

The Greek sculptor Phidias – fourth century BC – is known for the technical and artistic quality of his representation of the human being, full of dignity and nobility. His conserved masterpiece, the friese of the Parthenon, is still today a great symbol of European culture.

The medical models resulting this project should contribute to make disabled, injured or ill persons resemblant again to the ideal human beings of Phidias.

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Preoperative planning with the use of stereolithographic model



Fig. 1

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Introduction

The use of stereolithographic (STL) models in patients with large skull defects is largely accepted. More and more other indications for the use of rapid prototyping in medicine are being introduced.

A medical model has proven to be a useful tool for making implants, templates, surgical guides, but also for communication with colleagues or patients. In this article however a case is being presented in which a model has been used for preoperative planning.

Medical models are superior to 3D visualizations because they enable the surgeon to answer important questions during the surgical planning



Fig. 2

Continued on page 2 ▶

EDITORIAL

Welcome to the third edition of the Phidias Newsletter.

A central theme in this newsletter is the concept of a template to transfer a surgery planning into the operation theatre. Three articles will focus on this new and revolutionary concept.

Furthermore, you will find articles related to the use of RP models in surgery and an introduction to a new activity within the Phidias Network: The Validation Study.

In this study, co-ordinated by the German National Health Insurance (MDK), we will try to assess the usefulness of RP models by means of 700 questionnaires related to cases involving models.

We would like to invite you all to participate in this study by filling out as much of these questionnaires as possible.

For more information about the questionnaires and the incentive for filling them out, please contact your local network partner.

More information about the study can be read in the article by Joerg Wulf on page 6.

Kris Wouters
Materialise
Project Manager

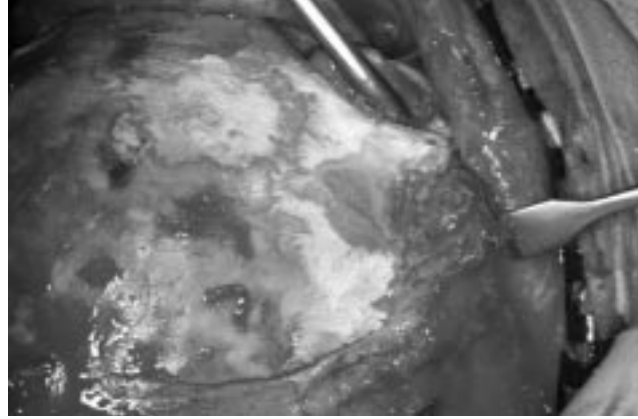


Fig. 3

and simulation of complex individual treatment. (Rapid Prototyping Technologies and Applications in Medicine, abstract of Presentation during CAS '99 Zeilhofer F, München/Germany)

Treatment Planning

A 21 year old male had been presented to the department of Cranio-Maxillofacial surgery with several injuries in his face after an assault. He also had a cosmetic complaint because of irregularities mainly of the temporo-frontal region of the skull, which were a result of an early operation in the childhood (a remodeling of the skull because of a scafocephaly) (fig. 1).

CT data of the patient had been gathered in order to make a STL model (Materialise, Leuven, Belgium) to get an idea of the nature which caused these irregularities (fig. 2).

The STL model showed several anatomical anomalies which needed surgical correction in order to get an acceptable cosmetic result.

The patient had been informed preoperatively based on of the STL model that the bulges on the frontal bone would be removed with surgical drills and that the concavities would be filled with Bone Source, a hydroxyapatite cement (Leibinger). Furthermore it had been decided to restore the right superior orbital rim with the same material.

Hydroxyapatite cement can be intraoperatively shaped and sets in vivo to an implant composed of microporous hydroxyapatite (HA). (P.D. Constantino et al, Archives of Otolaryngology-Head & Neck Surgery, April 1991).

Intervention

Surgery was performed, using endotracheal anesthesia, by making a coronal incision in order to show the right and left orbit.

The full exposure of the frontal irregularities had been obtained.

As planned bulges had been flattened with surgical drills and HA cement (10 g) had been used to even the frontal bone and to reconstruct the right orbital rim (fig. 3).

Patient had been discharged in good condition 3 days after operation. One month post-op the patient was checked and a good result had been seen (fig. 4).

Conclusion

Rapid prototyping offers a wide range of possibilities especially for cranio-maxillofacial patients.

The use of stereolithographic models can be an enormous help in preoperative planning, communication with colleagues and informing patients.

The precise information concerning the cranio-maxillofacial anomalies, the choice of implant material, the surgical approach and the preoperative information of the patient have been beneficiary to get a good result in such patients.

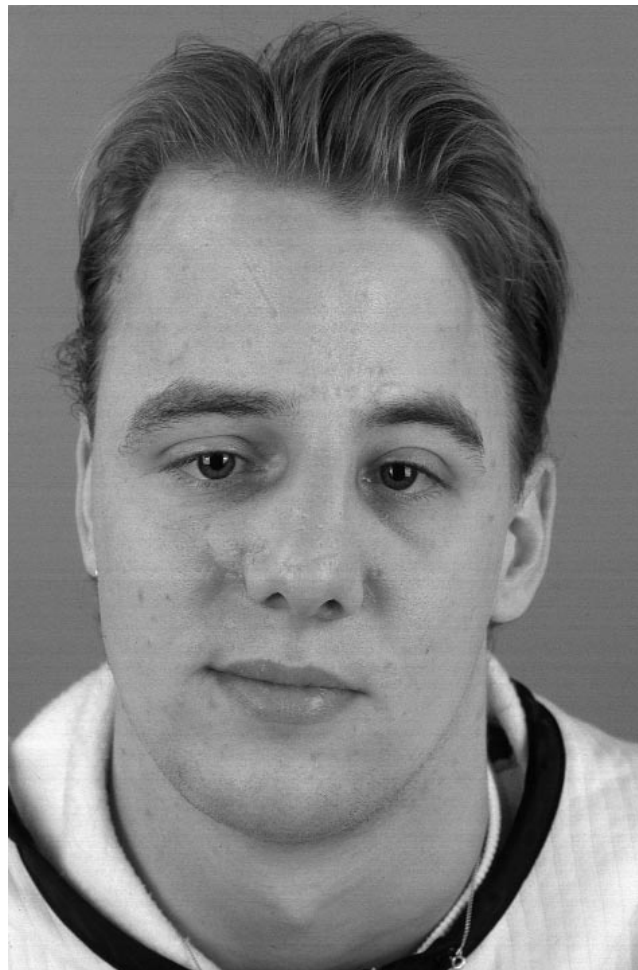


Fig. 4

Rapid prototyping in reconstruction of large calvarial defects

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Introduction

One of the most important indications for rapid prototyping models is the reconstruction of calvarial defects after trauma, tumor or infection.

One of the major problems is the evaluation of the area to be reconstructed. Here not only the size of the defect is of importance but also its three-dimensional shape.

Therefore it is not sufficient to create a rapid prototyping model of the skull including the area of defect, a 3D CT scan would be of the same properties. If an adequate reconstruction has to be provided, besides the model, a reconstruction of the defect area has to be manufactured.

The following case study is trying to give an example.

CASE STUDY

This 27 year old patient suffered a car accident with severe fracture of the forehead and the midface. Midface fractures were treated with miniplate osteosynthesis without complications. The fractured frontal bone had to be removed for decompression of the frontal brain (Fig. 1).

The patient who did not suffer from any neurological or psychic disorders complained about his appearance and asked for a surgical solution.

After helical CT-scan (Siemens Somatom plus 4®, Erlangen) a stereolithography solid skull model was manufactured (Fig. 2). The reconstruction of the defect was manufactured in stereolithography-technique as well in superposition-technique of the CT-scans using a scaled normal-CT from the manufacturer's database (Konform®, Cologne) (Fig. 3).

The defect model was transferred into biocompatible PMMA-resin (Fig. 4), and implanted into the defect site (Fig. 5).

The postoperative view shows the patient 4 weeks postoperatively without any complications (Fig. 6).

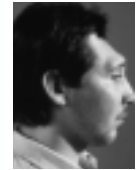


Fig. 1

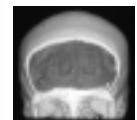


Fig. 2



Fig. 3



Fig. 4



Fig. 5



Fig. 6

Conclusion

The range of indications of rapid prototyping models should be concentrated onto defined groups of diseases or singular clinical cases.

Anyway if indicated, with a high accuracy and plasticity rapid prototyping models are a surgical tool of unbeatable features giving surgical outcomes never reached before.

Geometric accuracy in medical modelling

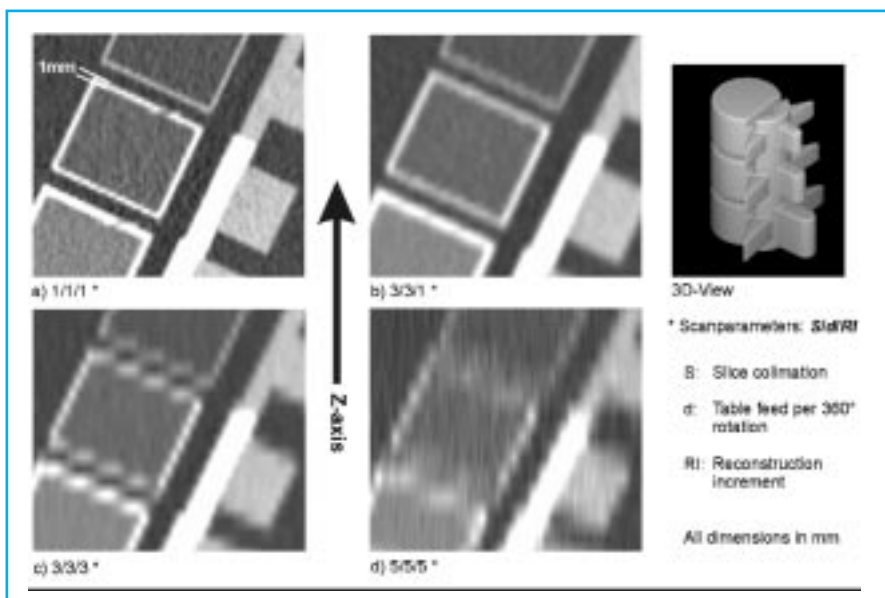
Proposal for a new study within the PHIDIAS network

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Introduction

During the last years medical modelling has been introduced to various medical fields. It has become an accepted technique for diagnosis, surgical planning and simulation. However, through all these years, quality assurance concepts have been neglected. Even the common question concerning the overall geometric accuracy of medical modelling remains largely unanswered. With the study described in this article, the Institute of Medical Physics, as co-ordinator of the Phidias Quality Assurance Workarea, plans to examine the geometric accuracy of medical modelling.

Figure 1: 3D-Reconstructions using different parameters [1]



The procedure of generating a medical model can be broken down into three major steps:

The CT scan for data acquisition, the image segmentation combined with data processing and the building of the model itself, using one of the available RPT technologies. Each of the steps has its own sources for geometric errors and distortions.

- The resolution and image quality of the CT scan is dependent on the parameters chosen. Figure 1 shows four multi planar reconstructions of the European Spine Phantom. The images have been reconstructed using different slice collimation/table feed per 360° gantry rotation/reconstruction increment. The differences in resolution of details can be seen easily.
- For segmentation a threshold-based algorithm is generally used. The problem is to find the best threshold for a given anatomy. Unfortunately, there is no global threshold applicable for all cases. A threshold chosen too low yields

a lot of noise and flying pixels in the segmentation. A threshold chosen too high will cause loss of detail and small structures in the model. These effects are shown in figure 2.

- The accuracy of the RPT modeller systems varies depending on the technology used. Shrinkage and distortion can be found. These effects are generally considered smaller than those of the first two steps.

The essential factors influencing geometric accuracy are summarised in table 1.

Study on geometric accuracy:

To examine the geometric accuracy in medical modelling a study using a phantom will be performed. The phantom representing the human head is currently being designed and built. Figure 3 shows the assembly of the bony structures. Dimensions for the phantom have been derived from the literature [2 - 4]. Some technical structures have been added.

Wedges representing the ears can be used to determine the spatial resolution in various directions. Optionally small metal balls can be included to simulate dental inlays. The bony structures will be build from materials equivalent to bone in CT value and the bony structures will be filled up and surrounded with tissue equivalent material.

Using the phantom the overall process of medical modelling, starting from CT scan via segmentation and data processing to RPT building of the model, can be performed. The result will be an RPT model of the bony structures

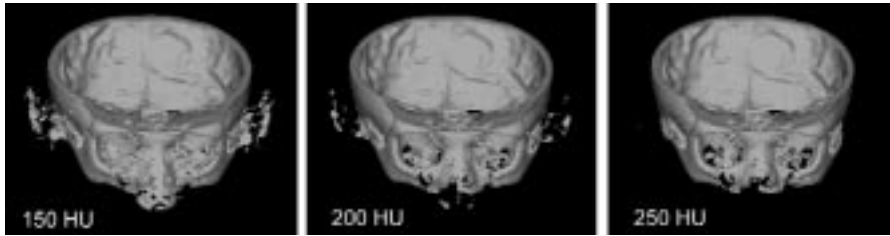


Figure 2: Effects caused by different thresholds

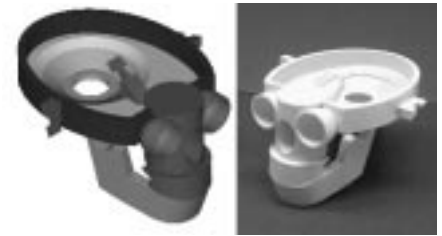


Figure 3: CAD representation of bony structure and picture of the phantom

of the phantom. This model will be measured, using a three dimensional high accuracy coordinate measurement machine. The results of the measurement (actual dimensions) can be compared to the known (desired) dimensions of the phantom. This yields data on geometric accuracy of the overall process. The whole testing procedure is diagrammed in figure 4.

To test the overall procedure as well as the single steps of the modelling process the study will be divided in five parts.

1. The first part of the study aims to test the overall geometric accuracy of medical modelling at different sites across Europe. The phantom will be circulated and the partners will be asked to build a model of the bony structures, using the same equipment and parameters as they use in their everyday cases.
2. For testing CT scanners the phantom will be scanned in various scanners using protocols derived from a reference protocol. Data processing will be performed always using the same parameters. All models will be built on the same RPT machine. It is planned to test the most important scanners suitable for medical modelling.
3. For evaluating a reference scan protocol, one CT scanner will be used to test suitable protocols. Data processing and model building will be done the same way as in the scanner test.
4. Different segmentation algorithms can be tested by using the reference CT scanner and protocol as well as the reference RPT modeller.
5. The last part of the study will be to test the accuracy of all kinds of RPT modellers. To do so, the CAD file of the phantom will be used as the basis for the RPT modeller. We hope to examine different RPT technologies as well as different stereolithography systems.

The models generated in all parts of the study have to be sent back to Erlangen for measuring. The Institute of Medical Physics will be the co-ordinator of this Phidias study and will perform the evaluation for all parts of the study.

Partners interested in joining the study should contact Jörg Schneider, phone: +49 9131 85 26 26 8, joerg@imp.uni-erlangen.de

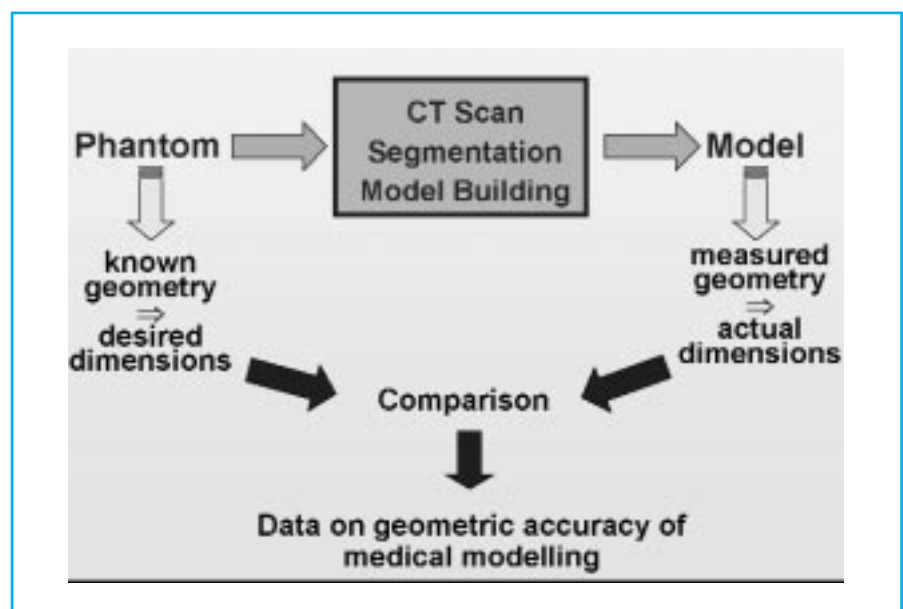
Literature

- [1] Kalender WA, Computed Tomography, Wiley & Sons, 1999
- [2] Voss, Herlinger, Taschenbuch der Anatomie, Bd. 1, 1985
- [3] Phantoms and Computational Models in Therapy, Diagnosis and Protection, ICRU Report 48, 1992
- [4] The Male And Female Adult Mathematical Phantoms, GSF-Bericht, 1986

CT scan	Data processing	Model generation
system characteristics	segmentation algorithm	accuracy of modeller
scan parameters (spiral CT)	parameters chosen	shrinkage
artefact reduction	influence of artefacts	distortion

Table 1: Factors influencing the geometric accuracy of medical modelling

Figure 4: Testing procedure diagram



Evaluation of medical rapid prototyping models

A multicentric European study

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In complex surgery a Medical Rapid Prototyping (RP) model of the patient's cranium which represents the detailed individual anatomical structure might be a very useful tool by means of which the quality of surgical planning as well as patient's treatment and outcome could be increased.

However a multicentric evaluation of this subject was not realized until now.

The Phidias Evaluation Study started in september 1999 and will end in April 2002. It is coordinated by Medizinischer Dienst der Krankenversicherung Schleswig-Holstein (MDK)-Germany. The study is based on a questionnaire (Evaluation of Medical Models) assessing case-related variables. It contains 56 questions that describe 6 aspects of a case where a Medical Rapid Prototyping model was applied.

The questionnaire was mailed

to the 40 partners of the Phidias Network who participate in this study and the partners were asked to distribute it among surgeons using models.

The questionnaires are to be completed by the operating surgeon.

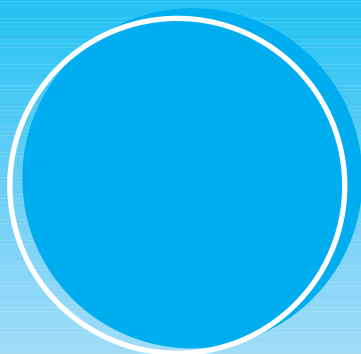
The resulting informations will be transferred into the database of the study.

The questionnaire (Evaluation of Medical Models) can be downloaded from the Phidias-homepage (<http://www.phidias.org>).

First results of the study will be published in spring 2000.

Phidias Global Workshop 2000

- Scientific presentations on RP models and drilling templates in surgery
- Internal project meeting



October 12-14, 2000

Leuven, Belgium

Information and submission of abstracts:

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Extended cranioplasty with prefabricated carbon fiber reinforced plastic implants

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Introduction

Extended osteoclastic bone defects require treatment for medical and cosmetic reasons. With advanced biotechnology and materials engineering an increasing number of various materials have been used, but no one seems to satisfy all demanded characteristics (biocompatibility, mechanical strength, full CT and MRI diagnostics). Furthermore the prefabrication of the prosthesis with exact fit and shape should be possible in order to reduce the operation time and to secure a satisfying cosmetic result. Carbon fiber reinforced plastic (CFRP) seems to meet all the requirements and has been used in our unit since April 1996.

Patients and methods

Presurgical management

Initially a helical volume CT data set (Somatom plus, Siemens, Erlangen, Germany) of the skull defect with the adjacent bone is acquired. The range should be chosen at least 3 mm shy of the borders of the defect with a slice thickness of 3 mm and a table

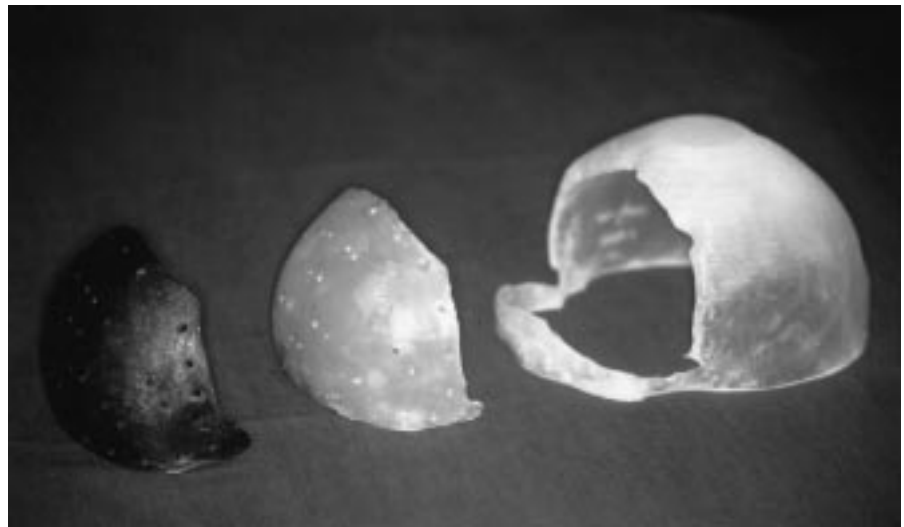


Figure 1: Stereolithographic model of a bifrontal defect, individually shaped wax template and final CFRP-implant

Figure 2: Implanted CFRP-prosthesis fixed with sutures showing excellent fit and shape



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speed of 3 mm/sec. This data are transferred to an industrial computer aided design (CAD) and manufacturing (CAM) company (Laserform Ltd., Vienna, Austria). An individual and accurate 3D model of the defect with adjoining bone structures is built up in a photohardening liquid resin using a numerically controlled laser beam catalyzing the polymerization of the plastic substance. After control of the plausibility of the 3D stereolithographic model regarding the correctness of the side and the dimension, a wax template is modeled by hand into the defect. In this simple way, the thickness and the margins of this wax model can be taken precisely from the borders of the defect without any relevant gap. The surface contours are formed in reference to the contours of the stereolithographic model. From this wax template, a CFRP-implant is fabricated (Sofamor-Danek GmbH, Subsidiary Deggendorf, Germany) by loosen mold (Fig. 1). This pre-operatively manufactured implant individually can be repeatedly steam sterilized by autoclaving.

Patient population and clinical presentation

From April 1996 till December 1998 we have performed 13 CFRP-cranioplasties in 12 patients (4 women, 8 men, mean age 48 yr, range 24-64 yr), with an extended bone defect. 3 defects were due to osteoclastic trepanation after head injury, 7 were caused by an infection of the free bone flap (3 after craniotomy for frontobasal reconstruction after trauma, 2 after resection of meningiomas and 2 after frontotemporal approach for aneurysmal clipping). The other



Figure 3a, b:
Extend bifrontal bone defect, before and after insertion of CFRP-implant



2 skull defects resulted from a primary osteomyelitis of the petrose bone and from a resorption of a free bone flap. The mean size of the defect to indicate the use of a CFRP-prosthesis was 9,9 x 6,9 cm. The mean period between craniectomy and elective cranioplasty was 6,5 months (range 5-8 months).

Operative treatment and follow-up

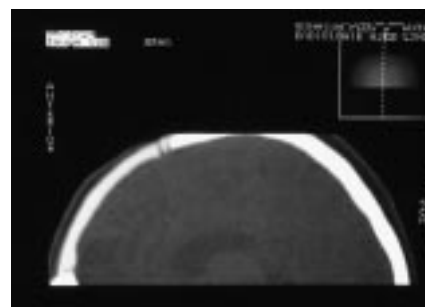
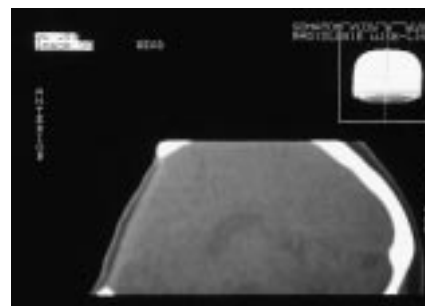
All patients were operated on in the same way. The pre-existing scar was reopened, the scar-tissue between galea and dura carefully dissected, and the calvarial margin of the defect exposed.

Subsequently, the CFRP-implant was fixed into the defect with sutures (Fig. 2), using the prefabricated perforations of the prosthesis and corresponding drill holes in the bone edges. The mean follow-up period was 20,7 months (range 3-33 months). The postoperative evaluation included clinical outcome and cosmetic result as well as postoperative CT or MRI-scan.

Results

The cosmetic result was excellent in 9 patients, leaving them with no external signs that a repair had been done except the scar (Fig 3 a, b). The fit and shape of the

Figure 4: Median-sagittal reconstructed CT-scan before and after insertion of CFRP-implant. Closely fitting implant with good contours and no artifacts shown on the CT-scans



implant was perfect or good in all cases but in the first patient with a frontotemporal defect. In this case there was the need for intraoperative reshaping of the prosthesis. It was also in the same case where the only postoperative aseptic infection occurred. In the others neither gaps nor mismatches between the border of the defect and the implant were observed. The average time required for insertion of a CFRP-implant was 80 minutes (range 60-140 minutes).

The postoperative CT-scan without artifacts showed closely fitting implants with good contours, no subdural hygromas occurred (Fig. 4a,b). There were no distortions observed on MRI-scans but signal void in the area covered by the implant, especially on T1-weighted SE images (Fig. 5). No implant mobility was observed.

Conclusion

The method of using individually matching prefabricated implants for reconstructing extended bifrontal bone defects is efficient and time saving. Although the reported cases represent only a limited experience the practical benefit of CAD/CAM-prefabrication for the patient and the surgeon is evident. It seems to be superior to the previously used methods. CFRP

could be a valuable new material for cranioplasty, combining many demanded characteristics for an implant. After the first series of 12 patients we conclude, that for cranioplasty of extended skull defects at the present the use of prefabricated CFRP-implants is the method and material of choice.

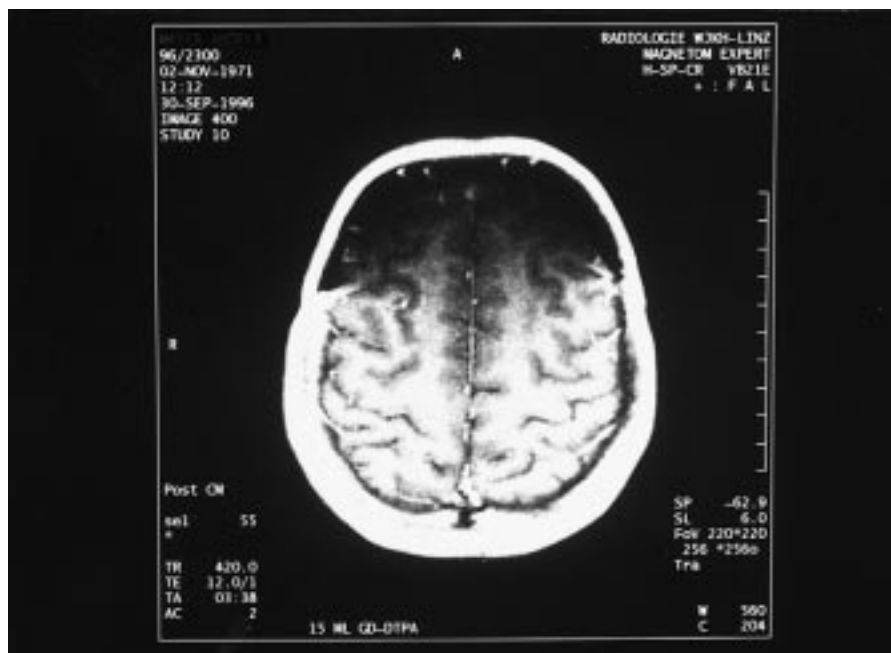


Figure 5: Axial T1-weighted MR-scan with contrast media, signal void occurs in the area of cranioplasty

Key Words

Carbon fiber reinforced plastic, Computer aided design, Computer aided manufacturing, Cranioplasty, Skull defect.

Tabel 1: Common implant materials for cranioplasty and demanded characteristics

	biocompatibility	mechanical strength & long-term stability	radio-lucency	MR-compatibility	CAD/CAM prefabrication
BIOMATERIALS					
autologous bone and bone graft	+	+/-	+	+	no
ALLOPLASTIC MATERIALS					
Plastics carbon fiber reinforced plastic (CFRP)	+	+	+	+/-	yes
polymethylmethacrylate (PMMA)	-	-	+/-	+/-	no
Ceramics calcium hydroxyapatite (HAP)	+	-	+	+	yes
Metals titanium	+	+	+/-	+/-	yes

Drilling templates for dental implantology

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Situation

Dental implants are biocompatible screws, placed in the upper or lower jawbone, on which teeth replacements are attached.

It is important that the implants are positioned in strong bone, in order to provide initial stabilisation and to help in osseointegration. The artificial teeth are connected to the implants via an abutment that goes through the mucosa.

So, the placement of the implants has to comply with two groups of considerations:

Surgical Considerations:

The implants should be mechanically stable, in bone that is suited for osseointegration, and they should avoid the sinus cavities and the inferior alveolar nerve.

Esthetical and dental-technical considerations: The artificial teeth should fit on the implants, and, especially for fixed reconstructions, they should cover the implants, in order to make them invisible.

The implants should also have an optimal direction, in order to support the biting forces.

However, when the implants are surgically placed, the future artificial teeth are not visible.



Very first case done with the SurgiCase templates

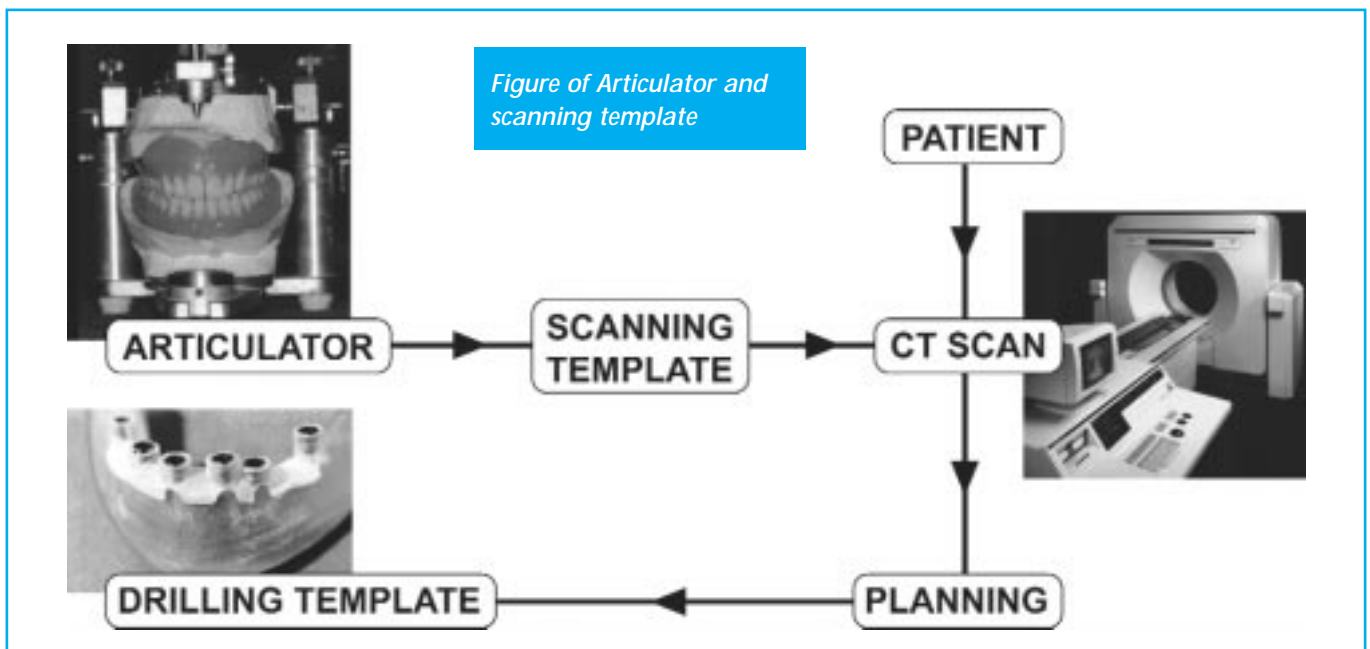
These future teeth are visible in the set-up placed in an articulator set-up, where the ideal esthetical positioning of the teeth is simulated in function of the residual teeth, and in function of the (planned) teeth of the opposite jaw.

In order to make a compromise between esthetical and surgical considerations, an ideal esthetical set-up is made in the articulator, and a scanning template is made from it. This scanning template is a temporary prosthesis of which the teeth are made in a radio-opaque material (a material that is visible in the CT scanner).

Next, the patient is scanned with a conventional CT scanner with this scanning template in his mouth.

Now you have all the elements visible in the CT images:

You can see the ideal esthetical positioning of the teeth, and you see the bone, the bone quality and also sinuses and nerves. These CT





*SugiCase
concept drawing*

Continued on page 12 ▶

SurgiCase screen

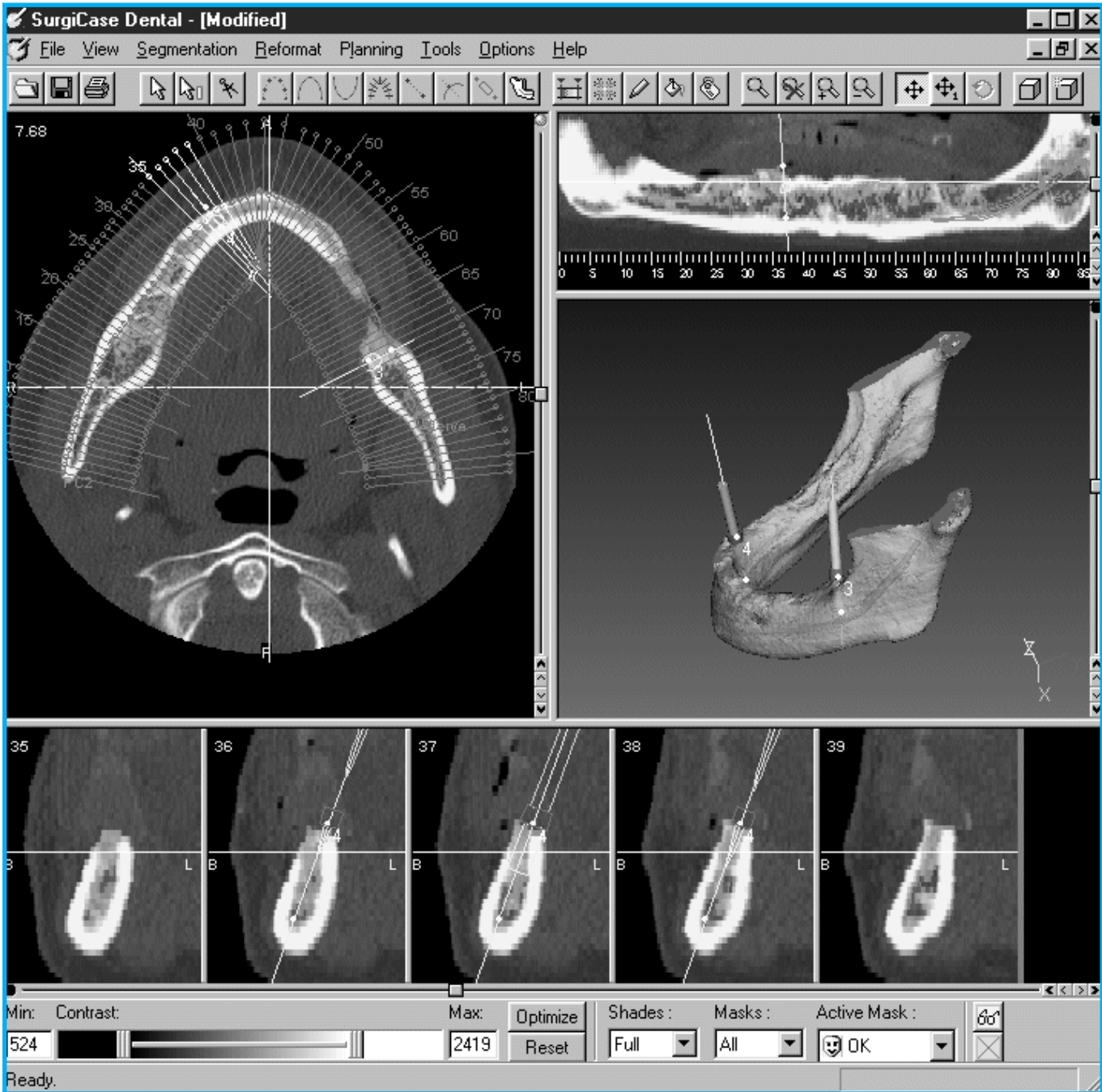




Figure of cross sectional CT image with bone and planned tooth

images can be used in the dental implant simulation software to perform a simulation of the implant positioning.

Dental Implant simulation.

In the SurgiCase Dental Implant simulation software, you start from the original CT images. On these axial images, the user can indicate the main axis through the jaw, and the software will automatically create panoramic and cross-sectional images. In these cross-sectional images the quality of the bone is clearly visible.

Next, you can indicate with the mouse where the implant should be positioned. This is typically done in the cross sectional images where the orientation of the implant relative to the tooth setup can very well be evaluated. Once you have created an implant, you can see it in all the images, and you can reposition it easily in all those images by a click and drag operation. Also on the 3D image, it is possible to position, move or rotate the implants.

The Missing Link.

At the end of the simulation, we

have the ideal positioning of the implants on the computer, but how can you be sure to perform the implantation in exactly the same way ?

SurgiCase Templates are solving this problem:

The template has at the bottom side exactly the same shape as the jaw bone. Because of the complex and irregular shape of the jawbone, the template has a unique and stable fit on the jaw. On the other side, the template has drilling cylinders that are positioned at exactly the same place and in the same direction as the implants in the simulation on the computer.

In the cylinders there are adaptable stainless steel tubes, which are guiding the drill during surgery.

The internal diameter of the tubes is adapted to guide the different drills that are used during implantation. The cylinders are adapted to the planned implant lengths, providing a physical stop for the drill in order to prevent drilling too deep.

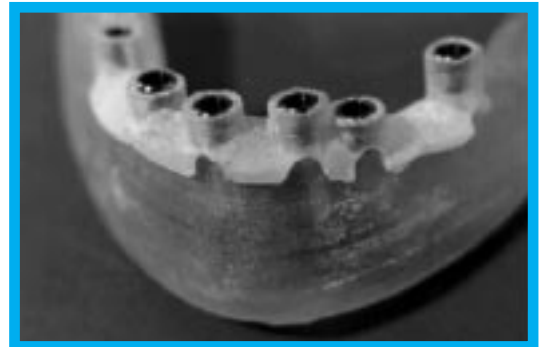
The template itself is made by Stereolithography in a bio-compatible material (USP Class 6) that can temporary be used in contact with body fluids.

Furthermore they can be sterilised with different methods.

Clinical Trials

The new methodology was tested and validated by multiple surgeons.

The first cases were mostly edentulous patients, where the templates were positioned completely on the bone. Today, the concept is also used for partially



SurgiCase template on model

edentulous patients, where the template is supported both on the bone and on the residual teeth, and for more complex cases involving e.g. Zygomatic fixtures. (see next paper in this Newsletter)

The clinical trials showed that the SurgiCase concept has a lot of advantages: By making a good compromise between esthetical and surgical considerations, it is possible to use less complicated and less expensive prosthetic reconstructions. In other cases, bone grafts can be avoided, because of the high precision of the implantation.

This development was done in the framework of the Brite Euram PISA project.

Partners in the project are:

Materialise (B),
Philips Medical Systems (NL),
DePuy – Johnson&Johnson (UK),
Ceka (B),
OBL (F),
Katholieke Universiteit Leuven (B),
University of Leeds (UK).

Drilling templates for Zygomaticus¹ fixtures

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The technique of preoperative planning of implants based on CT scans, and the drilling template, as explained in previous article, is extremely valuable and almost indispensable in complex cases, such as the placement of the Zygomaticus fixtures.

Indications for Zygomaticus fixtures

The most important indication for Zygomaticus fixtures is severe bone resorption in the posterior maxilla, making the placement of standard fixtures in that region impossible [1]. The Zygomaticus fixture is placed in the premolar region, it passes through the sinus close to the c of the zygomatic bone and perforates with its apex the cortical bone of the zygomatic bone clo-

to the 90-degree angle between the zygomatic arch and the lateral and medial surface of the frontal process of the zygomatic bone. The Zygomaticus fixtures will normally be combined with standard fixtures in the anterior region in order to provide enough support for the prosthetic reconstruction.

Preoperative planning and drilling templates for Zygomaticus fixtures

Preoperative planning

According to the clinical procedures prescribed by Nobel Biocare, conventional or computed tomography are highly recommended [1]. During the planning, it is important to determine: the thickness of the alveolar process to the maxillary sinus in the premolar region for bone

support of the Zygomaticus fixture, the thickness or width of the zygomatic body and the topography of the anterior wall of the temporal fossa, and the presence of concavities. The fixture should be placed as posterior as possible, with the fixture head as close to the alveolar crest as possible, and towards the lateral surface of the 90-degree angle in order to minimize or avoid the medial perforation of the bone. The SurgiCase planning software allows evaluating all those criteria, and especially the 3D reconstructions are very useful, see figures.

Design and production of the drilling templates

The design and production of the drilling templates proceeds as in the traditional cases for standard fixtures, except that an additional fortification is required, see figure 1, to cope with the high forces involved in zygomaticus hole preparation. The template especially its fortification should leave enough place for the retracted mucoperiosteal flap on palate.

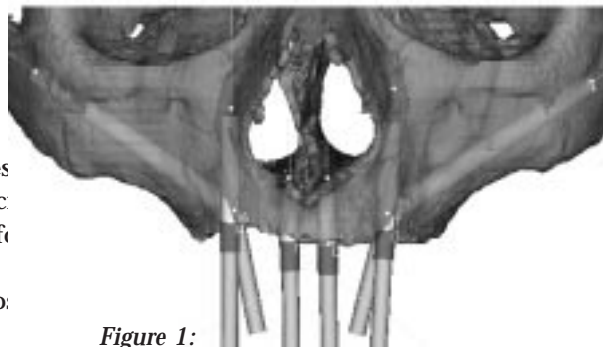
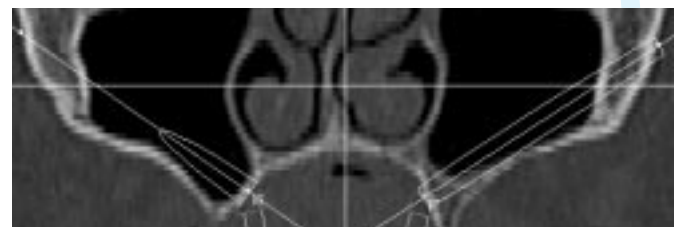
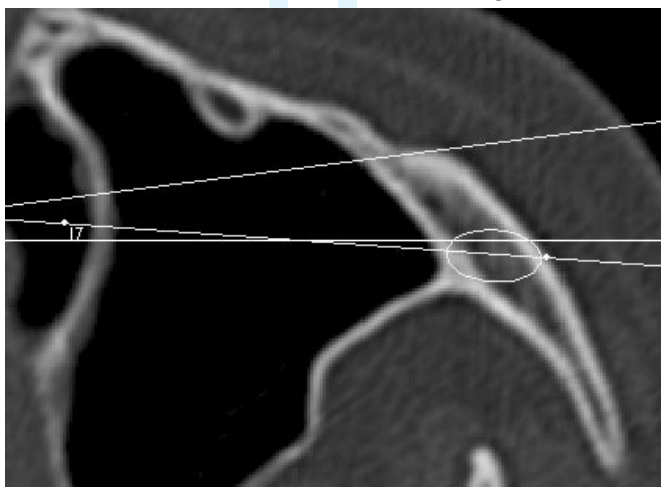


Figure 1:



Preoperative planning of two Zygomaticus fixtures combined with two paranasal fixtures and two short standard fixtures in the front. **Top:** 3D view with transparent shading. **Bottom left:** axial section showing the limited width of the zygomatic bone. **Bottom right:** coronal section, showing the severe bone resorption and the Zygomaticus fixtures passing through the sinus cavity.

Continued on page 14 ▶

A medical image-based drill guide for pedicle screw insertion:

Results of a cadaver study and three clinical trials

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Introduction

To enhance the safety and the security during pedicle screw insertions [1], a mechanical guiding method has been developed at K.U.Leuven in the framework of a European project on Personalized

Implants and Surgical Aids. Personalized drill guides are designed based on geometric information derived from CT-images of the patient's spine.

The drill guide or template fits exactly some selected areas of

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Drilling templates for Zygomaticus fixtures

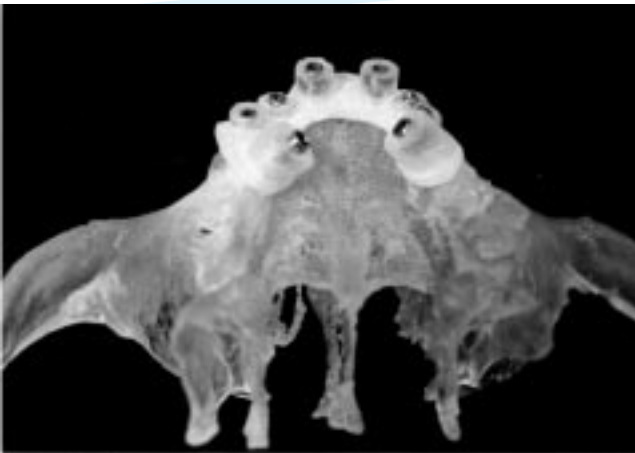


Figure 2: Drilling template for three standard and two Zygoma fixtures.

Surgical procedure

In the standard surgical procedure [1], the exposure in the posterior-superior direction to the lateral surface of the zygomatic bone is made up to the point of the 90-degree angle between the zygomatic arch and the lateral and medial surface of the frontal process of the zygomatic bone. A 1 by 5mm window on the lateral wall of the sinus is made close to the infrazygomatic crest. This sinus window is necessary to check the direction of the burr in the sinus cavity. A retractor is placed at the 90-degree angle to facilitate the 3-dimensional orientation of the drill.

In the adapted surgical procedure with drilling template, the position and orientation of the fixture is carefully planned in advance and the drill is guided in that direction. The surgeon does not have to find a good 3-dimensional orientation

in the direction of the 90-degree angle at the time of surgery. There is also no need to make a window on the lateral wall of the sinus to check the direction of the burr in the sinus cavity.

Clinical Applications

From February till September 99, 13 Zygoma cases with the drilling templates have been performed in Ziekenhuis Oost-Limburg, Campus St. Jan, Genk, Belgium. Fig. 3.

Discussion

- Placement of the Zygomaticus fixtures is often very critical due to the severe bone resorption and the limited thickness or width of the zygomatic

body. Thanks to the careful pre-operative planning that is transferred accurately to the operation by means of the drilling template, it is very easy to avoid following critical issues mentioned in the surgical procedures: penetration of the orbital floor and medial perforation of the zygomatic bone.

- The drilling template also prevents contact between the drill and the soft tissue.

- There is no need to make a window on the lateral wall of the sinus to check the direction of the burr in the sinus cavity.

References

[1] Zygomaticus fixtures, Clinical Procedures, Nobel Biocare, 1998.

Figure 3: Picture during surgery



*Figure 1:
General features of
the final drill guide
concept for lumbar
spine applications.*



the posterior part of the spinal segment and indicates the optimal drill path into the pedicles. Moreover, the tool is able to provide on-line information about the position of the tool inside the vertebra. This paper proposes a fourth generation prototype developed for and tested on a cadaveric spine and three patients.

Methods

Drill guides have been developed for the installation of screws into the pedicles of L2-L3-L4 segment of a cadaveric spine. Three clinical cases have been carried out installing pedicle screws in L3-L4-L5, L3-L4 and L2-L3 segments of three patients.

The 3D information of the spine is acquired from a CT-scanner, running in spiral 1/1 mode for the cadaveric spine and in 1.5/1.5 mode for the patients. After processing and segmenting (MIMICS software by Materialise N.V., Belgium), the CT-data is transferred to a 3D solids CAD design environment (UNIGRAPHICS software by EDS) that enables a fully parametric design of the drill guides.

The surgeon performs the pre-operative planning on the 3D visual representation of the CAD model of the spinal segment. Based on preliminary evaluations on a stereolithographic model of a spinal segment, the conceptual design of a drill guide resulted in a three point support structure using a large contact area on top of the spinous process and two small knife-edge areas on both transverse processes. The drill guides are produced in epoxy using stereolithography as a rapid prototyping technique. Metal inserts were manufactured of stainless steel to

provide an interface with the drill. Finite element simulations enabled to optimize the drill guide stability and stiffness. The deformations of a drill guide under loads simulating manual pressure by a surgeon on the template were calculated, and yielded negligible errors in the orientation of the drill holes.

The evaluation of the cadaver study suggested fundamental changes in the concept of the interface between template and vertebra. The three clinical cases (L3-L4-L5-segment with post-laminectomy at L4, L3-L4-segment, L2-L3-segment with spondylylyse at L3) were carried out using templates featuring a knife edge contact on top of the spinous process instead of a large area contact. Furthermore, to increase rotational stability, two additional contact points are provided on the lateral bounds of the upper facet joints (fig. 1). For use in the human body the templates for clinical use were manufactured in medical grade (USP class VI) acrylate resin (Stereocol by Avencia) using stereolithography and subsequently sterilized by steam.

Results

Surgeons of the University Hospital of Pellenberg K. U. Leuven performed the surgical intervention on L2, L3 and L4 of the cadaveric spine by applying the respective drill guides. The installation of the pedicle screws was successful for each of the three vertebrae. The surgeon experienced a good overall user-friendliness of the three drill guides. Drill guides for L2 and L3 created a unique fit and showed an excellent stability on the vertebra. Before obtaining this excellent fit, the removal of all soft tissue was

necessary on the contact area on the spinous process. Drill guide EL4 showed small support problems at the right transverse process of L4. This support deficiency was caused by a non-optimal orientation of the knife-edge support structure to the transverse process. However, a satisfying result was obtained adjusting the pressure put on the template by the surgeon. Post-operative CT-images showed a perfect position (position error < 1 mm) of the rods into the pedicles of L2 and L3. Although the surgeons considered the position of the rods into L4 as satisfactory, there was a slight deviation from the axis of the pedicle ($1 \text{ mm} < \text{position error} < 2 \text{ mm}$) (Fig. 2).

The cadaver study resulted in the adaptation of the concept by eliminating unwanted degrees of freedom of relative motion between template and vertebra in case of critically shaped support areas at the transverse processes. The rotational medio-lateral stability in the medial plane is enhanced by the addition of two spherical support points on the lateral bounds of the upper facet joint.

The collaborating orthopaedic surgeons suggested that large area contacts on the spinal process should be avoided since they need the removal of the spinal ligament. Therefore, a knife-edge contact is used that contacts the bony surface of the spinous process by locally penetrating the soft tissue. Special adaptations have been introduced for the L4-template of the second patient featuring a missing spinous

process at L4. In this case, the spinous process of L3 has been used as support.

The three operations were performed at the University Hospital of Pellenberg, K.U.Leuven. The surgeon experienced a good overall user-friendliness of the evolved template concept in each of the three cases. Thirteen of the fourteen screws are correctly installed (position error < 1 mm). One screw in L5 of the first patient showed a larger deviation from the pedicle axis due to a stability problem of the template during the drill action. This stability problem occurred because of the limited accessibility of the L5. Therefore, the width and the overall size of the template design have been optimized for the use in the narrow gap. The two other clinical cases benefited from this adaptation, as there were no accessibility problems during surgery.

The clinical cases showed the need for an optimized template width and in general an optimized overall size in order to increase the accessibility of the lower vertebrae.

The special cases (laminectomy and spondylolyse) illustrate the flexibility of the drill guide concept. An excellent stability was achieved for both cases.

Medical image based individualized drill guides present a cost-effective, and simple alternative to image guided surgery for applications in lumbar spine surgery. Post-operative RX and CT showed an excellent position of the screws in the pedicles, and the surgeons appreciated the ease of use of the drill guides during surgery. The surgeons mentioned a steep learning curve and a decrease of the application time. The drilling of the pilot holes in the pedicles of the third patient was a matter of minutes with a highly increased accuracy and safety.

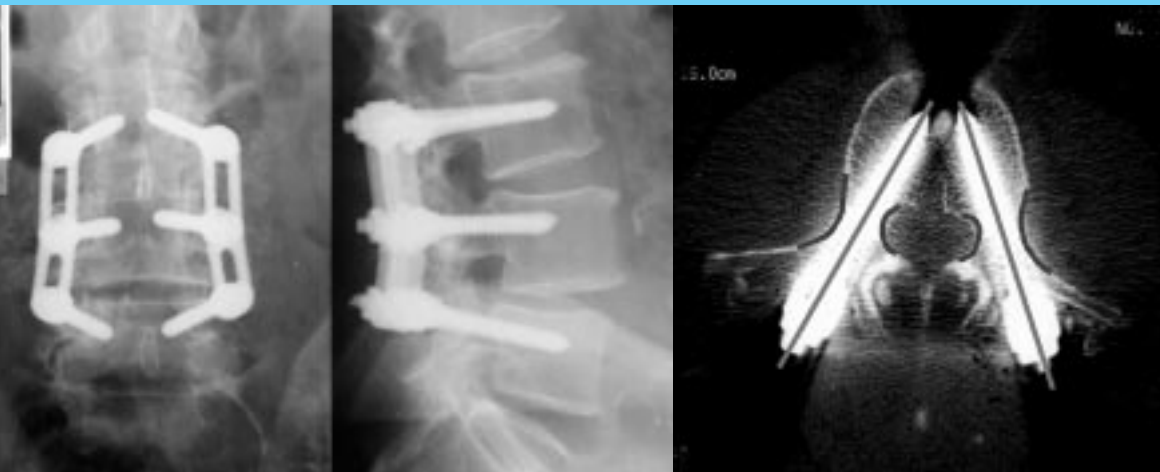


Figure 2: Post-operative RX and CT of a clinical case

Discussion

A complete procedure has been elaborated from the design and the evaluation of drill guides for pedicle screw insertion. The cadaver study and the clinical trials yielded three major recommendations for the improvement of the template design:

The contact area at the top of the spinous process must be small enough to minimize preparation time due to soft tissue removal. Knife-edge contact is required.

More rotational stability is obtained by using the lateral bounds of the upper facet joint for support.

Acknowledgments

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The aim of the Phidias Newsletter is to inform the vast majority of medical practitioners throughout Europe on the significant influence of Rapid Prototyping on the effectiveness of medical practice. This target will be reached via descriptions of selected cases where Rapid Prototyping has been taken into use.

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