
SPINAL INSTRUMENTATION

A New Spinal Stabilization System: Intercorporal Fixation Device for Thoracolumbar Stabilization

Yeni Bir Omurga Sabitleme Sistemi: Torakolomber Sabitleme İçin Omurga Cisimleri Arasına Yerleştirilen Tespit Cihazı

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Abstract: Anterior intercorporal fixation, different from the currently used techniques, was tested as a new stabilization system first in human cadaver and then was applied to a patient. Our device is a two directional screw system applied with anterolateral approach to the superior and inferior corpus end plates along the vertical axis of column vertebrae. This system which is composed of two screws with their fixing washers preventing rotational movement, and a connector was tested in human cadavers following animal trials. Its advantage over the other devices stems from its positioning into the corpus, the center of axial compressional loads, in the same direction as the force vector. This has been verified by means of biomechanical experiments and was applied then to a patient with L1 burst fracture. It is suggested that anterior intercorporal fixation with our device is suitable for routine clinical use due to its higher strength, simplicity and practicality in applications as compared to the other systems.

Key Words: Anterior instrumentation, intercorporal fixation, stabilization, thoraco-lumbar

Özet: Günümüzde kullanılan tekniklerden farklı ve yeni bir sabitleme sistem olarak, önden omurga cisimleri arası tespit önce insan kadavrasında denendi, sonra bir olguya uygulandı. Cihazımız, anterolateral yaklaşımla üst ve alt omurga cismi kırık tabakalarına omurga sütununun dikey eksenini boyunca uygulanan iki yönlü vida sistemidir. Bu sistem, dönme hareketlerini engelleyen pulları ile birlikte iki vida ve bir bağlantı parçasından oluşmaktadır ve hayvan çalışmalarını takiben insan kadavralarında denenmiştir. Diğer cihazlara göre yararı, omurga cismi içindeki durumunun, eksenel bası kuvvetlerinin merkezinde ve kuvvet vektörleri ile aynı yönde olmasıdır. Bu çalışma, biyomekanik deneyler neticesinde, L1 patlama kırıklı bir olguya uygulanmıştır. Sonuç olarak, önden omurga cisimleri arası tespit cihazı, yüksek direnci, kolay ve pratik uygulanabilir oluşu nedeni ile rutin klinik kullanım için tavsiye edilmektedir.

Anahtar Sözcükler: Omurga cisimleri arası tespit, önden cihaz takma, sabitleme, torako-lomber

INTRODUCTION

The main treatment of spinal instability is to provide fusion for the alignment of the natural anatomical construction. The accepted view to reach

this goal and to gain early mobilization is to provide spinal stabilization via spinal instrumentation. There exist anterior stabilization systems, posterior stabilization systems and anterior distraction systems currently in use today. Although these systems have

advantages and disadvantages over each other an ideal system that can resist spinal multivectoral forces is not yet available (16,17).

The currently used spinal stabilization systems display failures especially due to the axial and rotational direction of spinal multivectoral forces. Without the aid of a block bone graft, it is impossible for the posterior and anterior fixation systems to resist the axial forces. The corpus of the vertebra is the region that carries most of the axial forces. In order to achieve the maximum efficiency in resisting loads the stabilization instrument should be placed parallel to the axis of the applied forces. Regardless of the system used, cyclic axial compressional loads lead to metal fatigue. Failures occur in the existing fixation systems as they are subjected to loads at right angles. The technical faults during application of the block bone graft also cause failure. According to the authors, what would ensure greater success in the elimination of the perpendicular forces by changing the alignment of the device with respect to the vertebra.

The main disadvantage of posterior and anterior fixation systems is that they are exposed to forces in perpendicular direction especially under the axial compression loads. On the other hand the disadvantage of the anterior distractor systems is lack of fixations. Our device, developed with the principle of anterior intercorporal fixation, achieved high resistance particularly against axial compressional loads, and allows for satisfactory fusion.

Anterior intercorporal fixation is composed of screws that are applied vertically into the corpus at the mids of the intact upper and lower corpus end-plates, rotation-preventing washers that are nailed to the same locality following the application of the screws, and a connector. Thus, maximum strength is obtained in the direction of the axial force vector.

MATERIALS AND METHOD

Description of the System:

Our device consists of two standart spongiuous screws, two rotation- preventing washers, a connector, and two connector- fixing screws that connect the spongiuous screws to the connector, all made of stainless steel or titanium. Our device is developed to be used in thoracic and lumbar regions in order to gain stabilization following single segment corpectomy. If needed, there are different connector sizes which can be used in case of

multisegmental anterior and middle column insufficiency. Moreover, by attaching extensions to both spongiuous screws multisegmental stabilization can also be achieved. Spongiuous screws for thoracic and lumbar regions are of a standard length of 25 mm, with a tapered shaft (maximum diameter of 5 mm). The extension pieces have a standard length of 10 mm. In order to ensure interlocking in the system, the bottom section of the connector-fixing screw which goes into the connector is threaded.

The rotation- preventing washer is a plaque with 12 mm width and 22 mm length, with two 17 mm nails inserted into the corpus. On this plaque, on both sides of the hole which the spongiuous screw goes through, are small holes meant for maximum fusion. The connector is of 10 mm diameter cylindrical shape with 8 mm slots on both ends for the insertion of connector- fixing pieces, and is completely threaded on the surface. The connector is available in different sizes so that it can be applied depending on the distance that arises following corpectomy (the smallest 25 mm, the largest 80 mm). After completing the connections, the system is locked by tightening the octagonal nuts on the connector (Figure 1).

Biomechanical Tests

The material used in biomechanical experiments was made of an austenitic stainless steel (DIN 174431,4441,X2CrNiMo 18 15 3).

a. Compression Test: A uniaxial compression test was carried out on the implant sample. The test was conducted according to the ASTM E9 (12). The specimen was observed to tear at 2300 kp (22,5 kN).

b. Bending Test: Since the joints of the implant are exposed to bending under actual conditions these points were subjected to three points bending tests according to ASTM E6 and ASTM E8 (12). Maximum bending load was observed to be 220 kp (2158 N).

c. Notched Impact Test: This test is used to measure the energy absorbed by the materials when subjected to impact loads or during fracture under impact. The tests were conducted according to ASTM E23 by using a Zwick test machine (12). The measured impact energy was 4,6 kmp (46J).

d. Fatigue Test: This test measures the lifetime of material before failure under cyclic loading. Tests were conducted according to DIN 51228 by using a Denison Test machine. Measurement was made

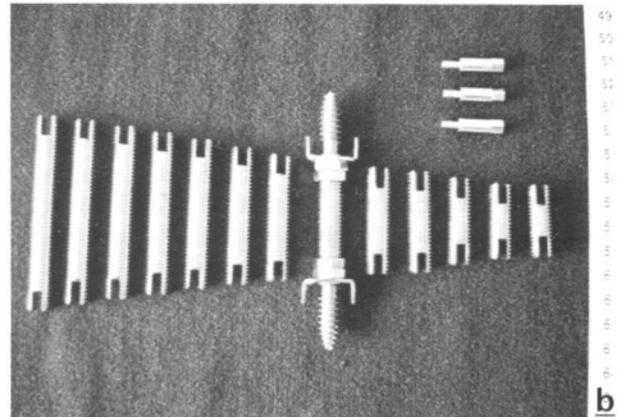
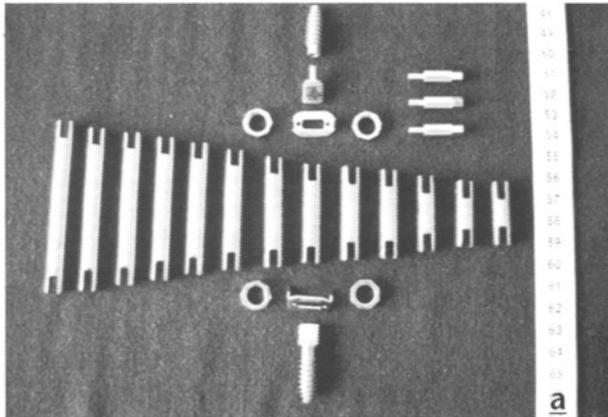


Figure 1, a, b: The Anterior Intercorporeal Fixation Device consists of two standard spongiotic screws, two rotation preventing washers, a connector, and two connector fixing screws that connect the spongiotic screws to the connector.

according to four different models with following results:

- a) 24'forward, 6'backward (Pmax=56,3 kg(550N), Pmin=14,1kg(138N)failure at 14.000 cycle (14x1000)
- b) 12'forward, 6' backward(Pmax=28,1 kp(276N),Pmin=14,1kp(138N)failure35,000 cycle(35x1000)
- c) 12'forward (Pmax=28,1 kp(276N),Pmin=0) failure at 45.000 cycle (45x1000)
- d) Lateral deflection 9'forward, 6'backward failure at 56.000cycle(56x1000)

e. Torsion Test: These tests were conducted under uniaxial vertical loading by using 2N and 343 N with a torquemeter. In these tests the device did not exhibit failure. Instead, the failure criteria was the onset of tear in the sample vertebra. The resistance against the torsional load increased 41 % when the tear length reached 5.11 mm. The reason for this was thought to be jamming of the trabecules. Changing the uniaxial load from 2N to 343N seemed to have any apparent effect on the test results.

Tearing was observed at 3047 Nmm.
Tear reached 5.11 mm at 4733 Nmm.

No biomechanical study was conducted on implants made of titanium.

Cadaver Study and Application

In this study, the device was applied to 11 cadavers following choosing the suitable screw in animal studies. The vertebral column was explored using classical anterolateral approach in human cadaver. Corpectomy was carried out in the target vertebra. First, the lower surface of the upper corpus is drilled for the insertion of the screw by using a right-angle chisel (Figure 2.1). Then, the spongiotic

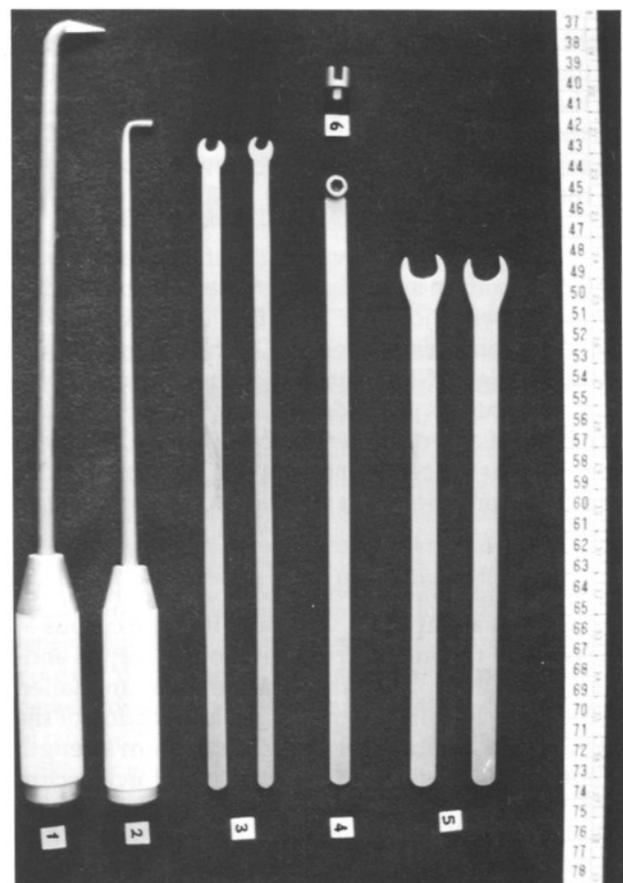


Figure 2: Instruments used for assembling the Anterior Intercorporeal Fixation Device. (1. Guide; used for opening the initial hole for screws by nailing into corpus, 2. Screw support; used for pushing the screw into corpus while the screw is being driven with the key, 3. Screw keys; used for applying the screw, 4. Female keys; used for applying the screw, and for turning the connector-fixing screws by attaching to the pieces no.5, 5. Connector-fixing screw keys; used for tightening the connector-fixing screws by attaching to the tip of the female key, 6. Nut keys)

screw is inserted into this hole by using a right angle screw supporter aided with a special type of key (Figure 2.2, 2.3). The same procedure is followed on the inferior corpus (Figure 3A). Following the insertion of screws into the superior and inferior vertebral bodies, the end plates are excised. Thus, an appropriate surface for the bone graft fusion around the system is obtained. The connector-fixing pieces are applied to both spongious screws (Figure 2.4, 2.5). The rotation-preventing washers are nailed onto the corpuses after attaching to the connector-fixing pieces (Figure 3B). Then the connector is inserted into the gap and the system is locked by tightening the pentagonal nuts on both sides (Figure 2.6, 3C). The graft is taken from costa and placed around the system to provide fusion (Figure 3D). Figure 4 demonstrates the application of the device to human cadaver. The rest of cavity is filled with bone chips. If a multisegmental fixation is desired the extension pieces can be applied between the spongious screw and the connector-fixing screw.

Case Report:

A 38- year-old woman was admitted to our clinic after a fall from height. She had paraparesis

and bilateral leg fractures. Spinal x-ray (Figure 5) and computed tomography revealed that she had 10 % compression fracture on Th 12 (Figure 6) and type B burst fracture on L1 vertebral body (Figure 7). With anterolateral approach, thoracotomy was performed. After decompression with L1 corpectomy our device was applied (Figure 8)

Early postoperative anteroposterior (Figure 9) and lateral (Figure 10) plain x-rays demonstrated the succesful application of the device. It was not needed to use extension pieces. The patient was set with thoracolumbar orthose after removing the thorax tube on postoperative second day. She was transported to the rehabilitation center on the postoperative tenth day. The movements were not restricted during the rehabilitation program with orthose. Four and half month later fusion was proved with radiological evaluation and the thoracolumbar orthose was removed. Six months later the patient was invited to control. She could walk without support. It was also demonstrated with spinal x-ray and computed tomography scanning that fusion was continued on the level where our device was applied (Figures 11,12,13).

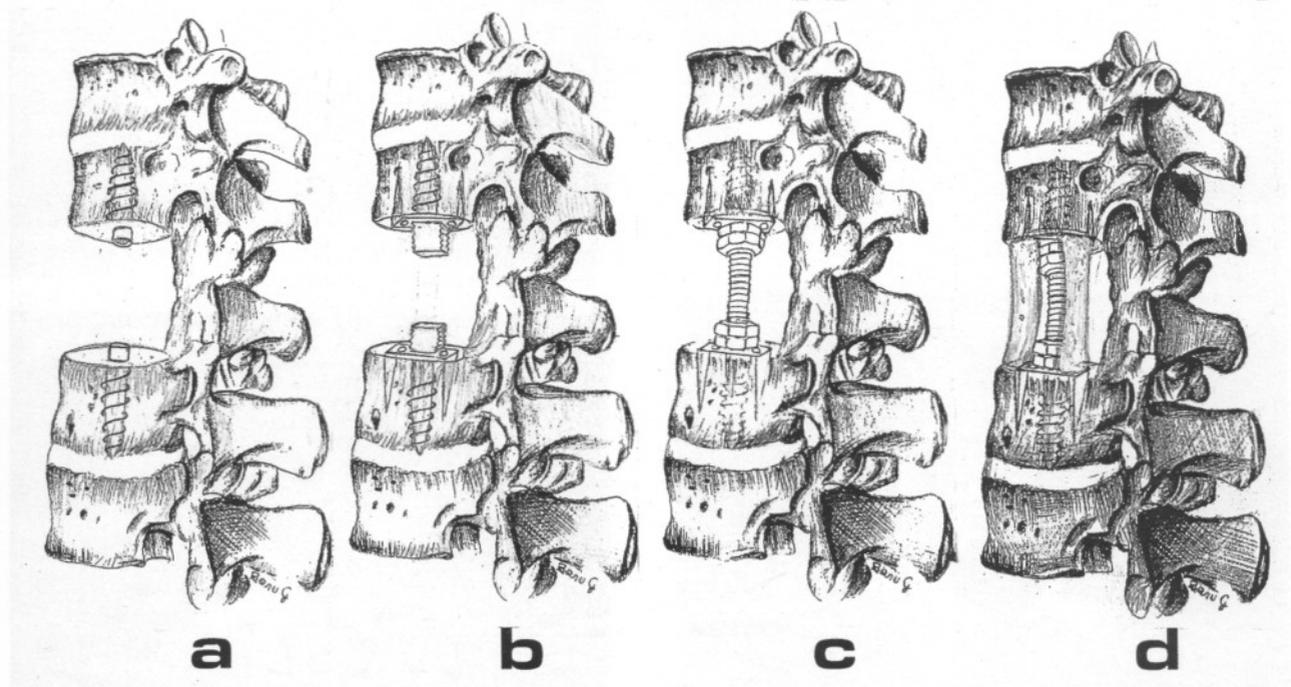


Figure 3, a) Screws as inserted into upper and lower corpuses, b) following the attachment of the connector-fixing screws to the back of the spongious screws the rotation-preventing washers placed over the screws and are nailed onto corpus, c) the connector of suitable length is placed and the system is locked by tightening the nuts on both sides, d) costa graft is placed over the system for fusion.



Figure 4: The Anterior Intercorporal Fixation Device as implanted to a cadaver and fused with costa graft.



Figure 5: L1 type B burst fracture, T12 10 % compression fracture.

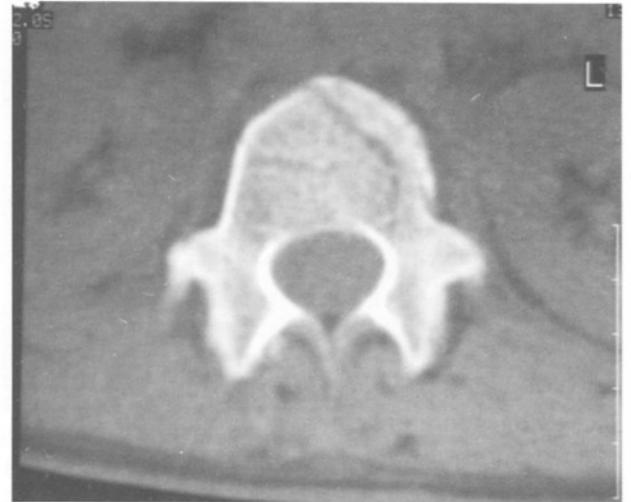


Figure 6: T12 compression fracture on axial computed tomographic scanning.

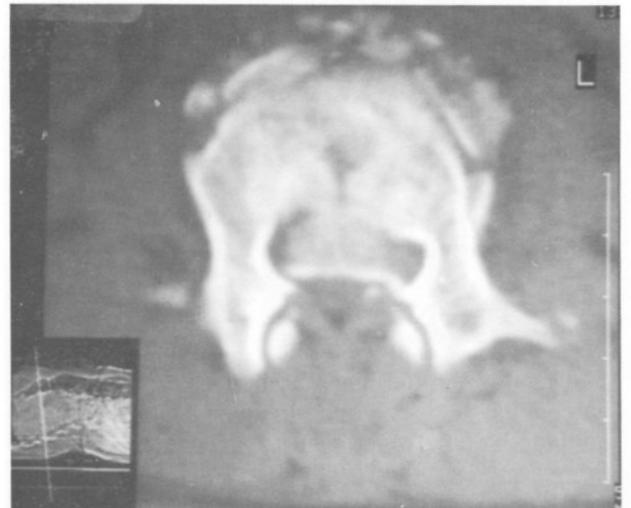


Figure 7: L1 type B burst fracture on axial computed tomographic scanning.

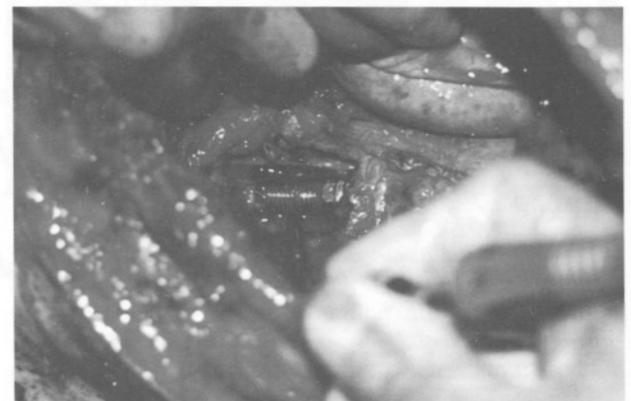


Figure 8: With anterolateral approach thoracotomy was performed and after decompression with L1 corpectomy the Anterior Inercorporal Fixation Device was applied.

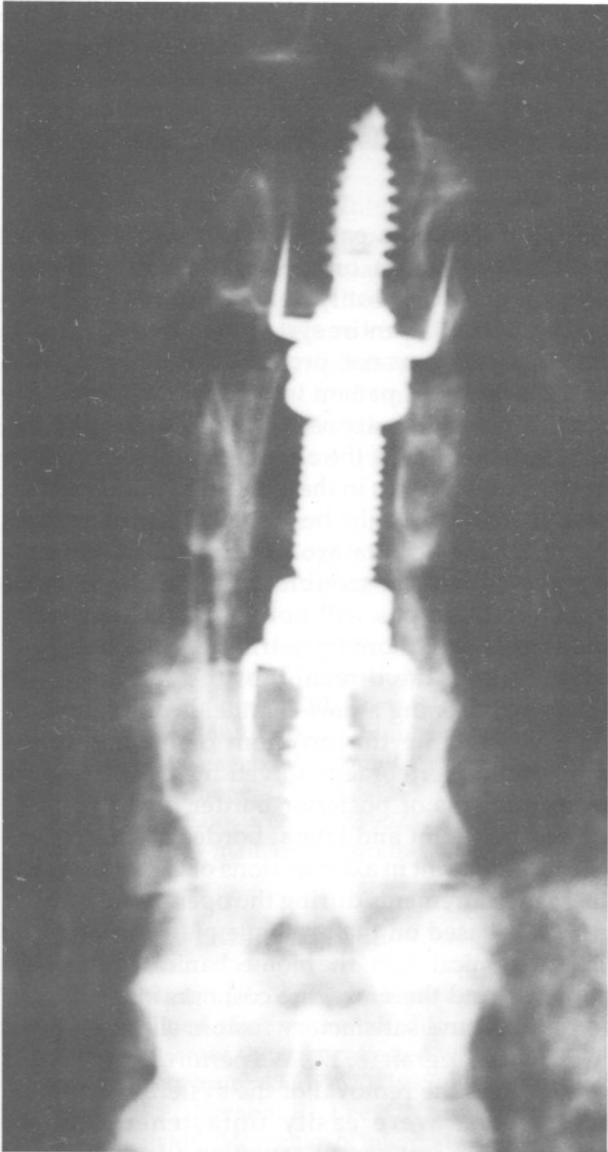


Figure 9: Anteroposterior X-ray film of the Anterior Intercorporeal Fixation Device.

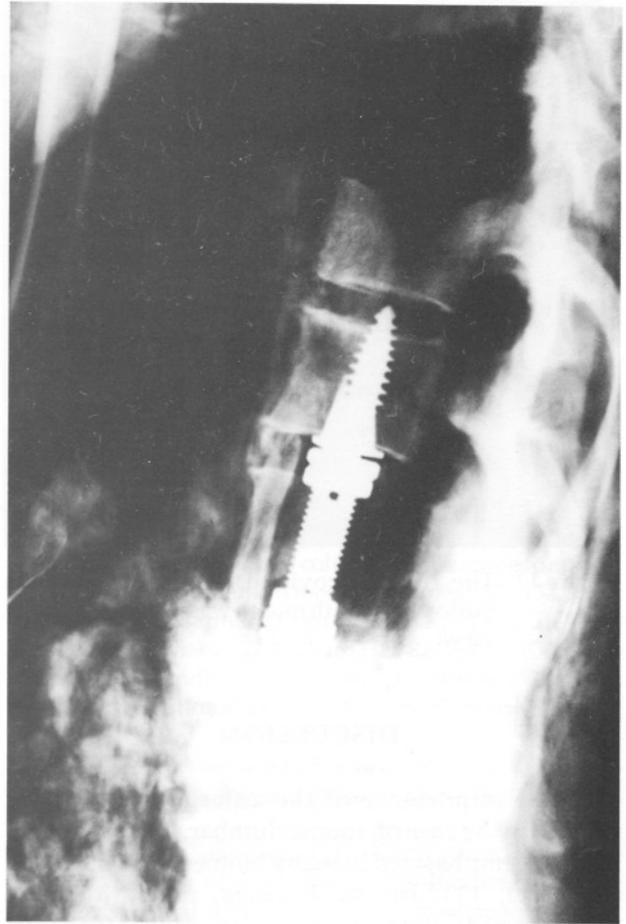


Figure 10: Lateral X-ray film of the Anterior Intercorporeal Fixation Device.



Figure 11: The screw at L2 level on postoperative 6th month was revealed with axial view.

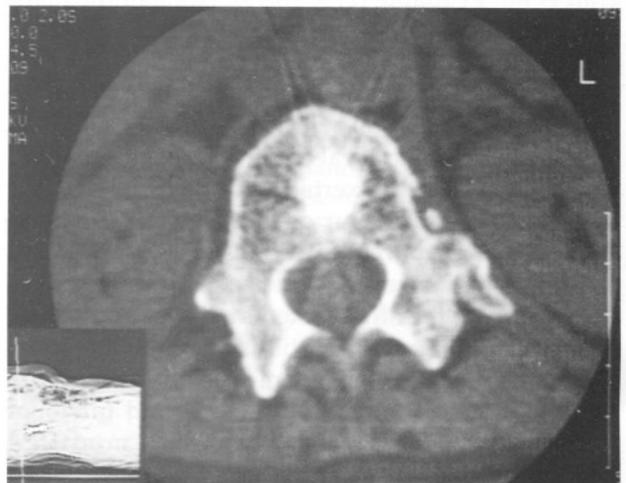


Figure 12: The screw at Th12 level on postoperative 6th month was revealed with axial view.



Figure 13: The fusion provided with costa graft on postoperative 6th month was proven with axial view.

DISCUSSION

The importance of the anterior and middle column in the case of, thoracolumbar, burst fractures has been emphasized in many biomechanical studies (4, 9, 10, 11). In these cases, many authors recommend posterior instrumentation in transpedicular way to provide stability following the application of anterior block graft either in the same operation or in a second session (7). Anterior and posterior instrumentation systems used today are especially insufficient against axial compression and torsional forces, if powerful tricortical block bone graft is not available (2, 3, 16,19). None of the man-made systems is as strong as the natural structure (16,17). Positioning of the existing anterior and posterior instrumentation systems in a perpendicular fashion with respect to the vertical force axis of the vertebral column leads to a relative increase in the load exerted onto the implant, and thus, causes failure. Our device which is based on anterior intercorporeal fixation is placed parallel to the anatomical force axis. Therefore, while it does not differ from the other systems in terms of resisting flexion and extension motions it is, as shown in biomechanical studies, more advantageous especially against axial compression and torsional forces (16). Rezaian's, Pinto and modified Harrington systems which are placed between vertebral bodies, being only temporary distractor systems, do not provide fixation (1, 5). While the

fusion region in Rezaian's and Pinto systems are quite small, the fusion region in the system reported here is larger, and therefore, more satisfactory. Since our system provides fixation, we can use it in osteoporotic patients and multipl segment involved cases.

Our device is easy to apply. In the cadaver study, application of the screws following the corpectomy took only ten minutes, while the application of the entire system required 35 minutes in total. There was not problem during application of the device to a patient with L1 burst. Only a few simple equipments are used during application. The only crucial point is the alignment of the connector and the other pieces in the same direction. Insertion of the screws should be done carefully without hurry. If the screws are misaligned placing the connector will be troublesome, and spongy structure of corpus will not allow for insertion of the screws once more by redrilling. Although small diversions in the direction of the screws can be tolerated, opening a new channel is quite difficult. In this example the problem of localizing the midpoint of vertebrae is solved by, calculating the measurements of posterior border of the corpus - corpus midpoint and lateral border of the corpus - corpus midpoint in axial sections of CT, than we use these measurements during the operation. Since our device is based on the principle of ' Fixation along the Anatomical Axis ' the biomechanical results were superior, and therefore, the costa graft is sufficient for a quick and satisfactory fusion, eliminating the need for block graft (8, 17). We performed with costa graft. When the removal of the system is required, the screws were easily unfastened without encountering any complication. In all other studies on sheep, cow and human cadavers the implant was easily removed without undoing the connector screws. Another advantage of this system over the other anterior stabilization systems is that removing only the pathological vertebra body is sufficient for the application without the need to expose the adjacent vertebra bodies.

Moreover, since the application is quite easy and the area is far enough from neural elements and important vascular structures, it is also thought that the risk of complication during application may considerably be reduced (6, 13,14,15,18). Since in the anterior and middle column insufficiencies the force vector of axial and rotational forces are in vertical direction, horizontally placed fixation systems are subjected to momental forces and these may cause

their failure. For a long time many instruments have been tried in the intercorporal space; Rezaian and Pinto systems are still used. Lack of fixation is the major disadvantage of these systems. By solving this problem our system has an advantage over others.

In conclusion, Anterior Intercorporal Fixation Device achieves resistance especially against the axial compressional and rotational forces, and provides short segment stabilization. Exposition of only the pathologic vertebrae corpus is adequate. Application of the system is quite safe, because this area is away from neural and important vascular structures. In addition to all with its practicability it needs to be improved to find widespread use.

Legal Note: This system is patented (TR 96 / 466 - June 4, 1996). Patent Cooperation Treaty/TR 97/00007. Approved by the international bureau (WIPO) in Austria.

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