QUALITY, SAFETY, AND VALUE OF INNOVATION IN SCOLIOSIS SURGERY: INTRAOPERATIVE SKULL FEMORAL TRACTION AND NAVIGATED SEQUENTIAL DRILLING

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Objectives
Posterior spinal instrumentation and fusion (PSIF) is a common and expensive surgery for the management of adolescent idiopathic scoliosis (AIS). Since 2010, our institution has implemented two surgical strategies to mitigate the growing costs associated with this surgery: first intraoperative skull femoral traction (IOSFT), then navigated sequential drilling (NSD). This study compares the clinical and financial impact for two different surgical strategies used for pedicle screw hole preparation: SNPD and a navigated awl technique, both used with IOSFT.

Methods
We reviewed the medical records of one hundred and twenty-five consecutive subjects who underwent a single-stage PSIF for the treatment of AIS between 2008 and 2015 at a single institution. We identified three cohorts based on the different surgical strategies used in the treatment of AIS: traditional techniques (n = 28), IOSFT (n = 45), and IOSFT plus NSD (n = 52). Primary outcomes focused on reportable quality indicators: operative time, prevalence of case requiring extended operating room time, need for blood transfusion, length of hospital stay, and total cost per surgery. Secondary outcomes included implant density, degree of spine deformity correction and complication rate.

Results
All primary outcomes improved significantly in the IOSFT and NSD cohort (p < 0.001). Mean operating time decreased by 59% - averaging from 462 to 185 minutes. Utilization of late operating room hours fell from 89% to 0%, transfusion rate from 64% to 1.9%, and length of hospital stay from 5 to 4 days. Comprehensive cost per case decreased by 24%. These savings were mostly accounted for by the reduced length of hospital stay and operating time.

Conclusions
The implementation of IOSFT and NSD delivered superior quality, safety, and value-of-care relative to the conventional awl technique. These surgical strategies were performed without increased risk of perioperative complications, while allowing us to reduce costs by 16% per case. The data presented may have significant implications in health resource utilization for scoliosis surgery. Prospective larger scale research is warranted to investigate the generalizability of our findings.

Disclosures:
PREOPERATIVE PREDICTION OF COST AND CATASTROPHIC COST (CC) IN ADULT SPINE DEFORMITY (ASD) SURGERY: FEASIBILITY ANALYSIS OF PREDICTIVE ANALYTICS TO ESTABLISH 90 DAY BUNDLED PAYMENTS


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Introduction
There has been increasing interest in cost prediction for bundled payment models and risk sharing initiatives. Catastrophic Costs (CC) outliers are typically excluded in bundled payment settings making their preoperative identification critical. Bundled payment models and risk sharing initiatives have been proposed as means of controlling ASD surgery cost, but these approaches require accurate cost prediction.

Methods
A predictive analytic model to preoperatively determine direct cost and CC outliers can be developed using a cohort of ASD surgeries with actual direct hospital costs. We modeled the direct cost based on prospective multicenter ASD data. We performed regression models (generalized linear regression and random forest) for direct costs and classification models (random forest) for CC for ASD surgery. The goal of the regression models was to explain the determinants of direct costs (patient, surgical and contextual factors). The goal of the CC models was to predict which patients would have a direct CC (> $100,000).

Results
210 ASD patients (83% women, 45% revisions) from 4 sites in 4 geographic US areas were included. Cost data were actual direct costs incurred to the hospital. Average index cost per patient was $75,772. 14.8% of patients had a cost above the $100,000 threshold. Direct cost could be predicted preoperatively using random forest models with an accuracy of 72.1% (Example case in Figure). Of total variance explained, 22.6% was site and surgeon fixed-effects. Top predictors of cost in order were: surgeon, number of levels fused, interbody fusion and site. Catastrophic cost was predicted with 90.4% accuracy and 87.7% AUC. In our sample alone, reducing the CC occurrence by one-third the associated savings would be $452,181. Across the US this savings would extrapolate to at least $80 million/yr.

Conclusion
This study demonstrates that direct cost in ASD surgery can be reliably predicted in a preoperative setting. CC outliers can be predicted with >90% accuracy preoperatively. The high degree of cost variance explained by factors such as site and surgeon suggest potential efficiency gains offered by standardization in patient selection and treatment strategies.
Disclosures:

INTRODUCTION

Surgeons may not have a thorough knowledge about the costs of particular devices or surgical equipment and the impact on overall costs of care. There are a variety of reasons for this including rapid technological advancement and price insensitivity. The purpose of this study is to determine whether surgeons will change their choice of implants/equipment once they are aware of the specific costs.

METHODS

A thorough bottom up case costing methodology was used to determine the costs of all implants used by a spine surgical service at a large tertiary care center. Costs were collected for an initial 5 month period (pre-blind) where surgeons were not aware of costs, followed by another 5 month period (post-blind) where detailed cost information was known. Three procedures, anterior cervical discectomy and fusion (ACDF), posterior cervical fusion and single level lumbar interbody fusions were included. Statistical analysis was undertaken with STATA software.

RESULTS

Costs decreased by $478 for instrumentation once actual prices were known but this result was not statistically significant (p=0.069). Only ACDF procedures demonstrated statistically significant cost savings of $754 (p=0.009) Procedural costs were also less ($297, p=0.194) as well as the total overall costs of admission ($401, p=0.228). There were no significant differences in surgeon costs or in health related quality of life (HRQOL) outcomes for patients.

CONCLUSION

Although costs decrease for implants in surgery when prices are known, this appears to have little or no effect on overall costs of care. Length of stay and operating room time appear to have equal or greater effects on global costs. Future efforts to encourage efficient cost savings should focus on practice patterns for similar conditions rather than limiting the use of certain implants.

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A DUAL SCREW TECHNIQUE FOR VERTEBRAL COMPRESSION FRACTURES USING ROBOTIC NAVIGATION IN THE OSTEOPENIC LUMBAR SPINE: AN IN-VITRO BIOMECHANICAL ANALYSIS

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Introduction

Neurological deficit following vertebral compression fracture (VCF) in patients with severe osteopenia requires decompression and stabilization. Multi-rod reconstruction techniques have been shown to maximize posterior fixation, but at present, utilize a single pedicle screw anchor point to support multiple rods. Robotic navigation technologies, developed to improve pedicle screw (PS) accuracy, may allow for insertion of PS and cortical screws (CS) within the same pedicle, providing 4 points of bony fixation per vertebra. Recent studies demonstrated radiographic feasibility for such a dual screw trajectory for posterior lumbar spinal instrumentation, but biomechanical characterization of the technique is presently lacking.

Purpose

Investigators quantified stability of 2-rod or 4-rod constructs of (1) bilateral pedicle screw and (2) bilateral dual pedicle and cortical screw (PSCS) techniques, in an in-vitro VCF model.

Materials and Methods

Fourteen cadaveric lumbar specimens (L1-L5) were divided into 2 groups (n=7) of similar bone density (t-score: -2.23±1.19 and -2.29±0.84 for PS and PSCS, respectively). VCF was simulated at L3. Group 1 was instrumented with PS; group 2 was instrumented with PS and CS. Operative constructs (L2-L4) included intact; bilateral PS with 2 rods (PS 2-rod); bilateral PS with 4 rods using rod-to-rod connectors (PS 4-rod); bilateral PSCS dual screw fixation with 2 rods affixed only at the PS (PSCS 2-rod); and bilateral PSCS dual screw fixation with rods affixed at PS and CS (PSCS 4-rod). Load control (±7.5Nm) testing was performed in flexion-extension (FE), lateral bending (LB), and axial rotation (AR). Maximum motion of operative levels was recorded and normalized to mean intact condition (100%). Comparisons were made between groups (significance at p<0.05).

Results

In FE and LB, for both groups, the following trend was observed: intact>2-rod>4-rod. In FE, PS and PSCS 2-rod fixation reduced intact motion to 74.0% and 74.2%, respectively; 4-rod fixation further reduced motion to 67.5% and 50.2%, respectively (all p>0.05). In LB, PS and PSCS 2-rod fixation reduced intact motion to 27.7% and 39.0%, respectively (both p<0.05); 4-rod fixation further reduced motion to 24.0% and 26.2%, respectively (both p<0.05). In AR, PS and PSCS 2-rod fixation increased intact motion to 105.3% and 117.0%, respectively; only PSCS 4-rod fixation reduced motion relative to intact, 85.4% (PS = 103.6%) (all p>0.05). No significant differences were observed between treatment groups (p>0.05).

Conclusion

This study provided the first biomechanical evaluation of a novel dual screw technique in a VCF model. Multi-rod reconstruction increased stability, regardless of single or dual screw technique. While 4-rod reconstruction with dual screws provided the most fixation in FE and AR, additional bony anchor points did provide improved stability compared to use of 4-rod reconstruction with pedicle screws and rod-to-rod connectors.
Disclosures:
INCREASED RADIATION BUT NO BENEFITS IN PEDICLE SCREW ACCURACY USING INTRAOPERATIVE CT BASED NAVIGATION COMPARED TO FREE HAND TECHNIQUE IN IDIOPATHIC SCOLIOSIS SURGERY

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Pedicle screws are crucial in surgical treatment of spinal deformities, however, screw insertion is demanding and inappropriately placed may result in complications. Navigation systems based on intraoperatively obtained three dimensional (3D) images were developed to prevent or minimize pedicle screws misplacements. However, there is a lack of data confirming superiority of navigation above other techniques. There are also concerns regarding increased radiation required during procedure.

The objects of this study were to compare accuracy of two methods of pedicle screws placement: intraoperative 3D image based navigation versus a freehand technique in patients with idiopathic scoliosis; and to evaluate the radiation received by patients in both methods.

Methods: 835 pedicle screws inserted by two surgeons in 49 patients who underwent posterior spinal fusion with all pedicle screw constructs for idiopathic scoliosis were included into the study. Study design involved alternating the use of the freehand technique and navigation to position pedicle screws in consecutive patients resulting in two groups; 451 pedicle screws navigated and 384 freehand. Two observers not involved in the treatment evaluated the position of the screws.

The pedicle breach was assessed on CT scans in sagittal and horizontal views according to grading system: grade 0 no pedicle wall violation, grade 1 perforation ≤2mm, grade 2 -2-4 mm, grade 3 perforation of >4 mm. Grades 0 and 1 were considered as a properly positioned, grades 2 and 3 represented malposition. The radiation doses from o-arm and c-arm used throughout the procedure were collected.

Results. We found no differences in accuracy between the freehand and navigated groups in terms of the proportion of screws that were properly positioned (96.8% freehand and 95.8% in the navigation group, respectively; p = 0.518). Grade 3 pedicle screws were observed only in the freehand group and were all located in the upper thoracic spine. Patients undergoing navigated pedicle-screw placement received a greater mean radiation dose than those whose screws were placed freehand (1070.5 ± 447 mGycm versus 390.5 ± 53 mGycm, p < 0.001).

Conclusions: We did not observe benefits of pedicle screw placement with CT-based navigation in patients with moderate idiopathic scoliosis undergoing primary surgery, but the patients experienced significantly greater exposure to radiation. Hence, cautious selection of method is essential to balance surgical safety and adverse effects of increased radiation.

Disclosures:
author 1: none
PEDICLE SCREW PLACEMENT WITH AUGMENTED REALITY SURGICAL NAVIGATION USING INTRAOPERATIVE 3D IMAGING
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Introduction: Several studies have shown that the use of a combination of intraoperative CT images and navigation, significantly improves pedicle screw placement accuracy. A new concept of surgical navigation system using augmented reality (AR) with intraoperative 3D cone beam CT (3D CBCT) was developed specifically for spinal surgery with non-invasive patient tracking.

Methods: Twenty consecutive patients were enrolled in this prospective study (14 deformity cases, 3 spondylolisthesis and 5 other clinical indications). The procedures took place in a hybrid operating room. An intraoperative 3D CBCT was acquired with a ceiling-mounted robotized C-arm with integrated optical video cameras to plan the direction of pedicle screw insertion after automatic identification of the pedicles (Philips Healthcare, the Netherlands). The direction of the screws were augmented to the video display of the surgical field. Accuracy was defined as the proportion of screws placed within the pedicle or encroaching the cortex. Three independent reviewers assessed the accuracy using the Gertzbein scale. Efficiency was assessed by measuring each part of the surgical procedure. Safety corresponds to clinical outcome, as well as radiation exposure to the patients and surgical staff.

Results: A total of 253 screws were placed using the AR navigation system yielding an accuracy of 94%. Thirteen of the 15 screws not considered as accurate had larger diameter than the pedicle. The total procedure time ranged from 232 to 548 min. In average, a quarter of the procedure time corresponded to the usage of the AR system to navigate the screws. The median time of screw placement was 4 minutes. The required time to perform 3D scans (for both planning and screw placement verification) including the time of the automatic identification of the pedicles accounted for an average of 2% of the total procedure time. The rest of the procedural time corresponded to the preparation of the surgical field exposure and closure, as well as implant placement (cages, rods, etc.). The patient radiation dose ranged from 14.1 to 51.4 Gy.cm2. The total cumulative staff occupational dose ranged from 0 to 3.2 μSv; corresponding to a small fraction of the main scatter radiation dose from the patient which ranged from 159.0 to 563.8 μSv.

Conclusion: AR navigation in a hybrid operating room demonstrated an accuracy of 94% at negligible staff X-ray dose. The time needed for screw navigation accounted for of the procedure time.
Disclosures:
KINESIOTAPING IN THE TREATMENT OF CHRONIC MECHANICAL LOW BACK PAIN: A RANDOMIZED CLINICAL TRIAL

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Background: Kinesiotaping (KT) is a widely used technique in the treatment of chronic low back pain (CLBP); however, benefits tested against a placebo have not been shown. Few clinical trials have been carried out using standardized guidelines not taking into account the physical examination of the patient as an indication selector factor.

Aim of the study:
1) Assess the effectiveness of KT in the treatment of CLBP when skin/fasciae mobilizing during exploration is shown to be a possible modifying factor of treatment effect.
2) Analyze the effect of fear-avoidance beliefs, anxiety/depression, and catastrophic ideation on NMB efficacy.

Methods: This is a double-blind randomized clinical trial with allocation concealment and intention-to-treat analysis. Sixty-two (62) patients with CLBP were randomly assigned to one of two possible treatment groups: the KT group or the placebo bandage group. Each study subject underwent four weekly treatments. The following variables were assessed pre-/post-treatment and at six months: Roland-Morris Disability Questionnaire (RMDQ), Numeric Pain Rating Scale (NPRS), EuroQol 5D-5L, Fear-Avoidance Beliefs Questionnaire, Pain Catastrophizing Scale, and Hospital Anxiety-Depression Scale.

Results: ANOVA showed significant differences regarding the main effects in impairment and pain only for the factor time. Statistically significant improvements of impairment and pain were determined post-treatment for both study groups. At six months, these changes were still significant and clinically relevant only for the KT study group. However, inter-group analysis revealed that neither variable showed significant mean differences at any evaluation time points. For the whole sample the prospective stepwise regression analysis for impairment at six months, only revealed catastrophic ideation as the variable that explains 22% of its variance.

Conclusions: KT in the treatment of CLBP is not significantly more effective than placebo bandage regarding impairment and pain. However, for the KT study group alone, a clinically relevant improvement is maintained for impairment at six months. Amongst the assessed psychological factors, only catastrophic ideations have a prognostic value in the degree of impairment.

Registry: ClinicalTrials.gov: NCT02604290.

Disclosures:
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COGNITIVE BEHAVIOURAL THERAPY SUPPORTED WITH INFORMATION AND COMMUNICATION TECHNOLOGIES IN THE TREATMENT OF CHRONIC LOW BACK PAIN: A RANDOMIZED CLINICAL TRIAL

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Introduction: The reported effectiveness of cognitive-behavioral therapy (CBT) for low back pain is mild or moderate. One way to increase the adherence and the therapeutic effects of face sessions of CBT could be through at home self-management with the aid of Information and Communication Technologies (ICTs).

Objectives: Assess 1- effectiveness of CBT in our environment comparing it with the rehabilitation treatment; 2- effectiveness of CBT when accompanied by ICTs (internet and mobile phone support), in comparison to only CBT and to the rehabilitation treatment.

Methods: This is a randomized three-arm, single blind, and parallel-group clinical trial. Two hundred (200) patients with chronic low back pain were randomly assigned to one of three possible study groups: the control group (n: 65) received back-school sessions, the CBT group (n: 72) received group sessions of CBT (n: 63), and the CBT+ICT group (n: 63) received the CBT treatment with telephonic support and an online program. The three groups received the same rehabilitation treatment. Pain, disability, quality of life, comorbidities, catastrophizing, fear-avoidance beliefs, anxiety, depression, pain coping strategies, and satisfaction with the treatment were assessed with the aid of validated questionnaires.

Results: There was an immediate significant and clinically relevant improvement of pain and impairment in the three groups at 3, 6, and 12 months. A decrease in maladaptive catastrophizing and fear-avoidance beliefs was observed in patients who received CBT. Patients in CBT+ICT and CBT groups showed significant reduction of pain, increase in the quality of life, and greater satisfaction with the treatment in comparison with isolated rehabilitation. Differences in pain, disability, and quality of life were not clinically relevant between the CBT groups with and without the support of the ICTs.

Conclusions. CBT leads to clinical improvement in patients with chronic low back pain, although the effect was modest. Contrarily to what was expected, internet and mobile support does not increase the effectiveness of the CBT on chronic low back pain, producing an effect that is similar to that of face-to-face sessions. Registry ClinicalTrials.org NCT01802671 Funded by the Health Research Fund (FIS). National Institute of Health Carlos III, Ministry of Economy and Competitiveness.

Disclosures:
SPINE SURGERY IN PATIENTS WITH LONG-TERM ORAL ANTICOAGULATION: A PROPENSITY SCORE MATCHED COHORT STUDY

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Introduction: Patients with long-term oral anticoagulation (OAC) have an increased risk for adverse events perioperatively. It is not known how OAC affects outcome specifically in spine surgery. The aim of the study was to compare patient rated outcome and complication rates between patients with and without OAC.

Methods: A single center retrospective cohort study was performed. Data were collected prospectively within the framework of EUROSPINE’S Spine Tango registry and retrospectively supplemented with information from patient charts and the hospital's administrative database. All patients with long-term OAC who had undergone elective spine surgery between 01/2005 and 06/2015 were included regardless of the specific perioperative anticoagulation management. A propensity score matched group of patients without OAC, who were operated over the same time period, served as controls. Primary outcomes were postoperative bleeding, wound complications and thromboembolic events up to 90 days after the operation. Secondary outcomes included other complications, intraoperative blood loss, length of hospital stay, death and patient rated outcome 3 months after the intervention.

Results: In a direct comparison to the propensity score matched control group (n=332), patients with OAC (n=332) were found to have a 3.4 fold (95% CI 1.3-9.0) higher risk for postoperative bleeding complications, while the risk for wound- and thromboembolic events was comparable between groups (Table 1). The higher bleeding risk was mainly driven by a higher incidence of extraspinal hematomas (3.3% vs. 0.6%, p=0.001), whereas the rate of epidural hematomas and hematoma evacuations was similar between patients with and without OAC (1.5% vs. 1.2% and 1.8% vs. 1.2% respectively, p=ns). Risk factors for adverse events among patients with OAC were mechanical heart valves, posterior neck surgery, intraoperative blood loss >1000ml, increasing age, female sex, BMI >30 and, according to a subgroup analysis of patients with available laboratory values (n=156), elevated 1- and 2-day postoperative PTT (Partial Thromboplastin Time) levels. Despite the increased incidence of bleeding complications, patient rated outcome 3 months after the surgery was comparable between the two groups, with substantial improvement being reported over the given time period by the majority of patients in both groups.

Conclusion: Although patients with OAC have a higher risk for complications after spine surgery, these complications can be managed so that the 3-month outcome is not affected. This information can be used when counseling patients undergoing elective spinal surgery for degenerative disorders.
Table 1: Primary Outcomes

<table>
<thead>
<tr>
<th></th>
<th>OAC (n=332)</th>
<th>Control (n=332)</th>
<th>RR</th>
<th>95% CI</th>
<th>p</th>
<th>OR*</th>
<th>95% CI</th>
<th>p</th>
</tr>
</thead>
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<tr>
<td>Any Hematoma</td>
<td>16 (4.8)</td>
<td>6 (1.8)</td>
<td>2.67</td>
<td>1.04 – 6.81</td>
<td><strong>0.040</strong></td>
<td>3.36</td>
<td>1.26 – 8.95</td>
<td><strong>0.015</strong></td>
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<tr>
<td>Epidural Hematoma</td>
<td>5 (1.5)</td>
<td>4 (1.2)</td>
<td>1.25</td>
<td>0.42 – 4.66</td>
<td>0.752</td>
<td>1.66</td>
<td>0.31 – 8.98</td>
<td>0.557</td>
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<tr>
<td>Other Hematoma</td>
<td>11 (3.3)</td>
<td>2 (0.6)</td>
<td>5.50</td>
<td>1.22 – 24.81</td>
<td><strong>0.026</strong></td>
<td>6.35</td>
<td>2.12 – 19.00</td>
<td><strong>0.001</strong></td>
</tr>
<tr>
<td>Hematoma Evacuation</td>
<td>6 (1.8)</td>
<td>4 (1.2)</td>
<td>1.50</td>
<td>0.42 – 5.32</td>
<td>0.541</td>
<td>1.46</td>
<td>0.41 – 5.18</td>
<td>0.559</td>
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<tr>
<td>Any Wound Complication</td>
<td>20 (6.0)</td>
<td>15 (4.5)</td>
<td>1.33</td>
<td>0.70 – 2.55</td>
<td>0.393</td>
<td>1.49</td>
<td>0.68 – 3.25</td>
<td>0.321</td>
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<tr>
<td>Major Wound Complication</td>
<td>12 (3.6)</td>
<td>6 (1.8)</td>
<td>2.00</td>
<td>0.75 – 5.33</td>
<td>0.166</td>
<td>1.79</td>
<td>0.61 – 5.27</td>
<td>0.293</td>
</tr>
<tr>
<td>Minor Wound Complication</td>
<td>8 (2.4)</td>
<td>9 (2.7)</td>
<td>0.89</td>
<td>0.36 – 2.17</td>
<td>0.807</td>
<td>1.17</td>
<td>0.40 – 3.47</td>
<td>0.775</td>
</tr>
<tr>
<td>TEE</td>
<td>2 (0.6)</td>
<td>2 (0.6)</td>
<td>1.00</td>
<td>0.14 – 7.10</td>
<td>1.000</td>
<td>1.00</td>
<td>0.14 – 7.18</td>
<td>1.000</td>
</tr>
</tbody>
</table>

*adjusted for antiplatelet use
Values are presented as n (%)

Disclosures: