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Intra-operative AR-supported rod bending in spinal surgery:

A cadaver study

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Abstract

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 Study Objective: The purpose of the study is to compare rod selection and rod bending in AR supporting technology with conventional Freehand (FH) rod bending technique.

 Methods: A cadaver study. For this in-vitro study, a human cadaver was prepared unilaterally

with 6 polyaxial pedicle screws between L1-S1. Eleven spine surgeons were asked to select and bend two custom rods, one with the support of AR technology using the 3D scanning method and another one in FH technique in their usual way. All rods were scanned by an independent laboratory and 3D deviations from an "Ideal Template Rod" (ITR) were calculated.

Introduction: In instrumented thoracolumbar fusion, optimal interplay of spinal alignment, screw position, and rod bending is critical to avoid mechanical overload. Augmented Reality (AR) can

Results: The 3D deviations were statistically significant lower at $\pm 2 \text{ mm}$ (16.2% vs. 40.0%; $p \le 0.001$) and at $\pm 6 \text{ mm}$ (0.0% vs. 1.3%; $p \le 0.001$) thresholds when AR technology was used. Mean total time for bending was 507s for AR and 393s for FH (p=0.126). The number of in-situ checks (p<0.001), rod length corrections (p=0.012) and x-ray controls (p<0.001) were significantly lower for AR supported technology.

Conclusion: AR technology can provide intraoperative data that support surgeons in bending rods that are more precisely adapted to the individual in situ conditions than is possible using FH techniques.

Keywords: Augmented reality; Rod bending; Spinal surgery; MIS

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INTRODUCTION

Mechanical failure is a relevant complication after posterior thoracolumbar fusion with Pedicle Screw Systems (PSS), frequently resulting in revision surgery. Revision rates range from 9% to 19% for degenerative indications within two years after primary fusion and rise considerably with increasing complexity of the procedure [1-4]. For Adult Spinal Deformity (ASD), retrospective analyses show revision rates of 13% to 28% 2 years postoperatively with even higher midterm risks of up to 56% at 5 years [5-13]. These figures are alarming, both from a medical and socioeconomic point of view, especially since studies indicate that revision rates tend to increase compared to earlier years [9]. In-depth analyses show that the majority of revisions are due to mechanical failure, which is always caused by mechanical overload [9-13].

The use of computer-assisted technologies is an option to improve the outcome of instrumented spinal fusion. Robotguided navigation is one such technology that has gained prominence in recent decades. It aims to make spinal fusion surgery safer and improve outcomes by better controlling the accuracy of pedicle screw placement. A critical review of the literature concludes that robotic navigation appears to be more accurate than the freehand technique and that it is associated with lower radiation exposure but longer surgeries [14]. Disadvantages of this technology are in particular the high costs, a large technical and logistical effort and the required experience in handling. Competent supervision of the first 25 robotic-assisted surgeries is recommended, regardless of whether the spine surgeons are experienced or less experienced [15]. According to a survey, computerassisted navigation does not fulfill the spine surgeons' expectations regarding usability, work-flow integration and cost-effectiveness [16].

While significant efforts are being made to improve screw placement accuracy through the use of technology, the assessment of intraoperative spinal alignment is an issue that has received relatively little attention. A recent investigation among spine surgeons in the United States found that intraoperative spinal alignment is assessed primarily by Carm or spot radiographs (84%) [17]. Although 88% of participants reported having access to a surgical navigation camera, it is used in only 40% of all deformity cases. Overall, satisfaction with the latest technologies for intraoperative spinal alignment monitoring is rated as moderate. Reasons include workflow disruption, lack of familiarity, cost, lack of desired information, and radiation exposure. Missing visualization of critical landmarks is one of the main causes of unsatisfactory postoperative alignment, especially in Minimally Invasive Surgery (MIS) [17].

To reduce the risk of mechanical failure, the loads acting on the PSS and surrounding tissues must be reduced. The biomechanical interaction of spinal alignment, screw position, and specific rod bending is critical in this context [18-21]. Augmented Reality (AR) is a technology that can possibly support the surgeon in this regard.

The objective of this study is to evaluate whether AR rod bending technology is a useful tool to assist surgeons in rod selection and bending, with the aim of adjusting the rods to the final position of the pedicle screw heads more precisely than is possible with the conventional Freehand (FH) technique.

MATERIAL AND METHODS

This in-vitro study uses a human spine cadaver specimen (MoViDo GmbH, Essen, Germany) to investigate the accuracy of rod bending in AR and FH technique. Since this is a cadaver study, a review by the Ethics Committee was deemed unnecessary.

METHODS

Eleven orthopedic and trauma spine surgeons with varying levels of experience participated in a cadaver workshop at ProSympos ZukunftsZentrum Zollverein in Essen, Germany, on September 19, 2022. A human spine was unilaterally prepared with 6 polyaxial pedicle screws and screw extenders (1st. generation, Neo Pedicle Screw System[™] (NEO); Neo Medical S.A., Villette, Switzerland) inserted percutaneously between L1 and S1 by an experienced spine surgeon of the group (Figure 1). For this setup, each study participant was asked to select and bend two custom rods (NEO: Ø5.5 mm x 300 mm titanium rod), one with the support of AR technology (study arm: ADVISE[™], NEO) using the 3D scanning method and another one in FH technique (control arm) in their usual way. For this, a NEO instrument set, a French bender, a rod cutter, a C-arm and an iPad with the ADVISE software (version R.2.0.0) were available. The time required (AR technique: time for scanning and bending; FH technique: time for bending) was registered with a standard stopwatch. Also, the number of rod length adjustments, in-situ checks, and radiographic controls were noted.



Fig. 1. Study set-up: human cadaveric spine with 6 polyaxial pedicle screws and their extenders (Neo Pedicle Screw System[™]) placed percutaneously between L1 and S1

Once all study participants had finished bending their two rods, the situs was opened, and an "Ideal" Template Rod (ITR) was formed with a flexible rod (Aluminum, Ø5 mm) under visual and radiographic control by an experienced spine surgeon of the group. To verify its fit, the template was fixed at S1 and L1, the most caudal and cranial levels, and a Computer Tomography (CT; Cios Spin, Siemens Healthcare GmbH, Erlangen, Germany) was taken. A perfect embedding of the template rod into the heads of all screws without any external forces confirmed the shape of the ITR.

INVESTIGATIONAL DEVICE

The device under investigation (ADVISE[™]) is a software that uses AR technology. It runs on standard Apple iPads and can be used during spine surgery to determine individual rod size and shape based on NEO pedicle screw extenders, also called guides. ADVISE[™] stands for Advanced Dynamic Visualization of Intraoperative Spinal Equilibrium. It works with a mean accuracy of 2mm point, 3mm distance and 2° angular axis displacement. The application is carried out radiation-free.

The surgical field is scanned three-dimensionally with the integrated iPad camera. The screw head positions are localized indirectly by detecting screw extenders, also known as guides, which are attached to the implanted screws (3D scanning method). For this, the software projects virtual guide templates onto the iPad screen, which must be matched with the camera image of the physical guides. Once the position of all guides on one side has been recorded, the software calculates and displays the minimum rod length and provides custom rod templates for the coronal and sagittal planes that best fit the pedicle screw heads for the given screw placement. Bending of the rod can be done over the iPad in 1:1 ratio screen along these templates (Figure 2). Another module that allows the surgeon to select from the available rods and virtually check their position in relation to the pedicle screw heads - supported by the software that determines the best possible position of the rod and suggests screw adjustments in mm for a better fit - was not used in this study. The option of integrating a desired correction into the 3D rod contour was

also not applied.



Fig. 2. Ex-situ bending of custom rods according to a template generated with augmented reality technology

3-D SCANNING AND MEASUREMENTS

All bent rods, including the ITR, were scanned and measured by an independent laboratory (Invers Industrievermessung & Systeme GmbH, Essen, Germany). The measurements were performed in a temperature-controlled measuring room at 20°C using a FARO Quantum S measuring arm with a FAROBlu laser scanner. Utilizing best-in-class blue laser technology, the scanner provides point cloud data of the highest accuracy with non-contact measurement capability. Data processing was performed with Polyworks 2022, a universal software for 3D analysis and quality control.

The ITR model serves as a reference for all other rods, those with AR support as well as those bent freehand. For 3D comparison of a rod with the ITR, both laser-scanned models were aligned with each other using the best-fit principle. On the basis of individual points on the surface mesh structure, about 68,000 to 97,000 depending on the rod length, the 3D deviations were calculated. Point measurements in the sagittal and coronal plane were taken in 1 cm increments, starting at 0 cm = P1 (cranially) and ending at 17 cm with P18 (caudally).

STUDY ENDPOINTS

The primary endpoint of the study is a comparison of the 3D deviation of a rod from the ITR, reported in percent of surface exceeding a \pm 2 mm limit for AR technique *vs.* FH technique [22].

Secondary endpoints are:

 A comparison of the 3D deviation of a rod from the ITR, reported in percent of surface exceeding a ± 6 mm limit for AR technique *vs.* FH technique [18].

- A comparison of the time required to bend a rod in AR technique *vs.* FH technique.
- A comparison of the number of rod length corrections performed in AR technique *vs.* FH technique.
- A comparison of the number of times a rod is placed in situ to verify its shape in AR technique *vs.* FH technique.
- A comparison of the number of x-ray controls to verify the shape of the rod in AR technique vs. FH technique.

In addition, descriptive evaluations are performed with respect to the deviations of a rod from the ITR at 18 measurement points in both the sagittal and coronal planes, each presented separately by bending technique. Also, correlation analyses are performed between a surgeon's level of experience (number of fusions performed per year) and the total time required for rod bending per bending technique.

STATISTICAL ANALYSIS

Qualitative parameters are described by frequency and percentage. For quantitative parameters, mean, Standard Deviation (SD), median, minimum and maximum are given. A T-test or a Mann-Whitney U-test is used to compare independent means, depending on the distribution of the data. For comparison of independent proportions, Fisher's exact test is performed and for correlation analyses, Spearman's Rho. Statistical significance is assumed at p<0.05. Statistical analyses are done using IBM SPSS Statistics (version 21).

RESULTS

The deviation of custom rods from the ITR is shown in figure 3 for the sagittal and in figure 4 for the coronal plane.



Fig. 3. Shape of the ideal template rod (green) and the custom rods bent in freehand technique (yellow) and with augmented reality support (blue) in the sagittal plane: left side = caudal, right side = cranial



Fig. 4. Shape of the ideal template rod (green) and the custom rods bent in freehand technique (yellow) and with augmented reality support (blue) in the coronal plane: left side = caudal, right side = cranial

PRIMARY AND SECONDARY STUDY ENDPOINTS

Pooled 3D deviations, given as a percentage of the surface exceeding a limit of $\pm 2 \text{ mm}$ and $\pm 6 \text{ mm}$, are listed in table 1.

| | AR | | | | | | | |
|---------------------------|----|-------|-------|-------|--------|-------|--|--|
| | N | Mean | Min | Max | Median | SD | | |
| Deviation +/- 2 mm [%] | 11 | 15.54 | 6.9 | 21.72 | 16.23 | 5.13 | | |
| Deviation +/- 6 mm [%] | 11 | 0.01 | 0 | 0.06 | 0 | 0.02 | | |
| | FH | | | | | | | |
| | N | Mean | Min | Max | Median | SD | | |
| Deviation +/- 2 mm [%] | 11 | 38.7 | 18.33 | 64.57 | 39.99 | 15.13 | | |
| Deviation +/- 6 mm [%] | 11 | 4.47 | 0 | 13.17 | 1.3 | 4.86 | | |

Table 1. 3D deviation of custom rods from the ideal template rod (ITR), expressed as a percentage of surface exceeding a threshold of ± 2 mm and ± 6 mm, shown by bending technique. AR = Augmented Reality Technology ; FH = Freehand Technique

The 3D deviation of custom rods from the ITR, expressed in percent of surface area exceeding a \pm 2 mm threshold, is statistically significant (p<0.001) different between rods bent with the support of AR technology and those bent with FH

technique (Figure 5, primary study endpoint). Statistical significance (p=0.001) can also be demonstrated for a limit of \pm 6 mm.



The mean total time for bending a rod is 507 seconds (range 357-828, median 441, SD 156) in the AR group and 393 seconds (range 121-670, median 373, SD 179) in the FH group. A comparison showed no statistically significant differences (p=0.126). The number of in-situ checks, rod length corrections, and x-ray controls are summarized in table 2. Comparisons between the two bending techniques showed statistically significant differences for all three criteria.

Fig. 5. Primary endpoint: distribution of the 3D percent deviation of at least ± 2 mm from the Ideal Template Rod (ITR) for rods bent with AR support compared to those bent with FH technique

Table 2. Number of in-situ checks (3-8 times combined in one group), number of rod length corrections, and number of x-ray controls (3-8 times combined in one group) needed for rod bending, shown by bending technique; AR = Augmented Reality Technology; FH = Freehand Technique

| | | Technique | | | | |
|----------------------------------|-----|-----------|---------|----|--------|--------|
| | | AR | | FH | | |
| | | N | % | N | % | р |
| # of in-situ checks (grouped) | 1 | 10 | 90.90% | 1 | 9.10% | |
| | 2 | 1 | 9.10% | 2 | 18.20% | <0.001 |
| | 3-8 | 0 | 0.00% | 8 | 72.70% | |
| # of rod length corrections | 1 | 11 | 100.00% | 5 | 45.50% | 0.012 |
| | 2 | 0 | 0.00% | 6 | 54.50% | |
| # of x-ray controls (grouped) | 1 | 10 | 90.90% | 1 | 9.10% | |
| | 2 | 1 | 9.10% | 2 | 18.20% | <0.001 |
| | 3-8 | 0 | 0.00% | 8 | 72.70% | |

DESCRIPTIVE EVALUATION

The mean deviations of the custom rods from the ITR at 18 measurement points are presented in figure 6 for the sagittal and in figure 7 for the coronal plane.



Fig. 6. Mean deviation in mm from the ideal template rod (ITR) of the rods bent with augmented reality support (AR; blue) and the ones bent in freehand technique (FH; yellow) at 18 measurement points, starting at 0 cm with P1 (cranially) and ending at 17 cm with P18 (caudally) taken in 1 cm steps in the sagittal plane. ITR = Ideal Template Rod; AR = Augmented Reality Technology; FH = Freehand Technique



Fig. 7. Mean deviation in mm from the ideal template rod (ITR) of the rods bent with augmented reality support (blue) and the ones bent in freehand technique (yellow) at 18 measurement points, starting at 0 cm with P1 (cranially) and ending at 17 cm with P18 (caudally) taken in 1 cm steps in the coronal plane. ITR = Ideal Template Rod; AR = Augmented Reality Technology; FH = Freehand Technique

Analyses showed a statistically significant correlation (p=0.04) with a strong negative relationship between the experience of the surgeon (number of fusions per year) and the total time needed (r=-0.785) for the FH technique, but not for AR.

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DISCUSSION

The results of the study indicate that AR technology can help match rod bending more precisely to the intraoperatively positioned pedicle screw heads, reduce the number of in-situ checks as well as rod length corrections, and decrease intraoperative radiation exposure while maintaining similar bending time. A 60% reduction in the proportion of rod area showing a relevant deviation of >2 mm from the "ideal" rod, and even of more than 99% when considering the mechanically critical limit of >6 mm, clearly demonstrate the potential of AR in spinal surgery using familiar, easy to use and readily available iPad technology [18,22].

About 82% of loosened screws are pulled-out during rod connection, clinically confirming the importance of the interaction between spine, screw head position, and rod profile [23]. If a rod does not fit perfectly into the heads of the pedicle screws, load must be applied to join the two. If correction is required and cannot be achieved in other ways, such intended reduction maneuvers using appropriately bent rods are necessary. In all other cases, the pedicle screw system is used for additional stabilization and fixation. In these cases, the implant and the spine are subjected to unnecessary and often unintentional stress due to mismatches that need to be overcome during tightening of the construct [21]. However, even in patients who require reduction, there is a risk that the assembly forces required to overcome unintended misalignments between the rod and pedicle screw heads will impair a planned reduction unnoticed. Often, special reducing tools are used that generate a significant uncontrolled force to overcome the mismatch. This affects not only the implant system and can, for example, prevent secure tightening of the set screw, but also the screw-bone interface and the surrounding tissue [18,24,25]. In a finite element analysis, Loenen et al. investigated the effects of coronal and sagittal misalignments of 6 mm between pedicle screw heads and rods [18]. To correct the misalignment, pulling forces of 1 kN were required, causing rotations of up to 3° in the motion segments, which in turn also affected adjacent segments. Thus, abnormally high forces were found in the facet joints, intervertebral discs, and vertebral bodies. The authors concluded that proper instrument alignment can help prevent clinical complications due to unintended biomechanical overloads [18]. This is also called for by other authors, who

found in their in vitro biomechanical studies that a residual gap of 5 mm overcome with persuasion devices leads to a significant reduction in the pullout strength of pedicle screws in both osteoporotic and normal bone [19,26]. But just fixing a polyaxial screw in a non-perpendicular orientation to the rod results in reduced pullout stiffness [27]. Recent studies have demonstrated that the risk of screw loosening increases significantly when the bone surrounding the screw has a high load factor, which is determined by the relationship between local load and bone quality [28].

Based on these findings, it is surprising that while much effort has been spent to make screw positioning more precise with the support of navigation technology, few approaches aim to adapt the bending of the rod as accurately as possible to individual requirements, especially since MIS techniques make monitoring difficult.

Thereby, it has been biomechanically proven that pedicle screws are subjected to significantly lower peak and residual loads due to rods whose bending is better matched to the respective screw positions by computer support [29,30]. In clinical use, patient specific computer-assisted bent rods have been shown to more accurately match the planned curvature than off-the-shelf rods, significantly reduce screw pullout rate, screw loosening rate, and rod breakage rate, improve sagittal balance and have a positive impact on clinical outcome and fewer complications [30-38].

Besides patients with osteoporosis, those with long fusions particularly benefit from patient-specific bent rods. As shown in figures 6 and 7, the ideal rod does not exhibit a consistent arc of curvature in either the sagittal or coronal plane, as might be expected. But individual curvatures are not reproduced at all by rods off the shelf, and freehand bending also shows considerable deviations, especially in the caudal region, resulting in high mechanical stresses in this area that could be avoided (Figures 6 and 7). The use of AR in complex clinical cases requiring longer fusions as shown in figure 8, and as in Adult Spinal Deformity (ASD), helps the surgeon to optimize customized rods that drop much more smoothly into the construct and reduce forces, particularly at the end segments where screw loosening and pullout are known to occur more frequently [39].













Fig. 8. (a) Pre-operative radiographs, CT and MRI of a 60yo male patient with severe back pain and multisegmental stenosis. The patient had received already 3 decompressive surgeries and has a walking distance <500 meters. (b) Anterior indirect decompression and sagittal realignement in lateral decubitus position by XALIF and OLIF technique (c) additional posterior percutaneous instrumentation using AR supported technology to scan the guides (screw extenders) with the integrated iPad camera. The software can identify the exact position of each screw head in both the sagittal and coronal planes. (d) The software calculates and displays a visualization of the rod shape on the iPad screen, here in the sagittal plane. (e) Final rod shaped according to the iPad visualization. (f) Post-operative radiographs.

Multiple shortening of an already selected and pre-bent rod is more frequently required in the freehand technique and may

THE JOURNAL OF ORTHOPAEDICS TRAUMA SURGERY AND RELATED RESEARCH also have a negative effect on the fit of a rod. In addition, repeated in situ checks of the rod length or fit and the X-ray controls increase the operating time and thus also the risk of infection [40]. However, this is offset by additional scan times in AR technology. Whether AR technology has the potential to reduce surgical time in long and complex fusion cases, such as scoliosis corrections, needs to be investigated in clinical trials. Furthermore, the present results suggest that the time required to bend a rod in freehand technique depends significantly on the experience of the surgeon. Radiation exposure in spine surgery is currently a frequently addressed issue, which is of high importance not only for patients, but especially for surgical staff [41-43]. The results of the study indicate that AR technology can help reduce intraoperative radiation, particularly in MIS.

The limitations of the present work relate particularly to the in vitro design, in which a single human specimen was used, so the results should be further confirmed in clinical studies. In recent publications, the first promising clinical experiences with this new technology were presented [44,45]. Especially in multilevel fusion, the authors conclude that the support to the surgeon during rod bending is of great value [44]. However, the accuracy of the ITR used as a reference can also be viewed critically. At present, it is neither in vivo nor in vitro possible to determine the design of an individual actually ideal rod. Nevertheless, attempts were made to come as close as possible to this by various means, including, in addition to the experience of the surgeon, the opening of the surgical field, a more flexible and thus easier to contour rod, non-forced insertion of the rod, and subsequent CT monitoring. Furthermore, the present study does not take into account the influence of possibly necessary corrective reductions by means of rod curvature. However, this was not the objective of this fundamental cadaver study on the precision of bending rods.

CONCLUSION

AR technology enables surgeons to access intraoperative real-time data that can support them in bending rods that are more precisely adapted to the individual in situ conditions than is possible using freehand techniques. The particular challenges here lie in the adequate lumbar lordosis adjustment but also in the attention paid to the coronal alignment - an aspect that is rarely considered in daily routine. It is likely that the advantages of rod bending with AR support are most effective in MIS and for complex deformity corrections. Therefore, further developments should consider long fusion constructs. In the long term, AR supported technology should combine preoperative planning data with real-time tracking of intraoperative reduction.

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ABBREVIATIONS

AR = Augmented Reality Technology, ITR = Ideal Template Rod, FH = Freehand Technique

CONFLICTS OF INTEREST

PK, MB, VM, RK, PW have consulting agreements including speaking fees and travel costs with Neo Medical SA.

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