 1.4 litre bottle. Considering the aforementioned costs, the batch was printed at a material cost of 14.96 euro. The E-Dent photopolymer was purchased at 372 euro/ 1kg bottle. The batch was printed in this case at a material cost of 59.84 euro.

It can be observed that material costs for the 3SP™ are four times higher than those of the 3DP™. Thus, for research applications with multiple concepts, manufacturing iteration using 3DP™ is more cost effective.

The costs of energy usage and salary expenses were estimated by calculating the production times for the part batches. Table 5 shows the manufacturing times for the medical prototypes.

The electric energy consumption for each machine considered was 0.92 KWh. For the 310 ZPrinter, the compressor consumption was also considered. The UV curing unit had the same energy consumption. The computers used for part modelling had an energy consumption of 0.3KWh. The energy price was considered at 0.12euro/KWh. From table 5, the duration of the two AM processes are as follows: 3 hours and 43 min of printing with 20 min of computer usage for the 3SP™ technology; 16 h and 5 minutes of printing with 3 h and 15 min of computer usage for the 3DP™ technology. The costs of the energy usage for each manufactured batch were calculated using the aforementioned values and were approximated at: 0.422 euro for the 3DP™ technology and 1.897 euro for the 3SP™ technology.

In order to manufacture the medical prototypes, an engineer and a technician were employed. The engineer was paid with an hourly fee of 3 euro/h and the technician 2 euro/h. Both worked throughout the manufacturing of the medical prototypes. Thus, the salary costs for the development and manufacture of the medical prototypes using 3DP™ were 52.75 euro and using the 3SP™ technology the costs weren109.2 euro .

Using the E-Dent photopolymer, the support structures removed can be recycled in usual plastics/ composites standards. The used parts are appropriate for medical grade recycling procedures. This quantifies to a reduction in cost of 25% of the overall price. The ZP 131 powder can be recycled right into another build platform and into the collection container of the machine. After shifting the remaining powder, this can be reused for another build. After anatomical tests the prototypes manufactured with 3DP™ cannot be recycled and were discarded appropriately. Due to these characteristics, a reduction in cost of 8% will be used in this last case.

After totaling all the above costs the tracheostomy concepts were manufactured with an average cost of 62.7 euro using the 3DP™ technology and 128.2 euro using the 3SP™ technology.

Conclusions

An array of AM technologies enables the fabrication of unique complex prototypes in the medical industry. Choosing the appropriate technology to manufacture a

specific medical prototype greatly influences the ability of the product to perform a predefined need driven function. The current study proposed the in-depth analysis of two AM technologies applied to the fabrication of custom medical prototypes with thin wall structures. A set of tracheostomy tube concept prototypes were used to design two individual build batches. In order to get optimum results from each technology, the processing parameters were customised for the particularities of the medical products. The main difficulty was to obtain functional geometries from the thin wall structures after all the manufacturing stages were finished. For the comparative evaluation of the AM technologies, three main criteria were assessed, namely: speed of fabrication, mechanical characteristics and manufacturing costs. After undertaking the procedural analysis, there was not an obvious optimum technology, each of the two presenting several different advantages.

Thus, the main advantages of the 3DP™ technology were as follows: Faster manufacturing process: almost three times faster than 3SP™; Up to four times cheaper than the 3SP™ in the proposed printing layout. Less qualified workforce required; Less material usage; Allows powder reuse; Better mechanical simulation results for ESTRN and RFRES.

For the 3SP™ technology, the advantages were identified as follows: Better surface finish after post processing operations; Better repeatability of the machine (more accurate parts); Better mechanical simulation results for FOS and URES; Better small feature definition; Allows recycling in usual plastics standards.

As the mechanical results were in the same range, the decisive factors for choosing the optimum AM technology were time and cost of fabrication. The overall costs of fabricating the bespoke medical prototypes with thin wall structures were of 62.7euro and respectively, 128.2euro The 3DP™ costs were three times smaller than the costs of manufacturing with 3SP™. Also, the speed of fabrication was four times lower in the case of 3DP™ over the 3SP™. Thus, the optimum technology that was chosen to further develop the tracheostomy concepts is 3DP™. The affordability, adaptability and ease of use of the machine, together with appropriate build batch design and the versatility of the used material, were the key factors in selecting 3DP™ as the optimum fabrication technology.

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