



Strain in Posterior Instrumentation Resulted by Different Combinations of Posterior and Anterior Devices for Long Spine Fusion Constructs

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Received 22 February 2016; revised 18 July 2016; accepted 19 September 2016

Abstract

Study Design: Clinically related experimental study.

Objective: Evaluation of strain in posterior low lumbar and spinopelvic instrumentation for multilevel fusion resulting from the impact of such mechanical factors as physiologic motion, different combinations of posterior and anterior instrumentation, and different techniques of interbody device implantation.

Summary of Background Data: Currently different combinations of posterior and anterior instrumentation as well as surgical techniques are used for multilevel lumbar fusion. Their impact on risk of device failure has not been well studied. Strain is a well-known predictor of metal fatigue and breakage measurable in experimental conditions.

Methods: Twelve human lumbar spine cadaveric specimens were tested. Following surgical methods of lumbar pedicle screw fixation (L2–S1) with and without spinopelvic fixation by iliac bolt (SFIB) were experimentally modeled: posterior (PLF); transforaminal (TLIF); and a combination of posterior and anterior interbody instrumentation (ALIF+PLF) with and without anterior supplemental fixation by anterior plate or diverging screws through an integrated plate. Strain was defined at the S1 screws, L5–S1 segment of posterior rods, and iliac bolt connectors; measurement was performed during flexion, extension, and axial rotation in physiological range of motion and applied force.

Results: The highest strain was observed in the S1 screws and iliac bolt connectors specifically during rotation. The S1 screw strain was lower in ALIF+PLF during sagittal motion but not rotation. Supplemental anterior fixation in ALIF+PLF diminished the S1 strain during extension. Strain in the posterior rods was higher after TLIF and PLF and was increased by SFIB; this strain was lowest after ALIF+PLF, as supplemental anterior fixation diminished the strain during extension, in particular, cages with anterior screws more than anterior plate. Strain in the iliac bolt connectors was mainly determined by direction of motion.

Author disclosures: CJK (reports grants from DePuy/Synthes Inc, during the conduct of the study; grants from Medtronic Sofamor-Danek, grants from Aesculap, grants from SI Bone, grants from Vertiflex, grants and personal fees from Medtronic, grants from Orthofix, grants from Integra Life Sciences Corporation, grants from Pfizer, grants from Spinal Kinetics, grants from MTF, grants from National Institutes of Health, grants from Globus, outside the submitted work); DI (reports grants from DePuy/Synthes Inc, during the conduct of the study); EML (reports grants from DePuy/Synthes Inc, during the conduct of the study; grants from Medtronic, grants from SI Bone, outside the submitted work); AN (reports grants from Synthes, during the conduct of the study); VVP (reports grants from Synthes, during the conduct of the study; grants from Aesculap, grants from Stryker, grants from SI Bone, grants from National Institutes of Health, grants from Medtronic, grants from Musculoskeletal Transplant Foundation, outside the submitted work); CB (reports grants from DePuy/Synthes Inc, during the conduct of the study); TB (reports grants from DePuy/Synthes Inc, during the conduct of the study; grants from Stryker Endoscopy, SMV Scientific, and Acumed outside the

submitted work); CMJC (reports grants from DePuy/Synthes Inc, during the conduct of the study; personal fees from DePuy/Synthes Inc, grants from Medtronic, grants from Aesculap, grants from Medtronic, grants from Vertiflex, grants from AOSpine, outside the submitted work); ELB (reports grants from Synthes, during the conduct of the study; grants from Medtronic, grants from Aesculap, grants from SI Bone, grants from Vertiflex, grants from Medtronic, grants from Synthes, grants from Orthofix, grants from Integra LifeSciences, grants from Anschutz Foundation, grants from OREF, grants from OMeGA, from null, from null, outside the submitted work).

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Research grant funding and instrumentation were provided by DePuy/Synthes.

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Conclusions: Different devices modify strain in low posterior instrumentation, which is higher after transforaminal and posterior techniques, specifically with spinopelvic fixation.

Level of Evidence: N/A.

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Keywords: Iliac fixation; ALIF; Pseudoarthrosis; Thoracolumbar fusion

Introduction

Currently long multilevel posterior instrumented fusion with spinopelvic fixation is widely used for surgical correction of spine deformity [1-6]. However, this treatment is quite expensive, having typical cumulative two-year costs ranging from \$40,000 to \$54,000, not including reoperation [7-9]. Reoperation with device replacement can more than double these expenses [7,10]. The cumulative rate of reoperation reaches 15% to 17% at the four-to five-year follow-up [11]. Around 30% to 40% of the reoperations are caused by device failure, including rod and/or screw fracture [11,12], having significant association with nonunion at the level of failure [13]. Clinical studies have shown that fixation to the sacrum and/or the pelvis is associated with different complications requiring additional treatment, including rod and screw failure [5,6,13,14]. Enhancing of the spinal correction and the construct stability can be reached by combining posterior instrumentation with anterior interbody devices. It improves the construct stiffness and decreases strain in the S1 pedicle screw [15]. Unfortunately, the impact of common, currently used devices on strain in posterior instrumentation has not been studied.

It has been shown in clinical studies that combination of posterior instrumentation with an interbody implant does not guarantee stable correction at long-term follow-up, in particular, corrected lumbar lordosis tends to decrease correlating with the interbody height loss [12,16]. It suggests loss of anterior support, which may increase stress within the rigid posterior instrumentation, and correspondingly increase the risk of failure. This effect can be explained by the fact that vertebral bone density is relatively low, and endplate is quite soft, with a stiffness that is significantly less than the stiffness of implants, causing subsidence [17]. Supplemental anterior fixation can decrease or eliminate this negative effect. In posterior transforaminal approaches, unilateral dissection of facet joint decreases mechanical function of the posterior spinal column [18]. Also, transforaminal fusion requires use of different cages with smaller footprints and absence of stiff fixation. It can decrease anterior support, increasing stress in posterior instrumentation and correspondingly risk of failure.

It was previously shown that strain, which is an index of micro-motion under the applied force, is a good predictor of metal fatigue and correspondingly risk of breakage [19]. This index is measured as a ratio of dislocation to the initial

status, and can be applied to define the impact of different mechanical factors on the risk of device failure in experimental studies. The purpose of the current study is evaluation of strain in the S1 screw, the rod between L5 and S1, and the iliac connectors/rod between the S1 and the iliac screws impacted by physiologic motion with various anterior and posterior fixation techniques.

Materials and Methods

Specimen description and preparation

Twelve cadaveric human lumbar spines with intact pelvis were obtained from Lonetree Medical Donation (Littleton, CO) and stored frozen at -20°C prior to surgical preparation and instrumentation. There were six male and six female donors; mean age was 67 (standard deviation, 10.4) and ranged from 41 to 79 years at death (Table 1). Before testing, the specimens were thawed and muscular tissues were removed, but ligamentous structures were left intact. The pelvises were potted in Smooth-Cast 321 (Smooth-On, Inc., Easton, PA) deep enough to cover the pubic crest but shallow enough to leave the sacrum unfixed and free to move. The proximal spine was also potted at L1 in the same epoxy resin for attachment to the test apparatus. The spines were instrumented as described below (using the current operative technique we employ with our operative cases), and 10 tests with different combination of posterior and anterior devices were performed consequently.

Test 1: for all 12 specimens, posterior instrumentation (PLF) with two 6.0-mm-diameter titanium rods and 6.0-mm-diameter pedicle screws (Pangea Spine System,

Table 1
Tested lumbar specimens.

Specimen ID	Sex	Age (year)	Height (cm)	Weight (kg)	40% of weight (N)
C110106	F	71	165.1	66.738	261.9
C110079	F	69	177.8	90.8	356.3
C101542	F	66	162.56	80.812	317.1
C110110	F	78	165.1	68.1	267.2
C110126	F	79	165.1	149.82	587.9
LMD00090	F	41	172.72	68.1	267.2
C110104	M	75	172.72	81.72	320.7
C110108	M	56	180.34	102.15	400.8
C110128	M	64	182.88	77.18	302.9
C110080	M	67	182.88	136.2	534.4
LMD00033	M	73	165.1	66.738	261.9
LMD00098	M	67	180.34	93.524	367.0

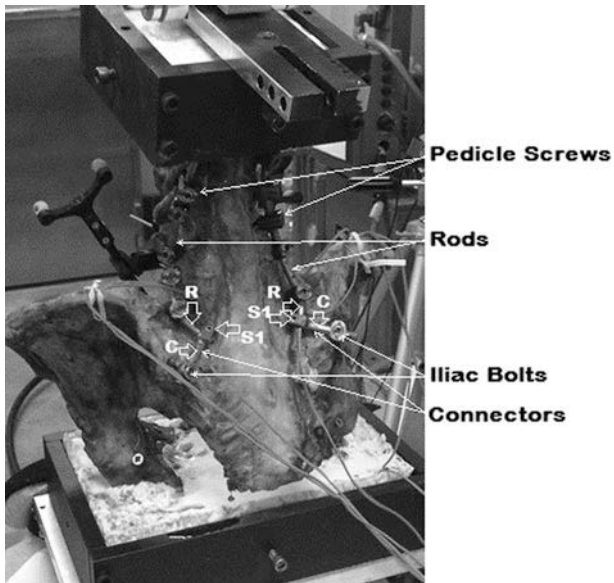


Fig. 1. Posterior instrumentation and strain gage placement. Places where strain was defined by strain gage: L5–S1 rods (R); S1 screw (S1); iliac bolt connector (C).

DePuy/Synthes, Raynham, MA) were placed bilaterally from L2 to S1. Iliac bolts were also placed without the connectors (Fig. 1). Mechanical testing was without the iliac bolts connected at this stage (Table 2). Test 2: iliac bolts were connected to the construct described above (Test 1) in all 12 specimens and the mechanical testing was repeated (Table 2). Test 3: for six specimens, a transforaminal approach was used (TLIF): the posterior rods were removed from both sides, and a unilateral facetectomy (three specimens were done from the right and three from the left) with posterior discectomy was performed at L5–S1. Trial spacers were used to determine the appropriate size of implant based on direct visualization and feel. This was followed by the placement of a T-Pal cage (DePuy/Synthes) (Fig. 2) and re-placement of the posterior rods with compression at L5–S1; then mechanical testing was performed without the iliac bolts connected (Table 2). Test 4: iliac bolts were connected to the construct described above for Test 3 and mechanical testing was repeated for all six specimens (Table 2). Test 5: for the other six specimens, an anterior discectomy and insertion of an interbody PEEK cage (SynFix-LR, DePuy/Synthes) was performed at L5–S1 (ALIF+PLF). This was done after the posterior rods were removed and a discectomy was performed according to our current operative technique. A trial spacer was used to determine appropriate size and was based on direct visualization and feel. The rods were then re-placed with compression across the L5 and S1 pedicle screws. Mechanical testing was performed without additional anterior fixation and without iliac bolts connected (Table 2). Test 6: iliac bolts were connected to the construct described above for Test 5 and mechanical testing was repeated for all six specimens (Table 2). Test 7: iliac bolts

were disconnected from the construct described for Test 6 and additional anterior fixation was performed with the ATB system (in three specimens; the other three had the anterior screws placed through the integrated titanium plate for the SynFix-LR cage) (DePuy/Synthes Raynham, MA) (Fig. 3), and the mechanical testing was repeated for all 6 specimens (Table 1). Test 8: iliac bolts were connected to the construct described above for Test 7 in all six specimens and the mechanical testing was repeated (Table 2). Test 9: iliac bolts were disconnected from the construct described for Test 8, and the ATB system (or SynFix screws) were replaced by the opposite fixation method (Fig. 4). In all six specimens, the mechanical testing was repeated (Table 2). Test 10: iliac bolts were connected to the construct described above for Test 9 in all 6 specimens, and the mechanical testing was repeated (Table 2).

All specimens were initially instrumented from L2 to S1 and with iliac bolts. Rods were precontoured at that time. Specimens were then preserved using our standard protocol. Testing, including disc preparation (either anterior or posterior) was performed on a single specimen at a time and took 30 minutes or less for each specimen. During testing, specimens were maintained with cadaveric solution to preserve the integrity of the soft tissues.

Strain was defined by strain gauges as a function of the voltage caused by local forces during testing. Strain gauges were selected according to the tested device size and attached to the following places at the right and left sides: (1) rods between L5 and S1 after appropriate contouring; (2) iliac bolt connectors (C2A-06-062LW-120; Micro-Measurements, Raleigh, NC); and (3) S1 screws (C2A-06-015LW-120; Micro-Measurements, Raleigh, NC) which were augmented by removing the proximal 5 mm of thread to create a smooth surface for mounting of the strain gauges. Gages were bonded to the device surface with M-Bond 200 adhesive (Micro-Measurements) and allowed to set for 24 hours. Strain gauges were affixed and instrumentation placed on the specimens after they had been appropriately thawed just prior to testing.

The spines were tested in a randomized order for sub-failure stiffness using an Instron 1321 servo-hydraulic test machine (Instron, Norwood, MA). The epoxy resin was used as the specimen's attachment point to the test apparatus. Flexion and extension were assessed using a triangular waveform, 0.25 Hz, 8 cycles, 6 Nm. Axial rotation test was conducted with a triangular waveform, 0.25 Hz, 8 cycles, 6 Nm, with 40% body weight compression load (Table 1).

Statistical data analysis

Statistical analysis was performed in a few stages: (1) analysis of variance (ANOVA) was applied for assessment of following characteristics of strain: distribution, mean, median, standard deviation, standard error of the mean, and 95% confidence interval; based on the results of this

Table 2
Design of the biomechanical tests.

Test specimen	Posterior L2/S1 instrumentation (bilateral rods and pedicle screws)							Interbody instrumentation		ATB Plate at L5/S1	Unilateral dissection of facet joint at L5/S1	Iliac bolts with rod connector	Specimen (n)
	Rods			Pedicle screws				Type of fixation	Interbody implant, L5–S1 (manufacturer)				
	n	Material (manufacturer)	Diameter (mm)	n	Material (manufacturer)	Length (mm)	Diameter (mm)						
1	2	Titanium (DePuy/Synthes)	6.0	12	Pangea Titanium (DePuy/Synthes)	45	6.0	Posterior	No	No	No	No	12
2	2	Titanium (DePuy/Synthes)	6.0	12	Pangea Titanium (DePuy/Synthes)	45	6.0	Posterior	No	No	No	Yes	12
3	2	Titanium (DePuy/Synthes)	6.0	12	Pangea Titanium (DePuy/Synthes)	45	6.0	Transforaminal	TLIF cage (T-Pal)	No	Yes	No	6
4	2	Titanium (DePuy/Synthes)	6.0	12	Pangea Titanium (DePuy/Synthes)	45	6.0	Transforaminal	TLIF cage (T-Pal)	No	Yes	Yes	6
5	2	Titanium (DePuy/Synthes)	6.0	12	Pangea Titanium (DePuy/Synthes)	45	6.0	Anterior and posterior	PEEK Cage (SynFix)	No	No	No	6
6	2	Titanium (DePuy/Synthes)	6.0	12	Pangea Titanium (DePuy/Synthes)	45	6.0	Anterior and posterior	PEEK Cage (SynFix)	No	No	Yes	6
7	2	Titanium (DePuy/Synthes)	6.0	12	Pangea Titanium (DePuy/Synthes)	45	6.0	Anterior and posterior	PEEK Cage (SynFix)	Yes	No	No	6
8	2	Titanium (DePuy/Synthes)	6.0	12	Pangea Titanium (DePuy/Synthes)	45	6.0	Anterior and posterior	PEEK Cage (SynFix)	Yes	No	Yes	6
9	2	Titanium (DePuy/Synthes)	6.0	12	Pangea Titanium (DePuy/Synthes)	45	6.0	Anterior and posterior	PEEK Cage with anterior screws (SynFix)	No	No	No	6
10	2	Titanium (DePuy/Synthes)	6.0	12	Pangea Titanium (DePuy/Synthes)	45	6.0	Anterior and posterior	PEEK Cage with anterior screws (SynFix)	No	No	Yes	6

ALIF, anterior lumbar interbody fusion; ALIF cage, SynFix with integrated titanium plate (DePuy/Synthes, Raynham, MA); ATB plate, anterior tension band system including titanium plate with fore 3.5-mm screws (DePuy/Synthes); NA, not available; PEEK, polyether-ether-ketone; TLIF, transforaminal lumbar interbody fusion; TLIF cage, T-Pal (DePuy/Synthes).

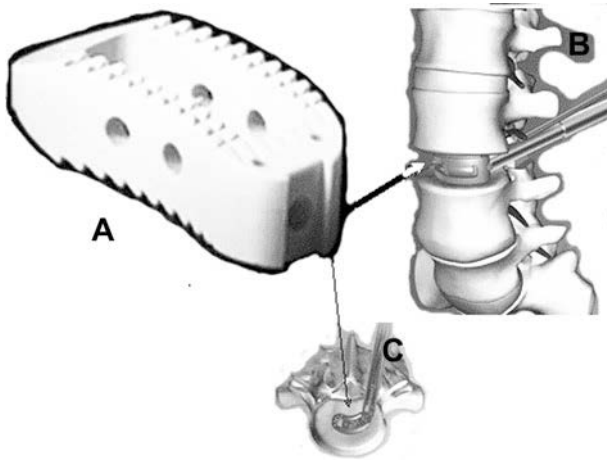


Fig. 2. TLIF cage: image (A); implantation after facet joint dissection, frontosagittal projection (B); and coronal projection (C). TLIF, transforaminal lumbar interbody fusion.

analysis, the Wilcoxon nonparametric test was selected for defining the statistical significance of difference between compared subgroups (p-value) [20]; (2) correlation between data obtained at right and left sides was defined by Spearman's test [20]; (3) a multiple-factor analysis to define the impact of the studied fixation types (10 tests) on strain in the studied device (S1 screws, posterior rods, and iliac bolt connectors) during flexion, extension, and axial rotation, and if significant impact was defined, comparative analysis of differences between the studied types of fixation was performed; (4) to elucidate the impact of the studied factors grouping analysis of results obtained during different tests was applied; and (5) a multiple regression analysis was performed to define combination of factors that provide the most significant impact on the strain in the

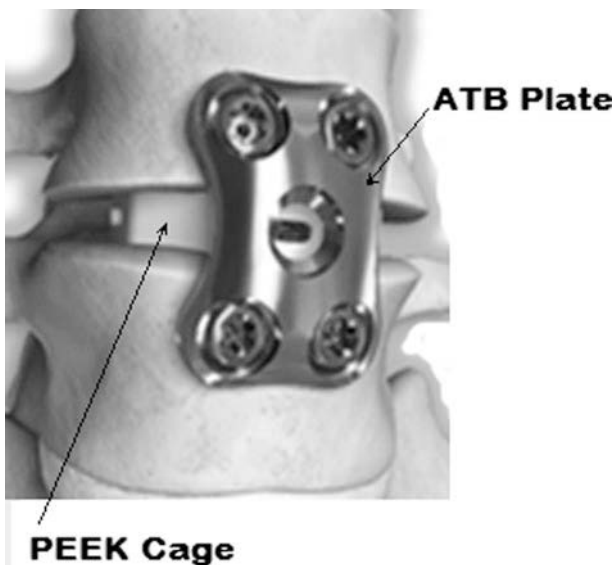


Fig. 3. PEEK cage with ATB Plate. PEEK, polyether-ether-ketone.

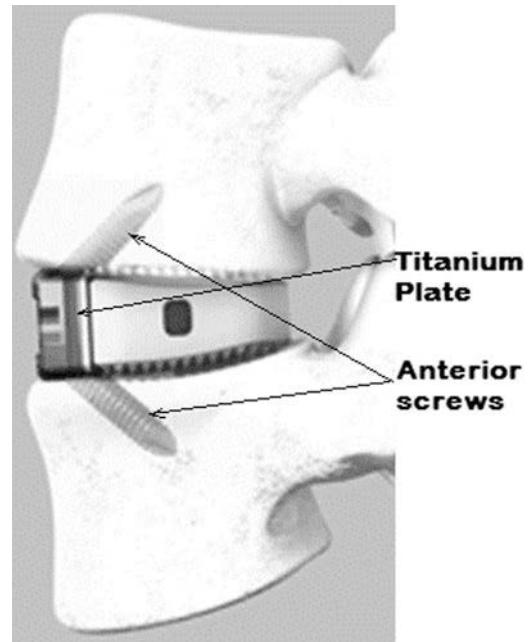


Fig. 4. PEEK cage with anterior fixation by screws. PEEK, polyether-ether-ketone.

studied posterior instrumentation at the tested conditions. To enhance the reliability of the obtained results, $p \leq .01$ was considered as statistically significant; p-values between .05 and .01 were regarded as conditionally significant, requiring further confirmation. The statistical analysis was performed using JMP 7.0.1 software (SAS Institute Inc., Cary, NC, www.jmp.com).

Results

General characteristic of strain and impact of direction of motion

Our results suggested that strain defined by strain gauges in posterior spinopelvic instrumentation is highly variable during physiologic range of motion and varied from 0.001 to 2.3 with right skewed distribution. The highest mean strain was revealed during rotation in S1 screws, 0.58 (95% confidence interval [CI]: 0.46, 0.59); and in iliac bolt connectors, 0.41 (95% CI: 0.28, 0.55) (Table 3). The correlation between right and left sides was strong, $0.5 < r < 0.8$ (Table 3). Direction of motion significantly modified strain; in particular, axial rotation with the same applied force caused on average more than two times higher strain in S1 screws and iliac bolt connectors ($p < .01$) than flexion and extension. This effect was statistically significant ($p < .001$) in all three tested fixations types (PLF, TLIF, and ALIF+PLF) but was not significant in rods (Table 3).

Impact of fixation type

The type of surgical intervention (fixation) significantly ($p < .0001$) modified the strain in the lumbosacral segment

Table 3
Distribution of strain in tested device depending on direction of motion (all surgical techniques combined).

Device	Correlation (R) between right and left sites		Direction of motion	Number of measurements (right and left)	Strain							p-value
	R	p-value			Distribution	Mean	Median	Min.	Max.	95% Confidence limits		
										Min.	Max.	
S1 screws	0.64	<.0001	Extension	144	Right skewed	0.21 ^A	0.11	0.01	2.1	0.15	0.26	<.0001
			Flexion	144	Right skewed	0.16 ^A	0.11	0.01	2.3	0.12	0.20	
			Rotation	144	Right skewed	0.58 ^B	0.38	0.03	4.8	0.46	0.59	
Posterior rods (L5/S1 segment)	0.72	<.0001	Extension	144	Right skewed	0.22	0.18	0.01	1.1	0.18	0.26	.344
			Flexion	144	Right skewed	0.26	0.13	0.01	1.3	0.20	0.31	
			Rotation	144	Right skewed	0.32	0.20	0.01	4.4	0.24	0.39	
Iliac bolt connector	0.57	<.0001	Extension	72	Right skewed	0.14 ^A	0.11	0.01	0.4	0.12	0.16	.0002
			Flexion	72	Right skewed	0.20 ^A	0.13	0.01	0.9	0.15	0.25	
			Rotation	72	Right skewed	0.41 ^B	0.24	0.01	2.8	0.28	0.55	

Levels not connected by same letter are significantly different (p < .01).

of the posterior rods (Table 4). In particular, ALIF+PLF provided approximately two times less strain (p < .01) in the posterior rods than a TLIF technique, specifically during flexion and extension, but not rotation (Table 4). This difference was less statistically significant between ALIF+PLF versus PLF but without facet joint dissection (Table 4). Strain in S1 screws and iliac bolt connectors did not show a significant difference between the studied types of fixation in our test conditions (Tables 5 and 6, Supplemental Digital Content).

Impact of spinopelvic fixation by iliac bolt

Application of spinopelvic fixation by iliac bolt showed a tendency to decrease strain in S1 screws, in particular, during rotation after PLF, TLIF, and ALIF+PLF, but revealed differences that were not statistically significant between compared subgroups (p > .05; Tables 7-9, Supplemental Digital Content). However, combining results of all types of fixation showed conditional significance for rotation (p = .048). At the same time, spinopelvic fixation by iliac bolt increased the strain in posterior rods after PLF

(p = .046; Table 7, Supplemental Digital Content; Fig. 5) and TLIF (p = .088; Table 8, Supplemental Digital Content; Fig. 6), specifically, during flexion. This effect was not revealed in ALIF+PLF (Table 9, Supplemental Digital Content). Combining the results of PLF and TLIF in flexion showed a statistically significant result (p = .005); in particular, the mean strain in posterior rods was 0.22 (95% CI: 0.12, 0.32) without iliac bolts, and 0.44 (95% CI: 0.32, 0.55) with iliac bolts.

Impact of additional anterior fixation by ATB system or anterior screws in ALIF+PLF

Additional anterior fixation decreased strain in S1 screws during extension by 2.5–3.0 times with conditional significance (p = .048) when the iliac bolts were disconnected. This effect was not significant (p = .261) if the iliac bolts were connected (Table 10, Supplemental Digital Content). The same effect was observed for strain in the posterior rods, but not statistically significant (p > .05; Table 11, Supplemental Digital Content).

Table 4
Impact of fixation type on strain in posterior rods (L5–S1 segment).

Device	Direction of motion	Type of fixation	Tests	n	Mean	Standard error of the mean	Standard deviation	95% confidence limits		p-value
								Min.	Max.	
Posterior rods (L5/S1 segment)	Combined	Anterior and posterior	5–10	216	0.21 ^A	0.02	0.32	0.16	0.26	<.0001
		Posterior	1–2	144	0.27 ^{AB}	0.02	0.25	0.21	0.33	
		Transforaminal	3–4	72	0.39 ^B	0.05	0.42	0.31	0.46	
	Extension	Anterior and posterior	5–10	72	0.17 ^A	0.03	0.23	0.11	0.22	.001
		Posterior	1–2	48	0.26 ^{AB}	0.03	0.23	0.19	0.33	
		Transforaminal	3–4	24	0.31 ^B	0.04	0.20	0.22	0.40	
	Flexion	Anterior and posterior	5–10	72	0.16 ^A	0.04	0.30	0.09	0.24	<.0001
		Posterior	1–2	48	0.28 ^{AB}	0.04	0.26	0.20	0.37	
		Transforaminal	3–4	24	0.43 ^B	0.06	0.31	0.30	0.56	
	Rotation	Anterior and posterior	5–10	72	0.30	0.07	0.39	0.19	0.40	.401
		Posterior	1–2	48	0.39	0.11	0.74	0.19	0.37	
		Transforaminal	3–4	24	0.42	0.13	0.64	0.16	0.69	

n, number of measurements (observations) used for statistical analysis including right and left sides.

Combined: extension, flexion, and rotation; levels not connected by the same letter are significantly different (p < .01).

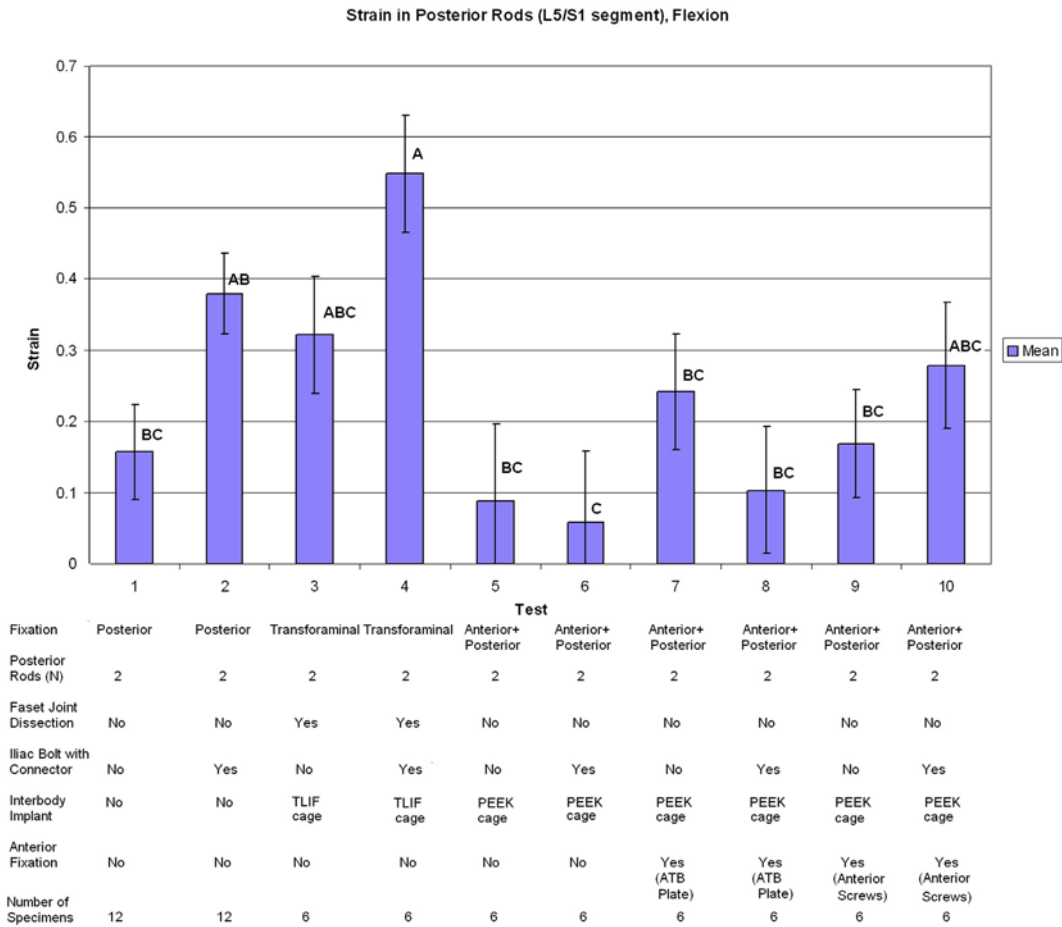


Fig. 5. Profile of strain in the L5–S1 segment of posterior rods caused by flexion at tested conditions. Levels of strain not connected by the same letter are significantly different, with p value $< .01$. Error bars show the standard error of the mean.

Impact of ATB system versus interbody cage with integrated locking screws for ALIF+PLF

Both types of anterior supplemental fixation provided similar impact on strain in the S1 screws (Table 12, Supplemental Digital Content). However, strain in the posterior rods was on average more than two times less when an interbody cage with integrated locking screws was used; this effect was conditionally significant during extension ($0.02 < p < .05$) and did not depend on the iliac bolt connection (Table 13, Supplemental Digital Content).

Multiple regression analysis

A multiple regression analysis allowed evaluation of a combination of factors that influenced strain in the posterior instrumentation the most significantly. In particular, the strain in L5–S1 rods depends on such factors as type of fixation, direction of motion, supplemental anterior fixation, and fixation by iliac bolts and can be approximated by the following equation (1):

$$l_r = 0.29 + X_1 + X_2 + X_3 + X_4 \tag{1}$$

where l_r is the strain in L5–S1 rods; X_1 matched to the fixation type: PLF (0.02), TLIF (0.08), and ALIF+PLF (–0.06); X_2 matched to the direction of motion: extension (–0.06), flexion (–0.03), and rotation (0.06); X_3 matched to the supplemental anterior fixation: no fixation (0.04), fixation by ATB plate (0.02), and fixation by cage with anterior screws (–0.07); and X_4 matched to the fixation by iliac bolts: yes (0.02), no (–0.02). The correspondence between calculated and measured values was statistically significant ($p < .001$) but not high: $R^2 = 0.1$; root mean square error (RMSE) = 0.27. Combination of two main factors influenced the strain in S1 screws: direction of motion and fixation to pelvis by iliac bolts (Equation 2):

$$l_s = 0.29 + X_1 + X_2 \tag{2}$$

where l_s is the strain in S1 screws; X_1 matched to the direction of motion: extension (–0.09), flexion (–0.13), and rotation (0.22); and X_2 matched to the fixation to pelvis by iliac bolts: yes (–0.05), no (0.05). The correspondence between calculated and measured values was moderate: $R^2 = 0.20$, RMSE = 0.27, $p < .001$.

Strain in Posterior Rods (L5/S1 segment), Extension

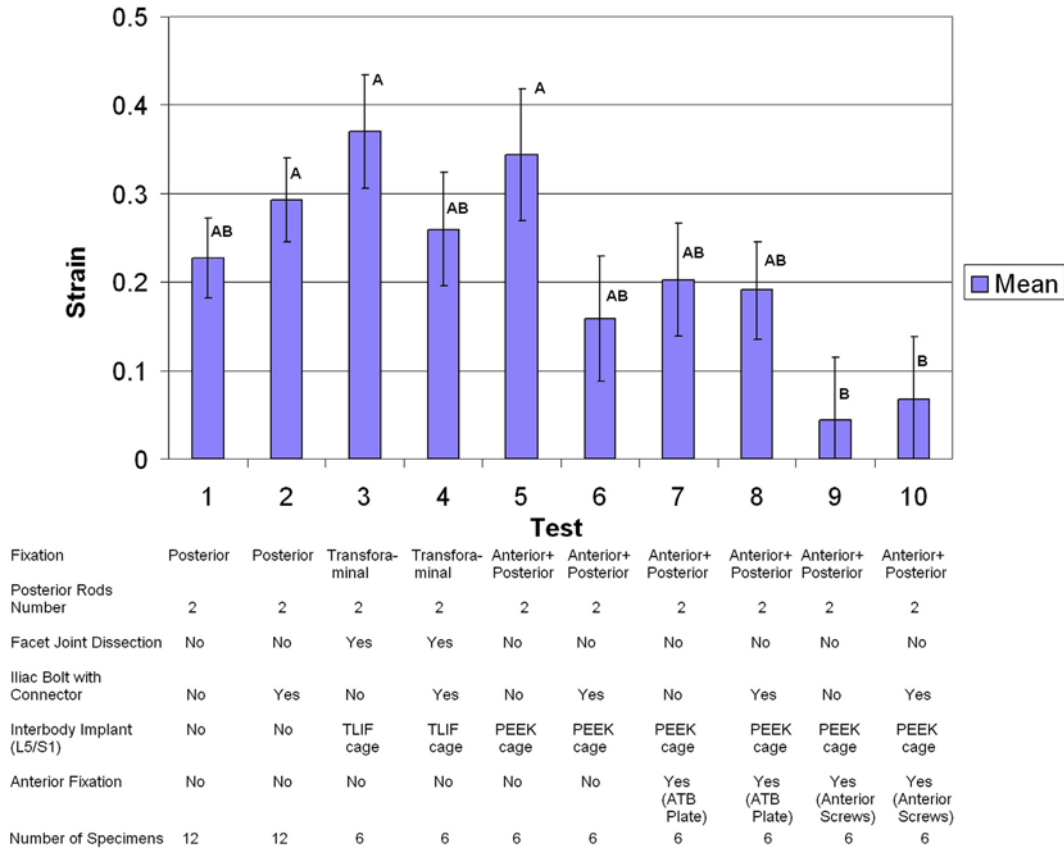


Fig. 6. Profile of strain in the L5–S1 segment of posterior rods caused by extension at tested conditions. Levels of strain not connected by the same letter are significantly different, with p-value < .01. Error bars show the standard error of the mean. Statistical package used: JMP 7.0.1 (SAS Institute Inc).

Strain in the iliac bolt connectors was mainly determined by direction of motion and by type of fixation (Equation 3):

$$l_i = 0.28 + X_1 + X_2 \tag{3}$$

where l_i is the strain in iliac bolt connectors; X_1 matched to the direction of motion: extension (−0.1), flexion (−0.05), and rotation (0.16); and X_2 matched to the fixation type: ALIF+PLF (−0.05), PLF (0.001), and TLIF (0.05). Correspondence between calculated and measured values was moderate: $R^2 = 0.13$, RMSE = 0.28; $p < .001$.

Discussion

The current study was focused on the evaluation of factors that impact strain during the physiological range of motion in lumbopelvic fixation, typically used for long posterior fusions. Strain is an index that can be used to predict device failure. We studied strain in the S1 pedicle screws, L5–S1 rods, and iliac bolt connectors/rod between S1 and the iliac bolt. It was shown that the direction of motion is a powerful factor, which impacts the device strain; in particular, the highest level of strain was caused

by axial rotation, specifically in S1 screws and iliac bolt connectors (Table 3). Of note, intervertebral support with a cage, inserted through an anterior approach, decreased the strain in S1 screws as shown previously [15]. However, in our study, this effect was most significant during extension when supplemental anterior fixation was applied, and particularly when the iliac bolts were not connected. This finding demonstrates that anterior support, even with supplemental fixation, provides only limited protection of the S1 screws mainly during sagittal displacement, specifically extension, and likely does not decrease impact of axial rotation. It suggests that S1 screws are at risk of fracture even if anterior instrumentation is used.

It was suggested that spinopelvic fixation enhances the stiffness and stability of constructs [6]. Our study demonstrated that it also tends to diminish the strain in S1 screws but increases the strain in the spinopelvic segment of the posterior rods, specifically during flexion, contributing to the risk of fracture (Fig. 5). This outcome corresponds with clinical findings [13,14]. An anteriorly placed interbody cage significantly decreased this strain during flexion and in combination with the addition of supplemental anterior fixation also decreases the strain during extension (Fig. 6).

Unfortunately, neither anterior instrumentation constructs had an impact on strain within rods during rotation. Of note, a transforaminal technique showed the maximal strain in rods during flexion and extension, with a tendency to rise after spinopelvic fixation with iliac bolts (Figs. 5 and 6). It suggested that posteriorly placed interbody cages could not compensate for instability caused by facetectomy for transforaminal discectomy. This also suggests that other techniques such as posterior lumbar interbody fusion may provide similar benefits to anterior methods. Unfortunately, we did not evaluate posterior lumbar interbody fusion specifically in our testing algorithm.

The strain in iliac bolt connectors mainly depended on the direction of motion, is maximum during axial rotation (Table 3), and is somewhat less in ALIF+PLF than that in PLF and TLIF. The effects of anterior supplemental fixation provided by a different device were close but not entirely equivalent. In particular, there were no differences in the S1 screws strain at extension when the ATB system or cage with integrated locking screws were applied (Table 12, Supplemental Digital Content); however, utilization of cages with integrated locking screws caused less strain in the lumbosacral segment of the posterior rods during extension than an ATB plate (Table 13, Supplemental Digital Content; Fig. 6). Theoretically this difference can be explained by the different slope of screw insertion in these devices; however, this finding was only conditionally significant and requires further confirmation.

Impact of the studied factors on strain in the posterior instrumentation considered was confirmed by the results of the multiple regression analysis. However, limited predictive value of the obtained equations suggests the presence of other factors that, likely, also influenced strain, and which were not taken into consideration in the current study. First of all, it relates to the quality of bone in the vertebrae and pelvis, and quality of material in the tested devices. Therefore, the presented results are limited by the absence of radiographic evaluation of the specimens before and after device insertion. It did not allow evaluation of such factors as bone mineral content, bone density, osteoporotic status of the operated vertebrae, and accuracy of the device placement as potential confounders. However, each specimen was tested against itself in each of the test conditions, limiting the effect of bone quality as a confounder.

Evaluation of the material quality in rods, screws, and iliac bolt connectors before implantation is also very important, and could be done by noninvasive tests based on ultrasound and/or electric impedance. Another limitation is linked with the relatively low number of specimens, which was not enough sometimes to get strong statistically significant results because of the high variability of strain. Thus, some of the obtained results require further confirmation. Also, there are many fusion techniques/devices available, and not all could be tested. Although the results are analyzed for the specific implants described, there may be other techniques that provide equivalent or better results.

Finally, as with all cadaveric tests, specimen integrity can affect results. Standard protocol for cadaveric testing was followed, and exposure of the specimens was limited to reduce the risk of tissue degradation as a confounding factor.

Conclusions

1. Application of interbody devices and surgical technique significantly modify strain in low posterior instrumentation for long multilevel posterior fusion; the maximal strain was observed in S1 pedicle screws and iliac bolt connectors, specifically at axial rotation. Insertion of an anterior interbody implant, specifically with anterior supplemental fixation, decreased the strain in S1 screws during sagittal motion but not during axial rotation.
2. The transforaminal technique causes maximum strain in the lumbosacral segment of the posterior rods, which increases after lumbosacral fixation with iliac bolts.
3. Spinopelvic fixation with iliac bolts contributes to decreasing strain in S1 screws but significantly increases strain in the lumbosacral segment of the posterior rods, specifically after posterior or transforaminal techniques. Combination of anterior and posterior techniques significantly decreases this effect, including the strain in iliac bolt connectors.
4. Interbody cages with supplemental fixation with integrated and locked anterior screws tend to decrease the strain in the lumbosacral segment of posterior rods better than an ATB system.

Supplementary Data

Supplementary data associated with this article can be found, in the online version, at <http://dx.doi.org/10.1016/j.jspd.2016.09.045>.

References

- [1] Burger E, Noshchenko A, Barton C, et al. Sagittal plane correction is correlated with quality of life at early followup in adult deformity patients. In: SICOT, editor. *International Society of Orthopaedic Surgery and Traumatology (SICOT), 36th World Congress, Guangzhou, China, September 17–19 2015*.
- [2] Smith JS, Shaffrey CI, Lafage V, et al. Comparison of best versus worst clinical outcomes for adult spinal deformity surgery: a retrospective review of a prospectively collected, multicenter database with 2-year follow-up. *J Neurosurg Spine* 2015;23:349–59.
- [3] Smith JS, Singh M, Klineberg E, et al. Surgical treatment of pathological loss of lumbar lordosis (flatback) in patients with normal sagittal vertical axis achieves similar clinical improvement as surgical treatment of elevated sagittal vertical axis: clinical article. *J Neurosurg Spine* 2014;21:160–70.
- [4] Keibaish KM. Sacropelvic fixation: techniques and complications. *Spine (Phila Pa 1976)* 2010;35:2245–51.

- [5] Edwards 2nd CC, Bridwell KH, Patel A, et al. Long adult deformity fusions to L5 and the sacrum. A matched cohort analysis. *Spine (Phila Pa 1976)* 2004;29:1996–2005.
- [6] Shen FH, Mason JR, Shimer AL, et al. Pelvic fixation for adult scoliosis. *Eur Spine J* 2013;22(suppl 2):S265–75.
- [7] Bydon M, Macki M, Abt NB, et al. The cost-effectiveness of interbody fusions versus posterolateral fusions in 137 patients with lumbar spondylolisthesis. *Spine J* 2015;15:492–8.
- [8] McLennis MM, Olchanski N, Kemner JE, et al. Budget impact of new rhbmp-2 formulation in patients undergoing posterolateral spinal fusion procedures for degenerative disc disease in randomized controlled trial (RCT). *Value Health* 2010;13:A305.
- [9] Carreon LY, Glassman SD, Djurasovic M, et al. RhBMP-2 versus iliac crest bone graft for lumbar spine fusion in patients over 60 years of age: a cost–utility study. *Spine* 2009;34:238–43.
- [10] Alvin MD, Lubelski D, Abdullah KG, et al. Cost-utility analysis of instrumented fusion versus decompression alone for grade I L4-L5 spondylolisthesis at 1-year follow-up: a pilot study. *Clin Spine Surg* 2016;29:E80–6.
- [11] Deyo RA, Martin BI, Kreuter W, et al. Revision surgery following operations for lumbar stenosis. *J Bone Joint Surg Am* 2011;93:1979–86.
- [12] Marchi L, Oliveira L, Coutinho E. Results and complications after 2-level axial lumbar interbody fusion with a minimum 2-year follow-up. *J Neurosurg Spine* 2012;17:187–92.
- [13] Barton C, Noshchenko A, Patel V, et al. Risk factors associated with rod fracture after osteotomy for adult spine deformity. In: *International Society of Orthopaedic Surgery and Traumatology (SICOT) 36th World Congress, Guangzhou, China, September 17–19 2015*.
- [14] Cho W, Mason JR, Smith JS, et al. Failure of lumbopelvic fixation after long construct fusions in patients with adult spinal deformity: clinical and radiographic risk factors: clinical article. *J Neurosurg Spine* 2013;19:445–53.
- [15] Fleischer GD, Kim YJ, Ferrara LA, et al. Biomechanical analysis of sacral screw strain and range of motion in long posterior spinal fixation constructs: effects of lumbosacral fixation strategies in reducing sacral screw strains. *Spine (Phila Pa 1976)* 2012;37:E163–9.
- [16] Rousseau MA, Lazennec JY, Saillant G. Circumferential arthrodesis using PEEK cages at the lumbar spine. *J Spinal Disord Tech* 2007;20:278–81.
- [17] Noshchenko A, Plaseied A, Patel VV, et al. Correlation of vertebral strength topography with 3-dimensional computed tomographic structure. *Spine (Phila Pa 1976)* 2013;38:339–49.
- [18] Harris BM, Hilibrand AS, Savas PE, et al. Transforaminal lumbar interbody fusion: the effect of various instrumentation techniques on the flexibility of the lumbar spine. *Spine (Phila Pa 1976)* 2004;29:E65–70.
- [19] Roessle ML, Fatemi A. Strain-controlled fatigue properties of steels and some simple approximations. *Int J Fatigue* 2000;22:495–511.
- [20] Glantz SA. *Primer of Biostatistics*. 6th ed. New York: McGraw-Hill Medical; 2005.