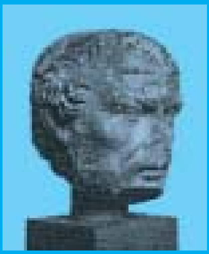
Phidias
RAPID PROTOTYPING IN MEDICINE



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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CURVATURE ACCURACY OF RP SKULL MODELS

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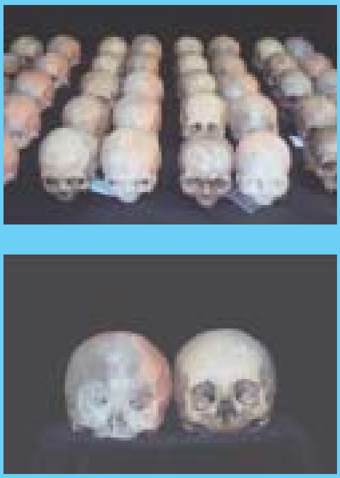

Figure 1 & Figure 2: Cadaver skulls and RP replicas

Introduction

Over the last decade there has been a growing interest among physicians in the technology of biomodeling for the purpose of facilitating diagnosis, pre-operative planning and communication between colleagues and patients.

The ability to physically replicate the morphology of anatomical structures has proven to be highly advantageous, certainly within the field of craniofacial surgery where explaining, planning and performing an operation is extremely difficult due to the complex and variable anatomy.

For cranioplasty – a type of neurosurgical intervention aiming to correct skull deformations and defects – for example, it has been shown [D'Urso, 1998; Haex, 1998] that the use of RP models reduces the operative time and risk, rendering the operation less strenuous both for the patient and for the surgeon.

Here, biomodels not only offer the benefits of an optimised preoperative planning but can also aid in the design and production of customized, biocompatible implants.

The idea is to use the models directly as a master or as a negative for shaping the desired implants needed for replacing bone fragments missing due to disease, trauma, and malformation or tumour resection. Theoretically, the implants fit precisely into the defect during surgery.

Still, though the technique definitively seems promising, reports have been made of preoperative modifications being necessary on occasion [D'Urso, 2000].

Inevitably, the question must be raised of how accurate skull models can be made using Rapid Prototyping techniques. Partially, the answer can be found in this paper.

The aim of the study was to perform a relative comparison of local skull curvatures measured on real specimens and their corresponding RP models.

Materials and Methods

Skull and Model preparation

For the purpose of this investigation a total number of 20 cadaver skulls were evaluated. The intracranial contents as well as the scalp were removed and the specimens were subjected to careful visual inspection, screening for bone disease, abnormalities and fractures. All skulls were intact and none showed signs of any pre-mortal osseous pathology of the donor.

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CURVATURE ACCURACY OF RP SKULL MODELS

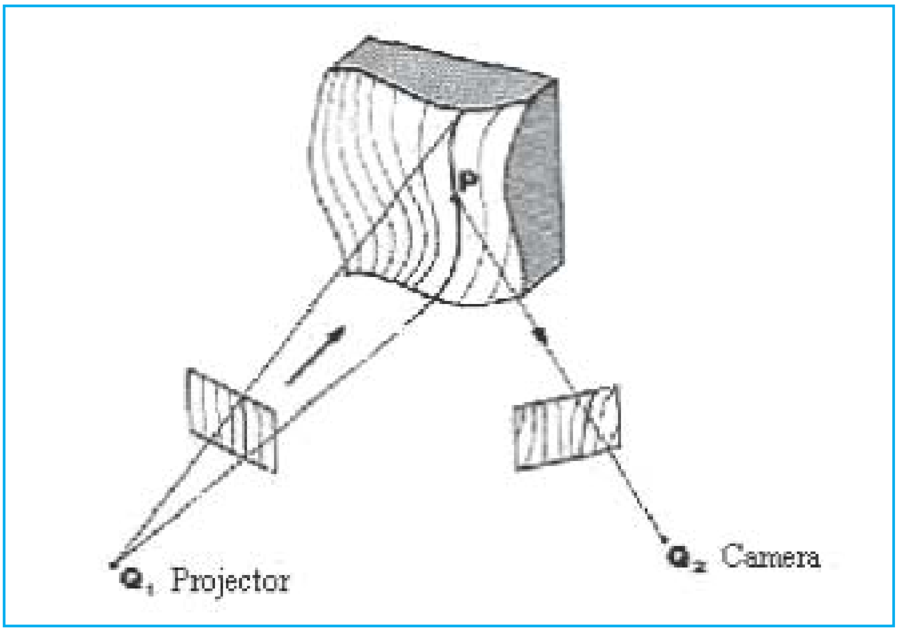

Figure 3: Rasterstereography principle [Frobin,1991]

The skulls were stored in a 1% formaldehyde watery solution, preventing both drying and decay. CT scans were taken with a slice thickness of 1 mm, using a CT-phantom (ESP) with known densities to calibrate the images [Dequeker, 1993; Kalender 1995].

Correct comparison of grey values obtained during different scan sessions was thus enabled, ruling out deviations between measurements due to differences in data manipulation.

The segmentation of the images was done using commercial software (MIMICS, Materialise, B), with threshold values being calculated skull by skull, based on the grey values of the phantom.

Finally, solid models were manufactured in an acrylic material using the stereolithography process (Materialise nv, B). [Fig.1&2]

Set-up

Information about the surface of skull and model was obtained with the Formetric System (Jenoptic, Jena, D), designed by Dr. Hierholzer et al. at the University of Münster. It is based on the principle of video rasterstereography, which is a method to measure surfaces by triangulation. The system exploits the fact that a regular light pattern, when projected onto an object, will deform in accordance to the curvature of the surface it strikes [Fig.3]. If the deformed grid pattern is registered by a video camera, the spatial coordinates of the points on the surface can be calculated afterwards.

Measurements

The measurements were performed at the Division of Biomechanics and Engineering Design. Skulls and models were measured pair wise, with the camera's field of view covering the occiput of the skull (i.e. the posterior side).

The positions of the models were identical to those of the corresponding skulls and in all cases a similar area of the anatomy was captured.

A computer was used to load the images made by the video camera and to calculate a point cloud with automatic reconstruction algorithms implemented in the Formetric software. For one biomodel however, no representative point cloud could be obtained.

Subsequently the data were not submitted to further analysis. The phenomenon was attributed to faulty point measurements caused by light reflecting off the interior surface of the partially translucent replica.

Calculation of local surface curvatures

After the measurements, the virtual point cloud models were used to extract information about the local curvatures[1]. This was done in the commercial software Matlab. Around each point, an area of 25 x 25 mm could be selected containing enough neighbouring points (i.e. a minimum of six) to approximate the local surface with a paraboloid, using the method of the least squares.

This further enabled the calculation of the two principal curvatures κ_1 and κ_2 at the surface point. Indeed, since a surface is a two-dimensional entity, two curvatures are needed for a complete description of the local shape [Frobin, 1982]. For the purpose of representation, the two curvatures were combined into one parameter known as the mean curvature H, given by the following equation:

$$H = (\kappa_1 + \kappa_2)/2$$

This parameter was used to classify the surface points, distinguishing different ranges by different colours [Fig.4] and separating convex areas from more concave ones.

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[1] The curvature is defined as the inverse of the radius of a best fit circle: $\kappa = 1/r$

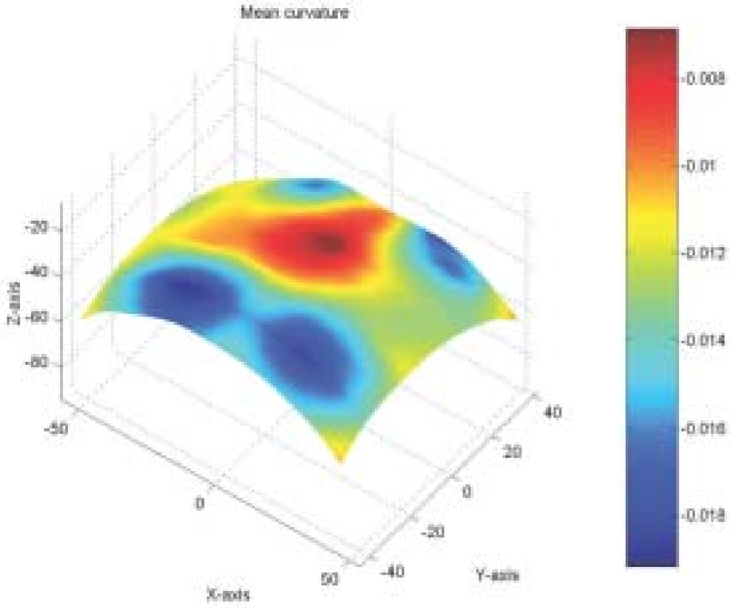

Figure 4:
3D plot of the measured posterior curvatures

Results

Based on the locally calculated mean values, plots were made giving the distribution of the curvatures over the entire posterior side of the skulls and the models. Matching the skulls to their replicas proved could be done quite straightforwardly, indicating a good resemblance between both. Table I gives an overview of some typical plots that were obtained.

In order to get a quantitative grasp of the fidelity of the curvature reproduction, the mean H values were calculated for the measured surfaces.

These values were given by:

$$\frac{\sum_{n}(\kappa_1 + \kappa_2)/2}{n}$$

in which n stands for the number of points in the point cloud representing a surface.

Table II gives the results of the calculations for the skulls and the corresponding models.

Finally, figure 5 shows how the mean H-values are related to each other. Ideally, without any differences between the curvatures, the relation between the calculated mean H-values for the skulls and the models would be one-on-one: y = x

Though this ideal relation was not found in the study, it was closely approximated. In conclusion, it is safe to say that using the RP technique of stereolithography, skull models can be created of which the curvature has been accurately replicated.

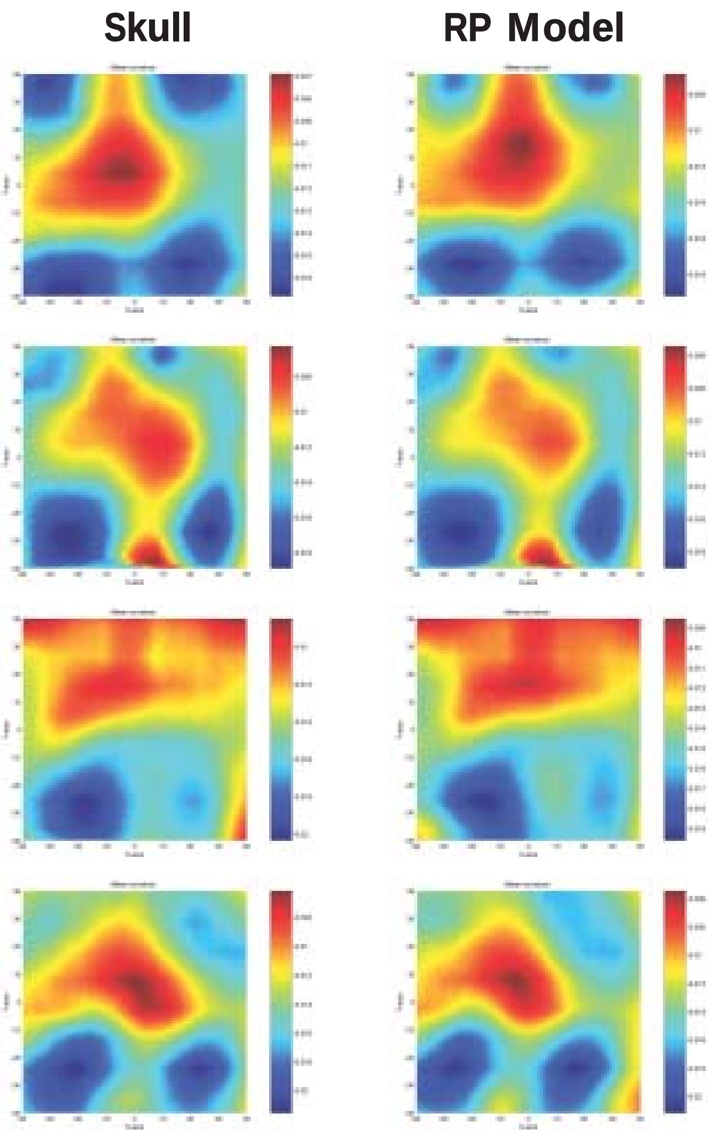

Table I

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CURVATURE ACCURACY OF RP SKULL MODELS

	Mean H skull [1/m]	Mean H Model [1/m]	Standard Deviation skull	Standard Deviation Model
1	11,9	12,0	3,6	3,8
2	10,5	10,7	3,9	4,1
3	11,8	11,6	3,7	3,4
4	11,3	10,9	3,4	3,3
5	13,0	13,0	4,5	4,0
6	11,2	11,2	3,4	3,0
7	11,4	11,4	3,5	3,3
8	12,4	12,2	4,5	4,4
9	11,6	11,3	2,9	2,7
10	12,4	12,4	3,2	3,0
11	12,2	11,8	3,8	3,7
12	11,2	11,0	3,2	3,1
13	13,0	13,1	4,7	4,7
14	12,2	11,6	4,2	4,1
15	10,6	11,0	3,2	3,2
16	11,2	10,9	3,1	3,0
17	11,2	11,1	3,1	3,0
18	11,4	10,8	3,4	3,9
19	11,7	12,3	4,1	3,6

Table II

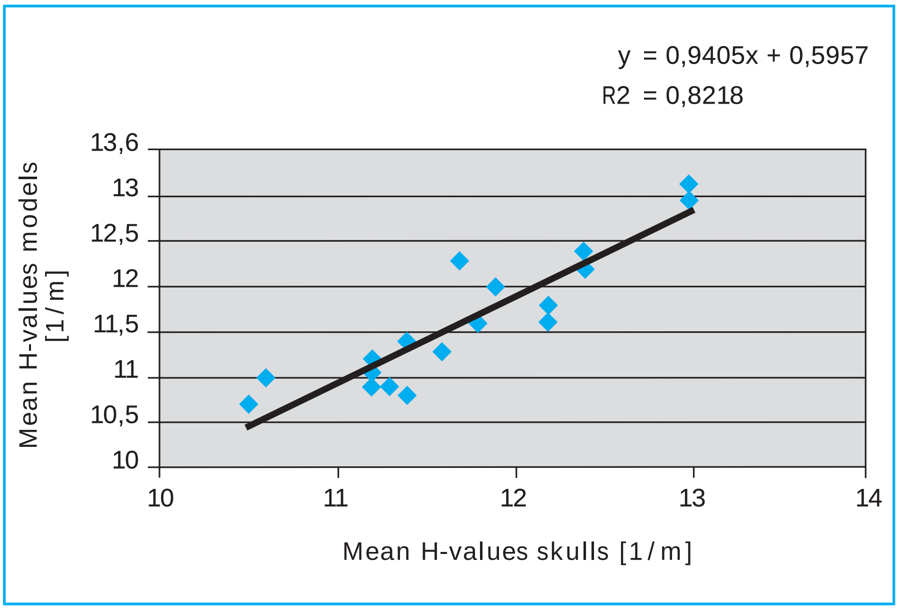

Figure 5:
Relation between the mean H-values for skulls and models

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Accuracy in Medical Modelling

Final results of the Phantom – based Multi-Center Study of the PHIDIAS network

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1. Introduction

Today, medical modelling is used by various experts throughout the world as a means for diagnosis, surgical planning and simulation. While the clinical practice with medical models has become more and more daily routine for those experts, quality assurance aspects, especially the geometric accuracy of producing the models, has long been neglected. With this article we would like to present the results of the PHIDIAS accuracy study which has been presented in the PHIDAS newsletter #3 [1].

The study aimed to examine the accuracy of medical modelling based on a semi-anthropomorphic phantom of the human head. It was carried out by the Institute of Medical Physics, as coordinator of the PHIDIAS Quality Assurance Workarea, in cooperation with several partners of the PHIDIAS network on sites all over Europe.

1.1 Manufacturing a medical model

The procedure of manufacturing a medical model can be broken down into three major steps: The CT scan for acquisition of anatomical data of the patient, the image segmentation using dedicated software packages combined with data processing and finally the building of the model itself, using one of several 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 scan parameters chosen as well as on the characteristics of the CT scanners.

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From the project manager’s desk

*Phidias
Network
Administration
Wim Versluys*

The Phidias Project has come to an end and this last newsletter focuses on the results of the studies that were done. You can read all about the accuracy of medical models and what the results are of the validation that was done by questionnaires during these last few years. It’s the first time studies like this have been performed this broad in the field of medical modeling so the results will be of interest to everybody who take CT-scans for, builds or works with medical models.

The most elaborate studies were the validation study managed by the MDK Schleswig Holstein and the accuracy study on the phantom Gustav managed by the IMP Institute. They are the most widely executed studies in the field and will give you a broad range of results on the accuracy and the usefulness of medical modeling in surgery.

To the side from that, there was also an accuracy study on real skulls and their RP copies, like that you can see the anatomical correctness of the models compared to the real skull.

In the last year we’ve also started a study on the fit of surgical guides on the bone but the results of this will be published later as it was not ready in time for this newsletter, however you can find the details on the study in this newsletter.

One more specific topic was treated for its accuracy and that is the curvature of RP model skulls for the use in cranioplasty.

I would like to thank everybody who was involved in these studies for their time and effort. I would also like to thank the people who organized the Phidias workshops for their help in getting this field in medicine move forward. I hope everybody will keep on working for the further development of RP in the medical area.

Good luck to everybody and I hope we will keep in touch.

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Accuracy in Medical Modelling

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- In most cases data segmentation is carried out using a threshold-based algorithm. Unfortunately, the result of a threshold-based segmentation may vary strongly, depending on the threshold chosen.
- The accuracy of the RPT modeller systems varies depending on the technology used. Shrinkage and distortion can be found.

In this study, the overall accuracy as well as the influence of certain aspects and parameters of the medical modelling procedure have been examined.

2. Material and Methods

2.1. How to Determine Geometric Accuracy?

For the studies, a semi-anthropomorphic phantom of the human head was designed and built. Based on this phantom, a procedure was developed to determine the accuracy of medical modelling (Figure 1).

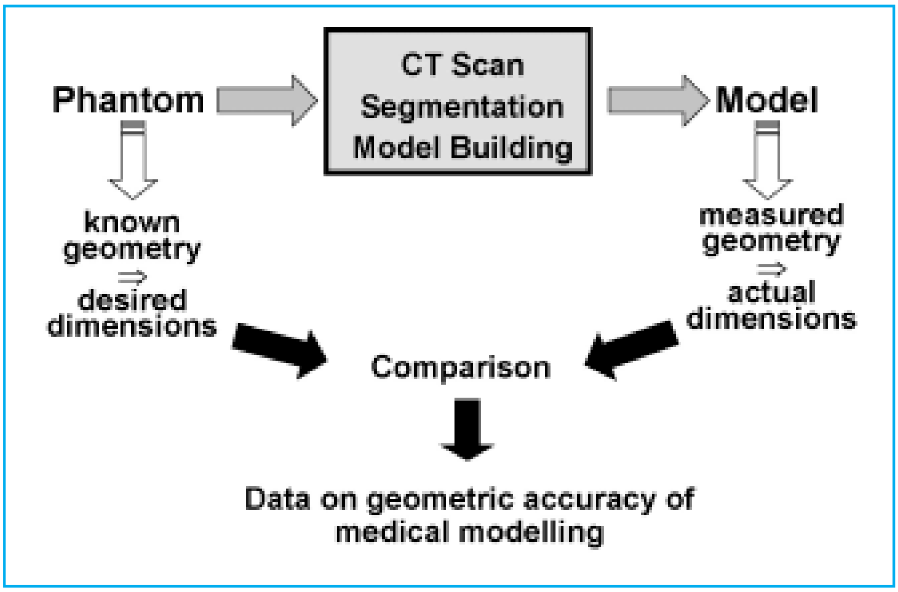

Figure 1: Testing procedure diagram

The phantom is used to carry out the process of medical modelling. At the end of the process, a model of the phantom has been manufactured. This model is then measured and the dimensions of the model are compared to the dimensions of the phantom, which are known from the design stage and have also been measured during the building of the phantom. The result of the comparison yields data on the accuracy of medical modelling.

With this procedure the overall accuracy of medical modelling can be derived. By skilful variation of only one parameter of the medical modelling process, while not changing the other parameters, the influence of certain aspect and parameters can also be determined.

2.1.1. The Semi-anthropomorphic Head-Phantom: "Gustav"

The phantom (Figure 2), which was named "Gustav", was designed by the IMP and manufactured by QRM GmbH, Möhrendorf, Germany, using Computer Aided Design and Computer Aided Manufacturing tools. The internal structures (bony structures) are made of a special material representing the base of the skull, the jaw and the orbital cavities. The material has a CT-value of about 540 Hounsfield Units (HU), making it equivalent to human bone. The bony structures are surrounded by a different material representing soft tissue. This material has a CT-value of about 40 HU, which is equivalent to human soft tissue. The dimensions of the different structures and the overall phantom where derived from the literature [2-4].

Figure 2:
The PHIDIAS phantom, "Gustav"

2.1.2. Measuring and Comparing Phantom and Models

All measurements were carried out using a Zeiss UPMC 1200 coordinate measuring machine (CMM), Carl Zeiss GmbH, Oberkochen, Germany (Figure 3), which is available at the Institute of Quality Management and Manufacturing Metrology of the Friedrich-Alexander-University Erlangen-Nuremberg.

The CMM measures features of a model by means of keying the surface with a diamond sphere (Figure 3a). It does so fully automatically, following a program specially developed for this study.

This program was designed to acquire about 100 characteristics of each model (e.g. thickness, flatness and roundness of structures). Some examples for characteristics acquired are shown in Figure 4.

The first part to be measured in this study was the bony structure of the phantom before it was moulded into the soft tissue material. This yielded the dimensions and characteristics of the phantom, which is the "gold standard" for the models. During the study, all models produced were measured with the CMM, always following the same programmed procedure. The measured characteristics were then compared to the gold standard of the phantom.

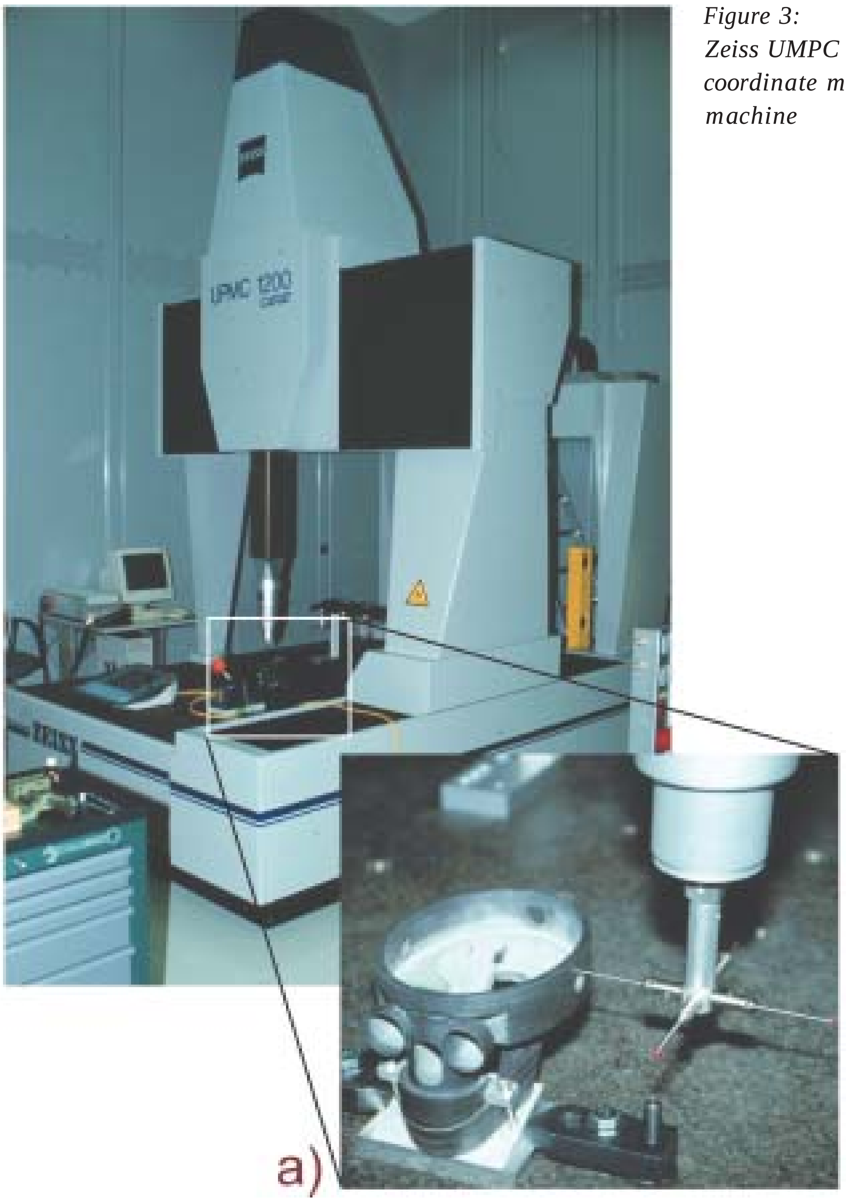

Figure 3: Zeiss UMPC 1200 coordinate measuring machine

2.2. Conducted Studies

To examine the overall accuracy of medical modelling as well as the influence of certain aspects and parameters, several studies where conducted.

2.2.1 Overall accuracy

The phantom was circulated to five different partners of the PHIDAS network in Scotland, France, Austria, Belgium and Germany. The partners were asked to carry out the whole process of medical modelling (CT-scan, segmentation and data processing, model building) with the phantom and to use exactly the same procedures, technologies and settings they would use for a regular clinical case. The models were then sent to Erlangen and measured.

2.2.2. Influence of CT Scan Protocol

The influence of the CT protocol was determined by placing the

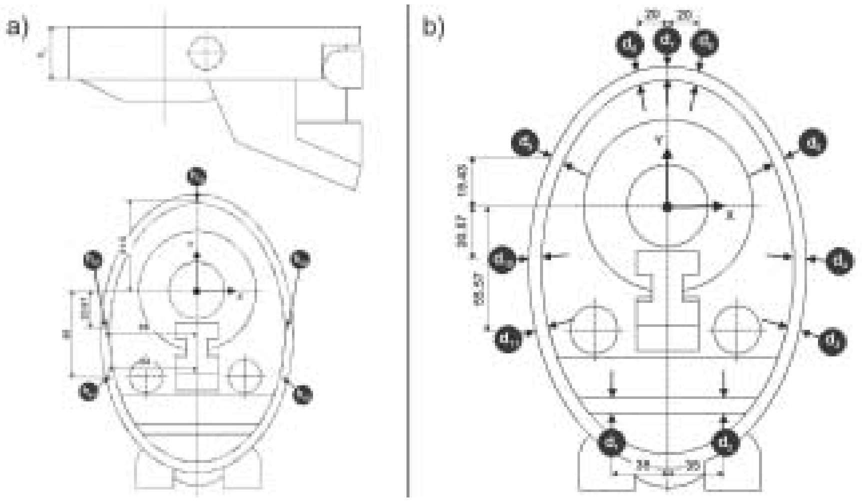

Figure 4: Example of characteristics of models acquired by CMM

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STUDY ON THE ACCURACY OF SURGICAL GUIDES IN DENTAL

INVESTIGATION AIM

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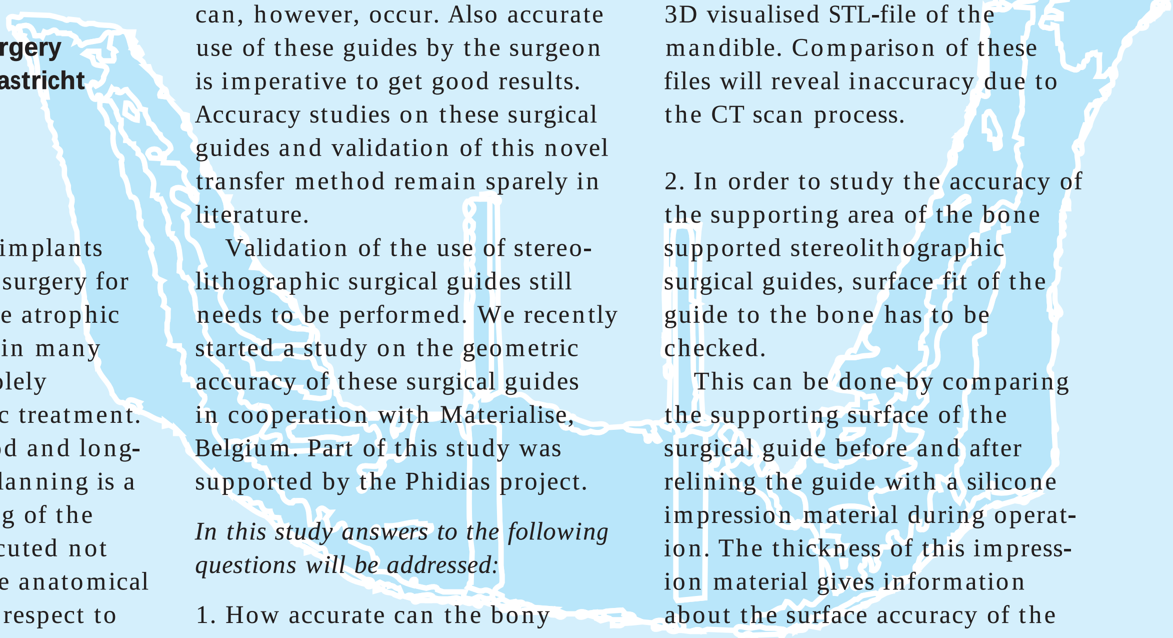


Investigation Purpose

The use of endosseous implants in cranio-maxillofacial surgery for the rehabilitation of the atrophic maxilla or mandible is in many instances superior to solely conventional prosthetic treatment. In order to achieve good and long-term results, optimal planning is a prerequisite. Positioning of the implants has to be executed not only with respect to the anatomical situation but also with respect to the prosthetical demands.

Therefore alveolar arch relation, occlusion and position of the denture teeth has to be visualised at the same time as the visualisation of the bony structures. Special designed software such as Simplant or Surgicase allows generating three-dimensional images of the maxilla or mandible. Even bony density in the area of future implant location can be taken into account.

Implants can virtually be planned in a three-dimensional environment. The transfer of the implant planning to the patient in the operation theatre, however, stays the main problem. Stereolithographic surgical guides can help in this transfer.

Hereby the wanted position and angulation of each implant as planned in the pre-operative 3D planning can be transferred to the patient in the operation theatre durante operationem. During the stereolithographic fabrication procedure of these surgical guides, geometric distortion and inaccuracy can, however, occur. Also accurate use of these guides by the surgeon is imperative to get good results. Accuracy studies on these surgical guides and validation of this novel transfer method remain sparely in literature.

Validation of the use of stereolithographic surgical guides still needs to be performed. We recently started a study on the geometric accuracy of these surgical guides in cooperation with Materialise, Belgium. Part of this study was supported by the Phidias project.

In this study answers to the following questions will be addressed:

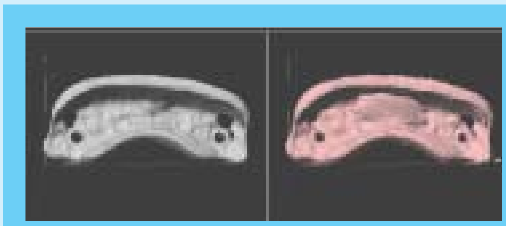
1. How accurate can the bony structures of the maxilla and mandible be visualised after processing of the CT scan data? What is the anatomical accuracy of the 3D acquisition and scanning process?
2. What is the fit and accuracy of the supporting area of intra-oral bone supported surgical guides?
3. What is the overall accuracy of the transfer by stereolithographic surgical guides in clinical practice? How accurate is the pre-operative planning of the implants transferred to the patient in the operation theatre?

Material and Method

1. To study the anatomical accuracy of the acquisition and processing of the CT scan data, CT will scan an unfixed mandible with different protocols. Subsequently, the mandible will be macerated and bony structures will be scanned in a high-resolution 3D laserscan. The laserscan measurements of the mandible will be compared to the measurements performed on the 3D visualised STL-file of the mandible. Comparison of these files will reveal inaccuracy due to the CT scan process.

2. In order to study the accuracy of the supporting area of the bone supported stereolithographic surgical guides, surface fit of the guide to the bone has to be checked.

This can be done by comparing the supporting surface of the surgical guide before and after relining the guide with a silicone impression material during operation. The thickness of this impression material gives information about the surface accuracy of the surgical guide. Measurement data can be plotted and visualised on the CAD model of the guide using colour code.



STEREOLITHOGRAPHIC IMPLANTOLOGY

3. To study the overall accuracy of this transfer method, comparison of the pre-operative planned position and angulation of the implants to the existing post-operative position and angulation of the implants has to be performed. Patients will therefore be scanned before and after the operation with the same CT scan protocol. Evaluation of these data will reveal the difference in position and angulation of the implants compared to the planning. Distance deviation (dx, dy and total distance d) between planned and placed implant, for both entry and exit point (after correction for z-position) and angle deviation between the axis of the planned and placed implant (global angle as well as angles after projection onto saggital, coronal and transverse planes) can be calculated for every implant.

RESULTS AND CONCLUSIONS

The study is currently in progress. The aim of the study is to provide and evaluate the clinical accuracy of bone supported stereolithographic surgical guides in dental implantology. Results of this study will be incorporated in the PhD thesis of the main author.

We would like to thank the Materialise and Phidias Team for their kind support.

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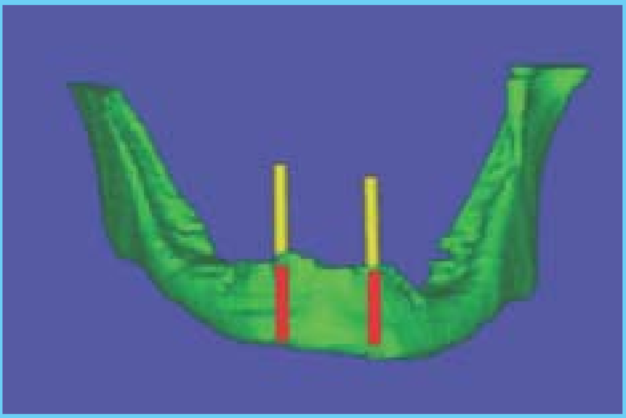

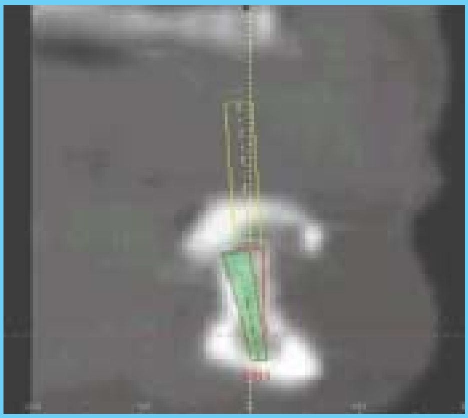

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Accuracy in Medical Modelling

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phantom in a Siemens Somatom Plus 4 CT scanner and scanning it five times with different scan parameters, always using spiral mode. The parameters for the different scans are shown in Table 1.

The five datasets were always processed with the same parameters and technologies, models were built on the same RPT system and measured on the CMM.

ID	Parameters	Resolution	Details	
Prot 1	1/1/0,5	High	S/FpR/RI	
Prot 2	1/1/1		S:	slice width in mm
Prot 3	2/2/1	⇩	FpR:	feed per rotation in mm
Prot 4	2/3/1		RI:	Reconstruction increment in mm
Prot 5	3/3/2	Low	All scans:	120 kV, 200 mA, FOV: 210 mm, 512_ Matrix

Table 1: Different scan protocols

2.2.3. Influence of CT Scanner Type

The phantom was scanned with four different CT Scanners (Marconi MX 8000, General Electrics Highspeed CT/I, Siemens Volume Zoom, Siemens Somatom Plus 4) to determine the influence of CT Scanners on the accuracy of the models. For all scans the same scan parameters were chosen, if possible (Spiral scan, 120 kV, 140 mA, slice thickness: 1 mm, Pitch: 1, reconstruction increment: 1 mm, rotation time: 1 s, field of view: 21 cm). For some of the scanners the desired parameters were not available. In this case, parameters as close as possible to the desired parameters were chosen.

To prevent an influence of the phantom positioning during the CT scan, the phantom was placed in the CT on a special holder. This holder ensured repetitive positioning in all scanners. This holder was only used in this part of the study.

The four CT datasets were sent to Erlangen and all four were processed, using the same tools and parameters. Four models were built on the same RPT system with standard parameters. The models were measured.

2.2.4. Variation due to segmentation

To examine the influence of segmentation (different tools as well as different operators carrying out the segmentation), one of the CT datasets (Prot 3) was distributed to different partners of the PHIDIAS network. The partners were asked to do the segmentation with their tools and send back the segmented data (in STL or CLI format) to Erlangen. In Erlangen models were built from all datasets on the same RPT system with standard parameters, and the models were measured.

The following tools were used in this study: VoXim by IVS AG, Chemnitz, Germany / VTC, Public Domain software / Mimics by Materialise, Leuven, Belgium (simple threshold and threshold with manual corrections / local threshold) / Analyse by Mayo Clinic, Jacksonville, Florida, USA / IMP research algorithm, IMP, Erlangen, Germany.

Each segmentation was carried out by a different operator using a different package, so the results of this study show the influence of the software used combined with the influence of the subjective opinion of the operator.

2.2.5. Influence of the threshold

One of the CT datasets (Prot 3) was segmented five times by simple thresholding, each time with a different threshold. All other parameters were left unchanged. Models were built with standard parameters and then measured. The thresholds used were 200 HU, 250 HU, 300 HU, 350 HU and 400 HU.

2.2.6. Accuracy of RPT Systems

The study on the accuracy of the RPT systems was not based on the phantom itself but on the computer-aided design file of the phantom. This file was loaded into AutoCAD 14, Autodesk Inc., San Rafael, California, USA and exported as an STL file. This file was then distributed to several

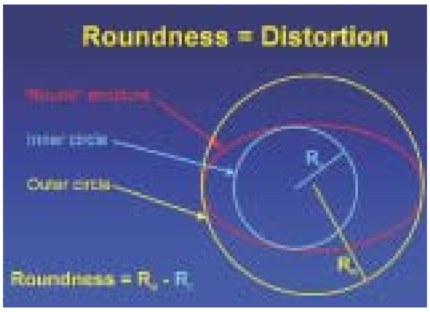

Figure 5:
Definition of roundness

partners of the PHIDIAS network, who built models from it using different RPT systems. The models were sent back to Erlangen for measuring.

The following RPT systems were used to build the models in this part of the study:

- Stereos 200, EOS GmbH, Planegg, Germany
- FDM 300, Stratasys, Eden Prairie, MN, USA
- 3D Printer, Z Cooperation, Burlington, MA, USA
- Thermojet Printer, 3D System, Valencia, CA, USA
- SLA 250, 3D System, Valencia, CA, USA
- DTM Sinterstation 2000, MER cooperation, Tucson, AZ, USA
- Standard service SLA machine, Materialise, Leuven, Belgium
- Next day service SLA machine, Materialise, Leuven, Belgium

3. Results

From the large amount of measured data, four important characteristics for the geometric accuracy have been derived for each model.

- Deviation of structure dimension in scan plane (DiP)
- Deviation of structure dimension perpendicular to scan plane (DpP)
- Roundness of structure in scan plane (RiP)
- Roundness of structure perpendicular to scan plane (RpP)

The "deviation of structure dimensions" is the difference between a dimension of the model and the same dimension of the phantom. As the orientation of the CT scan plane was expected to have a major influence on the accuracy, the accuracy was calculated separately for structures in the scan plane and structures perpendicular to the scan plane. Therefore it was assumed that the phantom was always scanned in a "supine" position. This assumption has proven to be correct during the study. The dimensions used for the calculation of the deviations are shown in Figure 4a and 4b. For the results given in this section, the mean deviation for all measured dimensions for each characteristic was calculated.

Roundness is a characteristic commonly used in industrial measuring procedures. It indicates how round a structure is.

The definition of roundness is displayed in Figure 5.
To determine the roundness of a structure, the real form of the structure is acquired by the CMM.

The biggest possible circle fitting in the structure is then calculated as well as the smallest possible circle enclosing the structure.
This means, that a perfectly round structure has a roundness of 0 mm and the less round the structure is, the higher the value of roundness will be.

We have found roundness to be a very good measure for distortion. The phantom features six round holes (three in, three perpendicular to the scan plane) with a measured roundness of less than 0.03 mm. The roundness of the same holes in a model will give an indication of the distortion associated with the medical modelling process.
The evaluation of the roundness has been performed for structures in the scan plane and structures perpendicular to the scan plane separately. For the results given in this section, the mean roundness for three structures is given. The structures are displayed in Figure 4a, upper section.

When analysing the derived data for different aspects of the process, one has to keep in mind

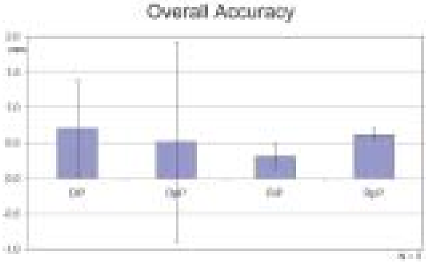

Figure 6:
Results: Accuracy of overall process

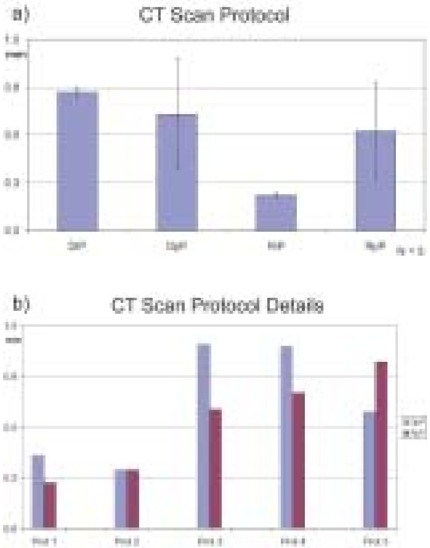

Figure 7:
Results: Influence of the CT scan protocol

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Accuracy in Medical Modelling

Final results of the Phantom – based Multi-Center Study of the PHIDIAS network

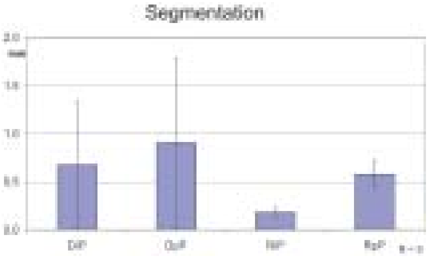

Figure 8:
Results: Variation due to segmentation by different users

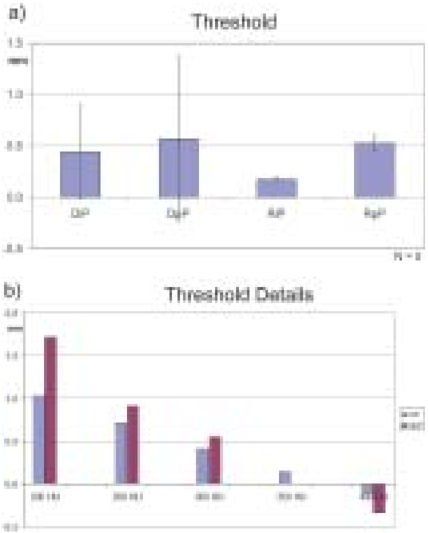

Figure 9:
Results: Influence of threshold

that the examination of one aspect of the medical modelling process is always influenced by the other aspects as well.

A high mean value combined with a low standard deviation for a certain aspect indicates that a different aspect of the process is the reason for the high mean value and the examined aspect has little influence. If the standard deviation is high, regardless of the mean value, an influence of the examined aspect on the overall accuracy is indicated.

3.2.1 Overall accuracy

For the overall process it was found that the structures of the average models were about 0.5 mm to 0.7 mm thicker than the phantom (Figure 6). It was also found that there is a large variation in the accuracy of model structures, especially for structures perpendicular to the scan plane.

Distortions (roundness) were found to be 0.3 mm in plane and 0.6 mm perpendicular to plane.

3.2.2. Influence of CT Scan Protocol

Different scan protocols showed to have a large influence on structures perpendicular to scan plane (Figure 7a). DpP were found to have a standard deviation of 0.3 mm, RpP of 0.25 mm while the standard deviation for DiP and RpP were found to be small (< 0.025 mm).

Figure 7b shows the results for DpP and RpP in detail. While the values for DpP do not show any clear pattern, for RpP a correlation between resolution of the scan protocol and distortion of structures perpendicular to scan plane can be found.

3.2.3. Influence of CT Scanner Type

The influence of the type of CT Scanner was found to be very low in comparison to the influence of other parameters and steps. Numerical results can not be given here, as the deviations found in this part of the study are assumed to be caused by other reasons than by the used CT scanner type.

3.2.4. Variation due to segmentation

When comparing models built from one CT scan but segmented by different people with different software tools (Figure 8), large deviations between the models can be seen, especially for DiP (0.7 mm) and DpP (0.9 mm). However, the variation in roundness was found to be smaller. One of the models produced in this part of the study was of such a poor quality that it could not be measured by the CMM.

3.2.5. Influence of threshold

The threshold was found to have an influence on the dimension of structures, since large standard deviations were found for DiP and DpP (Figure 9a). The influence on the roundness is small.

Figure 9b clearly indicates that there is a direct correlation between the threshold chosen for segmentation and the deviation of model structures from phantom structures. According to these results one would have to choose a threshold of 350 HU to 400 HU to get a model with the same dimensions as the phantom.

However, there is a second effect associated with the threshold. This is the reproduction of fine structures. In case of the phantom, the orbital cavities serve as a reference for fine structures. Their wall thickness ranges from 0.5 mm to 1.5 mm and is clearly defined. Figure 10 shows the effect which the threshold has on fine structures. To have all structures reproduced a threshold of 200 HU had to be chosen. With higher thresholds, more and more of the fine structures failed to be reproduced. At 400 HU, nearly all of the orbital cavity was found to be missing.

With a threshold of 200 HU, however, the fine structures where completely reproduced but the walls of the orbital cavity of the model were built by an average of 1.4 mm thicker than the walls of the phantom's orbital cavities.

3.2.6. Accuracy of RPT Systems

The determined accuracy for different RPT Systems is displayed in Figure 11. Most of the commonly used systems were found to produce deviations of less than 0.25 mm for DiP and DpP. The distortions (roundness) found are better than 0.5 mm for most systems. One system (Z-corp.) had built a model for which the structures are up to 1.8 mm too thick, while two other systems (Materialise Next Day and SLA 250) built structures about 1 mm to small.

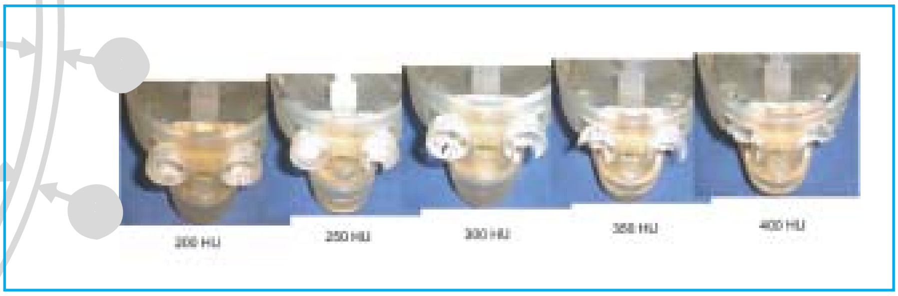

Figure 10: Influence of threshold on reproducibility of fine structures

4. Discussion

This study has produced numerous results and interesting conclusions can be drawn by comparing the findings of the different parts of the study.

For the overall process it was found that the structures of models are in most cases reproduced bigger than the original. It was also found that there is a large variation when the process is carried out at different sites. This is most likely caused by the difference in systems and parameters used at the different sites.

One aspect with major influence on the accuracy is the CT scan protocol. From the accuracy viewpoint it is advisable to chose a protocol with high spatial resolution and spiral CT should be mandatory. Of course, when defining a CT scan protocol, there are various effects that need to be accounted for, not only the accuracy of a model.

The type of CT scanner used for data acquisition was not found to have a direct influence on the accuracy of the model. However one practical observation was made in the CT scanner type study. There is a limit to the resolution that can be achieved with each scanner. The limiting factor for short scan ranges is the minimum slice collimation. For long scan ranges the limiting factor can be the power of the CT system's x-ray tube and the maximum "x-ray on" time which is available for the given scanner and scan protocol. As CT scans for medical modelling in a lot of cases imply long scan ranges, it is therefore advisable to use CT scanners with high power x-ray tubes. Modern multirow CT scanners will offer new solutions for long-range-high resolution scans.

The factor which was found to have the biggest impact on the accuracy is the data segmentation. The part of the study comparing the segmentations carried out by different persons showed that the variation between the results of segmentations is very high. Analyzing these results in combination with the results on the influence of the threshold, we conclude that all segmentations were carried out with a threshold that caused the models to be built too big.

The choice of a threshold is obviously a very important and a very difficult decision. Low thresholds will yield too big models; high thresholds will cause fine structures not to be reproduced. Unfortunately, this makes it impossible to find a "correct" threshold. It must also be mentioned that image segmentation by thresholding is always dependent on the data used. Therefore, the results of this study can only be used to show the effects of the threshold on the phantom and its models. The same general effects will be found for real models; however, the absolute thresholds will be different.

A solution to the threshold problem may be to work with different thresholds for different regions of the models.

This approach has the drawback of very intensive user interaction. A more promising solution should be the development of new, more sophisticated segmentation algorithms.

The results of this study indicate that most of the RPT systems available today seem to have a good accuracy. The numerical results need to be interpreted with caution, as only one model has been built per RPT system for this part of the study.

5. Conclusion and Outlook

We have presented a study to evaluate the accuracy in medical modelling. This study is based on a semi-anthropomorphic phantom

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Accuracy in Medical Modelling

Final results of the Phantom – based Multi-Center Study of the PHIDIAS network

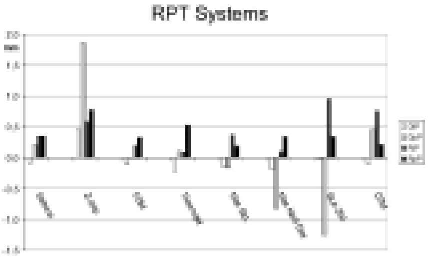

Figure 11:
Results: Accuracy of RPT Systems

of the human head. With the help of the phantom we have examined the accuracy of the overall process as well as the influence of different steps and aspects involved in the process. Over 30 RPT models of the phantom have been built (Figure 12) using different settings, parameters and systems. All models have been analysed by means of a coordinate measuring machine.

The results show that in the normal process used for clinical cases, the structures of the models have been reproduced bigger than the original structures in the phantom.

The most important aspects of the medical modelling process in terms of accuracy are the choice of the CT scan protocol and the segmentation of the dataset, especially the threshold chosen for segmentation. The CT scan protocol should yield high resolution data.

The segmentation is very difficult and no explicit recommendation can be given here other than it should be done by an experienced user and that care should be taken.

Most of the RPT systems used in medical modelling seemed to offer satisfactory accuracy.

There is one question that remains open. "What accuracy is needed in medical modelling?" This study can not give an answer, it can only show what accuracy is typically available. In most cases it was found that the accuracy is better than 1 mm with an average of about 0.5 mm. However, the accuracy is very dependent on some of the parameters involved in the process.

This accuracy may be good enough if medical models are used for diagnosis, patient information or basic surgical planning and simulation. If the accuracy is also good enough for more demanding surgical procedures (in terms of accuracy) like manufacturing of individual implants, needs further investigation.

For the future we expect an increase in accuracy, as modern CT scanners will offer the ability to use CT scan protocols with higher resolution. We also hope that the development of sophisticated segmentation algorithms will provide better solutions and results for the segmentation.

6. Acknowledgment

We would like to thank all the partners in the PHIDIAS network who have contributed to this study in so many ways. Without their support, this study would not have been possible. A special thanks to Martin Connell in Edinburgh whose numerous suggestions and great backup helped so much to make this study what it is.

Special thanks also go to Johannes Coman at QRM, who is the father of Gustav and he has done a tremendous job building the phantom. Also we would like to thank our colleagues at the Institute of Quality Management and Manufacturing Metrology for conducting all the measurements on the phantom and the models.

Figure 12:
Gustav and his family at CAS2001

Finally we would like to thank the European Union for sponsoring this study as part of the PHIDIAS network.

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The Phidias Validation Study of Stereolithographic Models

PRELIMINARY REPORT

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Introduction:
The validation study started in September 1999. Questionnaires were mailed to 38 partners of the Phidias Network. The study is co-ordinated by Medizinischer Dienst der Krankenversicherung Schleswig-Holstein, Germany. The partners were asked to distribute the questionnaires among surgeons who apply stereolithographic models. Until February 2002, 253 questionnaires could be transferred into the database of the study. The end of the project is approaching and the rate of questionnaires we are receiving is higher than ever before.

We would attempt to transfer as many questionnaires as possible into the final database.

Therfore the number of 253 cases that are evaluated in this short report will not be the final state.

The report will be presented in the final Phidias Workshop in March 2002, and in furthermore you will probably be able to download it from the Phidias Web Page

Results:
The study population consists of 115 male and 138 female patients (mean age: 48,1 years). 27 surgeons participated in this survey.

They reported different reasons, as to why they applied models. (Figure 1)

There is a tendency of an increasing focus on dental implants, where planning models are considered as usefull. Even in orthopedic surgery models are used more frequently now than in the first year of this validation study. However, this is not as impressing compared to the developement in dental implant applications.

In the following topics the preoperative application of the model lead to a change of decisions. (Figure 2).

The model had impact on the decision making with respect to the details and even the general surgical concept. In some cases the application of a planning model lead to a change of the compostition of the surgical team and influenced the sequence of steps of intervention.

The major reasons as to why planning models are considered useful are:

Communication with medical doctors and patients, anatomical orientation and simulation of intervention. (Figure 3)

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Indication for medical model

Neoplasia	**n = 56**	**22 %**
Trauma	**n = 43**	**17 %**
Congenital anomalies	**n = 32**	**13 %**
Orthognathic surgery	**n = 18**	**7 %**
Implant/cranial	**n = 15**	**6 %**
Dental implant surgery	**n = 74**	**29 %**
Orthopaedic surgery	**n = 11**	**4 %**
Other diagnosis	**n = 4**	**2 %**
Total	n = 253	100 %

Fig. 1

Reasons for using planning model

Enhancement of diagnostic quality	**109**
To produce an implant preoperatively	**108**
Improvement of surgical plan	**183**
To prepare a drill guide for a resection	**31**
To achieve the patient's agreement	**99**
As an orienting aid during intervention	**123**
Simulation of intervention preoperatively	**105**
Other reasons	**36**

Fig. 2 **n = 253**

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The Phidias Validation Study of Stereolithographic Models

PRELIMINARY REPORT

In addition a decrease of operation time was reported by 62% of all surgeons. The range of saved time was between < 25 minutes to > 2 hours and 15 minutes, depending on the intervention that was performed.

There were evident advantages reported regarding other imaging modalities, i.e. CT and MRI. (Figure 4).

Conclusion:
By using stereolithography we are able to apply 3D-models with accurate human anatomy.

Our preliminary results suggest that the reproduction of complex anatomic structures by Rapid Prototyping Techniques is also useful in complex surgical interventions.

How did preoperative planning change the decision?

Planning of skin incision	**34**
To operate or not	**66**
General surgical concept	**131**
Detail of the surgical concept	**167**
Composition of the surgical team	**77**
Positioning of patient on operating table	**22**
Selection of osteosynthetic material	**94**
Selection of instruments and devices	**115**
Implantation site of osteosynthetic material	**108**
Sequence of steps of intervention	**121**

Fig. 3 **n = 253**

Compared to other imaging modalities, the planning model had influence on

	Little	Average	Heavy
Precision and quality of bone transplant	**1**	**4**	**35**
The precision and quality of osteotomies	**3**	**2**	**94**
Communication with other medical doctors	**8**	**11**	**134**
Communication with patient	**17**	**6**	**164**
The "safety feeling" during intervention	**17**	**19**	**156**

Fig. 4 **n=253**

Index

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.**

The newsletter is published two times per year and is circulated to 3000 medical practitioners throughout Europe.

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