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Pullout performance comparison of pedicle screws based on cement application and design parameters

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Abstract

Pedicle screws are the main fixation devices for certain surgeries. Pedicle screw loosening is a common problem especially for osteoporotic incidents. Cannulated screws with cement augmentation are widely used for that kind of cases. Dual lead dual cored pedicle screw has already given promising pullout values without augmentation. This study concentrates on the usage of dual lead dual core with cement augmentation as an alternative to cannulated and standard pedicle screws with cement augmentation. Five groups (dual lead dual core, normal pedicle screw and cannulated pedicle screw with augmentation, normal pedicle screw, dual lead dual cored pedicle screw) were designed for this study. Healthy bovine vertebrae and synthetic polyurethane foams (grade 20) were used as embedding test medium. Test samples were prepared in accordance with surgical guidelines and ASTM F543 standard testing protocols. Pullout tests were conducted with Instron 3300 testing frame. Load versus displacement values were recorded and maximum pullout loads were stated. The dual lead dual cored pedicle screw with poly-methyl methacrylate augmentation exhibited the highest pullout values, while dual lead dual cored pedicle screw demonstrated similar pullout strength as cannulated pedicle screw and normal pedicle screw with poly-methyl methacrylate augmentation. The dual lead dual cored pedicle screw with poly-methyl methacrylate augmentation can be used for osteoporotic and/or severe osteoporotic patients according to its promising results on animal cadaver and synthetic foams.

Keywords

Pedicle screw, pullout strength, dual lead dual cored pedicle screw, cannulated screw, cement augmentation

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Introduction

Pedicle screws (PSs) are used in several spinal surgeries to fix a certain segment of vertebrae. Screw loosening with pullout is the main challenge. Especially for the osteoporotic cases, reducing the risk of pullout failure is crucial. For this reason, several studies were completed by previous researchers. Design parameters were changed to increase the pullout strength of PSs.[1] Screw design studies continued with thread design. It is stated that greater flank overlap area (FOA) increases the pullout strength. In this manner, several screw types were designed and tested with higher FOA.[2,3] However, increasing FOA decreased the inner diameter of the screw which may cause torsional failures and screw breakage. As an alternative, conical cored screws were designed to balance the torsional strength drawbacks. For normal screws, conical core became golden standard as a design parameter.[4]

In addition to different core designs, thread design such as dual lead is an advantage for a PS by providing faster insertion time which is vital.[5] The idea of dual lead dual cored (DLDC) screws had already been tested by Yaman et al.[6] as the state of the art design parameter. They studied DLDC screws on synthetic foams and ovine vertebrae. Their study proved that DLDC screws have higher pullout strength than normal pedicle

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Table 1. Test groups.

Group	Pedicle screw type	Augmentation technique	Embedding medium	Number of tested specimen
1	NPS	N/A	PU foam (grade 20)	5
2	NPS	Before insertion of PS	PU foam (grade 20)	5
3	CPS	After insertion of PS	PU foam (grade 20)	5
4	DLDC PS	N/A	PU foam (grade 20)	5
5	DLDC PS	Before insertion of PS	PU foam (grade 20)	5
6	NPS	N/A	Animal cadaver	5
7	NPS	Before insertion of PS	Animal cadaver	5
8	CPS	After insertion of PS	Animal cadaver	5
9	DLDC PS	N/A	Animal cadaver	5
10	DLDC PS	Before insertion of PS	Animal cadaver	5

NPS: normal pedicle screw; PU: polyurethane; DLDC PS: dual lead dual cored pedicle screw.

screws (NPSs). However, the cement application of a dual cored screw has not been investigated before. It is obvious that using a dual core significantly increases the pullout performance of screw. The underlying physics behind this is the greater FOA at the distal side of the screw which increases the amount of bone material between thread pitches. On the proximal side of the screw, the less pitch height of PS increases the holding strength on cortical bone of the pedicle. This is an important result because 60% of the pullout strength of the PS is provided by the pedicle.[7] The pedicle part of the vertebrae can be defined as a tube covered with cortical bone and filled with trabecular bone. This design uses the advantage of both trabecular bone including vertebral body's structure and the advantage of compact cortical bone's holding power.

Expandable pedicle screws (EPSs) were also designed to increase the initial strength of screws.[8,9] On the other hand, revision surgeries are problematic for the EPSs due to the bone in-growth through the expanded fins of expandable screws.[10]

After the invention of cement augmentation, the usage of cannulated screws had been taken place for osteoporotic incidents.[11] Design studies were also conducted to increase the pullout strength of cannulated screws.[12] Several cement types were also investigated previously.[13] Chen et al.[14] studied the side holes of cannulated screws to reduce the risk of cement leakage to the spinal canal without reducing the holding strength. According to this, side holes were started to be placed close to the distal tip of the screw. However, this reduced the cement exudation for the cannulated screw.

To increase the effect of cement on such applications, NPSs were used with cement. In this application technique, after the tapping, cement is injected through the pedicle with the aid of appropriate cement injection tool. Then the screw is inserted to the pedicle. After the hardening of cement, the structure becomes rigid enough. Chen et al.[15] studied the comparison of cannulated screws and normal screws with cement application. Chao et al.'s[16] study cited the advantages of prefilling cement material and approved that there is no extra risk of leakage to the spinal canal. This is an encouraging study on the usage of NPSs with cement for such cases including low bone mineral density.

In this study, as an advantageous screw design, DLDC screws were used with cement and compared with both normal screws and cannulated screws on synthetic foam materials and bovine vertebrae. The aim of this study was to show that using DLDC screws with cement application can withstand the higher pullout loads as cannulated screws.

Experimental procedure

Design parameters

The test groups were divided into five as follows: NPSs, DLDC PSs, NPSs with poly-methyl methacrylate (PMMA) augmentation, DLDC PSs with PMMA augmentation, and cannulated pedicle screw (CPS) with PMMA augmentation. These groups can be seen in Table 1. The PSs were all polyaxial and manufactured by Osimplant Medical Devices (Ankara, Turkey), having 7.5 mm diameter and 50 mm length. NPSs were conical cored. CPSs had a cannula and two slots at the proximal side of the screw, which allow cement augmentation after screw insertion. DLDC PSs were previously designed[6] as having two different core diameters to use the advantage of cortical and cancellous bone and double lead to have lesser insertion time. These three different PS designs can be seen in Figure 1.

Embedding medium

To test five different applications of PS, 13 healthy bovine vertebrae and 25 polyurethane (PU) blocks were used as test medium. PU blocks (Grade 20) which contain polyol and polyisocyanate were produced and characterized in our clinical biomechanics laboratory according to ASTM F1839.[17] The blocks were manufactured in cube shape, having $5\,cm \times 5\,cm \times 5\,cm$ dimensions.

The animal cadavers were supplied from Turkish Meat and Milk Board. The vertebrae were obtained from female healthy calves aged averagely 2 years. The

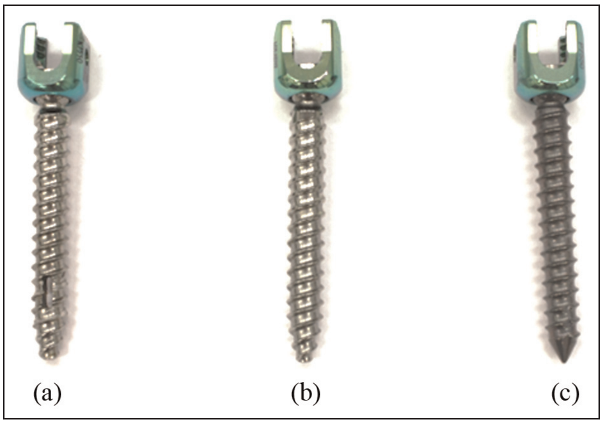

Figure 1. (a) Cannulated, (b) dual lead dual cored, and (c) normal pedicle screw designs.

specimens were then carefully dissected from surrounding tissue for the tests.

Application technique

The PU blocks had pilot holes having 40 mm depth and 5 mm diameter at the center of the foams. Non-augmented PSs and CPSs were inserted directly through the blocks.

For augmentation process, PMMA was chosen as a cement material which increases the holding strength of PS significantly and has been shown as a gold standard.[5] Cement powder and monomer were mixed together until they become liquid enough within the limits of curing time for screw insertion. This mixture was filled into a 10-mL syringe, and for augmented groups, each specimen was injected with 2 mL of cement.

PMMA was injected through the cannula of CPS. On the other side, cement was directly augmented through the pilot hole for augmentation of DLDC PSs and NPSs. Once the pilot holes were filled with cement, the screws were inserted. After careful dissection of healthy thoracic and lumbar bovine vertebrae, the same procedure was applied for the animal cadaver tests. All screws were inserted with free hand technique by the same surgeon for both animal cadaver and synthetic bone-like material. Cement application techniques both before and after insertion of the PS can be seen in Figure 2.

Imaging

After test preparations, the anteroposterior (AP) and oblique radiographs of one sample from each group were taken to examine the perforation of the screw and cement distribution before and after tests. The AP and oblique radiographs of a group on bovine vertebrae can be seen in Figure 3. All radiographs were taken with the aid of Shimadzu (Japan) RADspeed X-Ray machine placed in the Yenimahalle Education and Research Hospital, Ankara.

Pullout tests

After radiographic imaging, axial pullout tests were conducted considering ASTM F543[18] standards. The PSs were pulled out with Instron 3300 testing frame (UK). The crosshead speed was 5 mm/min, while maximum load of the machine is 50 kN. While the PS was subjected to axial load, load–displacement values were recorded and plotted. The test apparatus of pullout tests can be seen in Figure 4.

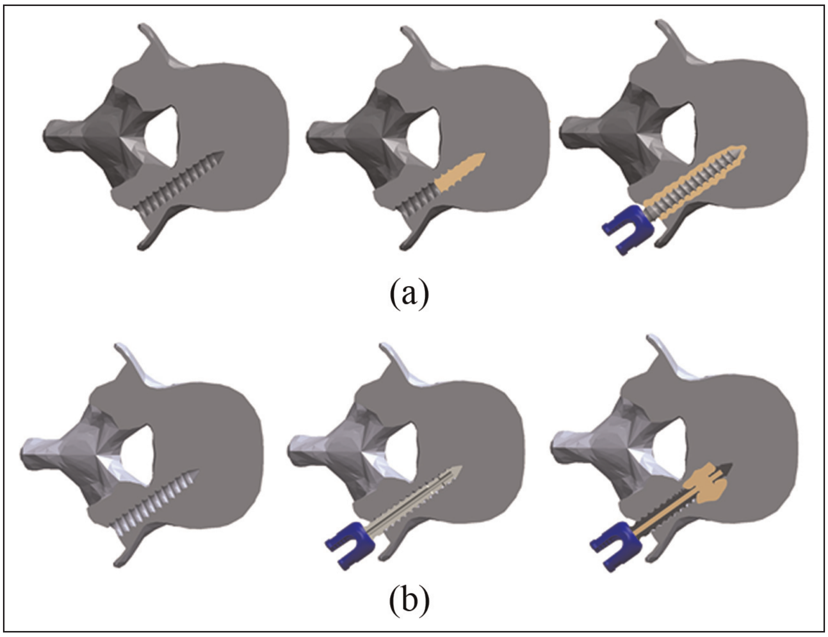

Figure 2. Cement application techniques both (a) before and (b) after insertion of the PS.

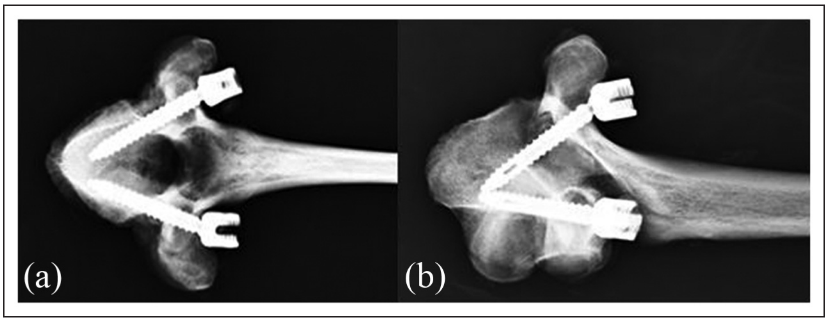

Figure 3. (a) Transverse and (b) oblique radiographs of bovine vertebrae inserted with pedicle screws.

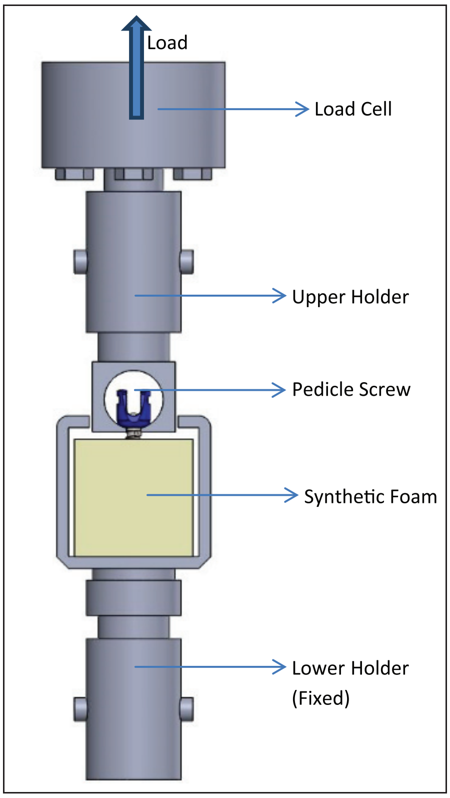

Figure 4. Test apparatus of pullout tests.

Statistical analyses

To evaluate the difference between those five groups (NPS without cement application, DLDC PS without cement application, NPS with cement application, CPS with cement application, and DLDC PS with cement application) embedded into two different materials, the maximum pullout values of each specimen were determined from load–displacement curves. The mean pullout value was then calculated for each group. Mean pullout loads were statistically analyzed with unpaired two-tailed Student t-tests. The difference between groups for $p < 0.05$ was accepted as significant.

Experimental results

The mean pullout values and standard deviations are given in Table 2. To compare the results between tested groups, bar graphs can be seen in Figure 5. For each group, the pullout tests were repeated five times and load–displacement curves were obtained. Afterward, the load–displacement curve which reflects the mean of all those five samples was plotted for each group. The comparison of all mean load–displacement curves can be seen in Figure 6. Additionally, the p values which show whether the difference between groups is significant are given in Table 3.

On synthetic foams, DLDC PS with PMMA augmentation showed the highest pullout strength with 2895 N. This value was significantly higher ($p < 0.05$) than all other groups (NPS, NPS with PMMA, CPS with PMMA, and DLDC PS). Second highest pullout value was provided by PMMA augmented NPS with 2024 N, which is 30% lower than the DLDC PS with PMMA augmentation ($p = 0.00592$).

DLDC PS followed the PMMA augmented NPS with 1979 N, which is significantly lower ($p = 0.00178$) than the DLDC PS with PMMA augmentation.

Table 2. Mean pullout and standard deviation values of test groups.

Groups	Synthetic foam		Bovine vertebrae	
	Mean pullout value (N)	Standard deviation	Mean pullout value (N)	Standard deviation
NPS	1437	61.5	846.3	71
NPS with PMMA	2024	148.3	2337.6	260.2
CPS with PMMA	1335.3	21.6	2461.3	668.4
DLDC PS	1978.7	163.4	2310.7	821.6
DLDC PS with PMMA	2895.3	352.3	3917.3	541

NPS: normal pedicle screw; DLDC PS: dual lead dual cored pedicle screw; PMMA: poly-methyl methacrylate.

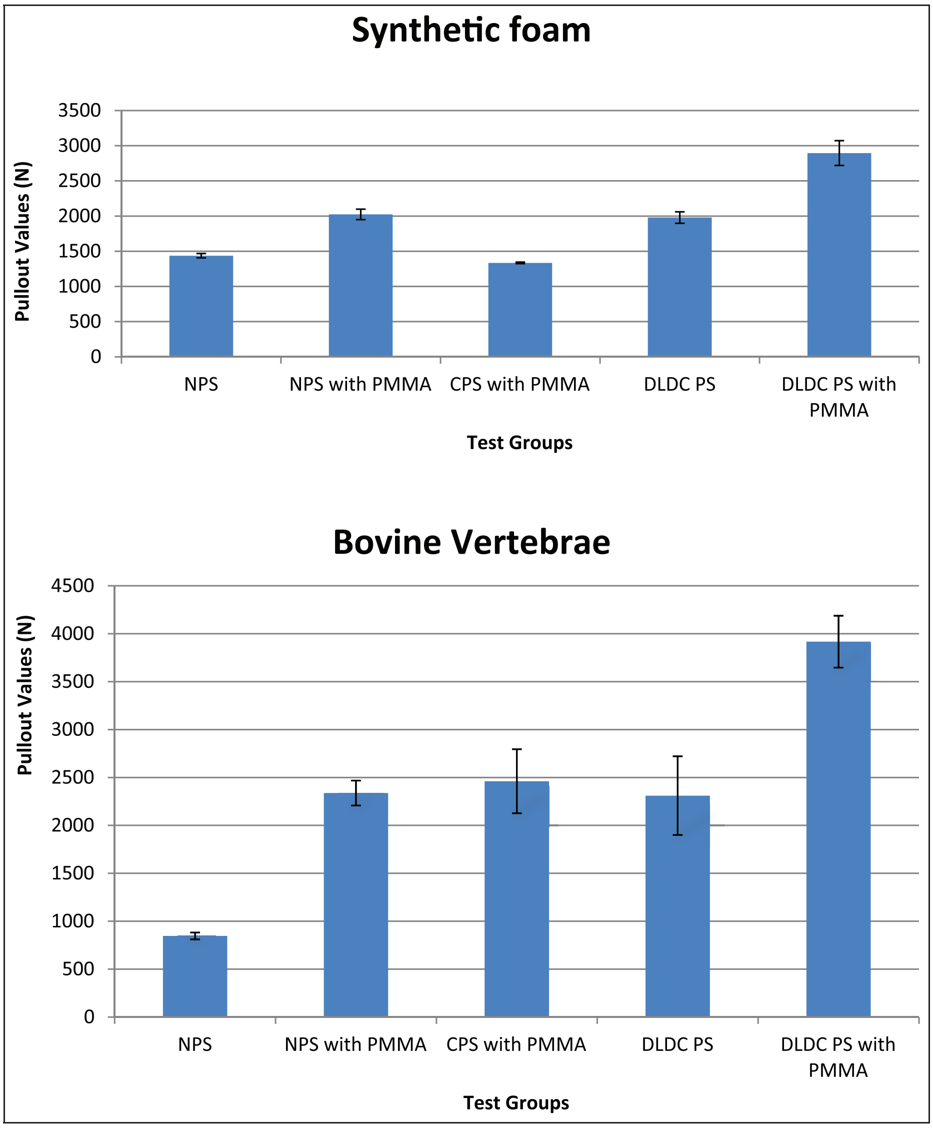

Figure 5. Mean pullout values with standard variation bars for tested groups.

Although PMMA augmented NPS demonstrated slightly higher holding strength than DLDC PS, the difference between these groups was not significant ($p = 0.17014$). Standard PS's mean pullout value was 1437 N, which is significantly lower than DLDC PS with PMMA, NPS with PMMA, and DLDC PS having p values of 0.00068, 0.00056, and 0.00656, respectively. As a result, NPS could only provide the 72% holding strength of a DLDC PS. Finally, cannulated screw showed the lowest pullout strength with 1335 N. This value is also significantly lower than DLDC PS with PMMA ($p = 0.00107$), NPS with PMMA ($p = 0.00017$), and DLDC PS ($p = 0.00242$). However, the mean pullout of CPS with PMMA was not significantly different from NPS.

On bovine vertebrae, DLDC PS with PMMA augmentation also showed the highest performance than the other four groups with 3917 N, and this value was significantly higher than all other groups. Second, CPS with PMMA augmentation showed 2461 N, which is 37% lower than PMMA augmented DLDC PS. NPS with PMMA augmentation and DLDC PS followed the CPS with 2337 and 2310 N mean pullout strength, respectively. CPS ($p = 0.03336$), NPS with PMMA ($p = 0.02431$), and DLDC PS ($p = 0.04020$) provided significantly lower pullout strength than DLDC PS with PMMA. However, there was no significant difference between those three groups (CPS vs DLDC PS $p = 0.76930$, CPS vs NPS with PMMA $p = 0.98915$, NPS with PMMA vs DLDC PS $p = 0.73938$). The lowest pullout strength was demonstrated by NPS with 846 N. This pullout value is significantly lower than DLDC PS with PMMA ($p = 0.00301$), CPS with PMMA ($p = 0.00812$), NPS with PMMA ($p = 0.00001$), and DLDC PS ($p = 0.04145$). Consequently, NPS showed 63% lower pullout strength than DLDC PS on bovine vertebrae.

DLDC PS, NPS with PMMA, and CPS with PMMA showed similar pullout strengths with 2310, 2337, and 2461 N, respectively. These three groups demonstrated significantly higher pullout strength than NPS with 846 N.

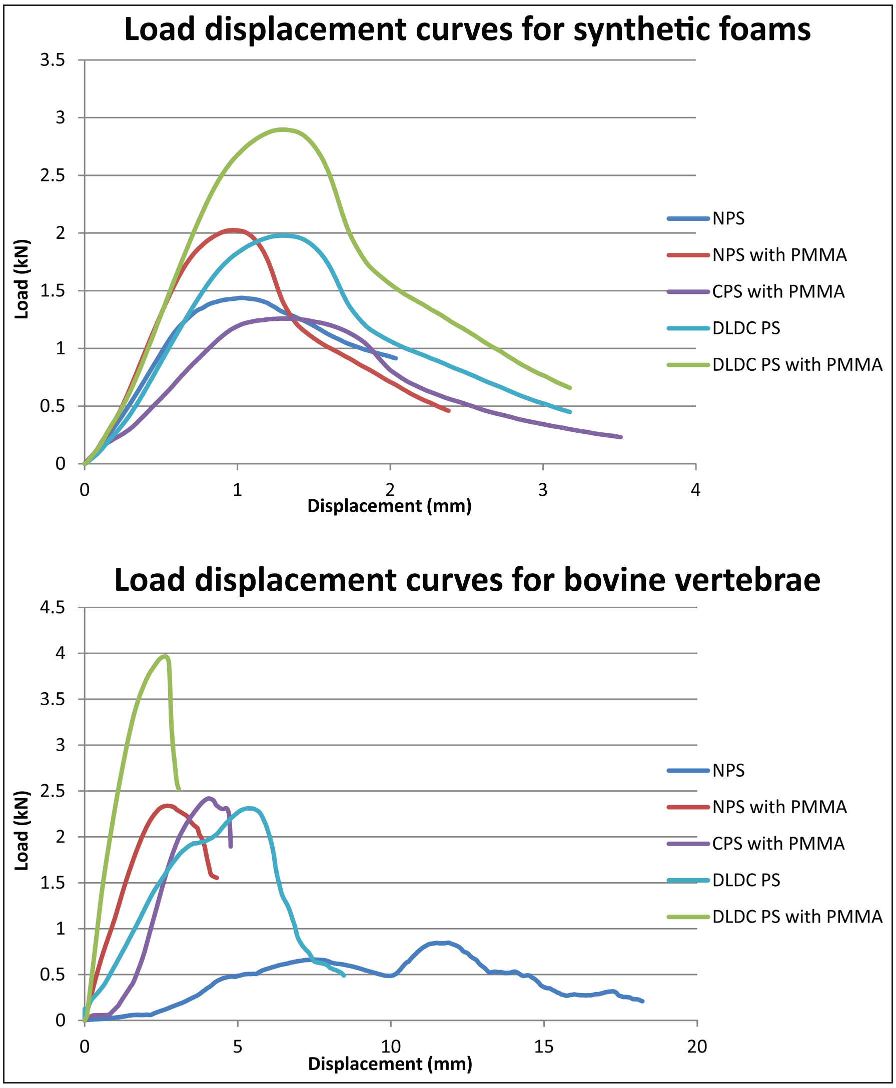

Figure 6. Load–displacement curves for tested groups.

Table 3. P values between test groups.

Test groups	Synthetic foam	Bovine vertebrae
NPS versus NPS with PMMA	0.00056*	0.00001*
NPS versus CPS with PMMA	0.22058	0.00812*
NPS versus DLDC PS	0.00656*	0.04145*
NPS versus DLDC PS with PMMA	0.00068*	0.00301*
NPS with PMMA versus CPS with PMMA	0.00017*	0.98915
NPS with PMMA versus DLDC PS	0.17014	0.73938
NPS with PMMA versus DLDC PS with PMMA	0.00592*	0.02431*
CPS with PMMA versus DLDC PS	0.00242*	0.76930
CPS with PMMA versus DLDC PS with PMMA	0.00107*	0.03336*
DLDC PS versus DLDC with PMMA	0.00178*	0.04020*

DLDC PS: dual lead dual cored pedicle screw; PMMA: poly-methyl methacrylate.
*Significant difference with $p < 0.05$.

Discussion

Holding strength of a PS is crucial especially for osteoporotic incidents.[19,20] Researchers tried to increase the holding strength of a PS by several screw designs such as different core geometries[4,21] and thread designs.[2] However, it is not always possible to provide enough strength with only PS design for the patients who have lower bone mineral densities. Hence, cement augmentation of PSs is widely used for spinal surgeries. Studies agreed on the significant effect of PMMA augmentation on PS's pullout strength.[14–16]

A CPS is designed to allow cement augmentation through its cannula, while a solid PS can be augmented before screw insertion. Cannulated screws can decrease the risk of cement leakage into the spinal canal by allowing the cement exudation only from the distal tip of the PS. On the other hand, for severely osteoporotic incidents, it could be hard to obtain enough stability with cementing only the distal part of the screw. Hereby, augmentation of PS before or after screw insertion can be chosen according to case.

These two augmentation types were already investigated by Chao et al.[16] and Chen et al.[15] Chao et al.[16] tested the pullout strength of cement augmentation before and after the screw insertion. They showed that the prefilled PSs showed higher pullout strength and lower extraction torque, which is an important result for revision surgeries. Likewise, Chen et al.[15] tested solid screws with prefilled augmented and cannulated screws with augmentation after insertion of the screw. Solid screws showed significantly higher pullout strength than cannulated screws. The main aim of this study is to investigate the pullout performance of DLDC screws with and without cement augmentation as an alternative to cement augmented cannulated and standard PSs.

The prior properties of a DLDC PS were already investigated by Yaman et al.[6] on PU foams and ovine vertebrae. Their study proved that DLDC screws have higher pullout strength than NPS. However, the cement application of a dual cored screw has not been investigated before.

Additionally, the pullout strengths of DLDC PS with and without augmentation, CPS, NPS with PMMA augmentation, and NPS (as a control group) were compared with each other to see the design effect of non-augmented and augmented DLDC PS in this study. Consequently, the results showed that DLDC PS with PMMA augmentation showed significantly higher pullout strength than all other groups for both synthetic foams and bovine vertebrae. The underlying reason of such high pullout strength provided by augmented DLDC PS is that DLDC PS has greater FOA at the distal part of the screw. Therefore, this allows the screw to be filled with more cement.

In addition, DLDC PS demonstrated promising results with its prior design advantages as CPS with PMMA and NPS with PMMA augmentation for both embedding mediums, which is an important result when the cement leakage would be taken into account. Non-augmented NPS showed the lowest pullout strength for both groups, as expected.

On synthetic foams, CPS with PMMA augmentation showed results similar to NPS. It is an unexpected result that the CPS showed insignificantly lower pullout strength than NPS without augmentation. However, during perforation of the CPS through embedding medium, the cannula is filled with the embedding material. In other words, while twisting the screw through the foam, the fenestrated parts were stopped up with PU foam. On the application of cement through the cannula, the injection tool pressurizes the cement. However, the cement pressure is still not enough to open the stopped up holes. This leaves the system in a non-cement augmented stage. This phenomenon was not seen on bovine samples.

NPS with PMMA augmentation was studied by Bostan et al.[22] on calf vertebrae with PSs having 0.5 mm smaller core diameter (6 mm) and showed 2163 N pullout strength. Milcan et al.[23] stated that NPS with PMMA augmentation demonstrated 2550 N pullout strength on bovine vertebrae. Besides, NPS with PMMA provided 2797 N holding strength at Renner et al.'s study.[24] Our results about NPS with cement augmentation (2338 N with 6.5 mm cored PS) are parallel with the values stated in the literature. When all these studied pullout strengths are considered, it is obvious that DLDC PS with PMMA augmentation (3917 N) provides 36% higher pullout strength than NPS with PMMA augmentation on bovine vertebrae. The holding strength provided by DLDC PS with PMMA (3917 N) is even higher than an EPS (2873 N) that was investigated by Lei et al.[25]

Furthermore, as the most important result of this study, DLDC PS without augmentation could provide as high pullout strength as CPS and NPS with PMMA augmentation. Therefore, to avoid the risk of cement leakage, one can prefer DLDC screw without augmentation to CPS and NPS with cement augmentation on healthy cases.

Limitations to study

This study provided the pullout strength of DLDC screws with and without augmentation on healthy animal vertebrae and synthetic foams. The usage of this PS on osteoporotic cases could be a great future work. Additionally, it is important to see the cement distribution inside the vertebral body. The finite element analyses of cement distribution inside the vertebral body could be an important future work of this study. This study compared the initial strengths of the systems. Comparing the cyclic toggling effect may also be an interesting future study.

Conclusion

In summary, results of this study can be considered as follows:

1. PMMA augmentation both before and after screw insertion significantly increases the pullout strength of a PS.
2. DLDC PSs without cement augmentation can provide enough pullout strength as CPS and NPS with

PMMA augmentation on healthy animal vertebrae and PU blocks.
3. Considering its high pullout values, DLDC PS with PMMA augmentation could be an alternative to EPS for osteoporotic and severely osteoporotic incidents.

Declaration of conflicting interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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