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Possible usage of cannulated pedicle screws without cement augmentation

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Abstract.
BACKGROUND: The use of pedicle screws is becoming increasingly popular for spinal surgery practice as the technology advances. Screw pullout due to bone quality and loading conditions is one of the most common problems observed after pedicle screw fixation. Several solutions were studied to prevent screw pullout. These can be investigated under three main categories: screw design, expandable screws and cement augmentation.
OBJECTIVE: This study aimed to investigate the pullout performance of cannulated screws without cement augmentation on synthetic foams.
METHODS: Artificial fusion process for PU is described and validated in our previous studies. For this study six newly designed cannulated pedicle screws were artificially fused to PU foam and pullout test were conducted according to ASTM F543 standard testing protocols.
RESULTS: According to the results of post-fusion pullout tests, worst performed cannulated screw design was S3H on healthy bone simulating PU foam. However, pullout strength of unilaterally three holes including (S3H) design was purchased with two times higher loads when compared to control group. Solid cored screws were purchased with 671 N where this value was 1450 N for S3H design.
CONCLUSIONS: This study provided that using cannulated pedicle screws without cement augmentation for the cases with healthy bone can be a reliable alternative to classical screws. To the knowledge of the authors this is the first post-fusion study investigating cannulated pedicle screws without cement augmentation.

Keywords: Cannulated pedicle screw, pullout, cement augmentation, post-fusion

1. Introduction

Pedicle screw insertion is a very common fixation method used for spinal deformities, tumors, vertebral fractures, vertebral infections and degeneration [1]. Bone quality directly effects the bone fractures. Low bone mineral density is more prone to fracture. Even smaller loads can cause bone fractures. Besides, healthy bones (higher bone mineral density) can also be fractured when exposed to higher loads. Both of the broken cases can be fixed and stabilized with pedicle screws.

Screw pullout is one of the most common problem following spinal pedicle screw instrumentation. Several solutions were studied to prevent screw pullout. These can be investigated under three main categories: screw design, expandable screws and cement augmentation [2–12]. Design studies on screw core geometry (cylindrical or conical), number of threads, flank overlap area, pitch diameter, dual lead and dual core were investigated by researchers.

Expandable screw seems to be more advantageous than most of the screw types when the comparison carried out on primary biomechanical strength. The contra conical geometry of the screw body after expansion is the most remarkable advantage that offered by expandable screws. However, the most critical challenge on the usage of expandable screw is revision surgeries. Revision became quite impossible due to the new bone

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formation between the expanded screw tip after fusion [8].

Cannulated screws were also studied as alternatives of solid cored or expandable screws. Cement types, position and numbers of radial holes, cement injection technique were also investigated to increase the pullout performance especially for osteoporotic vertebrae. Most of the works focused on the usage of two types of cement. One is calcium based [9, 19–22] and the other is poly-methyl-meta-acrylate (PMMA) [9,13–15]. Researchers have found out that screws with Ca phosphate injection had 3 times higher pullout strength, compared to screws without cement augmentation [16].

Some researchers combined expandable screws and cement augmentation in their studies [6, 15, 17]. Researches indicated that expandable screws with cement augmentation had 43% improved pullout strength [15] According to Cook et al. [17] expandable screws with cement augmentation had two or three times higher pullout strength than only solid cored screws for osteoporotic cases.

This study investigated the possible usage of cannulated screws without cement augmentation. The main motivation under this phenomenon is the bone-ingrowths mechanism through radial holes/slots. To understand this effect, previously designed and validated six different types of cannulated screws were used. In addition, a solid cored screw was also tested as a control group. Samples were tested under two main conditions. To determine the primary strength of screw standard solid PU foam blocks were used as testing medium. Secondly, artificial fusion process was applied to all designs and control group to determine the post-fusion pullout strength.

2. Materials and method

2.1. Design parameters

Six different cannulated screw designs were used in this study. In addition, Solid cored classical pedicle screw with same geometrical features and thread/core type of cannulated screws was also tested as control group. Figure 1 depicts the design parameters for screws and the denotations. All cannula diameters were 2 mm and radial holes were drilled with a diameter of 1.5 mm. Slots were milled with a 2 mm diameter end-mill cutter. All holes and slots were drilled/milled unilaterally and bilaterally. Hole and slot types are given in Fig. 2. All designed screws were having 6 mm outer diameter and 45 mm length and made of Ti alloy namely, Ti6Al4V [18]. On the designation of designed screws first capital letter represents the unilaterality (S) or bilaterality (D) of the holes and slots. Additionally,

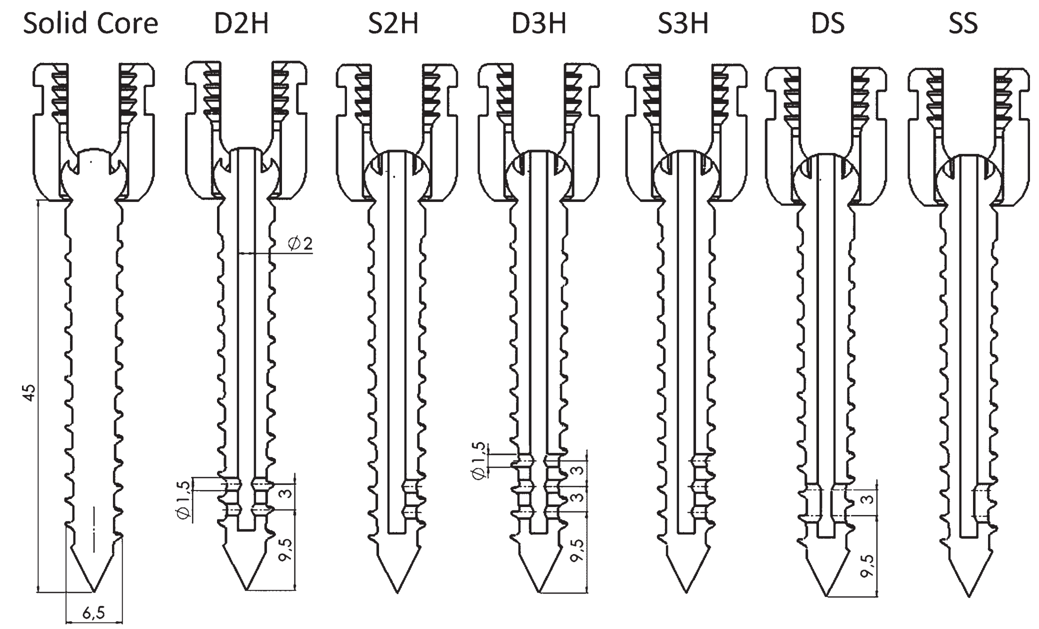

Fig. 1. Design parameters of cannulated screws.

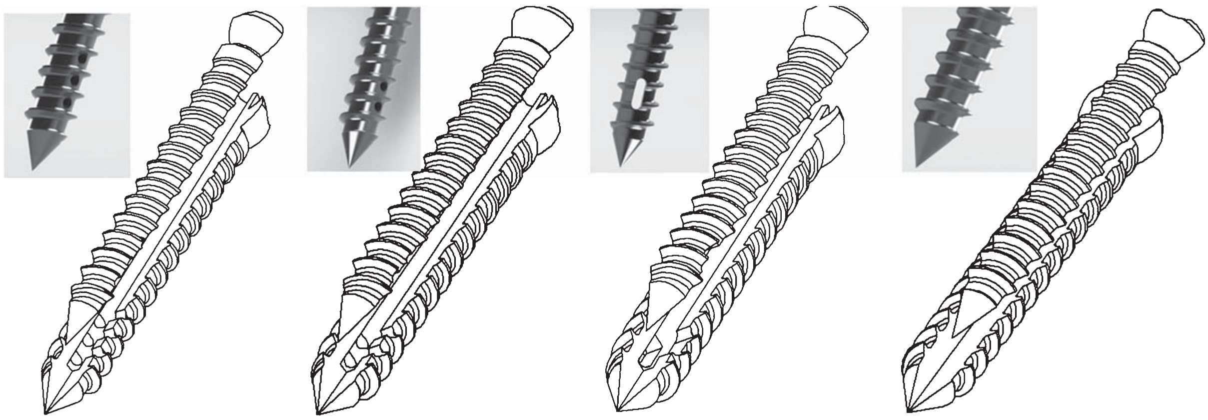

Fig. 2. Cross section and illustration of hole/gap types. Three holes, two holes and slot including designs with solid cored screw design. (From left to right).

2 H, 3 H, S represents the two holes, three holes and slot, respectively.

2.2. *Embedding medium and artificial fusion process*

Embedding medium was synthetic foam. Polyurethane (PU) foam is standard testing material for orthopedic implants. Different grades of PU foam were described in ASTM F1839 [19]. Two different grades of PU foam were used in tests. Grade 40 PU foam was used as healthy bone simulating/mimicking material. Similarly, Grade 10 PU foam was used as osteoporotic bone simulating material. Mechanical properties of the PU foams were briefly described in Table 1. Additionally, PU foam was used in two different forms. First, solid foam blocks were as used as all standard applications. After the insertion of each cannulated screw 2 ml PMMA cement was injected with appropriate hand tool. Second, a new technique was applied namely, artificial fusion process. This process was firstly raised by Arslan et al. [20] to understand the effects of radial holes on pedicle screw pullout strength after the fusion. Same method of artificial foaming process was used in this study.

Table 1
Mechanical properties of polyurethane foam

	Density (g/cm^3)	Standard dev.	Compressive strength (MPa)	Standard dev.
Grade 10	0.16	0.005	2.5	0.2
Grade 40	0.64	0.01	35	0.5

Polyurethane contains two components. One is polyol and the other is polyisocyanate. On the production of polyurethane foam mixing these two components is the main step. When one mixed these two components of polyurethane mix starts to foam with an exothermic reaction. In our study, after mixing these two components with appropriate ratios in a close volume die, screws were inserted to the die just before the foaming process as shown in Fig. 3. This procured the bone in growth simulation through the radial holes/slots of the cannulated screws. Curing time of the mixture was 20 minutes; however tests were performed 24 hours after the curing process [20].

3. Experimental procedure

Pullout Tests: Pullout test setup is given in Fig. 4. PU blocks with inserted screws were placed to test setup as described in figure. Pullout tests were carried out to the screws according to the ASTM F543[21] standard testing protocols. Screws were embedded in to the foam 30 mm from the distal end (tip). Tests were performed with Instron 5569 testing frame (UK). Pullout rate (cross head speed) was 2 mm/min. Load versus displacement data was recorded during the tests. The failure criterion was the threshold of the pullout force over than 80% (pullout occurrence).

After completing the tests statistical analysis were performed on test results. Student-*t* test was applied to understand whether the differences between two groups are significant or not. Statistical comparison is given in Table 2.

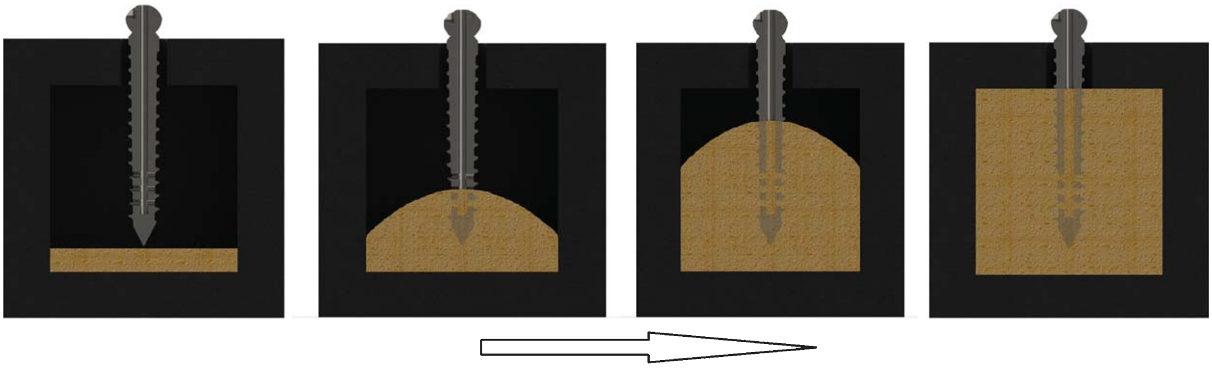

Fig. 3. Foaming Process: Simulation of bone fusion.

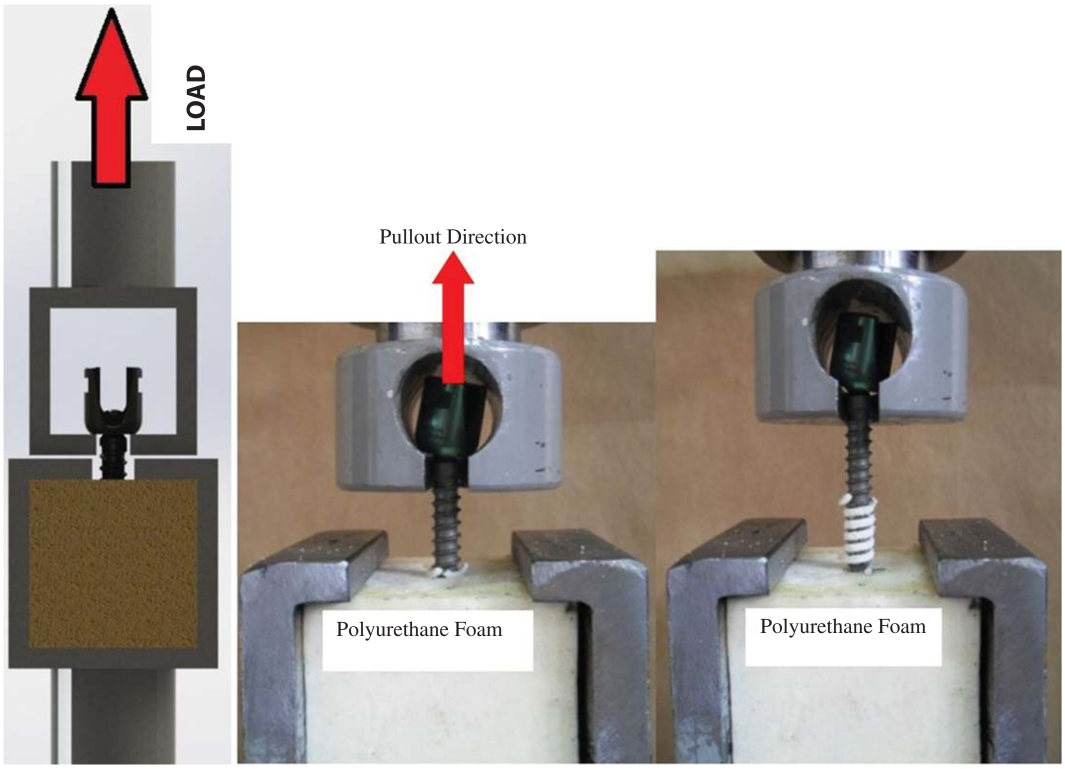

Fig. 4. Pullout test setup. From left to right; Schematic view, before pullout and after pullout, respectively.

4. Results

Primary fixation (without fusion occurrence) and post fusion pullout strength comparison is given in Table 3. According to the test results, bilateral hole/slot including designs were exhibited close to two times higher pullout resistance than unilateral hole/slot including designs among all designed screws when the comparison carried out on Grade 40 PU foam. For instance, maximum pullout forces were 1586 N and 2784 N for S2H and D2H screws, respectively. Similarly, maximum pullout force difference between D3H and S3H was 1931 N while the pullout strength of S3H was 1450 N. In addition, maximum pullout strengths were 2228 N and 3031 N for SS and DS screws, respectively.

Table 2
Statistical comparison of pullout test results for different designs

Grade 40		Grade 10	
Comparison	p values	Comparison	p values
Solid Core & S2H	0.00716*	Solid Core & S2H	0.00303*
Solid Core & D2H	0.00033*	Solid Core & D2H	0.00167*
Solid Core & S3H	0.01140*	Solid Core & S3H	0.00332*
Solid Core & D3H	0.00000*	Solid Core & D3H	0.00023*
Solid Core & SS	0.00517*	Solid Core & SS	0.00040*
Solid Core & DS	0.00000*	Solid Core & DS	0.00089*
S2H & D2H	0.00156*	S2H & D2H	0.20388
S2H & S3H	0.59811	S2H & S3H	0.71678
S2H & D3H	0.00023*	S2H & D3H	0.41399
S2H & SS	0.09447	S2H & SS	0.86235
S2H & DS	0.00042*	S2H & DS	0.60925
D2H & S3H	0.00073*	D2H & S3H	0.34793
D2H & D3H	0.02717*	D2H & D3H	0.01454*
D2H & SS	0.13961	D2H & SS	0.12560
D2H & DS	0.28109	D2H & DS	0.05079
S3H & D3H	0.00014*	S3H & D3H	0.20938
S3H & SS	0.04995*	S3H & SS	0.78704
S3H & DS	0.00023*	S3H & DS	0.36084
D3H & SS	0.01590*	D3H & SS	0.17105
D3H & DS	0.02357*	D3H & DS	0.74448
SS & DS	0.04291*	SS & DS	0.39423

*Statistically significant difference ($p < 0.05$).

According to the results of post-fusion pullout tests, worst performed cannulated screw design was S3H on healthy bone simulating PU foam. However, pullout strength of S3H design was purchased with two times higher loads when compared to control group ($P < 0.05$). Solid cored screws were purchased with 671 N where this value was 1450 N for S3H design.

Contrary to the tests carried out with grade 40 PU foam, cannulated screws without cement augmentation exhibited similar performance between straddle and bilateral hole/slot including designs when embedding medium is osteoporotic (Grade 10 PU foam). S2H and D2H screws were purchased with 978 N and 787 N pullout forces ($P = 0.20$), respectively. Similar to this, S3H, D3H, SS and DS screw designs were also purchased with pullout force of 919 N, 1095 N, 954 N and 1057 N, respectively. There were no significant differences between groups (Table 2).

Similar to Grade 40 tests, pullout strength of solid cored screw was three times lower than the worst performed cannulated screw design. The minimum pullout force was 787 N for D2H screws. This results were obtained from Grade 10 PU foam (osteoporotic case) used tests after artificial fusion process. Solid cored screw exhibited 236 N pullout strength after fusion in osteoporotic synthetic foam material.

5. Discussion

Pullout tests that conducted on solid PU foam blocks were the simulation of early stage pullout phenomenon. On the other hand, artificially fused PU cases were the simulation of post fusion performances of the designed screw. One should be aware that early stage pullout is still very important problem. However, the results of post-fusion tests are the scenario of further stages of fixation. Fusion generally takes 3–5 months for spinal fusion surgery patients. This study's main focus is on the possible usage of cannulated screws without cement augmentation for fusion occurred cases. To state the difference between primary fixation performance and post fusion cases two embedding medium with two different bone qualities were used in tests.

The main advantage of the cannulated screws is the prevention of the pullout for osteoporotic cases. In addition, this study focused on possible usage of cannulated pedicle screws without cement augmentation. Taking the advantage of osteointegration through the radial holes/slots was the main hypothesis for the study.

Table 3
Pull out test results. Comparison table of artificial fusion and cement augmentation

Sample ID	Pull-out (Grade 40)		Pull-out (Grade 40)		Pull-out (Grade 10)		Pull-out (Grade 10)	
	Max. Force (N)	St.D.	Max. Force (N)	St.D.	Max. Force (N)	St.D.	Max. Force (N)	St.D.
Solid Core	671	60	671	60	236	17.4	236	17.4
S2H	1586	400	3034	232.9	978	258	432	46.9
D2H	2784	407	2795	20.5	787	163	498	22.9
S3H	1450	388	2782	262.4	919	243	511	52.8
D3H	3381	146	2768	107.8	1095	151	492	19.6
SS	2228	625	3104	98.08	954	146	491	23.6
DS	3031	229	2936	170.3	1057	206	462	16
	Artificial Fusion		Cement Augmented		Artificial Fusion		Cement Augmented	

Artificial fusion process was played a critical role while defining the post-fusion pullout performances of screws.

Chen et al. [22] studied pullout and torsion forces in a couple of designs. Chen mentioned the critical role played by radial holes for cement leakage into the spinal canal. The risk of cement leakage increases, when the holes are too proximal. Furthermore, the position of side holes is more essential for pullout strength than number of holes.

S2H screws were pulled out at 1586 N after fusion, while a similar one, S3H screws, and were pulled out at 1450 N. In the meantime, SS screw pulled out at 2228 N. Furthermore, measurements after osteoporotic (grade 10 synthetic PU foam) fusion revealed pullout results for D3H and DS fusion as 1095 N and 1057 N, respectively. Pare et al. investigated pullout strength in cannulated screws, and reported the highest pullout strength as $572\,\mathrm{N} \pm 274\,\mathrm{N}$ [23]. This figure corresponded to half of the pullout strength obtained for grade 40 PU foam used cases, while it was lower than the pullout strengths obtained for all grade 10 PU foam used cases of this study. Chen et al. [22] reported 320 N as an average value obtained for non-fusion pullout tests applied on foam, which is three times lower than the best performance obtained for screw design without cement augmentation in our study. As regards comparison to the expandable screws, Wu et al. [15] obtained maximum pullout strength of 1200 N in osteoporotic human cadaveric spine with cement augmented expandable screws. We obtained 1095 N, which is higher than that obtained for expandable screws without cement augmentation, solid cored screws and PMMA cannulated screws in Wu's study. Becker et al. [13] conducted a similar study in osteoporotic human cadaveric spine. They compared PMMA balloon kyphoplasty to vertebroplasty. The screw pullout strength in solid core screwing in vertebroplasty measured 920 N. This is 20% lower than the pullout strength obtained after artificial fusion in our study. Evans et al. [13] conducted a study on frozen bovine vertebrae. Their results reported an increase in pullout strength, from 1203 N to 1970 N, after PMMA augmentation. Our new design showed increasing results for pullout strength of screws without cement augmentation, from 671 N to 3381 N, in healthy bone after fusion. Some researchers studied calcium based cement in cannulated screws as an alternative to PMMA. In their study, Gao et al. [6] found that the pullout strength for cannulated screws with calcium apatite injection was 995 N in the osteoporotic spine. This figure is 10% lower than the best result achieved in our design without cement augmentation. Rohmiller et al. [24] compared pullout strengths on human cadaveric spine after calcium sulphate and PMMA injection, and reported that the highest pullout strength for PMMA was 1320 N, whereas this was 1105 N for calcium sulphate injection. Our new design is as strong as calcium phosphate after artificial fusion process. This is very close to our results measured for the foam modeling healthy bone. Based on this, we can conclude that our design has obtained 3381 N with the foam modeling healthy bone (grade 40 PU foam), which is approximately three times higher than the strength obtained by Rohmiller with calcium sulphate injected screws. Moreover, Hasemi et al. [25] conducted a multi-comparison in their synthetic foam. They studied the pullout strength of several cannulated screw designs on foam. Highest pullout strengths were recorded as 861 N with PMMA and 688 N with solid core screw without cement augmentation. This was found as 671 N in our study.

All these studies indicated that pullout strength increased in cannulated screws without cement augmentation, when fusion took place. Cement augmentation is a very common and effective practice. Screw pullout is more common during the early phase, when fusion has not yet taken place. However, our study indicated that cannulated screws without cement augmentation is an alternative to solid cored screws for healthy bone cases.

6. Conclusion

This study showed that using cannulated screws without cement augmentation for the cases with healthy bone can be a reliable alternative to solid cored screws. To the knowledge of investigators this is the first study comparing pullout strength for several cannulated screw designs after the artificial fusion process. The main limitation of this study was using living tissues for the more realistic results. However, using synthetic foams is accepted in literature to decrease the bone quality bias. In addition, finite element analysis can be carried out for such study. The number of tests and design parameters are highly enough for such a study. The finite element analysis and further investigations of designs can be a future work of this study.

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