

Relationship of Height and Weight to Maximum Safe Pedicle Screw Diameter in the Lumbar Spine

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Abstract

Background Safely performing instrumented spinal fusion requires an intimate knowledge of anatomy and variations. Pedicle screw position and size have implications on intraoperative and post-operative complications. While pre-operative planning with Computed Tomography (CT) scan measurements may be the safest way to judge trajectory and maximal screw size, it is not standard practice for many spine surgeons. We investigated how height and weight correlated with PD. We hypothesized that these routinely obtained, non-invasive measurements would provide an easily referenced data point to aid in perioperative estimation of maximum safe pedicle screw diameter (MSPSD).

Methods Coronal cuts of the lumbar spine were assessed to obtain transverse outer cortical PD as measured through the isthmus at lumbar vertebrae one through five. We assessed whether height, weight, and BMI significantly correlated with PD in our diverse population.

Results Height and weight were found to significantly correlate with PD. Height explained roughly 10% of the variance in PD, weight explained only 3-4%, and BMI nearly 0%. There were significant differences in this theoretical safety profiles between the "Taller Height" and "Shorter Height" groups for the majority of pedicle screw sizes at L1 through L3. Significant differences between the populations at L4 and L5 were only seen for 8.0 mm screws at the L4 level. At L5, 100% of the "Taller Height" and "Shorter Height" subjects' pedicles could safely accommodate pedicle screws up to 8.0 mm in diameter.

Conclusions We previously reported on the significant difference in PD between different races. The results of this study provide yet another variable to be considered when making radiographic assessments of pedicle diameter.

Background

An intimate knowledge of vertebral anatomy and anatomic variations is essential for surgeons performing instrumented lumbar spinal fusion procedures. With the majority of current constructs relying mainly on transpedicular screw fixation, particular attention must be paid to pedicle anatomy. Biomechanical studies have supported the trend toward pedicle screw constructs showing pedicle screw pullout strength is superior to sublaminar titanium cables and sublaminar hooks [1].

In general, instrumented spinal fusion procedures have shown a steady trend of increasing volume over the last decade. One review looked at over 200,000 admissions for spinal surgery in high volume hospitals from 2005 to 2014 to identify trends in lumbar spinal fusion. These hospitals performed 765.5 lumbar procedures per year on average. Over the 10-year period, the number of fusion procedures in all hospitals studied increased 55% (from 9,685 to 15,002 per year) while non-fusion procedures decreased 39% (from 12,344 to 7,574) [2]. Minimizing failure and complication rates is imperative for such a high volume and expanding surgery.

The importance of precision when inserting pedicle screws is best appreciated when analyzing the possible failures and complications associated with inaccuracy. Particularly, and the basis of this study, erroneous screw selection and/or placement could lead to intraoperative and postoperative injury. Neurologic, meningeal, bony, and/or vascular injuries can all occur secondary to misguided or improperly sized pedicle screws. Lonstein et al retrospectively reviewed imaging of 915 spinal fusions involving 4,790 pedicle screws (76.3% lumbosacral procedures). They found 2.4% of patients had complications attributed to the use of pedicle screws. These complications included nerve root irritation, screw breakage, pedicle fracture, and dural tear [3]. In a survey analysis of 617 spinal fusion surgeries where pedicle screws were utilized, Esses et al showed an incidence of screw misplacement in 5.2% and pedicle fracture in 2.3% of patients. In terms of postoperative complications, this same study showed 2.9% screw breakage as well as lower incidence of nerve root injury, screw loosening, and screw cutout or back out [4].

Additionally, insufficient pedicle screw fixation theoretically contributes to failure of spinal fusion and postoperative pseudoarthrosis, although this is heavily debated in the literature [5]. One retrospective review showed an incidence of pseudoarthrosis of 14% and iatrogenic instability of 5%; complications collectively referred to as Failed Back Surgery Syndrome (FBSS) [6]. The consequences of FBSS include patient dissatisfaction, continued back pain, and possible need for revision surgery.

Biomechanical studies have examined pedicle screw size and its relation to construct stability. One such study examined pullout strength of various pedicle screw diameters utilizing finite element analysis for 720 trials. The authors identify the expected finding that pedicle screws of larger diameter increase pull out strength as well as vertebral fixation strength while decreasing the stress around the screws [7].

Misenhimer et al studied pedicle diameter (PD) and maximum safe pedicle screw diameter (MSPSD) in cadaver models. After progressive and sequential loading of pedicles with increasingly larger screw diameter they found that plastic deformity of the pedicles preceded fracture or cutout when the screw was larger than the endosteal diameter or within 80% of the outer cortical diameter as measured by Computed Tomography (CT) scan. After fracture or screw cutout, there was no cortical purchase within the pedicles [8]. Another study by Yongjung and Lenke showed that with appropriate tapping of the pedicle, safe pedicle expansion up to 200% the internal pedicle diameter can be appreciated [9].

The surgical goal, therefore, is to insert the safest maximum sized pedicle screw for each pedicle. This customized approach theoretically increases the stability of the instrumentation construct while minimizing the risk of iatrogenic injury from pedicle fracture. Larger pedicle screws within the safe range for a given pedicle also translate to a decrease in screw pullout and screw breakage. The accompanying reduction in motion at the fusion site from building stronger constructs theoretically lead to less incidence of pseudoarthrosis as well.

While pre-operative planning with CT scan measurements may be the safest way to judge trajectory and maximal screw size, it is not standard practice for many spine surgeons. Commonly, spine surgeons utilize a preoperative radiographic assessment and/or intraoperative fluoroscopic assessment method

for screw selection. This practice involves heavy reliance on surgeon experience and ability to account for variations in image magnification. It also necessitates quality imaging, which can be highly variable based on patient body habitus, radiology technician skill, and patient positioning. Of note, navigated spinal instrumentation also allows direct measurement of PD and is one of the reasons this technique is increasing in popularity.

The goals of the present study were to investigate how height and weight correlated with pedicle diameter. We hypothesized that these routinely obtained, non-invasive measurements would provide an easily referenced data point that can aid in perioperative estimation of MSPSD. The analysis was two-tailed. First, we investigated whether height, weight, and BMI significantly correlated with PD in our diverse population. Previous studies have demonstrated positive correlation between some of these variables. One such study using digital caliper measurement of PD in cadavers showed that taller and heavier subjects had statistically significant larger PD [10]. A similar CT based study on a Turkish population demonstrated that transverse PD values are directly proportional to subject height [11]. In the second part of the analysis, we subdivided the study population to investigate both ends of the height spectrum. We evaluated the theoretical safety profiles of a range of pedicle screw sizes in taller and shorter subjects. To our knowledge, this is the first study to assess theoretical pedicle screw safety in this manner.

We previously reported on the significant difference in PD between different races and its utility in perioperative planning for posterior lumbar spinal fusion surgery [11]. Our large CT based anatomic study will further supplement the available anatomic data on pedicles and thus the preoperative radiographic and intraoperative fluoroscopic assessment methods for estimating MSPSD.

Methods

Approval from our institution's Investigational Review Board was obtained. A retrospective review of CT scans of the abdomen and pelvis that were performed over a two week period at seven hospitals within a single health system were analyzed. Using abdomen and pelvis studies rather than lumbar spine scans allowed for screening of a population of 270 patients with a wide height and weight range who presented with chief complaints not related to back pain.

Lumbar spine coronal images were used to obtain transverse outer cortical PD. Measurements were taken through the isthmus of left and right pedicles of all lumbar vertebrae. Using a standardized protocol allowed for the best comparison between patients despite the irregular shape of the pedicle. CT "Bone Window" formatting allowed for sharp contrast between cortices and soft tissue which further enhanced measurement accuracy.(Fig. 1).

Those excluded from the study were patients with prior lumbar laminectomy or fusion (with or without instrumentation), patients whose scans did not allow full visualization of all five lumbar segments, patients with lumbarized or sacralized segments, and patients with scoliosis. In total, 2,700 lumbar pedicles were measured.

Patient height, weight, and BMI as recorded on the visit that the CT scan was performed were recorded for all study patients. For all data analysis the average PD from left and right pedicle measurements at each level was used. Data was analyzed for correlation between height versus PD, weight versus PD, and BMI versus PD. A Pearson product-moment correlation coefficient was computed to assess the relationship between PD and each variable. We used a significance level of 0.01 (2-tailed)

Next, we analyzed both ends of the height spectrum in our data pool (“Taller Height” and “Shorter Height”), and MSPSD for each population was assessed. “Taller Height” subjects were 177.80 cm (70 in) and above and “Shorter Height” subjects were 157.48 cm (62 in) and below. We calculated the percentage of each group that could safely accommodate a range of pedicle screw sizes (4.0 mm to 8.0 mm). We intentionally used the smaller value of 80% of the outer cortical diameter (based on the Mesienhimer study) as our conservative estimate of MSPSD and cross-referenced our data for all lumbar vertebrae within these populations [8]. Significance of these findings was assessed using Fisher’s Exact Test (one-sided). All data analysis was carried out by a Senior Research Statistics Analyst.

Results

The mean height, weight, and BMI for our population were found to be 166.78 cm, 77.25 kg and 27.78 kg/m², respectively. Mean height, weight and BMI were reported with standard deviations, minimum and maximum values (Table 1). The mean PD for the entire population at each vertebral level were: L1- 7.34 mm, L2- 7.68 mm, L3- 9.18 mm, L4- 10.99 mm, and L5- 14.36 mm. The PD means at each level were reported along with standard deviations, minimum and maximum values (Table 2).

We found a positive correlation between height and PD as well as weight and PD at all lumbar vertebrae. However, we did not find a significant correlation between BMI and PD at any lumbar level (Table 3). The Pearson coefficient of determination was used to describe how much variance was due to height at each level. We found that at lumbar levels L1, L2, L3, and L4 there is a medium (>9.0%) explanation for variance in PD due to height ($R^2=.113$, $R^2=.099$, $R^2=.093$, $R^2=.102$, respectively). The explanation of PD variance due to height was found to be smaller (1.0-9.0%) at the fifth lumbar vertebra ($R^2=.070$).

When analyzing the effect of weight on PD using Pearson coefficient of determination, only small explanations of variance were found representing 3-4% of the PD variance at each lumbar spinal level. Interestingly, BMI explained almost 0% of the variation in PD.

Analysis of the “Taller Height” and “Shorter Height” groups showed the theoretical safety range of various pedicle screw sizes (4.0 to 8.0mm) at each lumbar spinal level (Figures 2-6). Using the conservative MSPSD of 80% of outer cortical pedicle diameter, there were statistically significant differences in the theoretical safety profiles between the “Taller Height” and “Shorter Height” groups for the majority of pedicle screw sizes at L1 through L3. (Tables 4-6). Due to the larger PD in both taller and shorter height populations at L4 and L5 (as compared to L1 through L3), large safety profiles were seen for most pedicle screw diameters at these levels; thus, statistically significant differences between the populations

at L4 and L5 were only seen for 8.0 mm screws at the L4 level. At L5, 100% of the “Taller Height” and “Shorter Height” subjects’ pedicles could safely accommodate pedicle screws up to 8.0 mm in diameter (Tables 7 & 8).

To provide some clinical perspective, we looked at the MSPSD that would be safe in 90% of our population at each level, in each group. The “Taller Height” group could safely accommodate up to 5.0 mm screws at L1 and L2, 6.0 mm screws at L3, and 8.0 mm screws at L4 and L5 90% of the time. In the “Shorter Height” group, the smallest analyzed screws size (4.0 mm) was found to be safe in only 89.74% of subjects. At L2 in this sub-population, 4.0 mm screws were found to be theoretically safe. At L3 and L4 the MSPSD in 90% of subjects increased to 5.5 mm and 6.5 mm, respectively. As mentioned, L5 pedicles in all patients in both sub-populations could safely accept up to 8.0 mm screws. (Tables 4-8).

Discussion

As mentioned, there are devastating complications that can be minimized by appropriate pedicle screw size selection. Since the lumbar spine pedicles show such inter-subject variability, an understanding of anatomic relationships can contribute to perioperative radiographic assessment by surgeons performing instrumented spinal fusion. Fortunately, there are multiple patient factors that can enhance the estimation of PD, and therefore MSPSD.

In this study we demonstrated both height and weight significantly correlated with PD, and BMI did not correlate with PD. Height explained a greater amount of the variability in PD at all lumbar vertebral levels. These findings support the prior studies Gulec [10].

While height and weight are helpful adjuncts, there is no universal rule for appropriately sizing pedicle screws. Analyzing the “Taller Height” and “Shorter Height” groups from our overall study population allowed for assessment of MSPSD for subjects on both ends of the height spectrum. The data provides theoretical safety profiles for a range of pedicle screw sizes in each of these sub-populations. Our findings suggest that taller patients (> 177.8 cm or 70 in) can more commonly accept larger diameter pedicle screws (without increased risk of pedicle fracture) than shorter patients (< 157.48 cm or 62 in). Due to the larger PD in the lower lumbar segments, surgeons can be more confident using larger pedicle screws at L4 and, especially, L5. These data help stress the importance of surgeon experience and judgment in safe pedicle screw size estimation.

In the authors’ opinions, the most accurate method for preoperative planning is use of CT measurements to judge trajectory and estimate MSPSD. As mentioned, this is not standard practice for many spine surgeons. For surgeons using radiographs for pedicle screw size estimation, height and weight are easily obtained, non-invasive measurements that can easily be referenced preoperatively and intraoperatively. It is important to note that these values alone are insufficient to safely select appropriate pedicle screw size. Combined with surgeon experience and other available anatomic data however, height and weight may allow for better and safer interpretations of proper screw size.

A major strength of this study was the large, diverse population pulled from multiple hospitals within a large health system. Our data was also obtained by a single observer which allowed for more standardized measurements. Confirmation by a more senior physician, served to enhance the inter-observer reliability.

One limitation of this study was that theoretical MSPSD is based on the assumption that the pedicle screw will be inserted into the center of the pedicle. Deviation in any direction brings the screw threads closer to the cortex and risks pedicle breach. Another limitation is that we used CT scans of the abdomen and pelvis rather than the lumbar spine. The benefit of this approach was that data was collected on a population of patients that presented with chief complaints unrelated to back pain, and therefore served to eliminate any anatomic variation due to pathology of the lumbar spine. However, it is possible that processes that cause back pain, such as degenerative disc disease, can cause changes in pedicle morphology that would be missed by our study design.

Expanding the pool of available anatomic data on lumbar pedicles can only serve to benefit spine surgeons who perform spinal fusion procedures. Further studies may be able to combine other non-invasive anatomic data to provide better estimation of MSPSD for each given pedicle in each given patient.

Conclusion

Height and weight showed the expected positive correlation with lumbar pedicle diameter in our large diverse population. These non-invasive measurements, more-so height, would be useful adjuncts to the experienced spine surgeon's estimation of maximum safe lumbar pedicle screw diameter.

Abbreviations

Computed Tomography (CT)

Maximum safe pedicle screw diameter (MSPSD)

Failed Back Surgery Syndrome (FBSS)

Declarations

Ethics Approval: Approval for this study was obtained from the Northwell Health Institutional Review Board prior to initiation of data collection

Availability of data and materials: The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Competing Interests: The authors declare that they have no competing interests.

Funding: No funding was obtained for this study

Authors' contributions: JL, JA, RS, MG, LL, GK, and KG all have made substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data; have been involved in drafting the manuscript or revising it critically for important intellectual content; given final approval of the version to be published. All authors read and approved the final manuscript.

References

1. Hitchon, Patrick W., Matthew D. Brenton, Andrew G. Black, Aaron From, Jeremy S. Harrod, Christopher Barry, Hassan Serhan, and James C. Torner. 2003. "In Vitro Biomechanical Comparison of Pedicle Screws, Sublaminar Hooks, and Sublaminar Cables." *Journal of Neurosurgery*99 (1 Suppl): 104–9.
2. Jancuska, Jeffrey M., Lorraine Hutzler, Themistocles S. Protopsaltis, John A. Bendo, and Joseph Bosco. 2016. "Utilization of Lumbar Spinal Fusion in New York State: Trends and Disparities." *Spine*41 (19): 1508–14.
3. Lonstein, J. E., F. Denis, J. H. Perra, M. R. Pinto, M. D. Smith, and R. B. Winter. 1999. "Complications Associated with Pedicle Screws." *The Journal of Bone and Joint Surgery. American Volume*81 (11): 1519–28.
4. Esses, S. I., B. L. Sachs, and V. Dreyzin. 1993. "Complications Associated with the Technique of Pedicle Screw Fixation. A Selected Survey of ABS Members." *Spine*18 (15): 2231–38; discussion 2238–39.
5. Raizman, Noah M., Joseph R. O'Brien, Kirsten L. Poehling-Monaghan, and Warren D. Yu. 2009. "Pseudarthrosis of the Spine." *The Journal of the American Academy of Orthopaedic Surgeons*17 (8): 494–503.
6. Waguespack A, Schofferman J, Slosar P, Reynolds J. Etiology of long-term failures of lumbar spine surgery. *Pain Med.* 2002 Mar;3(1):18-22. PubMed PMID: 15102214.
7. Matsukawa, Keitaro, Yoshiyuki Yato, Hideaki Imabayashi, Naobumi Hosogane, Yuichiro Abe, Takashi Asazuma, and Kazuhiro Chiba. 2016. "Biomechanical Evaluation of Fixation Strength among Different Sizes of Pedicle Screws Using the Cortical Bone Trajectory: What Is the Ideal Screw Size for Optimal Fixation?" *Acta Neurochirurgica*158 (3): 465–71.
8. Misenhimer, G. R., R. D. Peek, L. L. Wiltse, S. L. Rothman, and E. H. Widell Jr. 1989. "Anatomic Analysis of Pedicle Cortical and Cancellous Diameter as Related to Screw Size." *Spine*14 (4): 367–72.
9. Kim YJ, Lenke LG: Thoracic pedicle screw placement: free-hand technique . *Neurol India.* 2005, 53:512–19. 10.4103/0028-3886.22622
10. Güleç, A., B. K. Kaçira, H. Kütahya, H. Özbiner, M. Öztürk, Ç. S. Solbaş, and I. E. Gökmen. 2017. "Morphometric Analysis of the Lumbar Vertebrae in the Turkish Population Using Three-Dimensional Computed Tomography: Correlation with Sex, Age, and Height." *Folia Morphologica*76 (3): 433–39.

11. Albano, Joseph, Jonathon Lentz, Robert Stockton, Vincent DePalma, Michael Markowitz, Maximillian Ganz, Gus Katsigiorgis, and Kanwarpaul Grewal. 2019. "Demographic Analysis of Lumbar Pedicle Diameters in a Diverse Population." *Asian Spine Journal*, January. <https://doi.org/10.31616/asj.2018.0195>.

Tables

Table 1: Mean height, weight, and BMI for the study population (reported with standard deviations, minimum and maximum values).

	Mean	Standard Deviation	Min	Max
Height (cm)	166.78	9.44	142.24	198.1
Weight (kg)	77.25	20.67	38.6	170.8
BMI	27.78	6.76	15.56	61.24

Table 2: Mean PD for the study population at L1-L5 vertebra (reported with standard deviations, minimum and maximum values).

	Mean	Standard Deviation	Min	Max
L1	7.34	1.65	3.12	12.5
L2	7.68	1.57	4.28	13.88
L3	9.18	1.72	5.2	15.92
L4	10.99	1.79	5.78	17.26
L5	14.36	2.11	8.88	20.5

Table 3: Correlation of height weight and BMI to lumbar pedicle diameter.

		L1	L2	L3	L4	L5
Height	Pearson correlation	0.336*	0.314*	0.305*	0.32*	0.264*
	Sig. (2-tailed)	<.001	<.001	<.001	<.001	<.001
Weight	Pearson correlation	0.212*	0.182*	0.19*	0.187*	0.176*
	Sig. (2-tailed)	<.001	0.001	0.001	0.001	0.002
BMI	Pearson correlation	0.06	0.044	0.059	0.051	0.068
	Sig. (2-tailed)	0.294	0.44	0.298	0.371	0.233

Table 4

L1	Screw Size (mm)	Required PD (mm)	Taller Height >177.8cm (n=40)		Shorter Height <157.48cm (n=39)		p
			# Unsafe PD	% Safe PD	# Unsafe PD	% Safe PD	
	4	5	0	100.00	4	89.74	0.0547
	4.5	5.625	2	95.00	7	82.05	0.0713
	5.00	6.25	3	92.50	9	76.92	0.052
	5.50	6.875	5	87.50	23	41.03	*0.0001
	6.00	7.5	9	77.50	30	23.08	*0.0001
	6.50	8.125	15	62.50	34	12.82	*0.0001
	7.00	8.75	20	50.00	36	7.69	*0.0001
	7.50	9.375	23	42.50	39	0.00	*0.0001
	8.00	10	31	22.50	39	0.00	*0.0013

Table 5

L2	Screw Size (mm)	Required PD (mm)	Taller Height >177.8cm (n=40)		Shorter Height <157.48cm (n=39)		p
			# Unsafe PD	% Safe PD	# Unsafe PD	% Safe PD	
	4	5	0	100.00	1	97.44	0.4937
	4.5	5.625	0	100.00	4	89.74	0.0547
	5.00	6.25	1	97.50	6	84.62	0.0503
	5.50	6.875	5	87.50	14	64.10	0.0143
	6.00	7.5	8	80.00	23	41.03	0.0004
	6.50	8.125	14	65.00	31	20.51	0.0001
	7.00	8.75	17	57.50	37	5.13	0.0001
	7.50	9.375	24	40.00	38	2.56	0.0001
	8.00	10	31	22.50	39	0.00	0.0013

Table 6

L3		Taller Height >177.8cm (n=40)		Shorter Height <157.48cm (n=39)		
Screw Size (mm)	Required PD (mm)	# Unsafe PD	% Safe PD	# Unsafe PD	% Safe PD	p
4	5	0	100.00	0	100.00	1
4.5	5.625	0	100.00	1	97.44	0.4937
5.00	6.25	0	100.00	1	97.44	0.4937
5.50	6.875	0	100.00	3	92.31	0.1156
6.00	7.5	1	97.50	8	79.49	*0.013
6.50	8.125	5	87.50	13	66.67	*0.0254
7.00	8.75	9	77.50	19	51.28	*0.0135
7.50	9.375	13	67.50	29	25.64	*0.0002
8.00	10	17	57.50	34	12.82	*0.0001

Table 7

L4		Taller Height >177.8cm (n=40)		Shorter Height <157.48cm (n=39)		
Screw Size (mm)	Required PD (mm)	# Unsafe PD	% Safe PD	# Unsafe PD	% Safe PD	p
4	5	0	100.00	0	100.00	1
4.5	5.625	0	100.00	0	100.00	1
5.00	6.25	0	100.00	1	97.44	0.4937
5.50	6.875	0	100.00	1	97.44	0.4937
6.00	7.5	0	100.00	2	94.87	0.2406
6.50	8.125	0	100.00	3	92.31	0.1156
7.00	8.75	1	97.50	4	89.74	0.1715
7.50	9.375	3	92.50	9	76.92	0.052
8.00	10	4	90.00	14	64.10	*0.006

Table 8

L5		Taller Height >177.8cm (n=40)		Shorter Height <157.48cm (n=39)		
Screw Size (mm)	Required PD (mm)	# Unsafe PD	% Safe PD	# Unsafe PD	% Safe PD	p
4	5	0	100.00	0	100.00	1
4.5	5.625	0	100.00	0	100.00	1
5.00	6.25	0	100.00	0	100.00	1
5.50	6.875	0	100.00	0	100.00	1
6.00	7.5	0	100.00	0	100.00	1
6.50	8.125	0	100.00	0	100.00	1
7.00	8.75	0	100.00	0	100.00	1
7.50	9.375	0	100.00	0	100.00	1
8.00	10	0	100.00	0	100.00	1

Tables 4-8: Safety profiles for pedicle screws sized 4.0 to 8.0 mm in diameter in “Taller Height” and “Shorter Height” groups. P-values represent significant differences between the two groups (denoted by an asterisk). L1, L2, L3, L4, and L5 are show in Table 4, Table 5, Table 6, Table 7, and Table 8, respectively.

Figures

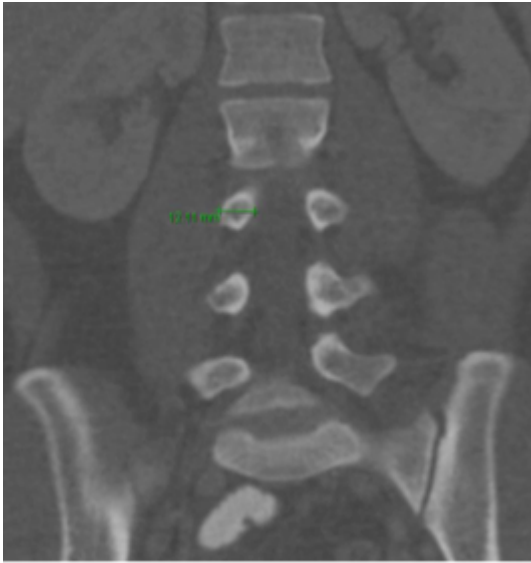


Figure 1

Sample measurement of a right L3 pedicle diameter. The transverse outer cortical pedicle diameter measures 12.11 mm.

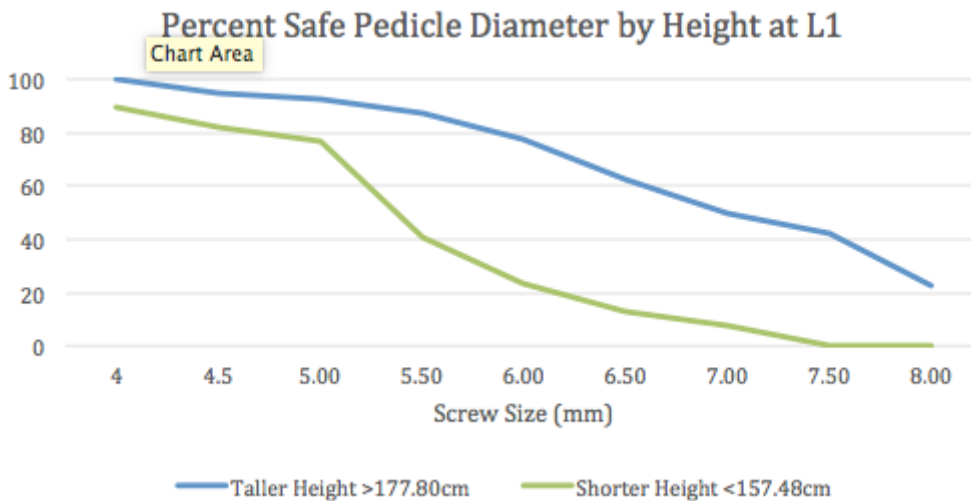


Figure 2

Graphs depict the theoretical safety profiles for a range of pedicle screw sizes in subjects from the “Taller Height” and “Shorter Height” populations. Safety is defined as screw diameter less than or equal to 80%

of the measured outer cortical pedicle diameter. L1, L2, L3, L4, and L5 are shown in Figures 2, 3, 4, 5, and 6, respectively.

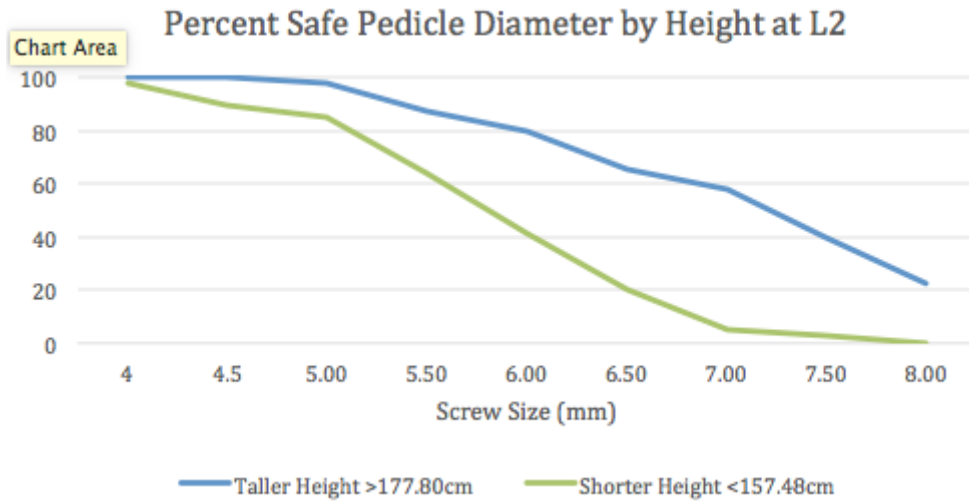


Figure 3

Graphs depict the theoretical safety profiles for a range of pedicle screw sizes in subjects from the “Taller Height” and “Shorter Height” populations. Safety is defined as screw diameter less than or equal to 80% of the measured outer cortical pedicle diameter. L1, L2, L3, L4, and L5 are shown in Figures 2, 3, 4, 5, and 6, respectively.

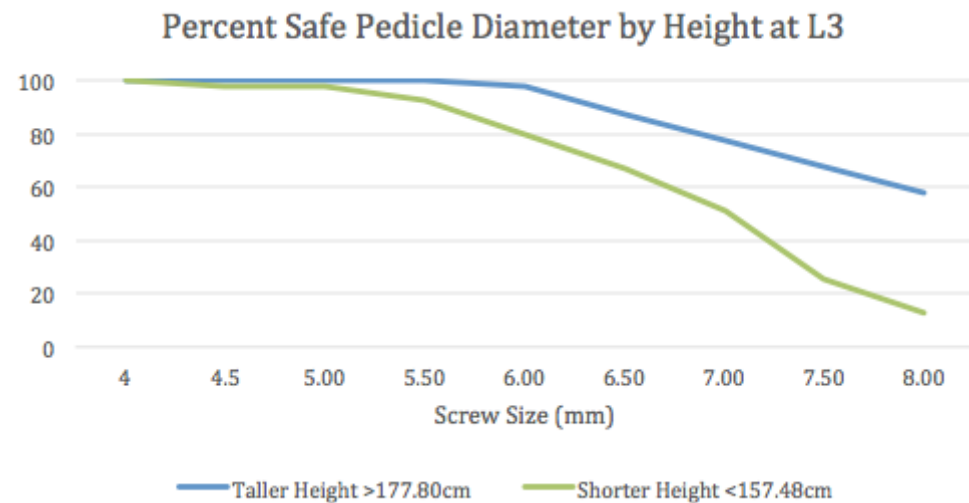


Figure 4

Graphs depict the theoretical safety profiles for a range of pedicle screw sizes in subjects from the “Taller Height” and “Shorter Height” populations. Safety is defined as screw diameter less than or equal to 80% of the measured outer cortical pedicle diameter. L1, L2, L3, L4, and L5 are shown in Figures 2, 3, 4, 5, and 6, respectively.

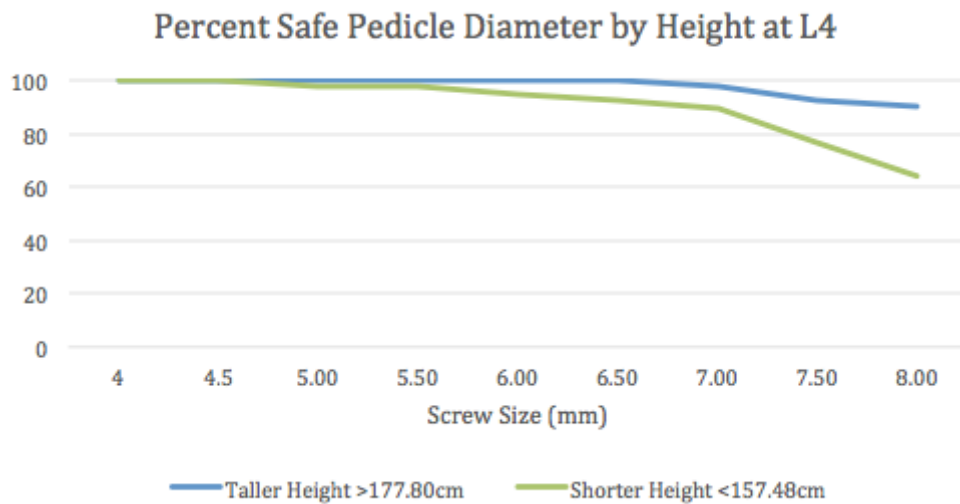


Figure 5

Graphs depict the theoretical safety profiles for a range of pedicle screw sizes in subjects from the “Taller Height” and “Shorter Height” populations. Safety is defined as screw diameter less than or equal to 80% of the measured outer cortical pedicle diameter. L1, L2, L3, L4, and L5 are shown in Figures 2, 3, 4, 5, and 6, respectively.

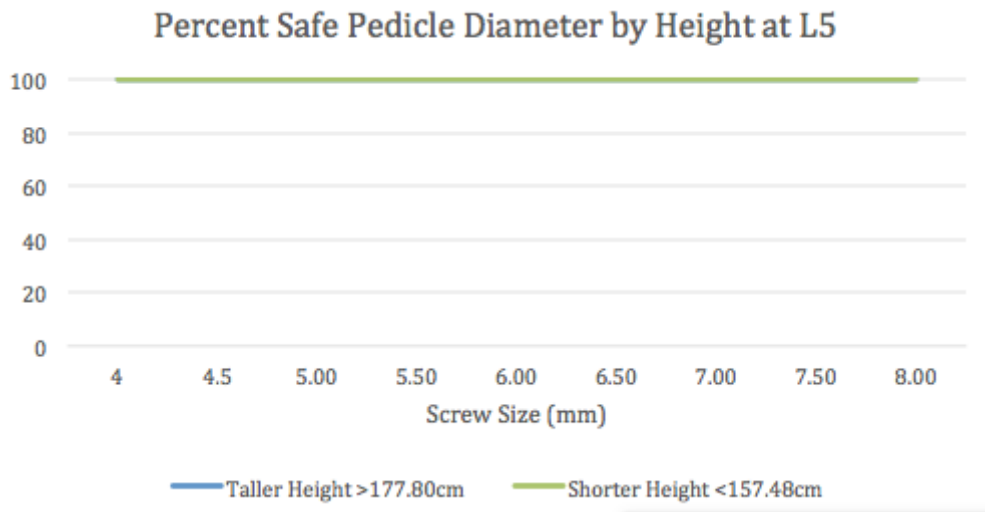


Figure 6

Graphs depict the theoretical safety profiles for a range of pedicle screw sizes in subjects from the “Taller Height” and “Shorter Height” populations. Safety is defined as screw diameter less than or equal to 80% of the measured outer cortical pedicle diameter. L1, L2, L3, L4, and L5 are shown in Figures 2, 3, 4, 5, and 6, respectively.