SCREW PULL-OUT TESTS FOR THE İBN-İ SİNA TRANSPEDICULAR SPİNAL INSTRUMENT

Tarık YAZAR* **Feza KORKUSUZ*** **Yener YENİ***

Transpedicular spinal implants are known to be the most effective systems in the treatment of burst fractures. However, migration, pull out and pedicle screw breakage are the most troublesome issues of these systems. The İbn-i Sina universal transpedicular system is developed to overcome such difficulties. The anterior portion of the pedicle screw of the İbn-i Sina instrument is specially designed to improve contact between the spongious bone of the vertebral body and the posterior portion that will remain inside the pedicle is similar to a cortical screw. This modification is suspected to improve the stability of the system. Two types of the İbn-i Sina screws, mainly the original design and the AO type screws of three sizes (5.5 mm, 6.5 mm, 7.5 mm), were compared with the same size and length of Alıcı, Isola and TSRH pedicle screws. sizing of the screws was performed using the results of a previous anatomical study in which the standard of the pedicle sizes of the Turkish population was estimated. a quadrangular frame was developed to perform the experiments. The vertebral bodies were placed obliquely into the frame to allow the pedicle screw to be pulled in the vertical direction. All tests were performed on the M 30 K (Lloyd, UK) mechanical testing device. Pedicle screws of the above mentioned spinal systems were furthermore evaluated by photoelasticity after placing them into epoxy resin (Araldit D + HY 951, Ciba-Geigy, İstanbul). Early results of the experiment suggest that the İbn-i Sina type pedicular screws are as stable and powerful as any other universal screw design. Loads up to 2500 N and 3000 N caused the pull out of the 6.5 mm AO type screw and the original design İbn-i Sina screw respectively. The results suggest a slight improvement in the stability with the new design.

Transpedicular implants are effectively used in the maintenance of stability in spinal fractures and deformities. A new spinal instrument, the so called "İbn-i Sina Spinal Instrument" is recently introduced and its screw design is evaluated by this study. Two different screws of the İbn-i Sina instrument were evaluated by the screw pull-out tests and the results were compared to that of the TSRH instrument. The original design of the screw was more effective than the AO design. the pull-out strength increased as the diameter of the screw increased. The original design of the İbn-i Sina pedicle screw is as effective as the TSRH transpedicular screw occurred in the İbn-i Sina screw. Further improvements in the metal of the screw is essential for the İbn-i Sina transpedicular screw. A special frame was designed to be able to apply the pedicle screw pull-out tests.

Key Words: *Spine, Biomechanics, Pedicle Screw, Pull-Out Test, İbn-i Sina Instrument.*

INDRODUCTION

Various transpedicular spinal instruments have been introduced to function as a load transmitter in the stabilization of vertebral fractures or in the correction of spinal deformities such as scoliosis. As Rahmatalla previously stated, their designs incorporate many factors, including anatomical considerations, the mechanical strength required for the intended function, and biocompatibility of the materials (1, 2, 3, 4). All these systems depend upon the ability of a screw to maintain a purchase in the pedicle until fusion is secure (5). Although only a few clinical studies presented pedicular screw pull out cases, screw breakage or loosening is more frequently encountered complications following transpedicular spinal fixation (6, 7, 8). Using the pedicular screw pull out test, sufficient data can be obtained on the security of transpedicular spinal fixation devices. The biomechanical requirements of a pedicle screw may well differentiate from other bone screws as the pedicle itself is a cylinder of cancellous bone surrounded by cortical bone in all directions. The alteration in the diameters of the pedicles, age of the patient, rate of osteoporosis should all be considered in the assessment of secure fixation. In a previously presented study the diameters of the pedices in the thoracolumbar region were evaluated in order to establish a standard for the Turkish population (9). According to the data obtained from this study, the so called "İbn-i Sina pedicular screw pull out strength was compared to the TSRH pedicular screw in an experimental study. The pedicle screws of the original design were found to be as effective as the AO style screw in terms of their pull out strength; the pull out strength of the

* Departman of Ortopaedic Surgery and Traumatology, Ankara University Medical School, İbn-i Sina Hospital, Samanpazarı, Ankara, Turkey

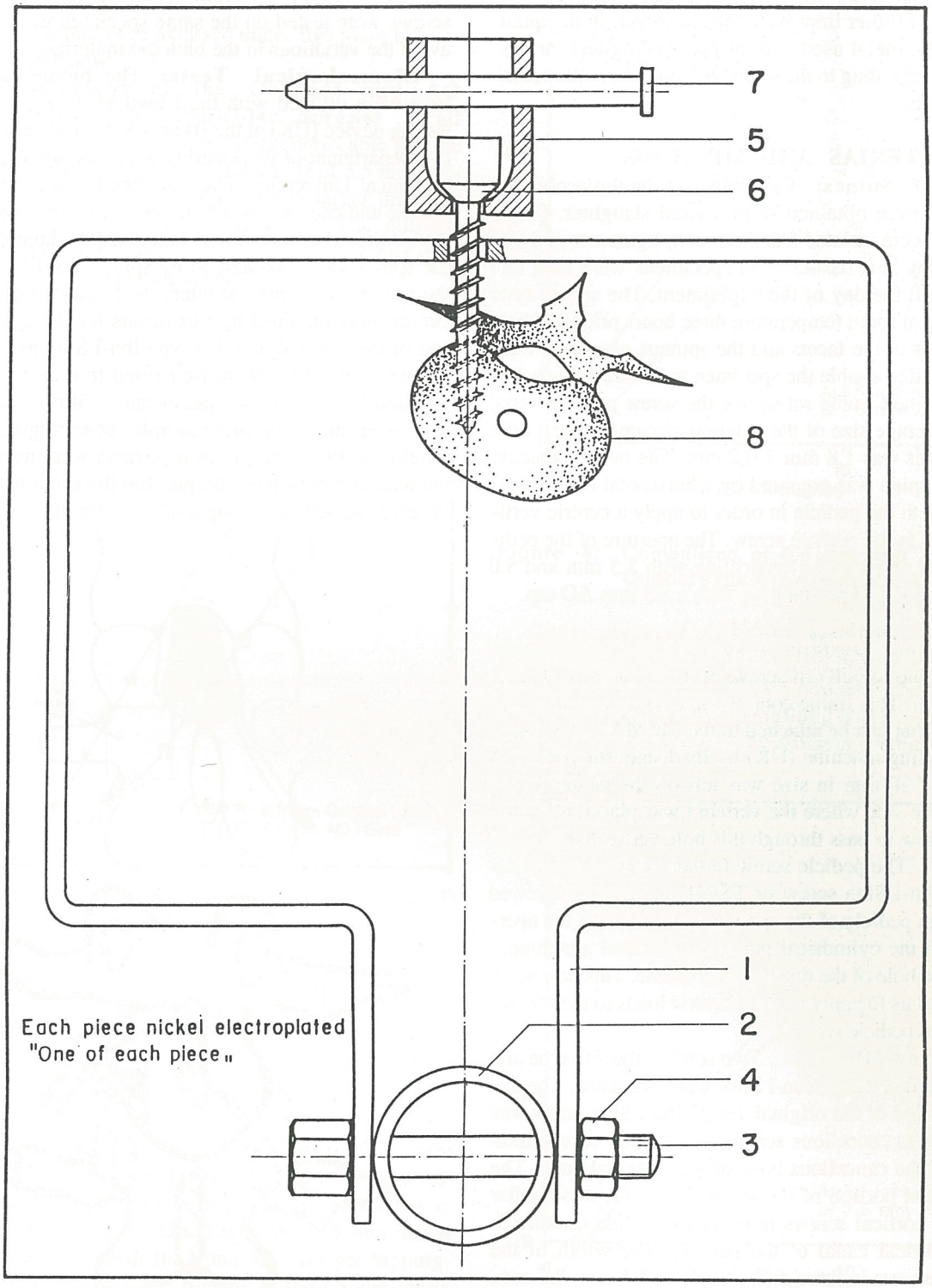

Figure 1: Schematic drawing of the special frame design for the screw pull-out tests.

İbn-i Sina screw was also comparative to the TSRH screws. Further improvements, however, in the quality of the metal used and fatigue loading tests are essential regarding to the screw deformation under eccentric loads.

MATERIAS AND METHODS

Calf Spines: Calf spines of the throacolumbar region were obtained from a local slaughter. Single spines were isolated free from their ligaments and surrounding soft tissues. The specimens were kept in -20°C till the day of the experiment. The spines were thawed at room temperature three hours prior the tests. The tips of the facets and the spinous processes were removed to enable the specimen to fit into the specially designed frame set-up for the screw pull out tests. The average size of the external circumference of the predicles was 1.8 mm ± 0.2 mm. The outer trabecula of the spine was prepared by a horizontal cut perpendicular to the pedicle in order to apply a centric vertical pull to the pedicle screw. The aperture of the pedicle was prepared by predrilling with 3.5 mm and 5.0 mm drills, and pre-tapping with a 5.5 mm AO tap.

Frame Design: A special frame was designed to be able to pull out screws from the pedicle (Figure 1 and 2). This frame consists of a single quadrangular frame that can be attached to the Lloyd M 30 K material testing machine (UK) by its distal articulation. A hole of 20 mm in size was left on the center of the opposite side where the vertebra was placed allowing the screw to pass through this hole vertically in to the pedicle. The pedicle screw (either original or AO design İbn-i Sina screw or TSRH screw) was screwed into the pedicle of the spine passing through the aperture of the cylindrical prepared proximal attachment and the hole of the quadrangular frame. This new setup enabled us to apply vertical centric loads to the securely fixed pedicle screws.

Screw Designs: Two screws, the AO type and the original design İbn-i Sina, were evaluated. The distal portion of the original design İbn-i Sina screw was similar to cancellous screws to maintain secure fixation at the cancellous bone of the vertebral body. The proximal portion of the screw, however, was similar to the cortical screws in order to provide fixation in the cortical canal of the pedicle. The width of the screws were in three different sizes; 5.5 mm, 6.5 mm, and 7.5 mm. The length of the screws were 55.0 mm for the İbn-i Sina screws, and 40 mm for the TSRH screws. The two different types of the İbn-i Sina screws were tested on the same specimen in order to avoid the variations in the biologic material.

Biomechanical Tests: The biomechanical tests were utilized with the Lloyd M 30 K material testing device (UK) at the Biomechanic Laboratory of the Department of Engineering Sciences, Middle East Technical University. The test speed was 2 mm per minute and each screw was tested to failure. The tests were adjusted in room temperature and the humidity of the spines were maintained by spraying saline on to the specimens in regular intervals. Load-deformation curves were obtained by this means for the comparison of the original and AO type İbn-i Sina pedicular screws. The resutls were first fitted to a first degree polynomial using least squares curve fitting method. Moreover, the curve fitted samples of each group belonging to the same group of screws were averaged out among themselves and put into the same batch to observe the pull-out strength of each design.

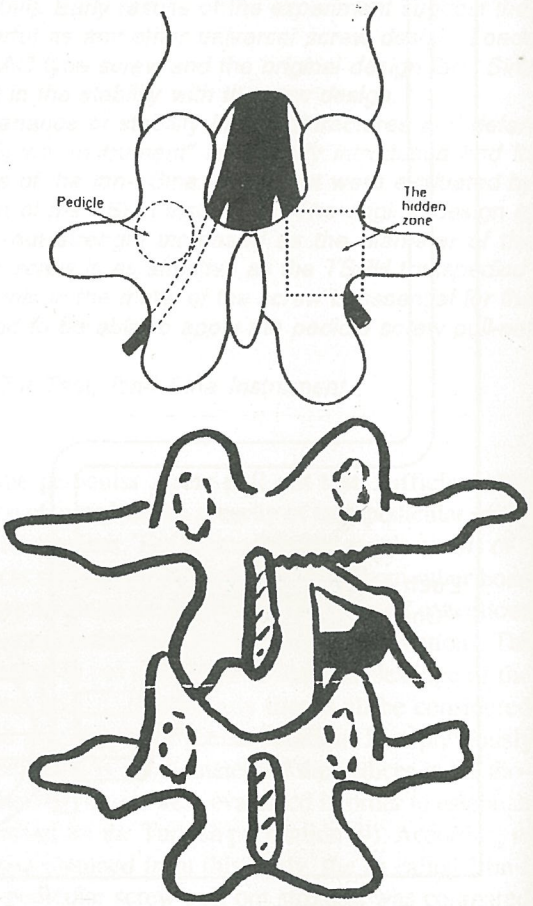

Figure 2: The experimetal setup and frame during the experiment.

RESULTS

The results were assessed under five main titles as presented below:

Comparison of the Original and AO Type ibn-i Sina Pedicular Screws: At all load levels considered, it is clearly noticeable that the pulled-out length for the original type of 5.5 mm İbn-i Sina pedicle screw is significantly larger than that for the AO type screw (Figure 3). The pull-out strength of AO type screw is about 15 % larger than that of the original type screw.

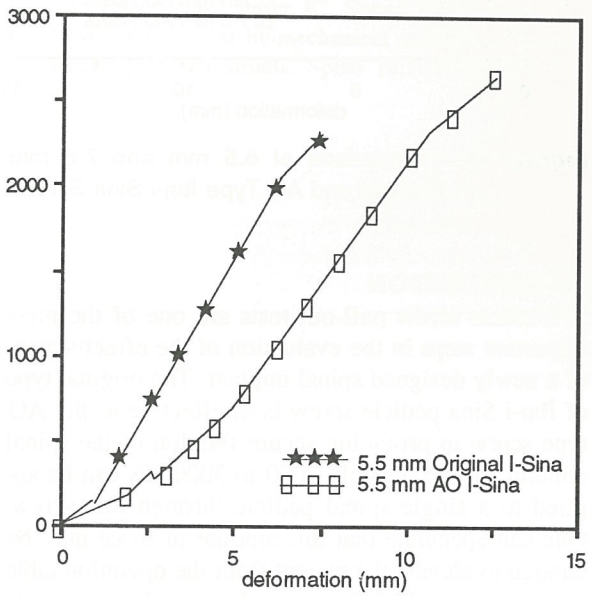

Figure 3: Comparison of the Original and AO Type İbn-i Sina Pedicular Screws

Comparison of 6.5 mm and 7.5 mm Original Type İbn-i Sina Screws: The pulled-out length for the 7.5 mm original İbn-i Sina screw is significantly larger than that of the 6.5 mm screw with 5.0 mm pre-drilling and 5.5 mm pre-tapping (Figure 4). The pull-out strength of the 7.5 mm screw is almost twice that of the 6.5 mm screw.

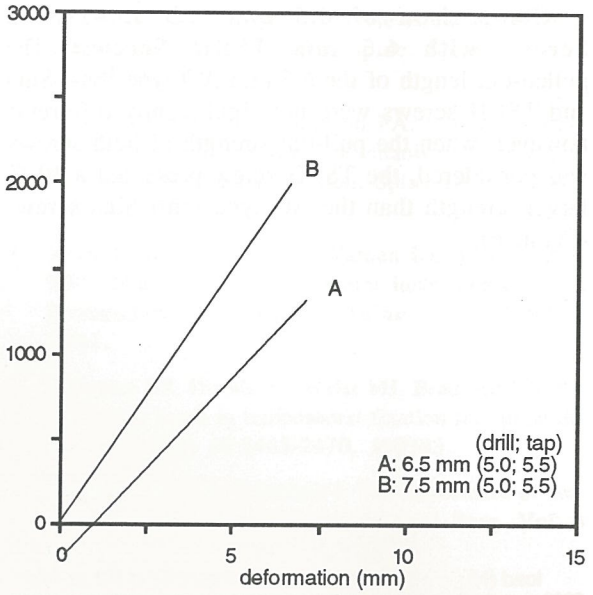

Figure 4: Comparison of 6.5 mm and 7.5 mm Original Type İbn-i Sina Screws

Comparison of 6.5 mm and 7.5 mm AO Type İbn-i Sina Screws: The pulled-out length and pull-out strength of the 6.5 mm and 7.5 mm AO type screws with 5.0 mm predrilling and 5.5 mm pre-tapping were not significantly different (Figure 5).

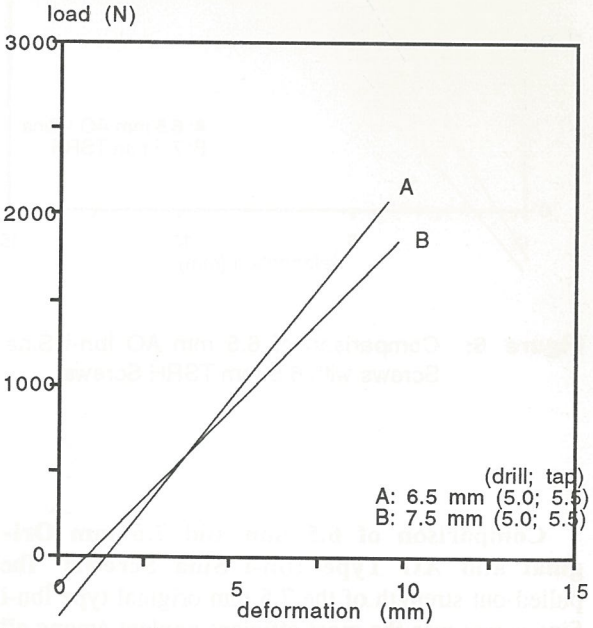

Figure 5: Comparison of 6.5 mm and 7.5 mm AO Type İbn-i Sina Screws

Comparison of 6.5 mm AO İbn-i Sina Screws with 6.5 mm TSRH Screws: The pulled-out length of the 6.5 mm AO type İbn-i Sina and TSRH screws were not significantly different; however, when the pull-out strength of both screws was considered, the TSRH screw presented a 30 % larger strength than the AO type İbn-i Sina screw (Figure 6).

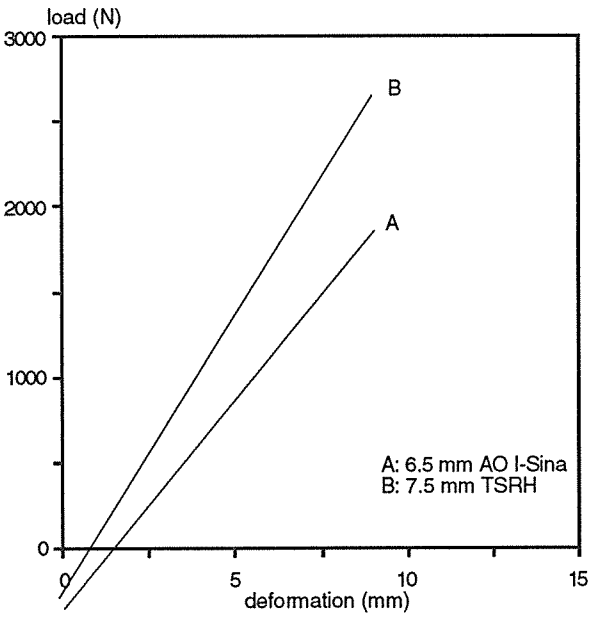

Figure 6: Comparison of 6.5 mm AO İbn-i Sina Screws with 6.5 mm TSRH Screws

Comparison of 6.5 mm and 7.5 mm Original and AO Type İbn-i Sina Screws: The pulled-out strength of the 7.5 mm original type İbn-i Sina screw was the most efficient implant among all screw sizes and desgns (Figure 7).

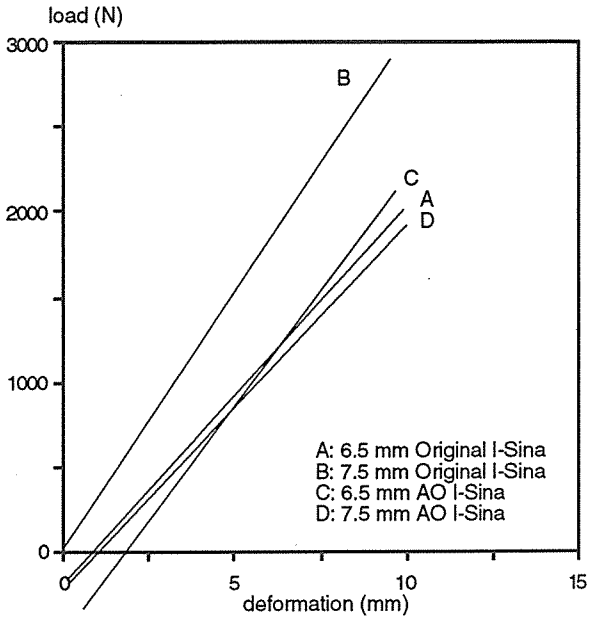

Figure 7: Comparison of 6.5 mm and 7.5 mm Original and AO Type İbn-i Sina Screws

DISCUSSION

Pedicle screw pull-out tests are one of the most important steps in the evaluation of the effectiveness of a newly designed spinal implant. The original type of İbn-i Sina pedicle screw is as effective as the AO type screw in providing secure fixation of the spinal column. Approximately 2000 to 3000 N's can be applied to a single spinal pedicle through this screw. One can speculate that this amount of force may be enough to elevate the patient from the operation table during surgery. This force, on the other hand may allow forceful manipulation of the spinal implant in the vertical direction. The larger the screw size, the more effective is the pull-out strength. In other words, the largest screw that will properly fit into the pedicle should be applied since secure spinal fixation is desired. Pre-drilling and pre-tapping are other factors that influence the pull-out strength. In constant pre-tapping with a 5.0 mm tap and 3.5 mm pre-drilling, the strength of the smallest size of screw is superior to the larger screw compared to the aperture that is prepared with the 5.0 mm drill (unpublished data). The only circumstance need to be improved in the İbn-i Sina screw is the quality of the metal that is used, as the 316 L stainless steel is deformed in eccentric loading (Figure 7). The data of this experiment indicates

that the İbn-i Sina Spinal instrument may be securely used in the clinical field as soon as the material problem is overcome by means of the pull-out strength of the pedicle screws.

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