J Korean Neurosurg Soc 37 : 217-222, 2005

Laboratory Investigation

Biomechanical Testing of Anterior Cervical Spine Implants : Evaluation of Changes in Strength Characteristics and Metal Fatigue Resulting from Minimal Bending and Cyclic Loading

Sung-Bum Kim, M.D., Koang-Hum Bak, M.D., Jin-Hwan Cheong, M.D.,
Jae-Min Kim, M.D., Choong-Hyun Kim, M.D., Seong-Hoon Oh, M.D.

Department of Neurosurgery, School of Medicine, Hanyang University, Seoul, Korea

Objective : To achieve optimal fit of implant, it is necessary to bend the implant during spine surgery. Bending procedure may decrease stiffness of plate especially made of titanium and stainless steel. Typically titanium suffers adverse effects including early crack propagation when it is bent. We investigate whether 6 degree bending of titanium plates would decrease the stiffness after full cyclic loading by comparing with non-bending titanium plates group.

Methods : Authors experimented 40 titanium alloy plates of 57mm in length, manufactured by 5 different companies. Total 40 plates were divided into two groups (20 bent plates for experimental group and 20 non-bent plates for control group). Twenty plates of experimental group were bent to 6 degree with 3-point bending technique and verified with image analyzer. Using the electron microscope, we sought for a initial crack before and after 3-point bending. Mechanical testing by means of 6000 cyclic axial-compression loading of 35N in compression with moment arm of 35mm-1.1Nm was conducted on each plate and followed by the electron microscopic examination to detect crack or fissure on plates.

Results : The stiffness was decreased after 6000 cyclic loading, but there was no statistically significant difference in stiffness between experimental and control group. There was no evidence of change in grain structure on the electron microscopic magnification.

Conclusion : The titanium cervical plates can be bent to 6 degree without any crack or weakness of plate. We also assume that minimal bending may increase the resistance to fatigue fracture in cervical flexion-extension movement.

KEY WORDS : Cervical plate · Titanium · Minimal bending · Stiffness · Cyclic loading.

Introduction

Instruments for spinal surgery have been developed by advancement of spinal biomechanics. Developed instruments have also contributed in successful treatments of several spinal disorder.

Recently, titanium and titanium alloy have been widely used for spinal fixation devices. More than 70% of the hook, screw, and rod systems were made of titanium and titanium alloy[8]. The increasing popularity of titanium may be closely related to its greater compatibility with Magnetic Resonance Imaging[7-9,12,20]. Other advantages would be less allergenicity, corrosivity, and fibrogenicity than stainless stee[12,15,16,18,21].

Despite these advantages, it has been recognized that the stiffness of titanium is significantly decreased by scratches or marks on its surface[5]. This property, termed notch sensitivity, is not a problem when it is implanted without being scratched or bent. However, in the use of an anterior cervical plates, it is commonly necessary to bend the implant with French bender during surgery to achieve optimal fit to cervical lordosis. After this procedure, anterior cervical titanium plates are always notched in some way, which may decrease the stiffness of plates and cause early crack propagation and lead to plates fracture with metal failure.

To our knowledge, the notch sensitivity of titanium and titanium alloy in cervical plates has not been widely recognized by the manufacturers or other researchers. We investigated that 6 degree bending of cervical plates with 3-point bending technique, commonly used in anterior cervical plating, would lead to weakening of plates at the point of stress risers and affects the load bearing capacity of the cervical plate. The purpose of this study is to compare the stiffness of titanium cervical plates after cyclic loading between 6 degree with 3-point bending plates and non-bent control plates.

• Received : June 25, 2004 • Accepted : October 19, 2004
• Address for reprints : Koang-Hum Bak, M.D., Department of Neurosurgery, School of Medicine, Hanyang University, Gyomun 1-dong, Guri 471-701, Korea
Tel : 031)560-2325, Fax : 031)560-2327
E-mail : pkh2325@hanyang.ac.kr

Materials and Methods

Authors experimented 40 titanium alloy plates of 57mm, which are usually used for anterior cervical plating after 2 level corpectomy. 40 titanium alloy plates are produced by 5 companies [Acromed (Acroplate, Cleveland, OH, USA), Aesculap (ABC, Tuttlingen, Germany), Codman (ACP, Johnson & Johnson Professional Inc. Raynham, MA, USA), Sofamor-Danek (Orion plate, Memphis, TN, USA), Synthes (CSLP, Paoli, PA, USA)].

Total 40 plates were divided into two groups (20 bent plates for experimental group and 20 non-bent plates for control group). Twenty plates of experimental group were bent to 6 degree with 3-point bending technique using French bender and verified with image analyzer. The other 20 plates of non-bent control group were experimented as they were manufactured.

Using the scanning electron microscope(SEM), each plate was meticulously inspected for scratches or crack before testing. A plate found to be cracked in any way was discarded.

Confirmation of early crack formation after bending

Plates of experimental group (6 degree bent by French bender) were examined under the SEM by 5, 500 magnifications to detect the change of fine structure and early crack formation. Digital images of the features of interest were recorded.

Cyclic loading

Testing was conducted in air at an ambient room temperature of 24C° by using a 5-Hertz sinusoidal waveform. A 5Hertz frequency was chosen to expedite the completion of each test. It is recognized that these tests provide a useful means of comparing the mechanical performance of different implants.

To measure changes of stiffness related to cyclic loading, MTS 858 Bionix test systems (MTS System Corp.; Minneapolis, MN, USA) with an axial-compression load transducer was applied to both experimental group and control group (Fig. 1). Each plate of experimental group and control group was fixed to axial-compression load fixture with moment arm of 31mm length. Axial-compression load was continuously applied to plates until it reaches for 35N, then loading was stop and plates returned to the initial figure by elastic force, which was defined as one cyclic loading. Mechanical testing of 6000 cyclic loading in axial-compression with moment arm of 35mm-1.1Nm was conducted on each plate (Fig. 2).

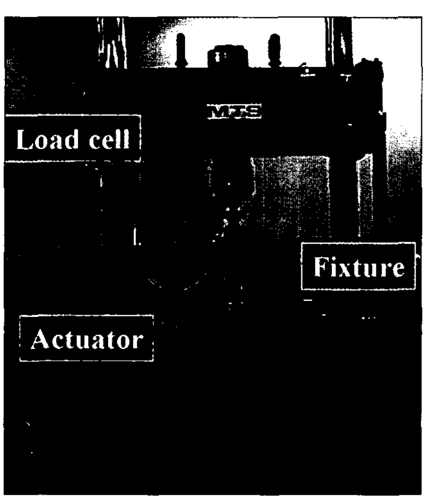

Fig. 1. Illustration of MTS 858 Bionix test system (MTS System Corp.; Minneapolis, MN, USA) which provide 6000 cyclic loading of 35N in axial-compression with moment arm(35mm - 1.1 Nm). After both end side of plate is fixed on fixture, actuator and load cell move up and down to give axial-compressive loading and sense the loading of 35N to stop loading.

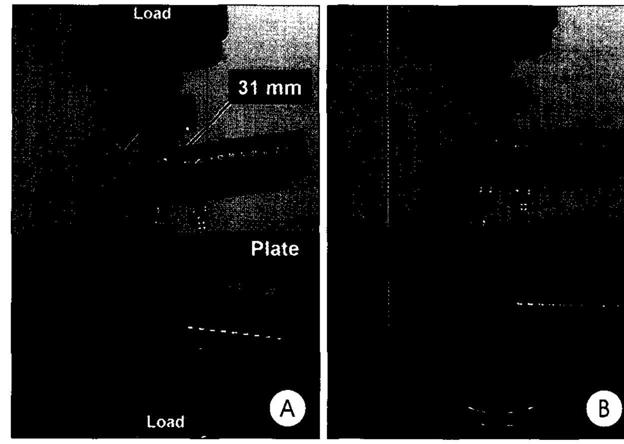

Fig. 2. Close-up view of MTS 858 Bionix test system(MTS System Corp.; Minneapolis, MN, USA) A : Cyclic loading of 35N in axial-compression with moment arm of 31mm. B : After axial-compressive loading of 35N, moment arm move to the previous location by plate itself elasticity.

Measurement of stiffness after cyclic loading

Changes of stiffness before and after the cyclic loading were measured in each plate of experimental group and control group. Stiffness (stiffness : S) was measured by change degree of moment (moment : M) in comparision with displacement angle of plates (angle : θ). Moment was calculated by times of force (newton : N) and displacement length of each plates (mm : L) ($S = M/\theta$, $M = N \times L$). Stiffness was recorded in each time of cyclic loading on computer which is connected on MTS 858 Bionix test systems (Fig. 3, 4) (stiffness after 1th loading : S1, stiffness after 6000th loading : S6000).

Average stiffness of each plate after first cyclic loading and last 6000th cyclic loading were calculated, and decline ratio of average stiffness value in experimental group and control group was also measured [decline ratio of average stiffness : (average S1-average S6000)/average S1].

Detection of crack formation after cyclic loading

After cyclic loading of axial-compression, each plate of experimental group and control group were examined carefully,

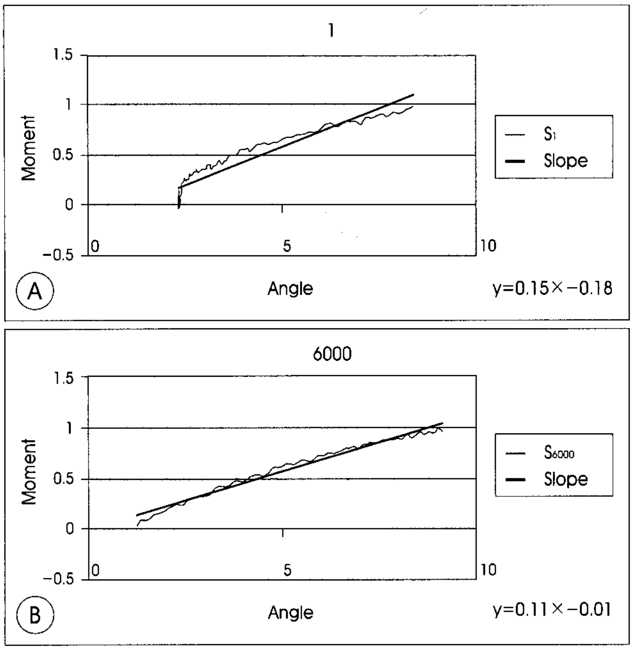

Fig. 3. Example of stiffness curves of Acromed plate in control group. Slope becomes gentle after 6000 cyclic loading comparing with first cyclic loading. A : Stiffness curve of first cyclic loading B : Stiffness curve of 6000 cyclic loading.

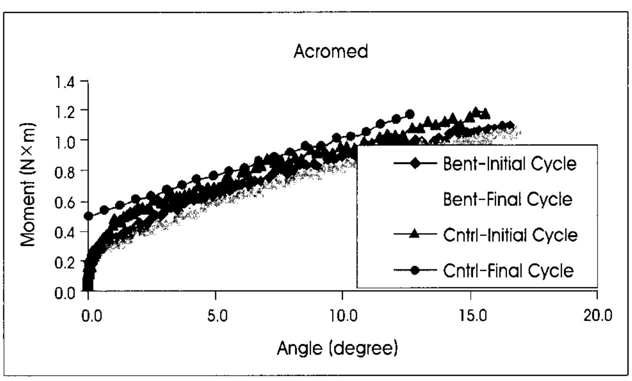

Fig. 4. Example of stiffness curves of Acromed plate in control and bent group of first and 6000 cyclic loading. All 4 curves are close together, which suggest little difference in stiffness among groups.

using electron microscope by 5 magnifications, 500 magnifications to detect the crack.

Statistical Analysis

Changes of stiffness after 6000 cyclic loading were analyzed statistically between experimental group and control group. Mann-Whitney verification test was performed to determine whether a significant difference existed between two groups. All statistical analyses were performed with SPSS 10.0 for windows (Statistical Package for Social Science, Chicago, USA). Statistical significance for comparisons occurred at a P value less than 0.05.

Results

Confirmation of early crack formation after bending

Although scanning electron microscopy (magnification, ×5) of 6 degree bent experimental group showed indentation on surface of plate, any changes of fine structure were not detected on SEM of 500 diameters magnifications (Fig. 5).

Changes of stiffness after cyclic loading

Mean stiffness of experimental group after first cyclic loading was 0.44±0.21N/mm, which decreased to 0.31± 0.21N/mm after 6000th cyclic loading. In control group, mean stiffness after first cyclic loading was 0.34±0.24N/mm, after 6000th cyclic loading, it decreased to 0.13±0.07N/mm. Stiffness of both experimental group and control group decreased after full cyclic loading. Mean stiffness of control group after each cyclic loading was lower than that of experimental group.

Decline ratio of mean stiffness on experimental group was 29.5%, that of control group was 62.6%. Although control group was more prominent in decline ratio of mean stiffness than experimental group, there was no statistically significant difference of mean stiffness after full cyclic loading on both experimental and control group (P=0.25)(Fig. 6).

Detection of crack formation after 6000 cyclic loading

Scanning electron microscopy of experimental group showed shallow indentations on low power field (magnification, ×5). After magnify to high power field (magnification, ×500), however, there was no evidence of change such as crack formation or fissure in grain structure (Fig. 7).

Discussion

Over the past several years, titanium and titanium alloy have become the materials of choice for spinal fixation devices. This popularity results mainly from the decrease in magnetic resonance imaging(MRI) artifact, as compared with that of stainless steel[5,7]. Other advantages include its lighter weight, greater biocompatibility,

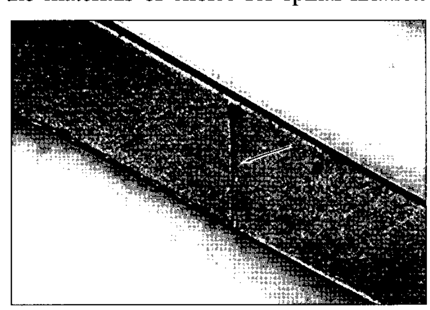

Fig. 5. Photograph of scanning electron microscope which obtained from the titanium alloy cervical plate after 6 degree, 3-point bending before cyclic loading. Indentation (long arrow) is detected on electron microscope (magnification,×5).

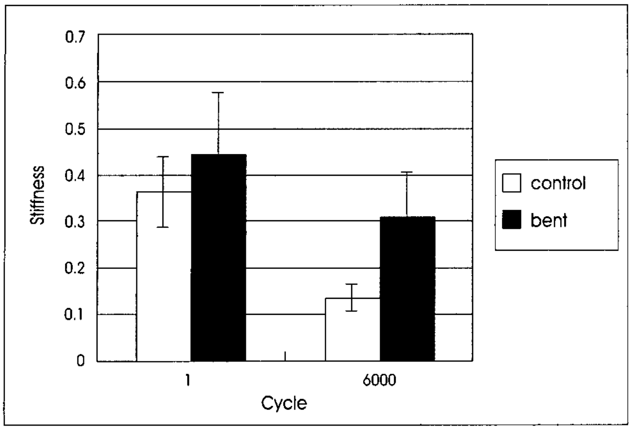

Fig. 6. This graph shows the mean stiffness of bent and control group after first and 6000 cyclic loading. The stiffness is decreased after 6000 cycling but there was no statistically significant decrease in stiffness after cycling between bent and control group.

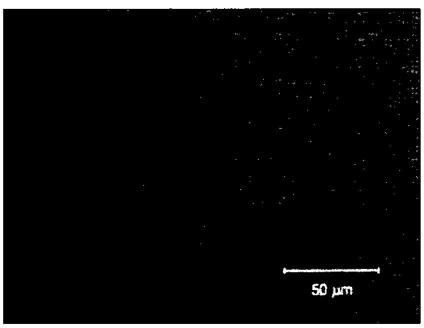

Fig. 7. Photograph of scanning electron microscope which obtained from the titanium alloy cervical plate after 6 degree, 3-point bending and 6000 cyclic loading. After magnification of indented area, deep fissure or crack is not seen on electron microscope (magnification, ×500).

less corrosivity, less fibrogenicity, and wider availability[12,16].

In spite of its predominance, multiple studies have demonstrated the decrease in stiffness of titanium when its surface of the implant is scratched or notched. This property of titanium has come to be known as notch sensitivity[5,8,16]. The notch sensitivity of titanium has been demonstrated in spine, orthopedic trauma, and total joint[2,3,6].

In cervical anterior interbody fusion with cervical plate, this property of titanium is important because the plates are nearly always notched in some way by bending the plate with French bender to match the contour of the cervical lordosis. Biomechanical changes of plates could exert a serious effect on metal fatigue and stiffness which may lead to implats failure. Failure of implants including such plates could seriously result in nervous damage or complication.

There have been various report for implants failure of titanium. Baldwin et al[1] reported a case of titanium cervical plate fracture after 8 months of cervical anterior plating on C3-4-5. They insisted that crack was apparently initiated with the contouring of the plate, located at the weakest point, and with subsequent stress, it propagated and led to fracture. They recommended that titanium implants should be subjected to a minimum of bending during implantation to avoid failure of this type, because stress intensification and low-cycle fatigue will result at the weakest area of the plate.

On the review of the biomechanical principles of titanium, it has mechanically lower modulus of elasticity than stainless steel, which means implants of the same dimensions are less stiff. Under the same bending conditions, titanium plates deform approximately twice as much as the same plate made of steel[17]. The fatigue behavior of titanium is better than that of stainless steel under conditions of low deformation and at lower loads but not under conditions of higher deformation[17]. However, the lower stiffness of titanium means that for specimens of the same dimensions under the same bending loads, titanium will deform more than steel, a situation in which the fatigue resistance of titanium is inferior.

There have been many studies that compared the fatigue life of titanium alloy with other materials such as posterior rod and screw constructs. Dick et al[5] had a biomechanical study comparing the fatigue life of stainless steel, titanium alloy, and commercially pure titanium rods that were notched using techniques unavoidable to spine surgery. They insisted that use of the French bender and connecting bolts on a titanium rod creates notches, which cause a statistically significant decrease the fatigue life of the rods.

They concluded that caution should be needed when bending connectors from titanium rods in situations wherein fatigue life is a concern. Their results did not correspond to our results. They used 4-point bending which was different to this study. Four-point bending would make the more notch than our 3-point bending. This situation may be responsible to decreasing the fatigue life of the titanium rods. Pienkowski et al[19] compared titanium alloy and stainless steel constructs of two different designs, concluding that, whereas stainless steel constructs are stiffer than titanium alloy, the fatigue life is a function of both the design and the material. Stambough et al[22] also insisted similarly to the report of Pienkowski that fatigue characteristics was a function of the design, not the material. In our test, we choose 40 titanium alloy plates from 5 different companies, and 5 different kinds of design. Different kind of design, although equally divded into two groups, would result in inadequate comparison between the two groups. This would be the short of our study.

However, One of the interesting results of our study is that mean stiffness of 6 degree with 3-point bending groups is unexpectedly higher than non-bending groups. Another is that decline ratio of mean stiffness on control group after cyclic loading was, although there are no statistically difference between the two groups, higher than that of experimental group. These results may be contradictory with previous literatures insisting that the deformation of titanium alloy decreased the stiffness and led to serious biomechanical changes. We assume that minimal bending without crack formation may increase resistance to cervical flexion-extension movement. We also deduce that proper matching of plate to the contour of the cervical lordosis with bending would be resistant to cervical loading.

Limitation of the study was the questionable clinical relevance of the testing setup. Although the number of cycles and rate of loading were chosen to provide adequate fatigue of the specimens without unreasonably extending the testing time, cyclic loading may be considered by some to be clinically unrealistic, because actual cervical movement include not only flexion-extenstion but also rotation, lateral bending. Several studies have shown that beyond 5000 to 6000 cycles, the load deformation curves do not change appreciably[4,10,14], which was for these reasons that 6000 cycles were chosen. On the point of degree of bending, 6 degree bending would be clinically unrealistic.

Some plates could be bent more, some less in practical surgical field. Degree of bending might depend on the cervical segmental lordotic curve and the level. Gore et al[11] estimated a normal range of the cervical lordosis and suggested that local average kyphosis at one disc space was estimated to be 9° and average segemental lordosis with reversals was 4°. These are the grounds for 6 degree experimental bending test in current study.

Another limitation of the study is that our research was incomplete vitro biomechanical study. Although stiffness of plates is important to support the biomechnical stability, plate fixation screw associated with vertebral body is the momentous factor of supporting the biomechnical stability in cervical anterior interbody fusion[13]. We overlooked the variables of plate fixation screw, and bone fusion, which signifies that loading force to cervical plate after complete bone fusion would be much lower than when it was fixed to vertebral body immediately.

This research would give a confidence to many spine surgeon that 6 degree bending of titanium plate does not make serious biomechanical changes such as decreasing the stiffness of cervical plate after cyclic loading. It rather provide the plate with resistance to flexion-extension load.

Many further research proving critical angle of safe bending to prevent fracture of plates, and clinically more realistic studies including cadaveric study are prerequisite to evaluate the better bone fusion condition, and improvement of plates to keep their stiffness until bone fusion would be required for preventing biomechanical failure.

Conclusion

Despite many reports that deformation of titanum alloy is closely related to serious biomechanical changes, we found that there was no statistically significant difference in mean stiffness after full cyclic loading between both experimental and control group. In conclusion, titanium cervical plates can be bent to 6 degree without any crack or weakness of plate. It is also our finding that minimal bending without crack formation would make the stiffness of resistance to cervical flexion-extension movement increase.

References

1. Baldwin NG, Hartman GP, Weiser MW, Benzel EC : Failure of a titanium anterior cervical plate implant: microstructural analysis of failure. Case report. **J Neurosurg 83** : 741-743, 1995
2. Banovetz JM, Sharp R, Probe RA, Anglen JO : Titanium plate fixation: a review of implant failures. **J Orthop Trauma 10** : 389-394, 1996
3. Cook SD, Thomas KA : Fatigue failure of noncemented porous-coated implants : a retrieval study. **J Bone Joint Surg 73** : 20-24, 1991
4. Cunningham BW, Sefter JC, Shono Y, McAfee PC : Static and cyclical biomechanical analysis of pedicle screw spine constructs. **Spine 18** : 1677-1688, 1993
5. Dick JC, Bourgeault CA : Notch sensitivity of titanium alloy, commercially pure titanium, and stainless steel spinal implants. **Spine 26** : 1668-1672, 2001
6. Dick JC, Brodke DS, Zdeblick TA, Bartel BD, Kunz DN, Rapoff AJ : Anterior instrumentation of the thoracolumbar spine : a biomechanical comparison. **Spine 22** : 744-750, 1997
7. Disegi JA : Magnetic Resonance Imaging of AO/ASIF stainless steel and titanium implants. **Injury 23** : 1-4, 1992
8. Ebraheim NA, Rupp RE, Savolaine ER, Reinke D : Use of titanium implants in pedicular screw fixation. **J Spinal Disord 7** : 478-486, 1994
9. Ebraheim NA, Savolaine ER, Stitgen SH, Jackson WT : Magnetic resonance imaging after pedicular screw fixation of the spine. **Clin Orthop 279** : 133-137, 1992
10. Goel VK, Voo LM, Weinstein JN, Liu YK, Okuma T, Njus GO : Response of the ligamentous lumbar spine to cyclic bending loads. **Spine 13** : 294-300, 1988
11. Gore DR, Sepic SB, Gardner GM : Roentgenographic findings of the cervical spine in asymptomatic people. **Spine 6** : 521-524, 1986
12. Gotman I : Characteristics of metals used in implants. **J Endourol 11** : 383-389, 1997
13. Kim CH, Ryu KY, Seok KS, Kang DG, Kim SC : Instrument Failure in Anterior Cervical Plate Fixation. **J Korean Neurosurg Soc 32** : 436-442, 2002
14. Liu YK, Njus G, Buckwalter J, Wakano K : Fatigue response of lumbar intervertebral joints under axial cyclic loading. **Spine 8** : 857-865, 1983
15. Long M, Rack HJ : Titanium alloys in total joint replacement : a materials science perspective. **Biomaterials 19** : 1621-1639, 1998
16. McGeachie J, Smith E, Roberts P, Grounds M : Reaction of skeletal muscle to small implants of titanium or stainless steel : a quantitative histological and autoradiographic study. **Biomaterials 13** : 562-568, 1992
17. Perren SM, Buchanan JS : The concept of biological plating using the limited contact dynamic compression plate. **Injury 23** : 1-41, 1991
18. Pfeiffer M, Brennwald J, Buchler U, Hanel D, Jupiter J, Lowka K, et al : Implants of Pure Titanium for Internal Fixation of the Peripheral Skeleton. **Injury 25** : 87-89, 1994
19. Pienkowski D, Stephens GC, Doers TM, Hamilton DM : Multicycle

mechanical performance of titanium and stainless steel transpedicular spine implants. **Spine 23** : 782-788, 1998
20. Rupp RE, Ebraheim NA, Wong FF : The value of magnetic resonance imaging of the postoperative spine with titanium implants. **J Spinal Disord 9** : 342-346, 1996
21. Shannon C, Thull R, von Recum A : Types I and III collagen in the tissue capsules of titanium and stainless steel implants. **J Biomed Mater Res 34** : 401-408, 1997
22. Stambough JL, Genaidy AM, Huston RL, Serhan H, El-khatib F, Sabri EH : Biomechanical assessment of titanium and stainless steel posterior spinal constructs : Effects of absolute/relative loading and frequency on fatigue life and determination of failure modes. **J Spinal Disord 10** : 473-481, 1997