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Biomechanical Analysis of A Turkish-Made Posterior Spinal Instrumentation System

Part I. Evaluation of Pedcile Screw Pullout Strength

Türk Malı Bir Posterior Spinal Enstrumantasyon Sisteminin Biyomekanik Analizi

Bölüm I. Pedikül Vidası Sıyırma Direncinin Değerlendirilmesi

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ABSTRACT

OBJECTIVE: To determine the pullout strength of a Turkish-made pedicle screw (Tıpsan Posterior Instrumentation System, Tıpsan Tıbbi Aletler, İzmir, Turkey) compared to another well-known system (VSP System, DePuy AcroMed, Raynham, MA, USA).

METHODS: A series of pedicle screw axial pullout tests were performed in 14-week-old calf vertebrae. A sample size of 8 for both screw types was used to quantify pullout performance determined by peak load and stiffness.

RESULTS: The mean peak loads were 1892 ± 554 N for Tıpsan and 1959 ± 594 N for VSP screws. The difference was statistically insignificant ($p>0.05$). The mean stiffness values were also similar for the two screw types: 1063 ± 192 N for Tıpsan and 1126 ± 155.8 N for VSP screws ($p>0.05$). The mean insertional torque of the Tıpsan screw (3.89 ± 0.66 Nm) was significantly greater than those of VSP screws (2.68 ± 0.57 Nm) ($p=0.0016$).

CONCLUSION: Tıpsan screws provided sufficient pullout strength when compared to another well-known system as demonstrated by the similar peak load and stiffness results. The authors therefore consider the Tıpsan screw to be equal to its imported counterpart for use in a pedicle fixation system.

KEY WORDS: Biomechanics, bone screws, lumbar vertebrae, testing, torque

ÖZ

AMAÇ: Türk malı bir pedikül vidasının (Tıpsan Posterior Enstrümentasyon Sistemi, Tıpsan Tıbbi Aletler, İzmir, Türkiye) sıyırma direncini iyi bilinen başka bir sistemle (VSP Sistemi, DePuy AcroMed, Raynham, MA, ABD) karşılaştırarak değerlendirmek.

YÖNTEM: 14 haftalık dana vertebraları kullanılarak bir seri aksiyal sıyırma testi gerçekleştirildi. Her vida tipi için 8 örnek kullanılarak maksimum yük ve direngenlik değerleriyle temsil edilen sıyırma dirençleri saptandı.

BULGULAR: Ortalama maksimum yükler Tıpsan vidaları için 1892 ± 554 N, VSP için 1959 ± 594 N bulundu. Fark istatistiksel olarak anlamlı değildi ($p>0.05$). Yine, ortalama direngenlikler iki vida tipi için benzer bulundu: Tıpsan için 1063 ± 192 N ve VSP için 1126 ± 155.8 N ($p>0.05$). Tıpsanın ortalama giriş torku (3.89 ± 0.66 Nm) VSP değerinden (2.68 ± 0.57 Nm) belirgin şekilde yüksekti ($p=0.0016$).

SONUÇ: İyi bilinen bir yabancı sistemle karşılaştırıldığında, benzer maksimum yük ve direngenlik değerlerinin gösterdiği üzere, Tıpsan vidaları yeterli bir sıyırma direnci göstermiştir. Bu yüzden yazarlar, bir pedikül fiksasyon sisteminde kullanıldığında Tıpsan vidasını ithal muadiliyle eşit olarak değerlendirmiştir.

ANAHTAR SÖZCÜKLER: Biyomekanik, kemik vidaları, lomber vertebralar, test, tork

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INTRODUCTION

Pedicle screw fixation is one of the most popular ways of performing spinal instrumentation. Many new devices and screw designs have been marketed for this purpose. When such a new device is manufactured, its biomechanical properties should ideally be evaluated in vitro before its clinical use (14).

Today, many Turkish-made spinal instrumentation systems are commercially available in Turkey. Although they have widespread usage in the country, their effectiveness needs to be validated. To the author's knowledge none of these systems have been evaluated biomechanically and their effectiveness demonstrated in comparison to a well-known imported counterpart although their mechanical properties as a metal product have been investigated. This may create an excuse for those spinal surgeons who do not use Turkish-made spinal instruments and prefer more expensive foreign systems. If it could be proven Turkish-made systems are comparable to their imported counterparts, it might help develop domestic medical industry and also save foreign currency.

The aim of this two-part study (Part I. Pullout strength of the screws, Part II. Stability and strength of the construct) was to determine the biomechanical properties of a Turkish-made spinal instrumentation device (Tıpsan Posterior Instrumentation System, Tıpsan Tıbbi Aletler, İzmir, Turkey). In the present study, we evaluated the pullout strength of the screws of the system in comparison to a well-known foreign system. Stability and strength performance of this posterior instrumentation system, as a whole construct, will be the subject of the second part of this study.

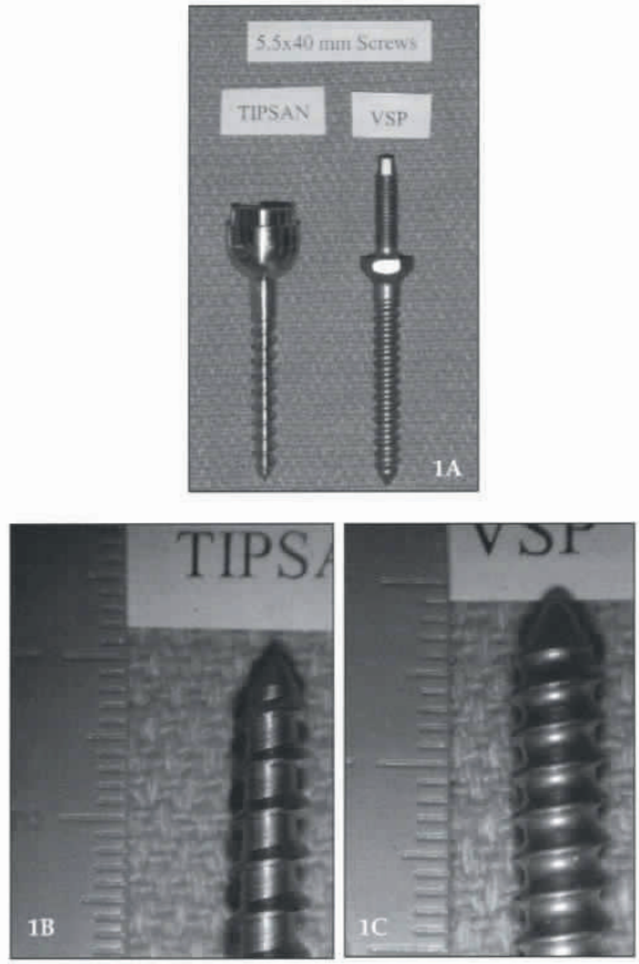

Figure 1A,B,C: TIPSAN and VSP screws.

Table I. Screw characteristics

	Shape	Major diameter (mm)	Minor diameter (mm)	Thread depth (mm)	Pitch (mm)
Tıpsan	Conical	5.5	3.60-3.10	0.93	3
VSP	Cylindrical	5.5	4	0.75	2.2

MATERIALS AND METHODS

Study design and screw characteristics

We performed a series of axial pullout testing using calf vertebrae. The 5.5x40 mm size of Tıpsan Posterior Instrumentation System and VSP System (DePuy AcroMed, Raynham, MA, USA) pedicle screws were compared (Figure 1A, 1B, 1C). The characteristics of the two screw types are shown in Table I. Both screw types were made of titanium. A sample size of 8 screws per test group was used to quantify pullout performance.

Specimen preparation and screw placement

Two fresh lumbar calf spines (L2-L5) were obtained for biomechanical testing. The specimens were 14 weeks old. Each was debrided of surrounding soft tissue and disarticulated into 8 individual vertebrae, yielding 16 pedicles for screw insertion. The screws were inserted into either the right or left pedicle such that each vertebra had one VSP and one Tıpsan screw. The right-left pairing was reversed at successive vertebral levels. Both screw types were inserted in a similar fashion and using standard technique. No tapping was performed. The screws were inserted manually and insertional torques during screw implantation were recorded using a digital torque meter, with a resolution of ±1%

(Tohnichi MFG, Co., LTD, Tokyo, Japan). Each vertebral body was then embedded in a prone position into a square aluminum gripping fixture surrounded by cerrobend molten metal (Cerro Metal Products Co., Bellefonte, PA), leaving the pedicles exposed (Figure 2).

Testing

The pullout was performed utilizing a materials testing apparatus (MTS Alliance RT/10, MTS Corp., Eden Prairie, MN). All specimens were clamped into a polyaxial jig that permitted pure axial pullout while minimizing residual stresses in the gripping fixtures (Figure 3). Screws were pulled at a rate of 1.0 mm/min to failure. Failure was defined as the peak load, just prior to a rapid decline in load during screw withdrawal. The load - displacement data were recorded during testing of each specimen. Stiffness was calculated as the slope of the linear region of the load-displacement curve before yield point.

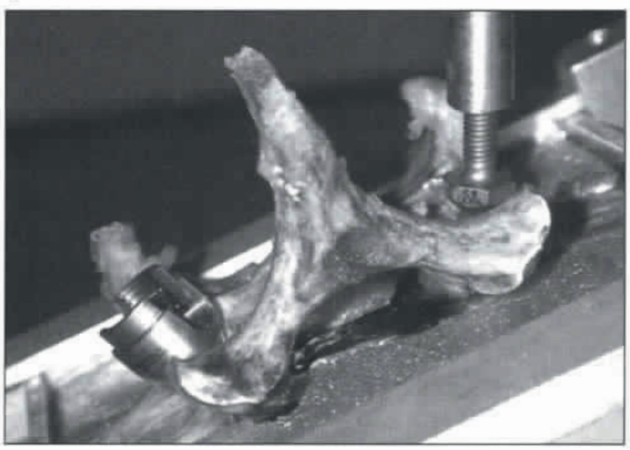

Figure 2: Each vertebra was embedded in molten metal surrounding the vertebral body, leaving the pedicles exposed.

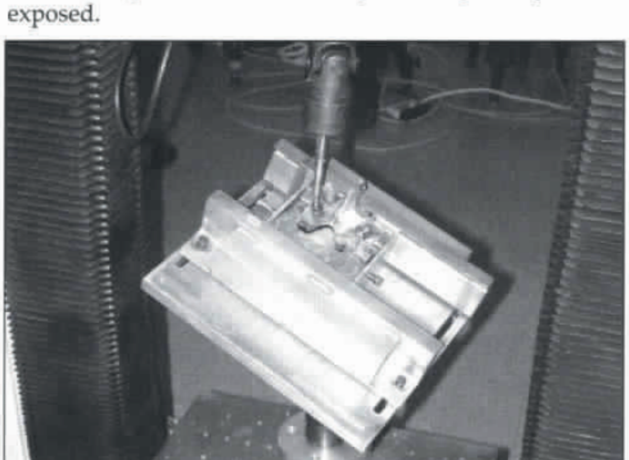

Figure 3: Specimens were clamped into a polyaxial jig that permits pure axial pullout.

Analysis of data

Descriptive statistics and paired t-test were used to detect differences between peak load, stiffness and insertional torque values of the two screw types using a statistical software package (Graphpad Prism 3.02, Graphpad Software Inc., San Diego, CA).

RESULTS

Approximate dimensions and sagittal section of a typical specimen after screw failure is presented in Figure 4A and 4B.

The results for the mean values and standard deviations of peak load, stiffness, and torque of insertion are shown in Table II.

The mean peak loads were 1892 ± 554 N for Tıpsan and 1959 ± 594 N for VSP screws (Figure 4). The difference was statistically insignificant when analyzed using a paired t-test ($p>0.05$).

The mean stiffnesses values were also similar for both screw types: 1063 ± 192 N for Tıpsan and 1126 ± 155.8 N for VSP screws ($p>0.05$) (Figure 5).

Figure 4A: Sagittal view of a typical specimen after screw failure

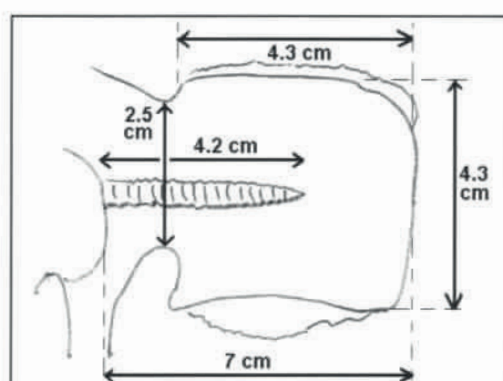

Figure 4B: Approximate dimensions of a typical specimen in sagittal view

The only statistical difference between the screw types was in insertional torques: 3.89 ± 0.66 Nm for Tıpsan and 2.68 ± 0.57 Nm for VSP screws (p=0.0016) (Figure 6).

Table II. Mean values and standard deviations of peak load, stiffness, torque of insertion, pedicle fill ratio, and growth plate-screw distance for TIPSAN and VSP screws (n=8 for each screw types).

Screw	Peak Load (N)		Stiffness (N/mm)		Torque (Nm)	
type	Mean	SD	Mean	SD	Mean	SD
Tıpsan	1892	554	1063	192	3.88	0.66
VSP	1959	595	1126	156	2.68	0.57

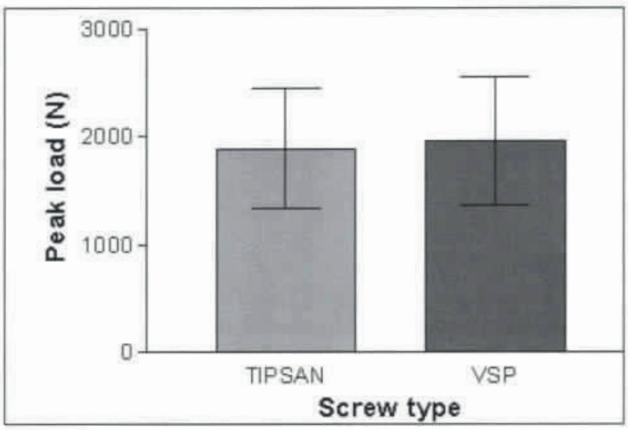

Figure 5: Mean peak loads of Tıpsan and VSP screws

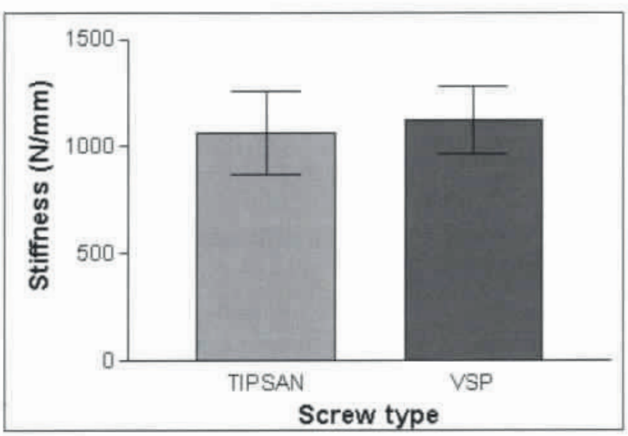

Figure 6: Stiffnesses of Tıpsan and VSP screws

DISCUSSION

Screw loosening may make a significant contribution to implant failure. Pullout tests are therefore considered to be one of the most useful tests to assess the bone-screw interface in pedicle screw systems, although in vitro pullout tests do not necessarily match the clinical mode of screw failure.

In pullout tests, there are many factors associated with the holding power of screw in bone. These factors may be divided into four groups: I. Screw characteristics [screw design and diameter (9, 24), material (15)], II. Insertion technique [hole preparation technique (5, 13), extent of cortical purchase (12, 17, 18), depth of screw penetration (8), topography of the screw in the bone (7), and triangulation of screws (1, 3, 4, 6, 11, 16)], III. Bone quality [architecture of the bone and bone mineral density (6, 16, 21)], and IV. Testing methods [loading scheme, rate of loading]. Keeping all the other factors the same and consistent, it is possible to compare effects of two different screw designs on pullout strength.

Besides its accessibility and low cost, numerous advantages make the bovine model a frequently preferred material for the screw pullout testing: Swartz (22) and Wilke (23) suggested that calf spines generally had similar physical, anatomic, and mechanical properties to human spine. While the bone densities of cadaveric specimens vary widely, calf vertebrae show similar bone density due to lack of osteoporosis. In addition, it has been stated that calf spines offer a good specimen-to-specimen similarity and structural consistency (19).

In the present study, it was found that Tıpsan screws have peak load and stiffness values similar to those of VSP screws, although the two screws had quite different designs. The main components of the screw are the head, the core, the threads, and the tip (2) (Figure 7). The core is the main shaft of the screw without threads. The diameter of the core is referred to as the minor (or inner) diameter of the screw. If the core diameter is the same throughout the whole

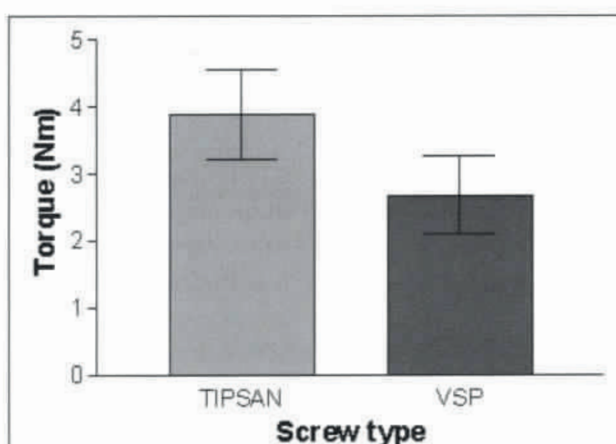

Figure 7: Torques of Tıpsan and VSP screws

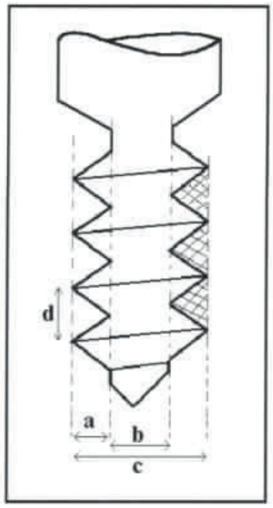

Figure 8. Screw anatomy (a: thread depth, b: minor diameter, c: major diameter, d: pitch)

length of the screw, the screw is called cylindrical. If the core diameter is tapered, i.e., gets thinner at the tip, the screw is called a conical screw. The largest diameter of the screw measured at tip of the thread is the major (or outer) diameter. The distance between the two threads is called the pitch. It was proposed that the main design elements affecting screw pullout strength are the major diameter and thread depth (20). The pullout performance of the screw is directly related to the amount of bone between screw threads (Figure 8, shaded area). The deeper the threads, the more amount of bone purchased and the better the pullout strength. The shape of the thread depends on the thread angle that is measured as the angle that deviates from a line drawn perpendicular to the shaft of the screw. There is a balance between optimal thread depth, angle, and pitch.

Since Kwok et al (10) demonstrated that conical and cylindrical pedicle screws have comparable holding strengths and that screw profile (with similar dimensions) has little effect on axial pullout strengths in cadaveric bone, Tıpsan screws were compared with VSP screws despite their design differences. The Tıpsan and VSP screws were the same in major diameter and length, but they differed in shape, inner diameter, thread depth, and pitch. While the VSP screw had a cylindrical shaft, the Tıpsan screw had a slightly tapered (conical) design. Kwok et al also concluded that a conical screw design increases torque of insertion. Our findings regarding insertion torque and pullout strength in calf specimens were concordant with Kwok et al's results.

Although the Tıpsan screw has threads that are a little bit deeper than VSP, the difference is quite small (0.95 mm versus 0.75 mm). The main difference between the shapes of the two screws was pitch distance. The Tıpsan screw has greater pitch distance than the VSP screw (3 mm versus 2.2 mm). We thought this difference contributed to the Tıpsan screw's far greater insertional torque values than the VSP screw. Pitch can be defined as the inverse of the number of threads per inch and is equal to distance the screw advances with one turn. Thus, the Tıpsan screw had to reach same depth with much less turn, probably leading to increasing torque values. The other factor causing the difference between the insertional torque values might be different thread angles.

The most frequently used data regarding screw performance in pullout studies is peak load. Several studies have investigated screw displacement before failure and/or energy absorption of the screw before failure. Skinner et al (20) concluded that screw pitch has no effect on peak load, but has an effect on screw displacement before failure. The same study found an increase in the pitch of the screw that would increase the amount of displacement before failure. In our study, we did not use values of screw displacement before the failure and used stiffness values to show changes of screw displacement along with the peak load instead. We could not find any difference between the Tıpsan and VSP screws in their stiffness values, although their pitch distances were different.

In the current study, Tıpsan screws proved to have enough pullout strength showing similar peak load and stiffness results compared to another well known system. The authors therefore consider the Tıpsan screw to be equal to its imported counterpart for use in a pedicle fixation system.

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