



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 frieze 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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MODELS BY 3D-ULTRASOUND

Zeilhofer H-F*, Sader R*,
Kliegis U**,
Kirst B.***, Schörner J***,
Kadegge G****, Nuber B*****



Fig. 1: Water bath with liquid medium based on silicone

- * Department of Oral and Maxillofacial Surgery, University of Technology Munich
- ** nordcom medical systems Co., Kiel
- *** Institute for Microtechnology, Technical College of Munich
- **** KL-Technik Co., Planegg
- ***** Viewpoint Bildverarbeitung Co., Wessling

Priv.-Doz.Dr.Dr. Hans-Florian Zeilhofer
Department of Oral and Maxillofacial Surgery
University of Technology Munich,
Klinikum rechts der Isar
Ismaninger Str. 22, D-81675
Munich/Germany
Tel.: +49 89 4140 2932
Fax +49 89 4140 2934

Email:
zeilhofer@mkg.med.tu-muenchen.de

SUMMARY

Medical rapid prototyping models of the skull built by computer tomography have high rank in craniofacial surgery for planning corrections of osseous deformities. But for the planning of soft-tissue alterations 3D CT models are not sufficient. The solution for representing soft tissue-structures in high quality is the manufacturing of rapid prototyping (RP) models built by 3D sonographic data.

Since 1997 a new 3D-ultrasound technique for model building was developed and tested in a pilot project. Aim was the automated representation of bone surfaces, cartilage and soft-tissue structures like the skin for operation planning. For 3D-data acquisition a transducer independent 3D-ultrasound system was used. After data acquisition the different structures were segmented separately. Using the segmented data a stereolithographic model was built whereby the different structures could be represented color-coded in one model.

Up to now for diagnostic and operation planning there were used 4 skull models of childs with craniofacial deformities, 7 surfaces of the iliac crest, 9 noses and 3 ears. Prospectively, the amount of information gained by the models was compared to conventional diagnostics.

The first results of the clinical application of color coded medical RP models show a new approach for preoperative planning in reconstruction surgery. Surgery can be simulated in a very individual way, which is not possible with visualization methods. Investigating skeletal and soft-tissue structures of the skull an objective measurement and documentation could be achieved.

A main use can be achieved also in building individual custom patterns for 3D tissue engineering.

KEYWORDS

**3D ultrasound,
color coded stereolithography,
tissue engineering**

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MODELS BY 3D-ULTRASOUND

INTRODUCTION

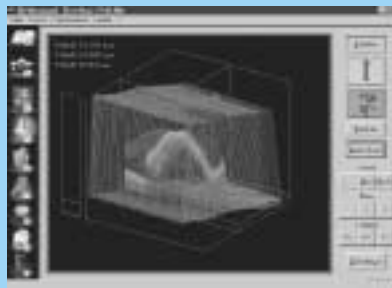
Medical rapid prototyping models of the skull built by computer-tomographic (CT) data rank high in craniofacial surgery for preoperative planning and simulating the correction of osseous deformities. But for planning of soft-tissue alterations 3D CT models are not sufficient. With 3D visualization of ultrasound data the first step was attained to build rapid prototyping models built by sonographic data.

First feasibility studies aimed at the representation of bone structures [1,2,4]. But bone structure representation is no specific domain of ultrasound. Therefore, the first model results were not useful for clinical application [3]. Since 1997 the first automatic manufacturing method of soft-tissue models by sonographic 3D data has been developed by an interdisciplinary team at the Department of Oral and Maxillofacial Surgery of the University of Technology of Munich. Aim of this method was the automated representation of bone surfaces, soft-tissue and cartilage for operation planning.

METHODS AND MATERIALS

The method of manufacturing 3D ultrasound models is based on a new way of color coded compound display of different tissue classes in individual rapid prototyping models [12]. The first representation was a stereolithographic color coded model of the nose. The prototype proved the feasibility of 3D ultrasound soft-tissue models [5,11].

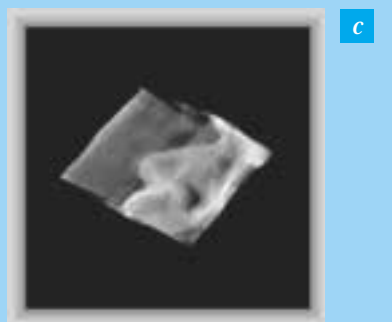
Fig. 2a-c:
3D visualization of a 3D-ultrasound data set of a nose
a: block visualisation, original 2D-slices are marked blue,
b: 3D-plane visualisation,
c: volume visualization (gradient weighed projection),
d: volume visualisation (maximum intensity depth weighed projection)



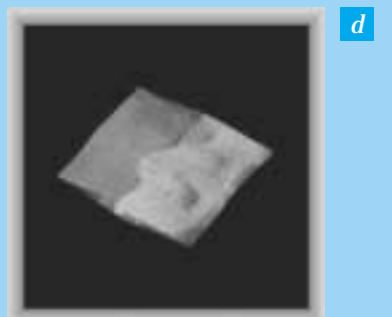
a



b



c



d

Acquisition of ultrasound data
For 3D data acquisition a transducer independent 3D ultrasound system was used. For representing complex formed tissue (nose, ear) a medium is necessary to link the transducer to the skin surface. Normally a hydrous gel is used to reduce the high impedance between air and tissue which decreases sufficiently the sonic reflex. But the gel is not sufficient for a sonographic representation of e.g. the nose. Also soft pads of a gel are unfit for the complex anatomy of the nose, which should not be deformed. The transducer can't be put on directly. Transducers usual in trade have a technological gap of 1 cm [5]. For the Munich pilot project a new method for sonographic data acquisition was developed. To immerse complete soft-tissue without deforming a liquid medium based on silicone was used (s.fig.1). The applied 13 MHz transducer guarantees a high resolution representation of subtle cartilage structure.

For data acquisition frequency and penetration depth of the transducer were feed in the 3D workstation to give the system objective metric parameters. By B-scan images the plane of section distance value mostly sizes about 1.0 mm. Data within the plan and between planes must be interpolated to adapt to the resolution of the modelling process [5,6]. With the new method sonographic 3D data acquisition was generated and visualized within some minutes (fig.2a-d).

Prerequisites for rapid prototyping models
After data acquisition tissue struc-

tures (growing volume, edge detection) were segmented semi-automatically by algorithms based on filter and grey tone [7]. Different structures (skin, cartilage, bone) were segmented separately (s.fig.3a-e). Using the segmented data a stereolithographic model was built by a rapid prototyping system whereby the different structures could be represented color-coded in one model. In this model skeletal structures were built in transparent technique and interior soft-tissue structures in color code technique [5,11].

Rapid Prototyping Techniques

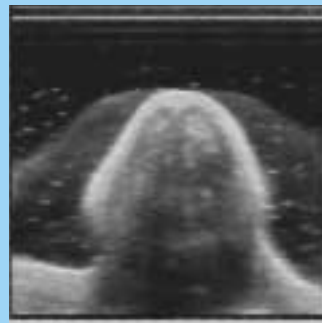
There are different rapid prototyping techniques on the market. For a description of some of these techniques, see Phidias no. 1, December 1998.

One of the best known, Laser Induced Stereolithography (STL), was developed in 1982 by Charles Hull to build industrial 3D mould models and prototypes. Medical models built with stereolithographic technology based on computer tomography (CT) data is used since the early nineties [10]. CT data are especially appropriate for modelling the skeletal skull.

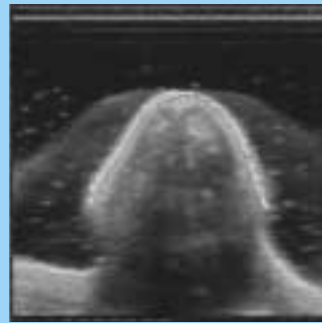
SLA is especially precise and appropriate for modelling complex structures [8,3,6]. SLA models can be sterilized. They are transparent and show all cavities. They are very applicable for surgical planning and simulating with rotating and oscillating instruments [8].

For color coded models separately segmentation data of different structures is necessary [7]. The building parameters have to show different color scales, e.g. the nose model from transparent to dark brown. The colors of different anatomical structures are achieved by modification of the laser exposure [11].

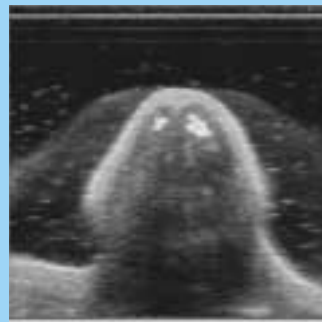
Two monomere acrylat or epoxid resins were used for color coded medical RP-models based on 3D sonographic data. For modelling nose prototypes epoxid resin was used, because the stereolithography machine (SOMOS 6100) was filled



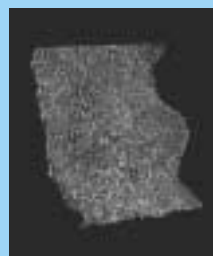
a



b



c



d



e

*Fig. 3a-e: 3D segmentation of the soft-tissue structures of a nose
a: sonographic cross section of the nose,
b: segmentation of skin surface,
c: segmentation of cartilage,
d: segmented 3D data set
e: surface visualisation*

with this material and the exposure parameter could be applied [5].

RESULTS

Up to now 24 individual color coded models based on 3D sonographic data of patients were used for diagnostic and surgery planning: 4 skull models of children with craniofacial deformities, 7 models showing the surface of the iliac crest, 9 models of noses and 3 models of ears. Prospectively, the amount of information gained by the models was compared to conventional ways of diagnostics (fig. 4a-d).

SLA models of the nose first were approved for planning surgical corrections on cleft palate patients with nose deformities. Preoperative volume, shape and donor site of ear cartilage transplant could be defined by analyzing the cartilaginous deficits and simulating on model operation modalities [11].

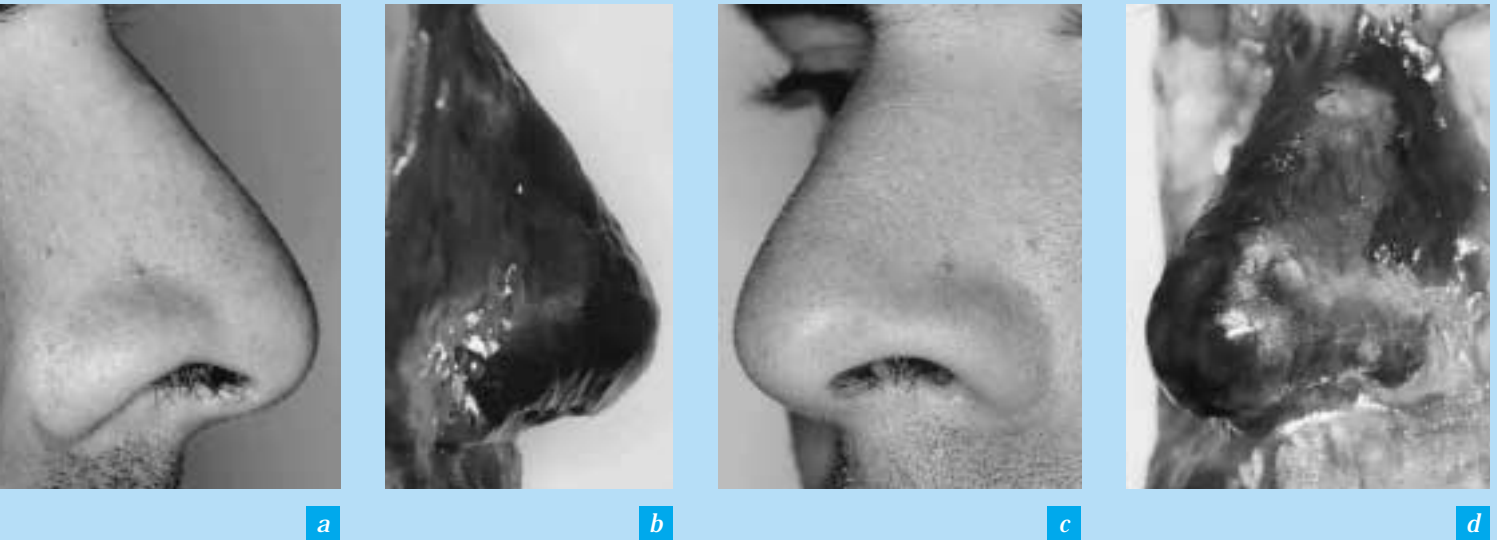
Those first results of the clinical application of color coded medical RP models showed a new approach for preoperative planning in reconstruction surgery. Surgery can be simulated in a very individual way, which is not possible with visualization. Investigating skeletal and soft-tissue structures of the skull an objective measurement and documentation could be achieved.

A main use can be achieved also in building individual custom patterns for 3D tissue engineering. These tissue structures have to meet the biomechanical or physiological requirements of skull structures or they should serve as structures for cell layers.

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MODELS BY 3D-ULTRASOUND

Fig. 4a-d: Human nose and color coded medical RP model (stereolithography) by a 3D ultrasound data set. Side view (a,b) and frontal view (c,d)



Conclusion of the pilot study with SLA models of ultrasound data:

- High compliance (no radiation)
- Ready for clinical application
- Preoperative planning and simulation
- Variety of indication (individual 3D surgical planning, tissue engineering).

OUTLOOK

Multimodal medical rapid prototyping of 3D ultrasound data

Different imaging modalities inclusive ultrasonography are generally applied to the same craniofacial patient. These different imaging modalities with their specific advantages were combined via a precise merging by means of numerical optimization methods, developed by an interdisciplinary team of the University of Technology Munich [9]. The

superimposition of morphological and functional data represent a new diagnostic approach. This aspect leads also to the building of color coded models based on multimodal data sets. Another interdisciplinary group is now working on those models [10,11].

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Lisbon Workshop

The Use of Stereolithography for Pre-Operative Planning



On the 17th of June this year, the first Portuguese workshop about medical modelling with the title "The Use of Stereolithography for Pre-Operative Planning" took place in Lisbon.

This event, sponsored by Phidias Network, counted about 80 participants from all part of the country. Most of the participants were Maxillofacial and Plastic Surgeons, Orthodontists and Implantologists. The presentations made were innovative to the public - resulting in an enthusiastic and interested attitude from the audience. The workshop comprised presentations from Dr Jan Haex and Dr Jules Poukens of the University Hospital of Maastricht, Niels Moos of the Danish Technological Institute, Mr Wim Versluys of Materialise, Dr Henk Verdonck of the University Hospital of Rotterdam and Dr Guglielmo Ramieri of the University Hospital of Torino. The workshop was organised by Agiltec (R&D institute) in a partnership with Brainstorming, Medical Engineering Services. Brainstorming is a young portuguese company aiming at development and application of high technology systems for medical applications. The concept of the local Phidias Network workshop was ideal for them to promote medical modelling and at the same time support their local pioneering role.



First statistical

collected in the Phidias-validation study

Ch. Erben MA, K.D. Vitt MD,
J. Wulf MD

Medizinischer Dienst der
Krankenversicherung
Schleswig-Holstein (MDK),
23554 Lübeck, Germany

Introduction

The aim of this multicentric European study is to determine data concerning the application of stereolithographic models especially in craniomaxillofacial surgery.

Therefore a questionnaire based survey is performed assessing case related variables taking in to account diagnosis, indication and benefits of stereolithographic

models with regard to different phases of surgical procedure: preoperativ planning and intra-operative application of the model to overall outcome after surgical intervention.

The validation study started in september 1999. Questionnaires were mailed to 40 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 october 2000 ninety-seven questionnaires could be transferred into the database of the study.

RESULTS

The study population consists of 41 male and 56 female patients (mean age 45,7 years). The reported diagnosis that related to the application of the model can be divided into three main groups:

1. 39 % malignant neoplasia,
2. 33% trauma, including fractures of face and bone, and
3. congenital anomalies of skull and face.

There were different reasons reported by the surgeons, why a model was applied

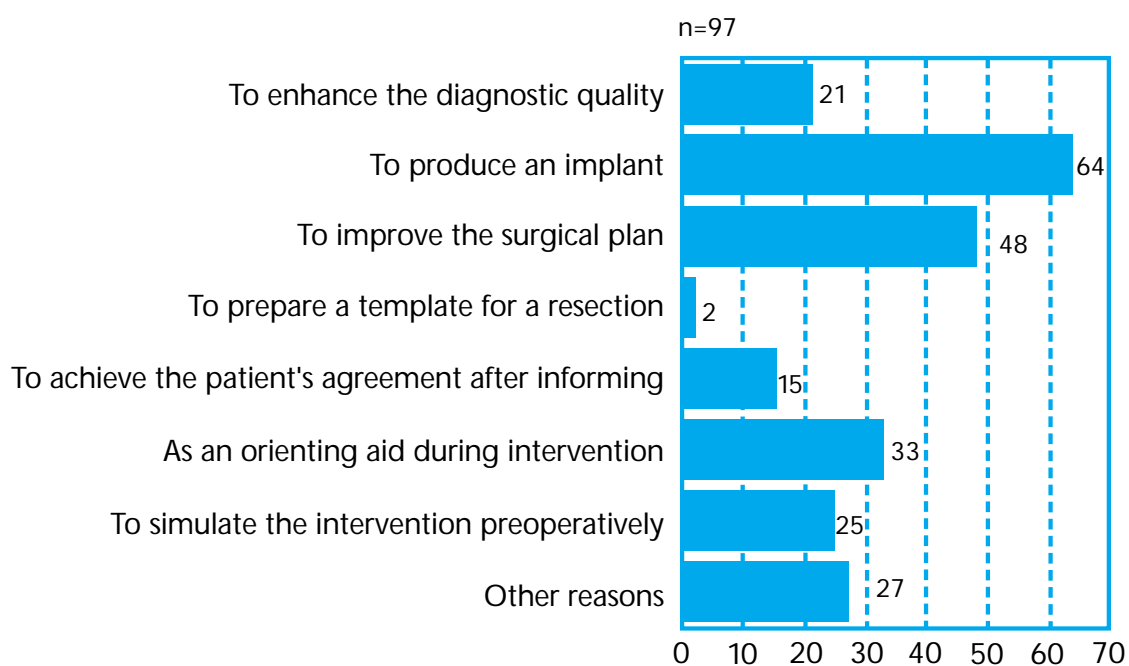


Figure 1

analysis of data

of stereolithographic models

Preoperatively, in 42 % of the reported cases the surgical intervention was simulated on the model. The influence of the simulation was considered as much better (41%) or better (51%) in comparison to the same intervention without simulation.

The simulation effect increased with the number of similar operations of each surgeon ($p < 0,05$). However, this effect was less high if a surgeon had an average experience in using planning models ($p < 0,01$).

If an implant was adapted preoperatively, its fit was considered as gapless in 95,5 % of all cases.

Due to the use of the model 76 % of the surgeons reported a decrease of operation time.

The average saved time was 33,8 minutes if the model only was used preoperatively, 26,3 minutes if the model was used intraoperatively and 58,6 minutes if the model was used pre- and intraoperatively.

Although only 31% of the surgeons believed that the surgical result was unachievable without the model, 78 % thought, that the model based outcome was either better or much better.

Overall the model use was considered as very useful or useful (67 %) but never reported as useless.

Discussion

A view on the structure of all outcome items shows in addition to the general effect of the model, described as useful and helpful for the treatment, that there are several dimensions of special effects in using the stereolithographic model.

The main effects concern:

- 1. planing-quality,*
- 2. communication,*
- 3. procedure quality.*

By increasing the number of evaluated questionnaires, we will obtain more information, whether this outcome structure might be confirmed and – if it is – under what circumstances the mentioned special effects are more or less important. We would like to ask all Phidias partners and surgeons to help us to increase the database of the validation study by mailing us the completed questionnaires.

In the following topics the preoperative application of the model lead to a change of decision

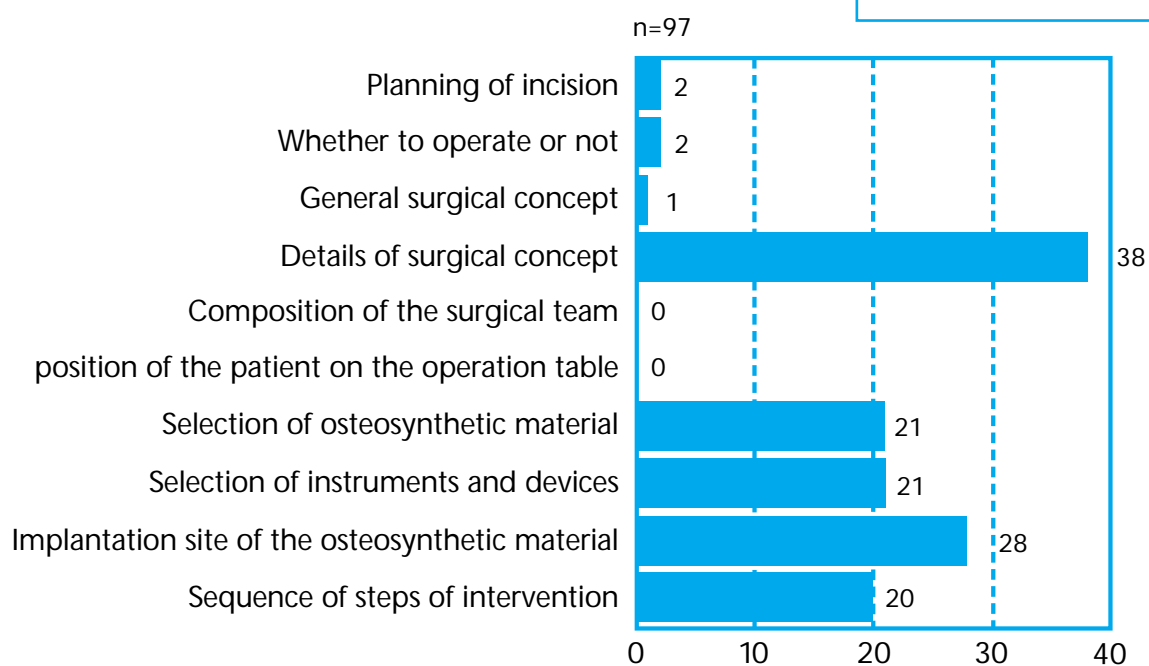


Figure 2

Quality assurance phantoms for bone densitometry

R Milner, E Berry, †AJ Marsden, AH Smith, MA Smith
Medical Physics and Centre of Medical Imaging Research, University of Leeds, UK.

†Keyworth Institute and Mechanical Engineering, University of Leeds, UK.

E-mail: r.milner@leeds.ac.uk
www.comp.leeds.ac.uk/comir

ware upgrades installed, so a stringent quality assurance programme is essential for effective clinical monitoring. To provide the most realistic assessment of in-vivo densitometer performance, we have by Rapid Prototyping developed a phantom that incorporates the range of mineral densities found in the patient population and also replicates the anatomical features of the bones being monitored.

The phantom models were produced by filling the moulds with a mixture of epoxy resin and an appropriate amount of bone analogue grade hydroxylapatite, and this allowed individual vertebrae to be produced in a range of mineral densities (Figure 2).

The completed phantom
The vertebral models were cemented together to produce the spine phantom. A low attenuating

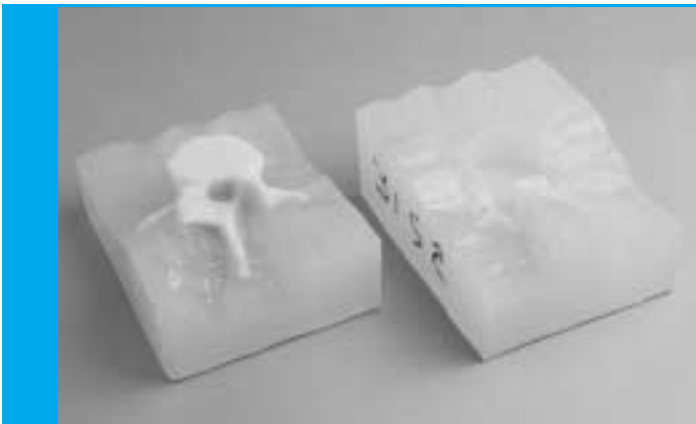


Figure 1. Silicon mould tool produced from an RP nylon master



Figure 2. Individual vertebra made of epoxy resin and bone analogue grade hydroxylapatite

Introduction

Bone densitometry is used in clinical practice to establish bone mineral status in suspected cases of osteoporosis, and to monitor mineralisation in patients currently receiving treatment or recalled for further assessment. As the annual rates of change in mineralisation levels in most patients are comparable with the reproducibility of the technique, it may be necessary to perform sequential measurements over a significant period of time to establish the efficacy of treatment. During this period major components may be replaced in the system and soft-

Generation of computer models

The biomedical image processing package AnalyzeAVW® (Mayo Foundation) was used to segment selected lumbar vertebrae from CT images taken from the Visible Human Project™ Female dataset. A smooth surface was reconstructed using geomagic Wrap® (Raindrop Inc) and CAD files were generated in formats suitable for display and for transfer to the rapid prototyping system.

Rapid prototyping

Selective Laser Sintering was performed using a DTM Sinterstation System to produce nylon masters of three lumbar vertebrae. The nylon masters were used to create silicon mould tools (Figure 1).

material was inserted between each section to simulate intra-vertebral discs and to give realistic separations. A phantom suitable for paediatric studies has been developed by scaling the adult L4 image and producing 5 further vertebral models in a more appropriate size and density range (Figure 3). An analysis image of this phantom produced by a Lunar "Prodigy" instrument is shown in Figure 4, demonstrating that the phantom has densities covering the range seen in patients.

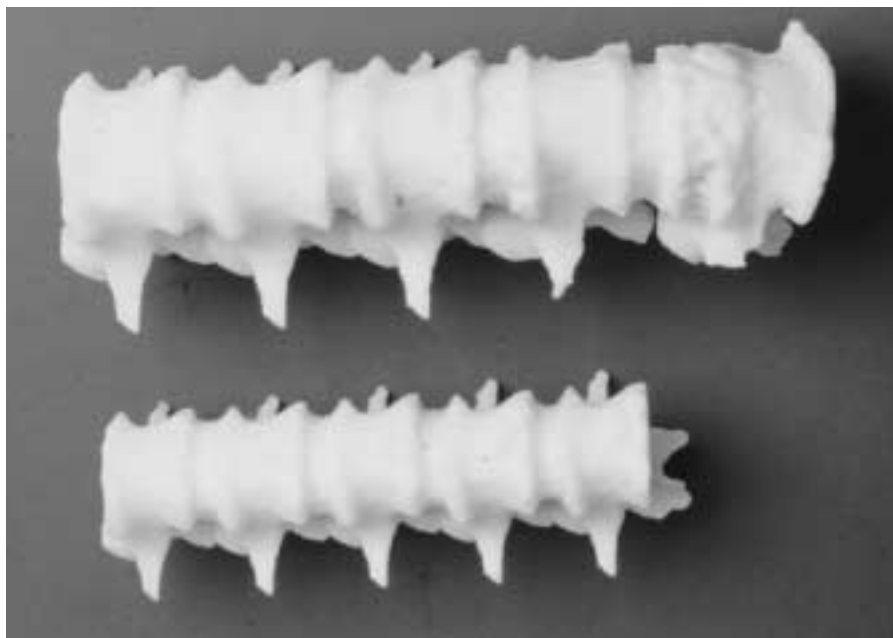


Figure 3. Completed adult (above) and paediatric (below) spine phantoms

Discussion

In patients who have already sustained some degree of vertebral collapse, densitometry alone may not reflect true bone status. It has been suggested that in such cases spine morphometry may provide additional useful information. For those densitometers which incorporate software to evaluate morphometry the quality assurance phantom described here, which incorporates the geometric characteristics of vertebral bodies, would provide an ideal method of monitoring instrument performance when using such software. This modelling technique has the potential to replicate the common vertebral deformities produced by osteoporosis and is generalisable to other application areas.

Acknowledgements

This article was presented as a poster at the 14th International Bone Densitometry Workshop, Warnemünde, September 2000. The authors are participants in the Phidias network (BRRT-CT98-5051). The authors thank the National Library of Medicine for making available data from the Visible Human Project™: an anatomical data set developed under a contract from the NLM by the Departments of Cellular and Structural Biology and Radiology, University of Colorado School of Medicine.

www.nlm.nih.gov/research/visible/

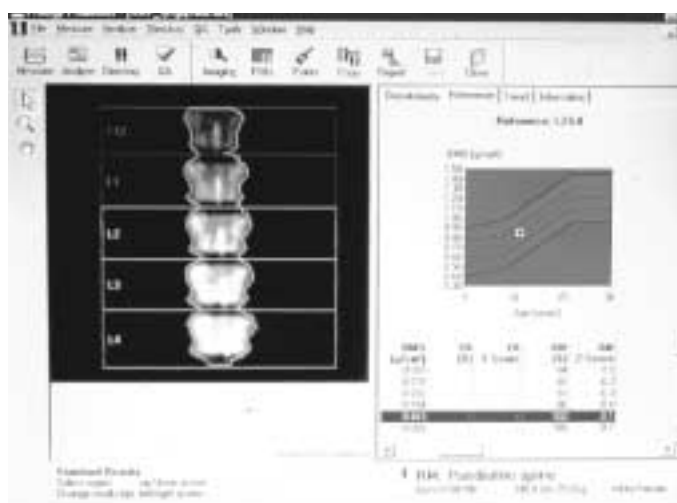


Figure 4. Screen shot of analysis image acquired by Lunar "Prodigy" instrument. The BMD figures refer to groups of vertebrae, the values for individual vertebra range from 0.45g/cm at T 12 to 0.95g/cm at L 4.

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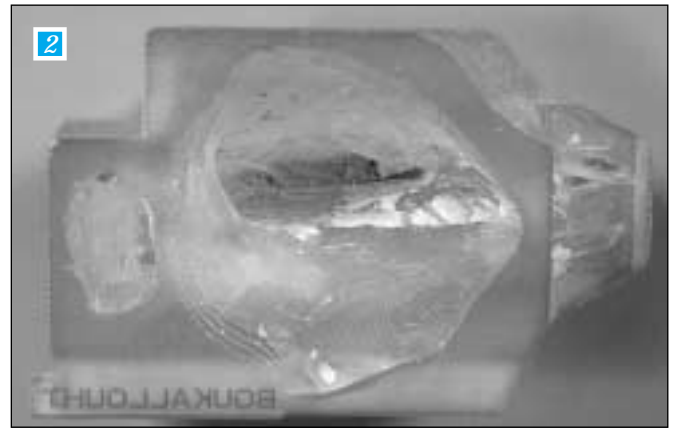
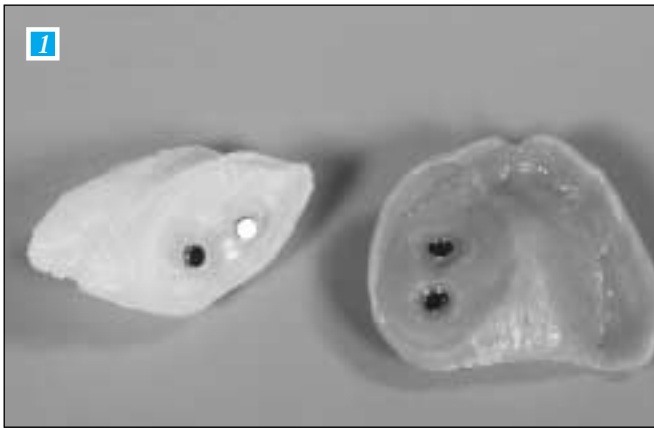
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Contact:
 Prof. Dr. Willi A. Kalender
 Institute of Medical Physics
 University of Erlangen-Nürnberg
 Krankenhausstr. 12
 D-91054 Erlangen
 Germany
 Tel. +49 9131/8522310
 Fax +49 9131/8522824

The soft-tissue model



H.W.D Verdonck,dds
Maxillofacial prosthodontist
Academic hospital Rotterdam
Academic hospital Maastricht
Holland
E-mail hverdonck@interstate.nl

Fig. 1: stereolithographic soft-tissue model of a maxillary defect

Fig. 2: first obturator out of the soft-tissue model

Fig. 3: first obturator adjusted to the cheek

Fig. 4 : alginate impression on top of the obturator to make the dental prostheses

Fig. 5 en 6: soft-tissue model of a combined intra-extra oral defect

Fig. 7: final silicone obturator and dental prosthesis connected by magnets.

Most times stereolithographic models are used on the "bone level", this means that one uses a model that is an accurate replica of the bony structures of the patient. However, about 5 years ago L. Visch, dds, at that time maxillofacial prosthodontist at the Daniel den Hoed Clinic Rotterdam, developed a method to create an obturator based on a stereolithographic model of a patient after (hemi) maxillectomy .

In this case the model has to be a replica of the soft tissues of the defect.

The most common treatment for malignant tumors of the maxilla (upper jaw) is surgical resection. In many cases this results in a defect of the maxilla and a direct communication between the oral cavity and the maxillary sinus and/or the nasal cavity. These patients experience large problems in eating, drinking and speaking because food

leaks through the nose and speech sounds very nasal.

These defects can be closed surgically by means of free flaps or prosthetically.

If one chooses for the latter option one has to make a so called obturator-prosthesis.

This prosthesis fills out the defect and restores functions like eating, drinking and speech and supports the cheek.

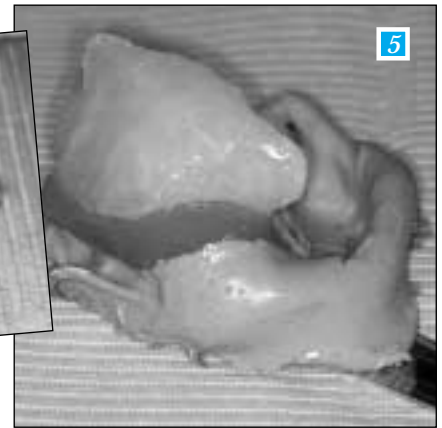
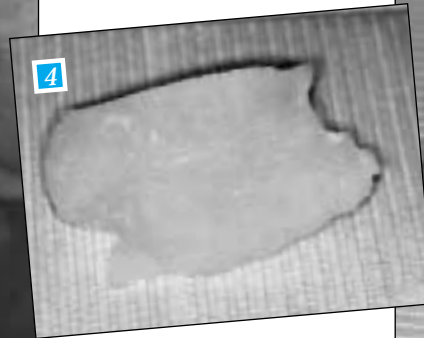
In order to make such an obturator the prosthodontist usually makes an impression of the defect, this is not very pleasant for the patients because the tissues lining the defect can be very tender.

There is a limit to the accuracy of the impression, you cannot get all the undercuts of the defect in the impression. These undercuts play an important role in the retention of the prosthesis.

There is another way to get a model of the defect: stereolithography.

The soft-tissue model

from a CT-scan



When after surgical resection of the tumor the tissues have healed a CT scan is made. This is the base for the stereolithographic soft-tissue model. Once we have the model we block out the undercuts which we don't need for the retention of the obturator and pour silicone in the model. In this way we get an accurate obturator which fills out the defect. This obturator is fitted in the patient, the only adjustment we have to do is correcting the support of the cheek because when making the CT scan the patient does not wear his prosthesis so the cheek collapses. This adjusted silicone obturator is transferred into a definite one.

We place this final obturator in the patient's defect and then make the impressions for the dental prosthesis. The silicone obturator and the acrylic dental prostheses are connected together by means of magnets.

I also use this technique in patients having a resection of the soft palate and combined intra- (hemimaxillectomy) extra oral defects.

The advantages of the stereolithographic soft-tissue model are:

- it is less aggravating for the patient
- the treatment of patients having a trismus is much easier
- it is more accurate than making an impression

In the near future I will expand the application of the soft-tissue models to the field of the facial prostheses meaning making ear prostheses based on a CT scan.



from a CT-scan

From the project manager's desk

The Phidias Network is now running over two years and a half. Since the beginning of the project, we have had a lot of promotion for medical Rapid Prototyping by means of this newsletter, several local or specific topic workshops, presentations, articles, and so on.

One of the important tasks of the project is to assess the usefulness of using RP models in surgery. The German National Health Insurance (MDK) is processing questionnaires that evaluate, on a European scale, the use of a model in surgery.

By the end of the project, we hope to have an objective study analysis, indicating that, at least under certain circumstances, the use of RP models increases quality of life for the patient, improves the surgical result and reduces overall costs. Once this is proven patients, model users and model providers will profit from this in many ways.

In this edition of the Phidias Newsletter, a summary of the first descriptive and statistical results is being presented by MDK. These results indicate already clearly that models have a positive effect on the outcome and cost of a surgery.

The results will be more precise and numeric if we can expand the data-pool further. Therefore, I would like to invite all readers to contribute to this study either directly by filling out questionnaires as a surgeon or indirectly by asking clinicians to fill out as many of these questionnaires as possible.

Phidias Network Administration
Kris Wouters

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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.

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

Editor:
Niels Moos
Danish Technological Institute
Teknologiparken
8000 Aarhus C - Denmark
Phone: +45 72 20 17 12
Fax: +45 72 20 17 17
E-mail: niels.moos@teknologisk.dk

Editorial Board:
Dr. Farid Taha
University Hospital of Amiens
Kris Wouters
Materialise N.V. Leuven
Niels Moos
Danish Technological Institute

Layout:
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