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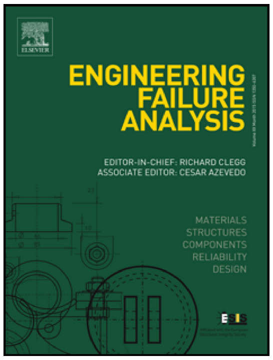

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ABSTRACT

In this study, the mechanical properties of a novel dual-core pedicle screw were compared with a commercially available cylindrical screw. In order to evaluate and compare their mechanical performance, a series of axial pullout, quasi-static and dynamic bend tests were conducted. In the pullout tests, three polyurethane (PU) foams (density: 0.16, 0.32 and 0.64 g/cm^3) were used to compare the pullout strength between both screw types. The ultimate static strength of each screw was determined by a series of quasi-static cantilever bend tests. Dynamic tests were performed with a peak forces corresponding to 10%, 30%, 40%, 50%, 65% and 75% of the ultimate static strength of each screw type. Each specimen was subjected to a sinusoidally varying load which continued until the specimen fractured or reached 2.5 million cycles. The results of the pullout force indicated that the dual-core screws had higher pullout strength, in each PU foam, compared to cylindrical screws, however, the differences were not statistically significant. The average stiffness of dual-core screw during pullout from the 0.16 and 0.32 g/cm^3 PU foams was significantly higher ($p < 0.05$). In quasi-static tests, results of ultimate bending load; bending stiffness and structural stiffness were significantly higher for dual-core screws ($p < 0.05$). During the dynamic bending tests, the dual-core screws had longer fatigue lives for all loading levels. It was observed that the fatigue failures for both screw types occurred either at the head-shank junction or between third and fourth thread. In conclusion, the findings of this study indicated that the dual-core screw design has improved mechanical performance compared to the cylindrical design, with the exception of pullout resistance, which showed no significant difference.

Keywords:

Pedicle screw; Pullout; Design; Quasi-static test; Dynamic test.

1. INTRODUCTION

Pedicle screws are used as fixation for posterior stabilisation systems for the lumbar spine [1-3]. They are inserted into the isthmus of the pedicle and used for connecting vertebrae to rods. Currently, there are many different designs of pedicle screws available on the market, which differ both in the thread, the geometry of the core and the outer diameter. The thread of the pedicle screw can be square, buttress or V-shaped, while the core and outer diameter geometry can be conical, cylindrical and dual-core.

Although pedicle screws are widely used in the treatment and stabilisation of the spine, cases of screw failures, in particular breakage and loosening, are still being reported. The incidence of screw breakage has been reported to range between 3% and 7.1% of procedures and often occurs around the thread-shank junction of the screw [4-6]. Fracture is likely to occur due to bending fatigue or due to a loading situation that exceeds the load-bearing capacity of the screw. Screw loosening leading to pullout is the next common complication associated with pedicle screws, which is reported to range between 0.6% and 11% [7]. Loosening is more likely to occur due to a weak screw-bone interface and continuous bending forces applied to the head of the screw, which are causing micro-movements of the distal part of the screw. Pedicle screw failures are dangerous for the patients, as they can result in instability of fixation and may lead to more complicated problems, resulting in corrective surgery [8].

Previous work has shown that factors, such as the geometry of the thread and screw shaft, have a great impact on both bending and pullout strength [9]. Cho et al., [10] stated in their study that the outer diameter of the pedicle screw determines the pullout strength, while the core diameter determines the fatigue strength. Lill et al. [11] evaluated the pullout resistance of a dual-core screw and showed that it had a higher pullout strength compared to a cylindrical screw. Other studies have shown that the screws with a more conical core are more resistant to breakage and loosening, compared with cylindrical screws [12,13].

The aim of this study was to evaluate and compare the mechanical performance of a completely new design of the dual-core screw with a commercially available cylindrical screw, particularly their response to pullout and bending forces. For this purpose axial pullout, quasi-static and dynamic bend tests were conducted.

2. MATERIALS AND METHODS

Pedicle Screws

Two different pedicle screw designs, made by S14 Implants (Pessac, France), were investigated: a commercially available cylindrical screw - BFus 2; and a novel dual-core screw BFus 2+, both with a major diameter of 5.5 mm and different lengths of 45 mm and 45.7 mm, respectively (Figure 1). The geometry of the screws differs mainly in the size of the core diameter, the geometry of the neck, thread profile and the flank overlap area (FOA) (Figure 2). The FOA is the projected area of the bone that is covered by the threads of the screw [14]. It is defined as follows:

$$FOA = [\pi/4 \times (D^2_{outer} - D^2_{inner})] \times l/p$$

where D_{outer} and D_{inner} are the projected areas of the outer and inner screw diameter, respectively, *1* is the length of the threads, and *p* is the thread pitch.

The first screw type has a V-shaped thread and a cylindrical core up to 3/4 of its thread length. The second screw type is characterized by a double lead (Figure 3a), buttress thread and dual-core connected by a conical transition. Geometrically, the thread of the dual-core screw varies down the shank. At the proximal end, it is characterized by a larger core diameter (4.5 mm) with low and broad threads, designed in order to grip in dense, cortical bone (Figure 3b). From the midpoint of the shank to the tip, the thread has a smaller cylindrical core (3.8 mm) with tall and thin threads, designed for anchoring into spongy cancellous bone. The dual-core screw thread has a smoother transition between the base of the thread and inner diameter due to a fillet which helps reduce stresses in the screw (Figure 4b) [4]. Both types of screws were manufactured from a medical grade titanium alloy, Ti-6Al-4V (TA6V ELI), in accordance with ASTM F136 [15]. The detailed dimensions of each screw type are listed in Table 1.

[insert Figure 1]

Figure 1: Pedicle screws: a) 5.5 mm cylindrical screw; b) 5.5 mm dual-core screw

[insert Figure 2]

Figure 2: Illustration of the geometric changes made to the screw design. The letters in the photo indicate: A - The geometry of the neck; B - Core diameter; C - Thread profile.

[insert Figure 3a]
a)

[insert Figure 3b]
b)

Figure 3: Detailed view of the dual-core screw geometry: a) Dual thread; b) A - Cortical core profile, B - Cancellous core profile

[insert Figure 4a]
a)

[insert Figure 4b]
b)

Figure 4: Thread profile: a) Cylindrical screw; b) Dual-core screw

Table 1 Specification of the pedicle screws employed in this study.

Screw type	Outer diameter (mm)	Core diameter (mm)	Length (mm)	Shaft length (mm)	Pitch (mm)	Thread depth (mm)	**FOA (mm^2)
Cylindrical	5.5	3.7	45	40	2.5	0.9	104
Dual-core	5.5	*4.5 †3.8	45.7	41.3	2.5	*0.5 †0.85	†99

**Dimension corresponding to the cortical portion of the screw*

†Dimension corresponding to the cancellous portion of the screw

***FOA value for 20 mm test depth*

Pullout tests

Three rigid polyurethane (PU) foams were used for the pullout tests: grade 10 (density: 0.16 g/cm^3), 20 (density: 0.32 g/cm^3) and 40 (density: 0.64 g/cm^3), as specified by ASTM F1839 [16]. All foams were supplied by Sawbones® Europe AB (Malmö, Sweden) as blocks (130 mm x 180 mm x 40 mm). A smaller block (43 mm x 60 mm x 40 mm) was cut from the main blocks for each test. The mechanical properties of the foams enable them to be used as osteoporotic, normal and higher than normal bone models [17,18]. This eliminates variability that would occur with human samples, in order to provide more reliable results [15-17]. In this study, the conditions of the pullout test for pedicle screws followed ASTM F543 [19]. Pilot holes of 3.5 mm diameter, as specified by the manufacturer, were drilled perpendicular into a PU test block to guide the insertion of each screw. Each screw was inserted at the centre of a foam block to a depth of 20 mm, through a pullout fixture, which is described in detail in Figure 5. This fixture was previously used by Patel et al. [20] and strictly followed ASTM F543. In this case, FOA calculated for embedded parts of both screws, were comparable and had values of 104 mm^2 and 99 mm^2 for cylindrical and dual-core screws, respectively. The screws were hand-tightened, using a bespoke tool provided by the manufacturer. The pullout fixture was then attached to an ELF 3300 materials testing machine (Bose Corporation, ElectroForce Systems Group, Minnetonka, MN, USA). The lower fixture of the test assembly, used to secure the foam block, was clamped to the base of the testing machine. Due to the load limit of the ELF 3300, being 2000 N, a Universal Testing Machine (INSTRON TT-CM A0093, UK) was used during the pullout test involving the PU foam grade 40.

[insert Figure 5]

Figure 5: Pullout test setup: 1 - Pullout axis; 2 - Pedicle screw; 3 - Test block grip; 4 - PU foam test block; 5 - Pullout rig; 6 - Pullout force.

Each screw was pulled by its head and along the axis perpendicular to the top surface of the test block. Nine axial pullout tests were performed for each screw type. All tests were performed in displacement control at a rate of 5 mm/min. The load-displacement curves were recorded and the screw pullout strength was defined as the maximum force sustained before pullout. The same screws were used for all tests. This has been justified, as Young's modulus of the PU foam, according to the specification ASTM F1839, [16] ranged from 0.3 MPa to 934 MPa, [17] whilst Young's modulus of titanium alloys ranged between 100 GPa and 120 GPa [21]. The tensile strength for the highest density PU foam grade 40 was 19 MPa [Sawbones® Europe AB, Malmö], whilst the ultimate tensile strength for titanium alloys was reported as 1 GPa [22]. It should be noted that the screws showed no sign of observable damage or deformation as a result of the tests.

Quasi-Static Bend Test

Five tests for each screw type were conducted for the quasi-static cantilever bending tests according to ASTM F2193 [23]. All tests were performed to obtain the ultimate static strength of each screw, defined as the maximum force before either plastic deformation or breakage. In order to rigidly constrain the head of the screw, the original polyaxial head was removed and replaced with a custom-made stainless steel head. Next, a test specimen was mounted in the ELF 3300 testing machine in a specially designed mini-vice (Figure 6). The threaded region of each screw where the load (F) was applied was embedded into a test block made from rigid polyurethane foam (grade 40). All tests were performed in displacement control at a rate of 0.2 mm/s. The exposed length of the screws and the bending moment arm (L) were recorded and kept constant for all tests. The load-displacement curves were recorded. The loading continued until plastic deformation of the screws occurred.

[insert Figure 6]

Figure 6: Schematic view of the mounting for the quasi-static test: 1 - Pedicle screw; 2 - Custom made head; 3 - Mini-vice jig; 4 - Securing screw; 5 - Pin; 6 - Test block; R - Exposed length; L - Bending moment arm; F - Load.

Dynamic Bend Test

With the same setup as quasi-static tests, dynamic tests were performed for six specimens of each screw with peak forces corresponding to 10%, 30%, 40%, 50%, 65% and 75% of the ultimate static strength of each screw type, defined in quasi-static tests. Each specimen was subjected to a sinusoidally varying load at a frequency of 5 Hz and a constant load ratio, R (F_{max}/F_{min}), of 10 according to ASTM F2193 [23]. All tests were performed until the sample fractured or 2.5 million cycles, determined as having an infinite fatigue life, were reached [23]. Additionally, fracture surfaces of the screws that failed during the dynamic bend tests, were viewed using a low magnification stereomicroscope (Wild M3Z Heerbrugg Stereo Microscope, Switzerland). The investigation allowed qualitative examination of the screw surface to identify the fracture morphology.

Statistical Analysis

The results were analysed using SigmaPlot 12.5 (Systat Software Inc.). A two samples t-test was used to compare the differences between the mean values obtained during pullout and quasi-static bending tests. The variation of the pullout strength according to the different PU foam densities was analysed by a one-way analysis of variance (ANOVA) with the Holm-Sidak post-hoc method. The level of significant difference was defined as $p < 0.05$.

3. RESULTS

Pullout test

The pullout strength for each investigated screw design was recorded. As the screws were extracted, the load increased sharply and then dropped rapidly when the screw stripped the polyurethane foam (Figure 7a). In all tests, the failure mode was shear of the PU foam surrounding the screws and the threads showed no observable damage or deformation. The PU foam filled the gaps between the screw threads as they were pulled out of the synthetic bone block (Figure 7b). Table 2 shows the mean values of screw pullout force and stiffness for the cylindrical and dual-core pedicle screws. Pullout force was defined as a maximum load at failure of the PU foam and pullout stiffness as the slope of the linear elastic region of the curve before the yield point. Though not significantly different ($p > 0.05$), the mean value of pullout force of dual-core screws was higher than that of the cylindrical screws in all three polyurethane foam grades. The average stiffness of dual-core screw during pullout from the grade 10 and 20 PU foams was significantly higher comparing to cylindrical screw ($p < 0.05$). Though not significantly different ($p > 0.05$), the mean value of stiffness in PU foam grade 40 was higher for dual-core screws (1525.3 N/mm and 1445.7 N/mm for dual-core and cylindrical, respectively). The screw displacement at the point of peak load was less than 2 mm for the screws embedded in foams grade 10 and 20, and less than 3 mm for the foam grade 40. The results of the ANOVA showed that there was a significant ($p < 0.05$) effect of foam density on the average value of pullout force and stiffness. Both values were higher in the foams with higher density (Figure 8).

[insert Figure 7a]	*[insert Figure 7b]*
a)	b)

Figure 7: a) Examples of load-deformation curves in pullout tests for three different PU foams; b) Typical pullout failure - Dual-core screw extracted from PU foam.

Table 2 Mean (± Standard Deviation) pullout force and stiffness of screws in PU foam models.

PU Foam Grade	**Pullout Force (N)**		**Stiffness (N/mm)**	
	Cylindrical	Dual-core	Cylindrical	Dual-core
10	235 ± 16	243 ± 10	321 ± 24	356 ± 25
20	914 ± 44	919 ± 46	817 ± 127	917 ± 54
40	3340 ± 181	3349 ± 271	1446 ± 117	1525 ± 146

[insert Figure 8a]

Figure 8: a) Mean (± Standard Deviation) values of pullout force for each screw in different PU foam models.

[insert Figure 8b]

Figure 8: b) Mean (± Standard Deviation) values of stiffness for each screw in different PU foam models, (*Significant at $p < 0.05$).

Quasi-Static Bend Test

All of the screws failed either due to permanent deformation (yielding) of the thread or the formation of a crack in the region between the third and fourth threads (Figure 9a, 9b) in the quasi-static bend tests. The failure modes were consistent with the mean load-displacement characteristics for both screws, shown in Figure 9c. For the dual-core screw, there was a rapid rise in force for a small displacement followed by a large displacement with a little increase in force. The trend is observed for the cylindrical screw, with the addition of a reduction of a force that proceeded failure. The bending stiffness was defined as the slope of the initial linear region of the curve; 0.2% offset yielding strength and structural stiffness (El_e) were defined according to ASTM F2193 [23]. The results show that the dual-core screws had significantly higher mean values of bending ultimate load; bending stiffness and structural stiffness ($p < 0.05$) (Table 3). While there were no significant differences between values of bending yield load ($p > 0.05$). The failure load data obtained from the quasi-static bending tests was used as an absolute upper limit when choosing subsequent bending fatigue load values.

Table 3 Mean (± Standard Deviation) quasi-static structural properties of the screws.

Screw design	**Ultimate Static Load (N)**	**Bending Yield Load (N)**	**Bending Stiffness (N/mm)**	**El$_e$ (N·m^2)**
Cylindrical	525 ± 15	272 ± 29	126 ± 4	1.25 ± 0.04
Dual-core	721 ± 8	284 ± 65	156 ± 24	1.55 ± 0.24

[insert Figure 9a]	*[insert Figure 9c]*
[insert Figure 9b]	c)

Figure 9: a) Plastic deformation of dual-core screw; b) Failure of cylindrical screw; c) Mean quasi-static bending force-displacement trends for each screw.

Dynamic Bend Test

In the dynamic bend tests, the screws deformed gradually during loading. The tests were ended at the moment at which the deformation abruptly increased and the samples failed. Both cylindrical and dual-core screws were able to complete 2.5 million cycles under 10% and 30% of the ultimate bending loads but failed for the remaining load levels of 40%, 50%, 65% and 75%. During testing, it was observed that the dual-core screws had longer fatigue lives for all loading levels. Moreover, the magnitude of load levels in the dual-core screws was significantly higher than in cylindrical screws ($p < 0.05$) with an average increase of 38%. The biggest differences between fatigue lives of both screw types occurred at 40% and 75% load levels with a 204% and 192% increase, respectively. It was observed that the fatigue failures for both types of screws occurred either at the head-shank junction or between third and fourth thread (Figure 10). Figure 11 shows optical microscope (OM) images of the fracture surfaces of both screw types, for 50% and 75% load levels. The area of the origin of the crack, the crack propagation and failure are clearly seen and marked. For the cylindrical screw, at a 75% load level, the final failure was brittle and occurred at the head-shank junction. The fracture at the lower loading level of 50% occurred between the third and fourth thread. The photo of the surface clearly indicates that the cracks were initiated at the thread root and that final failure was brittle, following the crack propagating across the cross section of the thread. The situation was reversed in case of the dual-core screw failures. Fracture occurred at the head-shank junction for the lower loading level (50%), and between the third and fourth thread for higher load (75%). In this last case, the crack does not seem to initiate at the base of the thread, but slightly further down the shank. Additionally, in Figure 11d, besides the fracture surface, the fragment of the star-shaped cavity in a screw head with a rough machining finish can be seen. In any case, no significant plastic deformation of the screw was observed. The deformation of the PU foam blocks where the load was applied was insignificant in both the yielding and cyclic tests. Table 4 and Table 5 present the results of the cyclic tests for both types of pedicle screws. Figure 12 shows fatigue (F-N) curves for both cylindrical and dual-core screws, where it can be seen that each point showed a regular trend.

[insert Figure 10a]	*[insert Figure 10b]*
[insert Figure 10c]	*[insert Figure 10d]*

Figure 10: a) Cylindrical screw - 75% load level; b) Cylindrical screw - 50% load level; c) Dual-core screw - 75% load level; d) Dual-core screw - 50% load level. (Visible as well the “blu tack” used in order to keep screws in place).

[insert Figure 11a]	*[insert Figure 11b]*
[insert Figure 11c]	*[insert Figure 11d]*

Figure 11: Stereo microscope images of broken pedicle screws fracture surface. a) Cylindrical screw - 75% load level; b) Cylindrical screw - 50% load level; c) Dual-core screw - 75% load level; d) Dual-core screw- 50% load level. The letters in the photography indicate: A – Initiation of the crack; B – Fatigue crack propagation; C – Brittle failure.

Table 4 Results of the cyclic tests for the cylindrical screw.

Cylindrical Sample Nº	**Ultimate static strength (%)**	**Peak force (N)**	**Cycles to failure**	**Position of failure**
1	75	390	2290	Head-shank junction
2	65	340	7489	Head-shank junction
3	50	260	32772	Third or fourth thread
4	40	210	129640	Third or fourth thread
5	30	160	2500000	No visible cracks/Reached run-out
6	10	50	2500000	No visible cracks/Reached run-out

Table 5 Results of the cyclic tests for the dual-core screw.

Dual-core Sample Nº	**Ultimate static strength (%)**	**Peak force (N)**	**Cycles to failure**	**Position of failure**
1	75	540	6693	Third or fourth thread
2	65	470	13818	Third or fourth thread
3	50	360	47454	Head-shank junction
4	40	290	393663	Head-shank junction
5	30	220	2500000	No visible cracks/Reached run-out
6	10	70	2500000	No visible cracks/Reached run-out

[insert Figure 12]

Figure 12: Fatigue curves obtained by plotting the sinusoidal force peak value in relation to the number of cycles to failure, N. All results are taken from Table 4 and Table 5. The results of the test that did not fail are presented as the unfilled squares and triangles.

4. DISCUSSION

Pedicle screws are often the weakest part of a posterior stabilization device that consists of rods and screws [24]. Thus, improving the biomechanical performance of pedicle screws is crucial for good clinical outcomes of posterior rod fixation systems [25].

The present study sought to determine whether the new dual-core screw design with a double start (BFus 2+) would provide improved pullout resistance as well as increased bending and fatigue strength compared with the commercially available single-threaded, cylindrical screw (BFus 2). In this study, standardized polyurethane foams were used rather than vertebrae to minimize bias from anatomic characteristics and bone density.

It was found that the dual-core screws had a higher pullout strength in each PU foam, however, the differences were not statistically significant. Moreover, the dual-core screws had significantly higher bending strength and longer fatigue lives at each loading level when compared to cylindrical screws.

Pullout strength is strongly associated with the screw design, especially its internal and external diameter, and thread profile [14,26,27]. According to previous studies, [28] increasing the inner diameter at a constant outer diameter, reduces the flank overlap area and as a result decreases the pullout strength. Thread design is another feature that affects the pullout strength [14,29]. In the present study, the thread pitch was equal for both screws, however, the screws differed in the thread profile. The cylindrical screw had a single, V-shaped thread while a dual-core screw had a double start buttress thread. Both investigated screws were inserted into foam blocks to a depth of 20 mm according to ASTM F543 [19,30,31]. Therefore, only the distal parts of the threads of both screws were taken into account during the pullout tests, and the corresponding FOA were comparable and had values of 104 mm^2 and 99 mm^2 for cylindrical and dual-core screws, respectively. The results of the pullout tests in three different foams have shown that the characteristics of the dual-core pedicle screw have not significantly increased resistance to pullout force compared with the cylindrical screw. Therefore, neither the double start nor the buttress thread profile significantly influenced the pullout resistance of the screw. However, whether the double lead has any effect on pullout strength is debatable. Brasiliense et al. [32] compared dual threaded pedicle screw with the standard screw. The results of their study showed that the dual threaded screws exhibited higher pullout strength on high-density foams and lower on low-density foams compared to standard screws. This suggests that a dual lead is a more suitable solution for healthy bone cases. Mummaneni et al. [33] conducted similar studies and compared the pullout strength of dual lead and single lead pedicle screws in human vertebrae. However, in this case, the obtained results were similar to the present study and suggested that the pullout strengths of those two screws were not significantly different from each other. Yaman et al. [27] compared pullout performance of three different screw designs: conical, dual threaded and dual-core with a double thread. In their studies, they used PU foams and ovine vertebra as a testing medium. In all cases, the highest pullout strength values were noted for dual-core and dual threaded pedicle screw. Yaman et al. [27] have also observed that double threaded screws provided them with doubled insertion depth with same screwing round. Also in the present study, it was observed that the dual-core screw with its double lead provided faster insertion time into test blocks than a cylindrical screw, which is an important consideration for surgeons.

The results of the quasi-static bending tests showed that the pedicle screw with dual-core geometry had significantly higher bending strength compared to the cylindrical design. During tests, all dual-core screws underwent plastic deformation, but no cracks were observed, whereas more than 50% of the cylindrical screws fractured between the third and fourth thread. In the present study dual-core screws have shown significantly longer fatigue lives compared to the cylindrical type at each loading level. Due to limited amount of samples, the dynamic tests were carried out using one screw per loading level. The authors realise that it is not ideal, nevertheless, based on obtained results we can clearly observe the pattern within the samples tested. During fatigue testing, all investigated screws failed, except the ones under 10% and 30% loading levels, both lasting 2.5 million cycles. Failures in all cylindrical screws were located at the head-to-shaft junction for the higher load levels (65%, 75%) and between the third and fourth thread for the lower load levels (40%, 50%). The situation was reversed in the case of the dual-core screws. The mode of failure was therefore repetitive, and observed fracture sites agree with the results obtained by Griza et al. [4] where the most common site of screw failure was at the junction of screw's hub and threaded part or in the middle section of the threaded part.

Previous studies [10] have shown that core diameter (CD) of the pedicle screw greatly influences its bending performance and fatigue life. The bending strength of a screw is proportional to the section modulus (Z), which is in turn proportional to the cube of the core diameter ($Z \sim CD^3$). Therefore, even a slight change of the CD has a significant impact on the bending strength of the screw. Moreover, as the most frequent sites of pedicle screw breakage are usually located at the proximal part of the screw, the geometry of the neck also plays an important part in a bending strength. For this reason, tapering of the CD may also reduce the risk of screw breakage at the thread end. By comparing different designs, Chao et al. [13] proved that the conical screws achieved higher bending strength than cylindrical designs.

In general, the dual-core screw was more difficult to deform or break and more durable during fatigue, compared with the cylindrical design because of the thicker core diameter at the proximal area of the screw and the reinforced geometry of the neck. The results from the quasi-static bending tests of the cylindrical screws suggest that the highest stress concentrations causing failure occurred in the region between the third and fourth thread. This could be due to the fact that at this point the core diameter of the screw slightly changes size, but also because of the thread geometry. Griza et al. [4], have suggested that pedicle screws with a small thread root radius should be avoided, as it may be a source of undesired stress concentrations that can lead to breakage. Contrary to a cylindrical screw, the thread of the dual-core screw had a thread root radius (Figure 4b), which probably helped reducing stress and avoid fracture. After analysing the fracture surfaces of the cylindrical screws, it could be concluded that the lack of thread root radius may be the starting point of the crack propagation, leading to complete failure. These features may be a contributing factor to the failures in the static tests and a mode of failure in the cyclic tests. Based on the literature, the factors that improve the bending strength and pullout strength are opposed [12,13,25]. As a result, screws that perform well under bending may not effectively resist loosening.

This study focused on comparing the pullout and bending strength of two different designs of pedicle screw. In the present study, a new dual-core screw design has shown much better biomechanical performance comparing to a commercially available cylindrical design, apart from pullout resistance.

5. CONCLUSIONS

A completely new design of the dual-core pedicle screw BFus 2+ (S14 Implants, France) has been for the first time, mechanically tested and compared to a commercially available cylindrical screw BFus 2 (S14 Implants, France). This paper sought to determine whether the dual-core design would provide better pullout resistance as well as increase bending and fatigue strength compared with the cylindrical design.

Pullout test

- The design characteristics of the dual-core screws did not significantly improve the pullout strength.
- Screw pullout force significantly increased as the PU foam density increased.
- In all tests, the failure mode was shear of the PU foam surrounding the screws and the screw structure showed no sign of observable damage or deformation.
- It was observed that the insertion of the dual threaded (dual-core) screws into the foam blocks was faster compared to cylindrical version.

Quasi-static bending

- The dual-core pedicle screw has significantly higher bending strength compared to cylindrical type. The modification of the screw’s neck and geometry of the core has significantly improved its bending stiffness and structural stiffness.

Dynamic bending

- The dual-core screws had longer fatigue lives for all loading levels. Moreover, the magnitudes of load levels in dual-core screws were significantly higher than in cylindrical screws ($p < 0.05$) with an average increase of 38%.

The findings of this study indicated that the dual-core pedicle screw has shown better mechanical performance than the previous cylindrical version, with the exception of pullout resistance, which showed no significant difference.

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CONFLICT OF INTEREST

The authors declare that they have no conflict of interest.

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Highlights

- The design characteristics of the dual-core screws did not significantly improve the pullout strength.
- The dual-core pedicle screw has significantly higher bending strength compared to cylindrical type.
- The dual-core screws had longer fatigue lives for all loading levels.
- In all investigated examples the fracture occurred either at the head-shaft junction or in the proximal part of the threaded shank.

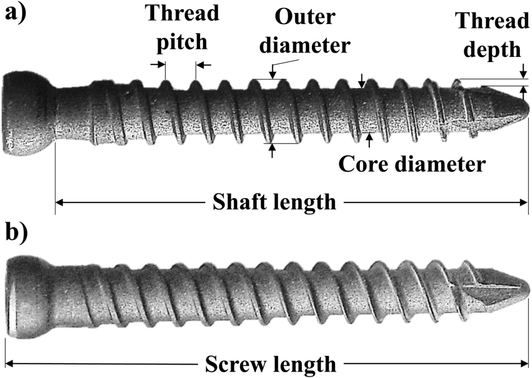

a)
Thread pitch
Outer diameter
Thread depth
Core diameter
Shaft length
b)
Screw length

Figure 1

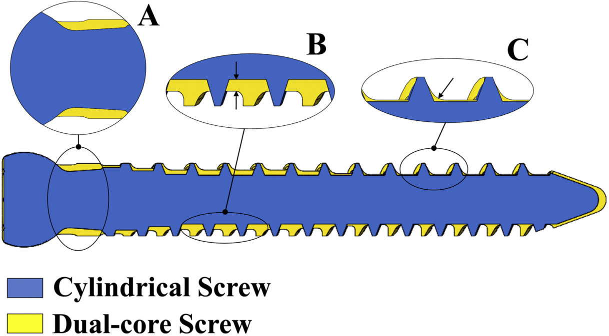


Figure 2

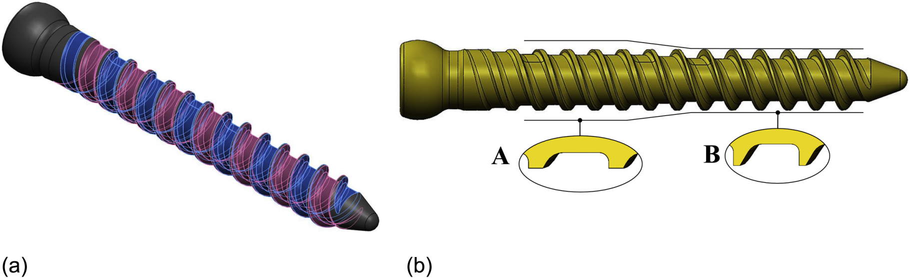
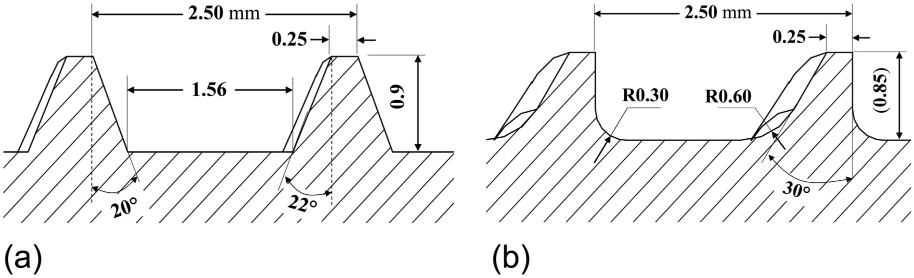


Figure 3



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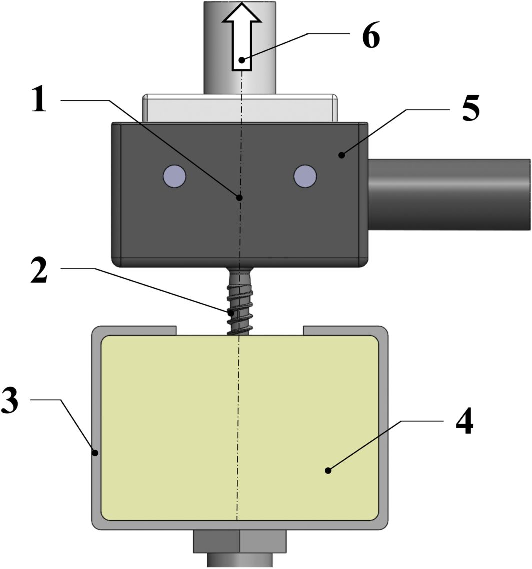


Figure 5

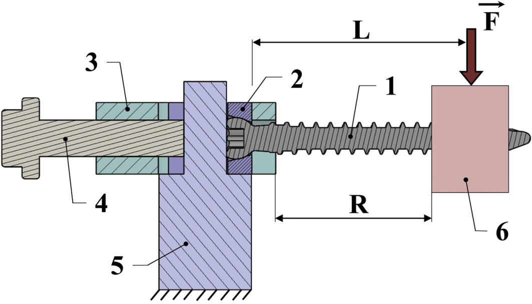


Figure 6

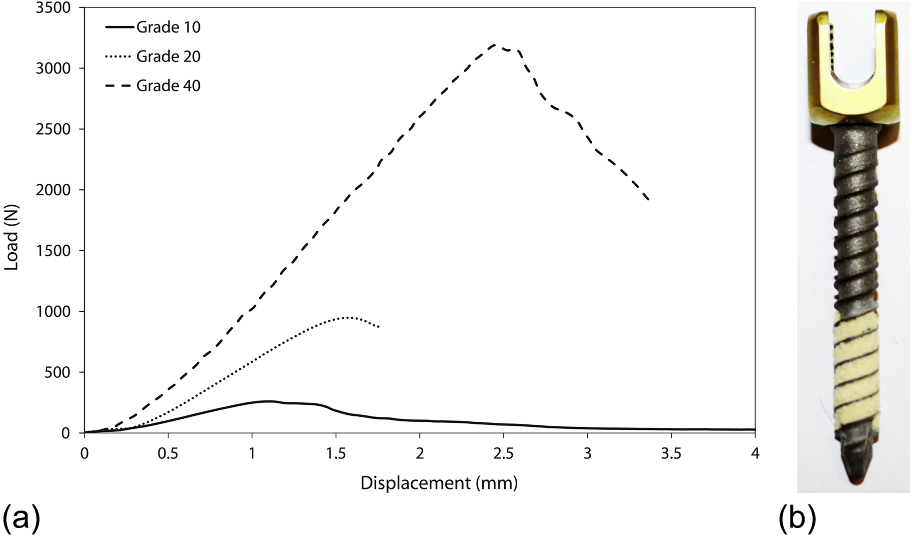
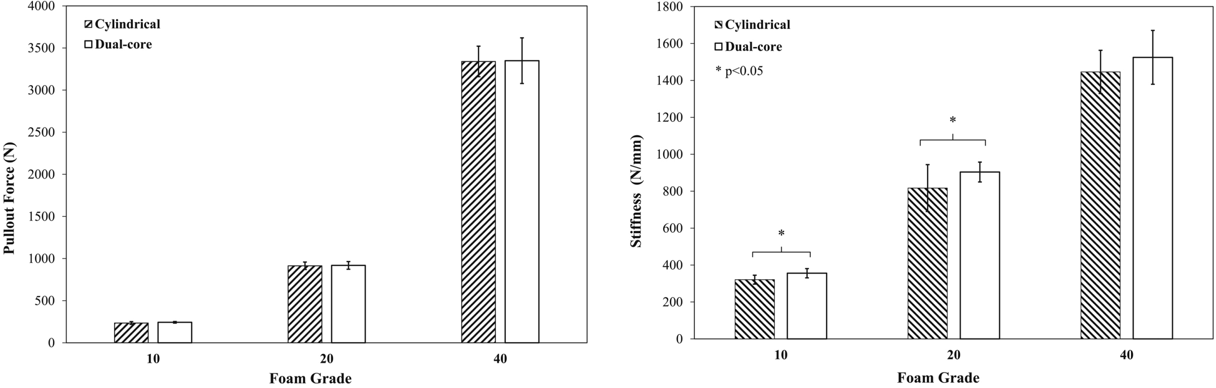

3500
3000
2500
2000
1500
1000
500
0
Load (N)
0
0.5
1
1.5
2
2.5
3
3.5
4
Displacement (mm)
Grade 10
Grade 20
Grade 40
(a)
(b)

Figure 7


4000
3500
3000
2500
2000
1500
1000
500
0
Pullout Force (N)
▨ Cylindrical
☐ Dual-core
10
20
40
Foam Grade
1800
1600
1400
1200
1000
800
600
400
200
0
Stiffness (N/mm)
▨ Cylindrical
☐ Dual-core
* p<0.05
*
*
10
20
40
Foam Grade

(a) (b)

Figure 8

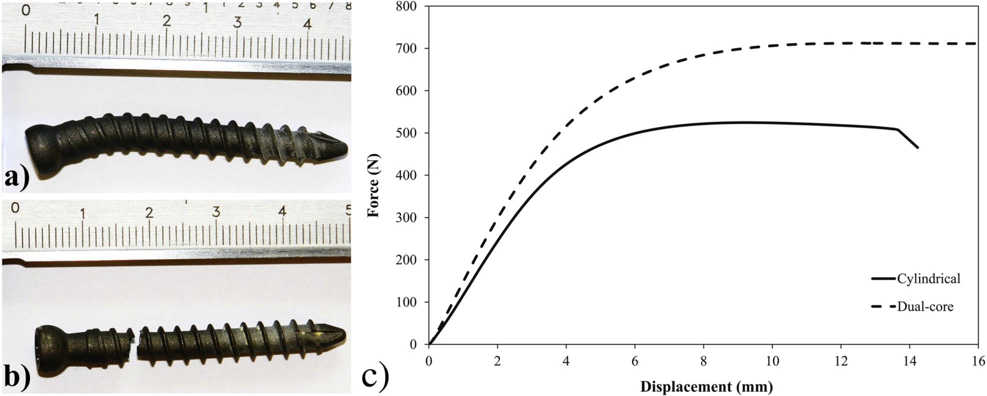

a)
b)
c)
Force (N)
Displacement (mm)
800
700
600
500
400
300
200
100
0
0
2
4
6
8
10
12
14
16
Cylindrical
Dual-core

Figure 9

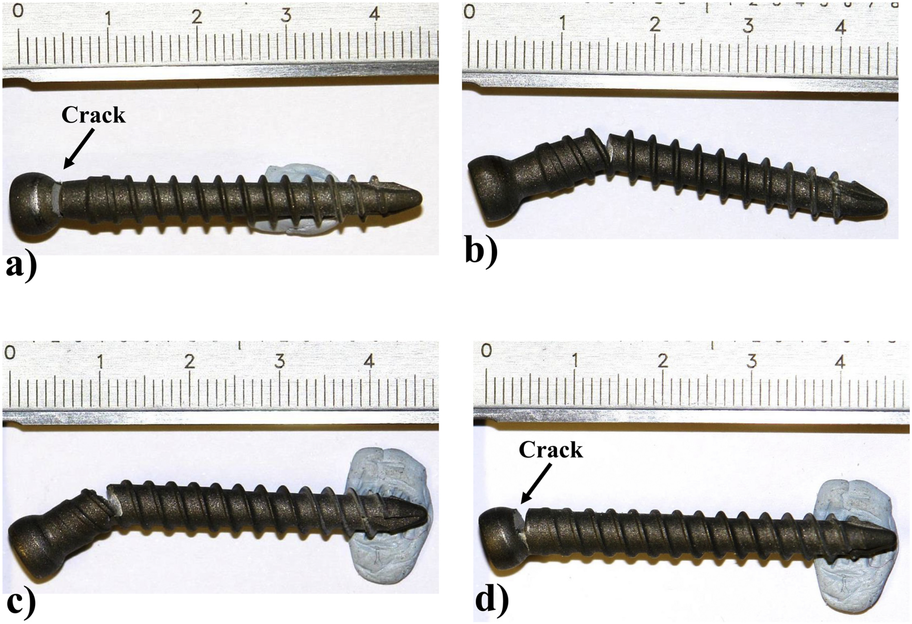


Figure 10

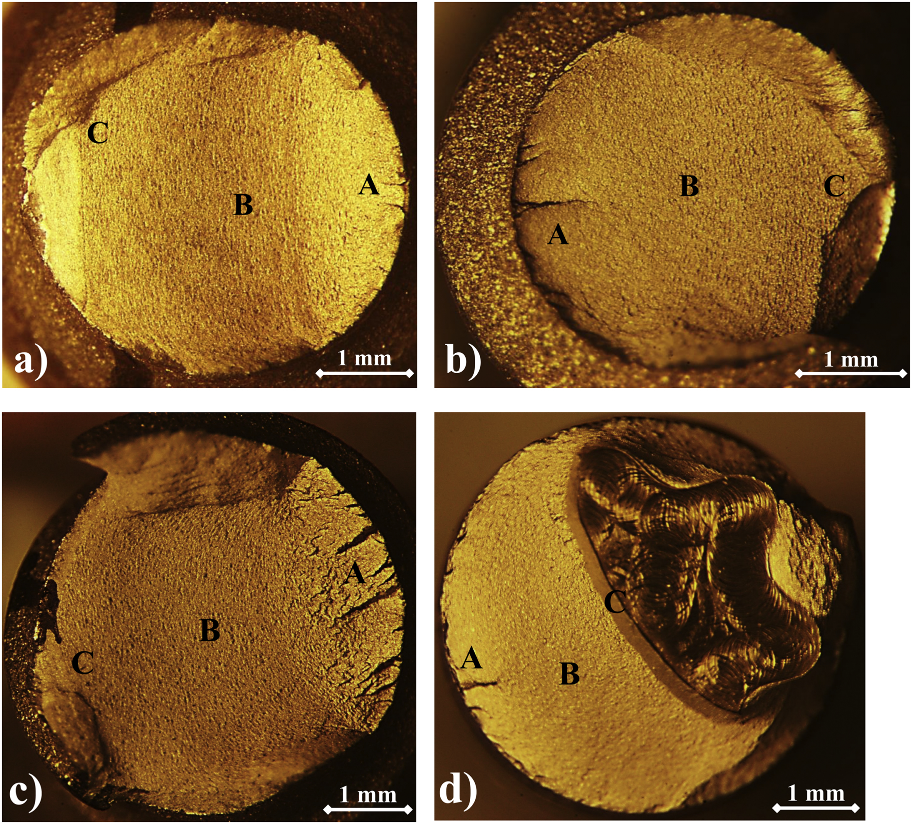


Figure 11

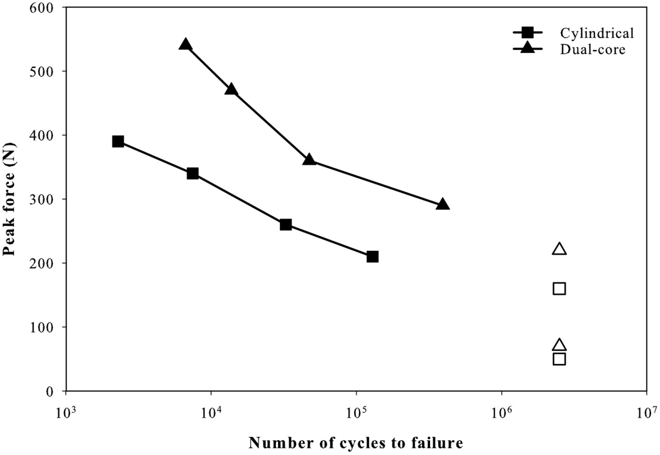

Cylindrical
Dual-core
Peak force (N)
0
100
200
300
400
500
600
10^3
10^4
10^5
10^6
10^7
Number of cycles to failure

Figure 12