Evaluation of direct and indirect additive manufacture of maxillofacial prostheses

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Abstract

Aims: The efficacy of computer-aided technologies in the design and manufacture of maxillofacial prostheses has not been fully proven. This paper presents research into the evaluation of direct and indirect additive manufacture of a maxillofacial prosthesis against conventional laboratory-based techniques.

Methods: An implant/magnet retained nasal prosthesis case from a UK maxillofacial unit was selected as a case study. A benchmark prosthesis was fabricated using conventional lab-based techniques for comparison against additive manufactured prostheses. For the computer-aided workflow, photogrammetry, Computer Aided Design (CAD) and Additive Manufacture (AM) methods were evaluated in direct prosthesis body fabrication and indirect production using an additively manufactured mould.

Qualitative analysis of position, shape, colour and edge quality was undertaken. Mechanical testing to ISO standards was also used to compare the silicone rubber used in the conventional prosthesis with the AM material.

Results: Critical evaluation has shown that a Computer-aided workflow utilising can produce a prosthesis body that is comparable to that produced using existing best practice. Technical limitations currently prevent the direct fabrication method demonstrated in this paper from being clinically viable.

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Conclusions: This research helps prosthesis providers understand the application of a computer-aided approach and guides technology developers and researchers to address the limitations identified.

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Introduction

Increasing patient numbers, the need to improve process efficiency, the desire to add value to the profession and the lack of access to maxillofacial prostheses provision in some areas of the world has led researchers to investigate the potential benefits of computer-aided technologies. Technologies such as three-dimensional surface scanning, Computer Aided Design (CAD) and Rapid Prototyping/Additive Manufacturing (RP/AM) have been applied in a number of research cases yet they are not in widespread clinical application. Within the published literature, computer-aided technologies have been employed in different ways, the most common method being to digitise pattern design and incorporate this into conventional mould and final prosthesis production. (1-12) These methods rely on lab-based methods to produce moulds or time-consuming techniques such as vacuum casting. Computer-aided mould tool production has also been attempted, (13) however the techniques presented were not sympathetic to the skills of maxillofacial prosthetics, prosthodontics or anaplastologist professions and were not able to address the subtlety of design that makes a facial prosthesis realistic.

Previous research has predominantly been reports of individual cases and have not attempted critical evaluation. Consequently, they do not provide robust evidence to support or dismiss either the clinical efficacy or cost effectiveness of computer-aided technologies. Such evidence is recognised as critical to the adoption of a high value, technology-based approach. (14) A more recent, comprehensive review concluded that “the full benefits of digital technologies will only be achieved through the adoption of an appropriately devised, implemented and evaluated work flow”. (15)

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Furthermore, silicone elastomer is proven in clinical application, material characteristics have been identified, (16) but how this compares to currently available RP/AM materials has not been explored.

This paper addresses the limitations of previous research and considers three aspects of evaluating the effectiveness of computer-aided technologies in facial prosthesis production: workflow, aesthetic outcome and material characteristics.

Computer-aided methods were evaluated through a case study and controlled experiments to ISO standards. Through consultation with the prosthetist undertaking the case, criteria for aesthetic evaluation were established and barriers encountered in previous research were considered. This helped to ensure an appropriate and intuitive process with outcomes that could be evaluated.

This paper also compares the physical properties of an AM material that could be used in the fabrication of facial prosthetics with those of a benchmark silicone commonly used in facial prosthesis production.

Methods

A magnet retained nasal prosthesis case was chosen as a case study to compare computer-aided with conventional methods. The patient had undergone a rhinectomy (total nose removal) following cancer and had been wearing a prosthesis for 2 years prior to this revision. Informed patient consent was

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obtained and the study was undertaken as part of routine treatment to provide a new prosthesis. This ensured that minimal additional procedures were required. The processes are illustrated in figure 1.

Insert figure 1

On reviewing available AM technologies it was apparent that no existing technology is capable of producing a realistic, detailed, coloured facial prosthesis directly. Therefore, an analysis of existing workflows revealed two possible applications of AM that could potentially improve the efficiency of prosthesis construction, whilst maintaining a viable outcome:

i) Direct AM prosthesis production of the body of the prosthesis from a digital design, which could then be wrapped in a thin layer of colour matched, detailed silicone

ii) Indirect production of the prosthesis body in a colour matched silicone by moulding in a mould produced from a digital design and made using AM.

Both approaches relied on 3D photogrammetry to capture patient anatomy data and FreeForm CAD for the initial design of the prosthesis form. A benchmark prosthesis was also fabricated by a highly skilled, chief maxillofacial prosthetist with 22 years experience using conventional methods based on recognised best practice and published literature. (17) This is shown in figure 2.

Insert figure 2

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Common stage - Patient scanning and design

A base plate was fabricated using light cure acrylic material (TranSheet, Dentsply, York, USA) on the original replica cast. This was also coated in a grey paint to aid three-dimensional topography capture.

Photogrammetry (3DMD, Face Capture system, Atlanta, USA) was used to capture the facial topography with the base plate in position and with the patient's original prosthesis (since they were happy with the shape). The proprietary 3D Patient (3DMD) software used to create a STereoLithography (STL) file of the two data sets. Figure 3 shows the resulting mesh structure around the nasal area.

Insert figure 3

The STL data were imported into the CAD software, FreeForm Modelling Plus (Version 11, SensAble Technologies, Boston, USA) as 'digital clay' models with 0.2mm edge sharpness using the 'hole filling' option. FreeForm has previously been shown to be an appropriate software application for the computer-aided design of prostheses . (18,6,7)

Areas of the face where the prosthesis margins required positive pressure to form a blended seal with the skin were adjusted using the 'smudge' tool to press and reduce the thickness of skin by 1-2mm. The 'tolerance map' tool was used to gauge the depth of the modification (figure 4).

Insert figure 4

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The digital face was then converted to a 'buck' model, which protects it from further modification. Areas of 'clay' representing air voids were then built up and the model turned into a 'buck' which prevents further unwanted modification (figure 5).

Insert figure 5

The original prosthesis form was used as the basis for the new version. This was modified to re-introduce nostrils, blend in to the surrounding anatomy and had texture details added using techniques previously described. (19) The final result is shown in figure 6.

Insert figure 6

Indirect Approach – mould design

A copy of the completed design was made to assist in mould design. The 'buck' model of the face was subtracted in a Boolean operation, leaving the prosthesis form. The main volume of the form was selected, then 'inverse selection' and 'delete' were used to remove any stray unattached pieces of 'clay'. The edge sharpness was refined and smoothed to 0.18mm, which improved the smoothness of the margins. The digital prosthesis form is shown in figure 7. The 'reduce for export' option was used reduce the STL file to 50MB to make it manageable by a modern desktop computer.

Insert figure 7

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Mould design was then undertaken in FreeForm. The copy of the prosthesis joined to the face was used to create the outer mould surface. The nostrils were blocked off with 'clay' to avoid major undercuts. A copy of the completed design was then made. A line representing the mould edge was drawn on the surface of the model around 15mm offset from the prosthesis margin. The 'emboss with curve' tool was used to create an overlaying shell with a thickness of 2.5mm on the model copy. The original version of the design was then used to perform a Boolean subtraction, leaving just the outer shell representing the top section of the mould. A flat section around the centre of the mould was created to allow the mould to be clamped together.

The lower mould section was created on the face model by building up 'clay' material to represent the internal cavity and leaving a cavity into which the silicone prosthesis would be formed. The design was 'shut off' with the outer mould at the nostril openings and the area around the base plate was kept clear to allow silicone to encase them. Care was taken to avoid large undercuts that would prevent the prosthesis from being released from the mould. An area of the face around the nose was selected to form the rear section of the mould tool. This was shelled to 2.5mm thick and the rear section removed to reduce material and therefore cost. A flat area corresponding to that on the outer shell was also created to allow the mould to be clamped together. The final mould design is shown in figure 8.

Insert figure 8

Indirect Approach - Additive Manufacture

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The two mould sections were fabricated using 3D printing (ProJet HD 3000 Plus, 3D-Systems, Rock Hill, USA) in Xtreme High Definition mode (the resolution of the machine in this mode is given as 750 x 750 x 1600 DPI (x-y-z) and the layer thickness is 16 μm). This provided sufficient detail to reproduce the textures created in the computer model and a smooth surface finish. The build took 16 hours, 40 minutes. Once complete, the wax supporting material was removed from the mould halves (90 minutes at 80°C in a temperature controlled oven) and they were cleaned and grit blasted to create a smooth, matt surface finish (approximately 30 minutes of manual labour).

The 3D printed mould was used to complete the prosthesis body by moulding silicone in a manner similar to conventional methods. A base shade colour matched silicone (Reality Series, Spectromatch Ltd., UK) was first mixed and used as the basis for creating different tones and shades that matched the surrounding skin. The inner surface of the front mould was painted with a mixture of base shade and variations to match the local surrounding anatomy colours and flocking to mimic capillaries before being packed out with the base shade. The mould was then closed and clamped ready for curing (figure 9). Figure 10 shows the final result.

Direct Approach

The direct prosthesis body production method used “Polyjet modelling” 3D printing process (Objet Connex 500, Objet Geometries, Rehevot, Israel) in a soft, transparent, acrylate-based material (TangoPlus – an Objet trade name) with a specified Shore hardness of 26-A. This was the only available AM process capable of producing objects in a soft material with similar physical properties to the

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silicone rubber typically used in prosthesis production. However, at the time of the study the material was not approved for clinical application or undergone skin sensitivity trials.

Insert figure 9

Insert figure 10

The directly manufactured prosthesis body resulted in a clear transparent form. Therefore a novel method was required to produce a realistic colour matched surface. A High Consistency HC20 silicone (Technovent Ltd, Newport, UK) was mixed with base shade and flocking. This was mill rolled to create a thin pliable sheet approximately 0.4mm thick. This was wrapped around the prosthesis pattern which had been pre-coated with G604 Primer (Technovent Ltd) used to form a strong adhesive bond. Another layer of silicone sheet was then wrapped over to create a stronger colour and the edges blended out by pressing against a hard surface with a metal sculpting tool. This was cured at 60°C for 3 hours. The final result is shown in figure 11.

Insert figure 11

Qualitative rating of aesthetic outcome

Of the three production methods, only two were judged clinically viable and worth rating in terms of aesthetic quality: the conventionally produced prosthesis and CAD/AM mould version.

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Photos looking straight on, at a 45° angle and side on were taken to record the aesthetic result of each prosthesis. The set of three images for each prosthesis was printed on separate sheets for the reviewers to rate the results. 19 people who worked within the hospital unit in other dental specialties, but were blinded to the design and construction methods used were asked to evaluate the prostheses.

A Likert 5 point rating scale was used to evaluate 4 aspects of prosthesis appearance: positional accuracy, shape, colour and quality of edge. A student t–test (2 tails, type 2, p=0.05) was also used to identify the significance between the results.

Material Testing

Since no specific standard yet exists for evaluating the performance of AM-produced samples, mechanical testing was undertaken as a pilot study to provide a benchmark. Three aspects of mechanical performance were tested: Tensile testing, elongation at break (ISO 37:2005) and tear strength (ISO 34-1:2010). Each test was repeated 5 times for each material at room temperature (approximately 21^{o}C).

Three-dimensional computer models were made of the test specimens using computer-aided design software (ProEngineer Wildfire 4, PTC, Needham, MA, USA) according to the dimensions specified in the ISO standards. The CAD files were exported as STL files (Figure 12 & figure 13) suitable for AM. All of the samples were produced in a single build using an Objet Connex 500 in TangoPlus material (Objet Ltd., Rehovot, Israel).

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For the benchmark comparison, test specimens were produced from a non-coloured silicone rubber (M511, Technovent Ltd., Newport, UK). This is the same chemistry of silicone that was used for the traditionally manufactured silicone prosthesis, but sold by a different company and was not pre-coloured. Test specimens were cut from a cast sheet of the silicone by mechanical die cutter to the same ISO specifications.

Insert figure 12

Overall length A/mm	**Width of ends B/mm**	**Length of narrow portion C/mm**	**Width of narrow portion D /mm**	**Transition radius outside E/mm**	**Transition radius inside F/mm**
115	25.0±1	33±2	6±0.4	14±1	25±2

Table 1. Dimensions of the tensile test bar

Insert figure 13

Overall length A/mm	**Width of ends B/mm**	**Length of cut C/mm**
≥100	15±1	40±5

Table 2. Dimensions of the tear test strip

Tensile testing and elongation at break were ascertained using a Lloyds LR50KPlus testing machine set with a 1kN load cell and an elongation speed of 500mm/min. The same Lloyds testing machine was used to establish tear strengths; a 1kN load cell was used and the specimens were fixed into two crossheads and torn at the speed of 100mm/min.

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Results & findings

Aesthetic outcomes

The results of the Likert scale ratings are shown in tables 3 and 4.

Conventional	**Mean**	**Std. Dev.**
Position	3.158	1.068
Shape	2.474	1.219
Colour	3	1.202
Edge	1.947	1.129

Table 3. Mean average ratings and standard deviations of aesthetic quality for the conventionally produced prosthesis

RP mould	**Mean**	**Std. Dev.**
Position	3.842	0.834
Shape	4	0.745
Colour	3.842	0.688
Edge	3.526	0.772

Table 4. Mean average ratings and standard deviations of aesthetic quality for the RP mould produced prosthesis

The student t-test results are shown in table 5.

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Aesthetic factor	Significance
Position	0.034241
Shape	0.000043
Colour	0.011873
Edge	0.000014

Table 5. Student t-test results identifying significance between the rated aesthetic outcomes of each prosthesis

Mechanical properties

The calculation of tensile strength is:

$$\frac{}{}$$

Where Ts—tensile strength (MPa), Fm—maximum force (N), W—width of the gauge section (mm), t—thickness of the test length (mm). The average dimensions, maximum force and tensile strength values of selected materials are shown in Table 6.

Testing Sample	Average maximum force(Fm)/N	Average width (W)/mm	Average thickness (t)/mm	Average tensile strength (Ts)/MPa	Std. Deviation
TangoPlus	19.05	6.02	2.99	1.1	0.068605

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M511 Maxillofacial silicone rubber	61.46	6.01	3.00	3.4	0.14988

Table 6. Average dimensions, maximum force and tensile strength values of TangoPlus and M511 silicone

Elongation is defined as the increase of the length of narrow portion (ΔL) subjected to a tension force, divided by the original length of the test sample (L). It also can be named as strain (ε). The calculation of strain is shown as:

The average values of elongation at break for TangoPlus and M511 silicone rubber material are shown in table 7.

Test sample	**Elongation at break (%)**	**Std. Deviation**
TangoPlus	365.36	11.08873
M511 Maxillofacial silicone rubber	1181.87	34.88931

Table 7. Average values of elongation at break for TangoPlus and M511 silicone rubber

The calculation of tear strength is shown as follows:

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Where F—the maximum force/N, d—the median thickness of the test piece/mm. The curves of tear load versus extension are shown in figure 14. Table 8 shows the average tear strength of M511 silicone and TangoPlus material.

Insert figure 14

Testing sample	**Average tear strength N.mm^{-1}**	**Std. Deviation**
TangoPlus	0.897	0.057764
M511 Maxillofacial silicone rubber	5.471	1.009447

Table 8. Average tear strength of M511 silicone and TangoPlus material

Discussion

The qualitative rating results indicated a high degree of confidence that the digital mould design and production process created an aesthetically acceptable prosthesis. The results demonstrate a significant difference in favour of the AM mould prosthesis over the conventional version in all aspects, but especially in edge quality. Given that the final prosthesis was also produced in a suitably biocompatible material, with demonstrated clinical acceptance, it provided a prosthesis that was fit for purpose and viable for use. The shape was also rated significantly better on the digital version, perhaps due to the ability to analyse and adjust it from viewing angles that are more difficult to achieve when observing a patient sat in a chair (figure 15).

Insert figure 15

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From a process perspective, computer-aided technologies improved flexibility of working for the prosthetist. Design work was undertaken independently of the patient and mould production was semi-automated. The computer-aided mould technique described also has the potential to remove a full day of clinic and waiting between processes for the patient. Conventional stages of taking a physical impression and hand carving were condensed into two short consultation periods, the first to 3D capture the facial topography and the second to colour match the silicone and final fit the prosthesis.

The research presented also highlights specific limitations of using a computer-aided approach. These can be classified as process, cost, material and technical limitations.

Despite demonstrated improvements in process flexibility, further, in depth measurement of the resources and time taken to fabricate prostheses is required in order to accurately determine the actual cost and overall viability of computer-aided technologies. This is challenging when dealing with low case numbers and with every case being unique, but essential if a computer-based approach is to be widely adopted in clinical practice. Even with process efficiency savings, there is a significant offset in the cost of technology investment and machine time that should be considered if critically comparing the economics of each method.

Although the concept of direct AM body production was demonstrated, the mechanical testing results highlight the limitations that prevent it being used in the manufacture of a definitive prosthesis. Whilst the TangoPlus material currently represents the closest match to the physical properties of the benchmark silicone, it is not sufficiently robust. TangoPlus has a tensile strength of just 1.06MPa and a tear strength of less than 1N/mm, which when subjected to daily wear and tear would likely result in

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premature breakdown of thin wall sections. Since the AM material used is an acrylate-based, ultraviolet-curing photopolymer, prolonged exposure to ultraviolet light and other weathering may cause further degradation of mechanical properties and this should be investigated in future work. Further studies with a larger sample number would also be necessary in order to thoroughly evaluate the deviation in mechanical properties in RP-produced components.

In order to make the direct AM fabrication process viable, it would be necessary to additively manufacture prostheses in a suitably biocompatible material with mechanical properties closer to the benchmark silicones currently used. The ability to selectively print multiple materials and transparent materials means that, in principle, the Objet process could be expanded to also selectively print colour to produce a colour matched prosthesis body in a soft, pliable material. However, this would require a great deal of materials and process research and development and means that the adaption and development of an existing AM system may still not entirely result in the desired products due to inherent restrictions in the machine's initial fundamental design. It may therefore be more viable and valuable to consider the development of a dedicated AM system that fully met the needs of this application.

Another aspect that requires further technical refinement is digital base plate design. Due to technology limitations of photogrammetry or any other currently available 3D surface scanning technique, it is not possible to capture the relatively large volume of the gross facial topography and the very small abutment or magnet details in the same scan with sufficient resolution and accuracy. Refinement of computer-aided techniques in base plate and retention mechanism design would enable an entirely digital prosthesis creation route. Experiments to refine suitable techniques are on-going.

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Conclusions

Two alternative methods of using computer-aided technologies were used to produce a facial prosthesis. The method utilising the AM produced mould resulted in a prosthesis that was judged by experts to be clinically acceptable and rated superior to a benchmark prosthesis produced using conventional methods. Despite the potential for using AM to produce a prosthesis body directly, poor mechanical properties and un-tested biological responses of the chosen material currently prevent it from being used in clinical application. Further research is required to test the biological response of AM materials, improve the mechanical properties and optimise the digital design process around direct fabrication. Further work is also necessary to incorporate base plate design to create an entirely digital process.

Both computer-aided methods enabled the prosthetist to work in a more flexible manner without relying on long patient consultations. They also reduced the length of consultation time for the patient, who only had to attend for a surface scan, then a colour match on a separate day.

This research contributes towards the understanding of how computer-aided technologies may most effectively be used in clinical extra-oral prosthesis cases and provides direction to future research efforts.

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Illustrations and tables

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Figure 12: The image of tensile testing sample (ISO 34-1:2010)

Figure 13: Tear test sample (ISO 37:2005)

Figure 14. Tear load versus extension for M511 silicone and TangoPlus

Figure 15. Viewing the prosthesis design from below with a measurement plane used to evaluate positioning

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