Rapid manufacture of custom-fitting surgical guides

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Abstract

Purpose – The computer-aided design (CAD) and manufacture of custom-fitting surgical guides have been shown to provide an accurate means of transferring computer-aided planning to surgery. To date guides have been produced using fragile materials via rapid prototyping techniques such as stereolithography (SLA), which typically require metal reinforcement to prevent damage from drill bits. The purpose of this paper is to report case studies which explore the application of selective laser melting (SLM) to the direct manufacture of stainless steel surgical guides. The aim is to ascertain whether the potential benefits of enhanced rigidity, increased wear resistance (negating reinforcement) and easier sterilisation by autoclave can be realised in practice.

Design/methodology/approach – A series of clinical case studies are undertaken utilising medical scan data, CAD and SLM. The material used is 316L stainless steel, an alloy typically used in medical and devices and surgical instruments. All treatments are planned in parallel with existing techniques and all guides are test fitted and assessed on SLA models of the patients' anatomy prior to surgery.

Findings – This paper describes the successful application of SLM to the production of stainless steel surgical guides in four different maxillofacial surgery case studies. The cases reported address two types of procedure, the placement of osseointegrated implants for prosthetic retention and Le Fort 1 osteotomies using internal distraction osteogenesis. The cases reported here have demonstrated that SLM is a viable process for the manufacture of custom-fitting surgical guides.

Practical implications – The cases have identified that the effective design of osteotomy guides requires further development and refinement.

Originality/value – This paper represents the first reported applications of SLM technology to the direct manufacture of stainless steel custom-fitting surgical guides. Four successful exemplar cases are described including guides for osteotomy as well as drilling. Practical considerations are presented along with suggestions for further development.

Keywords Medical sciences, Lasers, Stainless steel, Computer aided design, Surgery, Prosthetic devices

Paper type Case study

1. Introduction

Over the last decade, rapid prototyping (RP) techniques have been employed widely in maxillofacial surgery. This has tended to concentrate on the reproduction of exact physical replicas of patients' skeletal anatomy which surgeons and prosthetists use to help plan reconstructive surgery and prosthetic rehabilitation (Heissler *et al.*, 1998; Eufinger and Wehmoller, 1998; Petzold *et al.*, 1999; Joffe *et al.*, 1999; Winder *et al.*, 1999; D'Urso *et al.*, 2000; Bibb and Brown, 2000; Webb, 2000; Sanghera *et al.*, 2001; Hughes *et al.*, 2003).

Developments in this area are moving towards exploiting advanced design and fabrication technologies to design and produce implants, patterns or templates that enable the fabrication of custom fitting prostheses without requiring a model of the anatomy to be made (van der Sloten *et al.*, 2000; Bibb *et al.*, 2002; Eggbeer *et al.*, 2004; Evans *et al.*, 2004; Singare *et al.*, 2005). However, there is also growing desire from clinicians to conduct more of the surgical planning using three-dimensional computer software. Whilst several approaches have been undertaken in the application of computer-aided surgical planning the problem of transferring the computer-aided plan from the computer to the operating theatre remains. Two solutions exist to transfer the computer plan to the operating theatre, navigation systems and surgical guides. The use of navigation systems is a specialist field in itself and will not be described here. However, research presented by Poukens *et al.* (2005) suggests that navigation and the use of surgical guides are both accurate enough for surgical purposes. RP technologies provide a potential method of producing custom-fitting surgical guides depending on the nature of the planning software used.

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Previous work on the application of RP technologies in the manufacture of surgical guides has concentrated on the production of drilling guides for oral osseointegrated implants (Sarment *et al.*, 2003a, b; Di Giacomo *et al.*, 2005). Indeed, developments have now led to dental implant planning software and stereolithography (SLA) drilling guides being offered commercially (SimPlant, SurgiGuides, Materialise N.V., Technologielaan 15, 3001 Leuven, Belgium). There has also been a limited amount of research carried out in the use of surgical guides for implant placement in facial prosthetic rehabilitation and orthopaedic surgery (Goffin *et al.*, 1999; Goffin *et al.*, 2001; Bibb *et al.*, 2003a, b; Verdonck *et al.*, 2003; van Brussel *et al.*, 2004). This paper will describe one drilling guide case study but will also report on three case studies involving the use of surgical guides incorporating osteotomies (saw cuts through bone), which has not been previously reported.

In order to be appropriate for the manufacture of surgical guides the RP processes have to be accurate, robust, rigid and able to withstand sterilisation. Owing to these requirements, the majority of surgical guides have been produced using SLA and to a lesser extent selective laser sintering (SLS). However, the use of these technologies has necessitated local reinforcement of the guides using titanium or stainless steel tubes to prevent inadvertent damage from drill bits and the use of low-temperature sterilisation methods such as formaldehyde or ethylene oxide.

The recent availability of systems capable of directly producing fully dense solid parts in functional metals and alloys has provided an opportunity to develop surgical guides that exploit the advantages of direct layer-additive manufacture whilst addressing the physical deficiencies of previous SLA and SLS guides. The ability to produce end use parts in functional materials means that processes such as these may be considered rapid manufacturing (RM). Surgical guides produced directly in hardwearing, corrosion resistant metals require no local reinforcement, can be conveniently autoclaved along with other surgical instruments and are much less likely to be inadvertently damaged during surgery. The use of much stiffer metal materials also enables surgical guides to be made much smaller and thinner whilst retaining sufficient rigidity. This benefits surgery as incisions can then be made smaller and the surgeon's visibility and access is significantly improved.

2. Methods

For the benefit of comparison and to illustrate the potential benefits of the new approach, this section begins with a brief description of the existing and previous methods utilized for the planning of the placement of osseointegrated implants for prosthetic retention. Previously, osteotomy surgical guides have not been routinely produced. The section then describes the new approach to the planning, rapid design and manufacture of surgical guides undertaken in the cases reported in this paper. The following section describes four individual cases where the approach has been successfully employed.

2.1 Existing and previous practice

The placement of osseointegrated implants for retention of an ear prosthesis relies on highly accurate placement of the implants. This case is the most commonly undertaken for the retention of prosthetic ears where typically two implants are placed into the bone at the side of the head (the mastoid process and other parts of the squamous temporal bone). Accurate placement of the implants is critical to the aesthetic results of the final prosthesis.

Previous methods of planning the placement of implants and transferring the plan to surgery have involved bringing the patient into the clinic for a planning session. The planning is undertaken on the patient and the ideal prosthesis location is marked on the patient's skin with ink. These ink markings are then transferred to a transparent plastic template that has been made before the planning session by vacuum forming over a plaster cast of the patient's soft tissues at the implant site. In order to transfer this plan to surgery the template is placed on the patient's soft tissue. The location of the implants is then transferred to the surface of the bone by use of a hypodermic needle and sterile ink. The skin is then incised and reflected to reveal the bone surface with the ink spots indicating the planned implant locations.

The disadvantages of this procedure are that it requires a patient visit to the clinic for planning, which is time-consuming and costly for the patient and clinical staff. The mobility of soft tissue can also lead to inaccuracies when it is used as a planning surface. These inaccuracies can lead to misplacement of the implants which in turn leads to poor aesthetic results. Often the ink marks transferred to the bone are unclear once the skin flap is retracted. Most importantly, the procedure provides no diagnostic information as to the quality or thickness of the bone at the implant sites. On occasion the bone may be found to be inadequate at surgery and the surgery time is increased as alternative sites are investigated.

Previous research in the application of RP and computer-aided planning of the placement of osseointegrated implants for prosthetic retention utilized computed tomography (CT), SLA and RP software to plan the placement of implants digitally and transfer the plan to surgery by designing and producing a custom-fitting SLA surgical guide (Bibb *et al.*, 2003a, b). This research demonstrated that this approach offered several benefits. The use of computer-aided planning enabled the bone quality and thickness to be assessed prior to surgery and computer-aided planning eliminated the need for the patient visit a planning clinic. The SLA surgical guides were shown to be more accurate than the previous ink-needle planning method described above.

However, disadvantages remained with this process. SLA was limited to one suitable material that had been tested to a recognized standard and shown to be of a sufficiently low toxicity. In order to provide a surgical guide of sufficient stiffness the guide was made several millimetres thick. In addition, the material required low-temperature sterilisation methods such as ethylene oxide, which are more time-consuming and expensive than sterilisation by autoclave. The ability to design the guide was also limited to primitive shapes and lacked sophistication.

A consideration of the physical properties showed that although the surgical guides are not subject to great physical stresses that are likely to lead to yield or brittle failure there are many disadvantages apparent. Good stiffness is required so that the guide will maintain its shape accurately under handling and placement during surgery. Good wear resistance is necessary to prevent inadvertent damage when using hardened, sharp tools such as drills and saws. Typically, local metal reinforcement is used with SLA guides. Low-glass transition temperatures or melting points necessitates inconvenient, costly and more time-consuming low-temperature sterilisation methods. Whilst the physical demands placed on surgical guides do not require the ultimate physical properties of metal materials, it is clear that the much higher stiffness, wear resistance and temperature resistance of metal materials offers potential benefits in the manufacture of custom-fitting surgical guides.

2.2 The SLM surgical guide method

This section describes the general approach taken to planning, designing and producing the surgical guides reported in the following case studies. Suitable patients were identified by the clinical partners and in all cases CT scans that had already been acquired for diagnosis and planning of their entire treatments were subsequently utilised for the planning of the surgeries described in the case studies below.

Step 1: 3D CT scanning

All of the patients were scanned using three-dimensional CT (1 mm slices with 0.5 mm overlap) to produce three-dimensional computer models of the anatomical structures required. The CT data were exported in DICOM format, which was then imported into medical data transfer software (Mimics, Materialise N.V.). This software was used to generate the highest possible quality STL data files of the patients' soft tissue and skeletal anatomy. The STL files were then imported into the computer-aided design (CAD) software.

Step 2: computer-aided surgical planning and design of the surgical guide

The CAD package used in this study (FreeForm®, SensAble Technologies, Inc. 15 Constitution Way, Woburn, MA 01801, USA) was selected for its capability in designing complex, arbitrary but well-defined shapes that are required when designing custom appliances and devices that must fit human anatomy. The software has tools analogous to those used in physical sculpting and enables a manner of working that mimics that of the maxillofacial prosthetist working in the laboratory. The software utilises a haptic interface (Phantom® Desktop haptic interface; SensAble Technologies, Inc.) that incorporates positioning in three-dimensional space and allows rotation and translation in all axes, transferring hand movements into the virtual environment. It also allows the operator to feel the object being worked on in the software. The combination of tools and force feedback sensations mimic working on a physical object and allows shapes to be designed and modified in an arbitrary manner. The software also allows the import of scan data to create reference objects or "bucks" onto which objects may be designed. The use of this software in the design of custom-fitting prostheses, the design techniques utilised and its benefits have been previously recognised and reported (Eggbeer *et al.*, 2004; Eggbeer, 2006; Evans *et al.*, 2004; Verdonck *et al.*, 2003).

First, the data of the patients' anatomical structures were imported into the CAD software. To plan the placement of implants for the retention of a prosthetic ear the patient's unaffected ear was copied and laterally inverted (mirrored). The clinicians then positioned this ear relative to the head to provide the best possible aesthetic reconstruction. This enabled the ideal position of the implants to be identified. Cylinders of the appropriate size were positioned to represent the implants. The soft tissue data were then removed from view so that the location of the implants on the bone could be evaluated. The bone was assessed to ensure adequate quality and thickness and if necessary the implant locations were adjusted. A surgical guide was then designed to fit onto the bone surface surrounding the immediate area of the implants. The guides were designed to be between 1 and 2 mm thick and to cover areas of anatomical shape that would assist positive location on the bone surface. The position of the implant cylinders was transferred to the guide design by Boolean subtraction to leave holes indicating the necessary drilling locations. Digital design tools were also used to create embossed features on the surgical guide such as an orientation marker and patient name. Finally, when the designs were completed to the clinicians' satisfaction the bone data were subtracted from the surgical guide as a Boolean operation. This left the surgical guide with the fitting surface as a perfect fit with the anatomical surface.

For the osteotomy guides the necessary surgery was simulated by using the software tools to cut and reposition the different bone structures as they would be in surgery and subsequent treatment. When the clinicians were satisfied with the surgical plan the surgical guide was designed. This was achieved by designing a guide based on the bone surface immediately surrounding the location of the osteotomy. The guides were designed to be between 1 and 2 mm thick. The osteotomy was transferred to the guides by projecting the cutting line through the guide design and using this to create an aperture in the guide design sufficiently larger to enable access of the saw blade and thorough irrigation of the area during the cutting. Digital design tools were used to add features to assist surgery such as handles. As with the drilling guides, when the designs were completed to the clinicians' satisfaction the bone data were subtracted from the surgical guide as a Boolean operation to leave the surgical guide with a precisely fitting surface.

An example of embossed details is shown in Figure 1, including orientation marker, drill size (3 mm) and the patient name (some letters have been deleted from the image in order

Figure 1 Example of embossed features

to maintain patient anonymity). The final designs were then exported as a high-quality STL for rapid manufacture using the Selective Laser Melting machine (SLM 250 – MTT Technologies Ltd, Whitebridge Way, Whitebridge Park, Stone, Staffordshire, ST158LQ, UK).

Step 3: rapid manufacture

In order to successfully build the surgical guides on the SLM machine (MTT Technologies Ltd) adequate supports had to be created using RP software (Magics, Materialise N.V.). The purpose of the supports was to provide a firm base for the part to be built onto whilst separating the part from the substrate plate. In addition, the supports conduct heat away from the material as it melts and solidifies during the build process. Inadequate support results in incomplete parts or heat induced curl, which leads to build failure.

Recent developments in support design have resulted in supports that have very small contact points, which have improved the ease with which they can be removed from parts and the substrate. However, all of the surgical guides were oriented such that the amount of support necessary was minimised and avoided the fitting surface of the guide. This meant that the most important surfaces, that is the fitting surfaces, of the surgical guide would not be affected or damaged by the supports or their subsequent removal. An illustrative example of the orientation and supports generated is shown in Figure 2 (the patient name has been obscured to maintain patient anonymity).

The surgical guides described in this paper were all produced in the same manner. The part and support files were sliced and hatched using the SLM software with a layer thickness of 0.050 mm. The material used was 316L stainless steel spherical powder with a maximum particle size of 0.045 mm (particle size range 0.005-0.045 mm) and a mean particle size of approximately 0.025 mm (Sandvik Osprey Ltd, Red Jacket Works, Milland Road, Neath, SA11 1NJ, UK). The laser used was a 100 W fibre laser using a maximum scan speed of 300 mm/s and a beam diameter 0.150-0.200 mm.

Figure 2 Example of minimised supports

Step 4: finishing

Initially, supporting structures were removed using a Dremel hand-held power tool (Dremel, 4915 21st Street Racine, WI 53406, USA) using a reinforced cutting wheel (Dremel, Reinforced Cutting Disc, Ref. Number 426). However, more recently improved design of the supports has eliminated the need for cutting tools as the supports contact the part at a sharp point that can be broken away from the part easily using pliers. This type of support structure can be seen in Figure 4.

The SLM parts described in these case studies were well formed with little evidence of the stair-stepping effect resulting from the thin layers used and showed a fine surface roughness. This roughness was easily removed by bead blasting to leave a smooth, matte surface finish. The parts were then sent to the hospital for cleaning and sterilisation by autoclave.

Step 5: evaluation

All of the SLM surgical guides were test fitted to SLA models of the patients' anatomy to ensure a precise fit to the required area for each specific patient. The locations of the osteotomies and drilling sites were assessed and checked by the clinicians to ensure they accurately represented the surgical planning before proceeding to surgery.

3. Case studies

To date 12 cases have been undertaken by the partners involved in this collaboration. These cases have included four Le Fort 1 osteotomy guides for maxillary distraction osteogenesis, two cutting and drilling guides for mandibular distraction and six drilling guides for osseointegrated implant placement for prosthetic retention. Four individual case studies are shown here as illustrative examples.

Case 1 – drilling guide

This case involved the planning and insertion of craniofacial osseointegrated implants in the side of the skull. Osseointegrated implants are titanium screws that are driven into the bone and allowed to heal. They are then exposed through the skin to form secure anchorages for prostheses. In this case, three implants were required, two were for the retention of a prosthetic ear and one to support a bone-anchored hearing aid. It was crucial that the implants were precisely sited as the aesthetic result of the prosthesis depended on their location. The data describing the patient's skull, soft tissue and remaining unaffected ear were obtained from 3D CT data and imported into FreeForm CAD. The data of the unaffected ear was laterally inverted and positioned for optimum aesthetic results. This allowed the ideal implant sites to be planned. Once the implant sites were chosen, the surgical guide was designed as described above. Figure 3 shows a screen grab of the skull surface, cylinders indicating the drilling sites and the surgical guide design. The design incorporated embossed details for the patient name (the name has been removed from the image to maintain patient confidentiality) and orientation. The part was then oriented, supported (shown above in Figure 2) and built using SLM as described above. The guide was sterilised by autoclave and used successfully in surgery, as shown in Figure 4.

Case 2 – mandibular distraction osteogenesis

This case involved designing a guide for both osteotomy and drilling required for the accurate placement of the distraction

Figure 3 Screen grab of the surgical guide planning and design

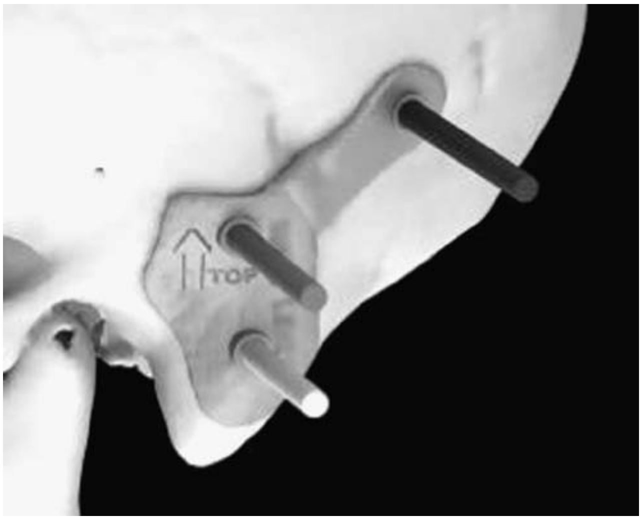
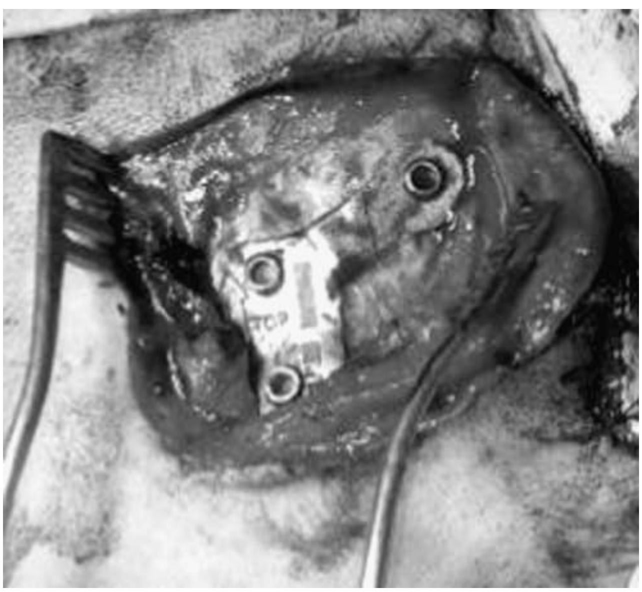


Figure 4 The surgical guide in use



devices for mandibular distraction osteogenesis. The surgery was first simulated using SimPlant CMF (Materialise N.V.), which enabled the correct positioning of the distractors to be established, as shown in Figure 5. The planned data were then transferred to FreeForm CAD where the surgical guides were designed to locate on the mandibular notch and around the anterior and posterior surfaces of the ramus. The guide indicated both the location of the osteotomy cut and the drilling sites required for the screws that retained the distractor with the correct vector (shown in Figure 6). The guide was built using SLM as stated in the methods, sterilised by autoclave and used in surgery. The guide proved effective in accurately transferring the computer plan into surgery (Figure 7).

Case 3 – two stage osteotomy/distractor guide

Although surgical guides specifically for drilling have been produced using RP techniques for some years the application

Figure 5 Surgical planning screen capture showing placement of distraction device

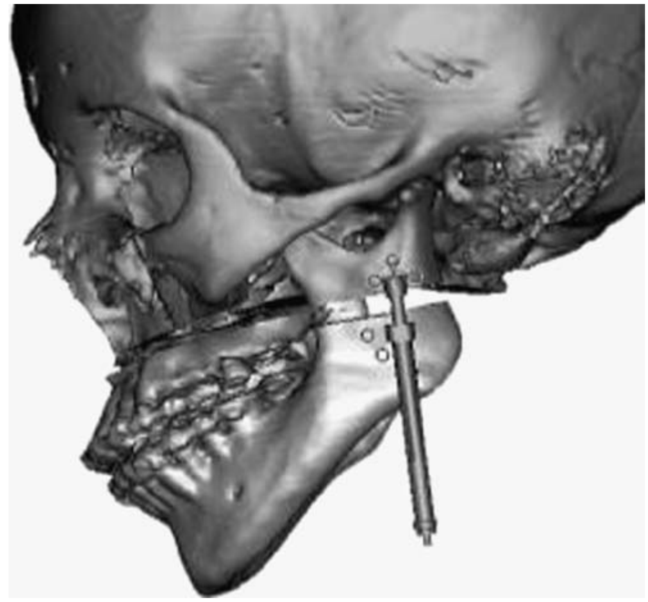


Figure 6 Distraction guide design

of surgical guides to maxillofacial osteotomies had not been previously reported. This case was the first attempt at a maxillofacial osteotomy guide. The surgery performed in this particular case involved distraction osteogenesis to correct deformity resulting from cleft palate. This required a Le Fort 1 osteotomy, which is a cut across the maxilla under the nose in order to separate and move the upper jaw in relation to the rest of the skull. During distraction osteogenesis the maxilla is gradually moved in relation to the rest of the skull by mounting it on two devices that use precision screw threads to advance the position by a small increment each day

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Figure 7 SLM distraction guide

(typically 1 mm). The small increment induces bone formation in the gap thus avoiding a bone graft. The advancement of the maxilla (upper jaw) corrects a deformity, for example one caused by inhibition of growth secondary to repair of cleft lip and palate. In this case, in order to reposition the maxilla in the correct place before the distraction stage, a second cut had to be made to remove some bone from the skull. A surgical guide was designed for each cut (Figures 8 and 9). The guides consisted of a flat edge along which an oscillating saw blade could be directed. As the cut is made either side of the nose, a handle was added to join the two sides of the guide together and enabled the surgeon to hold the device more easily. The parts were built using SLM as described above. The guides were sterilised by autoclave and successfully used in surgery (Figures 10 and 11).

Case 4 – combined osteotomy and drilling guide

This was another cleft palate case to be treated through distraction osteogenesis and therefore required a Le Fort 1 osteotomy. However, unlike the previous case this one only

Figure 8 Osteotomy plan and first guide

Figure 9 Second guide

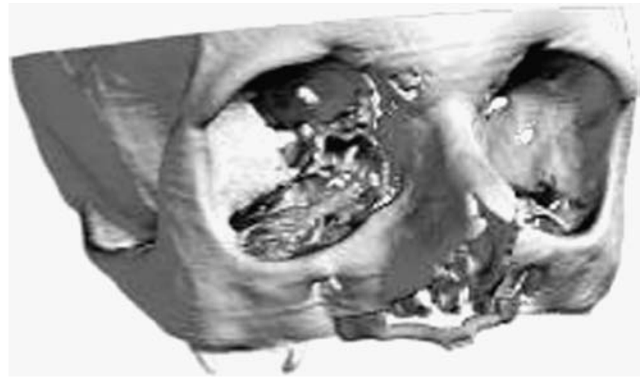


Figure 10 The two osteotomy cutting guides

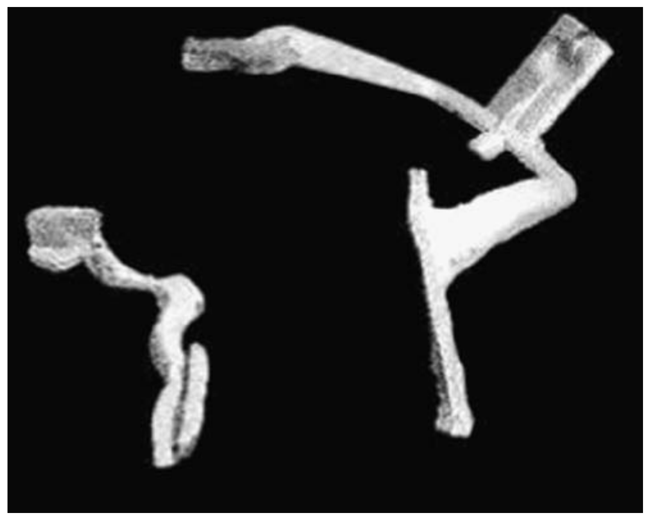


Figure 11 The first guide in theatre

required a single cut. This case was also more ambitious and the intention was to include the drilling holes for the distraction devices as well as a slot for the osteotomy. The slot was made sufficiently wide to allow the saw blade to move freely and to allow sufficient irrigation during cutting. The lower edge of the slot is made flat and parallel to the direction of the cut in order to provide a reference surface on which the flat saw blade rests. As the cut is in two places on either side of the nose, the software design tools were used to join the two parts together into one device, see Figure 12.

The distraction devices are supplied with flat fixation arms incorporating screw holes. These arms must be bent to fit the contours of the bone where they are attached in a manner that is secure and provide the correct movement vector. However, during the design of this surgical guide it was discovered that there was no way to satisfactorily simulate the bending of the distractor attachment plates using the CAD software. Whilst it was theoretically possible to design and manufacture custom fitting plates and laser weld them to the distraction devices the manufacturer of the devices would not allow these modifications to be made to their devices.

The design of the osteotomy guide was therefore finalised, supported (shown in Figure 13) and built as described above. As the bending of the distractor fixation arms could not be simulated in CAD they were planned and pre-bent in the maxillofacial laboratory using a SLA model of the patient's skull. The drilling positions for the screws holding the distractor to the bone were transferred from the SLA model onto the SLM guide and the holes drilled in the laboratory (Figure 14). The final guide was sterilised by autoclave and successfully used in surgery as shown in Figure 15. This particular guide enabled a significant reduction in surgery time but more importantly allowed the correct positioning of the distractor and thus the correct vector/direction of the distraction process.

4. Results

The surgical guides described in these case studies were all assessed by the clinicians before being used in surgery. The fit and location of the devices were all checked on SLA models of the patients' skeletal anatomy. All of the devices reported here were deemed satisfactory for surgical use by the clinical team. All of the SLM surgical guides displayed good accuracy and

Figure 12 Patient data and surgical guide design

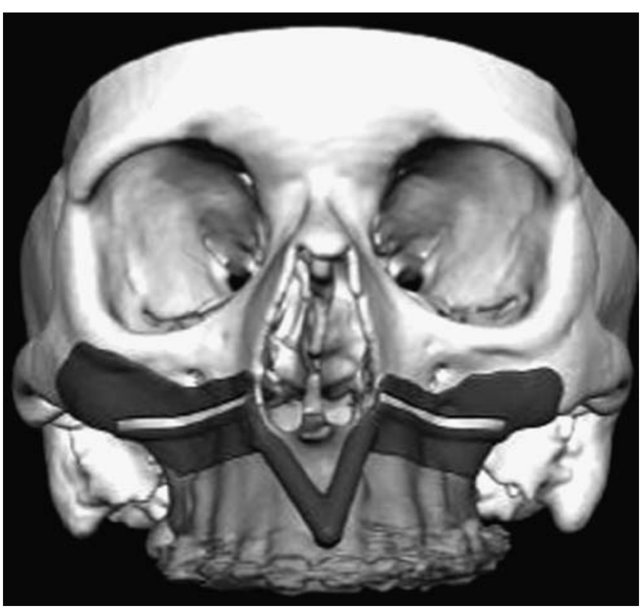


Figure 13 The surgical guide and supports

Figure 14 The surgical guide fitted to SLA model

Figure 15 The guide fitted to the patient during surgery

fitted the patients' anatomy as expected. The guides located on the intended anatomical site and when seated correctly resisted movement indicating a precise fit between the guide and the anatomy. There were no problems experienced sterilising or using the guides. The guides all resulted in some time savings in theatre but much more importantly enabled the surgery to be carried out with much greater accuracy and with a much better end-result/outcome for the patient.

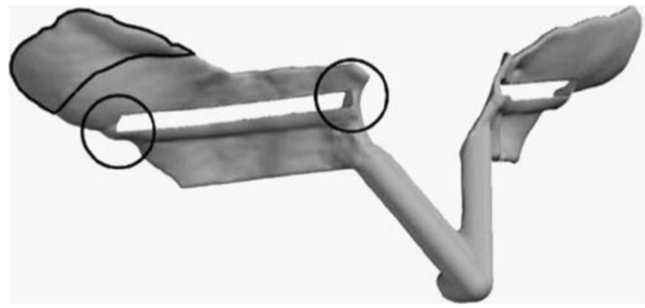
The time and cost of guide production compared favourably to previous RP methods such as SLA. This is due to relatively rapid build times and lower materials costs. Time and cost savings were realised by the use of autoclave sterilisation rather than alternative low-temperature methods.

5. Discussion

The surgical guides described in these case studies were all deemed successful by the clinicians and contributed to successfully and accurately transferring computer-aided planning to surgery. Whilst the clinicians observed time savings in theatre compared to previous techniques the unique nature of each case and the comparatively small number of cases undertaken make quantifiable data difficult to establish. Overall, costs were lower compared to SLA due to slightly lower material costs per kilogram and comparable build times. Cost and time for sterilisation was reduced compared to SLA but as the devices are sterilised in batches along with other surgical equipment exact details are difficult to measure. Detailed time and cost comparisons will be addressed in future research by the collaborators as more cases are completed. The drilling guides used for osseointegrated implant placement have proved to be very successful being thinner, more rigid, more hardwearing and easier to sterilise than previous methods. The thickness of 1-2 mm was found to provide sufficient stiffness for the production of these guides. The incorporation of embossed orientation markers and patient names was also shown to be beneficial and could help prevent errors in surgery.

However, the osteotomy guides proved more challenging to design. When these cases were attempted, there was no previous experience or publications to build on and given the experimental nature of the cases undertaken, the results were deemed to be encouraging. Design improvements have been identified from the cases undertaken so far. For example, the better positioning of handles has been identified from observing the use of the guide shown in case study 3. Another example was found when conducting case study 4. Fitting the surgical guide to the SLA model of the patient's skull indicated that the guide did not require such a large extent of the fitting surface. Therefore, the fitting surface of the guide was reduced by the maxillofacial prosthetist in the laboratory as shown in Figure 16. Assessing this particular guide also highlighted potential weaknesses at the ends of the cutting slots where inadvertent bending may occur. These design improvements will lead to significantly better osteotomy/distractor guides which will be investigated in future case studies. However, the more fundamental problem of using the approach described here to include the bending and fitting of distractor fixation plates will need to be investigated in future research by exploring other software applications and techniques.

Figure 16 Areas for design improvement



6. Conclusions

These successful case studies have demonstrated that SLM is a viable RM method for the direct production of maxillofacial surgical guides for both osseointegrated implant placement (drilling) and osteotomies (cutting). The stainless steel surgical guides produced using the SLM process have been shown to be comparable in terms of accuracy, quality of fit and function to surgical guides previously produced using other RP processes such as SLA. The time and cost of manufacturing the guides using SLM is comparable to other RP processes.

These case studies have confirmed that SLM surgical guides can realise potential benefits compared to other RP methods. The SLM guides described in these case studies have demonstrated superior rigidity and much enhanced wear resistance. This has enabled the guides to be thinner and smaller, which in turn has led to benefits of smaller incisions and improved access for the surgeon. These factors also eliminate the need for a secondary process to incorporate local reinforcement of the guides as is the case with SLA. This saves time and reduces costs. Another significant benefit is that stainless steel guides are more convenient and more cost effective to sterilise using standard autoclave procedures. The osseointegrated implant placement guides proved very successful and presented no major difficulties in terms of design, manufacture or use in surgery.

However, the case studies involving the osteotomy guides have led to the identification of several design improvements that will be incorporated in future cases. These case studies also highlighted the limitations of current software in the planning and design of surgical guides that can combine both osteotomy and the pre-surgical bending of the fixation plates used to attach distraction osteogenesis devices. Whilst these case studies have suggested that significant time savings could be achieved, more research is required to analyse the work flow and costs incurred to establish the overall cost effectiveness of the use of SLM surgical guides in complex maxillofacial surgeries. These areas will be explored in the future research of the collaborators.

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