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Part I
Advances

Navigation, Robotics, and Intraoperative Imaging in Spinal Surgery

Florian Ringel, Jimmy Villard, Yu-Mi Ryang, and Bernhard Meyer

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Abstract Spinal navigation is a technique gaining increasing popularity. Different approaches as CT-based or intraoperative imaging-based navigation are available, requiring different methods of patient registration, bearing certain advantages and disadvantages. So far, a large number of studies assessed the accuracy of pedicle screw implantation in the cervical, thoracic, and lumbar spine, elucidating the advantages of image guidance. However, a clear proof of patient benefit is missing, so far. Spinal navigation is closely related to intraoperative 3D imaging providing an imaging dataset for navigational use and the opportunity for immediate intraoperative assessment of final screw position giving the option of immediate screw revision if necessary. Thus, postoperative imaging and a potential revision surgery for screw correction become dispensable.

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Different concept of spinal robotics as the DaVinci system and SpineAssist are under investigation.

Keywords Spinal navigation • Image guidance • Robotics • 3D-Fluoroscopy • Intraoperative spinal imaging

Introduction

While the use of navigational systems is established for cranial neurosurgical procedures since many years, the application of navigation or image-guidance systems for spinal surgery is gaining increasing popularity during recent years. With the technical development of navigation and instrument tracking in the early 1990s, attempts were started to adapt navigation to spinal surgery but were initially hampered by the limited options to attach reference arrays to the surgical target structure. The first successful navigated implantation of a pedicle screw was reported in 1995 [33, 34]. From there on spinal navigation was refined and feasible systems are available nowadays. At present, major applications for spinal navigation are the implantation of pedicle screws in the lumbar, thoracic, and cervical spine. However, few studies assessed the feasibility of navigation systems for anterior approaches to the spine and tumor surgery of the spine.

With the refinement of spinal navigation, the necessity of intraoperative imaging became increasingly important to provide accurate registration of the spine to the navigation system. Intraoperative fluoro imaging or CT imaging is currently available for immediate automatic registration of the spine to the image-guidance system.

Another evolving technology in spinal surgery is robotics. Systems of different robotic technology are under investigation and a miniature bone-mounted robot is commercially available for the robot-assisted implantation of thoracic, lumbar, and sacral pedicle screws.

Spinal Navigation

The spine brings out certain challenges for the surgeon due to its complex 3D anatomy and combination of solid bone and delicate neuronal and vascular structures in close proximity. The standard surgical exposure of the spine allows a 2-dimensional visualization of a complex 3-dimensional body only, and instrumentation needs a large amount of spatial sense to appreciate the exact position of implants in a 3D vertebral body. Conventional orientation at the spine is achieved by a combination of identification of surface anatomy and in most cases 2-dimensional fluoroscopic imaging. However, identification of surface anatomy gets progressively hampered by the advent of minimally invasive approaches to the spine and an increasingly older population of spine patients with significant degenerative changes masking known surface anatomy. In those cases an adequate orientation at the spine gets a

significant challenge. Therefore, spinal navigation is increasingly attractive by providing the surgeon with additional spatial information enhancing the accuracy of surgical procedures and additionally making repetitive intraoperative fluoroscopy unnecessary. This can significantly increase implant position accuracy as shown especially for sacral, lumbar, thoracic, and cervical pedicle screws while reducing the amount of intraoperative radiation exposure. While the reduction of radiation exposure is a welcome by-product for the patient it carries more importance for the active spinal surgeon receiving a significant amount of radiation exposure during daily spinal procedures. Therefore, the potential advantages of spinal navigation are on the one hand an increased surgical accuracy by an enhanced orientation especially in spinal instrumentation and on the other hand a reduced radiation exposure during surgery for the spinal surgeon and OR staff. Due to these advantages navigation undergoes an increased use in spinal surgery.

So far, the most common use of spinal navigation is for posterior implantation of pedicle screws in the sacral, lumbar, thoracic, and also cervical spine. Furthermore, some groups assessed its applicability for anterior spinal procedures as tumor resection or anterior cage or disc prosthesis implantations.

Techniques of Spinal Navigation

Major differences in the presently available techniques of spinal navigation are related to the modality of imaging used for navigation, whether it is pre- or intraoperative CT imaging, intraoperative 2D fluoroscopy, or intraoperative 3D fluoroscopy, and the method of registration of the imaging dataset to the patients' anatomy. While in the beginning of spinal navigation, CT-based methods were mostly used, intraoperative imaging especially 3D fluoroscopy is currently increasingly used and, thereby, registration methods are changing from paired point or surface matching methods to automatically registration of the intraoperative fluoroscopy imaging dataset.

Preoperative CT-Based Navigation

The classical mode of spinal navigation is preoperative CT-based navigation. A preoperative CT scan of the pertinent spine region is transferred to the navigation system and after attachment of a reference array to the spine the imaging dataset is registered to the anatomy of the spine. Several different matching algorithms are available including paired point matching, region matching, or CT-fluoro matching. Using the technique of paired point matching, anatomical distinct points are marked in the CT dataset and the respective points are presented to the navigation system by the use of a pointer after attachment of a reference array to the spine for registration.

When using region matching the navigation system constructs a 3D model of the spine and random surface points on the spine are presented to the system. The system matches the cloud of points to the corresponding fitting area of the 3D spine object.

A third method of registration is CT-fluoro matching. When using this technique the preoperative CT is matched to intraoperative 2D-fluoro images of the spine taken from different angles to the patient.

Major influencing factor for the accuracy of the navigation is the accuracy of the registration of the patient's anatomy to the imaging data set. When using CT-based navigation this is hampered by the changed intersegmental relation depending on patient position. While the patient is usually in supine position in the scanner he is turned to prone position for posterior surgery and the spatial relation of vertebral bodies can change in comparison to the CT position. Therefore, several registrations can be necessary for a multisegmental instrumentation.

In a cadaver study Holly et al. assessed the accuracy of paired point matching alone in comparison to paired point matching supplemented with surface matching of the cervicothoracic spine [14]. Though the addition of surface matching decreased the registration error, the navigational accuracy did not differ between the two techniques compared. The authors concluded that paired point matching should be sufficient for cervicothoracic instrumentation.

Due to the changed intervertebral relations between imaging and the surgical position, standard protocols suggest the registration of each spinal level of interest, i.e., single-level registration. In a study of 45 patients undergoing lumbar pedicle screw insertion, the option of multilevel registration was compared to single level registration accuracy [38]. The authors found a single-time multilevel registration to be sufficiently accurate for lumbar pedicle screw implantation in their series of patients.

Independent of the registration technique used, a careful and repeated control of registration accuracy during surgery is necessary using distinct points of anatomy to verify registration and to decide whether a further level needs additional single-level registration or whether registration accuracy is sufficient for adjacent levels.

Intraoperative Imaging-Based Navigation

In contrast to preoperative CT-based navigation, several options for the use of intraoperatively acquired images for navigation are available. The most basic version of intraoperative imaging-based navigation is the so-called virtual fluoroscopy where lateral and ap fluoroscopy images taken intraoperatively are registered to the patients' anatomy and used for navigation [9]. However, when compared to the conventional approach of lateral and ap fluoroscopy imaging during spinal instrumentation, the approach of virtual fluoroscopy does not add additional information but avoids repeated imaging and time-consuming repositioning of the c-arm from lateral to ap imaging and reduces radiation exposure. Registration for virtual fluoroscopy is usually performed automatically by tracking of the c-arm during image acquisition.

With the availability of 3D c-arms rotating around an isocenter, 3D-fluoro-based navigation became possible. A c-arm automatically rotates around a spinal region of interest acquiring repeated images during the orbital scan around the isocenter.

Comparable to a CT scan the acquired fluoro images are reconstructed to a 3D image of the spine and multiplanar reconstruction of the images are available for navigation. In comparison to preoperative CT imaging the problem of intervertebral changes of relation during scanning and surgery are no longer a limitation and registration is performed automatically by tracking of the c-arm and the spine during the imaging scan making further registration steps unnecessary. After simultaneous image acquisition and registration, spinal navigation is immediately possible after verification of the registration accuracy. Thereby, time-consuming registration steps are unnecessary, the problems of intervertebral spatial relation changes are omitted, and re-registrations for adjacent vertebral bodies become needless.

Navigated Posterior Spinal Instrumentation

Major application of spinal navigation is for posterior instrumentation of the cervical thoracic and lumbar spine where fixation of the necessary reference array is easily achievable. The vast amount of available literature assessed the feasibility and accuracy of the implantation of pedicle screws. A meta-analysis published by Kosmopoulos in 2007 summarized the accuracy of navigated pedicle screw instrumentation and compared it to non-navigated pedicle screws [26]. The authors assessed 130 studies including 69 clinical and 41 cadaveric articles and had a total of 37,337 navigated and non-navigated pedicle screws in their database. Of the in vivo population, the non-navigated subgroup of 12,299 pedicle screws showed a median accuracy of 90.3 % compared to a median accuracy of 95.1 % of 3,059 navigation-assisted pedicle screws irrespective of the spinal level. These numbers give an overall impression of the superiority of spinal navigation with respect to pedicle screw placement accuracy. However, when filtering for spinal levels cervical and lumbar pedicle screws are more accurately placed with the use of navigation while the median accuracy of thoracic pedicle screws was 94.3 % without and 82.2 % with the assistance of navigation on first sight.

Lumbar Pedicle Screw Insertion

The vast majority of literature on spinal navigation evaluated the accuracy of lumbar pedicle screw instrumentation and results of several well-conducted studies support the accuracy advantage of navigation-assisted placement of lumbar pedicle screws. Already in 2000 a prospective randomized trial revealed a pedicle breach rate of 13.4 % without navigation compared to 4.6 % with the use of navigation [28]. The rate of pedicle breaches above 4 mm was reduced from 1.4 to 0 % by image guidance. The meta-analysis by Kosmopoulos assessed the position of 1,674 non-navigated screws in comparison to 864 navigated lumbar pedicle screws and reported a median rate of accurate screws of 79.0 and 96.1 %, respectively [26].

Thoracic Pedicle Screw Insertion

In comparison to the lumbar and cervical spine, the thoracic spine has the most unfavorable relationship of spinal canal diameter and cross-sectional surface of the contained neuronal structures resulting in a small safety space medial to the bony pedicles. Furthermore, pedicle diameters are small increasing the complexity of an accurate screw implantation. Therefore, spinal navigation seems to be attractive for posterior thoracic instrumentation especially in situations with scoliotic deformities and a rotated anatomy.

However, as mentioned above a meta-analysis revealed median accuracies for thoracic pedicle screws to be 94.3 % without compared to 82.2 % with the assistance of navigation in the thoracic spine [26]. However, the authors confined that numbers are based on 6 pure thoracic articles only and that statistical aspects result in the reported accuracy differences. When using the more accurate geometric mean accuracy of 63.1 % without and 85.1 % with navigation as suggested by the authors, the advantage of navigation for the placement of pedicle screws in the thoracic spine becomes evident. Later studies support the advantage of thoracic spinal navigation. Rajasekaran et al. assessed the advantage of navigation in a prospective randomized study of 33 patients treated for thoracic deformities with posterior instrumentation using navigation with intraoperative 3D fluoroscopy or conventional non-navigated fluoroscopic guidance [43]. While 23 % of the non-navigated screws, only 2 % of the navigated screws showed pedicle breaches. In addition, the average screw insertion time was reduced from 4.61 to 2.37 min by the deployment of spinal navigation. In a retrospective study of 300 navigated and 185 non-navigated thoracic pedicle screws for adolescent idiopathic scoliosis, the probability of a potentially unsafe screw was reduced 3.8 times by navigation [60]. Furthermore, the odds of a significant medial breach and intraoperative screw removal were 7.6 and 8.3 times less in the navigated group, respectively. Again, Han et al. revealed a higher accuracy and reduced surgical time of thoracic pedicle screw instrumentation including the upper thoracic spine when navigated in patients with thoracic spine fractures [13].

Thus, increasing evidence is accumulating supporting the advantage of navigation in thoracic pedicle screw insertion, as well.

Cervical Posterior Instrumentation

Cervical instrumentation possesses an outstanding complexity due to the proximity of the bony spine, neuronal structures in the spinal canal, and the vertebral artery.

Within the upper cervical spine transarticular C1-2 stabilization carries a significant risk for vertebral artery injury and vertebral artery lacerations are estimated to occur in 2.2 % of transarticular non-navigated instrumentations [66]. Also the less risky Goel/Harms technique using lateral mass screw in C1 and isthmic screws in C2 reduces the risk of vertebral artery injury, however, the available bony volume for exact screw placement is limited and suboptimal screw placement can be a problem [47].

In the subaxial cervical spine the implantation of lateral mass screws does not carry significant risks of a neurovascular injury, however, the implantation of cervical pedicle screws offers extremely limited space for a deviation of the implanted screw from the ideal trajectory between the spinal canal medially and the vertebral artery laterally between C3 and C7 and therefore has a significant risk for neurovascular injury by an inaccurate screw position.

Due to these reasons spinal navigation became increasingly popular for cervical posterior instrumentation especially for transarticular C1–2 instrumentation and pedicle screws from C3 to C6. So far, several case reports and retro- or prospective studies evaluated the feasibility and accuracy of screw implantation using CT-based navigation or intraoperative 3D fluoroscopy.

Using a human cadaver model Ludwig et al. assessed the accuracy and safety of cervical pedicle screw implantation comparing three techniques: (1) using surface landmarks, (2) performing laminotomies providing additional visual and tactile control, and (3) using a computer-assisted surgical guidance system [31]. By the additional visualization of surgical landmarks by a laminotomy, the number of correct screw positions increased from 12.5 to 45 % and the incidence of critical perforations dropped from 65.5 to 39.6 %. The use of a navigation system could further increase the rate of correct screw positions to 76 % while reducing the rate of critical perforations to 10.6 %. Thereby, the authors could show a clear benefit of the use of image guidance for the implantation of cervical pedicle screws, however, in a cadaver model, only.

Several studies assessed the feasibility and accuracy of the use of navigation for the placement of cervical pedicle screws in patient series. Most studies used the technique of preoperative CT-based navigation while few assessed intraoperative 3D imaging as basis for navigation.

A single prospective study compared the implantation of cervical pedicle screws in 52 consecutive patients with or without navigation [46]. Ninety-two screws in 20 patients were implanted without the use of a navigation system while 167 pedicle screws in 32 patients were implanted by CT image guidance using a navigation system and a surface matching algorithm. None of the implanted screws in either group caused a neurovascular complication; no screw needed a revision but 8.6 % of the non-navigated screws versus 3.0 % of the navigated screws showed a violation of the bony cortex. The authors concluded that the use of navigation in the implantation of pedicle screws from C3 to C6 reduces the rate of screw misplacement and, thereby, might reduce the incidence of neurovascular injuries.

Apart from this study no other study prospectively compared the incidence of screw misplacements and neurovascular injuries by the implantation of pedicle screws in the cervical spine.

The accuracy of three-dimensional fluoroscopy-based computer-assisted cervical pedicle screw placement was compared to the conventional technique in a retrospective clinical study [16]. One hundred twenty-six screws in 30 patients were placed with the conventional technique compared to 150 screws in 32 patients using 3D fluoroscopy-based navigation. While the rate of pedicle perforations was not significantly changed by the application of a navigation system (27.0 %

conventionally vs. 18.7 % navigated), the rate of pedicle perforations ≥ 1 mm was significantly reduced by the use of image guidance. The odds ratio of a pedicle perforation when using the conventional in comparison to the navigated technique was 2.72 for a perforation of ≥ 1 mm and 3.89 for a perforation of ≥ 2 mm, thus demonstrating the advantage of 3D fluoroscopy-based navigation over the conventional technique.

In a meta-analysis assessing pedicle screw placement accuracy, 1,089 cervical pedicle screws placed without the use of navigation were compared to 114 placed with the use of image guidance. The application of a navigation system increased the median accuracy from 93.3 % (range, 71–100 %) to 99.4 % (range, 98.8–100 %) [26].

For posterior stabilization of atlantoaxial instabilities the method of transarticular C1–2 screw fixation as described by Magerl or the C1 lateral mass C2 pedicle or isthmic screw stabilization as described by Goel and Harms are widely used as standard. However, during these procedures especially when using the transarticular technique, the vertebral artery is at significant risk for injuries. Approximately 20 % of cases are not amendable to transarticular screw fixation due to a high riding vertebral artery in C2 [39]. Therefore, navigational guidance can significantly increase the safety of these procedures. Acosta et al. retrospectively reviewed a series of C1–2 transarticular instrumentation using image guidance and reported a 92 % rate (33 of 36 screws) of well positioned screws at which 8 of 33 screws could not have been safely placed without image guidance [2]. Three of 36 screws missed the lateral mass of C1.

In another retrospective series of 60 patients all 109 implanted transarticular screws were evaluated at correctly placed without any neuronal or vascular injury [21]. Using the C1 lateral mass C2 pedicle screw technique, the conventional fluoroscopy guidance was compared to 3D fluoroscopy image guidance in another series [70]. The authors reported 95.8 % versus 83.3 % of correct screw positions in the navigated versus the conventional group, respectively. In both groups no neuronal or vascular complications occurred.

Since different methods for spinal navigation exists the question of which method provides the highest precision and accuracy arises. Few studies assessed the difference between the navigational options of CT-based navigation, 2D fluoroscopy navigation, and 3D fluoroscopy navigation. Therefore, a recent meta-analysis assessed available studies on pedicle screw insertion techniques with navigation for the accuracy with different navigation methods [58]. From 35 clinical studies and 6,063 screws, the median accuracy for CT navigation was 90.76 % compared to 85.48 and 97.16 % with the use of 2D or 3D fluoroscopy navigation, respectively. When analyzing for specific spinal levels the accuracy of 2D fluoroscopy-based navigation was comparable to CT-based navigation for the lumbar spine while CT-based navigation showed a significant advantage in the thoracic spine. Due to the small numbers of publications related to 3D-based navigation a further analysis with respect to certain spinal levels was not performed by the authors. However, the overall accuracy of 3D fluoroscopy-based navigation was superior to CT-based navigation.

Functional Outcome of Navigated Pedicle Screw Implantation

Though the accuracy of pedicle screws in the cervical, thoracic, and lumbar spine is increased by the application of navigation, the question arises whether this increase in accuracy translates into a clinical benefit for the patient with respect to outcome. A meta-analysis assessed 23 studies regarding avoidance of neurological complications, improved pain relief, improved fusion rates, and better health outcome by the use of navigation [64]. While 93.3 % of the implanted screws were placed accurately with navigational assistance 84.7 % of the analyzed non-navigated screws were accurate resembling an increased accuracy by navigation. No reported cases of neurological deterioration were found in the navigated patients but 2.3 % of the non-navigated patients revealed neurological complications, however, this difference did not reach a statistical significant level. Fusion rates, pain relief and health outcome data were too sparse to be assessed in a reasonable manner. Therefore, to present the proof of a clinical benefit for the patient by the use of navigation is missing. But, since the overall incidence of neurological complications and screw revisions is low, the lack of evidence for a clinical benefit must be interpreted as caused by the too low number of patients included in comparative studies assessing clinical outcomes, so far. Since accuracy is increasing, the number of complications, secondary screw failures, and revision rates must be expected to decrease which should be proven by further studies assessing patient outcome as well, beyond pure imaging-based accuracy assessments.

Other Navigated Spinal Procedures

Though the feasibility and advantage of navigation is well-established for posterior spinal instrumentation, only few studies assessed the role for navigation for other spinal procedures especially anterior procedures. Anterior transnasal or transoral odontoidectomies with the assistance of CT-based navigation were performed in two series of three patients each reporting a good accuracy and reduced radiation exposure by navigation [11, 63]. Furthermore, concerning the cervical spine, Hsu et al. described a case of anterior image-guided resection of a cervical chordoma [15]. Most other reports on anterior navigated spinal surgery describe procedures of the thoracic spine [3, 4, 7, 18, 23, 36, 53, 62] while three cadaver studies evaluated the use of navigation for lumbar artificial disc replacement [19, 45, 55]. Following a cadaver feasibility study Assaker et al. performed a navigated anterior thoracoscopic procedure for a thoracic disc herniation in a patient [3, 4]. Johnson et al. reported on their experience in a series of 16 patients undergoing thoracoscopic image-guided discectomies and concluded a high accuracy, efficiency, and safety of the procedure. Vaccaro et al. reported an increased accuracy of anterior thoracic screw placement by the use of navigation in a cadaveric study [62]. Further studies assessed navigation for thoracic ossification of the posterior longitudinal ligament [53], Potts disease [7], thoracolumbar corpectomies [36], and costotransversectomies for thoracic

disc herniations in five cases [23]. Overall, navigation for anterior procedures of the spine is still evolving. Current problems include the fixation of the navigational reference array and registration of the navigation dataset to the patients' anatomy.

Radiation Exposure

During conventional fluoroscopy-assisted spinal instrumentations, the surgical staff and the operated patient are exposed to a significant amount of radiation, which is usually increased when using minimally invasive techniques. Especially for the operating personnel in active spine units this can result in a significant yearly dose of radiation. Several phantom studies assessed the effect of spinal navigation on patient and surgeon exposure [22, 44, 54, 56] while only few studies evaluated this topic during surgical procedures. Gebhard et al. [10] quantified and compared the intraoperative radiation dose to the patient using conventional fluoroscopy assistance and different types of navigation, i.e., CT-based navigation, 2D fluoroscopy-based navigation, and 3D fluoroscopy-based navigation for the insertion of pedicle screws. The authors reported a duration of exposure and dose of 177 s and 1,091 mGy for the standard approach, 75 s and 432 mGy when using CT-based navigation, 66 s and 664 mGy with the assistance of c-arm-based navigation, and 40 s and 152 mGy with 3D intraoperative fluoroscopy-based navigation. Thus, the duration and dose of radiation to the patient is significantly reduced by the application of navigational techniques, however, the exposure of the surgeon is sparsely evaluated, so far. The radiation exposure of the operating room personnel during the application of intraoperative O-arm imaging is considerably low when adhered to the necessary safety distance as reported lately [1]. In our own series of patients the radiation exposure of the patient and surgeon was assessed in a setting using intraoperative 3D fluoroscopy-based navigation for thoracolumbar instrumentation in comparison to the conventional fluoroscopy-assisted approach (unpublished results). The radiation dose at the level of the eye, chest, and dominant forearm of the surgeon was detected with digital dosimetry. By the use of navigation the exposure of the eye, chest, and forearm of the surgeon was reduced 4.6, 3.8, and 3.4 times, respectively, while the cumulative dose for the patient was reduced 2.7 times with the use of navigation. Thereby, surgeon and patient radiation exposure are significantly reduced by the application of navigation during otherwise radiation intensive spinal instrumentation.

Drawbacks of Spinal Navigation

Apart from the well-proven advantages of spinal navigation its use is associated with certain drawbacks, which the operating surgeon has to be aware of. It is important to bear in mind that the imaging information provided by spinal navigation represents a virtual reality and the relation to the anatomic reality needs repetitive

verification, i.e., repeated checks for the registration accuracy for each vertebral level operated on. With increasing distance from the reference array attached to a spinous process, the likelihood of a decreasing accuracy increase, which could make additional registrations necessary. Especially if the imaging position of the patient is not the position during surgery the change of intervertebral relations could result in inaccuracies. Furthermore, any minor displacement of the reference array will result in systematic inaccuracies. Moreover, the implementation of spinal navigation is associated with a steep yet present learning curve changing the workflow of spinal instrumentation, which is a change of habits especially for experienced spine surgeons. Though spinal navigation provides the surgeon with a detailed view of otherwise hidden 3-dimensional anatomy, the appraisal of plausibility still requires a detailed knowledge of surgical spinal anatomy especially of pedicle screw entrance points and angulation of trajectories for continuous reconciliation of navigation information and patient anatomy.

Since the initial implementation of spinal navigation is associated with a learning curve and changed workflow during spinal instrumentation it seems not advisable to reserve it to selected cases. Only the consequent use of image guidance for all spinal cases including pedicle screw instrumentation can accelerate the workflow, increase the experience, and thus exploit the advantages of spinal navigation for challenging instrumentations.

Spinal Robotics

The spine as a rigid bony construct seems to be an appealing field to be exploited by robotic technologies. At present two commercially available systems, the DaVinci (originally developed for minimally invasive endoscopic procedures) and the SpineAssist (developed for spinal instrumentation) have been assessed for spinal procedures. Additionally, few groups adjusted experimental robotic systems for the use in spine surgery [25, 27, 37]. The two commercially available systems follow a completely different philosophy. While the DaVinci translates the surgeon's movements and manipulations to the surgical field via robotic arms without any form of image guidance, the SpineAssist is an image-guidance system leading the surgeon to preplanned trajectories for spinal instrumentations leaving the surgical steps in the hand of the surgeon.

DaVinci

The DaVinci (Intuitive Surgical Inc., Sunnyvale, USA) is an FDA- and CE-approved robotic system which consists of a four-armed robot positioned close to the patient and a console where the surgeon sits, manipulating the robot. The surgeon views a 3D high-resolution image of the surgical field at the console. He manipulates

control handles at the console and movements of these handles are translated to the surgical field by the robotic arms. The system has been broadly used in abdominal and thoracic surgery in urology, gynecology, and general surgery for endoscopic minimally invasive procedures. It is not associated with any form of image guidance and its major aim is the translation of the surgeons movements to the surgical field filtered for physiological tremor and scaled to improve surgical precision.

However, limitations of the system for spinal surgery are the lack of bone-cutting instruments and sufficient force to perform curetting and rongeur actions. Nevertheless, a number of experimental and clinical case studies assessed DaVinci with regard to its applicability in spinal surgery.

Using a porcine model ALIF procedures using DaVinci were performed via a retroperitoneal or transperitoneal approach and general feasibility of the technique was shown using one animal for each study [24, 68]. Furthermore, it was tested for posterior procedures including laminotomy, laminectomy, and dural suturing in another porcine model using one animal [41]. However, larger experimental studies are pending at present.

Furthermore, in humans the robot was applied for a transoral odontoidectomy in a patient with basilar invagination and another study assessed this application in a cadaver experiment [29, 69]. Case reports describe its use for a retroperitoneal transdiaphragmatic laparoscopic resection of a thoracolumbar neurofibroma, a thoracoscopic resection of a paravertebral mediastinal neurogenic tumor, and a transperitoneal resection of a lumbosacral tumor [32, 49, 67].

Thus, so far, the data on the applicability of DaVinci in spinal surgery is sparse and its capability to perform instrumented spinal procedures remains questionable. Further studies assessing the feasibility of DaVinci for spinal procedures are missing and its application is purely experimental at present stage.

SpineAssist

SpineAssist is an FDA- and CE-approved miniature robot for the posterior thoracic and lumbar instrumentation. It consists of a miniature robot, which has the size of a soda can and a workstation for control of the robots motion. The robot has a hexapod design featuring six degrees of freedom. It serves as a positioning aid to pre-planned trajectories and therefore has to be seen as an advancement of spinal navigation guiding the surgeon to preplanned trajectories. While during standard navigation instruments have to be aligned to preplanned trajectories in a free-hand manner demanding complex hand-eye coordination, SpineAssist guides the surgeons to these trajectories using the robotic technique.

Prior to surgery a CT scan of the respective spinal segments is necessary and implant trajectories have to be planned which is possible at an office desktop computer. The imaging dataset including the planned trajectories is then transferred to the SpineAssist computer workstation. During surgery the robot per se is attached to the spine, i.e., it is spine mounted. Different ways of attachment are available including

(1) attachment of the robot by a clamp to a spinous process and stabilization by K-wires in an adjacent spinous processes, (2) attachment of a hover bar on which the robot is mounted to a spinous process and the iliac crest bilaterally, or (3) attachment of the hover bar to a spinous process and the OR table, the so-called bed mount.

The spinal anatomy is registered to preoperative CT images by CT-fluoro matching using the intraoperative C-arm. After registration the robot is attached to the spine and guides the surgeon to the pertinent preplanned trajectories. Through a drill guide positioned by the robotic arm, channels for spinal implants, primarily pedicle screws, can be drilled by the surgeon, i.e., the actual surgical act remains in the hands of the surgeon.

The accuracy of the robotic system per se has been shown in several in vitro experiments [30, 59, 65].

In an initial clinical series of 15 patients reported from Israel, the SpineAssist worked properly in six cases where lumbar pedicle screw positions as controlled by postoperative CT scans were accurate and as planned. Nine out of 15 cases were identified where the system did not work as smoothly as expected. Problems as insufficient CT-fluoro matching, dislocation of the tool guide by soft tissue pressure or surgeon's pressure on the tool guide, or failure of adjustment of the robotic trajectory to the preplanned trajectory were encountered [5]. However, those problems were majorly overcome and further successful case series were reported. Sukovich et al. described 14 cases of lumbar and sacral pedicle screw insertion, out of which 93 % of cases were successful and 96 % of implanted screws were within 1 mm of their planned trajectories [57]. In 2009 Pechlivanis et al. reported on 31 patients undergoing a PLIF procedure with robot-assisted percutaneous pedicle screw insertion of 133 screws [40]. Screw position was evaluated according to the Gertzbein Robbins classification and 98.5 and 91 % screws showed a deviation of <2 mm of the ideal trajectory in the pedicle in axial and longitudinal plane, respectively. A multicenter retrospective study of robotically inserted thoracic, lumbar, and sacral pedicle screws and guide wires assessed 3,271 trajectories by intraoperative fluoroscopy and 646 by postoperative CT scan for its accuracy [8]. The study summarizes the experiences with the use of SpineAssist at 14 different centers in the United States, Germany, and Israel between 2005 and 2009. Forty-nine percent of the reported cases were performed in a percutaneous fashion. 83.6 % of all planned screw/guide wire insertions were successfully executed under robotic guidance, while 16.4 % had to be performed manually due to registration failures, robot reachability errors, device failures, mechanical movements, and abortion by the surgeon. Of 3,271 SpineAssist-guided implantations controlled by intraoperative fluoroscopy, 98 % were assessed as acceptable. Of 646 screws evaluated by postoperative CT scans and compared to planned trajectories mean deviation of the screw position from the preoperative plan was 1.2 ± 1.49 and 1.1 ± 1.15 mm in axial and sagittal plane, respectively. 98.3 % of pedicle screw was accurate as defined by Gertzbein Robbins criteria, i.e., showed a critical violation of below 2 mm. Kantelhardt et al. retrospectively compared a series of robotic-guided percutaneous or open thoracic, lumbar, and sacral pedicle screw insertions to a historical group of open conventional screw implantations [20]. 94.5 % of 250 robotically inserted screws

compared to 91.5 % of 286 conventionally implanted screws were accurate as assessed by postoperative CT imaging. There was no difference between the accuracy of robotically assisted open or percutaneous screw implantations. The intraoperative X-ray exposure per screw was reduced from 77 s using the conventional technique to 34 s in robot-assisted cases.

Therefore, in non-controlled case series the accuracy of SpineAssist seemed to be superior to conventional fluoroscopy-guided pedicle screw insertion in thoracic, lumbar, and sacral spine.

However, a recently published prospective randomized single center trial-assessed lumbar and sacral pedicle screw insertion accuracy by SpineAssist in comparison to the traditional free-hand fluoroscopy-guided technique [48]. In this series 60 patients requiring mono- or bisegmental lumbar pedicle screw instrumentation were randomized to conventional screw implantation versus SpineAssist-guided instrumentation. Screw accuracy was assessed by postoperative CT scans and classified according to Gertzbein Robbins. Ninety-three percent of conventional implanted versus 85 % of robot-assisted screws were classified as Gertzbein Robbins grade A or B by an independent blinded radiologist and thus as accurate screws. The overall surgical time was not different between groups as well as the radiation exposure, which was 1.9 min for the whole case. But, for robot-assisted cases a preoperative CT scan is necessary and trajectory planning demands additional time. Therefore, though SpineAssist showed a superior accuracy in several patient series this advantage could not be proven in a prospective randomized trial.

Though the overall accuracy of the robot per se seems to be not debatable, several aspects related to the robot-spine interface could contribute to these accuracy problems: (1) the attachment of the robot to the spine might not be stable enough and minor displacements could lead to inaccuracies and (2) soft tissue pressure to the drilling canula could lead to displacements, therefore, the anchorage of the canula to the screw entry point needs further refinement to increase accuracy.

Apart from its main purpose – pedicle screw insertion – SpineAssist is promoted for the use in GO-LIF (guided oblique lumbar interbody fusion), a fusion technique described by Grob in 1996 [12] which has not received great attention in spine surgery since then. GO-LIF applies bilateral transpedicular-transdiscal screws for lumbar stabilization together with an interbody cage. SpineAssist provides the planning tools for screw trajectories and the intervertebral cage for GO-LIF procedures. The protocol for a European multicenter trial to assess the safety and efficacy of GO-LIF using robot-assisted screw implantations has been published; however, results of this study are pending at present [6].

In summary, SpineAssist is a miniature spine mounted robot for surgeons' guidance to preplanned trajectories. Several case series could report good accuracy for thoracic, lumbar, and sacral pedicle screw insertion while a prospective randomized trial failed to reveal an advantage of SpineAssist over the conventional free-hand fluoroscopy-guided technique. Certain refinements of the robotic system with regard to spine attachment and drill canula stability might enhance the system and improve accuracy over conventional techniques. However, these refinements as well as GO-LIF results need to be awaited before further judgment of SpineAssist.

Intraoperative 3D Imaging

Since decades 2D fluoroscopy is used for intraoperative imaging during spinal instrumentation guiding implant positioning by ap and lateral fluoroscopy. For final control of correct implant positions, a postoperative CT is performed at many institutions since intraoperative 2D fluoroscopy does not allow for a reliable evaluation of implant position. If postoperative CT imaging would show an unacceptable misplaced screw, a secondary surgery for screw repositioning was necessary. In cases where CT-based navigation was used, an additional preoperative CT scan was necessary.

The option of intraoperative 3-dimensional imaging can change this workflow significantly. Different options of intraoperative 3D imaging are available which are intraoperative 3D fluoroscopy or intraoperative computerized tomography, while intraoperative MR imaging has a minor role in spinal surgery. Intraoperative 3D fluoroscopy or computerized tomography allows for image acquisition necessary for navigation with the patient in its final position for surgery, abolishing the problem of intervertebral relation changes which is encountered if patient position during preoperative imaging (supine) is not the same as during surgery with navigation (prone). This leads to an increased multilevel accuracy making multiple registrations unnecessary. Furthermore, intraoperative imaging devices are usually tracked by the navigation system and automatically registered which makes a time-consuming registration by paired point matching or surface matching expendable, thereby, allowing minimally invasive procedures without wide exposure of the spinal surface anatomy.

After spinal instrumentation another intraoperative 3D scan allows for control of implant position and the option of immediate implant correction obviating secondary surgery due to implant misplacement. The experiences with intraoperative CT imaging and 3D fluoroscopy have been summarized by several authors [16, 17, 35, 50–52, 61, 71].

While intraoperative 3D fluoroscopy systems allow for a limited extent of imaging volume which has, depending on the system used, a maximal cubic volume of 15 cm side length, intraoperative CT allows for an unlimited imaging volume at the cost of a higher logistic OR complexity and lower flexibility, however, increased image quality.

A recent development of intraoperative imaging is robotic multi-axis 2D or 3D fluoroscopy. With this technique the c-arm is controlled by a robotic arm, which automatically adjusts to changed patient positions caused by changes of the operating table. The system provides 3D images by a fast robot-guided scan around the isocenter. First experiences with this system in spinal surgery have been reported recently [42].

Conclusion

While the benefits of spinal navigation with regard to instrumentation accuracy have been consistently shown for pedicle screw placement in the cervical, thoracic, and lumbar spine, its feasibility for anterior spinal procedures is still evolving and need

further assessment. Spinal robotics seems a promising advancement of non-robotic image guidance, however, some aspects of the mostly promoted system needs further refinement. Intraoperative 3D imaging in combination with spinal navigation can refine the workflow of spinal procedures.

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Sagittal Balance, a Useful Tool for Neurosurgeons?

Jimmy Villard, Florian Ringel, and Bernhard Meyer

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Abstract New instrumentation techniques have made any correction of the spinal architecture possible. Sagittal balance has been described as an important parameter for assessing spinal deformity in the early 1970s, but over the last decade its importance has grown with the published results in terms of overall quality of life and fusion rate. Up until now, most of the studies have concentrated on spinal deformity surgery, but its use in the daily neurosurgery practice remains uncertain and may warrant further studies.

Keywords Sagittal balance • Instrumentation • Fusion rate • Quality of life

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Introduction

With the advent of new instrumentation devices and instrumentation techniques over the past decades, any correction of the spinal architecture has been made possible. For quite a while, spine surgeons, especially those dealing with scoliosis, have focused on the correction of the coronal balance. Although some authors have advocated in the early 1970s the need to assess the sagittal balance in order to achieve an adequate correction of spinal deformity, the lack of adequate implants made the sagittal correction difficult. With the experience of long-term follow-up of the coronal balance correction through Harrington rods and the bad functional outcomes of the posttraumatic kyphosis, the correction of sagittal balance reappeared to be a hot topic in the past decade. Its importance has grown with the published results in terms of overall quality of life and fusion rate. There is actually also growing evidence that it is not only important to consider the spinal and pelvic parameters in spinal deformity but also in any spinal fusion. Undoing so might lead to unsuccessful outcomes including pain, adjacent segment degeneration, and pseudarthrosis even in the case of short instrumentations.

Imaging

The external aspect of the body and spine shape is unfortunately a bad predictor of the spine and pelvis morphology. Except for some seldom and low-radiating technique preferred in pediatric scoliosis (Moiré bands) that are still used for the bracing follow-up of scoliosis, X-ray is the gold standard for the evaluation of the spine morphology and pelvis parameters. The technique is called conventional or digitalized teleradiography and is a widely used technique. Morvan et al. [1] proposed a standardized way for imaging of the sagittal spinal balance. The distance between the subject and the 30*90 cm vertical cassette should be more than 2.5 m. An attenuation filter should be used over the cervicothoracic area. Mean parameters are 90 kV/100 mA for the lateral view and 70 kV/160 mA for the frontal view, which means a quite high X-Ray dose. In order to be able to evaluate the patient balance and to decrease the artifacts due to the projection of the humerus on the spine in the lateral view without modifying the spine shape, the following parameters for the evaluation of sagittal balance are commonly recommended: the patient is asked to stand in an erect position, looking horizontally, both feet on the same alignment, 20–25 cm between the 2 ft, upper arm fingers tip on the clavicle. This technique is preferred over the technique where arms rest on a vertical support because the height of the support can influence the overall patient's sagittal balance. In order to be able to assess the bending compensatory mechanism of the knees, we must visualize the patient from skull base to the 10 cm upper part of the femurs. The conventional radiographs can be digitalized and analyzed with some dedicated softwares [2, 3]. Several constructors propose digital systems where the X-ray tube and the receptor translate vertically. The patient positioning is in both cases the same.

Nobel prize winner in 1992, G. Charpak, developed a high sensitive xenon particle detector. In the EOS® system (Biospace, Paris, France) two of these detectors are mounted on a C-arm and scan all or part of the patient's body. This allows for

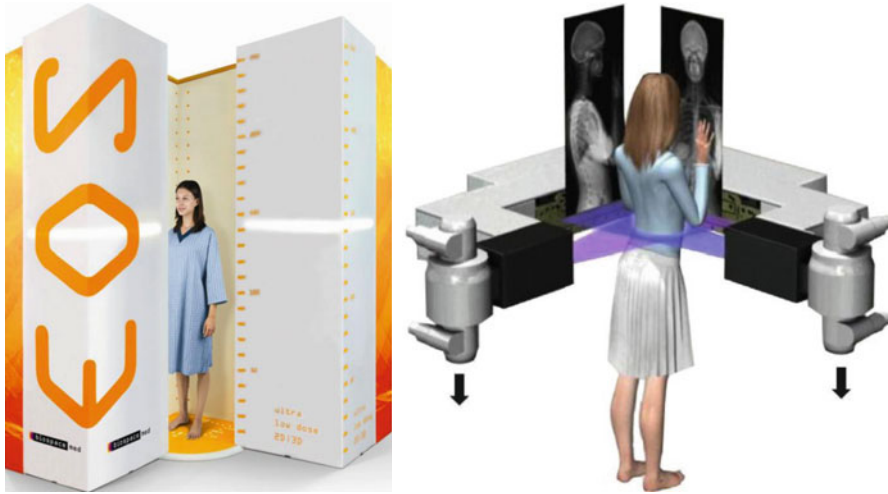


Fig. 1 EOS system and principle of scanning acquisition

frontal and lateral X-rays of a patient to be carried out simultaneously. Two variable gain detectors detect line by line an extremely high contrast digital radiograph (>30,000 gray levels), while the dose administered to the patient is 80–90 % smaller as the conventional imaging. Moreover, due to the simultaneous acquisition of sagittal and frontal view, it is possible with appropriate software and a bone morphing technique to construct a 3D bone envelope weight-bearing image of the spine, pelvis, and lower limb. Axial plane is particularly useful to visualize the rotational abnormalities. These features, and particularly the low radiation dose, the absence of parallax distortion, and the ability to assess a 3D imaging of the standing patient, represent a real progress in the imaging of the spine (Figs. 1 and 2).

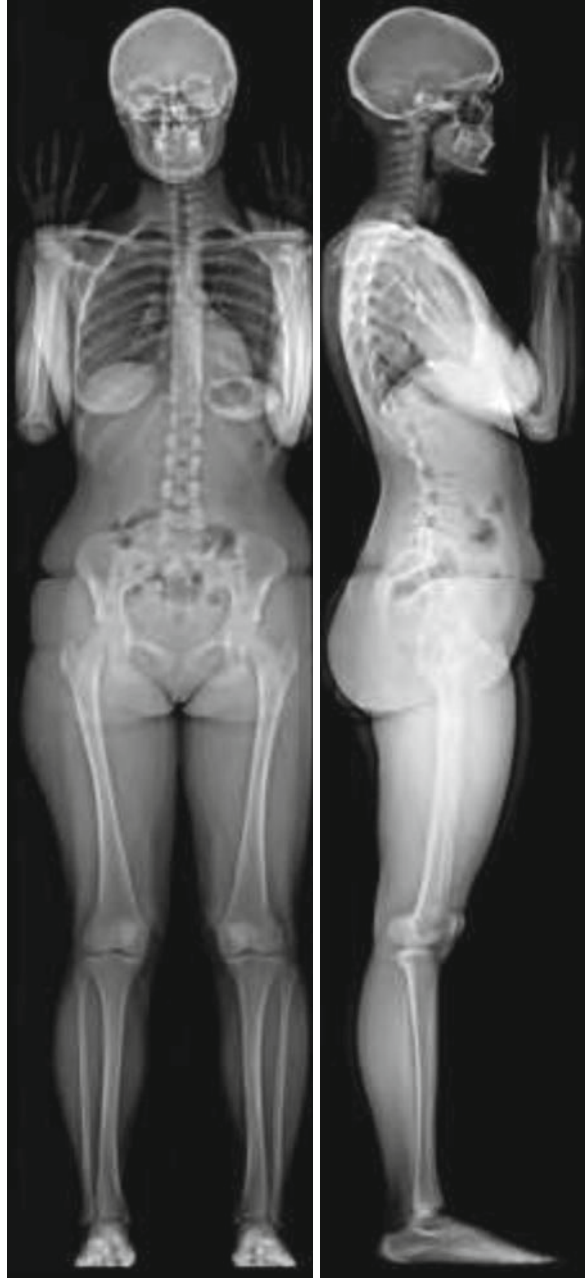
Parameters

Spinal Parameters

Many studies of sagittal balance of healthy and low back pain volunteers have been published in the past [4–8], and the authors have analyzed the standing X-Rays using the Cobb angles technique for the assessment of the lumbar lordosis (LL), thoracic kyphosis (TK), and cervical lordosis (CL). The spinal parameters in standing position are defined as follow:

- *Lumbar Lordosis* (LL): angle between L5 and T12
- *Thoracic Kyphosis* (TK): angle between T12 and T1
- *Cervical Lordosis* (CL): angle between T1 and C1
- *Cobb Angle* (CA): angle between the most tilted endplates

Fig. 2 Example of EOS whole body images



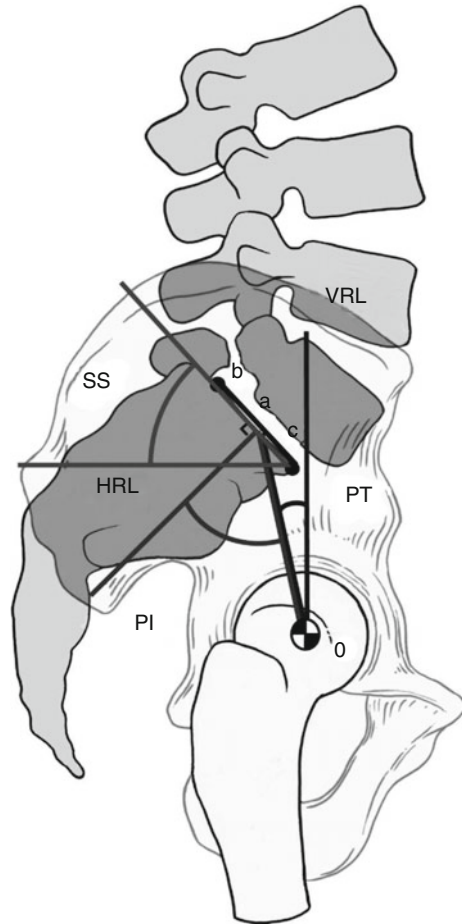
Recently, the division of the spine into the three spine segments (cervical, thoracic, and lumbar) has been contested [9]. Roussouly and Pinheiro-Franco [10] proposed a functional segmentation of the spine curve in the sagittal plane, where the

limits of the curves are defined by the point where the orientation of the curves changes. As a consequence, there can be short and long lumbar lordosis, when the lumbar curvature extends to the lower thoracic area for instance. The contribution of each lumbar vertebra increases progressively from L1 to S1, therefore 2/3 of the overall lordosis is shown in the lower lumbar spine L4–S1 [11, 12], which is a crucial parameter to take into account when instrumenting the lumbar spine.

Numerous authors have considered the center of C7 as the crucial point of the global sagittal balance [5, 9–11, 13, 14], also because it can easily be seen on long sagittal X-rays.

- *C7 plumb line (C7PL)* is often defined as the horizontal distance between a vertical line originating in the center of the C7 vertebral body with respect to the posterior-superior corner of S1 [5, 13–15]. Some authors refer to it as the horizontal distance between C7PL and the center of the femoral heads (negative value if anterior to the femoral heads and positive value behind). Kuntz et al. [15] have noted in their review of the literature that the C7PL parameter was a stable, reliable index of the sagittal balance, being maintained in narrow ranges for alignment of the spine over the pelvis and femoral heads. The vertical line originating in the center of C7, also called *sagittal vertical axis (SVA)* and often misnamed as the C7PL, describes the cumulative balance of the sagittal curves of the spine. In a population with balanced spine the C7PL is generally located at the level or behind the posterior edge of the sacral endplate [16]. Instead of measuring the linear distance and in order to reduce magnification effects through imaging, some authors [11, 17, 18] advice to use the spinosacral angle or ratio parameters: *C7PL-sacrofemoral distance (SFD)* ratio. This ratio is equal to zero when the sagittal vertical axis is exactly on the posterior corner of the sacrum, one when the sagittal vertical axis projects exactly on the bicoxofemoral axis, it is negative when the axis is posterior to the sacrum, and more than one when the axis is anterior to the femoral heads. In the normal population the value of this ratio is -0.9 ± 1 [11]. Bridwell [19] defines normal sagittal balance, which he defines as the C7PL within 6 cm of the posterior-superior corner of the S1 body.
- *Spinosacral angle (SSA)* is an angle between the center of C7 to the center of the sacral plate and the sacral plate line itself. It quantifies the kyphosis of the whole spine. In the normal population the mean value of SSA is $135^\circ \pm 8$ [16].
- *Gravity line (GL)*: the location of the body's center of gravity with respect of the sagittal spine morphology is considered an important determinant of spinal stability and balance. Historically, authors [5, 13, 20, 21] believed that the C7PL was at the same place in the sagittal plane as a line passing through the patient's center of gravity. Gangnet et al. [22] and Roussouly et al. [9] assessed the center of gravity line by measuring the location of the sum of the ground reactive forces. They showed that the C7PL and the GL are not located in the same position. Since then, assessment of the gravity line (GL) has gained interest among spine surgeons in the evaluation of the global balance in normal subjects [16, 22–24] and in patients with spinal deformity [25–28].

Fig. 3 Sagittal pelvic parameters based on standing radiograph. The pelvic incidence (*PI*) is constant for each person. Sacral slope (*SS*) and pelvic tilt (*PT*) are variable dependent on the version of the pelvis about the hip axis (*O*). *VRL* vertical reference line, *HRL* horizontal reference line (Reproduced with permission from O'Brien et al. [93])



- *C7PL vs GL?* Although *C7PL* and *GL* are parameters of sagittal balance, they measure different aspects of the spinal balance. *C7PL* is a good parameter for the spinal balance whereas *GL* better assesses the global balance. On a technical point of view, *GL* needs dedicated devices, but on the other hand provides information regarding the mechanical stresses sustained by the spine and does not require full spine radiographs.

Pelvic Parameters

Jackson et al. [6, 7] analyzed the pelvic balance (alignment of the sacropelvis over the hips) and characterized the pelvis with the pelvic radius (distance between the center of the hip axis and the S1 reference point) and the sacral inclination (angle between a

vertical line through the posterior-superior corner of S1 and a line drawn parallel along the pack of the proximal sacrum). While few authors still use this technique for assessing the sagittal balance [29], most of the literature is based on the pelvic parameters proposed by Daring et al. [30] and more recently by Duval-Beaupère et al. [31] and Legaye et al. [32]: the pelvic incidence (PI), pelvic tilt (PT), and sacral slope (SS) angles are used to describe the shape and orientation of the pelvis.

These parameters remain actually the most widely accepted and used parameters. They were described by Legaye et al. [32] like this (see also Fig. 3):

1. The *pelvic incidence* (PI), defined as the angle between the line perpendicular to the sacral plate at its midpoint and the line connecting this point to the axis of the femoral heads. It is an anatomical parameter, unique to each individual, and independent of the spatial orientation of the pelvis. The anatomical components involved in the make-up of this parameter are the first three sacral vertebrae, the sacroiliac joints, and the posterior segment of the iliac bone. This parameter could be considered as a constant because it is an anatomical one, independent of the position of the pelvis, the mobility of sacroiliac joint being considered negligible, and independent of the age once growth is completed [33].
2. The *sacral slope* (SS), defined as the angle between the superior plate of S1 and a horizontal line. A vertical sacrum is described by a low value, a horizontal sacrum by a high value.
3. *Pelvic tilt* (PT), defined as the angle between the line connecting the midpoint of the sacral plate to the femoral heads axis and the vertical.
4. The overhang of S1 with regard to the femoral heads commonly also called the *sacrofemoral distance* (SFD) defined as the distance between the bicoxofemoral axis and the projection to this level of the midpoint of the sacral plate. It is expressed in millimeters. A point posterior to the bicoxofemoral axis is considered positive, a point anterior to this axis is considered negative.

These last three parameters reflect the sagittal orientation of the pelvis. A geometric construction using the complementary angles reveals that

$$PI = PT + SS.$$

Studies have shown that these parameters have very low intra- and interobserver variations [34]. Both the spinal and the pelvic parameters are highly interdependent and it is now well-established that there is a strong correlation between the PI and SS and the sagittal curves, especially the LL [30, 32, 35]. In the analysis of standing lateral X-rays of a cohort of 160 asymptomatic young adult volunteers, Berthonnaud et al. [36] have shown that they can be considered as an open linear chain linking the head to the pelvis where the shape and orientation of each successive anatomic segment are closely related and influence the adjacent segment. In fact, any change in one of these parameters induces a change in the others in order to ensure an economical sagittal balance [31]. The only fixed parameter is the pelvic incidence.

Table 1 Definitions of spinopelvic sagittal parameters

Parameter	Definition	Values in asymptomatic adults (°) ^a
Pelvic incidence (PI) ^b	Angle between the line perpendicular to the S1 end plate at its midpoint and the line connecting this point to the middle axis of the femoral heads	48–55
Sacral slope (SS)	Angle between the line connecting the superior end plate of S1 and a horizontal line	36–42
Pelvic tilt (PT)	Angle between the line connecting the midpoint of the sacral plate to the middle axis of femoral heads and a vertical line	12–18
Lumbar lordosis (LL)	Angle from the superior end plate of L1 to the caudal L5 end plate	43–61
Thoracic kyphosis (TK)	Angle from the superior end plate of T4 to the inferior end plate of T12	41–48
C7 plumb line	Distance from a vertical line drawn from the center of the C7 vertebral body to the inferior-posterior corner of the body of L5	<3 cm

^aValues are means from studies including adult subject aged 20 to 85 years who did not have any symptoms or history suggestive of spinal disease

^bStudies evaluating PI in men and women have generally not found a difference in the mean value

Normal Values

Normal values of sacropelvic parameters have been published for pediatric [37], adult [2, 15, 36, 38, 39], and elderly subjects [20]. Boulay et al. [38] and Janssen et al. [39] did not find any significant difference in sacral slope (SS), pelvic tilt (PT), or pelvic incidence (PI) when comparing asymptomatic adult females with males. Hammerberg and Wood [20] evaluated 50 asymptomatic subjects aged 70–85 years and did not find any relationship between increasing age and sacropelvic parameters of balance and morphology, but they suggest that the mean PT and PI in their study were higher than those observed previously in younger adult populations. Mac-Thiong et al. [33] study presents the largest cohort of asymptomatic adults without spinal pathology in the literature dedicated to the evaluation of sagittal sacropelvic morphology and balance. Their study specifically describes the age- and sex-related changes in sacropelvic morphology and balance in 709 asymptomatic adults without spinal pathology. In normal adults, PI is expected to fall between 48° and 55°, PT between 12° and 18°, and SS between 36° and 42. Values outside those ranges could potentially predispose to the development of spinal pathology (Table 1).

Analysis and Interpretation of the Pelvic Parameters and Values

The whole pelvis can rotate around the femoral heads, increasing PT when it rotates backwards (retroversion) and decreasing in anteversion. Both PT and SS are position parameters and the rotation of the pelvis around the femoral heads

axis is one of the best mechanism of regulation of the sagittal balance [41]. Mac-Thiong et al. [42] suggested in the analysis of the large cohort that the non-pathological upper limit of PT would be ideally <50 % of PI. Since SS cannot be negative in the erect position, the retroversion is limited by the value of PI. Pelvic incidence is mentioned above as a fixed and determined parameter. The lower PI values are around 30°, which implies a vertical position of the pelvis and a short pelvic ring with femoral heads just below the sacral plate [41]. Patients with a low PI have therefore a small capacity to compensate their sagittal imbalance through pelvis retroversion and are more prone to spinal pathologies. On the other hand, patients with high PI need a big LL to be balanced and are more prone to post-fusion problems related to an insufficient lordosis in the instrumented segments.

The pelvic orientation will affect the entire sagittal profile of the spine. Stagnara et al. [17] demonstrated the strong relation between the lumbar lordosis and the tilt of the sacral slope. More recently, Duval-Beaupère et al. [31] showed that lumbar lordosis to be proportional to sacral slope. Global spinal balance involves harmonization with overlying lumbar lordosis and thoracic kyphosis [36]. The TK tends to increase with age and shifts the C7PL anteriorly [24] and leads to a small retroversion increasing PT to keep the body center of gravity line in position slightly behind the femoral heads [16, 24].

Sagittal Balance and Quality of Life

Many studies [19, 43–48] have shown that spinal sagittal balance is an important determinate of quality of life. In particular, patients with fixed sagittal imbalance tend to expend more energy in gait and standing position and have pain. Glassman et al. [44] have shown that positive sagittal balance (defined in the study as C7PL anterior to the posterior-superior corner of S1) in the adult patient with a spinal deformity negatively impacts quality of life. They compared multiple radiographic measures in 298 patients and evaluated their health related quality of life (HRQOL) with different scores: Scoliosis Research Society-29 Index, SF-12, and Oswestry Disability Index (ODI). They demonstrated that sagittal balance is the most important and reliable radiographic predictor of clinical health status. Patients with positive sagittal imbalance reported worse self-assessment in pain, function, and self-image domains, whereas coronal imbalance correction is unlikely to result in a significantly better clinical outcome.

In a review of 73 patients with adult scoliosis, Mac-Thoing et al. [47] confirmed this. They measured the C7PL and assessed the GL with a device that calculated the center of pressure from the ground reaction forces during X-ray acquisition (Patent pending, FASK Biomechanics Laboratory, Minneapolis, MN). Their study confirmed that the sagittal spinal balance measured from the C7PL with respect to S1 >6 cm was correlated with poor ODI scores (>34) and that sagittal GL >6 cm was also associated with higher risk of having a poor ODI.

Role of Sagittal Balance in the Development and Treatment Strategies of Spinal Pathologies

The restoration of sagittal spinal balance has been directly related to improvement of pain and function after spine surgery [6, 44, 46, 49, 50]. Therefore, it is important for spine surgeons to realize that fusion of any mobile region of the spine limits the ability of the spine to adapt to any sagittal imbalance and may result in an increased risk of fixed sagittal imbalance. Regardless of the disease process, pelvic retroversion is a sign of unbalanced spinopelvic alignment and all attempts should be made to promote a LL consistent with patient's PI [51, 52].

Degenerative Disease

The analysis of sagittal balance appears to be an essential step in the management of lumbar degenerative diseases, especially when a fusion is planned [32, 36, 50, 53, 54]. Several studies have addressed the sagittal parameters in the low back pain population [6, 53, 55, 56]. Their data suggest that patients with low back pain have a more proximal and smaller lordosis (LL 56.3° vs 60.9°), a vertical sacrum (SS 47.2° vs 50.4°), and more hip extension. They present similar C7PL and TK as the control population, reflecting the compensation mechanisms used to balance the spine.

Berrey et al. [57] evaluated the pelvic parameters in 85 patients with lumbar degenerative disease: disc herniation (DH), degenerative disc disease (DDD), and degenerative spondylolisthesis (DSPL) and compared their sagittal balance parameters with age-matched control asymptomatic patients. They showed that DH and DDD patients had a normal PI value; whereas patients with DSPL had a significantly greater PI than the normal population. SS was significantly diminished and PT increased for the three diseases. Concerning the spinal parameters, all three diseases presented significantly less LL and an anterior translation of the C7PL. Only DH and DDD patients had less TK. A flat back with significant reduction of both the LL and the TK therefore characterizes DH and DDD patients. These changes are both structural due to the loss of disc height and postural secondary to the research of an analgesic posture. The compensatory mechanism for the loss of LL is a retroversion of the pelvis [6]. Rajnic et al. [56] already proved this in patients with DH, showing a straight spine and a significant decrease in the LL and the SS.

Aono et al. [58] confirmed the role of an increase of PI in the development of DSPL in a 12-year prospective study, following 142 healthy perimenopausal women. The incidence of newly developed DSPL was 12.7 % and a multivariate analysis showed that high PI was an independent predictor of DSPL. This significant increase of the PI in patients with DSPL tends to suggest that the shape of the pelvis is the main predisposing factor for DSPL and shows the impact of the sagittal profile in pathogenesis of the degenerative spondylolisthesis.

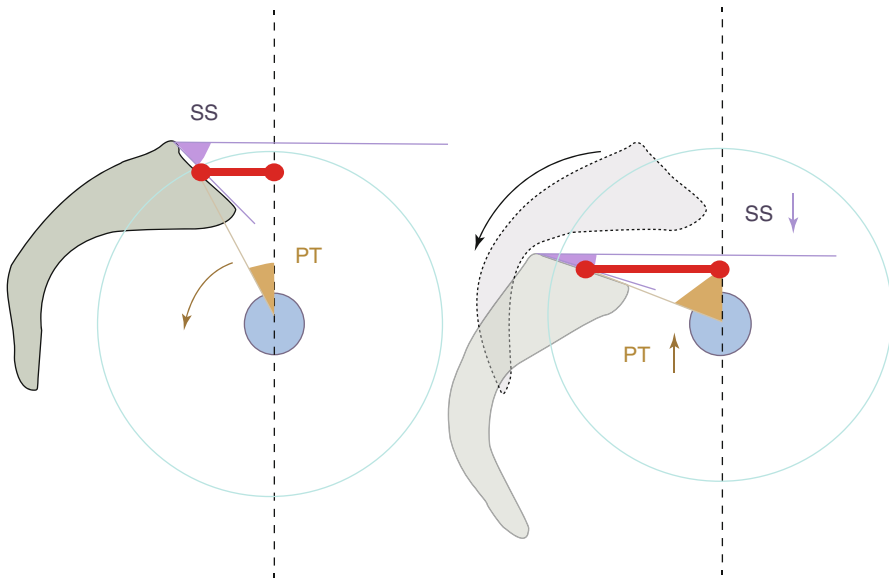


Fig. 4 Pelvis back tilt mechanism. Increase of pelvis tilt results in posterior placement of sacrum related to the coxo-femoral heads thus increasing the sacro-femoral distance (*red lines*)

Compensatory Mechanisms

Recent studies [50, 54, 59, 60] have shown that it is important to assess the sagittal balance before planning surgery for lumbar degenerative pathologies. It is important to recognize the different compensatory mechanisms in order not to underestimate the surgical correction needed. Barrey et al. [18] reviewed the compensatory mechanisms of sagittal unbalance described in the literature.

In the spine area, the first compensatory mechanism is the reduction of the thoracic kyphosis that limits the anterior translation of the axis of gravity. This leads to a flat spine and is possible for younger patients with mobile spine and more markedly in patients under 45 years old [56, 57]. As already mentioned above, low back pain patients tend to have less distal lordosis, a more vertical sacrum and a more proximal lumbar lordosis [6, 53]. This loss of lordosis is compensated by either multi- or unisegmental hyperextension predominantly at the upper lumbar spine. This mechanism is efficient to place the vertical spinal axis posteriorly, but generates lots of stress on the posterior elements and exposes to the risk of retrolisthesis. Moreover, the posterior spine muscles trying to restore some lumbar lordosis become rapidly painful, contributing to the overall back pain [61].

The next compensatory mechanism is the posterior tilting of the pelvis. This results in a more posterior placement of the sacrum and so increasing the sacro-femoral distance, again limiting the anterior shift of the vertical spinal axis (Fig. 4). Lots of studies [6, 53, 55, 57, 62] have shown that low back pain patients are characterized by a lower SS and higher PT. These patients might appear globally

balanced but at the cost of a pelvic retroversion. It is therefore important to recognize these patients in order to restore the appropriate lordosis to fit the pelvic parameters especially if instrumentation is planned [50, 61]. Some studies provide formulae to calculate the “normal” PT for a given pelvic PI [35, 63]. Mac-Thiong et al. [42] suggested that the non-pathological upper limit of PT is ideally under 50 % of the PI.

Compensatory mechanisms take also place in the lower limbs by a knee flexion [60, 64], evaluated by the pelvi-femoral angle defined by Mangione and Senegas [65] or the femoral shaft angle [66] (see below).

Planning Surgery for Degenerative Pathologies

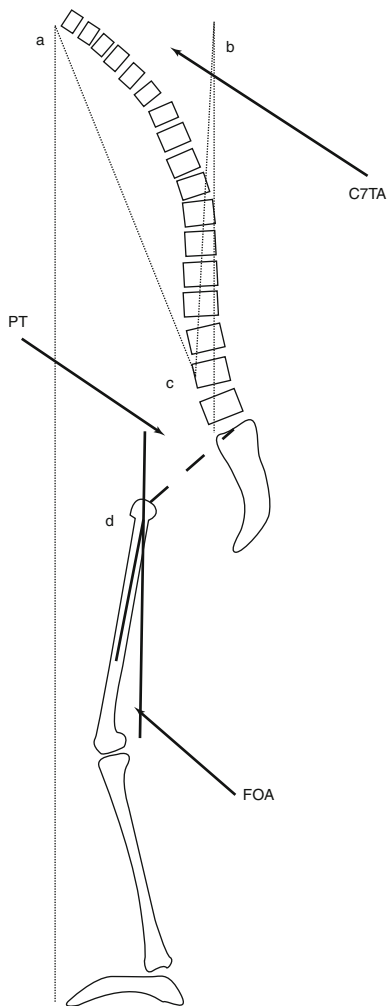
The main problem in the daily practice is to determine how much correction a patient needs to maintain or to correct its sagittal balance. Many studies [40, 67, 68] have insisted on the importance of restoring adequate LL, even for short instrumentations, to avoid a fixed sagittal imbalance (FSI), also known as flat back deformity. As mentioned above, the overall spine shape will adapt to pelvic morphology mainly PI, mostly through LL but also through the adaptability of all other spinopelvic parameters [32, 69]. Legaye and Duval-Beaupere [52] showed that patients with high PI needed greater than normal LL for optimal sagittal balance and may be more vulnerable to any loss of LL. In order to assess the needed correction when planning a surgery, Le Huec et al. [66] proposed a simple method: the full balance integrated technique or FBI technique. Three angles are needed (see Fig. 5):

- *Angle of C7 translation (C7TA)*: In order to restore a global balance, the C7PL must be translated vertically over the sacral endplate. The actual position of C7 is a, the future position over the sacral endplate is b. The C7TA is the angle between these two points and the tip of the L4 vertebra (point c). L4 is chosen since it is the apex of the lumbar lordosis in a normal population [63].
- *Angle of femur obliquity (FOA)* is measured as the inclination of the femoral axis to the vertical. This angle shows the compensation mechanism of knee flexion and is easily measured on a total spine X-Ray if the first 10 cm of the femur shaft are seen.
- *Angle of tilt compensation (PTCA)*: in order to take the compensation mechanism of pelvic retroversion into account and to keep the evaluation as simple as possible, the authors [66] proposed the simple following rule: if the PT is between 15° and 25°, PTCA = 5°; if PT is >25° PTCA = 10°.

The overall correction is then: FBI angle of correction = C7TA + FOA + PTCA.

To achieve this angle of correction, various techniques can be used, depending on the amount of correction needed. Multilevel anterior release and interbody fusion can be used to correct a flexible sagittal imbalance [68, 70, 71]. TLIF or PLIF procedures can be used to enhance lumbar lordosis [72]. For fixed sagittal imbalance, more demanding surgeries are needed to achieve adequate restoration of the sagittal

Fig. 5 Preoperative planning. *C7* translation angle: *C7TA*. Midpoint of *C7* inferior plateau (*a*) is translated on the plumb line ascending from the mid part of the *S1* plateau (*b*). Point *c* is on the anterior cortex of the selected vertebra for osteotomy, which is mainly *L4* vertebra. Femur obliquity angle: *FOA*. Femur flexion is measured as the angle between the femoral axis and the plumb line (*d*). Pelvis compensation angle: *PTA*. Pelvic tilt is measured as usual: line between center femoral head to mid part of *S1* plateau and vertical line. If *PT* between 15 and 25: add 5°. If *PT* superior 25° add 10°



balance. Interpedicular osteotomy often called Smith-Peterson Osteotomy implies resection of the laminae, the facets, and ligamentum flavum. This creates a 1-cm gap that is closed down by compression of the screws to shorten the posterior column and provides a 8°–10° correction per level [66]. An anterior cage, located as anteriorly as possible, guarantees the best long-term correction.

To achieve bigger correction, a pedicle subtraction osteotomy should be considered. This technique was originally described by Scudese et al. [94] for rigid anterior and posterior columns such as in ankylosing spondylitis. This technique permits a correction through all three columns from a posterior approach, thereby maximizing the healing potential. The correction is from 24° to 35° in the lumbar spine, depending on the technique used and 25° in the thoracic spine [19, 73].

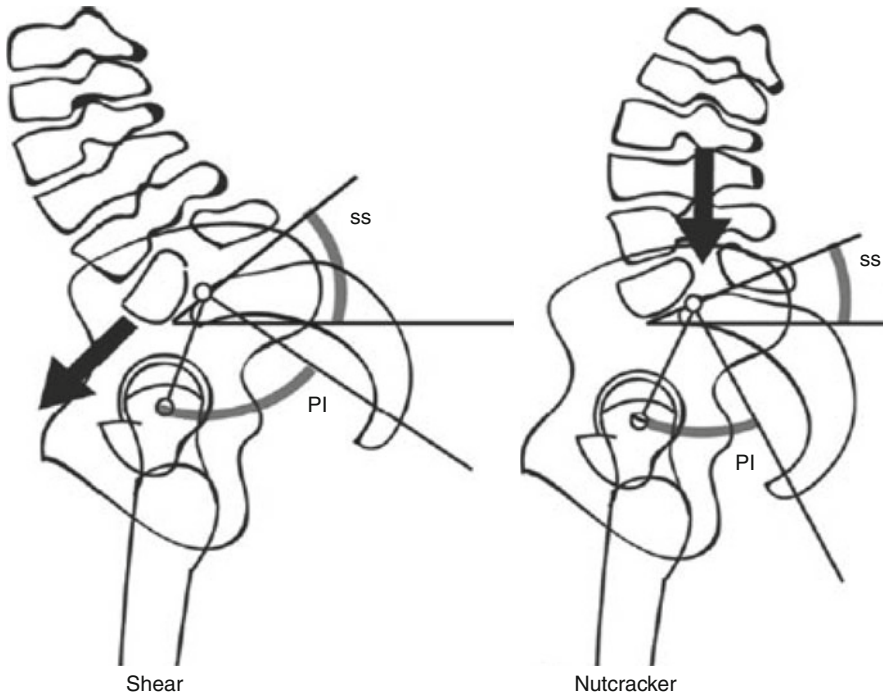








Fig. 6 The shear and nutcracker spino-pelvic postures reported by Roussouly et al. [80] in low grade spondylolisthesis

Isthmic Spondylolysis and Spondylolisthesis

Many studies [51, 74–84] have addressed the relationship between spondylolisthesis or isthmic spondylolysis and sagittal balance. They showed that an elevated PI was related to the development, the progression, and the severity of spondylolisthesis. Roussouly et al. [80] analyzed 82 patients with low-grade spondylolisthesis. They reported two subgroups, patients with a high PI and high SS that provokes high shear stresses at the lumbosacral junction, the “shear type.” The other subgroup present with a low PI and a smaller SS leading to an impingement of the posterior elements during extension, causing a “nutcracker” effect on the isthmus at L5 (Fig. 6).

Recently, the Spinal Deformity Study Group proposed a classification of spondylolisthesis based on spinopelvic posture [79]. The degree of slip is first assessed (<50 % or ≥ 50 % slip) and then the sagittal balance is measured with the PI, SS, PT, and C7PL (Fig. 7). For low-grade spondylolisthesis (Meyerding grade 1 and 2), three types of sacropelvic balance can be found:

- Type 1: the “nutcracker type” with a PI lower than 45°
- Type 2: corresponds to patients with normal PI values (45° – 60°)
- Type 3: corresponds to the shear type described above with $PI > 60^\circ$

Slip grade	Sacro-peivic balance and morphology	Spinal balance	Type
	Nutcracker ($PI < 45^\circ$)	—	 Type1
Low-grade	Normal pelvic incidence ($PI \geq 45^\circ$ and $< 60^\circ$)	—	 Type2
	High pelvic incidence ($PI \geq 60^\circ$)	—	 Type3
	Balanced (high SS / low PT)	—	 Type4
High-grade		Balanced ($C7 \leq \text{hip axis}$)	 Type5
	Unbalanced (low SS / high PT)	Balanced ($C7 > \text{hip axis}$)	 Type6

PI: Pelvic incidence
 SS: Sacral slope
 PT: Pelvic tilt

Fig. 7 Spinal Deformity Study Group classification of lumbosacral spondylolisthesis

For high-grade spondylolisthesis, the overall balance should be assessed first, using the graph provided by Hresko et al. [82] (Fig. 8). Balanced pelvis patients (low PT and high SS) are grouped in type 4 and unbalanced patients presenting a retroverted pelvis and a vertical sacrum (high PT and low SS) must further be divided in two groups, with a balanced spine ($C7PL > 3$ cm) or unbalanced spine ($C7PL \geq 3$ cm) (Fig. 9). The six types are depicted on Fig. 10. A recent study [85] proved substantial inter- and intraobserver reliability of this classification.

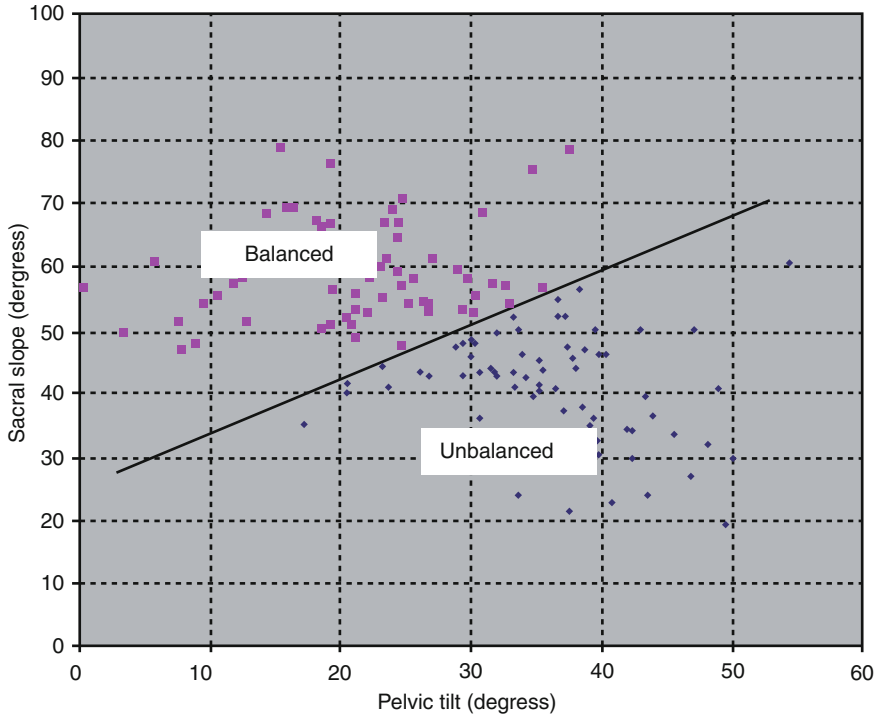


Fig. 8 Determination of sacropelvic balance in high-grade lumbosacral spondylolisthesis (balanced vs. unbalanced sacropelvis). Original scatter plot of 133 patients with high-grade spondylolisthesis with subgroups based on K-means cluster analysis described by Hresko et al. [82]. X axis is pelvic tilt and Y axis is sacral slope. Groups are divided by a line of $Y = (0.844835X) - 25.021$

Treatment Protocol for Spondylolisthesis

Most treatment protocols proposed in the literature have mostly focused on the slip grade. For low-grade spondylolisthesis, surgery is recommended for patients unresponsive to conservative therapy while it is recommended for all high-grade spondylolisthesis. The presence of different pattern of sagittal imbalance in this pathology suggests that the underlying biomechanics involved is different from one type to the other and the treatment protocol should be therefore changed accordingly. The SDSG classification organizes the subgroups of spondylolisthesis in an ascending order of severity and therefore helps to define the surgical strategy. Up until now, there is still debate about the need for reduction in the surgical treatment of spondylolisthesis. Hresko et al. [82] state that this failure to obtain a consensus opinion regarding the role of reduction is due to the lack of sacropelvic balance analysis in the higher spondylolisthesis grades. While no distinction between the SDSG grade 4, grade 5, and 6 has been made in most published studies, the results of reduction gave very variable results. They propose accordingly reduction of the spondylolisthesis in grades 5 and 6 with an unbalanced sacropelvis. Mac-Thiong et al. [83] and

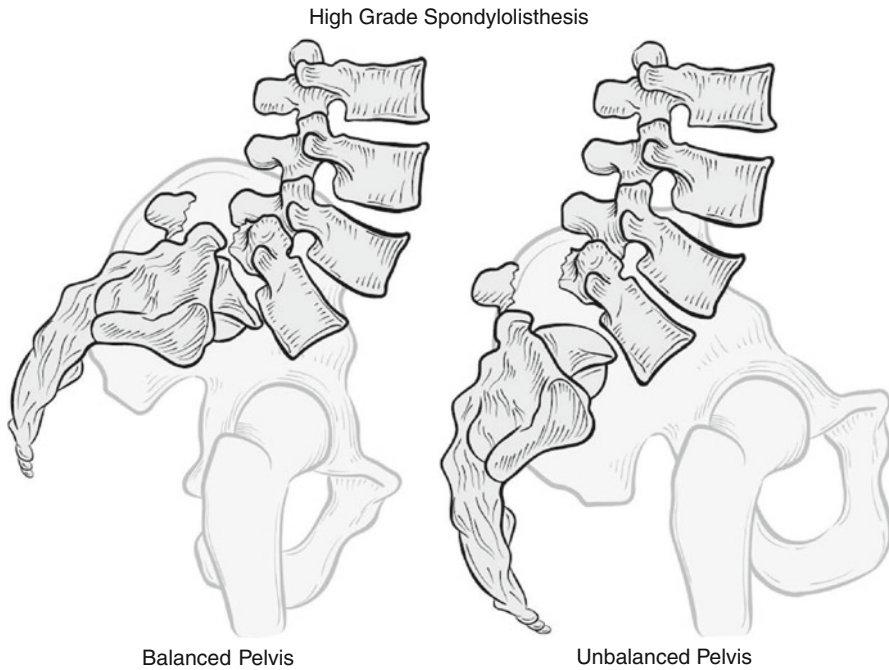


Fig. 9 Sagittal view of spinopelvic alignment in high-grade spondylolisthesis: balanced and unbalanced pelvis (Copyright 2007 Medtronic Sofamor Danek USA, Inc.)

Labelle et al. [86] later confirmed the importance of this subdivision and treatment strategy for grades 5 and 6 were. Outcome studies fail in this field before definitive treatment algorithm for L5–S1 spondylolisthesis, but since the high-grade spondylolisthesis is so heterogenous, the treatment therapy must be adapted accordingly. In summary, Labelle et al. [79] suggest the following treatment strategies:

- Grade 4: Forceful attempts at reduction of the deformity are not required and simple instrumentation and fusion after postural reduction may be sufficient to maintain sagittal balance.
- Grade 5: Reduction and realignment should be preferably attempted, but if in difficult cases simple instrumentation and fusion may be sufficient to maintain sagittal alignment since spinal alignment is maintained.
- Grade 6: Reduction and realignment is mandatory.

Outcomes After Spine Surgery

Fixed sagittal imbalance (FSI) may result from loss of adequate LL after spinal fusion, resulting in positive sagittal balance. Gottfried et al. [40] described the importance of the PI for the development of FSI. In fact, patients with high PI

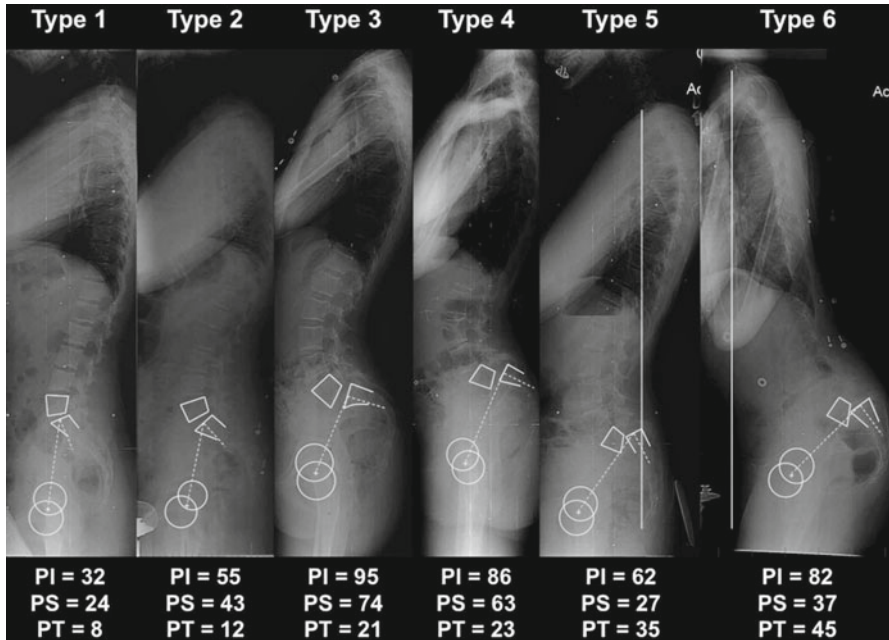


Fig. 10 Typical cases of lumbosacral spondylolisthesis described in the Spinal Deformity Study Group classification. *PI* indicates pelvic incidence, *PT* pelvic tilt, *SS* sacral slope

require greater than normal LL to achieve sagittal balance. Any loss of LL in the instrumentation will therefore be less well tolerated by high PI patients. Patients with high PI will most of the time have a low relative LL even in the presence of normal-appearing LL and are at risk for delayed complications, including implant failure or loosening and adjacent segment degeneration due to the increased sollicitation of the mobile segments. They showed that FSI patient had a typical spinopelvic profile: high PI and PT and low LL and TK compared with aged-matched controls. Kim et al. [49] showed that net kyphosis ($TK + PI - LL$) $> 45^\circ$ was a statistically significant predictor of suboptimal sagittal balance for patients who underwent long spinal instrumentation [87].

Kyu-Jung Cho et al. [88] studied the risks factors of sagittal decompensation in long instrumentation for degenerative lumbar scoliosis. They showed that 42 % of the patients with degenerative deformity would decompensate sagittal balance after long instrumentation and fusion. The most significant risk factor was a preoperative sagittal imbalance ($C7PL > 5$ cm). Their study confirmed that PI was another significant factor, a “normal” correction of the LL in patients with high PI lead to higher sagittal decompensation rate after surgery. Insufficient lumbar correction can also lead to implant failure because of the increase of the posterior tension on the implants.

Park et al. [89] showed the impact of high PI in the development of ASD (adjacent segment degeneration). They evaluated the correlation between ASD and

pelvic parameters in patients with spondylolytic spondylolisthesis and showed that the postoperative PI in patients with ASD (70.8°) was statistically significantly higher than in patients without ASD. They also proved that there was no difference in the degree of postoperative PI in patients without ASD (51.1°) compared to the PI of a healthy population (51.4°).

Ignoring the sagittal profile in primary spinal fusion is shown to be a common reason for revision surgery [90, 91]. Etminam et al. [92] showed that restoration of sagittal balance was highly improving the fusion rate in case of postoperative lumbar pseudarthrosis.

Conclusion

Many articles have stretched over the past few years the importance of maintaining and restoring a correct sagittal balance of the spine. Also this was mainly an orthopedic concern at first, these studies have shown that regardless of the specific surgical treatment or pathology involved, maintaining or rebalancing the spine's sagittal balance results in a positive outcome in terms of stability, fusion rate, and pain. Segmental fusion and short instrumentations as performed by neurosurgeons have therefore to be planned considering the whole spine sagittal balance. Also patients have more means of compensating the sagittal balance in short instrumentations, unsuccessful long-terms outcomes might ensure. Therefore, routine measurement of the sagittal parameters and careful planning of the instrumentation should be done to ensure adequate lumbar lordosis and sagittal balance even in short instrumentations.

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Novel Surgical Approach in the Management of Longitudinal Pathologies Within the Spinal Canal: The Split Laminotomy and “Archbone” Technique: Alternative to Multilevel Laminectomy or Laminotomy

Peter Banczerowski, László Bognár, Zvi Harry Rappaport, Róbert Veres, and János Vajda

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Abstract Multilevel laminectomy to open the spinal canal carries the risk of spinal deformities and instability. With the aim of preserving and reconstructing the posterior structures the authors developed a novel, minimally invasive, multilevel spinous process splitting and distracting laminotomy approach with or without complementary corticocancellous iliac crest or PEEK cage “archbone” grafting. The technique allows exploration of the spinal canal and the removal of intramedullary pathologies. Moderate enlargement of the spinal canal with preservation of the majority of posterior structures is also possible, so that muscle attachments remain intact and postoperative complications are substantially reduced.

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This surgical approach, while fulfilling the requirements of previous laminotomy techniques, helps to prevent damage to the crucial posterior stabilizers of the spine. In contrast to conventional spinal canal approaches, preservation of the majority of posterior structures is possible, leaving muscle attachments on the spinous processes and laminae completely intact.

Furthermore, the procedure for exposure and decompression of the spinal canal is a suitable method for all spinal segments, the cervical, thoracic, and the lumbar spine in all age groups.

Keywords Bone graft • Cage • Intramedullary tumor • Laminotomy • Laminectomy • Spacer • Split • Splitting laminotomy

Introduction

The most common procedure to visualize the spinal canal and remove lesions in and around the spinal cord has been laminectomy [6, 14, 26]. Two major groups of such pathologies are segmental as well as longitudinal. Segmental lesions, like neurinomas and meningiomas (juxtamedullary tumors), or cavernomas and hemangioblastomas (intramedullary lesions) need 1–3 segmental approaches. However, the longitudinal ones, like ependymomas and astrocytomas, require multilevel laminectomy.

According to the literature, multilevel laminectomy may lead to spinal deformities, instability, sUBLuxation, spreading of hematoma, and scar tissue within the spinal canal and loss of the posterior bony protection of the spinal cord [6, 9–11, 20, 22, 29–31]. Postlaminectomy kyphotic deformity is one of the most known long-term complications of the classic dorsal surgical procedures (Fig. 1a, b). The surgical correction of this deformity is difficult and in most cases not curative (Fig. 2).

Several authors have reported on the usefulness of laminoplasty for the removal of spinal cord tumors [6, 18, 23, 24]. Various kinds of laminoplasty techniques have been described with osteoplastic posterior spinal arch reconstruction in tumor removal as well as in degenerative cases [6, 13, 15, 17, 18, 23, 24, 27–29]. The conventional posterior approaches invariably separate the muscle attachments from the spinous processes and laminae [14, 25, 26]. Damage to these muscles and bony connections can lead to persistent axial pain, cervical malalignment, and spinal instability [1, 7, 8, 12, 25]. Other investigators in trying to preserve the integrity of the spinal column and prevent the atrophy of these muscles reattach the extensor musculature [32] or preserve the attachments of the semispinalis cervicis and multifidus muscles [25]. All of these steps extend the inherently time-consuming surgery with additional risks.

To follow the principle of less invasiveness and the simplest preservation of attachments of musculatures, the split laminotomy technique (Fig. 3) for surgery of multilevel lesions located within the spinal canal was introduced by us 11 years ago. The method was first proven successful for pediatric cases [3].

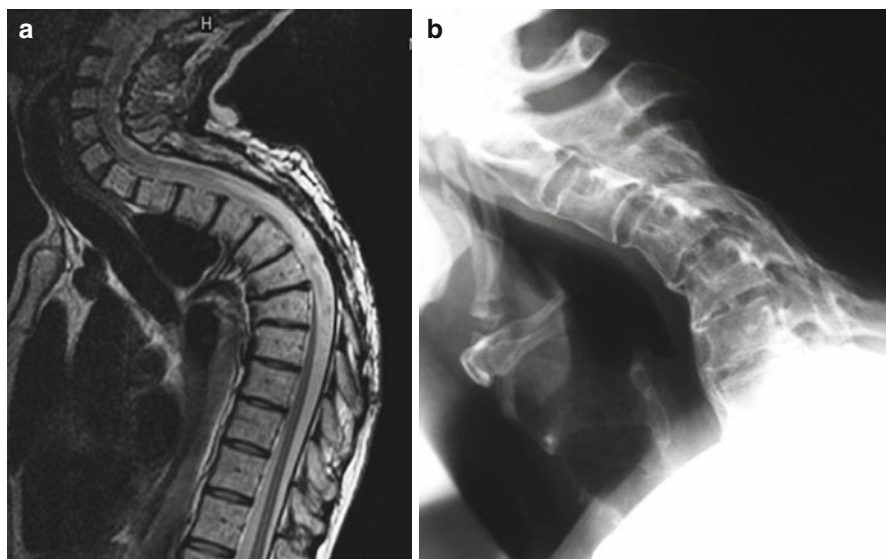
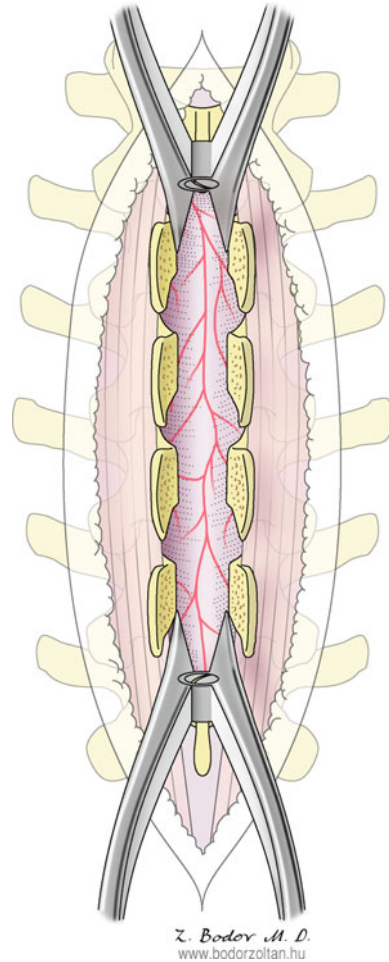


Fig. 1 Sagittal T2-weighted MR image (a) at the cervicothoracic region and lateral view fluoroscopy picture (b) at the cervical region of the spine show the postlaminectomy kyphotic deformity



Fig. 2 Lateral view fluoroscopy picture shows the surgical intervention of postlaminectomy kyphotic deformity at the cervical region. The correction is often difficult or impossible

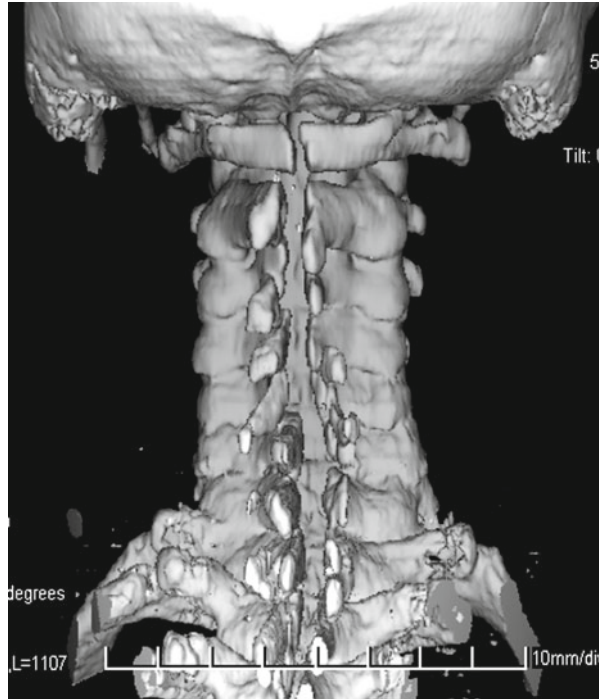
Fig. 3 Illustration of the multilevel split and distracted spinous processes



A multilevel splitting of spinous process and lamina has subsequently been applied to older age groups at our institutes in Hungary and Israel with similar benefits. The distracting laminotomy technique (Figs. 3 and 4) was then developed to explore intramedullary spinal pathologies with the aim of preservation of the functional unity of the main posterior structures. This leaves muscle attachments intact and reduces postoperative complications. It has been shown that the split laminotomy approach is suitable to remove intramedullary pathologies located mainly in the midline [2]. In addition, this method has been applied to other types of spinal diseases, not only for the cervical but also for the thoracic and lumbar regions.

If total resection of an intramedullary tumor is not possible due to infiltration of the surrounding spinal cord or in cases where the regrowth of malignant tumor is to be expected, enlargement of the spinal canal is needed. The multilevel spinous process splitting and distracting laminotomy technique with a complementary

Fig. 4 3D CT reconstruction image shows the multilevel split spinous processes in the cervical and upper thoracic region



corticocancellous iliac crest auto graft between the split laminae was suitable for moderate spinal canal permanent enlargement and decompression (Figs. 5 and 6).

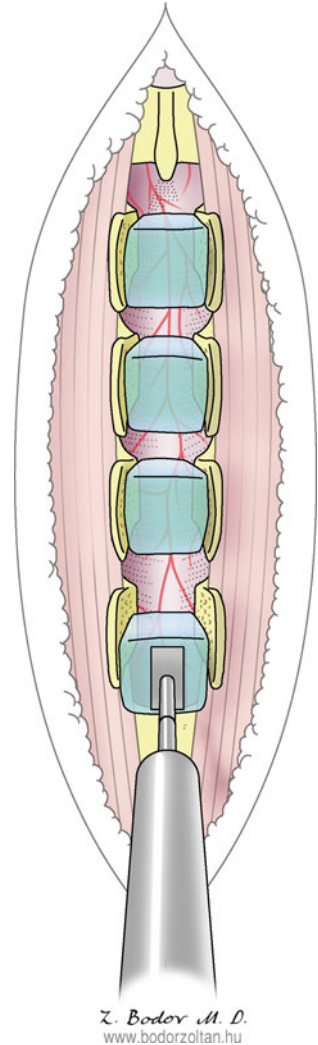
To avoid both short- and long-term bone harvesting area complications, as well as to shorten the time of the surgical procedure, the use of different interbody spacers is widely accepted for spinal surgical procedures. To achieve the necessary enlargement of the spinal canal and decompress the spinal cord, polyether-ether-ketone (PEEK) cages have been implanted between the split laminae (Fig. 7). With the PEEK cage implantation, all of the donor site complications, and the possibility of late-time bone graft resorption or compression are avoided. The bony healing throughout the spacer is similar to the iliac crest bone graft procedure. Solid fusion between the osteotomized parts can be shown at about 12 months after the implantation [21].

Surgical Techniques

1. Spinous process splitting and distracting technique

The patients were positioned either sitting or prone for cervical and prone for thoracic and thoracolumbar procedures. A special midline posterior approach was used. The skin, fascia, nuchal (in the cervical region), and the supraspinous ligament were incised in the midline. The interspinous ligaments and muscles were

Fig. 5 Illustration of the multilevel split and distracted spinous processes with the complementary iliac crest grafts between the facing bony parts of the spinous processes

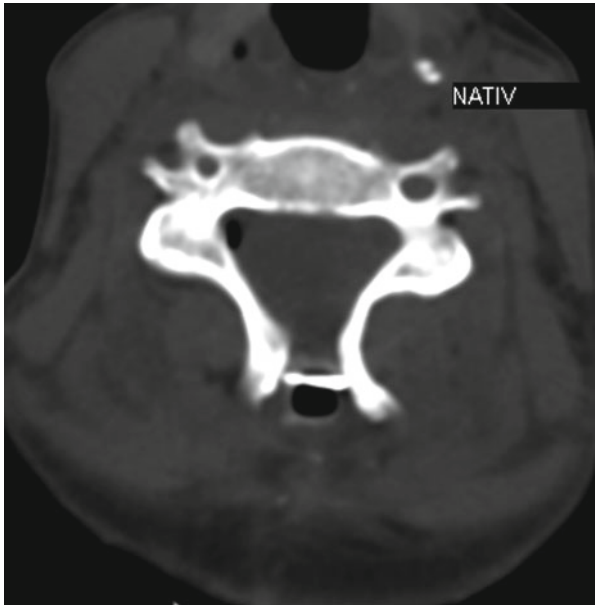


dissected longitudinally between the spinous processes without injuring the attachments of the interspinous muscles; then the ligamentum flavum was removed in the middle part to expose the midline epidural space above and below the intended levels. In some cases, involving the upper and mid-thoracic region of the spinal column, it was necessary to remove a small bony part of the angle of the cephalad vertebral arch in the midline, due to the oblique location of the spinous processes. The spinous processes were split in the midline with an oscillating saw or an extra long (35 mm) craniotome blade (laminotome, GR 004 Zeppelin/Adeor D-82049 Pullach Germany) (Fig. 8a, b). The cut plane of the spinous processes and the laminae were separated and distracted with Cloward-type retractors (Fig. 9). It is important to accurately fit the end of the retractors to the inner cortex

Fig. 6 Postoperative axial CT scan image shows the distracted spinous process and the graft between the facing bony parts in the thoracic region allowing moderate enlargement of the spinal canal



Fig. 7 Postoperative axial CT scan image shows the distracted spinous process and the PEEK cage between the facing bony parts in the cervical region allowing moderate enlargement of the spinal canal



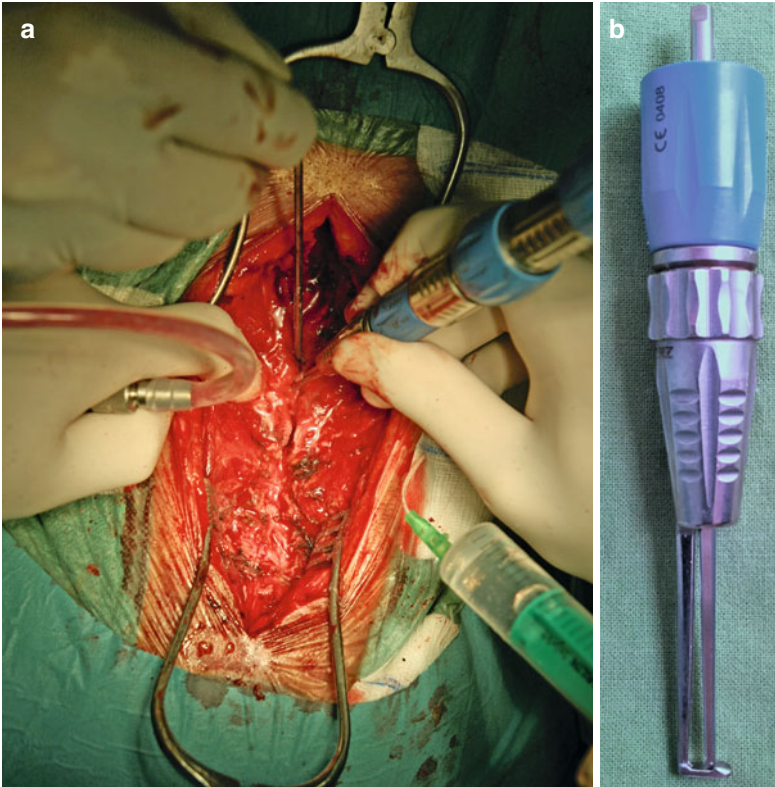
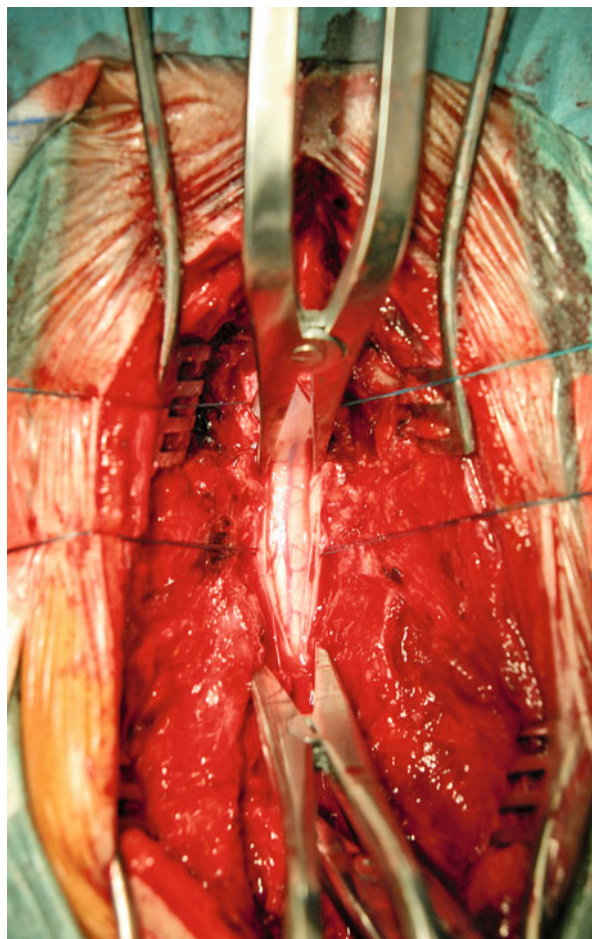


Fig. 8 The intraoperative photograph shows the spinous process splitting in the midline (a) with a specially lengthened craniotome blade (laminotome) (b)

of the vertebral arch immediately above the dura. This is facilitated by visualizing the epidural space and opening the retractor with gentle but progressive force in order to prevent the fracture of the spinous process during distraction. Two retractors were applied for each laminae to help step by step distraction of the bone. All muscle attachments to the spinous processes and laminae and the laminae themselves were completely preserved. In cases of intramedullary lesions, the dura was opened and the pathology was removed (Fig. 10). If the lesion was visible on the dorsal surface of the cord, a longitudinal posterior direct surgical approach was used with one exception. In case the lesion was hiding entirely intramedullary, surgery continued via midline myelotomy.

The same principle was applied for ependymomas and astrocytomas. Debulking of the tumor was performed before searching for a cleavage plane. Tumor resection was continued until the tumor could clearly be differentiated from the surrounding spinal cord (satisfactory surgery). Hemangioblastomas and cavernomas were removed en bloc without debulking and bipolar coagulation was used to reduce blood flow and to shrink the lesion.

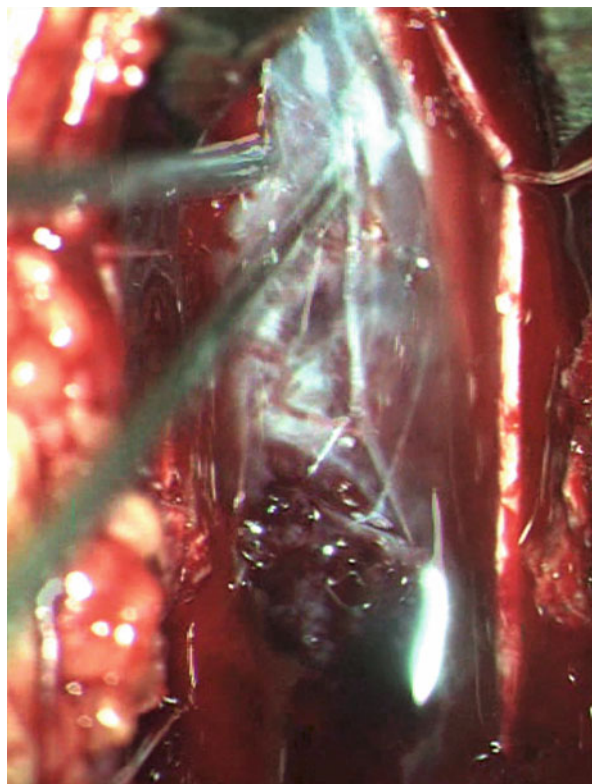
Fig. 9 Intraoperative photograph shows the distraction of spinous processes and laminae by Cloward-type retractors. The separated and distracted laminae open the operating field and after the opening of the dura the dorsal surface of the spinal cord becomes visible



Following removal of the space-occupying lesions, the dura and the spinous processes were closed and the facing parts of the processes were sutured directly to each other (Fig. 11). In cases, where the dural sac did not need enlargement, a simple 5-0 or 6-0 nonabsorbable suture was used still under the operating microscope for a watertight closure.

If tumor histology was malignant or only debulking of an infiltrative tumor was performed, duraplasty was carried out. We used a bay leaf-shaped liodural patch and 5-0 or 6-0 nonabsorbable sutures in a watertight manner under the operating microscope, which was rotated during the sewing process to the appropriate side of the dural edge. The duraplasty proved to be technically difficult and time-consuming across the available operative corridor. In some cases the dura had to be left open and the surface was covered with a dural flap, overlaid with fibrin glue. TachoSil (Nycomed UK Ltd. High Wycombe, HP10 0HH United Kingdom) has recently been used as alternative to duraplasty with excellent

Fig. 10 Intraoperative photograph shows the tumor removal under operating microscope

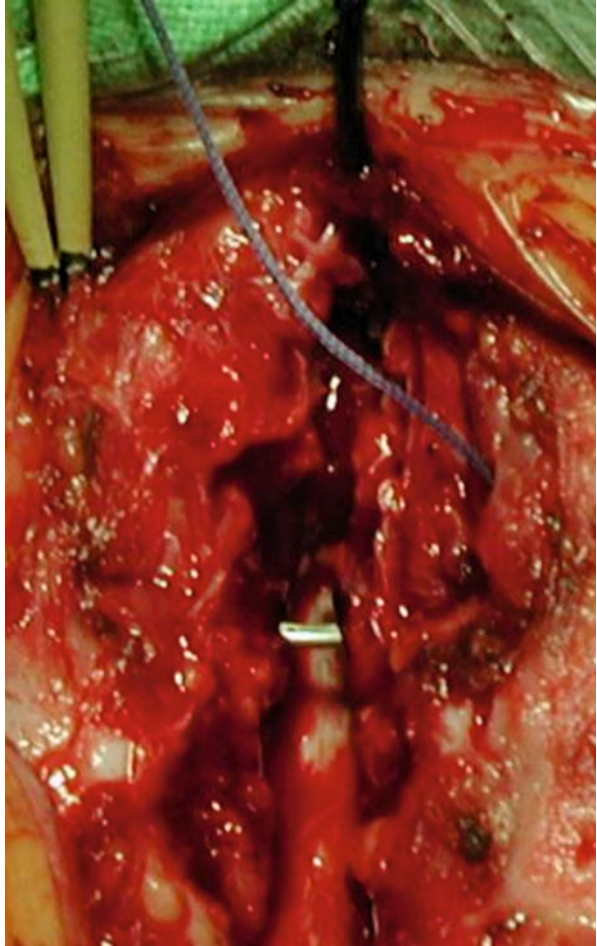


results. In terms of dural decompression, complete closure of the CSF spaces, simplicity, and operating time, this method can be highly recommended.

2. *Spinous process splitting and distracting technique with complementary cortico-cancellous iliac crest autografting*

If total resection of an intramedullary tumor was not possible due to the lack of a recognizable cleavage plane (diffusely infiltrative tumors), a bony decompression was carried out to create more intraspinal space. To avoid the laminae returning to their original position and with the aim of a moderate enlargement of the spinal canal, a tricortical iliac bone graft was placed between the bony parts facing each other (Fig. 6). The space between the distracted laminae was first measured, then the posterior iliac crest was approached and a graft of appropriate size and shape was cut with an oscillating saw, shaped with a drill, and inserted between the osteotomized parts of the spinous processes and underlying laminae in a manner similar to the anterior cervical iliac bone grafting technique, taking care to avoid compression of the spinal cord. Precise insertion and continuous control of the inner edge of the graft during insertion were necessary to avoid penetration of the graft into the spinal canal. The technique resembles the placement of an “arch stone” into the arch of a vault in architecture. We borrowed the concept and modified the phrase to “archbone” for surgery.

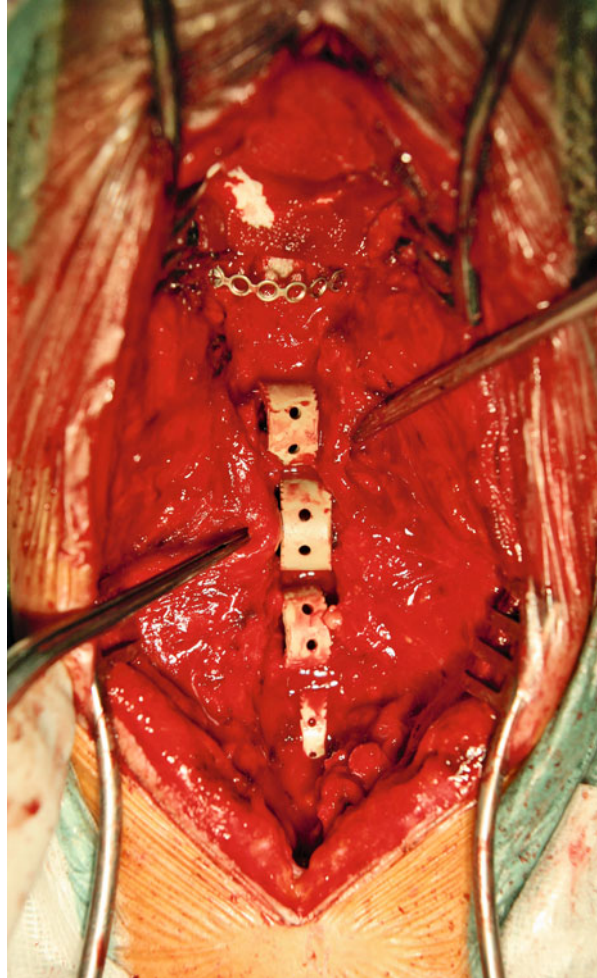
Fig. 11 Intraoperative photograph shows the suture of the facing parts of the processes directly to each other



3. *Spinous process splitting and distracting technique with complementary PEEK cage grafting*

To avoid donor site complications, we slightly modified the surgical procedure in 5 cases, inserting hemostatic gelatin sponge-filled PEEK cages. The SOLIS Cervical Cage (Stryker Spine SAS, Z.I Marticot – 33610 Cestas France) was used. This cage has a D-shaped design, with 4° wedge configuration. It has serrations on the top and the bottom face and incorporates titanium spikes for fixation. The cage is available in two footprints and a variety of heights ranging from 4 to 12 mm. The cage was inserted between the laminae with the plane side of the D-shaped cage facing toward the spinal cord, and the convex side of the cage facing outward (Figs. 7, 12, and 13). The wedge shape of the cage prevents it sliding out, while the serrations at the top and the bottom sides prevent it sliding into the spinal canal. The strong grasping power of the retracted laminae,

Fig. 12 Intraoperative photograph shows the distracted spinous processes and the PEEK cages between the facing bony parts



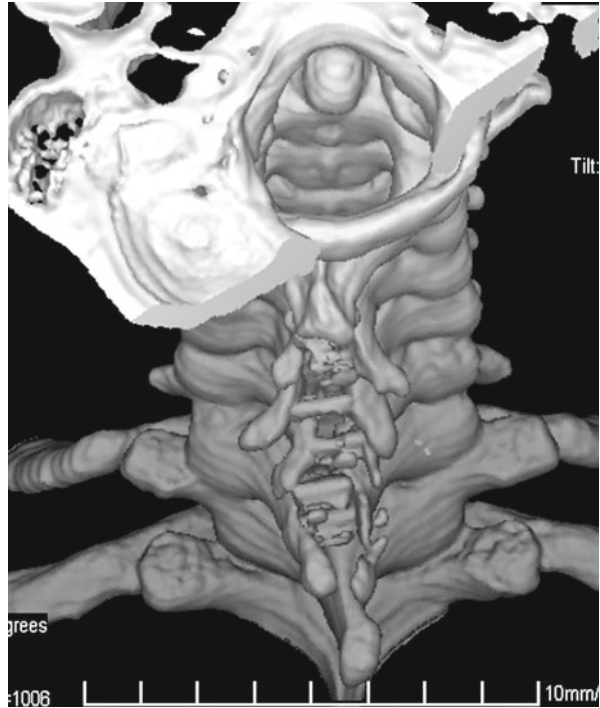
when returning to their original position and the two pairs of titanium spikes, located both sides of the cage, fixed it firmly in place.

After grafting, the Cloward-type retractors were removed. The split spinous processes were sutured to each other with Vicryl (Ethicon, Inc., Sommerville, NJ) by passing the sutures through drilled holes in each half. Finally, the fascia and the skin were closed.

Results of the Previous and Current Studies

The studies carried out in our institutes on the usage and advantages of the split laminotomy approach are summarized below.

Fig. 13 3D CT reconstruction image shows the multilevel split spinous processes in the cervical region with the PEEK cages between the facing bony parts



The method was first shown to be successful in pediatric cases and was published in 2004 [3]. Six children underwent split laminotomy for their spinal lesion. The ages ranged from 1.5 to 7 years. The mean was 3.4 years, and the median was 3 years. The pathologies treated were two tethered cord cases, one ependymoma, PNET, lipoma, and epidural bleeding from a dural arteriovenous fistula. The affected spinal locations included the cervicothoracic, the thoracolumbar and the lumbar regions. The duration of follow-up ranged from 5 to 15 months with a mean of 8.6 months.

Perioperative data of pediatric patients who underwent split laminotomy showed excellent results. The postoperative hospital stay was shortened, early mobilization was feasible, and wound reactions (inflammation signs, pain, limitation of movements, guarding) were none or minimal. The postoperative neurological course showed no complications related to the novel approach to the spinal canal.

Bony changes on control imaging studies were strikingly less traumatic, and in patients younger than 4 years, the signs of the splitting procedure had even disappeared. No alteration in the spinal column alignment could be detected. Split laminotomy prevented the development of kyphoscoliosis in children after intraspinal surgery. It also prevented the development of a myodural cicatrix. Although split laminotomy provided a slightly narrower operative field compared to Raimondi's laminotomy, it was still wide enough for the management of the lesions as well as the spinal cord. With a slight tilt of the microscope (keyhole surgery), dentate ligaments were easily cut on both sides in all cases.

This new technique seemed superior to the previously introduced laminotomy and alternative laminectomy methods since it helped the spinal column to return to its full anatomical and functional status. The midline opening of the spinal canal gave a keyhole approach in which the laminae were not separated from the muscles and the disintegration of the vertebral arch was minimal. Operative time was much shorter than the traditional laminotomy and even laminectomy.

The next study revealed the usefulness of the spinous process splitting and distracting technique in adults was published in *Neurosurgery* in 2008 [2]. The technique were applied with or without complementary iliac bone grafting in 19 adult patients with different pathologies located within the spinal canal (Figs. 3, 4, 5, and 6). The technique is a slightly modified for adults as compared to children [3].

There were nine women and ten men in this series, with a mean age of 48 years (range 32–64 years) at the time of surgery.

The affected spinal location included the cervical in 7, the cervicothoracic in 4, the thoracic in 5, and the thoracolumbar region in 3 cases. The highest number of split lamina was 6. The split spinous processes were closed directly to each other in 13; in 6 cases a tricortical iliac bone graft was placed between the facing bony parts.

The average follow-up was 15.4 months, with a range from 8 to 36 months. One patient was lost to follow-up after 8 months.

Histological results were as follows: 7 intramedullary astrocytomas (Grade I pilocytic astrocytoma, 1 case; Grade II, 4 cases; Grade III, 2 cases), 8 ependymomas, 2 cavernous hemangiomas, 1 multilevel epidural hematoma caused by a dural AVM, and 1 hemangioblastoma.

Surgery was considered satisfactory in tumor cases when the resection was continued only until the tumor could clearly be differentiated from the surrounding spinal cord. In the cavernoma and hemangioblastoma cases, complete removal of the multilevel lesions located within the spinal cord was achieved in all patients. The midline opening of the spinal canal gave a keyhole approach, achieving an adequate view of the intraspinal space for surgery in its entire longitudinal extension. Under the operating microscope the operating field was sufficient for lesion removal (Fig. 10). The practice of tumor removal did not differ considerably from conventional strategies and practice, and surgery through the newly developed approach did not affect the extent of resection. The completeness of surgical removal depended on the cleavage plane in tumor cases and not on the approach.

This technique required a relatively short operative time for the approach. The mean duration of the whole surgical procedure, including intraspinal surgery, was 159 min (range, 90–290). The mean blood loss was only 158 ml (range, 48–442), as detachment of the muscles was avoided. A dural tear occurred in one case when using the oscillating saw for the splitting process, but injury to nervous structures was never observed. After the more frequent use of the laminotome, no more dural tears were detected.

Autograft donor site pain was observed as the most frequent hip graft complication in our limited series. The incidence of postoperative local pain was lower, within acceptable limits, and early mobilization was allowed. The average length of hospital stay was 7.2 days (ranged 5–14).

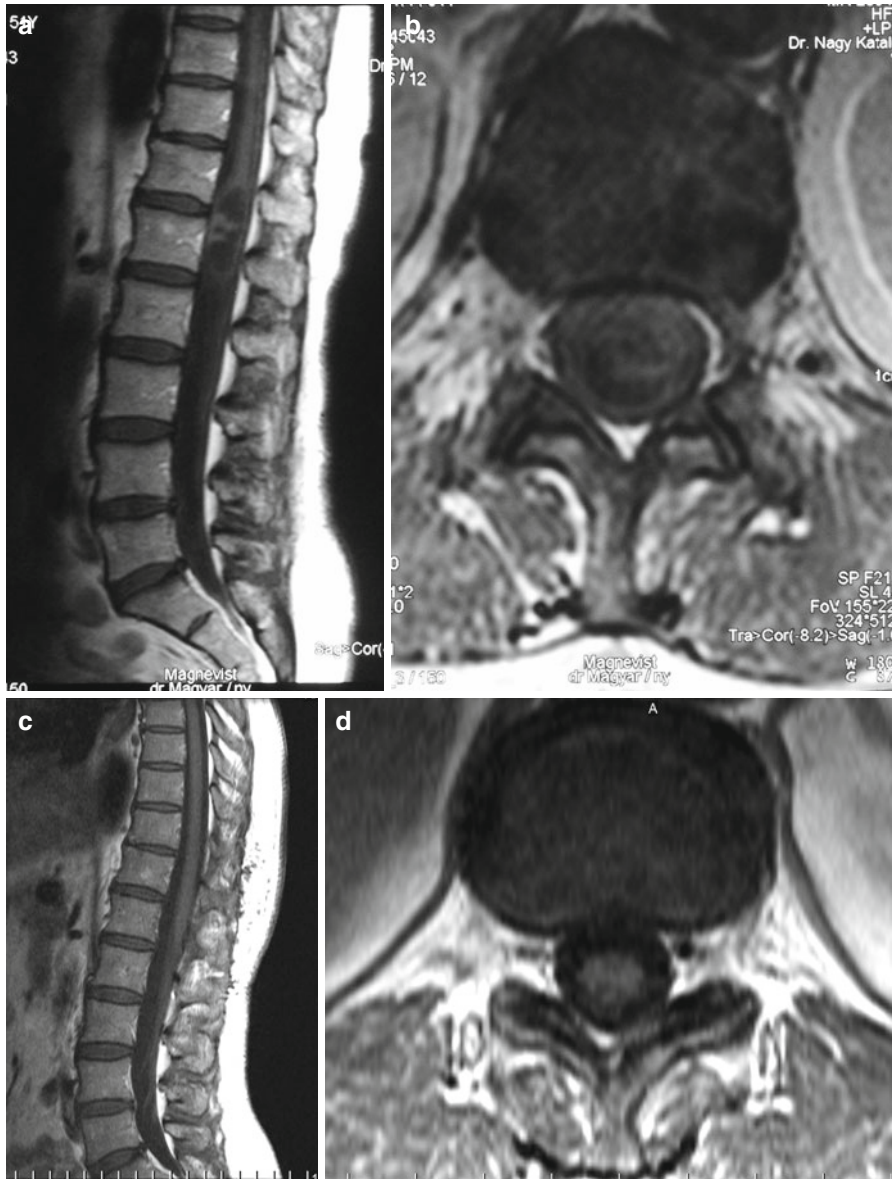


Fig. 14 Sagittal (a) and axial (b) T1-weighted MRI images with contrast material show an intramedullary ependymoma in the thoracolumbar region (D12-L1) before and 1 year after the surgery (c, d). No change of the posterior spinal column elements in their functional integrity

On postoperative neurological follow-up, no complications were related to this novel approach to the spinal canal. To confirm the extent of resection, all patients underwent 2-month postoperative MRI evaluations (Fig. 14a–d). Of the 8 ependymomas, 6

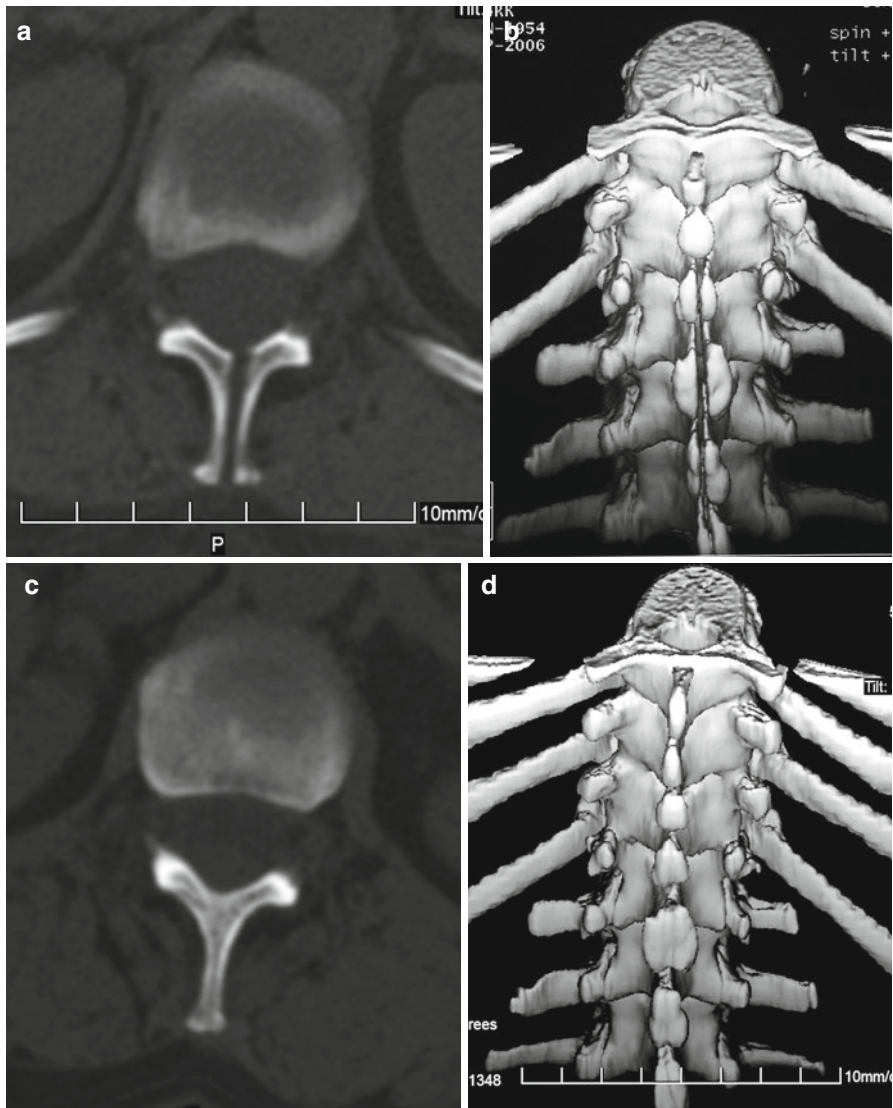


Fig. 15 Postoperative axial CT scan (a) and 3D reconstruction images show the split spinous processes in the thoracolumbar region that were directly closed after tumor removal (b) and the bony healing 1 year later (c, d). No change of the posterior spinal column elements in their functional integrity

(75 %) had been completely and 2 (25 %) partially removed. Of the 7 astrocytomas, 2 (28.7 %) had been completely, 1 (14.3 %) subtotally, and 4 (57 %) partially removed. Cavernomas and hemangioblastoma had all been completely removed.

In 51 of the 57 (89.5 %) spinous processes that were split, bony healing was observed on CT scanning (Fig. 15a–d). Fracture of the spinous process was seen in

Fig. 16 Postoperative axial CT scan shows a traumatic fracture of the body of the vertebra and spinous process without dislocation or hints of functional disintegration



9 (15.8 %) and traumatic bony changes of the body of the vertebra in the midline in three levels (5.2 %) (Fig. 16); these were without clinical significance and showed complete healing at a later imaging. Instability was not detected in any of the patients by flexion or extension lateral radiographs.

The next study demonstrated the usefulness of PEEK cages inserted between the split and distracted spinous processes with an amplified experience in the adult population. It was published in *Biomechanica Hungarica* [21] in 2010.

Multilevel splitting of spinous process and distracting laminotomy technique with or without complementary auto- or allograft insertion were used in 38 (19 cases from the previous study included) adult patients with intramedullary lesions, located in various level of the spinal cord from CIII to LI. The split spinous processes were closed directly to each other in 24 patients (Fig. 15a, b). The number of split laminae was 3–6. In 9 cases a tricortical bone graft (Fig. 6) and in 5 cases a heterologous PEEK spacer was inserted in between the facing bony parts (Figs. 7, 12 and 13).

The average follow-up was 18.7 months, with a range from 7 to 19 months. Histological results were as follows: 15 intramedullary astrocytomas (Grade I pilocytic astrocytoma, n:2; Grade II, n:7; Grade III, n:6), 16 ependymomas, 3 cavernomas, 2 dural arteriovenous malformations, one longitudinal spinal edema following embolization of an intramedullary arteriovenous malformation, and one hemangioblastoma.

Moderate enlargement and permanent decompression of the spinal canal was achieved with the insertion of homologues tricortical iliac crest bone graft or heterologous PEEK spacer. The use of PEEK cages between the osteotomized bony faces required shorter operative time compared to the classic iliac crest bone grafting method.

In our cases the mean duration of the complete surgical procedure was 118 min with the range of 91–145 min. No dural tear occurred in our small series. Injury to nervous structures was not observed.

The incidence of postoperative local pain was lower and within acceptable limits (VAS: 2–5). Furthermore, the patients needed smaller doses of analgesic medications, and early mobilization was possible. The average length of hospital stay was 6 days (range 5–7).

Neither the inserted homologous bone graft nor the PEEK cage with the incorporated titanium spikes disturbed the evaluation of the spinal cord on MRI images. Out of the 15 astrocytomas, four were removed completely, three were removed subtotally, and eight were partially removed. Out of the 16 ependymomas, 13 were removed completely and 3 were partially removed, as confirmed by postoperative MRI scans at 2 months. Cavemomas and hemangioblastomas were completely removed. The complex intramedullary AVM was closed via endovascular microcatheters and an immediate spinal cord decompression by distracting split laminotomy followed so as to prevent devastating spinal cord edema.

Some partial fractures of the spinous process were shown on early postoperative CT scans in all groups, without clinical significance. Instability was not detected in any of the patients by flexion or extension lateral radiographs.

Since the publication of our reports [2, 21], a further cohort of patients underwent split laminotomy to approach longitudinal lesions within the spinal canal with favorable results. Twenty seven cases of intramedullary tumors were explored, 65 % in the cervicothoracic, 35 % thoracolumbar areas. Twenty were ependymomas with radical removal in 16 of them. In the six cases of astrocytoma, all of them underwent a subtotal removal and a distracting decompression of the spinal canal to prevent future increasing intramedullary pressure. One case of hemangioblastoma located in the thoracic segment needed a split laminotomy during this period and could be removed completely. As our experience has grown, operating time has steadily decreased without untoward complications.

Furthermore we no longer hesitate to extend the laminar splitting in order to reach supra- and infra-lesional syrinxes, when presented, as in one case of splitting ten segments (Fig. 4).

Discussion

Multilevel laminectomy for exploring the spinal canal to remove spinal cord lesions involving more levels has the longest history in neurosurgical strategy and still commonly used [4, 14, 26], despite conventional posterior approaches, which may involve multilevel laminectomies and facetectomies, leading to spinal deformities and instability [6, 9–11, 20, 22, 29–31]. These complications should nowadays be unacceptable, especially in the younger age groups with benign intraspinal tumors. These patients have a long life expectancy and will suffer from a significant handicap for the rest of their lives if a postlaminectomy kyphotic deformity develops. The split laminotomy technique prevents this serious complication.

With the aim of preserving and reconstructing the posterior structures and of preventing the frequently reported postoperative complications, various kinds of

laminoplasty techniques have been described [6, 13, 15, 17, 18, 23, 24, 27–29]. Several publications deal with different techniques of reconstruction of the laminar roof, which proved to be a valuable alternative to laminectomy. Investigators often use implants involving increased costs [29].

Kurokawa [17] modified the open-door technique, but because of technical difficulties and the risk of cord injury, it has not been widely accepted [5, 28]. The development of a thread wire saw by Tomita [28] led to further modification of the spinous process splitting laminoplasty technique. The advantages of this technique are that the posterior arch can be reconstructed symmetrically, and there is a low risk of hemorrhage, as fewer veins are located in the dorsal midline epidural space [5, 28].

We used an oscillating saw or in most cases an extra long (35 mm) craniotome blade, named laminotome (Fig. 8) to achieve splitting of the spinous process with no complication. In our experience, the oscillating saw proved to be less advantageous than the laminotome as the control of the edge of the saw blade during the splitting procedure took considerably more time and was less effective.

The literature emphasizes the important role of the deep extensor muscles, especially in the neck. The multifidus and the semispinalis cervicis muscles act as dynamic stabilizers of the cervical spine [19], together with the important static stabilizing structures including the ligaments and intervertebral joint capsules. Once these muscles have been detached, it is impossible to reconstruct the complicated anatomy [25]. The integrity of the nerves is also important, because if they are injured preservation of the muscles becomes meaningless [33]. To minimize damage, a procedure was developed by Shirashi in which the attachments of the semispinalis cervicis and the multifidus muscles to the spinous process are left intact [25].

The spinous process splitting and distracting laminotomy technique fulfills the requirements of other minimal invasive laminotomy techniques, in that it is quick and even less invasive. The operative time is shorter in comparison with the laminar roof reconstruction technique [29] and the transverse placement laminoplasty [6] in intraspinal surgery. However, we believe that this is only partially due to the approach and reconstruction of the posterior structures; it also depends on the duration of tumor removal. The minor blood loss is also comparable with these other techniques [6, 29].

The midline opening of the spinal canal gives a keyhole approach in which the laminae and the spinous processes are not separated from the muscle attachments and disintegration of the vertebral arch and the spinous process is minimal. The intracranial cavity is approximately spherical and it is possible to obtain a good view through one keyhole. On the other hand, the intraspinal cavity is cylindrical and longitudinal, necessitating the “longitudinal extension of the keyhole” for achieving an adequate view of the intraspinal space [16]. Theoretically, the number of vertebral segments involved in the surgical process is unlimited. This method is suitable not only for the cervical but also for the thoracic and lumbar region.

The spinal canal can be opened in this fashion to visualize both sides of the lateral dural curve; the width of horizontal exposure is up to approximately 1.5 cm.

The operative field is restricted compared to laminectomy, but according to the key whole principle, it is still enough under the operating microscope for the surgery of lesions located within the spinal canal, especially of intramedullary lesions. The approach did not affect the extent of resection or the neurological outcome in our experience. It is suitable to remove extra- or intradurally located dorsal lesions and most intramedullary pathologies. The field given by the stepwise in and out positioned spacers is enough to achieve the same quality of watertight closure of the dura as in routine multiple laminectomy.

In children the scope of surgical indications is probably wider, being suitable for lesions located within the spinal canal around the cord, as the elasticity of the spinal arch is much more pronounced, allowing for a wider field for manipulation.

Intraoperative identification of the cleavage plane makes the removal of intramedullary tumors possible. If there is no recognizable plane in cases of infiltrative or malignant intramedullary tumors, tumor removal is not continued at all costs, as this could be dangerous and unnecessary for the patient, in agreement with Brotchi's explanation [4]. If partial tumor removal is performed, bony decompression of the spinal canal is indicated to provide more intraspinal space for the in general gradual growth of the residual tumor while preserving the posterior structures of the spine and the attachments of the muscles.

The approach is not primarily intended for the laterally or ventrolaterally located intradural tumors, confined to one side; the technique has no proven value in these cases, where a dorsal unilateral, partial hemilaminectomy or hemilaminectomy, approach is the treatment of choice in our practice.

The split laminotomy technique can be modified – when enlargement of the spinal canal becomes necessary – by placing a tricortical graft between the facing split bony parts of the spinous process. The degree of enlargement of the spinal canal depends on the elasticity of the arches, the force of distraction, and the size of the inserted bone graft. The compressive force between the closing laminae does not allow the graft to penetrate into the spinal canal after its placement; likewise the compressive force and the sutured split laminae prevent the slipping out of the bone graft as well. Another incision is needed to remove the graft from the iliac crest. This procedure is well tolerated but sometimes can be painful and holds a potentially higher risk for wound infection. Because of the donor site morbidity, it is worth considering the use of heterologous grafts or allografts.

The surgical procedure was modified to achieve the enlargement of the spinal canal by placing heterologous spacers between the facing split bony halves of the spinous process. With this modification of the split laminotomy technique, no iliac crest bone graft needed, and all complications of the graft harvesting procedure are avoided.

Fusion of the grafted iliac bone with the split bony faces and the bony healing of osteotomized faces of the spinous process were seen in most cases (89.5 %) during follow-up. Healthy bone infiltration was detected through the PEEK cages as well. The bony healing between the osteotomy sites was in agreement with findings of the literature in connection with posterior arch reconstructions of the cervical canal in

spondylotic myelopathy cases [28], and with reconstructions of the lamina roof for a posterior approach [6, 29].

To achieve satisfactory decompression for the dilated medulla, one needs to enlarge the dural sac as well. For that, dural patch was sutured over the opened dural edges, but recently Tachosil patch was simply used to gain a watertight covering. In no case were CSF leak or meningocele experienced.

It is more difficult to perform a complete distraction of the spinous process and the lamina in adults than in pediatric cases [2], because the spinal arch is less elastic and more fragile. In the elderly, elasticity is reduced and fractures are more frequent in osteoporotic patients. It is easier to distract the relatively thinner and more elastic arches in the cervical region than in the thoracic or lumbar part of the spine. The final break of the split lamina is easier and more straightforward in children than in older age groups.

Traumatic bony changes can be observed rarely in the body of the vertebra, mainly in the midline, and fracture of the spinous process can also occur. It was observed in around 16 % of the distracted laminae on routinely performed postoperative control CT studies, increasing in frequency with age. If the end of the retractors was not accurately fit to the inner cortex of the vertebral arch immediately above the dura in the epidural space, partial fracture of the spinous processes was more frequent during the distraction.

Theoretically, the compliance and elasticity of the spinal arches, the facet joints, the capsules, and the ligaments together allow enough movement under the distraction process to prevent irreversible damage to these structures. In case of the rarely observed overload distraction, these structures moved together and traumatic bony changes occurred in the midline of the body of the vertebra without clinical significance, only seen on CT.

A wide range of spinal deformities following intraspinal surgery has been reported in the literature. The development of a spinal deformity is a multifactorial process [29]. In our series, no newly developed instability, spondylolisthesis or kyphotic deformity was observed. Although the clinical and radiological results are very promising, the limited follow-up time precludes conclusions regarding the long-term results of the procedure, especially with respect to kyphotic deformity. The bony protection of the spinal canal and the function of the paraspinal muscles were restored, and we observed better cosmetic results in comparison to the laminectomy technique. The minimal invasive splitting laminotomy technique allows the incision to be limited to the immediate region of exploration of the spinal canal, as with this method tissue retraction is minimized and there is excellent access to the affected area. The preservation of the spinous processes and the restoration of the inter- and supraspinous ligament complex maintains the normal posterior median furrow, which is often lost with other more destructive techniques.

Based on our 10-year experience, the technique appears to be safe at all spinal segments (the cervical, thoracic, and lumbar spine), with an acceptable complication rate. Furthermore, it proved to be suitable for removing different, mainly intramedullary spinal pathologies located in the midline.

Our previous papers and presentations on the split laminotomy technique have been received with enthusiasm. It remains to be seen how widely it will be tried and with what experience. Generally it is difficult to estimate how widespread a newly offered method is until papers and reports are presented, but usually they are published when the authors could add something to it. The present authors do not think that split laminotomy is for virtuoso surgeon, but the learning curve takes time similarly to every newly developed method. It is relative simple to perform and gives the usual necessary space to manipulate within the spinal canal. The newly offered procedure has been adopted by several other groups (mainly in Hungary and Israel) with similar results since its first presentation. Wherever this method was tried, to our best knowledge, it has been used ever since, with different levels of dexterity.

The procedure may be more readily adopted in the pediatric age, where the approach is easier and the consequence of laminectomy in a growing child may lead to long-term spinal deformities.

Our modified, minimally invasive, novel technique enables the surgeon to obtain a sufficient field for exploring different spinal pathologies that do or do not require spinal canal decompression, with preservation of the posterior structures of the spine and the attachments of the muscles.

Conclusions

The minimally invasive multilevel spinous process splitting and distracting laminotomy approach with or without complementary iliac or PEEK “archbone” grafting is a safe and effective surgical management, suitable for exploring different longitudinal pathologies located in the spinal canal. The laminae and the spinous processes are not separated from muscle attachments, disintegration of vertebral arches and spinous processes is minimal, and damage to the essential posterior stabilizers of the spine is prevented.

Its major advantage is that unnecessary surgical exposure and tissue trauma, common in cases of longitudinal pathologies in the spinal canal requiring multilevel laminectomies, are reduced. Functional integrity of dorsal structures of the spinal column not directly involved in the pathologic process can be preserved. The operative procedure is safe, much less time-consuming, and simple.

Proposals for the Future

Although considerable experience has been gathered in using split laminotomy with or without distracting decompression technique, data on long-term follow-up in terms of clinical and mechanical consequences are still needed. Is there any age group or type of pathology that benefits more or does not benefit from the enlargement of the spinal canal in the long run? How long is the widened diameter of the

spinal canal preserved? Which distracting material gives the best chances of reopening of the spinal canal if necessary?

Nowadays intraoperative monitoring of numerous neuro-functions has been included in our routine. It seems that studies in this field will significantly lead to better results.

Further development of intraoperative imaging control and of more appropriate instrumentation will play a considerable role in improving surgical efficacy.

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Surgery for Kyphosis

Mehmet Zileli

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Abstract Kyphosis is a difficult topic of spinal surgery, and its management contains many controversies. Surgical management needs consideration of different aspects of the kyphotic deformity such as neurological status, the presence of spinal cord compression, angle of the kyphosis, the quality of bone, and accompanying diseases. In case of significant cord compression and neurological compromise, anterior surgery should have the priority. However, in smooth-angled kyphosis and ankylosing spondylitis patients, deformity can easily be reduced by a posterior-only approach. Since they have no neurological deficits, and large spinal canals, most suitable patients for pedicle subtraction osteotomy are the patients with ankylosing spondylitis.

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In lumbar kyphosis one-level pedicle subtraction osteotomy (especially at L2 or L3 levels), in thoracic kyphosis multilevel osteotomies, and in cervicothoracic kyphosis an osteotomy at C7–T1 level should be preferred.

Pedicle subtraction osteotomy is a technically demanding procedure that requires surgeons to perform meticulous technique and consider biomechanical issues to achieve satisfactory results and avoid complications. An attempt to correct the rigid fixed spinal deformity is a difficult task and requires the capability of a highly experienced spine surgeon. Although the physical outcome and patient satisfaction of surgical treatment is quite good, risks and complications should always be considered by both the physician and patient.

Keywords Kyphosis • Sagittal plane deformity • Ankylosing spondylitis • Pedicle subtraction osteotomy • Deformity correction

Introduction

Kyphosis is a sagittal spine deformity that may cause significant disability, pain, and neurological deficits. Kyphosis may be due to trauma, infection such as tuberculosis, ankylosing spondylitis, Scheuermann disease, degenerative diseases, and osteoporotic compression and iatrogenic reasons usually after multilevel laminectomy.

This chapter aims to review the surgical techniques to correct thoracolumbar kyphosis and diminish the neurological deficits caused by compression of the kyphotic deformity. Cervical kyphosis will not be reviewed in this manuscript.

History

Surgery to correct the kyphosis was possibly first attempted in Pott's disease. In 1945, vertebral osteotomy to correct spinal deformity in ankylosing spondylitis was first introduced by Smith-Peterson [27]. Smith-Peterson and coworkers [27] have reported their results in six patients by applying a single posterior osteotomy and hyperextension of lumbar spine. Postoperatively the patients were placed in plaster immobilization. The results were satisfactory, and patients could stand erect and were able to see ahead.

LaChapelle [16] have performed a two-stage osteotomy for thoracolumbar kyphosis under local anesthesia at L2–L3 level. After removal of posterior elements in first stage, he had performed an anterior osteotomy to place bone grafts into the disc space under general anesthesia 2 weeks later. He then placed the patient in a plaster jacket. Briggs and coworkers [4] and have used similar technique and again without internal fixation.

First articles reporting posterior osteotomy declared a significant incidence of major complications with mortality up to 10 % and paraplegia 30 % [4, 16, 27].

Rupture of the aorta, acute gastric dilation, and superior mesenteric artery thrombosis have also been reported.

Since anterior opening-wedge osteotomies pose a particular risk to rupture or obstruct the aorta [1, 18], Scudese and Calabro [24] have modified the Smith-Peterson osteotomy by removing the disc at the selected level together with the superior portion of the body. They claimed that aortic or inferior vena cava obstruction is less likely by shortening posterior part of the spine and not opening the disc space and anterior longitudinal ligament in front.

Simmons [25] has done osteotomy of the cervical and lumbar spine by using local anesthesia, which allows continuous intraoperative monitoring of neurologic status. However, with recent surgical techniques, the use of general anesthesia, and early mobilization by internal fixations, morbidity and mortality have markedly decreased [5, 11, 13, 19, 20, 23].

In 1985, Thomassen [30] first reported a transpedicular closing-wedge osteotomy in treating ankylosing spondylitic kyphosis. This technique has been widely used for correcting kyphosis of various kinds with good results.

Etiology

There are many causes of kyphosis which are summarized below:

- (a) *Congenital*: Congenital vertebral body and posterior element anomalies, fusion defects, and segmentation abnormalities may result in progressive flexion deformity. Without surgical intervention, the deformity is progressive.

The congenital kyphosis is radiographically classified as failure of formation (Type 1), failure of segmentation (Type 2), and mixed deformity (Type 3) [20, 36, 37].

- (b) *Ankylosing spondylitis*: Ankylosing spondylitis belongs to a group of seronegative spondyloarthropathies. The incidence of the ankylosing spondylitis is estimated 1.4 % of the general population [8]. It goes with remission and exacerbation periods and primarily affects the spine and hip joints causing progressive bone fusion resulting with ossification of the intervertebral disc, narrowing of joints, and osteoporosis and fusion of the spine. Spinal fusion starts from lumbar level and progresses cranially to the cervical spine. Whole spine is now like a long bone and susceptible to fractures. A progressive flexion deformity may result with a disabling kyphosis.

A severely disturbed sagittal contour, loss of horizontal gaze resulting to inability to see the front and especially the sky, and social and psychological isolation are results of severe kyphosis. Besides, respiratory restriction and a higher risk for trauma occur. Although not a strong indicator, HLA-B27 antigen is a test for searching ankylosing spondylitis. Besides, the attachment of sacroiliac joints is an important indicator of the disease. Kyphotic deformity can be measured by the Cobb method and the chin-brow technique.

Trauma in ankylosing spondylitis may also cause kyphosis. Although fractures occurring in ankylosing spondylitis patients are potentially very disabling, even lethal, they may sometimes be unrecognized and cause insidious kyphosis with mild pain. The majority occur in the lower cervical spine and often result in quadriplegia [2, 9, 22, 29, 31].

- (c) *Trauma*: Thoracolumbar fractures and dislocations may result with kyphotic deformity if not properly treated [5]. Kyphosis after trauma may be accepted as a long-term complication which can lead to further deterioration in function and quality of life.
- (d) *Infection*: The most frequent infection causing kyphosis is tuberculosis, or the so-called Pott’s disease. Besides, other infections, primary or iatrogenic spondylodiscitis, may also cause kyphosis in chronic forms.
- (e) *Degenerative*: Degenerative diseases, especially in the lumbar spine, may change the sagittal balance and cause the so-called flat back deformity and sometimes significant kyphosis [12].
- (f) *Postlaminectomy*: Postlaminectomy kyphosis is more frequent in cervical spine. However, especially in pediatric ages, multilevel laminectomies in thoracic and lumbar spine can also cause kyphotic deformity.

Clinical and Radiological Evaluation

From the physician’s point of view, there are mainly two types of kyphosis: (a) kyphosis without neurological deficits and (b) kyphosis with neurological deficits. For a good management planning, the bone density, angle of the kyphosis, age of the patient, associated disorders, and comorbidities should also be evaluated (Table 1).

The normal values of physiological thoracic kyphosis (T2–T12) vary between 30° and 50°. Lumbar lordosis varies between 45° and 70°. The sagittal vertical axis passes 2 cm of the posterior superior corner of S1.

The C7 plumb line is the line drawn perpendicular to the floor from the centrum of C7 body. It must cross from the posterior superior edge of S1 end plate. If the

Table 1 Kyphosis classification

	<i>According to etiology</i>
	(a) Congenital
	(b) Ankylosing spondylitis
	(c) Trauma
	(d) Infection
	(e) Degenerative
	(f) Postlaminectomy
	<i>According to neurological deficits</i>
	(a) Kyphosis without neurological deficits
	(b) Kyphosis with neurological deficits
	<i>According to angulation</i>
	(a) Sharp-angled kyphosis
	(b) Smooth-angled kyphosis

plumb line is anterior to the S1, it is called positive sagittal balance which indicates a hyperkyphosis. If the C7 plumb line is dorsal to the S1, it is called negative sagittal balance which indicates a hyperlordosis.

Spinal deformity can be clinically measured by the “chin-brow technique.” A line drawn from the brow to the chin intersecting the vertical axis would give approximate angle of kyphosis. It is a practical method to measure the angulation clinically without direct X-rays.

Radiologic assessment should include a whole-spine standing direct roentgenogram including hip joints. For evaluation of the flexibility, a flexion-extension view should also be obtained.

With assessment of radiographic images, the site of the primary deformity should be determined. This will be the site of major surgical correction. The amount of bone to be resected at each level can then be measured.

Magnetic resonance images will also be valuable to obtain information about bone density and edema and other abnormalities, such as congenital problems and tethered cord syndrome.

Treatment Planning

Surgical indications are summarized in Table 2. The indications are quite variable and more related with etiology of the kyphosis.

- (a) *Cord compression*: If it causes significant cord compression, the principle of the surgery must be to decompress the apex of the kyphotic deformity. At the same session, deformity correction may also be tried. Kyphosis due to trauma, Pott’s disease, and some congenital diseases are most frequent reasons for kyphosis with neurological deficits.
- (b) *Pain* may be the only symptom in traumatic, degenerative, osteoporotic kyphosis. In that instance, the aim of the surgery must be deformity correction together with fusion.
- (c) *Respiratory problems* are a late complication of severe kyphosis. Surgery should aim to prevent respiratory failure. However, in severe kyphotic cases with significant restriction of respiration, the surgery under general anesthesia will pose significant risk.
- (d) *Deformity* itself can cause significant disability and may be the primary aim of the surgery. Ankylosing spondylitis is a good example to that situation. If the angle of the kyphosis exceeds 75°, patients are not able to see the faces of the other persons when sitting and standing. They cannot walk easily. To correct their sagittal balance, they try to flex their knees and hips.

Table 2 Surgical indications in kyphosis

Neurological deficits—mostly due to sharp-angled severe kyphosis
Pain not responding to conservative treatment
Respiratory insufficiency
Kyphosis exceeding 75°

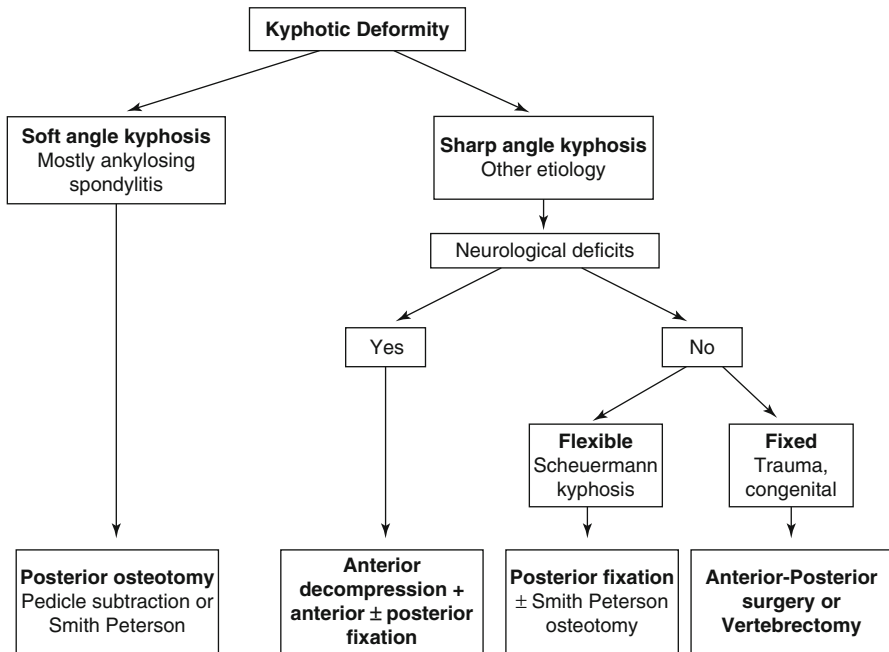


Table 3 Algorithm for surgical management of kyphosis

In general, an anterior surgery is necessary if kyphosis is with neurologic deficits and if the angle of kyphosis is more than 70°. Posterior techniques with osteotomy is necessary, if there is a long curvature kyphosis, if the short curvature thoracic kyphosis is between 30° and 70°, or if lumbar kyphosis is more than 20°.

Decision making in kyphosis management is not well defined, and there are many options for surgery. Table 3 gives a personal algorithm for surgical management.

General Precautions

Before surgery, specific problems that might result in intraoperative complications should be evaluated.

- (a) *Respiratory function* may be diminished by kyphotic deformity, especially in severe thoracic kyphosis. Besides, ankylosis of the ribs may restrict chest expansion. As a result, postoperative use of a ventilator may be necessary.
- (b) *Intubation difficulty* may pose an important problem especially in ankylosing spondylitis patients. Deformity in cervicothoracic junction and ankylosis of temporomandibular joints are the reasons for that. Fiber-optic intubation may be helpful. In some cases a tracheostomy may be necessary.

- (c) *Nutritional status*: Ankylosing spondylitis patients may have associated ileitis or colitis. The nutritional status of the patient may be worse.
- (d) *Osteoporosis*: Bone density is another condition that must be evaluated well. Geriatric patients and patients with ankylosing spondylitis are prone to diminished bone density. In case of significant osteopenia, special planning of fixation should be anticipated.
- (e) *Hip joints*: If hip joints are ankylosed and a flexion deformity is developed, correction of this problem, i.e., hip replacement, should proceed before kyphosis correction.

Surgical Techniques

In thoracolumbar kyphosis, anterior surgery is necessary mainly for decompression of the spinal cord. If there is no cord compression, posterior-only approaches may be used. However, both for correction purposes and stabilization of the vertebral column, posterior surgery is necessary. Table 4 summarizes the surgical techniques.

Van Royen and De Gast [34] have classified the posterior osteotomies as follows: (1) opening-wedge osteotomy, (2) polysegmental wedge osteotomies, and (3) closing-wedge osteotomy. There is no consensus on the literature of which technique is more suitable for surgery of kyphosis correction.

- (a) *Rod reduction and fixation*: This technique may be applied for more flexible kyphosis, and good candidates are patients with degenerative kyphosis and Scheuermann disease. Rods are first placed on the proximal screws, then the rods are pushed to the distal screws by reducing the hyperkyphosis and connected to the distal part of the construct [19] (Fig. 1).

Kyphosis in Scheuermann disease can be managed by an anterior apical release and fusion before posterior rod compression instrumentation and closing-wedge lamina resection. A report by Johnston and coworkers [13] has examined the necessity of anterior spinal fusion and concluded that a posterior-only surgery with posterior compressive instrumentation with threaded rods is sufficient.

- (b) *Smith-Peterson osteotomy*: This an extension osteotomy and is originally described by Smith-Peterson in 1945. Osteotomies are done by removing the posterior elements completely at the disc level. Then, the spine is extended through the osteotomized segments and disc spaces. It causes approximately

Table 4 Type of surgical techniques in kyphosis

(a) Rod reduction and fixation
(b) Smith-Peterson osteotomy
(c) Pedicle subtraction osteotomy
(d) Combined anterior-posterior surgery
(e) Vertebral column resection
Posterior-only resection
Anterior-posterior resection

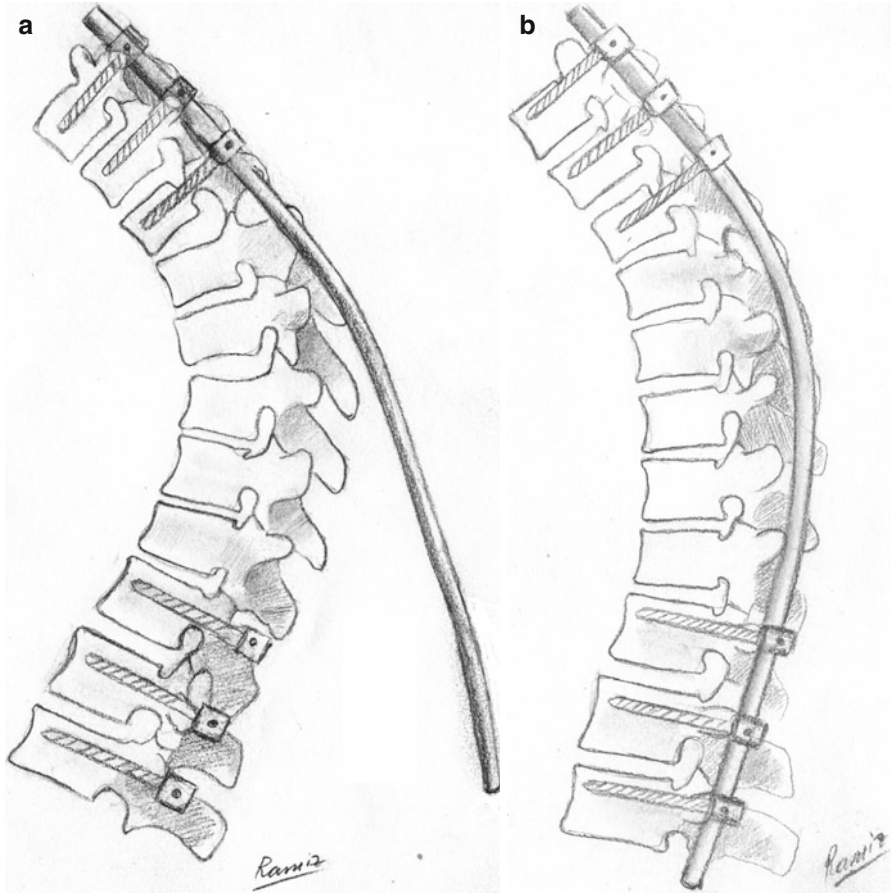


Fig. 1 Rod reduction and fixation technique for flexible kyphosis. The upper and lower segments of the kyphosis are anchored whether by screws or hooks; after placing and tightening both rods on the upper vertebra, rods are pushed ventrally and placed on the lower screws by achieving some kyphosis correction

10–15° of correction at each level (Figs. 2 and 3). The main risk of this technique as originally described is rupture of the ventral part of the disc and anterior longitudinal ligament, resulting to stretching of the abdominal viscera which may cause rupture or obstruction of the aorta. Some surgeons prefer to place anterior strut grafts after posterior instrumentation [16].

- (c) **Pedicle subtraction osteotomy:** This is an approach resecting posterior elements, both pedicles and a part of the body in a wedge style (Fig. 4). The main advantage is that the whole procedure can be done by a posterior-only approach.

Thirty to thirty-five degrees of lordosis can be achieved with this technique. If the surgeon expects more degrees of correction, osteotomies must be performed

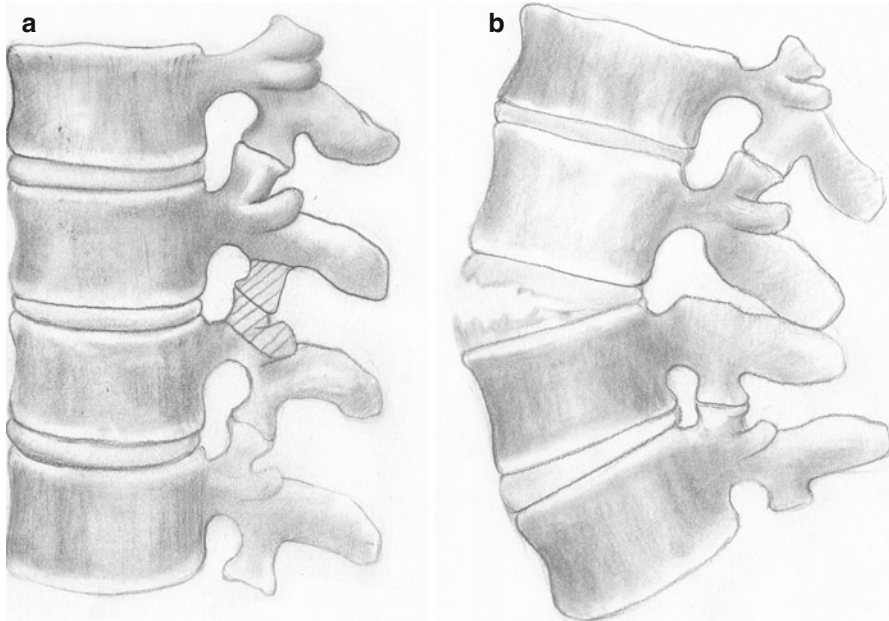


Fig. 2 Smith-Peterson osteotomy in one level. Only a part of the lamina and facet joints is removed, and a kyphosis is reduced by deflection of the table. The ventral part of the disc space opens and even anterior longitudinal ligament may rupture during this reduction

in multiple consecutive levels. For example, 100° of kyphosis may be corrected by three-level pedicle subtraction osteotomy.

The so-called egg-shell procedure is to enter the vertebral body via pedicles and remove spongy bone inside the body by leaving the cortex of the body like a shell of an egg. Then, compressive instrumentation would result in collapse of the body and result with lordosis. This procedure, however, poses a risk that the posterior part of the body may retropulse the spinal canal and cause spinal cord compression.

Pedicle subtraction osteotomy is performed by a careful resection of the posterior elements than decancellation of the body via a transpedicular route. I perform this procedure under operation microscope, remove transverse processes and lateral margins of the pedicle, enter the body using a high-speed drill, and go through till the anterior longitudinal ligament. At last, I push the posterior cortex of the body ventrally and excise the posterior longitudinal ligament. Afterwards, the entire spine is extended through the osteotomy site using deflection of the operating table and sometimes by additional compression of the adjacent pedicle screws on the rod. After closing the gap, the dura must be observed carefully, and any kinking or compression by lamina must be avoided to prevent neurological deficits.

If it is a whole-spine—thoracic and lumbar—kyphosis, correction may be achieved through lumbar osteotomy, and relordosation is accomplished. Thomasen

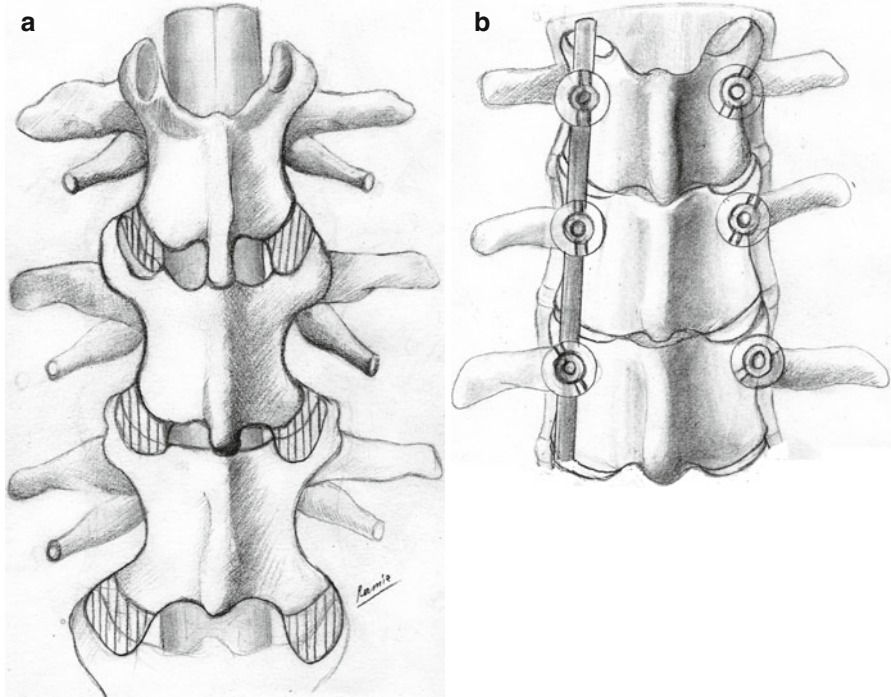


Fig. 3 Smith-Peterson osteotomy in multiple levels. One-level osteotomy cannot provide more than 15–20° reduction. By multilevel osteotomies, more correction in a smooth-angled kyphosis may be achieved

has chosen the L2 vertebra for posterior osteotomy [30]. Although he has used plates and metallic wires posteriorly in some patients, he also has placed the patients in a plaster jacket for 3 months. Simmons [26] has used Harrington compression system for thoracic deformity. With the advent of new pedicle-based internal fixation techniques, plaster jackets have been abandoned today [3, 28, 34].

- (d) *Combined anterior-posterior surgery*: This is advocated in severe deformity with significant compromise to the spinal cord. If a combined anterior-posterior osteotomy is chosen, thoracotomy is performed from the convex site of the deformity. In both approaches a ventral cage with grafts should also be placed.

Anterior strut grafting has also been advocated after Smith-Peterson osteotomy to support anterior column [10, 16]. LaChapelle [16] has first performed a posterior laminectomy and osteotomy under local anesthesia and, 2–3 weeks later, an anterior surgery under general anesthesia and excised the intervertebral disc and applied autologous bone grafts inside the disc space. He then applied a plaster brace for 6 months.

- (e) *Vertebral column resection*: This is the procedure of choice in severe rigid deformities. Although a combined anterior-posterior osteotomy may be chosen

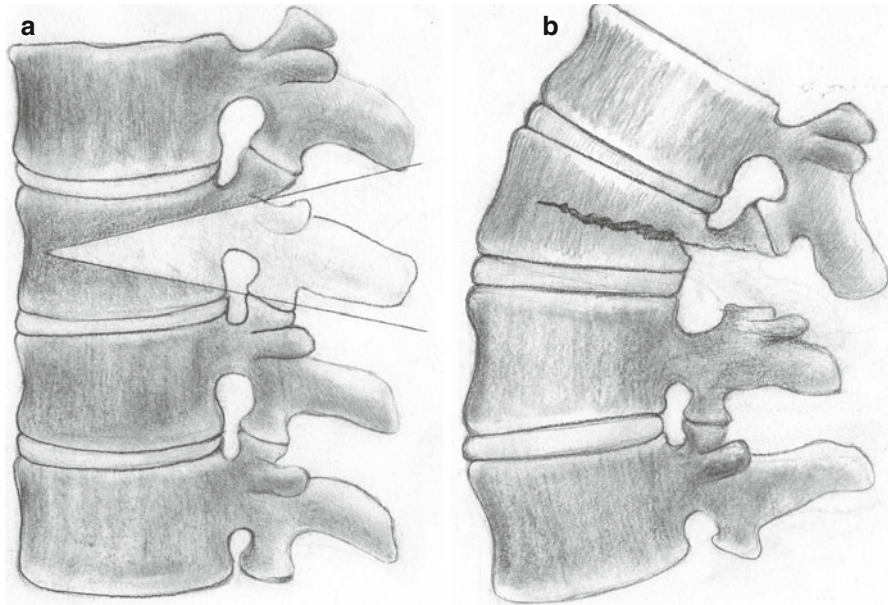


Fig. 4 Pedicle subtraction osteotomy. This technique is done by removing lamina, facet joints, pedicles, and transverse processes on both sides. Posterior part of the body removal is deepened till anterior longitudinal ligament by creating a wedge of the body. I push the hidden posterior cortex of the body ventrally to prevent retropulsion during reduction. This type of osteotomy does not distract the ventral disc or ligament and causes some shortening of the spine. Approximately 30° of kyphosis reduction may be provided in one level

in some instances, deformities 90° or more can easily be handled with a posterior-only approach, since the deformity facilitates it. Some surgeons prefer a circumferential decompression and instrumentation in the same stage [21].

Chen and coworkers [7] have claimed that in severe sharp-angled kyphosis, a shortening procedure will be too risky, and they advocated the resection of the apex of the kyphosis, corrected the segment with two rods, and placed a cage in the resected segment ventrally.

Operative Positioning and Anesthesia

Early reports on posterior kyphosis surgery have used local anesthesia [26]. Smith-Peterson and colleagues have used general anesthesia with the patient lying in the prone position. Adams [1] has performed the surgery with the patients lying on their side.

For cervical osteotomy, Simmons [26] and Law [17] have also used local anesthesia in sitting position on a dentist's chair. Urist [32] has used general anesthesia

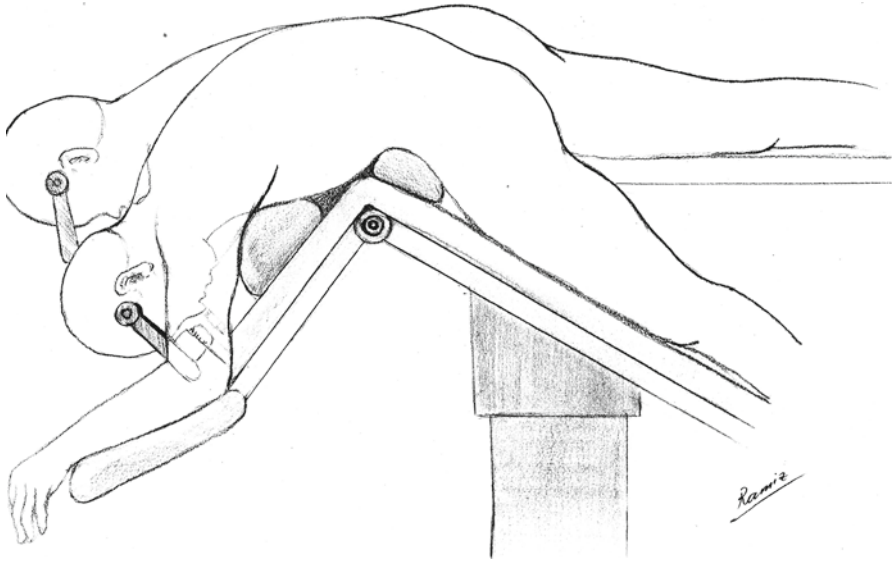


Fig. 5 Positioning of the patient in operating table and correction by deflection of the table

for cervical osteotomy. Two reasons for local anesthesia are observing the neurological function and difficulty of intubation [26].

We always preferred general anesthesia and prone position with three-pin head holder. We seldom used sitting position. The surgeon must be prepared to change the position of the table and correct the deformity after completing the osteotomy (Fig. 5). Although it is advocated to use spinal cord monitoring, we did not use it in any of our cases.

Some surgeons recommend to place a nasogastric tube since the superior mesenteric artery may be stretched over duodenum resulting in gastric dilation [15].

Technical Considerations in Lumbar and Thoracolumbar Junction Kyphosis

Posterior-only surgeries in lumbar spine is easier than thoracic and cervical spine, because the retraction of the cauda equina is possible and reduction is not hard as is thoracic spine with rigidity provided by the ribs. In patients with ankylosing spondylitis, a patient will resume a more erect position, diaphragmatic ventilation will be possible, and compression to the abdominal structures by the edges of the ribs will be reduced.

In smooth-angled kyphosis at the thoracolumbar junction, an osteotomy at L2 level will be sufficient. In lumbar kyphosis, L3 may be the level of choice.

Technical Considerations in Thoracic Kyphosis

The previous reports have tried not to implement reduction of thoracic kyphosis with posterior-only approaches. Simmons [26] has recommended anterior and posterior combined approaches in severe thoracic kyphosis.

It is our intention also to be more cautious at the thoracic levels during correction by a posterior osteotomy. We believe that multilevel pedicle subtraction osteotomies by gaining a 30° reduction at each level and meticulous observation of the spinal cord to be sure that there is no kinking of the dura should be applied.

Simmons has advocated an osteotomy in the midlumbar spine, in case the dorsal kyphosis is associated with a loss of lumbar lordosis or if the thoracolumbar deformity is less than 40° [26]. We believe that in smooth-angled kyphosis involving both thoracic and lumbar levels, the midpoint of osteotomy should be L2.

Technical Considerations in Cervicothoracic Kyphosis

Cervicothoracic kyphosis is a more disabling problem than thoracolumbar kyphosis. The field of vision is severely restricted, and the patient cannot open his/her mouth. Because of excessive loads on craniocervical junction, atlantoaxial subluxation may develop. Dyspnea and dysphagia may happen because of compression of trachea and esophagus.

The first experience of cervical osteotomy is from the 1960s. Urist [32] is the first surgeon performing osteotomy of the cervical spine in 1958. In 1962 Law [17] made an extensive report of this technique. Law has performed osteotomy under general anesthesia at any level below the second cervical vertebra. Internal fixation was done with wire or plates, and then the patient was placed in a Minerva cast.

In 1972, Simmons has recommended cervical osteotomy under local anesthesia and in sitting position because of intubation difficulty [25]. One other advantage of surgery under local anesthesia is the patients report on paresthetic pain along the distribution of the cervical roots and prevent damage to the roots. Another difference from Law's approach is the site of osteotomy which was at C7 or T1. The vertebral artery compromise is unlikely at that level since it enters the foramen at C6 level. Besides, C8 and T1 roots are less eloquent roots and can be mobilized easily. Simmons has not used internal fixation and placed the patient in a halo cast after surgery which was worn for 4 months (Fig. 6).

The technique we use for cervicothoracic kyphosis is a C7 osteotomy. I consider that kinking of the vertebral artery at upper levels may pose a great risk and stretching of C8 nerve roots is unlikely. We choose the prone position and use a Mayfield three-pin head holder. The most difficult part is the intubation of the patient. The difficulty comes not just from the deformity, but also the ankylosis of temporomandibular joints causes immobility. A fiber-optic intubation in an awake patient and using nasal route may be helpful in severely deformed patients.

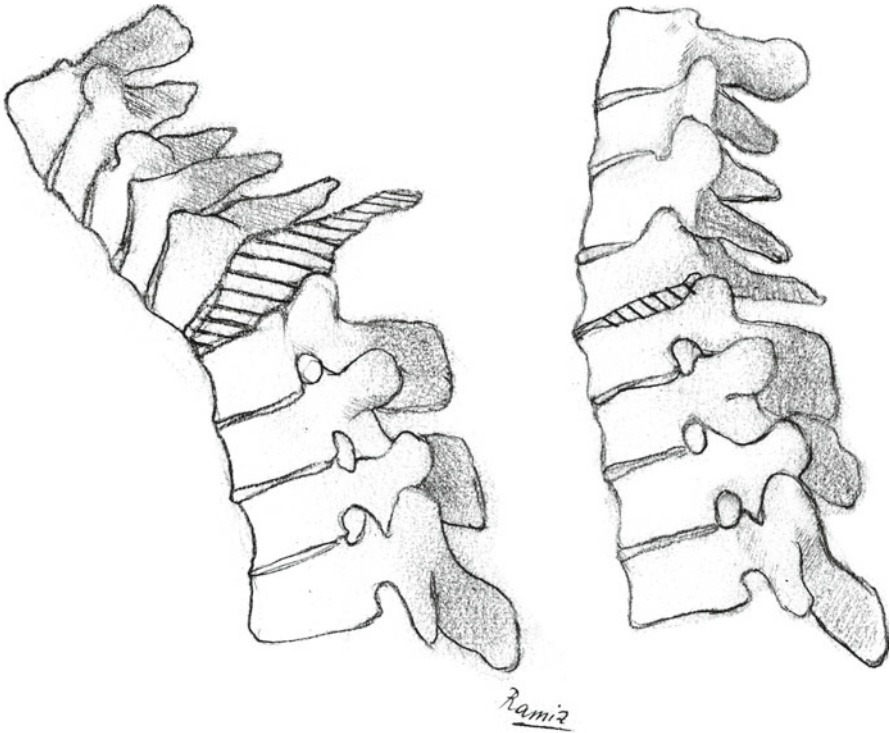


Fig. 6 Posterior osteotomy of C7 vertebra and correction. C7 is chosen since that will not compromise the vertebral artery. Special attention to C8 roots is necessary

After removing C7 spinous process, both pedicles and posterior part of the vertebral body are removed using a high-speed drill. Both C8 roots were mobilized. Then, by holding the head with both hands, the Mayfield head holder is released and the head is extended carefully, and the gap between C6 and T1 lamina is closed. The dura and roots are observed again to be sure there is no kinking and impingement. A posterior screw system two levels up and two levels below is then applied in corrected position. The patient is let to walk the next day using a rigid collar.

Complications and Outcome

There are many reported complications in kyphosis correction:

- (a) *Neurological worsening*: Neurologic compromise could result from spinal cord compression as a result of inadequate decompression [33] or subluxation [10]. In Simmons' series [26] using single-level wedge osteotomy in 90 patients, seven (8 %) developed L3 root or cauda equina compression.

(b) *Aorta rupture and death*: This complication is reported in earlier series with posterior osteotomies causing rupture of the anterior longitudinal ligament that loads stretching forces to the aorta. The first report for aortic rupture in correction of ankylosing spondylitis is in 1956 by Lichtblau and Wilson [18]. Law [17] presented a large sample of kyphotic correction and reported a 10 % risk of death associated with surgical intervention. In patients with ankylosing spondylitis, inflammatory changes may cause the fibrosis of cardiac vessels and the aorta, and the aorta weakens and becomes prone to rupture from aneurysms. There are some other reports describing aortic rupture due to lumbar extension osteotomy during surgery or late after surgery [6, 14, 35].

Besides, by elongation of the anterior column, a stretch of the superior mesenteric artery over duodenum may cause gastric dilation and vomiting [26].

- (c) *Respiratory problems*: This is possible especially in patients with preoperative restriction of the lung capacity.
- (d) *Infection* is a common complication in long-lasting and instrumented spine surgeries.
- (e) *Correction loss*: Loss of correction may happen by many reasons such as inappropriate surgical planning, pseudarthrosis, osteopenia, and smoking.

In a report of 33 patients with lumbar pedicle subtraction osteotomy, Bridwell and coworkers [3] reported that 7 had pseudarthrosis, 2 had acute angular kyphosis, and 5 had transient neurologic deficits whose deficits resolved after central canal enlargement. Overall patient satisfaction was good, and they concluded that the clinical result with pedicle subtraction osteotomy is reduced with pseudarthrosis in the thoracic or lumbar spine and subsequent breakdown adjacent to the fusion. The results with a degenerative sagittal imbalance etiology were worse, and the complications were higher. They found that central canal enlargement is a critical issue in surgical management of thoracolumbar kyphosis.

Ikenaga and coworkers [11] have examined the rate of complications after pedicle subtraction osteotomy in a clinical series and reported 48 complications in 67 patients. There were 6 intraoperative, 4 perioperative (during first 2 weeks), and 38 late postoperative complications. Among late complications, there were adjacent-segment collapse, 8 (12 %); progression of kyphosis without collapse, 10 (15 %); infection, 2 (3 %); pseudarthrosis, 7 (10 %); and instrumentation failure, 3 (4 %). Additional surgery was necessary in 7 patients (10 %).

Personal Series

Between 1992 and 2011, 62 patients with thoracic and lumbar kyphosis were surgically treated. The mean age is 38 (between 6 and 70 years); male/female ratio is 32/30. Etiology of kyphosis were congenital (21), ankylosing spondylitis (13), degenerative diseases (7), trauma (7), infection (4), previous laminectomy (4),

Table 5 Etiology of kyphosis in 62 patients who were surgically treated

Etiology of kyphosis	<i>n</i>
Congenital	21
Ankylosing spondylitis	13
Degenerative	7
Traumatic	7
Postlaminectomy	4
Infection	4
Tuberculosis	2
Scheuermann disease	2
Myelomeningocele	1
Osteoporotic	1

Table 6 The type of surgery performed in personal series

Posterior osteotomy and reduction with pedicle fixation	36
Posterior fixation with interbody fusion	11
Anterior decompression and reduction with fixation	7
Combined anterior and posterior surgery with fixation	8

Scheuermann kyphosis (2), tuberculosis (2), myelomeningocele (1), and osteoporotic compression (1) (Table 5).

There were soft angle kyphosis in 15 patients (cervicothoracic 3, thoracic 3, thoracolumbar 9). Remaining 47 patients had a sharp-angle kyphosis in either cervicothoracic junction (T1, 1 case; T3–4, 4 cases), thoracic spine (T6, 1 case; T7–8 2 cases; T8–9, 1 case; T9, 1 case; T10, 1 case; T11–12, 2 cases; T12, 4 cases; T12–L1, 2 cases; L1, 10 cases), or lumbar spine (L1–2, 1 case; L2, 3 cases; L3, 4 cases; L3–4, 5 cases; L4, 2 cases; L4–5, 3 cases).

The type of surgery performed for this series was posterior osteotomy and reduction with pedicle fixation (36), posterior fixation with interbody fusion (11), anterior decompression and reduction with fixation (7), and combined anterior and posterior surgery (8) (Table 6).

Results: Significant reduction could be achieved in 57 cases. Neurological deficits did not worsen in patients with preoperative deficits. Complications of surgery were hardware failures (5 cases), loss of correction (8 cases), wound problems and local infection (12 cases), and CSF leakage (3 cases). There were no neurological complications. Figures 7, 8, 9, and 10 are some examples from our personal series.

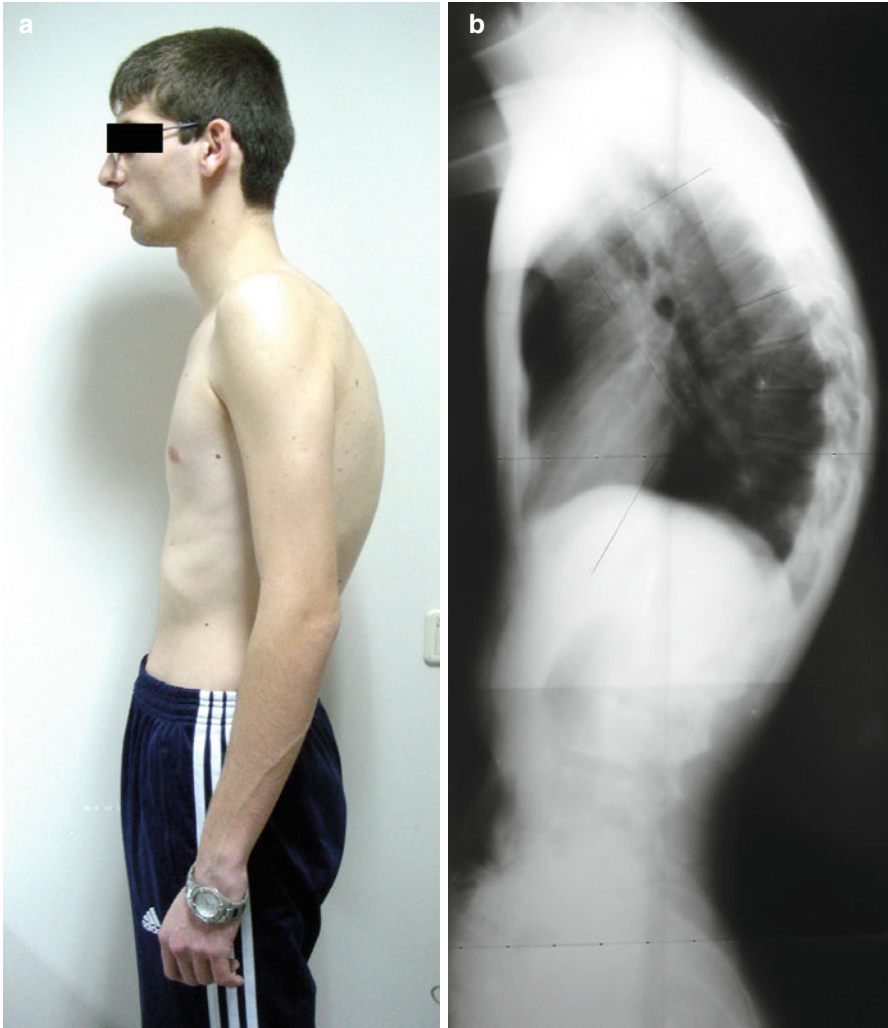


Fig. 7 A 21-year-old male with Scheuermann kyphosis (a, b). Smith-Peterson osteotomies were performed at T6–7, T7–8, T8–9, and T9–10 levels. T2–5 and T9–12 pedicle screw fixations were performed, and a compressive correction on rods was performed through a posterior-only approach (c, d). Postop direct radiographs (e–g) and posture (h) show the reduction of the kyphosis

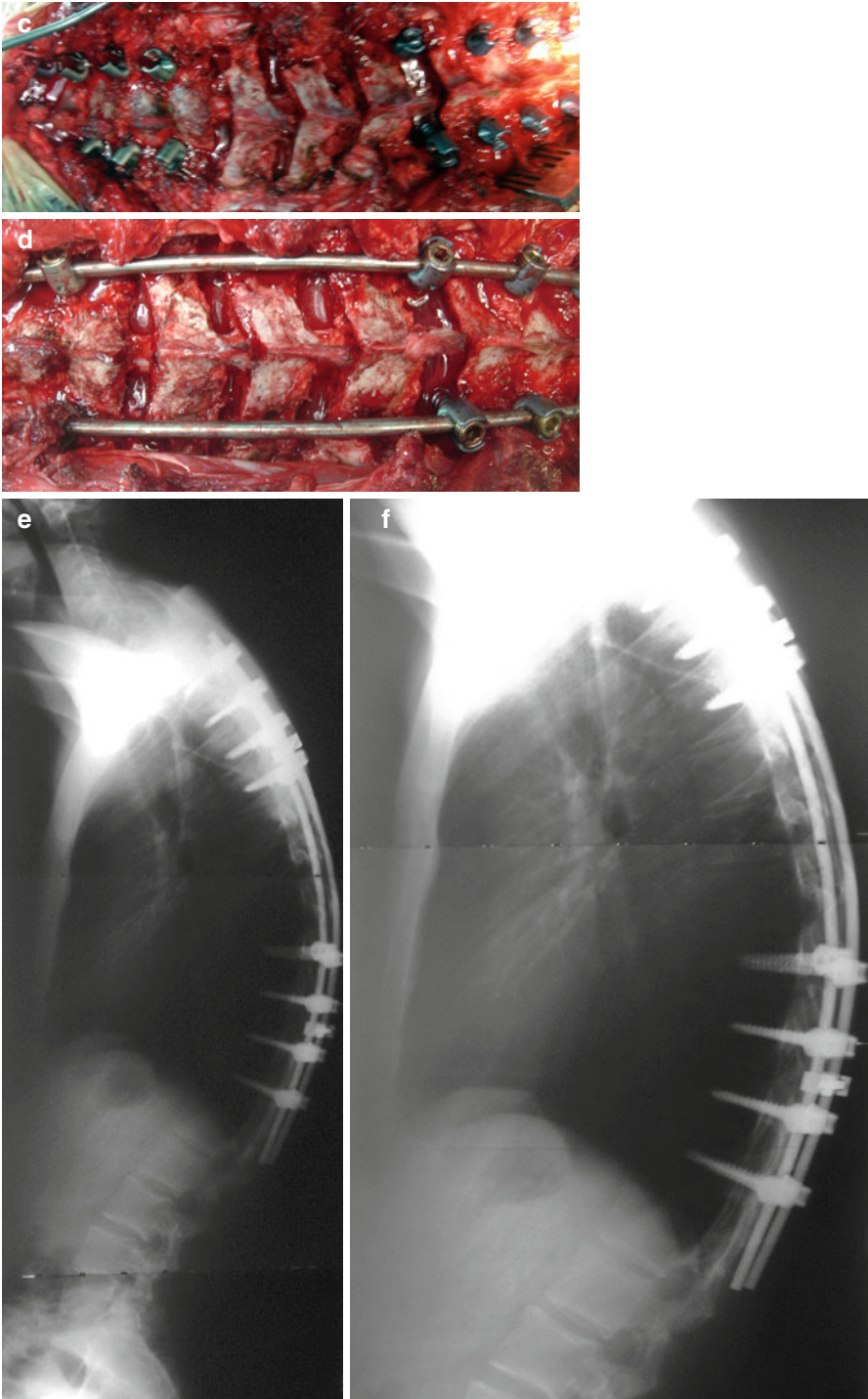


Fig. 7 (continued)

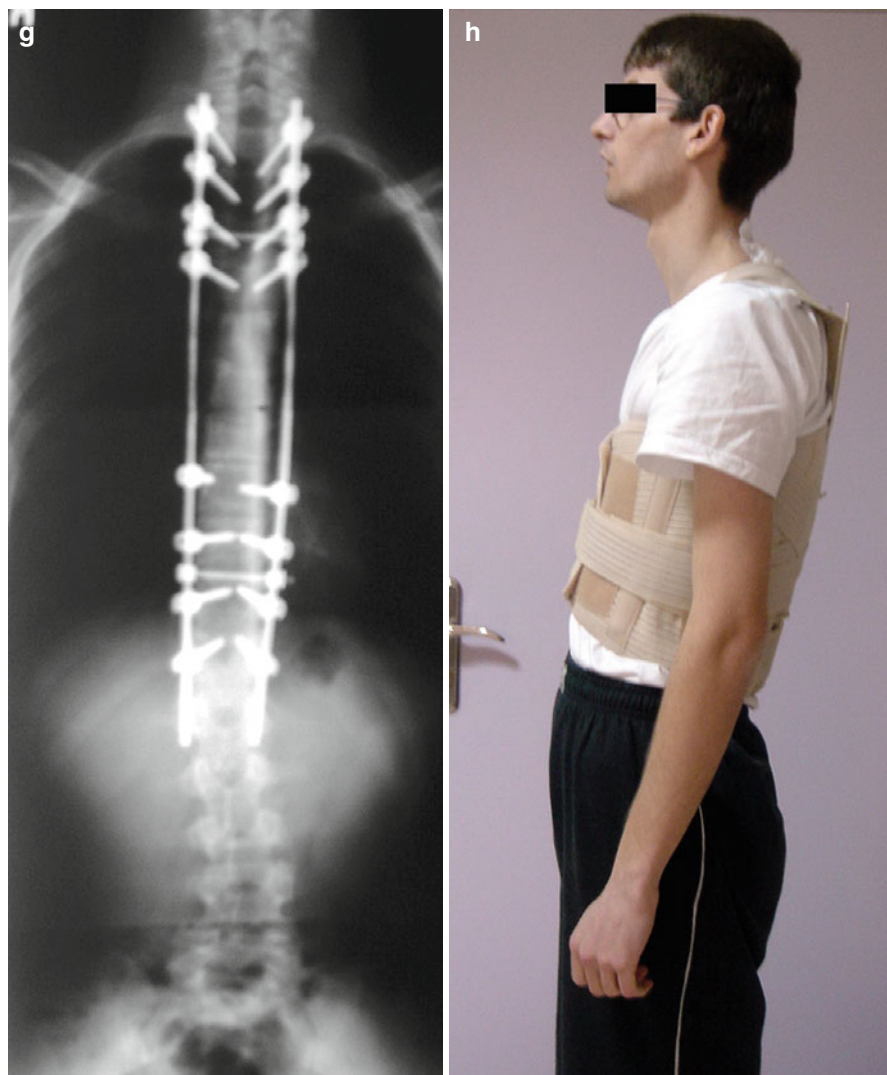


Fig. 7 (continued)



Fig. 8 A 42-year-old male with severe thoracolumbar kyphosis. He suffers from ankylosing spondylitis for 20 years. He was not able to walk in erect position and look at the faces of other persons and also the sky when standing (**a, b**). The kyphosis was approximately 100° (**c-f**). A four-level pedicle subtraction osteotomy was performed (**g-j**), and an excellent reduction could be achieved (**k-n**). Note the degree of kyphosis on the operating table before (**g**) and after (**j**) surgery



Fig. 8 (continued)

Fig. 8 (continued)



Fig. 8 (continued)

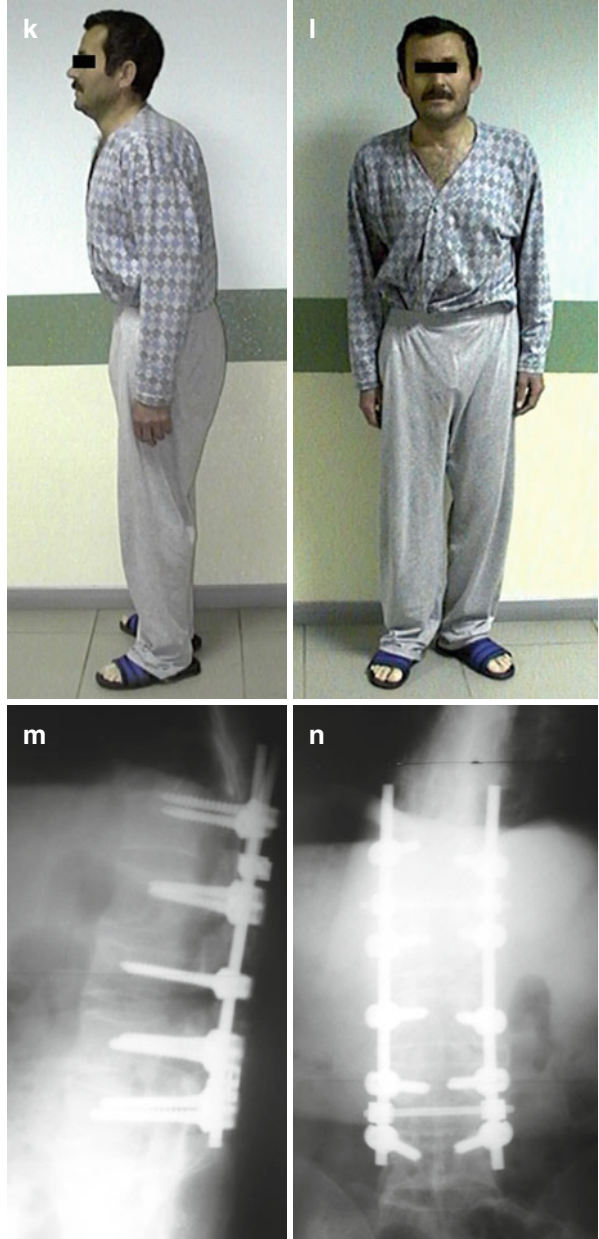




Fig. 9 A 34-year-old male with ankylosing spondylitis for more than 10 years. He had kyphosis more prominent on cervicothoracic junction in addition to some lumbar kyphosis (a–c). Intubation was not difficult; however, you can note the degree of deformity in supine position (d). After a C7 posterior osteotomy, both C8 nerve roots are visualized (e). The gap at the osteotomy site is closed using manual extension with the release of Mayfield head holder (f). C5 and C6 lateral mass and T1 and T2 pedicle screw fixations were performed (g). Postoperative photograph 2 days after surgery depicts the amount of correction and recovery of the forward gaze angle (h). Postoperatively he used a SOMI brace for 8 weeks

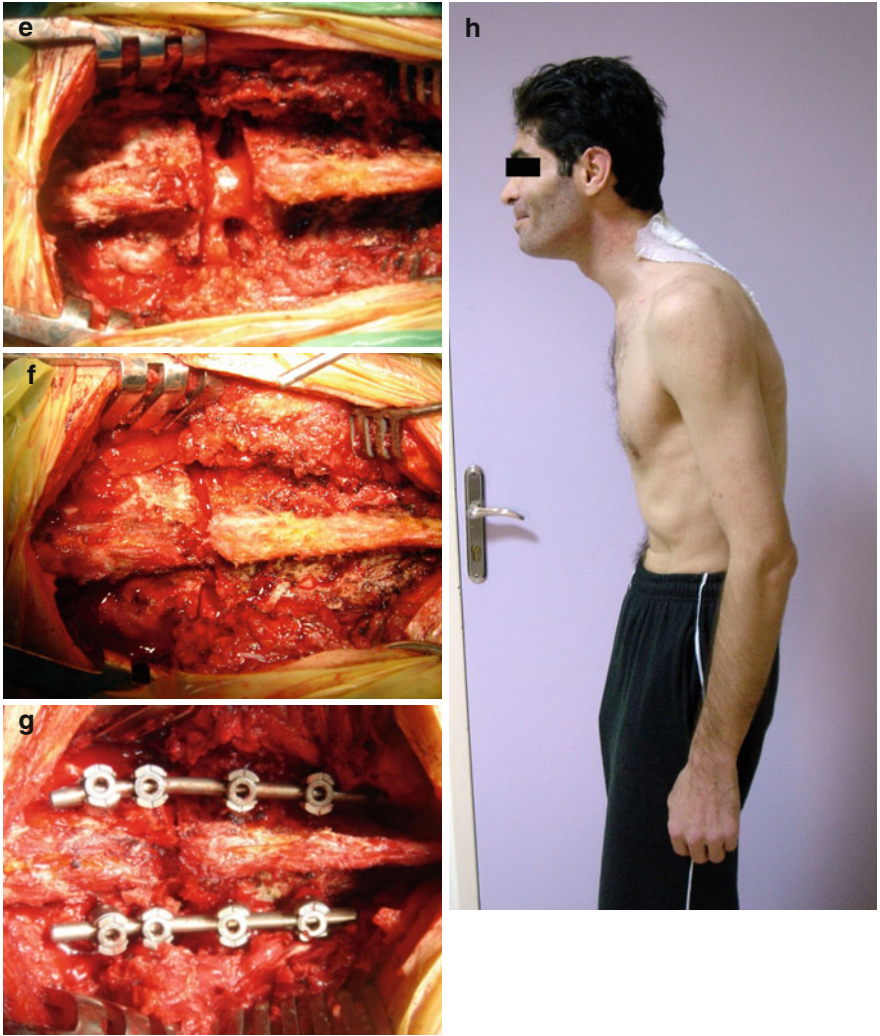
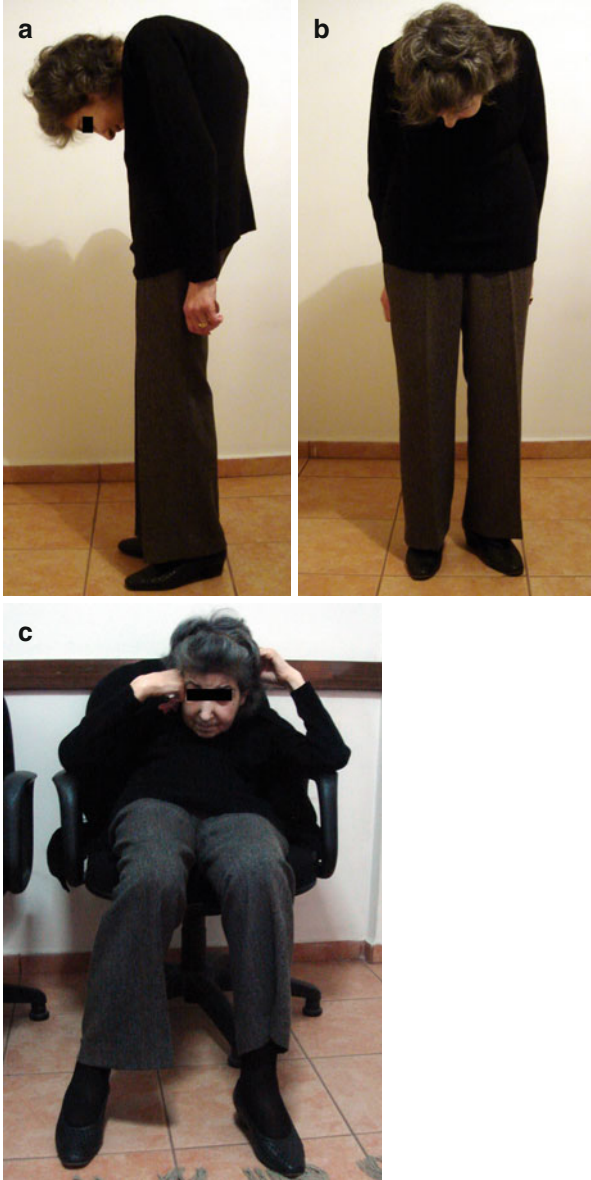


Fig. 9 (continued)



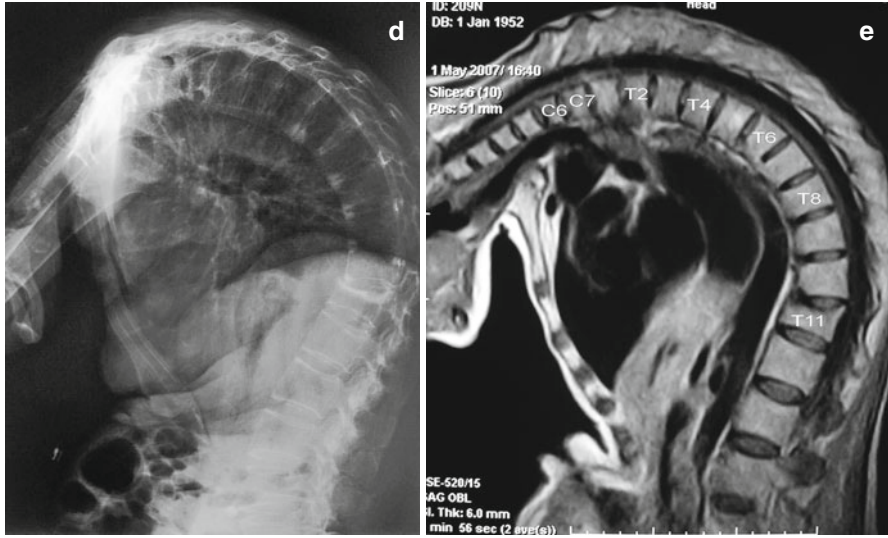


Fig. 10 (continued)

Fig. 10 A 51-year-old female admitted with severe cervicothoracic kyphosis. She has been diagnosed with ankylosing spondylitis for 15 years. She was unable to look at the faces of other people when she was standing, and her chin was on her sternum with 1 cm distance between (a–c). She had difficulty of swallowing due to compression of the esophagus by manubrium sterni (d, e). Also she described abdominal pain due to xiphoid compression to the abdomen. We planned to perform a two-stage surgery with posterior osteotomies on 7 levels, cervical and thoracic (e). The first stage was performed in sitting position. The hardest part was intubation and could be performed with fiber-optic bronchoscopy (f). Pedicle subtraction osteotomies were performed at T4, T6, T8, and T11 levels (g), and pedicle screw fixation was performed (h). At the end of the first session, it was possible to place fingers under the mandible (i). Two weeks later, the second stage of surgery was performed with the patient on prone position (j) with osteotomies at C6–7, C7–T1, and T2–3 disc levels. The previous rods were removed, and new rods were inserted from C6 to L3 (k). Significant reduction was achieved by deflection of the head on Mayfield head holder (l). She stayed in intensive care unit for 1 month and recovered well with significant deformity correction (m–r). Block 1 (a–c, o, p, r) Pre- and postoperative photographs of the patient. Block 2 (d, e, m, n) Pre- and postoperative direct radiographs and sagittal MR. Block 3 (f–i) Stage 1 surgery, thoracic osteotomies. Block 4 (j–l) Stage 2 surgery, cervicothoracic osteotomies



Fig. 10 (continued)



Fig. 10 (continued)

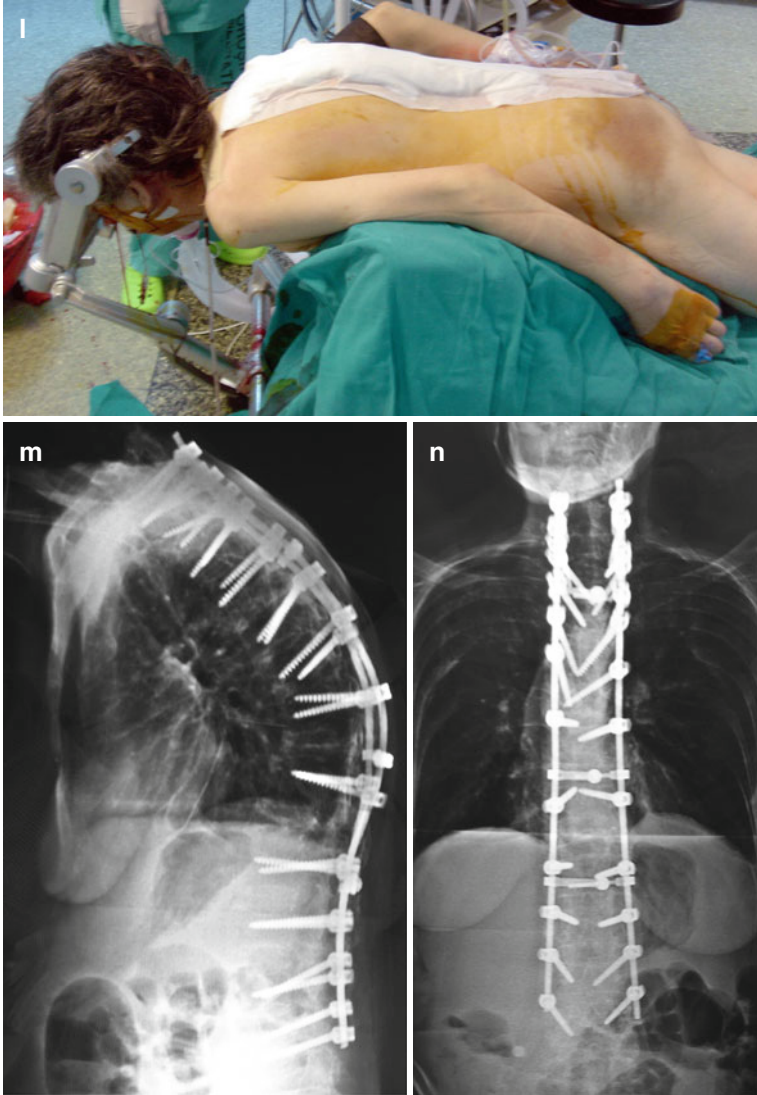
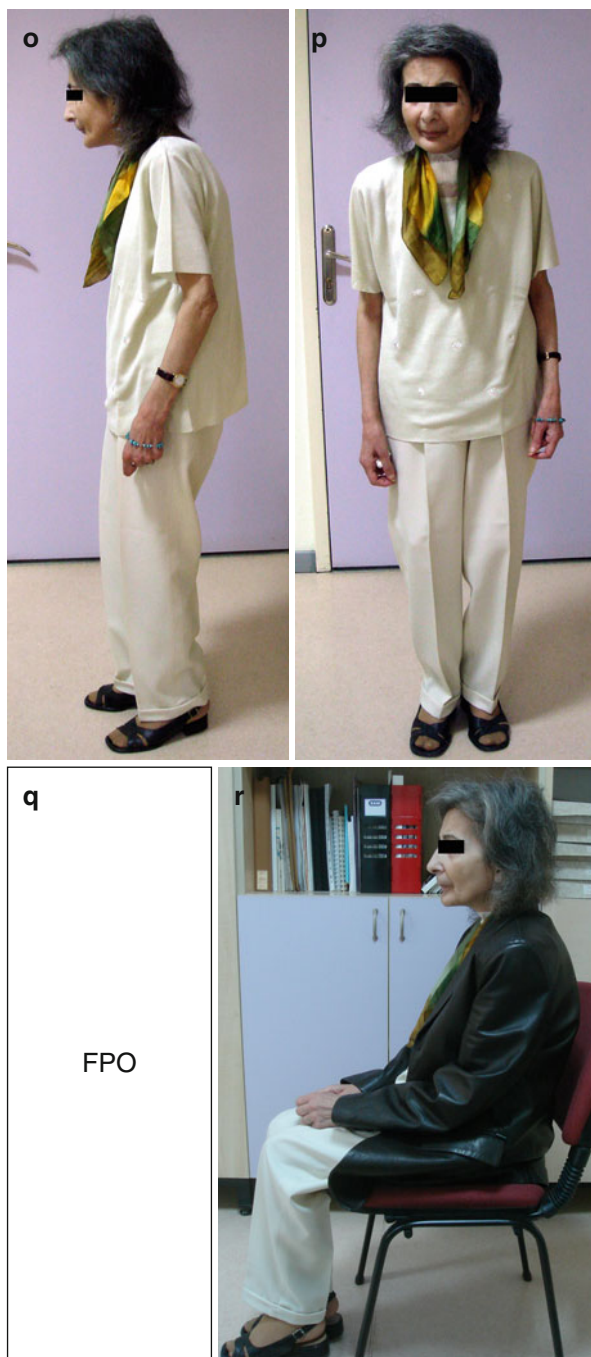


Fig. 10 (continued)

Fig. 10 (continued)



Conclusion

Surgical management of kyphosis needs consideration of different aspects of the kyphotic deformity such as neurological status, the presence of spinal cord compression, angle of the kyphosis, the quality of bone, and accompanying diseases. In case of significant cord compression and neurological compromise, anterior should have the priority.

However, in smooth-angled kyphosis and ankylosing spondylitis patients, deformity can easily be reduced by a posterior-only approach. Since they have no neurological deficits, and large spinal canal, most suitable patients for pedicle subtraction osteotomy are the patients with ankylosing spondylitis.

In lumbar kyphosis one-level pedicle subtraction osteotomy (especially at L2 or L3 levels), in thoracic kyphosis multilevel osteotomies, and in cervicothoracic kyphosis an osteotomy at C7–T1 level should be preferred.

Pedicle subtraction osteotomy is a technically demanding procedure that requires surgeons to exercise caution to achieve satisfactory results while avoiding complications. An attempt to correct the rigid fixed spinal deformity in ankylosing spondylitis is not an easy task and requires the capability of a highly experienced spine surgeon. Although the physical outcome of surgical treatment is beneficial, risks and complications exist that demand awareness by both the physician and patient.

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Part II

Standards

Cervical Disc Arthroplasty: A Critical Review and Appraisal of the Latest Available Evidence

Andreas K. Demetriades, Florian Ringel, and Bernhard Meyer

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Abstract Anterior cervical discectomy and fusion (ACDF) has been a very successful procedure in the management of cervical radiculopathy and myelopathy. Concerns with adjacent segment disease and the desire to preserve physiological motion have led to technological and clinical efforts for cervical disc arthroplasty. The suggested move to cervical disc replacement has led to this latter procedure being one of the most scrutinised surgical treatments in the twenty-first century. Short- and medium-term prospective randomised clinical trials and systematic reviews show cervical disc replacement to be at least as good as ACDF as regards the clinical outcomes in the management of degenerative cervical spondylosis. This is logical since the neural decompression procedure is essentially the same. However, the rationale for arthroplasty over arthrodesis has been built on two main proposed roles: the preservation of segmental motion and the prevention of adjacent segment disease. Whilst results thus far show that this first role seems to be achieved, its clinical significance is as yet unproven; the second is so far not proven. In addition, the long-term fate of the implants is also unknown. Long-term safety and efficacy, therefore, still await further clinical studies.

Keywords Anterior cervical discectomy and fusion (ACDF) • Cervical total disc replacement (C-TDR) • Cervical fusion/arthrodesis • Cervical arthroplasty/disc replacement • Radiculopathy • Myelopathy • Adjacent segment disease (ASD) • Motion preservation

Introduction

The treatment of spondylotic cervical radiculopathy and/or myelopathy with anterior cervical discectomy has been a successful treatment for several decades [22, 49]. It has evolved from pure discectomy to discectomy with fusion to prevent postoperative kyphosis and neck pain. Technical advances in allografts have led to a shift from iliac crest autograft fusion to the use of cages, and complications are of low incidence. There remains, however, concern about the biomechanical effect of a fused segment upon the kinematics and potential subsequent disc degeneration upon its adjacent level [25], hence the interest in motion preservation and cervical total disc replacement (C-TDR).

The first artificial cervical disc was reported in 1964 by Reitz and Joubert, who treated a series of patients with cervicobrachialgia, and in 1966 by Fernstrom who used a stainless steel ball-shaped prosthesis in a small series of patients [18, 47]. These studies lacked follow-up beyond 12 months, and their implants were abandoned due to hypermobility and subsidence. Further interest in cervical arthroplasty did not come until 1991 with the first generation of Cummins-Bristol ball-and-socket, metal-on-metal implant. Its use was limited by disc space and facet joint overdistraction, limited motion and screw complications [13]. Further improvements led to the Bristol-Cummins/Frenchay/Prestige disc. Technical developments led to the design of a metal-on-plastic prosthesis by Bryan, the first of which was used in 2000. There are now several such devices, with either CE mark (in Europe) or FDA approved (in the USA) or investigational status, and to date several thousand operations have taken place worldwide.

In this review, we revisit the rationale for T-CDR, its indications and contraindications, the surgical and postoperative considerations and biomechanics. We review the latest clinical evidence from trials, systematic reviews and meta-analyses in relation to the clinical outcomes, paying particular attention to the issues of motion preservation, adjacent segment disease, neurological recovery and patient satisfaction, with single- and multi-level arthroplasty. We also review the specific complications of heterotopic ossification, inadvertent fusion (autofusion), postoperative kyphosis, vertebral fracture and implant failure. We conclude with the unanswered questions and need for future work.

The Rationale for Cervical Total Disc Replacement (C-TDR)

The rationale for a total disc replacement in the cervical spine was borne out of concerns for altered biomechanics that arise with an ACDF. Motion-preservation technology has been developed to preserve motion at the segments of the cervical spine, as such motion was observed to be lost with ACDF both at the index operated level and at adjacent segments, leading to adjacent segment degeneration, which when clinically relevant is termed adjacent segment disease (ASD). The theory behind adjacent segment loss of motion is that it is due to an increased rate of degeneration secondary to an initially increased range of motion, but with raised intradiscal pressures, next to the fused segment where motion is lost [17]. The specific underlying aetiology of ASD has not been proven; however, cumulative risks as high as 25 % have been reported at 10 years post ACDF [25]. The rationale therefore of cervical arthroplasty is to provide anterior neural decompression whilst allowing motion preservation and preventing ASD and possible reoperation.

Whilst it is generally accepted that ACDF alters the kinematics of the cervical spine and that cervical spondylosis is a natural consequence with aging, it is still unclear whether adjacent segment degeneration is a natural progression or a consequence of fusion, or whether it is a natural phenomenon accelerated by fusion. In Hilibrand's oft-quoted study, multilevel ACDF had less ASD than single-level ASD,

Table 1 Indications and contraindications for cervical disc arthroplasty

Indications for C-TDR	Contraindications for C-TDR
Symptoms and findings referable to a pathology between C3 and T1	Spinal infection/active malignancy
Failed conservative management for a minimum of 6 weeks	Osteoporosis/osteopaenia/metabolic bone disease
Radiculopathy/myelopathy with or without axial neck pain due to spondylosis	Rheumatoid arthritis/autoimmune disease
Radiculopathy/myelopathy with or without axial neck pain due to disc herniation	Trauma/acute traumatic disc herniation
1 or 2 vertebral levels	Severe spondylosis/disc height loss >50 %
Radiologic confirmation of spinal cord and/or nerve root compression that corresponds to the symptomatology	Ankylosing spondylitis
	OPLL (ossification of the posterior longitudinal ligament)
	DISH (diffuse idiopathic skeletal hyperostosis)
	Instability on dynamic radiographs, translation >3 mm, rotational difference between adjacent levels >11°
	Kyphosis
	Prior laminectomy or laminoplasty or same-level ACDF
	Facet arthropathy
	Predominantly posterior stenosis
	Axial neck pain as the sole symptom
	Extreme obesity/BMI >40
	Insulin-dependent diabetes mellitus/chronic steroids

suggesting the inclusion of all degenerative levels in the original procedure [25]. Hilibrand, though, comments in a follow-up article that ASD may be related to natural history [26].

Non-biomechanical advantages of TDR include the avoidance of discomfort and complications associated with harvesting an autograft such as an iliac crest graft—pain, infection and pelvic fracture [7]—and the risk of viral transmission, non- or delayed or malunion, pseudoarthrosis and subsidence with an allograft [19].

Indications and Contraindications

The indications are drawn from the clinical trials that have been used to assess the efficacy and safety of C-TDR [1, 3, 33] (Table 1).

Such ‘on-label’ indications are limited to the selection criteria within the trials, yet more indications are added once a device becomes approved. The cervicothoracic junction, for instance, is a level which trials have excluded; it represents the

transition from the highly mobile cervical spine to the relatively immobile thoracic spine. Likewise, the C2/3 level has not been studied either and arthroplasties at such levels should be regarded with caution due to the lack of evidence. As regards the levels operated, there have been reports of three or more levels treated with C-TDR, some with better results than single-level operations [45].

Surgical Considerations

Whilst the procedure for C-TDR is similar to ACDF, there are some technical considerations that are prerequisite to a successful arthroplasty. A total discectomy is required with removal of all osteophytes to prevent impeded motion and to minimise the risk of inadvertent fusion, as well as the risk of dynamic foraminal compression. Therefore, bilateral nerve root decompression is necessary even in unilateral radiculopathy, and identification of the proximal nerve root serves as a landmark of adequate decompression. The resection of the posterior longitudinal ligament (PLL) is not always removed in ACDF [59], but its complete resection is even more important in C-TDR as this will ensure complete decompression as well as mobilisation of the disc space, allowing parallel restoration of the disc height and symmetrical segment mobility. The cartilaginous endplates are removed whilst preserving the bony endplates, to facilitate the even implantation of the device and its symmetrical contact. More so than in ACDF, the fluoroscopically guided midline insertion of the implant is required so as to allow appropriate motion along its centre of rotation. A correctly sized implant must be selected, with maximal endplate coverage and not excessive height. Overdistraction of the disc space can lead to facet joint distraction and overload, nerve root stretching and eventual reduction of motion [28]. In cases where due to body habitus it is difficult to visualise the interspace, consideration for fusion rather than arthroplasty should be given. Similar consideration should be given when there is ossification of the PLL, where the risk of heterotopic ossification, a poorly understood event, with subsequent inadvertent fusion may occur. The manufacturer's recommendations should be adhered with regard both to the technique and to patient selection.

The potential complications as they relate to the approach are similar to ACDF and include nerve root injury, cord injury, oesophageal injury, vertebral artery injury, vertebral body fracture, dysphonia, dysphagia, durotomy, airway compromise due to postoperative haematoma and implant failure. Earlier reports of arthroplasty using the Bryan prosthesis, for example, reported 4 % radiculomyelopathy, 4 % dysphagia/dysphonia and 1 % symptomatic haematoma [44], but later reports actually showed a lower incidence of dysphagia with cervical arthroplasty than with fusion [35].

Postoperative Considerations

The use of a collar is not required. Physiotherapy can start from the first postoperative day and should address flexibility and strengthening. A home exercise regime

can be useful. Return to work can be assessed on a case-by-case basis, without specific restrictions and as soon as the patient feels ready. Compared to cervical fusion, return to work after cervical arthroplasty has been reported to be earlier [55].

Design Considerations: Kinematics and Biomechanics

The aim of any cervical arthroplasty is to mimic as close to normal as possible the physiological motion and kinematics, whilst preserving alignment and stability across a motion segment. The biomechanical properties of C-TDR will depend on short- and long-term stability, the material interfaces, articulation geometry and centre of rotation, which are the main characteristics of an artificial cervical disc.

The methods employed to ensure good short-term fixation to the endplates include anchoring teeth, a keel and vertebral screws. Long-term stability requires osteointegration, and this can be encouraged with osteoconductive surfacing, titanium wire mesh, plasma-sprayed titanium, porous cobalt-chromium and hydroxyapatite. Good short- and long-term fixation will prevent subsidence and subluxation.

The articulating interface can be metal on metal, metal-on-polymer composite, ceramic-on-polymer composite, totally polymer composite and ceramic on ceramic. The majority of designs feature metal alloys and polymer. Metal alloys reduce the risk of metal wear, fracture or corrosion. Titanium is preferred for its modulus of elasticity, which is similar to bone, and its limited MRI artefacts, but it is at risk of wear and notching. Cobalt-chromium is preferred for its wear features and durability, but at the expense of MRI artefact. Stainless steel has a high modulus of elasticity and a higher rate of subsidence. Ceramic design has even better wear resistance and durability as well as MRI compatibility, but is subject to manufacturing challenges and reduced shock absorption. Polymers have lower stiffness, with higher wear.

Implants can be modular (i.e. with replaceable components) or non-modular. Kinematic classification of discs includes non-articulating, uni-articulating or bi-articulating. Based on the degree of freedom between the articulating surfaces and as such the gliding motion permitted, the devices are classified as unconstrained, semi-constrained, constrained or biomimetic.

Biomechanically, the restoration of disc space height has an effect on the facet joints. Disc designs try to balance a simulation of physiologic motion; unconstrained implants allow translation, against the risk of increased shear and torsion forces on the facet joints, because their unfixed axis of rotation distributes load away from the device-bone interface. In unconstrained implants it is the ligaments and joints that define the extremes of motion. Constrained devices allow less than physiologic motion and reduce facet joint load, but their fixed axis of rotation demands greater surgical precision during placement. On the one extreme there is the risk of subluxation and on the other suboptimal motion preservation with inadvertent fusion.

As regards the centre of rotation, there are differences from level to level in the physiologic cervical spine; it is usually in the posterior half of the upper portion of the

vertebra below the disc. This is termed the finite axis of rotation (FAR) in sagittal plane motion, as in flexion and extension. This FAR progressively moves more superiorly under the endplate and closer to the disc, as one moves craniocaudally through the cervical spine. The sagittal axis of rotation continuously changes with the flexion and extension of the motion segment. Not fixing the axis of rotation is the design advantage of unconstrained prostheses; preliminary studies have demonstrated preservation of the FAR and range of motion in the coronal and sagittal planes at the treated level with unconstrained and semi-constrained implants, as well as good durability.

Overall, the optimum device kinetics are unclear and device selection is individualised. The difficulty lies in that long-term multifactorial biomechanical data will be required, including disc height, facet loading, device design and implant positioning within the intervertebral space [20] (Table 2).

Clinical Evidence

Randomised Controlled Trials (RCTs)

Six randomised controlled trials assessed the safety and efficacy of cervical disc arthroplasty in comparison to ACDF in single-level disease; another assessed two-level disc disease. Most of these failed to mention if analysis was intention-to-treat, blinding of assessors and of patients, though it was acknowledged that blinding the treatment provider in a surgical trial with such instrumentation was impossible [10].

Mummaneni et al. (Prestige ST Prosthesis by Medtronic Sofamor Danek) [38]

This was an FDA (Federal Drug Administration)-regulated IDE (investigational device exemption) study to evaluate the safety and effectiveness of the Prestige ST cervical disc prosthesis compared to ACDF. This prospective, randomised, multicentre trial reported outcomes on 421 (out of the recruited 541) patients at 2 years randomly assigned to single-level ACDF or T-CDR. The conclusion was that Prestige ST arthroplasty was as safe and effective as fusion and maintained physiological motion. There were no statistically significant differences in reoperation rate at the index level (1.9 % Prestige ST vs. 3.4 % ACDF), but the adjacent-level surgery rate was higher with ACDF (3.4 % vs. 1.1 %, $p=0.0492$). Clinical evaluation was with NDI (Neck Disability Index), VAS (Visual Analogue Scale) and SF-36 (short form 36). Neurological success, defined as a maintained or improved neurological status, was better in the arthroplasty group (92.8 % vs. 84.3 %), both groups showing significant improvement from preoperatively, but with no significant difference between them. The arthroplasty patients returned to work at an average of 45 days postoperatively versus 61 days after ACDF. Two limitations were the incomplete data collection and

Table 2 Design characteristics of common cervical arthroplasty implants

Device	Manufacturer	CE mark status	FDA status	Materials	Articulation	Primary fixation	Constraint	Relative constraint	Centre of rotation
Bryan	Medtronic Sofamor Danek	Received	Approved	Titanium endplates, metal on poly, polycarbonate urethane nucleus	Biconvex nucleus articulating with endplates	Drill technique	Unconstrained	Low	Variable, at the centre of the mobile nucleus
ProDisc-C	Synthes	Received	Approved	Chrome-cobalt, metal on poly, UHMWPE	Ball and socket	Keel	Semi-constrained	High	Fixed, inferior to disc space
Prestige ST	Medtronic Sofamor Danek	Received	Approved	Metal on metal, stainless steel	Ball and trough	Anterior flanges with screws	Semi-constrained	Low	Variable, superior to disc space
Porous coated motion (PCM)	Cervitech	Received	IDE trials	Chrome-cobalt, metal on poly, UHMWPE	Ball and socket	Ridges, press fit	Semi-constrained	Low	Variable, inferior to disc space
Kineflex C	SpinalMotion	Received	IDE trials	Metal on metal, chrome-cobalt-molybdenum with titanium plasma spray	3-piece disc with biconvex mobile core	Keel and serrated surfaces	Semi-constrained translation with unconstrained rotation	Low	Variable

the presentation of mean scores without standard deviation, precluding estimation of effects that could be used in a meta-analysis with any degree of confidence [10].

Murrey et al. (ProDisc-C Prosthesis by Synthes) [39]

This was an FDA-regulated IDE study to evaluate the safety and effectiveness of the ProDisc-C prosthesis compared to ACDF for single-level disease. This prospective, randomised, multicentre trial reported on 209 patients with up to 2-year follow-up. The conclusion was that ProDisc-C is a safe and effective surgical treatment for patients with disabling cervical radiculopathy because of single-level disease and that clinical outcomes were either equivalent or superior to fusion. Both groups showed improvement in all clinical parameters (NDI, VAS, SF-36, neurological recovery), improvements being higher with arthroplasty but not with statistical significance. One significant difference is the lower reoperation rate with arthroplasty (1.8 %) compared to ACDF (8.5 %) ($p=0.033$). There was also a statistically significant improvement in the number of patients not requiring strong opiates or muscle relaxants after arthroplasty. Motion preservation was achieved in 84.4 % of ProDisc-C patients, with $\geq 4^\circ$ maintained motion relative to preoperative baseline at the index level. One limitation of this trial relates to the plots with distributions of scores, where the standard deviations were not clear; also unclear was whether the error bars were referring to standard error, standard deviation or confidence intervals [10].

Sasso et al. (Bryan Disc Prosthesis by Medtronic Sofamor Danek) [50]

This was an FDA-regulated IDE study to evaluate the safety and effectiveness of the Bryan disc prosthesis. It was a prospective, randomised, 3-centre clinical trial, reporting the 24-month outcomes in 115 patients assigned to T-CDR or ACDF. The conclusion was that arthroplasty with the Bryan prosthesis compared favourably with fusion. This was because there were statistically significant ($p<0.05$) improvements in NDI, VAS for neck pain and SF-36 PCS. VAS for arm pain and SF-36 MCS were equivalent at 24 months; four patients in the control group required surgical intervention and three patients in the investigational group required ACDF for adjacent-level disease. The main limitation of this report was a large (61 %) loss to follow-up at 24 months and the resultant selection bias. A systematic review recalculated the reported results and found no statistical significance [10].

Nabhan et al. (ProDisc-C Prosthesis by Synthes) [40]

This was a prospective randomised trial in Germany assessing the effectiveness of ProDisc-C against fusion at 1 year in 49 patients. The conclusion was that motion was preserved with arthroplasty at 1 year and that clinical outcomes were similar in the two groups. A recalculation of these results showed statistically significant improvement in arm pain and neck pain scores with arthroplasty ($p<0.05$) [10].

Coric et al. (Kineflex|C Prosthesis by Spinal Motion) [12]

This was an FDA-regulated IDE study to evaluate the safety and efficacy of a metal-on-metal prosthesis (Kineflex|C). This was a prospective, randomised, multicentre trial comparing arthroplasty to ACDF in single-level spondylotic radiculopathy in 269 patients. Its conclusions at 2 years were a comparable clinical outcome between the two procedures: significant motion preservation at the index level with arthroplasty and significantly reduced radiological ASD with arthroplasty. There were no differences in the reoperation rates in the two groups.

Zhang et al. (Bryan Disc Prosthesis by Medtronic Sofamor Danek) [65]

This prospective, randomised, controlled, 3-centre clinical trial was held in China and compared the outcomes in 120 patients randomised between ACDF and T-CDR in the local population. At 2-year follow-up, the arthroplasty achieved the desired motion preservation, whereas ROM was reduced in the fusion group ($p < 0.001$). There was no significant difference between the two groups with respect to the baseline changes in NDI and VAS for neck or arm pain. One patient in the C-TDR group and three patients in the ACDF group required reoperations due to adjacent segment disease, with another reoperation in the fusion group for disc prolapse at a nonadjacent level.

Cheng et al. (Bryan Disc Prosthesis by Medtronic Sofamor Danek) [11]

This prospective, randomised single-centre controlled trial assessed the efficacy of arthroplasty versus fusion in two-level cervical disc disease. In 65 patients and with 2-year follow-up, both groups had statistically significant improvement in all outcome measures at 2 years with respect to their preoperative scores. The arthroplasty group showed better clinical outcomes (arm pain VAS, neck pain VAS, SF-36, NDI) in comparison to the ACDF group. There was no autofusion and no heterotopic ossification; motion preservation was 93 % in the Bryan group. The main limitations were the small sample size and the single-centre study arrangement (Table 3).

Update Reports on RCT Cohorts

The 5-year outcomes of the Prestige RCT were reported in 271 of the 541 (50 %) randomised patients [8]. Radiological assessment showed no implant migration and preserved angular motion in the arthroplasty group with an average 6.5°. Clinical improvements reported previously by Mummaneni [38] were sustained in both groups. The clinical improvement was statistically significantly better in the arthroplasty group as assessed by NDI, VAS and SF-36 up to 3 years, but results converged by 5 years. There was no statistically significant difference in the rates of

Table 3 Prospective randomised controlled trials comparing cervical disc arthroplasty and arthrodesis for 1- or 2-level disc disease

Study	Implant	No. of levels	Number C-TDR:ACDF	Mean age (years)	Follow-up (months)
Mummaneni et al. [38]	Prestige ST	1	276:265	43	24
Murrey et al. [39]	ProDisc-C	1	103:106	42	24
Nabhan et al. [40]	ProDisc-C	1	19:21	Not specified	12
Sasso et al. [50]	Bryan	1	56:59	46	24
Coric et al. [12]	Kineflex C	1	136:133	44	24
Zhang et al. [65]	Bryan	1	60:60	45	24
Cheng et al. [11]	Bryan	2	31:34	45	24

reoperation for ASD. This is an important report; in the medium-term arthroplasty maintains improved clinical outcomes and does exhibit motion preservation, which is one of its aims, but its effect on ASD is unproven [8].

Delamarter et al. provided a further analysis of the ProDisc-C IDE patients [39], as well as a further 136 patients with continued access, with a minimum of 4-year follow-up. NDI and VAS scores were improved from baseline but not different between groups ($p < 0.0001$); there was a statistically higher risk for reoperation in the fusion group at the index or adjacent level (2.9 % vs. 11.3 %), but both groups showed good clinical results at longer-term follow-up [15].

Sasso et al. provided an update to their original trial with the Bryan prosthesis, giving 4-year clinical outcomes of their prospective, randomised controlled trial for single-level disc disease [50, 51]. This medium-term follow-up showed persistence of the greater improvement in the Bryan disc cohort in the NDI and neck pain scores ($p < 0.001$); the arm pain score ($p = 0.028$), which was improved in both groups from baseline; and SF-36 PCS ($p = 0.007$). The mean range of motion for the Bryan disc was maintained from 8.08° at 2 years to 8.48° at 4 years. Total and serious adverse event rates were similar between the groups. Overall, this showed that the arthroplasty group maintained its superior outcomes [51].

A cross-sectional analysis of the Prestige ST and Bryan IDE studies [38, 50] looked at the effect of arthroplasty in myelopathic patients [48]. In this subset of 199 subjects, patients in both the arthroplasty and fusion groups improved at 24 months after surgery; improvement was similar between the groups, with no neurological deterioration in the arthroplasty group, suggesting myelopathy due to single-level disease can be treated with arthroplasty [48].

Nonrandomised Medium-Term Comparative Studies

Several comparative studies exist where the limitations are lack of randomisation, retrospective follow-up and lack of long-term follow-up. Data, however, is generally in agreement with higher level evidence from RCTs, and experience with respect to motion preservation seems to be converging to the same conclusion. A

Table 4 Medium-term prospective follow-up studies on cervical arthroplasty

Study	Implant	No. of levels	Number C-TDR:ACDF	Mean age (years)	Follow-up (years)
Burkus et al. [8]	Prestige	1	276:265	43	5
Delamarter et al. [15]	ProDisc-C	1	103:106 + 136 further C-TDR with continued access	43	4
Sasso et al. [51]	Bryan	1	181:138		4
Goffin et al. [21]	Bryan	1 or 2	89 single and 9 two levels	43 and 49	4–5
Peng et al. [43]	Prestige LP	1 or 2	25 single and 15 two levels	44	2.9
Quan et al. [46]	Bryan	1 or 2	15 single and 6 two levels	46	8

small prospective study compared the outcomes between the Prestige LP arthrodesis for one- or two-level disease. At a mean of 2.9-year follow-up, both groups improved clinically with statistical significance from preoperative levels but with no intergroup difference. Motion was preserved [43]. Motion preservation at 4–6 years is also reported in a prospective but nonrandomised European multicentre study using both single-level and multilevel arthroplasty [21]. Another study with an even longer prospective follow-up of 8 years reported on 21 patients who received the Bryan arthroplasty for one- or two-level radiculopathy; clinical improvement was maintained and so was a satisfactory ROM (10.6°) in 21/27 (78 %) segments that were still mobile. Heterotopic ossification (HO) was high at 13/27 (48 %) and restricted motion in nine cases. Adjacent segment degeneration was evident in 4/21 (19 %). It may be possible that HO increases with time [46]. Specific outcomes will be addressed in the next section (Table 4).

Clinical Outcomes

Does C-TDR Reduce the Incidence of ASD?

The hypothesis that cervical fusion increases the physical strain upon adjacent segments and accelerates their degeneration led to the development of arthroplasty, a non-fusion procedure aimed at preserving normal disc kinematics. However, even though this has been the prevailing argument in promoting cervical disc arthroplasty, adjacent-level degeneration has not been adequately studied in the randomised controlled trials of ACDF versus C-TDR and was not even a main outcome measure. Of the several multicentre randomised trials on different prostheses, which studied in excess of 1,000 patients, only Mummaneni et al. had reported the number of operations at adjacent levels [38]. A systematic review by Botelho et al. found no clinical evidence of reduction in adjacent-level degeneration with cervical arthroplasty [6]. A recent meta-analysis came to the same conclusion that with the available evidence it cannot be concluded that C-TDR can significantly reduce the

postoperative rate of adjacent segment degeneration or disease [61]; the incidence of adjacent segment disease after T-CDR was 8.8 % and after ACDF was 13 %, but this was not statistically significant. This conclusion was limited by the quality of available evidence; only five studies were included in the meta-analysis. This has limitations due to insufficient effectiveness, possible publication bias with under-reporting of negative results and overestimation of the intervention effectiveness. The authors themselves warned that their conclusion should be seen with caution until further specific data are available. The most conclusive evidence does come from very recent prospective randomised clinical trial data. Nunley et al. specifically evaluated the outcome data of patients treated for 1- and 2-level cervical disc disease to assess adjacent-level disease. At the median follow-up of 42 months, 14.3 % ACDF and 16.8 % T-CDR patients developed and received treatment for ASD. Importantly, the risk of developing adjacent segment degeneration was equivalent at a median 38 months after both ACDF and TDA procedures [41].

As such, there is currently no convincing high-level evidence that T-CDR prevents ASD more than ACDF. Furthermore, the question remains as to whether fusion or arthroplasty leads to accelerated degeneration as opposed to natural progression of the disease. Multifactorial risk factors, such as the presence of adjacent-level degeneration at the time of first surgery, kyphosis, single-level fusion or fusions that end adjacent to the commoner levels of degeneration (C5/6 and C6/7), are not easy to eliminate by substituting fusion with arthroplasty. The different disc designs may also play a part, but it is questionable whether enough data will be available for adequately powered studies for individual implants.

Reoperation Rate

The incidence of adjacent segment disease requiring surgery after anterior cervical discectomy and fusion was recently addressed in a 10-year cohort and found to be 5.6 % [60]. There is mixed evidence from level II studies as to the significance of secondary surgery associated with ACDF and T-CDR. One trial found no revisions in either group [11], whereas in the ProDisc-C trial, secondary surgical procedures were performed in 1.9 % of arthroplasty patients and 8.5 % of fusion patients. Implant revision was required in 4.7 % of the ACDF patients, and 2.8 % of the ACDF patients had supplemental fixation; no arthroplasty patients required revision [39]. Anderson et al. reported a statistical significance of more serious adverse events and reoperations occurring in the fusion group [2]. And more recently, Burkus et al. reported clinical and radiographic outcomes from a trial using the Prestige disc; there were statistically significant differences between the arthroplasty and fusion groups with regard to the reoperation rate and supplemental fixation procedures performed subsequent to the index procedure. Rates for surgery at adjacent levels were lower in the arthroplasty group, but this difference was not statistically significant [8]. Overall, the data supports arthroplasty as an at least equivalent procedure to fusion.

Preservation of Motion

It is unclear whether motion preservation is correlated to improved clinical outcomes. Evidence from prospective RCTs has shown that single-level arthroplasty maintains an average motion of 2.36–9.36° in flexion and extension compared to 0.5–0.95° in the fusion groups. In multilevel arthroplasty, kinematic assessment showed a 7.9° range of motion (ROM) with the Bryan disc in dynamic X-rays at 2 years versus a 0.5° range with ACDF ($p < 0.001$) [11]. Sagittal ROM at the implanted level was significantly reduced, as expected, with fusion and preserved with arthroplasty. At both the adjacent upper and lower levels, sagittal ROM was maintained with arthroplasty; it was significantly reduced after fusion ($p < 0.001$) at the level above and maintained but less than with arthroplasty at the level below [30]. Long-term data, device-specific follow-up and clinical correlation will be essential in determining the fate of arthroplasty, since motion preservation is the hallmark of the rationale for its use.

Neurological Recovery

Both ACDF and T-CDR are meant to achieve neural decompression—of roots and cord—and it is not surprising that no statistically significant differences were shown between them in early neurological success rates around 90 %. Later follow-up at 2 years supports the non-inferiority of arthroplasty regarding neurological recovery [24, 38, 39]. Data from Burkus et al. show a statistically significant neurological status maintenance or improvement after T-CDR over ACDF at 24 and 36 months, with convergence of results by 60 months [8].

Alleviation of Cervicobrachialgia

There are a variety of mixed results. The Neck Disability Index (NDI) has been reported to be significantly better after T-CDR over ACDF at 3 months, but this advantage seemed to neutralise by 2 years [39]. In other studies such an advantage was indeed preserved at 2 years [11, 24]. VAS reports of arm pain intensity and frequency, however, were not significantly different at 24 months between the two groups [24, 39]. More recent data from Burkus et al. in a trial with the Prestige disc show significant improvements in NDI scores, SF-36 PCS scores and neck and arm pain scores; these were achieved by 1.5 months in both groups and sustained at 5 years [8]. It is difficult to definitively conclude whether T-CDR is superior to ACDF, which itself has been a very successful procedure, but some studies suggest it is at least equal in alleviating neck pain and brachialgia.

Patient Satisfaction

Conflicting results are available from different studies as to the presence and timing of a statistically significant difference between T-CDR and ACDF as assessed by SF-36. In one trial, T-CDR had better SF-36 physical component summary (PCS) and mental component summary (MCS) scores at 12 months, but this difference was not significant at 24 months [24]. In another prospective randomised study, there was a significant difference in favour of arthroplasty at 2 years [11]. SF-36 PCS scores at 2 years were 45–50. SF-36 MCS was similar also at 2 years at around 50.

Multilevel T-CDR Versus Multilevel ACDF

The effectiveness and safety of multilevel T-CDR in comparison to multilevel ACDF was addressed by a randomised clinical trial using the Bryan disc [11]. Assessment as per Odom's criteria at 2-year follow-up showed excellent overall success in 80 % cases of ACDR versus 68.8 % of ACDF. Functional outcome, as measured by the Neck Disability Index (NDI), was comparable in the two treatment groups preoperatively, but at 2-year follow-up the NDI improved from 50 to 11 in ACDR versus 51 to 19 in ACDF, a significant difference ($p=0.2$) [11]. Another study, however, showed no statistical significance between the groups of fusion and arthroplasty [30]. This same study found no significant differences in pain relief, assessed using the Visual Analogue Scale (VAS) for neck and arm pain. Differences, however, were detected ($p=0.01$) by Cheng et al.; pre-op VAS for neck pain reduced from 7.3 to 1.5 at 2 years with T-CDR and from 7.1 to 2.6 with ACDF. The VAS for brachialgia reduced from 7.1 pre-op to 1.5 at 2 years after arthroplasty, compared to a change from 7.2 to 2.7 with fusion. Patient-reported outcome using SF-36 PCS was significantly better at 24 months with arthroplasty (35 pre-op and 50 post-op) than fusion (34 pre-op and 45 post-op) ($p=0.01$) [11].

Multilevel T-CDR Versus Single-Level T-CDR

Several studies provide evidence for the overall success of arthroplasty, as per Odom's criteria [42]. Goffin et al. reported their 6-year results: excellent/good results in 90 % of single-level cases and 100 % of two-level cases, comparable overall neurological success, comparable NDI improvement from 40 pre-op to 20, lower VAS scores for arm and neck pain in the two-level cases, and SF-36 PCS 47 versus 51 for one versus two levels [21]. Other studies, however, reported nonstatistically significant results in SF-36 PCS at 2 years, together with a return to work rate of 70 % for single-level and 46 % in two-level T-CDR ($p=0.09$). No significant

difference was shown in biomechanics either [27]. Pimenta et al., on the other hand, reported in their 3-year outcomes after arthroplasty with the PCM disc that after multilevel arthroplasty, there was a significantly better improvement than after single-level arthroplasty [45]. Their cohort included up to four-level arthroplasties. Sekhon et al.'s study of up to three-level arthroplasties using the Bryan disc showed a significant improvement in pain scores at 12 months in patients who had previously undergone cervical fusion or posterior foraminotomy [52]. Whilst there are no major significant clinical differences between single- and multilevel arthroplasty, initial results demonstrate safety and efficacy; however, further information is required as regards both adjacent segment biomechanics and long-term results [4, 29].

Return to Work and Cost-Effectiveness

Whilst there were no significant differences in the return to work at 24 months in the ProDisc trial, the Bryan group patients returned to work an average 13 days earlier than the fusion group patients. The return to work was also shorter with arthroplasty in the Prestige trial [24, 38, 39]. Length of hospital stay was not different. An economic assessment of C-TDR (Prestige) and ACDF found the total direct cost per patient to be \$431 lower on average in the arthroplasty group, with those patients working an average of 38 days longer and producing an average productivity gain of \$6,547; at 2 years arthroplasty was associated with an average savings of \$6,978 per patient [37]. If further studies show this to be consistent and if clinical data prove the long-term non-inferiority of arthroplasty, then it could become a cost-effective and efficient treatment.

Hybrid Arthroplasty and Fusion

A reasonable concern would be that in a hybrid fusion/arthroplasty there could be increased biomechanical stress on the disc prosthesis, due to its placement adjacent to a fused level, which could potentially predispose to device malfunction or dislocation. Such fears have not been proven. In fact, cadaveric biomechanical studies have shown that a hybrid construct seems biomechanically advantageous over two-level fusion in reducing both compensatory adjacent-level hypermobility and loads required to achieve a predetermined ROM [31]. Such advantage has also been shown in clinical studies. A prospective analysis of arthroplasty combined with fusion versus two-level fusion in cervical two-level disc disease showed better results in the hybrid surgery group with respect to NDI recovery at 1 and 2 years ($p < 0.05$): less postoperative neck pain at 1 month and 1 year ($p < 0.05$), no difference in brachialgia relief, faster C2–C7 ROM recovery and less adjacent ROM increase [54]. Improved neurological outcomes for radiculopathy and myelopathy have been reported, with observed as expected motion preservation at arthroplasty levels as well as fusion at the fused levels [5]. There are no randomised trials for hybrid arthroplasty/fusion.

Specific Complications

Heterotopic Ossification (HO) and Inadvertent Fusion

The major concern when implanting a motion-preserving implant is autofusion and the potential loss of motion. An unpredictably high rate (18 %) of HO was observed in a prospective multicentre trial using the Bryan disc, at 1-year follow-up; 62 % of these (11 % of the study population) had less than 2° motion at the affected level. Older male patients were identified as potential risk factors [32]. HO has been classified in a scale ranging from grade 0 (no HO) to grade IV (complete ankylosis) [34]. HO has subsequently been observed in other devices also. Only 34 % of patients in a study with ProDisc-C did not have HO; the rate of ossification that led to restriction of motion was 10 % [36]. A 4-year follow-up of the same prosthesis revealed significant HO (grade III or more) in 45 % and segmental ankylosis in another 18 % [56]. A study of 71 patients assessed HO with T-CDR using the Mobi-C disc; at a mean follow-up of 21 months there was radiological HO in 28 %. This did not affect clinical outcome as assessed by VAS for neck pain, VAS for arm pain, SF-36 PCS, SF-36 MCS and NDI. The mean ROM increased from 8.1° preoperatively to 10.2° postoperatively, though 4 prostheses that had grade IV HO had fused. No specific risk factors were identified.

In an attempt to assess the role of the implant in HO, Yi et al. examined retrospectively three types of artificial disc in 170 patients. The overall rate of HO was 40.6 %; occurrence rate was 21 % in the Bryan prosthesis group, 52.5 % in the Mobi-C group and 71.4 % in the ProDisc-C group. The Bryan group showed statistically longer survival than the other groups. Differences in the design, biomechanical characteristics, endplate articulation component and surgical procedure were suggested as contributing factors for the different rates of HO [64].

It has been postulated that HO may be related to surgical trauma to the longus colli muscle, and recommendations include limited muscle retraction, ample intraoperative irrigation to clear the bone dust from high-speed drilling and nonsteroidal anti-inflammatories (NSAIDs) postoperatively [36]. A study specifically looking at the clinical relevance of HO, not verified by the previously mentioned series, found the overall rate of HO to be 42 % and no difference in the functional scores with or without HO. Motion preservation $\geq 3^\circ$ was preserved in 94 % with HO [5].

Overall, it seems that HO after T-CDR is common and with variable incidence in short- to medium-term studies. It also seems that it does not influence clinical outcome in the majority of cases. Segmental motion, in addition, seems to be preserved and the rate of complete fusion is low (<10 %). What remains unanswered is whether HO is a sign of a slowly progressing fusion, though midterm results up to 5 years do not suggest this. What is unknown is whether motion preservation were to be a temporary achievement, how this would affect ASD and would it be economically worthwhile.

Postoperative Kyphosis

One of the aims of cervical arthroplasty is to maintain normal sagittal balance and lordosis and therefore normal ROM and biomechanics, even though there is no evidence that sagittal imbalance affects clinical outcome [63]. Kyphosis, such as that reported after arthroplasty with the Bryan disc, may be due to pre-existing kyphosis, lack of lordotic profile on the implant, hyperlordotic patient positioning, asymmetric endplate preparation, overdrilling of the dorsal vertebral endplate and suboptimal insertion angle of the prosthesis [62].

Vertebral Fracture

This is a particular risk of those prostheses that have a keel for initial anchoring. The chisel or drill action, such as required in ProDisc-C, has been reported to be associated with avulsion and sagittal split vertebral fractures. Multilevel T-CDR may mean two keel osteotomies in the same vertebra and in the same sagittal plane, predisposing to a fracture [14], though this can happen in a single-level arthroplasty too [57]. A posterior avulsion fracture can lead to cord compression [53]. Consideration should be given to age; bone density; osteopaenia; comorbidities and medications, such as steroids in asthmatics; and surgical technique as predisposing factors.

Implant Subsidence and Wear

Implant migration is uncommon. In a prospective analysis of 96 Bryan implants in 74 patients, there were two cases of migration: one intraoperative migration in a two-level case and one migration at 3 months which was associated with segmental kyphosis, where the inferior endplate of the device migrated posteriorly causing neck and bilateral shoulder pain, but no myelopathy. This series also included the first reported implant failure with the Bryan prosthesis, a partial dislocation in extension, in a patient who had exhibited segmental hypermobility preoperatively [44]. In multilevel arthroplasty, malalignment in the coronal and sagittal planes might be a risk factor for endplate migration [16], but level II evidence from prospective studies has not shown this [45]. It is worth bearing in mind that similar complications of subsidence or plate migration also occur during ACDF with a cage or graft and that instrumentation-specific complications, such as those in ACDF, would reduce with experience.

Recent concern about wear debris is reasonable given the physical motion across a bearing surface. Debris can induce a cytokine-mediated inflammatory reaction with subsequent osteolysis, but this has only been rarely reported [58].

Hypersensitivity reaction to metal implant ions has also been described, leading to pseudotumour formation comprising chronic inflammatory debris and causing myelopathy [9, 23].

Conclusion

ACDF has been a very successful procedure in the management of cervical radiculopathy and myelopathy. The proposed move to cervical disc arthroplasty has led to this latter procedure being one of the best scrutinised surgical treatments in the twenty-first century. Short- and medium-term prospective randomised clinical trials and systematic reviews show T-CDR to be at least as good as ACDF as regards the management of degenerative cervical spondylosis. Clinical outcomes are as good as ACDF, and this makes sense since the neural decompression procedure is essentially the same. However, the rationale for ACDF over ACDF has been built on two main proposed roles: the preservation of segmental motion and the prevention of adjacent segment disease. Whilst the first seems to be achieved, its clinical significance is as yet unproven; the second is so far not proven. In addition, the long-term fate of the implants is also unknown. Long-term safety and efficacy still await further clinical studies.

Future Directions

The future of T-CDR revolves around motion preservation and the prevention or not of ASD. The acquisition of long-term clinical data will hopefully elucidate whether ASD is a natural progression of spondylosis or an event accelerated by fusion. If the latter proves to be the case, long-term data can also help clarify whether arthroplasty can help decelerate ASD or whether it is an expensive form of delayed fusion.

It is, therefore, paramount that we:

1. Continue collecting prospective data from the patients that participated in the original RCTs so far and continue updating clinical outcomes and revising the rates of ASD, motion preservation and reoperation.
2. Understand heterotopic ossification and its role in autofusion and ASD. The longer-term rates in these two issues will effectively determine the future of cervical arthroplasty, as they remain the two main theoretical rationales for its use.
3. Undertake subgroup analyses, for example, between soft- and hard-disc disease and foraminal versus central canal stenosis.
4. Continue technical appraisal and evolution of implants, to answer questions such as their life expectancy, long-term wear, hypersensitivity and inflammation characteristics.
5. Perform newer and better designed RCTs addressing clinical, radiological, quality of life and cost-effectiveness issues.

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Pedicle-Based Non-fusion Stabilization Devices: A Critical Review and Appraisal of Current Evidence

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Abstract Over the last decades, spinal fusion has become one of the most important principles in surgical treatment of spinal pathologies. Despite the undoubted benefits of fusion surgery, there are several drawbacks associated with this technique, including adjacent segment degeneration and pseudoarthrosis. Based on biomechanical data, dynamic stabilization of the spine is intended to ameliorate adjacent level degeneration by stabilizing vertebral motion in defined planes and mimicking natural spine movements.

In this paper, we review the literature and discuss past and present pedicle-based non-fusion dynamic stabilization devices. Although there is a paucity of high-quality prospective trials, studies have indicated both promising and disappointing results. In comparison to 360° fusion surgery, the perioperative risk seems to be lower. Other complications like screw loosening, however, have been reported with

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various systems, while a reduction of adjacent segment disease has not yet been demonstrated. The necessary degree of restabilization to achieve pain-free motion seems to vary greatly between patients and current systems are far from perfection. If these problems can be solved, dynamic stabilization may nevertheless be an important option of spinal surgery in the future.

Keywords Low back pain • Non-fusion techniques • Dynamic stabilization • Pedicle-based devices

Introduction

Lumbar degenerative disc disease affects adults in middle and advanced age. Pain is the leading symptom and occurs as low back pain, unilateral or bilateral sciatica, and as combined lumbar and sciatic pain. In most of the patients, conservative methods are appropriate to treat the symptoms successfully. If severe symptoms persist and can no longer be tolerated by the patient, an operative procedure is indicated [20]. Although disc degeneration is one reason for chronic low back pain, painful motion due to instability of the lumbar spine is considered to be a major cause for symptoms. Because of the fact that abnormal motion does not cause back pain in all cases, the definition of instability has been updated to include abnormal movement at the joint surface and altered load transmission [9].

Over the last decades, spinal fusion has become one of the most important principles in surgical treatment of spinal pathologies [4]. Despite the undoubted benefits of fusion surgery, there are several complications associated with this technique, including adjacent segment degeneration and pseudoarthrosis [5, 18]. Biomechanical and long-term clinical studies have shown that fusion surgery can cause increased rates of adjacent vertebral segment degeneration with an incidence in the range of 5.2–100 % [8, 13, 19].

To prevent adjacent segment degeneration, different types of motion preservation surgeries have been developed. A remote expectation is that once normal motion and load transmission – by stabilizing vertebral motion in defined planes – are achieved, the damaged disc may repair itself and the controlled motion may also decrease the secondary effects of fusion, unless the degeneration is too advanced [32].

Based on the location and the way the different devices work, the posterior dynamic stabilization systems can be classified in three types: (1) posterior interspinous spacers, (2) posterior pedicle fixation-based dynamic stabilization devices, and (3) total facet replacement devices [16]. This paper will summarize and discuss pedicle-based non-fusion stabilization devices, e.g., dynamic rod and screw systems and total facet replacement devices.

Clinical Evidence

Dynamic Rods

Graf Ligamentoplasty

The use of the Graf ligamentoplasty system to treat low back pain without fusion was first published in 1992. The device used titanium pedicle screw anchors into the vertebra, both superior and inferior to the symptomatic level and a braided polypropylene tension band to link the titanium pedicle screws. Due to compression on the posterior annulus, it was claimed that Graf's system allowed annular tears to heal, but initial outcomes from Graf ligamentoplasty showed only modest improvements in functional ability and required high rates of reoperation [9]. Different case series reported the use of the Graf ligamentoplasty. Grevitt et al. reported improved Oswestry disability indices (ODI) from 59 to 31 %, but also an increasing rate of postoperative radiculopathies, so that prophylactic foraminal decompressions were recommended [10]. On the one hand, Markwalder et al. described the Graf ligamentoplasty as an acceptable alternative to fusion surgery and to provide long-term pain relief. On the other hand, however, a significantly higher reoperation rate after Graf ligamentoplasty was detected [12, 22].

Recent randomized evaluations reported better clinical outcomes in patients that underwent Graf ligament placements versus fusion. If the patient presents with spondylolisthesis or flexion instability, a Graf ligamentoplasty is claimed to be a good choice. The device, however, also produces a significant increase in lateral canal stenosis, especially when patients exhibited preexisting degenerative changes in the facet joints or in the infolding of the ligamentum flavum, owing to the marked lordosis of the segment instrumented [9]. Overall, there is not enough clinical evidence to support the use of this early dynamic stabilization technique, which thus does not currently play a role in spinal surgery.

FASS

The FASS (fulcrum-assisted soft stabilization) system was developed by Sengupta and Mulholland with the intention to eliminate the most common disadvantages of the Graf system: (1) increased lordosis, with the narrowing of the lateral recess, leading to root entrapment and (2) increased loading of the posterior annulus. The fulcrum is placed between the pedicle screws, in front of the ligament, and acts by distracting the posterior annulus. The elastic ligament is placed at the heads of the pedicle screws, posterior to the fulcrum, and maintains lordosis. The fulcrum transforms the compressive effect of the elastic ligament into an anterior distraction force that unloads the disc [9, 33].

DSS

The dynamic stabilization system (DSS) was developed by Sengupta et al. as an improvement of the FASS system to reduce the risk of early device failures [34]. The DSS-I consists of a titanium spring, made of a 3-mm cross-sectional diameter of spring-grade titanium wire. The DSS-II system consists of an elliptical coil spring, made from 4-mm spring-grade titanium rods. The authors reported the results of a study with 16 patients treated with the DSS for single-level mechanical back pain associated with disc degenerations. Mean ODI scores decreased from 65 to 27 %, and VAS scores decreased from 7.3 to 3.7 within a 2-year follow-up. There were no reports of device failure [34].

Dynamic Neutralization System (Dynesys)

Dynesys (Zimmer, Warsaw, IN) was developed in 1994 as a semirigid dynamic pedicular fixation system [36]. This system uses conventional titanium alloy pedicle screws, polyethylene (PET) cords, and polycarbonate urethane (PCU) spacers. The pedicle screws on each side are connected by the PET cord. Therefore, the system resembles the Graf ligamentoplasty system, first described in 1992, in which conventional pedicle screws are linked by a braided polypropylene tension band [30]. This band locks an entire segment in extension, leading to compression of the posterior annulus. Furthermore, rotational range of motion is limited. In theory, the Graf system unloads the anterior portion of the intervertebral disc which is considered as one of the origins of low back pain. The posterior compression was considered to allow healing of posterior annulus tears.

Mid- and long-term results demonstrated mediocre outcomes and relatively high revision rates. It was proved that the system may lead to narrowing of the lateral recess as well as the neuroforamina with compression of nerve roots as a result. Furthermore, increased load on the posterior annulus may even increase discogenic back pain, as opposed to the original theory [12, 32].

In Dynesys, however, the PCU spacer encases the PET cord similar to a sleeve. The spacers are not elastic and therefore limit the amount of extension in the treated segment. More important, if lordosis is maintained, the spacers become weight-bearing in extension and therefore unload the posterior annulus. The overall range of motion in the treated segment is reduced significantly [12, 38].

Indications for Dynesys include degenerative diseases of the lumbar spine with instability and functional or structural spinal canal stenosis. Dynesys is contraindicated in all conditions which are accompanied by structural deficiencies such as bone tumors, fractures, and osteoporosis. Furthermore, lytic and isthmic spondylolisthesis as well as higher-grade degenerative spondylolisthesis should not be treated with Dynesys [31].

Bothmann et al. performed a retrospective study including 54 patients treated with Dynesys. Eighty-one percent suffered from radicular pain and 59 % had neurological deficits. All patients did unsuccessfully undergo conservative treatment

for at least 3 months. The indication for semirigid lumbar fusion was spinal canal stenosis in 41 %, degenerative disc diseases in 28 %, spondylolisthesis 1° in 26 %, and segmental instability in 6 % of all cases. Eighty-one percent of the patients additionally underwent nerve root decompression; in 15 % of cases, an additional PLIF was performed. 72.5 % of the patients scored good to excellent clinical results postoperatively. Pain scores as well as functional scores improved significantly when additional nerve root decompression was performed. In total, 27.5 % had to undergo revision surgery due to postoperative complications such as screw loosening, screw breakage, and degeneration of an adjacent segment [2].

A study published by Grob et al. included 50 patients treated with Dynesys in a retrospective study. Indications for Dynesys included degenerative disc disease and stenosis-associated lumbar instability. Thirty-one patients were available for a 2-year follow-up. Lower back pain improved in 67 % and radiating pain in 64 %; however, 33 % of the patients reported no change or worsening of lower back pain or radiating pain. Revision surgery was performed in 19 % [11]. The worsening of lower back pain might have been caused by hypermobility of the segments adjacent to the dynamic fixation, possibly resulting in a progression of degeneration of these segments, which was shown in biomechanical analyzes [37].

Stoll et al. demonstrated positive results in their multicenter trial including 83 patients. Dynesys was used in cases of segmental instability combined with spinal canal stenosis, degenerative disc disease, or revision surgery. In 67 %, nerve root decompression was performed additionally. The VAS back pain scale improved from 7.4 to 3.1, the VAS leg pain scale from 6.9 to 2.4, and the Oswestry disability index from 55 to 23 % [36].

A review performed by Anand and Baron concluded that Dynesys may be a useful technology in selected patients. Heterogeneous indications as well as heterogeneous techniques may lead to undesired results. In future, however, semirigid systems such as Dynesys that lead to decompression of the posterior portion of the intervertebral disc may become more important due to the need for disc stabilization in disc restoring procedures [1].

A 6-year follow-up observation of dynamic stabilization adjacent to single-level fusion did not show any radiological or clinical benefit in patients with asymptomatic initially degenerated adjacent segments. Because of the missing benefit and the fact that the authors also observed a high number of implant failures, they do not recommend the dynamic fixation adjacent to a fusion [27].

Hoff et al. compared sequestrectomy alone to additional transpedicular dynamic stabilization – using the Dynesys device – for lumbar disc herniations. Thus in a reasonable percentage of patients, solely sequestrectomy leads to unsatisfying results; the addition of a dynamic stabilization does not lead to a clinical benefit in case of symptomatic disc herniations and initial segment degeneration at a long-term follow-up. In combination with a high rate of necessary reoperations, the authors do not recommend the use of dynamic stabilization for this indication at the moment [14].

In a recent study by Hoppe et al., 39 patients were included in a retrospective study with a mean follow-up of 7.2 years. In all cases, surgery was performed at the L4/5 level.

The indication was limited to symptomatic degenerative lumbar spondylolisthesis, and additional bilateral decompression was performed in all cases. Back pain improved in 89 % and leg pain in 86 %. Twenty-one percent required further surgery [15].

NFlex Controlled Stabilization System

The NFlex controlled stabilization system (Synthes Spine Inc., West Chester, PA, SA) consists of polyaxial titanium alloy pedicle screws that are fixed to a semirigid polycarbonate urethane-sleeved rod. The integrated polycarbonate urethane (PCU) spacer is surrounded by a central titanium ring, to which a pedicle screw is locked. The controlled pistoning of this spacer along the axis of the central titanium core provides a shock absorber effect, reducing the overall rigidity of the construct [6].

Jeffrey et al. published a retrospective analysis of 65 NFlex cases. With a mean follow-up period of 25.6 months, the mean VAS score improved from 8.1 preoperatively to 3.8 postoperatively ($p < 0.001$), representing a 53 % improvement. Functional status also showed significant improvement, with a mean preoperative ODI score of 44.5 improving to 21.8 ($p < 0.001$) postoperatively, representing a 51 % improvement. The incidence of adverse events and reoperation was not inconsistent with the authors' experience with rigid fusion [6].

AccuFlex Rod System

The AccuFlex system (Globus Medical, Inc.) is a pedicle screw-/rod-based construct that combines Protex (Globus Medical, Inc.) 6.5-mm pedicle screws with a double helical cut made within a standard 6.5-mm rod and is approved by the Food and Drug Administration for lumbar fusions when used in conjunction with an anterior interbody device. The AccuFlex rod has undergone extensive biomechanical testing. The results of these tests demonstrated an adequate fatigue life [21]. In a clinical case series of 20 patients, Reyes-Sanchez et al. demonstrated that after a 2-year follow-up, 83 % of patients showed clinical benefits but 22 % required hardware removal due to fatigue [28].

Isobar TTL

The Isobar TTL system (Scient'x USA) is composed of a titanium alloy rod with a dampener made of stacked titanium alloy o-rings and received FDA clearance for use as an adjunct to spinal fusion in 1999 [9]. The system allows a small amount of both axial and angular motion via this dampener. Perrin and Cristini reported a retrospective study of 22 patients. During the 8.27-year follow-up period, 68.2 % of the patients reported mild leg pain and 72 % of the patients reported no or mild back pain. The adjacent level was also shown to be protected by the Isobar TTL system [25].

CD Horizon Legacy PEEK Rod

The CD Horizon Legacy PEEK rod (Medtronic Sofamor Danek, Memphis, TN) is composed of polyetheretherketone and is more flexible than the titanium rods [9].

Bioflex Spring Rod Pedicle Screw System

The Bioflex system (Bio-Spine Inc.) is a pedicle screw-based system that is composed of rod-shaped nitinol with one or two loops to confer stability in flexion, extension, and lateral bending. Nitinol is an alloy of titanium and nickel, also called the “memory metal” due to its ability to return to its original shape after deformation [9]. Kim et al. published the results of 103 patients treated with the Bioflex system alone or in combination with rigid fixation (PLIF+ Bioflex). The authors observed that the range of motion (ROM) in looped segments that were treated with PLIF was significantly reduced, but the changes in the ROM in looped segments without PLIF were not significant. The authors concluded that the Nitinol Bioflex dynamic stabilization system achieved stabilization while simultaneously permitting physiological movement which in turn decreases the degeneration of adjacent segments [17].

Dynamic Screws

Cosmic Posterior Dynamic System

The Cosmic posterior dynamic system (Ulrich medical) is a pedicle screw-based dynamic stabilization system. The device has been used as non-fusion technique in spinal stenosis with or without mild degenerative spondylolisthesis. A calcium phosphate-coated hinged pedicle screw head is the main character of the system allowing minimal segmental motion.

Biochemical in vitro studies showed in a 1-level pedicle screw-rod construct, hinged-dynamic screws allowed a quantity of motion that was substantially closer to normal motion than that allowed by rigid pedicle screws. Both systems altered kinematics similarly. Less load was borne by the hinged screw construct, indicating that the hinged-dynamic screws allow less stress shielding than standard rigid screws [3].

Another biomechanical analyses – published by Schmoelz et al. – showed that after bisegmental decompression, the ROM in all motion planes was restored to the range of intact segments by the implantation of the Cosmic device [29].

In a prospective observational designed study, Stoffel et al. presented 103 patients that were consecutively treated using the Cosmic system for painful degenerative segmental instability spinal stenosis between April 2006 and December 2007 [35]. Preoperatively MRI and myelography/CT and clinical parameters (general/

neurological examination, visual analogue scale (VAS), Oswestry disability index (ODI), SF-36, and Karnofsky (KPS)) were recorded and repeated in defined intervals. Full data was collected in 100 out of 103 patients (65f/38m, median age 65a), mean follow-up was 15 months, and dynamic stabilization was performed as first-tier surgery in 43 cases and as second-tier therapy in 60 cases. Decompression of the neuronal structures was necessary in 83 cases. Degenerative pseudospondylolisthesis was present in 51 patients, and osteochondrosis or macroinstability without olithesis was present in 52 patients. One-level operation was performed in 47 cases, two-level in 47, and three-level in 9 cases.

The analyzes showed 3 cases of early reoperation due to misplaced screws, 8 cases of hematomas or impaired wound healing and one case of a misjudged instability/stenosis of adjacent motion segments but no case of postoperative neurological deterioration (transient/permanent). Later reoperations within the follow-up period were necessary in 10 patients due to symptomatic advanced degeneration of an adjacent segment ($n=6$), persistent stenosis/disc protrusion of an instrumented segment ($n=3$), secondary screw loosening ($n=2$), or osteoporotic fracture of an adjacent vertebra ($n=1$). Dynamic stabilization led to significant improvement of pain (VAS preop, 65 ± 1 ; post-op, 21 ± 2 , $p < 0.001$) and performance (KPS preop, 70 ± 1 ; post-op, 82 ± 1 , $p < 0.001$) and a significant reduction of back pain-related disability (ODI preop, 51 ± 1 %; post-op, 21 ± 1 %, $p < 0.001$). The results of the SF-36 were summarized in a mental and in a physical health component. Both components reflect a statistically significant improvement of the subjectively felt health between the preoperative status and the status at last follow-up (norm-based SF-36: mental preop, 44; post-op, 48; physical preop, 41; post-op, 46, $p < 0.01$).

A multicenter study initiated by von Stempel et al. using the Cosmic screws demonstrated similar results [20]: between May 2004 and January 2005, six orthopedic and neurosurgical departments recruited 139 patients treated with Cosmic for stabilization without fusion. Indications for surgery were low back pain, sciatica, and neurogenic claudication after failed conservative therapy. Age, sex, weight, ODI score, and 10-point VAS score were recorded in each patient. Additionally, the height of the intervertebral discs (IVH) and lordosis were measured radiographically. Data from 185 patients with a follow-up of at least 24 months were recorded. Twenty-four patients were excluded due to a combination of instrumentation with bony fusion and another 22 patients were lost to follow-up. Decompression of neural structures was performed in 70 patients, 26 % of which had previous surgery in the index level. In the remaining 69 patients without decompression, 30 % had previous surgery. Patients without decompression demonstrated an improvement in ODI of 49.3–24.5 % after 2 years, whereas those with decompression showed improvement of 48.7–20.6 %. Pain decreased from 7.4 to 2.4 and from 7.1 to 2.7 on the 10-point VAS in patients without and with decompression, respectively. Changes in IVH and lumbar lordosis were not detected. Eleven patients underwent revision surgery, five of them with deep wound infection, the others because of adjacent level instability, hematoma formation, broken or loosened screws, and osteoporotic fracture. In eight patients radiolucent areas around the screws were documented, without clinically need of revision. There were no screw misplacements.

A multicenter prospective randomized controlled trial comparing Cosmic-based dynamic stabilization with 360° fusion (pedicle screw instrumentation plus interbody cage) is currently underway in Germany to establish class I data.

Total Facet Replacement Devices

TOPS: Total Posterior Arthroplasty System

The total posterior arthroplasty system (TOPS) uses a pedicle screw-based posterior arthroplasty prosthesis that was developed to provide dynamic, multiaxial, and 3-column stabilization while preserving normal motion [9]. A study of 29 patients who were treated with the TOPS for spinal stenosis and/or spondylolisthesis at L4-5 due to facet arthropathy showed that the clinical status improved significantly following treatment with the TOPS device [23]. ODI score decreased by 41 %, and the 100-mm VAS score decreased by 76 mm in a 1-year follow-up. There was no device-related failure.

TFAS: The Total Facet Arthroplasty System

The total facet arthroplasty system (TFAS) is a posterior non-fusion stabilization device to treat moderate to severe spinal stenosis using prosthetic metal joints to replace degenerated joints as used in knee and hip arthroplasty [9]. An in vitro study in nine human cadavers showed that after a wide range of decompressions on the neural elements, TFAS overcame the need for fusion by stabilizing the surgically modified spine in a manner similar to intact vertebrae while restoring the physiologic kinematics [26].

Conclusion

Fusion surgery has been used as a predominant technique to treat degenerative spinal disorders for decades. Adjacent segment disease is supposed to occur due to a transfer of load from a stabilized motion segment to the adjacent level. Biomechanically, a dynamic stabilization device should restrict (painful) motion to a physiological level, thus controlling pain and avoiding adjacent segment degeneration. Most pedicle screw-based systems so far, however, have either been too rigid almost imitating fusion or prone to mechanical failure. The rigidity of, e.g., the Dynesys system has been held responsible for a high rate of screw breakage and loosening. These hardware failures are compensated by lower perioperative morbidity in comparison to 360° fusion, as interbody work increases OR time and complication rates.

Compared to rigid stabilizations, short-term results with a follow-up of up to 2 years promise similar clinical outcomes for dynamic pedicle screw-based stabilization [24] but also demonstrated the abovementioned increased rate of revisions [7]. Due to the problems of screw loosening, dynamic stabilization devices are not an option to treat osteoporotic patients [9]. Overall, clinical results from uncontrolled prospective and retrospective series vary greatly, and both patient cohorts and surgical techniques are heterogenous. For hybrid constructs, combining rigid and dynamic pedicle screw-based systems, hardly any clinical data has been published.

The benefit of the currently available dynamic stabilization systems with respect to adjacent segment disease is still questionable, as an advantage over fusion surgery could not yet been demonstrated. Many devices like facet joint arthroplasty systems are still experimental. As a randomized comparison of dynamic stabilization versus 360° fusion is lacking, there is currently not sufficient evidence to support (or refuse) pedicle screw-based dynamic technology.

Proposal for the Future

Complication rates and long-term revision rates of fusion surgery particularly for chronic low back pain dramatically call for other surgical options in lumbar degenerative disc disease. Adjacent segment disease is posing a prominent clinical problem in these patients. Some authors argue for optimizing sagittal balance to avoid this sequel of fusion, but the relationship of sagittal balance and adjacent segment disease is still a matter of debate. Regardless of the applied technique of fusion, a dynamic stabilization that eliminates painful motion without increasing stress on adjacent levels should be beneficial. This theoretical demand, however, potentially requires a different stiffness for each individual patient.

Future research must thus be dedicated to develop (1) diagnostic tests, which identify the individual biomechanical situation of the patient, (2) less rigid dynamic stabilization devices with (3) lower revision and hardware failure rates, and ideally (4) devices with variable or a wide range of different stabilization magnitudes. Maybe future implant generations will fulfill these tasks or biological approaches will be developed that render mechanical solutions unnecessary.

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Juvenile Chronic Arthritis and the Craniovertebral Junction in the Paediatric Patient: Review of the Literature and Management Considerations

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Abstract

Introduction Juvenile chronic arthritis (JCA) is a systemic disease of childhood affecting particularly joints. JCA is a heterogeneous group of inflammatory joint disorders with onset before the age of 16 years and is comprised of 7 subtype groups. The pathogenesis of JCA seen in the cervical spine is synovial inflammation, hyperaemia, and pannus formation at the occipitoatlantoaxial joints resulting in characteristic craniovertebral junction findings. Treatment of craniovertebral junction instability as a result of JCA is a challenge. The best treatment strategy may be difficult because of various radiological and clinical severities. A review of the literature and management considerations is presented.

Review No randomised controlled trial or systematic review on this subject has been published. Only experts' opinions, case reports, and case series have been described. Thirty-four studies have been reviewed in this study. Involvement of the cervical spine in patients with JCA can lead to pain and functional disability. The subtypes that usually affect the cervical spine are the polyarticular type and systemic onset type and rarely the pauciarticular type. The most common cervical spine changes related to JCA are as follows: (1) apophyseal joint ankylosis at C2–C3, (2) atlantoaxial subluxation, (3) atlantoaxial impaction, (4) atlantoaxial rotatory fixation, and (5) growth disturbances of the cervical spine. The incidence of severe subluxations has decreased in the last decade as result of antirheumatoid drugs and biologicals. However, neurological compromise still occurs in JCA patients necessitating surgical treatment.

Conclusion Whenever the cervical spine is involved in rheumatoid arthritis patients without neurological deficits, conservative treatment is legitimate. Once patients develop neurological signs and symptoms, surgical treatment should be considered with particular focus to age, severity of the disease, and general health condition. Skilled anaesthesia is crucial and the surgical procedure should only be carried out in centres with experience in craniovertebral junction abnormalities.

Keywords Rheumatoid arthritis • Craniocervical junction • Atlantoaxial • Paediatric

Introduction

The craniovertebral junction (CVJ) has been identified as the most complex joint of the axial skeleton from both anatomical and kinetical point of view. The main features ensuring stability of the region, while allowing movements of the head and neck to take place, are (1) the bony structure of the axis with its odontoid process; (2) the transverse ligament of the atlas, a thick, strong band which holds the odontoid process in contact with the anterior arch of the atlas; and (3) the alar ligaments, two strong rounded cords arising one on each side of the upper part of the odontoid process, passing upwards obliquely and laterally inserted into the occipital bone.

Cervical spine instability in children is rare and can be caused by many factors. Although it most frequently occurs in the upper cervical spine, all vertebrae bodies from the occiput to the thoracic spine may be involved [11]. CVJ instability of non-traumatic origin represents 27 % of all the CVJ instabilities in the paediatric age group. The presence of different anatomical and motion abnormalities of the osteo-ligamentous elements may result in severe spinal cord compression [14].

Juvenile chronic arthritis (JCA) is a systemic disease of childhood affecting connective tissue, particularly joints. Different names and slightly differing definitions are used throughout the world; the entity JCA is used in Europe and juvenile rheumatoid arthritis (JRA) in the United States. The main difference between JCA and JRA is the inclusion of juvenile spondyloarthropathies (i.e. ankylosing spondylitis, inflammatory bowel disease, psoriatic arthritis) in the European but not in the US criteria for the disease [20].

JCA is a heterogeneous group of inflammatory joint disorders with onset before the age of 16 years [33]. JCA is comprised of 7 subtype groups based on the clinical presentation: systemic arthritis, oligoarthritis, rheuma factor-positive polyarthritis, rheuma factor-negative arthritis, enthesitis-related arthritis, psoriatic arthritis, and undifferentiated JCA [10, 12].

Anatomical and biomechanical differences between the developing child and the adult account for the different patterns of injury in these two groups. A thorough knowledge of the anatomy, embryology, and normal development of the paediatric cervical spine is essential to understand its specific problems and avoid pitfalls [11].

Review

No randomised controlled trial (RCT) or systematic review on JCA with cervical spine involvement has been published [31, 32]. Only expert's opinions, case reports, and case series have been described. PubMed and Embase were used to search for relevant studies and articles. Nine-hundred and nineteen studies were selected and their abstracts reviewed from 1960. Thirty-four studies were included in this review.

Cervical Spine Involvement in Juvenile Chronic Arthritis

In patients with JCA the cervical spine is often affected, leading to pain, disability, and functional limitations [20]. The pathogenesis of JCA seen in the cervical spine is synovial inflammation, hyperaemia, and pannus formation at the occipitoatlanto-axial joints resulting in characteristic craniovertebral junction findings (Table 1).

The subtypes that usually involve the cervical spine are the polyarticular and systemic onset types; only rarely does the oligoarticular type affect the cervical spine [15]. The incidence of cervical spine involvement varies among the different subtypes of the disease; 45 % of all patients with juvenile chronic polyarthritis were

Table 1 Different cervical spine involvements in JCA

Cervical spine involvement in JCA
Anterior atlantoaxial subluxation
Anterior erosions of odontoid process
Apophyseal joint ankylosis
Atlantoaxial impaction
Fusion C2–C3
Growth abnormalities, change in the longitudinal and circumferential growth between adjacent vertebral bodies and decreased disc height
Occipitoatlantoaxial rotatory fixation (OAARF)
Soft-tissue calcification appearing adjacent to the ring of the atlas. The aetiology is unknown but may reflect excessive traction producing osteophytes secondary to hypermobility
Subaxial subluxation

Table 2 Review of cervical spine involvement in JCA

Study	N	AAS	AAI	Ankylosis	Odontoid erosion	Subaxial subluxation	Growth disturbance vertebra	Cervical spine involvement
Fried et al. [9]	92	5 (5 %)	–	4 (4 %)	–	–	–	31 %
Hensinger et al. [15]	121	14 %	–	28 %	19 %	3 %	(28 %)	–
Laiho et al. [19]	18	5 (28 %)	–	12 (67 %)	–	3 (17 %)	–	94 %
Laiho et al. [20]	159	27 (17 %)	39 (25 %)	65 (41 %)	–	10 (6 %)	41 (26 %)	62 %
Kjellberga and Pavloub [17]	82	4 (5 %)	13 %	15 (18 %)	12 (15 %)	–	–	35 %
Elhai et al. [6]	57	19 (33 %)	6 (10 %)	8 (14 %)	11 (19 %)	4 (7 %)	9 (16 %)	65 %

reported to have clinical symptoms due to cervical spine involvement [3], whereas only two out of 46 patients (4 %) with the oligoarticular subtype showed cervical spine involvement [4]. Cervical spine involvement usually occurs in the first 1–2 years from the onset of the disease and presents with stiffness [11]. The radiographic manifestations of JCA differ from the adult form and include the following: relatively late destruction of articular cartilage and bone, growth disturbances, spondylitis of the cervical spine with associated vertebral subluxation and ankylosis of the apophyseal joint, and micrognathia [15]. Several studies on JCA with cervical spine involvement have been published (Table 2). Radiographic examinations have documented cervical spine involvement in 31–94 % of the patients with JCA. Erosive changes around the odontoid process occurred in 15–19 % of the patients with the polyarthritic and systemic onset subtype. The most common cervical spine changes related to JCA are listed below:

1. Apophyseal joint ankylosis (Fig. 1)

Apophyseal joint ankylosis, or fusion, constitutes a characteristic cervical spine change in JRA. Apophyseal joint ankylosis at C2–C3 level is the most frequently noted cervical spine abnormality which has been reported 4–67 % of the patients with JCA. It may result in growth disturbances of the cervical spine, especially in patients with early onset subtype (Table 2).

Fig. 1 Apophyseal joint ankylosis of the subaxial cervical spine. Also atlantoaxial subluxation in a patient with JCA



2. *Atlantoaxial subluxation* (Fig. 1)

Anterior atlantoaxial subluxation (AAAS) is defined as an increase of the space between the anterior arch of the atlas and the odontoid peg. The anterior atlantodental interval (AADI) is the space between the anterior aspect of the dens and the posterior aspect of the anterior ring of the atlas. In children, AADI more than 5 mm on lateral radiographs indicates instability [21, 27]. This is more than the 3 mm rule in adults because of an increased cartilage content of the odontoid and ring of the atlas in children as well as the increased ligamentous laxity in children. In children with rheumatoid arthritis, the AADI is frequently more than 3–5 mm, without disruption of the transverse ligament. The space available for the spinal cord (SAC) or posterior atlantodental interval (PADI) is a more useful measure in this situation. It is defined as the distance between the posterior aspect of the dens and the anterior aspect of the posterior ring of the atlas. SAC or PADI less than 13 mm may be associated with neurological symptoms. Spinal cord compression caused by atlantoaxial subluxation may result in a devastating traumatic quadriplegia or sudden death. More commonly it produces spasticity of extremities, tetraparesis, or weak and atrophic hands.

The normal range of motion of the atlantooccipital joint is not well defined [11]. The prevalence of anterior atlantoaxial subluxation in JCA patients varies between 5 and 33 % in different studies (Table 2).

3. *Atlantoaxial impaction (AAI)*

Cranial settling or atlantoaxial impaction is another serious complication of long-standing rheumatoid arthritis. This occurs when the skull and C1 begin to settle down on the cervical spine, and the commonly eroded odontoid process will be located more cranially, leading to impingement of the brainstem or craniovertebral junction. According to some authors, the compression of the medulla oblongata and vertebral arteries is the aetiology of sudden death among patients with rheumatoid arthritis who experience cranial settling. AAI occurs in 10–25 % of patients with JCA (Table 2).

4. *Atlantoaxial rotatory fixation (AARF)*

Injury to the atlantoaxial joint capsules or ligaments can result in atlantoaxial rotatory subluxation. If reduction of this subluxation does not occur, ligamentous or joint capsule contraction can result in AARF. Atlantoaxial rotatory fixation typically causes the head to be held slightly flexed, tilted 20° to one side, and rotated 20° in the opposite direction from the head tilt, the so-called Cock-Robin position. Risk factors for chronic or irreducible AARF include ligamentocapsular contractures, fibrous formations within the synovial joint, inflamed adherent synovial surfaces, osseous union between C1 and C2, and abnormal facet deformities [10]. The C1–C2 rotatory dislocation is classified into four types: type I simple rotatory displacement without any anterior shift, type II rotatory displacement with anterior shift less than 5 mm, type III anterior shift greater than 5 mm, and type IV rotatory displacement with posterior shift. Definitive treatment for types III and IV includes open reduction, C1 laminectomy, and occipitocervical internal fixation and fusion [10]. Atlantoaxial rotatory fixation may also develop after trauma, upper respiratory tract infection (Grisel syndrome), rheumatoid arthritis, congenital conditions of Down syndrome, Morquio and Marfan syndrome, and surgery of the neck.

Diagnosis and management of atlantoaxial rotatory subluxation is challenging because of its variability in clinical presentation. Although several treatment modalities have been defined, there is no consensus on the most appropriate therapy [2].

Occipitoatlantoaxial rotatory fixation (OAARF) is a rare condition involving fixed rotational subluxation of the atlas in relation to both the occiput and axis. Atlantoaxial rotatory fixation appears to precede OAARF in most cases, as untreated AARF may cause compensatory counterrotation and occipitoaxial fixation at an apparently neutral head position [10].

5. *Growth disturbances in the cervical spine*

Inflammatory changes of the cervical spine are common, and growth disturbances of cervical vertebrae in patients with JCA have been described in 16–28 % of patients. This is probably caused by the inflammatory disease and/or its more aggressive pharmacotherapy. The spinal canal diameter was only slightly smaller in the JCA group [7].

In general, patients with severe JCA have smaller cervical vertebral bodies. They also have more variations in the sizes of their own vertebrae, representing growth disturbances of individual vertebral bodies. Laiho described that the fourth cervical vertebra was abnormally small in 41 patients (26 %) [20].

Radiological Examination

As in adults, standard radiographs remain an important diagnostic tool of paediatric cervical instability [8, 22, 26]. Plain neutral radiographs of the cervical spine are often hard to interpret. However, additional flexion/extension views can show instability in this region. Magnetic resonance imaging (MRI) is the method of choice to detect spinal cord compression and intramedullary signal abnormalities. Nevertheless, MRI studies are not able to provide information on the functional involvement of the cervical spinal cord. MR imaging provide optimal information on soft issue and potential presence of craniocervical stenosis. MRI easily depicts the space available for the spinal cord. Presently, there is no dispute that a sagittal diameter of <13 mm may be associated with neurological symptoms or signs. However, spinal canal stenosis without cord compression on neutral cervical position may exist since the anteroposterior diameter of the cord is usually some millimetres narrower than the canal itself. Possible compression is present when no cerebrospinal fluid can be discerned between the cord and the surrounding soft-tissue structures, and definite cord compression is present when the spinal cord shows indentation.

Computed tomography (CT) may be performed to better define the osseous anatomy of the craniovertebral junction, atlantoaxial relationship, and the odontoid process.

Oren et al. reported on MRI of the cervical spine in 20 patients (mean age 10 years) with a preliminary diagnosis of juvenile rheumatoid arthritis (JRA). In all patients conventional x-rays of the cervical spine were obtained, and the relationship between clinical status and MRI findings were evaluated. Two patients with clinical manifestations, including neck pain and diminished range of motion, exhibited significant pathologic features on radiogram and MRI, the latter providing more detailed information. Among 18 patients who had no complaints of their cervical spines, 3 patients (16) had soft-tissue involvement, pannus formation, or erosions on the surface of atlantoaxial joints; only four patients (20 %) had erosions on plain x-ray views. An MRI should be performed in every patient with a probable diagnosis of JRA since the early diagnostic ability of MRI allows early therapeutic intervention [25].

Arthritic changes in the cervical spine can be detected at a young age on plain lateral cephalometric radiographs and should be evaluated when available. Cervical spine involvement is seen in 21–94 % of patients with JCA. The large range in frequencies depends on the severity of the disease of patients examined and the age of the patients when the radiographs were taken [17].

By contrast, anomalies of the craniovertebral junction in otherwise normal individuals are rare, the most common being atlantooccipital assimilation, which occurs in 1–2 % of the normal population [5].

Clinical and roentgenographic follow-up examinations of patients with JCA suggest that neurologic complications are less likely to develop in these patients than in patients with adult rheumatoid arthritis (RA). The neurologic sequelae of cervical spine involvement in adult rheumatoid arthritis have been well documented. Compression of the spinal cord or medulla oblongata can develop secondary to basilar invagination, atlantoaxial subluxation, or subaxial instability in RA [9].

The paediatric cervical spine has the distinguishing feature of being able to adapt to an abnormal situation of one or the other of the two segments. Thus, a decrease in upper cervical spine mobility results in an adaptive increase in the rotatory mobility of the lower segment. Range of motion of both of these segments decreases as the child gets older, being limited by osteoligamentous structures ensuring mechanical stability during growth. Cervical instability mainly affects the upper cervical spine, particularly between C1 and C2.

Studies have reported that atlantoaxial instability can be a feature of juvenile and adult ankylosing spondylitis (AS), reactive arthritis, juvenile idiopathic arthritis, and rheumatoid arthritis. Spondylarthritis in childhood and adolescence refers to a family of rheumatic diseases with overlapping clinical features that may cause peripheral arthritis and often enthesitis at an early age and may span through adulthood [19, 23].

Conservative Treatment

If the cervical spine is involved in patients with JCA without neurological deficits, conservative treatment with physical therapy and antirheumatoid drugs is an option. Once patients develop neurological signs and symptoms, surgical treatment should be considered with respect to the age, the severity of the disease, and general health condition. In fact, after the age of 10–12 years, the sequel of paediatric and adult cervical trauma becomes similar [14]. A treatment algorithm for patients with JCA and craniovertebral junction pathology is shown in Fig. 2.

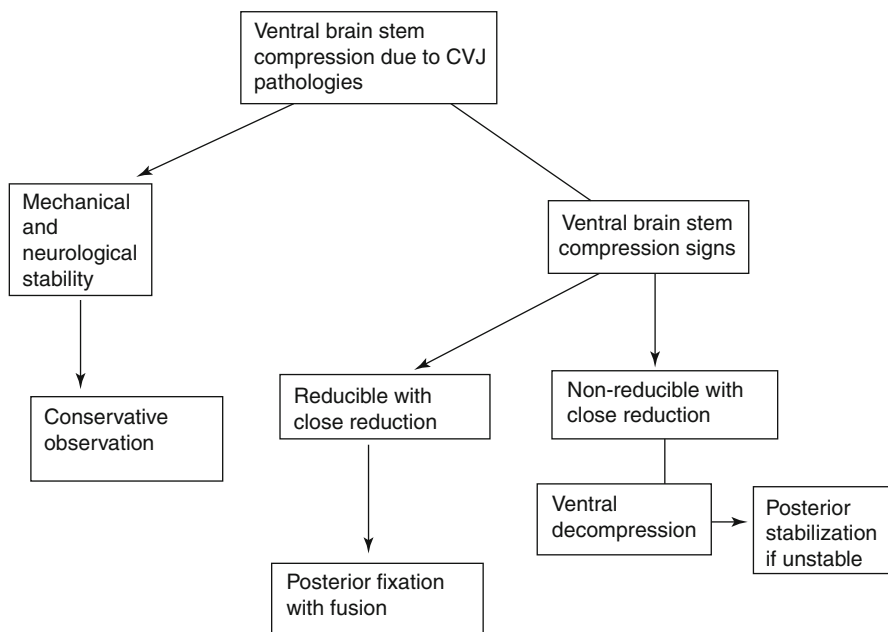


Fig. 2 Treatment algorithm of paediatric patients with craniovertebral junction anomalies

Epidural lipomatosis, a condition characterised by abnormal unencapsulated accumulations of fat on or outside the dura, is rare [1]. However, it should be considered in the differential diagnosis of JCA patients receiving high-dose and/or prolonged corticosteroid therapy who present with neurologic signs and symptoms referable to the spinal cord.

It is noteworthy, however, that most advances in the treatment of JCA were performed during the past decade with the advent of biotherapies. Consequently, the prevalence and characteristics of radiological cervical involvement in JCA persisting into adulthood in the current era remain unknown [6].

Anaesthetic Evaluation

A potential risk of AAS and AAI is the difficulty that is often encountered when inducing general anaesthesia. Micrognathia and stiffness or instability of the neck make intubation difficult, and care must be taken to avoid fracture of an already compromised odontoid process or neurological deterioration [17]. If the patient's predisposition to atlantoaxial dislocation is recognised, excessive head movements during general anaesthesia should be avoided. Otherwise, this may result in severe neurological deficits or quadriplegia.

Timing of Surgery

The optimal time for surgery may be early in life in order to prevent neurological deterioration by spinal cord compression. In asymptomatic patients, the current recommendations for surgical decompression with fusion are <14 mm space available for the cord or cervical instability >8 mm. Patients with 5–8 mm of cervical instability, with clinical evidence of spinal cord impingement, and patients with a deteriorating neurological condition warrant surgical treatment. Transoral excision of the anterior soft-tissue mass should be considered in order to achieve immediate and direct anterior decompression of the spinal cord and in cases of unreasonably hazardous posterior fusion. However, after atlantodental fixation the anterior located pannus mass will resolve, making anterior transoral surgery not always necessary. Even in paediatric patients with catastrophic neurological conditions, a prompt and aggressive management of CVJ instability is justified since remarkable clinical improvement is possible [14].

Operative Treatment

The major goals of surgical treatment of CVJ instability are neural decompression with stabilisation and fusion of the spine. The type of fixation depends on the age of the patient with the resultant bone quality and anatomical dimensions. Generally,

screw fixation is the most stable solution although wiring techniques can also be used in smaller and younger patients. The surgical fixation techniques performed in adults are not always possible in children. Lateral mass screw placement is often the best option with the lowest complication rate. Pedicle screws offer the best mechanical strength by achieving three-column fixation. They do, however, carry a significant risk of injury to the vertebral artery, spinal cord, and exiting nerve roots. Different wiring techniques are available if screw fixation is too risky. Spinous process and facet wire techniques not only are safer than sublaminar wires but also have equivalent biomechanical strength. Because of the high complexity of these surgeries, custom made implants are often used and necessary to be able to treat this pathology. Complications such as infection, pseudarthrosis, malalignment, nerve root injury, spinal cord lesion, implant failure, and extension of the fusion are potential problems with all techniques.

Once patients are severely incapacitated or ventilator dependent, the prognosis of surgical decompression and fixation is very poor. Preoperative traction can be suitable for improvement of the patient's neurological status and alignment of the cervical spine [29, 30].

Transoral Decompression

In 1962 Fand and Ong approached irreducible CVJ pathologies with transoral decompression and reported high mortality and morbidity rates. Today, with advances in microsurgery and diagnostic tools, this region can be easily reached and results have much improved [18].

The commonly accepted paradigm for neuroradiologically demonstrable irreducible C1–C2 dislocation with anterior neural compression is surgical decompression by the transoral route.

The transoral approach is accepted as a safe procedure with an aid of specially organised retractors. A split mandibular osteotomy is possible to gain a wide operative field for odontoid resection. Guyuron reported that about 25 % of patients with juvenile rheumatoid arthritis tend to have complications with the mandibular micrognathia, undeveloped and retropositioned mandible, and trisms, which make the birdface deformity [16].

There are three advantages of initial transoral excision of the anterior extradural soft-tissue elements in patients with severe spinal cord compression. Firstly, transoral surgery is performed with the head extended, a position in which any anterior atlantoaxial subluxation is reduced and the available subarachnoid space is usually enlarged. Secondly, adequate anterior decompression permits safer posterior fusion. And thirdly, excision of the anterior soft-tissue mass is often the only way to achieve direct and immediate decompression of the spinal cord, which will possibly contribute to improvement of established neurological deficit.

However, when preoperative dynamic manoeuvres and traction show a reducible deformity, neural decompression may be obtained by reduction of the dislocation and fixation and fusion with posterior instrumentation.

Optimal stabilisation after transoral dens resection is still a controversial issue in the literature. Neurological impairment due to instability can be prevented in most cases. However, if there is instability in addition to ventral compression, the need for stabilisation in these cases is accepted [18]. Posterior decompression and fusion following anterior decompression can usually be performed under the same anaesthesia. Many similar posterior occipitocervical implants with unique advantages and disadvantages have been described, and many alternative fixation methods used in surgery in recent years have been reported [18].

C1–C2 Fixation

An option of surgical treatment of atlantoaxial rotatory fixation can be C1 lateral mass screws and C2 pedicle screws with a temporary transverse rod across the atlas and axis to secure a three-column fixation to derotate the subluxed atlas into anatomical alignment. Rods are then connected between the C1 lateral mass and the C2 pedicle screws and fusion obtained with autologous grafts [28]. Goel et al. proposed a posterior approach to this pathology by opening the facet joints posteriorly, excising the capsules, and sectioning of the large C2 ganglion with stabilisation by a C1–C2 plate and screw construct [13]. An always posterior strategy for irreducible C1–C2 dislocation has also been recommended by Visocchi et al. It is also known that the pathologic stickiness of the atlantoaxial complex in AARF progressively increases with the duration of pretreatment delay. Also, irreducibility in a case of rheumatoid arthritis may develop as a consequence of the high grade of synovitis and adhesion of the thick pannus. In such a scenario, an anterior release procedure may be necessary. Surgical OAARF treatments have included open reduction followed by C1–C2 arthrodesis, occiput C1–C2 arthrodesis, and C1–C2 transarticular screw fixation. Direct posterior reduction of basilar invagination and C1–C2 subluxation can be achieved without anterior decompression.

Intraoperative reduction of C1–C2 subluxations can be technically challenging when one uses traditional techniques (e.g. wiring and transarticular screw fixation). Wiring techniques are limited in their ability to achieve and maintain adequate reduction intraoperatively. Transarticular screw techniques are excellent for maintaining alignment, but they do not enable reduction very well. The advantage of the C1 lateral mass screw with C2 pedicle screw constructs provides the surgeon with the ability to independently manipulate C1 and C2 as well as the ability to maintain reduction for fusion. In certain patients, the anomalous course of the vertebral artery precludes the safe placement of C2 pedicle screws. In these instances, translaminar (or intralaminar) screw placement in C2 can provide an alternative fixation point in C2 without threatening injury to the vertebral artery [24, 34].

Conclusion

Conservative treatment is a legitimate option in patients with JCA without neurological deficits. Once patients develop neurological signs and symptoms, surgical treatment should be considered. Prophylactic surgical decompression and fusion can be performed when the space available for the spinal cord is <14 mm or if there is cervical instability >8 mm. Depending on the age and bone quality of the patients, different types of surgical fixations can be used: occipitocervical screw fixation with transarticular or pedicle screw placement as well as hooks or wiring techniques.

Multidisciplinary tailored treatment of craniocervical instability with rigid internal fixation is recommended in regard to effective long-term results, even in severely symptomatic children with CVJ abnormalities [14]. The long-term stabilisation of the CVJ, without undesired effects on the developing spinal structures, and overall clinical improvement are major end points related to the evaluation of effectiveness of surgical management of symptomatic CVJ abnormalities in children [14]. In case of CVJ instability of malformative origin, it is mandatory to tailor the operative technique and the surgical devices to the anatomical features of each patient and to the experience and technical skill of individual surgeons as well as anaesthetists.

Skilled anaesthesia is crucial and the surgical procedure should only be carried out in centres with experience in CVJ abnormalities.

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