

INNOVATIVE DEVELOPMENTS IN VIRTUAL AND PHYSICAL PROTOTYPING

Edited by
Paulo Jorge Bártolo et al.

 **CRC Press**
Taylor & Francis Group
A BALKEMA BOOK

Innovative Developments in Virtual and Physical Prototyping

Editors

Paulo Jorge Bártolo
Ana Cristina Soares de Lemos
Ana Patrícia Oliveira Tojeira
António Mário Henriques Pereira
Artur Jorge Mateus
Ausenda Luís Avelar Mendes
Cyril dos Santos
Dino Miguel Fernandes Freitas
Helena Maria Bártolo

Henrique de Amorim Almeida
Igor Marques dos Reis
Juliana Rosa Dias
Marco André Neves Domingos
Nuno Manuel Fernandes Alves
Ruben Filipe Brás Pereira
Tatiana Marisa Fernandes Patrício
Telma Margarida Dias Ferreira

*Centre for Rapid and Sustainable Product Development
Polytechnic Institute of Leiria, Portugal*



CRC Press

Taylor & Francis Group

Boca Raton London New York Leiden

CRC Press is an imprint of the
Taylor & Francis Group, an Informa business

A BALKEMA BOOK

Table of Contents

Preface	XIII
Committee Members	XV
 <i>Keynotes</i>	
idea ² Product Lab™ – A low cost alternative to introduce AM in South Africa <i>D.J. de Beer</i>	3
Additive Manufacturing-assisted scaffold-based Tissue Engineering <i>C.K. Chua, M.J.J. Liu & S.M. Chou</i>	13
 <i>Biomufacturing</i>	
Ultrastructural analysis of the hDSC interactions with biodegradable 3D scaffolds <i>S.E. Duailibi, M.T. Duailibi, L.M. Ferreira, F.A.O. Tanaka, J.P. Vacanti & P.C. Yelick</i>	25
Individual contour adapted functional implant structures in Titanium <i>C. Schoene, R. Stelzer, P. Sembdner, L. Betrol, J. Markwardt, B. Reitemeier & G. Engel</i>	29
New approaches to prototype 3D vascular-like structures by additive layer manufacturing <i>E. Bassoli, L. Denti, A. Gatto, A. Paderno, G. Spalletta, N. Zini, V. Strusi, D. Dallatana & R. Toni</i>	35
A novel protein-based scaffold with macro- and micro-structural features for tissue engineering applications <i>M.J.J. Liu, S.M. Chou & C.K. Chua</i>	43
Surgical training and post-surgery evaluation using rapid prototyped biomodels <i>L. Queijo, João Rocha, Paulo Miguel Pereira & Manuel San Juan</i>	51
The calibration of continuous Digital Light Processing (cDLP) for the highly accurate additive manufacturing of tissue engineered bone scaffolds <i>D. Dean, J. Wallace, A. Siblani, M.O. Wang, K. Kim, A.G. Mikos & J.P. Fisher</i>	57
Fabrication and characterization of biodegradable composite scaffolds for Tissue Engineering <i>T. Serra, M. Navarro & J.A. Planell</i>	67
Spatially varying porosity with continuous path plan for hollowed tissue scaffolds <i>A.K.M.B. Khoda, I.T. Ozbolat & B. Koc</i>	73
Heterogeneous tissue scaffolds for spatiotemporally controlled release kinetics <i>I.T. Ozbolat, A.K.M.B. Khoda, M. Marchany, J.A. Gardella & B. Koc</i>	79
Medical application of rapid prototyping in orthopedics surgical planning <i>C.B.L. Ulbrich, C.A.C. Zavaglia, T.P. Leivas & F. Teixeira</i>	85
Polycaprolactone-based scaffold plus BMP-2 in a sheep thoracic spine fusion model <i>M. Yong, F. Melchels, C. Vaquette, D. Hutmacher, C. Adam, M. Domingos & P. Bartolo</i>	89
Development of functional graded device of PCL/PG by Selective Laser Sintering for drug delivery applications <i>G.V. Salmoria, P. Klauss, K. Zepon, L.A. Kanis & C.R.M. Roesler</i>	93
Flexible PCL tube scaffolds by winding of micro-extruded filaments <i>K. Ragaert, L. Cardon & J. Degrieck</i>	99

Surgical training and post-surgery evaluation using rapid prototyped biomodels

Luís Queijo & João Rocha

Instituto Politécnico de Bragança, Bragança, Portugal

Paulo Miguel Pereira

Serviço de Neurocirurgia do Hospital de S. João, Porto, Portugal

Manuel San Juan

ESTII – Universidad de Valladolid; CIBER – Centro de Investigación Biomecánica y Ergonomía, Valladolid, Spain

ABSTRACT: The biomedical use of Rapid Prototyping Technologies (RP) had great developments in the last years, especially as supportive tools for tissue growth, direct or supportive technology for implant fabrication or as tool for personalized biomodels production applied to studies, this research will focus on this last type of usage in continuation of previous work developed with RP as an aid of surgery procedures. Biomodels can play an important role as a complementary diagnostic method to medical staff (Queijo et al. 2010). The usage of RP technologies for biomodels production, in Lytic Spondylolisthesis surgical training and as a tool for post-surgery evaluation, is presented in this paper.

1 INTRODUCTION

3D replicas of vertebral spine sections are useful in diagnosing, planning and surgery simulation, visualization and manipulation. To patients it is important, allowing them to understand their pathologies nature, surgical proceedings performed by surgeon (Madrado et al. 2008) as well to reduce anxiety facing surgery need (Queijo et al. 2010). In this study it will be presented a procedure to manufacture the needed biomodels to fulfill these requirements. These allowed a better support to surgery practice by a previous analysis to the patient condition in the form of a segmented biomodel and the surgery planning by a biomodel representing the corrected spine section and the medical devices applied.

All physical biomodels were constructed based in the 3D digital models reconstructed from patient CT (Computerized Tomography) scans, where image segmentation techniques were performed.

The manufacturing technique used was Three Dimensional Printing (TDP) once this technique can provide the needed resolution and surface finishing needed to proper visualization and manipulations, associated to a manufacturing low cost.

1.1 *Lytic spondylolisthesis*

With bipedal posture most of the loads transmitted to the lumbar spine pass through the posterior elements of the vertebrae. The isthmus (pars interarticularis) is the

thinner part of the posterior vertebral arch and hence, the least resistant to fatigue.

Accordingly, stress fracture of the isthmus is a common occurrence among young active adults and particularly, among participants in some sports like diving, swimming, weightlifting, gymnastics and running.

With this fracture the vertebral body, pedicle and superior articular processes become separated from the inferior articular processes and hence from the vertebra below. This condition creates the possibility of slippage between the vertebrae.

The term spondylolisthesis is used to identify the anterior translation in the sagittal plane of a vertebra (and the spine above it) relative to the vertebra below. There are several aetiologies but the lytic or isthmic type, as described above, is the most common. In a lytic spondylolisthesis there is a bilateral defect of the isthmus (pars interarticularis).

The slippage between the vertebrae can cause the exiting nerve roots (the nerves exiting the spinal canal at this level, through the intervertebral foramina) to be squeezed causing leg pain and difficulty in walking. When this occurs, a surgical treatment may be necessary to decompress the nerves and stabilize the spinal segment (to avoid further slippage) with or without reduction of the deformity.

1.2 *From CT images to 3D digital models*

The fabrication ability of 3D physical models depends exclusively of the existence, in proper format, of a 3D digital model. This digital model, used as .stl type

file can have several proveniences, most commonly segmentation image or CAD software. As this last one allows the manipulation of 3D digital models by adding, subtracting or changing some of his features, the first ones are essential to perform image reconstruction and obtain the digital models from 2D image data files.

Most of these images come from CT or MRI scans in the form of cross sectional images from the study areas, according human axis (axial, coronal and sagittal) and obeying to the international standards in Digital Imaging and Communications in Medicine – DICOM.

Models quality is directly connected with the interval between images that is also a compromising solution between object structure size and the amount of radiation to which the patient is subjected.

3D digital models are obtained recurring to image segmentation techniques where several operations are performed in order to distinguish the main object – bone structures, in this case, from the main tissues by the application of masks according with the gray gradient in Hounsfield scale (HU). These masks allow a posterior rendering process that reconstructs the structure in a tridimensional image.

1.3 Rapid prototyping – three dimensional printing

The logical following step after the 3D digital model rendering is the fabrication of the physical biomodel that will allow a better visualization allied to his manipulation. The technology applied to this fabrication is rapid prototyping, often called additive manufacturing or fabrication that represent a new group of non-conventional techniques introduced in the medical field and provide high reproducibility and elevated capacity to quickly produce very complex 3D shapes (Gibson 2006) (Bártolo et al. 2009).

Once 3D digital model is obtained, his form is exported in the format of a .stl file where all the surfaces are converted into a triangle mesh allowing to be imported by any 3D print manager software. Next step is a hidden process where the print manager divides the model contained in the .stl file in several slices that are re-encoded and will constitute another file type that is sent to the printer—a .sli file.

Manufacturing processes available today, as Fused Deposition Modeling (FDM), Stereolithography (SLA), Selective Laser Sintering (SLS), Tridimensional Printing (TDP or 3DP) and Laminated Object Manufacturing (LOM) among other specific processes, bring a wide range of choice over building materials and outcome biomodel mechanical characteristics, as well as costs. A more detailed description over each one of this processes and over biomodeling process can be found in previous work (Queijo et al. 2010).

Despite several rapid prototyping techniques available, each one with his own characteristics, the chosen to produce these biomodels have been three dimensional printing (TDP) in the variation from ZCorp®.

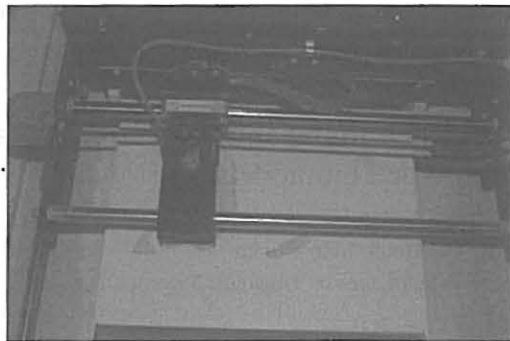


Figure 1. ZCorp's TDP printer in action.

This process allows biomodels fabrication with good visualization characteristics, manipulation possibility and with a cost that is substantially lower than other alternate methods.

ZCorp's TDP technique uses a composite powder as building material bonded by an aqueous media that is jetted by a printing head, similar to any 2D printer, as can be seen in figure 1. Once the models are built some stability must be provided to the surfaces (that are pulverous) in order to give rigidity and manipulation ability. This stabilization is, usually fulfilled by the impregnation with another bonding media such as cyanoacrylate.

1.4 Medical case description

The images belong to a 30 year-old male complaining of bilateral pain along the inferior limbs progressing over the past 5 years.

The imaging studies yielded a bilateral L5 isthmus lysis and an anterior slip of L5 over S1 of about 50% of the superior endplate of S1 (lytic spondylolisthesis). Moreover, there was a small posterior slip of L4 over L5. Together, these two slips result in an anterior translation of the vertebral body of L5 compared to L4 and S1.

In face of a progressive clinical course, a surgical treatment was proposed to the patient in order to decompress the nerve roots and to fix the vertebrae, avoiding further slips among them.

During the surgery the facet joints L4–L5 and L5–S1 were removed unilaterally and the discs L4–L5 and L5–S1 were excised as well. Multiaxial pedicle screws in titanium alloy (MAST™ Legacy™, Medtronic Inc, Minneapolis, MN, USA) were inserted bilaterally in the pedicles of L4, L5 and S1 and connected to two longitudinal 5.5 mm diameter rods using a percutaneous system (Sextant™ Reduction™, Medtronic Inc.). PEEK cages (Capstone™, Medtronic Inc.) were inserted in L4–L5 and L5–S1 disc spaces and were filled with local bone. Extra bone chips were inserted in the disc spaces around the cages to enhance interbody fusion rate. Translational torque was applied to

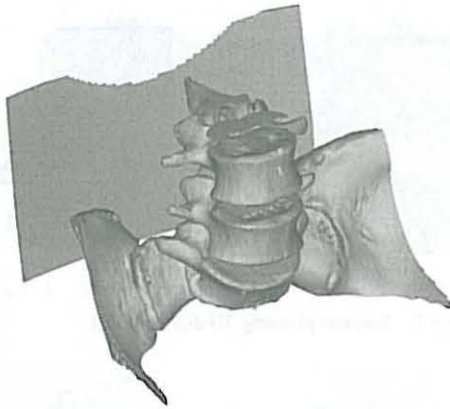


Figure 2. Image segmentation – Rendering without mask processing.

the L5 screws through the Sextant™ Reduction™ system in order to try to achieve a better sagittal alignment of the vertebrae.

In the postoperative CT scan we found an appropriate placement of the implants, but a very limited correction of the deformity.

2 METHODOLOGY

Along methodology description, each biomodel production phase is intercalated with the facts related in medical description. For better contextualization it was decided to divide themes.

Ethically, patient should provide authorization for TC images to be used and these should be, as soon as the process allow, made anonymous (once TC systems register patient's information). In this process, 2D images are imported to segmentation software where will be treated to rebuild the desired spinal area.

2.1 Image segmentation

First of phases in the procedure consists in defining gray values interval corresponding to HU units in Hounsfield scale to isolate the maximum of our object of work – the section of spine, including L3, L4 and L5 vertebrae and most of sacrum. As first iteration, have been adopted a range of values defined as standard to bone tissue and set between 226 and 1196 HU. This process created a mask that has covered each image pixel which value is included in the chosen range and painted it in a selected color. Rendering process based on the created mask showed us that despite the chosen range is close to the desired, once has rejected most of the unwanted surrounding tissues there still having some adjustments to be made before following to the next step – figure 2. Range HU values were then settled between 200 and 1196.

The following step consisted in rectifying each structure, frame by frame until a coherent digital model

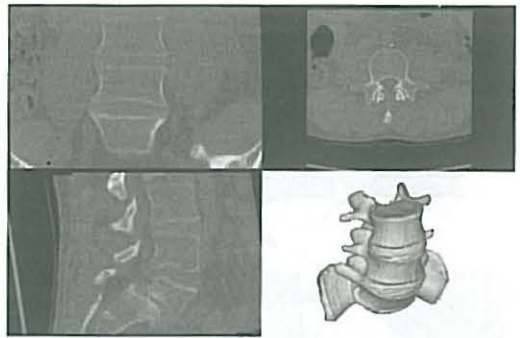


Figure 3. Image segmentation – Mask processing and 3D previewing.

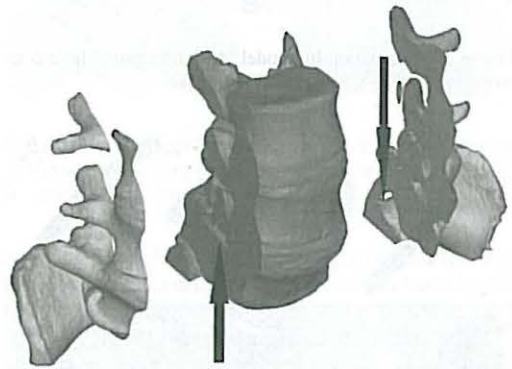


Figure 4. Pedicle cut-sections 3D digital model.

is carried out, as seen in figure 3. Unwanted structures as CT table and iliac bone showed in figure 2 have been removed once those are irrelevant to the study. In this process and to allow a better and individualized visualization we have decided to isolate each one of the structures with an individual mask.

After obtained the reconstructed 3D digital model it is already visible the constriction in L5–S1 conjugation holes as well as the front slippage of L5 vertebra. This way, it was decided to produce a biomodel with pedicle cut sections where the constriction and the slippage could be better observed. Digital model have been manipulated by orthogonally cutting all masks in L5 pedicle regions. The result can be seen in figure 4 where critical areas are marked.

Once 3D digital model is fully defined it has been exported as a .stl file and manipulated by 3D print manager.

2.2 Evaluation biomodel

In 3D print manager, as long as get an estimated building time and materials consumption, it is possible to define model orientations over building area.

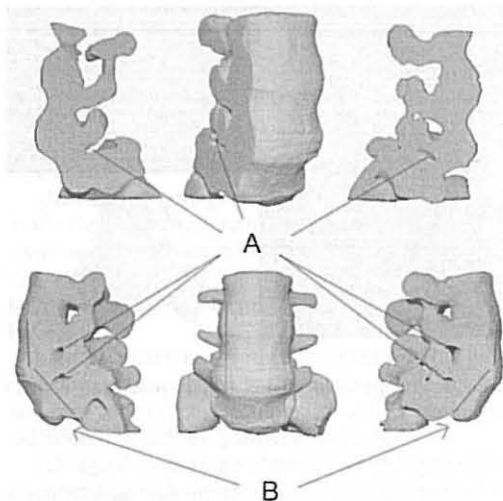


Figure 5. Evaluation biomodel. A – conjugation hole constriction; B – L4–L5 and L5–S1 slippage.

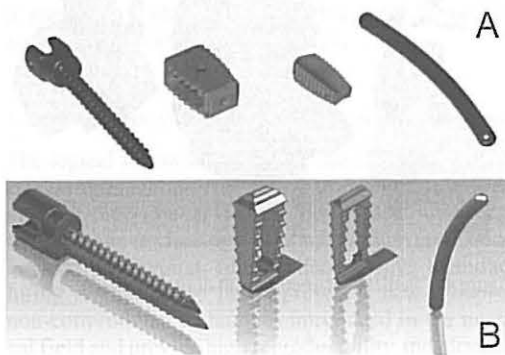


Figure 6. Multiaxial pedicle screw, PEEK cages and longitudinal rod: A – real devices; B – 3D modeled devices.

Once settled building parameters, biomodel fabrication is done, layer by layer, followed by surfaces stabilization as final procedure, as described in previous work (Queijo et al. 2010).

Through physical biomodel, shown in figure 5, has been visualized patient condition in the constricted conjugation holes and vertebra slippage and evaluated possible pedicle vertebral screw-bars insertion points and angulations that would bring L5 vertebra to a most favorable position.

Also, this model has been shown to the patient to explain him the nature of his pathology and the need for a surgery where the lower vertebrae would be fixed with medical devices, represented in figure 6.

2.3 Surgical planning biomodel

After those definitions, with previously CAD modeled pedicle screws, PEEK cages and longitudinal rods, in

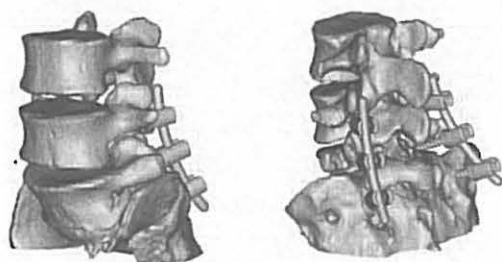


Figure 7. Surgical planning 3D digital model.

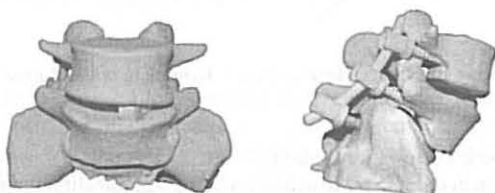


Figure 8. Medical device positioning validation biomodel.

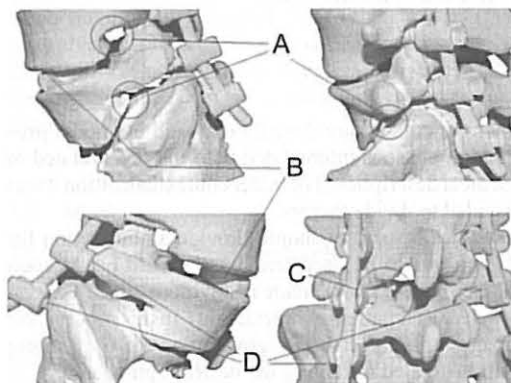


Figure 9. Validation biomodel details: A – critical nerve root areas; B – PEEK cages positioning; C – Possible facet removal area; D – Pedicle screw orientation and positioning.

3D CAD software (figure 6) and exported to .stl files, all bone structures are repositioned.

As defined previously, vertebrae repositioning is done to allow a bigger clearance in the conjugation holes and a reduced slippage between L4–L5 and L5–S1 and, then, matched with medical devices resulting in a complete 3D digital model as shown in figure 7 that have been built for a new evaluation and positioning validation (figure 8).

In surgical planning biomodel it is possible to see, after repositioning, the interference between bone structures that will conduct to possible bone removal, the detailed pedicle screw positioning and orientation and the need in accessibility to position intervertebral cages, as can be seen in details from figure 9.

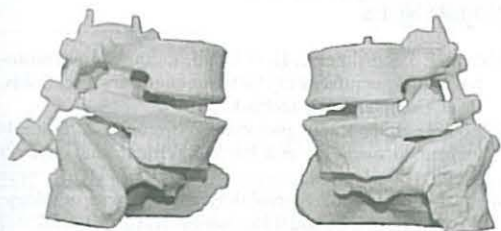


Figure 10. Post-surgery biomodel.

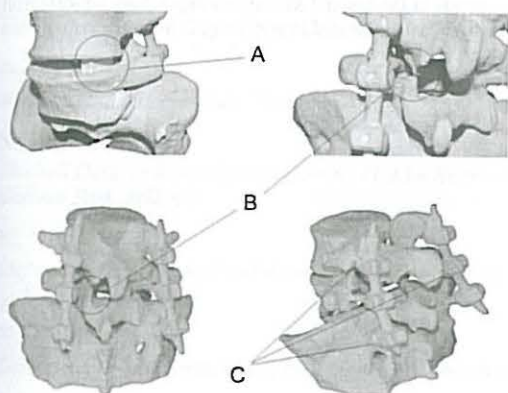


Figure 11. Post-surgery biomodel details: A - PEEK cage fixing L4-L5 vertebrae; B - Facet and partial pedicle removal to allow cage positioning; C - Pedicle screw implants with longitudinal rods.

2.4 Post-surgery biomodel

Post-surgery biomodel (figure 10) is obtained following the same procedure as for evaluation biomodel. Based in patient post-surgery TC images, 3D digital model has been reconstructed with the particularity of being needed two distinct range in Hounsfield scale—one for the bone, as settled previously and another to metallic medical devices settled in 1400–2976 HU. Reconstruction, in this case, become harder once there is a considerable presence of noise in TC images, due to the ray dispersion in presence of metallic devices.

Once combined the two masks generated for bone and for metal, the result is a 3D digital model that is exported to a .stl file and then fabricated. This biomodel allow a comparison between what has been planned and what was achieved in the surgery due to all conditionings. Figure 11 shows the details in post-surgery biomodel.

3 CONCLUSIONS AND FURTHER WORK

As previously demonstrated, through rapid prototyping technologies and a multidisciplinary collaboration it is possible, in a short period of time, to build biomodels

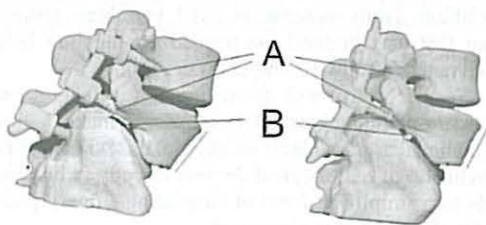


Figure 12. Biomodel comparison front view: pre-surgery (left) and post-surgery (right). A - PEEK Cage placement detail.

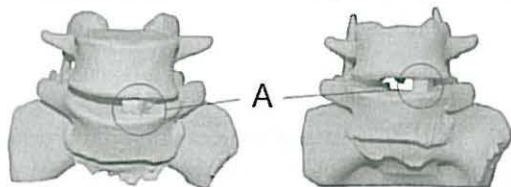


Figure 13. Biomodel comparison left view: pre-surgery (left) and post-surgery (right). A - pedicle screw positioning; B - conjugation hole clearance.

allowing not only a complementary diagnose method for 3D visualization of complex areas but also valuable tools for surgical applications.

In this case, it has been possible to show evaluation biomodel to the patient and explain, supported by a simplified form of visualization, the cause of pain and the reason of surgery need. Patient becomes aware that the only way to relief long time pain was fixing vertebrae to avoid a continuous degeneration of his condition.

Another advantage of biomodels is their uses as a complimentary diagnose allowing medical staff to observe medical images in a 3D way.

Patient condition was properly defined through evaluation biomodel that enabled to identify the amount of slippage between L4-L5 and L5-S1 vertebrae as well the compression in the nerve roots caused by this slippage that constricted conjugation holes. It then becomes clear that it would be difficult to bring L5 vertebra close to a satisfactory position.

Through positioning biomodel were defined adequate insertion points and the needed orientation to pedicle screws. Also, in this case, were defined which bone structures needed to be removed to allow proper cage insertion as well the needed vertebra repositioning. It becomes more or less clear that nerve root decompression would be achieved not all by vertebrae repositioning but also by bone structures removal (right L5 pedicle and facet) as can be seen in figure 9 detail C.

Post-surgery biomodel allowed a comparison between what was planned and the achieved result (figures 12 and 13). It was confirmed that possible vertebrae repositioning was limited, allowing a

medium 3 mm increase in axial vertebrae distance but that was granted the needed conjugation holes clearance to fully decompress nerve roots.

Further work will focus in the evaluation and surgery planning biomodels in order to make them as functional as possible. If succeeded, this will allow the inclusion of real medical devices directly in biomodels as a simplified form of simulating surgery phase of medical devices placement.

This type of surgery becomes frequently dependent on surgeon's decisions and unknown factors occurring during surgery, so there is a need to investigate further cases with personalized manufacturing tools to allow proper pedicle screw placement and orientation, also known as surgical guide.

REFERENCES

- Bártolo, P. J. S., Almeida, H. & Laoui, T. 2009. Rapid prototyping and manufacturing for tissue engineering scaffolds. *Int. J. Comput. Appl. Technol.*, 36, 1-9.
- Gibson, I. 2006. Rapid prototyping: from product development to medicine and beyond. *Virtual and Physical Prototyping*, 1, 31-42.
- Madrado, L., et al. 2008. Stereolithography in spine pathology: a 2-case report. *Surgical Neurology*.
- Queijo, L. et al. 2009. A prototipagem rápida na modelação de patogenias. 3.º Congresso Nacional de Biomecânica. Bragança. Portugal.
- Queijo, L. et al. 2010. A surgical training model manufacture using rapid prototyping technology. *Innovative Developments in Design and Manufacturing-Advanced Research in Virtual and Rapid Prototyping*, 175-179.