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Evaluating pedicle screw primary stability with an instrumented hammer

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1. Introduction

Spinal instrumentation is a cornerstone in modern spinal disorders treatment, offering immediate structural support. A common approach consists in securing metallic rods to pedicle screws (PS) inserted within the vertebrae. The long-term success of this approach depends on the biomechanical anchoring of the PS within bone tissues, known as its primary stability (Gao et al., 2019). Factors such as bone preparation, patient characteristics and screw design influence PS primary stability. When primary stability is insufficient, micromotion at the bone-implant interface can occur, increasing the risk of implant loosening. Despite its importance, current intraoperative assessments rely on the surgeon's proprioception, leaving room for errors. However, when the destructive nature of the assessment method is not a concern, mechanical testing like axial pull-out can be implemented (ASTM F543–17). This study aims to determine whether the impact-based analysis method (IBAM) can be used to evaluate PS primary stability.

2. Methods

2.1 Full Factorial Design

A central composite design (Cano et al., 2012) was used to compare two quantitative methods assessing PS primary stability: IBAM and pull-out testing. The present design of experiment was structured around three factors — bone density ([10-15] PCF), screw length ([20-35] mm), and pilot hole diameter ([60-80] % PS Ø) — selected

for their well-established influence on PS primary stability (Carmouche et al. 2005). These factors defined a cubical space, with vertices representing extreme high/low factor combinations. To analyze the sensitivity of both methods to PS stability, each response variable was modeled as a first-degree interaction model and factors effects were evaluated (Cano et al., 2012).

2.2 Impact-Based Analysis Method (IBAM)

IBAM was conducted for each factor combination by applying 20 low-amplitude axial impacts with an instrumented hammer on a screwdriver sleeve engaged with the PS inserted inside an artificial bone sample (see Fig. 1). The response variable, Δt , was extracted using a signal processing technique derived from a previous work of our group (Tijou et al. 2018). The temporal indicator Δt represents the averaged time difference between the two local maxima of the force signals $s_i(t)$ recorded for each impact $\#i$ (see Eq. 1).

$$\Delta t = \frac{1}{20} \sum_{i=1}^{20} (t_{i,2} - t_{i,1}) \quad (1)$$

2.3 Pull-Out Testing

Following the IBAM, a quasi-static pull-out test was conducted at 2 mm/min using a uniaxial tensile testing machine on each experimental setup. The maximum force required to extract the PS from the artificial bone sample, defined as the pull-out force F , was used as the response variable.

Results and discussion

The observed ranges for the response variables were, for the temporal indicator $\Delta t = [598-1278] \mu s$, and the pull-out force $F = [200-1003] N$. Table 1 ranks the effects of the factors and their interactions based on their influence on Δt and F . The main effects of the factors dominate, with bone density (ρ) and screw length (L) accounting for about 40% and 25% of the response variables variation, respectively. While the pull-out force F is affected by all pairwise interactions, IBAM does not capture the interaction between screw length and pilot hole diameter (D). However, L*D effect on the pull-out force is at least twice as small as the main effects of the factors. Hence, IBAM provides an estimation of the PS primary stability comparable to pull-out testing. Moreover, the effects on the temporal indicator Δt and the pull-out force F follow opposite trends: while F increases with greater rigidity in the experimental setup, Δt decreases under the same conditions (as shown by Tijou et al. 2018). The first-degree interaction models, developed based on these effects, achieve high accuracy, with adjusted R^2 values of 0.89 for IBAM testing and 0.98 for pull-out testing. However, despite their precision, these models fail to capture the full complexity of PS primary stability in a clinically relevant setting and therefore cannot be used for predictive purposes.

Table 1. Factor and interaction effects on the response variables. † means $p < 0.05$

Effect	Temporal indicator $\Delta t [\mu s]$	Pull-Out force $F [N]$
ρ	-139.7 †	195.6 †
L	-86.4 †	148.5 †
D	56.8 †	-84.0 †
$\rho * L$	31.8 †	78.5 †
$\rho * D$	-30.7 †	-44.0 †
$D * L$	-24.6	21.0 †
$\rho * L * D$	4.1	-9.4

Credit: JG.

3. Conclusions

This study illustrated how an instrumented hammer could provide an assessment of pedicular screws' primary stability. The temporal indicator Δt , recorded with the instrumented hammer, decreases with the

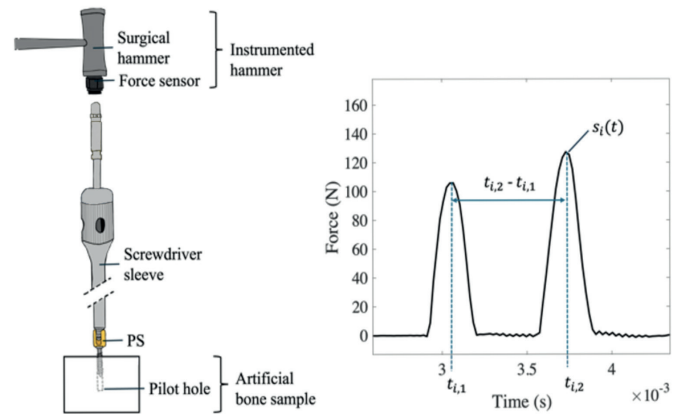


Figure 1. Experimental setup for each factor combination (left). Example of a force signal $s_i(t)$ for an impact #i recorded with the instrumented hammer (right).

Credit: JG.

overall rigidity of the impacted system which affects the screw biomechanical anchorage. These results demonstrated consistency with prior findings of our group, reinforcing the hypothesis that IBAM could serve as a reliable and objective technique for intraoperative assessment of implant primary stability. Notably, integrating this method into clinical practice could help surgeons improve the success rates of spinal surgeries, enhance patient outcomes, and reduce the risk of complications. However, the potential influence of the impact force on the PS primary stability was not specifically investigated in this study and should be considered as a limitation to this work.

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Conflict of Interest Statement

None.

Contributor Roles

JG: Conceptualization, Methodology, Data curation and analysis, Writing original draft; EW & YP &

GR & GH: Funding acquisition, Conceptualization, Methodology, Writing-review & editing. MD & AD & CHFL: Conceptualization.

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