BRE2-CT92-0326
BE/ 5930 PHIDIAS

PHIDIAS

laser Photopolymerisation models based on medical Imaging, a Development Improving the Accuracy of Surgery

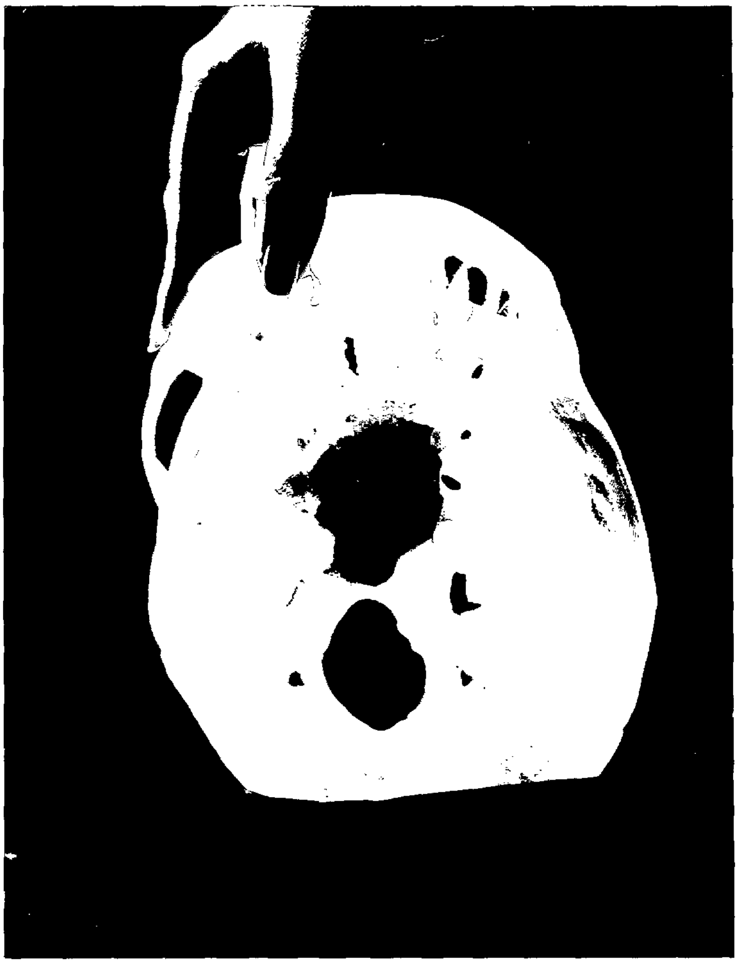
SYNTHESIS REPORT

Materialise NV, Belgium

Katholieke Universiteit Leuven, Belgium
Siemens AG, Germany
Zeneca Specialties, United Kingdom

1. Introduction

The PHIDIAS[1] project aims to build three dimensional (3D) medical models derived from tomography-based medical images (CT, MR). By laser photopolymerisation (stereolithography) even complex models can be generated very fast in low toxicity materials, as illustrated in the next figure.



Typical PHIDIAS model of soft tissue rumor *in the skullbase*

As the ultimate 3D representation, solid medical models can be very helpful during the preparation of complex surgery. Their main estimated use is the following :

- providing visual and tactile documentation for diagnosis, therapy planning and didactic purposes. The medical model facilitates communication between surgical team members and patients.
- enabling accurate planning and simulation of interventions. For instance, in facial surgery, life-size individual models of the patient's skull are used to rehearse osteotomies, enabling to measure displacements in advance.
- serving as a master or negative for prosthesis or implant production.

---

[1] The Greek sculptor PHIDIAS -fourth century BC- is known for the technical and artistic quality of his representations 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 from this project should contribute to make disabled, injured or ill persons resemblant again to the ideal human beings of PH IDIAS.

in the last few years, several (mainly cranio-facial) surgeons started to use medical models in the preparation of complex surgery. The results are very promising and in some cases even spectacular.
However, all these activities are isolated efforts of different research groups, which do not result in a global solution.
The Phidias project aimed to investigate the full process of making medical models and to streamline the process from the patient in the scanner until the operation preparation.

One of the first objectives of the project was to investigate the requirements for the different applications and to answer to these needs with new technological deveiopments.
The request for lower costs and shorter lead times has pushed the developments of faster and more reliable CT imaging techniques, easy segmentation tools and faster production machines.
in order to use the models in the theatre room, iow toxicity resins were developed with different sterilisation possibilities.
To differentiate between different structures in one model (e.g. tumour and skull base) a new process was developed: Colour Stereolithography.

2. Partners in the Phidias Project

Materialise (Belgium) is a software deveioper for Rapid Prototyping applications with research activities in the medical applications of Rapid Prototyping : together with the Dept. of Mechanical Engineering from the University of Leuven, it has years of experience on resin experiments, laser drawing strategies, for Laser Photopolymerisation and data preparation for medical applications.

Materialise is integrating the research results as co-ordinator of the project. Being the rapid prototyping knowiedge centre within the project, it is concentrating on software for the technical data preparation and the laser photopoiymerisation process on a dedicated experimental set-up. it supplies test parts and medical models, the ultimate materiaiisation of the research results, for validation to the different medical centres.

Siemens Medical Systems [Germany), the major CT-scanner manufacturer of Europe, leads the investigation to generate images with iess distortions and artefacts.

Zeneca Specialities (UK), having many years of experience with UV-curable polymers in the medical field, is developing the resins that are suited for the medical models produced by laser photopoiymerisation and develops the new Colour Stereolithography resins.

The Laboratory for Medical imaging Research of the KU-Leuven (Belgium) is working on tools for efficient image segmentation and flexible 3D visualisation and manipulation that can be interactively controlled by the responsible radiologist. The Radiology department of the academical hospital Gasthuisberg of the KU-Leuven is charged with the user requirement analysis and validation by different surgeons.

3. Research activities and results

3.1 User Requirements and Validation

The use of accurate medical models of living patients a new idea in medical practice. The full potential of such models is not yet clearly identified. Therefore an analysis of user requirements and a protocol to validate the use(fullness) of 3D models in different subspecializations needs to be established.

The interaction with surgeons from these different fields is essential to cover as wide an application area as possible. Sample models were manufactured in function of the first empirical requirements and then evaluated following the validation protocol.

a. Quality requirements for medical SL-models

KU Leuven (Dept. of Radiology) used a questionnaire approach to gather a precise description and definition of quality requirements for medical SL-models. Thirty surgeons from Belgium, France, Germany and the USA were contacted. This validation group consisted out of 4 neurosurgeons, 7 maxillofacial surgeons , 2 traumatologists, 9 orthopedic surgeons, 2 nose-ear-throat surgeons, 4 orthodontic and paradontic surgeons , 2 plastic and reconstructive surgeons.

While using SL-models in clinical practice these surgeons were asked to answer questions about different quality features of stereolithographic models that need to be fulfilled for bone surgery. Quality requirements include accuracy, surface detail, transparency, colour, size, disarticulation, mirror models, rigidity, temperature resistance, toxicity, production time and price.

Different surgical subfields stress different quality requirements. Submillimeter accuracy (0,2mm to 0,3mm) is required for occlusion fitting of teeth and implant design in maxillo-facial surgery and orthodontic and paradontic surgery. Accuracy between 0,5 and 1 mm is required for pre-operative bending osteosynthesis plates (e.g. in mandibular reconstructions) and also in posttraumatic and degenerative spinal disease. The remaining surgeons accept a geometric accuracy of the SL model between 1 and 2mm.

Critical anatomical areas in which these surgeons report to need high surface detail (avoiding pseudoforamina, pseudofusions and stair casing artefacts) are: maxilla and mandible for dental implant preparation and osteosynthetic plate bending, high surface detail of orbital walls for correction of en(ex)ophthalmies, skull base neuroforamina, skull vault for implantation of skull plasties (no stair casing), articular surfaces of joints (e.g. coxofemoral, distal radio ulnar joint and feet bones), vertebral anatomy in complex congenital, posttraumatic and degenerative spinal disease.

Semi-transparent as well as complete opaque SL-models are required. Semi-transparency is validated useful to evaluate surrounding topography of f.e. maxillo-facial and spinal area. Complete opaque models are preferred if surface and shape perception becomes more important, such as for modelling cranial vault plasties and evaluation of the shape of the distal radio ulnar joint.

Most of the surgeons find colours useful. Colour(s) are supposed to be especially useful in highlighting the ‘surrounding topography. Simultaneous visualisation of coloured teeth, dental *roots* and mandibular nerve canal through a semi-transparent mandible would be very helpful in paradontic and maxillofacial surgery planning.

Also from the didactical point of view colours are suggested to facilitate information transmission. The colour of complete opaque models is described as being preferentially “bony white”. if image acquisition and segmentation would permit to isolate also additional soft tissue components (cartilage, vessels, muscles), then different colours for different tissues are appreciated much more important.

Differentiation between cortical bone and trabecular bone is required to plan implant stabilisation (e.g. hip implants, dental implants), to guide screw positioning and to evaluate the quantity of bone grafts that may be available.

Scaled models {reduced size in order to decrease production time and price) are validated acceptable for visualisation of global anatomy of limbs, pelvis and spine. The scale factor should be simple and indicated on the SL-model. Real size models are required for the remaining areas and for all surgery planning, simulation and implant preparation.

Not all surgeons require a model of the complete anatomical area. Limiting the skull model to only the anterior skull half from the supraorbital region towards the hard palate is sufficient for local orbital corrections. If skull distortion is more extended, SL models of the whole skull (from cranial vault up to the mandibula) are required for correct evaluation of the three-dimensional esthetic reconstruction. Correction of complex feet deformities needs models of both complete feet.

Selectively coloured mandibula channel

The following disarticulations are required for shape and surface evaluation or for graft and implant design: mandible, distal radio ulnar joint, coxofemoral joint, hindfoot bones and vertebral bodies. The SL model should also keep the information about the non-disarticulated position of the joint bones (need for reference points). Split models were required for skull base evaluation (deroofing the skull vault) and for spinal disease (sagittal and coronal cuts). Deroofing the skull vault may sometimes hinder surgery simulation (e.g. surgery simulation of forehead correction in unilateral coronal synostosis).

Mirror models are very helpful to evaluate qualitatively as well as quantitatively the reconstruction of unilateral deformities (f.e. of the skull vault, orbital cavity and feet}.
A duplicate SL model was reported as useful by two surgeons. It served as reference during surgery simulation on the second model and was used to evaluate the difference between pre- and postoperative anatomy,
All surgical subspecialities required non-flexible, relatively hard resins in order to guarantee accuracy, to resist to mechanical forces of surgery simulation (screwing, sawing, drilling, bowing plates) and implant preparation (heat and high pressure resistance) and to simulate bony resistance during surgery. Low irritation to skin, eyes and respiratory tract is expected during manipulation of these models and surgery simulation. Heat resistance for sterilisation is required if these models are manipulated by the surgeon during surgery. If SL-models could serve as implants, biocompatibility will become an additional requirement.

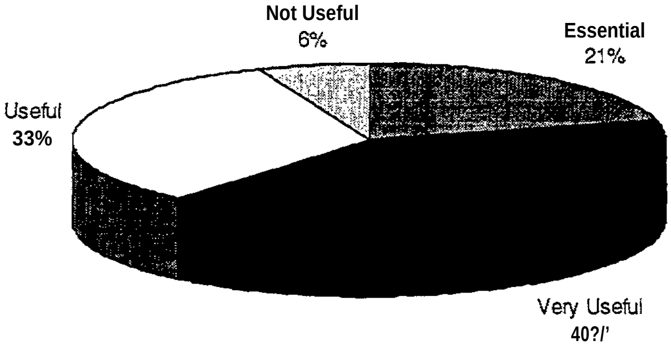
If these models can be produced within 12 hours and 3 days, they can be used for posttraumatic applications (spinal trauma, skull trauma).
Most of the surgeons accept a production time between 1 and 4 weeks.
An acceptable price label for these SL-models varied between 300 and i 000 US$. Surgeon’s motivation depends upon the degree of difficulty, risk and price for the different surgical operations and whether reimbursement for these models exists or not.

b. Validation of the medical models

During the project, models were made with the techniques developed in the project.
This means that those models were made with experimental resins, machines, software and interfacing methods. Some of the models which were produced in the beginning of the project did suffer from these ‘beta-conditions’: This has to be taken into account when examining these validation results.
Different types of cases were selected in which a model could be used.

To gain more insight into the impact of this new medical tool, KU Leuven developed a validation questionnaire in which SL-models are compared to the cheaper, faster and easier obtainable alternative of static pseudo-3D images (surface renderings).
The questionnaire consists of 12 (mainly multiple choice) questions to be filled out by the surgeon using a SL-model for diagnosis and therapy planning. These questions cover three main topics:
1. what is the diagnostic contribution of the S1 model?
2. does the SL model fulfil the surgeon’s requirements?
3 does the SL model alter patient’s treatment?

The overall usefulness is represented in the graph below:



Overall **assessment** *of usefulness of SL models based on a validation of 48 patients by 25 surgeons.*

The 3 models reported as not useful contained too many pseudoforamina or produced perception difficulties due to transparency. In 10 patients (3 skulls, 4 feet and 3 implant preparations for alveolar crest augmentation), the SL model was scored as being essential. Unique spatial information due to real time perception and palpation, better insight into osteotomy site and direction, improved bone graft and implant design were the main benefits reported.

3.2 Image Acquisition

In order to produce high quality and high accuracy models, the image generation is extremely important. If artefacts are introduced during the image generation it is impossible to correct them later on.

Siemens concentrated its work on developing new spiral scanning techniques which reduce the artefacts and give better spatial resolution.
Spiral CT, the most adequate method to scan people in order to achieve uniform models, was investigated further to improve its 3D contrast and spatial resolution. Noise characteristics of spiral CT were simulated and weighting schemes for section interpolation were developed. The simulation results were interpreted and summarised : it is possible to improve present interpolation algorithms.

Theoretical considerations on object adaptive 3D interpolation for Spiral CT were elaborated. Different possible object adaptive 3D interpolation methods were analysed with respect to z-axis resolution and artefact behaviour.

Two algorithms for object-adaptive 3D interpolation were simulated :

- VLTI - variable linear tilled interpolation
  VNTI - variable non-linear tilted interpolation

The results were encouraging on simple geometric objects. Consequently VLTI and VNTI were tried on geometrical phantoms (in collaboration with KUL) and clinical data with promising results. Phantom studies were continued for validation. The trials showed the expected excessive calculation times and proved the need for appropriate, dedicated hardware which was in use by the end of the project.

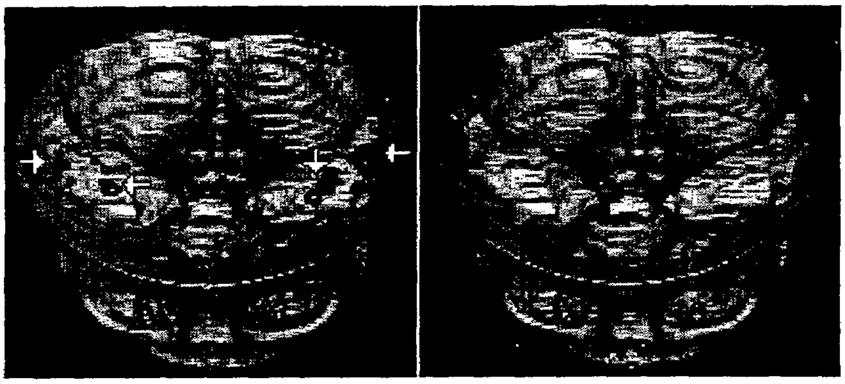
Expansion / Contraction object-adaptive 3D interpolation (ECAI) was implemented. The ECAI performance was investigated and simulated. It showed optimisation problems due to excessive calculation times on standard hardware.

Siemens has been concentrating its efforts on stepping artefacts caused by inconsistencies in the interpolated data and 'Flying pixels' due to inhomogenity of noise and spatial resolution. Also homogeneity artefacts are investigated. Motion artefacts can be considered minimised by the use of Spiral CT where the short scanning periods reduce the risk of moving patients during scanning.

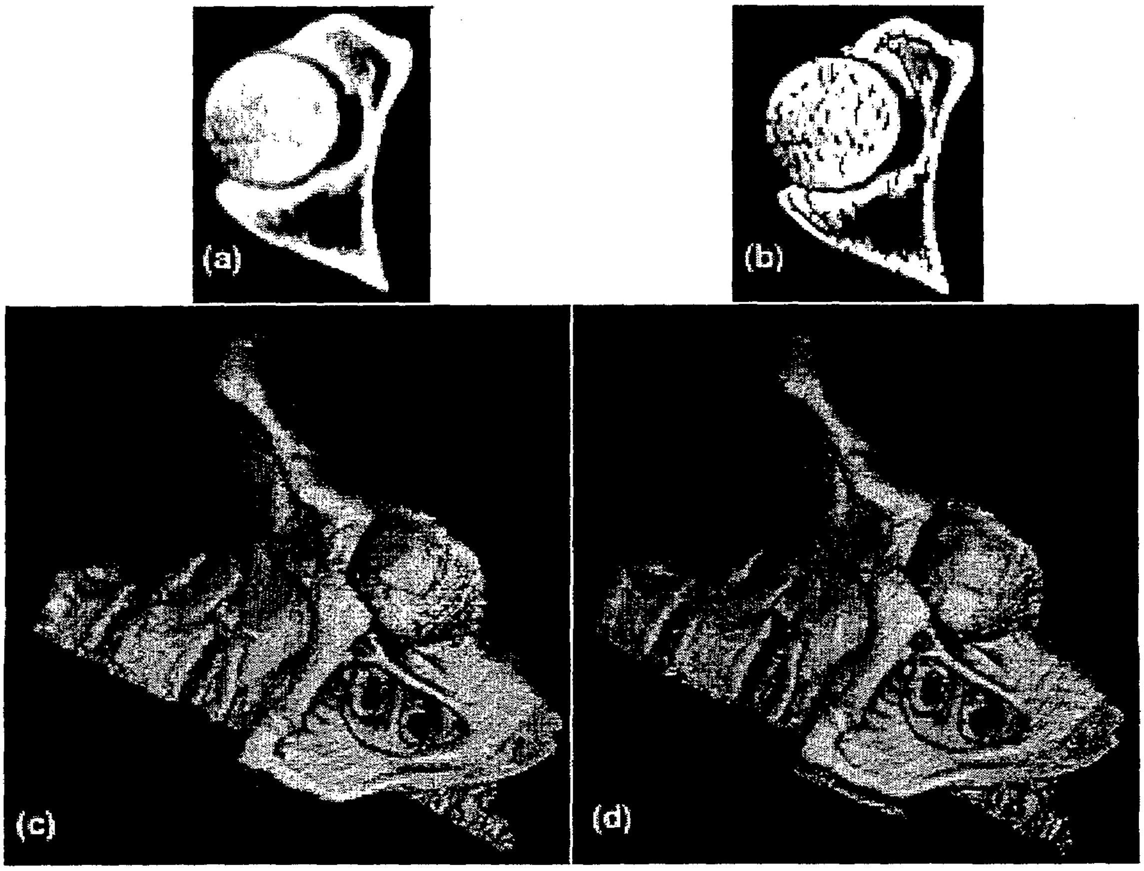
3.3 Segmentation for Medical Models.

The standard procedure to select bone out of CT images is thresholding. All pixels which have a value higher than the threshold value are assumed to belong to the bone. This binary thresholding is only successful for large bone structures which have a high density. Very tiny structures or bone structures with low density will have a value under this threshold (undersegmentation). Other structures will be so "close to each other that the area in between will have values above the threshold (oversegmentation).
Primary solutions for both problem areas have been developed by KU Leuven (Lab. for Medical Imaging Research) via image enhancement algorithms. These algorithms will take into account both the contrast and the gradation in the images.

This is illustrated by these figures :



Two 3D visualizations derived from the same Spiral CT data set. The result on tfre left is obtained by a simple thresholding approach. The problem of undersegmentation is illustrated clearly by the presence of pseudoforamina (little holes in the bone structure that do not correspond to any physical evidence) in the skull base (pointed out by arrows). The result on the right is obtained by the use of image enhancement techniques developed in PHIDIAS.



Disarticulation of different bone structures is often necessary’ in joint areas such as femural head and acetabulum pairs in the pelvic region. However binary thresholding results in oversegmentation. invoking the need for manual separation and hence a large amount of user interaction. Figure (a) shows a part of one thresholded slice (the disc corresponds to the femural head that needs to be separated) . Figure (b) shows how image enhancement techniques can be used to automatically disarticulate the femural head from the acetabulum. Figure (c) shows a 3D visualization of the manually separated acetabulum. The resulting 3D visualization (d) of the automatic method shows a smoother disarticulate acetabulum surface.

In order to examine the accuracy of the Spiral CT imaging, a phantom study was performed on the European Spine Phantom (ESP). In this study bone segmentation on Spiral CT is approached by an image generation method based on a man-made phantom. Knowledge of the exact geometry (and of the uncertainty on its phantom implementation) is used in two sets of experiments. In the interactive approach, results obtained are deviating 0.7 mm (on average) from the ESP measures (the worst case being 2.0 mm, the bests case 0.0 mm). Elimination of sources possibly biasing this result, has lead to a model-guided experiment. Starting from a match of the model description to the image volume data, measurements perpendicular to model edges are carried out.

A major conclusion is that, for the optimal spiral CT acquisition, a submillimeter accuracy can be obtained, in principle, in all spatial dimensions when segmentation techniques based on local photometry (gradient, local thresholding) are used. As this acquisition is employed in imaging for oral surgery - the surgical subfield requiring submillimeter accuracy - the requirement for submillimeter accurate models can be met here.

The work on interaction on 3D shaded visualizations has been extended towards the concept of virtual sculpting. The later concept means that personalised virtual surgical accessories can be positioned and shaped, based on segmented models.

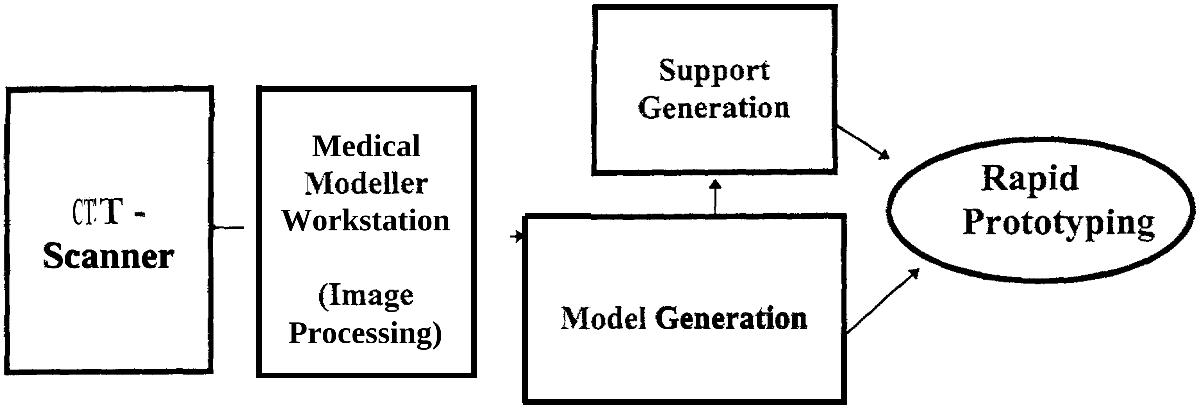
Materialise implemented the Medical Modeller Workstation software as a portable software (PC & X-Windows on UNIX) which is developed for easy segmentation focused on model production. Special effort has been spent in connecting algorithms (region growing) and segmentation in different colours as preparation towards the colour Stereolithography.

The connecting algorithms make sure that there are no flying pixels and/or disconnected pieces which would cause problems during the model building.

The segmentation of different structures in different colours has an easy human interface, and the final result is shown in three dimensions on a high quality multi colour rendering.

The interface towards the Colour Stereolithography machine is done via different segmentation masks.

The result is a software system for interfacing from a medical scanner (mostly a CAT or CT scanner) to Rapid Prototyping. By the separation into different modules it can be tuned for every situation.



3.4 Laser Photopolymerisation Resins for Medical Models

In terms of the resin development there were two main objectives:
- a non toxic resin, which can be used in theatre room.
- a resin system which can be selectively coloured.

Both of these aims were fulfilled in the Phidias project:

a. Low toxicity resin

Zeneca colorable and clear resins are formulated with raw materials which have minimal toxicity and are TSCA and EINECS registered so that the final resin when processed or used by the end users such as surgeons would have a good clean safety profile. A number of samples were submitted for Ames (genotoxicity), skin sensitisation, acute oral and dermal and eye irritation testing. These involved extensive testing of liquid resin to anticipate the handling of liquid at Service Bureaux and recommending handling procedures for SL resin. Selected resin samples including clear resin and colorable resins were submitted for testing. Results to-date indicated that Zeneca resins have low skin sensitisation, oral, dermal, and eye irritation with negative limited Ames (genotoxicity) results.
Furthermore, FDA approved USP class VI tests were carried out on selected Zeneca clear and colorable resin. Both resins passed when tested for USP class VI, indicating the safe nature of the Zeneca resins in the cured state so that models will be safe in close contact to the patient during operating procedures.

initial sterilisation experiments with clear samples at Leuven showed no significant change in the mechanical properties after sterilisation under four different sterilisation conditions (2 x steam, EO and formaldehyde). Further work involved testing of colorable formulations at Queens Medical Centre (Nottingham, UK) under high temperature steam (136 0C for 30 minutes cycle) and low temperature steam (75 0C for 60 reins cycle} and at Leuven hospital under steam (121 0C and 134 0C), formaldehyde (80 0C) and ethylene oxide (55 0C). Results showed that no discoloration or change in dimensions was found from contact with Ethylene Oxide, Formaldehyde and low temperature steam. However colour fading with high temperature steam was noticed.
Nevertheless, the effect of high temperature steam on colour fading of earlier samples was less pronouced.

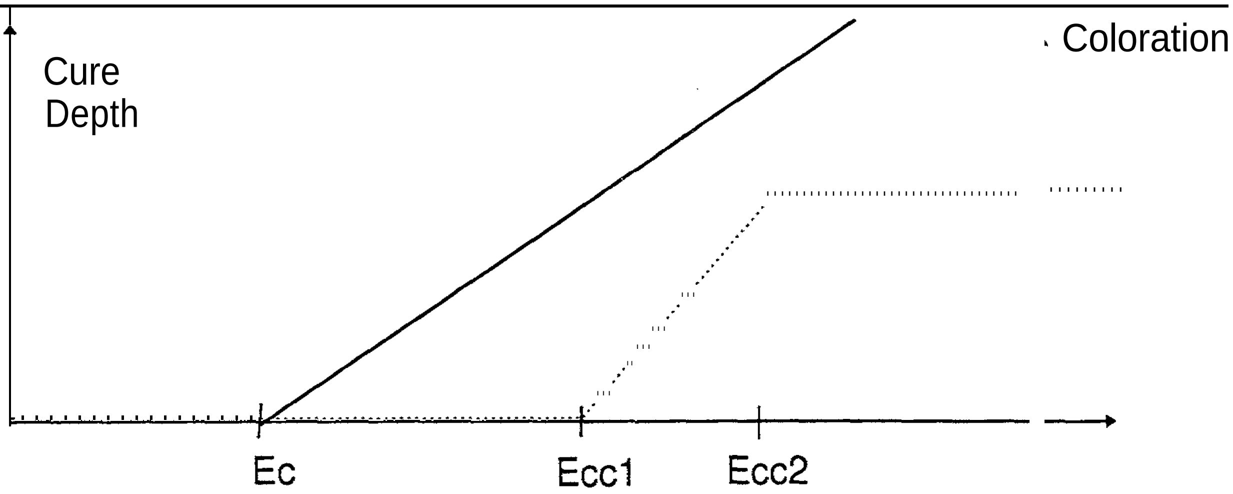
b. Colourable Resin system

A new resin system was developed by Zeneca and tested by Materialise which enables selective coloration.

After study of both the chemical background (by Zeneca) and the machine implications (by Materialise) it was decided to work with a one Laser System instead of a two Laser System. The same Laser will be used for curing and for coloration. The principle is that the critical energy to start the coloration process must be sufficiently higher than the critical curing energy.

In accordance to the curing parameter Ec(Critical Curing Energy) we define two new parameters for the coloration energy :

Ecc1 : is the critical energy for the coloration : it is the energy at which a first colour is noticeable.
Ecc2 : is the second critical energy for the coloration : it is the energy at which the maximum coloration is reached.



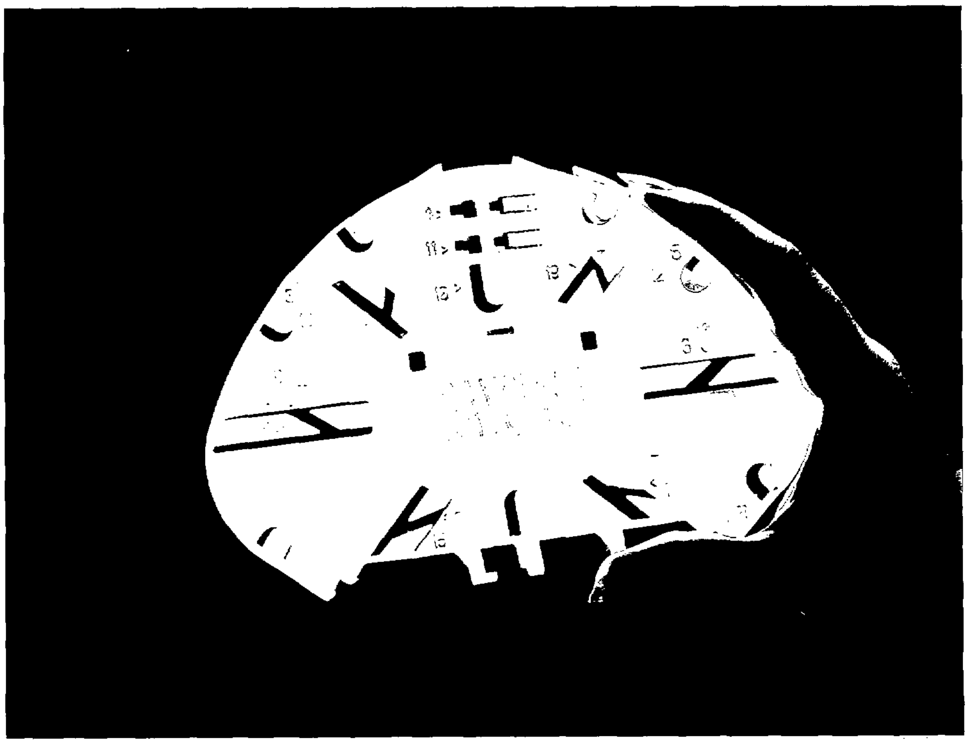
A test similar to the 'Window pane" test was designed to measure Ecc1 and Ecc2. Different windowpanes with different energies are compared in function of coloration. Visually it can be determined which panes are coloured and from which pane on the colour is not improving anymore. These visual results were confirmed with a colour measurement machine at Zeneca.

The initial formulations suffered from the problem that Dp (slope of the curing curve) was too low which caused coloration before the desired cure dept is reached. Other iterations showed a better Dp, and Eccl was substantially higher than Ec.

The first colour stereolithography parts (world wide ?) were made at Materialise at Tuesday April 4th. They were little bars (8mm x 30 mm x 6mm) with the name "MATERIALISE" in blue inside the parts.

Different cases were selected in which colour could add an extra value. Models were made for the following applications :

- Bone tumour. (Phidias model)
- Soft tissue tumour (inside the nose and going to skull base)
- Model of a schisis patient whose teeth were selectively coloured.
- Jaw bone with coloured mandible channel.
- Labelling of the models.
- Some technical applications.



The results of the Phidias project have spin-off potential in technical applications

3.5 The Laser Photopolymerisation Process

Although tomographic (CT, MR) data generation is layer based, the much higher spatial resolution of stereolithographic models requires interpolation in all three dimensions. Tools are required to manipulate the image derived data and to calculate support structures to support the models in a skilled way. The medical model can have complex shapes and details, unfamiliar for a technical operator. The removable supports need to be very distinctive.

In order to use the medical models in traumatological cases, the build time of the models needs to be reduced by intelligent control of the manufacturing process.

After the image processing is done with the software described in 3.3, the data is further processed towards the Rapid Prototyping machine and the model is made with a special Laser Polymerisation set-up.

a. The calculation towards the Rapid Prototyping machine

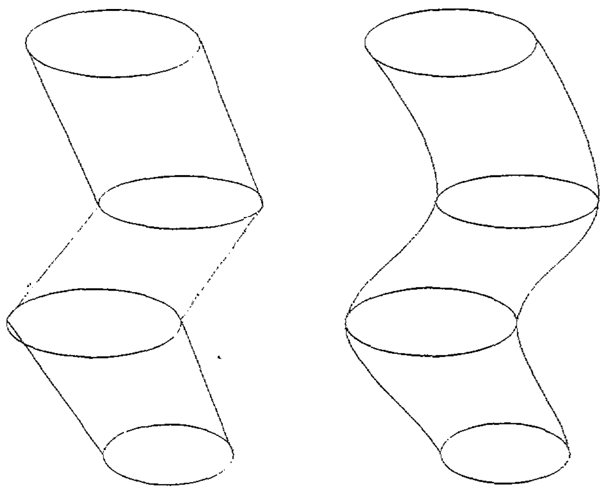
The software interfaces from the Medical Modeller Workstation to any kind of Rapid Prototyping system. Where the Workstation is used to define the regions to be processed and to display the segmentation result, this software will interpolate the data and interface directly to the RP machine. Because of this direct interface and because of the higher order interpolation algorithms it produces the most accurate models in a very short time (scanner images" to SLA machine in 1 hour).

As the pixel sizes of the input images vary from 0.2 to more than 1 mm, a resolution enhancement technique is necessary when creating RP models. If the model would be created at the resolution of the input images, it would show much stairstepping and hide the natural curvature of the surface. Two techniques are used to increase the resolution of the contours :

1. A bilinear interpolation increases the in-plane resolution of the contours with a factor of up to 100. For the segmentation of cortical bone this increases the accuracy of shape and size.
2. An inter plane linear interpolation or cubic spline convolution is performed to decrease the slice thickness of the data set. Slice thickness of 1 to 3 mm are very common for the input images, whereas the slice thickness used on the RP machines is normally lower than 0.25 mm (down to 0.1 mm).

Materialise has implemented algorithms for cubic interpolation in Z, X and Y direction. Because of the morphological forms of the medical models, we know in advance more ore less how they will look like : human organs or structures do not have sharp edges or very irregular forms. We can take benefit of this knowledge by performing a cubic spline convolution between four adjacent scans.

A Cubic interpolation will give smoother surfaces as shown in the next figure. The left figure shows the linear interpolation, the right one shows the cubic spline. The cubic interpolation sheme gains importance when the difference between subsequent slices gets larger than 1 mm.

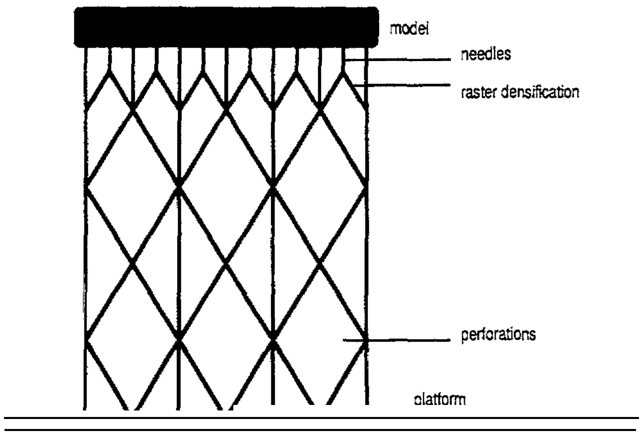


This cubic spline convolution was implemented in a three-dimensional way, tested and compared with the linear method.
The linear interpolation is faster and gives good results in cases with small slice distances (1 mm). Cubic interpolation gives smoother surfaces. From an accuracy point of view, the influence is limited,
In the case of flat and tiny structures, there is simply not enough information present in the images to make a good interpolation.
If two subsequent contours are not overlapping, it is impossible to know whether there is a hole or whether the regions need to be connected.

This is one reason for the so tailed “pseudo foramina" : holes in the models who are not real holes.

The system also includes contour based support generation. A graphical user interface has been added to work on the layer based support structures. 3D visualization of the contour information is made possible. The editing of the support structures to add or remove elements is implemented in a user friendly environment that allows complex manipulations, such as trimming on stacks of layers.

A new support building style was introduced : perforated supports. (patent pending)



Normally supports are composed of crossing walls, for perforated supports we make perforations in these walls. In this way a structure is formed which has the same strength in the vertical direction, but which has much less material.

It has four main advantages :

- Reduced building time: up to 5 times faster than normal supports.
- Drainage of liquid resin out of the support structures.
- Less material consumption (less polymerised material)
- Reduced contact support-part.

The second and third advantage together can result 7 times less material for the supports structures !

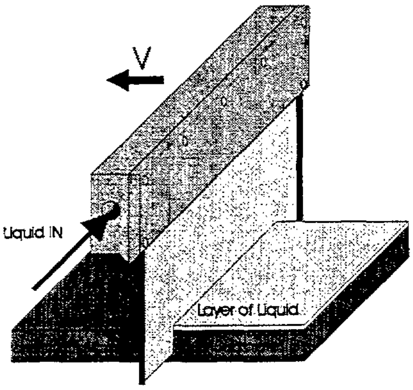
For most RP systems (3D Systems, Stratasys, EOS,...) the machine files are directly generated by the interfacing software. For Rapid Prototyping systems without a direct layer interface, an STL interface is also included. Via matrix reduction it is possible to reduce the number of triangles while maintaining a good quality.
The software runs on Silicon Graphics and RS 6000 workstations, and also on 486 PC (with at least 16 Mb RAM)

b The Medical Modeller Machine

On one hand, most of the technical achievements related to the laser photopolymerisation process are usable on advanced, but standard, stereolithography machines. Special support building and scanning algorithms, as well as the resins with low toxicity and even colour, can run on standard machines.

On the other hand the important objective of speed in medical applications was hard to achieve due to the slowness of standard recoating systems. For this purpose a lot of effort has been invested in the development of a new recoating system and in this aspect the prototype Medical Modeller Machine is very specific.

In most of the present stereolithography machines a blade is used to carry out the recoating process. it has been found that this recoating system is a very time-consuming step in the process. (e.g. a skull of 150 mm high with a layer thickness of 0.25 mm = 150 / 0.25 layers = 600 layers at 30 sec / layer = 18000 sec = 5 hours !!!).



The new recoating technique that has been investigated is based on the curtain recoating technique. A fluid is forced to flow through a narrow gap by means of a pump. The fluid will flow out of the gap as a liquid curtain. By imposing this curtain a relative velocity to a substrate a thin layer of liquid can be created on top of the substrate.

The technique is mainly used in the photography industry where very thin layers of coatings are depositioned on a support material.

This new system tries to overcome the shortcomings of the common recoating system making use of a blade. The blade system is mainly a very slow system. Recoating time per layer can vary from 20 seconds (for easy parts) to 1 minute (for difficult parts like e.g. skulls). The system described here will only take about 5 seconds per layer which can mean a enormous time profit for the creation of a complete skull.
The blade system also has some problems when “difficult” parts are built (so-tailed trapped volumes like also some skulls). The curtain recoater should also resolve these problems.

A first set-up has already been built in which the new recoater is tested. The curtain coater head has been designed through which the resin is pumped by means of a pump. At the bottom of the head there is a gap of ca. 0.2 mm. In the head there is a pressure chamber in order to create an equal pressure throughout the gap. The resin that is flowing beside the vat is recuperated in the container. Up till now layers of resin have been created with a thickness of 0.5 to 0.1 mm and this in a time span of less than 5 seconds.

Apart from the fast recoating, it also shows advantages in the field of support structures. Due to the more gentle application of a new layer of resin, the turbulence in the resin is reduced. This implies that less support structures can be used. It also implies that the system is less disturbed by small defects in the support structures that can cause complete failure of the model in the standard recoating.

4. Conclusions.

The Phidias project has proved that it is possible to produce accurate medical models based on medical image data. The selective colouring of medical models has been developed, so that all relevant information from the images can be transferee to the surgeon.

Each element in the process chain for the manufacturing of medical model has been elaborated in the project.

Improvements have been made to the images generated with Spiral CT, the most suited approach for medical model data acquisition. The noise level and artefacts due to spatial inhomogeneities have been reduced.

Approaches to enhance the results of image based segmentation have been investigated and implemented. This has resulted in a user-friendly environment for the medical data processing.
A special image enhancement technique to prevent over- and undersegmentation has been developed. Thanks to this approach the interactive efforts required for tasks such as femur and pelvis separation in the hip joint can be reduced up to 90 %. in addition the quality of the resulting surface improves.
Support for 3D interaction in regions of interest pointed out on the 3D surfaces has been implemented by a virtual sculpting approach. This development can be seen as a step towards custom made implants in the future.

The treatment of the medical images can be controlled by a medical doctor. The medical decisions are thus separated from the technical ones required for the actual manufacturing.

The technical data preparation has been speeded up. This implies interpolation to the layer thickness of the laser photopolymerisation process and contour based automatic support generation. Also the speed of the part building was drastically reduced during the project, from 30 hours to 5 hours for a specific part.
Both medical and technical software provide facilities to produce models with selectively coloured regions.

Low toxicity resin was developed to make medical models that can be used in the theatre room. They may even get in contact with the patient during the operation.
Highly innovative is the development of a selectively colourable resin that fulfils the low toxicity requirement. This resin can also be used on the standard stereolithographic equipment currently installed.

Validation of the results has been performed on an technical and clinical level.

The accuracy of medical models is limited by the accuracy of the medical images and the equipment used for scanning. However, it is possible to overcome the resolution limitations of the scanner with intelligent interpolation approaches. For specific applications, accuracy up to a few tenths of a millimeter can be reached. This reasures that implants can be based on medical models.

The clinical validation in the Phidias project has been one of the first studies that goes beyond individual case reports. 30 surgeons from Belgium, France, Germany and the USA were contacted for the user requirements : 4 neurosurgeons, 7 maxillofacial surgeons , 2 traumatologists, 9 orthopedic surgeons, 2 nose-ear-throat surgeons, 4 orthodontic and paradontic surgeons , 2 plastic and reconstructive surgeons. 25 of them have been using models for validation in the treatment of 48 patients.
The overall assesment of the models by 25 surgeons proves that the initial thesis of the project is true. Medical models help reconstructive surgeons to make their patients again resemble the ideal human being of the Greek sculptor Phidias.

Model with coloured teeth (schisis patient)