Proceedings in MANUFACTURING SYSTEMS
Proceedings in Manufacturing Systems, Volume 7, Issue 2, 2012 ISSN 2067-9238

DESIGN AND RAPID MANUFACTURING OF PATIENT-SPECIFIC SPINAL SURGICAL GUIDES: A SURVEY

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Abstract: *The approach of customizing the surgical instrumentations and using them along with computer-aided surgical planning and advanced imagining techniques for increasing the accuracy and reliability of surgical procedures represents a trend in the medical field. It implies cooperation between engineers and medical specialists (radiologists, surgeons, etc.) for all the process steps: computer tomography/magnetic resonance imaging (CT/MRI) scanning of the patient, medical modelling of the anatomical areas of interest, planning surgery and designing the guide, choosing the material and manufacturing process, building the guide, sterilizing and using it in the operation room. Patient-specific guides can mach exactly patient bone structures and help materializing the planned trajectory for drilling, tapping or cutting. Therefore, these guides improve accuracy of the surgical procedure, helping the surgeons to better orient during intervention, decreasing the surgery time, costs and risks of infections. The main objective of the current paper is to present a review of different patient-specific guides used for pedicle screws insertion in human spine. The paper investigates the design criteria (anatomical landmarks system, stability, precision, unique placement, etc.), material and Rapid Manufacturing issues related to this application field and presents critical views on different surgical guides designs. Based on this analysis, several proposals for improving the spinal drill guides placement accuracy are presented.*

Key words: *rapid prototyping, design, surgical guides, survey, accuracy, pedicle screws, spine.*

1. INTRODUCTION

Rapid Manufacturing (RM) processes (such as Stereolithography – SLA, 3D Printing – 3DP, Fused Deposition Modelling- FDM or Selective Laser Sintering – SLS, to mention only the most frequently used) build objects in an additive manner by successively adding horizontal layers of material which are corresponding to the sections created by the intersection of a 3D CAD model with parallel planes oriented perpendicular to the building direction [1 and 2]. These layers of material are formed by selectively solidifying a fotocurable liquid resin, laser sintering powder material, depositing thermoplastics extruded through a nozzle or bounding powder materials using a liquid binder. This particular method of generating solid objects allows building geometrical complex prototypes otherwise difficult to obtain using traditional manufacturing technologies, which recommends it for medical applications where the patient specific anatomy (available by computer tomography – CT or magnetic resonance imaging – MRI) is imposing an individual solution (i.e. prototype) for each patient/clinical case [3]. The standard workflow for obtaining a physical model from patient scanning data is presented in Fig. 1, while Fig. 2 presents an example for the prototype of the third lumbar vertebra (L3), manufactured using FDM on a Dimension 3D Printing Machine.

RM processes are usually used in medical application for visualization purposes, surgical planning and simulations – enhancing the communication with the patient or other medical specialists [3 and 4], for obtaining scaffolds for tissue engineering [5] or implants with controlled architecture [6] and for manufacturing prosthesis [7] or surgical templates [3 and 8]. For all these applications which require low production volumes, complex geometrical shapes and patient customization, RM processes represent the best manufacturing solution.

The current paper presents a review of different patient-specific guides for spine surgical procedure of inserting screws in vertebral pedicles, all these templates being manufactured using RM processes. This approach represents an alternative to the free-hand technique, which requires experience and has a long learning curve, or to the use of advanced imaging navigation systems, which are expensive and therefore not available in all hospitals. Due to anatomical issues, an accurate placement of screws in cervical spine and mid and upper thoracic spine is a difficult task. During surgery, after exposure, the visual identification of the screw entry point is followed by several steps, which are repeated at each spine level: cannulating the pedicle along the planne

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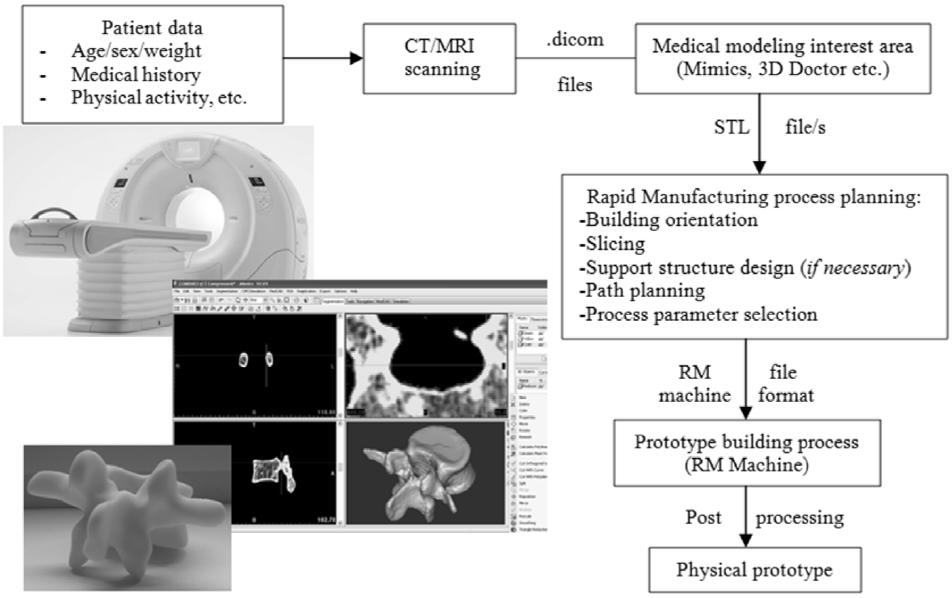

Fig. 1. Standard workflow for the design and rapid manufacturing of prototypes for medical applications.

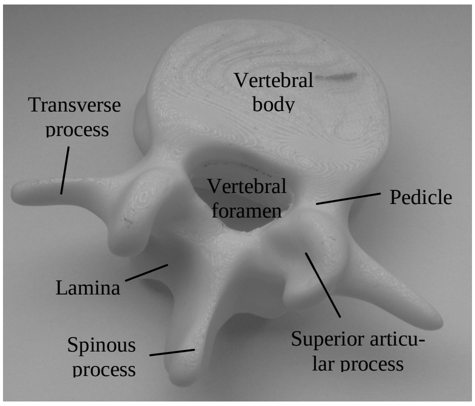

Fig. 2. FDM prototype of L3 vertebra.

trajectory, probing in order to find potential pedicle breaches, tapping and inserting the screw.

Moreover, surgical templates are very useful in percutaneous medical procedures and for reducing the X-ray radiation exposure during surgery. Their use was clinical proved to increase accuracy by transferring the tools trajectories from computer-aided planning to surgery for different types of surgeries (orthopedics, cranio-maxillofacial, etc.). Specific design criteria for pedicle screw guiding templates, anatomical landmarks, as well as aspects regarding the material issues and Rapid Manufacturing methods are discussed in this paper. Based on this analysis, several proposals for improving the spinal drill guides placement precision are presented.

2. PATIENT-SPECIFIC GUIDES FOR PEDICLE SCREW INSERTION

Currently, an increase of the reliability and accuracy of implantation techniques or other orthopaedic surgery procedures is possible with the use of intra-operative radiological control. The irradiation during these procedures is higher for percutaneous surgery in which, for making the incisions as small as possible, the anatomical landmarks identification requires the use of interventional radiology. In the last couple of years, intra-operative navigation system were developed and implemented in the operation room for visualizing the patient anatomical structure without the use of interventional radiology. However this approach, based on pre-operative images acquisition and on an anatomical landmarks system set at the beginning of surgical intervention, still presents problems due to a very complicated calibration process and to the fact that the static landmarks established at the beginning of surgery do not always maintain their position during the whole surgical procedure, which obviously leads to imprecision. In this context, the use of patient specific surgical templates which guides the cutting, drilling or tapping trajectories required for preparing the bones for screws, rods or plates implantation and fixation, offer a higher precision because are personalized to the patient and are designed to respond to the surgeon requirements, i.e. from a constructive-functional point of view they offer all the elements for an efficient utilization – dimensions, shapes, adjustment possibilities, material properties, etc. and for an ergonomically point of view are easy to use and place in a correct position during surgery. These patient-specific templates are used, for example, as cutting blocks or as positioning jigs in hip or knee surgery [9 and 10], as drilling guides for increasing implantation accuracy in spine, dental or reconstructive skull defects surgeries [3].

Screws placement in vertebrae pedicles is a frequently used procedure for the posterior stabilization of the spine with documented advantages over other methods of spinal fixation. Its difficulty is related to the small dimensions of pedicles (especially for cervical and upper thoracic vertebrae), to their variability in terms of dimensions, shape and spatial orientation (especially for patients with spinal deformities), as well as to the vicinity of nerve roots and vascular structures. Therefore, for increasing screws implantation accuracy in vertebrae pedicles, drilling guides customized for each patient and each vertebral level can be used (Fig. 3).

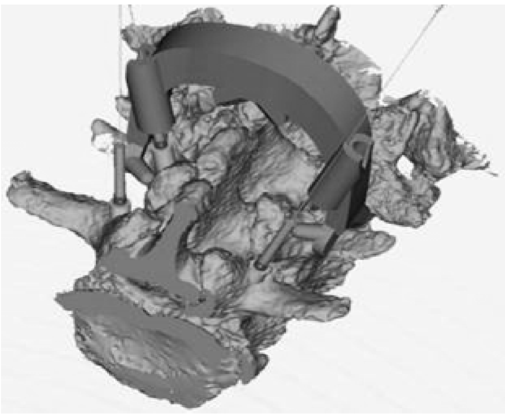

Fig. 3. Design of a guide for pedicle screws implantation [11].

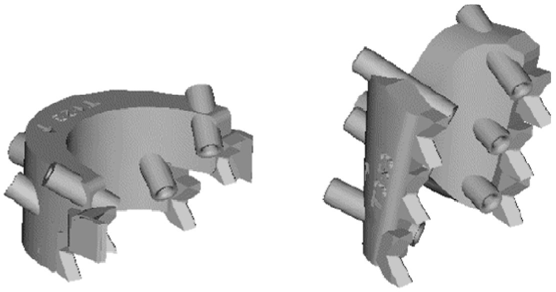

Fig. 4. Multiple guides design for pedicle screw insertion [12].

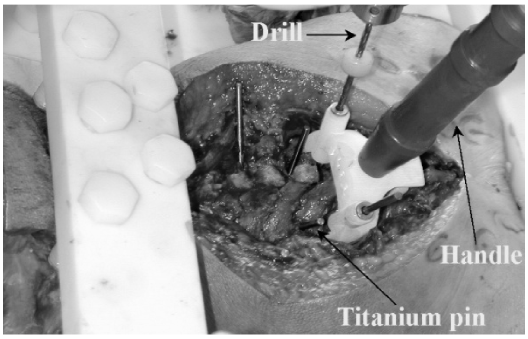

Fig. 5. Multiple guides for pedicle screw insertion – intra-operative image [12].

The use of patient-specific surgical guides was first reported by Van Brussel et al. [11] for inserting pedicle screws in vertebral spine. These devices were built based on the 3D medical model of the patient' spine and they used the spinous process as a negative for shaping the guides. Based on this work, Berry et al. [12] proposed different designs for cervical, thoracic and lumbar spine, for one level of the spine or for multiple levels (Fig. 4). Figure 5 presents an intra-operative image showing the use of a drill guide from duraform polyamide manufactured with SLS process [12].

Also, Porada et al. [13] describes a design methodology for a personalized drill guide, the drilling trajectories being specified in the planning software and then imported in Mechanical Desktop for designing the guide. The prototype is designed to materialize the drilling paths, its shape being built as supported on the transverse and spinous processes (Fig. 6). Another design criterion is the stability, the guide being held by surgeon with hand during surgery. Moreover, the shape of this guide is designed so that to be placed in the correct position without the excision of too much soft tissue, which is not the

Fig. 6. Pedicle screw insertion design with V-shape knife edges – intra-operative image [13].

case with other solutions using surface-surface fit approach [14 and 15]. The drilling guides designed and manufactured using laser sintering process were tested for validating the design and for assessing the accuracy and repeatability in use.

Birnbaum [16] also uses the reverse engineering approach, based on patient scanning data, for designing a drill guide for pedicle screw spine implantation. The novelty proposed is that the guide is manufactured from a transparent material which contributes to a better placement of the guides surfaces over the vertebra bone surfaces.

In [17] the authors present a drill guiding device for inserting screws in vertebral pedicle manufactured via FDM from medical ABS. The guide is designed as a block of material, the 3D model of the vertebra and of the guide being obtained using an in-house software package (Fig. 7). The guide is materializing the traditional insertion trajectory along the pedicle axis, no attention being paid to the ergonomic issues (the template being difficult to use due to its shape).

Goffin et al. [18] designed two spinal drilling templates with clamps, one connected only to the lamina of the second cervical vertebra, not considering the spinous process as interface, while the other was connected to the lamina and also interfacing the spinous process. These designs were tested on a cadaver and the results showed that the first device could not provide enough stability and accuracy.

Ryken et al. presents two studies regarding the design of personalized drilling guide for cervical pedicle screws implantation. The first study is assessing the feasibility of different RM process for manufacturing spine surgical templates, based on patient CT data and on predefined drilling trajectories [15], while the second study [19] is a laboratory investigation in which the designed guide is used for placing 3.5mm pedicle screws in C3-7 vertebrae of 4 cadavers. The drilling template fits the posterior

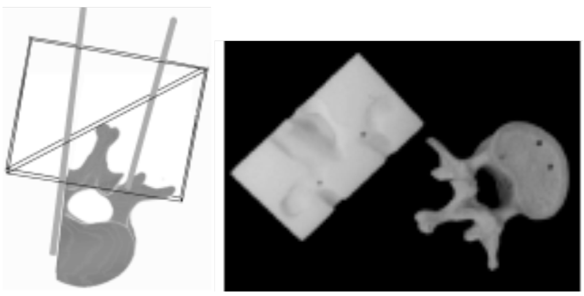

Fig. 7. Design of a block guide for pedicle screw insertion [17].

Fig. 8. Design of a drill guide placed on a cadaver vertebra [19].

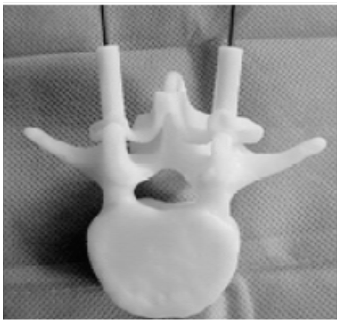

Fig. 9. Virtual and physical prototype of a spinal drilling guide for lumbar spine [22].

surface of the cervical vertebra providing a larger contact surface (Fig. 8). This solution provides better stability, but requires the removal of soft tissue in order for the guide to come in contact with the vertebra bone structure.

Also, Owen presents in [20] a design for a drill guide to match, in a surface-surface manner, the posterior surface of the right side of the fifth cervical vertebra.

Lu et al. [14, 21, and 22] presents the design process of two surgical guides for cervical vertebra C2 and lumbar vertebra L2, modelled in a surface-surface manner. A 3D model of the vertebra is built in Mimics and then exported in UG Imageware for determining the screw diameter and pedicle orientation. The insertion trajectory is along pedicle axis and it is established by the surgeon based on the patient scanning data, bone quality, pedicle orientation, etc. The guide is designed, as the most part of the solutions presented in the literature, considering the spinous process as major anatomical landmark. The prototype was manufactured using a medical polymer, Somos 14120, on a SLA machine. The accuracy of the drill templates was tested [22] on 9 patients for positioning 17 pedicle screws (Fig. 9).

The study presented by Ma [23] is dedicated to the development of drilling guides for thoracic spine. The standard approach already discussed is applied, the guide being designed as a negative of the posterior vertebral surface. Comparison between the accuracy of pedicle screw insertion with and without a guide is made for 214 screws. The results showed an improvement of screw placement precision with the use of navigational templates, the evaluation being made on plain radiographies and CT scans. Also, this paper gives information on the time necessary to design and manufacture a drill guide for one vertebra (1h) and the cost of material and manufacturing (50USD).

A design novelty is proposed by Kashani in [24]. Based on CT scanning data of a patient spine, a surgical drilling guide which fit on the vertebra surfaces is designed for providing the possibility of changing the drill diameter.

Salako presents in [25] two designs, one based on a surface-surface registration method and the other on a point-to-surface registration method with 6 supporting points, both using as main landmark the spinous process. The second design has the particularity of being reusable, by changing the position of drill guide components, but due to its complexity and relatively large number of parts, we consider it difficult to use during surgery. Moreover, comparing to other research presented above, no clinical studies were performed for testing this design.

Literature mentions also design solutions which are materialized by metal guides [26 and 27], but these are not considered in the current paper.

2.1. Design criteria

The surgical guides personalized for each patient must be designed so that their positioning and orientation during surgery to ensure: stability, unique placement, precision, easy placement and use, as well to offer possibilities for checking position (e.g. transparency or control probes). Also, the drill guides should be designed to be placed and pressed by hand in the right position and they must maintain this position along the whole surgical procedure.

The most important part of the design process is to establish the anatomical landmarks and the number and position of supporting points in order to satisfy the already mentioned conditions. These issues are also patient-dependent and they are established by the surgeon in the planning stage of the surgery. Pre-operatively, analysing the bone quality and CT/MRI scans of the interest area/s (for determining the pedicle isthmus and pedicle orientation) and according to the specific surgical approach and chosen entry points for the screws, the surgeon establishes the available bone surface and anatomical reference system, insertion direction, diameters for the K-wires, diameter and length of the screw/s and desired safety limits.

The drilling guides for inserting pedicle screws should contain as common geometrical features:

1. Cylinders, which materialize the planned drilling trajectories and indicate the depth of the drilling;

2. Supports, designed in relation to the anatomical landmarks for ensuring placement stability (avoiding rotation during use) and a unique positioning of the guide on the vertebra;

3. Connection arches, for linking cylinders and supports in an ergonomic manner.

There are several possibilities to design these supports starting from the available anatomical landmarks. The first approach is to consider the guide shape as negative of the vertebra bone surface (which requires accurate tissue excision from the posterior surface of the vertebra). The other approach uses V- or U-shape knife edge supports to fit on the transverse process, spinous process and/or lamina.

Research showed that, in order to increase guide placement accuracy on the vertebra, spinous process should be mandatory used as reference. Therefore, the guide could be designed as the negative shape of the spinous process or could have V or U knife-shape edges to support on the spinous process. Also, in case of guides containing V-shape knife edges for supporting on lamina or/and transverse process, these should be positioned as closed laterally as possible from the spinous process, while maintaining stability.

Regarding the design of connection arches, geometrical features which can allow the use of a handle are preferred. This handle helps the surgeon to press the drill guide in place and to maintain it in this position along surgery and it can be reused after sterilization.

2.2. Material issues

The main conditions for the material of the surgical guide are biocompatibility, sterilization and price. Autoclaving involves changes in some properties of materials (such as dimensional stability, deformation, water absorption or mechanical properties), Berry et al. mentioning in [12] that duraform polyamide, as an example, satisfies the above mentioned conditions.

Also, Bibb et al. [8] describe the advantages of using patient specific drill guides using Rapid Manufacturing processes (such as Stereolithography), and considers the material issue, mentioning that plastics are not entirely suitable for these applications due to the danger of small chips removal during the drill use. Therefore, metallic prototypes are presented as an alternative, being manufacture using Selective Laser Melting process. In this case, a higher cost of these devices should be considered.

2.3. Accuracy evaluation of the pedicle screw placement

Screws placement in the vertebra pedicle is firstly evaluated during surgery by palpation and then post-operative using plain radiography in two planes (transverse and sagittal) or CT scans.

Literature [28-29] presents several classifications for evaluating pedicle screw position, which considers two classes (“in” or “out”), three classes (“in”, “out” and “questionable”) or four classes (“entirely within the pedicle”, “medial or lateral pedicle wall breach less than 2 mm”, “medial or lateral pedicle wall breach equal to 2-4 mm”, “medial or lateral wall breach more than 4 mm”).

The most comprehensive screw position classification is proposed by Zdichavsky [30] and it is based on comparing the position of the pedicle screw and its diameter in relation to the pedicle and the vertebral body, six cases being possible.

Also [31] presents the framework for a training systems which uses Competitive Hopfield Neural Networks for the automate determination of the pedicle screw position within a polyurethane test vertebra.

4. DISCUSSION AND CONCLUSIONS

The main conclusion of literature analysis shows the advantages of using patient specific guides for accurately transferring the tools trajectories from computer-aided planning to surgery.

This conclusion is based on the clinical tests performed using different designs, which shows not only an accuracy improvement but also a decrease of the surgery time. Also, RM proved to be suitable for these types of applications, their accuracy, prototypes stiffness and materials range satisfy the imposed criteria.

In all analysed papers the guides design starts from patient CT/MRI data and includes the same steps for obtaining the drill guide virtual prototype (medical modelling of the anatomical areas of interest, choosing the landmark system and the number of supporting points/surfaces, planning surgery and then designing the guide accordingly using a reverse engineering approach and, usually, a commercial 3D CAD software) as described in Fig. 1.

The drilling guide designs are different due to the landmark systems used in the modelling process. However, middle posterior surface of the spinous process represent an anatomical reference used by all the researchers and, in order to improve stability, supports are designed to fit also transverse process in a point-to-surface or surface-to-surface approach. Also, all the guides have support structures which are in contact with the posterior surface of lamina and/or transverse process.

The most recent works in the field presents drilling guides with surface-surface fit between the vertebra and the template, case in which the positioning precision of the template depends on the accuracy of soft tissue removal. In this context and in order to increase the placement precision, we propose to build the guides from transparent material. This solution can be applied if Stereolithography is used as a manufacturing process.

Also, we propose that all the guides to have holes for inserting probes with scales for verifying the correct placement of the guide, before executing the drill, by comparing the measured dimension with the corresponding dimension from the medical virtual model.

In this sense a design solution is presented in Fig. 10 and uses the surface of the spinous process as main reference in a surface-to-surface approach, while the other points of support are on the transverse process.

The guide design includes as geometrical feature three holes for inserting probes with scale, which help assessing the correct positioning of the guide on the vertebra.

We also propose the development in a collaborating environment of a working protocol for design/manufacturing guiding device for orthopaedics surgery, by integrating different sets of tools, applications

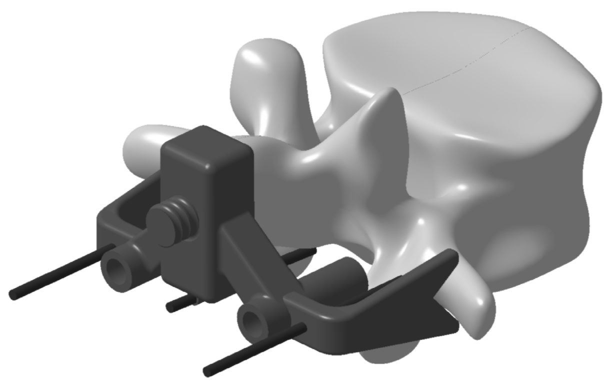

Fig. 10. Design of a drill guide for L3 vertebra.

and advanced medical modelling methods with CAD, CAE, CAM, Reverse Engineering (RE) and RM techniques. This way the exchange of medical and technical information is facilitated and a degree of automation is ensured to a process which otherwise has to be totally resumed for each patient/clinical case.

ACKNOWLEDGEMENTS: The work has been co-funded by the Sectoral Operational Programme Human Resources Development 2007-2013 of the Romanian Ministry of Labour, Family and Social Protection through the Financial Agreement POSDRU/89/1.5/S/62557.

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