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Basic Science

Impact of bone density and integrated screw configuration on standalone anterior lumbar interbody construct strength

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ABSTRACT

Background: In anterior lumbar interbody fusion (ALIF), the use of integrated screws is attractive to surgeons because of the ease of implantation and no additional profile. However, the number and length of screws necessary for safe and stable implantation in various bone densities is not yet fully understood. The current study aims to determine how important both length and number of screws are for stability of ALIFs.

Methods: Three bone models with densities of 10, 15, and 20 pounds per cubic foot (PCF) were chosen as surrogates. These were instrumented using the Z-Link lumbar interbody system with either 2, 3, or 4 integrated 4.5 × 20 mm screws or 4.5 × 25 mm screws (Zavation, LLC, Flowood, MS). The bone surrogates were tested with loading conditions resulting in spine extension to measure construct stiffness and peak force.

Results: The failure load of the construct was influenced by the length of screws (p=.01) and density of the bone surrogate (p<.01). There was no difference in failure load between using 2 screws and 3 screws (p=.32) or when using four 20 mm screws versus three 25 mm screws (p=.295).

Conclusion: In our study, both bone density and length of screws significantly affected the construct's load to failure. In certain cases where a greater number of screws are unable to be implanted, the same stability can potentially be conferred with use of longer screws. Future clinical studies should be performed to test these biomechanical results.

Introduction

Anterior lumbar interbody fusion (ALIF) accounts for 16% of interbody fusions, and the number of patients over 30 years old undergoing ALIFs is increasing [1]. Through its retroperitoneal approach, ALIF provides direct visualization and efficient access to the entirety of the intervertebral disc ventral surface. This results in more comprehensive discectomies and placement of the largest possible interbody cages to allow for the largest fusion bed [2,3]. ALIFs may exist as standalone constructs with anterior plates, or they may be supplementally stabilized with posterior fixation [4]. Standalone ALIF procedures have been found to be safer, less costly, quicker, and less invasive [5,6]. However, anterior plates and interference screws may be more difficult to implant because of vascular anatomy [7]. It is also well recognized that extensive retraction of the great vessels increases risk of injury [8,9] especially in patients with vascular anomalies and adhesions from prior abdominal surgeries [3,8]. In some cases, it is not possible to implant the traditional number of screws and the use of a reduced number has been suggested to decrease surgical time and morbidity [10].

Implantation with a reduced number of screws has previously been studied but without accounting for bone density [10], which plays a major role in determining bone-screw interface strength [11]. More specifically, among patients over 50 years old seeking spine surgery consultation, it has been documented that 46.4% have osteopenia and 31.1% have osteoporosis [12]. These patients are at risk for complications earlier in the postoperative course [13] and have more cases of post-surgical complications [14].

The main objective of the study is to evaluate the role of bone density in determining the minimal number of screws needed in ALIF to preserve construct strength. Furthermore, we also aim to evaluate if longer screws

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Fig. 1. Experimental setup used to load the bone surrogates in a simulated spine extension.

can confer similar stability with fewer screws. We hypothesize that for higher bone densities, there is no difference in stability with the number of screws used; for lower bone densities, the use of longer screws can confer similar stability with fewer screws.

Methods

Groups

In order to standardize testing conditions, polyurethane foam bone surrogates were used, as indicated by the ASTM F543–17. The surrogates were machined out of polyurethane foams (Pacific Research Laboratories, Inc. Vashon, WA) compliant with the ASTM F1839–08. Three bone models with densities of 10 (0.16 g/cmˆ3), 15 (0.24 g/cmˆ3), and 20 (0.32 g/cmˆ3) PCF were chosen, representing osteoporotic, normal, and higher than normal bone densities [11]. In order to guarantee consistency in the hardware instrumentation, holes of 2.7 mm in diameter were drilled at an angle of 30° and a distance of 17 mm using a Tormach 1100 CNC machine. The segments were then instrumented using the Z-Link lumbar interbody system with 8° of lordosis and either 2, 3, or 4 integrated 4.5 × 20 mm screws or 4.5 × 25 mm screws (Zavation, LLC, Flowood, MS).

Table 1
Experimental results with detailed statistical differences within same densities of the considered bone surrogates.

Bone surrogate density [PCF]	Number of screws	p value 2 screws vs 3 screws	p value 3 screws vs 4 screws	Screws length [mm]	Failure load [N] ± SD		Construct Stiffness [N/mm] ± SD	
10	2	p=.87 (load)		20	65.0	8.3	7.6	0.9
		p=.19 (stiffness)		25	88.5	8.5	9.3	1.9
	3		p<.01 (load)	20	68.4	5.2	9.3	0.4
			p<.01 (stiffness)	25	92.4	10.5	9.3	0.7
	4			20	113.5	8.2	12.0	1.3
				25	144.6	14.1	16.4	1.1
15	2	p=.32 (load)		20	83.0	8.1	10.3	1.2
		p=.26 (stiffness)		25	144.7	11.0	17.7	2.6
	3		p=.02 (load)	20	98.0	6.3	13.9	2.0
			p=.01 (stiffness)	25	177.7	10.0	19.9	2.7
	4			20	169.8	3.1	20.4	0.7
				25	271.9	8.3	26.6	2.6
20	2	p=.23 (load)		20	131.8	11.6	22.4	6.9
		p=.82 (stiffness)		25	181.7	14.8	21.6	4.1
	3		p<.01 (load)	20	151.9	9.1	19.5	2.1
			p=.02 (stiffness)	25	206.9	9.7	25.9	2.6
	4			20	295.8	21.9	31.5	8.1
				25	401.1	12.2	43.6	3.3

Mechanical testing

The bone surrogates were tested through two rigid fixtures connected to the Instron 8872 (Norwood, MA) testing machine. The fixtures were shaped to host the bone surrogates free to rotate around a transverse shaft placed at a distance of 27.5 mm from the surrogate midpoint. The surrogates were loaded at a rate of 10 mm/min, resulting in a motion mimicking human spine extension (Fig. 1). The displacement was actuated until failure, defined as a 90% reduction of applied load. Load-displacement data was acquired at a frequency of 100 Hz and in 1 N increments. Peak force values were recorded as failure loads. Construct stiffness was calculated as the slope of the obtained load-displacement curves.

Statistical analysis

For each experiment, the quality of the linear regression for the estimation of the construct stiffness was evaluated through the regression coefficient. Three-way ANOVA was performed to evaluate the effects of the number of screws, density, and screw lengths, while T-Test was used for specific differences. Level of significance was set at 0.05.

Results

Failure loads

A total of 54 experiments were conducted, consisting of three permutations of each of the three densities (10, 15, and 20PCF), instrumented with two, three, and four screws, in length of 20 and 25 mm (see Table 1). The recorded failure loads ranged from 65.0N±8.3 for the low-density surrogate implanted with only two screws to 401.1N±12.3 for the highest density bone surrogate with four screws.

As shown in Fig. 2, the failure load of the construct was influenced by the number of screws ($p<.01$), the length of screws ($p=.01$), and the density of the bone surrogate ($p<.01$).

There was no difference in failure load between using two screws and three screws ($p=.32$), regardless of density. However, when instrumented only with 20 mm screws, the use of four screws resulted in a higher failure load than three screws ($p<.01$, see Table 1). The construct instrumented with four screws in 20 mm and 25 mm length had a failure load that spanned from 113.5N±8.2 to 401.1N±12.2, respectively, for the lowest and highest densities ($p<.01$).

Stiffness

Construct stiffness was influenced by density ($p<.01$). For densities up to PCF 15, the use of three 25 mm screws showed no difference in stiffness compared to the use of 4 shorter screws ($p>.05$, see Table 2). In terms of construct stiffness, the use of four screws had values ranging from 12.0 N/mm±1.3 to 43.6 N/mm±3.3 for the lowest and highest densities respectively ($p<.01$). Among all densities, the use of three 20 mm screws resulted in a reduction of stiffness compared to four 20 mm screws ($p=.03$). For the lowest density, use of three 25 mm screws did not result in a greater stiffness than with three 20 mm screws ($p=.29$). However, the highest density did show improvement for the same configuration ($p=.03$).

Post-hoc power analysis

Post-hoc power analysis revealed that the three repetitions chosen were enough to evaluate differences among all the configurations, except for the differences between the configurations with two and three screws. Evaluating the differences in stiffnesses between these two configurations required repetitions that ranged from 4 for densities of 10 PCF and 15 PCF instrumented with 20 mm screws to a maximum of 37 for the configurations in PCF 20 with 20 mm screws.

Discussion

ALIF stability is important to reliably achieve fusion. Lack of stability has been linked to increased rates of pseudarthrosis, subsidence, and implant failure [15–17]. While ALIFs supported with additional posterior fixation often provide superior biomechanical stability, they are associated with increased costs, longer operative times, higher perioperative blood loss, and higher postoperative morbidity [16,5,18,6,19]. In addition, the increased dissection necessitated by posterior fixation may increase the risk of implant failure and adjacent-segment disease [20].

The number of screws necessary for adequate fixation of ALIF cages has been investigated previously [10]. However, none of these studies did not control for screw length, which may confound the results [21,22,10]. Our findings indicate that four 25 mm screws resulted in higher failure loads when compared to fixation with four 20 mm screws across all bone densities. Use of three 25 mm screws had similar failure loads to four 20 mm screws, further reinforcing the importance of screw length.

A cadaveric study by Kornblum et al. performed on eight spines showed no statistical differences in the range of motion between three

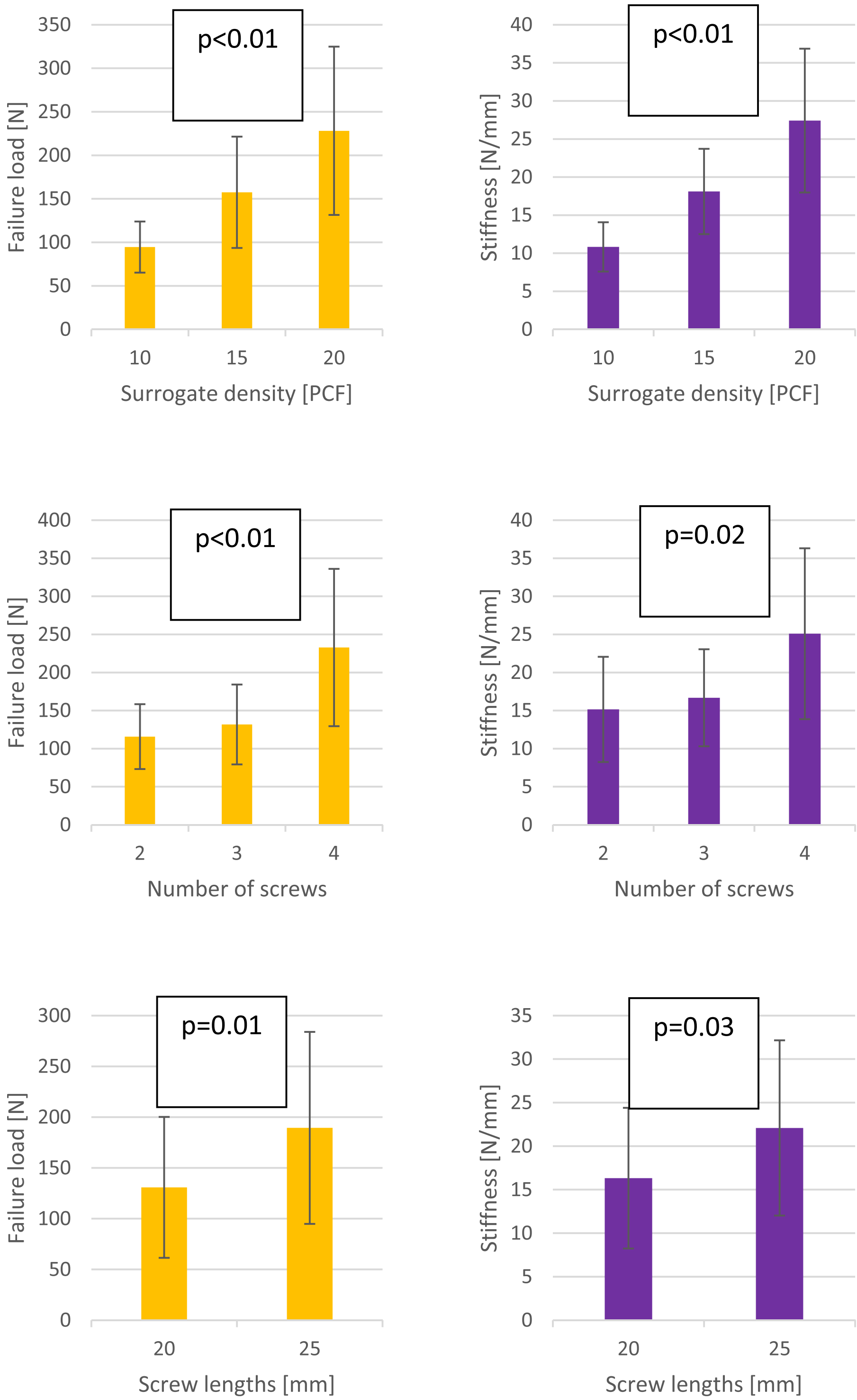

Fig. 2. Experimental results in terms of Failure loads [N] and Stiffness [N/mm] for specimens grouped in relation to the bone surrogate density, number of screws, and screw lengths used.

and four integrated screws in a stand-alone ALIF cage, with an observed trend of greater motion with only three screws [10]. While the authors did not include a measure of power in disclosing the identified significance, the documented trend agrees with our findings.

While screw length proved to be an important consideration, the density of the bone surrogates played an even larger role in some studies [23,24]. Hitchon et al. instrumented cadaveric spines with two of either 12, 14, or 16 mm screws. They found that pullout strength was strongly related to screw length for all screws ($p=.0002$), but also found an even stronger correlation between pullout strength and bone mineral density ($p<.0001$). [23]. Palmer et al. found that doubling screw length for ALIF plate constructs translated into approximately twice the pullout strength, while doubling the density of the bone surrogate approximately tripled the pullout load [24]. Our study demonstrated similar results, suggesting that although longer screw length confers significant ALIF stability, patient bone density may be more important in determining failure. Furthermore, Okuyama et al. and Kanno et al. have shown that decreased bone density correlates with higher rates of screw loosening and nonunion [25,26]. Therefore, bone quality should be accounted for before implantation of ALIF cages. For cases of low bone density, it

Table 2
Efficiency of longer screws in compensating for the missed screw in relation to the considered densities in terms of failure loads and stiffnesses.

Failure loads [N]			
	4 screws in 20 mm	4 screws in 25 mm	3 screws in 25 mm
PCF 10	113.5±8.2	144.6±14.1 p=.03	92.4±10.5 p=.05
PCF 15	169.8±3.1	271.9±8.3 p<.01	177.7±10.0 p=.26
PCF 20	295±21.9	401±12.2 p<.01	206.8±9.7 p=.002
Stiffness [N/mm]			
PCF 10	12.0±1.3	16.4±1.1 p=.01	9.3±0.4 p=.08
PCF 15	20.4±0.7	26.6±2.6 p=.02	19.9±2.7 p=.08
PCF 20	31.5±8.1	43.6±3.3 p=.07	25.9±2.6 p=.31

may be necessary to utilize longer screws. This could also be relevant when implantation of four screws may not be possible. However, surgeons should critically scrutinize pre-operative CT scans to determine the longest length for safe screw implantation [27].

Although there are numerous studies on the effects of screw length and diameter for pedicle fixation [25], there is little literature on the characteristics of stand-alone integrated ALIF screws. Our study found there were no differences between 2 and 3 screws in failure load or construct stiffness. This was true at all densities and may suggest that implanting two screws may suffice when a third cannot be implanted. However, a substantial difference was found in failure load and stiffness between three and four screws when screw length was controlled.

Limitations of the study

There were several limitations to this study. Use of bone surrogates allowed for reproducibility of testing; similar materials were used by Palmer et al. and Amirouche et al. [11,24]. However, the homogenous structure of the surrogates did not precisely represent the more heterogenous nature of human bone. These results should be corroborated with cadaveric testing. An additional limitation comes from the level of densities considered in the current study. We did not include specimens with density of 0.08 g/cmˆ3, which have been used to characterize extremely osteoporotic densities [28]. Therefore, our conclusions should not be considered relevant to extreme osteoporotic cases for which standalone fusion is ruled out [29].

The testing mechanism we utilized only considers loading through spine extension, as this has been shown to be an area of vulnerability for ALIFs with and without fixation [5]. We did not consider spine movements other than extension and variations in the chosen lumbar interbody fusion device. Other mechanisms to be considered should be flexion and axial rotation [5,17].

Our mechanism for testing, although providing standardized values for experimentation and comparison, differs from the in vivo mode of construct failure, which involves cyclic loading mechanisms [24]. Additional parameters may also affect ALIF construct stability, including screw insertion angle and screw diameter. However, these are outside the scope of this study and may be examined on future studies [30,31]. Clinically, standalone ALIF implants are at risk for instability, subsidence, and construct failure. This ultimately implies a risk for pseudarthrosis once implanted in patients. The literature reports a 10% overall risk of pseudarthrosis for standalone ALIF without supplemental posterior instrumentation [32,33]. With additional supplementation, whether by posterior instrumentation or anterior plating, the rates for development of pseudarthrosis decrease. However, the stability conferred by different numbers of integrated screws using a standalone ALIF implant has not been as well studied. Kornblum et al. studied “stability” of various standalone ALIF constructs as defined by loss of ROM following implantation of hardware [10]. No other studies have examined the various values of stiffness of constructs as ours has.

Conclusion

The number of screws implanted has significant implications for ALIF cage stability. Furthermore, bone quality plays an equally crucial role in determining construct strength. Longer screws can mitigate the detrimental effects of low bone density and a reduced number of screws in determining construct strength. Future clinical studies should be performed to test these biomechanical results.

Declaration of competing interest

There is no conflicts of interest.

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The study was deemed not human research by the Institutional Review Board of our Institution.

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