Modern Thoraco-Lumbar Implants for Spinal Fusion

Roberto Delfini Alessandro Landi Cristina Mancarella Fabrizio Gregori *Editors*

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Preface

Pathologies of the spine are one of the main reasons why the patient requires medical care, so in the last years, the number of spinal procedures performed worldwide has increased markedly. Thoraco-lumbar spine is the most affected segment by disc degenerative disease, trauma, tumour and infectious diseases, which are mainly treated with what is actually considered the gold standard: spinal fusion.

Despite the development of motion preservation surgical techniques, spinal fusion remains the most widely used technique in the world. A great effort has been made to develop new techniques for spinal fusion. Furthermore, great attention has been paid to reduce the invasiveness of both well established and new procedures and to improve the accuracy of pedicle screw insertion, to increase the safety of the patients and their outcome.

This book aims to give an update on the newest techniques and evolutions, with the help of experienced worldwide Spinal Surgeons who use such techniques on a routine basis.

Such revision can be useful to spinal surgeons, both neurosurgeons and orthopaedics, to be up-to-date in an extremely dynamic field, where "innovation" and "minimally invasive" are the keywords, and to fully understand the techniques, their indications, contraindications and limits.

Physiotherapists, osteopaths and sanitary personnel who work in the spinal pathology field can also have the chance to know better the techniques used in the patients that they treat after the surgical procedure, in order to have a full comprehension of what has been done.

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1 The Role of Neuronavigation in Lumbar Spine Surgery

Gualtiero Innocenzi

The need to improve accuracy and safety in the placement of pedicular screws is one of the main concerns of all spine surgeons. The different methods available to navigate the spine during surgical procedures may help to increase the correctness of instrumented spine surgery. Obviously, this point is particularly relevant in percutaneous and minimally invasive spinal surgery [\[3](#page-21-0), [4](#page-21-0), [7](#page-21-0), [26](#page-22-0)].

The first clinical experiences of frameless spinal stereotaxis were reported in the literature in the early 1990s. In the literature, the acronyms to define frameless spinal navigation stereotaxis are image-guided surgery (IGS), computer-assisted surgery (CAS), and computer-assisted navigation (CAN) [[7,](#page-21-0) [10\]](#page-21-0).

Kalfas et al. were the first to publish, in 1995, a series of 30 patients operated on with a frameless stereotactical procedure [[15\]](#page-21-0).

The crucial point is that instrumented spine surgery requires an accurate knowledge of the shape, the size, and the orientation of anatomical elements, particularly the pedicles, that are not in the visual field. The conventional methods to steer pedicular screws placement are based on intraoperative fluoroscopy that allows to check only two dimensions. The third one must be inferred by the surgeon, and, especially in anterior-posterior (AP) projections, the landmarks may be difficult to interpret [\[26\]](#page-22-0).

1.1 Methods

Today we have three basic kinds of 3D spinal navigation:

- Systems based on preoperative CT images
- Systems based on intraoperative images acquired with a cone-beam CT (CBCT)

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Fig. 1.1 The basic methods of spinal navigation

– Systems based on intraoperative images acquired with a portable multi-detector CT (MDCT) (Figs. 1.1 and [1.2](#page-12-0)) [\[26](#page-22-0), [29](#page-22-0)].

The essential components of a 3D system are:

- An image-processing computer workstation
- An infrared camera

Fig. 1.2 The main differences between 2D fluoroscopy-based method and 3D CT-based method to navigate the spine. With fluoroscopy, the surgeon must deduce the third dimension and is directly exposed to radiation. A 3D navigation system allows to see directly the three planes of the anatomy

- A reference array made up of reflective spheres, attached to the spinous process of the interested level
- An arrangement of passive reflective spheres mounted on the surgical tools

The infrared light, projected by the camera toward the surgical field, is reflected by the spheres and then sent to the computer workstation. This reckons the data received. Hence, the position of the surgical tool is visible on the screen of the workstation, superimposed on axial, coronal, and sagittal radiological planes.

The decisive step in navigated procedures is the "registration," the process through which the images and the surgical anatomy are "matched."

The technique of the registration depends on the navigation system adopted and on the kind of surgery: whether open or percutaneous.

With a preoperative CT-based system, the matching process is performed directly by the surgeon who may use a "paired-point" or a "surface matching" technique that are detailed in Figs. [1.3](#page-13-0) and [1.4](#page-13-0) [[13,](#page-21-0) [26\]](#page-22-0).

If an intraoperative CBCT or MDCT is used, the registration process is an automatic one, without any significant surgeon input.

In Sect. [1.5,](#page-19-0) we will see how many sources of possible mistakes are inherent in this crucial moment of the navigation.

Once the registration is completed, the workflow starts with the choice of the entry point and the planning of the trajectory of the screw. The camera tracks the surgical

Fig. 1.3 Our usual operative setting for spinal navigation

Fig. 1.4 The workflow in preoperative CT-based system starts with the acquisition, before surgery, of a CT in prone position. The intraoperative images acquired with a C-arm are then matched with the preoperative ones

Fig. 1.5 The planning of trajectory of pedicular screw in percutaneous technique

Fig. 1.6 The guided piercing of the pedicle on the left and the insertion of screw along the planned way on the right

tools, and, following the images displayed on the screen, the surgeon selects the adequate caliper, length, and orientation of the pedicular screw (Figs. 1.5 and 1.6).

During the navigated surgical procedure, any fluoroscopic control is not necessary. At the end of the surgery, the correctness of the screws' placement is checked through a CT acquisition before the closure or, if an intraoperative CT is not available, an AP and LL fluoroscopy.

1.1.1 How to Assess the Screws' Placement

Before analyzing the differences of the results between free-hand technique and navigated technique as well as among the different available techniques of navigation, it is useful an attempting to define a method to evaluate the accuracy of the

screws' placement. Kosmopoulos and Schizas, in their meta-analysis, found 35 different methods to assess screws placement (but some are only slight modifications of others) [\[17](#page-21-0), [30](#page-22-0)]. There are, in essence, two critical points:

The first one is: we have, on one side, an "in/out" way to evaluate the position of the screws; all those violating the cortical bone are "out," whatever is the degree of the cortical breach. On the other side, we have extremely graduated or incremental methods, like that proposed by Gerbzstein and Robbins [[11\]](#page-21-0). These authors distinguish five different groups: (1) when the screw is entirely within the pedicle; (2) if the encroachment is $\langle 2 \text{ mm}$; (3) if it is between 2 and 4 mm; (4) when it is between 4 and 6 mm; and (5) if the screw is more than 6 mm (i.e., about the screw size). If the first way may be too much rough, the other one may result impractical in clinical routine. At this regard, we have also to consider the concept of "safe zone," a space interposed between the pedicles and the neural elements. Lien relieved, according with other authors, that this space is greater superiorly and laterally than medially and inferiorly. The distance of the roots from the lateral surface of the pedicles is in the range of 2.4–9.4 mm, and it is smaller in the low lumbar levels [\[8](#page-21-0), [9](#page-21-0), [19](#page-21-0)].

The second critical point regards the radiological planes on which the screws' location is evaluated: if coronal and sagittal planes are also considered, the incidence of cortical violations is higher than when only axial plane is analyzed.

For these reasons, there are so relevant differences among papers regarding screws' placement accuracy. And then every comparison among different methods of navigation in terms of accuracy and misplacement must be cautiously considered, not forgetting the differences among different descriptive statistics [\[17](#page-21-0)].

1.1.2 Comparison Between Free-Hand Technique and Navigated Technique

With the limitations reported in the above paragraph, we may compare the results of surgeries supported only by 2D fluoroscopy and the navigated procedures, globally considered.

In a meta-analysis on papers regarding large series of patients, operated on with and without the help of navigation systems, Verma et al. relieved there were no reported cases of neurological complications in the navigated procedures, whereas there was an incidence of 2.3% of these complications without navigation aid. The accuracy of screws placement (evaluated with different methods) was of 93.3% with navigation and of 84.7% without it [[31\]](#page-22-0).

If the difference in terms of complications in favor of navigational procedures was not statistically significant, the advantage of navigation in terms of accuracy $(93.3\% \text{ vs. } 84.7\%)$ was statistically relevant [[31\]](#page-22-0).

Referring to fusion rate and functional outcome, there are no literary sources to compare the results of navigated and conventional techniques [\[31](#page-22-0)].

The lack of visualization of bony landmarks makes the guidance of a 3D navigation system particularly advantageous in percutaneous procedures.

Hence, it is of remarkable interest the comparison between 2D fluoroscopic navigation and 3D stereotactic navigation in percutaneous transpedicular screws' insertion. With this aim, Bourgeois et al. compared their series of 599 patients, operated percutaneously with the guide of intraoperative CBCT, with ten papers, reporting series of percutaneous procedures, assisted by 2D fluoroscopy [\[3](#page-21-0)]. In the 3D-navigated series, there was a rate of pedicle breach of 1.15% on per-patient basis and 0.33% on per-screw basis. In the 2D series, the lowest rate of incorrect screw placement was 9% per patient and 1.7% per screw.

Compared with conventional percutaneous screws' placement, the 3D technique presented an absolute risk reduction of 17% [\[3](#page-21-0)].

Other studies confirm that 3D navigation systems lessen the rate of screws misplacement in percutaneous procedures [[3,](#page-21-0) [17,](#page-21-0) [25\]](#page-22-0).

1.1.3 Comparison Among the Different 3D-Navigated Techniques

3D navigation systems based on intraoperative CT (CBCT or MDCT) present the following main advantages over the systems based on preoperative CT:

- Automatic registration process instead of a manual one and, thus, less probability to make mistakes in this crucial moment of navigation.
- The CT images are acquired with the patient in prone position on the surgical table, with no risks of incongruence due to the possible changes of vertebrae position after the induction of anesthesia and muscle relaxation.
- The possibility to perform a CT control at the completion of surgery and, thus, to revise a misplaced screw before the closure [\[4](#page-21-0), [16](#page-21-0)].

In an accurate comparison between a series of patient operated with a preoperative CT-based system and a series in which an intraoperative CT (O-Arm) was used, Costa et al. observed the following advantages with O-arm: higher accuracy in screws placement (95.2% vs. 91.8%), shorter mean operative time (92 min vs. 128 min), merging procedures less time consuming (1.15 min vs. 6.5 min), and shorter mean insertion time per screw (2.9 min vs. 3.8 min) [[4,](#page-21-0) [5\]](#page-21-0).

1.1.4 Spinal Navigation in Pediatric Patients

In children with deformity, the risk of screws' misplacement is higher than in adult patients due to the smaller pedicle size and of a relevant coronal deformity [\[18](#page-21-0)].

In pediatric population, the 3D navigation systems improve the accuracy of screws' placement. Larson reports a rate of accuracy of 96.4%, compared with an 84.3% of studies where the assessment was based on postoperative CT and the procedures were without navigation [[18\]](#page-21-0).

Luo reports a series of young children (range 1–10 years), in whom the screws were implanted from C1 to L5 for different types of congenital deformities. In his navigated series, the accuracy rate was 97.8%, significantly higher than the 90.9% reported by Baghadi in a non-navigated series of the same age group [\[2](#page-21-0), [20](#page-21-0)].

In addition to a safer screw placing, 3D spinal navigation offers another remarkable advantage in scoliosis surgery. A CT performed after the screws' insertion allows to revise or remove the malpositioned screws before the correction maneuver, reducing the risk of loss of fixation and screws' migration during this act [\[2](#page-21-0), [18,](#page-21-0) [20](#page-21-0)].

1.2 Uses of Spinal Navigation Other than Screws' Placement

If the improvement of correctness and safety in pedicular screw placement is the main reason to use navigation systems, we also have to consider there are other procedures, in instrumented spinal surgery, that may be usefully supported by a stereotactic guidance system.

In our personal experience, we found navigation useful to perform a transpedicular vertebral biopsy. In cases in which we proceed to stabilize a spine, jumping the pathological vertebra and putting the screws above and below it, we complete our surgery taking different samples within the pathological body, through a transpedicular route. The availability of a navigation system allows us to be sure to have wholly centered the critical areas of the lesion (Fig. 1.7).

Fig. 1.7 A tumor of D10. The navigation system guide the surgeon in the screws' placement and in the tumor samples taking

Another useful employment of navigation is the accomplishment of a PLIF or a TLIF. We may make traceable the spacer holder, putting on its end a reference array with a clip. With this method, it is possible to avoid fluoroscopy to check the progression of the spacer within the interbody space.

As pointed out by Rahmathulla, an analogous guide may be adopted in performing also lateral approaches to the spine. Recently, Joseph et al. reported a positive experience in 3D CT-based navigation in lateral lumbar interbody fusion (LLIF) [\[14](#page-21-0), [26](#page-22-0)].

1.3 Limits and Pitfalls

The use of spinal navigation is not devoid of limits and pitfalls. Firstly, it determines the appropriate setup of operating room (OR). The correct setting of the different parts of the surgical arrangement (surgical table, nurse table, imaging workstation, infrared camera, etc.) must allow a clear direct line of sight among the infrared camera, the reference arc, and the tool handled by the surgeon (Fig. 1.8).

The correctness of surgical maneuvers, like the sterile draping of CT, may affect the accuracy of the navigation: the sterile drape must be seamless and arranged in order to prevent to be caught between the shields of the O-arm or the gantry of a MDCT and the reference arc or the K-wires inserted in the pedicles.

Fig. 1.8 The sight line among the infrared camera, the reference arc, and the tool handled by the surgeon must be clear

As mentioned above, the registration is of utmost importance. With the intraoperative CT, this step is automatic, but errors may occur in any case. For example, in open surgery, it is advisable to perform the registration after the completion of the approach, to avoid motion-related mistakes. Breathing-related movements can also interfere with the acquisition of images; a cooperation by anesthesiologist, in order to hold patient's respiration in this phase, is needed.

In essence, once the registration has been accomplished, the surgeon and the nurse have to avoid whatever change of position of the table, of the patient, and of the reference arc.

Another possible source of inaccuracy may be the excessive distance of the pedicle engaged from the reference as well as the duration of surgery. Quinones-Hinojosa et al. reckon that there is a loss of accuracy of 3 mm in 7% of patients at three levels distance from the reference arc. The same grade of inaccuracy is observed in 17% of patients after 1 h of surgery.

In any case, during surgery, it is recommended to check the reliability of the system placing periodically the probe on a known anatomic landmark, like the spinous process. In this way, it is possible to compare the real position of the tool to that appearing on the screen [[26\]](#page-22-0).

1.4 The Problem of the Learning Curve

A learning curve exists in any surgical procedure. Different studies demonstrated that the correctness of screw placement improves with the increasing acquaintance of the surgeon with the navigated techniques, and there is a progressive shortening of the surgical time. And it is an obvious remark. Wood et al. observed, in a continuous series of 150 surgeries, that the rate of screws adjustment decreases from 16% in the first 50 cases to less than half of that rate in the last 50 cases [[12](#page-21-0), [33\]](#page-22-0).

But we believe that, as clearly pointed out by Meyer, not only the training is deciding to master navigational techniques. It is fundamental not to limit these procedures to selected cases and make them part of the surgical routine [[22\]](#page-21-0).

1.5 The Problem of Radioexposure

Villard reports that the accumulated radiation dose for the surgeons, in nonnavigated procedures, is higher than in navigated ones 9.96 times to the thorax, 5.06 times higher to the eye, and 6.53 times to the forearm [[32\]](#page-22-0). These data are of relevant importance on the plane of occupational health, considering the radiation exposure for spinal surgeons, during screw placement, which is 10–12 times higher than in non-spinal orthopedic procedures [[32\]](#page-22-0).

The radiation dose for the patients is higher in non-navigated technique: 1884 cGy cm² versus 887 cGy cm² in navigated surgeries.

The usage of intraoperative CT implies almost no radioexposure for the surgeon and the personnel of the operating room because the initial and the final images acquisition are performed with the staff out of the OR. During the insertion of the screws, there is no need to make checks with fluoroscope. It remains the problem of the radiation exposure for the patients. It could be partially softened, according to Abul-Kasim, modifying the standard protocols proposed for O-arm by the manufacturer. Without any impact on the images quality, it could be possible to reduce radiation doses for the patients from 5 to 13 times [[1\]](#page-21-0).

Nevertheless, a special reflexion must be done on the use of intraoperative CT in children. In Sect. [1.1.4](#page-16-0), we have reported the advantages of its usage in pediatric procedures. At the same time, according to Richerand, we have also to consider that intraoperative CT-based surgeries imply a significantly more radiation to the child than with C-arm (1.44 mSv for the CT group versus 0.34 mSv for C-arm group). These differences are more pronounced in obese patients. Then, a "judicious" use of intraoperative CT is recommended in these patients, limiting it to the anatomic regions in which the screw placement is more difficult.

1.6 Cost-Effectiveness

The acquisition and maintenance of intraoperative CT are highly expensive, and the costs of a surgical equipment must be considered in comparison with the expected benefits.

The available studies, focused on the analysis of cost-effectiveness of the usage of an intraoperative CT-based navigation system, demonstrate that the adoption of intraoperative CT may be cost-saving in centers with high-volume procedures.

Referring to the number of revision surgeries per year in a navigated and a nonnavigated group, Dea et al found a rate of 0.8% at 1 year after navigated procedures and a rate of 6% in conventional series. This data corresponds to an incremental cost-effectiveness ratio of \$ 15.961 per reoperation avoided in CAS group [[6\]](#page-21-0).

Comparing the cost-effectiveness of a system based on preoperative CT to those of one based on cone-beam intraoperative CT (O-arm), Costa reported the mean cost of a single procedure with O-arm is about 255 euros less than the cost of the other system (difference of 3.8%) [[5\]](#page-21-0). Another reason of economical convenience is that the possibility to control, before the closure of the operation, the screws' placement avoids a number of postoperative CT scans/year corresponding to the number of the patients operated on yearly.

Conclusions

3D spinal navigation techniques improve the accuracy and safety of instrumented surgery. A routine employ of these techniques hastens the learning process. The surgeon must be always aware that a navigation system is an extremely useful support but doesn't replace a perfect knowledge of the spinal anatomy and a scrupulous surgical technique.

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2 Imaging in Lumbar Spine Surgery: The Role of Intraoperative CT Scan

Giuseppe Calvosa, Miria Tenucci, Matteo Galgani, and Stefano Vallini

The first clinic application of the image-guided spine surgery (IGS) dates back to 30 years ago; since then, its technological improvements have become relevant, making the intraoperative navigation a widely used procedure [\[1](#page-28-0), [2](#page-28-0)].

The computer-guided pedicle screws' insertion has considerably improved this surgery technique accuracy and repeatability [\[3](#page-28-0)[–12](#page-29-0)].

The IGS allows the surgeon to use tridimensional reconstructions of the patient's anatomy. On the navigator screen, the surgeon can in real time watch the position of their surgical tool in the surgery field (Fig. [2.1](#page-24-0)).

An external camera tracks all surgical instruments using a passive array (reflected sphere) or active array (led). This tacking system has a reference array fixed to the patient [[13–18\]](#page-29-0).

Using the 3D navigation, the surgeon can simultaneously check the multilevels of spinal anatomy, making it helpful when percutaneous operations or deformity operations are performed (Fig. [2.2](#page-24-0)).

The IGS made spinal surgery safer and with more reliable results.

The spinal navigation systems can use images acquired from preoperative CT or intraoperative CT scan; in the first case, the surgeon must make a point-to-point record by matching the preoperative CT image with the surgical operating anatomy of the patient.

In the case of the computerised spinal navigation system, the images recorded from intraoperative CT in the operating room will be automatically recorded and sent to the navigator without the surgeon's participation. In this particular case, the external camera situates the position of the CT scan in respect of the fixed reference array (Fig. [2.3](#page-25-0)).

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Fig. 2.1 Intraoperative image; the surgeon watching the patient's anatomy on the navigation screen places the screw

Fig. 2.2 Navigation images in multilevels. The blue guide shows the trajectory of the pedicle screws

Fig. 2.3 CT scan and fixed reference array

The use of the intraoperative CT scan increases the accuracy of procedures and reduces the operative time eliminating the variability due to the action of the surgeon's manual recording [[19–22\]](#page-29-0).

The intraoperative CT scan, where the patient is prone in the operating room, deletes another possible cause of error due to the patient position, which is usually supine during the preoperative CT. This variation of the position can be significant when the spine injuries are unstable, like in traumas or particular cases of degenerative deformity [\[23](#page-29-0)].

Another advantage of having an intraoperative CT scan allows supervising the right screws' position before completing the procedure, removing the likelihood of going back to the operating room after a few days in order to correct the misplaced screws.

In our centre, we use the intraoperative CT spinal navigation for every surgical operation, and this has been essential to overtake the learning curve in the shortest time possible.

We use O-arm Medtronic (come beam CT) that moves 360° around the prone patient on the operative field; all the obtained images are automatically recorded by the navigator (stealth station Medtronic), which re-elaborate them to have clearer high-quality 3D images.

Fig. 2.4 The position of the screw

We have reviewed records of 1500 consecutive screws with a 98% amount of correct placement, according to the most recent literature revisions; in this percentage we consider the grade 0 and 1 of the Gertzbein and Robbins classification [[24,](#page-30-0) [25\]](#page-30-0). The position of the screw was classified into five grades according to the violation of the pedicle cortex: (0) no violation, (1) up to 2 mm, (2) from 2 to 4 mm, (3) from 4 to 6 mm and (4) more than 6 mm (Fig. 2.4).

The intraoperative CT-based navigation has a significant role in the re-operation cases, where the anatomy results undermined and the surgeon cannot find the usual landmarks; the external camera replaces the surgeon's sight so that he can see their instruments moving on the several levels on the navigator screen. This system guides him through the dense arthrodesis and tissue scars (Fig. [2.5](#page-27-0)).

Even in several deformity cases, the spinal navigator, using the multilevel vision, helps the surgeon to nullify anatomic alterations due to the deformity in order to find the right peduncle (Fig. [2.6\)](#page-27-0).

It is well known that spinal surgery, using computer navigation, has a learning curve [[26\]](#page-30-0); from their personal experience, the authors are convinced that we need a habitual use of it, to get to the end of the learning curve of the navigation system and the use of intraoperative CT scan. In this way our surgical team has reached a plateaued in 5 months.

After 4 years of use of CT intraoperative-based computer-assisted navigation system, according to the literature, we can state that at the end of the learning curve, the surgical timing reduces significantly.

Fig. 2.5 Virtual view through the dense arthrodesis

Fig. 2.6 Intraoperative image of navigating adult scoliosis

Fig. 2.7 Intraoperative CT scan control performed with O-arm. Evaluation of positioning of the pedicle screws in scoliosis

Thanks to the possibility to run a new scan before completing the intervention, the risk of going back into surgery to correct misplaced screws is irrelevant (Fig. 2.7).

Surgeons should not underestimate the importance of having an intraoperative CT scan also for reducing the exposure to ionising radiation, to which doctors and nurses of the operating room are exposed during the spinal surgeries performed with the only fluoroscope [\[19](#page-29-0)].

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The Robotic Arm Guidance Systems: Principles and Indications

Enrico Tessitore, Granit Molliqaj, Claudio Schonauer, and Bawarjan Schatlo

3.1 Introduction

The quest to improve safety and invasiveness of surgical procedures has been a driving force in surgical innovation. The origin of minimally invasive procedures such as arthroscopy can be tracked back to the nineteenth century (Nitze; 1706–1848) who devised the first modern cystoscope in 1879 to perform operations [[1\]](#page-42-0). Thereafter, the laparoscopy has been developed, which utilize flexible fiber-optic cameras. The first laparoscopy of the peritoneal cavity has been done in 1901 by George Kelling [\[2](#page-42-0)]. The first laparoscopic cholecystectomy was performed in 1987 by Mouret [[2\]](#page-42-0). In contrast to a century of minimally invasive surgery, the introduction of robotics into the realm of surgery is more recent. Robotic automation is aimed at performing a feat which is usually a human task at least as accurately and swiftly. Due to the complexity and delicacy of spinal anatomy, the first application of robotics only emerged at the turn of the millennium as imaging capabilities and computing power to process 3D data in real time reached the critical mass to be used in surgical applications.

Although spine surgery is a vast field for a surgeon, today's robotic spine surgery applications currently cover a rather limited set of tasks which can be grossly divided into trajectory assistance and dissection.

Technology is constantly evolving and tries to approach the complex needs of spine surgery, because surgeons' interest in robotic guidance for spinal implant placement is increasing. In view of the continual evolution of technology, the spinal surgery is also trying to take advantage of this improvement which may be

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particularly useful in patients with challenging anatomy [[3\]](#page-42-0). Thus, some of these technologies as minimally invasive endoscopic spine surgery were supplemented by the robotic-assisted spine surgery these last years.

Indeed, pedicle screw insertion can be a real challenge especially in patients with spinal deformity such as scoliosis and revision surgeries where the anatomic landmarks have been altered [\[3](#page-42-0), [4](#page-42-0)].

Many important structures, as the spinal cord, nerve root, and vessels in front of the vertebral bodies, are in close relationship with the pedicle [\[5](#page-42-0)]. We can easily understand that a slight error in direction may result in a significant error in the position of the screw, with the risk of neurological deficits or vessels damage. The complications related to pedicle screws misplacement range from 1% up to 54% in the literature [[3,](#page-42-0) [4,](#page-42-0) [6\]](#page-42-0).

Therefore, improving accuracy and safety in pedicle screw insertion has led to the innovation of multiple new techniques such as image guidance with navigation, intraoperative imaging, and robotic-assisted spine surgery [\[3](#page-42-0)]. Some publications suggest that these additional aids have improved the accuracy of pedicle screw placement [[3,](#page-42-0) [4\]](#page-42-0).

3.2 Motivations for Robotic System Usage

The pedicle diameters of thoracolumbar pedicle vary from 4 to 10 mm. It is easy to admit that a slight error in direction may result in a significant error in the position of the screw, with the risk of nerve or vessel damage [[3\]](#page-42-0). Robotic system might be useful for increasing accuracy and safety in spinal instrumentation. Despite malposition rates with conventional screw placement techniques being high, clinical relevant complications related to screw misplacement are rare and occur in <0.5% [\[7](#page-42-0), [8\]](#page-42-0). The term "screw misplacement" is not clearly defined and depends on the grading systems used. A screw with discreet breach of pedicle cortex may still have proper biomechanical properties and lack of neurological deficit. Thus, we could define the screw misplacement as a screw with the ability to generate neurological or biomechanical complications, rather than a radiological misplacement [\[7](#page-42-0)]. This would explain the discrepancy in the literature between a high rate of misplacement screws but a low rate of associated deficits [\[7](#page-42-0), [8](#page-42-0)].

Moreover, robot-guided spine surgery offers other advantages, such as the possibility of a minimally invasive surgery with more safety and accuracy, smaller incision, less blood loss, less paravertebral muscle disrepair, lower infection rates, and thereby a faster recovery and shorter hospital stay. All of these contribute to a reduction of costs [[9\]](#page-42-0). A robotic assistance could ideally improve accuracy by avoiding physiological tremor and allows an endless reproducibility for repetitive motions and holding tools for long periods [[9\]](#page-42-0).

To date, the use of robotic assistance requires intraoperative verification by fluoroscopy to ensure the reliability of the robot. However, once the confidence gain is

Fig. 3.1 The Renaissance® guidance system, Mazor. With permission from Mazor Robotics, Inc.

confirmed and guaranteed, then the robotic surgery will allow a significant reduction in radiation for patients and healthcare providers [[10\]](#page-42-0).

Two robot designs are distinguished: supervisory-controlled systems and masterslave systems:

1. *Supervisory-controlled systems* assist the surgeon in finding a trajectory, which was previously programmed into the robot.

The *Renaissance* (Mazor, Caesarea, Israel; Fig. 3.1) and the *ROSA Spine* (Medtech, Montpellier, France; Fig. [3.2\)](#page-34-0) both fulfil this purpose. These systems are useful to help guide a trajectory for a biopsy, kyphoplasty, or pedicle screw placement based on pre- or intraoperative 3D imaging. Trajectories in the "supervisory-controlled" systems are designated on the robot console or prior to surgery. In contrast, "master-slave" systems enable surgeons to translate surgical maneuvers on a console, which are translated in real time into movements at a remote, otherwise inaccessible or deeply seated surgical site.

2. *Master-slave systems* translate human input into a robotic movement. The Da Vinci (Intuitive Surgical Inc.) system performs these maneuvers. The surgeon maneuvers four robotic arms from a remote console. The robotic arms contain tools that can hold instruments and perform complex tasks. This robotic system is widely used in urology, gynecology, and other surgical disciplines. Recently, it has been used in spine surgery to perform a discectomy for anterior lumbar interbody fusion (ALIF) interventions [\[11](#page-42-0)], but its application in spine surgery has remained anecdotal.

Fig. 3.2 The Mazor X™ guidance system. With permission from Mazor Robotics, Inc.

3.3 Commercially Available Spine Robotic Systems

3.3.1 The Spine Assist® and Renaissance® Guidance Systems, Mazor

The Mazor Spine Assist system was the first CE- and FDA-approved system for instrumented spine surgery. The Renaissance is the updated version of preexisting Spine Assist. The systems consist of a miniature construction with two discs connected by six linear actuators. The lower disc is connected to a mounting platform, while the upper disc can be connected to extension arms, which can hold instruments. This semi-active robotic spine surgery system indicates the direction of pedicle screw trajectories and can be used for all tasks requiring the cannulation of bone throughout the thoracic, lumbar, and sacral spine (Fig. [3.1\)](#page-33-0).

Spine surgery with Renaissance consists of four basic steps: preoperative plan, mount, 3D synchronization, and surgery. The first step starts before entering the operating room with a preoperative planning on a computer or the robot console in the operating room. The patient's CT scan is uploaded to create a 3D model of the patient's spine. Trajectories can be planned in axial, coronal, and sagittal views. The software provides a multitude of visualization options warranting ample opportunity to plan screw angle and rod alignment. Intraoperatively, the patient is in prone position as usual. In order to obtain optimal registration results, no radio-opaque covering, cables, and monitoring equipment should be lying over or around the operated segments.

Prior to the registration and referencing procedure, the surgeon can choose any of three options to mount the system in the operating field which require a different disposable instrument kit:

- (a) Spinous process-mount: This option requires bilateral surgical exposure of a spinous process followed by rigidly fixing a clamp and two additional pins in a spinous process above and below. This option is most useful in cases where decompression is intended.
- (b) Minimally invasive kit (multidirectional bridge mount or hover-T mount): These mounting platforms are rigidly attached to a spinous process and bilateral iliac crest pins inserted through stab-incisions. This bone-mounting option ensures a fixed robot with the patient's vertebrae and avoids error due to patient's breathing or motion.

In order to indicate the mounting platform special location on fluoroscopy, a 3D marker is attached onto it. Two fluoroscopic images of the 3D marker and spine are taken in AP and oblique views. The software then automatically matches the intraoperative images to the corresponding locations on the preoperative CT and registers and synchronizes the CT base surgical blueprint. Each vertebra is registered separately, independent of anatomical landmarks, so that deformities or previous operations do not affect accuracy. Alternatively, an intraoperative CT scan performed with a reference array can be uploaded in which case fluoroscopy is unnecessary.

To begin the surgical procedure, the surgeon selects the target vertebra from the preoperative plan. The robotic guidance arm is secured to the mounting platform. The robot steers toward the chosen trajectory. After mounting the extension tool, a cannula is inserted. After a stab incision through skin and fascia, the cannula is inserted further until the surface of the bone is reached. The bone surface can be flattened using a "Peteron." Then, a spiky anchor cannula is inserted after which drilling can be performed. After drilling, a Kirschner wire is inserted, and the extension arm can be removed. The procedure is repeated for all vertebrae. Depending on the image adapter used (9 or 12 in.), only a limited number of vertebrae can be registered in a reference frame. Therefore, for every about three to four segments, a new registration is required.
3.3.2 The Mazor X™ Guidance System

The Mazor X^{TM} spine assist system is a new platform that was unveiled earlier in July 2016 by Mazor Robotics. This system comprises three main processes, namely, preoperative analysis and surgical planning, intraoperative guidance, and intraoperative 3D verification (Fig. [3.2\)](#page-34-0).

Concerning the first process, a computer application called "X-Align" is used. This module creates by computing, a preoperative analysis, and alignment by measuring the spine and simulating the patient's anatomy and the tools to use, evaluating how things are lining up, in order to ensure they are used in a correct and precise alignment. Subsequently, a treatment plan is prepared on the basis of the analysis. Then an arm mounted on the surgical table and the patient's bone is used with a 3D camera optical tracking to accurately guide the tools according to the surgical plan. A real-time 3D verification is used during the procedure to verify the placement using fluoroscopy X-ray, visual tracking, or other imaging systems.

3.3.3 The ROSA™ Guidance System, Medtech

ROSA™ Spine has been developed by Medtech Company and corresponds to an image-guided system, which combines robotic assistance in positioning tools according to planned trajectories and navigation features (Fig. [3.3](#page-37-0)). This guidance system includes a mobile base with an industrial robot arm with six degrees of freedom. In addition, a full-fledged navigation system with an infrared camera and a touch-screen console serve to track the patient's movement, plan trajectories intraoperatively, and if necessary, help the surgeon navigate intraoperatively. In contrast to the previously discussed Mazor system, the ROSA spine requires intraoperative 3D imaging. Its software does not allow for 2D referencing, and therefore, preoperative trajectory planning is not possible.

After inserting the iliac crest bolt, 3D imaging is performed (at present, referencing is only possible using the O-arm, but trials using flat-panel fluoroscopy devices are under way).

The surgeon then plans the trajectory of the screws using the console. Thereafter, the ROSA platform with the robot arm is installed to a patient's side and the surgeon in the opposite side. The navigation platform with camera is placed to patients' feet. The robot arm guides the surgeon to perform drilling and Kirschner wire analogous to the Mazor system [\[12](#page-42-0)].

3.3.4 AQrate® System, KB Medical

The AQrate® system includes a robotic arm and a platform with software (Fig. [3.4\)](#page-38-0). The robotic arm is placed beside the patient and stabilized at the operating table. A steering handle is attached to the end of the robot arm on which standard surgical instruments can be attached. The robotic arm permits through its six-axis force sensor to offer a haptic steering and force feedback. The robot guides the position of the

Fig. 3.3 The ROSA™ guidance system, Medtech. With permission from Medtech, Inc.

instruments at the entry point and gives the trajectory. Once the instrument in place, the robot holds the path while the surgeon performs the remaining steps by manipulating the steering handle as if he was holding the instrument itself. This device allows a minimally invasive spinal surgery by allowing percutaneous surgery.

3.4 Current Literature on Robotic Spine Surgery

The need of more accuracy and safety in spinal instrumentation has led to the development of different guiding systems. However, surgeons' opinion differs on the usefulness of robotic surgery. The existing literature on the subject is essentially

level II or III of evidence (Table [3.1\)](#page-39-0). The lack of good quality data makes it difficult to draw any firm conclusions about this new technology.

3.4.1 Current Available Literature on Mazor Robotic Systems (Spine Assist, Renaissance)

The systematic review of literature concerning the comparison between the Spine Assist system from Mazor versus conventional freehand procedures with fluoroscopy found mixed results. Roser et al. published in their single-center randomized controlled trial that 99% of screw were satisfactorily with robotic assistance and 98% in freehand group. Another prospective analysis with the Spine Assist system showed that up to 98.3% of screws were within 2 mm of the preoperative planning [\[13\]](#page-42-0).

Fig. 3.4 AQrate® system, KB medical. With permission from KB medical, Inc.

Author	Study type	System		Level of evidence
Devito DP. et al Spine 2010	Retrospective, multicenter study 840 procedures RA	Spine Assist MAZOR	SpineAssist offers enhanced performance in spinal surgery when compared to free-hand surgeries, by increasing placement accuracy and reducing neurologic risks.	IΙI
Kantelhardt SR, et al Eur Spine J 2011	Single centre retrospective cohort study	Spine Assist MAZOR	112 consecutive pts undergoing thoraco-lumbar pedicle screw implantation divided into two groups: 57 pts FG $(n = 286)$ screws), and 55 pts RA ($n = 250$) screws). Radiation exposure was significantly less in robot- assisted cases	П
Ringel F. et al Spine 2012	Single centre randomized trial: 60 patients (30) FG; 30 RA)	Spine Assist MAZOR	Accuracy of the conventional FG technique was superior to the robot-assisted technique. Attachment of the robot to the spine seems a vulnerable aspect as well as slipping of the implantation cannula at the screw entrance point.	I
Roser F. et al Neurosurgery 2013	Single centre RCT. 37 patients $(10 \text{ FG}$; 8 IG and 18 RA)	Spine Assist MAZOR	With comparable accuracy and acceptable time elapsed for the navigation procedure, the radiation time and dosage in the navigation and robotic groups were substantially shorter.	I
Hu X, et al Eur Spine J 2013	Prospective clinical series $(102$ patients)	Renaissance MAZOR	98.9 % of screws were successfully and accurately implanted and 1.1 % were malpositioned. "Tool skiving" was thought to be the inciting issue with the misplaced screws.	ΠI
Schatlo B., Tessitore E. JNS Spine 2014	Prospective non randomized matched cohorts (55 RA, 40 FG)	Spine Assist MAZOR	Robot-guided pedicle screw placement is a safe and useful tool for assisting spine surgeons in degenerative spine cases, Nonetheless, technical difficulties remain and fluoroscopy backup is advocated.	П
Hu X_{n} Lieberman I. Clin Orthop Relat Res 2014	174 consecutive patients 5 groups according to experience	Renaissance MAZOR	The success rate of robotic- assisted pedicle screw placement increased after the first 30 patients and was maintained at that rate over the remaining time period.	Ш

Table 3.1 Current literature on robotic spine surgery

(continued)

RCT randomized control trial, *RA* robot-assisted, *FG* freehand group, *Pts* patients Category A + B: According to Gertzbein and Robbins classification

A retrospective multicenter study published by Devito et al. founded a rate of 98% of clinically acceptable screw placements using the Spine Assist robot. No permanent nerve damage occurred using the robot, although 89.3% of screws were intrapedicular and 9% of screws showed a minor pedicle breach [[14](#page-42-0)]. Nevertheless, simple X-ray films were used in this series to assess accuracy of screw placement. Subsequently, Kantelhardt et al. performed a retrospective comparison and obtained an accuracy rate of 94.5% in the robot group compared with 91.4% in conventionally placed screws [\[15\]](#page-43-0). Van Dijk et al. obtained 97.9% of good accuracy in their retrospective review of 112 patients operated by minimally invasive spine surgery using robotic guidance [\[16\]](#page-43-0). More recently, a matched cohort comparison study from 2014 showed more accuracy by robot placement (91.4%) compared to conventional fluoroscopy (87.2%) [[10](#page-42-0)].

Conversely, Ringel and colleagues highlighted a superior accuracy with the conventional freehand technique compared to the Spine Assist robot technique with, respectively, 93% and 85% of good positions. They observed that most of the malpositioned screws in the robot group were too lateral. The lesser accuracy may be due to the fact that they attached part of the robotic system to the operating table, leaving the risk of movement between the patient and the system [[17\]](#page-43-0). Another reason might be the phenomenon of a cannula sliding off an irregular bone surface [\[17](#page-43-0)].

3.4.2 Current Available Literature on Rosa Spine, Medtech

Lonjon et al. published a prospective case-matched analysis of 20 patients and reported a higher rate of precision with ROSA Spine assistance (97.3%) as compared to the freehand technique (92%). Four implants in the RG were placed manually following failed robotic assistance [\[12](#page-42-0)]. Chenin et al. published in 2016 their experience with ROSA™ Spine robot for minimally invasive transforaminal lumbar interbody fusion. They concluded that the combination of this device with intraoperative CT enables accurate and safe instrumentation [[18\]](#page-43-0).

3.5 Learning Curve

In spine surgery, lower rates of robot-assisted pedicle screw misplacement were found as soon as surgeons crossed the 25-case mark using the first-generation Mazor system [\[19](#page-43-0)]. A more recent study based on the second-generation Renaissance system suggests that there is no added risk of screw malposition even during the first few cases [\[20](#page-43-0)]. Nonetheless, in order to gain trust in the way the system works, we would recommend a conservative approach and close monitoring during these initial cases. A conservative method of incorporating the robot into the work flow would be to first use it during the open technique and test the robot to see how it performs by verifying the indicated trajectories with known anatomic landmarks [\[10](#page-42-0)]. Percutaneous screw placement where no visual control is possible can then be initiated after satisfactory results were obtained during this controlled learning period. In comparison, desirable results with the Da Vinci system were obtained after 30 cases for hysterectomy compared to open surgery [[21\]](#page-43-0) and at over 150 for prostatectomy [\[22](#page-43-0)].

3.6 Radiation Exposure

Radiation exposure in conventional spine surgery remains significant and can be a burden on healthcare personnel. As in navigated surgery, robot-assisted surgery can help reduce radiation significantly. In a study by Roser et al., radiation was reduced by about one half [\[9](#page-42-0)].

3.7 The Future of Robotic Spine Surgery

The global market for the spinal robotic-assisted surgery is steadily growing. To date, according to the report by ReportsnReports.com, it is estimated at \$ 26 million and could reach \$ 2.77 billion by 2022. Indeed, aging of the population leads to increase indications for spine surgery for degenerative disorders. Thus, reduction of medical costs becomes a considerable challenge. Robotic surgery could help by the benefits it would offer by enabling a minimally invasive approach and reducing the postoperation care cost by reducing the rate of complications and length of hospital stay.

In the near future, robotic surgery will eventually help for more complex spine procedure, such as the craniocervical fixation techniques. In addition, robotic surgery could be very useful in case of very deforming and complexes spinal pathologies such as ankylosing spondylitis and rheumatoid cases which are challenging for spine surgeons. Its use in complex cases of spinal trauma with significant changes on anatomical landmarks might be useful as well [\[23](#page-43-0)].

The final aim to achieve through robotic use in surgery is to offer the possibility to operate away from the patient while preserving the performance of repetitive and accurate tasks. The next step in the development of robotic surgery would be to use telepresence to allow the surgeon to control console at greater distance from the patient. Thus the surgeon would operate away from the robotic arm mounted on the patient. It will

also improve intraoperative sterility allowing operating remotely while the patient is in a sterilized closed room, which will reduce the rate of infection. Another progress object would be to improve the robotics systems and make them capable of replicating the tactile feel and sensations to the surgeon during the operation.

Conclusions

In conclusion, robotic-assisted spine surgery is in its infancy and appears to be promising in improving clinical outcomes. However, more data are required as prospective randomized multicenter studies to assess the impact of these robotic-assisted spine systems on clinical outcomes of patients. It is essential to assess whether the robotic-assisted spine surgery provides better accuracy and safety compared to conventional spinal surgery, and not to be coaxed by the marketing strategy.

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4 The Robotic Arm Guidance System: Applications and Limits

Vejay Vakharia and Hani J. Marcus

4.1 Introduction

The placement of pedicle screws in the thoracolumbar spine was first reported by King et al. in 1944 to avoid the complications associated with the conventional treatment of external bracing and prolonged bed rest [\[1](#page-53-0)]. Krag et al. subsequently developed the first pedicle screw and rod system called 'The Vermont Spinal Fixator' in 1986 [[2\]](#page-53-0). More recently percutaneous pedicle screw systems have been developed to minimize soft tissue injury, allowing less post-operative pain and earlier mobilization.

The proximity of critical neurovascular structures to the trajectory of pedicle screws mean breaches of the pedicle walls can result in neurological deficits. Pedicle screw insertion therefore requires a high degree of accuracy relating to the anatomical entry point and angles of insertion in both medio-lateral and cranio-caudal axes. At present, most surgeons use anatomical landmarks or C-arm fluoroscopy to guide pedicle screw placement [[3\]](#page-53-0). Reported accuracies for such methods are difficult to compare due to study heterogeneity but vary between 28% and 94% with a median accuracy of 90% [[4\]](#page-53-0).

Over the last two decades however a number of robotic systems have been developed to further improve the accuracy of pedicle screw placement [\[5](#page-53-0)]. Here, we review the evidence that robot-assisted (RA) pedicle screw placement confers an

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advantage over conventional free-hand (FH) placement and explores the limits of existing robotic platforms.

4.2 Applications

In all, over a dozen robotic systems have been applied to pedicle screw placement [\[6](#page-54-0)]. However, few of these systems have made the leap from the laboratory to firstin-human studies, and fewer still are commercially available, including SpineAssist (Mazor Robotics, Israel) and ROSA (Medtech, France). Both of these represent supervisory-controlled systems, in which the surgeon plans the trajectory and the robotic arm and then autonomously positions itself to guide pedicle screw placement.

4.2.1 SpineAssist

The SpineAssist robot was first introduced in 2004 as MARS (the Miniature Robot for Surgical procedures) [\[7](#page-54-0)]. This featured a high fidelity actuator with six degrees of freedom (three of translation and three of rotation) permitting targeting accuracies of <0.1 mm and weighing <200 g. Prior to surgery, pre-operative imaging is used to define the desired entry and target points for the pedicle screws at each level to be instrumented on a 3D computer-generated model. The manufacturers provide three different means of attaching the robot to the spine. The first of which is through the use a spinous process clamp that is augmented through the placement of Kirschner wires (K-wires) into the spinous processes cranially and caudally. The second method is through the use of a radiolucent T-frame, which is attached to the patient via two Schanz pins or K-wires inserted into the posterior superior iliac spines bilaterally and a K-wire inserted into a cranial spinous process. The third method utilized a platform fixed to a cranial spinous process using a K-wire and a caudal 'bed mount' fixed to the operating table to improve the rigidity. Reference imaging is then acquired in the form of two fluoroscopic images (AP and 60° oblique) to which the robot and 3D computer-generated model of the trajectory are registered. The robot is then attached to the radiolucent frame, and the guide arm aligns to the pre-planned trajectories defining the entry point and direction of pedicle screw insertion. The procedure can be performed in either an open or percutaneous fashion. In the open procedure the dorsal exposure of the vertebra is performed prior to insertion of the drill through the guide arm to the desired depth within the pedicle. The pedicle screw can then be inserted along the same trajectory. The procedure is then repeated at each level in which pedicle screw insertion is required. In the percutaneous procedure, the trajectory guidance is used to mark the initial skin incision prior to the insertion of a custom designed dilator and guide tool. The drill is then inserted through the guide tool followed by a K-wire over which a cannulated screw can be placed. Fluoroscopic images are then attained following screw

placement to confirm satisfactory screw positioning. Due to the anchoring of the robot to the spinous process, any further movement of the patient following the reference imaging will not invalidate the registration provided the spinous process is in continuity with the rest of the vertebra. This prevents the need for further fluoroscopy during the procedure and therefore reduces both patient and surgeon irradiation.

To date two randomized control trials specifically comparing RA to FH pedicle screw insertion have been completed, and the third is still ongoing having only provided interim results (Table 4.1). The first randomized control trial was

	Study type	Study group	Outcome score	Key results	Other
Kim et al. [9]	Randomized control trial	$N = 40$ $RA (P) = 20$ $FH = 20$	CUSUM analysis Gertzbein and Robbin(A)	RA 95% FH 91% Not statistically significant	(a) Monosegment PLIF (b) Peteron technique (c) Iliac crest visualization
Ringel et al. $\lceil 8 \rceil$	Randomized control trial	$N = 60$ $RA (P) = 30$ $FH = 30$	Gertzbein and Robbin (A&B)	RA 85% FH 93% Not statistically significant	No difference in radiation exposure
Roser et al. [11]	Randomized control trial	$N = 28$ $RA (P) = 18$ $FH = 10$	Gertzbein and Robbin(A)	RA 99% FH 98% NA 92% No statistical analysis performed	Interim results
Schizas et al. $[12]$	Prospective cohort study	$N = 34$ $RA(O) = 11$ $FH = 23$	Rampersaud scale (A&B)	RA 95% FH 92% Not statistically significant	No difference in radiation exposure
Kantelhardt et al. [13]	Retrospective cohort study	$N = 112$ $RA(O) = 55$ $FH = 57$	Wiesner and Schizas scale $(0 \text{ and } 1)$	RA 95% FH 92% (p < 0.05)	RA resulted in: (a) Reduction in radiation exposure (p < 0.02) (b) Reduction in post-op opioid requirement (p < 0.004) (c) Reduction in post-op infection rate ($p < 0.04$) (d) Reduction in total hospital stay $(p = 0.009)$

Table 4.1 Studies evaluating robot-assisted pedicle screw placement

(continued)

Table 4.1 (continued)

performed by Ringel et al. in 2013 [\[8](#page-54-0)] and in combination with the study by Kim et al. [[9\]](#page-54-0) is the highest level of evidence available. Here, 60 patients were enrolled into having FH insertion of 152 screws (30 patients) and RA insertion of 146 screws (30 patients). There was no difference in the pre-operative baseline demographics of the patients with regard to age, sex, BMI and number of levels for fixation. Using the Gertzbein and Robbins scales, screws that were either entirely within the pedicle or breaches of $\lt 2$ mm (positions A and B) were considered satisfactory. Pedicle screw insertion was satisfactory in 93% of FH compared to 85% of RA cases ($p = 0.019$). Total fluoroscopy time was used to assess surgeon and patient radiation exposure and did not reveal any difference between the two study arms. The authors acknowledged that this may reflect a lack of experience and confidence when using RA and as such may reduce with further use. Given the lack of a favourable result for RA compared to FH, it is somewhat surprising that the authors advocate its further use. They felt a number of factors contributed to inaccuracies that once corrected for could improve the accuracy further. The authors felt that the attachment method recommended by the manufacturers of using a single cranial K-wire and a caudal bed mount attached to the operating table may be insufficient. In one case the implantation of the left-sided screws was accurate, but the right-sided screws were too lateral. The authors felt that was likely due to dislocation of the robot from the spine due to only a single K-wire

maintaining contact with the patient. Furthermore, analysis of the misplaced RA screws revealed lateral deviation at the bony entry points. They felt this was most likely due to skidding of the cannula along the steep superior articular process during the initial screw entry. In addition a potential error in the placement of S1 screws was thought to occur through deflection off the iliac crest due to the steep convergence angles of the screws. This could not be assessed in the planning software during initial screw trajectory assessment by Ringel et al. and could have resulted in over medialisation of the S1 screws.

The second randomized control trial was undertaken by Kim et al. [[9\]](#page-54-0) in patients undergoing monosegment posterior lumbar interbody fusion (PLIF), for degenerative or spondylotic spondylolisthesis and central canal stenosis, through RA or FH techniques. Accuracy was assessed using a cumulative summation test (CUSUM). The CUSUM test is a quality control monitor that has been implemented in a number of different surgical settings and is particularly useful in assessing surgical performance and learning curve during the implementation of a new procedure or technique [[10](#page-54-0)]. In total 80 pedicle screws were inserted into 20 patients in each of the RA and FH arms of the study. Pedicle screw placement was assessed based on the Gertzbein-Robbins scale applied to post-operative CT scans. Results showed that there were no significant differences in baseline demographics between the cohorts pre-operatively. Screw placement entirely within the pedicle (grade A) was not statistically significant with placement in 95% of RA and 91% of FH pedicle screws. The main difference between this and the study by Ringel et al. is the consideration of only grade A pedicle screw placement as satisfactory and the addition of the Peteron technique. This involves the introduction of a specially designed Peteron instrument with teeth at the distal end. The instrument is used to flatten and smooth the proposed entry point of the screw such that drilling can proceed without lateral skidding. Furthermore, a more recent software upgrade allows visualization of the iliac crests during the planning stage such that the S1 pedicle screw trajectory is no longer impinged upon by the iliac crest and therefore not deflected medially. Kim et al. also used the 'bed mount' technique of robot stabilization in 85% of cases and the spine clamp in the remainder. Unlike Ringel et al. [[8\]](#page-54-0), they did not find that was a factor that contributed to inaccuracy. CUSUM analysis is also a means of assessing cumulative accuracy of surgical interventions when new technology is introduced to ensure that performance is no worse than the current standard of care. It has been employed as an early warning system in which when the cumulative performance crosses a particular decision threshold, the procedure is said to be 'substandard' and the procedure should be stopped or have corrective measures introduced to prevent subsequent patients from harm [\[10\]](#page-54-0). The use of such a statistical process control has been shown to detect inadequate performance much earlier than other statistical methods. The results of the CUSUM analysis in this randomized control trial revealed a steep learning curve that can be overcome, as in this case, through a brief manufacturersponsored training course and a training set of five clinical cases. Operative time, radiation exposure and post-operative complications and hospital stay were not assessed in this study.

An ongoing single-centre randomized control trial by Roser et al. [\[11](#page-54-0)] has to date only published interim results in 40 FH, 36 navigation-assisted (NA) and 72 RA pedicle screws in 37 patients. Accuracy of the pedicle screws was determined using the Gertzbein and Robbins scale. Only when the screw was entirely within the pedicle (position A) was this considered satisfactory. Ninety-eight percent of FH, 92% of navigation-assisted and 99% of RA pedicle screws were found to be satisfactory. The study aims to randomize a total of 120 patients (40 in each of the three arms). Radiation exposure was measured as both the total fluoroscopy time and the total radiation dose measured using a dosimeter. Radiation time was FH 31.5 s, NA 10.4 s and RA 16 s. Given that only one quarter of these have been recruited, the authors have not performed any statistical evaluation. The full results of the trial are therefore awaited.

Non-randomized cohort studies have been performed prospectively and retrospectively by Schizas et al. [\[12](#page-54-0)] and Kantelhardt et al. [[13\]](#page-54-0), respectively. Schizas et al. undertook a single-centre prospective cohort study in which 34 patients undergoing thoracolumbar pedicle screw fixation were divided into 64 screws in 23 patients in the FH group and 64 screws in 11 patients in the RA group. Two independent observers rated post-operative CT scans using the Rampersaud scale. Screw position either entirely within the pedicle or breaches within 3 mm of the pedicle wall (positions A and B) was considered satisfactory. This study found 92% of the FH and 95% of RA screws were satisfactory. This was not statistically significant. Radiation exposure was also not found to be significantly different. Kantelhardt et al. performed a retrospective cohort analysis comparing RA 250 pedicle screws in 35 percutaneous and 20 open cases with 286 FH pedicle screws in 57 open cases. In this study the Wiesner and Schizas scale was utilized in which screws that were entirely within the pedicle or with encroachment of the cortical bone (grade 0 and 1) were deemed satisfactory. This was achieved in 94.5% of RA and 91.5% of FH pedicle screws ($p < 0.05$). In total 1% of the RA compared to 12.2% of the FH pedicle screws required revision, although this was not statistically significant. Comparison of total radiation exposure, measured as total fluoroscopy time, was 27 s for percutaneous RA, 43 s for open RA and 77 s for open FH cases, indicating a significant reduction in surgeon and patient irradiation ($p < 0.02$). There was no different in the average time per screw placement between RA and FH cases in this study. Post-operatively this study revealed a significant increase in the requirement for opioid analgesics from 38% percutaneous RA and 67% open RA to 89% open FH ($p < 0.004$). Intraoperative dural tears were seen in 4.7% of RA and 9% of open FH cases whilst post-operative infections occurred in 2.7% RA and 10.7% open FH cases ($p < 0.04$). Total hospital stay was also reduced to 10.6 days in RA from 14.6 days in FH procedures ($p = 0.009$). Both of the non-randomized studies by Kantelhardt et al. and Schizas et al. failed to provide a prospective power calculation. In addition it is unclear whether there were any significant baseline differences in the patients in the RA and FH groups that could have impacted on the outcome.

Schatlo et al. [\[14](#page-54-0)] performed a retrospective matched cohort comparison of 244 RA pedicles screws placed in 55 patients and 163 FH pedicle screws in 40 patients. Of the patients in the RA group, they were subdivided into open RA in which 83 pedicle screws were inserted in 17 patients percutaneous RA in which 161 pedicle screws were inserted in 38 patients. The RA procedures employed the spinous process clamp method of attaching the robot to the patient. Baseline patient demographics were closely matched although there were fewer males in the open RA and BMI was higher in the open FH compared to the percutaneous RA group. Pedicle screw accuracy was assessed from post-operative CT scans by a blinded neuroradiologist using the Gertzbein and Robbins scales in which those that were entirely within the pedicle or with $\langle 2 \rangle$ mm breach (A and B) of the wall were "clinically acceptable". There was no statistically significant difference between the RA and FH groups with 91.4% and 87.1% achieving satisfactory position. There was no difference in infection rate between the RA (1.8%) and the FH (2.5%) groups. In one case a FH screw resulted in a painful radiculopathy at the level of L4 and therefore required revision. Total operative time was non-significantly longer in the RA groups. Blood loss was significantly lower in the RA group falling from a mean of 375 ml to 713 ml ($p < 0.01$). There was no difference in the length of hospital stay between the two groups. Post-operative pain was assessed as the cumulative dose of morphine and did not show any significant difference. Similar to Ringel et al., Schatlo et al. describe a discrepancy in the planned and radiographic robot entry points on lateral fluoroscopy despite accurate registration and attribute this to the entry cannula sliding off the steep superior articular facet. They feel modification of the technique through choice of a flat entry point or tightly securing the cannula teeth on the bone may improve the lateral deviation errors. Overall radiation expo-

sure was not recorded between the two techniques. A single retrospective cohort study of patients has been performed in spondylodiscitis in whom pedicle screw fixation was performed through percutaneous RA and FH methods [[15\]](#page-54-0). The authors chose this cohort of patients to ascertain whether percutaneous RA pedicle screw placement could prevent direct inoculation of the implants. In total 121 FH pedicle screws were placed in 24 patients, and 341 RA pedicle screws were placed in 66 patients. Accurate screw placement was assessed using the Wiesner and Schizas classification in which pedicle screws that were entirely within the pedicle or in which there was a breach of <3 mm were classified as satisfactory. Satisfactory screw placement was achieved in 90% of the percutaneous RA and 73.5% in the FH group. Five percent of the FH required revision for misplacement compared to 0.6% in the percutaneous RA group. There was no difference in the median operating time between the two techniques. Radiation exposure was assessed using total fluoroscopy time and revealed a significant reduction in the FH group of 0.4 min compared to 0.94 in the RA group ($p < 0.0001$). There was no difference in intraoperative dural tears, and post-operative CRP was significantly less in the RA group. Total hospital stay reduced from 18 days in the FH group to 14 days in the RA group. There was no difference in post-operative back and leg pain when assessed using a visual analogue scale.

It has been suggested that the biggest utility of RA pedicle screw placement would be deformity correction surgery in which the traditional anatomical FH trajectories for pedicle screw placement do not hold [\[16](#page-54-0)]. There is a paucity of studies in the published literature relating to this, and only a single retrospective review of 55 adolescent patients undergoing correction of idiopathic scoliosis has been reported without a control cohort [\[17](#page-54-0)]. Accurate screw placement was defined as pedicle screws entirely within the pedicle or breaches <2 mm. Of the 662 pedicle screws placed with RA, 93% were satisfactory. The authors describe a reduction of medial screw malposition through planning pedicle screws based on prone preoperative CT images. Further case-control studies are required to provide direct comparison to FH techniques in this patient population.

A single prospective control trial in cadaveric specimens has also been undertaken by Lieberman et al. [[18\]](#page-54-0). Ten cadavers underwent RA pedicle screw insertion in which 15 surgeons placed 197 screws compared to 2 cadavers in which 2 surgeons placed 32 screws in the FH group. Of note, in the RA group 14/15 surgeons were first time users of the SpineAssist robot, whilst 2/2 of the surgeons in the FH group were experts in this technique. Screw implantations were performed using both open and percutaneous implantations as described above. In the FH group, percutaneous pedicle screw placement was performed following conventional techniques using a Jamshidi needle. Screw trajectories were then assessed on post-operative CT scans by blinded raters using the Rampersaud scale in which only screw position entirely within the pedicle (grade A) was considered satisfactory. Deviation of the implemented from the planned pedicle screw trajectory in the FH group was 2.6 ± 0.7 mm compared to 1.1 ± 0.4 mm in the RA group ($p < 0.0001$). There was no difference in the accuracy of the RA screw placement between surgeons of varying experience and overall provided better consistency in screw placement. Radiation levels were measured using a dosimeter badge on the outside of a lead apron and a ring on the dominant hand of the surgeon in both the RA and FH groups. Radiation exposure was found to be 98.2% less per screw ($p < 0.001$) in the RA group compared to the FH group. Average pedicle screw insertion time was reduced from 6.27 ± 30.5 min in the FH group to 4.05 ± 1.08 min in the RA group. Of note, the single RA experienced surgeon was able to perform the procedure in as little as 2.75 min per screw indicating RA placement is quicker despite the learning curve.

Using a similar technique to pedicle screw placement the SpineAssist robotic system has also been retrospectively assessed for potential use in transpedicular vertebroplasty for osteoporotic or pathological fractures [[19\]](#page-54-0). In total 33 patients underwent 60 vertebroplasty procedures with an accuracy of 99%. Two complications (haemothorax and superficial wound infection) were reported. In comparison to published radiation exposure levels using the conventional FH technique, the authors claim RA reduces this by 74%. Further prospective case-control studies are required to substantiate this. The use of the SpineAssist robot has also been described for en bloc sacrectomy in a single case report [[20\]](#page-54-0).

4.2.2 Other platforms

Recently pedicle screw placement has been assessed using the ROSA™ (Medtech) robotic system in a single surgeon prospective case-control study [[21](#page-54-0)]. The same surgeon performed 40 RA screws in 10 patients and 50 FH screws in 10 patients. Screw

placement was assessed using the Gertzbein and Robbins scales in which screws entirely within the pedicle or breaches within 2 mm (grade A and B) were considered satisfactory. Satisfactory screw position was achieved in FH 92% and RA 97%, but this failed to achieve statistical significance. Radiation exposure to the patient was assessed as total fluoroscopy time was found to be double that of the RA group.

The da Vinci surgical system has been utilized to assist in retroperitoneal approaches for ALIF procedures in a series of animal studies [[22\]](#page-54-0), technical notes [\[23](#page-54-0)] and case series [[24\]](#page-54-0). The largest published series is a retrospective review of 11 patients by Lee et al. [[24\]](#page-54-0) in which the da Vinci system was utilized for the transabdominal approach and retroperitoneal dissection for access to the anterior disc space. All patients in this small study showed evidence of radiographic fusion and no intraoperative complications were encountered. No post-operative ileus or transfusion requirement was found, and none of the robot-assisted procedures required conversion to an open procedure.

4.3 Limits

Currently the projected cost of the SpineAssist robotic systems is in the region of \$1 million in the USA and consumables cost a further \$1500 per case. To offset this additional capital cost, procedures have been shown to be either safer, quicker or reduce radiation exposure of the surgeon and patient to be economically viable. Ideally, robotic systems that serve multiple operative uses would provide the best value for money, but the differing technical requirements imposed by cranial and spinal procedures make this difficult to implement. In addition, the introduction of any new technology requires training, not only of the surgeons but the entire theatre team. Technical support from manufacturers' representatives will likely need to be on hand to ensure smooth operation of the system until it is engrained into the surgical workflow. In the initial descriptions of the SpineAssist software, stability was an initial concern with the computer workstation crashing and rebooting during the surgery [[5\]](#page-53-0). Concerns regarding this have not been raised in the number of clinical studies mentioned above, but in all clinical uses of robotics, robust and continuous quality control measures are required to prevent this. Unlike other robotic systems used in neurosurgery such as the ROSA [\[21](#page-54-0)] and Neuromate (Renishaw) [[25\]](#page-55-0), the SpineAssist is a miniaturized system that does not require a large operating room footprint, but stability is reduced as a result of this. The SpineAssist robotic system currently has a number of different ways that it can be attached to the patient, and it is unclear which of these provides the optimal solution with regard to stability and accuracy. Larger robotic systems may be able to withstand stronger forces applied by the operating surgeon, and it remains to be seen whether lateral deviation of pedicle screws when applied to the steep surface of the pedicle entry point affects larger systems such as the ROSA. Technical improvements with time however have allowed the incorporation of different techniques, such as the Peteron technique [[9\]](#page-54-0), to potentially overcome the issue of lateral deviation by smoothing and flattening the pedicle screw entry point.

Conclusions

To date the evidence for robotic guidance systems in spinal surgery are both limited and inconclusive with meta-analyses not showing any categorical evidence in favour of a single technique [[16](#page-54-0), [26](#page-55-0)]. This is in part due to the variety of different rating scales used to assess outcome and a lack of consensus regarding what grade is considered satisfactory. The outcomes of the two randomized control trials that have been completed have shown differing results [\[9](#page-54-0), [8\]](#page-54-0), but crucially neither has shown a superiority of robotic systems against free-hand fluoroscopic-guided pedicle screw placement. A single study has compared free-hand to navigation-assisted, and robot-assisted pedicle screw placement has only published interim data and the rest is still awaited [\[11\]](#page-54-0). The differing results of the randomized control trials by Ringel et al. and Kim et al. have shown how experience and technical advancements from previous trials can improve accuracy [[9, 8\]](#page-54-0). In all instances, relatively novice robotic surgeons were compared with expert surgeons performing free-hand pedicle screw insertion. The benefit of robotic-assisted surgery is that the learning curve is relatively steep, and novice robotic surgeons may be able to place pedicle screws at a similar accuracy to expert free-hand surgeons with relatively less training time. It is vital however that early adopters of robotic techniques do so in a safe and responsible fashion ensuring that all preliminary training is gained under expert supervision. In addition robust mechanisms need to be instituted, such as the CUSUM test, to ensure any suboptimal outcomes as a result of novel techniques or technology are identified early to prevent patients from unrecognized harm [\[9](#page-54-0), [10](#page-54-0)]. As further experience with robotic systems increases, it is likely too that the patients will begin to accept their use in surgery as a whole, such as the gradual transition from open to minimally invasive surgery over the last two decades.

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5 3D Printed Tubular Guides for Pedicle Screw Fixation

Riccardo Cecchinato and Claudio Lamartina

5.1 Introduction

As described in the previous chapters, modern technologies have been applied in spinal surgery to improve vertebral instrumentation accuracy. Since their introduction in operating rooms, pedicle screw systems are widely used in the treatment of spinal pathologies. However, the great diffusion of this technique has triggered an increase in complications related to screw malpositioning. Recent studies show that the ratio of misplaced screws is very variable, depending on the type of underlying pathology (i.e., adolescent idiopathic scoliosis, adult deformities, trauma) and the relative experience of the surgeons. The rate of pedicle screws malposition varies between authors from 3.4% to 29.1% [\[1](#page-64-0)[–5](#page-65-0)]. This variability is partially attributed to the different pathologies enrolled in these studies. When considering deformity treatment, the rates of misplaced pedicle screws rise inevitably, and clinical complications due to aortic, pulmonary, or nervous lesions can become life threating [\[6](#page-65-0), [7\]](#page-65-0).

In the recent years, many different techniques have been adopted to reduce the rate of screw malpositioning and, thus, of related complications. Robotics, intraoperative CT guidance, and custom-made hardware are probably the most commonly used systems to improve the safety of screw positioning. Proper assessment of limits and benefits of these different systems is necessary, however. In case of intraoperative O-arm, for example, very high accuracy is obtained at the expense of very high exposure to radiations.

The previous chapters of this book have already explained in detail advantages and limits of CT and robotic navigation. The aim of this chapter is to focus on custom-made guides for pedicle screw implant.

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5.2 Custom-Made Pedicle Screw Navigation

The first proposals of guides for pedicle screw implant were made in the 1990s. In 1990 Pennig and Brug proposed a device made by a cylindrical plastic block with a handle [\[8](#page-65-0)]. Each cylinder had a metal ring that was aligned to the pedicle in the AP view. A metallic pin and subsequently a k-wire were introduced along the pedicle through the ring, establishing the direction on known anatomy of the pedicles at different levels. This was obviously a non-customized item but the first mechanical device to guide screw insertion. In the following years some papers were published on the first custom-made guides. These guides were prepared for cervical or thoracolumbar spine, with different designs depending on spinal region and manufacturer. In 2001 Jang et al. proposed a guide device to implant screws in thoracic spine with an accuracy of 94.2% [[9\]](#page-65-0). This hardware was tested on five human specimens, and the postoperative position of the screws was evaluated with a CT scan, showing a reduction of pedicle wall violation. Salako et al. proposed a feasibility study of patient-specific templates in 2002 [[10\]](#page-65-0), describing two different designs. The first was built using rapid prototyping, while the second is an adjustable device that can be adapted for use at different levels. No clinical data were provided in this paper. Two of the authors involved in this first manuscript produced a second study on this second device, that is, a transpedicular adjustable drill guide [[11\]](#page-65-0). The advantage of this system is that it can be used for many levels, as it could be adapted in its angles and directions. This device's adaptability, however, potentially decreases the instrument's precision and, therefore, pedicle screw accuracy. The results reported in the study seemed promising, although hardly conclusive due to the low number of positioned screws (22 screws). In 2009 Lu et al. published a paper on custom-made templates for lumbar spine [\[12](#page-65-0)]. They tested 36 pedicle screws in a cadaveric experiment and 22 screws in six clinical patients. However, the thickness and resolution of CT scan (0.625 mm slice thickness and 0.35 mm in-plane resolution) were not as precise as can be obtained by modern techniques, and these guides needed a k-wire implant before guide removal and screw positioning. This can obviously affect screw direction, especially in osteoporotic bone. No detailed results are provided in this paper, stating only that the system had a higher precision than other techniques. Nonetheless, the authors highlighted how "this method has not yet replaced imageguidance systems," highlighting how this technology was not sufficiently developed to substitute traditional techniques. More recently, the adaptation to the thoracic spine of these custom-made acrylate resin guides system was published in a paper after a test on specimens with the implant of 240 screws [[13\]](#page-65-0). These guides show better accuracy in respect to a control group where the same number of pedicle screws was implanted with a free-hand technique. A Chinese group published two different papers [[14,](#page-65-0) [15](#page-65-0)] on a custom-made guide system for lumbar instrumentation, using a 3D-printed plate that fits on each corresponding vertebra. Again, the technique requires the implant of k-wires along the tubes of the template, guide removal, and subsequent cannulated screw implant. This represents a theoretical limit due to the possibility of k-wire mobilization during guide removal or poor bone quality.

Improvement of the guide preparation and development and introduction of 3D print has significantly enhanced the custom-made guide technique. Modern computer softwares allow a more precise reconstruction of vertebral anatomy based on CT scan, and 3D printers can create tools with a submillimetric precision that was not possible only a few years ago. Regarding CT scans however, all these custommade templates are crafted based on a preoperative CT scan, giving the patient a high radiation dose. Even if this technique brings to a reduction of surgeons' exposure and consequently improved safety of operating theater staff, patients' radiation absorption is a main concern that should be carefully considered when using this kind of technology.

5.3 Medacta MySpine Custom-Made System

Medacta, a Swiss Company that has recently developed a 3D-printed tubular guide (Fig. 5.1), offers an interesting and innovative solution. These guides are crafted for each specific patient and are used to lead the direction of the preparing instruments and of the final screw.

As previously underlined, the main concern regarding intraoperative navigation with O-arm or similar technologies is the amount of radiation given to the patients.

Fig. 5.1 MySpine custom-made guide. Each guide has on its surface indications of the level and screw dimensions. For each level the corresponding vertebral reconstruction is provided. This allows the visualization of the contact points between guides and bone surface and the identification of the entry points

Fig. 5.2 Example of a low-dose CT scan (image on the *left*) compared to a normal CT scan (image on the *right*). With the low-dose protocol, the soft tissues adjacent to the vertebral body aren't clearly defined, and the bony trabecular pattern isn't well represented. However, the cortical vertebral bone has the same definition and can be used for a 3D reconstruction of the vertebra and consequently for the planning of custom-made guides

For example, the use of an intraoperative CT for the instrumentation of 17 vertebrae in a slim patient gives a mean dose of 32.4 milliSievert (mSv) $[16]$ $[16]$ or more than half of the US annual dose limit for surgeons (50 mSv) and almost 21 times the exposure for a spine X-ray (1.5 mSv). The total dose can raise up to 80.9 mSv if the patient is obese [\[16](#page-65-0)]. Such an exposure can cause complications related to radiations. Stochastic and deterministic effects of radiation exposure are well known, and the administration of X-rays to patients must be limited. This has been recently underlined in a paper that demonstrated an increased incidence of cancer in patients that were previously treated for adolescent idiopathic scoliosis [[17\]](#page-65-0). Moreover, surgeons are continuously exposed to radiations during their surgeries, due to the use of these kinds of intraoperative navigation systems. Ultimately, both patients and surgeons increase their risk of stochastic and deterministic effects due to radiation exposure.

MySpine technology allows a guided implant of the screws with a minimal radiation exposure for the patient and with no exposure for surgeons. Each guide is crafted based on a low-dose CT protocol that has been developed specifically for this technique. This protocol allows the patients to be exposed to a radiation dose that varies between 0.9 and 2.5 mSv for the analysis of 15–19 vertebrae. Obviously, with this low-dose exposure, the quality of the resulting images of CT scan is poor, but the cortical bone of the different vertebrae is trustworthily represented. Adjacent soft tissues and inner vertebral trabeculae aren't well shown, but this doesn't affect guides planning and crafting (Fig. 5.2).

Once the fusion area is determined and a low-dose CT scan is performed for the image acquisition of the patient's vertebral anatomy, a 3D model of the whole spine is created. Each individual vertebra is reconstructed and the ideal entry points and

Fig. 5.3 Example of a preoperative planning of the MySpine system. For each level (in this case T6), screw directions and dimensions are planned based on vertebral anatomy. Each parameter (sagittal and transversal angles, screw length and diameter, entry points) can be changed preoperatively by the surgeon. Once the planning is approved, the guides that will lead the screws in the desired final position are crafted and shipped

trajectory of the screws planned. Screw dimensions (length, diameter) are decided at this stage, based on anatomical features of each vertebra (Fig. 5.3). If the preoperative planning satisfies surgeon's needs, the tubular guides are crafted using a 3D printer. Otherwise the surgeon can change preoperative planning using specifically designed software. Each screw parameter is alterable: entry points, orientation on the transverse and sagittal planes, screw length and diameter. Regarding the guides, these can be planned as open, semi-open, or closed, depending on the spinous process fit. The semi-open or closed guides allow a more strong fit but supraspinous ligament section is mandatory. On the other hand the open configuration allows the preservation of the supraspinous ligament but decreases the contact between the guide and the bony tissue. This however doesn't affect guide stability and accuracy. The guides are made of medical grade polyamide with a powder particle size of 60 μm and a layer height lower than 0.1 mm, allowing a submillimetric precision. Each guide is provided with the corresponding vertebral model to verify the fit and check the entry points of the screws before applying them on the patient.

Each standard MySpine guide has a specific inferior surface that allows a perfect contact with the corresponding vertebral body. Three key contact points between guides and vertebrae are necessary: the spinous process, the laminae, and the transverse processes. These bony landmarks should be carefully dissected during spine preparation to avoid any violation of the bony contour of the posterior

arch. Soft tissues must be completely detached, allowing a direct contact between the guide and the bone. Any soft tissue that is left on the spine can change the fit of the guides on the vertebra and consequently affect screw precision. Once the spine is adequately dissected, the most cranial guide is inserted. Usually this guide has a cranial semi-open design, to allow the preservation of the upper part of the supraspinous ligament. Once the tubular guide is properly placed, the entry points can be identified and flattened with a burr. Awls and probes are then inserted in the tubular guide that drives the instruments in guided directions. Once the pedicle is prepared, the pre-planned screw is inserted along the tubes. An evolution of this system uses low profile guides with less contact points and a K-wire with cannulated instruments and screws. The advantage is to reduce spine dissection and muscle detachment, even if K-wire stability in poor quality bone can affect the final position of the screw. Once screws are inserted the screwdrivers are detached and the guide removed, and the surgeon moves caudally to the subsequent vertebra. Once the planned vertebrae are instrumented, rods are inserted and deformity corrected following the surgeon's preferred technique. Decortication of the spine and bone grafting are then mandatory to obtain spinal fusion and long lasting corrections.

MySpine accuracy has been preliminarily tested, and the results are exposed in two different papers published in 2014 and 2015. In the first manuscript, the system has been applied to four patients with severe scoliosis, with the implant of a total of 76 pedicle screws. In this series 84% of the screws were completely intrapedicular, and this value rose up to 96.1% considering the screws with <2 mm of pedicle violation. No hardware-related complications occurred, and no medial violation of the pedicle was observed.

The second paper on this system was published in 2015 in European Spine Journal. It was a cadaveric specimen study with the implant of 46 pedicle screws using the MySpine system. This study was carried out before the previous one, although published subsequently. After screw implant, CT scans were used to assess the position of the hardware. 91.3% of the implanted screws were fully inside the pedicle, with no grade B $(2-4 \text{ mm})$ or grade C $(>4 \text{ mm})$ pedicle violation, according to Gertzbein classification [\[18](#page-65-0)]. The mean deviation between the planned trajectories and the final position of the screws at the midpoint of the pedicle was 0.7 mm, the mean horizontal deviation was 0.6 mm, and the mean vertical deviation was 0.77 mm; the mean angular deviation in the sagittal plane was 1.74° and 1.32° on the transverse plane. These results indicate a very high accuracy of the system and satisfactory results in screw positioning. A demonstrative video on this technology has been published in European Spine Journal in 2014, where MySpine guides are used in a case of adolescent idiopathic scoliosis [[19\]](#page-65-0).

To definitively confirm the efficacy of MySpine in guiding pedicle screws along predetermined trajectories, a prospective randomized controlled trial is ongoing at the authors' center. This study is evaluating two groups of patients that are treated for severe spinal deformities (Fig. [5.4\)](#page-62-0) using a free-hand technique versus

custom-made guides. The goal of the study is to verify the accuracy and reliability of the system. The definitive results of the trial are not yet available, but preliminary results clearly suggest higher precision and the accuracy of Medacta MySpine technology, confirming it as a valid custom-made navigation system for pedicle screw implant.

Fig. 5.4 (a) Clinical case of a 39-year-old male with a congenital scoliosis due to a L1 hemivertebra. (**b**) The congenital malformation is clearly seen at a CT 3D reconstruction. (**c**) Postoperative full-standing X-rays after a T9-L4 fusion and three-column osteotomy using MySpine guides for pedicle screw implant. (**d**) Postoperative CT scan demonstrated a perfect placement of the screws in the vertebral pedicles even in this complex deformity case

Fig. 5.4 (continued)

Conclusions

In these last years, technological progress is providing new systems that can help surgeons in operating rooms. Custom-made pedicle screw navigation is one of the technologies that are rapidly and constantly developing. These systems are designed to be precisely adapted to each patient and to help surgeons in the positioning of pedicle screws, reducing the complication rates related to hardware implant. These systems have the advantage of reducing intraoperative radiations, a significant advantage both for patients and surgeons. Among the different proposals available on the market, Medacta MySpine presents two advantages: the first is the low-dose protocol used to obtain CT scans of patients' spine. This allows for a reduction of X-ray exposure of the patients and surgeons. Second, the precision of the 3D printer allows a perfect fit between the guide and the corresponding vertebra, increasing the accuracy of the system. The preliminary results of an ongoing randomized controlled trial already suggest higher accuracy of screw positioning inside the pedicles using the MySpine Medacta system, allowing for a reduction of complications related to screw misplacement.

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6 New Techniques and MIS: The XLIF Technique

Massimo Balsano, Alexandros Zachos, Giulia Raffaella Mosele, and Carlo Doria

6.1 Introduction

The anterolateral retroperitoneal approach to the anterior column of the spine has a long history of clinical success since its first reported use for Pott's disease and spondylolisthesis.

Today it is used for a variety of indications, including degenerative disc disease, spondylolisthesis, deformities, and posterior pseudarthrosis, among other conditions.

Anterior column access and stabilization is very well documented; today there are thousands of published articles on anterior, lateral, and anterolateral lumbar interbody fusion.

Conventional large open anterior approaches fell out of favor because of vessel injuries, presacral plexus injuries, urinary retention, retrograde ejaculation, and abdominal muscle weakness caused by the large incision and extensive anatomic dissection.

Subsequent efforts have been made to make the anterior approach safer, less invasive, and more reliable.

Regardless of the terminology used, the steps and the end objective are the same: access to the anterior column of the thoracolumbar spine from within the retroperitoneal space, removal of the intervertebral disc and preparation of the vertebral endplates, and insertion of a spacing interbody implant, with biologic grafting materials and internal fixation as necessary for the ultimate goal of realignment of the spine, decompression of neural structures, and interbody fusion.

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A more lateral retroperitoneal approach to interbody fusion, however, could accomplish the same objectives with significantly reduced exposure time, muscle dissection, and associated postoperative morbidity.

It would prevent ligamentous destabilization and the need for vascular mobilization while still affording superior exposure of the disc for optimal disc space preparation and implantation of a large implant that could span the disc space laterally for greatest stability and anatomic correction.

Access to the lateral aspect of the disc space, however, was historically limited by the psoas muscle and the nerves of the lumbar plexus that run through it.

Other benefits of the procedure include minimizing collateral soft issue trauma through a muscle-splitting approach, maintenance of the anterior and posterior longitudinal ligaments (ALL and PLL, respectively), allowing for disc height restoration while maintaining natural stability and alignment correction through ligamentotaxis, and the ability to place an interbody cage with wide apertures for fusion across the lateral borders of the dense apophyseal ring. Anterolateral fixation techniques allow for single incision interbody fusion and stabilization. Alternatively, various posterior instrumentation techniques can be employed, sometimes without repositioning the patient, and these include, but are not limited to, unilateral or bilateral pedicle screws, interspinous devices, plating, and unilateral or bilateral facet screws $\lceil 1-5 \rceil$.

Relative limitations of the XLIF approach may include pathologies at the L5–S1 level, as the access to this disc space may be prevented by the iliac crest or the position of the iliac vessels in relation to this disc space, vascular anatomy, and previous abdominal surgeries [\[6](#page-74-0), [7](#page-74-0)].

It should be noted that there exists an extensive literature on the surgical treatment of the XLIF procedures, with very important international case studies. Recently a special issue of the *European Spine Journal* (Vol. 24, Suppl. 3, 2015) has been edited focusing on the lateral access surgery, indicating how this less invasive procedure is becoming a standard procedure in the treatment of thoracolumbar pathologies.

6.2 Clinical Aspects

From a pathological and anatomic point of view, adult degenerative or de novo scoliosis is typically associated with degenerative changes of the spine whereby one or more degenerated intervertebral discs lose its integrity and collapse asymmetrically, creating an abnormal curvature in the coronal plane. Formally, this is characterized by the new presence of at least a 10° lumbar or thoracolumbar curvature in a skeletally mature patient. The curve is often rigid in lateral bending and may be accompanied by the loss of lumbar lordosis. Anterolisthesis and lateral listhesis may accompany degenerative scoliosis, and rotatory listhesis occurs in up to one third of patients, typically at the L3–L4 level. Foraminal stenosis on the concave side is very common, and the spinal canal may also be narrowed, causing central stenosis with neurogenic claudication symptoms.

The most common presentation of adult degenerative scoliosis is a combination of mechanical back pain and leg pain [[8\]](#page-74-0). Back pain may be caused by the deformityrelated spinal imbalance, and neurogenic or radicular symptoms are typical of spinal stenosis. Kyphotic deformity of the lumbar spine also may be present and will often result in increased patient-reported pain and reductions in functional ability. Usually the patients report that pain is reduced with rest and aggravated by standing, walking, bending, and other daily activities. Pain near the concavity of the curve may be caused by facet arthropathy, disc degeneration, or spinal instability. Patients with severe curves may have pulmonary compromise and severe rib cage pain from pelvic impingement on the side of coronal decompensation.

A spinal examination of patients with degenerative scoliosis should include a thorough neurologic examination. In patients with a history suggestive of claudication, vascular status in the lower extremities should be examined to rule out the vascular cause. The examiner should also assess the overall balance and flexibility of the spine in the coronal and sagittal planes. Pelvic obliquity, waist and shoulder asymmetry, and leg length discrepancy should be evaluated. The position of the hips and knees should be noted while evaluating general sagittal alignment, to assess any compensatory mechanisms. All patients should also be examined for coexisting hip, sacroiliac, and knee arthritis and associated contractures.

6.3 Imaging Evaluation

An assessment of spinal alignment requires appropriate and reliable imaging: Fulllength (36-in. film) standing anteroposterior (AP) and lateral freestanding radiographs must be obtained to properly evaluate both coronal and sagittal spinopelvic alignment. Proper positioning minimizes changes in the sagittal spinal contour and optimizes the spinopelvic axis. The patient should stand with the knees and hips in a comfortable position. In the lateral view, arms should be flexed and the hands placed on the clavicles. Alternatively, the patient may place his or her arms comfortably over the abdomen, with one hand holding the opposite wrist (these positions cause minimal change in spinal position while allowing for visualization of the spine $[9, 10]$ $[9, 10]$ $[9, 10]$ $[9, 10]$ $[9, 10]$). In both planes, the spine should be visible from C7 to the femoral heads distally. The femoral heads, pelvis, and lumbar spine should all be visible on a single 36-in. image. Because knee flexion is a compensating mechanism in sagittal imbalance, some methods of surgical planning require that 10 cm of the proximal femora be included in the lateral standing film.

In the lateral view, the femoral heads should overlap by at least 50%. The relationship between the head, the spine, the pelvis, and the lower extremities cues the physician into the overall global balance, including any compensatory mechanisms used to stand freely.

Reproducible technique will provide high-quality images, allowing for properly placed angles and lines used to trace spinopelvic parameters.

In coronal deformity evaluation, AP views in lateral bending are useful to assess flexibility of the spine. It is crucial to perform a complete assessment of the spine, considering mainly: pelvic incidence (PI), pelvic tilt (PT), sacral slope (SS), spinal vertebral alignment (SVA), spino-sacral angle (SSA), lumbar lordosis (LL), thoracic kyphosis (TK), thoracolumbar kyphosis (TH-LK), the Cobb angle, the central sacral vertical line (CSVL), the rotatory subluxation of the vertebrae, and the sacral and pelvic tilt.

In addition, MRI and CT imaging are essential for the evaluation of disc degeneration, joint diseases, stenosis, herniated discs, inflammatory lesions, quality of bone, etc.

Moreover axial MRI studies should be used to assess the anatomy at each level, including the position of the great vessels as well as the location and shape of the psoas muscle. Smith noticed that, in rare instances, mostly in the lower lumbar levels and often with transitional anatomy (L5–L6 segments), the psoas muscle is teardrop-shaped and is detached from the lateral border of the disc space. Compared with the standard anatomy at the lower lumbar levels, where the psoas muscle is more helmet-shaped and is attached laterally to the border of the disc space, this teardrop shape is likely to present approach challenges, because it is more likely that the plexus has migrated anteriorly and that the great vessels have migrated more posteriorly. In these cases, care must be taken to prevent neural and vascular injury. In some cases conversion to another surgical approach may be necessary in the absence of a viable surgical corridor [[11\]](#page-74-0).

6.4 Rationale for XLIF Approach

XLIF procedure permits to realize a valid corrective maneuver in the deformity afforded by interbody devices with wide coverage of the end plate and large aperture for bone grafting. With the added benefits of reduced complications and promising reported fusion success, XLIF is an attractive option for addressing degenerative scoliosis [\[12](#page-74-0)].

The less invasive nature of the procedure offers great advantages in the older population, which often presents with significant comorbidities. The published literature on XLIF reports minimal blood loss with low revision rates and fewer complications compared with alternative approaches [[13\]](#page-75-0).

The ability to use a large interbody device in the disc space enables the surgeon to achieve indirect decompression of the neural elements, which may obviate the need for direct posterior decompression [[14\]](#page-75-0).

Wider interbody devices resist subsidence via a larger footprint and offer a larger bone graft surface area and volume to facilitate bone growth and fusion. Controlled correction in the sagittal and coronal planes is afforded by bilateral release of the annulus and maintenance of the anterior and posterior longitudinal ligaments. Release of the annulus provides initial mobilization of the misaligned segment, and when the disc space is elevated, the anterior and posterior ligaments are placed under tension, helping to restore segmental alignment. The ability to correct alignment in the coronal, sagittal, and axial planes is possible because of the variety of cage heights and widths and lordotic and coronal tapers available (CoRoent® XL, NuVasive, Inc.).

The procedure integrates real-time discrete threshold neural monitoring (NeuroVision®, NuVasive, Inc.) with the ability to detect proximity and directionality of the nerves that form the lumbar plexus, which is especially important in the deformity, where the location of nerves might be aberrant.

6.4.1 Selection of Approach Side

When planning the approach, it is critical not only to assess which side of the disc is most desirable to approach but to also assess the trajectory of the XLIF approach at each level. The choice of side should depend on which side will best overcome any obstacles that could prevent a successful approach. To determine the side with the least obstructed access for the procedure, one should consider obstacles such as the iliac crest, blood vessels, lumbar plexus, and any bridging osteophytes.

In general, approaching the spine from the concavity allows for easier access to the L4–L5 level above the iliac crest, allows for some table correction of the scoliosis by positioning with the concavity up, and may allow for more complete release of bridging osteophytes [\[15](#page-75-0)].

6.4.2 Posterior Fixation Options

The choice of supplementation is based on the patient's deformity and the surgical objectives. The posterior procedure can consist of an open decompression, facet release and instrumented fusion, or percutaneous posterior instrumented fusion accompanied by minimally invasive decompression when required. In examples of limited deformity over a small number of segments, it may be reasonable to treat the patient with stand-alone XLIF or supplemental posterior fixation via facet screws or interspinous devices (Figs. [6.1](#page-71-0) and [6.2](#page-72-0)). On the contrary, when greater deformity is present or when several consecutive segments require treatment, bilateral pedicle fixation may be preferred for increased stability. When supplemental posterior bilateral fixation is used, higher fusion rates are observed, subsidence is reduced, and correction is maintained over time [[16\]](#page-75-0).

CASE #1: This 55-year-old woman presented with a de novo scoliosis, generated by a single affected disc in L3–L4 (Fig. [6.1a, b](#page-71-0)). She complains of severe low back pain, with right L3 radiculopathy. She rated her back pain as 8, 45, and 36, respectively. The radiographic appearances show a 25° Cobb scoliotic deformity and a good spinal balance. Considering the pain generator, the MIS solution was an XLIF concave right approach in L3–L4, inserting an asymmetric PEEK cage (CoRoent®, NuVasive, Inc.), plus a posterior fixation with $ILIF^{\circledast}$ (Fig. [6.2\)](#page-72-0), with optimal coronal correction, neuroforaminal decompression, increased interbody space, and maintenance of sagittal spinal alignment.

Fig. 6.1 A case of severe degenerative disease of L3–L4 and L4–L5 in post-laminectomy surgery (**a**) sagital and (**b**) coronal views

At 6 weeks the patient's back pain was reduced to 1, and ODI and SF-36 improved to 20 and 64, respectively.

CASE #2: This 75-year-old woman affected by chronic obstructive pulmonary disease and presented with a severe spinal sagittal disalignment (Fig. [6.3](#page-73-0)). She had severe disability with VAS 8, ODI 75, and SF-15. Sagittal parameters are PI 66°, PT 39°, SS 27°, TK + 25°, LL + 23°, SSA 112°, and SVA + 8.5 cm.

In this case, the primary objective of surgery is to restore the global sagittal balance by adjusting the sagittal lumbar spine. The planning was to perform a minimally invasive surgery with ACR-XLIF in L2–L3, L3–L4, and L4–L5, with hyperlordotic cages (20°) and ALL release. A posterior open surgery was performed
Fig. 6.2 T2 sagittal MRI image shows the severe degeneration (Pfirrmann 4) of the discs L3–L4 and L4–L5, with Modic signs

with a posterior pedicle fixation L1–S1 (Fig. [6.4a](#page-73-0), b). At 6 weeks after surgery, the patient had a very satisfactory recovery, with VAS of 2, ODI of 35, and SF-36 of 54. New sagittal parameters are PI 66°, PT 18°, SS 48°, TK + 25°, LL − 55°, SSA 134°, and $SVA + 2.5$ cm.

Conclusion Most of the adult degenerative deformity patients are advanced in age and present usually with many preoperative comorbidities, compromised general health, and reduced bone density. A valid assessment of the spine, globally, is crucial. Rather than attempting complete correction of deformity, the goal of surgical intervention in this population is relief of mechanical and neurogenic pain and improved function through decompression of symptomatic stenosis and correction of spinal imbalance [\[15](#page-75-0)].

A lateral approach to the degenerated disc space uniquely allows for release of the motion segment that typically becomes contracted with scoliosis. Release of the annulus helps to facilitate disc space mobilization and distraction, which in

Fig. 6.3 XLIF L3–L4 and L4–L5 with PEEK cages and posterior minimal invasive stabilization with percutaneous pedicle screws. Optimal clinical recovery and good sagittal alignment (**a**) sagital and (**b**) coronal views

Fig. 6.4 Complete clinical recovery 1 year after surgery. The images show an adequate fusion and the maintenance of lordosis and alignment of the spine (**a**) sagital and (**b**) coronal views

combination with the placement of a large laterally inserted interbody graft allows for restoration of disc height and may result in benefits of indirect neural decompression and improved lordosis.

The reduced morbidity afforded by the XLIF approach when compared with traditional surgical procedures makes this technique particularly appealing in the older patient population with adult degenerative scoliosis. It is important to note that the efficiency, safety, and speed afforded by the XLIF procedure should not tempt the surgeon to abandon established spine surgical principles.

The surgeon must always focus on appropriate neural decompression and achieving stability and spinal balance. In some cases, in the presence of fixed deformity, ACR with hyperlordotic cages provides a minimally invasive technique for the treatment of adult focal sagittal deformity. ACR can provide correction that is similar to three-column osteotomy focally, with reduction in morbidity to the patient [\[17–19](#page-75-0)]. As with all deformity surgical techniques, it is associated with a risk of major complications including vascular and neurologic injury and should be performed by surgeons who have had the required training and experience in deformity surgery and the XLIF approach.

In summary XLIF technique gives the opportunity to the surgeons to minimize the access complications, providing a safe and reproducible surgery.

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7 New Implants and Techniques in Minimally Invasive Spine Surgery: True Percutaneous Transforaminal Lumbar Interbody Fusion (pTLIF) with the Posterolateral Transforaminal Endoscopic Approach

Rudolf Morgenstern and Christian Morgenstern

7.1 Introduction

Percutaneous spine surgery is one of the most important fields in minimal invasive spine surgery (MISS). Its objective is to reduce invasiveness by avoiding wide tissue and bone dissection using progressive tissue dilatation. A broad array of procedures, implants, and devices have been introduced in the last decade in the field of percutaneous spine surgery $[1-5]$ $[1-5]$. As visual exposition is limited with this technique, the use of an intraoperative fluoroscope is typically mandatory for percutaneous spine surgery. Nonetheless, radiation can be progressively reduced once the learning curve has been mastered [\[6](#page-97-0)]. Outcome and surgery time have been shown to be similar to that of traditional open surgery, but the risk of infection and blood loss is reduced, scar tissue formation is minimized, and wound healing is faster than in traditional open surgery [[3,](#page-96-0) [7,](#page-97-0) [8\]](#page-97-0). Moreover, time to ambulation and to hospital discharge are considerably shorter than in open surgery [[9\]](#page-97-0), increasing the patient's comfort and satisfaction with the surgery.

The posterolateral approach is a well-known standard in endoscopic spine surgery [\[3](#page-96-0), [7](#page-97-0), [8,](#page-97-0) [10–13\]](#page-97-0) that consists of progressive soft tissue dilatation combined with optional bone reaming [[3,](#page-96-0) [14\]](#page-97-0) in selected cases. Recently, we employed the endoscopy-based posterolateral transforaminal approach to percutaneously place an interbody device into the intervertebral disk [[9,](#page-97-0) [15](#page-97-0), [16](#page-97-0)]. This represents a completely new bridge between the fields of endoscopic discectomy and percutaneous fusion

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Opticage G3

Fig. 7.1 Different fabrics of percutaneous interbody cages (**a**) B-Twin expandable implant (**b**) standard PEEK interbody cage (**c**) Opticage model G2 (**d**) Opticage model G3

surgery. Hence, this new application of the posterolateral approach opens a broad new array of possibilities with disruptive potential for spine fusion surgery. In a retrospective view, the author's experience as endoscopic spine surgeon was of critical importance for the development of this percutaneous fusion technique [\[3](#page-96-0), [6](#page-97-0), [8,](#page-97-0) [16\]](#page-97-0). Our first steps in percutaneous posterolateral fusion were done with the B-Twin expandable interbody implant [\[17\]](#page-97-0) (see Fig. 7.1a). Even though the initial design of this device was not pretended for endoscopic spine surgery, the implant's small size permitted access to the lumbar intervertebral space with the posterolateral approach through a skin incision of only 7 mm and introducing the implant under fluoroscopic and endoscopic control. The progressive development and evolution of percutaneous implants, approach and surgical technique is detailed further on.

7.2 The Posterolateral Transforaminal Approach for Percutaneous Fusion Surgery

The posterolateral approach for intradiscal access and percutaneous fusion is very similar to the classic endoscopic surgical approach $[9, 10]$ $[9, 10]$ $[9, 10]$ $[9, 10]$. The patient should be positioned prone in an articulated table, with the hips flexed at the level of the great trochanter using four contact cushions: A for the pelvis, B for the chest, C for the head, and D for the legs (see Fig. [7.2\)](#page-78-0). The hip flexion should be increased step by

Fig. 7.2 Patient is positioned prone on an articulated table, with the hips flexed at the level of the great trochanter using four contact cushions: A for the pelvis, B for the chest, C for the head, D for the legs. Image modified from Joimax GmbH web site (www.joimax.de)

step until the lumbar lordosis disappears. The aim of this flexed position is to increase lumbar vertebral distraction in order to allow an easier approach through Kambin's safety triangle [[11\]](#page-97-0). The fluoroscope should be tested in anterior/posterior (A/P) and lateral views on the articulated table in order to obtain a proper image of the disk level of interest (see Fig. [7.3](#page-79-0)). In target-oriented endoscopic surgery, the exact location of the skin's entry point depends on where the desired objective is placed (intradiscal up to intra-canal) [[8\]](#page-97-0). For the intradiscal access used in percutaneous fusion surgery, the transforaminal posterolateral approach at 60° from the posterior spine process is usually the optimal choice (see Fig. [7.4\)](#page-79-0). The end plates should be visualized in a parallel position using a Fergusson A/P projection. Now a line is drawn on the skin parallel to the superior end plate of the inferior vertebral body and 10 cm from the midline to the lateral are measured. However, the distance of 10 cm is patient dependent and should only be used as an approximation, as it could vary depending on the disk's level and the vertebral size of every individual patient [[7, 10](#page-97-0), [12](#page-97-0)]. After selecting the optimal axial view of the disk to be punctured in magnetic resonance imaging (MRI) (see Fig. [7.5](#page-80-0)), the optimal entry point should be planned by following these steps:

- 1. Take the distance over the midline (red arrow) from the skin to the middle of the disk.
- 2. Translate this distance to the horizontal skin plane (blue arrow).
- 3. Measure this distance on the MRI horizontal scale (yellow) as in Fig. [7.5.](#page-80-0)
- 4. This is the skin entry point aiming to the center of the disk (green arrow).

Fig. 7.3 Surgical set-up

Fig. 7.4 The posterolateral transforaminal approach allows bypassing the scar tissue of previous surgeries that employed posterior/dorsal approaches

If your trajectory hits on the vertebral facet (see green arrow in Fig. 7.5), a foraminoplasty will probably be required to optimally reach the intervertebral disk. The superior articular process (SAP) from the inferior vertebra can interfere with the entrance to the epidural space. In patients with a degenerated facet, the SAP could be an insurmountable obstacle even to access the intervertebral disk. In these cases, a foraminoplasty is mandatory to safely access the disk space. The caudal part of the neuroforamen is a safe region to access the canal and the epidural space [\[4](#page-96-0), [5\]](#page-97-0) without harming the neural structures like the exiting root or the dorsal root ganglion. Therefore, the foraminoplasty must be done using manual reamers aiming the caudal part of the neuroforamen as shown in Figs. [7.11](#page-84-0) and [7.15.](#page-88-0)

After proper patient positioning, the skin entry point needs now to be drawn on the patient's back (see Fig. [7.6\)](#page-81-0):

- First draw a line on the skin using a pen marker following the spine's midline in the A/P fluoroscopic view. A metal rod is helpful when marking the fluoroscopic disk level in A/P (see Figs. [7.6](#page-81-0) and [7.7](#page-81-0)). The end plates should be visualized in the Fergusson A/P projection in a parallel position (see Fig. [7.6](#page-81-0)). Draw a line on the skin using a pen marker parallel to the metal rod (see Fig. [7.6\)](#page-81-0).
- Now place the metal rod in an upright position at 90° to the desired disk level under lateral fluoroscopic control (see Fig. [7.7\)](#page-81-0). The tip of the rod needs to be projected on the anterior portion of the annulus. It is mandatory that both end plates are projected parallel in the lateral fluoroscopic view as well (see Fig. [7.7\)](#page-81-0). Take the vertical distance D on the lateral rod from the tip of the rod to the horizontal skin plane (see Fig. [7.8](#page-82-0)).

Fig. 7.5 Trajectories for a percutaneous intradiscal access with the posterolateral transforaminal approach. The yellow arrow corresponds to the distance of the skin markings that will indicate the entry point of the access needle

Fig. 7.6 Show the step by step marking of the skin to determine the entry point for the percutenaous posterolateral transforaminal approach into the disk

Fig. 7.7 Show the step by step marking of the skin to determine the entry point for the percutenaous posterolateral transforaminal approach into the disk

– Now the measured lateral distance D should be transferred to the horizontal line (see Fig. [7.8\)](#page-82-0). The translated distance D defines a square that points to the anterior part of the annulus (see Fig. [7.8](#page-82-0)). The diagonal line of the square cuts the skin at the exact entry point that aims to the center of the disk.

After marking the entry point with the skin marker, presurgical skin cleaning and sterile draping of the surgical field should be performed. Under anteroposterior and

Fig. 7.8 Show the step by step marking of the skin to determine the entry point for the percutenaous posterolateral transforaminal approach into the disk

lateral fluoroscopic control, an 18-G needle is inserted into the disk (Fig. [7.9](#page-83-0)) as described by Yeung and Tsou [\[10](#page-97-0)]. The skin is anesthetized with bupivacaine 2%, and the patient is kept conscious under light sedation during the surgical procedure when surgery time is expected to be less than 1 h. Otherwise full anesthesia and neuromonitoring are required.

Local anesthesia with sedation was used for a selected group of patients upon a patient's explicit request only and if written permission was granted by the anesthesia team. Some patients were operated under local anesthesia (bupivacaine and 1% lidocaine) with intravenous sedation, analgesia, and cardiopulmonary monitoring by an independent anesthesiologist who was present during the whole surgical procedure.

In patients undergoing full anesthesia, intraoperative neuromonitoring was systematically performed by an independent neurophysiologist that routinely collaborates with our clinic. Somatosensory evoked potentials (SEPs) and motor evoked potentials (MEPs) were employed during the whole surgical procedure to monitor all involved peripheral nerves. At specific situations during surgery (e.g., screw insertion, cage insertion, etc.), additional nerve stimulation was done to ensure that nerve roots were not compromised (nerve root distance was considered acceptable at signal intensities ≥ 10 mA).

A contrast discography with indigo carmine (Taylor Pharmaceuticals, Decatur, IL) diluted with iopamidol 300 1:10 can be performed to confirm the annulus' containment and in the mentioned cases with local anesthesia and sedation also the segmental level of pain generation. The needle trajectory is anesthetized with lidocaine 1% and the annulus border as well. Through an 8-mm skin incision, progressive tissue dilatation is achieved by placing a beveled cannula 7.5-mm outer diameter, in immediate contact with the foraminal border of the annulus (Fig. [7.10\)](#page-83-0).

Fig. 7.9 Posterolateral transforaminal 18-G needle insertion under anteroposterior and lateral fluoroscopic control image modified from [[9](#page-97-0)]

Fig. 7.10 Progressive tissue dilatation is achieved by placing a beveled cannula with 7.5-mm outer diameter in immediate contact with the foraminal border of the annulus

Fig. 7.11 Reamed foraminoplasty can be performed under fluoroscopic vision to undercut the superior facet and to enlarge the foramen

Bone reamers can be used to perform foraminoplasty [\[4](#page-96-0), [5\]](#page-97-0) under fluoroscopic vision allowing intradiscal access even to an extreme collapsed disk space (height \leq 5 mm). Reamed foraminoplasty can be performed under fluoroscopic vision to undercut the superior facet and to enlarge the foramen without touching or harming the neural structures (Fig. 7.11).

7.3 B-Twin Expandable Implant: Surgical Technique

The B-Twin interbody spacer (Disc-O-Tech Medical Technologies Ltd., Herzliya, Israel) (see Fig. [7.1](#page-77-0)a), is a titanium expandable device with a jacking-up mechanism that provides additional stability to the end plates in the axial plane. This prevents rotation and allows a good bone integration. We employed this device in a series of 107 cases [[17\]](#page-97-0) with the described percutaneous posterolateral approach as a standalone device. No discectomy or partial discectomy was performed, preserving the natural annulus' shape and stability.

In a first step, the procedure consists of bone reaming under direct endoscopic control to widen the foramen. Even for level L5–S1 the approach has been improved thanks to the evolution of endoscopic reaming techniques [[3\]](#page-96-0). The transforaminal access can be visualized by use of an endoscope [\[15](#page-97-0)] similar to a transforaminal discectomy or foraminoplasty. The author used endoscopic visualization to show the exiting root and the epidural space (see Fig. 7.12). This proved to be important during the earlier cases for the confirmation of accessibility of the intervertebral disk space. In a second step, the B-Twin expandable device was used as a disk spacer to partially restore or to maintain the height of the collapsed disk. Finally, the endoscope can be used to confirm visually the decompression of the exiting nerve root. In addition, the exiting root can be mobilized under direct endoscopic vision with a flexible probe [\[3](#page-96-0)] (Ellman International, Hewlett, NY) (Fig. [7.11](#page-84-0)). After retrieving the endoscope, the implant can be inserted and expanded under fluoroscopic control. The skin is sutured, and the anteroposterior and lateral fluoroscopic controls were printed for case records.

To our best knowledge, this was the first reported experience with an expandable spacer being implanted by the endoscopic transforaminal approach in the lumbar spine. In this study, placing one or two B-Twin spacers into the same disk level was associated with a similar outcome. The intervertebral expansion of the spacer provided decompression of the neural structures and facet joints with a minimum invasiveness to the surrounding structures. Moreover, additional stability to the disk especially in case of slight instability or grade 1 spondylolisthesis was also achieved with the implant's expansion. One of the technical difficulties was the irreversibility of the spacer once expanded, preventing its relocation when it had been improperly placed. In these cases, extraction of the device especially under local anesthesia was very problematic. Hence, a new implant with a modified design would be desirable. In addition, an expandable spacer with a higher bone-implant-bone contact surface would also be desirable.

The technical limitations of the B-Twin expandable implant inspired the design and production of a new expandable implant (Opticage™, Interventional Spine, Inc., Irvine, CA, USA) with a larger bone-implant contact surface and a relocation mechanism that allowed the repositioning and re-expansion of the cage until correct sagittal balance is achieved (Figs. [7.1](#page-77-0) and [7.13](#page-86-0)).

Fig. 7.12 (*left*) Endoscopic visualization shows the exiting nerve root and the epidural space (*middle*) placement of the endoscopic cannula in A/P and (*right*) sagittal views

Pre-op CT-scan Post-op CT-scan

Fig. 7.13 (*left*) Pre-operative CT scan of a patient with DDD and spondylolisthesis grade I-II at L5/S1 (*right*) post-operative CT-scan showing considerable restoration of the original disk height with a fully expanded Opticage at L5/S1 and posterior fixation devices to stabilize the segment image modified from [[9\]](#page-97-0)

7.4 Percutaneous PerX 360°™ System: pTLIF Surgical Technique

The Opticage™ (Interventional Spine, Inc., Irvine, CA, USA), see Figs. [7.1](#page-77-0)c and d, is a titanium expandable cage that has an adjustable height from 9 to 14 mm by turning a handle with torque control. The cage automatically locks at the desired height and allows expansion/retraction and repositioning. The use of an expandable cage permits the instrumentation to be small, as the disk access can be done with a small annulotomy of just 7-mm diameter. The Opticage has an expansion strength of 1600N, and once expanded the graft can be directly injected into the implant. In comparison to the B-Twin cage, the Opticage has higher contact surface, and its convex surface allows an optimal adaptation to the end plate's shape during the expansion process (see Fig. 7.13). The expandable interbody implant was not designed as a stand-alone fusion device and should be used with supplemental posterior spinal fixation [\[9](#page-97-0), [15\]](#page-97-0) (i.e., facet screw fixation systems, interspinous devices and posterior pedicle screw-and-rod systems) to achieve a 360° vertebral fusion (also see the following section for further details on posterior fixation devices).

Regarding the surgical technique, the patient is operated in a prone position and in forward flexion, as mentioned before. The patient's position on the table should be adjusted to facilitate the approach to the disk, especially at level L5–S1, by increasing forward hip flexion but avoiding a kyphotic correction of the lumbar lordosis. The patient should be prepped and draped using a sterile technique. In a first step, the percutaneous posterolateral transforaminal approach is performed as mentioned in the prior section.

A special percutaneous insertion tool (Optiport™, Interventional Spine Inc., Irvine, CA, USA) was developed for the transforaminal disk access. Combining the percutaneous approach with an endoscopic view of the soft tissues helped to develop the design of the telescopic instruments. The use of an endoscope to visualize the exiting root and the epidural space was very important during the earlier cases [[3,](#page-96-0) [6](#page-97-0)] in order to confirm the safety of the percutaneous surgical approach. Now, if the surgeon considers it appropriate, the Optiport instrumentation can be used separately under fluoroscopic control only or in combination with an endoscopic system. The ability to endoscopically visualize the neuroforaminal disk access may be of particular importance when the presence of conjoined nerve roots or furcal nerve in the neuroforamen is suspected [\[13](#page-97-0)] (see Fig. [7.12](#page-85-0)). The Optiport allows progressive tissue dilatation by inserting the three stages of this telescopic instrument of 12.5-mm outer diameter (Fig. 7.14) through a 15-mm skin incision. A foraminoplasty can optionally be performed to enlarge the caudal part of the foramen to insert the instrument without harming the exiting root (see Fig. [7.15\)](#page-88-0). The foraminoplasty could also be performed with the sharp edges of the telescopic instrument (stages 1 and 2) (see Fig. 7.14), by rotating the instrument $\pm 45^{\circ}$ around the longitudinal axis. Care should be taken to ensure that the smooth side of the telescopic instrument remains always oriented toward the exiting nerve root (see Fig. [7.16\)](#page-88-0). The beveled cannula (stage 3 of the telescopic instrument) is then inserted until reaching contact with the annular wall. The careful rotation of the bevel will protect

cutting edges of instrument

Fig. 7.14 Telescopic instrument with the three stages for posterolateral transforaminal disk access Image modified from [9]

Fig. 7.15 Images (**a**) and (**b**), bone reamer into L4–L5 performing a foraminoplasty. Image (**c**), Optiport stage 1 on the annulus

Fig. 7.16 Image (**a**), Optiport stage 1 on the annulus. Image (**b**), Optiport stage 2 on the annulus. Image (**c**), Optiport stage 3 on the annulus

the exiting root (Figs. 7.16 and [7.17](#page-89-0)). Afterward, stages 1 and 2 are removed by pulling back the instruments through the beveled cannula. A percutaneous working channel to the intervertebral disk has now been created such that surgical procedures can be performed through the Optiport. A standard discectomy should be performed through the Optiport to remove a minimum of 80% of the disk nucleus from the treatment level. Partial integrity of the annulus should be maintained to contain the interbody implant. The end plate cartilage and the remaining disk materials are removed with curettes and rasps (see Fig. [7.17\)](#page-89-0). The percentage of end plate preparation is similar to that described for standard TLIF through the traditional posterolateral approach, as the telescopic access instrumentation can be moved around $\pm 30^\circ$ in a vertical-transversal plane and rotated 360 $^\circ$, allowing access to 60–80% of the disk. Once adequate discectomy has been achieved, demineralized bone matrix (DBM), beta-tricalcium phosphate (ß-TCP) mixed with stem growth factors, or autogenous bone graft should be placed into the anterior and lateral recesses of the intervertebral disk. Then, the interbody implant is filled with DBM, ß-TCP, or autogenous bone. The cage is then inserted through the beveled cannula

Fig. 7.17 Image (a), 12.5-mm Optiport cannula on the disk protecting the exiting nerve root. Images (**b**) and (**c**), paddle eroder grasping the end plates

Fig. 7.18 Opticage G3 insertion and expansion

and expanded under a C-arm fluoroscopic lateral control (Fig. 7.18). The most recent generation of Opticage ("G3 generation," see Fig. [7.1](#page-77-0)d) allows injecting the graft material directly through the implant. Hence, this way a better graft distribution around the expanded cage can be achieved. Finally, A/P and lateral control X-rays are taken (Fig. [7.19\)](#page-90-0), and the skin is sutured with reabsorbing Vicryl 00 (Figs. [7.20,](#page-90-0) [7.21](#page-90-0), and [7.22\)](#page-91-0).

This percutaneous posterolateral approach with foraminoplasty and progressive tissue dilation allows a less invasive access to the intervertebral disk than the classic MIS TLIF approach. It requires only a small skin incision of 15 mm and eliminates the excision of the superior facet, which would have been necessary for a classic MIS TLIF $[1]$ $[1]$. The posterolateral approach is also very useful for revision surgery

Fig. 7.19 Final fluoroscopic control images of an expanded Opticage and an interspinous spacer as posterior fixation device (*left*) A/P view (*right*) lateral view

Fig. 7.20 (**a**) Titanium rods with transpedicular screws. (**b**) Transfacet screws in AP and lateral view

Fig. 7.21 (**a**) Titanium dynamic rods with transpedicular screws. (**b**) PEEK dynamic rods with transpedicular screws. (**c**) PEEK rods with transpedicular screws

[\[9](#page-97-0)], as this percutaneous approach allows the surgeon to circumvent the dorsal scar tissue from previous surgeries and access the disk without the dissection of the soft tissue structures and adherent scars in the epidural space (see Fig. [7.4](#page-79-0)). Furthermore,

Fig. 7.22 CT scan postoperative control of an expanded Opticage at L4/L5 with posterior fixation devices. Note in the axial view how the Opticage was placed crossing the midline in order to achieve optimal biomechanical stability

the smallest skin incision for a TLIF found in the literature $[1, 2]$ $[1, 2]$ $[1, 2]$ was 30 mm in length for a classic MIS TLIF approach which required time from surgery to ambulation of 3.2 ± 1.9 days and a hospital stay of 9.3 ± 2.6 days [[1\]](#page-96-0). In contrast, for this new endoscopically assisted transforaminal percutaneous TLIF (pTLIF) approach, the incision was of only 15 mm in length, with a median time to ambulation of 6 h and a total median total post-operative hospitalization time of 26 h [[9\]](#page-97-0). The expansion of the interbody implant gives immediate stability to the posterior fixation (Fig. [7.13](#page-86-0)) which allows the patient to stand and walk, usually around 4 h after surgery without low back pain or radicular pain due to the DDD or segmental stenosis [\[9](#page-97-0)]. This approach can also be helpful in cases of mild and moderate central stenosis. The cage's expansion indirectly decompresses the operated level and straightens the ligamentum flavum through ligamentotaxis, resulting in a considerable posterior decompression of the foramina and the central canal at the operated level (see Fig. [7.23\)](#page-92-0). In cases of severe central stenosis, an additional unilateral foraminoplasty can be helpful to decompress the lateral recess (see Fig. [7.24\)](#page-92-0).

From 2011 to 2017 we performed in our facility in Barcelona, Spain a singlecenter, single-surgeon prospective study of 40 non-randomized, sequential cases with the percutaneous insertion of the Opticage expandable implant using the aforementioned posterolateral transforaminal approach (pTLIF procedure). These 40 Opticage pTLIF cases had a mean age of 61.7 ± 14.6 (range 26.1 to 84,4) years and 28 (60%) were female. For 4 cases (10%) one Opticage was inserted in two separate levels, respectively during the same surgery, while the remaining 36 cases obtained

Fig. 7.23 (*left* and *middle*) Pre-operative axial and sagittal MRI views showing a severe left foraminal stenosis at level L4/L5 (*right*) post-operative lateral MRI view showing a considerable restoration of the original height of L4/L5 after Opticage expansion. An additional unilateral foraminoplasty can be performed during the Opticage placemente to decompress the lateral recess

Pre-op Central and Foraminal stenosis Post-op foraminoplasty

Fig. 7.24 (*left* and *middle left*) Pre-operative lateral and axial CT scan views of a case with severe central stenosis (*middle right* and *right*) post-operative axial and lateral CT scan views showing a considerable posterior widening of the central canal and the foramina through indirect decompression after the expansion of the Opticage

Interbody implant	$L2-L3$	$L3-L4$	$L4-L5$	$L5-S1$	Total
B-Twin		10	54	50	114
PEEK cage					10
Opticage	4		24		44
Total		19	84	61	168
Percentage	2.3%	11.4%	50%	36.3%	100%

Table 7.1 Overall disk level distribution of the employed interbody devices

a single Opticage per surgery, resulting in a total of 44 implanted Opticages for this case series, see Table 7.1. A total of 17 cases (41%) had had prior surgery of the lumbar spine (revision surgery cases), while 23 cases were operated for the first time on the lumbar spine (primary cases). The overall disk level distribution is shown in Table 7.1. The pre- and post-operative visual analogic scale (VAS) and Oswestry Disability Index (ODI) [\[23](#page-98-0), [25\]](#page-98-0) scores of the Opticage pTLIF cases can

Table 7.2 Mean ± Standard Deviation values for pre- and postoperative VAS and ODI scores for 38 Opticage pTLIF cases (2 cases were lost before 6 months of follow-up) with a mean follow-up of 33.4 ± 20.6 months. Significant differences (p <0.001) were found between the pre- and postoperative scores.

				2 years or
Opticage Preop	Post-op	1 month 3 months 6 months 1 year		more
	VAS back 6.8 ± 2.0 5.0 ± 2.6 3.9 ± 2.2 2.9 ± 2.1 2.7 ± 1.9 2.9 ± 1.9 2.8 ± 1.6			
VAS leg	7.1 ± 2.2 4.7 ± 3.3 3.1 ± 2.6 2.1 ± 2.4 1.6 ± 2.1 1.1 ± 1.9 0.3 ± 0.7			
ODI	31.9 ± 7.5 26.4 ± 10.6 21.4 ± 9.1 17.9 ± 8.6 15.9 ± 8.0 15.2 ± 6.2 12.9 ± 6.3			

be seen in Table [3.](#page-94-0) Significant differences ($p < 0.001$) were found between the preand postoperative VAS and ODI scores with Student's paired T-test. The overall results for the 40 Opticage pTLIF cases according to MacNab classification [\[24](#page-98-0)] were 23 Excellent (58%), 13 Good (32%), 2 Fair (5%) and 2 Poor (5%). These last two cases were lost before 6 months of follow-up and therefore consequently classified as Poor. In conclusion, the Opticage pTLIF obtained an overall of 90% of Excellent and Good results with a mean follow-up of 33.4 ± 20.6 months and a median post-operative hospitalization time of 25h.

A percutaneously introduced and expanded interbody implant with percutaneous posterior fixation is less invasive than open surgery and, in addition, allows a convenient distraction and reduction in cases of spondylolisthesis (Fig. [7.13\)](#page-86-0). The expansion of the cage restores the original disk's height and adds stability to the posterior construct (see Fig. [7.22\)](#page-91-0). Hence, the cage's expansion size should be determined by the surgeon [[9](#page-97-0), [15](#page-97-0)] during the expansion to achieve the desired disk height. In contrast, for a classic MIS TLIF [\[1](#page-96-0), [2](#page-96-0)], it would have been necessary to cut the inferior portion of the lamina, superior and inferior articular processes, and ligamenta flava. Hence, our new percutaneous TLIF (pTLIF) approach seems to be a promising, less invasive surgical technique for patients with DDD or spondylolisthesis up to grade II and for revision surgery.

7.5 Posterior Fixation Devices

Posterior fixation is mandatory in order to achieve a 360° interbody fusion after placing an interbody fusion device into the anterior column. For an optimal 360° interbody fusion, the intervertebral cage should be positioned in the anterior part of the intervertebral disk [\[18](#page-97-0)], a kyphotic deformity should be avoided, and correct sagittal balance should be achieved under fluoroscopic intraoperative control. An expandable cage that allows repositioning until these parameters are met is extremely useful. In contrast, in order to avoid further invasiveness and complement the percutaneous placement of the expandable interbody device as explained before, posterior fixation devices should also be placed with a percutaneous approach. Several surgical percutaneous approaches [\[1](#page-96-0), [2](#page-96-0)] have been described and implemented in clinical routine for placing transpedicular screws and rods.

Several posterior fixation systems [\[1](#page-96-0), [2](#page-96-0)] can be used depending on the surgeon's preferences and the patient's demographic parameters, like age, physical activity, gender, bone quality, adjacent segment conditions [[19\]](#page-97-0), etc. In our studies, we used

Posterior fixation	Stand alone	Transpedicular screws and rods	Transfacet screws	Interspinous devices
B-Twin	14			
PEEK cage		10		
Opticage		24		

Table 7.3 Overview of the employed posterior fixation devices for different interbody implants

for most of our patients transpedicular screws with rigid titanium rods, dynamic titanium rods, dynamic PEEK rods, or standard PEEK rods (see Fig. [7.21\)](#page-90-0), as a posterior fixation (see Table 7.3). Alternatively, for selected patients with a clear indication, transfacet screws (see Fig. [7.20](#page-90-0)) and titanium interspinous devices [\[20](#page-97-0)] (see Fig. [7.19\)](#page-90-0) were employed. As a general rule, the rigidity of the posterior fixation will depend on the expected postoperative biomechanical demand and stress on the construct: for example, an active patient with a high level of physical activity would require shock absorbing rods (like PEEK rods or dynamic titanium rods with a damper system). In any case of spondylolisthesis, the posterior fixation should be done with transpedicular screws and titanium (in low-grade cases possibly also with PEEK rods). Transfacet screws or interspinous devices should be avoided for these cases with a high grade of instability. The surgical indication of interspinous devices in cases with instability are still controversial, given a recent outcome study [\[20](#page-97-0)] reporting good results in cases with spondylolisthesis.In our experience, transfacet screws and interspinous devices should be avoided in cases with moderate and high grade of intervertebral and/or facet instability.

7.6 Complications

In the aforementioned studies $[9, 15, 17]$ $[9, 15, 17]$ $[9, 15, 17]$ $[9, 15, 17]$ $[9, 15, 17]$ $[9, 15, 17]$ $[9, 15, 17]$ with the posterolateral percutaneous approach, the most frequent post-operative complication was a transient ipsilateral dysesthesia in approx. 5 to 10% of the operated cases. Specifically, in our study with 40 Opticage pTLIF cases, four cases (10%) reported transient post-operative ipsilateral dysesthesia. All dysesthesia cases resolved after 1–3 months with a combination of oral corticoid treatment with prednisolone 6 mg/day, gabapentin 75 mg every 8 h, and oral analgesia with NSAID. Only one out of our first cases reported a partial quadriceps paresis that resolved spontaneously after 3 days postoperatively. No further neurological impairments were reported. In our opinion, in most cases the dysesthesia is a consequence of the instrumental manipulation required to access the disk. Neural structures, like the exiting root or the dorsal root ganglion, are very sensitive to manipulation and can be perturbed especially during the placement of the cannula through the neuroforamen. A small intervertebral cage and corresponding small access instruments (preferably a cannula with an outer diameter of 9 mm or less), as well as a systematic foraminoplasty prior to the cannula's insertion into the disk, especially at the L5–S1 level, are recommended to avoid dysesthesia. In our experience, even though neuromonitoring is recommended for all pTLIF cases with general anesthesia, it may fall short to avoid dysesthesia as it primarily

monitors the motor function of the nerve roots. Hence, the learning curve of the posterolateral transforaminal approach should not be underrated [[6\]](#page-97-0), because, like with every surgical technique, skill and training in this approach are required to bypass the neural structures in the neuroforamen and avoid dysesthesia, especially at the beginning of the learning curve $[21]$ $[21]$. In our own experience, once the learningcurve has been mastered, a pTLIF can be safely completed in approx. 20 min. of surgery time for a regular level like L4/L5 (posterior fixation not included).

In our pTLIF study, radiological controls were performed after 6 months and 1 year after surgery. Additional X-rays studies or CT scans were only indicated in patients with fair or poor clinical evolution (e.g., the fusion case shown in Fig. 7.25 was found incidentally when the patient presented 24 months after surgery for reassessment complaining of recurrent pain in the SI joint of 2 month's duration). In contrast to our previous study with the B-twin implant [\[17](#page-97-0)], no case of pseudoarthrosis, non-union and subsidence was observed during a mean follow-up of 33.4 months for our 40 Opticage pTLIF cases. This is probably due to the increased endplate contact area of the Opticage compared to the B-Twin implant. Two cases with spondylolisthesis degree 1 with interspinous devices as posterior fixation [\[20](#page-97-0)] required supplemental posterior support with screw and rods due to a persistent instability in the first postoperative month that was reported with postoperative dynamic X-rays. This conflicts with the reported successful outcome of interspinous devices for cases with a similar indication [[20\]](#page-97-0).

Conclusions In this chapter we have presented an innovative surgical approach that we call percutaneous posterolateral transforaminal interbody fusion (pTLIF), with new expandable implants combined with posterior fixation devices that allows a full percutaneous 360° fusion of the lumbar spine. In our opinion, pTLIF has disruptive potential for lumbar interbody fusion due to its true percutaneous approach, efficacy and safety. The posterolateral transforaminal approach with foraminoplasty and progressive tissue dilatation allows a less invasive approach not only for

Fig. 7.25 Preoperative spondylolisthesis L5–S1 grades II–III (**a**). Postoperative reduction after Opticage™ expansion and posterior screw fixation (**b**). Evidence of bony fusion 24 months after surgery (**c**) Image modified from [\[9](#page-97-0)]

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endoscopic discectomy but also for percutaneous placement of an expandable interbody fusion device into the intervertebral disk. Since 2005 the author has performed pTLIF in more than 168 cases with different interbody devices (B-Twin expandable device, PEEK cages, Opticage). pTLIF requires only a small skin incision of 15 mm and eliminates the excision of the superior facet, which would have been necessary for a classic MIS TLIF $[1, 2]$. Due to the less invasive handling of the surrounding structures, time to ambulation can be reduced to a median of 6 h and the median post-operative time until hospital discharge to 25 h. The outcome for the pTLIF procedure presented here with 33 months of mean follow-up is comparable to that of the standard TLIF. However, intensive training and surpassing a learning curve were necessary to master the transforaminal endoscopic access in the early beginning [\[6](#page-97-0), [16](#page-97-0)] until the approach instruments were adapted and optimized for pTLIF. The author's experience with more than 1200 endoscopic discectomy cases [3, [6,](#page-97-0) [8\]](#page-97-0) and expandable implants [\[9](#page-97-0), [17](#page-97-0)] were critical for the development and design of a new expandable implant (Opticage) and the percutaneous access instrumentation (Optiport) [[9,](#page-97-0) [15](#page-97-0)]. These developments, including the new instruments and the new expandable Opticage, allow now an easy and safe full percutaneous access to the intervertebral disk without the need of an endoscope. The new pTLIF instrumentation (Optiport) now shortens the learning curve for new adopters unfamiliar with the endoscopic transforaminal approach. The reported outcome of excellent and good results was similar in all our studies with the percutaneous posterolateral endoscopic approach independently of the interbody device that was employed [\[9](#page-97-0), [15](#page-97-0), [17](#page-97-0)] (88%, 89%, and 90%, respectively). These results underline the simplicity, efficacy and safety of pTLIF. In conclusion, pTLIF is a safe and fast technique for trained surgeons to perform a full percutaneous interbody fusion in the lumbar spine without an endoscope and with a shortened learning curve. In our opinion, the pTLIF technique presented here has disruptive potential and opens the way for ambulatory, out-patient interbody lumbar fusion surgery.

Technical Note The Opticage expandable device and the Optiport percutaneous instrumentation by Interventional Spine Inc. were acquired in 2017 by Depuy-Synthes, a Johnson and Johnson company. Commercial names, fabrics and models may have changed or may change in the future.

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8 New Techniques and MIS: The Minimally Invasive TLIF

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8.1 Introduction

Transforaminal lumbar interbody fusion (TLIF) was first described by Harms and Rolinger in 1982 [[1\]](#page-104-0), and it has proved to be effective in the treatment of patients with degenerative instability or deformity $[2-6]$. Several authors have reported high rates of fusion and pain control, but some concerns still exist regarding the morbidity of the procedure in terms of blood loss, soft tissue injury, length of hospital stay, and complication rates $[7-10]$ $[7-10]$. In order to address these issues, Foley et al. described in 2003 a minimally invasive lumbar interbody fusion based on the use of sequential dilatation, tubular retraction, and percutaneous screw/rod placement resulting in a less tissue damage and potentially in a better patient outcome [\[11](#page-105-0), [12\]](#page-105-0). Several studies have shown that minimally invasive TLIF (Mi-TLIF) and open posterior or transforaminal lumbar interbody fusion have similar results in terms of pain improvement and fusion rate [[13–15\]](#page-105-0). Proponents of Mi-TLIF cite a decreased operative blood loss and shorter hospital stays compared with open procedures, while opponents argue a longer operative and fluoroscopic time [\[13](#page-105-0), [14](#page-105-0), [16](#page-105-0)]. Some authors report a lower rate of complications in Mi-TLIF procedure, while others have point out a higher readmission and revision rate [[13,](#page-105-0) [14](#page-105-0), [17](#page-105-0)]. Unfortunately current evidence examining Mi-TLIF versus open procedures is of low quality and precludes firm conclusions regarding the comparative effectiveness of the two procedures.

Here we report our experience with Mi-TLIF describing the technique and focusing on patient outcomes and radiological result.

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8.2 Indication and Patients Population

From 2004 to 2015, 221 patients were treated with Mi-TLIF consisting of bilateral percutaneous screw/rod placement and insertion of interbody cage by a monolateral transforaminal route.

Indications were the following: grades I and II isthmic-type spondylolisthesis (86 cases), grades I and II degenerative spondylolisthesis (32 cases), degenerative disc disease (59 cases), and recurrent lumbar disc herniation with radiculopathy (44 cases). Multiple-level surgery was performed in only 35 patients.

All the patients had severe back pain that was evaluated by Oswestry Disability Index (ODI) and Visual Analog Scale (VAS). All patients with degenerative spondylolisthesis and recurrent disc herniation had a disabling monolateral radicular pain sometimes associated with a nerve root weakness. Patients treated for degenerative spondylolisthesis and recurrent disc herniation were operated on by this technique only if the pain was monolateral and they were approached by the same side of the pain.

Postoperatively ODI and VAS scores were evaluated before discharge, at 3, 6, and 12 months follow-up visit, and then annually. Radiological assessment (lumbar X-ray or CT scan) was performed at 3, 6, and 12 months and then every year until fusion was observed (Fig. 8.1). Radiographic fusion was assessed using the anterior fusion grades described by Bridwell et al. where grades I and II are considered as solid fusion while grades III and IV as [\[18](#page-105-0)].

Fig. 8.1 Illustrative case. (**a**, **b**) Preoperative lumbar X-ray and MRI showing a grade II isthmictype spondylolisthesis; (**c**) postoperative X-ray demonstrating the correct screws and cage placement with reduction of the listhesis

8.3 Technique

Once the patient is in the prone position, the pathologic level is identified by fluoroscopy. Entry points for a percutaneous pedicle screws insertion are marked on the skin on both side of the spinous process. Small skin incisions are made on the previously identified entry points and carried down to the fascia. With the aid of fluoroscopic vision, pedicles are identified, K-wire is positioned, and cannulated screws are inserted through the pedicle in the vertebral body. Then the screws are attached to the tubular extensions, the K-wire is removed, and a further K-wire is placed in the facet joint ipsilaterally to the side where the cage will be inserted (Fig. 8.2). Sequential dilators were passed over the K-wire until a tubular retractor can be place in site and expanded to provide a 2.5–4.0 cm operative field and a pedicle-to-pedicle exposure. The facet joint and the lateral aspect of the lamina are removed, the corresponding nerve root is identified, and the disc is approached. Once discectomy is performed, the interbody space is widened by screw distraction, and end plates are freed from the cartilaginous tissue using curettes and end plate scrapers. The distraction of the interbody space is an important aspect of the procedure because it allows an adequate nerve root decompression and facilitates cage insertion as well as spondylolisthesis reduction. Once the end plates are properly prepared, the autogenous bone obtained from the resected lamina and facet is mixed with demineralized bone matrix and placed within the interbody space anteriorly and contralaterally to the annulotomy. The cage is then inserted under fluoroscopic vision and placed anteriorly in the disc space where the bone is stronger and the risk of end plate rupture is lower. Rods are positioned bilaterally and tightened to the screws applying a

Fig. 8.2 Intraoperative image showing screws attached to the tubular extensions on the left side and three K-wires on the right side; the more proximal and the more caudal are those used to insert the screws, while the central one will be used to introduce the tubular retractor

compression to avoid cage displacement. Final fluoroscopic control is done, and then wounds are sutured. The day after the procedure, the patient is able to stand up, and a lumbar X-ray is performed in the orthostatic position.

8.4 Results

The mean operative time was 168.3 and 227.6 min for single and multilevel surgery. No patients needed blood transfusions. Mean hospital stay was 4.2 days.

The mean preoperative ODI and VAS scores were 55.6 and 7.3. Follow-up period ranged from 2 to 6 years (mean, 4.1 years). Pain improvement at 1 and 2 years follow-up was observed, respectively, in 175 and 184 of the 221 patients (79.1% and 83.2%) with a mean ODI and VAS reduction of 14.7 and 3.5 at 1 year and 13.9 and 3.1 at 2 years.

Fusion rate was 75.1% at 1 year (166 of 221 patients) and 84.1% at 2 years (186 of 221 patients). Pseudoarthrosis (grades III and IV) was observed in 34 patients (15.3%), but only four patients require a supplemental surgery to repair the nonunion.

Twenty-one of the 221 patients (9.5%) had perioperative adverse events (from the day of surgery to 12 weeks after) consisting of dural tearing (eight cases), cage subsidence (six cases), wound infection (three cases), cage mobilization (two cases), and radiculopathy due to screw malpositioning (two cases). Only six patients (2.7%) required a second surgery (two patients with wound infection, the patients with cage mobilization, and the patients with screw malpositioning). The cases of dural tearing were repaired during the first surgery with muscle, fascia, and fibrin glue, and they did not develop a fluid wound collection. The six cases of cage subsidence were not re-operated on. Two of them developed an interbody fusion; the others ended in pseudoarthrosis that none required a second surgery.

Symptomatic adjacent segment disease was observed in 14 patients (6.3%), and it consists of spinal stenosis (seven cases), herniated lumbar disc (five cases), and spondylolisthesis (two cases). All patients need a second surgery to relieve pain.

8.5 Discussion

There is a growing body of literature demonstrating that Mi-TLIF and open procedures have similar rate of clinical outcome on radiographic fusion [\[13–15](#page-105-0)], justifying the use of a minimally invasive approach that can reduce the soft tissue trauma. In our experience, Mi-TLIF has provided good results at 1 and 2 years follow-up in both pain improvement and radiographic fusion (mean ODI and VAS reduction of 14.7 and 3.5 at 1 year and 13.9 and 3.1 at 2 years; fusion rate of 75.1% at 1 year and 84.1% at 2 years) (Fig. [8.3\)](#page-103-0).

The mean operative time and fluoroscopic exposure were superior to that of an open procedure. However these results were affected by our learning curve that has made first procedures more time-consuming to those we perform now [\[19](#page-105-0), [20\]](#page-105-0).

Fig. 8.3 One-year postoperative CT scan showing good interbody fusion of the treated levels

In fact, as the number of performed Mi-TLIF raised, the operative time has become shorter so that actually no clear differences in surgical time exist between minimally invasive and open procedure. Nevertheless fluoroscopic time still remains a problem in Mi-TLIF procedure because the relevant anatomy is not directly visible and fluoroscopic views are frequently required to confirm the safe and accurate placement of screws and cage [\[16](#page-105-0)].

As reported by other authors $[13–16]$ $[13–16]$, also in our experience, blood loss was minimal, with no cases requiring blood transfusion, and the length of hospital stay was short (mean 4.2 days). In fact, the reduced soft tissue trauma offered by the Mi-TLIF not only decreases blood loss but also improves postoperative pain, so allowing the patient to walk the day after the procedure and consequently providing a faster discharge at home.

Recent reviews have reported similar or lower rates of complications in Mi-TLIF compared to open procedures [[13,](#page-105-0) [14](#page-105-0), [21](#page-105-0)], while other studies highlighted a higher rate of revision surgery. In our series only 21 of the 221 patients (9.5%) had perioperative adverse events, and only six patients (2.7%) required a second surgery. The complications we have to deal with were dural tearing (eight cases), cage subsidence (six cases), wound infection (three cases), cage mobilization (two cases), and radiculopathy due to screw malpositioning (two cases). These complications are the same reported in a recent meta-analysis of 513 patients by Wong et al. [[22\]](#page-105-0) in which the incidence of durotomy, instrumentation failure, neurologic deficits, and wound infections were, respectively, 5.1%, 2,1%, 0.8%, and 0.2%.

Pseudoarthrosis and symptomatic adjacent segment disease had to be considered as late complications of the Mi-TLIF that usually occur after the first year

from surgery [[23\]](#page-105-0). In our series, 34 cases of pseudoarthrosis and 14 cases of symptomatic adjacent segment disease were seen. Patients with pseudoarthrosis were asymptomatic or symptomatic but without significant pain or disability so that only four of them require a supplemental surgery to repair the nonunion (open posterolateral fusion). The others were treated by medications, physiotherapy, and epidural steroid injections. On the other hand, the pain referred by the patients with symptomatic adjacent segment disease was very disabling and not relieved by nonoperative treatment. This led to a second surgery consisting of laminectomy and supplemental fixation with posterolateral fusion in the seven cases of spinal stenosis, herniotomy in the five cases of herniated disc, and open TLIF with reduction and supplemental fixation in the two cases of spondylolisthesis.

Conclusion

Minimally invasive transforaminal lumbar interbody fusion (Mi-TLIF) is an effective technique in the treatment of patients with degenerative instability or deformity. The benefits related to the reduced soft tissue trauma and shorter hospital stay certainly offset its increased equipment cost, thus leading to an increased use of this procedure in the recent years.

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9 New Techniques and MIS: The Awake TLIF

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9.1 Introduction

Awake transforaminal lumbar interbody fusion (Awake TLIF)—itself a modern technique—is descended from procedures and devices reaching centuries into the past. This surgical procedure includes a variety of interventions designed to avoid general anesthesia, chief among which is the use of an endoscope. The endoscope was invented in 1806 by Bozzini, and the earliest major series of endoscopic procedures (limited to thoracic and abdominal explorations) were described by Desormeaux in 1912 and 1914. Concurrently, the earliest technique of spinal fusion was pioneered by Hibbs in 1911 [[1\]](#page-116-0). After a century of refinement, endoscopy has expanded into various surgical specialties, now including spinal neurosurgery.

Spinal endoscopy truly began with the work of Dr. Parviz Kambin, who first published the technique of endoscopic percutaneous nucleotomy in 1973 [\[2](#page-116-0)]. Today, his approach to the disc space has been adapted as the endoscope-assisted awake TLIF. This procedure represents a key step in the development of minimally invasive (MIS) techniques in spinal neurosurgery. As the population of spine surgery patients continues to age, MIS procedures offer less tissue destruction, reduced blood loss, and a faster recovery. These factors may allow treatment in a patient too frail for conventional open surgery.

With these considerations, this chapter will describe the indications, technique, outcomes, and complications of the awake TLIF procedure. We will also explore the applicability of this procedure in the larger context of MIS spinal surgery and improved postoperative recovery.

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9.2 Surgical Technique

9.2.1 Anesthesia and Patient Positioning

The most distinguishing characteristic of awake TLIF is that patients do not have to undergo general anesthesia with endotracheal intubation. Patients are titrated to a light or moderate degree of sedation with a continuous intravenous infusion of ketamine and propofol, with a nasal cannula or facial mask supplying oxygen. No intraoperative narcotics are given. One advantage of conscious sedation without general anesthesia and intubation is improved feedback and interaction with the patient. The surgeon is thus warned of intraoperative nerve irritation and can avoid serious neural damage.

The patient is positioned in either the prone or lateral position (surgeon's preference). While the lateral position offers more convenient airway management, this anatomic orientation is unfamiliar to most surgeons, and the working posture is relatively uncomfortable while operating. In contrast, the prone position is a common and comfortable posture to most spine surgeons. However, airway maintenance is critical during a prone-positioned awake TLIF and usually requires an experienced anesthesiologist. The prone position on a Jackson table was almost always adopted in the authors' institute. Jackson tables allow the lumbar spine to maintain a lordotic angle, which is important for the reduction of spondylolisthesis and the restoration of spine curvature with fusion. Therefore a Jackson table is preferred over an arch frame support system (e.g., a Wilson's frame), which decreases the lordosis curve. The patient is prepared and draped in a normal sterile fashion. A transparent drape is preferred, allowing the surgeon and anesthesiologist to observe the patient's reactions and status directly.

9.2.2 Incision and Endoscopic Discectomy

The lumbar spine is visualized with intraoperative fluoroscopy and checked for the target level. A right- or left-sided flank 8-mm skin incision, 8–10 cm away from the midline, is made after local analgesia. The distance away from the midline varies according to patients' anatomy and obesity status. One way to estimate the incisional location is to measure the approaching angle and distance from the midline on a preoperative magnetic resonance image (MRI) or computed tomography (CT) scan.

An 18-gauge spinal needle and Nitinol wire are utilized to access Kambin's triangle through a transforaminal route (Fig. [9.1](#page-108-0)), followed by the placement of a succession of dilators guided by the Nitinol wire. The serial dilators allow safe access to the disc space and can actually lift the disc height. A working channel is then established, and the endoscope is inserted for direct visualization of intervertebral disc (Fig. [9.2\)](#page-108-0). Discectomy is carried out using micropituitary rongeurs and curettes specifically designed for endoscopy. Electrocautery can further shrink the cartilage.

Fig. 9.1 Intraoperative view of fluoroscope when Kambin's triangle is accessed with a spinal needle

Fig. 9.2 Working channel for endoscope

The exiting nerve root of the upper vertebral level and the traversing nerve root of the lower vertebral level are also inspected directly with the endoscope. Any disc fragment that caused compression to the nerve root is removed completely. The pulsation of the nerve root is fully visualized and may serve as evidence of freedom from compression. Hemostasis is managed by endoscopic electrocautery, continuous irrigation, and hemostatic agents.

Fig. 9.3 Intraoperative view of fluoroscope. The end plate is cleaned and prepared with a drill (*left*), back-bite instrument (*middle*), and stainless brush (*right*)

9.2.3 Interbody Fusion

Another small diameter working port for interbody fusion instruments is inserted under the guidance of Nitinol wire and serial dilators. The intervertebral disc space is further cleaned, and the end plate is prepared with a drill, expandable butterflyfeatured blade, back-bite instrument, and stainless brush (Fig. 9.3). A curved probe can be utilized to confirm completion of cartilage removal and end plate preparation. A balloon, which can be filled with radio-opaque contrast, is inflated in the disc space to demonstrate the thoroughness of discectomy and to evaluate the size of the intervertebral cage required (Fig. [9.4](#page-110-0)). Recombinant human bone morphogenetic protein (rhBMP)-2 is inserted into the disc space to facilitate bone fusion. Instead of the rigid cage commonly used for regular MIS-TLIF, an expandable cage (OptiMesh cage, Spineology) is then placed into the disc space. The OptiMesh cage is filled with allograft matrix, which is able to inflate and lift the disc height, and reduced by the spondylolisthesis (Fig. [9.4](#page-110-0)). The OptiMesh cage should be placed anteriorly and centrally to enhance lumbar lordosis.

9.2.4 Percutaneous Screw and Rod Fixation

Pedicle screws are placed percutaneously with true anterioposterior (AP) fluoroscopic imaging. Small skin incisions are made for each screw. When the C-arm is aligned to produce a true AP image, Jamshidi needles are docked on the base of each transverse process, adjacent to the lateral aspect of facet joint. The Jamshidi needle is advanced 2 cm into the bone without breaching the medial wall of the pedicle. At this point, the tip of the Jamshidi needle should be at the junction of the

Fig. 9.4 A balloon, which can be filled with radio-opaque contrast, is inflated in the disc space (*left*). The OptiMesh cage, placed in the disc space, is filled with allograft matrix, which is able to inflate and lift the disc height (*right*)

pedicle and vertebral body. The Jamshidi needle is further advanced into the body and then exchanged with K-wire. The depth of the Jamshidi needle and K-wire can be checked with lateral-view fluoroscopy. The Jamshidi needle shaft is then removed, while the K-wire is kept inside the vertebral body. The K-wire is vital during the screw placement and should always be held in place (Fig. [9.5\)](#page-111-0). Insertion of the insulated sheath, awl, and tap is performed step by step under the guidance of the K-wire before placement of each percutaneous screw. The procedure of percutaneous screw placement may vary depending on the instrument system used. Rods are inserted percutaneously in an extension maneuver. This allows the spine to be further realigned for spondylolisthesis and better lordosis curvature. Final set screws are tightened and locked in position (Fig. [9.6](#page-111-0)).

9.2.5 Wound Closure and Postoperative Care

Each small incision made for the endoscope and percutaneous screws is sutured and closed layer by layer in the normal fashion. There is usually no drain placement required.

Due to the nature of the non-general anesthesia in awake TLIF, patients' recovery from surgery is quite fast and favorable. There is usually less consumption of analgesic and narcotic medications. The majority of the patients are discharged from the hospital on postoperative day 1.

Fig. 9.5 The true anteroposterior fluoroscopic imaging technique for the insertion of Jamshidi needles and K-wires

Fig. 9.6 The spondylolisthesis is reduced after inserting expandable cage and screws and rod placement

Further postoperative care was much the same as with a standard TLIF procedure. A lumbar brace was recommended. Lifting heavy weight, excessive forward bending, and smoking were relatively prohibited. Nonsteroid anti-inflammatory drugs were not suggested for pain control in the first several months after surgery to avoid interfering with the bone growth. Regular follow-up clinic visits and radiographic film examination for bone fusion are recommended.

9.3 Important Elements of Awake TLIF

Standard MIS-TLIF is performed throughout the world with the assistance of the surgical microscope. While successful outcomes and a low-risk profile can be accomplished with the standard MIS-TLIF, surgeons desire even less tissue injury and blood loss, faster recovery, and shorter hospital stays. Fundamental technical changes were required to achieve an even less invasive surgery, the awake TLIF (Table 9.1).

Anesthesia is one of the most significant aspects of any operation. Awake TLIF is possible only with the aid of awake anesthesia. Awake anesthesia generally involves (but is not limited to) an oxygen supply without endotracheal intubation, airway management of a prone-positioned patient, adequate status of conscious sedation with intravenous infusion of propofol, and intraoperative organ status monitoring. This usually requires an experienced anesthesiologist to deal with the entire situation intraoperatively. Postoperative recovery is a part of awake anesthesia. Proper management of postoperative pain, fluid status, organ metabolism, glucose and insulin metabolism, and homeostasis requires a multidisciplinary team, consisting of neurosurgeons, anesthesiologists, the recovery unit, and nurse practitioners. Awake anesthesia also involves the concept of enhanced recovery after surgery (ERAS®), which is scarcely applied in the neurosurgical field. ERAS is discussed in greater detail below.

Standard MIS-TLIF requires a tubular or expandable retractor and a microscope to access the targeted structure. Dissection and injury of subcutaneous and muscular tissue are inevitable with this approach. With the evolution of illumination and camera systems, Dr. Parviz Kambin first visualized and removed a herniated lumbar disc using endoscopic instruments in 1988. Endoscopy advanced the era of direct visualization to image-assisted surgery, allowing surgeons to cut an 8-mm incision and operate with the aid of a high-resolution scope lens and image screen. The soft tissue injury is minimal, as there is no real tissue dissection during the establishment of the endoscopic working channel. The discectomy and fusion procedure is then performed inside the 8-mm working channel with specialized instruments, which minimize trauma to the surrounding tissues.

It is more restrictive to insert a rigid and conformal cage device into intervertebral disc space through a small working channel for interbody fusion. Intraoperative nerve root and dural injury is possible and may cause serious sequela such as cerebrospinal fluid (CSF) leakage, paresthesia, or motor deficit. Proper cage sizing must be carefully considered as well. Previous case series reported a high risk of cage migration with rigid stand-alone percutaneous titanium cages in endoscope-assisted

TLIF [[3\]](#page-116-0). Other series have adopted expandable cages, for example, the expandable mesh cage (OptiMesh cage, Spineology), the titanium expandable cage (Opticage, Interventional Spine Inc., Irvine, CA, USA), or the B-twin expandable spinal spacer, to achieve interbody fusion. Much less complications of cage migration were reported using an expandable cage. In addition to migration, cage subsidence and pseudo-arthrodesis have been documented using expandable cages. Since posterolateral fusion is less feasible, solid interbody fusion is necessary for awake TLIF. Bone morphogenetic protein (BMP)-2 is another key to the success of solid interbody fusion. BMP-2 is one of the most potent growth factors to induce mesenchymal stem cell and osteoprogenitor cell differentiation into osteoblasts. Recombinant human bone morphogenetic protein (rhBMP)-2, a highly osteoinductive bone graft, is inserted before expandable cage to promote interbody arthrodesis in awake TLIF.

The percutaneous screw and rod fixation system is one of the hallmarks of minimally invasive spine surgery. It also plays an important role in awake TLIF. Before the interbody fusion is robust following awake TLIF, percutaneous screws and rods help to hold the spine in a fixed position and facilitate bone union. The percutaneous method of screw and rod insertion helps to minimize surgical trauma.

Local analgesia is achieved with the aid of $Exparel^{\circledast}$. Exparel[®] is a long-acting liposome injection of bupivacaine, which is indicated for administration to the surgical site for postsurgical analgesia. Twenty milliliters of Exparel® is injected into the musculocutaneous tract of the percutaneous screws to achieve excellent pain control for a few days. It must be certain that Exparel® is not injected into disc space. Additionally, Exparel® is an amide-type local anesthetic which is metabolized by the liver and so should be used cautiously in patients with hepatic disease.

It must be emphasized that the OptiMesh, Exparel®, and rhBMP-2 are currently off-label use for the United States Food and Drug Administration (US-FDA).

9.4 Surgical Indications and Limitation

The introduction of MIS-TLIF is a revolutionary step in the progress of lumbar fusion surgery. The awake TLIF procedure is even more minimally invasive than MIS-TLIF under the assistance of endoscope. The surgical indications for awake TLIF are very similar to those of MIS-TLIF, with trivial differences and more restrictions (Table [9.2](#page-114-0)). The most common indications for awake TLIF are spondylolisthesis, degenerative disc disease, recurrent lumbar disc herniation, and spondylosis of the lumbar spine.

Awake TLIF is suitable for patients of relatively morbid status, advanced age, or those who are not good candidates for general anesthesia but in whom spinal fusion is mandatory (e.g., in Parkinson's disease). Since Parkinson's disease generally deteriorates after general anesthesia, awake TLIF is advantageous in these patients.

Patients with previous posterior lumbar surgery may also benefit from awake TLIF. Awake TLIF avoids the midline scar tissue by means of a transforaminal approach from an oblique angle. Another potential advantage of awake TLIF over

Indication	Limitation
Major indication	Severe deformity
Degenerative disc disease	Scoliosis
Recurrent lumbar disc herniation	High-grade spondylolisthesis (\geq grade II)
Spondylosis	Pathology variation
Spondylolisthesis	Circumferential spinal stenosis
Relative advantageous	Disc migration
Advanced age	Median/paramedian disc herniation
Severe obesity	Anatomic variation
Prior midline posterior spine surgery	Conjoined nerve root
Morbidity contraindicated to general	$L5-S1$ level
anesthesia (Parkinson's disease, Alzheimer	
dementia etc.)	
	L4–L5 level with high-rising iliac crest

Table 9.2 Indications and limitation of awake transforaminal lumbar interbody fusion (TLIF)

regular MIS-TLIF or conventional open TLIF is for severely obese patients, although this has not been fully studied. Surgeons would be able to avoid the impediment of soft tissue depth with the awake TLIF, while soft tissue pressure is still somewhat problematic for the MIS or conventional open TLIF.

There are some limitations that the surgeon must consider in each case. As the awake TLIF approaches the intervertebral disc through an oblique transforaminal angle, anatomical limitations must be evaluated. The relationship between the targeted intervertebral disc and the iliac crest must be carefully examined prior to forming a surgical plan. The L5–S1 intervertebral disc is accessed with difficulty, as the iliac crest and/or the L5 transverse process may be roadblocks. Targeting the L4–L5 intervertebral disc in a patient with a high-rising iliac crest can be technically challenging, especially in male patients who tend to have a more steep and uprising iliac crest.

A conjoined nerve root may account for some intraoperative neural injury during endoscopic discectomy. Patients with this anatomic variation may be at increased risk for damage. The best way to avoid this potential complication is by early recognition and diagnosis with magnetic resonance imaging (MRI) and computed tomography (CT) imaging [\[4](#page-116-0)].

Variation in the pathology itself may also limit the effectiveness of the awake TLIF. Median/paramedian disc herniations, axillary-type disc herniations, and disc migration caudally or cranially are reported to have remarkably higher chances of incomplete removal after endoscopic discectomy [\[5](#page-116-0)]. Other pathology requiring thorough decompression of neural elements may not benefit from awake TLIF, since it can hardly be achieved by endoscopic surgery (e.g., cauda equina syndrome). Severe degenerative lumbar spinal stenosis with circumferential dural and nerve root compression by disc herniation, bone spur, hypertrophic facet, and ligamentum flavum is also a relative contraindication for awake TLIF. These patients tend to have bilateral signs/symptoms and require bilateral decompression for relief.

High-grade spondylolisthesis (≥grade II spondylolisthesis) and severe scoliotic deformity may be relative contraindications for awake TLIF as well. Due to the deformation of anatomic structures, access to Kambin's triangle can be technically demanding. The complex positions of the intervertebral disc, nerve root, dura, facet joint, and bony structures vary widely from normal anatomy and make these patients more susceptible to nerve or dural damage during the first approach to Kambin's triangle.

9.5 Outcomes

Endoscopic approaches such as the awake TLIF offer a variety of advantages as compared to traditional open or standard MIS-TLIF [[6\]](#page-117-0). General anesthesia can be avoided, and the smaller incision and dissection reduce intraoperative tissue damage, blood loss, and complications. With an experienced surgeon, operative times are typically reduced as well. These benefits translate postoperatively to a reduction in hospital stay, early ambulation, and less development of scar tissue in the surgical wound [\[7](#page-117-0), [8\]](#page-117-0). Clinical metrics have demonstrated significant improvements in leg and lower back pain in a number of cases series [\[7–10](#page-117-0)]. Finally, a large majority of patients who have undergone endoscopic spine procedures are satisfied with their results [[7,](#page-117-0) [11,](#page-117-0) [12\]](#page-117-0).

9.6 Complications

A Japanese nationwide retrospective study reported a 2.1% incidence of intraoperative complications in endoscopic spine procedures [[13\]](#page-117-0). The most common complication was dural tear (75%), which can be more difficult to repair endoscopically. Other complications included nerve root injury, facet fracture, hematoma, and surgical error. While it has never been reported, conversion to open surgery is another possible complication. Similarly, conversion from local to general anesthesia may be required intraoperatively, and great care must be taken to maintain the patient's airway in the prone position. Strict time limits should therefore be imposed on endoscopic procedures to avoid this potential complication.

Potential perioperative systemic complications common to all surgical patients can be seen in awake TLIF patients. These may include deep vein thrombosis, pulmonary embolism, stroke, respiratory or cardiovascular complications, etc., as well as local complications such as wound infection. However, significant reductions in systemic and local complications have been reported in patients undergoing endo-scopic spine surgery [\[6](#page-117-0)].

Postoperatively, typical complications in spine surgery are also seen with the awake TLIF. Disc herniation recurrence has been reported [[14\]](#page-117-0), as has cage migration and subsidence [[3\]](#page-116-0). Both of these complications have required revision surgeries. To avoid cage failure, recent studies have employed expandable cages, which have largely avoided migration as far as 3 years postoperatively [\[8](#page-117-0), [9](#page-117-0), [14](#page-117-0), [15](#page-117-0)].

9.7 Discussion

MIS techniques in spinal surgery such as the awake TLIF, by reducing surgical trauma, hold the promise of a swifter return to normal function for patients postoperatively. It follows that a shorter convalescence period should translate to an earlier discharge and thus reduced costs for patient and hospital alike. These savings have been demonstrated in large-scale financial analyses [\[16](#page-117-0), [17](#page-117-0)].

The Enhanced Recovery After Surgery® (ERAS) Society has been working toward these goals by researching and implementing practices designed to minimize the postoperative hospital stay in patients undergoing surgery in a variety of disciplines [[18\]](#page-117-0). Their protocols include intraoperative practices such as MIS techniques and minimal anesthesia—both of which are achieved with the awake TLIF. However, the majority of interventions take place outside of the operating room. Preoperatively, careful patient selection and optimization are key factors for achieving a rapid discharge, as is patient preparation immediately before surgery. Postoperatively, early mobilization and reduced use of narcotic opioids both help patients regain independence, facilitating their transition from hospital to home recovery.

While there are as yet no official ERAS protocols in neurosurgery or spine surgery, current literature contains reports which suggest a number of well-evidenced interventions in spinal surgery [[19\]](#page-117-0). The adoption and further investigation of these practices—including MIS techniques such as the awake TLIF—now remain in order to assess the applicability of ERAS principles to spinal neurosurgery.

Conclusion

The awake TLIF is an innovative procedure, involving awake anesthesia, a refinement of minimally invasive surgical technique, the adoption of multiple advanced technologies in spine surgery, and the concept of enhanced recovery after surgery. With the success and evolution of awake TLIF, neurosurgeons will be able to further improve postoperative recovery, achieve a more cost-effective operation for spinal disease, and push the limits of minimally invasive spine surgery, ultimately providing superior outcomes for all the patients with spine disease.

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10 New Techniques and MIS: The Cortical Bone Trajectory Screws—Indications and Limits

Keitaro Matsukawa

10.1 Introduction

Cortical bone trajectory (CBT) has been developed as an alternative to the traditional trajectory (TT) for lumbar pedicle screw insertion [[1\]](#page-129-0). CBT starts at the pars interarticularis and follows a craniolaterally directed path through the pedicle (Fig. [10.1\)](#page-119-0). In comparison with TT screws, which are inserted along the anatomical axis and achieve their stability mainly in cancellous bone from the pedicle to the vertebral body, CBT screws maximize thread contact with the higher-density cortical bone by markedly altering the screw path [\[2](#page-129-0)]. Because the cortical bone is less affected by the osteoporotic process than the cancellous bone, CBT may reduce the incidence of screw loosening and subsequent fusion failure. Biomechanical studies have demonstrated that the CBT technique, even with shorter and smaller screws, provides a higher pullout strength [[1,](#page-129-0) [3](#page-129-0), [4\]](#page-129-0), higher insertional torque [[5\]](#page-129-0), stronger resistance to cycles of cranio-caudal loading [[6\]](#page-129-0), and similar stability of the screwrod construct compared with the TT technique [[7\]](#page-129-0). CT analyses revealed that Hounsfield units along CBT were four times higher than those along TT [[8\]](#page-129-0), and this difference was more marked when comparing osteoporotic and elderly patients with the general population [\[9](#page-129-0)].

Additionally, screw insertion from a more medial and caudal entry point allows us to minimize the procedure-related morbidity: (1) minimizes paraspinal muscles dissection and retraction $[10-12]$, (2) lessens iatrogenic facet joint injury supradjacent to the fused segment [[13\]](#page-129-0), and (3) avoids injury to the posteromedial branch of the nerve root passing near the mammillary process [[14\]](#page-130-0). The direction away from the neural elements leads to a lower risk of neurologic injury, contributing to reduce the surgeon's stress in clinical practice. Thus, this technique has attracted attention

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Fig. 10.1 Comparison between the traditional trajectory and cortical bone trajectory. The entry point of CBT requires less soft tissue dissection compared with that of TT. (used with permission from Medtronic Inc. (Memphis, TN, USA))

as a new minimally invasive method for lumbar spinal fusion, especially in osteoporotic patients. The purpose of this paper is to describe indications, limits, and pitfalls of the CBT technique from biomechanical and clinical standpoints.

10.2 Indications

10.2.1 Pathology

The CBT technique is indicated for almost all spinal disorders without spondylolysis and severe spinal deformity. It is best suited for short segment fusion as a minimally invasive method but can be effectively adapted for long-segment fusion due to the anchoring ability to achieve rigid spinal fixation.

This technique has a biomechanical advantage as an alternative to the traditional fixation technique, particularly in poorly trabeculated osteoporotic bone. Osteoporosis is characterized by decreased bone strength and is becoming more frequent with the aging of the population. Despite several efforts to enhance the strength of the bone-screw interface in the osteoporotic spine, problems of screw loosening, which may lead to the loss of correction and nonunion, have not been resolved. Santoni et al. first reported the superiority of CBT screws in osteoporotic cadaveric lumbar spines (mean age, 80.8 years) [[1\]](#page-129-0). According to their report, CBT

Fig. 10.2 Comparison of sagittal and axial direction between the traditional trajectory and cortical bone trajectory. CBT is directed $25-30^{\circ}$ cranially in the sagittal plane and 10° laterally in the sagittal plane. There is a tendency in the axial plane to gradually increase the difference between medial angle of the traditional trajectory and lateral angle of cortical bone trajectory from L1 to L5. *TT* traditional trajectory, *CBT* cortical bone trajectory

screws (average 4.5-mm diameter and 29-mm length) demonstrated a 30% greater uniaxial pullout strength and equivalent characteristics against toggle loading than TT screws (average 6.5-mm diameter and 51-mm length). Another author also compared the fixation strength of the screw-rod construct using CBT with that using TT under physiological cyclic loading in the osteoporotic lumbar spine [[15\]](#page-130-0) and showed increased fixation of the CBT construct in the lower lumbar spine.

One of the noteworthy indications of CBT is as a salvage procedure. Salvaging pedicle screws is necessary in cases of errors in screw placement, poor fixation resulting in screw loosening, and pseudoarthrosis, and increasing the diameter and length of screws and augmenting the screws with cement are conventional methods to improve the integrity of the bone-screw interface. CBT, which follows a different screw path from the traditional anatomical pedicular trajectory, can be another valid option for fixation failure (Fig. 10.2). Supporting this, Calvert et al. conducted a cadaveric study to investigate the fixation of CBT and TT screws when each was used to rescue the other in the setting of a compromised screw track (revision surgery) [\[16\]](#page-130-0). They concluded that CBT and TT screws each retain adequate construct stiffness and pullout strength for revision at the same lumbar level.

Traditional trajectory **Cortical bone trajectory** Cortical bone trajectory

Fig. 10.3 Finite element models showing distribution of the equivalent stress on the vertebra. Illustration of a 54-year-old woman with loading of the pullout strength on the sagittal plane (*upper row*) and axial plane (*bottom row*). The various colors indicate the magnitude of the stresses. Moderate stresses occur in the pedicle for the traditional trajectory. CBT demonstrates higher stress concentrations within the posterior element

Contrary to TT screws which achieve 60–80% of the fixation strength within the pedicle [[17](#page-130-0)], CBT screws utilize the anatomically denser bone of the posterior elements to enhance fixation (Fig. 10.3). This feature indicates the possibility of CBT application for lumbar pathology with compromised vertebral bodies, such as vertebral spondylitis, compression fracture, and combination with vertebroplasty [\[18\]](#page-130-0).

10.2.2 Spinal Level

The CBT technique is applicable for the thoracolumbar spine from T9 to S1 and can be used for multilevel fusion without severe deformity requiring correction. Care should be taken when placing screws in the upper lumbar vertebrae. Because of a narrow and medialized pars and small pedicle [[2\]](#page-129-0), there is a potential risk of pars and pedicle fracture, leading to fixation failure.

For the lower thoracic vertebrae, the thoracic CBT technique has been reported [\[19](#page-130-0)]. The trajectory starts at the 6 o'clock position of the pedicle and is directed straight forward in the transverse plane and ends up at the posterior third of the superior vertebral end plate. A cadaveric biomechanical study revealed that thoracic CBT screws demonstrated a 54% higher insertional torque than the traditional pedicle screws by contacting with the anatomically denser bone regions of the pedicle and vertebral body. Surgeons should note the following fact that, compared with thoracic CBT, lumbar CBT can involve a high level of purchase in the cortical bone with the posterior element and contribute to superior fixation with respect to the anatomical variations in bone density in the vertebrae.

In an attempt to engage with the sacral cortical bone, penetrating the S1 superior end plate screw (PES) technique has been introduced [[20\]](#page-130-0). The trajectory starts at more medial points than the traditional sacral pedicle screw and penetrates the densest sacral bone of the proximal end plate without any risk of neurovascular injury. This technique demonstrated a 141% higher insertional torque than the traditional monocortical technique. One advantage of the PES technique is that the PES anchors are collinear with CBT screws and an S2 alar iliac screw when utilizing the CBT technique for multilevel fusion to the sacrum.

At the thoracolumbar spinal level, CBT is superior to TT with regard to both the biomechanical aspect and less surgical invasiveness, particularly in the lower lumbar spine. From a biomechanical aspect, the lower spine has a larger pedicle than the upper spine and involves difficulty in obtaining optimal filling within the subcortical bone of the pedicle when using TT [\[15](#page-130-0)]. In contrast, CBT screws can achieve rigid fixation, regardless of the pedicle size, by increasing contact with the abundant cortical bone between the pars interarticularis and inferior part of the pedicle in the whole lumbar spine $[2, 21-23]$ $[2, 21-23]$ $[2, 21-23]$. In terms of less invasiveness, the anatomical characteristics of the lower spine, such as the deep-seated screw entry point, large amount of paraspinal muscles, and larger medialized pedicle axis, necessitate extensive muscle dissection and traction to implant a pedicle screw in a convergent direction from a more lateral entry point (Fig. [10.2\)](#page-120-0). This tendency is more marked in the case of obese patients with a deep surgical corridor.

10.3 Future Advantage to Prevent Fusion Disease

Several clinical studies have assessed surgical outcomes using CBT. In the shortterm results, the CBT technique facilitates similar clinical and radiologic outcomes with low surgical morbidity and blood loss and a short postoperative hospital stay compared with the TT technique [[11,](#page-129-0) [24\]](#page-130-0). More interestingly, a recent study of 177 patients who underwent posterior lumbar interbody fusion for degenerative lumbar spondylolisthesis (82 controls by the TT technique; 95 by the CBT technique) reported a 3.2% rate of symptomatic adjacent segment disease (ASD) using the CBT technique and a 11% rate using the TT technique during a 3-year postoperative follow-up ($p < 0.05$) [[25\]](#page-130-0). The development of ASD is one of the major undesirable factors and an inevitable complication after lumbar spinal fusion, which requires further surgical treatment. Spinal fusion alters the biomechanical properties on the nonoperated adjacent segment and shows symptomatic degeneration. However, the

Fig. 10.4 Adjacent cranial facet violation following screw insertion. CT scans show adjacent cranial facet violation (*left*) and no violation (*right*). The selection of the optimal entry point sufficiently caudal from the inferior border of the facet joint and leaving the screw proud about 5 mm from the dorsal lamina to maintain safe distance from the facet joint are essential to reduce the risk of violation

essence to achieve spinal fusion is the same even though a diversity of minimally invasive surgical techniques (including percutaneous pedicle screw, CBT, lateral interbody fusion, etc.) are applied in clinical practice. From this point of view, reducing the incidence of ASD is a meaningful advantage of using the CBT technique, probably due to reducing the posterior soft tissue dissection and avoiding iatrogenic injury to the cranial facet joint during placement of the proximal pedicle screws (Fig. 10.4) [\[13](#page-129-0), [26,](#page-130-0) [27](#page-130-0)]. In the future, CBT may become a standard procedure and be used as a "reducing ASD fusion technique" regardless of the bone density or generation.

10.4 Limitations

10.4.1 Spondylolysis

There is a definite limitation on indicating the CBT technique for spondylolytic vertebrae because the pars interarticularis is a key structure for the fixation of CBT [\[28\]](#page-130-0). Spondylolysis is defined as an anatomical defect in the pars interarticularis that allows separation of the vertebral body from the lamina and inferior facet joint, leading to anterior translation of the affected vertebra. The traditional pedicle screw system is the gold standard for the surgical treatment of isthmic spondylolisthesis due to a strong vertebral anchoring capacity, and it has led to favorable clinical outcomes. If CBT is applied to isthmic spondylolisthesis, one could easily insert screws along a craniolaterally directed path

Traditional trajectory **Cortical bone trajectory**

Fig. 10.5 Finite element models showing distribution of the equivalent stress on the spondylolytic vertebra. Illustration of a 54-year-old woman with loading of the pullout strength on the sagittal plane (*upper row*) and axial plane (*bottom row*). The *various colors* indicate the magnitude of the stresses. Both TT and CBT screws demonstrate similar moderate stresses in the pedicle. CBT lacks higher stress concentration at the posterior element compared with that in the normal vertebra (Fig. [10.3](#page-121-0))

because the entry point of CBT can be effectively confirmed under direct visualization after the complete removal of the floating lamina.

From an anatomical aspect, the cortical bone is most concentrated between the pars interarticularis region and inferior part of the pedicle [\[21](#page-130-0)–[23\]](#page-130-0); however, a spondylolytic vertebra lacks these regions on which CBT screws rely for most of their stability (Fig. 10.5). A biomechanical study on the fixation strength of pedicle screws in spondylolytic vertebrae revealed that CBT screws provided similar pullout strength to TT screws, but CBT constructs showed a significantly lower vertebral fixation strength compared with TT constructs [\[28\]](#page-130-0). The absence of a solid purchase in the cortical bone in the posterior lamina, in spite of penetrating the sclerotic surface at the pars defect, and the divergent trajectory of CBT screws were suggested to be the causes of this drawback. Surgeons should note that (1) the fixation strength of the construct is a critical factor to achieve better bony fixation rather than that of a single screw itself, and (2) the TT technique is superior for spondylolytic vertebrae to the CBT technique, even though the latter can reduce muscle dissection.

Similarly, relative contraindications include a lack of pars conditions secondary to a wide decompression and an iatrogenic pars fracture [\[29](#page-130-0)]. When applying the CBT technique to a pars defect with careful pre- and intraoperative considerations, special attention must be taken to select large-sized screws and to place screws sufficiently deep into the vertebral body for better fixation and effective load sharing [\[30](#page-130-0), [31](#page-130-0)].

10.4.2 Rotational Spinal Deformity

Some biomechanical studies suggested that CBT screws provided less rigid fixation on lateral bending and axial rotation. A cadaveric biomechanical study showed that the CBT screw-rod construct exhibited almost the same stability as the TT construct; however, when the intervertebral disc was left intact or a transforaminal lumbar interbody fusion implant was used, the TT construct was significantly stiffer than the CBT construct during lateral bending and axial rotation [\[7](#page-129-0)]. Another biomechanical study using the finite element method revealed that the CBT pairedscrew construct showed significantly higher vertebral fixation on flexion (51%) and extension (35%) and a significantly lower vertebral fixation strength on lateral bending (20%) and axial rotation (37%) compared with the TT construct, although a single CBT screw demonstrated a significantly higher pullout strength and higher resistance to multidirectional loading than a TT screw [[3\]](#page-129-0). The weaknesses on lateral bending and axial rotation using CBT were universally observed regardless of the BMD; therefore, the disadvantage of the CBT construct (the features of a divergent and short lever arm from the medial axis) could be associated with these results.

On the basis of these biomechanical results, two essential points are recommended. One point is enhancing each screw's fixation within a construct. The selection of the optimal screw path and screw size, which varies widely among surgeons, is important to obtain the best fixation strength. According to previous studies investigating these issues, the optimal screw path should be directed 25–30° cranially along the inferior border of the pedicle to achieve maximum contact with the hard bone of the lamina and end up around the posterior third to posterior half of the superior vertebral end plate to distribute the loads applied to the vertebra effectively (Fig. [10.6\)](#page-126-0) [\[32](#page-131-0)]. A finite element study using L4 vertebrae showed that the ideal screw size for CBT is a diameter larger than 5.5 mm and length longer than 35 mm so as to be placed sufficiently deep into the middle column of the vertebra [\[33](#page-131-0)]. We always select screws of 5.5 mm in diameter and 35–40 mm in length for the middle or lower lumbar spine.

The other point is to adopt countermeasures against torsional motion for the whole construct. For example, preservation of the facet joint during the interbody procedure [\[34](#page-131-0)], placement of a large interbody graft [[35,](#page-131-0) [36](#page-131-0)], and addition of a cross-link connector are effective strategies [\[37](#page-131-0)]. Among them, the addition of a cross-link can be applicable for all fusion procedures and pathological conditions and improve the stability on lateral bending and axial rotation. Because of the short distance between two bilateral rods, surgeons usually have to use a fixed-type crosslink and place the bilateral rods in parallel positions for easier connection.

Fig. 10.6 Ideal screw trajectory. Postoperative CT scans of an illustrative case (L4–L5 posterior lumbar interbody fusion for degenerative spondylolisthesis) showing ideal screw positions

CBT screws cannot sufficiently transverse through the instantaneous axis of rotation and fail to deliver a rotational force to the anterior vertebral body to enable vertebral rotation; thus, the CBT technique should be avoided in cases of severe deformity with horizontal vertebral rotation necessitating torsional motion to correct the spinal alignment.

10.5 Pitfalls

10.5.1 Pars and Pedicle Fractures

One of the specific complications using the CBT technique is a potential risk of entry point and pedicle fractures during screw insertion [[38](#page-131-0)]. Fractures start at the pars interarticularis, spread to the circumferential bony margin, and sometimes may continue to the pedicle wall. The highly dense cortical bone around its screw path and the proximity of the entry point to the bony margin at the pars play critical roles in the occurrence of these fractures [[2](#page-129-0)]. The following five technical points are mandatory to avoid unintentional fractures which lead to a loss of fixation: (1) to identify the screw entry point under direct visualization by exposing an anatomical landmark of the lateral margin of the pars; (2) to determine the optimal entry point at least 3 mm medial to the lateral pars; (3) to design the extent of bony decompression to maintain a safe distance, at least 3 mm, from the screw hole and the margin of resection; (4) to tap a hole line to line relative to the diameter of the planned screw; and (5) not to impinge the screw head on the dorsal lamina to avoid the "hubbing" phenomenon [\[39](#page-131-0)].

To reduce the possibility of pars and pedicle fractures resulting in immediate screw failure, surgeons should keep in mind a bony margin of at least 3 mm around the entry point and verify the proper entry point and trajectory under fluoroscopic guidance (Fig. 10.7).

10.5.2 Slip Reduction

Close attention should be paid on conducting the surgical procedure with CBT for degenerative spondylolisthesis. When the traditional pedicle screw system is applied

Fig. 10.7 Entry point. Anteroposterior radiograph (*left*) and intraoperative photograph (*right*) with screw markers. An *arrow* shows the entry point for the right L4 screw. The *solid* and *interrupted curves* represent the lateral pars and bony resection line, respectively

for slip reduction, inserted pedicle screws can allow an increase of the interbody disc height and reduce the slipped vertebra before interbody cage placement. On the contrary, CBT screws should be inserted after the decompression and subsequent interbody work, because the screw heads sit down on the median position and interfere with cage placement. Then, the correction procedure by anteroposterior directional force (connecting bilateral rods with the cranial pedicle screws inserted to the slipped vertebra) is performed under the setting of a previously implanted cage. As a consequence, friction may occur between the vertebral end plate and interbody cage surface and inhibit the transmission of the corrective force on lifting the slipped vertebra. However, this may not have an adverse effect on the surgical procedure, and excellent radiologic outcomes for degenerative spondylolisthesis (preoperative % slip, 23% ; 2-year-postoperative % slip, 3.8%) and a lower rate of correction loss were reported, probably due to the strong anteroposterior pullout strength of CBT screws [[40\]](#page-131-0).

10.5.3 Screw Loosening

Pedicle screw loosening, which is confirmed as radiologic lucency around the screw, is caused by both stress shielding of the vertebral body due to load distribution through the pedicle screw and cyclic toggle loading at the bone-screw interface. Osteoporosis also contributes to the progression of screw loosening by a decrease in bone strength and increase in bone fragility. The majority of reports have demonstrated a lower incidence of CBT screw loosening [[24,](#page-130-0) [41\]](#page-131-0), although some authors have reported the opposite results [\[42](#page-131-0), [43](#page-131-0)]. These results should be interpreted with caution because various parameters (including wide individual variations of lumbar pathology, bone quality, and age as well as screw size, screw trajectory, size or position of the interbody cage, and fusion procedure) can influence the occurrence of screw loosening and sometimes cause biased results. More research with long-term clinical and radiological results is necessary to better elucidate the influence of CBT on screw loosening.

Theoretically, the amount of the load applied to the vertebrae is equal whether pedicle screws are inserted via TT or CBT; however, the surface area of the bonescrew interface using CBT (φ 5.5 \times 35 mm: 546 mm²) is about 36% lower than that using TT (φ 6.5 \times 40 mm: 853 mm²) [\[44](#page-131-0)]. Stresses on the bone-screw interface using CBT are markedly higher than those using TT due to a higher portion of mechanical stress per unit area. Once CBT screw loosening has occurred, development of the micromotion of the screw induces the acceleration of bone encroachment around the screw, which is associated with decreased implant rigidity, delayed or incomplete fusion, and poor clinical results. Maintaining screw fixation until bony arthrodesis may play a critical role in determining the risk of screw loosening. Therefore, increasing the initial fixation of screws and promoting bony union by the appropriate use of an interbody graft are reasonable approaches for reducing the loosening rate [[3,](#page-129-0) [32](#page-131-0), [35](#page-131-0), [36\]](#page-131-0). A previous biomechanical study using a finite element method revealed that not only increasing engagement with the denser cortical bone but also improving the vertebral load distribution contributes to a reduction of the mechanical stress on the bone-screw interface [[33\]](#page-131-0). A longer screw toward the posterior third to posterior half of the superior end plate from the pars interarticularis can pass the instantaneous axis of rotation, have a larger thread surface area, and thus effectively transmit the load applied to the vertebrae. At the same time, the countermeasures against torsional motion mentioned above, such as the addition of cross-links, minimization of the facet joint resection to access to the disc, and the strong reconstruction of an anterior/middle vertebral column are essential to reinforce fixation. To achieve better screw fixation and bony fusion, surgeons need to recognize both the fixation strength of a single screw and that of the spinal construct.

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11 New Techniques and MIS: The Interspinous Fixation Devices

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11.1 Introduction

The treatment of vertebral instability has evolved over the years with the aim of searching and developing the most effective and less invasive procedure to reduce and to neutralize dynamically the metameric hypermobility; pedicle screw fixation (PSF) has been widely employed to reach vertebral fixation and fusion and still remains the "gold standard" technique [\[1](#page-146-0), [2](#page-146-0)]. PSF is associated with well-known risks [[3](#page-147-0), [4\]](#page-147-0) such as increased rates of cerebrospinal fluid leakage, fracture of the pedicles during screw insertion, transient/permanent injury to nervous structures, and deep wound infections. Furthermore, as a result of muscle dissection and long operative times, some disadvantages can be evident, such as postoperative back pain and long postoperative recovery time [[5\]](#page-147-0). There are risks of exposure to ionizing radiations for the surgeon and the whole operating room staff, other than for the patient, due to the use of fluoroscopic guidance for the implantation of pedicle screws (PS) [[4,](#page-147-0) [6\]](#page-147-0). The muscle dissection related to surgical exposure leaded to the development of minimally invasive procedures, at the cost of increased exposure to ionizing radiations. This has led to the development of a lot of different devices, some of them used indiscriminately in recent years but with questionable long-term results. In this context, a major role was played by interspinous devices, generally used in degenerative lumbar spine disease. Interspinous posterior device (IPD) is a term used to identify a relatively recent group of implants employed in the treatment of lumbar spinal degenerative disease. This kind of device is classified as part of the group of the dynamic stabilization systems of the spine. The concept of dynamic stabilization has been actually replaced by the principle of dynamic neutralization of the hypermobility, with the intention of clarifying that the primary aim of this kind of systems is not

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the preservation of the movement but the dynamic neutralization of the segmental hypermobility, which is at the base of the pathological condition. The surgical indications for the implantation of an IPD are the spinal stenosis and neurogenic claudication, assuming that its function is the enlargement of the neural foramen and the decompression of the roots forming the cauda equina in the central part of the vertebral canal. Recently, it has been noticed that those devices have significant problems in terms of clinical follow-up, since the action exercising on the vertebral body has an appreciable effect on the biomechanics of the lumbar spine. This is why in the last few years new devices have been introduced, the so-called interspinous anchors (IA) or interspinous fusion devices (IFD). Those differ from the IPD as their aim is the fusion of the spinous processes on which they are anchored, and therefore the target is spinal stabilization by arthrodesis and not the dynamic neutralization of the hypermovement. The question that requires response is: are those devices able to replace arthrodesis with plates and screws in lumbar instability?

11.2 Historical Background

The first interspinous implant for the lumbar spine was developed in the 1950s by Knowles. Owing to flaws in design, material, surgical technique, and applied indications, its use was soon abandoned. The first modern interspinous device, the Wallis system, was developed by Abbot Spine in 1986, and it was used primarily in patients with recurrent disk herniation. It was a "floating system" that was comprised of a titanium spacer placed between the spinous processes and secured with two Dacron ligaments wrapped around the spinous processes. This system was not initially marketed commercially while waiting for long-term follow-up results. In a reported prospective trial, the application of the first generation Wallis device improved outcome in patients who underwent a second discectomy. Despite favorable results, Senegas thought that the device could be improved. A second generation of the Wallis device, slightly different in shape, and composed of polyetheretherketone (PEEK), was used with other surgical procedures, to reduce pain severity in cases of moderate disk degeneration, central spinal stenosis, and significant lower back pain. The Minns device was the first "soft" interspinous spacer indicated for sagittal plane instability. The implant was a dumbbell-shaped silicone spacer created to off-load the facet joints and decrease the intradiscal pressure. Despite the promising in vitro results, no further clinical application was published to date, and it is unclear whether the implant advanced much further than the laboratory settings. In the 1990s, several other IPD devices displaying significant differences in design, materials, surgical techniques, and indications appeared in Europe and South America, for which there are ongoing trials of evaluation for a host of clinical indications. Kaech et al. first reported on the interspinous "U" (Coflex) suggesting that it was indicated for protection against adjacent level disk disease and restabilization of a lumbar laminectomy. Caserta et al. reported on the DIAM implant, which was indicated for a number of conditions, including degenerative disk disease, herniated nucleus pulposus, and lumbar instability. The X-Stop device (Medtronic, Tolochenaz, Switzerland) was

approved by the US Food and Drug Administration in 2005 for the treatment of neurogenic intermittent claudication secondary to lumbar stenosis. In October 2012, the US FDA approved the coflex® Interlaminar Stabilization® device for the treatment of lumbar spinal stenosis. It is the first and only FDA-approved device offering nonfusion, motion preserving interlaminar stabilization post direct surgical decompression. IPDs have then evolved during the years, being classified in not restricted and restricted, based on the presence or the absence of a dynamic control of the movements in extension only or both flexion and extension. For example, X-Stop, Bacjack, Aperius, etc. are classified as not restricted IPD, while Coflex, Diam, Wallis, etc. are classified as restricted IPD on the base of their biomechanical properties. Following this biomechanical principles, in the last decades, a further evolution has brought to the development of the IFD, whose aim is the interspinous bone fusion. The aim of those devices is not the dynamic neutralization of the hypermovement such as IPDs, but the bone fusion with a complete block of the metameric movement. On the basis of this principle, IFDs can't be classified as movement dynamic control systems, because their aim is the osseous fusion of the segment, being completely different from IPD.

11.3 Interspinous Fusion Devices IFD or Interspinous Anchors IA

Their aim is the interspinous bone fusion, a surgical technique already described many years ago: The first attempts of interspinous fusion, described and employed by Hibbs and Albee during the second decade of 1900, did not show an adequate primary stabilization; they were therefore abandoned. The main function of the interspinous anchors differs from the other interspinous devices; in fact the (hypothetic) main goal of IPDs is the motion preservation of the metamere involved by a degenerative disease; unfortunately those devices couldn't obtain this function because they altered the physiological biomechanics of the metamere and of the entire lumbar spine, promoting and not preventing the degenerative cascade. The IFD, instead, has a completely different basic concept: the aim is to block the hypermotion through an interspinous bone fusion. In this way they could stop the degeneration and immobilize the metamere. Theoretically the surgeon, with the insertion of those devices, should obtain a stabilization of the metamere with a really minimally invasive surgical approach, without using screws and rods. The most implanted IFDs are ASPEN, AXLE, BACFUSE, etc., followed by a relevant number of extremely similar devices which were developed during the years.

11.3.1 ASPEN (Lanx)

The ASPEN device is an alternative to pedicle screws in achieving fusion; it delivers simplified posterior stabilization and renewed anatomical alignment through a minimally invasive implant and can be used in single- or multilevel constructs. The FDA

approved the use of ASPEN device in one-level or two-level degenerative pathology. ASPEN can be employed alone or as an adjunct to interbody fusion and/or posterior fusion with decompression in treatment from T1 to S1. It provides an alternative to more conventional means of fixation such as pedicle screws or anterior plates (Fig. 11.1). This device is an alternative to dynamic interspinous spacers for the treatment of spinal stenosis and to conventional means of fixation to achieve fusion. Proprietary spiked-plate design provides reliable bone fixation. The interspinous implant serves to support the formation of fusion and decompression by fixation, load sharing, and interspinous process spacing, while decompressing spinal canal. It has an offset shape to accommodate multilevel placement with a wide range of sizes for patient variations.

11.3.2 BacFuse (Pioneer)

This device is used alone or as an adjunct to interbody fusion and/or posterior fusion with decompression in treatment from T1 to S1. It has a spiked-plate design that provide spinous process fixation. The BacFuse decompresses the spinal canal while supporting the formation of interspinous fusion.

Recently those devices have gone through an evolution, with the creation of expansion devices and cardanic compression devices that allow the distraction and the compression of the segment during the surgical procedure. These new devices allow to model the orientation of the segment toward compression, increasing the pressure on the cage and assuring a better interbody fusion. These are advanced spinous process fixation systems that were developed to address some of the disadvantages of traditional stabilization devices. The implant has unique telescoping

Fig. 11.1 ASPEN interspinous fusion device

plates that allow surgeons to fixate and compress spinous processes to restore sagittal alignment and facilitate a reliable interbody fusion. The device's large contact area provides a strong anchor point from which is possible to apply compression between the adjacent spinous processes during the surgical procedure, and it offers optimal stability during the fusion process. These systems are easy to use and the quick procedure offers minimal exposure, dissection, muscle trauma, and blood loss as well as protection of neural structures. The devices have a large bone graft window and are intended for use with bone graft material and are not intended for stand-alone use. These devices are designed to support the formation of fusion and decompression by fixation and interspinous process spacing, while renewing anatomic alignment. These implants have an adjustable, fenestrated core and adjustablelength plates which allow for expansion and compression. The in situ compressibility allows surgeons to control the lordosis at the treated level, while the adjustable sizing allows for an optimized anatomical fit. Bone graft material is then packed within the hollow post of the implant.

11.4 Surgical Technique

These devices could be implanted by a minimally invasive approach; through a very short median skin incision (extended from the upper spinous process to the lower spinous process) of about 3–4 cm, the surgeon must expose the upper and lower lamina of one side of the metamere. Using a specific minimally invasive instrumentation (Fig. 11.2), the device must be implanted between spinous processes using a technique similar to the one used for the insertion of a classic interspinous spacers. After radiological intraoperative check, the device must be blocked in the desired position. After this, in the interspinous space, using a specific instrument, a cruentation of the bone must be performed and bone chips could be inserted (Fig. [11.3\)](#page-137-0). The mean duration of the surgical intervention is 40 min, and the blood loss is

Fig. 11.2 Intraoperative view of low profile instruments for an IFD implant **(a)** minimally invasive instrument **(b)** device which has to be implanted

Fig. 11.3 Intraoperative view of the surgical technique: (**a**) exposure of the surgical field, (**b**) preparation and enlargement of the interspinous space, (**c**) cruentation and bone exposure of the interspinous space, (**d**) positioning of the interspinous fusion device in the interspinous space

extremely poor. It is important to underline that a TLIF technique could be added to this device with the aim of obtaining a 360° fusion with only a monolateral minimally invasive approach.

11.5 Biomechanics of IFDs

If we consider that interspinous devices IPD can be implanted in stenosis of mild and moderate degree, being the stenosis central or foraminal, or in the low-grade spondylolisthesis without spondylolysis (with poor or at least controversial results), we give for granted that the degenerative lumbar cascade, as described by Kirkaldy-Willis, is in the active phase. The degenerative lumbar spondylosis in active phase has as a first step the damage of the intervertebral disk, whose degree of degeneration is related to the entity of the damage and to the persistency of the damage itself in time. Normally, the biomechanic behavior of the lumbar spine is subject to the rule of spine loading. According to this rule, the axial load of the body is discharged, and consequently neutralized, on the intervertebral disk and on the posterior structures (articulations, ligaments, and muscles) in proportions of 80% and 20%, respectively. Any disk degeneration transfers the axial load to the posterior elements of the spine, determining an inversion in the distribution of

the axial load, related to the loss of viscoelastic and shock adsorber properties of the disk itself. This condition promotes the insurgence of a functional overload of the facet joints, determining a greater mechanical stress than the physiological one, with consequent hyperlaxity of the facet joints, reduced competence of the articular capsule and hypermobility of the lumbar segment. The hypermobility stimulates the inflammatory reaction in the adjacent tissues, activating chemokines (fractalkine in particular) in the ligamentum flavum, promoting the chemotaxis in the ligamentum itself. The inflammatory cells cause extracellular matrix degradation of the ligamentum, determining loss of elasticity and hypertrophy. It is well documented the role of fractalkine in the development of numerous inflammatory diseases (rheumatoid arthritis, dermatitis, etc.) and in ligaments and joints involved in inflammatory processes caused by instability (e.g., joint capsules, ligaments, and synovium). The inflammatory process involves these tissues so the fractalkine overexpression is activated; thus causing the recruitment of mononuclear cells within the LF feeding the inflammation and causing vascular injury and angiogenesis. Moreover such an increase in mononuclear activity causes a proliferation of fibroblasts (for overexpression of TGF beta mRNA resulting in increased collagen fibers) and inflammatory cells in LF. This inflammatory cell activity in the LF causes rupture of the extracellular matrix (for activation of metalloproteinase MMP2) due to the elastin degradation, resulting in loss of elasticity of the ligament and subsequent hypertrophy. The collapse of the intervertebral disk causes ligamentum flavum redundancy, and its prominence in the vertebral canal reduces the diameter of the canal itself, determining spinal stenosis. Only in this phase, the articular hypertrophy generates foraminal stenosis, the collapse of the disk generates ligamentous stenosis, and the stenosis becomes symptomatic, but the main pathological substrate remains the hypermobility. The treatment of a hard or soft stenosis has necessarily to be strictly linked to the concept of vertebral instability as basic pathological condition. The introduction in the market of fusion interspinous devices is relatively recent, so there are less studies regarding the biomechanical effects of these devices mainly focused on the ROM reduction compared to pedicle screw constructs. Kettler et al. performed a biomechanical in vitro study on a different version of the Coflex interspinous implant, called Coflex Rivet, in which the device is screw-fixed to the spinous processes. The new device was tested for flexibility and load transfer, and, unlike the original Coflex implant, it is shown to increase stability only in extension as described in other biomechanical studies. Compared to the defect condition (bilateral hemifacetectomy with resection of the flaval ligaments), both implants had a strong stabilizing effect in extension. Also Coflex Rivet strongly stabilized in flexion and was able to compensate the destabilizing effect of the defect in axial rotation and lateral bending. The authors believed that the biomechanical characteristics of this new implant might even make it suitable as an adjunct to fusion, which would be a new indication for this type of device. Wang et al. conducted a biomechanical study on the CD HORIZON SPIRE fixation system. The authors compared the stability provided by the SPIRE with unilateral and bilateral pedicle screw system in destabilized spines with or without anterior allograft support. Used alone, or in

conjunction with an interbody cage, the SPIRE provided a great stability in flexion and extension and the limitation of motion appears to be equal to bilateral pedicle screw system. In lateral bending and axial rotation, the SPIRE had a less stabilizing effect, and it reduced motion equal to unilateral pedicle screw system. In the recent biomechanical study conducted by Karahalios et al. [\[7](#page-147-0)], the ASPEN device was compared with other devices standing alone and in conjunction with anterior lumbar interbody fusion (ALIF) procedure. The authors found that the stand-alone ASPEN device decreased significantly the ROM in extension and flexion with less effects on the ROM in lateral bending and axial rotation. The use of ASPEN device and ALIF had a stabilization effect immobilized equal to ALIF and pedicle screw system and superior to ALIF and anterior plate system. The authors concluded that ASPEN device could be an alternative implant to pedicle screw system and anterior plate system when used in conjunction with ALIF. The use of the ASPEN device resulted in flexion at the index level, with a resultant increase in foraminal height. Compensatory extension at the adjacent levels prevented any significant change in overall sagittal balance. Kaibara et al. [[8\]](#page-147-0) conducted a biomechanical study on ASPEN interspinous fixation device in combination with transforaminal lumbar interbody fusion (TLIF) and other posterior fixations in human cadaver spines. The use of the stand-alone ASPEN device significantly reduced motion in flexion and extension, and the outcomes were similar to the effects obtained with the use of TLIF and bilateral pedicle screw system. In lateral bending and axial rotation, ASPEN device with and without TLIF showed inferior stability to bilateral pedicel screw. TLIF supplemented with ASPEN device and unilateral screw system provided equal stability as in TLIF with bilateral pedicle screws. The authors suggested the ASPEN device as a possible alternative to pedicle screw systems. In 2013, Techy et al. conducted a biomechanical study to evaluate the effect of the use ASPEN device as augmentation of an interbody cage or a pedicular screw fixation. After implantation of the ASPEN device to augment the interbody cage, there was a significant decrease in the ROM of 74% in flexion-extension (FE), but there was no significant change in lateral bending (LB) and axial rotation (AR). The construct with unilateral pedicle screws showed a significant reduction of FE by 77%, LB by 55%, and AR by 42% compared with control spine. The bilateral pedicle screw construct reduced FE by 77%, LB by 77%, and AR by 65% when compared with the control spine. The authors concluded that ASPEN device, which is used to augment an interbody cage, was able to provide FE stability comparable with the bilateral pedicle screw fixation. However, it provided minimal stability in LB and AR unless further augmented with pedicle screws $[9-14]$. Similar results were obtained by the study published by Gonzalez-Blohm et al. in 2014. In this study, the authors evaluated the biomechanical performance of the ASPEN as a stand-alone device after lumbar decompression surgery and as supplemental fixation in a posterior lumbar interbody fusion (PLIF) construct. They suggested that the ASPEN device may be a suitable device to provide a flexion-extension balance after a unilateral laminotomy. PLIF constructs with ASPEN device and pedicle screw fixation performed equivalently in flexion-extension and axial rotation, but the PLIF-bilateral pedicle screw construct was more resistant to lateral bending. The authors recommended further biomechanical and clinical evidence to strongly support the use of this interspinous fusion device as stand-alone or as supplemental fixation to expandable posterior interbody cages.

On the basis of these comparative studies, some observations are mandatory:

The main goal of IPD is motion preservation while IFDs have a different base concept: if the substrate of lumbar stenosis is the hyper-motion, the only way to stop the degeneration is to block it; this goal is achieved through the bone fusion. So IFD's aim is not the motion preservation but the bone fusion and the immobilization of the metamere. These devices have a double function, related to their possible association with TLIF interbody fusion.

- 1. Stand-alone: spinous process fusion of a spinal motor unit after placement of the device in distraction or in neutral position. If the device is implanted in distraction, the biomechanical alteration persists, because the axial load is altered, but the pathological segment is stabilized by the osseous fusion. The degenerative process can progress toward the adjacent segments, with the development of an adjacent segment disease ASD.
- 2. TLIF interbody fusion: this seems to be the best use for IFD. This surgery is recommended in cases of monolateral radiculopathy with foraminal stenosis due to facet hypertrophy. The surgical procedure includes arterectomy to perform a TLIF, complete decompression of the foramen and of the nerve root, associated with the implant of a device in neutral position (not in distraction)

This technique offers several advantages:

- (a) The execution of a TLIF allows to perform a monolateral decompression and the insertion of an anterior intersomatic cage. The cage, in relationship with its width, can restore the physiological lumbar lordosis and leave unaltered the sagittal balance of the lumbar spine.
- (b) The insertion of the cage in TLIF technique allows a higher fusion rate than the one obtained in PLIF technique, in relation with the most anterior position of the cage and of the width of the cage itself.
- (c) The insertion of the device in neutral position stabilizes the segment in his physiological position, without distracting the segment.
- (d) This procedure allows to perform a circumferential fusion with an exclusively posterior and monolateral approach, preserving muscular insertions and posterior tension band.

11.6 Personal Experience

We report the results obtained in our department with the use of IFDs as a standalone or in association with TLIF interbody cage in degenerative lumbar spine and to analyze the main surgical indications for the implant of an IFD.

• *Materials and methods*: from January 2010 to December 2013, 60 patients were enrolled in our prospective study. The inclusion criteria were (1) symptoms related to degenerative pathology of the spine such as low back pain and radicular pain, without neurogenic claudication ,(2) MRI positive for monolateral or bilateral stenosis, synovial cyst, and disk herniation, (3) radiological aspects of microinstability, (4) spondylolisthesis no more than I° in the dynamic X-rays, and (5) failure of conservative treatment. All patients have been studied with level I radiological exams (lumbosacral X-rays in static and dynamic projections) and level II (CT and MRI scans of the lumbosacral spine). The parameters evaluated on X-rays were Van Akkerveekens distance, Ullman lines, and Hadley's S curve. In CT scans, the Fujiwara grading and the facet tropism were evaluated. The preoperative and postoperative radiological evaluation was performed by two different neuroradiologists of the same institute, and the controversies about diagnosis were solved by consensus. Of these 60 patients, 40 underwent IFD surgery, while 20 with an analogous clinical and radiological status underwent pedicle screw fixation with open technique and posterolateral fusion, stand-alone or in association with interbody cage with TLIF technique. The surgical choice was directly depended from the surgeon's experience. All surgeries were performed by two surgeons of the same institute with general anesthesia. VAS and an Oswestry scale evaluation tests were administered to all patients during follow-up checks and compared with the preoperative values. Furthermore, all patients performed a dynamic lumbosacral X-ray a year after surgery to evaluate the fusion rate of the devices. The mean follow-up time at January 2015 was 34 months (range 12–60 months). We finally compare the two groups performing an analysis about clinical and radiological status at follow-up.

11.7 Results

Forty patients were treated with IFD for lumbar degenerative pathology. The patients were 18 males and 22 females. Their mean age was 57.6 years with a range between 35 and 76.

- In eight patients, a foraminotomy and the implant of an IFD for a low-grade instability and bilateral foraminal stenosis have been performed.
- In 11 patients, the device was applied on two levels for a double-level low-grade instability (Fig. [11.4\)](#page-142-0).
- In 21 patients, the implant of an IFD was associated with the placement of an interbody cage with TLIF technique for a grade I listhesis, without pelvic or sacral indexes for high slip progression risk. In five of those patients, a recurrent lumbar disk herniation was evidenced (Figs. [11.5](#page-142-0) and [11.6\)](#page-143-0).
- In two patients, the device was implanted at L3–L4, in 16 patients at L4–L5, and in 11 patients at L5–S1. In ten cases, the device was implanted at a double-level L4–L5 and L5–S1, in one patient at a double-level L3–L4 and L4–L5.

Fig. 11.4 Double-level IFD implant

Fig. 11.5 One-level IFD implant with decompression and TLIF interbody fusion

Fig. 11.6 One-level IFD implant with decompression, removal of synovial cyst, and TLIF interbody fusion

The patients with a single-level stand-alone IFD assumed the standing position on the first postoperative day. The patients with IFD and TLIF assumed the standing position on the second postoperative day. All patients were discharged 3 days after
surgery $(\pm 1 \text{ day})$. The patients treated with pedicle screws and rods assumed the standing position on the first or second postoperative day and were discharged 5 days after surgery $(\pm 2 \text{ days})$. The mean duration of surgery for a one-level ISA was 50 min \pm 15 min; the mean duration for an IFD and TLIF was 130 \pm 15 min (Fig. 11.7).

In four patients, the device was removed for nonfusion. In three of those patients, the device was implanted stand-alone. In one case, there was a worsening of the symptoms after surgery with a double-level IFD. The patient was then treated with pedicle screw fixation. In 27 patients, we registered an improvement of pain if compared to the preoperative values (mean VAS improvement 7.6 points; Oswestry scale registered an improvement of 65%). The remaining nine patients had an

Fig. 11.7 CT scan with bone sequences showed the bone fusion in a double-level IFD implant

improvement of pain without the restoration of a complete wellness, with a mean improvement in VAS scale of 5.2 points and of 36.4% in Oswestry scale. Blood loss in patients treated with IFD was inferior if compared to blood loss of the patients treated with screws and rods (mean values 83 ml and 230 ml, respectively). Among all the patients treated with pedicle screw fixation, two patients developed an adjacent segment syndrome, with the need of revision surgery to extend the implant to a cranial segment. Fourteen patients had an improvement in VAS scale of a mean value of 4.5 and of 32.5% on Oswestry scale; the remaining six patients had a more evident improvement in the tests (72.5% in Oswestry scale and 7.4 in VAS scale). The fusion rate was higher in the group treated with pedicle screws (100%) and in the group treated with IFD was 90%; in the remaining 10% the nonfusion required further surgery. All the patients who encountered nonfusion had a grade I spondylolisthesis: three patients had a stand-alone ISA and one patient had a double-level IFD. All the patient treated with IFD and TLIF showed fusion during follow-up. Fusion was reached on a mean period of 4 ± 2 months in both ISA and pedicle screw groups.

11.8 Discussion

In the effort to reduce the invasiveness of the fusion systems (reduce trauma on the adjacent musculature and facets) and the risks related to pedicle screw placement, during the years new implants and less invasive procedures have been developed, such as IFD. When posterior constructs were used as supplemental fixation to expandable posterior cages (PLIF), it was observed that IFD provided comparable stability to that of the BPSS for flexion-extension and axial rotation but not for lateral bending ROM [\[15](#page-147-0)]. An IFD in adjunction to an interbody cage inserted with LLIF technique, according to Doulgeris [[2\]](#page-146-0), has a good reduction of the ROM in flexion-extension and lateral bending, but an inferior reduction of the ROM in axial rotation, if compared to interbody cage and PSF. Gonzalez-Blohm [[2\]](#page-146-0) found an inferior reduction of the ROM in the movements of lateral bending and axial rotation given by the IFD if compared to PSF, but a major reduction in the extension movement. Wang [\[16](#page-147-0)] found similar results in his study. In our group of patients, in four cases, there was a therapeutic failure of the implant with IFD, needing surgical revision with removal of the device and the insertion of screws and rods. The treatment considered as the gold standard for low-grade instability is not well defined. Some centers usually treat them with surgical fixation with screws and rods, with the well-known procedure-related complications. In literature many studies report the complications related to screw malposition, depending also from the surgeon's experience, from the improvement of imaging techniques and from the use of neuronavigation. The surgical exposure needed to the positioning of pedicle screws is usually extended until the complete exposure of the transverse processes, causing major muscular trauma and delaying the postoperative discharge and the complete recovery. The placement of an IFD requires a less extended surgical exposure, even if it is associated with the placement of an interbody cage with TLIF technique, therefore reducing the trauma on paravertebral muscles and the intraoperative

bleeding, promoting the postoperative recovery of the patient and reducing his postoperative pain. The placement of the device, instead of pedicle screws, is under the direct visual control of the surgeon, so that it does not require intraoperative fluoroscopic controls. In this way, both the patient and the surgeon are less exposed to ionizing radiations. The radiological check after the placement of IFD needs to exclude an eventual distraction with the related kyphotization of the involved segment. The placement of the IFD in a neutral position allows to avoid distraction and all the typical consequences related to the dynamic interspinous devices, to maintain the sagittal balance unaltered and to prevent functional overload on posterior articular masses. In our experience, the results obtained with IFD are satisfying: 27 patients on 40 had a notable improvement of pain (67.5%). Nine on 40 had a slight improvement of pain (22.5%), with a global improvement in 90% of the cases. Ten percent of the patients had not a clinical improvement. Patients treated with IFD had a short hospital stay if compared to patients who underwent surgery performed with pedicle screws. Even if the IFD is a helpful instrument, its clinical indications have to be really clear. They cannot be considered as universal substitutes for pedicle screws. Analyzing the four failures reported in our study, we can notice that two of them were treated with stand-alone ISA and were related to grade I spondylolisthesis. This clinical condition raises many doubts on its feasibility. We have also highlighted how the best clinical results (clinical situation) and radiological results (bony fusion) have been obtained on patients treated with IFD and TLIF more than patients treated with stand-alone or double-level IFD. The combination of IFD and TLIF offers a better substrate for the fusion given by the interbody cage associated with the global reduction of the range of motion of the spinal motor unit similar to that obtained with pedicle screws. The minor surgical invasiveness and the minor muscular trauma might have influenced the outcome (Oswestry and VAS) of the patients treated with IFD and TLIF.

Conclusions On the basis of our experience, we can consider the IFD as valid substitutes of pedicle screws and rods, only if:

- 1. They are associated to an interbody TLIF cage and are not used stand-alone.
- 2. The surgical indications for the placement of the device are well identified and include only low-grade spondylolisthesis and not spondylolisthesis of a grade superior to the first.

They might also be a suitable solution for recurrent lumbar disk herniation.

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12 New Techniques and MIS: The Interfacet Fixation with Facet Wedge Device

René Hartensuer and Maarten Spruit

12.1 History of Facet Fixation

Where do we come from?

Some may ask why facet fixation is presented in a book of new techniques and MIS. Indeed, as early as 1944 King published a technique to remove the facet cartilage as much as possible and combined it with a trans-facet screw fixation [\[1](#page-166-0)].

In 1949, McBride described the options for dorsal fusion involving the resection of the facet joint surfaces and the insertion of bone blocks [\[2](#page-166-0)].

Although this technique failed to catch on, it clearly gives us an impression that the facet joints are an essential factor in the stability of the dorsal spine.

Back in 1959 Boucher described a modification to the King's technique. He used longer screws. The screws have been directed toward the pedicle. The use of additional bone graft resulted in lower rate of pseudarthrosis [[3\]](#page-166-0).

On the basis of this description, implants (e.g., trans-facet pedicle screw) have been developed which, like the procedure described by Boucher, are designed to lock the facet joints. These offer the prospect of minimally invasive dorsal spondylodesis and, particularly in extension and flexion, offer kinematic results that are comparable with pedicle screws in respect of primary stability [\[4](#page-166-0)].

One other option for dorsal instrumentation, particularly for supporting anterior fusion implants, involves translaminar screw fixation [\[5](#page-166-0)]. This technique was successively perfected by Magerl and colleagues and produces dorsal stabilization by locking the facet joints with a translaminar screw [\[6](#page-166-0)]. This technique was presented

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to be an improvement of a technique of trans-articular screw fixation first described by King [\[1](#page-166-0)] and modified by Boucher [\[3](#page-166-0)].

Yet another option for achieving primary stability by locking the facet joints is to use a facet interference screw. In biomechanical investigations, this has shown characteristics similar to those of translaminar screw fixation in terms of primary stability [\[7](#page-166-0)].

Most of these long known techniques can prove adequate biomechanical stability and some respectable results in clinical trials. However, the state of the art of instrumentation today remains to be the use of pedicle screws.

Despite the development of new minimally invasive techniques for pedicle screw instrumentation, there is still a need for corresponding approach-related morbidity if posterior fusion need to be achieved. This has not been possible via MIS to date with percutaneous pedicle screw systems.

The Facet Wedge is a new development designed to achieve both adequate primary stability and permanent fusion through locking of the facet joints after resection of the joint cartilage in combination with angular stable screw fixation of the anterior and inferior articular process.

It was a refined technique and is based on the described knowledge of the importance of the facet joints for stability and spinal fusion. By rigidly fixing the facet joints, a primary stability is achieved [[8\]](#page-166-0). This was investigated in comparison to pedicle screw fixation and will be described later in this chapter. The design of these tiny titanium implants intents to allow bony fusion.

12.2 Clinical Applications and Results of Traditional Facet Fusion and Fixation

Some efforts have been achieved in the last decades to improve the success rate in spinal fusion. After trans-pedicular schanz' screw placement was introduced by Magerl, short segmental reduction and repositioning were possible [\[9](#page-166-0)]. However, Magerl combined this technique with translaminar facet fixation at the level to be fused.

After the use of a spinal fixateur was refined to be internal, which was presented by Dick et al. in 1985, the segmental stability could be further improved, so that no additional fixation was advised by the authors [\[10](#page-166-0)]. Both Magerl and Dick developed this technique by treating instable fractures to the spine.

In 1988 Steffee and Sitkowski combined posterior interbody fusion techniques with posterior trans-pedicular instrumentation. Since then, pedicle screw fixation also in degenerative situations has been widely used to potentially improve fusion rates. Actually 75% of patients were satisfied after surgery and fusion rates in single level are reviewed to be around 90% using interbody fusion techniques Interestingly, no specific technique showed to be superior [\[11](#page-166-0)].

Pedicle screw systems have been constantly refined by industry. Optimized operation techniques, reposition tools, different materials and screw designs, and other features led to improved handling but also to improved costs.

This leads to the question, if some of the described "old" techniques can effectively stabilize and degenerated segment sufficient for fusion.

Aeply et al. described a consistently good result over time using translaminar fixation of the facet joint. Seventy-four percent of their patients who were operated between 1887 and 2004 for various degenerative conditions of the lumbar spine reported good outcome on average 10 years after surgery [\[12](#page-166-0)]. Some authors presented data from which they concluded that translaminar facet screws stand-alone [\[13](#page-166-0)] and in circumferential fusion to be justified [[14\]](#page-166-0).

So far, translaminar screw fixation is considered to be a technically simple, costeffective, and reliable method to stabilize a lumbar or lumbosacral segment. It is further considered to be used in low-grade degenerative listhesis and to augment an anterior lumbar interbody fusion. Fusion rates are reported to be high and complication rates are reported to be low [[15\]](#page-166-0).

Even there is a minimized hardware usage in these techniques, the reported techniques remained to traditional open surgery. Some attempts to overcome this fact resulted in developing a guide for percutaneous placement [\[16](#page-167-0)] and a technique of a fluoroscopy assisted percutaneous method to insert translaminar facet screws [[17\]](#page-167-0). Both techniques have been described to be an adjunct to an interbody fusion. This fact seems to be important, so no posterior fusion can be achieved by using these minimally invasive techniques. This seems to be in analogy to percutaneous pedicle screw instrumentation.

This leads to the development of a new implant to combine some of the above mentioned properties of facet fixation and fusion techniques. The new technique should provide adequate stability stand-alone and in addition to interbody fusion techniques. It should be used in traditional open surgery as well as in minimally invasive fashion to lead to solid fusion resulting in true spondylodesis.

12.3 Development of a Modern Minimal Invasive Device

Facet fusion aims to fuse the only true synovial joints of the lumbar vertebral spinal motion segment. Instead of straight forward fixation with a screw through the joint using a King [\[18](#page-167-0)], Boucher [\[3](#page-166-0)], and Magerl [[19\]](#page-167-0) technique, the ultimate aim of fusing a synovial joint should be removal of cartilage, preparing rough bone surfaces and fixation of the joint. The Facet Wedge spinal system was developed following these principles of fusion. Basic surgical steps to obtain fusion are approach to the joint, opening the capsule, entering the joint, removal of cartilage, and creating a rough bleeding bone surface and fixation in an as stable way as possible.

Despite the fact that facet joints are designed to constrain motion, facet fixation will eliminate motion as much as possible to obtain fusion. A prominent feature of a vertebral motion segment is the intervertebral disc as well. Many fusion options aim to achieve intervertebral fusion following the same steps and principles as displayed for synovial joint fusion. As removal of (part of) the disk causes an intervertebral defect, the application of autologous tricortical bone graft, allograft such as femoral rings, and in particular cages [\[20](#page-167-0)] of various materials filled with bone or

bone substitute is necessary to obtain intervertebral fusion. Pedicle screw fixation aiming at 360° stabilization of the vertebral segment accomplishes maximum stability and high fusion rates as a result.

Facet fixation and fusion are primarily a way to optimize 360° fusion constructs [\[14](#page-166-0), [21\]](#page-167-0). The primary target of Facet Wedge fusion is to create additional stability of a fusion construct to fix a vertebral motion segment using bilateral facet joint fusion devices. As the anatomy and biomechanics of the vertebral motion segment are unique, the introduction of a titanium wedge into the facet joint space with a locking plate attached to the wedge is considered the next step in facet joint fusion. A rough surface with sharp teeth will enhance fixation of the device and improve primary stability. The teeth are arranged as rails which will stop the translational motion of the implant in the facet joint space. Further fixation is achieved with two 30° diverging screws that are inserted and locked in the plate. Holes in the wedge allow for bony bridging between the superior and inferior articulating process surfaces (Fig. [12.1\)](#page-152-0).

Development of a new device requires novel ideas to approach the facet joint and apply the suggested principles of fusion. A minimal invasive access is preferred as minimal tissue damage will improve outcome and speed up recovery [[22,](#page-167-0) [23\]](#page-167-0). This applies to different types of minimal invasive fusion techniques [[24\]](#page-167-0).

The primary step therefore might be a K-wire-guided system to access, prepare, and fuse the facet joint with the Facet Wedge system. However, considering the anatomy and the orientation of the lumbar facet joints, a true minimal invasive approach is difficult. In many cadaveric tests, it was found out that percutaneous fluoroscopically guided K-wire-guided placement of this particular device was not reliable on a routine basis. This is probably due to the angle of the facet joint in the transverse plane (Fig. [12.2\)](#page-153-0) and to the difficulty to have a perfect fluoroscopic image of the degenerative facet joint. Direct visualization of the facet joint is eminent for perfect Facet Wedge positioning. The Wiltse approach used in a less invasive way is most logical to find the facet joint by blunt dilator dissection. Minimal invasive retractors can be used to have direct visualization facilitated by microscope or loupe glasses. Once direct vision is obtained, a K-wire can be introduced in the facet joint.

An important tool is the so-called facet joint finder that is introduced over the K-wire. Once the finder is in the joint, the joint capsule can be identified and opened. If necessary osteophytes can be removed to create a flush surface of the facet joint that will allow for proper seating of the Facet Wedge and plate. The K-wire may be reoriented in the joint and then serve as a guide for the instruments to remove cartilage and prepare the joint for the fusion device (Fig. [12.3\)](#page-153-0). In bilateral application of Facet Wedge, it makes sense to approach the contralateral side first before introducing the device. Unilateral wedge introduction did cause considerable difficulty to open the contralateral side in cadaveric testing. Therefore, it is recommended to always prepare both sides before implant introduction.

Once the implant is introduced over the K-wire, the screw fixation will turn it into a stable construct (Fig. [12.4a–c\)](#page-154-0). Further stability will be achieved with bone fusion through the holes in the wedge, which can be visualized on CT (Fig. [12.5](#page-155-0)).

Implant

Kirschner wire hole Enable guided insertion over Kirschner wire

Rails

Stop translational motion and generate contact between subchondral bone and implant

Fig. 12.1 Facet Wedge system features

12.4 Operation Technique

(Important steps—no complete instruction)

- 1. Positioning in prone position on a radiolucent table.
	- *Attention*: No direct reposition can be performed using the Facet Wedge
- 2. Mark the cranial (cr), the caudal (ca) border of the facet joint, and the midline (M). Also mark the midline offset (mo) to enter trajectory of the joint space (Fig. [12.6\)](#page-155-0).

instrument for facet joint preparation

- 3. Incision (ca. 2 cm) and paraspinal approach to the joint using a retractor. After remaining soft tissue is removed, the facet joint capsule can be visualized (Fig. [12.7\)](#page-156-0).
- 4. The capsule needs to be opened to visualize the joint entry. If necessary, osteophytes have to be removed. After the joint is opened, a tool so-called "Facet Opener" should be inserted (Fig. 12.3). This tool is cannulated and allows to place the k-wire (2.0 mm) in the correct position (Fig. [12.8](#page-156-0)).
- 5. A cannulated rasp is then used to remove the superficial cartilaginous layers of the joint surface to expose bleeding bone. The rasp also works as a trial. There are three sizes of rasps/trials (S, M, L) corresponding to the implant size (Fig. [12.9\)](#page-157-0).

Fig. 12.2 Facet joint

in transverse plane

Fig. 12.4 Facet finder (**a**), facet rasp (**b**), Facet Wedge in situ with two screws (**c**)

Fig. 12.6 X-ray planning of the correct incision and approach

- 6. After cartilage removal and insertion of an optimal sized trial/rasp, a reamer is pushed over the inserted trial/rasp to remove bone on the facet joint entry to create flat surface for optimal implant seating (Fig. [12.10](#page-157-0)). This procedure is to be performed on both sides.
- 7. The tools except the k-wire are then removed, and the correct sized Facet Wedge which is filled with bone (or bone substitute) can be inserted using the k-wire (Fig. [12.11\)](#page-158-0).

fusion

Fig. 12.5 CT of Facet Wedge system

demonstrating bony facet

Fig. 12.7 Visualization of the joint capsule using a retractor

Fig. 12.8 A k-wire is placed in the joint space

Fig. 12.10 After the cartilage is removed, a reamer is used to flatten the surface of the facet joint

Fig. 12.9 The joint is prepared using a cannulated rasp. The rasp also works as a probe. According to the used rasp (S, M or L), the correct implant size can be chosen

Fig. 12.11 The Facet Wedge is filled with bone or bone substitute and is inserted in the prepared joint space

8. The inserting tool also works as a screw guide. Before awling or screw insertion, the K-Wire needs be removed. Screw placement into both parts of the facet is then prepared by an awl. After awling in one part of the facet, a self-locking screw is inserted (Fig. [12.12](#page-159-0)). Then the screw guide can be turned, and the second screw into the other part of the facet can be prepared and placed (Fig. [12.13\)](#page-160-0). Both screws are secured by tightening the screw to the recommended 1.2 Nm torque.

12.5 Biomechanical Evaluation of the Facet Wedge

The only true articulation in the lumbar and lumbosacral spine is the facet joint. Therefore, it is consequent to fix this joint directly for segmental stabilization. This consideration is not new and its history is described above. Traditional translaminar facet screws are more comparable to a threaded bolt than to a "real" screw without

Fig. 12.12 The inserter also works as a drill guide and guides the selflocking screws

any compressing across the facet joint. Several biomechanical studies found that pedicle screw fixation and facet fixation showed similar biomechanical characteristics with some limitations [[25,](#page-167-0) [26\]](#page-167-0).

In order to evaluate the kinematic properties of primary stability of the Facet Wedge, a biomechanical study was performed using a robotic based spine tester [\[8](#page-166-0)] (Fig. [12.14](#page-161-0)).

In the evaluation study, the Facet Wedge (FW), the translaminar screw fixation (TLS), and the polyaxial pedicle screw system (PS) all produced a significant reduction in the ROM in all directions of motion of an intact motion segment.

Ultimately, all three posterior systems proved to be capable of effectively stabilizing an intact motion segment, which is consistent with other studies [\[25, 26\]](#page-167-0).

In comparison of various posterior systems in order to stabilize an intact motion segment, the translaminar screw fixation was equivalent to trans-pedicular screw fixation in respect of primary stability for extension and flexion which was in line with the existing published findings for the translaminar screw [[25\]](#page-167-0). A similar behavior is described for screw fixation of the facet by the Boucher technique [\[27](#page-167-0)], although

this was not investigated in the evaluation study. For extension and flexion, the Facet Wedge showed a trend—albeit without reaching statistical significance—toward superiority in ROM compared to pedicle screw instrumentation and translaminar screw fixation.

In the intact, idealized natural specimen, all implants (FW, PS, TLS) showed equivalent stabilities in respect of axial rotation. In lateral bending, translaminar screw fixation was significantly inferior to the pedicle screw system. This weakness of the facet screw in lateral bending has also been described by other study groups [[4\]](#page-166-0). Here, the Facet Wedge proved to be equivalent to pedicle screw instrumentation in terms of primary stability also in lateral bending in the intact motion segment.

The comparable stiffness in the elastic zone for all directions of motion, with a tendency toward inferiority for the facet screw in lateral bending and axial rotation, underlines the kinematic properties for the pedicle and facet screws [\[4](#page-166-0), [25](#page-167-0), [27\]](#page-167-0). Here, too, the Facet Wedge tended to be superior to the facet screw.

So, from a biomechanical point of view, the Facet Wedge seems to be a real alternative to stabilize an intact motion segment concerning primary stability.

Fig. 12.14 Experimental setup and X-ray from the evaluating study of the Facet Wedge

Consequently, the potential of this new technique was further evaluated concerning its kinematic properties in combination with an anterior interbody fusion device. For that reason, a lateral inserted inter somatic cage was used.

The bilateral instrumentation with the Facet Wedge in combination with the cage showed kinematic results comparable with those for the pedicle screw instrumentation also for axial rotation and lateral bending.

Fig. 12.15 Hybrid construct with contralateral Facet Wedge in MISS TLIF (Case provided by Prof. Dr. Frank Kandziora, BG Hospital, Frankfurt, Germany)

Even though an anterior interbody cage was used, the evaluation study tried to simulate a kind of TLIF situation using Facet Wedge. For that reason, the facet joint on one side was resected and a pedicle screw instrumentation was performed. On the contralateral side, Facet Wedge was used. By evaluating this condition, a tendency toward a deterioration in the ROM for extension, flexion, and lateral bending was observed after resection of a joint facet with pedicle screw instrumentation and a contralateral Facet Wedge. The increase in the ROM for axial rotation in comparison to bilateral Facet Wedge instrumentation was statistically significant. On the other hand, the results for axial rotation also were well below those for the intact state. The extent to which the results for unilateral pedicle screw instrumentation with a contralateral Facet Wedge can be incorporated in the known procedures for stabilization after a trans-foraminal approach [\[28](#page-167-0)] will need to be answered in future studies, although its use here seems reasonable (Fig. 12.15).

The results of the evaluation study confirm a high primary stability for the Facet Wedge, whether in a traditional combination or as a stand-alone solution.

12.6 Indications and Clinical Results

The objective of the Facet Wedge system is to fix and fuse the facet joint. As explained before in the previous parts of this chapter, this can create a very stable primary stability of the vertebral motion segment. The mechanical testing showed no significant differences between translaminar screws, pedicle screws, and Facet Wedge for ROM and stiffness in all motion directions of flexion, extension, axial rotation, and side bending. This would imply that Facet Wedge could be used as a stand-alone posterior fusion device instead of pedicle screws and rods.

For sure the success of fusion will depend on the overall stiffness of the degenerative lumbar vertebral motion segment that should be fused. The less degenerative the disk, the more residual motion can be expected and the more stability should be used to have successful fusion. In other words, when one considers Facet Wedge for stand-alone fusion, the overall degenerative state of the vertebral motion segment should be evaluated.

One more aspect to consider is the need to do decompression for spinal stenosis. Obviously the decompression may include removal of part of the hypertrophic facet such as the processus articularis inferior and superior to open up the lateral recess. Such a decompression may limit the safe use of Facet Wedge. The contact surface of bone to the wedge will be reduced and the screw fixation will be inadequate.

The number of levels to be fused with Facet Wedge stand-alone should be limited. The mechanical testing has been limited to single-level constructs. From a mechanical point of view, the stiffness of multilevel constructs with Facet Wedge stand-alone will be reduced, and success of fusion therefore is at risk.

The success of facet fusion has been underlined in particular for supplementary fixation to intervertebral fusion such as anterior- and lateral interbody fusion. These construct configurations have been tested, and the potential for motion reduction with Facet Wedge is substantial.

For anterior lumbar interbody fusion (ALIF) of L5–S1, a cage and plate construct have been reported as safe and effective [[29,](#page-167-0) [30](#page-167-0)]. However, other studies document less favorable results of stand-alone ALIF with PEEK cages and plate fixation [\[31](#page-167-0)]. Not all stand-alone ALIF cages can be effectively used at other levels than L5–S1. The vascular anatomy, especially at L4–5 and in cases with transitional vertebrae, may limit exposure and the safe application of a plate. Turning the patient prone after cage introduction for mini-open facet fixation resents a safe alternative for true 360° fusion.

Many lateral lumbar fusion approaches (for instance, extreme lateral interbody fusion (XLIF) and direct lateral interbody fusion (DLIF)) include posterior instrumentation to increase stability of this kind of constructs. Facet fusion can provide this additional stability. Hybrid constructs have been reported recently [[32, 33\]](#page-167-0), but the Facet Wedge system presents an alternative way to fuse the facet and provide the supplementary stability required for lateral lumbar fusion techniques to be successful.

Hybrid constructs using Facet Wedge may also be an option for MISS Transforaminal lumbar interbody fusion (TLIF). On one side pedicle screws are used, and the facet is removed to introduce the cage. Instead of two pedicle screws, a Facet Wedge may be used to fuse the contralateral facet joint that remained intact (Fig. [12.15](#page-162-0)).

Failure of stand-alone ALIF (Fig. [12.16](#page-164-0)) may also require additional posterior instrumentation and fusion.

Fig. 12.16 Sagittal CT image of nonunion after stand-alone ALIF L4–5

Many alternative instrumentation options are available. Facet Wedge fixation is clearly indicated for supplemental facet fusion after nonunion of ALIF. The wedge technique will aim at fixation and fusion (Fig. [12.17](#page-165-0)), which will avoid the need to add posterolateral bone graft.

Indications for Facet Wedge system:

- Stand-alone mono-segmental in situ facet fusion with (limited) or without decompression
- Facet arthritis: fixation and fusion of the facet joint
- Supplementary fixation after anterior cage (ALIF, DLIF, XLIF)
- Supplementary fixation after failure of stand-alone anterior cage
- Supplementary contralateral facet fixation after MISS TLIF

Contraindications:

- Damaged facet joints after decompression
- Unilateral stand-alone application
- Instability of posterior elements
- Spondylolisthesis
- Osteoporosis
- Infection
- Tumor

Fig. 12.17 Coronal CT image 6 months after Facet Wedge L4–5 showing facet fusion

12.6.1 Clinical Results

Limited data are available of clinical results of fusion with the Facet Wedge system. Satisfactory results have been communicated for supplemental facet fixation after failure of anterior cages such as ALIF and for contralateral facet fusion in MISS TLIF.

Mehren published an abstract recently [[34\]](#page-167-0). Yet no studies have been reported in literature. Currently a multicenter study is ongoing as part of a postmarked evaluation. The study will include 25 cases with 2-year follow-up. Results are not available yet.

12.7 Tips and Tricks

As described before in this chapter, the Facet Wedge system is a K-wire-guided system. Appropriate positioning of the K-wire is eminent for safe preparation of the joint and Facet Wedge introduction. Malpositioning or migration of the K-wire may damage neural structures, soft tissue, and even large blood vessels.

Using the facet finder first will lead the way into the facet joint and guide safe K-wire insertion.

When in doubt, use fluoroscopy to find out where the K-wire exactly is. A miniopen approach is safe and speeds up the procedure time.

Finally, before introduction of the wedge in bilateral application, first prepare the contralateral side.

12.8 Perspective

The Facet Wedge offers an innovative approach for mechanical locking of the facet joint combined with angular stable anchorage in both the anterior articular process and the inferior articular process.

Accordingly, it appears to combine the principles of mechanical friction-based locking and screw fixation of the facet block. The hope is that, based on the morphology of the implant and the fact that the joint cartilage is removed during insertion, genuine spondylodesis can be achieved by bone fusion of the facet joints.

If the hoped for fusion behavior is confirmed, the Facet Wedge would be the first dorsal fusion implant to be inserted by a minimally invasive (mini-open) procedure.

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13 Expandable Cages and Minimal Invasive Approaches to the Thoracolumbar Spine for Anterior Column Reconstruction

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13.1 Introduction

We consider spine stability as its aptitude to counterbalance and react to physiological loads moving its *functional spinal units* inside what we consider the physiological range of movements. Bone, ligaments, muscles, and global spine shape all contribute to the vertebral column stability. It is commonly accepted that the socalled anterior column, including disk and vertebral body, bears most of the mechanical charges during every day activities, so its integrity is essential to preserve spine function. Lack of anterior support is commonly related to spine injuries as a consequence of conservative treatment of underestimated lesions or following inadequate posterior fixation. Moreover, primary tumors and spinal metastases affect the vertebral body in 90% of the cases frequently causing impending fractures or pathologic fractures as a result of bone substitution by newly formed tissue. On the other hand, tumor resection generally leaves the anterior column unsupported requiring a reconstructive step during the same surgery. Spine infections commonly start involving the intervertebral disk, but, if not recognized and treated in the early stage, they will also compromise the adjacent vertebral bodies causing bone destruction and spine instability. Finally, in the last decades, severe osteoporosis has become a common cause of anterior column incompetence following fragility fractures that are difficult to treat because most of posterior and anterior fixation systems are not designed for osteoporotic bone. In conclusion, anterior column restoration is a common issue in spine surgery and brings different questions concerning both surgical approach and type of anterior support to select, making operations challenging and difficult to standardize.

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13.2 Historical Overview

Anterior approach to the thoracolumbar spine can be prepared through the thoracic cavity, through the abdomen or both depending on the level to treat and its extension. Originally, surgical approaches were directly derived from the general surgeons' practice being nonspecifically focused on the vertebral column. These approaches were frequently prepared by an access surgeon and resulted in unnecessarily invasive procedures burdened by perioperative complications and long postoperative hospitalizations. In the last decade, minimal invasive approaches to the thoracic and lumbar spine were developed together with new instrumentation appositely renovated, to help the surgeon avoiding unnecessary anatomical injuries during surgery. As a result, classic thoracotomy turned into video-assisted mini-thoracotomy and, in selected cases, into thoracoscopy. Transperitoneal approaches to the lumbar spine were with time abandoned and substituted by retroperitoneal approaches that progressively became minimal invasive, thanks to special designed self-retaining retractors [\[1](#page-180-0)]. Restoration of the anterior support was initially achieved by methyl methacrylate or bone grafting that still remains the gold standard material in order to achieve fusion [\[2\]](#page-180-0). Unfortunately, bone graft alone frequently showed inadequate primary stability and support; therefore metal hardware, such as cancellous bone screws, had to be added to prevent graft subsidence while waiting for a solid fusion to occur. Than titanium meshes to be filled with bone graft became available on the market satisfying both the need for fusion and primary stability, as the metal spikes at each edge of the cage could be impacted against the vertebral end plates. Those cages were available in different diameters, and they could be cut in the desirable length straight during surgery. Afterward, modular *Polyether-ether-ketone* (PEEK) and carbon fiber vertebral body substitutes became available. The reason for adopting these new materials was related to their translucency (useful in tumor surgery) and in order to accelerate fusion as their elasticity module was closer to that of bone [\[3](#page-181-0)]. Nevertheless, concerning this last feature, their efficacy has never been proven. Titanium cages, outfitted with an expansion mechanism able to lengthen them to the desired size once inserted in the operatory filed, appeared on the market nearly two decades ago but were initially disregarded by most surgeons because of their complexity. As primary stability also depends on the possibility of adding preloading forces while placing the anterior support to fill the vertebral gap, new expandable cages fulfilled this need and, compared to the first prototypes, can now be inserted easily in the gap before activating the expansion mechanism. Finally, the use of angulated or orientable end plates allows the surgeon to follow the natural spine alignment in the different tracts of the thoracolumbar spine.

13.3 Anatomical and Biomechanical Consideration on Thoracolumbar Spine

The thoracolumbar spine consists of 17 vertebras that progressively change in shape as we move from T1 down to L5. Vertebral body and disks gradually increase their dimensions as the load they have to bear increases. Facet joint orientation turns from the

sagittal plane, in the cranial tract, to the coronal plane as we get close to the sacrum, as the range of movements that every functional spinal unit must accomplish changes. This circumstance, together with the fact that most of the thoracic vertebras are connected to the rib cage through ligaments and joint capsules, provides a wide range of movement in the lumbar tract, while the thoracic spine remains relatively stiff. This link to the rib cage, also known as "fourth column" [\[4](#page-181-0), [5\]](#page-181-0), provides stability to the thoracic spine that is more resistant to share forces and less prone to get kyphotic under mechanical stress. Conversely, the thoracolumbar junction connects the stiff part to the most mobile part of the thoracolumbar spine concentrating share forces during trunk flexionextension and rotation movements. As the gravity line normally falls anterior to the thoracolumbar junction, it is commonly accepted that the anterior part of the vertebral column is subject to the highest loads due to vertebral body weight, postural changes during normal activities, and preloading effects due to ligaments traction and muscles tone. Furthermore, the compression forces applied against vertebral bodies and disks increase as we move up from L5 to L1 because the distance between the gravity line and the vertebral body also increases [\[6\]](#page-181-0). This fact, and the presence of solid iliolumbar ligaments connecting L4 and, more strongly, L5 to the pelvis, explains the reason because post-traumatic kyphosis is frequently seen in the thoracolumbar junction while is rare in lower lumbar spine as some authors highlighted in clinical studies [\[7\]](#page-181-0). On the other hand, the posterior tension band, which includes posterior vertebral arch, ligaments, and muscles, acts to counterbalance these compression forces from posterior, and it can effectively work only if the anterior column (vertebral body and disks) is intact. Whenever the anterior support from the vertebral body and/or disks fails, the tension band becomes unable to support axial loads and the spine becomes unstable [\[8\]](#page-181-0). Recent studies highlighted the importance of respecting the physiological sagittal curves of the spine performing deformity surgery and degenerative elective surgery in general. Although there is no total consensus concerning sagittal parameter measurement and their relative importance in planning surgery is quite clear that a spine fusion may lead to further spine imbalance and junctional kyphosis if sagittal alignment is neglected. As there is no reason to believe these rules are not valid in post-traumatic deformity surgery, than deep attention must be paid in planning anterior column reconstruction (ACR) surgery for anterior column incompetence whenever a fixed or mobile deformity is associated. More in general, all the biomechanical aspects highlighted here above must be taken into account planning surgery as a mechanical failure after an ACR may cause the anterior support dislocation into the thoracic or abdominal cavities and bring severe complication like vascular injuries. Such complications are lifethreatening and always require major revision surgery that is always challenging and sometimes needs to be carried out in an emergency situation.

13.4 Surgical Approaches

In the last 10 years, minimal invasive or less invasive approaches to the anterior aspect of the thoracolumbar spine have been emphasized in order to minimize access related complication and pain, reducing patient hospitalization. Although everything that is beneficial to the patient is generally well accepted, we should remember that this new

surgery requires specifically designed surgical instruments, some of which are disposable, that generally increases the cost for the hospitals. Nevertheless, those higher costs are counterbalanced by a shorter hospital stay, so, at the present time, the trend toward minimal invasive approaches seems reasonable. In our institution, a recent review of 22 cases comparing ten minimal invasive lumbar approaches to 12 standard retroperitoneal approaches showed in the former procedures a reduced postoperative pain (3.2 points less at the VAS scale) and a shorter hospital stay (2.8 days less on the average). Obviously, whenever the primary target differs from anterior support restoration, like in primary tumors resection surgery, then the surgical approach must be tailored to the aim of surgery and the type of approach comes to be less important.

13.4.1 Thoracic Spine

T1 is generally reached via left retropharyngeal approach in case of favorable anatomy. The left side is preferred to avoid injuries to the recurrent laryngeal nerve. Sternal manubrium splitting may be necessary in some cases [\[9\]](#page-181-0). The T2–T5 tract is commonly considered the hardest to approach both by standard lateral thoracotomy and both adopting a sternal splitting. Whenever a posterior surgery is planned, then anterior column reconstruction should be planned from posterior as well [[10](#page-181-0)]. The lower thoracic spine can be easily reached by lateral standard thoracotomy, minithoracotomy, or thoracoscopy. The mid-part is easier to access from the right side to avoid the aorta. Surgical incision should be performed straight above the level to treat using a radiologic landmark, especially if a minimal invasive approach is planned. Retropleural approach is theoretically feasible in young patient but requires a moderate extension of the surgical incision posteriorly, and, anyway, the pleura is frequently violated despite the surgeon effort [\[11\]](#page-181-0). T12 is generally approached from the left side, as the diaphragm needs to be pushed down in the abdominal cavity and these maneuvers result more difficult and may damage the liver on the counter lateral side. Depending on the local anatomy, a minimal splitting of the diaphragm at the costovertebral angle might be necessary if addictive L1–T11 plating has to be performed. Surgeons currently approaching the thoracic spine via thoracoscopy report less postoperative pain and shorter hospital stay in their patient compared to those undergoing standard thoracotomy [\[12](#page-181-0)]. On the other hand this procedure requires expressly designed instrumentation and a quite long learning curve.

13.4.2 Lumbar Spine

L1 can be easily approached via left mini-thoracotomy in the same fashion as for T12. The posterior insertion of the diaphragm needs to be detached to remove the vertebral body and insert the support, but this is not a major issue and it is generally not burdened by postoperative complications. Most authors recommend reinserting the muscle before the final closure, but this is not always feasible once the cage or the plate is set in place. L2–L4 tract can be approached from the left via a retroperitoneal transpsoas approach [\[13](#page-181-0)]. A 7 cm skin incision is made just above the level

Fig. 13.1 Twenty-seven-year-old female, L3 burst fracture 4 months before, neurologically intact. Anterior column mechanical incompetence is seen in lateral view standing X-ray (**a**) and CT scan (**b**). Reconstruction is made by expandable cage and plating to neutralize share forces due to trunk rotational movements (**c** and **d**)

Fig. 13.2 Same case as in Fig. 13.1. Intraoperative X-ray imaging (**a**) and clinical view (**b**) of the left retroperitoneal minimal invasive transpsoas approach. A 7 cm incision allows exposing L3 vertebral body and half of the adjacent vertebra to perform an L2–L4 anterior fusion. Abdominal muscles are splitted along their fibres to reduce the risk for late laparocele

to treat. Abdominal muscle layers are progressively split along their fiber course until the retroperitoneal space is reached. The abdominal content in its peritoneal sac is moved in front by blunt dissection paying attention not to damage the ureter along its course. Psoas splitting is also done along its fibers by mean of an appositely designed retractor (Figs. 13.1 and 13.2). Neuromonitoring is strongly suggested during this step to avoid injuries to the lumbar plexus. Compared to the standard approach, the transpsoas one gives major advantages in terms of bleeding, postoperative pain control, and hospital stay, also decreasing the risk of hyatrogenic laparocele. The minimal invasive approach to L5 comes directly from the disk replacement surgery [\[14](#page-181-0)]. Skin incision can be transverse below the umbilicus or vertical 4–5 cm left from the midline. The rectus abdominis and its fascia are opened along the muscle fibers a few centimeters from the midline to reach the retroperitoneal space. The abdominal content is gradually dislocated from the left to the right side until the L5–S1 space is reached. Again the ureter needs to be identified and protected during the surgical procedure. In order to reach the disk space above, the major vessels need to be mobilized after ligating the lumbar ascendant vein.

13.5 Preoperative Planning

In recent trauma, MRI can give information on the spinal canal encroachment and spinal cord and, most important, on the posterior longitudinal ligament complex (PLC) integrity [[15](#page-181-0)]. Other basic information required are anterior gap longitudinal extension (to be measured on CT scan 2D reconstruction images both along the posterior and anterior wall lines), local kyphosis and scoliosis if present, and superior and inferior adjacent end plates size. From the abovementioned data depends the implant size although these data are not enough to move in the operatory room. Surgical strategy also relies on multiple further aspects that strongly influence type of surgery, approach, and implant choice. The most important factors are presence of fixed or flexible deformity and previous surgery, with or without posterior instrumentation, and the previously mentioned PLC integrity. Anterior column reconstruction (ACR) alone is feasible in case of no deformity or corrigible deformity; therefore preoperative planning, in ancient trauma, must include flexion-extension and lateral bending X-rays. If incorrigible kyphosis depends on anterior ligament shortening or anterior bone bridging (new callus formation), then ACR only can be still considered, but surgical strategy will include anterior ligament release or bone bridging excision. In these cases, the anterior aspect of the vertebral column needs to be exposed at the chosen level. This can be done by moving in front the major vessels by blunt dissection after ligating and cutting the segmental arteries and veins. Posterior fusion (spontaneous or surgical, with or without instrumentation) and fixed deformity together are a contraindication to ACR alone, and posterior osteotomy (and/or hardware revision) should be considered instead. ACR will follow in case an anterior gap is left after posterior correction (Fig. [13.3](#page-174-0)). As the cage body is generally smaller compared to its end plates, then a complete corpectomy is generally unnecessary, and the surgeon can leave a bone shell in the front and in the contralateral side to protect the major vascular structures from unwanted injuries. On the other hand, disk removal and vertebral end plate preparation should be impeccable. The surgeono must take care not to break the bone surface during this step to ensure the largest contact between bone and cage end plates and favoring fusion. Expandable cages are very helpful in correcting local kyphosis via anterior approach nevertheless, the risk of cage subsidence through the vertebral end plates during this maneuver is high, especially if the patient bone stoke is not satisfactory.

Accordingly, preoperative dual X-ray absorptiometry scan is strongly suggested in adult patients before a kyphosis correction by ACR, and this procedure should be considered in any case hazardous in female older than 50 and male older than 60. In such cases, vertebral body augmentation by cement ingjection can be achieved during the anterior approach, before cage expansion, reducing the risk for vertebral endplates failure. Relevance of PLC in surgical planning will be discussed later (Sect. [13.6.5\)](#page-177-0).

13.6 Choosing the Right Instrumentation

13.6.1 Expandable Cages

Cage dimension is defined during the preoperative workup but must be confirmed by direct measurement of the anterior gap in the operatory room, and then the cage body is filled by bone graft ore bone substitute. Cage end plates size should be as close as possible to that of the adjacent vertebra's to provide the largest contact surface and leave enough room for additive bone grafting. As the epiphyseal ring is considered the strongest part of the end plate, a direct contact between the cage and this aspect of the vertebra is desirable. Recently, end plates in the shape of the XLIF cages (larger than the vertebral end plate on the coronal plane) have become available on the market and can be helpful in osteoporotic patient as they always provide a direct contact with epiphyseal rings at least at the lateral aspects of the vertebral body (Fig. [13.1\)](#page-172-0). Cage length, before its expansions, should be no more than 3–4 mm shorter than the gap to fill to have at least 1 cm of lengthening available. This is to achieve adequate primary stability through preloading after cage expansion. Angulated end plates are fixed on the cage before its insertion and its final angle (sum of the two end plates

Fig. 13.4 S1 fracture and L5 burst fracture in a 27-year-old male seen in sagittal (**a**) and coronal (**b**) CT reconstruction. Emergency treatment consisted of posterior decompression and lumboiliac fixation is seen on lateral (**c**) and AP (**d**) standard X-rays

Fig. 13.5 Same case as in Fig. 13.4. Standard X-rays showing anterior reconstruction by expandable cage with angulated end plates completed 4 months after trauma, once sacral fracture is healed (**a** and **b**). Iliac screws are substituted by sacral screws 3 months later (**c** and **d**)

angles) should perfectly match the adjacent end plates inclination, if no correction is required (Figs. 13.4 and 13.5). Conversely, if we intend to correct a kyphotic deformity, then we will consider the sagittal angle we want to obtain. Cage expansion is generally achieved by a mechanical apparatus that, for safety reasons, is self-limiting once a certain pressure against the end plates is achieved. Once the cage location is considered satisfactory, then it can be released from its holder, and the expansion mechanism is finally locked by a safety screw. Hydraulic expansion mechanism is also available and allows the surgeon to check pressure continuously through a manometer. On the other hand, these systems are more complicated and sometimes more expensive. No matter the type of mechanism one would choose the most important point is that, once opened, the cage must be very ease to engage with the proper cage holder, to re-collapse and relocate in a different position, as this eventuality is

Fig. 13.6 L4 solitary metastasis from renal cell carcinoma in a 50-year-old male seen on CT scan (**a** and **b**). Reconstruction after vertebrectomy by modular carbon fiber cage: cage connection to the posterior instrumentation is visible on standard X-rays (**c** and **d**)

common during surgery. Cages with variable angle end plates are also available and can be placed in the gap with loose end plates and then expanded to enable the best contact with the adjacent surfaces. The further step consists in locking the end plate angle and further lengthens the cage to obtain primary stability through preloading.

13.6.2 Titanium Mesh

As no internal mechanism is enclosed, they provide the largest space to receive bone graft thus improving chances for fusion. Furthermore, they are cheap as their cost is five to six times less compared to the previous type. On the other hand, they need to be cut manually during the surgical procedure; the contact surface is minor and occurs through residual spikes coming from the mesh pattern manual cut. Cage handling must be careful as those spikes may hurt o.r. staff hands during the surgical maneuvers. An internal titanium ring can generally be placed inside both extremities of the cage (at least in the largest diameter ones) to improve stiffness and contact surface. For this reason and because an effective preloading cannot be obtained during surgery, primary stability in stand-alone ACR is inadequate and not advisable. Vice versa, in case of ACR following posterior surgery not requiring sagittal correction, they remain a viable and economic option.

13.6.3 PEEK and Carbon Fiber Modular Cages

The abovementioned concerns about primary stability outfit modular cages as well. The cage is preassembled and filled with graft in OR just before being set in place. Contact surface is generally higher compared to titanium mesh but not primary stability, as there are no metal spikes at the edges. For this reason, in some cases, a connection set (in the fashion of artificial pedicles) between the cage and a posterior instrumentation is also provided to enhance primary stability. Nevertheless, their use is appreciated in tumor surgery because material translucency prevents from CT or MRI artifacts allowing a precocious diagnosis in case of local recurrence (Fig. 13.6). Their cost is generally between that of titanium mesh and expandable cage depending on the number of modules used. Finally, PEEK expandable cages recently became available in the market possibly combining the advantages of both technologies.

13.6.4 Others

Poly-methyl methacrylate (PMMA) is still used as a low-cost option in oncologic patient with poor prognosis, especially to fill small gaps during palliative surgery. Its primary stability is negligible, so it is always used in combination with an anterior or a posterior instrumentation. The use of allograft as a vertebral body substitute has been abandoned because of no primary stability and because it cannot guarantee a long-term support due to the so-called creeping substitution. Furthermore, it requires long modeling work in the operatory room in order to match the gap and it is expensive too.

13.6.5 Role of Posterior Instrumentation and Additive Anterior Plating

A sound ACR can effectively counterbalance compression forces in case of anterior gap, as long as the PLC is intact or artificially substituted by a posterior instrumentation. Conversely, an anterior cage alone will not provide effective stability against share forces during trunk rotation. Since the PLC is intact, an anterior plate located during the ACR surgery will supply this need avoiding unnecessary posterior fixation (Fig. 13.7). If PLC incompetence is present, as it may happen after posterior laminectomy or in case of persistent elongation following posttraumatic kyphosis, then an anterior stand-alone cage may act as a fulcrum when flexion-distraction forces are applied to the vertebral column. In those cases a posterior instrumentation should be associated to the anterior procedure. A posterior instrumentation with a

Fig. 13.7 Post-traumatic anterior column incompetence in PLC intact spine (**a**). ACR can adequately compensate flexion/compression forces (**b**). Lateral plate is nonetheless necessary to balance share forces due to trunk rotation (**c**)

Fig. 13.8 Post-traumatic anterior column incompetence in PLC injured spine (**a**). Stand-alone ACR cannot compensate neither flexion-distraction nor torsion forces (**b**), so posterior fixation is mandatory (**c**)

Fig. 13.9 Fifty-nine-year-old male. T12–L1 instability due to a former spondylodiscitis in a paraplegic patient is seen on sitting position X-rays (**a**) and CT scan (**b**). Reconstruction involves both the posterior column by pedicular screws instrumentation and the anterior one by two-level expandable cage (**c**)

cross-link device will also neutralize share forces occurring during trunk rotation movements (Figs. 13.8 and 13.9). Lateral plate mechanical prerequisite to neutralize share forces is angular stability screws locked to the plate. It is also desirable to have a couple screws at each extremity of the plate. Furthermore, bicortical screws will increase stability, as well as a plate compression mechanism if available.

13.7 ACR in Spine Deformities

So far, we considered ACR in a normally shaped spine; nevertheless, lack of anterior support can affect patients with congenital or acquired deformities such as degenerative or idiopathic scoliosis. The basic principle of obtaining the maximum contact between the cage end plates and the adjacent vertebrae remains unchanged but is more difficult to obtain because scoliosis is, in fact, a tridimensional deformity. The easiest way to address the problem is to consider separately vertebral end plates obliquity in the coronal plane and kyphotic deformity in the sagittal plane. So, in order to compensate at our best end plates inclination, we will use one of the cage oblique end plates to achieve the best contact in the coronal plane and the opposite to equalize the sagittal deformity if coexistent. Subsequently preparing our expandable cage in OR before placing it, we must remember that the two metal end plates should be rotated 90° one respect to the other, to obtain the right inclination in both coronal and sagittal plane. If any spine realignment is required, it has to be done from posterior before ACR because in these cases spine must be stabilized before cage expansion as it may cause an unpredictable result in an unstable scoliotic spine (Figs. 13.10 and [13.11\)](#page-180-0). As the maximum cage end plates obliquity available in the market at present is around 15°, deformity higher than 30° in the coronal plane will not allow a satisfactory cage contact with the adjacent vertebrae. In such cases, we can customize a titanium mesh directly in the operating room to fill the anterior gap. Additive lateral fixation during the ACR surgical time is desirable to counteract share forces that are generally high in a scoliotic spine. Here again, standard plates will not fit the scoliotic curves, so better use an old fashion system in which a lateral rod can be freely connected to the screws previously placed in the vertebral bodies.

Fig. 13.10 Anterior column incompetence due to a thyroid metastasis in T11 in a patient previously fused for an idiopathic scoliosis is seen on CT scan (**a** and **b**). Reconstruction is made by expandable cage using the inferior end plate obliquity to compensate the scoliotic curve in the coronal plane (**c** and **d**)

Fig. 13.11 Intraoperative view of the case in Fig. [13.9](#page-178-0). A standard retroperitoneal approach, at least three times wider than a minimal invasive one, is used for tumor debulking and ACR

Conclusions

New technologies made ACR procedures less invasive and more effective during the last 10 years. Nevertheless, like before, full understanding of spine biomechanics and sagittal balance rules as well as accurate preoperative workup is necessary to plan an effective ACR that should always be patient tailored. New technologies and minimal invasive approaches are welcome as far as they guarantee at least the same effectiveness as standard techniques. Complications, even though reduced in comparison with the older procedures, are still present and may involve spinal cord, major vessels, urinary tract, and every organ inside the thoracic and/or abdominal cavity possibly leading to death. Therefore, patients should be exhaustively informed about these potential complications, and surgery should be performed once its actual need is recognized. Anamnesis, diagnosis, previous surgery, patient bone stock, and many other factors are still mandatory choosing surgical approach and implant type.

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14 New Techniques and MIS: The Thoracoscopic Approach

Francesco Signorelli and Massimiliano Visocchi

14.1 Introduction

The video-assisted thoracic surgery (VATS) has gained growing popularity in the last two decades as an alternative to open thoracotomy for the treatment of several spinal conditions and now represents a keyhole in the field of "minimally invasive surgery" to the thoracic spine.

Since the early 1900s, a thoracoscopic approach was used as a diagnostic tool to evaluate pleural disease. The first report of a thoracoscopic approach was published by Jacobaeus in 1910 to diagnose and lyse the tuberculosis lung adhesion $[1-3]$. With the discovery of streptomycin in 1945 for tuberculosis treatment, there was a decreased in clinical application of thoracoscopy for such condition [[4\]](#page-189-0). In the late 1980s, the technology of endoscopic surgery has dramatically improved. Lewis in 1991 had repopularized the use of VATS for pulmonary disease treatment. In 1993, Mack published the first study of endoscopic approaches to spinal disorders, reporting ten patients with various thoracic spinal pathologies that were effectively operated on endoscopically [\[5](#page-189-0)].

14.2 Indications

VATS has been used extensively in spinal deformities such as scoliosis. The use of VATS in spine surgery included the treatment of thoracic prolapsed disk diseases [\[6](#page-189-0), [7\]](#page-189-0), vertebral osteomyelitis [\[8–11](#page-189-0)], fracture management [[12\]](#page-189-0), vertebral interbody fusion [\[6](#page-189-0)], tissue biopsy $[8, 13]$ $[8, 13]$ $[8, 13]$ $[8, 13]$ $[8, 13]$, and anterior spinal release and fusion without $[4, 4]$ $[4, 4]$ [14–22\]](#page-189-0) or with instrumentation (VAT-I) for spinal deformity correction [[23–](#page-189-0)[25\]](#page-190-0). As

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the knowledge and the comfort of using such techniques expanded, the indications extended to corpectomy for tumor resections [[26–32\]](#page-190-0).

Although VATS can be performed in such many spine conditions, it is most beneficial in the treatment of scoliotic deformity, when there is a need to a multilevel approach, from the upper to the lower thoracic spine. On the contrary, other conditions where the pathology is localized to one or two segmental levels, like thoracic disk prolapse or infection, can be managed with mini-open thoracotomy as an alternative to open traditional procedure.

The absolute contraindication for VATS includes ones' inability to tolerate single-lung ventilation, FEV 1 less than 50% [\[13](#page-189-0)], dense pleural adhesion, respiratory insufficiency, empyema, and failed prior thoracotomy surgery.

Video-assisted thoracoscopic surgery (VATS) has advantages over open thoracotomy, such as less postoperative pain and morbidity, earlier mobilization leading to shorter hospital stays and lower costs, and smaller scars.

14.3 Surgical Anatomy and Technique

The majority of VATS approaches is from the right side for pathology involving the middle and upper thoracic spine because there is a greater working spinal surface area lateral to the azygos vein than that to the aorta [\[26](#page-190-0)]. Below T-9, a leftsided approach is made possible that the aorta has moved away from the left posterolateral aspect of the spine to an anterior position as it passes through the diaphragm.

14.3.1 Surgical Techniques

Following induction of anesthesia with the placement of a double lumen intubation tube, the patient is turned to the left lateral position, with the right side of the chest upward. This position is maintained by flexion of the downside hip and knee and secured by using surgical tapes. An axillary roll is positioned to prevent pressure on the dependent shoulder [\[33–35](#page-190-0)].

Following the deflation of the lung and the introduction of the thoracoscopy instruments, the involved vertebra is identified under fluoroscopy and the segmental artery identified.

Regarding placement of thoracoscopic instruments, several strategies are possible.

In an *anterolateral approach*, the surgeon stands on the patient ventral side, and more spinal levels can be approached form each portal especially in the presence of a large thoracic kyphosis.

Anterolateral approach also provides a surgical plane dissection between the azygos vein and the vertebrae. The spine could be fenced by temporary gauze placement in this plane thus maintaining a clear visual to the spine and adding extra protection to the anterior spinal structures during spinal release [[23\]](#page-189-0).

In a *combined anterolateral and posterolateral approach*, the portals are first placed along the anterior axillary line for spinal release and fusion [\[16](#page-189-0), [20](#page-189-0), [22](#page-189-0)] and then replaced posterolaterally for spinal instrumentation [[23\]](#page-189-0). A disadvantage is the potential danger of working with instrument from an anterior to posterior direction into the spinal canal.

In an all *posterolateral approach*, all access portals are placed between the midand posterior axillary lines [[24,](#page-189-0) [25\]](#page-190-0). The surgeon stands to face the back of the patient; both discectomy with fusion and instrumentation could be performed via these posterolateral portals without the need of additional anterolateral portals.

Comparing with conventional posterior instrumentation and fusion, an all posterolateral approach carries increased technical difficulties in performing a thorough discectomy and a lack of protection to the anterior vascular structure during the anterior longitudinal ligament release.

14.3.2 Discectomy

A successful intervertebral fusion and deformity correction requires a thorough discectomy [\[13](#page-189-0)] and end plate clearance. The parietal pleura on the spinal column is incised longitudinally along the peak of the disk where it is most avascular.

Intervertebral segmental vessels should be cauterized slowly, layer by layer; clear surgical field with minimal bleeding facilitates the thoracoscopic procedure.

Once the intervertebral disk is exposed beneath the pleura, the annulus is incised by a long handled no. 15 scalpel blade. A pituitary rongeur is used to remove the annulus disk complex. The cartilaginous end plates are separated from the subchondral vertebral bone by using a sharp cut Cobb elevator; and the final clearance of the disk space is carried out by a combination of straight and angled pituitary rongeurs and cup curettes.

Partial released of the anterior longitudinal ligament (ALL) is often adequate [\[25](#page-190-0)], and the residual ALL may assist in retaining the bone graft in the disk space. The posterior longitudinal ligament (PLL) is not incised during anterior spinal release and may act as a protective barrier to the spinal cord.

The resection of the proximal 2 cm of rib head (except when the level was below T11) is required to achieve thorough clearance at the posterolateral corner of the disk [\[6](#page-189-0)]. The foraminal ligaments are then cut to expose the superior edge of the pedicle. The superior part of the pedicle is resected to expose the spinal canal.

14.3.3 Spinal Deformity Correction

14.3.3.1 Portal Localization

Incisions for the thoracoscopic ports are centered over the ribs. Entry into the chest is made over the cephalad and caudal edges of each rib resulting in eight entry portals from just four chest wall incisions. Typically, the third and ninth rib incisions are placed at the mid-axillary line, while the fifth and seventh rib incisions are at the

posterior axillary line. If the instrumentation needs to be performed from T6 to L1, the incision array is moved caudally, onto the fourth, sixth, eighth, and tenth ribs [\[36](#page-190-0)].

A 2-cm skin incision is cut parallel to the rib. Lung ventilation in the operative side is blocked, and one-lung ventilation on the nonoperative side is achieved. The partial pleura on the chest wall is incised at the superior border of the rib. Gentle dissection must be employed to avoid iatrogenic pulmonary parenchyma injury during the first portal insertion. The remaining portals are inserted under direct thoracoscopic vision.

14.3.3.2 Spinal Fusion

Following after discectomies, segment of the rib under the skin incisions are removed via open rib harvesting technique and rib cutter. This provides autogenous rib graft for intervertebral body fusion and a possible thoracoplasty effect. Alternatively, the rib graft can be harvested via a closed endoscopic technique [[37\]](#page-190-0), or iliac crest graft could be used [[17\]](#page-189-0).

14.3.3.3 Vertebral Bone Screw Insertion

The vertebral screw entry point is located just anterior and inferior to the corresponding rib head. Instrument directed into the spine should be placed perpendicular to the imaginary plane between the X-ray tube and the image intensifier on either ends of the C-arm. This would avoid iatrogenic spinal canal penetration by instruments $[36]$ $[36]$.

The exact techniques of screw insertion will depend on the particular type of thoracoscopic instrumentation used. The final screw position should be in the middle of the vertebral body and parallel to its vertebral end plates. Bicortical screw purchase is preferable. It is critical to ensure that each screw head is placed against the near cortex of each vertebra.

Instrumentation systems that allow for small screw length increments (e.g., 2.5 mm per interval) are preferable to avoid the placement of excessive long screws, where the screw tip could impinge on the aorta on the contralateral side of screw insertion [[36\]](#page-190-0).

14.4 VATS Results in Various Spine Conditions

14.4.1 Thoracic Disk Disease

Rosenthal and Dickman reported the results of 55 consecutive patients undergoing VATS discectomy [\[7\]](#page-189-0). Seventy-nine percent of the radiculopathic patients recovered completely. When compared the VATS results to their patient treated by costotransversectomy or thoracotomy, they found VATS was associated with 50% less blood loss and an hour less operative time. Anand and Regan [\[6](#page-189-0)] reported their results of 100 consecutive cases of thoracic disease treated by VATS. They classified the disease according to the symptoms: Grade 1 (pure axial), Grade 2 (pure radicular),

Grade 3A (axial and thoracic radicular), Grade 3B (axial with lower leg pain), Grade 4 (myelopathic), and Grade 5 (paralytic). An overall subjective patient satisfactory rate was 84%, and objective long-term clinical success was obtained in 70% of patients at 2 years.

14.4.2 Spine Fracture

Dickman et al. reported a comparable outcome in fracture management between VAT-vertebrectomy and open thoracotomy group [[26\]](#page-190-0).

14.4.3 Spine Tumor

Many authors had described the use of VATS in management of primary and metastatic spinal tumors [[9,](#page-189-0) [28,](#page-190-0) [30–32\]](#page-190-0). Konno et al. reported the use of a combined hemi-laminectomy with medial facetectomy via a standard posterior approach and thoracoscopic resection for the management of five dumbbell-type thoracic cord tumors. No instrumentation was used. All patients regained their ability to walk. There was no recurrence of tumor and spinal instability at 3 years after the operation. In a series of 41 patients with metastatic tumor decompressed by VATS, there were two (5%) perioperative deaths, and both were related to respiratory complications [\[29](#page-190-0)].

Moreover thoracoscopy was increasingly used for vertebrectomy in the mid-1990s [[26\]](#page-190-0). As the knowledge and the comfort of using such techniques expanded, the indications extended to vertebrectomy for tumor resections [\[26](#page-190-0), [27](#page-190-0)]. The improved exposure, reduction in operative time, and blood loss, as well as improved recovery times, were notable. As a matter of fact, a thoracoscopic-assisted anterior approach could reduce the duration and the morbidity of a vertebrectomy without affecting oncological management.

14.4.4 Vertebral Osteomyelitis

The use of VATS to obtain tissue confirmation for a faster and more reliable diagnosis of thoracic spinal tuberculosis has been reported [[8\]](#page-189-0). Endoscopic approach to the treatment of thoracic vertebral osteomyelitis may reduce the surgical morbidity that is otherwise untolerated in these sick patients [[9–11,](#page-189-0) [29\]](#page-190-0).

Vertebral tuberculosis constitutes 50% of all cases, 44% of which occur in the dorsal spine [\[38](#page-190-0)]. Thoracoscopic surgery obtains radical debridement, leading to a direct visualization of the dural sac and kyphotic deformity correction with interbody cage and anterior screwing [[39\]](#page-190-0). Huang et al. showed the reliability and effectiveness of thoracoscopy in the management of ten patients with dorsal tuberculous spondylitis [[9\]](#page-189-0). There was no recurrence of infection at the 24-month follow-up examination.

Muckley et al. reported the management of three elderly patients with pyogenic vertebral osteomyelitis and epidural abscess by VAT-I [[11\]](#page-189-0). Radical debridement; ipsilateral pedicle resection of the pathological vertebrae, leading to direct visualization of the dural sac; and spinal canal decompression were performed. Interbody fusion and kyphotic deformity correction were achieved with an expandable titanium interbody fusion cage containing autogenous bone graft and gentamycinimpregnated collagen sponge. The construct was further stabilized with an anterior fixation system. There was no recurrence of infection and no loss of postoperative kyphotic correction at 2 years. Operative time and blood lost were comparable to open techniques.

14.4.5 Scoliosis Correction

Thoracoscopic surgery for scoliosis can be performed in two forms: anterior spinal release with fusion without [[4, 14–18](#page-189-0), [20–22](#page-189-0)] or with anterior instrumentation [[23–](#page-189-0) [25\]](#page-190-0). Anterior spinal release is used for severe or rigid curves or in young patients where there is a need to achieve anterior and posterior spinal fusion, as the first stage of a two-stage procedure. The second stage is conventional posterior fusion and instrumentation [\[40](#page-190-0)].

Arlet published a meta-analysis of anterior thoracoscopic spine release in scoliotic deformity surgery [\[41\]](#page-190-0). He found an average of four to seven disks was excised with an operative time varied between 150 and 240 min. The average Cobb angle of the structural curve was 65°. The percentage of curve correction was 55–63% after VATS and posterior spine fusion. The total complication reported was 18%, and most were pulmonary complications noted in patients with neuromuscular deformity. In one series, the author noted a 28% cost increased in VATS when compared to standard thoracotomy. The conversion rate from VATS into thoracotomy found in series with over 100 cases was from 0 to 3% [[15–20](#page-189-0)].

Liu operated on patients with adolescent idiopathic scoliosis either performing thoracoscopic fusion or anterior instrumentation. The author found no difference in outcome between the two groups with regard to postoperative Cobb angle, thoracic kyphosis, and lumbar lordosis at different time points in 2 years. Operative time was significantly longer than for conventional posterior instrumented fusion (7 h versus 4 h); blood loss was less; and ICU stay was longer with the thoracoscopic method compared to posterior instrumentation [[36\]](#page-190-0).

Newton et al., in a report to the Scoliosis Research Society in 2002, compared anterior thoracoscopic instrumented fusion to anterior open and posterior instrumented fusion in a cohort of patients from a number of surgeons. He found similar outcomes in all three approaches. There was a trend toward better correction in the posterior instrumented group, but the differences were not statistically significant.

14.5 Complications

Complications associated with thoracoscopic procedures are similar to those of open thoracotomy, with variations in the incidence. In addition, anesthesia, patient positioning, port placement and access, and instrument manipulation also contribute to other specific complications [[42\]](#page-190-0).

Complications related to anesthesia are mainly related to single-lung ventilation: incorrect placement, inaccurate tubing size, and over- or underinflation of the bronchial cuff that can lead to air leaks into the operated lung [\[43](#page-190-0)]. Some patients may also have pulmonary blebs, which spontaneously burst and cause a pneumothorax, resulting in hypercarbia, hemodynamic instability, and even venous gas embolism. Ventilation-perfusion mismatch resulting in arterial desaturation may occur secondary to both lungs being perfused while one lung is ventilated [[43\]](#page-190-0).

Lateral decubitus positioning may affect the brachial plexus either by pressure on the side the patient is lying on or by over-abducting the arm on the operated side.

Regarding complications related to endoscope placement, injury to the lung parenchyma and other vessels may occur [\[10](#page-189-0), [43](#page-190-0), [44\]](#page-190-0) as the initial port is placed blindly. Lung adhesions may be the cause of lung injury during port placement and postoperative air leaks.

Injury to large intrathoracic vessels may also occur with instrumentation. Endoscopic instruments and retractors placed in the chest cavity can cause injury to the lung parenchyma and to large vessels in the chest cavity, leading to air leaks postoperatively and excessive blood loss intraoperatively [[10,](#page-189-0) [43,](#page-190-0) [45](#page-190-0), [46](#page-190-0)]. Burns from the tips of the endoscopes may occur when they get extremely hot. Postoperative intercostal neuralgia may occur as a result of pressure on the intercostals nerves by rigid thoracoscopic ports or during trocar placement [\[10](#page-189-0), [29](#page-190-0), [43\]](#page-190-0). McAfee et al. [\[10](#page-189-0)] reported intercostal neuralgia as the most common complication encountered in VATS in spinal disorders (7.7%), followed by symptomatic atelectasis (6.4%). Other VATS-related complications that have been reported are excessive (>2000 cc) intraoperative blood loss (2.5–5.5%) [[10,](#page-189-0) [29\]](#page-190-0), pneumonia (1–3%) [\[15](#page-189-0), [20,](#page-189-0) [29\]](#page-190-0), wound infections $(1-3\%)$ [\[20](#page-189-0), [29](#page-190-0)], chylothorax (1%) [20, 29], hemidiaphragm [\[10](#page-189-0)] and pericardial penetration [[29\]](#page-190-0), tension pneumothorax [[15,](#page-189-0) [47\]](#page-190-0), and long thoracic nerve injury [\[25](#page-190-0)].

Proper techniques, such as entering the chest very gently, avoiding the neurovascular bundle, placing all ports other than the initial port under endoscopic monitoring, and visualizing instruments from entry to exit, can avoid injury to the diaphragm and large intrathoracic vessels.

Obtaining an adequate emergency, vascular control in thoracoscopic surgery is potentially difficult. Sucato et al. has highlighted the possibility of injury to the thoracic aorta from vertebral body screws at the apex of the scoliotic curve [[39\]](#page-190-0). This is because the thoracic aorta often lies on the left side of the vertebral body in scoliosis instead of the more anterior position in normal patients, and inappropriately long screws inserted from the right side could penetrate the thoracic aorta.

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