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May "Dubel" be a Solution for Pullout Problem of the Pedicle Screws at Osteoporotic Spine?

"Dübel" Osteoporotik Omurgadaki Pedikül Vidası Sıyrılmalarına Çözüm Olabilir mi?

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ABSTRACT

AIM: To improve the strength of stabilization systems currently used in osteoporotic spinal fractures, essentially by increasing the fixation force of pedicle screws.

MATERIAL and METHODS: Six human cadaveric vertebrae were used. Bone mineral densities of the specimens were measured with Dual Energy X-ray Absorptiometry in order to assess the osteoporosis. All vertebrae were found to be severely osteoporotic. Standard pedicle screws were applied to left pedicles of vertebrae. Pedicle screws reinforced by fixing plugs "Dubel" were applied to right pedicles of vertebrae. Afterwards the vertebrae were embedded in acrylic casts to prevent possible fracture of the osteoporotic vertebrae and to obtain a correct vertical pull-out vector. The biomechanical pullout tests were performed with biomechanical testing machine. Pullout forces in each group were recorded and compared with Mann-Whitney U test.

RESULTS: The pedicle screws strengthened by "Dubel" were found to be four times stronger than the standard pedicle screws, in the osteoporotic human cadaveric vertebrae.

CONCLUSION: "Dubel"-augmented pedicle screws may contribute to developing better stabilization systems for osteoporotic thoracolumbar fractures needing surgery and in the revision of the previous fusion surgeries of the spine.

KEYWORDS: "Dubel", Osteoporosis, Pedicle screw, Revision, Thoracolumbar fracture

ÖZ

AMAÇ: Osteoporotik spinal fraktürlerde güncel olarak kullanılan stabilizasyon sistemlerinin gücünü; özellikle pedikül vidalarının omurgaya daha güçlü tutunmasını sağlayarak artırmaktır.

YÖNTEM ve GEREÇLER: Altı insan kadavra omuru kullanıldı. Örneklerin kemik mineral dansiteleri, dual enerji x-ışını absorpsiometri kullanılarak ölçüldü ve hepsi de ileri derecede osteoporotik bulundu. Her omurun sol pedikülüne kullanımdaki standart pedikül vidası, sağ pedikülüne ise "dübel" ile güçlendirilmiş pedikül vidası implante edildi. Daha sonra omurlar, test sırasındaki olası kırıkları önlemek için akrilik içine gömülüp biomekanik test makinasıyla çekme testleri yapıldı. Her iki gruptaki vidaların çekme kuvvetleri kaydedilip, gruplar Mann- Whitney U testi kullanılarak karşılaştırıldı.

BULGULAR: Çalışmada, osteoporotik insan kadavra omurunda, "Dübel" ile güçlendirilen vidaların standart pediküler vidalara göre dört kat daha güçlü olduğu bulundu.

SONUÇ: Pediküler vidaların "dübel"le desteklenmesinin cerrahi girişim gerektiren osteoporotik torakolomber kırıklarda ve daha önceki füzyon ameliyatlarının revizyonunda da kullanılabilecek daha iyi stabilizasyon sistemlerinin geliştirilmesi yolunda ümit verici olabileceğini düşünmekteyiz.

ANAHTAR SÖZCÜKLER: "Dübel", Osteoporoz, Pedikül vidası, Revizyon, Torakolomber fraktür

INTRODUCTION

Osteoporosis is a metabolic disease of the bone characterized by reduction in the bone mass (5), and may lead to skeletal fragility, spontaneous fractures, spinal instability and deformity, which in turn may cause chronic pain and neurological deficit (16). Osteoporosis-associated fractures most commonly involve the hip, spine or wrist (15). Spinal stabilization and spinal fusion are widely used for the treatment of osteoporotic vertebral fracture and spinal deformity.

This study was planned to overcome the insufficiency of the stabilization systems used in osteoporotic vertebral fractures requiring surgery and to minimize the complications encountered during or after the surgery. In this study we planned to use a fixing plug *"Dubel"* to increase the pullout force of the pedicle screws from the osteoporotic vertebrae and by this way to strengthen and increase the performance of the stabilization systems.

MATERIAL and METHODS

Six previously formaldehyde-embedded human cadaveric vertebrae were obtained from our Department of Anatomy with the consent of the ethics committee.

The specimens were divided into two groups. Group 1 was only pedicle screw applied group and Group 2 was pedicle screw with "*Dubel*" applied group.

Bone mineral density (BMD) of the cadaveric vertebrae were measured by Dual Energy x-ray Absorptiometry (DEXA) before the procedure and the values are presented in Table I. To obtain a vertical pullout force; pedicle entry points and gravity centers of the each vertebra were calculated. Twelve titanium alloy pedicle screws (Blackstone, USA) were used in this study. Pedicle screws were applied to the left pedicles of the each vertebra (Group 1). Dimensions of the "*Dubel*" used in the study (Fisher Germany Art. –Nr 58106) was 5x30 mm, and there were 7 threads of 1mm depth. A 4 x 40 mm drill hole was made in the right pedicles before the application of the "*Dubel*". "*Dubel*"s were inserted into the pedicle pilot holes before the application of the pedicle screws (Group 2) (Figure 1). After insertions of the screw to the holes, the specimens were embedded in 50 cc acrylic casts (Figure 2) to prevent possible fracture of the osteoporotic vertebrae and to obtain a correct vertical pullout vector.

X-rays of the each specimen were taken to analyze the screw depth and angles. The biomechanical pullout tests were performed with a biomechanical testing machine (Instron 850, USA). A one sided vertical pullout force of 10 N/sec was applied to the specimens (Figure 3), and pullout forces at fatigue points were recorded for Group 1 and 2 (Figure 4, 5, Table II).

RESULTS

The pullout forces of the specimens were recorded (Table II).

The mean pullout force was 447.335 ± 53.251 Newton for Group 1 and 1671.091 ± 312.186 Newton for Group 2.

The difference was statistically significant (p= 0.003) when the two groups were compared with Mann Whitney U test.

The pullout forces of the "*Dubel*"-augmented pedicle screw group (Group 2) were 4 times higher than the pedicle screw only group (Group 1).

Figure 1: Application of "*Dubel*" to the right pedicle of the osteoporotic vertebra.

Figure 2: Specimen embedded in acrylic cast. Right pedicle has screw with "*Dubel*" and left pedicle has screw only.

Figure 3: Pullout test of the specimen with the Instron 850 biomechanical testing machine.

Table I: DEXA Analysis of the Specimens as BMD and T-Scores.

	BMD	T-SCORE
N1	0.739	-2.20 (%76)
N2	0.786	-2.34 (%75)
N3	0.720	-1.69 (%80)
N4	0.593	-3.31 (%66)
N5	0.771	-3.02 (%64)
N6	0.949	-1.23 (%88)

Table II: Table Showing Pullout Tests of Both Groups

Vertebrae	Group 1 (N)	Group 2 (N)
N1	456,09102	1408,33454
N2	421,13604	1445,09282
N3	504,93851	3222,41895
N4	232,89658	1344,57666
N5	235,06436	1204.03225
N6	634,03215	1402,12445

DISCUSSION

Osteoporosis and osteoporosis-related spinal deformities are a major health care problem. When osteoporosis cause problems requiring surgery such as fracture, deformity and stenosis, the surgical correction is challenging and carries a risk of construct failure due to the diminished bone mineral density and high comorbidity rates of the subjects. A high comorbidity rate and complications like post-instrumentation vertebrae fractures, pseudoarthrosis, and screw pullouts are common.

Several studies have been performed to minimize construct failure and revision surgeries in osteoporotic patients. Several biomechanical, biological, and biomaterial-oriented techniques have been described in the literature to overcome the complications encountered in this group of patients (25)

Multi-segmental stabilization is recommended in the osteoporotic spine (11, 18). To prevent failure in multilevel constructs, polymethylmethacrylate (PMMA) cement augmentation of the rostral pedicle screws is one option (11). Laminar hooks, sublaminar wires and pedicle screws are used with segmental constructs. At the caudal end of the osteoporotic spine, bilateral iliac screws and bicortical screws can be used (10, 30).

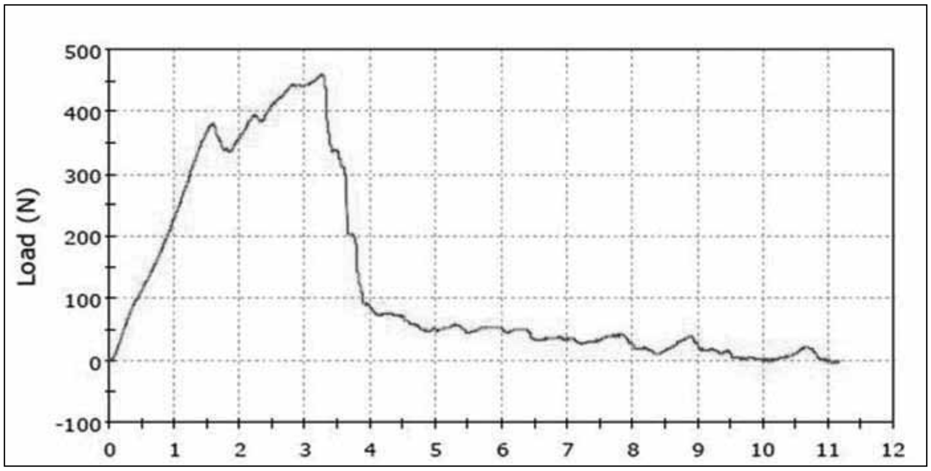

Figure 4: Graph showing pullout values of the screw without "*Dubel*". The peak pullout value was 456.09102 Newton for this specimen.
*The X axis is time (t)

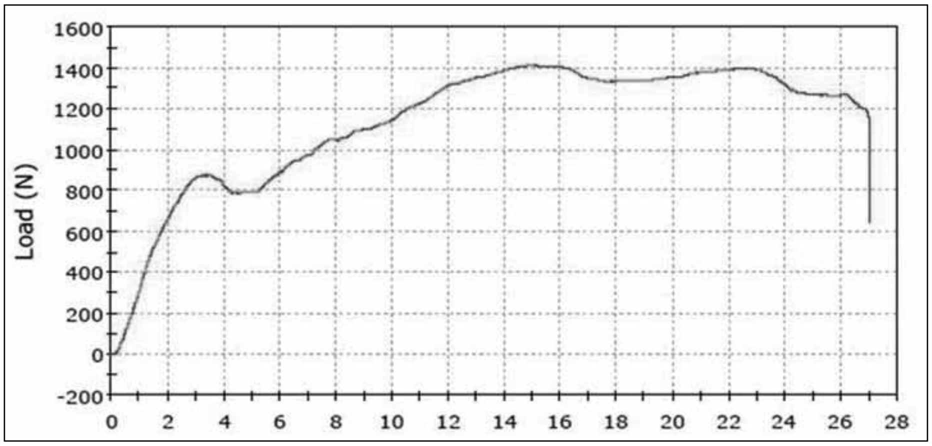

Figure 5: Graph showing the pullout values of screw with "*Dubel*". The peak pullout value for this specimen was 1408.33 Newton.
*The X axis is time (t).

To overcome the failure at the bone-screw interface that may result in screw pullout, several new approaches have been developed. The use of PMMA cement for pedicle screw augmentation has been reported in literature (4,6,23,24,27) Kyphoplasty–based or vertebroplasty-based pedicle screw augmentations are performed to yield significantly greater pullout strength (1, 6, 28). PMMA, calcium phosphate and injectable bioactive ceramic resins have all been used to augment vertebral screws (7- 9, 12, 17, 20, 21, 23, 26, 29, 31,32).

Bicortical screws have also been used to obtain stronger pedicle screw fixation compared to the cortical-cancellous bone screw fixation only. However, various anterior intra and extra abdominal organs and vascular structures may be injured (13,14,22). The use of hydroxyapatite-coated pedicle screws can improve pedicle-screw contact, bone fusion and mineralization that may increase the screw pullout strength (33). Implanting two-small pedicle screws into one pedicle to improve fixation is another reported option (19).

We compared the pullout forces of standard pedicle screws to that of pedicle screws augmented with "*Dubel"* at osteoporotic human cadaveric vertebrae in this study. In every tested subject, the "*Dubel"*-augmented pedicle screws achieved approximately 4 times higher pullout force than that of the pedicle screw only group (p=0.003), which confirmed our initial hypothesis.

Comparing our results with other pullout studies where different methods to improve pullout strength of the pedicle systems had been used, we found that "*Dubel"* was better than the double screw technique (19) and PMMA augmentation of the pedicle screws (6). PMMA augmentation of the pedicle screws increases pullout strength 2-3 fold (6) and the double screw technique provides a 7.5% increase (19). As we previously mentioned, "*Dubel"*-augmented pedicle screws had a 4 times higher pullout force, which is very satisfactory for osteoporotic vertebra.

We searched the literature but failed to find any studies on transpedicular "*Dubel"* augmentation of pedicle screws. This system may also help to achieve successful results in the pedicle screw revision surgery.

The use of human cadaveric vertebrae as in our study is the gold standard for in-vitro biomechanical studies on the spine. DEXA was used to calculate the BMDs of the vertebrae, and it is superior to x-ray for diagnosing osteoporosis.

Pullout forces of the standard pedicle screws and "*Dubel"*-augmented pedicle screws were tested at the same vertebra to enable a proper comparison in our study.

PMMA-augmented pedicle screws may cause pedicle fractures while PMMA leakage into the spinal canal may cause additional neurological deficits (2, 3).There is no risk of PMMA leakage with our system, and the system led to 4 times higher pullout values.

One of the shortcomings of this study is that the material used in the "*Dubel"* is not biocompatible but this can easily be overcome with the use of "*Dubel"*s manufactured from biocompatible materials such as polyetheretherketone, titanium, or even allograft bones.

It is hoped for the future that "*Dubel"*-augmented pedicle screws may contribute to developing better stabilization systems for osteoporotic thoraco-lumbar fractures needing surgery and in the revision of the previous fusion surgeries of the spine.

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The "*Dubel*" in the study is under consideration for a utility model application at the Turkish Patent Institute.

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