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CAD/CAM-assisted breast reconstruction

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keywords: computer-aided design, computer-aided manufacturing, 3D laser scanning, breast reconstruction, rapid prototyping, tissue engineering scaffolds

Abstract

The application of computer-aided design and manufacturing (CAD/CAM) techniques in the clinic is growing slowly but steadily. The ability to build patient-specific models based on medical imaging data offers major potential. In this work we report on the feasibility of employing 3D laser scanning with CAD/CAM techniques to aid in breast reconstruction. A patient was imaged with 3D laser scanning, an economical and facile method for creating an accurate digital representation of the breasts and surrounding tissues. The obtained model was used to fabricate a customised mould that was employed as an intra-operative aid for the surgeon performing autologous tissue reconstruction of the breast removed due to cancer. Furthermore, a solid breast model was derived from the imaged data and digitally processed for the fabrication of customised scaffold for breast tissue engineering. To this end, a novel generic algorithm for creating porosity within a solid model was developed, using a finite element model as intermediate.

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1. Introduction

Computer-aided design and manufacturing (CAD/CAM) techniques allow for the fabrication of tailor-made complex parts with high precision [1]. CAD/CAM were first introduced into the clinic in the 1990s, assisting surgeons to more accurately reconstruct defects after trauma or tumour resection [2]. Medical techniques such as magnetic resonance imaging (MRI), computed tomography (CT) and 3D laser scanning provide patient-specific digital 3D models [3]. An array of CAM techniques among which selective laser sintering [4], stereolithography [5] and fused deposition modelling (FDM) [6] can be employed to create physical models. These models were first and still mainly used clinically for pre-operative planning of complex surgical procedures [7]. Another application of CAD/CAM is in dentistry, where it was shown that implantations performed using customised drill guides built by stereolithography have greatly improved accuracy when compared to those performed using conventional surgical guides [7, 8]. Furthermore, the combination of medical imaging and CAD/CAM has been employed to create moulds for customised implant fabrication [9]. While all of these applications make indirect use of the built parts, over the last decade more and more materials have been developed for CAM that allow for direct use *in vivo*. Especially within the realm of tissue engineering, CAD/CAM approaches are increasingly being used to prepare anatomically correct scaffolds with tuneable properties [10].

A relatively new clinical area of application of these techniques is breast reconstruction. Despite recent advance in breast cancer therapy, mastectomy (removal of the breast) is still an important option in treatment. Breast reconstruction after mastectomy does not only improve the aesthetic appearance, it also alleviates the considerable impact breast removal or deformities have on the psychological well-being of patients [11]. Currently, breast reconstruction is performed using non-degradable silicone implants or by transplantation of autologous tissue flaps consisting of skin, fat, muscle and connected vasculature [12]. A different, promising approach that is under development is based on tissue engineering [13]. Multiple studies have demonstrated the creation of vascularised adipose constructs based on vascular pedicles and stem cell seeded scaffolds; current developments are directed to upscaling towards clinically relevant volumes [14-16].

3D Laser scanning has proven a valuable tool for imaging the breast region [17]. Using this technique one can obtain quantitative patient-specific 3D data on breast shape and size with comparable accuracy to MRI scanning, at much lower cost [18]. In this work we report on the feasibility to employing 3D laser scanning with CAD/CAM techniques in the area of breast

reconstruction. We explore the fabrication of personalised moulds for autologous tissue reconstruction and potential breast tissue engineering scaffolds employing 3D laser scanning and CAD/CAM.

2. Experimental

2.1 Image acquisition

Image acquisition was performed on a 46-year-old female patient who suffered from an invasive ductal carcinoma, after informed consent. 3D laser scanning was performed from three angles (0° or frontal, and -30° and $+30^\circ$ oblique anterior) of the patient in an upright position with arms abducted in a 90° angle as described previously [19], employing a Vivid 910 dot-laser scanner with built-in high-precision camera (Konica-Minolta, Marunouchi, Japan). The images were imported in Rapidform2006 (Inus Technology, Seoul, Korea), a CAD-software, and merged into a single shell-object that represents the surface in a 180° view (full frontal side) [20].

2.2 Mould-assisted autologous reconstruction

The CAD model for the mould was generated in Rapidform by selecting the healthy breast plus surrounding area on the surface model, and mirrored to replace the affected breast. A solid model was created from this 3D mirror image by extruding the surface to a thickness of 5 mm. The obtained solid model was meshed and exported via surface tessellation language (STL file format). The mould was then fabricated from an acrylic polymer (tradename Fullcure 720) by 3D printing (Objet Eden 350, Billerica, USA). It was sterilised by scrubbing with iodine and chlorhexidine, and used several times during surgery to orientate and contour the free tissue flap and adjust volume and shape of the reconstructed breast. The mould-assisted surgery was performed on 3 patients, and their satisfaction was assessed by a survey using a points scale of 1 up to 4 points for outcomes such as shape, symmetry and feel.

2.3 Scaffold design and fabrication

In Rapidform, a surfacing algorithm was employed to create a virtual chest wall, by interpolation between two horizontal lines; 1 cm below the clavicle (crossing the sternum at the height of the second intercostal space) and 1 cm below the lower breast fold. As the thoracic wall is not naturally perfectly symmetrical, the thoracic wall of the diseased half was mirrored to the donor side, through a perpendicular mirroring plane crossing the thorax in the middle. Then a deviation analysis was performed, which determines the distance between the breast surface shell and the thorax shell for a large number of points. The breast border was defined as the colour change from blue (1 mm distance) to green (2 mm

distance). The healthy breast surface shell and the mirrored thoracic shell were excised along this borderline and joined (seamed) together to obtain a watertight shell model of the solid breast. This was finally mirrored to obtain a shell model for the contralateral site that is to be reconstructed. Using Rapidform's surface generation tools a set of NURBs surfaces were created to match the shell model and exported as a solid part in the IGES file-format.

Many Finite Element Analysis (FEA) applications include tools for subdividing volumes into various element types including tetrahedra. The FEA package Abaqus/CAE (Dassault Systèmes, Vélizy-Villacoublay, France) was used to create a tetrahedral mesh within the solid model. The density of the tetrahedra is governed by the positioning of the seed points on the NURBs surface boundaries; meshes were created with average seeding distances of 6, 9 and 16 mm. The mesh geometry, i.e. the nodes and connectivity, is saved as an Abaqus Input file (.INP), which also is the input file for the newly developed program NetCreate.exe (Windows version downloadable as Supplementary Data). The program was run on the model using different values for the strut thickness: 0.5, 1, 2 and 3 mm, resulting in 4 different STL-files. The solid model and three porous models (of seeding distances and strut thicknesses) were fabricated on an FDM apparatus (Stratasys Dimension SST 768, Eden Prairie, USA) from acrylonitrile-butadiene-styrene (ABS) copolymer.

3. Results

3.1 Image acquisition

The 3D laser scan data obtained from 3 angles were imported in the CAD-software and combined to a single solid object representing the patient's breasts and surrounding thorax region. Figure 1 depicts a schematic of the 3D laser scanning setup, the individual acquired images and the combined image. It comprises a 180 ° surface model of the full frontal side of the patient.

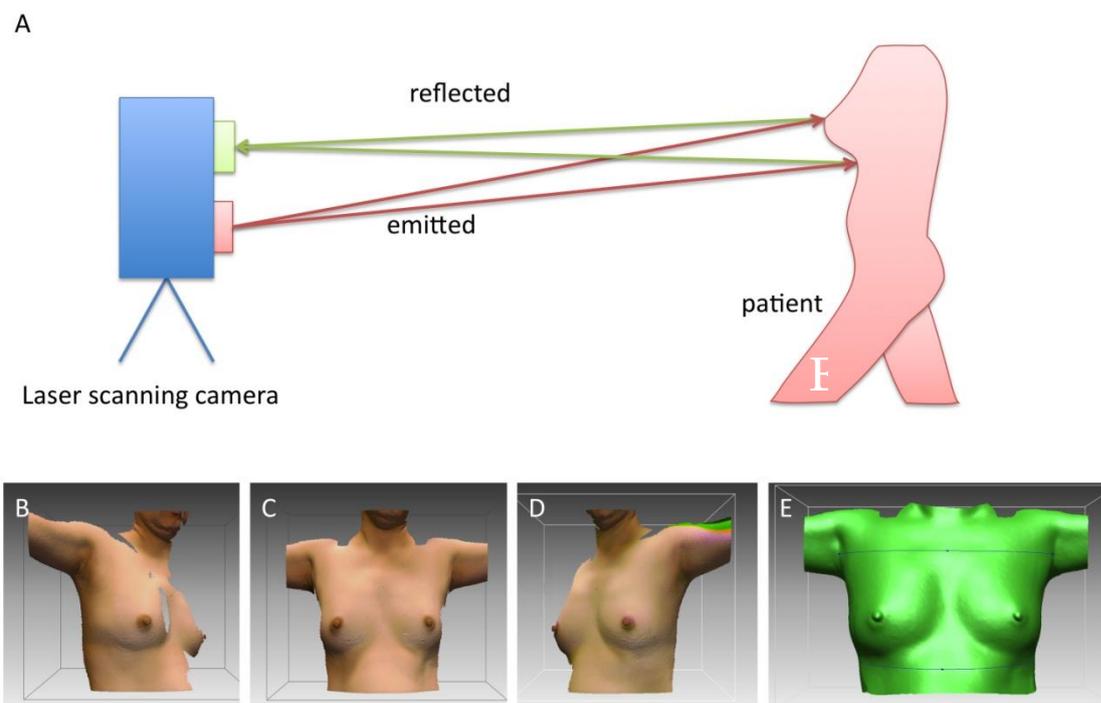


Figure 1: Imaging of body contours using 3D laser scanning. A. Setup: commercial dot-laser scanner records reflected laser beams. B. C. D. Output images of the patient at an angle with respect to the laser beam path of -30° , 0° and 30° respectively. E. Surface model combined from the images B, C and D.

3.2 Autologous tissue reconstruction using CAM-mould

Our long-term aim is to provide a CAD/CAM-based solution to the breast reconstruction field following a tissue engineering approach. However, 3D laser imaging and rapid prototyping can already be employed for better outcomes in surgery employing the current golden standard, which is autologous breast reconstruction. This was demonstrated by fabricating a personalised mould from the obtained surface model, which then could be used as an intra-operative aid for the reconstruction of the patient's breast as depicted in Figure 2. The healthy breast (patient-left) with surrounding thoracic area were selected in the surface model, mirrored and extruded to 5 mm thickness to generate a solid model. This part was subsequently manufactured by 3D printing in a shape-stable, transparent mould. The fabricated mould precisely reproduced the surface of the healthy breast. The mould was repeatedly used by the surgeon as a template throughout the entire free-flap breast reconstruction procedure. Firstly, it helped to orientate and contour the flap after translocation from the donor site to the recipient side. After removal of excess parts of the flap, the mould was used again to reaffirm the positioning and shaping of the flap before final placement was carried out. The surgeon found that the mould was a very helpful aid in reconstructing and shaping the breast, resulting in a more perfect shape and higher degree of

symmetry. Moreover, the patients of this case study reported a higher satisfaction of the surgery outcomes than the control group with respect to symmetry and shape of their breasts (3 points for the mould-assisted group versus 2 points for the control group on a scale of 4).

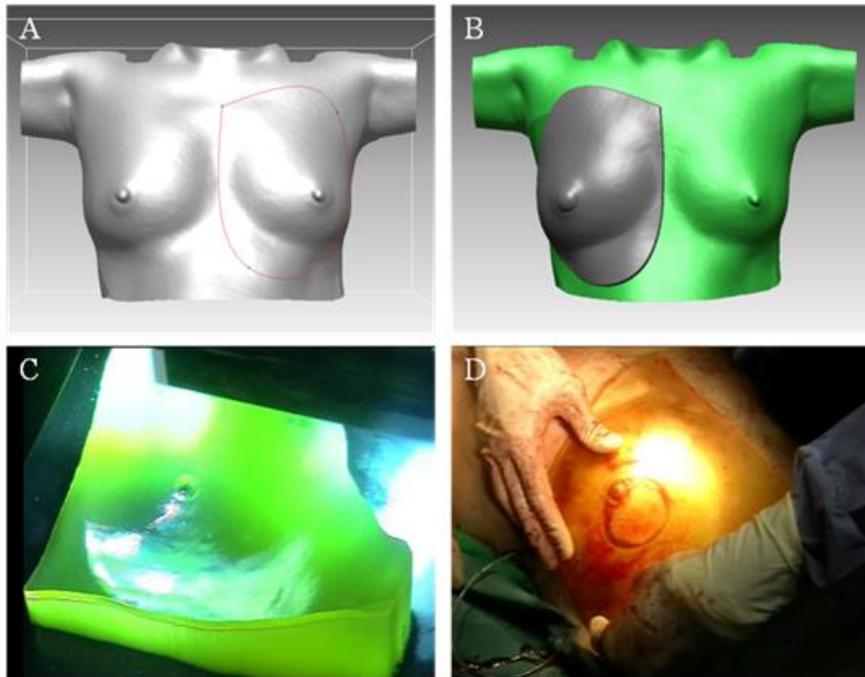


Figure 2: Mould-assisted autologous tissue breast reconstruction. A, B. The healthy breast and surrounding parts of the thorax are selected and mirrored to create a design for the targeted shape. C. Transparent silicone mould (5 mm thick) on support (green). D. Intra-operative use of the mould to assess the volume of required tissue and to shape the breast in flap transplantation-based reconstruction.

3.3 Virtual breast reconstruction

After imaging of the patient, a number of modelling steps in CAD software have to be taken to extract a solid (and finally a porous) model of the breast from the surface model.

Following Kovacs *et al.* [17], the borders of the breast region were defined at 1 cm below the clavicle to 1 cm below the lower breast fold. By applying a surfacing interpolation algorithm between these borders (Figure 3A), a virtual chest wall was reconstructed that resembles the natural thorax shape (Figure 3B). The colour scaling in Figure 3C (deviation plot) indicates the distance from the chest wall (here in purple); from blue (1 mm) over green (2 mm) and yellow to red (10 mm). The deviation plot shows a substantial asymmetry between the patient's healthy (+) and the size-increased diseased (#) breast. Therefore, the CAD-model for the reconstructed breast was obtained by taking the healthy breast and creating a mirror image. The model was excised at the breast boundary, defined as the border between the blue and green area. Then, the diseased breast was virtually removed and replaced by the

modelled chest wall for the whole right side of the patient's thorax. Finally, a copy of the healthy breast model was mirrored and placed on the chest wall with a precise fit. Figure 3D shows the final result after virtual breast reconstruction.

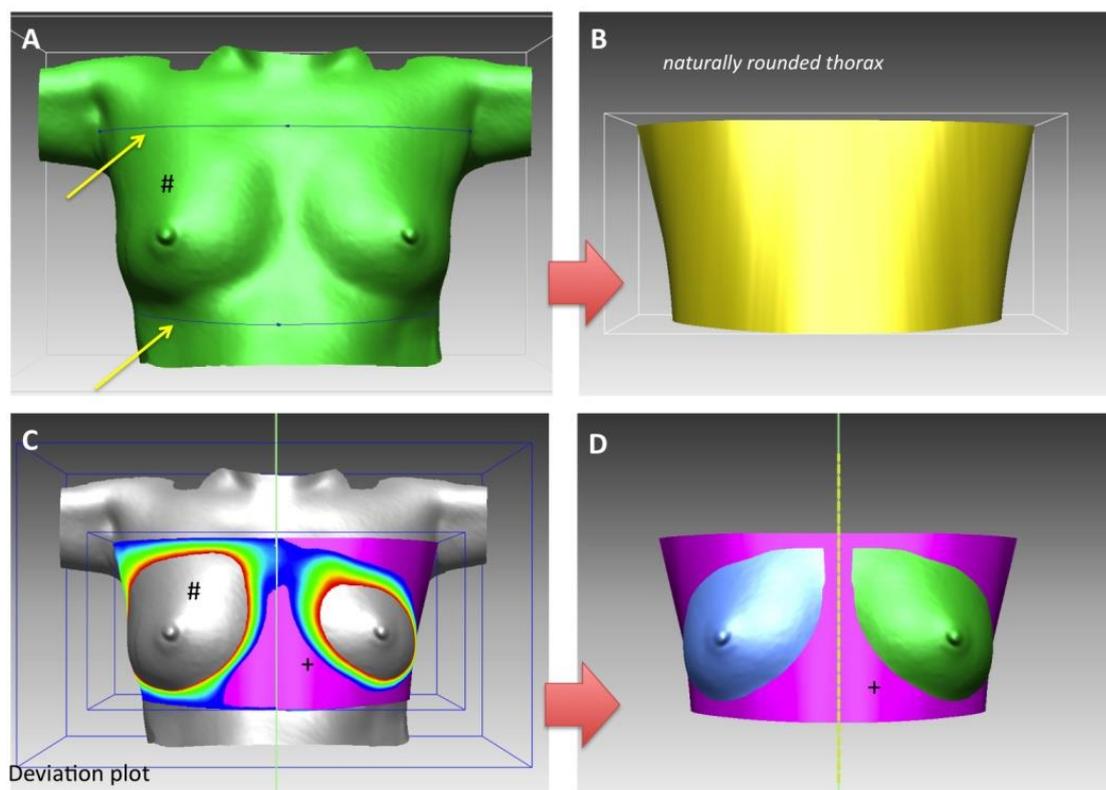


Figure 3: Virtual breast reconstruction. A, B. The thoracic wall shape (panel B) is interpolated from the upper and lower horizontal lines indicated by arrows (panel A). C. The boundary of the healthy breasts (+) is determined from the deviation plot. D. result after virtual reconstruction: a copy of the healthy breast is mirrored to obtain an even-sized and -shaped reconstructed breast (in blue).

Figure 4 quantifies the asymmetry in the pre-operative condition and compares it to the situation after virtual mastectomy, and reconstruction. The colour scaling and isolines in the contour plots (bottom row of Figure 4) indicate the distance of each point from the coronal plane. It is evident that the diseased breast is larger and differently shaped than the healthy breast. The middle images show the situation after virtual mastectomy. The modelled thoracic wall follows the curvature of the native thorax well, as indicated by the gradual change in colour from just below the clavicle to the right midaxillary line and the sternum. Finally, the right panel images show a complete restoration of symmetry in the reconstructed situation, with smooth colour gradients.

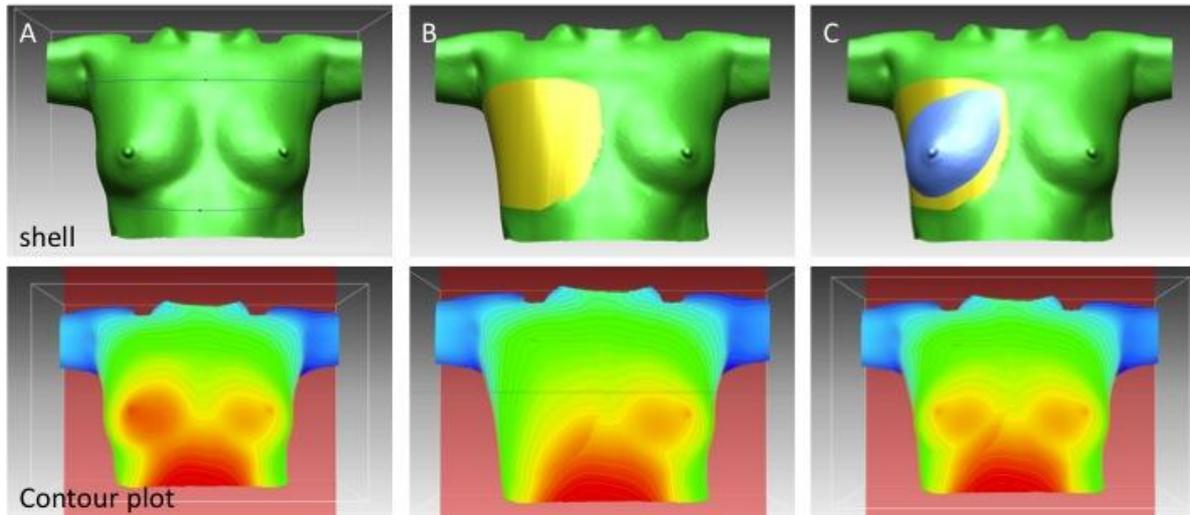


Figure 4: Asymmetry correction after virtual reconstruction (C) as opposed to pre-operative situation (A) and after mastectomy (B). Top row: 3D shells showing the native scanned surface in green, the reconstructed breast in blue and the modelled thoracic wall in yellow. Bottom row: Contour topology showing improved symmetry after reconstruction.

3.4 Creation of a patient specific scaffold for breast reconstruction

In order to enable computer-aided manufacturing, a solid model needs to be derived from the surface model. Here, a solid model of the breast was created by merging the surface of the anterior part of the breast with the surface model of the algorithm-fitted chest wall. Porosity was generated in the solid model using a newly developed generic method. In order to be practically applicable in the clinic, a method for creating personalised porous scaffold designs for individual patients needs to allow for versatility but at the same time require only few manual handling steps and little specific expertise. Here, we used the combination of an established method and a newly developed program to create porosity in a personalised imaging-based model in a highly automated manner. First, tetrahedral volumetric meshes were created as intermediates, using established methods and a common finite-element modelling (FE) analysis software package. For the second step, an algorithm was designed and employed to create struts of a given thickness around each edge length of all tetrahedrons, joining at their intersections to create a water-tight model with finite-sized struts. An example is given in Figure 5, where a single tetrahedron element is depicted. The algorithm takes the FE mesh and a number representing a strut thickness (ST) as inputs. It then creates struts using the given thickness for each side of the tetrahedron, by creating a triangle on each face of each tetrahedron that leaves a distance of ST to the edge of the tetrahedron. The four newly formed triangles are connected to form the inner surfaces of six prism-shaped solid struts, with the original triangular tetrahedron faces forming the outer surfaces. In this way, struts are grown from the faces inwards, such that the outer shape is

preserved. These steps are repeated for all individual elements, resulting in a porous interconnected strut-architecture. At the end, an STL file is written that describes all nodes and surfaces of the generated porous scaffold.

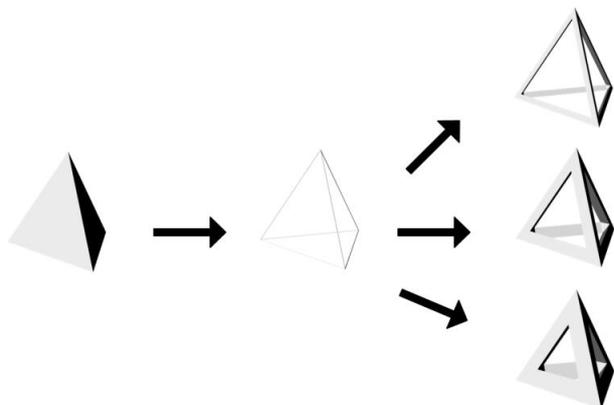


Figure 5: Example of generation of porosity on a single tetrahedron. From left to right: solid tetrahedron from a finite element model; wireframe model of connected vertices; porous tetrahedron elements with different strut thicknesses.

The developed algorithm forms a generic new method for creating porous models from (medical) imaging data. The creation of an FE mesh geometry from imaging data is an established and commonly performed procedure, often used in biomechanics [21]. With the breast FE model as input, 3 tetrahedral meshes were created with different seeding distances (SD) of 16, 9 and 6 mm, with decreasing distance corresponding to increasing numbers of nodes and elements, i.e. increasing complexity. The program that was developed to generate porous models requires minimal computational power (taking approximately one second on a standard office computer, running as a stand-alone 17 kilobyte-sized Windows application). The code is presented as Supplementary Information and the Windows application itself is available for download as Supplementary Data.

By variation of the ST value, structural parameters such as the porosity and available surface area can be adjusted. In Table 1, these properties are presented for the breast scaffold created from the 3 tetrahedral meshes, using different values for the strut thickness. A decrease in ST value results in increased porosity and decreased surface area, with more detailed meshes (using smaller SD values) requiring smaller ST values to get a similar porosity as compared to more coarse meshes. SD/ST ratios of approximately 5 to 20 lead to porosity values of ca. 60-95 %, which are relevant to tissue engineering. Higher values lead to highly porous scaffolds that would either be too difficult to manufacture or very fragile, whereas lower values lead to nearly solid models with closed-cell (non-interconnected)

pores. Figure 6 depicts a selection of the porous models of the breast scaffold with different SD and ST input values.

Table 1: Structural parameters of scaffold models. For each combination of seeding distance and strut thickness, the resulting porosity (P) and surface area (A) are given, as well as the number of nodes and elements of each tetrahedral mesh and the size of the STL file. The data printed in *italic* correspond to the physical prototypes depicted in Figure 7.

seeding distance (mm) → strut thickness (mm) ↓	16 mm	9 mm	6 mm
3	<i>P = 65 %</i> <i>A = 191 cm²</i>	P = 5.4 % N/A	P = 3.7 % N/A
2	P = 82 % <i>A = 191 cm²</i>	P = 31 % N/A	P = 7.0 % N/A
1	P = 95 % <i>A = 348 cm²</i>	<i>P = 76 %</i> <i>A = 920 cm²</i>	P = 57 % <i>A = 1 404 cm²</i>
0.75	P = 97 % <i>A = 274 cm²</i>	P = 86 % <i>A = 775 cm²</i>	<i>P = 73 %</i> <i>A = 1 293 cm²</i>
0.5	P = 98.6 % <i>A = 191 cm²</i>	P = 93 % <i>A = 573 cm²</i>	P = 87 % <i>A = 1 025 cm²</i>
0.25	P = 99.7 % <i>A = 100 cm²</i>	P = 98 % <i>A = 315 cm²</i>	P = 96 % <i>A = 595 cm²</i>
number of nodes	94	533	1387
number of elements	251	1850	5512
size of STL file (MB)	1.0	6.5	18.6



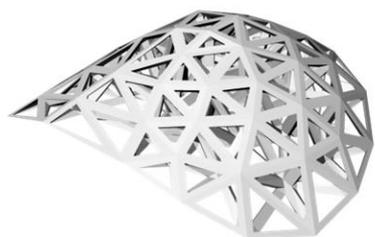
16 mm SD / 3 mm ST (P = 65 %)



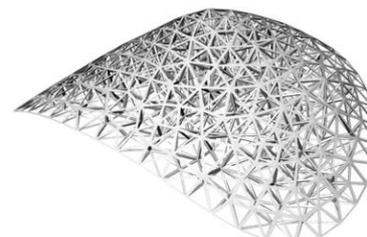
9 mm SD / 1 mm ST (P = 76 %)



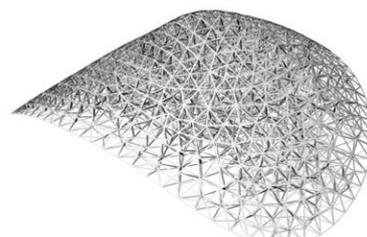
6 mm SD / 0.75 mm ST (P = 73 %)



16 mm SD / 2 mm ST (P = 82 %)



9 mm SD / 0.5 mm ST (P = 93 %)



6 mm SD / 0.25 mm ST (P = 96 %)

Figure 6: Generation of porosity in breast scaffold. Scaffolds depicted are based on meshes with 3 different seeding densities (16, 9 and 6 mm distance), each for two different values of strut thickness. The models in the top row were prototyped and are depicted in Figure 7.

The program writes an STL file as output, which can be read by most CAM software packages for manufacturing using for example stereolithography, 3D printing or fused deposition modelling. The solid breast model and three porous models based on 16, 9 and 6 mm seeding distance and 2, 1 and 0.75 mm respective strut thickness were fabricated by FDM from non-degradable ABS copolymer for demonstration purpose; their photographs are depicted in Figure 7. The built porous models are mechanically very stable due to the high interconnectivity of the struts. Our examples demonstrate the feasibility to import the mesh data generated by the program into CAM controlling software to build mechanically strong physical models.

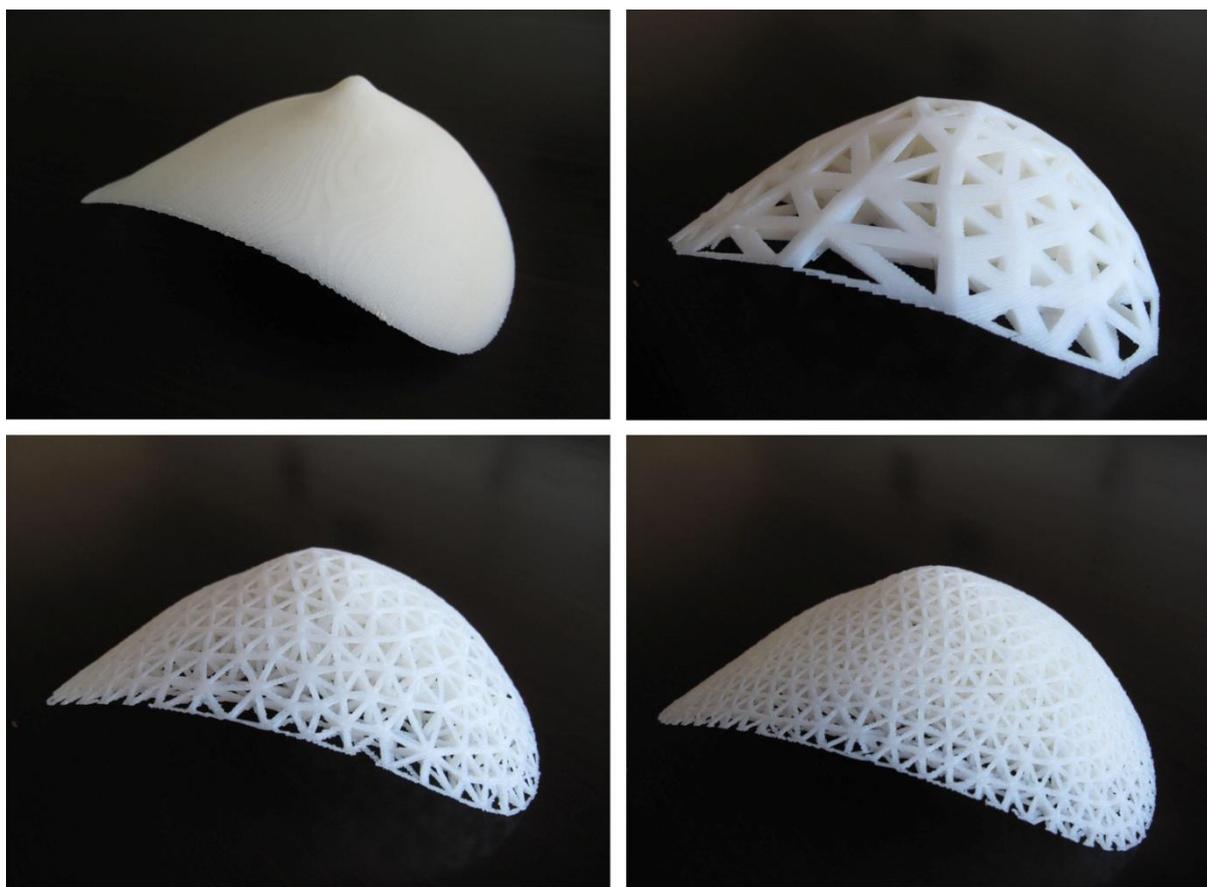


Figure 7: Physical prototypes of one solid and three porous models for a personalised tissue engineering scaffold, manufactured by fused deposition modelling. The porous models were created using the described program, employing seeding distances of 16, 9 and 6 mm, and strut thicknesses of 3, 1 and 0.75 mm, respectively.

4. Discussion

The application of computer-aided design and manufacturing (CAD/CAM) techniques from bench to bedside is growing slowly but steadily. The ability to build patient-specific models, customised drill guides and implants based on medical imaging data sets offers major potential in improved surgical outcomes, and the relatively high cost per built part as compared to mass-produced goods is justified for surgeries of high anatomical complexity [9].

Breast reconstruction is a relatively new clinical area of application of CAD/CAM-techniques. and the incidence rates are high: over 300,000 reconstructions are performed on a yearly basis in the US alone [13]. Breast reconstruction is currently performed using implantable prostheses or by autologous tissue transplantation. Prostheses are generally composed of a vulcanised silicone rubber sac filled with saline solution or liquid silicones. Although the use of such non-adaptive, acellular implants only rarely leads to severe complications, the formation of a rigid, fibrous scar tissue capsule surrounding the implant known as capsular contracture is commonly observed. The capsule formation is due to a foreign body reaction, and can lead to severe pain as well as deformation leading to spherically shaped or asymmetric breasts [22]. The transplantation of autologous tissue flaps (skin with subcutaneous fat and (re)connected vascular network) gives quite better results with a natural appearance and feel. In this work, we have demonstrated the feasibility to employ CAD/CAM as an aid for autologous breast reconstruction, by fabrication and intra-operative use of a personalised mould. A case study on three patients revealed an improvement in patient satisfaction on the obtained shape and symmetry of mould-assisted breast reconstruction. Since 3D laser scanning can also be employed to assess the quality of breast reconstructions post-operatively [23], the added value of future mould-assisted reconstructions can be determined in a quantitative manner (in terms of symmetry). Moreover, it enables to assess the quality of autologous breast reconstruction compared to the use silicone implants over time, as remodelling and capsular contracture can be imaged and quantified.

Although autologous tissue reconstruction shows good results with highly symmetrical outcomes aided by CAD/CAM-techniques, it still has clinical limitations. The procedure is associated with long duration of anaesthesia (5 to 10 hours) with considerable blood loss, and with problems at the donor site including wide, unsightly scars, abdominal weakness, abdominal bulge or hernia [12]. To bypass these problems, researchers have recently started exploring the possibilities to perform breast reconstruction following a tissue engineering approach. Adipose tissue has been engineered *in vitro* from adult stem cells (adipose-derived (hASC) or bone marrow-derived (BMSC) [24]. *In vivo*, first successes have been realised to

form completely differentiated, vascularised adipose tissue that remained stable for up to 6 months [14].

Here we demonstrated a novel generic route to generate breast scaffold designs from medical imaging data. The approach is both versatile and patient-specific, and at the same time allows for a high level of automation, requiring minimal manual handling or specific expertise. For this, we made use of established methods to create volumetric tetrahedral meshes for finite element modelling, as is often done in biomechanical studies [25]. A specific advantage of these tetrahedral meshes is that they possess a high degree of strut interconnectivity, resulting in optimal mechanical stability, even at high porosities. Subsequently, struts of a given thickness were designed around each edge of all tetrahedrons by a generic program based on a newly developed algorithm requiring minimal computational power. Using the presented method, one can generate porous models that have the overall organic shape of any scanned tissue, built up from fully connected struts. The porosity and pore size can be tailored independently by controlling the density of seeding points in the meshing step, and by choosing an appropriate strut thickness, respectively. As in general with tissue engineering scaffolds, the optimal porosity will be determined by a trade-off between mechanical properties (highest for low porosities) and pore volume available for new tissue formation (highest for high porosities) [26]. Other factors determining optimal porosity and pore size will be the resolution and accuracy of the employed CAM method, and the used material. At this time we have had the availability of an FDM machine with a fairly coarse resolution, using ABS as a construction material. Several biodegradable scaffold materials have been developed for different additive manufacturing technologies, and more are expected to evolve over the coming years [5, 27-30]. Here we present a clinically viable route to design manufacturable breast tissue engineering scaffolds from patient-specific imaging data to be used with a variety of CAM techniques and materials.

Ongoing and future work include the preparation of breast scaffolds using appropriate biomaterials, i.e. showing the desired mechanical properties, support for cell culture and tissue formation, and degradation at the required rate. In *in vivo* adipose tissue engineering studies we are focussing particularly at neovascularisation using the vessel loop technique, as supplying all cells with nutrients and oxygen will be a major challenge in scaling the volumes of engineered tissue up to clinical relevance.

The possibility to laser scan a breast surface and make a physical prototype was first demonstrated in 1998 [31]. Imaging and CAD/CAM technology have improved significantly since then, enabling to obtain accurate personalised digital models of body parts, and to

fabricate functional scaffolds. With the current work, the clinical use of CAD/CAM for breast reconstruction has come a step closer.

5. Conclusions

In this study we have shown the added value of computer-aided design and manufacturing (CAD/CAM) for breast reconstruction. 3D laser scanning is an economical and facile method for creating an accurate digital representation of the breast and its surrounding chest wall. Such models can be used to fabricate customised moulds that aids the surgeon in shaping the breast during autologous tissue reconstruction, improving overall shape and symmetry of the reconstructed breasts. Moreover, a solid breast model can be derived and digitally processed for the fabrication of customised scaffolds for breast tissue engineering. With a future focus on adipose tissue engineering, the current work provides a stepping stone towards CAD/CAM-assisted, tissue engineering-based breast reconstruction.

Supplementary Data

The porosity generating algorithm is available as Supplementary Data, and can be downloaded as a Windows-executable NetCreate.exe. In addition, the tetrahedral mesh file with 9 mm seeding distance BreastTetMesh9mm.inp is made available online.

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