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RESEARCH ARTICLE

The Evaluation of Pullout Tests of An Expandable Newly Designed Screw

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Summary

Biomechanical evaluation of pullout forces of newly designed cortical screws with openable tips was done in the tibia bone of the young bulls. Newly designed expandable titanium 14 cortical screws with openable tips were inserted in fresh tibia bone. Of these screws, 7 were used as controls. The bones were fixed with polymethylmethacrylate after the insertion of the screws. Screw heads were attached to a custom device and prepared for pullout tests. The elastic modulus values (Newton/mm^2), yield forces (Newton) and maximum forces (Newton) of expandable and control groups were assessed. The median of yield forces (Newton) of expandable cortical screw group was found to be statistically higher than that of normal group (P=0.025). The median of maximum forces of expandable cortical screw group was found to be significantly higher than that of normal group (P=0.003). In the comparison of paired groups, it was found that the pullout forces of expandable cortical screws were significantly superior to that of normal control group. In the light of these results, it was concluded that such kind of newly designed screws are able to contribute to fracture fixation in the future, allowing more bone contact without enlarging the diameter of the screw.

Keywords: *Expandable screw, Pullout test, Fracture, Bone*

Ekspanse Olabilen Yeni Tasarım Bir Vidanın Sıyırma (Pullout) Testlerinin Değerlendirilmesi

Özet

Ucu açılabilir yeni tasarlanmış kortikal vidaların sıyırma kuvvetlerinin biomekanik olarak değerlendirilmesi genç boğaların tibia kemiğinde yapıldı. Yeni tasarlanmış ucu açılabilir 14 kortikal titanyum vida taze tibia kemiğine yerleştirildi. Bu vidaların 7 tanesi kontrol grubu olarak kullanıldı. Vidalar yerleştirildikten sonra kemikler polimetilmetakrilat ile fikse edildi. Vida başları özel bir alete bağlandı ve sıyırma testi için hazırlandı. Elastik modulus değerleri (Newton/mm^2), akma kuvveti (Newton) ve maksimum kuvvet (Newton) değerleri ucu genişleyebilen ve kontrol gruplarında değerlendirildi. Ucu genişleyebilen kortikal vida grubunun ortalama akma değerleri istatistiksel olarak normal gruba göre daha yüksek bulundu (P=0.025). Genişleyebilen kortikal vida grubunun maksimum güçlerinin ortalaması normal gruba nazaran önemli derecede yüksek bulundu (P=0.003). Eşlendirilmiş grupların karşılaştırılmasında genişleyen kortikal vidaların pullout kuvvetlerinin normal kontrol gruplara nazaran önemli derecede yüksek olduğu bulundu. Bu çalışmalarımızın ışığı altında yeni tasarlanmış böyle vidaların vida çapını genişletmeksizin daha fazla kemik kontağına izin vererek gelecekte kırık fiksasyonuna katkıda bulunabileceği tartışıldı.

Anahtar sözcükler: *Genişleyebilen vida, Çekme testi, Kırık, Kemik*

INTRODUCTION

The bone screws are commonly preferred especially in stabilization of fractures. The maximum force that can be transferred between the screw and the bone establishes the insufficiency of osteosynthesis. That maximum load is named

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as pullout strength (PS) [1]. It is difficult to assess the pullout strength of a screw. Various factors affect it. These factors are the bone features, screw diameter, screw type, predrilling and tapping [2].

The best solution to enhance the efficacy of the screws used for osteosynthesis is to make changes in design of the screw. Especially with the screws having expandable tip a better bone fixation can be achieved by enlarging the diameter of screw tip, allowing further bone contact without enlarging the diameter of the screw itself inserted in the bone [3].

The bone-screw interface is faced as a weak link in fracture fixation. An inaccurate screw fixation causes to screw loosening, implant insufficiency, loss of reduction and nonunion. The distortion of bone-screw interface occurs especially in loading condition [4].

In our present study, it was planned to assess bio-mechanically in the tibia bone the pullout strengths of a newly designed cortical screw, which has an expandable tip after the insertion into the bone.

MATERIAL and METHODS

The designs of 14 titanium cortical screws with expandable tips were drawn using AutoCAD program. Processing details were created by master cam program *(Fig. 1)*. Then, these screws designed were processed (manufactured) on Spinner TC 600 lathe. When the anatomical structure of the screws were evaluated, the length of the screw was 60 mm. The screw was designed to have an outer diameter of 7 mm; a screw thread root of 4.5 mm; a screw thread crest of 1.3 mm and a pitch of 2.7 mm. The screw was consisted of 2 *pieces* (*Fig. 2A* and *2B*). The first piece was the main screw *(Fig. 2A)*, the second one was created in an ergonomic design that provides expansion of the tip of the screw, passes throughout the hole in the middle of the main screw and is able to be fastened proximally to the main screw to maintain the expansion permanently *(Fig. 3A)*. It was determined that the outer diameter of the screw reaches to 8 mm by expansion of the tip. So, it was observed an increase in outer diameter by the rate of 14.2% *(Fig. 3B)*. A groove was made at the outer side (of the head of the screw) to connect the screw head to the device that performs the pull test in pullout test *(Fig. 3B-X)*. The tibia bones used in the study were obtained from 18-month-old Black Pied breed young bulls in the mean live weight of 500-550 kg; the fresh bone blocks of 7x4 cm in size were used *(Fig. 4)*. The 14 screws were inserted into bones according to the procedure. Seven of them were expanded. All of the prepared screw-bone systems were radiologically evaluated to eliminate an osseous pathology or an inaccurate insertion of the screw.

Biomechanical Assessment

These studies were evaluated by performing a pre-study using pulling devices located in the laboratories of the Department of Mechanical Engineering of Istanbul Technical University. Screw Driven Type Testing Machine (Schimadzu brand name, autograph type AG, IS, 50 KN model) was used. This device that is able to do computer-assisted measurements with very accurate loads was

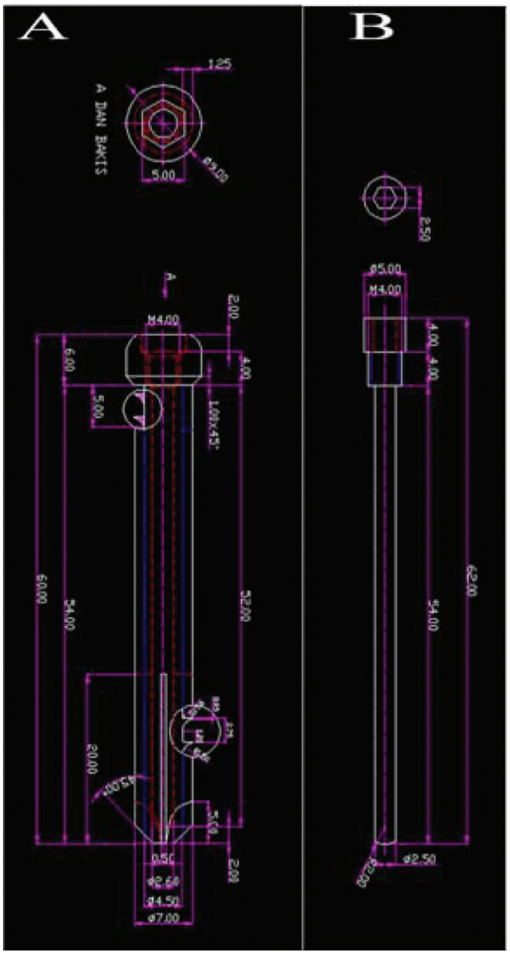

Fig 1. The AutoCAD design of the main component and the second component that allows expansion of the screw

Şekil 1. Vidanın ana komponenti ve genişlemesine izin veren ikinci komponentinin AutoCAD programı ile tasarımı

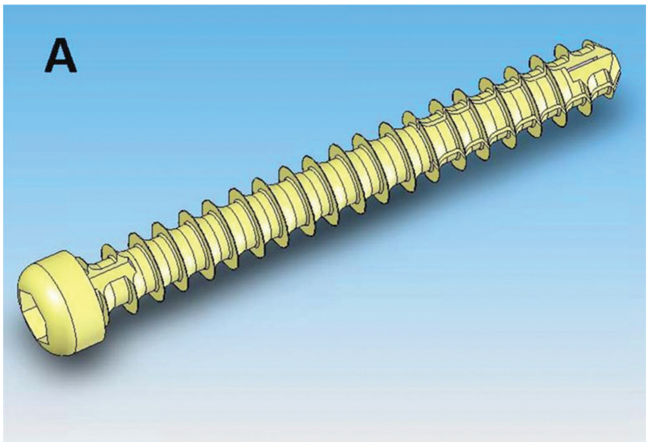

Fig 2A. The main component of the screw

Şekil 2A. Vidanın ana komponenti

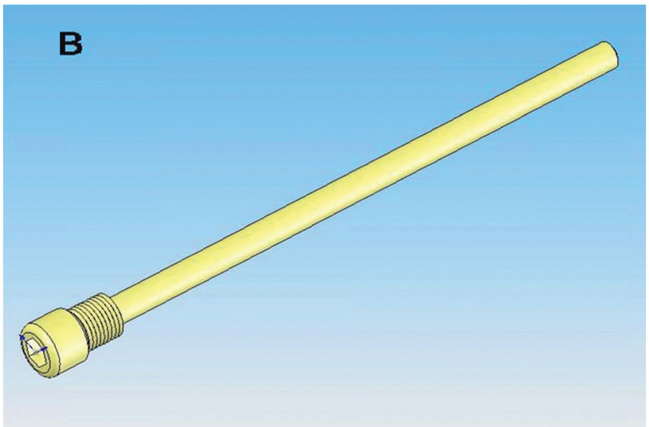

Fig 2B. The second component of the screw

Şekil 2B. Vidanın ikinci komponenti

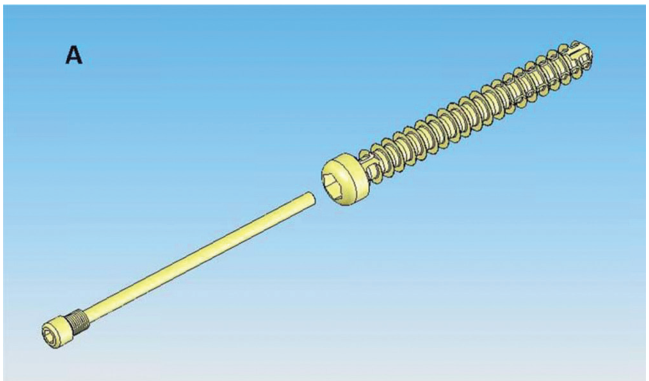

Fig 3A. The second screw component that allows expansion of the screw tip and locks of the main piece after the screw has been expanded

Şekil 3A. Vida ucunun genişlemesine izin veren ve vida ucu genişledikten sonra ana parçayı kilitleyen vidanın ikinci komponenti

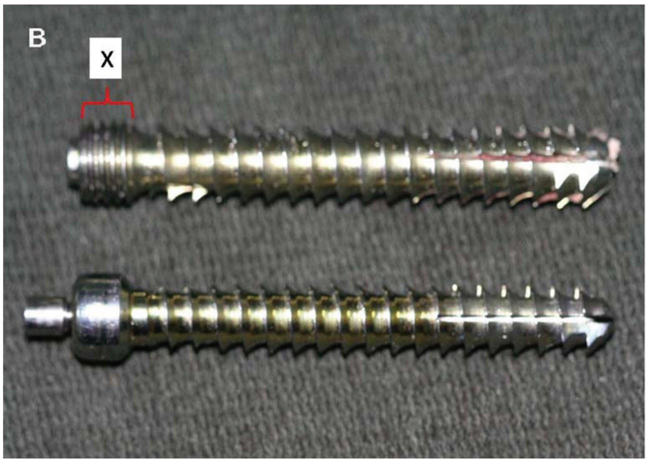

Fig 3B. X. The thread provided to connect the screw head to the pulling device for the pullout test

Şekil 3B. X. Çekme testi için çekme aletine vida başının bağlanmasını sağlayan yiv

prepared for our test. Under stroke control, the strength was measured by pulling at a constant velocity with the movement of the upper part of the device. This procedure was applied over single axis on axial plane. A test velocity of 10 mm/min was chosen throughout pulling. At the end of the test, strength-elongation graphics were obtained and documented.

Fig 4. Fixing of the screw with methylmethacrylate after insertion into the bone and the connection to the pulling device

Şekil 4. Kemiğe yerleştirildikten sonra metilmetakrilat ile vidanın tespit edilmesi ve çekme aletine bağlanması

RESULTS

Of all of the screws exposed to pulling test, elastic modulus values (Newton/mm^2), yield forces (Newton) and maximum forces (Newton) were assessed (*Table 1, 2* and *Fig. 5, 6*). The results were compared statistically. Statistical analyses were performed by NCSS 2007 pack program. For the assessment of the data, Mann-Whitney U test for the comparison of paired groups and the definitive statistical methods (median, standard deviation) were used. The results were evaluated at the significance level of $P<0.05$.

The mean of the yield forces of the group of the expandable screws was found to be statistically higher than that of normal group ($P=0.025$). The mean of the maximum forces (Newton) of the group of the expandable screws was determined to be significantly higher than that of normal group ($P=0.003$) *(Table 3)*.

Table 1. *The elastic modulus, yield force and maximum force values of normal group*
Tablo 1. *Normal grubun elastik modulus, akma kuvveti ve maksimum kuvvet değerleri*

Normal Grup	Elastic Modulus (New/mm²)	Yield Force (Newton)	Maximum Force (Newton)
1	2381.45	1445.23	1624.14
2	2724.19	1410.12	1713.83
3	2211.39	1328.75	1345.31
4	2197.44	1647.19	2002.11
5	1969.45	1691.72	1731.95
6	2186.86	1536.88	1595.63
7	3000.23	1597.81	1722.97

Table 2. *The elastic modulus, yield force and maximum force values of expandable group*
Tablo 2. *Ekspanse olabilen grubun elastik modulus, akma kuvveti ve maksimum kuvvet değerleri*

Ekspandable Group	Elastic Modulus (New/mm²)	Yield Force (Newton)	Maximum Force (Newton)
1	2660.07	1495.94	1791.80
2	1875.77	3410.78	3555.00
3	2573.00	2662.19	2695.47
4	3428.17	2957.34	2998.59
5	2795.62	3037.66	3535.00
6	2528.35	1680.16	2328.75
7	2021.86	1598.20	2615.00

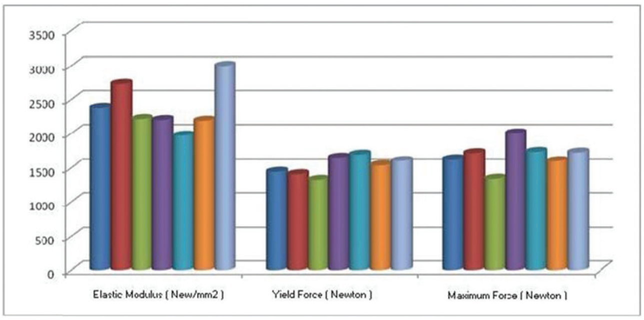

Fig 5. The elastic modulus, yield force and maximum force values of normal group

Şekil 5. Normal grubun elastik modulusu, akma kuvveti ve maksimum kuvvet değerleri

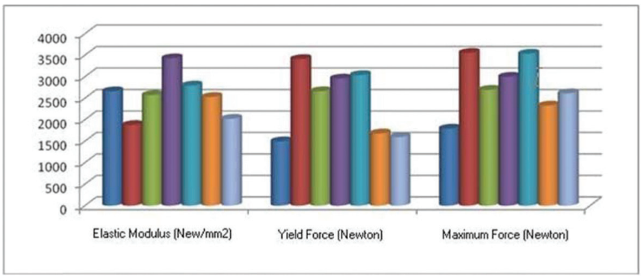

Fig 6. The elastic modulus, yield force and maximum force values of expandable group

Şekil 6. Ekspanse olabilen grubun elastik modulus, akma kuvveti ve maksimum kuvvet değerleri

In the comparison of paired groups, it was observed that the pullout strengths of the expandable cortical screws were significantly superior to that of normal controls *(Fig. 7)*.

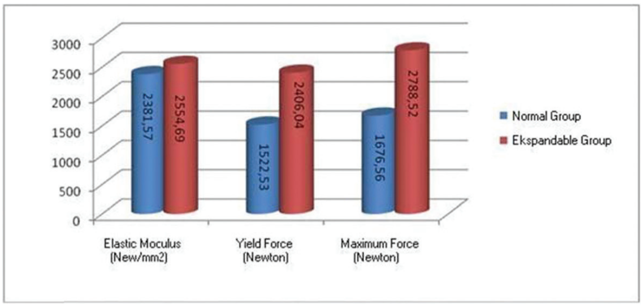

Fig 7. Comparison of the means of elastic modulus, flow force and maximum force of the normal and expandable groups

Şekil 7. Normal ve ekspanse olabilen grubun elastik modulus, akma kuvvet ortalamalarının karşılaştırılması

Table 3. *Comparison of the means of elastic modulus, yield force and maximum force of the normal and expandable groups*
Tablo 3. *Normal ve ekspanse olabilen grubun elastik modulus, akma kuvveti ve maksimum kuvvet ortalamalarının karşılaştırılması*

Comparison of Groups	Normal Group	Ekspandable Group	Median	P
Elastic Modulus (New/mm²)	2381.57±358.41	2554.69±512.83	20	0.565
Yield Force (Newton)	1522.53±133.04	2406.04±794.33	7	0.025
Maximum Force (Newton)	1676.56±196.48	2788.52±636.72	1	0.003

DISCUSSION

Many factors can affect the holding strength and insertional torque at the bone-screw interface. These factors are the screw thread, screw design, self-tapping/non-self-tapping screws, coating of the screw, unicortical or bicortical insertion [2,5,6].

The advantages of the screws with sharp-shaped threads should include ideally insertion of the screw, minimal soft tissue irritation and easing of the maximal screw holding power. The insertion of the screws with more than one thread is easier and they do not cause to cortical injury. In the studies carried out, it was observed that the insertion of the screws with 4 full threads was easier and had the highest level of the holding-strength [7].

The high level of screw osseointegration has being tested to ameliorate the screw fixation. For this purpose, titanium screws are recommended. Because, titanium material has a higher level of biocompatibility and better osseointegration character compared to stainless steel. The reason of why we preferred titanium material is the biocompatibility character of titanium. However, direct bone-screw contact is absent in titanium screws either [4]. Enhancing the bone-screw contact has been achieved by either the changes in screw design or enhancing the bone-screw interface relation via coating of the screws with osteoconductive materials [4,8].

It was determined that coating the screws with osteoconductive materials provided a maximum fixation power that was significantly higher than that of standard screws [4]. Such kind of technological innovations have some risks in aspects of rigid fixation after surgery besides an additional burden of cost. Because, establishing a bone-screw interface relationship after application of such materials takes a certain period of time. But, the screws with expandable character have the opportunity to create a rigid fixation from the beginning.

The main purposes of easily applicability and effectiveness of the screw designed are very important in screw design. The thought of designing such kind of screw was arisen from the problems encountered with the traditionally applied screws. The problems especially encountered during practice with cancellous and osteoporotic bones lead us to pursuit an alternative screw design. The important steps in the practice of screws with expandable character were thought to overcome the problems particularly encountered with the pedicular screws [9]. For the problems occurred in vertebral surgery during the application of pedicular screws and in revision surgery, many authors suggested the enlargement of screw dimension, careful care and attention for the preparation of the screw hole, the use of full-threaded screw and bone cement support [3,11-17].

The usefulness of such kind of alternative screw designs and the implementations to increase the screw stability is a matter of debate. Because, we should consider the possible injury in the bone with newly designed screw application, exothermic reactions due to the biocompatible cement when used and the problems that can occur in revision surgery.

In conclusion, considering all of these studies carried out, the best solution may be the changes to do in screw design. Therefore, the use of expandable screw may provide a better bone fixation by enlarging the dimension of screw tip, allowing more bone contact without increasing the dimension of the screw itself inserted into pedicle [3].

When the screw structures were studied, it was found that a screw with wider dimension was more powerful than a screw with narrow dimension. A wide screw in dimension is stronger than a narrow screw [17]. Although the pullout strength of a screw changes with the size of the screw, it is also due to the situation whether the bone is osteoporotic or not [15]. In addition, it was determined an association between the pullout strength of the screw and the cortical thickness of the bone [18].

The studies suggesting the ability of evaluating of the pre-surgery screw fixation power by bone density measurement put the osteoporosis factor forward in the screw fixation [16,17,19]. Despite the problems related to the osteoporosis and the problems arising from the bone, the attempts enhancing the implant stability have always been regarded [20]. For example, it was investigated whether the therapy with the combination of alendronate and calcitriol given pre-operatively contributed to the stability of the implants coated with hydroxyapatite in osteoporotic bone, increasing the mineral density of cancellous bone [21]. It is possible to increase the screw fixation power in the osteoporotic vertebrae using pedicle screws coated with hydroxyapatite [8].

In revision patients, the increase in the dimension of the screw didn't provide the bone-screw interface power and pedicle fullness; the stability was tried to achieve with the use of expandable pedicular screw [9,22].

Although it is argued that a wide screw don't increase the fixation power in osteoporotic bone, some researchers suggested that PMMA addition or some biological treatments on the surface of the screw increased the fixation power of the screw. Nevertheless, such problems like adverse effects of PMMA exothermic reaction and foreign body effect should be considered. Calcium phosphate cement (CPC) instead of PMMA was preferred as an option [10,14,21,23-25].

The success of the osteosynthesis is established by the maximum load that can be transferred between the screw and the bone. This maximum load is called as pullout strength (PS). In the light of the knowledge mentioned, PS is faced as a very important factor in osteoporotic bone [1].

The fact that the loss of fixation is more frequent in such cases especially with rheumatoid arthritis leads the researcher to find out alternative solutions such as the use of special plate screws for these cases [26].

Only the bone density itself cannot explain the changes related to the mechanical features of the bone-screw interface. The bone structure and particularly pedicle morphology affect the pullout load in vertebrae [27].

One of the several screw designs is whether the screw is self-tapping or not. The self-tapping cortical bone screws have increasingly been begun to use in recent years. Such kind of screws is that commonly used for fracture fixation. Even this type of screws has disadvantages especially when they are used in an osteoporotic bone. One of the most important disadvantages of this type of the screws is the increase of insertion torque needed during the insertion of the screw because of the increased contact force as the bone is actively drilled. This increased friction may contribute the screw insufficiency causing cortical injury even at microscopic level [1,28].

Andrew et al. biomechanically evaluated the performance of the self-tapping cortical screws (STS) considering the deep of the insertion of the screw. They saw that the incomplete screw insertion would cause to failure in both osteoporotic and normal bones [29].

The number of the threads is very important in the screw design. It is recommended the presence of at least three threads at the tip of the screw to avoid stripping the thread [7].

Although it has been explained many factors that may affect the holding strength of the bone-screw structure, it should be known that some malpractices in screw application may impair the results. It should be regarded that over-tightening of the screws results to future loosening and failure of the fixation in case of the excessive microinjury in the bone surrounding of the screw threads [30].

The feature of expendability of the tip part of our designed screws in a rate of 14.2% compared to the normal screw dimension after the insertion under normal conditions is very important. In the pullout tests that we performed bio-mechanically, suggesting a significant increase in the pullout strength of the screw after that expansion, we found that the mean of the maximum forces (Newton) of the expandable group were statistically significantly higher than that of the normal group (P=0.0003) *(Table 3)*. Moreover, it was observed that the mean of the flow forces (Newton) of the expandable group was statistically significantly higher than that of the normal group *(Fig. 7)*.

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