Augmented Reality-Supported Rod Bending in Multilevel Spinal Fusion Using the ADVISE Software

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■ BACKGROUND: **One of the most common reasons for poor patient outcomes and revision surgery in spinal fusion is hardware failure. Screw loosening or pullout occurs in up to one-quarter of all cases. It is known that even small screw–rod misalignments can cause significant mechanical overloads during rod fixation, which can result in hardware failure. To address this crucial surgical step, a novel augmented reality-assisted software was developed to generate custom rod templates that are precisely adapted to the individual patient.**

■ METHODS: **The novel software, which runs on a tablet, is used in spinal fusion surgery and is based on the use of a specific pedicle screw system, in which the polyaxial screw heads are connected to detachable guides. These guides can be recognized by the tablet camera and a light detection and ranging scanner. This image information is processed to determine the spatial positions of the screw heads and to calculate an ideally fitting rod template.**

■ RESULTS: **The calculated rod template is displayed in a 1-to-1 scale on the tablet screen. This template is used to cut and bend the rods of the pedicle screw system. Finally, the custom bent rod can be inserted into the screw heads without tension.**

■ CONCLUSIONS: **The augmented reality-assisted software is intended to give surgeons access to patient-specific intraoperative real-time data, helping them in bending rods that are more precisely adapted to the individual patient compared with the freehand technique.**

INTRODUCTION

Spinal instrumentation can be traced back to 1891. Hadra was the first to describe an attachment of steel wires at the cervical spine after posterior decompression.[1] Sustainable milestones in spinal fusion were reached in the 1950s by Paul Harrington using hooks and rods to correct scoliosis and in the 1970s with the introduction of pedicle screws for spinal deformity correction.[1,2] In parallel with the development of new fusion techniques, approaches, and indications, the number of spine surgeries worldwide also increased.[3,4] Despite the increasing operative experience and modern biomechanical research, spinal fusions are still accompanied by high complication rates, often requiring revision surgery. Frequent causes for revision include adjacent segment degeneration, infection, and pseudarthrosis.[5,6]

However, the most common reason for a poor outcome and revision surgery is hardware failure, for which screw loosening and screw pullout are the main contributors.[6-9] Studies have demonstrated loosening rates of ≤27% in patients with good bone quality and >60% in patients with osteoporosis.[8,10,11] The main risk factors for this complication, in addition to osteoporosis, are small-diameter screws, nonpolyaxial screws, lack of anterior support (e.g., intervertebral cage), excessive posterior decompression involving ligaments and facet joints, multilevel fusion, and an increased load on the pedicle screws (i.e., overloading).[2,10,12] A critical surgical step that significantly contributes to such overloading is rod fixation.[12,13] It is assumed that >80% of the screws are already loosened in this process because the screw heads and rods are misaligned.[8] Correcting this misalignment during rod reduction can create enough stress to cause screw pullout.[12,13] A recently reported Dutch finite element analysis calculated pulling forces between 700 and 1000 N for the correction of a screw–rod misalignment of 6 mm,[12] significantly greater than the known thresholds of 300 N for cancellous bone failure and 628 N for cortical

Key words
- ADVISE
- Augmented reality
- iPad
- Pedicle screw system
- Rod bending

Abbreviations and Acronyms
3D: Three-dimensional
ADVISE: Advanced dynamic visualization of intraoperative spinal equilibrium
AR: Augmented reality
PSS: Pedicle screw system

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fracture.[14] It is, therefore, of the utmost importance to avoid such misalignments. Surgical attentiveness and the use of polyaxial screws and ideally fitting rods are the key prerequisites for successful posterior fusion.

Augmented reality (AR) represents an opportunity to provide support to surgeons during rod bending. The ADVISE (advanced dynamic visualization of intraoperative spinal equilibrium) software (Neo Medical SA, Villette, Switzerland), which runs on an Apple iPad (Apple, Inc., Cupertino, California, USA), uses AR and light detection and ranging technology to determine the spatial position and distances of the pedicle screw heads intraoperatively. This information is processed, and the software generates a custom rod template that is precisely adapted to the individual patient.

The aim of our report is to describe the practical application of this new technology and visualize it with 2 cases and a **Supplementary Video** showing the intraoperative steps.

Video

Video available at www.sciencedirect.com

TECHNICAL NOTE

The basic requirement for the application of this technique in multilevel thoracolumbar spinal fusion is the use of the Neo Pedicle Screw System (Neo PSS; Neo Medical). A detailed description of the PSS has been previously reported.[2] The polyaxial screw heads are connected to detachable guides, which are detected by the ADVISE software during 3-dimensional (3D) scanning. After open or percutaneous placement of all pedicle screws, the ADVISE software running on an Apple iPad is started. To protect the device and avoid contamination in the surgical field, the iPad should be wrapped in a sterile, clear plastic envelope. The ADVISE software basically offers 2 modes: 3D scanning and marker detection. According to our experience, we report on the application of the 3D scanning method and review the marker detection later in the Discussion section. Before scanning, the surgeon specifies the position of the patient's head, depending on whether the scanning process is started on the left or right side. Next, the iPad camera is orbited around the surgical field for scene analysis to reference the light detection and ranging scanner, and the actual 3D scanning process is started. Based on the known size and shape of the physical guides, the software identifies the guides in the current camera image. This process is visualized by overlapping the virtual guides with the physical guides (**Figure 1**). Special coloring during the procedure finally confirms a successful scanning match. Once all the guides on one side have been scanned and their positions confirmed, the ADVISE software calculates the spatial position of all the screws and the distances between all the screw heads. This information is processed to generate a rod template that fits perfectly in length and curvature by accurately following the path through each screw head in the sagittal and coronal directions. The template is displayed on the iPad screen in a 1-to-1 scale (**Figure 2**) and can be used to cut and bend the rods of the PSS. Next, the same steps are performed for the opposite side. Finally, the rods are inserted and prefixed without tension by inserting the set screws with a torque limiter (2 Nm). Special markers on the set screwdriver indicates whether the rod is positioned stress free in all screw heads after pretightening. The set screws are finally tightened using the T-handle and the countertorque handle. The final tightening also releases the guides from the screw heads.

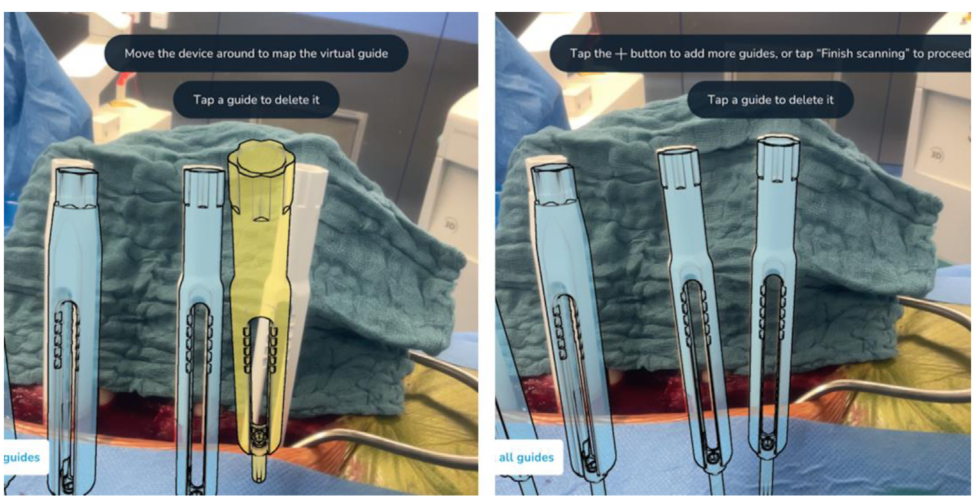

Figure 1. Three-dimensional scanning mode with the ADVISE (advanced dynamic visualization of intraoperative spinal equilibrium) software showing live view through the iPad camera. (*Left*) The vision algorithm attempts to find the physical guide furthest to the right. For this purpose, the software projects a virtual guide (*yellow*) onto the current live image. The 2 guides on the left have already been matched. (*Right*) The iPad camera must be rotated and tilted until the virtual and physical guides overlap. The color of the virtual guide changes from yellow to blue to confirm the scanning match.

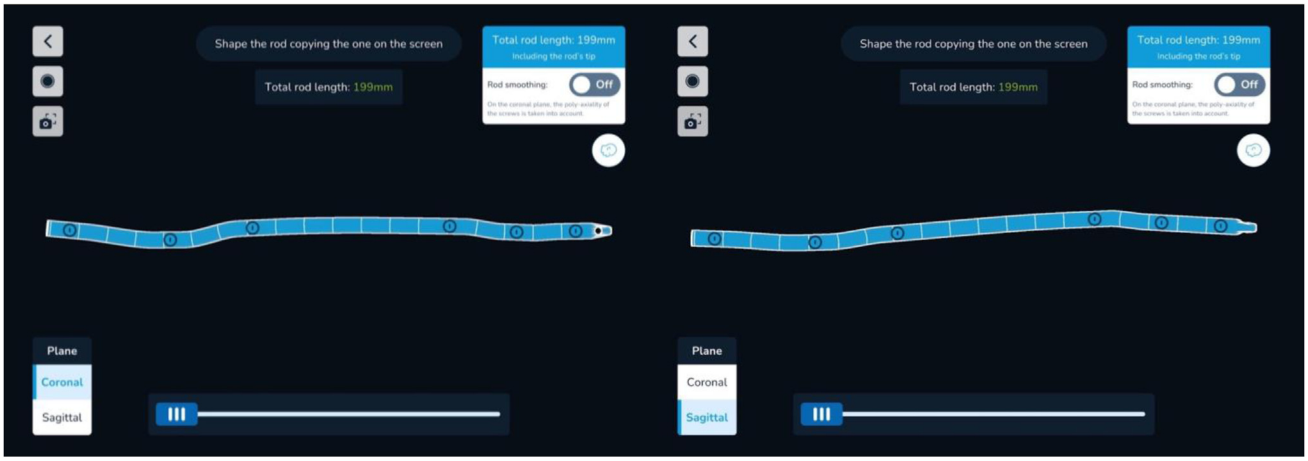

Figure 2. After the scanning process, the ADVISE (advanced dynamic visualization of intraoperative spinal equilibrium) software generates a precisely fitting virtual rod in terms of length and bending. The custom bent rod template is displayed on the iPad screen in a 1-to-1 scale, in both coronal (*Left*) and sagittal (*Right*) projections.

CASE REPORT

Patient 1

A 75-year-old female patient experienced an osteoporotic T11 fracture with kyphotic deformity resulting in increasing pain and limited mobility. Her surgical history was significant for cement kyphoplasty at T12 performed elsewhere. The current surgery included pedicle subtraction osteotomy of T11 to address the kyphotic deformity and cement-augmented dorsal pedicle screw fixation of T8—L3 (**Figure 3**). The **Supplementary Video** demonstrates the single steps of AR-supported rod bending with the ADVISE software. The patient provided written informed consent for the use and publication of the photograph and video material.

Patient 2

A 76-year-old male patient with metastatic prostate cancer presented to the emergency department because of progressive ataxia and paraparesis (ASIA [American Spinal Injury Association] grade D). Magnetic resonance imaging of the thoracic spine revealed multiple intraspinal extradural masses with spinal cord compression from T5 to T10 (**Figure 4**). Laminectomy of T5—T10 and intraspinal tumor resection were performed, including dorsal pedicle screw fixation of T5—T11 to prevent postlaminectomy kyphosis. Rod contouring was supported by the ADVISE software. The scanning procedure, template generation, and subsequent rod bending required no more than 10 minutes per side. Both rods were inserted and fixed without any tension. **Figure 5** shows the postoperative result. The patient provided written informed consent for the report of his case details and imaging studies.

DISCUSSION

Biomechanical and clinical studies have repeatedly described that overloading during rod fixation contributes significantly to mechanical failure, poor clinical outcomes, and the need for revision surgery.[2,8,12-14] Screw loosening or pullout, in particular, is known to be associated with a higher degree of disability and pain, potentially leading to revision surgery with screw replacement and extension of the posterior instrumentation.[2,6,11,15] This, in turn, can cause further problems (e.g., increased risk of infection, adjacent segment degeneration), with the patient caught in a vicious circle. Therefore, attention should be paid to

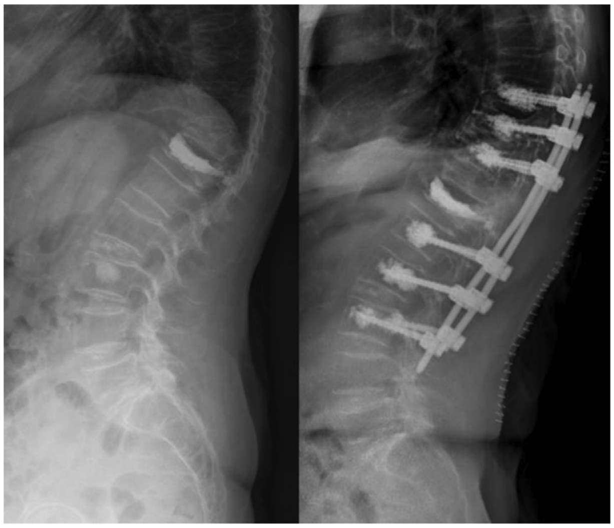

Figure 3. Pre- and postoperative radiographs of patient 1. (*Left*) Osteoporotic T11 fracture resulting in kyphotic deformity. The patient had already undergone cement kyphoplasty at T12. (*Right*) Postoperative imaging showing correction of kyphosis after pedicle subtraction osteotomy of T11 and cement-augmented dorsal pedicle screw fixation of T8—L3. The rods were bent using the ADVISE (advanced dynamic visualization of intraoperative spinal equilibrium) software.

Figure 4. Preoperative sagittal T2-weighted magnetic resonance image of patient 2 showing multiple intraspinal metastatic masses from T5 to T10. Critical spinal cord compression is seen at T8–T10. Subsequently, multilevel laminectomy, intraspinal tumor resection, and dorsal pedicle screw fixation of T5–T11 were performed.

bending the rods as precisely as possible with optimum matching to the screw head positions to achieve the most stress-free final fixation.

The ADVISE software is not the first attempt to provide support to the surgeon during this critical surgical step. In 2013, NuVasive (San Diego, California, USA) launched a special system (NuVasive Bendini) for computer-assisted rod bending. In a clinical study, Ohba et al.[15] compared the screw pullout and loosening rates between computer-assisted and manually bent rods during a 1-year follow-up period. They demonstrated clear advantages for the more precise rod bending achieved with the computer-assisted approach, with screw loosening rates and postoperative back pain significantly lower than those in the manual group.

The Bendini system includes multiple hardware components: a camera with a sterile digitizer for spatial recognition of the screws, a computer control unit with a monitor and associated software, and a mechanical rod bending device to execute the

Figure 5. Postoperative lateral and anteroposterior radiographs of patient 2. The rods were bent with the ADVISE (advanced dynamic visualization of intraoperative spinal equilibrium) software and are precisely adapted to the patient's anatomy.

bending instructions generated by the computer control unit. The ADVISE software, in contrast, is offered preinstalled on an iPad, saving storage space and investment costs.

We have used the ADVISE software for almost 6 months. To date, no major problems or limitations have occurred. Scanning the guides requires a little practice; however, the learning curve is steep. In most cases, creating an individual rod template requires no more than 5–10 minutes per side. Currently, the

Figure 6. Sagittal view of a complex rod template in a degenerative case. Conventional in situ rod bending in this case would be very challenging, time-consuming, and stressful for the screws.

software has only been applied for posterior fusions of ≥3 segments, because its usefulness in mono- and bisegmental fusion surgery seems to be limited. Also, the ADVISE software is an exclusive tool for the Neo PSS. At present, no compatibility with the screw systems of other manufacturers is available.

As stated, the software offers 2 scanning modes. The 3D scanning mode described in our technical note allows for visual acquisition of 10 screws per side. In the marker detection mode, the second option, ≤30 screws can be scanned. The latter requires special markers, which must be placed separately on the guides. This approach is particularly suitable for extension of existing posterior instrumentation. For this purpose, revision guides with markers can be attached to the already implanted screws and combined with the new screws. In addition, the markers are disposable and can be added optionally.

Our experience with this new technology is promising. Especially for multilevel fusion, the support to the surgeon during rod bending is of great value. In the **Supplementary Video**, the screw heads were placed coronally in line, and the pedicle subtraction osteotomy reduced the sagittal kyphotic angle. Thus, the risk of creating a mechanical overload by manually bending the rod was rather low. The anatomical conditions were also favorable in the second patient. However, other cases in our department show a much more difficult spatial placement of the screw heads. In these cases, application of the ADVISE software can achieve an optimized fit between the screws and the rod and, thus, control and reduce the mechanical stress during final fixation. **Figure 6** shows an example of a rod template created for a complex degenerative case. Manual freehand bending of such a rod would have been a time-consuming challenge.

Nevertheless, the anticipated clinical benefit of this new AR-supported technology needs to be proved in the long term. Therefore, the next steps will focus on evaluating the screw loosening rates and clinical outcomes during the follow-up period.

CRediT AUTHORSHIP CONTRIBUTION STATEMENT

Sebastian Antes: Conceptualization, Writing – original draft, Visualization. **Rene Moringlane:** Writing – review & editing, Visualization. **Kajetan L. von Eckardstein:** Writing – review & editing, Supervision.

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Conflict of interest statement: Kajetan L. von Eckardstein is a consultant to Neo Medical SA. The remaining authors have nothing to declare.

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