

# Rapid prototyping technologies in soft tissue facial prosthetics: current state of the art

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## **Abstract**

**Purpose** – Maxillofacial Prosthetics is faced with increasing patient numbers and cost constraints leading to the need to explore whether computer-aided techniques can increase efficiency. This need was addressed through a four-year research project that identified quality, economic, technological and clinical implications of the application of digital technologies in maxillofacial prosthetics. This article addresses the aspects of this research that related to the application of Rapid Prototyping (RP).

**Design/Methodology/Approach** – An Action Research approach was taken, utilising multiple case studies to evaluate the current capabilities of digital technologies in the preparation, design and manufacture of maxillofacial prostheses.

**Findings** – The research indicates where RP has demonstrated potential clinical application and where further technical developments are required. The paper provides a technical specification towards which RP manufacturers can direct developments that would meet the needs of Maxillofacial Prosthetists.

**Originality/Value** – Whilst research studies have explored digital technologies in maxillofacial prosthetics, they have relied on individual studies applying a single RP technology to one particular aspect of a prosthesis. Consequently, conclusions on the wider implications have not been possible. This research explored the application of digital technologies to every aspect of the design and manufacture of a series of maxillofacial prostheses. Unlike previous research the cases described here addressed the application of RP to the direct manufacture of substructures, retention components and texture. This research analysed prosthetic requirements to ascertain target technical specifications towards which RP processes should be developed.

**Keywords** Computer-aided design, rapid prototyping, prosthesis, maxillofacial, soft tissue

**Paper type** Research paper

## 1. Introduction

Patients who suffer from facial deformity, either, congenital, traumatic or from ablative surgery are treated by Maxillofacial Units using a variety of surgical and prosthetic techniques. Maxillofacial Prosthetics & Technology covers the treatment and rehabilitation of these patients by producing facial prostheses using artificial materials. Improvements in medicine, surgical techniques and in particular cancer survival rates are resulting in ever increasing patient numbers. However, these same drivers are also leading to higher costs, which is putting pressure on healthcare providers to improve efficiency during a period when the number of newly qualified Maxillofacial Prosthetists and Technologists is only matching the number retiring (Wolfaardt *et al.*, 2003).

These pressures have led researchers to explore whether the cost and time savings associated with advanced design and product development technologies can be realised in maxillofacial prosthetics. Technologies such as three-dimensional surface capture (3D scanning), three-dimensional Computer-Aided Design (3D CAD), and layer additive manufacturing processes (or Rapid Prototyping and Manufacturing – RP&M) have been investigated in maxillofacial prosthetic applications. However, the literature is mostly comprised of reports of single case studies that describe a given technology or application. Much early work involved making an anatomical form using RP processes such as stereolithography or laminated object manufacture (Chen *et al.*, 1997; Coward *et al.*, 1999; Bibb *et al.*, 2000; Chua *et al.*, 2000). This research however did not attempt to integrate the RP technologies into existing prosthetic practice or was limited to the production of an anatomical form that was used as a pattern for replication into more appropriate materials via secondary processes such as silicone moulds or vacuum casting. Later research attempted to use RP methods to produce moulds from which prosthesis forms could be moulded but these required extensive time and CAD facilities and did not attempt to exploit the advantages of RP processes that could be better integrated with existing prosthetic practice (Cheah *et al.*, 2003a; 2003b). Other researchers attempted to exploit the ability of the ThermoJet (3D Systems Inc., 333 Three D Systems Circle, Rock Hill, SC 29730, USA) process to produce prosthesis forms in a wax material that was comparable to the waxes used in the typical prosthetic laboratory (Verdonck *et al.*, 2003; Reitemeier *et al.*, 2004; Sykes *et al.*, 2004; Chandra *et al.*, 2005). This enabled a more integrated approach that incorporated the advantages of RP into the existing work flow. However, these studies lacked critical evaluation of the physical properties of the prostheses produced or the technical capabilities and appropriateness of the RP technologies used for developing an integrated and efficient digital prosthetic process.

A wider investigation was therefore required in order to explore how these technologies may be applied in combination to a variety of applications. The research described here was part of a wider project to investigate whether available design technologies could be successfully applied to produce gains in efficacy and efficiency in a busy maxillofacial unit. The work resulted in a PhD thesis which covers all of the work in greater detail than is possible in this paper (Eggbeer, 2008). Four case studies (with three previously reported) were explored over a four year period in collaboration with a regional Maxillofacial Unit and complemented by two technical experiments (with one previously reported). This article focuses on the aspects of the research that addressed the current capabilities and limitations of layer additive manufacturing technologies more commonly referred to as Rapid Prototyping and Manufacturing (RP&M) technologies in maxillofacial prosthetics. The paper summarizes four years of study and draws conclusions on the current state of the art of RP&M in maxillofacial prosthetics and includes recommendations and target technical specifications towards which future RP&M developments should be made in order to meet the needs of patients and clinicians in this field.

## 2. Methodology

The case studies were planned and carried out using an Action Research (AR) approach. AR methods utilise an iterative process of research design, research implementation and evaluation. AR approaches and case studies are typically applied in the social sciences for studying “real life” situations where the researcher cannot control all of the variables or the research environment (Yin, 2003). Typically, these involve complex, changing situations and small samples. The nature of maxillofacial treatment means that each case is unique and therefore repetitive, or series studies are not possible in a clinical setting, making the AR approach appropriate for this research. Therefore, the research was undertaken through iterative case studies, the findings from each case study informing the design and implementation of the subsequent case study or experiment. The practical methods utilised in each case study or experiment varied according to the needs of the individual case study. The methods and results for each case study are summarised in section 3. A number of the cases required flexibility and adaptation to unforeseen challenges. Throughout the research, a small number of complementary experiments were carried out to establish technical capabilities that informed subsequent case studies and did not require clinical investigation.

### 3. Summary of case studies

This section summarises the methods and results from the cases that directly employed RP&M technologies. Additional, complementary case studies and experiments were carried out into related digital technologies such as 3D scanning but are not reported here.

#### 3.1 Case Study 1 – Orbital prosthesis

This study was intended to explore the use of CAD and RP&M methods that had been identified in the literature. The case utilised Computed Tomography (CT), FreeForm Modelling Plus Computer-Aided Design software (SensAble Technologies Inc., 15 Constitution Way, Woburn, MA 01801, USA) and ThermoJet rapid prototyping (3D Systems Inc., 333 Three D Systems Circle, Rock Hill, SC 29730, USA) combined with conventional fitting and finishing techniques to produce the final prosthesis.

This case explored the idea that clinical three-dimensional CT data acquired for maxillofacial surgery purposes could also be subsequently applied to aid in prosthetic design and manufacture. As it would be inappropriate to undertake unnecessary CT scans without full clinical justification this work was based on exploiting existing CT scans that the patient had previously undergone for diagnostic or surgical planning reasons. This case demonstrated that such CT data was sufficient to capture the gross facial anatomy, but it could not capture fine details such as skin texture and wrinkles, for example at the corners of the eyes. This is because a typical CT scan taken for maxillofacial surgery will require a field of view wide enough to acquire images of the whole head; this would be typically 25 cm. A typical CT scanner in clinical use will have a pixel array of 512 by 512 leading to a pixel size of 0.488 mm. As skin textures typically have depths in the range 0.1 to 0.8 mm it is clear that the pixel size is too great to be able to adequately describe skin texture (Lemperle *et al.*, 2001). Whilst it is technically feasible that a CT scan could be optimised to enable the capture of skin texture the change in CT protocol required would increase scan time and X-Ray dosage for the patient that would be difficult to justify.

This case also indicated that FreeForm was an appropriate CAD tool for the design of the basic shape of a prosthesis based on the surface data captured from the patient. The ThermoJet process successfully manufactured the prosthesis form. It was noted by the prosthetist undertaking the case that the wax ThermoJet material was compatible with his conventional maxillofacial laboratory techniques. The wax prosthesis form was therefore finished and fitted to the patient in the normal manner. It was then used as a sacrificial pattern in the production of the final silicone rubber prosthesis. This case proved that the CAD and RP&M technologies described in the literature were appropriate for further development in facial prosthetics and was subsequently published (Evans *et al.*, 2004).

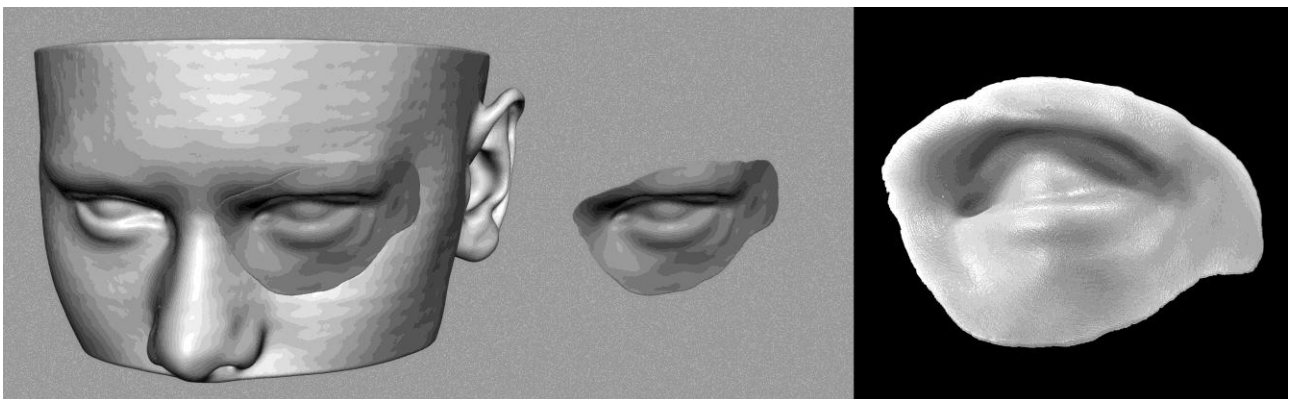
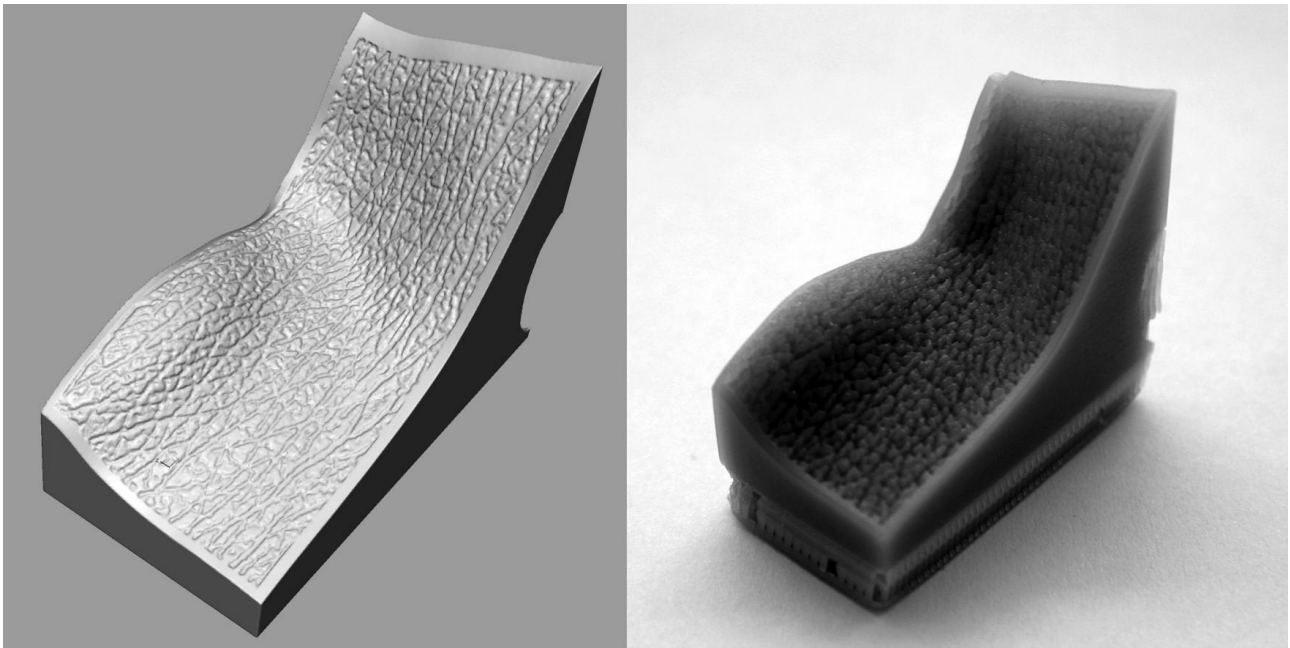


Figure 1: Orbital prosthesis designs in CAD and ThermoJet wax pattern

#### 3.2 Case Study 2 – Texture Experiment

The first case highlighted the importance of capturing and reproducing fine skin features such as wrinkles and texture. The experiment involved developing three-dimensional skin texture relief on an anatomical shape using FreeForm CAD and reproducing the relief at a series of depths identified from dermatology literature ranging from approximately 0.1 to 0.8 mm in depth (Lemperle *et al.*, 2001). The parts were produced using the ThermoJet process. The ThermoJet process was found to be capable of reproducing a convincing skin texture on a prosthesis and the study was published in 2006 (Eggbeer *et al.*, 2006a).



**Figure 2: Skin texture sample in CAD and ThermoJet wax pattern**

### **3.3 Case Study 3 – Auricular prosthesis A**

A review of the literature revealed that although RP&M had been used in maxillofacial prosthetics the cases had all addressed only the creation of the overall anatomical form of the prosthesis. The accepted “Gold Standard” for maxillofacial prostheses is the osseointegrated implant retained silicone prosthesis. Implant retained maxillofacial prostheses typically consist of multiple components, each having different physical requirements. A typical maxillofacial prosthesis will consist of the following items.

- Main body of the prosthesis to provide the anatomical form and appearance in a soft silicone material
- Rigid substructure to support the main body and provide a firm location for retention mechanisms
- Retention mechanisms in the prosthesis (clips or magnets)
- Retention mechanisms attached to the patient (bar for clips or magnets)

This case investigated the use of 3D scanning, CAD and RP&M techniques in the design and manufacture of a magnet retained ear prosthesis. 3D scanning was used to capture a plaster replica of the patient’s defect site and contralateral (unaffected) ear and then FreeForm CAD and ThermoJet technologies were used combined with standard fitting and finishing techniques. The resulting prosthesis showed that advanced technologies and RP&M could be used to develop a magnet retained ear prosthesis design and the case reported in 2006 (Eggbeer *et al.*, 2006b).

### **3.4 Case Study 4 – Auricular prosthesis B**

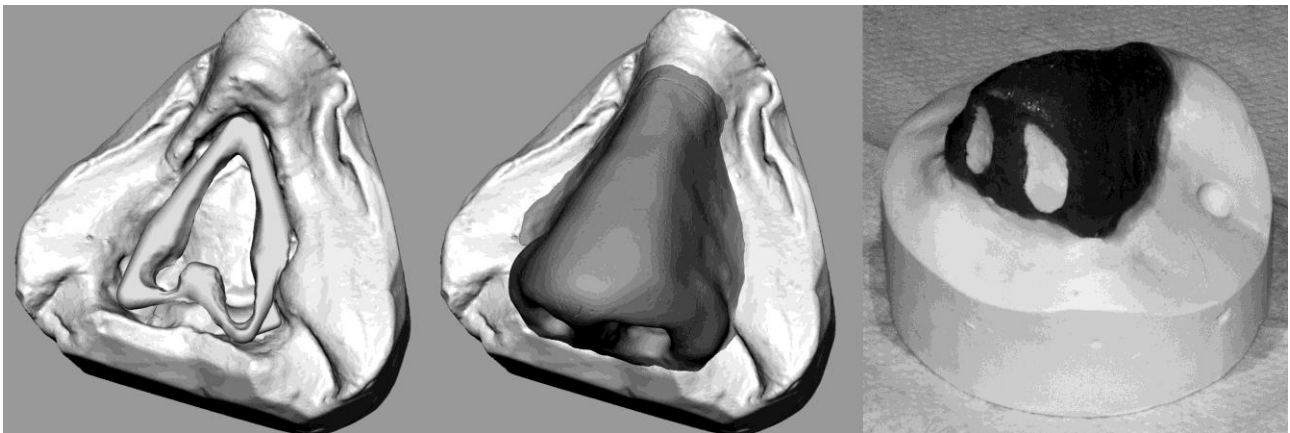
This built on the experience gained in the previous case but addresses the bar and clip retention method. As previously the defect site and contralateral ear were scanned and all of the prosthesis components were designed using FreeForm CAD. This case explored the application of a number of RP&M processes in the manufacture of the various prosthesis components. As it had been shown to be successful in previous cases the ThermoJet process was used to produce a wax pattern of the main body of the prosthesis. The rigid substructure of the prosthesis was attempted using stereolithography (SLA – 3D Systems Inc.). The design of the substructure incorporated the retention clips. The bar (which remains attached to the patient by the implants) is usually made from a suitable metal such as Titanium or Gold. In this case Selective Laser Melting (SLM – MTT Technologies Ltd., Whitebridge Way, Whitebridge Park, Stone, and Staffordshire, ST15 8LQ, UK) was utilised to produce the bar in 316L Stainless Steel. This study identified significant limitations in capturing sufficient detail of the implants abutments in order to design a precisely fitting bar. The stereolithography substructure proved adequate in design, rigidity and strength and was found to be very comparable to the physical properties of the light-cure acrylic materials that are typically used in current maxillofacial laboratories. However, it was readily apparent upon attaching and removing the substructure to the bar that the integral clips provided insufficient retention strength as they could be easily removed using very slight finger pressure. As the retention strength was so apparently low it was decided that accurate measurement of the retention force was redundant. In addition, it was also readily apparent that the service life would be insufficient for clinical use. Visible wear was apparent on the clips after fewer than 100 cycles of attachment and removal at which point the retention strength reduced to the point where the clips no longer functioned. The SLM bar demonstrated that the process had the potential to produce a clinically acceptable bar if the quality of the detail and finish could be enhanced. These findings were reported in 2006 (Eggbeer *et al.*, 2006c).



**Figure 3: SLM retention bar, SLA substructure and ThermoJet wax pattern**

### 3.5 Case Study 5 – Nasal prosthesis

This case was undertaken to apply the findings of the previous cases and compare them to entirely conventional methods. The case involved the design and manufacture of a nasal prosthesis incorporating magnetic retention. To overcome the limitations of 3D scanning the implant abutments described in previous cases, a 3D scan of a plaster replica of the patient's defect site was used rather than scanning the patient directly. The design was undertaken using FreeForm and stereolithography (was used to produce a rigid sub-structure and the ThermoJet process was used to produce the main prosthesis body in wax. This case demonstrated that digital methods (combined with conventional fitting and finishing) were capable of producing a clinically acceptable facial prosthesis. It was shown that there were no significant differences in the positional accuracy and reproduction of anatomical shape achieved by both techniques. The only significant difference was in the quality of the margin of the prosthesis. The margins of facial prostheses are made to be as thin as possible. This causes the silicone to become transparent and extremely flexible which allows the edge of the prosthesis to be closely adapted to the patients' skin and follow their facial contours without leaving a conspicuous gap. The digitally produced designed and manufactured prosthesis was not able to reproduce a sufficiently thin margin which led to a noticeable gap.



**Figure 4: CAD designs for nasal prosthesis and ThermoJet wax pattern**

In addition to investigating the technical capabilities of advanced technologies this case was also used to compare time and cost effectiveness. This case suggested that reductions in the overall design and construction time were possible when utilising digital techniques. The application of digital technologies in this case gave a one hour reduction in the time spent by the prosthetist and reduced the patient time spent in the clinic by two hours and thirty five minutes. Whilst these reductions in time do not appear hugely significant, the ability to go straight to colour matching effectively removes a much longer period where the patient must be either in clinic or waiting nearby. The waiting and in-clinic period may effectively be reduced from a day to a single morning of work.

Reduction in consultation and laboratory time was however offset by the additional stages of scanning and RP fabrication. Whilst this extra time does not require an operator, clinician or patient input, it does add to the overall delivery time. RP fabrication is typically an overnight process with an additional delay for postage if built by a service provider. The forty minute period required to set up scans and process the data was represented by four block periods: three, five minute sessions to set the individual scans up and a final twenty minute period to process the data. This effectively meant that the operator had to attend to the scanner despite being able to carry on with other work. The

same situation is reflected for the patient and prosthetist during periods between construction stages, such as material curing and boiling out of moulds.

Stage	Prosthetist time (minutes)	Patient time (minutes)	Setting / curing time (minutes)
Initial consultation and impression taking	50	50	Included
Production of stone replica	50	0	15
Base-plate design	40	15	0
Pattern design	195	140	0
Mould production	95	0	40
Colour match	60	60	0
Curing	0	0	75
Finishing	80	60	0
<b>Total</b>	<b>9 hours 30 minutes</b>	<b>5 hours 25 minutes</b>	<b>2 hours 10 minutes</b>

**Table 1: The time taken to construct the nasal prosthesis using conventional methods**

Stage	Prosthetist / operator time (minutes)	Patient time (minutes)	Setting / curing / fabrication time (minutes)
Initial consultation and impression taking	50	50	Included
Production of stone replica	55	0	15
Scanning and conversion to STL	40	0	120
Base-plate design	15	0	0
Pattern design	76	0	0
Pattern fabrication	15	0	180
Sub-structure fabrication	20	0	90
Mould production (assume same as conventional)	95	0	40
Colour match (assume same as conventional)	60	60	0
Curing (assume same as conventional)	0	0	75
Finishing (assume same as conventional)	80	60	0
<b>Total</b>	<b>8 hours, 30 minutes</b>	<b>2 hours, 50 minutes</b>	<b>8 hours, 40 minutes.</b>

**Table 2: Target specifications for RP&M technologies**

### 3.6 Case Study 6 – Direct manufacture of retention bar experiment

This experiment addressed only the design and direct manufacture of a prosthesis retention bar. To overcome the accuracy issues when capturing the implant abutments this experiment utilised a touch probe scan of a plaster cast of a patient's defect site (Roland Pix-30 – Roland ASD, 25691 Atlantic Ocean Drive, B-7, Lake Forest, CA 92630, USA). The design of the bar was undertaken using FreeForm and the bar produced directly using SLM. Unlike the previous attempts to produce a bar using SLM this bar was produced on an SLM machine specifically designed to produce small, accurate parts (SLM-100 – MTT Technologies Ltd.). The resulting bar proved to be a good fit when it was screwed on to the abutments located in the replica plaster cast. Accuracy and surface finish of the bar were deemed acceptable for clinical use by the prosthetists.



**Figure 5: SLM bar fitted to patient cast**

## 4. Discussion

The cases studies were analysed in three areas; quality, economic impact and clinical implications.

Quality refers to characteristics such as fit (marginal integrity of the prosthesis against the skin and fit between components), accuracy (anatomical shape and position), resolution (reproduction of folds, wrinkles, texture, and substructure components), and materials (mechanical and chemical properties).

### 4.1 Fit

The margins produced using traditional techniques were measured to range from 40  $\mu\text{m}$  to 130  $\mu\text{m}$  using a dial test indicator. Whilst some RP technologies are capable of producing very thin layers, most could not produce parts in a material that could be readily incorporated into the work flow of the maxillofacial prosthetist. The vast majority of maxillofacial prosthetic sculpting is carried out using wax. Currently available RP processes that are capable of sufficiently thin layers include Objet 3D printing (Objet Geometries Ltd.), Perfactory (EnvisionTEC), Solidscape (Solidscape Inc.), ThermoJet (3D Systems) and ProJet (3D Systems). Of these, only the Solidscape, ThermoJet and ProJet systems are capable of building in a wax-based material that could be incorporated into conventional lab techniques. The Solidscape machine was deemed too slow for the size and mass of the typical facial prosthesis. Although the ThermoJet process proved capable of producing patterns in an appropriate wax material and produced parts in 40  $\mu\text{m}$  thin layers, limitations with the CAD process and fragility of the wax meant that patterns were fragile and very thin edges were prone to breaking when support structures were removed. In order to produce sufficiently thin margins, the edges of the wax RP pattern were heated and blended into the lower section of the dental stone mould using flexible metal sculpting tools.

Despite some reports in the literature there is no recognised standard method of assessing the fit between maxillofacial prosthesis retention components, e.g. between bar and implant abutments (Brånemark, 1983; Jemt, 1991; Kan *et al.*, 1999). Clinical methods often rely on identifying gaps by visual inspection and finger pressure tests for movement. The cases reported here suggested that the SLM process was capable of producing a satisfactory bar but that the optical scanning methods were not able to capture data of sufficient quality directly from the patient to enable the design of the bar.

### 4.2 Accuracy

The accuracy of a maxillofacial prosthesis is essentially a subjective visual assessment. The prosthesis should be convincing in restoring the appearance of the particular individual. Therefore it is very difficult to assess the accuracy using a quantifiable system. The approach taken in these studies has been to assess the accuracy of the prostheses created using RP&M techniques to those produced using entirely conventional techniques. In case study 5, a five point



scale was used to rate the digital and conventionally produced prostheses in terms of quality of edge, positional accuracy and overall shape. Thirteen clinical staff from the Maxillofacial Unit at Morriston Hospital were asked to rate each of the prostheses based upon photographs provided of each prosthesis. All were blinded to the production methods used (none were involved in providing these prostheses) and the images were provided sequentially. Table 3 shows the results. The results were analysed using a paired, student t-test ( $p=0.05$ ) to identify the significance between the results.

In terms of edge quality, there was statistical significance in opinions between the two prostheses ( $P=0.003695$ ) in favour of the conventional prosthesis. The average score for the conventional prosthesis was 3 (st dev = 1.35). The average score for the digitally produced prosthesis was 1.8 (st dev = 0.93).

For positional accuracy, there was no statistical significance in opinions between the two prostheses ( $P=0.179533$ ). The average score for the conventionally produced prosthesis was 4.1 (st dev = 0.76). The average score for the digitally produced prosthesis was 3.5 (st dev = 1.2).

For shape, there was no statistical significance in opinions between the two prostheses ( $P=0.064649$ ). The average score for the conventionally produced prosthesis was 4 (st dev = 1.15). The average score for the digitally produced prosthesis was 3.2 (st dev = 1.1).

In this respect the RP methods used were deemed capable of producing an accurately formed and located maxillofacial prosthesis.

Feature	Poor			Fair			Average			Good			Excellent	
	A	B		A	B		A	B		A	B		A	B
Edge Quality	3	5		1	5		3	2		5	1		1	0
Positional Accuracy	0	1		0	1		3	4		5	4		5	3
Shape	0	1		2	1		2	6		3	3		6	2

**Table 3: Responses to aspects of prosthesis quality**  
**A = conventionally produced prosthesis, B = digitally produced prosthesis**

#### 4.3 Resolution and texture

Whilst the 3D scanners investigated in these cases proved able to accurately capture overall anatomical form very well the case studies demonstrated that 3D scanning technologies are not yet able to capture data of a sufficiently detailed nature to enable the reproduction of delicate skin folds, wrinkles and texture. This limitation was also apparent when attempting to capture the precise shape and location of implant abutments. The use of plaster cast replicas of patient anatomy showed that some touch-probe scanners are capable of scanning to a high enough resolution but these involve unwanted extra process steps resulting in higher costs and longer delivery times.

Case study 2, the texture experiment, demonstrated that CAD packages are able to create three-dimensional relief at an appropriate scale to produce convincing skin textures. It also demonstrated that the ThermoJet process was able to physically reproduce these textures over an anatomically shaped surface. However, whilst the experiment was successful on small samples the associated computer file sizes were large (in the order of 100 Mb). To apply texture in this manner to the surface of a large facial prosthesis may present difficulties due to large data file sizes. A large contributor to this problem is the fact that most RP&M technologies rely on the STL file format, which is very inefficient for describing highly detailed surface relief.

#### 4.4 Physical Properties

Attempts to incorporate retention clips into substructures manufactured using RP&M techniques proved unsuccessful. Whilst RP&M technologies were shown to be capable of producing a functioning retention incorporated into the rigid substructure to a sufficient accuracy the retention strength was poor and they wore rapidly reducing retention strength still further. As a prosthesis are likely to be applied and removed twice a day over a typical twelve-month service life retentive components should be expected to provide strong retention over 1,460 cycles. The RP&M retention clips proved to suffer an unacceptable loss of retention strength after fewer than 100 cycles.

Retention bars need to be small, stiff and have good surface finish to enable easy cleaning. Due to their proximity to the skin non-reactive metals are required, such as Gold, Cobalt-Chrome, Stainless Steel, Tantalum, Nitinol or Titanium. The bars produced in this study using 316L Stainless Steel and Cobalt-Chrome showed great potential and indicated that with optimised build parameters and minimal finishing a clinically acceptable bar can be produced using RP&M techniques.

To date silicone elastomer rubber has the most suitable physical properties for maxillofacial prostheses and can be colour matched to produce a highly convincing appearance (Aziz *et al*, 2003). Currently no RP technology is capable of producing a prosthesis in silicone rubber or with physical properties similar to those required. This remains a great challenge to the RP&M industry. In the cases reported here the optimum RP&M process available proved to be the ThermoJet process. The wax parts produced were successfully incorporated into the conventional prosthetic production process with adaptation to produce finer edges, add fine details or make minor adjustments to the shape.

#### **4.5 Economics**

The economic impact of changes in maxillofacial prosthetics is difficult to quantify because each case is unique and costs vary regionally. In the UK the situation is further complicated as some costs are direct, such as materials, whilst many of the greater costs are hidden in overheads and fixed costs, such as clinical staff salaries.

Digital techniques can potentially have a significant impact on the cost effectiveness of maxillofacial prosthesis delivery. The research undertaken, and illustrated in the time savings measured in the nasal prosthesis case study, explored the impact of the digital workflow compared to the traditional practice. As such, it is difficult to identify the individual impact that the RP&M technologies can have unless they are incorporated as part of a well resolved digital technology based work flow.

The time savings indicated in Tables 1 and 2 identified that there was potential for savings in direct costs and opportunity costs. Whilst the productivity of rapid prototyping technologies cannot be objectively assessed from a single case and there would be a learning curve associated with moving to a new procedure, the fundamental differences between a digital work flow and traditional techniques enables a more flexible approach to work flow management and reduces the necessity of patient attendance at clinics. Data acquisition can be undertaken rapidly and efficiently in a clinical setting. This enables the design stages to be scheduled and undertaken at the discretion of the prosthetist without requiring the patient to be present. The reduction in both the duration of patient attendance and the number of occasions they are required to attend would result in significant savings in travel, accommodation and missed appointments (referred to as “Did Not Attend”). In addition, the saving to the patient in terms of time away from home or work is also beneficial.

In a digital work flow the physical production of prosthetic components can be achieved in a small batch basis which would enhance the cost effectiveness of running RP&M machines in a clinical setting. However, current technologies would require a level of investment that would be difficult to justify for all but the largest and busiest prosthetic units. Clearly future developments in this area depend on the identification of a market opportunity. Maxillofacial prosthetics is relatively small when compared with other medical sectors, which combined with the varying models of healthcare delivery across different nations makes estimating the size of the facial prosthetics market extremely difficult. However, the demand for facial prosthetics is increasing with the improved detection and surgical intervention of head and neck cancer. A survey conducted by Watson *et al* (2006) found that maxillofacial prosthetists in 50 hospitals in the UK produced 4259 prostheses annually. This includes other work typically undertaken by maxillofacial prosthetists such as breast, nipple, hand and finger prostheses.

Whilst the UK enjoys a comprehensive of maxillofacial prosthetics service through the National Health Service other nations that rely on healthcare insurance have lower levels of provision. However even taking that into account it would be reasonable to anticipate similar levels of activity throughout countries in Western Europe, North America, Japan, Australia and New Zealand. Using UK figures, a crude estimate based on population sizes would suggest that more than 64,000 facial prostheses are made each year in the wealthiest nations. However, there is potentially enormous demand for facial prostheses throughout the developing world that is currently unmet. The developing world could benefit greatly from rapid, low cost methods of providing many thousands of facial prostheses. It is therefore reasonable to suggest that a potentially valuable global market could be developed for RP processes dedicated to the manufacture of facial prostheses.

#### **5. RP&M Specification**

This research analysed current best practice in prosthetic design and manufacture to identify key characteristics of prostheses. These characteristics were used to identify target specifications for digital technologies that would meet the particular needs of maxillofacial prosthetics. It is anticipated that dissemination of these target specifications will enable the RP&M industry to adapt or develop processes and machines specifically for the rapid and cost effective production of maxillofacial prosthetics. Table 4 contains the target specifications for RP&M technologies.

Bar structure	
Material	Stiffness approximately equal to or greater than 18 carat (75% gold) >75 GPa Suitable to polish Bio-compatible
Resolution	Sufficient to build 1.3mm diameter holes with sharp detail
Pattern	
Wax material	Softening temperature in the order of 35-43°C; Melt point approximately 60 to 63°C; 0% flow at 23°C as per ISO standard 15854:2005; In the order of 25-30% flow at 37°C (specification of Anutex wax by Kemdent)
Resolution	Equal to or better than a ThermoJet printer 300x400x600 dpi at 40µm layer thickness
Sub-structure / clips	
Resolution	Equal to or better than an Objet or Perfactory; Objet = 600x300x1600 dpi, Perfactory = 90µm minimum pixel size; 15µm minimum layer thickness
Material	Wear / fatigue resistant (approximately 1460 cycles to represent 1 year of use). Clips approximately 150 Kg/mm <sup>2</sup> hardness equivalent 18 carat gold Able to bond to the prosthesis body Resist hot water at 90°C during mould release Hydrophobic (will not soften in the sustained presence of moisture / body fluids) Water sorption equal to or less than 0.6 mg/cm <sup>2</sup> (that of heat-processed acrylic)
Other	Clip strength should be adjustable
Prosthesis body	
Colour	Production process capable of creating millions of colours from digital colour matches of a patient's skin wrapped around a CAD model
Resolution	Equal to or better than a ThermoJet printer 300x400x600 dpi at 40µm layer thickness
Material	A20-30 Shore hardness, >500% elongation at break, >16kN/m tear strength, 4.8N/mm <sup>2</sup> tensile strength
Environment	Degradation resistant to UV light, dirt and body secretions

**Table 4: Target specifications for RP&M technologies**

## 6. Conclusions

This research has highlighted the fact that RP&M technologies have not been developed specifically towards the needs of maxillofacial prosthetics. However, whilst much research has demonstrated the potential effectiveness of RP&M technologies in maxillofacial prosthetics the research described here has indicated that this potential cannot be fully exploited by currently available technologies. The full benefits of digital technologies will only be achieved through the adoption of an appropriately devised, implemented and evaluated work flow. In addition, RP&M technologies need to be developed to address the specific materials and process requirements of the field of maxillofacial prosthetics.

## 7. References

- Aziz, T., Waters, M. and Jagger, R. (2003), "Analysis of the properties of silicone rubber maxillofacial prosthetic materials". *Journal of Dentistry*. Vol. 31, pp. 67-74
- Bibb, R., Freeman, P., Brown, R., Sugar, A., Evans, P. and Bocca, A. (2000), "An investigation of three-dimensional scanning of human body surfaces and its use in the design and manufacture of prostheses", *Proceedings of the Institution of Mechanical Engineers. Part H, Journal of Engineering in Medicine*, Vol. 214 No. 6, pp. 589-94.
- Brånemark, P. I. (1983), "Osseointegration and its experimental background", *Journal of Prosthetic Dentistry*, Vol. 50, pp. 399-410.
- Chandra, A., Watson, J., Rowson, J. E., Holland, J., Harris, R. A. and Williams, D. J. (2005), "Application of rapid manufacturing techniques in support of maxillofacial treatment: evidence of the requirements of clinical application", *Proceedings of the Institution of Mechanical Engineers, Part B: Journal of Engineering Manufacture*, Vol. 219 No. 6, pp. 469-76.

- Cheah, C. M., Chua, C. K., Tan, K. H. and Teo, C. K. (2003a), "Integration of laser surface digitizing with CAD/CAM techniques for developing facial prostheses. Part 1: Design and fabrication of prosthesis replicas", *International Journal of Prosthodontics*, Vol. 16 No. 4, pp. 435-41.
- Cheah, C. M., Chua, C. K. and Tan, K. H. (2003b), "Integration of laser surface digitizing with CAD/CAM techniques for developing facial prostheses. Part 2: Development of molding techniques for casting prosthetic parts", *International Journal of Prosthodontics*, Vol. 16 No. 5, pp. 543-8.
- Chen, L. H., Tsutsumi, S. and Iizuka, T. (1997), "A CAD/CAM technique for fabricating facial prostheses: a preliminary report", *International Journal of Prosthodontics*, Vol. 10 No.5, pp. 467-72.
- Chua, C. K., Chou, S. M., Lin, S. C., Lee, S. T. and Saw, C. A. (2000), "Facial prosthetic model fabrication using rapid prototyping tools", *Integrated Manufacturing Systems*, Vol. 11 No. 1, pp. 42-53.
- Coward T. J., Watson R. M., Wilkinson I. C. (1999), "Fabrication of a wax ear by rapid-process modelling using stereolithography". *International Journal of prosthodontics*. Vol. 12 No.1, pp. 20-27
- Eggbeer, D., Evans, P. and Bibb, R. (2006a), "A pilot study in the application of texture relief for digitally designed facial prostheses", *Proceedings of the Institution of Mechanical Engineers. Part H, Journal of Engineering in Medicine*, Vol. 220 No. 6, pp. 705-14.
- Eggbeer, D., Bibb, R. and Evans, P. (2006b), "Assessment of digital technologies in the design of a magnetic retained auricular prosthesis", *Journal of Institute of Maxillofacial Prosthetists and Technologists*, Vol. 9, pp. 1-4.
- Eggbeer, D., Bibb, R. and Evans, P. (2006c), "Towards Identifying specification requirements for digital bone anchored prosthesis design incorporating substructure fabrication: a pilot study", *International Journal of Prosthodontics*, Vol. 19 No. 3, pp. 258-63.
- Eggbeer, D., (2008), PhD Thesis "The Computer Aided Design and Fabrication of Facial Prostheses", University of Wales Institute Cardiff, Cardiff, UK
- Evans, P., Eggbeer, D. and Bibb, R. (2004), "Orbital Prosthesis wax Pattern Production using Computer Aided Design and Rapid Prototyping Techniques", *Journal of Maxillofacial Prosthetics & Technology*, Vol. 7, pp. 11-5.
- Jemt, T. (1991), "Failures and complications in 391 consecutively inserted fixed prostheses supported by Brånemark implant in the edentulous jaw: a study of treatment from the time of prosthesis placement to the first annual check up", *International Journal of Oral and Maxillofacial Implants*, Vol. 6 No. 3, pp. 270-6.
- Kan, J. Y., Rungcharassaeng, K., Bohsali, K., Goodacre, C. J. and Lang B. R. (1999), "Clinical methods for evaluating implant framework fit", *Journal of Prosthetic Dentistry*, Vol. 81 No. 1, pp. 7-13.
- Lemperle, G., Holmes, R. E., Cohen, S. R. and Lemperle, S. M. (2001), "A Classification of facial wrinkles", *Plastic Reconstructive Surgery*, Vol. 108 No. 6, pp. 1735-50.
- Reitemeier B., Notni G., Heinze M. (2004), "Optical modeling of extraoral defects". *Journal of Prosthetic Dentistry*, Vol. 91, No. 1, pp. 80-4.
- Sykes, L. M., Parrott, A. M., Owen, P. and Snaddon, R. (2004), "Applications of rapid prototyping technology in maxillofacial prosthetics", *International Journal of Prosthodontics*, Vol. 17 No. 4, pp. 454-9.
- Verdonck, H. W. D., Poukens, J., Overveld, H.V. and Riediger, D. (2003), "Computer-Assisted Maxillofacial Prosthodontics: A new treatment protocol", *International Journal of Prosthodontics*, Vol. 16 No. 3, pp. 326-8.
- Watson, J., Cannavina, G., Stokes, C. W. and Kent, G. (2006), "A survey of the UK maxillofacial laboratory service: Profiles of staff and work", *British Journal of Oral & Maxillofacial Surgery*, Vol. 44 No. 5, pp. 406-10.
- Wolfaardt, J., Sugar, A., Wilkes, G. (2003), "Advanced technology and the future of facial prosthetics in head and neck reconstruction", *International Journal of Oral Maxillofacial Surgery*, Vol. 32 No. 2, pp. 121-3.
- Yin, R. K. (2003), *Case study research: Design and methods*, 3<sup>rd</sup> ed. Sage Publishing, London, UK.