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"Safety Sling" Against Pedicle Screw Loosening in Lumbar Spinal Fusion

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Background Context: Spinal fusion with pedicle screw fixation is widely used for stabilization, yet its long-term success is often limited by mechanical complications such as screw loosening and pull-out.

Purpose: Pedicle screw loosening and pull-out are major complications of instrumented spinal fusions, biomechanically caused mainly by excessive flexion moments. A "safety sling" (a textile band looped around the spinous processes) could prevent excessive loading on pedicle screws during flexion. The goal of this study is to examine the biomechanical effectiveness of the safety sling concept on construct strength during simulated lumbar flexion in human spinal segments.

Study Design: Biomechanical cadaveric study.

Materials and Methods: Twenty-four human lumbar segments were biomechanically tested under simulated flexion loads using an established biomechanical setup. Four groups (n = 6 each) were compared: (1) pedicle screw instrumentation alone, (2) instrumentation with a dorsally attached safety sling (consisting of a 10 mm textile band around the segmental spinal processes), (3) instrumentation with midline decompression, and (4) instrumentation with midline decompression plus safety sling. All specimens underwent increasing flexion loads until failure to assess the safety sling's effect on construct resilience.

Results: The safety sling demonstrated a significant improvement in flexion moment resilience: Median failure load increased by factor 2.06 with an intact midline (60.6 Nm (47.2; 85.2) with safety sling *versus* 29.4 Nm (21.4; 32.9) without, $P = 0.026$) and by factor 2.60 in decompressed segments (75.7 Nm (53.4; 76.5) with safety sling *versus* 29.1 Nm (25.6; 43.1) without, $P = 0.026$).

Conclusion: The concept of a "safety sling" (looping a band around the segment's spinal processes) is a highly effective supplementary measure for enhancing primary construct strength during spinal flexion in pedicle screw constructions. By reducing the load on the screw-bone interface, this approach represents a promising strategy to reduce flexion-induced loading at the screw-bone interface.

Clinical Significance: Incorporating a safety sling into pedicle screw constructs may reduce flexion-induced mechanical loading of pedicle screw constructs in the early postoperative period.

Level of Evidence: According to the Oxford Centre for Evidence-Based Medicine 2011 Levels of Evidence, this biomechanical cadaveric study provides Level 5 evidence.

Keywords: lumbar spine, spinal stabilization, fusion, pedicle screws, screw loosening, pull-out strength, flexion biomechanics, spinous process, construct stability, cadaveric study

Introduction

Spinal fusion surgery with posterior pedicle screw instrumentation is a gold standard for treating degenerative spinal diseases, providing rapid pain relief and reliable short-term outcomes.[1,2] However, long-term complications, such as pedicle screw loosening, leading to persistent pain, neurological impairment, and reduced functional outcomes,[3–5] are frequent and require revision surgery in 2% to 12% of the cases,[6] especially in patients with poor bone quality due to osteoporosis[7,8] or exposure to excessive flexion movements.[9] IN osteoporotic patients, loosening rates may reach 62.8%,[10] significantly impacting surgical success.

Traditional strategies to mitigate screw loosening has involved the use of larger or longer pedicle screws,[11] dual-threaded screws,[12] cement augmentation,[13] or additional implants.[14] Modifications on screw design and trajectories can enhance screw fixation strength by 13% to27%,[15] while cement augmentation may increase strength by 25% to as much as 348%,[15–18] although the highest values derive from simplified pullout tests and advanced techniques as expandable screws.[19] Despite

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its potential to enhance fixation, cement augmentation carries significant risks, including cement leakage, pulmonary embolism, and adjacent vertebral fractures—particularly in osteoporotic patients[13]—highlighting the need for alternative, biomechanically stable, and safer alternatives.

Screw loosening primarily occurs in association with spinal flexion movements[20–25] at the screw-bone interface. Under normal conditions, ventral body weight is balanced by the dorsal musculature, resulting in predominantly axial compression forces acting on the intervertebral disc, which functions as a hypomochlion. These axial forces exert minimal stress on the screw-rod construct; only 10% of the force is transferred to the posterior instrumentation, while the vertebral body and intervertebral disc absorb about 90%.[26] Thus, axial loading alone is unlikely to cause screw loosening, even in osteoporotic bone.

In contrast, during high flexion movements, when dorsal musculature fails to adequately counteract the resulting torques, substantial bending moments are transmitted to the instrumentation. This is especially problematic in rapid movements—commonly referred to as “surprise movements”—during which electromyographic studies have shown a muscle reaction delay of ∼0.75 seconds,[27] leaving passive structures to absorb bending moments. Such loading scenarios can occur during everyday activities, such as picking up objects or rising from a seated position.

Dorsal load-bearing elements—including the interspinous and supraspinous ligaments (ISL/SSL) and the spinous processes—play a critical role during flexion[25]and serve to offload the intervertebral disc during high-torque events in the intact spine (Fig. 1). However, in the context of spinal instrumentation, where the dorsal load path is interrupted, this protective mechanism is compromised. Consequently, the resulting forces act with a considerable lever arm on the pedicle screws, creating a “crowbar effect” that increases the risk of screw loosening or pullout (Fig. 2).

To mitigate this risk, a mechanical solution may be a dorsal tension band, or safety sling, applied around the spinous processes across the instrumented segment, serving to absorb bending moments and prevent their transmission to the screw-rod system and thereby offering protection against screw pullout (Fig. 2). This concept is based on the U-shape and the elasticity of the screw-bone interface, permitting sufficient distention of the spinous processes under flexion moments and transferring load to the posterior structures. The concept of a dorsal tension band itself is derived from the concept of Vertebropexy[28–34] a stand-alone application for spinal stabilization as an alternative to spinal instrumentation.

This study aimed to investigate the biomechanical effect of a safety sling during isolated flexion in a cadaveric human model, analyzing two extreme scenarios: (i) instrumentation without decompression, representing intact bone, and (ii) instrumentation with midline decompression, representing maximal bone weakening.

The safety sling is designed as a posterior tension band augmentation and can therefore exert a mechanical effect primarily under flexion loading, when tensile forces develop across the posterior column. In other loading modes, the safety sling is not anticipated to meaningfully influence construct mechanics; consequently, biomechanical testing was intentionally limited to flexion.

Importantly, the present focuses on comparing the primary mechanical stability of the two implant configurations under identical experimental conditions. As the safety sling is intended to augment construct stability during the early postoperative phase, its biomechanical effect is independent of biological processes such as fusion mass formation or bone remodeling. Accordingly, the absence of fusion mass simulation does not affect the comparative assessment of primary stability between the investigated implant constructs.

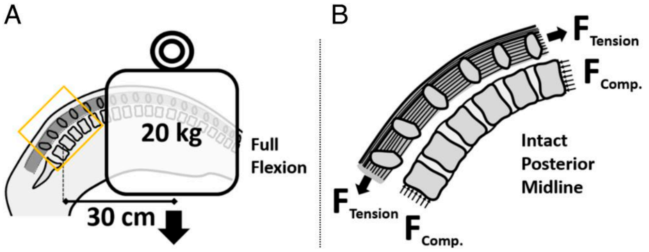

Figure 1. Spinal flexion in an intact spine with the midline remaining intact. (A) A human torso in full flexion with 20 kg simulating upper body weight at 30 cm distance from the lumbar spine (center of rotation) under maximum mechanical stress. (B) Compressive forces (F Comp.) on the anterior side and tensile forces (F Tension) on the posterior side of the spinal column.

Material and Methods

Dissection and preparation

The study received approval from the responsible state investigation review board. Fourteen frozen human cadaveric spines (Science Care, Phoenix, AZ; eight male, six female; aged from 38 to 88 yr, BMI between 17.7 and 44 kg/m^2) were thawed and divided into segments of two vertebrae. CT scans (SOMATOM Edge Plus, Siemens Healthcare GmbH, Erlangen, Germany) were performed to rule out bony defects and to estimate the average trabecular bone mineral density (BMD), calibrated with a bone density calibration phantom (QRM GmbH, Möhrendorf, Germany). The average BMD of the vertebral body trabecular bone was determined based on three axial cuts.[35] The reported density for each segment resulted from the average of the two corresponding vertebrae.

Next, the specimens were carefully dissected and pedicle screws (Medacta Unconstrained Screw Technology–cannulated polyaxial reduction pedicle screws ØxL [mm]; 6×45, 50, 55) were inserted by an orthopedic surgeon. Then, using custom 3D-printed adapters, the segments were mounted on a uniaxial testing machine (Zwick/Roell, Zwick GmbH, Ulm, Germany) with a dedicated setup simulating spinal flexion.

Part I–Spinal Instrumentation With Midline Preservation

Eight lumbar spines were divided into three segments each (T12–L1, L2–L3, L4–L5; total of 24 segments). Twelve segments were allocated for preliminary calibration of the experimental setup, refining the protocol, and ensuring repeatability of measurements. The remaining 12 segments were further divided into two groups: a control group (six segments) and a test group with the safety sling as an add-on (six segments). All segments were instrumented with pedicle screws and rods. The midline structure remained intact. The safety sling was simulated with a 10 mm wide textile tape (Jakob Müller Group), a recently developed material manufactured from polyester, used for soft tissue approximation and securing correct load transfer with osteoconductive properties such as tissue ingrowth and

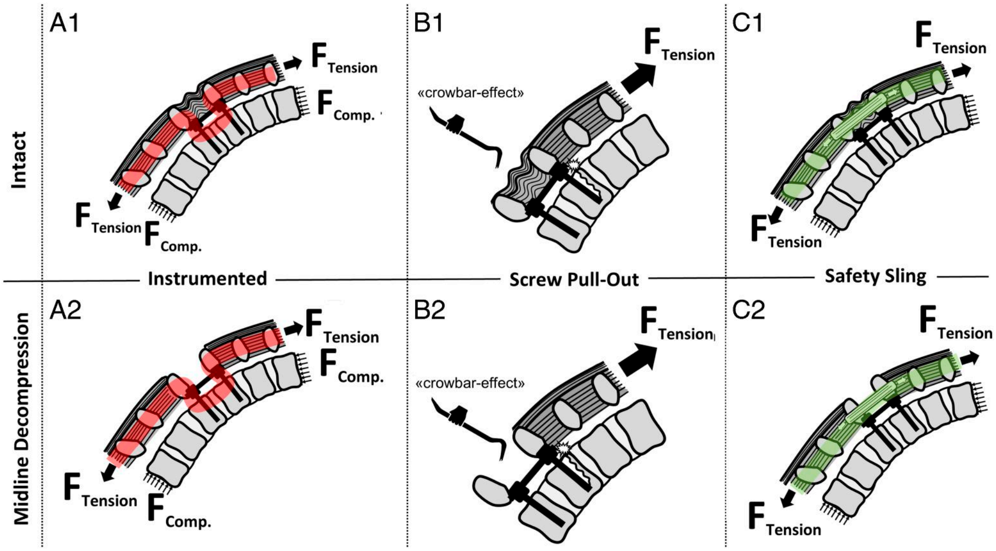

Figure 2. Biomechanical effect of the safety sling during flexion. (A1–A2) Spine with disrupted posterior tension band before and after midline decompression, showing force distribution and stress. (B1–B2) "Crowbar effect" increases screw pull-out risk. (C1–C2) Safety sling reduces stress on screws by redirecting tensile forces through the sling.

remodeling.[36] Compared with other materials used in pilot tests, the textile polytape offers a broader contact surface on the spinous process, enhancing stability and load distribution. The safety sling was attached around the spinous processes of the cranial and caudal vertebra and tensioned using a screw-clamping mechanism until a subtle torque increase indicated full engagement, ensuring a slack-free system. The safety sling is illustrated in Figure 3.

Part II–Spinal Instrumentation With Midline Decompression

In the second part, six lumbar spines were, as described in the first part of the experiment, divided into 12 segments of two vertebrae each (T12–L1, L1–L2, L2–L3, L3–4, or L4–L5) and further divided into a control group and a test group with the safety sling. All segments were instrumented with pedicle screws and rods after undergoing midline decompression.

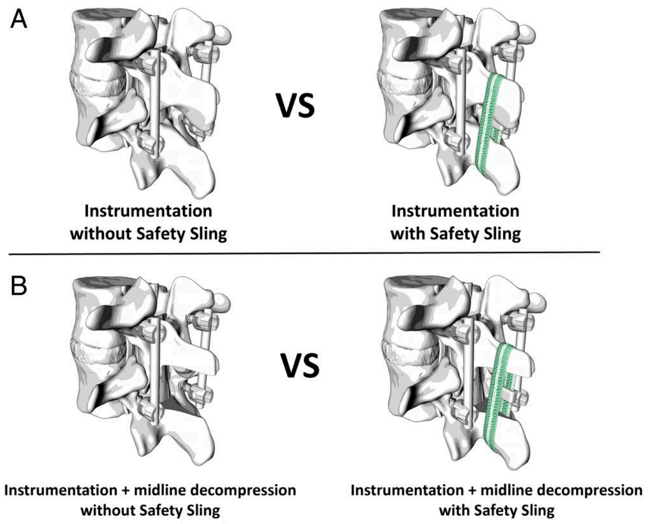

Figure 3. Illustration showing the safety sling configuration on the right side—with (B) and without (A) midline decompression—compared with a spinal segment without the safety sling on the left side—with only instrumentation (A) and with instrumentation and midline decompression (B).

Midline decompression involved complete resection of the interspinous and supraspinous ligaments and the ligamentum flavum, along with bony decompression of the central portions of the adjacent spinous processes, laminae, and medial facet joints. This approach achieved adequate decompression of the spinal canal and both lateral recesses. Decompression was considered sufficient when unobstructed access to the entire disc space in the cranio-caudal direction and to the lateral aspect of each recess (defined by the medial border of the caudal pedicles) was obtained.

The safety sling was attached over the decompressed segments from the test group as a means of reconstructing the posterior tension band, as seen in Figure 3.

Biomechanic Testing

The spinal segments were mounted on a uniaxial testing machine and subjected to load-controlled stepwise flexion until failure.

This used setup, developed over the years, was based on initial experiments on human torsos reduced to a minimal specimen model with inverse load configuration. This used setup, established in previous studies,[33] accurately simulates flexion loading while accounting for posterior tension forces and preserving physiological force paths. By virtually splitting instrumented segments into cranial and caudal parts and applying inverse calculations, the setup enables targeted assessment of the transition region between instrumented and native spinal segments (Fig. 4), with proven accuracy for interspinous fixations.

Data Analysis

Applied forces were adjusted for flexion angle by multiplying the measured force by the cosine of half the flexion angle. Torque was calculated as the product of adjusted force and lever arm

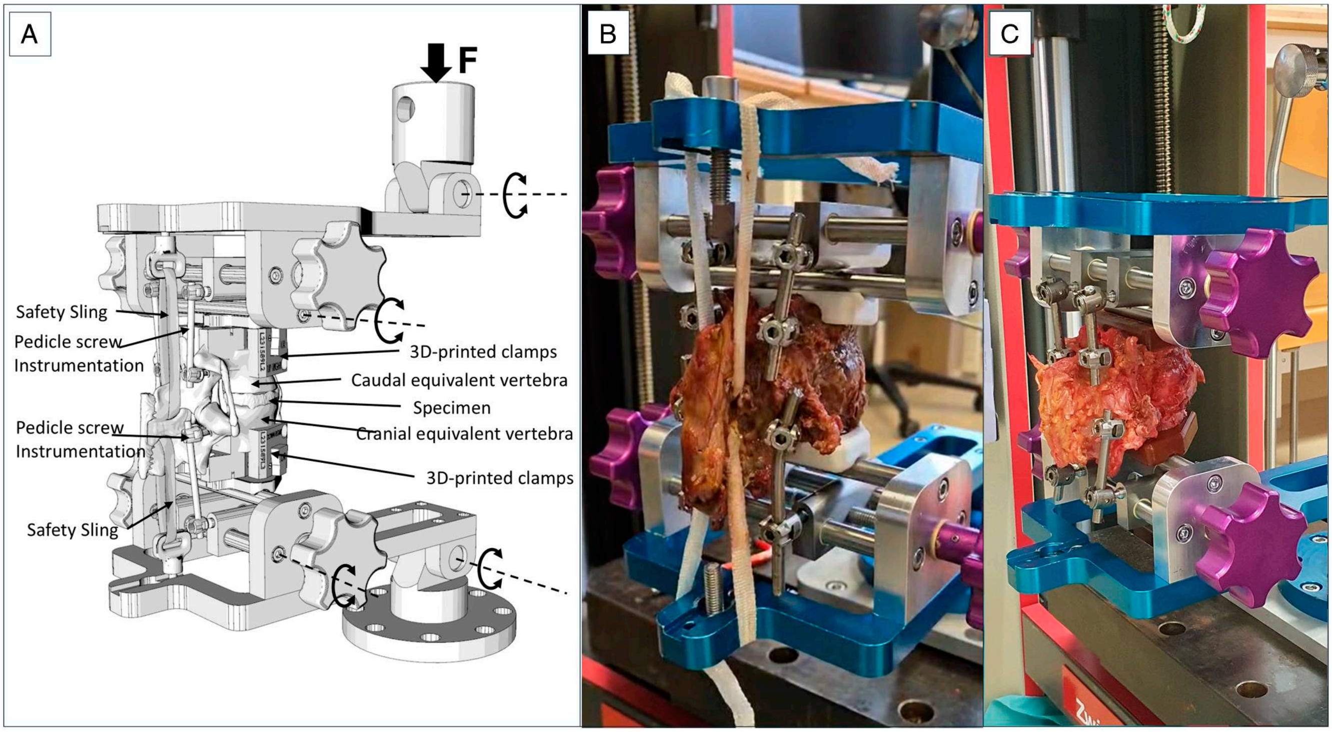

Figure 4. Biomechanical setup for spine flexion of fused segments. (A-B) illustration and picture of a spinal segment mounted on the Spine Flexer with 3D printed clamps and application of a safety sling, (C) picture of a spinal segment of the control group with instrumentation only and no safety sling.

(18.5 cm). The primary outcome was the effect of the safety sling on ultimate tensile strength.

Data analysis was performed in MATLAB (MATLAB 2020b, MathWorks, MA). BMD distributions in the different groups were compared using the Kruskal-Wallis test. Wilcoxon rank sum tests assessed the effect of the safety sling on maximal failure force for instrumentation-only (Part I) and instrumentation plus midline decompression (Part II). The significance threshold (α) was set at 0.05, and the *P*-value was corrected for multiple comparisons according to Bonferroni. Results are reported as "median (25th percentile, 75th percentile)".

Linear regression for each group, accompanied by their respective Spearman correlation coefficient and associated *P*-value, was used to assess the correlation between failure torque and BMD values.

Results

Failure Torques

The addition of the safety sling significantly increased failure torque in both configurations (Figs. 5–6 and Table 1). In midline-intact segments, failure torques rose from 29.4 Nm to 60.6 Nm (+106%, $P = 0.026$), while after midline-decompression, the addition of the safety sling improved failure torques from 29.1 Nm to 75.7 Nm (+160%, $P = 0.026$).

Failure Patterns

While cranial or caudal screw pullout was the only observed failure mode in the control groups, additional failure patterns in the safety sling-augmented groups were observed, such as spinous process fracture and posterior tension band failure. In the midline intact group with a safety sling, two segments failed due to spinous process fracture and four due to screw pullout. In the midline decompressed group with a safety sling, two segments failed due to screw pullout, two due to spinous process fracture, and two due to posterior tension band disruption.

Confounding Parameters (BMD, Spinal Segments, and Screw Length)

A Kruskal-Wallis test suggests that there was no significant difference in BMD distribution among the four considered groups (*H*-value = 2.39, $P = 0.496$). With a safety sling, the BMD was 89 mmHA/cm^3 [87, 128] for midline-intact segments and 118 mmHA/cm^3 [111, 122] for midline decompressed segments, resulting in a combined BMD of 114 mmHA/cm^3 [88, 125]. Without a safety sling, the BMD was 96 mmHA/cm^3 [71, 108] for midline-intact segments and 107 mmHA/cm^3 [86, 123] for midline decompressed segments, resulting in a combined BMD of 104 mmHA/cm^3 [83, 116].

A weak, nonsignificant positive correlation between BMD and failure torque was revealed ($\rho = 0.230$, $P > 0.05$). This absence of significant association was consistent across all test groups, suggesting that BMD did not disproportionately influence torque outcomes.

The tested spinal segments (T12–L1, L1–L2, L2–L3, L3–L4, and L4–L5) were evenly distributed across the four groups, ensuring a representative sampling of upper, mid, and lower lumbar levels in each. Segment distribution per group was as follows: in the nonaugmented, midline-intact group, T12–L1 was used twice, L2–L3 once, and L4–L5 three times. In the augmented, midline-intact group, T12–L1, L2–L3, and L4–L5 were each used twice. In the nonaugmented, midline-

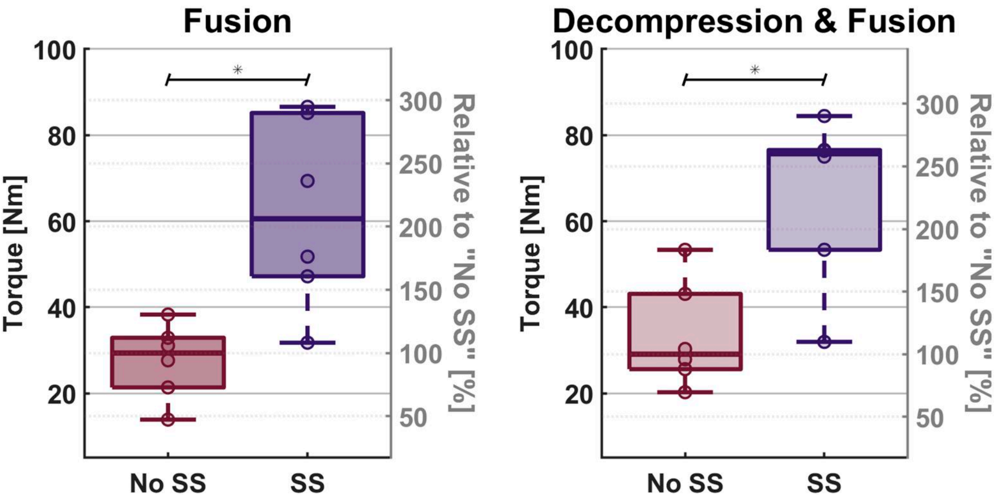

Figure 5. Effect of safety sling on maximum torque. Box plots show torque (Nm) to induce failure in fusion-only and decompression and fusion, with and without sling. Sling significantly increases torque; the secondary *y*-axis shows values relative to the control. Individual data points are overlaid.

decompressed group, T12–L1 was used twice, L1–L2 and L3–L4 once each, and L4–L5 twice. In the augmented decompression group, T12–L1 was used once, L1–L2 and L3–L4 twice each, and L4–L5 once.

Pedicle screws with a diameter of 6.0 mm were chosen in all cases to reduce dependency on screw thickness. Standard screw length of 50 mm was used in the majority of cases (n = 48); in five specimens (one in each nonaugmented group, one in the augmented, midline-decompressed group and two in the augmented, midline-intact group), a 45 mm screw was selected due to anatomic constraints, in order to ensure optimal fit and avoid cortical breach.

Discussion

This study evaluates the utility of a posterior safety sling as an add-on in lumbar pedicle screw instrumentation to increase biomechanical resilience against screw pull-out in flexion movements, particularly in challenging cases with midline decompression. The primary findings are: First, a posteriorly applied safety sling significantly increased flexion failure torques by more than factor two, in both midline intact and decompressed spinal segments. Second, altered failure patterns in posteriorly augmented spinal segments suggest redistribution of mechanical stress.

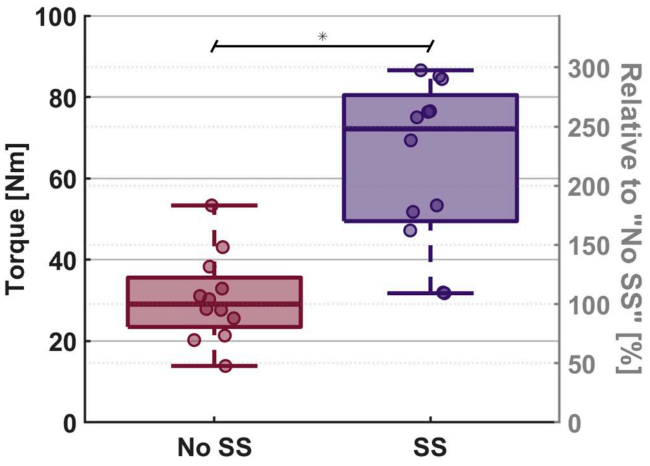

Figure 6. Pooled failure torque of control ("No SS") *versus* safety sling–augmented ("SS") segments. Box plots show torque (Nm) and percent relative to the control average (100%). Sling significantly (*) increases failure torque ($P < 0.05$); individual data points shown.

Enhanced Instrumentation Resilience Through Posterior Sling Augmentation

The sling significantly improved instrumentation resilience to flexion torques, outperforming controls regardless of decompression. The safety sling increased the median failure torque by a factor of 2.06 compared with the control group without decompression, and by a factor of 2.60 following decompression. These findings emphasize the safety sling's ability to redistribute mechanical stress from the pedicle screws to the posterior tension band, enhancing the overall stability of the construct. While other studies describing screw augmentation techniques, such as dual threaded pedicle screws, reported an improvement in pullout force by 19%,[12] the application of a dorsal safety sling technique achieved considerably greater reinforcement without depending on bone quality.

In the midline-intact instrumentation model, slackening of the supraspinous ligament is hypothesized to reduce posterior tension band support (Fig. 2 A2)—a deficit compensated by the safety sling. Similarly, in the midline-decompressed instrumentation model—where the physiological force transmission across the posterior column is interrupted—the sling demonstrated an ability to bridge the gap, maintaining posterior tension and reducing screw stress on the instrumentation.

The relevance of posterior load redistribution becomes especially clear when considering the behavior of the spine under rapid, unexpected loading conditions. A study by Wade *et al.*[27] showed that "surprise" loading—defined as a compression rate approximating the fastest muscular response time of the spinal column—led predominantly to annular-endplate junction ruptures in healthy ovine spines. These findings emphasize that even in anatomically intact spines, high-rate flexion loading can

Table 1

The Median and Quartiles of the Failure Torques for Each Group are Reported

	Failure Torque [Nm] (Median, 25th, 75th Percentile)	Increase With Safety Sling [%]	*P*
Instrumentation only, midline intact	29.4 (21.4, 32.9)		
Instrumentation with a safety sling, midline intact	60.6 (47.2, 85.2)	+106	0.026
Instrumentation, midline decompression	29.1 (25.6, 43.1)		
Instrumentation with a safety sling, midline decompression	75.7 (53.4, 76.5)	+160	0.026

Comparison of failure torque among instrumentation configurations with and without a safety sling.The relative increase in failure torque and the *P*-values are provided for both configurations (midline intact and midline-decompression).

overwhelm structural interfaces. In the context of spinal instrumentation, particularly with midline decompression, where the interspinous and supraspinous ligaments are disrupted and thereby the posterior tension band function is completely eliminated, this effect is amplified. Sudden trunk movement or unexpected loading can create a crowbar-like mechanism that translates flexion into focal stress at the screw-bone interface, especially when the natural posterior tension band is absent or disrupted. In such scenarios, the safety sling may play a critical protective role by compensating for the lost tension band and absorbing excess load.

Regarding potential effects on adjacent posterior ligamentous structures, the wrapping of the safety sling over the spinous processes may result in minimal damage of the interspinous ligament (ISL)[37] of adjacent segments. However, the ISL exhibits a predominantly oblique fiber orientation, such that only a small proportion of its load-bearing fibers are directly affected by the sling. Consequently, any local fiber involvement would be confined to a minor subset of the ligament and is unlikely to compromise posterior tension band function at adjacent levels under physiological conditions.

Altered Failure Patterns in Posteriorly Augmented Spinal Segments

The second important finding of this study is the shift in failure modes observed with posterior sling augmentation. While unaugmented segments consistently failed through pedicle screw pullout, sling-augmented segments demonstrated a broader spectrum of failure patterns, including spinous process fractures. This shift suggests a redistribution of flexion-induced loads across the posterior column and spreading of stress to other anatomic structures, protecting the screw-bone interface and contributing to higher failure loads.

Conceptually, the safety sling acts in parallel to the pedicle screw-rod system during flexion and reduces the load transmitted to the screw-bone interface in this loading condition. Preliminary force-sharing analyses from ongoing experimental work suggest that the safety sling can absorb a relevant proportion of the applied flexion load from the beginning of loading, with a minimum contribution of approximately one-third of the total tensile force.[38]

Clinical Importance and Future Directions

The high prevalence of screw loosening, particularly in osteoporotic patients underscores the need for adjunctive solutions providing effective stabilization without increasing procedural complexity or risk. Traditional methods, such as cement augmentation, carry significant drawbacks like the risk for cement leakage or embolism and the potential for adjacent vertebral fractures.[13] In contrast, the safety sling represents a mechanically simple posterior augmentation that enhances construct resistance to flexion without relying on cementation or bone quality–dependent anchorage.

Furthermore, by bridging decompressed segments, the safety sling's ability to diminish the destabilizing effects of midline decompression expands its clinical applicability.

Traditionally, patients are restricted from flexion after fusion surgery until bone remodeling is confirmed radiographically. By more than doubling primary flexion stability in a static model, a safety sling could allow flexion soon after—or even immediately following—surgery, potentially enhancing mobility and recovery. Whether this translates into altered postoperative rehabilitation strategies or improved clinical outcomes requires validation in cyclic biomechanical testing and prospective clinical studies. Future investigations should therefore focus on fatigue loading, adjacent segment effects, and in vivo performance to more comprehensively define the role of the safety sling in clinical practice.

Limitations

The presented study has several limitations. The experimental setup simplifies complex in vivo conditions, and even with great care of physiological simulation, certain anatomic and biomechanical factors could not be fully replicated. Furthermore, this study focuses solely on flexion loads and not on other loading directions such as extension, rotation, lateral bending, or axial compression. This flexion-only loading protocol was selected because the safety sling functions as a posterior tension band and is expected to influence construct mechanics exclusively under flexion loading. The findings of the study are based on cadaveric specimens that do not entirely reflect the variability of living tissue responses. Only the maximum failure load was assessed; cyclic load capacity and fatigue behavior were not directly tested. Nonetheless, we can assume that constructs with higher load-bearing capacity also exhibit greater fatigue strength, as suggested by previous biomechanical correlations. Differences in BMD are unlikely to introduce bias or confounding effects in the interpretation of torque measurements among the groups, since there was no significant association across the test groups and thus likely no major influence on the torque outcomes. Nevertheless, further investigations must be conducted on a larger group of osteoporotic specimens to confirm effectiveness in this vulnerable subgroup of patients. Finally, the sample size limits generalizability.

Conclusion

The addition of a safety sling more than doubled the flexion failure threshold of monosegmental pedicle screw constructs ($P = 0.026$) in both midline-intact and decompressed configurations.

By redistributing flexion-induced loads away from the screw–bone interface toward posterior structures, the safety sling increases the mechanical resilience of the fixation construct under flexion loading. Whether these biomechanical effects translate into reduced screw loosening or improved clinical outcomes requires further investigation and detailed clinical data.

Ethical approval

The state ethical committee Zürich has given approval for performing this study (Basec No. KEK-ZH-Nr. 2023-00040).

Conflicts of Interest

The last author (M.F.) reports being a consultant for 25 Segments (Balgrist University Hospital Startup), Arthrex and Medacta. M.F. and J.W. report being Co-founders of Moving Spine AG (Balgrist University Hospital Startup). M.F. serves as president of the board of Moving Spine AG. J.W. and F.C. are part-time employees at Moving Spine AG (Balgrist University Hospital Startup). The remaining authors report no conflicts of interest.

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