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ORIGINAL ARTICLE

An automatic and patient-specific algorithm to design the optimal insertion direction of pedicle screws for spine surgery templates

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Abstract Many diseases of the spine require surgical treatments that are currently performed based on the experience of the surgeon. For pedicle arthrodesis surgery, two critical factors must be addressed: Screws must be applied correctly and exposure to harmful radiation must be avoided. The incorrect positioning of the screws may cause operating failures that lead to subsequent reoperations, an increase in the overall duration of surgery and, therefore, more harmful, real-time X-ray checks. In this paper, the authors solve these problems by developing a method to realize a customized surgical template that acts as a drilling template. The template has two cylindrical guides that follow a correct trajectory previously calculated by means of an automatic algorithm generated on the basis of a vertebra CAD model for a specific patient. The surgeon sets the template (drilling guides) on the patient's vertebra and safely applies the screws. Three surgical interventions for spinal stabilization have been performed using the template. These have had excellent results with regard to the accuracy of the screw positioning, reduction of the overall duration of the intervention, and reduction of the number of times the patient was exposed to X-rays.

Keywords Spine surgery · Surgical template · Pedicle arthrodesis · Screw direction optimization · X-ray minimization

1 Introduction

The goal of this current work is the realization of a customized surgical template through a rapid manufacturing process—that is, a fabrication technique such as 3D printing for manufacturing solid objects—for pedicle screw insertion into the vertebrae. The procedure presented in this paper allows us to optimize screws' insertion direction inside the pedicle. The access point is chosen by the surgeon based on his own experience. The optimum insertion direction as well as the length and diameter of the screws are defined using a novel automatic algorithm [30] that follows a patient-specific vertebra computer-aided design (CAD) model obtained through a reverse engineering operation [31]. Using this procedure, the surgeon needs only to place the template on the selected area and put the screws inside special guides designed for specific vertebrae. This approach represents an alternative to the freehand technique, which is difficult and time-consuming to learn and requires considerable experience; another technique could be the use of advanced imaging navigation systems, which are expensive and unavailable in most hospitals globally. The surgical template is a support that guides the surgeon during several types of surgery that require the insertion

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of screws into a patient's bone. In this study, the template allows optimal positioning of pedicle screws into the vertebral body, drastically reducing the risk of a vertebra fracturing during surgery or screws that could subsequently come out of the vertebral body, affecting nervous or vascular systems. Furthermore, the customized surgical template allows for drastic reduction of intervention time, resulting in less stress for both patient and surgeon, reducing the probability of failure. Further advantages are reduction of patient blood loss, reduction of drugs administered, and a drastic reduction of exposure to X-rays to both the surgical staff and the patient.

2 State of the art

For posterior stabilization of the spine, a frequently used procedure is screw placement in vertebrae pedicles [23]. The small size of pedicles, the variability of their geometries and orientation (for example, due to spinal deformities), and the existence of nerve roots and vascular structures near the pedicles can represent challenging issues that cause problems for screw placement.

Accurate screw placement in a vertebra has always been a difficult task. During surgery, visual identification of the screw entry point is made, followed by several steps that are repeated at each spine level: cannulating the pedicle along the planned trajectory, probing to find potential pedicle breaches, and tapping and inserting the screw. Today, the use of radiological control allows for an increase in the reliability and accuracy of implantation techniques. For accurate placement of screws, the use of surgical templates—widely used as cutting guide [8]—are also very useful for reducing X-ray exposure during surgery.

Two key problems encountered during such surgeries concern the choice of entry point for the screws and the direction of the insertion. Surgeons literally must guess the correct entry point and direction. Once the entry point is fixed and the surgery has begun, even the most experienced surgeons may have to adjust or correct the direction of the screws. Incorrect positioning may cause operating failures, subsequent operations, and an increase in duration of surgeries, resulting in multiple harmful real-time X-ray checks [23]. In this work, we focused our attention on the insertion of pedicle screws inside vertebrae.

Over the last several years, operative navigation systems have allowed visualization of a patient's anatomical structure in the operating room without the use of interventional radiology. However, this approach is based on preoperative image acquisition and relies on an anatomical landmark system set at the beginning of surgical intervention; this still presents problems: First, the calibration process is complex, and second, the marks established at the beginning of the surgery maintain their position throughout the entire procedure, which leads to imprecision (the system is static and the spine itself can move) [23]. In this context, the use of patient-specific surgical templates offers more precision because the templates are personalized and designed to respond to the needs of the surgeon (the choice of the entry point and the knowledge about the optimal insertion direction). Further, from an ergonomic point of view, templates are easy to use and place correctly during surgery.

In the scientific literature, there are two different approaches for designing a template.

The first is to consider the shape of the guide as a negative of the vertebra bone surface. In this context, Van Brussel et al. [32] first introduced the use of patient-specific surgical guides for inserting pedicle screws in the spine in 1997; based on this work, the 2005 study by Berry et al. [3] proposed different designs for cervical, thoracic, and lumbar levels; in 2001, Porada et al. [24] presented a design procedure for a personalized drilling guide and Birnbaum [5] used a transparent material to produce the guides; in 2003, Yoo [34] fabricated a template using medical ABS; two additional studies on cervical level implantation [25, 26] showed predefined drilling trajectories and a laboratory investigation, respectively; in the second work, the template's larger contact surface provided better stability. In 2012, Ma et al. [15] compared the accuracy of pedicle screw insertion with and without a guide, proving that navigational templates improve screw placement precision. In 2012, Kashani [11] proposed a surgical drilling guide that offered the possibility of changing drill diameter, while Popescu el al. [22] demonstrated the framework for a training system that could automatically determine pedicle screw position.

The second approach uses supports to fit on the transverse process, the spinous process, or the lamina. Research has shown that increasing guide placement accuracy on the vertebra requires the mandatory use of spinous process as a reference. In this context, Goffin et al. [9] designed two templates with clamps: The first was not stable or accurate enough. It was connected only to the lamina of the second cervical vertebra without consideration of the spinous process as the interface. The second was connected to the lamina but also interfaced with the spinous process. Lu et al. [12–14] presented design processes for both cervical vertebra and lumbar vertebrae with an insertion trajectory along the pedicle axis. Salako also created two designs [27, 28]: The first was based on a surface–surface registration method, and the second on a point-to-surface registration method with six supporting points.

Concerning the preoperative definition of the ideal screw direction inside the vertebral body, most studies in the literature are based on prior identification of the ideal insertion direction of a screw chosen by an expert surgeon.

Recently, Sugawara et al. [29], using 3D design and printing technology, generated plastic templates with screw-guiding structures for each lamina for thoracic or cervicothoracic pathological entities; however, the trajectories were planned to penetrate the center of the pedicles using natural landmarks. In 2015, Kaneyama et al. [10] presented a midcervical pedicle screw insertion procedure with a template system that ensured accuracy and safety of the screw insertion by calculating screw deviation from the preplanned trajectory and evaluating screw breach of the pedicle wall. In this case, no optimized criteria were used for finding the right trajectories. Merc et al. [16] developed a method of pedicle screw placement in the lumbar and sacral regions using a multilevel drill guide template, created with the rapid prototyping technology and validated in a clinical study. In this latter case, the procedure was difficult to automate and required a cumbersome CAD procedure for finding the right trajectories for the surgical teams. Moreover, a multilevel template does not always guarantee excellent positioning. However, a few researchers, including Wiker and Tedla [33], developed a spinal surgery method that measured the smallest vertebra bow root diameter and used this to determine the best pedicle screw trajectory. Further, using the linear least-squares method, the researchers determined the optimal trajectories of each pedicle screw diameter and the maximum length [33]. A disadvantage of this method was that it allowed an eccentric trajectory determination—particularly for distorted pedicle anatomy—with consequent smaller maximum diameter and screw length determinations, resulting in biomechanically inferior constructions. In contrast, Pacheco [20] developed a procedure that always placed the trajectory concentrically through the pedicle. This procedure used the center point of the smallest cross-sectional area (isthmus) and then projected a computer line perpendicular to this circumscribed area in opposite directions, thereby determining the optimum trajectory. In Popescu et al. [21] presented a computer-aided methodology for generating the best trajectory for pedicle screw insertion. They used a commercial 3D CAD system for determining the pedicle insertion trajectory and calculating the pedicle isthmus. The external surfaces of the pedicle were sectioned with successive planes, each parallel to the coronal plane; the centers of each section were determined and then the axis line was generated, approximately equidistant from all the center points (mean line). The size of the screw was chosen as suitable for the smallest diameter of the pedicle based on the sections previously determined, with the thickness and cross section of the pedicle varying along its length.

The procedure presented in this current paper allows us to optimize the guide direction of a surgery template of pedicle screws to ensure that they are properly inserted inside the pedicle, starting from an access point chosen by the surgeon based on his experience. The optimum insertion direction, as well as the length and diameter of the screws are defined by means of a novel automatic algorithm [30] based on a patient-specific vertebra CAD model that is obtained by a reverse engineering operation [31].

3 Materials and methods

Currently, CAD/CAM software programs are widely used in the biomedical sector, not only for reconstruction that begins with medical images of biological tissues and for the realization of complex bone scaffolds [2, 17–19] but also for the design/production of devices auxiliary to classic procedures of surgery (for example, designing templates for screw placement). In our study, the realization of the template consisted of these basic steps:

- 3D CAD reconstruction of the vertebrae;
- Determination of the optimum insertion direction, plus the length and diameter of the pedicle screws using an automatic algorithm;
- 3D modeling of the template;
- Realization of the physical template model.

3.1 3D CAD reconstruction of the vertebra

The subject's spinal tract was acquired by CT scan. Using a medical image processing commercial software, the scan was segmented and rebuilt in a 3D workspace environment (see Fig. 1).

The 3D reconstruction of the vertebrae was imported into the CAD software Rhinoceros, used for 3D modeling of sculptured surfaces (free form). In Rhinoceros, all geometric entities are represented by non-uniform rational B-splines or NURBS. For the sake of simplicity, the characteristic planes of the spine (coronal, sagittal, and transverse planes) are assumed to be parallel to those of the CT machines scan reference system (see Fig. 2).

3.2 Determination of the optimum insertion direction, as well as length and diameter of pedicle screws by means of an automatic algorithm

In standard European operating practice, the straight line defining the ideal direction for screw insertion, should pass through the geometric center of the pedicle as well as through the external entry point. Once this external point is defined and identified, the surgeon then inserts the screw into the pedicle and, while remaining within the boundaries of the vertebra, ensures that the screw is inserted 80%

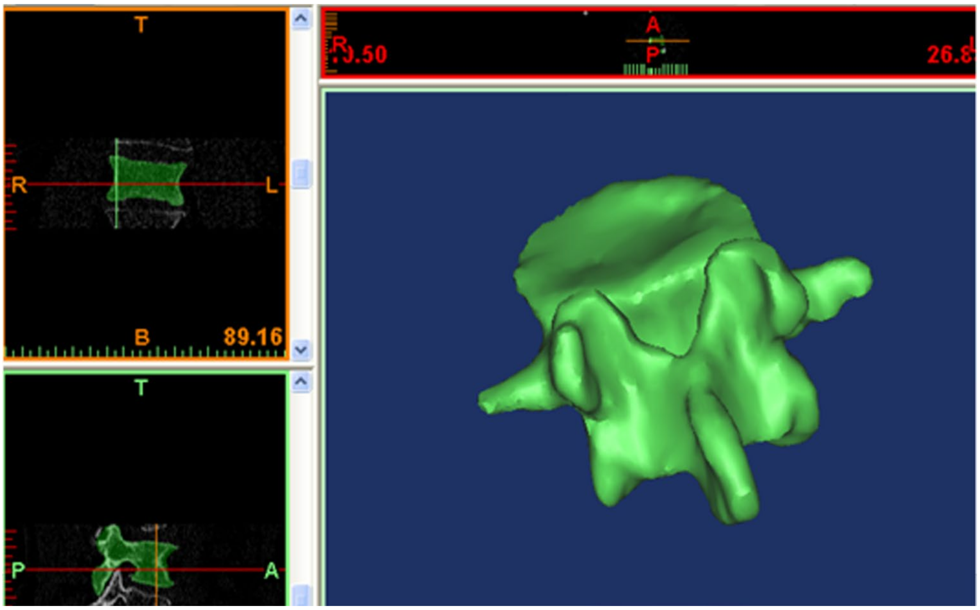

Fig. 1 3D model visualized in mimics

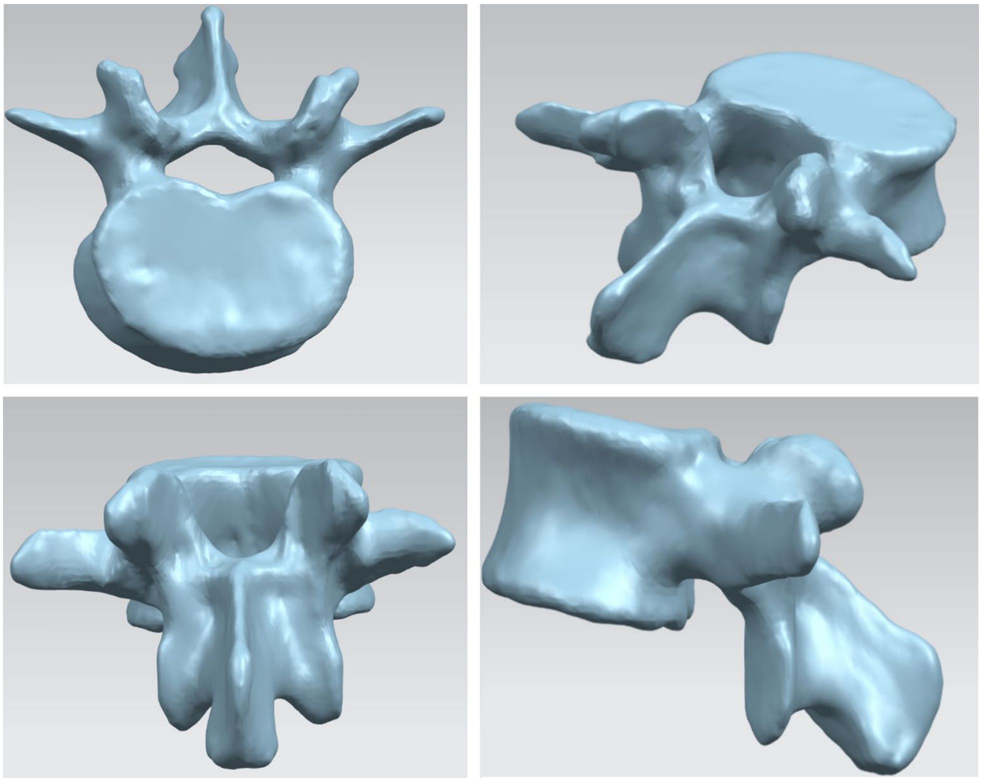

Fig. 2 Representation of the characteristic planes of the spine (coronal, sagittal, and transverse planes) on a vertebrae model imported into a Rhinoceros environment

of the depth of the vertebral body and becomes durable. The possibility of the screw—or even a short section of it—escaping the pedicle or the vertebral body could find it positioned within (or outside of) the vertebral hole; this is to be absolutely avoided since it could lead to a rupture of the pedicle or, worse, injuries to the circulatory or nervous structures. The orthogonal display mode in Rhinoceros makes it both simple and intuitive (even for a relatively inexperienced CAD user, such as a surgeon) to find the entry point on the pedicle. For example, in Fig. 3, we have

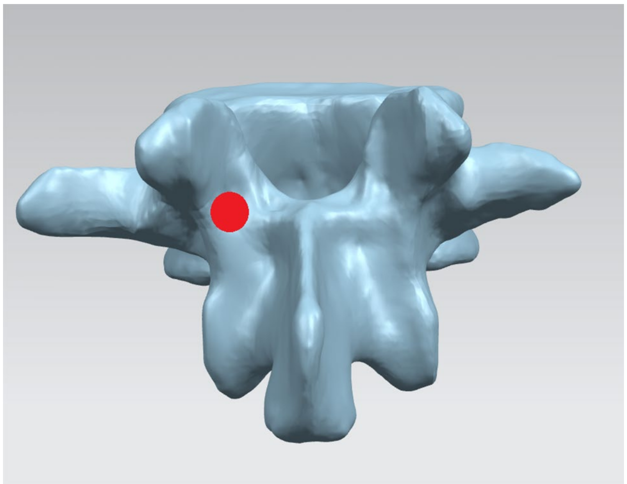

Fig. 3 Marker that defines the entry point of the pedicle screw inside the vertebral body

chosen a point directly under the facet joint, as is the usual procedure in Europe. The bundle of straight lines from which the ideal one must be chosen must necessarily pass through the marker above.

In this study, an automatic algorithm is used to identify the screw's ideal insertion direction. The algorithm works on pedicles, one at a time, and is based on purely geometrical unilateral constraints that make up the 3D workspace through which the screw must pass.

The algorithm for the identification of "optimum direction" for insertion of pedicle screws is written in a single source code using ANSYS Parametric Design Language (APDL). It inputs the three-dimensional CAD geometry of the external surface of the vertebrae in a file format [6] that can be imported by ANSYS software (IGES, CATIA, CATIA V5, PARASOLID, etc.). The algorithm consists of the following steps, described and accompanied by images in which the external surface of the pedicle is represented by a toroid, allowing for easier understanding of the implemented routine:

1. Identification of the three orthogonal planes of the vertebrae (sagittal, coronal, and transverse planes; see Fig. 2);
2. Location of the entry point "P" of the screw by the surgeon, based on his experience and judgment (see also Fig. 3);
3. Initial placement of the virtual "target surface" defined by any spherical cap having a radius length greater than the length of the pedicle, the center being the point "P" as defined in step 2;
4. Iterative cycle whereby, for each iteration, a point "p_i" lying within the "target surface" is randomly generated; simultaneously, the algorithm generates a straight line joining the points "P" and "p_i"; there is eventual deletion of the just-generated point "p_i" (and the straight line) if its relative line segment intersects the surface (defined in step 3) at least once. The cycle is interrupted when a predetermined number (depending on the desired level of accuracy) "n" of points on the "target area" is reached. This set of "n" points defines a new surface contained within the "target surface"; the generated segments—defining a sort of solid angle with its origin at the point "P" and its conclusion on a portion of the "target surface" defined by the points above—will be all contained inside the vertebrae (see Fig. 4);
5. Calculation of the centroid "C" of all the "n" defined points lying on the "target surface"; tracking the straight line $\overline{PC}$ will univocally define the "optimum direction" for the insertion of the pedicle screw (see Fig. 4);

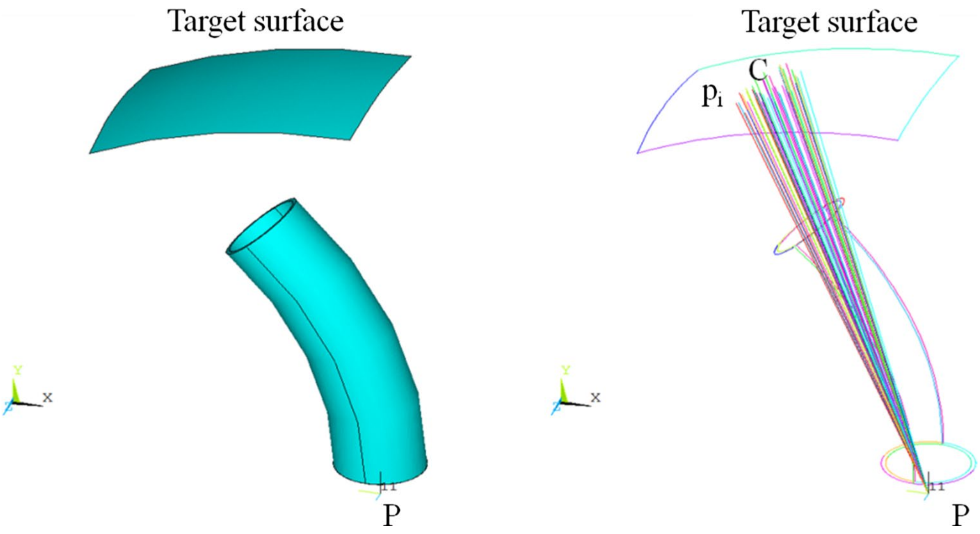

Fig. 4 Schematic representation of the solid angle (*right*) formed by the permitted insertion directions of the screw. For visualization purposes, the external surface of the pedicle (*left*) is represented by a toroid

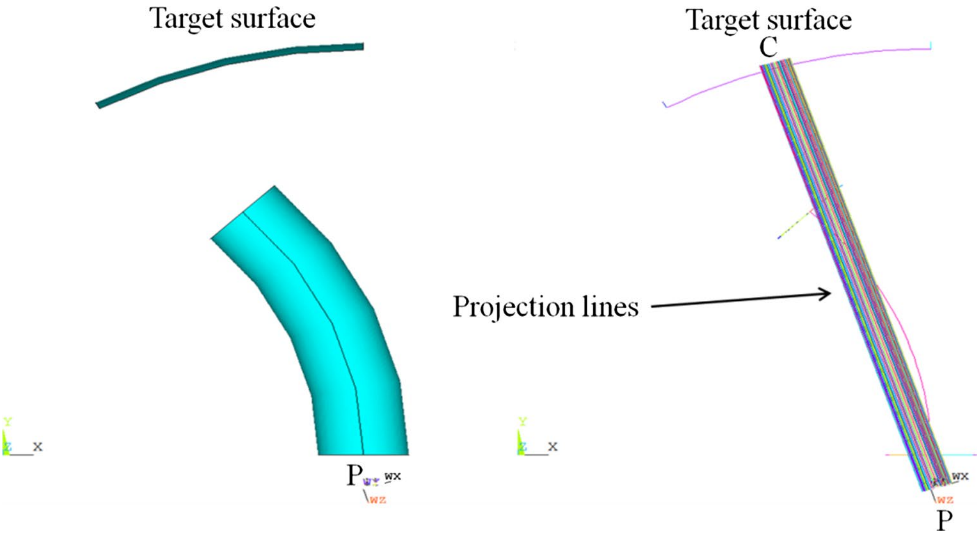

Fig. 5 Projection lines (*right*) used to create the crossing zone projection on the plane perpendicular to the optimum direction

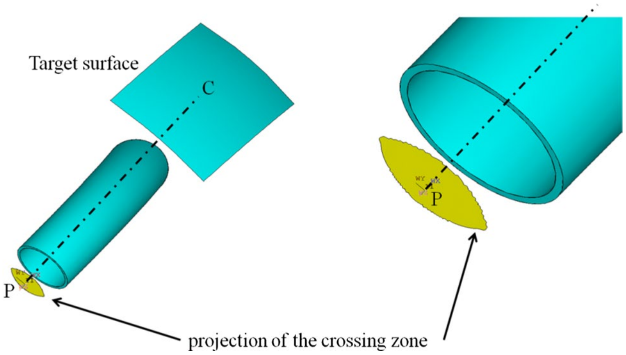

Fig. 6 *Left* optimum direction $\overline{\mathrm{PC}}$. *Right* crossing zone projection on the plane perpendicular to the optimum direction

6. Definition of the plane perpendicular to the "optimum direction";
7. Projection on the plane, identified in step 6, of the crossing zone and the line segment that defines the "optimum direction" (which degenerates into a point; see Figs. 5, 6);
8. Sizing of the screws' diameter "*D*" using a safety coefficient "*k*" with the dimensions, taking into account both the size of the projected area referred to in step 7 and bone density (based on the number of Hounsfield); this gives us information on the average thickness of the vertebrae's cortical bone. A routine calculates the minimum distance $d_{\min}$ between the perimeter of the projected surface, described in step 7, and the projection of the point "*P*." The radius of a screw is defined as: $R = kd_{\min}$ (see Fig. 7);
9. Determination of the maximum length of the pedicle screw: identification of a closed surface (defined by joining the sagittal plane, identified in step 1) and the surface obtained by cutting the whole external surface of the vertebra with the sagittal plane. Generation of the segment end points "*P*" (identified by the surgeon), the intersection point of the "optimum direction" (defined in step 6), and the closed surface above. The length "*L*" of this segment represents a reference for determining the length of the pedicle screw "L_s." To select an appropriate safety coefficient $h \in [0, 1]$, the length of the screw is defined as $L_s = Lh$. In this way, there is a guarantee that the screw tip goes into the vertebral body but not beyond the semi-vertebra and, therefore, does not come into contact with other screws.

The flowchart describing the algorithm's fundamental steps for finding the optimum direction and sizing the pedicle screw is shown in Fig. 8.

3.3 3D modeling of the template

Surgical templates personalized for individual patients must be designed to ensure stability, unique placement capability, precision, and easy placement/use; additionally, they must allow for the possibility of position checking (e.g., transparency probes). Furthermore, after a template has been placed and pressed by hand into the correct position, the template must maintain this position throughout the entire surgical procedure. This design element establishes the anatomical landmarks and position of the supporting points/surfaces to satisfy these conditions. In the procedure proposed herein, the surgeon preoperatively determines the available bone surface and the access point, whereas the algorithm defines the insertion direction, diameter for the Kirschner wire, diameter and length of the screws, and the desired safety limits.

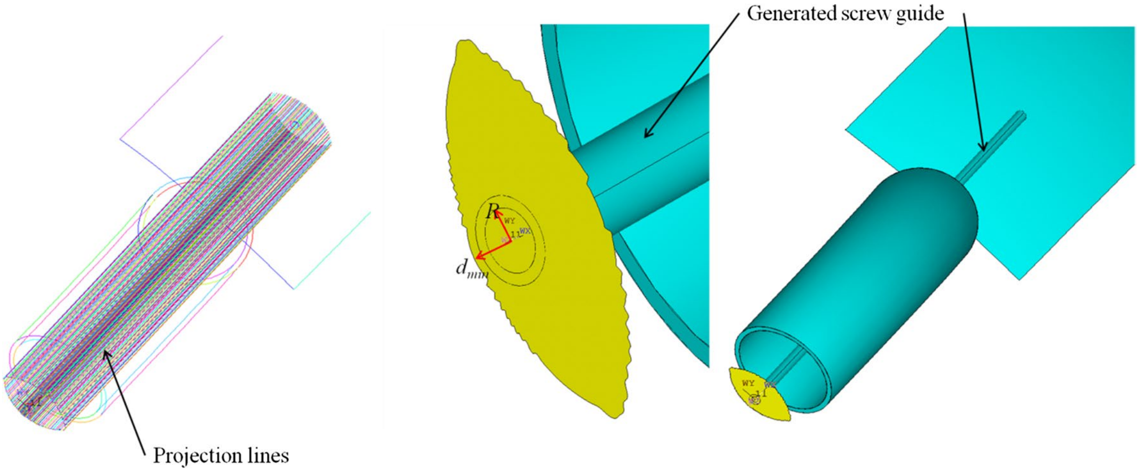

Fig. 7 *Left* projection lines. *Center* representation of d_{min} and *R*. *Right* schematic representation of the generated screw guide having the optimum direction as axis

The template proposed for this work is characterized by the presence of:

- Cylinders that act as guides for the planned drilling trajectories and indicate the depth of drilling;
- Supports designed in relation to anatomical landmarks and intended to ensure placement stability (i.e., preventing rotation during use), and the unique positioning of the guide on the vertebra;
- Connection elements for linking cylinders and supports in an ergonomic manner as needed.

We have filed a patent for this work [30, 31] that adopts the approach of using supports to fit the transverse process, the spinous process, and the lamina. As previously stated and reported in the literature, the use of spinous process as a reference should be mandatory to increase guide placement accuracy on the vertebrae.

To maintain the direction defined by the above-described algorithm (see Sect. 3.2), the surface of the template in contact with a vertebra has to match the external surface of the selected vertebra. This approach ensures the stability of the device during surgery; a poorly modeled template could affect the outcome, with serious consequences for the patient.

The template should have some anchor points. When operations are performed using rear access, we have observed that, in the course of surgery, the area that appears well skeletonized is the one closest to the spinous process; this appears to be a convenient anchoring element for positioning the template on the vertebra. The template should replicate the surface of the vertebra near the points of access to the pedicle. For this reason, the procedure used for creation of the templates involves selection of all the surfaces modeled as a triangle mesh (MESH approach) belonging to the areas of the spinal surface near the template, thereby setting up a single file that represents a polysurface.

This represents the "calque" of the area of the vertebra on which the template is used (see Fig. 9). Regarding the degree of approximation of the model, the vertebrae (even after skeletonization) shows surface irregularities that a micrometer reconstruction cannot handle. Therefore, on the one hand, it is desirable to maintain high levels of accuracy; on the other hand, we have a small bit of room that allows for deviation from the ideal configuration.

Exploiting the previously created axes that identify the optimum direction for drilling the pedicle, we proceed to create cylinders by modeling the surgeon's guide for the positioning of the metal drilling stems (see Fig. 10).

The length and shape of the tubular guides are chosen depending on the results of the application of the previously defined algorithm. The choice takes into consideration the geometrical critical issues and peculiarities specific to the case, as well as considering bone quality.

There are several methods for the 3D CAD modeling of the template. We have found that the MESH approach is more expensive in terms of human and machine operation time and provides results that are not esthetically excellent. However, the precision and accuracy of this approach obtains a true "calque" of the area of interest. A CAD model of the template is shown in Fig. 11, clearly showing its shape in different views, coupled with its corresponding vertebra.

3.4 Realization of the template's physical model

The main requirements for the choice of the surgical guide material are biocompatibility, ability to sterilize the

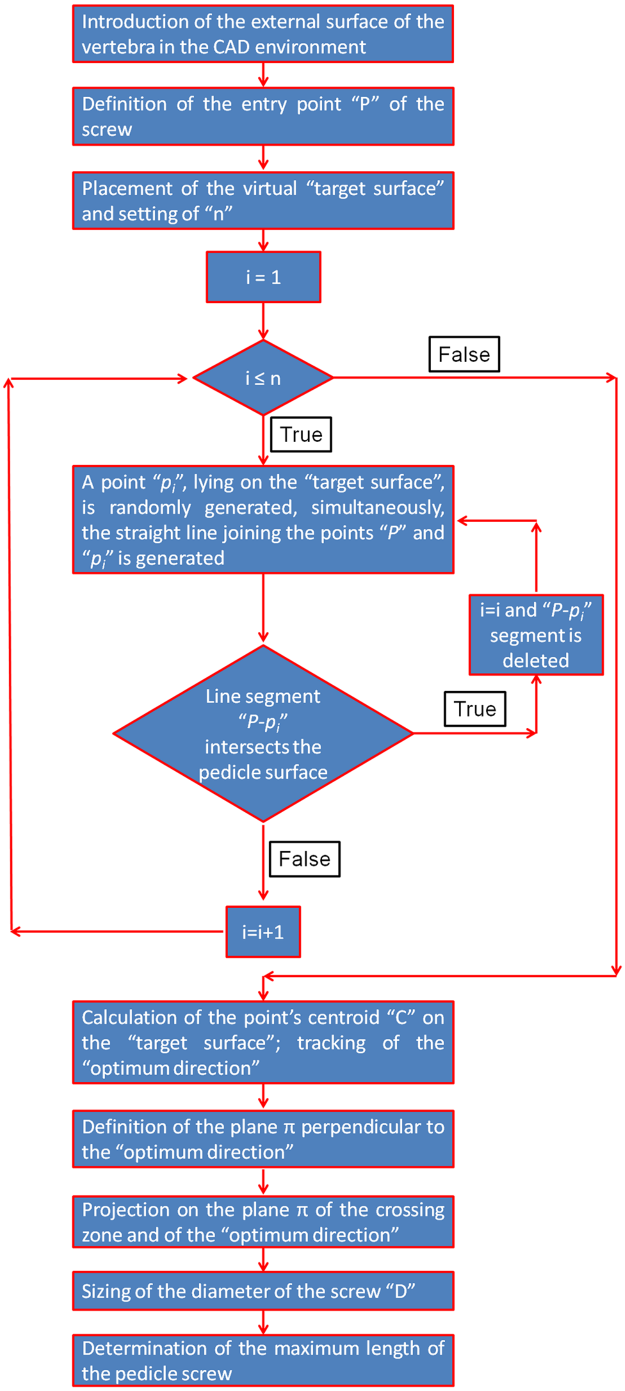

Fig. 8 Flowchart of the algorithm

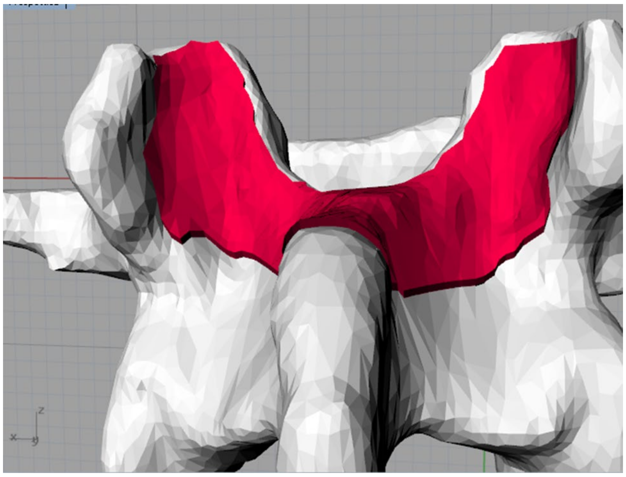

Fig. 9 Closed polysurface that represents the external surface of the template

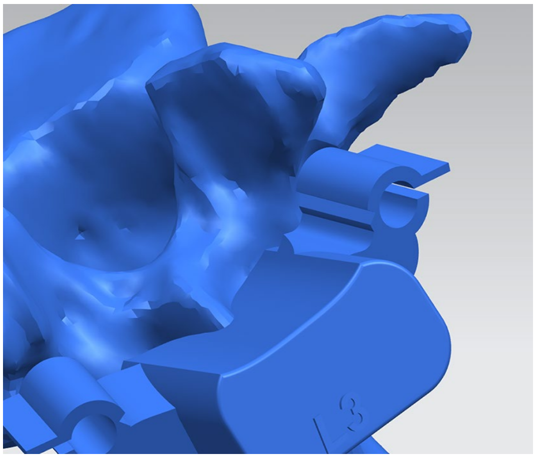

Fig. 10 Cylinder-shaped screw guide

material, and price. Autoclaving involves changes in some properties of a material, such as dimensional stability, shape, water absorption capabilities, or mechanical properties. Berry et al. mention in [3] that Duraform® polyamide, for example, satisfies the previously mentioned requirements. In addition, Bibb et al. [4] describe the advantages of using patient-specific drill guides made using Rapid Manufacturing processes (such as stereolithography). Bibb et al. [4] also consider the material issue, stating that plastics are not entirely suitable for these applications because small chips of plastic could break off when using the drill. Therefore, metallic prototypes are presented as an alternative to plastic. These are manufactured using a selective laser melting process. The higher cost of metallic devices should be taken into consideration.

When we considered the mechanical properties (stiffness/elasticity), biocompatibility, cost, and processing time, we turned our attention to polymeric biomaterials, such as photosensitive polyamide or MED610; in addition to good mechanical properties, these can be modeled easily at specific temperatures. The materials used to manufacture the surgical templates are certified for use in surgical interventions, as required by the UNI CEI EN ISO 13485. Our

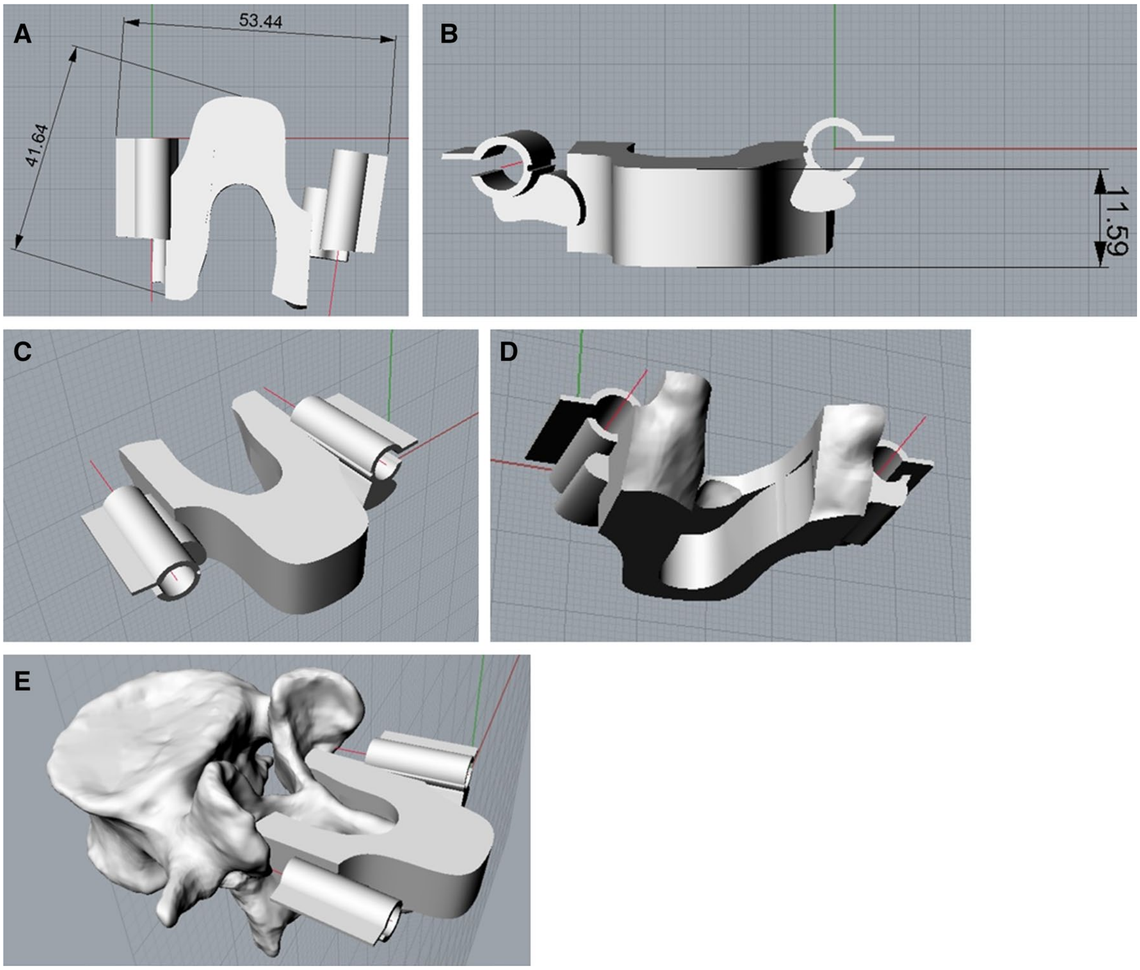

Fig. 11 **a** Top view. **b** Front view. **c** ISO front view. **d** ISO back-bottom. **e** Template coupled with vertebra

surgical template is a patient-specific device; in Europe, it does not need the CE mark (Law no. 46, 24 February 1997) but only generic approval by the Health Ministry toward the methodology of design, the manufacturing system, and the surgical procedure. These procedures are currently under assessment.

The templates were created using the following biocompatible materials: photosensitive polyamide and MED610. The prototyping technologies [7] used for this research were as follows: stereolithography, 3D photopolymerization technology, or selective laser sintering. The best results were obtained using the stereolithography technique using photosensitive polyamide as the basic material (see two examples in Fig. 12).

4 Results

Generally, the surgeries in question are characterized by a traditional rear opening and subsequent skeletonization for exposing the bone structure. For these operations, part of the supraspinous ligament is often removed, ensuring adequate exposure of the spinous process. In some cases, it is necessary to mill the vertebra's upper joints to ensure that screws can be inserted properly; in extreme cases, it may be necessary to do a laminectomy (that is, completely eliminating the lamina). The classic approach usually relies on a "pedicle probe" to identify the area of access that, in most cases, is located between the articular facet and the transverse process. The surgeon feels the geometry of the vertebra to identify the access points that are visible by means of X-ray but not visible in vivo (because of muscular structures and blood in the area). The surgical procedure continues with the insertion of a Kirschner wire (diameter from 2 to 3.5 mm) with corresponding X-ray controls tracking the insertion; together, this allows the surgeon to get an idea of the screw's trajectory. Generally, for each insertion, a minimum of two radiographic controls (on sagittal and coronal plane) are made. This routine is repeated until the trajectory is deemed appropriate, at which time the surgeon proceeds

Fig. 12 Drilling template prototyped models coupled with vertebrae models

to tapping the vertebra via the surgical screw tap (4 mm) and subsequent insertion of the screw (from 4.5 to 7 mm). The insertion of the screws usually requires a posteriori X-ray controls on the two planes above.

However, when the surgical template is used, part of the supraspinous ligament is first removed, ensuring adequate exposure of the spinous process. In some cases, as mentioned, it is necessary to mill the vertebra's upper joints to ensure the screws can be inserted properly. After preparations are complete, the template is applied manually, and the surgeon uses the template to perform a drilling test directly with the Kirschner frame or with a tap. Downstream of this operation, it is necessary to do a single radiographic control of vertebra to verify that the previously defined trajectories are good; at this point, the screws can be inserted. This procedure replaces the traditional procedure for the identification of both the pedicle and the ideal trajectory for screws, a procedure that involves longer time (stress and significant bleeding for the patient, stress and increased probability of error for the surgeon) and a longer exposure to X-rays for both the patient and the medical team. Furthermore, a reduction in the duration of a surgery implies a considerable cost reduction, as both personnel and equipment are used for a shorter period of time. Less time in surgery also implies less use of drugs and a consequent reduction in risks to the patient.

This procedure has been submitted to the Regional Ethical Committee for approval, and the surgeon who conducted the in vivo tests, under his own responsibility and after asking approval by the University Hospital's management, had used the new medical device and the new surgery procedure in several preclinical tests.

4.1 In vivo testing

4.1.1 First in vivo test

The in vivo tests were conducted after asking for and obtaining informed consent from the patients.

The first surgery involved the stabilization of the L2–L3–L4 levels to treat a lumbar spondylolisthesis at L4 level with a hernial protrusion. For this surgery, templates for L2 and L3 levels were prepared, primarily to evaluate the quality of screw insertions. The times required for L2 and L3 levels were compared with the time required for L4 level to determine the amount of reduction.

The templates were created by stereolithography prototyping using a biocompatible polyamide. The templates presented holes suitable only for Kirschner wire insertion. Completion of the templates required approximately 3 h.

It took about 100 min to insert two screws in L4 level (without the use of Dima) and 32 X-ray shots for the identification of pedicles and trajectories and to track the insertions of the screws.

In this particular case, the lumbar segment presented different polymorphisms that required careful skeletonization and removal of a large amount of bone tissue using a rongeur.

The orientation of the abnormal vertebra and the pedicular deformities had a negative impact on the time it took to detect pedicles and identify screw trajectories.

With the aid of the template in the L2 and L3 levels, the surgery took about 48 min and eight radiographic shots (initial trajectory control, insertion trajectory control, and final position control). The entire surgery for all three levels took a total of about 210 min.

Therefore, it was possible to estimate an application time for a screw of about 50 min without a template and 12 min using a template. Furthermore, we went from 16 radiographic shots per vertebra with no template to four radiographic shots with the template. The high quality of the screw insertions with the aid of the templates is shown in Fig. 13.

4.1.2 *Second in vivo test*

The second surgery involved a decompressive laminectomy with L3–L4–L5 stabilization to treat stenosis of the spinal canal with compression of a nerve root. For this surgery, a template for L5 level was created, and the time of the L5 level surgery was compared to that of the L3 and L4 levels to determine the amount of reduction.

The template was created through stereolithography prototyping using a biocompatible polyamide. The template also included an adapter that allowed for modulation of the Kirschner wire diameter. Furthermore, the template was strengthened with the introduction of connection elements (for linking cylinders) to ensure a satisfactory matching between the ideal and actual trajectories during the positioning and insertion phases of both the Kirschner wire and the screws (see Fig. 14). The creation of both the template and the adapters took approximately 120 min.

It took about 90 min to insert two screws in L3 and two screws in L4 (without the use of Dima) and 36 X-ray shots to identify pedicles and trajectories and track the insertions of the screws. In fact, many positioning errors occurred due to the morphology of the patient's spine. It took about 15 min of surgery and two radiographic shots (control trajectory and final screw position control) with the aid of the template for the level L5 (vertebra of which also presented a 13° rotation around the spine axis). The entire surgery for all three levels took about 180 min. Stabilization results are shown in Fig. 15.

In this second in vivo test, it took about 22.5 min for a screw insertion without a template and about 7.5 min using a template. Furthermore, we went from 18 radiographic shots for vertebra with no template to three radiographic shots with the template.

After those interventions, seven other surgeries have been conducted with very good results, using our guiding device (the surgical template) optimized in terms of the screws' guidance.

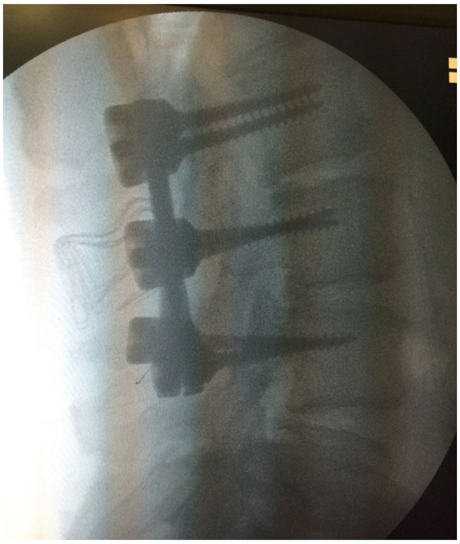

Fig. 13 Postsurgery radiographic shot in the coronal plane of the first in vivo test

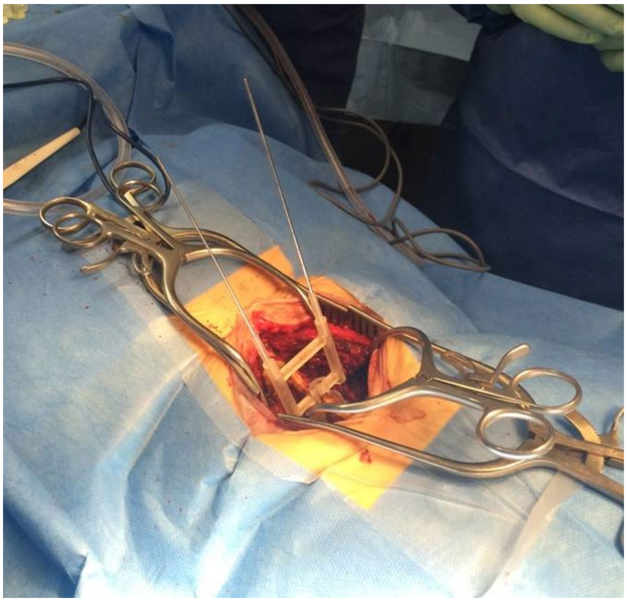

Fig. 14 Template with adapter and connection element

5 Discussion and perspectives

In this paper, we have presented a novel procedure for realizing a surgical template for pedicle screw insertions in the vertebrae. The template is manufactured using Rapid Manufacturing processes. The procedure allows us to optimize

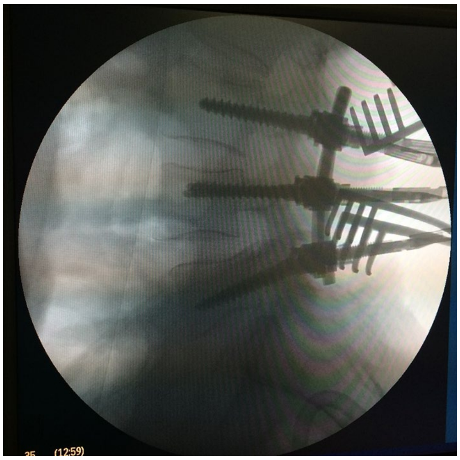

Fig. 15 Postsurgery radiographic shot in the coronal plane of the second in vivo test

the direction of screws to be inserted properly inside the pedicle's access point, chosen by the surgeon based on his own experience and according to his judgment. The optimum insertion direction and the length and diameter of the screws are defined by means of a novel automatic algorithm run based on a patient-specific reversed vertebra CAD model. In this procedure, the surgeon is required only to put the template on the chosen area and place the screws inside the special guides designed for that specific vertebra. This approach represents an alternative to the freehand technique (which requires considerable experience and a long learning curve) or to the use of advanced imaging navigation systems (expensive and not available in most hospitals). The use of this template allows for an optimized positioning of pedicle screws for insertion into the vertebral body. Use of a template drastically reduces the risk of screws coming out of the vertebral body and affecting the nervous or the vascular systems, or of the vertebra fracturing during the surgery. Furthermore, this procedure allows a drastic reduction of intervention times, resulting in reduced stress for both the patient and surgeon (reducing the probability of errors or failures), less bleeding for the patient, a reduction in the amount of drugs administered, and drastic reduction of exposure to X-rays for both the surgical staff and the patient.

After appropriately mediating the results—and even though the sample consists of only two elements that were obtained under different boundary conditions—in the present case we obtained the following results:

- Traditional procedure (no template): 36.25 min for a screw insertion and a total of 12.5 radiographic shots for each screw;
- Innovative procedure (with template): 9.5 min for a screw insertion with the aid of the template and two radiographic shots for each screw.

We must underscore that having used a novel experimental device, the surgeon paid great attention to carrying out the insertion of the screws. This led to a higher execution time. However, the duration of the surgeries fall within the range given by the local health trust of the Region Lazio [1]. For this reason, it is better to give importance to the percentage abatement of the average screw insertion time as measured with and without the template. In short, the time spent for the insertion of pedicle screws using the surgical template was reduced by approximately 74%, while the radiographic shots were reduced by approximately 84%. The surgery procedure remains the same but is improved in terms of precision, duration, and patient safety.

Furthermore, the creation of the template requires on average 1.5 man-hours and costs about 50 euros for the construction of the physical model (when creating it on behalf of a third party). The Italian Health Ministry Ethics Review Board approval has already been requested, and the tests of the proposed methodology (new surgery protocol) are now in progress on a wider sample of patients.

For future surgeries, the creation of templates for more complex geometries is planned; this will enable the treatment of vertebrae exhibiting excessive deformities by using created ad hoc substructures for the anchoring and stopping of the template on the vertebra.

Compliance with ethical standards

Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards.

Italian ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the Italian Law and have been approved by the Ethical Review Board of the San Giovanni di Dio e Ruggi di Aragona University Hospital in Salerno, where the trial/tests were conducted.

Informed consent All human participants have had the testing protocol explained, including the nature of the used medical devices and risks and benefits they might have while being treated with the new surgery device. Informed consent was obtained from all individual participants included in the study.

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