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Biomechanical comparison of pullout strengths of five cortical screw types: An innovative measurement method

Beş kortikal vida türünün çekme dayanımlarının biyomekanik olarak karşılaştırılması: Yenilikçi bir ölçüm yöntemi

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ABSTRACT

Objectives: This study aims to assess five different cortical screw types using artificial femurs, under equated testing conditions.

Materials and methods: We investigated the maximum force needed to cause deformation at screw-bone interface using fourth generation composite femurs by conducting separate pullout tests for each screw type. We normalized obtained results with traditional methods and cross-comparison. To conduct pullout tests dependent on screw dimensions, we eliminated the effect of bicortical bone thickness by equalizing the conditions of screw insertion.

Results: Non-locking screws with larger diameter and pitch depth required larger pullout forces to be extracted, showing statistically superior performance compared to locking screws with smaller dimensions. However, the statistical differences between the absolute pullout forces decreased after the traditional normalization of the results. We proposed a new normalization method based on solid geometric reasoning.

Conclusion: This novel approach showed that a screw type that appeared to show average performance, in fact, did not have statistically significantly different results than the top performers. Surgeons are not required to prefer larger dimension screws in small dimension host bones.

Keywords: Biomechanical comparison; cortical screws; pullout strength.

ÖZ

Amaç: Bu çalışmada beş farklı türde kortikal vida, eşdeğer test koşulları altında yapay femurlar kullanılarak değerlendirildi.

Gereç ve yöntemler: Dördüncü jenerasyon kompozit femurlar kullanılarak kemik-vida arayüzünde deformasyon için gerekli olan maksimum yük, her bir vida türü için ayrı ayrı çekme deneyi yapılarak incelendi. Elde edilen sonuçlar geleneksel yöntemler ve çapraz karşılaştırma ile normalize edildi. Çekme testlerini vida boyutlarına bağlı olarak yapmak için bikortikal kemik kalınlığının etkisi, vida yerleştirme şartları eşitlenerek ortadan kaldırıldı.

Bulgular: Büyük çaplı ve derin hatveli kilitsiz vidaların yerinden çıkması için daha büyük çekme kuvveti gerekti; bu vidalar daha küçük boyutlu kilitli vidalarla karşılaştırıldığında istatistiksel olarak daha üstün performans gösterdi. Bununla birlikte, saf çekme yükleri arasındaki istatistiksel farklılıklar, sonuçların geleneksel normalizasyonundan sonra azaldı. Katı geometrik akıl yürütmeye bağlı olarak yeni bir normalizasyon yöntemi önerildi.

Sonuç: Bu yeni yaklaşım, ortalama performans gösteriyor gibi görünen bir vida türünün aslında en iyi performans gösterenlerden istatistiksel olarak anlamlı farklı sonuçlara sahip olmadığını ortaya koydu. Cerrahlar küçük boyutlu konak kemiklerde daha büyük boyutlu vidaları tercih etmek zorunda değildirler.

Anahtar sözcükler: Biyomekanik karşılaştırma; kortikal vidalar; çekme gücü.

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Rigid internal fixation is considered the gold standard surgical treatment method for many long bone fractures.[1-3] Conventional plating was the exclusive method of choice for fracture fixation. However, recently, locked plating has been significantly used in the treatment of a great number of long bone fractures. Many studies demonstrated improved stability and fracture healing potential by use of locking plates.[4,5] However, in plating technique, screw failure is not a rare phenomenon, which mostly happens due to screw toggling, screw pullout, or screw fracture.[5,6] Therefore, cortical screw purchase is an important factor in the mechanical stability of fracture fixation.

Many studies have compared the pullout strength of cortical screws in long bone fixation. Cortical screw pullout tests in human and artificial long bones have been previously conducted to measure the pullout strength of variant screw types.[7-12] Most of the studies related to screw pullouts have focused mainly on axial pullouts in cadaveric animal bone and synthetic materials mimicking the properties of human bone.[16-22]

However, only a few studies examined multiple screw types with different dimensions on fourth generation composite (4GC) bones, under equalized test conditions. Previous studies have not focused solely on the screw tested, by making the host bone parameters (bone thickness, equal positioning of insertion sites) constant. Some studies used composite material to test pullout performances on different screw designs.[23-25] Still, normalization of pullout forces and comparative studies with previous works were not taken into consideration. Therefore, in this study, we aimed to assess five different cortical screw types using artificial femurs, under equated testing conditions.

MATERIALS AND METHODS

Cortical screws

The most common five screw types used in our orthopedic practice were included in this study which was conducted between March 2014 and July 2014 at Dokuz Eylül University (Figure 1). The types of the screws used are:

Type 1: Titanium, bicortical, self-tapping, non-locking, cortical screw (Model D-21/061137, TIPMED A.S., Turkey).

Type 2: Titanium, bicortical, poliaxial, self-tapping screw (Model NCB-DF, Zimmer, U.S.A.).

Type 3: Titanium, bicortical, self-taping, locking screw (Model D-21/116844, TIPMED A.S., Turkey).

Type 4: Titanium, bicortical, self-drilling, locking screw (Model D-21/171072, TIPMED A.S., Turkey).

Type 5: Stainless-steel 316L, bicortical, non-locking, cortical screw (Model D-21/060826 TIPMED A.S., Turkey).

The physical dimensions of the used screws are summarized in (Table I). In terms of dimensions, the screws were divided into two groups. The dimensions of type 1 and type 5 screws are identical; therefore, they were named as dimension group 1 (DG1). Meanwhile, types 2, 3, and 4 have identical dimensions; therefore, they were named as dimension group 2 (DG2). The outer and inner diameters, as well as the pitch depth of DG1 are larger than the DG2. The rest of the dimensions and angles are the same. The study was conducted in accordance with the principles of the Declaration of Helsinki.

Fourth generation composite femur

Fourth generation composite adult-sized left femurs (artificial) purchased from the same supplier (Model #3403, Sawbones, Vashon, WA, USA) were used. The femur cortical bones (n=10) had a density of 1.64 g/cm^3 and cancellous bone density of 0.27 g/cm^3. The used artificial femurs had an intramedullary canal diameter of 13 mm, shaft diameter of 27 mm, and length of 455 mm.

The diaphysis of the femur was separated from the distal and proximal metaphysis, leaving a 14 cm central section, shown as the zone between the white marking lines (Figure 2). Five holes 20 mm apart were drilled in all diaphysis samples and numbered from 1 to 5. The samples were placed together taking a common reference baseline, to ensure identical distance and separation of the insertion sites.

The mechanical testing system

The screws were extracted using a mechanical testing system (Autograph Precision Universal Tester, AG-X Series, Model AG-IS 10 kN, Shimadzu Corp., Japan), which is mentioned in the text simply

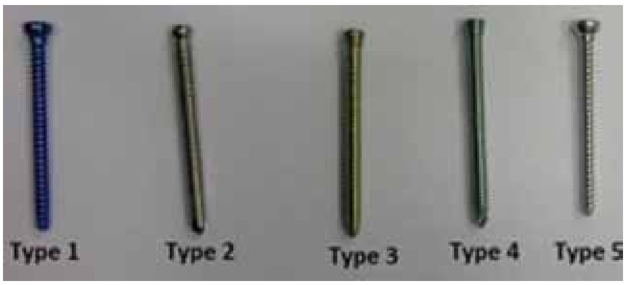

Figure 1. Screw types used in present study.

TABLE I

Physical dimensions of screws used in present study

	Type 1	Type 2	Type 3	Type 4	Type 5
Diameter (mm)	5.00	4.50	4.50	4.50	5.00
Core diameter mm)	3.65	3.15	3.15	3.15	3.65
Thread pitch (mm)	1.75	1.75	1.75	1.75	1.75
Thread depth (mm)	0.675	0.625	0.625	0.625	0.675

as Shimadzu. The Shimadzu was configured for displacement control at a fixed rate of 10 mm/minute and a tensile pre-load of 50 N.

Methods

Screw insertion

Two undersized, untapped, bicortical pilot holes of 3.2 mm in diameter were drilled in each femur, through anterior and posterior cortices at 20 mm and 40 mm locations distal to the mid-shaft line. Clinically, undersized pilot holes are used to avoid cracking and permit tighter "bite" of screw threads into bone.[25]

In order to avoid proximity effects, the holes were drilled 20 mm apart from each other. Screw alignment was carried out by using a rigid steel guide wire through the pilot hole. Each screw was inserted using a manual surgical screw driver through the anterior cortex; three or four threads beyond the posterior cortex, to ensure full engagement with bone, as in orthopedic surgery. Screws were not completely inserted to avoid generating residual forces along the screws' long axis.

To avoid any bias in screw insertion localization, the screw types were rotated equally around the insertion sites. Screw type was matched to the insertion site, at the beginning. Then, the screw type insertion sites were rotated. For example, type 1 screw was inserted in insertion site #1 and type 5 in site #5, in the first diaphyseal sample. In the second diaphyseal sample, type 1 was inserted in insertion site #2 and type 5 was inserted in #1. Thus, screw insertion site bias was eliminated, making the cortical thickness equal for screw types, in the overall test calculations.

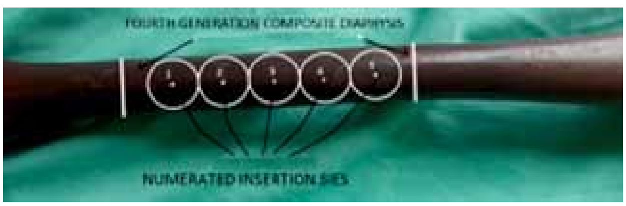

Figure 2. Numbered screw insertion sites on artificial femur diaphysis.

Biomechanical pullout tests

This study was conducted in our Biomechanics Laboratory, using the test set-up shown in (Figure 3a). A metal test jig (#4) was specially designed and custom-constructed to house the femur diaphysis shaft (#2) for extracting the inserted screws (#3). A horizontal supporting plate (#1) was devised to minimize femur bending, at the screw extraction site. A hole was drilled in the supporting plate to allow the pullout force (#6) on the screw head, to align in parallel with the screw's long axis (#5). Thus a pure pullout force was obtained, free of sub-vector forces, in another axis. Screws were extracted using the Shimadzu mechanical testing system with a configuration in agreement with prior screw pullout studies; a displacement control at a fixed rate of 10 mm/minute and an axial preload of 50 N.[22,25]

The force-displacement graphs were drawn on a computer monitor, using the direct outputs of the Shimadzu. The maximum pullout force was detected by studying the graphs. After every experiment, the screws were examined macroscopically for any failure. All of the screws used in the tests were examined and all of them were intact.

Data analysis

The force-versus-displacement graphs obtained were accepted as a raw data of each screw type. The pullout force was defined as the maximum force attained just before the instant of the screw-bone interface failure.[25] This instant is shown in Figure 3b, where it is the apex of the applied force-displacement graph. Pullout displacement was defined as total movement of the screw that takes place from the start of the test, until the occurrence of the maximum pullout. Displacements were recorded but not used, because pullout energy is the area under the applied force-versus-displacement curve. Since the energy is

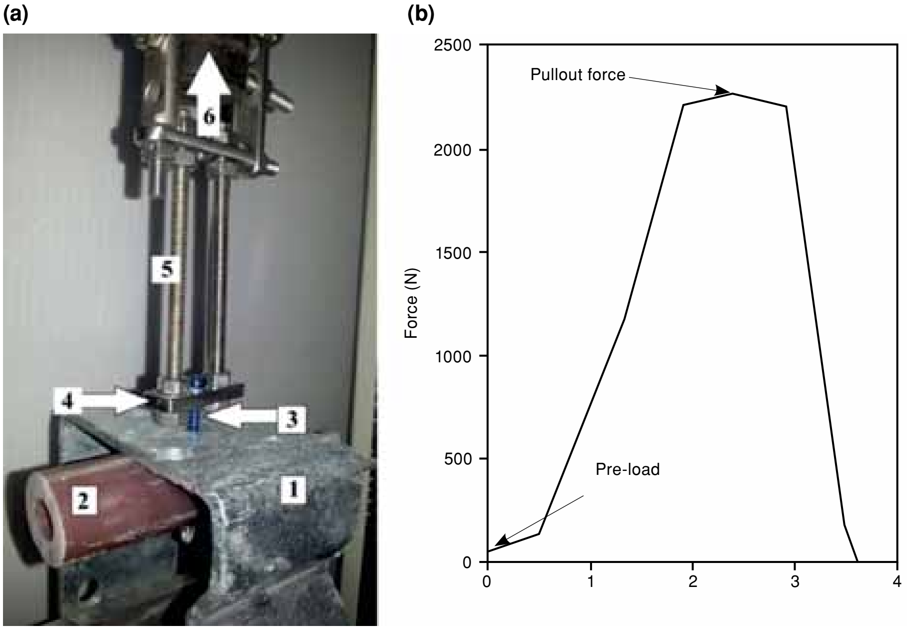

Figure 3. (a) Screw dimensions of dimension groups 1 and 2. **(b)** Typical raw data graph: force-versus-displacement.

dependent on the pullout force, it is not considered as an independent data; but, merely a calculated value of an already collected data. To increase visual understanding, the pullout forces of each screw type were sorted in an ascending order.

Statistical analysis

The pullout force values were evaluated by the software tool SPSS for Windows version 15.0 (SPSS Inc., Released 2006; Chicago, IL, USA). One-way analyses of variance (ANOVA) with $p<0.05$ were carried out on pullout forces, to detect statistical differences. Tamhane's T_2 test with $p<0.05$ was used for all post-hoc analysis to detect any specific pairwise differences. Post hoc power analysis tests were also carried out to determine if the number of femur specimens per screw type were enough. Power analysis was necessary to avoid statistical type 2 error; i.e. to detect all individual statistical differences that may have been present between screw types.

RESULTS

A typical force-versus-displacement raw data graph of a screw pullout test is provided in (Figure 3b). The same pattern was observed for all screw types. The graphs started with a 50 N pre-load, followed by a steep rise in the load, as extraction proceeded. A peak force was reached followed by a steep drop in the load, indicating the failure of the screw-bone interface. The drop continued as the screw moved relatively unhindered inside the insertion site. The maximum force (peak force) applied was named as the pullout force, similar to previous studies.[22,25]

Pullout measurements

The pullout forces were first tabulated, as they occurred during the tests. Then, they were sorted in an ascending order for each screw type. Type 1 recorded the highest pullout force, in every test and at every insertion site. Type 5 was the runner up, also scoring higher pullout forces than types 2, 3 and 4 at every insertion site. The two highest performing screw types were in DG1, to point to the fact that pullout force is highly dependent on the screw dimensions.

The mean of the pullout force was named as the absolute pullout force.[25] The absolute pullout forces of the screw types are shown in a bar chart (Figure 4a). The absolute pullout force for type 1 was the highest, whereas for type 3 it was the lowest. Hence, the force requirement performance of type 3 was the poorest, and for of type 1, was the best. Among the screws in DG2, type 4 required higher pullout forces than the rest. However, it can be concluded from absolute pullout forces that performance of DG1 screws was superior to that of DG2 screws.

The statistical results of the pullout forces are given in (Table II). Post-hoc power analysis is necessary to determine if enough specimens per group were present to detect all statistically significant differences. Usually a power of 80% is accepted as the minimum threshold. In present univariate analysis of variance,

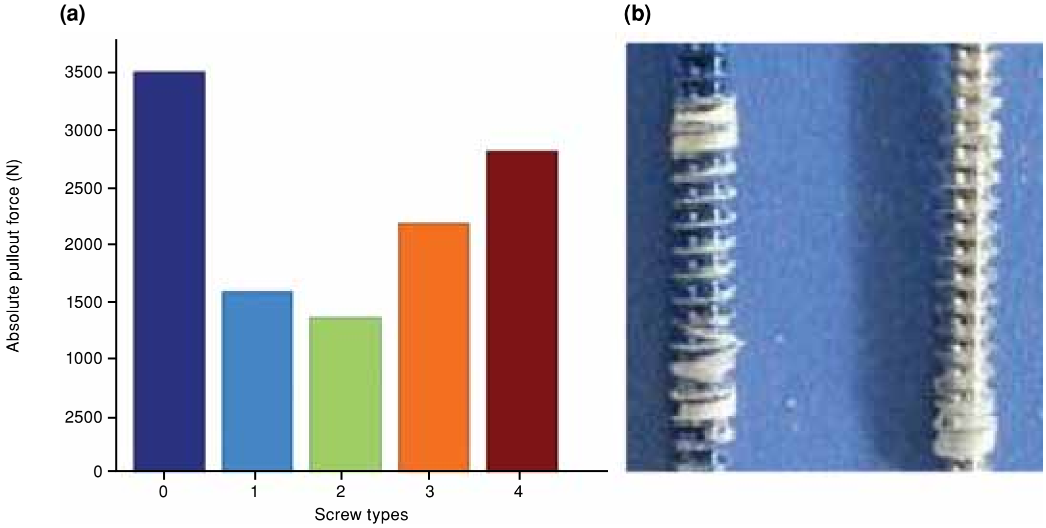

Figure 4. (a) Absolute pullout forces, according to screw types. **(b)** Volume of bone material sheared off from artificial femurs of present study.

the observed power was 100% (p=1,000) proving that enough number of samples were present in the test; contrary to the failing values in a previous work.[25] The thickness of bio-cortex at a specific drilled point on the femur diaphysis did not affect the results, because screw types were rotated at insertion sites.

Statistical difference was examined using the t test with a significance threshold at $p \leq 0.05$. The assumption of equal variances was justified at every test with $0.831 > p > 0.227$. Although the pullout force performance of type 1 was higher than type 5, no statistical difference was detected (p=0.114). Otherwise, type 1 pullout force was significantly different than the other screws with $p<0.05$. Type 2 pullout force values were not significantly different than type 3 (p=0.417) or type 4 (p=0.70), but significantly lower than type 5 (p=0.003). Type 3 pullout forces were significantly different (lower) than types 4 and 5 (p=0.011 and p=0.000, respectively). Type 4 pullout forces were not significantly different than type 5 values (p=0.107). According to ANOVA test's post hoc Tamhane's T_2 test results, types 1 and 5 were not significantly different (p=0.70). Types 2, 3, and 4 were not significantly different than each other. Thus, Tamhane's T_2 test results approved our previous DG1 and DG2 dimensional categorization. Finally, types 4 and 5 were not significantly different, placing type 4 one step closer to DG1 category.

For normalization, the traditional method [normalized absolute pullout force = absolute pullout force/(π × outer diameter × bicortical thickness)] was used.[22,25] The normalized absolute pullout force is defined as shear stress and expressed in N/mm^2.[22,25] The observed power was $p>0.999$, proving the existence of adequate specimens for each test.

TABLE II

Statistical results of pullout tests, obtained from SPSS

Screw type	n	Mean±SD	Standard error	Low. Boun.	Up. Boun.	Min.	Max.
Type 1	10	3506.80±940.89	297.54	2833.73	4179.87	1495.00	5071.00
Type 2	10	1591.00±658.19	208.14	1120.16	2061.84	786.00	2658.00
Type 3	10	1364.30±557.49	176.29	965.50	1763.10	648.00	2152.00
Type 4	10	2188.40±726.50	229.74	1668.70	2708.10	1074.00	3019.00
Type 5	10	2816.20±915.67	289.56	2161.17	3471.23	1261.00	4079.00
Total	50	2293.30±1088.83	153.98	1983.90	2602.78	648.00	5071.00

SD: Standard deviation; Min.: Minimum; Max.: Maximum.

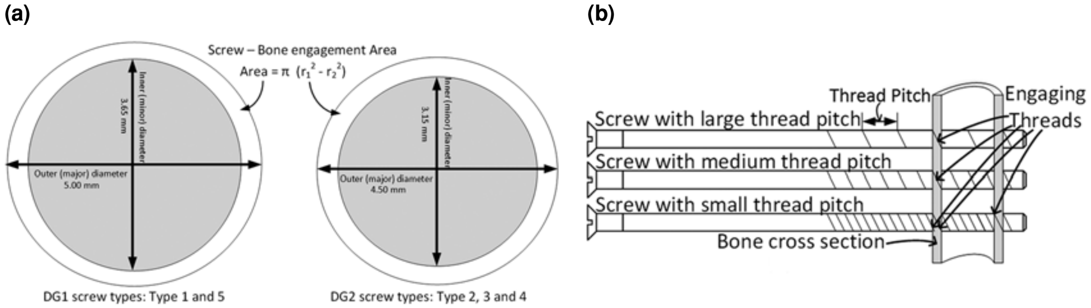

Figure 5. (a) Differing bone-screw engagement areas of dimension groups 1 and 2. **(b)** Different number of engaging threads for different thread pitches.

The outer diameter (5.00 mm) and thread depth (0.675 mm) of DG1 was larger than the outer diameter (4.50 mm) and the thread depth (0.625 mm) of DG2. The physical dimension differences did not change the order of the screw performance. Normalization led to the highlighting of the significant difference between type 1 and type 3.

According to ANOVA test results of normalized absolute pullout forces, types 1, 4, and 5 were not significantly different ($p>0.101$). Thus, type 4's performance was understood better, after its dimensions were taken into consideration. On the other hand, types 2, 4, and 5 were not significantly different than each other ($p>0.105$), which put type 4 in a lower performance group as well. The grouping of type 4 in two different performance groups gave rise to an inconclusive categorization of type 4 screws.

As reported in a previous study, screws pulled out from the femurs failed by shearing of bone matrix.[25] In all screw types, a volume of artificial bone matrix remained lodged in-between screw threads (Figure 4b). This shows that the three dimensional engagement of the screw is the product of thread depth and the area between the outer and inner diameters, which results in the volume of removed material. At the end of each test, all screws were examined for bending and cracking. No bending or cracking was found in the screws used in our tests.

DISCUSSION

The exact area of engagement between the screw and bone surfaces is indicated in Figure 5a. It is the area remaining between the outer and inner areas of the screw, i.e. the ring area formed by the thread depth of the screw. The engagement surface areas of the two screw groups DG1 and DG2 are different. However, the traditional normalization formula considers only the outer diameter and the biocortical thickness, which is not a true three dimension consideration. Substitute the radius $r=d/2$ (d=diameter of a circle) in the surface area formula of a circle $\pi \times r2 = \pi \times d2 \times ¼$, hence, the denominator of the traditional normalization method is misleading by a factor of $d/4$. Since biocortical thickness is constant in our experiments, it is not a factor in normalization calculations. Based on the above argument and the observations in Figure 4b and 5, we propose a new normalization method using the engagement area and thread pitch. The thread pitch affects the pullout force as it can be observed in Figure 5b. For small pitch values, the probability of multiple threads engaging the bone increases. Thus, the normalization formula becomes:

True normalized absolute data = absolute data/the engagement area × thread pitch. Engagement area is given by $\pi/4 \times$ [(outer diameter)2 - (inner diameter)2]. Using the definition in a previous study,[3] the true normalized absolute pullout force diagram becomes as shown in Figure 6.

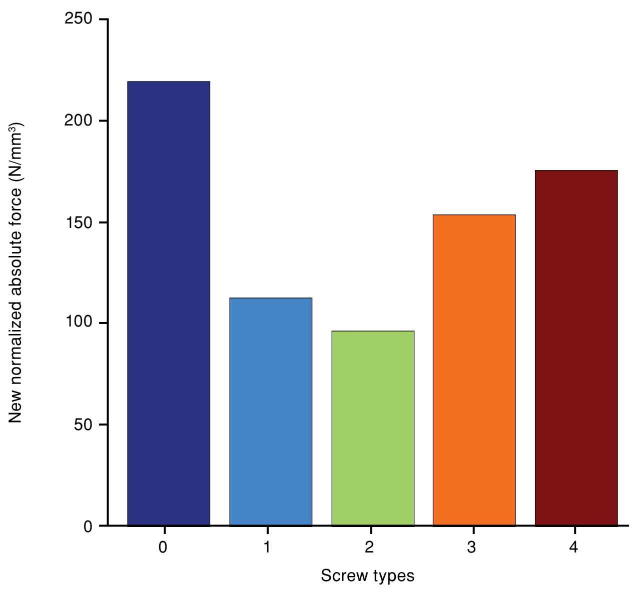

Figure 6. Absolute pullout forces normalized using our proposed method.

After our proposed normalization, the true normalized absolute force values varied between (96-219 Nmm^3). The Nmm^3 unit of measurement showed that our consideration is a three dimensional volume consideration. This is indeed supported by the volume of the sheared off bone matrix reported in our study and previous studies. The most striking observation of the ANOVA analysis result was that type 1 was significantly different than types 2 and 3 ($p=0.004$ and $p=0.001$, respectively), but not different than types 4 and 5 ($p=0.167$ and $p=0.705$, respectively). The difference between types 4 and type 5 decreased. The results promoted type 4 into the performance group of DG1, even though its dimensions are smaller than DG1. This is due to the fact that types 2, 3, and 4 were now divided by a true three dimensional denominator, rather than by a two dimensional denominator.

Multiple cortical screws are used in bone fixation systems. The failure of one or more screws loosens the grip of the system on the bone and causes unsatisfactory bone knitting. Therefore, prior knowledge of the pullout force required to disengage a specific type of a screw from a bone can be an advantage. So, the test results on absolute pullout or normalized pullout forces are an indication of the performance of a specific screw. In other words, the higher the normalized absolute force needed to cause disengagement, the higher the performance of a screw. Hence, types 1 and 5 are the best performers of our study.

Obviously, using screws with larger dimensions ensures the need for larger shear stresses to loosen a screw; and thus is safer for use in relatively large host bones. But in cases where the host bone has small dimensions, it is advisable to use the smaller screw type 4 since it has a considerably better performance compared to other screw types of the same dimensions.

Normalized pullout force is regarded as a more reliable measure of screw performance.[25] Moreover, extra effort is needed to get a more accurate result, by incorporating Chapman et al.'s formula to the overall results of a study.[26] We argue that the classical normalization formula is not specifically accurate because the outer diameter of the screw and the thickness of the bone are one dimensional lengths, in the same planes. The surface area approach given in Figure 5a seems to be a more realistic comparison method, because it defines the exact screw-bone engagement area and accounts for the bone volume sheared off. Therefore, inclusion of the thread pitch in our proposed normalization formula is also justified by the argument presented in Figure 5b, since it decides on the number of screw threads engaged to the bone. Consequently, the pullout force necessary to disengage a screw from the bone is dependent on the engagement area and the thread pitch.

Keeping the bone thickness constant helped the present study to focus only on the screws. Eliminating the bone thickness variable from consideration made comparison between screws simpler and more direct. The present study has three clear advantages compared to previous works. Firstly, the geometrically parallel set-up of the screw and the pullout mechanism axes (3 and 5 in Figure 3a) resulted in zero bending of the screws. Secondly, the present study has statistically satisfactory number of specimens. Thirdly, it can detect all statistical differences with post hoc powers over 80%.

Our study has some limitations. At the beginning of the tests, "toggling" was not considered, although it can be a clinical screw loosening and failure mechanism. In surgical real life operations, the screws are used together with fixation plates, which provide physical insertion site that re-enforces the screw. The insertion of the screw into the plate increases the pullout and toggling forces. During present study, no fixation plates have been used. The test setup only guaranteed that the pullout force was along the long axis of the screw to eliminate any deforming torques.

In conclusion, our results showed that screw types with larger outer diameter and pitch depth needed larger normalized pullout forces; i.e. had better performance. A new three dimensional pullout force normalization method that takes the screw-bone engagement surface area and the thread pitch into consideration was presented. The proposed normalization method verified the classic normalization method results, but also helped to credit the performance of a smaller dimension screw more than the classical method. Future mechanical tests and studies should be conducted to evaluate the newly described normalization method to find out if the method can be improved or better interpreted.

Declaration of conflicting interests

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