Advancing pedicle screw system: a descriptive analysis of novel innovative technology revolutionizing possibilities using intraoperative augmented reality imaging during spinal surgery

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ADVANCING PEDICLE SCREW SYSTEMS: A DESCRIPTIVE ANALYSIS OF NOVEL INNOVATIVE TECHNOLOGY REVOLUTIONIZING POSSIBILITIES USING INTRAOPERATIVE AUGMENTED REALITY IMAGING DURING SPINAL SURGERY

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ACKNOWLEDGEMENT

Dedicated to my family.

LIST OF ABBREVIATIONS

ADVISE – engl. *Advanced Dynamic Visualization of Intraoperative Spinal Equilibrium Software*

AF – lat. *Annulus fibrosus*

AR – engl. *Augmented reality*

CA – engl. *Computer Assisted*

CAN – engl. *Computer Assisted Navigation*

LOS – engl. *Length of stay*

NP – lat. *Nucleus pulposus*

PSS – engl. *Pedicle Screw System*

SSI – engl. *Surgical site infection*

1 INTRODUCTION

1.1 Problem Statement

The human spine, also known as the vertebral column, plays a fundamental role in providing structural support, mobility, and protection for the spinal cord, our most important neural pathway (1). For this reason, numerous spinal pathologies can affect the spine, leading to discomfort, pain and may significantly decrease the quality-of-life necessitating surgery.

Nowadays, every year, an estimated 4.83 million spinal surgeries are conducted worldwide (2). In many of these procedures, posterior fixation techniques or spinal fusion surgery is the state-of-the-art to treat spinal instabilities. Many are challenging and of high risk due to the spine's proximity to the spinal cord and the likelihood of nerve or spinal cord damage.

The procedure typically involves pedicle screw insertion via a minimal invasive posterior approach, where the screw heads serve as anchors for connecting plates or rods, which form a rigid stabilization of the spine (3). Relevant and crucial to this operation method is the precise low force insertion of the screw as well as the correct rod bending and alignment, which is tailored to the patient's anatomy, securely linking the vertebrae with the pedicle screws.

Despite increasing efforts to enhance the precision of screw placement through technological advancements, the evaluation of intraoperative spinal alignment remains an aspect that has not been dedicated to until recently.

Most recently, augmented guided navigation procedures for pedicle screw placement have been introduced into spine surgery. Elmi-Terander et al. demonstrated that using AR surgical navigation results in superior accuracy in screw placement compared to traditional free-hand surgical methods (4).

Yet, little has been done to approach the problem of rod bending. Manually bending the rod implant is a meticulous and time-intensive procedure. Many surgeons find themselves with difficulties in shaping and reducing the rods into the pedicle screw heads, with possibility of forceful reduction maneuvers, screw loosening or pull-outs leading to instances of mechanical failure, necessitating revision surgery. The development of more precise rod bending techniques can minimize surgical time and reduce the risk of complications, thereby enhancing overall procedural efficiency. Advances in robotic-assisted surgery and customized pre-contoured rods hold promise in addressing these challenges, potentially providing more consistent and accurate rod placement. This optimization is vital for enhancing visualization ultimately improving patient outcomes by averting mechanical overloading.

The goal of this study was to introduce a novel technology using augmented reality to display a virtual template for the target rod bending of the patients' anatomy by identifying trackable markers to estimate the 3D positions of the pedicle screw heads.

1.2 Anatomy

1.2.1 The vertebral column

The vertebral column serves as a critical support structure for the body's physical framework connecting bony and elastic structures enabling a high degree of stability while maintaining mobility on multiple levels such a ventral and dorsiflexion, lateral flexion, and rotation (5). In addition, it houses the nervous system, forming the spinal canal facilitating both movement and sensory perception (6).

Overall, the spine can be categorized into three primary sections: the cervical spine, the thoracic and the lumbar spine. The cervical and lumbar vertebrae naturally curve inward a term called lordosis. Kyphosis describes the outward curve in the spine, seen in the thoracic region.

This remarkable structure consists of 33 vertebrae categorized into 7 cervical, 12 thoracic, 5 lumbar, 5 sacral, and 4 coccygeal vertebrae (7) (Figure 1). These vertebrae, in conjunction with the skull, ribs, pelvis, and sternum, collectively form the axial skeletal system, playing a fundamental role in maintaining the body's form and function. Pathological conditions affecting the spine can result in severe consequences, significantly impairing an individual's quality of life.

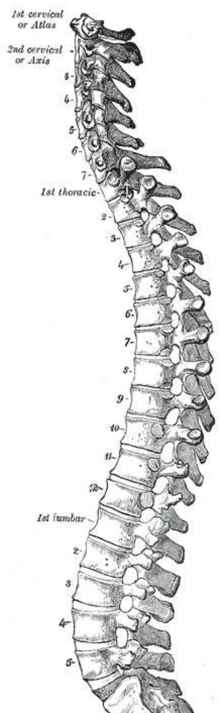


Figure 1. Anatomy of the vertebral column (8).

1.2.2 Structure of the vertebra

A typical vertebra is a remarkable and intricate anatomical structure, with each vertebra possessing unique characteristics, particularly from one region of the spine to another. Despite this variability, all vertebrae share a fundamental and essential structure that supports the spine's strength and function. The key components of a typical vertebra include the vertebral body, vertebral arch, and various vertebral processes (9) (Figure 2).

The vertebral body, a large cylindrical structure located at the anterior aspect of the vertebra, plays a vital role in providing strength and support to the spine. It is especially involved in bearing the weight of the upper body. As one progresses down the vertebral column, the vertebral bodies increase in size. These bodies are separated by intervertebral discs, which act as cushions, allowing for flexibility in the spine.

The vertebral arch, situated posterior to the vertebral body, consists of two pedicles and two laminae. The pedicles contain vertebral notches, both superior and inferior, which combine to create intervertebral foramina (10). Foramina serve as critical passageways for spinal nerves that exit from the spinal cord, connecting the central nervous system to the peripheral nervous system. The pedicles, laminae, and vertebral body collectively create the vertebral foramen, which encloses the entire spinal column, forming the vertebral canal. This canal is where the spinal cord is housed and protected.

In addition to the vertebral body and arch, a typical vertebra also features seven vertebral processes. These include two superior articular processes, two inferior articular processes, two transverse processes, and one spinous processes (11). These processes serve as attachment points for various ligaments and back muscles, contributing to the stability and movement of the spine. Collectively, these elements highlight the vertebra's complexity and its essential role in maintaining the structural integrity and flexibility of the spine.

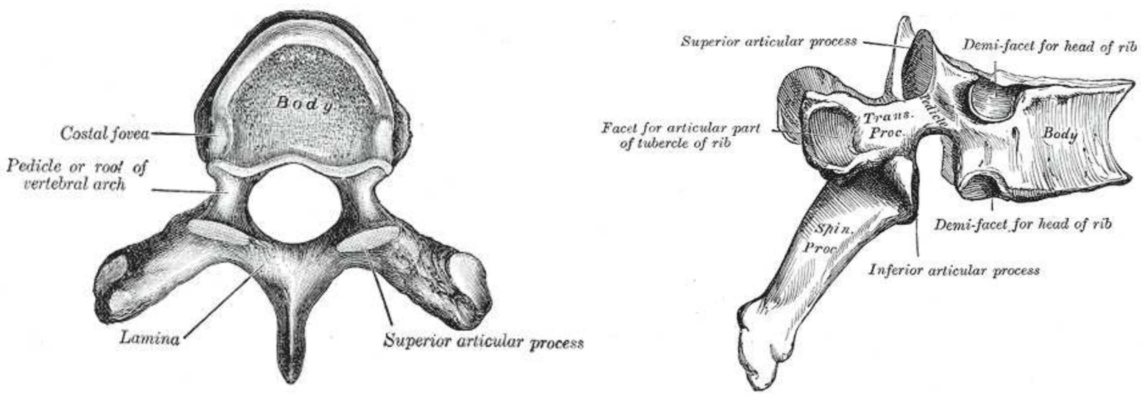


Figure 2. A typical thoracic vertebra, cranial and lateral view (12).

1.2.3 Intervertebral disc

The intervertebral disc is a crucial structure situated between adjacent vertebrae in the spinal column, functioning as a cushion and allowing flexibility while maintaining structural integrity. Comprised of complex elements, the intervertebral disc consists of the fibrocartilaginous ring named annulus fibrosus (AF), the nucleus pulposus (NP), and cartilaginous endplates, each contributing to its overall function (13). Due to their slightly wedge-shaped form, they contribute to the normal curvature of the spine. In addition, there is an increase in height from the thoracic to the lumbar spine downwards.

The AF is forming the outer ring of the intervertebral disc and is composed of concentric layers of fibrous tissue primarily made of type I collagen, consisting of fibrous lamellae obliquely intertwining, providing strength and resilience while containing the gel-like NF (14). At the center of the disc lies the NP, a gelatinous, hydrated core primarily composed of water, proteoglycans, and type II collagen (15). This structure provides compressive support, shock absorption, and allows for even distribution of forces within the disc, contributing to its ability to resist deformation (16). Surrounding the intervertebral disc, the cartilaginous endplates are thin layers of hyaline cartilage covering the superior and inferior aspects of the disc (17). These endplates facilitate nutrient and waste exchange between the disc and adjacent vertebrae, essential for the disc's metabolic functions and overall health (18).

As the intervertebral disc is subject to degenerative changes over the course of life, primarily due to the reduced water-binding capacity in bradytroph tissue, its elasticity decreases which leads to a gradual loss of its shock-absorbing function under axial load (19).

Moreover, the reduced water content in the intervertebral disc leads to the formation of tears in the AF (20). These changes result in instability of the motion segments. The pressurized NP pushes the damaged areas of the fibrous ring outward, causing a protrusion. If the fibrous ring is completely breached, it leads to an extrusion. When parts of the NP break away entirely, it is referred to as sequestration (21). Protrusion, extrusion, and sequestration can compress the spinal cord, nerve roots, and accompanying blood vessels, resulting in various symptoms such as lumbago, radicular pain syndrome, and cauda equina syndrome.

Overall, the degeneration process of the intervertebral disc is multifaceted, involving biochemical, structural, and functional changes. Understanding the progression and impact of disc degeneration is crucial for developing effective treatment strategies. Current therapeutic approaches range from conservative management, including physical therapy and pharmacological interventions, to surgical options like discectomy and spinal fusion, aimed at relieving pressure on neural structures and restoring spinal stability.

1.2.4 Spinal ligaments and musculature

The spinal column's stability and flexibility is dependent on a complex network of ligaments and muscles. The ligamentum flavum, anterior longitudinal ligament, posterior longitudinal ligament, interspinous ligaments, and supraspinous ligament are important in maintaining the structural integrity of the spine (22) (Figure 3). The ligamentum flavum, for instance, resides within the vertebral canal, connecting adjacent laminae and offering stability during flexion. Additionally, the ligament is tensioned in the upright body posture and stabilizes the spine in the sagittal plane. Conversely, the anterior longitudinal ligament extends along the front surface of the vertebral bodies, from the occipital bone to the first sacral vertebra, limiting excessive extension. The posterior longitudinal ligament, located within the vertebral canal, runs along the back of the vertebral bodies preventing excessive flexion and bulging of intervertebral discs (23).

The interspinous ligaments run between the spinous processes of adjacent vertebrae and serve to limit excessive flexion. Furthermore, it physiologically prevents vertebral slipping. The supraspinous, also known as the supraspinal ligament, stretches from the tips of the spinous processes of C7 all the way down to the sacrum. In the cervical spine, it transitions into the ligamentum nuchae and limits ventral flexion.

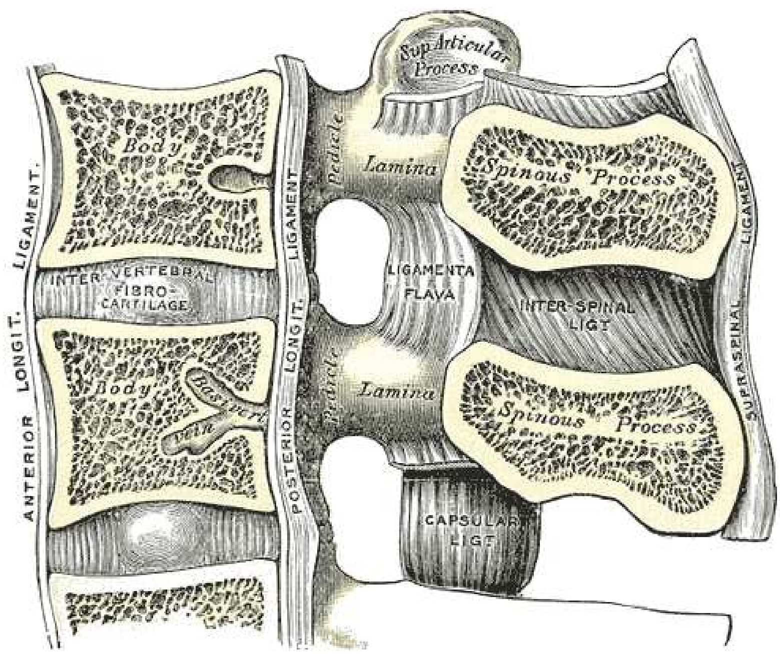


Figure 3. Median sagittal section of two lumbar vertebra and their ligaments (24).

Additionally, a series of muscles stabilize the ligamentous apparatus. The active musculature of the trunk is divided into two primary muscle groups: the ventral and the dorsal regions. Ventral muscles include the thoracic and abdominal wall muscles, which play key roles in respiratory and core functions. Dorsally, the musculature is primarily composed of the intrinsic back muscles, essential for maintaining posture and enabling spinal movements (Figure 4). Unlike the rest of the somatic musculature, these muscles are innervated by the dorsal branches of the spinal nerves and collectively referred to as the erector spinae muscle.

The medial tract is formed by a straight-running interspinal muscle system (including the spinal and interspinal muscles) and the obliquely running muscles of the transversospinal system (including the rotators muscles, multifidus muscles, and semispinalis muscles). The interspinal muscle groups are weakly developed in the lumbar spine region. The task of these shorter, deeper muscles is to coordinate the fine positioning of the vertebrae under load.

Laterally, the superficially located fiber masses of the longissimus and iliocostalis muscles extend to the lower ribs. These muscles, spanning many vertebral bodies, influence overarching movement patterns of the lumbar spine. Both the medial and lateral tracts are enveloped by the thoracolumbar fascia, thus guided within an osteofibrous tube.

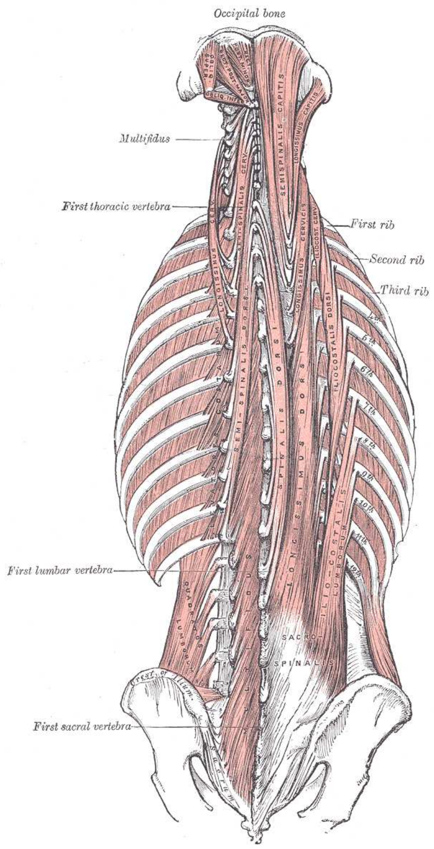


Figure 4. Autochthonous back muscles (25).

1.3 Pathology

1.3.1 Trauma

The greatest mobility of the spine can be found in the cranial area of the cervical spine and in the caudal part of the lumbar spine (26). In contrast, the thoracic segments are more restricted in its movement and kept in place due to the additional fixation and support by the ribcage. These transitions between highly mobile and relatively immobile sections of the spine create areas of vulnerability to traumatic spinal injuries (27). Notably, the thoracolumbar junction at the level of T10-L2 is considerably more susceptible to injury than the cervicothoracic transition.

Traumatic fractures of the vertebral body can result from direct or indirect forces applied to the spine (28). These forces can manifest in various forms, such as compression, extension, flexion, rotational trauma, or a combination of these factors (29). The global burden of disease study in 2019 reported a worldwide increase of 37.7% in vertebral body fractures between 1990 and 2019 (30). The gender distribution of traumatic spinal injuries indicates a higher susceptibility among men, with a male-to-female ratio of 3:1 (31). This trend is particularly notable in young men aged between 16 and 30 years, with a secondary peak observed among men over 50 years of age (32). Approximately 40-45% of cases stem from traffic accidents, closely followed by falls from heights—whether voluntary or involuntary—contributing to 15-30% of incidents (33). Sports and leisure-related accidents account for 15-25% of cases, with work-related accidents and aggression-related physical injuries making up a smaller percentage (34).

1.3.2 Osteoporosis

Osteoporosis, identified as a systemic condition characterized by diminished bone mass and alterations in the microarchitecture of bone structure, leads to heightened fragility and susceptibility to fractures (35). This pathophysiological shift impacts bone formation and breakdown processes on a cellular level that favors osteoclastic bone resorption (36). Osteoporosis based on underlying causes can be classified into primary and secondary.

Primary osteoporosis, constituting about 95% of cases, encompasses postmenopausal osteoporosis, notably prevalent in clinical practice (37). In Post-menopause, the estrogen deficiency shift disrupts the balance between bone formation and loss, resulting in a decline in cancellous bone mass. On the other hand, secondary osteoporosis, often referred to as senile osteoporosis, links to causes like malnutrition, prolonged corticosteroid therapy, and other factors (38). Statistics illustrate the significant impact of osteoporosis on fractures.

Approximately 225,000 patients in Germany suffer vertebral fractures yearly, with the risk of another vertebral fracture increasing by 5 to 25 times (39). In Germany, 22.6% of women and 6.6% of men aged 50 years or more were affected by osteoporosis in 2021(40).

In addition to laboratory results such a calcium, phosphate, alkaline phosphatase, gamma-GT and TSH, osteoporosis is diagnosed by measuring bone density. This is done by using dual X-ray Absorptiometry (DXA Scan) (41).

The World Health Organization established in 1994. that osteoporosis is diagnosed when bone density in the lumbar spine or the proximal femur, measured by dual X-ray absorptiometry (DXA measurement), drops by 2.5 standard deviations from the value of a 20 to 29-year-old woman (35). Depending on the T-score the classification is then divided into clinical stages of osteopenia, osteoporosis, and manifest osteoporosis.

1.3.3 Tumor

Bone tumors can be categorized into two groups based on their origin. Primary bone tumors develop directly from bone tissue, whereas secondary lesions are metastases originating from a primary tumor elsewhere in the body. With osteosarcoma, Ewing sarcoma, and chondrosarcoma being the most common primary bone cancers (42). Since this study focuses exclusively on secondary bone tumors, I will provide a more detailed explanation below.

Bone metastases occur primarily in carcinomas of the breast, prostate, lungs, kidneys, urinary bladder, thyroid and in malignant melanomas (43). Following the liver and lungs, the skeletal system is the third most common site for metastasis in the human body of which 2/3 are localized at different segments of the spine (44). The part of the vertebra most affected is the vertebral body in about 80% of cases, followed by the pedicle and spinous processes (45). Furthermore, bone metastases can be categorized based on their impact on bone structure. Osteolytic metastases trigger a signaling pathway resulting in bone tissue breakdown (46). This process ultimately leads to pathological vertebral fractures, spinal instability, or deformities, often causing compression on the spinal cord and subsequent neurological deficits.

Examples of osteolytic metastases include breast and melanoma metastases (47). Conversely, osteoblastic metastases stimulate bone growth. While these growths might cause myelonal compression, it's more due to their space-occupying effect rather than deformities resulting from fractures. Prostate carcinomas are examples of cancers that form osteoblastic metastases.

1.3.4 Infectious

Spinal infections are relatively rare in Western countries, with an incidence rate of 2 to 4 new cases per 100,000 residents (48). Nevertheless, the incidence is increasing, which is due to increasing life expectancy and increasing number of immunocompromised patients, e.g., due to diabetes mellitus, rheumatism, or tumor disease. The increase in intravenous drug users and infectious diseases such as HIV or hepatitis play an important role in this regard as well (49).

According to the German Federal Office of Statistics and international literature, there has been an increase in the incidence of spondylodiscitis over the last 10 years from 5.8/100,000 to approximately 30/250,000 (50) (51).

A distinction is made between spondylitis, which only affects and is localized to the vertebral bodies and spondylodiscitis which is affecting adjacent structures such as intervertebral discs and ligamentous structures. The spinal segment most affected by inflammation is the lumbar region (45-50%), closely followed by thoracic (35%) and cervical spine (3-20%), whereas the sacral region, except for the lumbosacral junction is rarely affected (52). Spondylodiscitis is a disease of the middle and higher Age, men are for reasons not yet known about two to three times more often affected than women (49).

There are several ways to divide the infections, for example by type of the pathogen or the route of infection. However, there is a not a uniform classification. Based on the type of the pathogen specific and nonspecific spondylodiscitis can be differentiated. The more common form, non-specific spondylodiscitis, is mainly caused by staphylococci, streptococci, enterococci, pseudomonas and brucella (53). Specific spondylodiscitis is caused by an infection by mycobacterium tuberculosis, less commonly salmonella typhosa, treponema pallidum or mycobacterium leprae (54). This contrasts with the non-specific infection which comes with a more slowly progressive, chronic course sometimes with multi-segmental manifestation (55).

Due to the existing route of infection, a distinction is made between exogenous and endogenous infection (55). Exogenous infections are mostly observed after operations, punctures or infiltration therapies, rarely after trauma. In the endogenous form the source of infection lies far from the spine itself. Infections can originate in the teeth, abdominal organs, or intrathoracic region and later spread to the bloodstream (hematogenous route) or to the lymphatic system (lymphogenous route) and travel to distant sites, including the spine. Once these pathogens reach the spinal area, they can colonize the vertebrae or intervertebral discs, leading to above mentioned conditions. Early diagnosis is crucial for effective treatment, which often involves a combination of antibiotic therapy to eradicate the infection and surgical intervention to debride infected tissue and stabilize the spine.

1.4 Posterior fixation technique

1.4.1 Overview

Posterior spinal fixation is a surgical procedure performed by orthopedic surgeons or neurosurgeons to stabilize the spinal column in cases of spinal instability, degenerative disc disease, traumatic injuries, and other spinal pathologies.

This intervention will restrict any movement between the fused vertebrae by using hardware such as screws, plates, or rods. The placement of these instruments is guided traditionally by fluoroscopy. Surgical intervention should be carried out if symptoms persist despite exhaustive conservative treatment efforts, a prescribed therapy program proves ineffective, or when evident signs of segmental instability progress alongside newly emerging neurological symptoms occur (56). The primary goal of surgery is to ameliorate the pre-existing painful condition and pre-empt any exacerbation in signs of instability. Surgery can be performed using various techniques, including dorsal, ventral, or lateral approaches, as well as mixed procedures (57). In addition to these different access routes, a distinction can also be made between an open and a percutaneous approach. Relevant for this study is the percutaneous minimal invasive posterior surgery procedure with pedicel screws. These pedicle screws are inserted through small incisions in the skin at the level of the individual vertebral bodies. In the open approach, on the other hand, a median incision is made over the entire length of the affected section of the spine. Today usually a screw-rod system is used. As with any surgery complication such as nerve damage, blood loss or infection can occur. Percutaneous dorsal instrumentation is increasingly being used due to the advantages of reduced soft tissue trauma.

The implants in spinal surgery have been significantly developed in recent years. More and more companies are now offering products that, in addition to stabilization criteria, particularly claim to preserve the functionality of the spine. The development is progressing rapidly, and an increasing number of products are being introduced to the market. However, the investigation and evaluation of the new technologies lag far behind. Only a fraction of the available methods and stabilization techniques in spinal surgery have been examined for their benefits so far.

1.4.2 Pedicle Screw Instrumentation

The procedure is carried out under general anesthesia. The patient is positioned in prone position on the operating table. Padding of the chest and pelvic area facilitates abdominal breathing and eases ventilation. This approach prevents positioning-related obstructions, allowing the patient to breathe freely through the abdomen.

After disinfecting the skin, the sterile covering is carried out. The pedicles of the vertebral bodies in which the screws will be placed, are visualized, and marked under radiological control in anterior-posterior and laterally view.

A paramedian, approximately 2–3 cm long incisions slightly lateral to the respective pedicle followed by gentle splitting of the muscles and fascia is performed. The pedicle is perforated with a hollow needle, for example a Jamshidi needle through the dorsal entry point, with the needle being gradually advanced to the posterior edge of the vertebral body (Figure 5.). Then a guide wire is inserted into the vertebral body. The direction and length of the screw can still be determined with the tapper.

After the pedicle screws have been inserted, the target wires are removed, and the screw placement is radiologically verified. The same procedure is carried out at the other vertebral levels to be stabilized. After inserting all pedicle screws, the longitudinal rods are subsequently introduced. These are inserted over 2 segments. The length of the rod is determined either directly at the ends of the working trocars above the skin level or by using a measuring template.

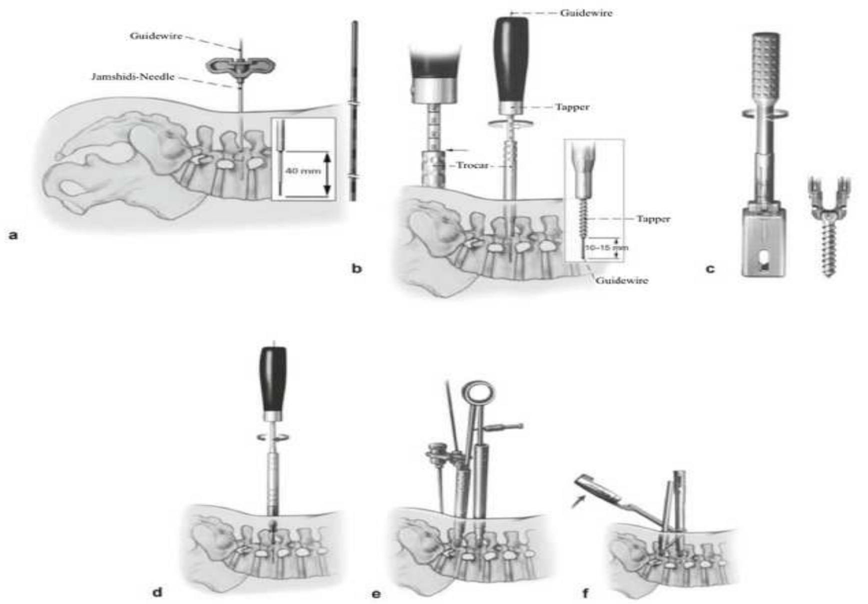


Figure 5. (58) Surgical steps: an Insertion of the guide wire into the pedicle b Pre-drilling the thread for the pedicle screw and reading the screw length on the tapper c Placing the pedicle screw on the screwdriver d Screwing in the pedicle screw e Determining the length for the longitudinal rod f Inserting the rod from caudal.

1.4.3 History

The surgical treatment of spinal deformity has consistently been a challenging and complex issue. During the 20th century, diverse surgery-related innovations were developed. Before the advent of spinal fixation techniques in the early 20th century, the management of unstable spinal conditions primarily revolved around non-surgical methods such as bed rest, traction, splinting, and bracing (59). The preference for non-surgical treatments was largely due to surgical morbidity caused by the absence of antiseptic practices, the lack of thermocautery, and inadequate anesthesia during the earlier periods of medical practice. Historical records show that methods of early traction and immobilization, dating as far back as Hippocrates in 400 BCE, were the predominant approaches for treating such conditions until the 20th century (60). Early spinal surgery initially gained importance in the treatment of trauma, infections, particularly in tuberculosis, poliomyelitis and in scoliosis. Until the development of antibiotic to treat tuberculosis and the discovery of a vaccine to eliminate polio, a large population of patients developed spondylitis and subsequent kyphoscoliosis. The first description of a spinal fusion operation occurred in the year 1891. by Hadra, using a silver wire to connect adjacent spinous processes in the treatment of unstable cervical fractures (61). In 1911. Hibbs and Albee used a fusion technique without instrumentation by removing the spinous processes and connecting the neighboring vertebrae by means of the separated spinous processes of a 9-year-old boy suffering a kyphotic deformity (62). Although this concept of no instrumentation-induced osseous fusion initially provided stabilization, it did rely on the use of casts and ultimately didn’t provide final deformity correction (63). In the late 1950s, Harrington faced the challenge of effectively treating neuromuscular scoliosis, particularly paralytic scoliosis resulting from poliomyelitis. In response to this need, he devised a spinal instrumentation system that utilized steel rods connected to hooks (64). This system aimed to correct deformities by reducing the curvature and by providing stability to the fused spinal segments. Upon improving the technique, Boucher was credited with the first method of internal fixation by placing a pedicle screw through the facet joint into the pedicle and thus extending it into the vertebral body which was at first seen to be too dangerous (65). Roy-Camille described the method of transpedicular stabilization in 1986 as a safe and reliable method in treating fractures, tumors, or in correcting deformities (66). The role of the pedicle, serving as a force carrier was also highlighted by Simpson in 1993 and thus underlined its major importance and further development of transpedicular stabilization systems (67). As mentioned above spinal surgery predominantly relied on the surgeon's anatomical knowledge and the use of intraoperative imaging, which had limitations in the accuracy of instrumentation. The introduction of computer-assisted navigation (CAN) has significantly transformed this field, enabling real-time, three-dimensional visualization of the spinal anatomy during pedicle screw placement. The first successful use of CAN was documented in 1995, which gained extensive research into its efficacy and potential benefits (68). CAN technology primarily involves preoperative and intraoperative imaging, typically using CT or MRI scans, which are integrated with intraoperative navigation tools to provide the surgeon real-time imaging with enhanced precision in procedures such as pedicle screw placement (69). Currently published studies consistently found superior screw placement accuracy when CAN was utilized with accuracy rates ranging from 86.1% to 99.7% (70)(71)(72). This approach not only improves the accuracy of instrumentation but also reduces radiation exposure (73). Overley et al. summarized currently available systems, including the Airo Mobile Intraoperative computer tomography (CT)-based Spinal Navigation (Brainlab©, Feldkirchen, Germany), the Stryker Spinal Navigation with SpineMask and the Stealth Station Spine Surgery Imaging and Surgical Navigation with O-arm (Medtronic©, Minneapolis, Minnesota) (74). Further research will be necessary to determine how robotic technology and AR products will enhance patient care.

1.4.4 The Neo Pedicle Screw System™ and Neo ADVISE™

The Neo Pedicle Screw System™ (PSS) allows the placement of sterile, single-use screws into the pedicle of the vertebral body. Neo Medical SA (Villette, Switzerland) has introduced a simplified approach to surgical instrumentation by offering only five versatile instruments that cater to a range of common indications, including tumor, trauma, degenerative conditions, and deformities shown in Figure 6. This streamlined approach aims to reduce the number of trays required during surgery while providing comprehensive tools capable of addressing various surgical needs. In addition, it comprises several differently sized rods, 14 screws, and several smaller tools.

The screws, pre-mounted on screw extenders are placed at multiple spine segments around the bone graft and act as anchor points for the rods (Figure 7.)

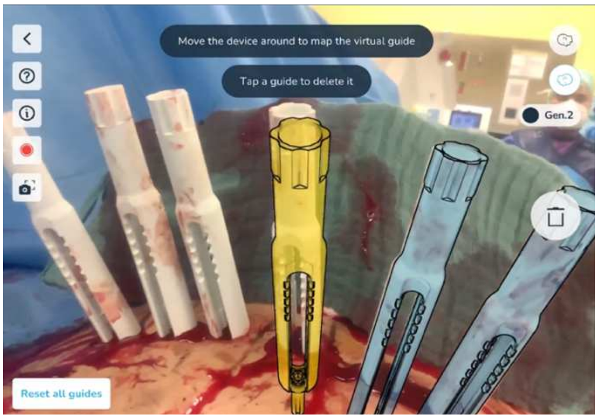
Figure 6. Neo Pedicle Screw System™, Instrumentation set (75).

Figure 7. Pre-mounted screws on screw extender.

The screws are designed to be adaptable for polyaxially or monoaxial use, being cannulated and fenestrated. The polyaxiality of the screw can simple be blocked inserting a wire that locks the screw head and restricts its movement. Provided with side holes or cut-outs, they allow in situ injection of bone cement or similar into the vertebral body through the screw itself.

The aim of using cannulated fenestrated screws is to achieve cementation of the thread of the screw especially if the patient's bone quality is not sufficient and pedicle screws no longer achieve sufficient anchoring in the pedicle and vertebral body. The Cement augmentation provides significantly increased strength in the osteoporotic bones.

Following K-wire guided fluoroscopy and exact pedicle screw placement, the screw extenders are scanned and detected intraoperatively by the Neo ADVISE™ (Advanced Dynamic Visualization of Intraoperative Spinal Equilibrium Software) software running on a tablet (iPad) that has been wrapped in a clear sterile plastic envelope. Figure 8. shows the 3D scanning mode via the tablet screen. The augmented reality technology projects a virtual guide (yellow) to identify the physical guide on the live image. Figure 9. shows the correctly scanned identification and thus changes from yellow to blue to confirm the match.



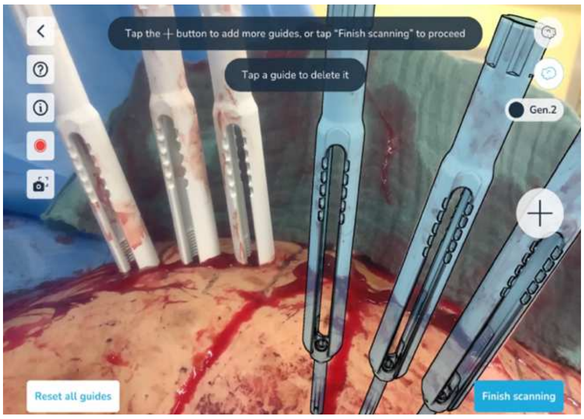


Figure 8. Scanning the screw extenders (76). **Figure 9.** Screw extenders identification (76).

After all screw guides have been scanned and matched on one side, the ADVISE™ software analyses the spatial position of all pedicle screw heads and calculates the exact distance and alignment between them. The software visualizes the offset in both planes relative to the screw heads and the selected straight rod. Screw adjustments are color-coded within the virtual screw heads, with green, orange, and red indicating different levels of adjustment. The color-coded feedback system allows for quick identification of screws that require significant adjustment.

Once this information is processed, the software generates a rod template in both the sagittal and coronal planes. This template precisely matches the required length and curvature by accurately following the path through each screw head. (Figure 10.).

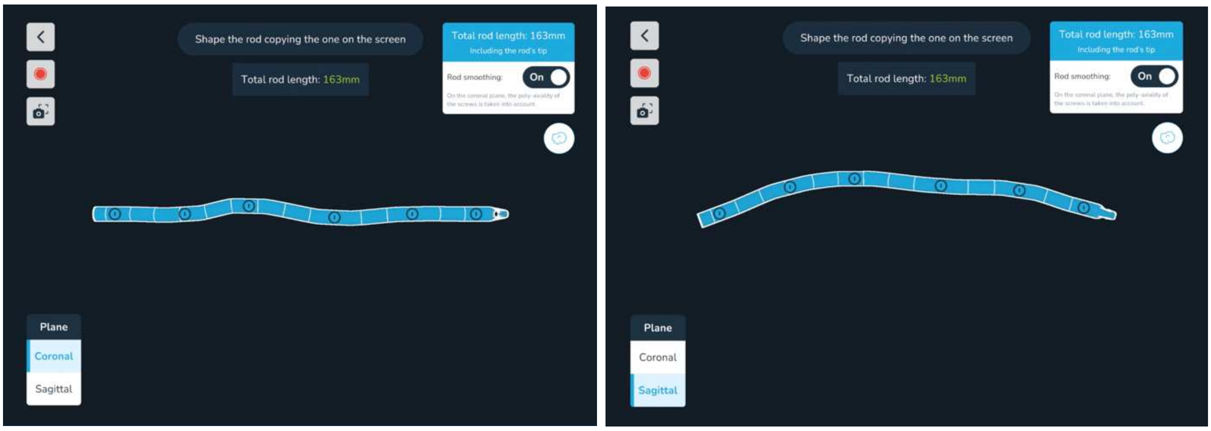


Figure 10. Visualization of the ideal rod in coronal and sagittal planes (76).

The individual rod template is displayed in a 1 to 1 scale on the tablet as shown which can then be used to cut and bend the rod accordingly (Figure 11.). The same steps are followed for the other side.

Figure 11. Rod bending using the tablets template in coronal and sagittal planes (76).

The rod is then tunneled beneath the fascia and threaded through the screw heads, being prefixed without tension. Using the screwdriver and corresponding nuts, the rod is pressed down onto the screw heads and secured with torque. A special marker on the screwdriver indicates whether the rod is positioned stress-free after pretightening.

2 OBJECTIVES

Aim of the study

The primary aim of this study is to evaluate the clinical outcomes, including the rate of intra- and postoperative complications, associated with the use of a novel augmented reality technology called the Neo ADVISE™ in combination with the Neo Pedicle Screw System™ in spinal surgery.

Hypothesis

We hypothesize that the Neo Systems, with its advanced intraoperative augmented reality imaging, will enhance the visualization and potentially improve the precision of rod bending during surgery. This system represents an innovative advancement in spinal stabilization technology.

3 MATERIALS & METHODS

3.1 Patients

All patients were treated with the NEO surgical technique used in a minimal percutaneous posterior approach in the Department of Trauma Surgery of the Regiomed Hospital Coburg in the period from March 2023 to February 2024.

Inclusion Criteria

1. Age ≥ 18 years
2. Patient has received NEO for primary posterior, non-cervical stabilization
3. Patient signed Informed Consent

Exclusion Criteria

1. active infectious process
2. signs of local inflammation
3. fever or leukocytosis
4. morbid obesity
5. pregnancy
6. any medical or surgical condition which would preclude the potential benefit of spinal implant surgery
7. any case not described in the indications

3.2 Study Design

This study was designed as a descriptive retrospective study conducted at the Department of Trauma Surgery at the Regiomed Clinic Coburg. All data were collected from the hospital's patient records between February 2023 to March 2024.

3.3 Data Collection

The information was obtained by accessing clinical records from the ORBIS hospital documentation system, operated by Dedalus. The specific group of patients was identified using the system's built-in search and filter functions. All patients who underwent percutaneous posterior fixation procedures including the Neo ADVISE™ system at the Coburg hospital's Trauma Surgery department from February 2023 to March 2024 were included in the dataset.

First, the following admission and patient data were collected: age and gender, indications, fracture height and stabilized segments. Next, operative-associated clinical data were then collected and included surgical duration, intra and postoperative complication and length of hospitals stay (LOS). Data has been anonymized to protect patient privacy; no Patient ID information is disclosed, ensuring patients remain unidentifiable.

3.4 Ethical Approval

The research plan, which had been prepared beforehand, was submitted to the Institutional Review Board (IRB) of the Medical School Regiomed Coburg. In accordance with §2 of the IRB's regulations, no objections were raised regarding the implementation of the research project. The study was conducted in compliance with the Declaration of Helsinki.

3.5 Intraoperative technique

In intubation anesthesia, the patient is carefully placed in the prone position on the operating table. The image intensifier is positioned and the vertebrae to be instrumented are marked on the skin with a felt-tip pen. This is followed by sterile cleaning and draping. Team time-out. Next, the incision is made at the level of the vertebrae to be instrumented on both sides, and the Jamshidi needles are inserted into the pedicles under radiological control. The correct position is verified using the image intensifier, and the guidewires are inserted, followed by the removal of the Jamshidi needles. Then, the screws from Neo Medical are inserted and based on the morphology the decision for or against cementation is made. Using a sterile-wrapped tablet, the screw extender above the skin is now scanned and identified. From the obtained data, the length, alignment, curvature, and shape of the rod in the coronal and sagittal planes are determined by the software, and the bending of the rod is performed by the surgeon using the provided data.

The rod is now tunneled beneath the fascia and threaded into the screw heads. It is then pressed down onto the screw heads using the screwdriver with the corresponding nuts and secured with a torque. Final X-ray is performed to check for correct implant placement. Fascial and subcutaneous sutures are placed, followed by skin sutures and a sterile dressing.

4 RESULTS

This study included a total of 31 patients treated with the Neo PSS and Neo ADVISE™ in the department of trauma surgery from February 2023. to March 2024. The mean age at the time of surgery was 72 years, ranging from 37 to 90 years. Of these were 15 female and 16 male patients. For patients demographics see Figure 12.

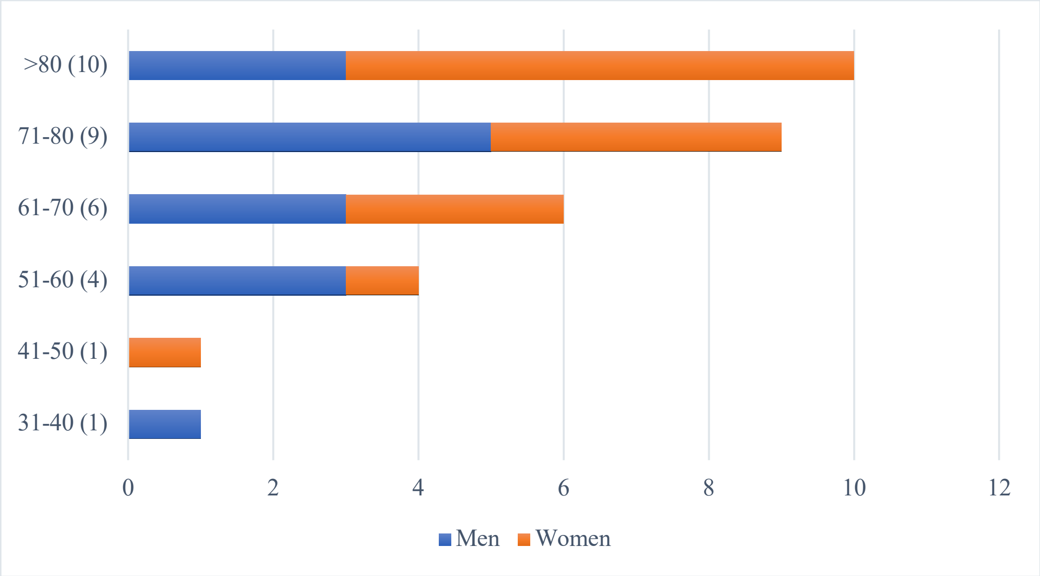


Figure 12. Age distribution of patients (total number of patients in six age groups).

Indications for percutaneous posterior stabilization were vertebral body fractures of the thoracic and/or lumbar spine. Causes of the vertebral fractures were trauma (32%), reduction in bone structure framework due to osteoporosis (29%), metastatic colonization of the spine (26%) and spondylodiscitis (13%) (Figure 13).

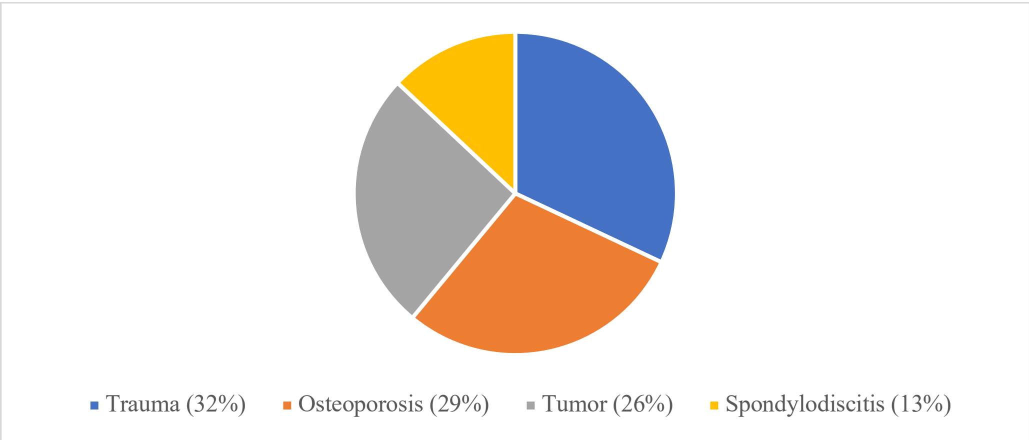


Figure 13. Causes of the vertebral fractures as indications for percutaneous stabilization.

The fracture location extended from T5 to L5. The most common segment affected was L1 (31%). The second most common segment affected was T12 (16%) and T7 (16%) followed by L3 (6%) and T6 (6%).

Patients were treated with thoracic, thoracolumbar, or lumbar posterior fixation. Most of the stabilizations (55%) took place on the transition between the thoracic and lumbar spine followed by the thoracic spine (35%) (Figure 14). The number of isolated lumbar spine stabilizations were significantly lower (10%). No interventions took place at the lumbosacral junction or sacral segment.

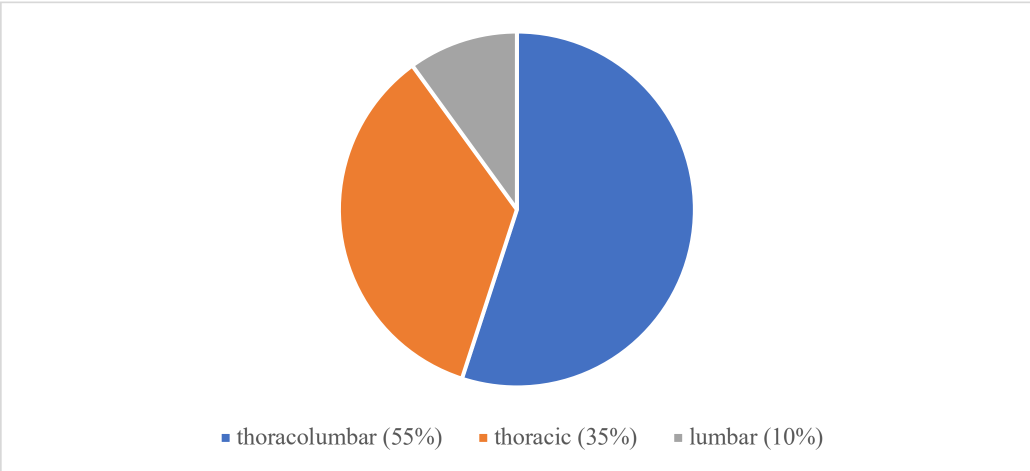


Figure 14. Stabilization segment for different spinal cord segment posterior fixation.

A total of 250 screws were placed, of which eight patients received cement augmentation. This corresponds to 8.1 screws per patient.

The postoperative length of stay (LOS), which was defined as the number of calendar days from the operation to hospital discharge was ranging from six to 67 days with a mean of 14 days.

The duration of the operation refers from the start of the first incision till the finish of the last suture. This entire duration of the operation (including scanning with the Neo ADVISE™ software) was ranging from 99 minutes to 293 minutes with a mean of 155 minutes. The specific durations for different surgical indications were as follows: tumor with decompression surgery averaged 175 minutes, trauma-related procedures averaged 155 minutes, osteoporosis associated surgeries averaged 142 minutes, and spondylodiscitis correlated surgeries averaged 139 minutes. The duration of the preoperative preparation was not considered.

Postoperative complications

A classification regarding postoperative complications was conducted and is illustrated in Table 1. No surgical complications were documented intraoperatively.

During the postoperative inpatient stay, complications occurred in 8 patients (25%). Of these five patients encountered medical complications. Three patients experienced postoperative anemia, necessitating the administration of erythrocyte concentrates. Specifically, two patients received one unit each, while the remaining patient received four units. One patient experienced postoperative urinary tract infection which was treated successfully with antibiotics.

Tragically, one patient deceased to septic multiorgan failure stemming from spondylodiscitis with epidural abscesses and known bilateral pleural empyema.

Two patients experienced mild temporary superficial surgical site infections (SSI), which did not necessitate operative wound revision surgery. Instead, these patients were managed conservative with wound dressings.

Furthermore, we present a single case wherein revision surgery became imperative due to implant failure, precipitated by a low-energy trauma incident. This occurred in a patient previously treated in our department using the same surgical technique.

Table 1. Complication and their frequency

Type of Complication	Number of Patients	Percentage (%)
Hospitalization		
Intraoperative surgical complication	0	0
Instrumentation and Hardware failure	0	0
Anemia	3	10
Urinary tract infection	1	3
Sepsis	1	3
Superficial surgical site infection	2	6
Revision Surgery	1	3
Total	**8**	**25**

5 DISCUSSION

Over the past several decades, AR has increasingly captured the interest of various surgical fields, as the field has transitioned from traditional techniques to advanced 3D imaging technologies particularly in the context of surgery.

This study describes an innovative method for clinical intra- and postoperative parameters during the hospital stay using the Neo PSS together with Neo ADVISE™ for posterior stabilization in patients with thoracic, thoracolumbar, and lumbar spine pathologies. The results provide a comprehensive overview of patient demographics, surgical specifics, and postoperative complications, offering valuable insights into the efficacy and safety of the procedure.

Patient Demographics and Surgical Indications

The cohort consisted of 31 patients with a mean age ranging from 37 to 90 years, including 15 (48%) female and 16 (52%) male patients. The age distribution highlights a higher incidence of spinal pathologies in older populations, particularly those aged 71-80 and above 80 years. This finding is consistent with the literature and the known correlation between aging and increased susceptibility to fractures due to conditions like osteoporosis (77).

The indications for percutaneous posterior stabilization were primarily vertebral body fractures due to trauma (32%), osteoporosis (29%), metastatic colonization of the spine (26%), and spondylodiscitis (13%). This diversity in etiology underscores the system's applicability across various pathological conditions affecting the spine. Studies have shown that osteoporosis and trauma are common causes of vertebral fractures, particularly in elderly populations.

The postoperative LOS depends on many different factors, such as associated injuries, complexity of the surgery, comorbidities, and post-hospital care. An extended LOS is linked to elevated infection rates, a higher occurrence of venous thromboembolisms, and an increased frequency of hospital-acquired delirium (78). We reported a mean hospital stay of 14 days.

For patients who experienced postoperative complications, the LOS increased by an additional 12 days on average, whereas it decreased by 2 days for those without complications. Minimizing the occurrence of postoperative complications can significantly reduce the length of hospital stays, thus optimizing healthcare resource utilization and improving patient outcomes.

Surgical Characteristics

Most stabilizations occurred at the thoracolumbar junction (55%), followed by the thoracic spine (35%), with fewer procedures targeting the lumbar spine (10%). This distribution reflects the higher mechanical stress and vulnerability of the thoracolumbar transition zone. The fracture location ranged from T5 to L5, with L1 being the most frequently affected segment (31%), followed by T12 and T7 (16% respectively). This pattern is consistent with the literature were L1 is the most common affected vertebral body vulnerable to fracture (79).

Eight (26%) out of 31 operated patients had their implanted screws additionally stabilized using cement augmentation. Spiegel et al. (80) and other authors (81) generally recommend cement augmentation starting at the age of 60 or in cases of osteoporotic bone to reduce the complication of screw loosening scenarios. In our study the decision for additional intraoperative cement augmentation was carried out in six patient suffering from osteoporotic fractures and in two suffering from a trauma. No extravasation of cement leaking from the augmented vertebrae was documented.

Factors such as technical upgrades of the surgery, experience of the surgeon or perioperative management at a hospital contribute to the duration of the operation. The duration of surgeries in this study varied significantly, ranging from 99 to 293 minutes, with a mean of 155 minutes. This variance reflects the complexity and extent of individual cases. Patients with underlying tumor pathology had on average the longest operation times. This can be explained because those cases received additional decompression surgery.

The lack of recorded time for specific tasks, such as individual rod bending using the Neo ADVISE™ software, rebending maneuvers, and rod fixation, suggests that these elements could also contribute to the overall duration but were not quantified in this study. From our perspective, AR-assisted stabilization appears to lead to a reduction in operating time, as compared by purely percutaneous stabilization techniques.

Postoperative Complications

The most important complications of dorsal instrumentation are infection and screw misplacement. In our study we report about no intraoperative complications or screw loosening rates during the hospital stay, indicating a high level of surgical precision and safety associated with the Neo Pedicle Screw System™. The observed postoperative complication rate in eight patients, representing 25%, is notably high. However, it's important to note that we recorded complications regardless of their direct relation to the surgical site or the procedure performed.

Clinically, there was one postoperative urinary tract infection. Urinalysis showed positive findings which resolved after administration of antibiotics. Furthermore, postoperative anemia occurred in three trauma patients, necessitating erythrocyte concentrate administration.

It can be assumed that due to the significantly higher average age of the patients and additional comorbidities the complication rate was increased.

According to the guidelines, SSIs are defined as infections that occur within 30 days after the operation, involving only the skin or subcutaneous tissue, and presenting at least one of the following signs or symptoms: pain or tenderness, localized swelling, redness, or heat. (82). Both patient-related and procedure-related factors have been identified to increase the risk for SSI, including obesity, diabetes mellitus, hypertension, and smoking (83). In our study, two patients developed superficial temporary SSI. This can be explained by the prolonged operative times of greater than 3 hours in one patient and greater of 2 hours in the other patient, as well as a greater number of stabilized segments. Both were managed conservatively with dressings and showed good healing during the hospital stay. In comparison, revision surgeries for infections following operative treatment of the thoracic and lumbar spine are generally described in 2.2% of all cases, while necessary surgical evacuations of hematomas occur in 1.8% (84).

In general, infections directly related to the surgery can lead to severe complications, including prolonged hospital stays and additional surgical interventions. The infection rate of 6.5% observed in our study on surgical interventions on the spine contrasts with rates reported in the literature, which can be as high as 13%. (85). According to Litrico et al. (86) the use of sterile single use instrumentation sets like the Neo PSS can reduce the infection rate to 2%.

One patient presented with spondylodiscitis with epidural abscesses and bilateral pleura empyema. Despite the successful surgical efforts of dorsal stabilization, cleaning out the abscess cavity with a sterile solution, followed by inserting a drain and the destruction of the pleural empyema by the thoracic surgeons the patient developed septic multiorgan failure and died during the hospital stay. According to the literature, clinical mortality for spondylodiscitis is reported to be between 2% and 17% (87). Early diagnosis would be of prognostic significance.

Research in literature indicates a considerable variability in the rates of pedicle screw loosening following thoracolumbar stabilization varying up to 15% in non-osteoporotic patients and even higher rates to up to 63% in osteoporotic patients (88). Incorrect screw placements and other surgical complications can lead to neurological symptoms (89). The correct screw anchoring into the pedicle was assessed radiological. New neurologic deficits (NND) are an inherent potential complication of spine surgery and literature shows an NND rate between 4.0% and 21.2% (90,91).

Notably, one patient required revision surgery due to implant failure after a low energy trauma. A dorsal stabilization in our department was initially performed six months ago using the Neo PSS for multisegmented spondylodiscitis in the thoracic and lumbar spine. The planned and recommended clinical X-ray follow-ups and additional ventral stabilization in the lumbar vertebrae 2 and 4 were not attended by the patient. As shown in this case, patient non-compliance can significantly compromise the outcomes of surgical interventions leading to an increased risk of re-injury, hardware failure and poor overall outcomes. The frequency of hardware failure can commonly be seen in lower instrumented vertebrae and is associated with greater fusion length (92). To conclude, the primary diseases, long-segment instrumentation, non-compliance, and the low energy trauma might all contribute to the revision surgery and cannot be directly linked to the initial surgery.

Comparison with Literature

Throughout the literature it is well established that AR has the potential to significantly impact surgical procedure by enhancing navigation, surgical planning, and by reducing operation times during surgery. In fact, pedicle screw placement is the by far the most frequently navigated step in spinal surgery nowadays by means of optical tracking systems or more recently by AR (93).

Little has been attributed to the challenge of rod bending. A study by Wanivenhaus et al. (94) demonstrated that the time for rod bending can be reduced by 20% using another form of AR technology, namely the HoloLens 2, in creating holographic rods that can be used as a template for bending. A computer-assisted (CA) rod bending system called the Bendini CA showed significantly lower rates of screw loosening one year postoperatively compared to the manual group (manual rod bending: 15.5% vs CA rod bending: 8.1%) in 53 patients (95).

At present, there are only few studies in evaluating the Neo ADVISE™ in spinal surgery which are suitable for direct comparison.

An early in-vitro biomechanical study by Atai et al. (96), eleven spine surgeons were asked to cut, and bend two custom rods, one with the support of the ADVISE™ AR technology and the other by free hand on a human spinal specimen. The study showed that the number of in situ checks, rod length corrections, and X-ray controls were significantly lower in the AR group.

The results of the different rod bending steps were not documented in our research. Final intraoperative X-rays however showed correct implant positioning in all patients. The significance of these intraoperative steps is highlighted by the findings of Obha et al. (97) who discovered that about 82% of all loosened screws seen at one year follow up in their study were dislodged during the rod connection phase of the surgery (Figure 15).

When a rod does not properly align with the screw locations during the assembly of the construct, the reduction force placed on the pedicle screws can weaken the screw-bone interface. Optimal alignment of the rod shape with the screw locations minimizes the loads on the screws, reducing the risk of screw pullout or loosening.

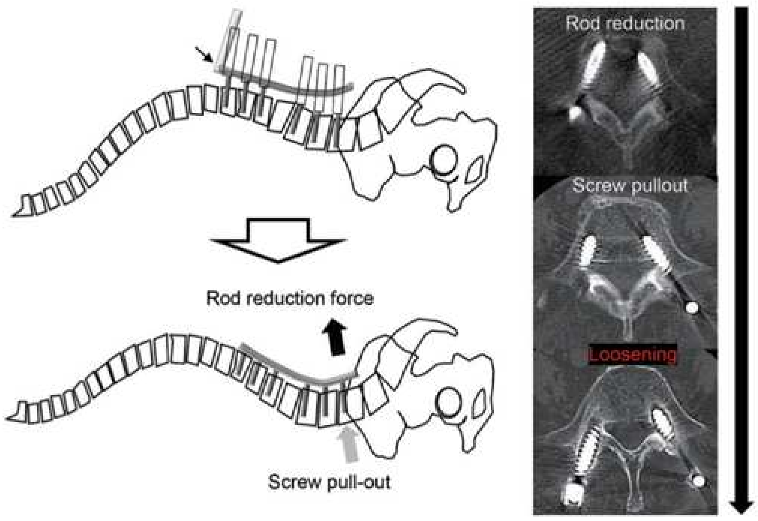


Figure 15. Patient subjected to thoracolumbar posterior fixation with radiological signs of screw loosening (97).

The exact duration for rod bending in spinal surgery is not universally standardized and can vary widely. In freehand bending, surgeons rely on their spatial understanding and experience which can result in significant variations in rod quality. A single case report study by Antes et al. (98) using the Neo ADVISE™ in a multisegmented pedicle screw fixation from T5 to T11 showed that the scanning, template generation and final rod bending required is less than 10 minutes per side. This time can be longer if multiple adjustments are needed to achieve the desired alignment, especially in complex deformity surgeries such as scoliosis. The overall operation time can vary greatly depending on the extent of the underlying pathology and the segments requiring stabilization as seen in our results. Moreover, tumors, particularly metastatic lesions may require additional time for thorough decompression, which is essential for relieving neural compression and ensuring postoperative stability. Given this wide range of variables influencing surgical time, direct comparisons across different studies becomes challenging.

The study conducted by Abdalla Y et al. (99), in which 150 patients underwent multilevel posterior stabilization using the Neo Pedicle Screw System™, is among the most comparable to our research. They observed a screw-based loosening rate in three patients and SSIs in four patients. These findings are significantly lower than the rates reported in the current literature, which often cite screw loosening rates to up to 60% depending on the underlying pathology and SSI rates to up to 10% in similar cohorts (100,101).The lower complication rates reported by Abdalla et al. could be attributed to several factors, including the advanced instrumentation of the Neo Pedicle Screw System™ which likely contribute to the reduced incidence of hardware-related complications.

Our findings are consistent with those of Abdalla et al., as we observed no intraoperative or postoperative complications related to hardware failure, such as screw loosening or pull-outs, and a low incidence of SSIs. This is noteworthy given that hardware failures and infections are common concerns in spinal surgeries, with reported rates of screw loosening and pull-outs being significant contributors to reoperation and patient morbidity.

Limitation

The study included 31 patients, which limits the generalizability of the findings. A larger sample size would provide more robust data and enhance the statistical power of the study. In addition, the follow-up period was limited to the immediate postoperative phase and hospital stay. Long-term and follow up outcomes, including the durability of the fixation, long-term complication rates, and functional recovery, were not assessed. More importantly, without a control group or comparison with other spinal stabilization systems especially with the focus on manual rod bending vs AR rod bending, it is difficult to definitively attribute the outcomes solely to Neo Pedicle Screw System™ and the Neo ADVISE™.

Furthermore, the study did not provide detailed information on key parameters such as the rod length, the number of rebending maneuvers required, and patient comorbidities. The placement of the pedicle screws was also not extensively discussed, which could influence the overall outcomes.

Given the limitations future research could focus on conducting multi-center studies with larger patient cohorts and control groups to enhance the generalizability of the findings. By addressing these areas, future studies can build on the current findings and provide more definitive conclusions regarding the efficacy and safety of Neo Pedicle Screw System™ and the Neo ADVISE™.

6 CONCLUSION

The posterior fixation technique using the Pedicle Screw System remains the gold standard in treating the above-mentioned pathologies. The aim of this work was to outline possible advantages using the Neo Pedicle Screw System™ minimally invasive surgical procedures for spinal surgery.

The absence of intra- or postoperative complications regarding the hardware positively reflects on the system's safety profile. The integration of AR rod bending techniques could further enhance surgical outcomes by improving precision and reducing operation times. This could potentially lower the incidence of postoperative complications and fasten patient recovery.

Key advantages observed in our study include the easy accessibility of the hardware, a simple learning curve, and the immediate intraoperative application. Furthermore, the system's patient-specific approach and radiation-free approach contribute significantly to its safety and efficacy.

In conclusion, the Neo Pedicle Screw System™ together with ADVISE™, demonstrates considerable promise in the surgical management of thoracic, thoracolumbar, and lumbar spine pathologies. While minor postoperative complications are not negligible, their effective management indicates that the benefits of this system outweigh the risks for many patients. The incorporation of AR supported rod bending techniques could further optimize surgical precision and success. Continued advancements in surgical techniques using new assistant technology will be crucial in optimizing outcomes for this patient population.

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8 ENGLISH SUMMARY

Objectives: In spine surgery, accurate rod bending is critical to achieving satisfactory fixation and minimizing mechanical stress. Augmented reality (AR) is a novel technology to assist in rod bending and has shown promising results in early studies. This study aims to provide our early experience evaluating efficacy with an AR software.

Material and Methods: All adult patients who underwent AR-assisted dorsal minimally invasive percutaneous fixation technique at the Department of Trauma Surgery, Regiomed Hospital Coburg, between February 2023 and March 2024 were included. Indications, patient's demographics, clinical characteristics (length of hospital stay (LOS), operation time (OT), and complications) were analyzed.

Results: During the hospital stay, we observed no intra- or postoperative instrument failures related to the use of a novel AR technology. Most stabilizations (n=17, 55%) occurred at the junction between the thoracic and lumbar spine. Complications included anemia (n=3, 10%), superficial surgical site infection (n=2, 6%), and septic multiorgan failure (n=1, 3%). One case (n=1, 3%) required revision surgery due to non-compliance following low-energy trauma.

Conclusions: The Neo ADVISE Pedicle Screw System™ used together with Neo ADVISE™ demonstrates effectiveness in managing various spinal pathologies, particularly at the thoracolumbar junction. While postoperative complications were noted, they were managed effectively, and no hardware related complication were documented. Future studies should focus on larger, multi-center cohorts and longer follow-up periods to validate these findings and explore the benefits of integrating augmented reality rod bending techniques.

9 CROATIAN SUMMERY

Ciljevi: U kirurgiji kralježnice, točno savijanje šipki ključno je za postizanje zadovoljavajuće fiksacije i minimiziranje mehaničkog stresa. Proširena stvarnost (AR) je nova tehnologija koja pomaže pri savijanju šipki i pokazala je obećavajuće rezultate u ranim studijama. Ova studija ima za cilj pružiti naše rano iskustvo u procjeni učinkovitosti s AR softverom.

Materijal i metode: Svi odrasli pacijenti koji su podvrgnuti AR-asistiranoj dorsalnoj minimalno invazivnoj perkutanoj fiksacijskoj tehnici na odjelu za traumatsku kirurgiju bolnice Regiomed Coburg, između veljače 2023 i ožujka 2024, su uključeni. Analizirane su indikacije, demografski podaci pacijenata, kliničke karakteristike (duljina boravka u bolnici (LOS), vrijeme operacije (OT) i komplikacije).

Rezultati: Tijekom boravka u bolnici nismo primijetili intra- ili postoperativne kvarove instrumenata povezane s korištenjem nove AR tehnologije. Većina stabilizacija (n=17, 55%) dogodila se na spoju između prsne i lumbalne kralježnice. Komplikacije su uključivale anemiju (n=3, 10%), površinsku infekciju kirurškog područja (n=2, 6%) i septički višesustavni zataj (n=1, 3%). Jedan slučaj (n=1, 3%) zahtijevao je revizijsku operaciju zbog nepoštivanja nakon niskoenergetskog traume.

Zaključci: Neo ADVISE Pedicle Screw System™, korišten zajedno s Neo ADVISE™, pokazuje učinkovitost u upravljanju različitim patologijama kralježnice, posebno na torakolumbalnom spoju. Iako su zabilježene postoperativne komplikacije, one su učinkovito upravljane i nije bilo komplikacija vezanih uz hardver. Buduće studije trebale bi se usredotočiti na veće, multicentrične kohorte i dulja razdoblja praćenja kako bi se potvrdili ovi nalazi i istražile prednosti integracije tehnika savijanja šipki uz pomoć proširene stvarnosti.