Computer-aided methods in bespoke breast prosthesis design and fabrication

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Abstract

This case study presents a method of utilising computer aided design technologies to provide bespoke, external breast prostheses. The technique is illustrated through a case study of a mastectomy patient. Photogrammetry methods were used to capture the breast form when supported by a brassiere and the unsupported breast and defect side. Computer aided design techniques were used to generate a digital prosthesis based upon the supported breast shape and with a fitting surface that matched the defect side. Furthermore, a two-part mould was designed and fabricated using rapid prototyping methods. A colour matched prosthesis was then fabricated in a gel-based, platinum cured silicone.

Keywords: computer aided design, breast prosthesis, rapid prototyping, additive manufacture
Introduction

Around 38,000 women were diagnosed with breast cancer in 2006 in England, Wales and Scotland\(^1\). In the 2007-2008 period in England and Wales, this resulted in 19,334 breast removals\(^2,3\). In England, there were 4,209 breast reconstructions and 7,786 breast prostheses in 2007-2008\(^2\). There are various options available to reconstruct the breast including autologous reconstruction and prosthetic implant\(^4\). These may require additional surgery, which may not be suitable or desirable. In the majority of these cases, brassiere retained, external prosthesis are provided.

The goal of an external prosthesis is to restore the aesthetic contours of the chest region and help to maintain good posture. The prosthesis should be comfortable to wear for long periods during the day and help to maintain good posture by counteracting the weight of the remaining breast\(^5\). Studies have shown that satisfaction is significantly associated with how well the prosthesis fits, the weight and movement\(^6,7\). Traditionally, prostheses are available commercially as ‘off the shelf’ in a range of sizes or are custom made, typically by maxillofacial prosthetists. Both are usually fabricated in a soft, skin-like silicone. The bespoke route offers an improved fit, better contour, improved colour match and therefore a more lifelike appearance. However, techniques used in the production of bespoke prostheses are time consuming, complicated and material intensive. There is also limited literature describing the typical, lab-based stages involved with producing bespoke breast prostheses\(^8\).
Lab-based techniques also do not account for the shape of the breast when it is supported by a brassiere. There remains a need to develop an efficient method of producing well fitted, patient-specific breast prostheses.

The introduction of computer-aided technologies such as three-dimensional topographic scanning, photogrammetry, computer aided design and Rapid Prototyping/Manufacturing (RP&M) into patient-specific medical applications has provided new opportunities to improve the delivery of prostheses and other patient-specific medical devices.\textsuperscript{9-13} However, an efficient production chain for the delivery of bespoke prostheses that match the contralateral, brassiere-supported breast has not been reported. This paper introduces a technique that utilises three-dimensional photogrammetry, haptic computer sculpting and RP&M manufacturing methods to produce bespoke breast prostheses.

**Methods**

Four patients to date have had a prosthesis fabricated using the technique described, however the methods will be illustrated through a single patient case study. An overview of the digital procedure are show in Figure 1. 

*Insert Figure 1*

A 3dMDtorso, four pod photogrammetry system (3dMD, USA) was used to capture the chest topography of the patient without a brassiere and with a plain, un-
patterned white brassiere. The anatomy was captured looking slightly upwards and
towards the breast fold (figure 1). Data acquisition took ~1.5 milliseconds and was
undertaken as part of a multi-patient clinic.

*Insert Figure 2*

Data processing took approximately 3 minutes and created a mesh of 363,346 and
190,441 triangles for the brassiere and non-brassiere wearing anatomy respectively.
The meshes represented surface topography of the chest area and also included a
colour map, which provided sufficient detail to create the final prosthesis. Figure 2
shows the surface topography captured of the patient’s chest with the defect.

*Insert figure 3*

The mesh data were exported as the *de facto* industry standard STL file
(STereLithography) and imported into Computer Aided Design (CAD) software for
prosthesis design (FreeForm Modelling Plus, version 10, SensAble Technologies).
FreeForm CAD was chosen due to its suitability when working with anatomical data
and tools analogous to conventional lab sculpting methods. The fill holes option
was used to create a solid model in the CAD software and an edge sharpness of
0.4mm chosen to provide sufficient detail. The unaffected side of the chest with the
brassiere on was copied, pasted and mirrored to the defect side on the second scan
(figure 3).
Software carving and shaping tools were used to further shape the digital prosthesis design to fit the defect side with the brassiere off and remove the brassiere strap. Particular attention was given to the fit of the prosthesis under the arm, which is an area of particular discomfort when wearing a stock sized prosthesis. Once satisfied with the contours, a Boolean subtraction operation was undertaken to form the fitting contours and leave just the digital prosthesis design. This could be checked for correct size and position using the with brassiere data (figure 4).

At this point, there were two options: 1) fabricate the prosthesis pattern using RP&M tools, then use lab techniques to create a mould, or 2) design a tool using the CAD software and produce that using RP&M technologies. Option 2 was chosen since this further reduced the dependence on lengthy lab-based techniques.

The parting line for the mould was first chosen and highlighted in FreeForm. This represented the most bulbous line around the rim of the prosthesis where the tool would split. This line was offset by 15mm using the ‘offset curve’ tool. Two, four sided patches were created using the split line and offset split line. These represented the splitting surface of the tool. A new empty piece of clay with an edge sharpness of 0.4mm was created for each tool part. The patches were given a thickness of 3mm using the ‘convert to clay’ tool to form the rim of each tool side.
The ‘emboss with curve tool’ was then used to create the cavities of each tool side with a thickness of 1.8mm on a copy of the prosthesis form. The rim sections were joined to the cavities for each tool side and holes with flanges created around the rim to allow the tool to be bolted closed. A Boolean subtraction operation was then undertaken with the prosthesis form used to remove material from the tool. A groove and corresponding ridge were also created around the rim to prevent silicone from leaking around the split line. Sprue injection and vent holes were then created on the top section of the mould to allow the final prosthesis material to be injected and air to escape. Optional holes and flanges can then be created, which allow the tool to be bolted closed. The completed mould design is shown in figure 5. The sections were exported as STL files.

Insert Figure 6

Magics (Materialise, Belgium) was used to support the two mould sections. The sections were fabricated in 0.15mm layers using Stereolithography (SLA 250/50, 3D-Systems Corporation, USA), in WaterShed XC resin (DSM Somos, USA). This resin was chosen due to its ease of hand finishing and translucency, which would make it easier to see when the mould was fully filled with silicone. The tool sections were built on edge to allow both to fit within the build volume. The build took overnight to complete. Once completed, the sections were cleaned and hand finished with glass paper to remove the layer steps and achieve a smooth matt surface.

The mould was then passed to the maxillofacial prosthetics lab.
Research has suggested that the weight of the prosthesis should match the remaining breast in order to prevent back and neck problems for the patient.\textsuperscript{14} However, all previous patients treated complained about the prosthesis weight. It was therefore decided to reduce the weight of the prosthesis from a theoretical 1,100g (if the prosthesis was entirely gel silicone-based) to a final weight of 845g using a low density, open cell foam polyurethane core. This was fabricated by part filling and contouring dental plaster within the mould to create an insert. This reduced the volume of the mould and formed the desired contour for the insert. A two-part, foaming polyurethane material (Technovent Ltd, UK) was injected into the mould and left to cure.

The SLA mould was first coated with a 1mm layer of silicone elastomer (M511, Technovent Ltd, UK) which was applied incorporating Cosmesil base colour pigments to achieve a ‘skin like’ colouration (Technovent Ltd, UK). The polyurethane core was placed on the lower half of the mould and the mould closed and bolted together. The catylisation of the elastomer was accelerated by heating the coated mould at 80\textdegree C. The silicone elastomer gel (M512, Technovent Ltd, UK) was pigmented to match the patient’s skin colour and then injected through the injection port with a syringe (figure 6).
The mould was left for 24 hours to allow the gel to set. Once set, the prosthesis was removed from the mould and trimmed to remove any flash from the moulding process. The injection port area was sealed over with a silicone nipple to complete the prosthesis. The completed prosthesis is shown in figure 7.

Insert Figure 8

From data capture to final prosthesis delivery took approximately 5 ½ prosthetist hours, plus additional automated fabrication time. Table 1 compares conventional, lab-based methods with the computer-aided method.

<table>
<thead>
<tr>
<th>Conventional</th>
<th>Computer-aided method</th>
<th>Resource Reduction / Opportunity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Take an impression. Create a replica model of the</td>
<td>Photogrammetry with bra and without bra</td>
<td>Time saving. Reduced material usage. Improved accuracy.</td>
</tr>
<tr>
<td>anatomy</td>
<td>Import data into FreeForm</td>
<td>Captures the defect and breast form in a brassiere.</td>
</tr>
<tr>
<td>Manually carve wax prosthesis form</td>
<td>Design prosthesis form using CAD</td>
<td>Time saving. More flexible working. No need for patient to be present. Reduced material usage.</td>
</tr>
<tr>
<td>Mould the prosthesis in a two part plaster mould</td>
<td>Identify and mark the tool split line</td>
<td>Automated split line identification. Reduced material usage.</td>
</tr>
<tr>
<td>Boil out wax residue</td>
<td>Design the tool sections</td>
<td>Time saving. Material saving. Mistakes easy to correct.</td>
</tr>
<tr>
<td>Apply separator</td>
<td>Export as STL data</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Orientate and support</td>
<td></td>
</tr>
<tr>
<td>for RP&amp;M process</td>
<td></td>
<td></td>
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<tr>
<td>------------------</td>
<td>---</td>
<td></td>
</tr>
<tr>
<td>Fabrication</td>
<td>Can be duplicated easily. Automated fabrication, but additional cost over conventional methods.</td>
<td></td>
</tr>
<tr>
<td>Hand finishing</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Create foam mould insert</td>
<td>Same as conventional</td>
<td></td>
</tr>
<tr>
<td>Apply colour matched silicone to the mould cavity.</td>
<td></td>
<td></td>
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<tr>
<td>Inject with skin tone colour silicone</td>
<td></td>
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<tr>
<td>Cure</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trim and deliver</td>
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</tr>
</tbody>
</table>

Table 1. A comparison of traditional methods and computer-aided highlighting the resource reduction and opportunities identified.

Discussion

The techniques described provided the patient with a satisfactory cosmetic result, which established symmetry with the healthy, brassier supported breast and that fitted well against the chest wall. Follow up reports by the breast care nurse team suggested that this helped to ensure stability and comfort of the prosthesis when the patient was mobile. The application of computer-aided technologies also provided other process benefits. Using photogrammetry removed the need for impression taking, which is labour and material intensive, time consuming, intrusive for the patient and messy. The advantages and limitations of photogrammetry and other three-dimensional topographic scanning methods compared to direct impression techniques have been discussed and in this case study, provided an ideal solution. The design stages did not require the patient to be present and...
FreeForm provided the ideal tool for shaping the prosthesis. Mould designing in FreeForm could be more intuitive and efficient, however it is estimated that it was still faster than conventional methods.

Alternative RP&M methods such as Selective Laser Sintering (EOS, GmBH, Germany), Z-Corp printing (Z Corporation, USA) and Fused Deposition Modelling (Stratasys Inc. USA) could also be viable for mould production, but would be more difficult to achieve the desired level of surface finish.

The high cost of computer-aided technologies has been reported as a limitation in patient-specific medical applications. However, given the process and prosthesis improvements and the related indirect cost savings associated with patients undergoing shorter consultations, the computer-aided method has clear advantages. The equipment also has application in many other patient specific device design and surgical scenarios.

The application of computer-aided technologies may also be used to quantify the target prosthesis weight, by measuring the remaining breast volume and translating this to the prosthesis form. Body posture is known to be compromised post mastectomy and providing a well matched prosthesis may help to reduce injuries and the need for physiotherapy.

Conclusions
The technique presented provided a prosthesis that accurately fitted the defect chest wall of the post mastectomy patient providing a comfortable fit and improved retention over an ‘off the shelf’ alternative. By designing the prosthesis digitally and using the mirrored contour of the breast within the brassier a better symmetry was achieved for the wearer.

Manufacturing a custom prosthetic appliance is more cost and labour intensive than an off the shelf solution. This technique has illustrated how computer aided methods are able to offer a cost effective alternative to the traditional labour intensive techniques by reducing the length of patient consultation, reducing the number of patient visits, reducing the quantity of materials used and providing a more flexible and repeatable method of working.

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Illustration captions

Figure 1. Illustration of the digital process tools

Figure 2. Illustration of the angle used to capture the breast contour and defect.

Figure 3. The surface topography captured using photogrammetry.

Figure 4. The mirrored breast form in CAD.

Figure 5. Checking the size and prosthesis position in CAD.

Figure 6. The completed prosthesis tool design in CAD.

Figure 7. Injecting the colour matched silicone.

Figure 8. The completed prosthesis.