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The influence on the contact condition and initial fixation stability of the main design parameters of a self-expansion type anterior cruciate ligament fixation device †

Jong-Dae Kim[1], Chae-Youn Oh[2] and Cheol-Sang Kim[3,*]

[1]*Department of Mechanical and Automotive Engineering, Jeonju University, Jeonju, Chonbuk 560-759, Korea*
[2]*Division of Precision Mechanical Engineering, Chonbuk National University, Jeonju, Chonbuk 561-756, Korea*
[3]*Division of Mechanical Design Engineering, Chonbuk National University, Jeonju, Chonbuk 561-756, Korea*

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Abstract

This paper proposes a self-expansion type anterior cruciate ligament fixation device. The proposed fixation device provides graft fixation force by maintaining contact with the bone tunnel. Since the device maintains contact with the bone tunnel by the force that expands by the self-driven elastic force of the device, the main design parameters that determine the performance of this device are the ring thickness and expansion angle. This paper develops the three-dimensional finite element models of the fixation device and bone. By simulation with the developed finite element model, this paper studies the influence of the main design parameters of the device on the maximum stress around the ring when grasping the fixation device. Through the analysis of the stress on the bone tunnel wall when the fixation device comes in contact with the bone tunnel, this paper shows the influence of the main design parameters of the fixation device on the contact condition. In addition, through the analysis of the migration that occur upon application of the pull-out force, this paper studies the influence of the main design parameters on the initial fixation stability of the fixation device.

Keywords: Anterior cruciate ligament; Ligament fixation device; Bone tunnel; Finite element method; Pull-out force; Stress distribution, Migration

1. Introduction

In the reconstruction of an anterior cruciate ligament damaged by excessive sports activity or a traffic accident, various kinds of graft and fixation devices have been used. The bone-patellar tendon-bone and hamstring tendon are widely used as grafts for reconstructing an anterior cruciate ligament [1, 2, 5]. Since the bone-patellar tendon-bone causes high morbidity on the donor site and can raise pain or functional instability after operation, the hamstring tendon has been used increasingly [1, 2, 5].

Various kinds of fixation devices have been developed to fix a hamstring tendon to the femur [4, 6, 8, 9, 17]. An interference screw type fixation device sticks the hamstring tendon directly to the bone by using screws. Such a fixation device initially provides high fixation strength after operation. However, it has been reported that the divergence of the screw from the longitudinal axis of the femur tunnel can cause the decline of fixation strength, pull-out of graft or tear of graft by threads. Also, the device can lead to inflammation on the synovium [2, 5, 16].

Some devices that suspend the graft on a button or post have also been frequently used [2, 5, 8, 17]. These fixation devices provide easy biological bonding because they allow the hamstring tendon to

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*Corresponding author. Tel.: +82 63 270 4284, Fax.: +82 63 270 2388
E-mail address: chskim@chonbuk.ac.kr

come in contact with the bone all around the circumference of the bone tunnel wall [13]. However, these devices have the disadvantages of requiring a second incision and prolonging the healing time due to the movement of the graft in the longitudinal and sagittal directions within the femur tunnel [2, 5].

The recent trend in rehabilitation after operation is the adoption of the "accelerated rehabilitation" method [14]. This method emphasizes the full-range motion of the knee joint and early weight bearing. In order to carry out this rehabilitation program, the fixation device used in the reconstruction of an anterior cruciate ligament must stand against the pull-out force of 500N at the early stage after operation [10]. Accordingly, it is required to develop a fixation device that has high initial fixation stability, causes minimum graft damage and allows simple operation.

This paper introduces an alternative fixation device for an anterior cruciate ligament reconstruction. The new fixation device maintains contact with the femur tunnel by its self-driven elastic force after operation. This paper develops the finite element models of the fixation device and femur to study the influence of the main design parameters of the device on the contact condition and the initial fixation stability.

2. Structure of the proposed fixation device

This paper proposes the self-expansion type fixation device consisting of three parts, as shown in Fig. 1. Since A-part of Fig. 1 is ring-shaped, it can deform elastically in the tangential direction. The elastic deformation of the ring part allows the part to act as a coil spring by providing elastic force in the tangential direction. B-part of Fig. 1 is the part of the fixation device that comes in contact with the femur tunnel. B-part has sharp wedges, as shown in Fig. 1. The upper side of the wedge is inclined at a constant angle and the lower side of it is at a right angle to the body. When the gap between the fixation device and bone is filled after operation, this arrangement of the wedge can significantly reduce the migration. C-part of Fig. 1 is the link part for suspending the graft.

Since this device maintains contact with the bone tunnel by the force that expands by the self-driven elastic force of the device, the main design parameters that determine the performance of the device

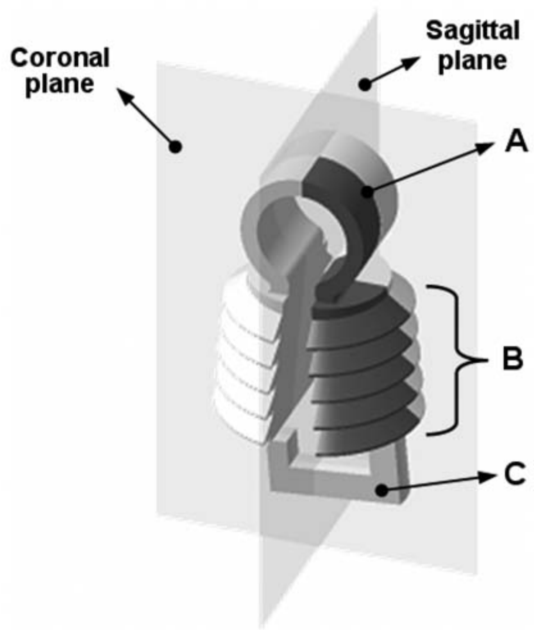

Fig. 1. A three-dimensional view of a self-expansion type anterior cruciate ligament fixation device.

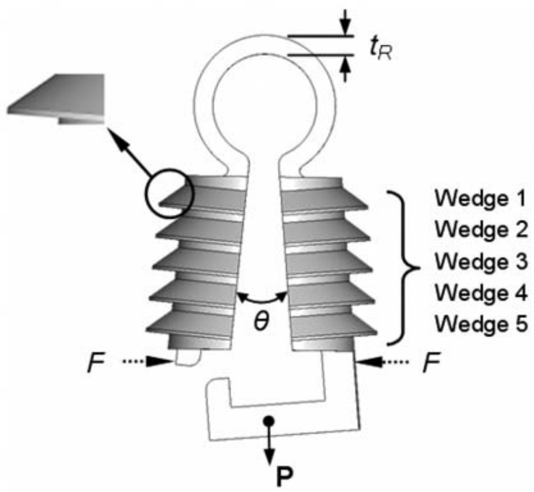

Fig. 2. Main design parameters and applied forces.

are the ring thickness (t_R) and expansion angle (θ). Fig. 2 shows the main design parameters and the locations where the grabbing force is applied to insert the device into the femur tunnel.

If the grabbed force is released after insertion, the ring-shaped part A of Fig. 1, which deforms elastically, tries to return to its original shape. Then, the wedges come in contact with the bone after operation. This contact force initially fixes the graft after operation.

Therefore, the proposed device can reduce graft damage because the graft does not come in direct contact with the sharp wedges. The device can significantly shorten operation time because coercive pushing force is not required to insert it into the bone tunnel, unlike an interference screw type device. The device does not require a second incision or a subordinate work for prevention of divergence of fixation device.

The most important issue of the proposed device is to design it in such a way as to secure the initial fixation stability through sufficient and uniform contact force with the bone. In order to maintain sufficient contact force, it is desirable that the elastic force provided by the elastic deformation of the ring part is sufficiently large and that the wedge uniformly contacts the bone tunnel wall as much as possible. If the elastic deformation of the ring part is enlarged to increase the elastic force, the stress in the central area of the ring part can exceed the yield strength of the device. In addition, if the ring thickness becomes too thick, the surgical operation can become difficult because huge amount of force would be needed to grab the fixation device for insertion.

3. Finite element modeling

This paper studies the influence of the main design parameters on the contact condition and the initial fixation stability by simulation. This paper developed the finite element models of the fixation device and the bone for the simulation.

The ring part A of Fig. 1 and the wedge part B are geometrically symmetrical with respect to the sagittal plane and coronal plane. The three-dimensional femur model provided on the internet was used as the geometry model of the femur [12]. The fixation device is inserted into a tunnel made in the femur model. Therefore, the part that is mechanically influenced by the fixation device is considered axisymmetric. Accordingly, this paper developed the quarter finite element model of the fixation device and the femur, as shown in Fig. 3. The finite element modeling and analysis of the fixation device and the femur were performed by using ABAQUS 6.5-1.

For the finite element modeling of the wedge part

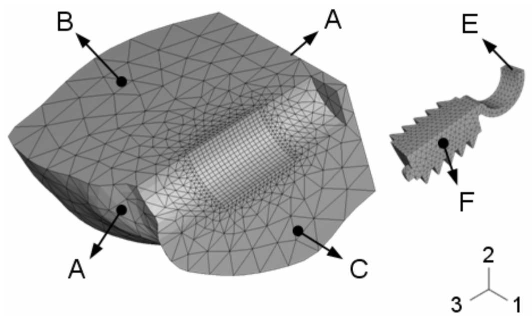

Fig. 3. The quarter finite element model of fixation device and femur.

of the fixation device, 20-node quadratic brick (C3D20) elements were used. For the finite element modeling of the ring and link part, 10-node quadratic tetrahedron (C3D10) elements were used. For the finite element modeling of the femur that contacts the wedge of the fixation device, 20-node quadratic bricks (C3D20) were used. For the finite element modeling of the remaining part of the femur, 10-node quadratic tetrahedrons (C3D10) were used. The number of finite elements used in the finite element modeling of the fixation device and the femur differed slightly according to the ring thickness and expansion angle.

To determine the proper number of elements for the fixation device and the femur modeling, stress convergence analyses were performed. Six finite element models of the fixation device were selected for the convergence analysis. The number of elements of those six models ranged from about 4,200 elements to about 110,000 elements. The analysis results showed that the maximum stress was not affected by the number of elements when more than 4,200 elements were used for the modeling of the fixation device. In addition, six finite element models of the femur were selected for the convergence analysis. The number of elements of those six models ranged from about 7,200 elements to about 100,000 elements. The analysis results showed that the maximum stress was not affected by the number of elements if more than 7,200 elements were used for the modeling of the femur. Thus, about 6,400 elements were used for the fixation device modeling, and about 8,300 elements were used for the femur modeling.

All materials were assumed to be linear, elastic, homogeneous and isotropic. Generally, an implant inserted within a human body is made of titanium alloy. Therefore, the fixation device proposed in this paper is assumed to be made of titanium alloy (Ti6Al4V). The elastic modulus and Poisson's ratio of the fixation device were set to 110GPa and 0.3, respectively [7, 15]. The elastic modulus and Poisson's ratio of the femur were set to 2,130MPa and 0.3, respectively [11].

The frictional coefficient defined between a bone and an implant significantly affects the simulation result. It is not easy to define a frictional coefficient for the simulation of the relative motion between an implant with sharp edges and a bone. The frictional coefficient between a bone and an implant has been tuned by comparing experiment values and simulation values or assigned a value arbitrarily [3, 18]. This paper intends to examine the effects of the ring thickness and the expansion angle on the contact condition and initial fixation stability of the proposed fixation device. Thus, this paper performed simulation for many combinations of design parameters and various frictional coefficients. Then, the frictional coefficient of 3.0, which gave stable convergence in all cases, was selected.

This paper carried out three kinds of simulation to emulate the three steps of the actual operation. The first simulation intended to analyze the stress applied on the ring part of the fixation device as grabbing the fixation device until the wedge is not touching the femur tunnel wall. The second simulation intended to examine the condition in which the wedge of the fixation device contacts the bone tunnel wall at removal of the grabbing force. The third simulation intended to examine the initial fixation stability by applying the pull-out force to the fixation device.

In the first and the second simulation, the displacements of parts E and A of Fig. 3 were constrained in all directions. The displacements of parts F and C of Fig. 3 were constrained in the direction of 1. The displacement of part B of Fig. 3 was constrained in the direction of 2. In the third simulation, the pull-out force was applied along the longitudinal axis (direction of 3). Therefore, part E of Fig. 3 constrained the displacement in the directions of 1 and 2. The same boundary condition as that of the first simulation was applied for the rest of the parts of Fig. 3. In the following second and the third simulation, the contact between the fixation device and bone was defined by using the surface-to-surface contact condition. The bone tunnel wall functioned as a master surface, while the wedges of the fixation device were set as a slave surface.

4. Simulation results

Three ring thicknesses of 1.0mm, 1.2mm and 1.4mm, and three expansion angles of 6˚, 8˚ and 10˚ were considered. Table 1 shows the maximum Mises stress that occurred on the ring part when the fixation device was grabbed to insert it in the bone tunnel. As the ring thickness and expansion angle increased, the maximum Mises stress increased. The ring thickness influenced more the maximum Mises stress than the expansion angle did. The yield strength of the material of this fixation device was 800MPa [7]. The yield strength was not exceeded for all ring thickness for the expansion angles of 6˚ and 8˚. However, when the expansion angle of the fixation device was 10˚, the maximum stress exceeded the yield strength for the ring thickness of 1.4mm. Therefore, the ring thickness should be less than 1.4mm when the expansion angle is 10˚.

When the grabbing force is removed after inserting the fixation device in the bone tunnel, the fixation device expands to its original position by the elastic force of the ring part. The wedge maintains contact with the bone tunnel wall by the self-expanding force. Figs. 4-12 show the stress distribution of the bone tunnel that is in contacts with the first, third and fifth wedges of the fixation device. The horizontal axis of Figs. 4-12 represents the normalized distance along the circumferential direction of a wedge. The point at that the bone tunnel begins to contact a wedge is set as the origin.

All maximum Mises stresses in Figs. 4-12 occurred at the first wedge. Table 2 summarizes the maximum Mises stresses that occurred on the bone tunnel wall.

Table 1. Maximum Mises stress on the ring part (unit: MPa).

θ \ t_R	1.00mm	1.20mm	1.40mm
6.00˚	368.60	450.80	564.60
8.00˚	485.60	602.40	734.40
10.00˚	605.60	735.00	882.50

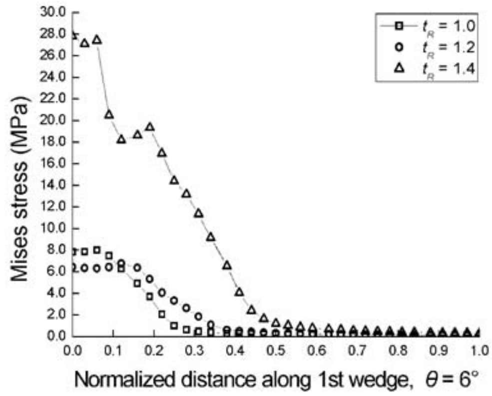

Fig. 4. Stress distribution of the bone tunnel wall; the first wedge and θ=6°.

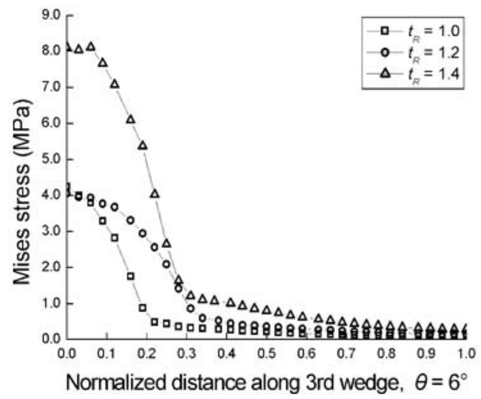

Fig. 5. Stress distribution of the bone tunnel wall; the third wedge and θ=6°.

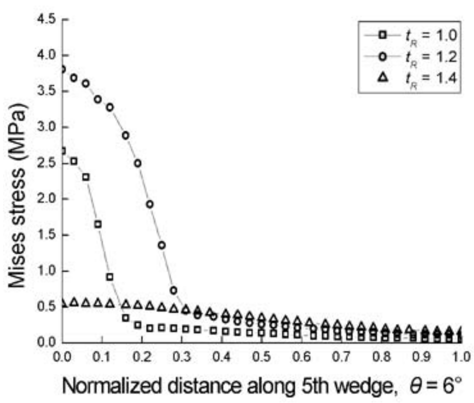

Fig. 6. Stress distribution of the bone tunnel wall; the fifth wedge and θ=6°.

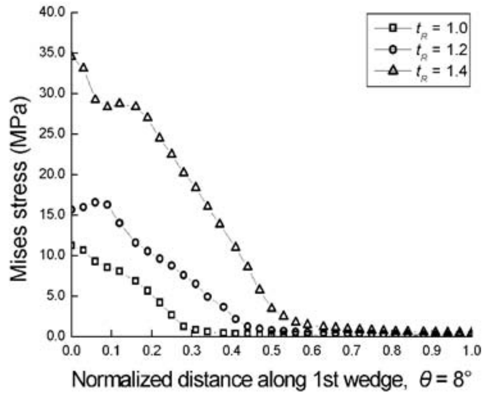

Fig. 7. Stress distribution of the bone tunnel wall; the first wedge and θ=8°.

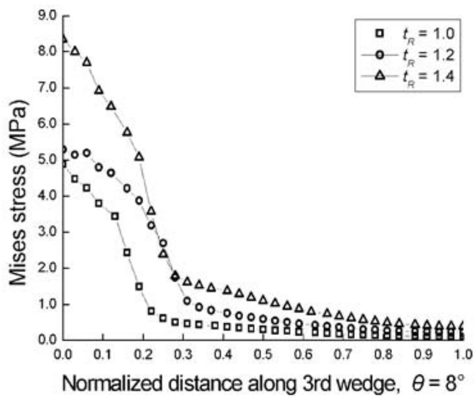

Fig. 8. Stress distribution of the bone tunnel wall; the third wedge and θ=8°.

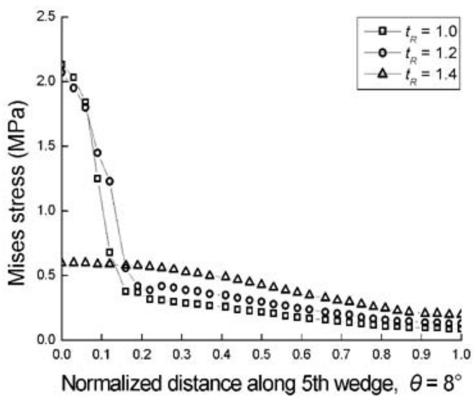

Fig. 9. Stress distribution of the bone tunnel wall; the fifth wedge and θ=8°.

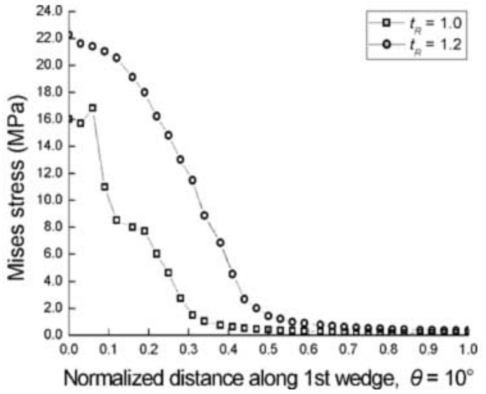

Fig. 10. Stress distribution of the bone tunnel wall; the first wedge and θ=10°.

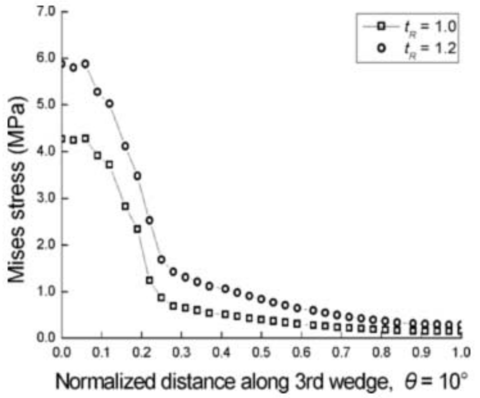

Fig. 11. Stress distribution of the bone tunnel wall; the third wedge and θ=10°.

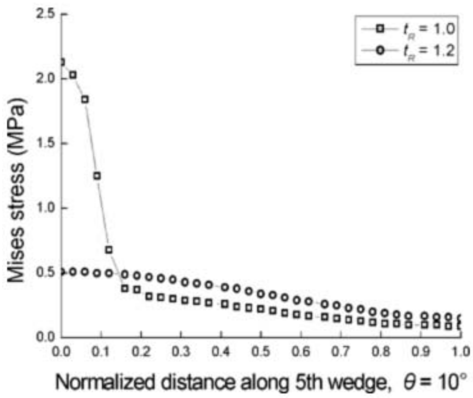

Fig. 12. Stress distribution of the bone tunnel wall; the fifth wedge and θ=10°.

Table 2. Maximum Mises stresses on the bone tunnel wall (unit: MPa).

θ \ t_R	1.00mm	1.20mm	1.40mm
6.00˚	7.98	6.77	27.80
8.00˚	11.21	16.58	34.55
10.00˚	16.82	22.26	-

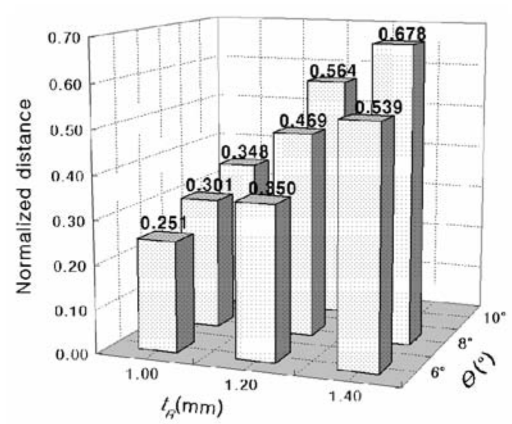

Fig. 13. Contact length between the first wedge and bone tunnel wall.

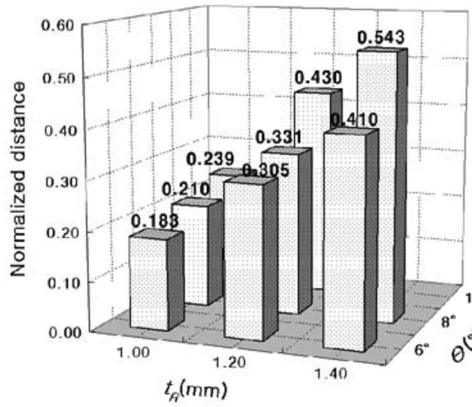

Fig. 14. Contact length between the third wedge and bone tunnel wall.

This paper considered the point at which the bone tunnel stress falls below 1MPa as the point of losing contact with the fixation device. Figs. 13-15 show the contact length between the first, third and fifth wedges and the bone tunnel, respectively.

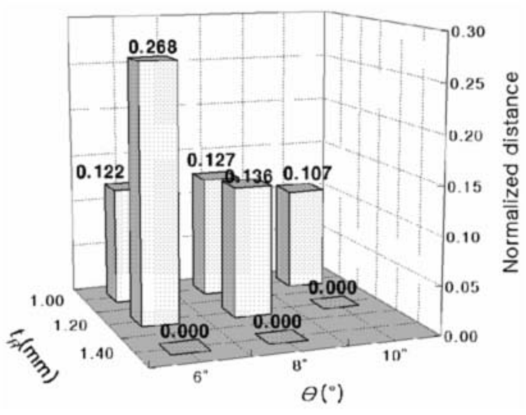

Fig. 15. Contact length between the fifth wedge and bone tunnel wall.

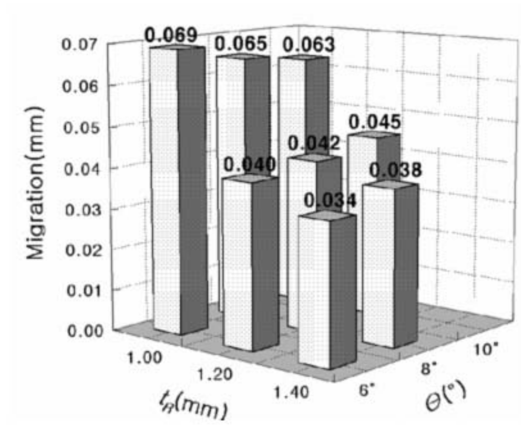

Fig. 16. Migration as according to the pull-out force applied to the fixation device.

From Figs. 4-12 and Figs. 13-15 it is found that, as the ring thickness and the expansion angle increased, the maximum stress on the bone tunnel increased. For all ring thickness and all expansion angles, the contact stress and contact length rapidly decreased as the wedge number increased.

Especially, when the ring thickness increased, the contact length rapidly decreased as the wedge number increased. When the ring thickness was 1.4mm, the fifth wedge hardly contacted the bone tunnel.

The stress distribution of the device with expansion angle of 6˚ and ring thickness of 1.2mm was almost identical for all wedges. As the expansion angle increased, the contact length extended in the first and the third wedge. Especially, when the ring thickness was 1.4mm, this tendency was remarkable.

When the expansion angle was small, the maximum stress and contact length did not show a big difference in the first wedge for the ring thickness of 1.0mm and 1.2mm. However, as the expansion angle increased, they showed a large difference. In the third wedge, the stress distribution and contact length for all ring thickness were similar to each other. In the fifth wedge, the wedge barely contacted the bone tunnel as the expansion angle increased. Thus, according to the selections of ring thickness and expansion angle, all five wedges of the fixation device may not perform their own roles, appropriately, for the initial stability after operation.

To determine the influence of the ring thickness and expansion angle on the initial stability of the device after operation, a simulation was performed. The simulation computed the migration of the fixation device upon application of the pull-out force of 500N to the fixation device, which is the force applied at the time of rehabilitation after operation. Fig. 16 shows the migration of the fixation device for all ring thickness and for all expansion angles.

As the ring thickness increased, the migration decreased. When the ring thickness was 1.4mm and the expansion angle was 6°, the migration was the smallest. When the ring thickness was 1.0mm, the migration decreased as the expansion angle increased. However, when the ring thickness was 1.2mm, the migration increased as the expansion angle increased. This tendency became more serious when the ring thickness was 1.4mm. This tendency resulted because the fifth wedge maintained contact with the bone and resisted the pull-out force in the case of a smaller ring thickness. However, as the ring thickness increased, a higher number wedge, especially the fifth wedge, and the bone hardly maintained contact (Fig. 15) and could not resist against the pull-out force.

5. Conclusions

This paper proposed the self-expansion type anterior cruciate ligament fixation device. The device provided graft fixation force by maintaining contact with the bone tunnel through its elastic force after operation. The device consisted of the ring part, the wedge part and the link part. In order to study the influence of the main design parameters on the contact condition and the initial fixation stability of the device, the three-dimensional finite element models of the fixation device and the bone were developed. In this paper, three ring thicknesses of 1.0mm, 1.2mm and 1.4mm, and three expansion angles of 6˚, 8˚ and 10˚ were considered. The ring thickness had more influence on the maximum Mises stress of the ring part than the expansion angle did. This paper showed that when the expansion angle was 10˚, the ring thickness must be less than 1.4mm because the maximum Mises stress was exceeded. As the expansion angle increased, the contact lengths of the first and third wedges were extended. However, as the wedge number increased, the contact length decreased. This tendency was remarkable as the ring thickness increased. This paper showed that all five wedges may not perform their own roles appropriately for obtaining initial stability after operation according to the selection of the main design parameters. The migration decreased as the ring thickness increased at the same expansion angle. However the migration increased as the expansion angle increased at the same ring thickness. This paper showed that it is desirable to design the fixation device so that all wedges uniformly maintain contact with bone to obtain initial stability after operation.

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References

[1] P. Aglietti, R. Buzzi, G. Zaccherotti and P. De Biase, Patellar Tendon Versus Doubled Semitendinosus and Gracilis Tendons for Anterior Cruciate Ligament Reconstruction, *The American Journal of Sports Medicine*, 22 (2) (1994) 211-218.

[2] J. Brand, A. Weiler, D. N. Caborn, C. H. Brown and D. L. Johnson, Graft Fixation in Cruciate Ligament Reconstruction, *The American Journal of Sports Medicine*, 28 (5) (2000) 761-774.

[3] M. Dammak, A. Shirazi-Adl and D. J. Zukor, Analysis of Cementless Implants Using Interface Nonlinear Friction - Experimental and Finite Element Studies, *Journal of Biomechanics*, 30 (2) (1997) 121-129.

[4] C. B. Frank and D. W. Jackson, Current Concepts Review - The Science of Reconstruction of the Anterior Cruciate Ligament, *Journal of Bone and Joint Surgery*, 79 (10) (1996) 1556 -1576.

[5] F. H. Fu, C. H. Bennett, C. Lattermann and C. B. Ma, Current Trends in Anterior Cruciate Ligament Reconstruction. Part 1 : Biology and Biomechanics of Reconstruction, *The American Journal of Sports Medicine*, 27 (6) (1999) 821-830.

[6] A. Harilainen, J. Sandelin and K. A. Jansson, Cross-Pin Femoral Fixation Versus Metal Interference Screw Fixation in Anterior Cruciate Ligament Reconstruction with Hamstring Tendons: Results of a Controlled Prospective Randomized Study with 2-Year Follow-up, *Arthroscopy: The Journal of Arthroscopic & Related Surgery*, 21 (1) (2005) 25-33.

[7] O. Kayabasi and Erzincanli, F., Finite Element Modeling and Analysis of a New Cemented Hip Prosthesis, *Advances in Engineering Software*, 37 (7) (2006) 477-483.

[8] P. Kousa, T. L. N. Järvinen, M. Vihavainen, P. Kannus and M. Järvinen, The Fixation Strength of Six Hamstring Tendon Graft Fixation Devices in Anterior Cruciate Ligament Reconstruction Part I: Femoral Site, *The American Journal of Sports Medicine*, 31 (2) (2003) 174-181.

[9] T. Kudo, H. Tohyama, A. Minami and K. Yasuda, The Effect of Cyclic Loading on the Biomechanical Characteristics of the Femur-Graft-Tibia Complex after Anterior Cruciate Ligament Reconstruction Using Bone Mulch™ Screw/WasherLoc™ Fixation, *Clinical Biomechanics*, 20 (4) (2005) 414-420.

[10] H. E. Magen, S. M. Howell and M. L. Hull, Structural Properties of Six Tibial Fixation Methods for Anterior Cruciate Ligament Soft Tissue Grafts, *The American Journal of Sports Medicine*, 27 (1) (1999) 35-43.

[11] T. L. Norman, G. Thyagarajan, V. C. Saligrama, T. A. Gruen and J. D. Blaha, Stem Surface Roughness Alters Creep Induced Subsidence and 'Taper-Lock' in a Cemented Femoral Hip Prosthesis, *Journal of Biomechanics*, 34 (10) (2001) 1325-1333.

[12] Pacific Research Labs, Vashon Island, WA., Third Generation Composite Femur, From: The BEL (Biomechanics European Laboratory) Repository, (2006) http://www.tecno.ior.it/VRLAB/researchers/repository/BEL_repository,html#std2_3.

[13] R. Robbe and G. A. Paletta, Soft-Tissue Graft in Anterior Cruciate Ligament Reconstruction, *Operative Techniques in Sports Medicine*, 12 (4) (2004) 188-194.

[14] K. D. Shelbourne and P. Nitz, Accelerated Reha-

bilitation after Anterior Cruciate Ligament Reconstruction, *The American Journal of Sports Medicine*, 18 (3) (1990) 292-299.
[15] H. Y. Sim, C. S. Kim and C. Y. Oh, Numerical Analysis on Stress Distribution of Vertebra and Stability of Intervertebral Fusion Cage with Change of Spike Shape, *Journal of Biomedical Engineering Research*, 25 (5) (2004) 361-367.
[16] A. Weiler, R. F. G. Hoffmann, H. J. Bail, O. Rehm and Südkamp, Norbert P., Tendon Healing in a Bone Tunnel. Part II: Histological Analysis after Biodegradable Interference Fit Fixation in a Model of Anterior Cruciate Ligament Reconstruction in Sheep, *Arthroscopy: The Journal of Arthroscopic & Related Surgery*, 18 (2) (2002) 124-135.
[17] T. Zantop, A. Weimann, M. Rummler, J. Hssenpflug and W. Petersen, Initial Fixation Strength of Two Bioabsorbable Pins for the Fixation of Hamstring Grafts Compared to Interference Screw Fixation: Single Cycle and Cyclic Loading, *The American Journal of Sports Medicine*, 32 (3) (2005) 641-649.
[18] Z. C. Zhong, S. H. Wei, J. P. Wang, C. K. Feng, C. S. Chen and C. H. Yu, Finite Element Analysis of the Lumber Spine with a New Cage Using a Topology Optimization Method, *Medical Engineering & Physics*, 28 (1) (2006) 90-98.

Jong-Dae KIM received the B.S. and M.S. degrees in Precision Mechanical Engineering from Chonbuk National University, Korea in 1993 and 1995, respectively. He then received his Ph.D. degree in Bionano System Engineering from Chonbuk National University, Korea in 2008. He worked at DAEWOO Electronic Components Co., Ltd., Korea for eight years from 1995. He is currently a full-time lecturer at the Department of Mechanical and Automotive Engineering in Jeonju University, Korea. Dr. Kim's research interests are in the area of biomechanics and robotics for rehabilitation.

Chae-Youn OH received the B.S. degree in Mechanical Engineering from Chonbuk National University, Korea, in 1982. He then received his M.S. and Ph.D. degrees in Mechanical Engineering from Iowa State University, U.S.A., in 1987 and 1990, respectively. He is currently a Professor at the Division of Mechanical System Engineering at Chonbuk National University in Jeonju, Korea. Dr. OH's research interests are in the area of biomechanics and haptics.

Cheol-Sang KIM received his B.S. and M.S. degrees in Mechanical Engineering from Chonbuk National University in Korea in 1980 and 1982, respectively. He then received a Ph.D. degree in Material Science at Universite de Louis Pasteur in Strasbourg, France in 1988. He spent two years at the Department of Bioengineering at University of Pennsylvania (U.S.A) as a Post Doc. fellow. Dr. Kim is currently an Associate Professor at the Division of Mechanical Engineering at Chonbuk National University in Korea. Dr. Kim's research interests are in the area of biomaterials for hard tissue replacements, design and analysis of implants and artificial organs, and anti-biofouling technology.