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Development of an ACL Anchor: Effects of the Design Parameters on the Performance of a New Anterior Cruciate Ligament Fixation Device

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Abstract

We investigated the biomechanical properties of a newly designed self-expansion type anterior cruciate ligament (ACL) anchor. The ACL anchor consists of the ring section giving the elastic force, the wedge for maintaining in contact with the femur tunnel wall and the link suspending hamstring graft or artificial ligament. The main design parameters that determine the performance of this device were the expansion angle (θ) and the thickness (t_R). The Ti6Al4V anchors were heated after inserting in a jig for 1 hour at 800℃ in a protective argon gas atmosphere and allowed to cool to room temperature in the furnace. In order to investigate the influence of the expansion angle and the thickness of the ring on the biomechanical properties of the anchor, the maximum pull-out load, stiffness and slippage of the ACL anchor were measured using the pull-out tester, and statistical analyses were also executed. The present results showed that the design parameters gave a significant effect on the performance of the self- expansion type of anchor. The pull-out load of the ACL anchors significantly increased as the thickness of the ring section was increased, having a similar trend for both expansion angles. The ACL anchor showed about 2.5 times higher values of the pull-out load than that of the minimum load (500N)required for the "accelerated rehabilitation". The optimum θ and t_R values of this ACL anchor were suggested to have sufficient resistance against the pull-out force, high stiffness and relatively low slippage after ACL reconstruction.

Key words: anterior cruciate ligament, ligament fixator, accelerated rehabilitation, self-expansion, interference screw

Ⅰ. INTRODUCTION

To reconstruct a damaged anterior cruciate ligament, fixation device and graft are mainly used [1, 4, 6, 8, 11, 22]. The strength of the fixation is well known as the weakest link in the stability of an ACL reconstruction rather than the strength of the graft itself in early postoperative period [4]. Accordingly, for the success of the reconstruction operation, it is very important to have enough initial fixation strength in early postoperative period.

Various types of the fixation devices have been developed to improve the initial fixation stability [4, 5, 8, 10, 17, 25]. It has been shown that in ACL fixators having same geometry, changes in the main design parameters like the length, the diameter or the taper could increase the strength of the fixation [14, 21]. Interference screw type devices closely stick the graft directly to the bone. They provide high fixation strength in early postoperative period. However, it has been reported that the divergence of the screw from the longitudinal axis of femur tunnel can cause the decline of fixation strength or tear of grafts by its threads. Also, the biodegradable polymer devices can lead to the inflammation on the synovium [4, 8, 20]. Some devices that suspend the graft on a button or post also have high fixation strength in early postoperative period. Easy biological bonding can be realized because they allow the graft to be in contact with the bone all around the circumference of the bone tunnel wall [4, 5, 8, 10, 17, 25]. But 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 bone tunnel [4, 8].

Until 1980s, the rehabilitation protocol was mainly used to

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prohibit weight bearing during a long period of time after an ACL reconstruction operation. But the recent trend in rehabilitation after operation is the adoption of the "accelerated rehabilitation" method that allows the full-range motion of the knee joint in early postoperative period and early weight bearing [18]. In order to carry out this rehabilitation program, it was suggested that the fixation device used in the reconstruction of an ACL must stand against a pull-out force of 500N at the early stage after operation [13]. Accordingly, it is required to develop an advanced fixation device that has high initial fixation stability, causes minimum graft damage and allows simple operation.

This paper proposes a new ACL anchor to maintain contact with the femur tunnel wall by its self-driven elastic force after operation. We expect that this new device will have high initial fixation stability and minimum graft damage. Pull-out test was performed to understand the effect of the biomechanical properties of the device and design parameters to the strength of the device. The maximum fixation force, stiffness and slippage of the ACL anchor were measured and statistical analyses were performed to investigate the effect of the expansion angle and the thickness of the ring section on the biomechanical properties.

II. STRUCTURE OF ACL ANCHOR

The ACL anchor consists of three main sections, as shown in Fig. 1. Section A is ring-shaped which can deform elastically in the tangential direction. The elastic deformation of the ring section acts as a coil spring by providing elastic force. Section B having sharp wedges in circumferential direction is the part that makes contact with the femur tunnel wall. Section C is the link part for suspending the graft or artificial ligament. The schematic diagram represents the ring thickness (t_R) and expansion angle (θ) that are the main design parameters to determine the performance of the device and the location where the grabbing force (F) is applied in order to insert the device into the femur tunnel.

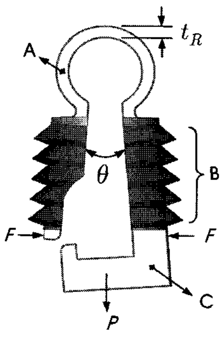

Fig. 1. Conceptual diagram of the proposed ACL anchor showing the sections (A,B,C), main design parameters (θ, t_R) and the applied forces (F, P).

The ACL anchor has its original shape at an angle θ prior to insertion as shown in Fig. 1. Force F is then applied using an instrument when the anchor is inserted into the femur tunnel. As the applied force is released after insertion, the ring-shaped section, which was deformed elastically, returns to its original expanded shape. Then, the wedges (section B of Fig. 1) which are in contact with the bone initially play the role of fixing the graft after operation.

The advantages of the ACL anchor are expected as follows: 1) It prevents the graft damage since the graft suspending on the link doesn't touch the sharp threads, 2) a sharp wedge shape may increase the contact force on the femur tunnel wall, 3) the self-expansion property of this anchor makes the operation easier because the anchor is automatically expanded after insertion by the elastic force of the ring section and 4) the anchor facilitates ACL reconstruction operation because it does not require the additional work like making a groove for preventing divergence of the fixation device or a second incision.

The most important issue 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 section has to be sufficiently large and that the wedges are uniformly in contact with the bone as much as possible. If the elastic deformation of the ring section is enlarged to increase the elastic force, the stress in the central area of the ring section can exceed the yield strength of the device. In addition, if the ring thickness becomes too thick, the surgical operation can become difficult because a huge amount of force would be needed to grab the fixation device for insertion.

III. MATERIALS AND METHODS

The pull-out test of the ACL anchor was performed to investigate the effect of the thickness of the ring section and the expansion angle on the initial fixation strength of the anchor.

The ACL anchors used in the test was made of Ti6Al4V. As shown in Fig. 2, the expansion angle was maintained by heat treatment of the anchor after inserting in a jig. They were heated for 1 hour to 800℃ in a protective argon gas atmosphere and allowed to cool to room temperature in the furnace [9]. As shown in Table 1, all of the anchors were classified into six groups made up by the expansion angle (7.2° and

Table 1. Classification of test groups according to the expansion angle (θ) and thickness of ring section (t_R) of the ACL anchors.

Groups	θ (degree)	t_R (mm)	Samples
A	7.2	1.0	5
B	7.2	1.2	5
C	7.2	1.4	5
D	11.5	1.0	5
E	11.5	1.2	5
F	11.5	1.4	5

11.5°) and the ring thickness (1.0mm, 1.2mm and 1.4mm). Five samples for each group were made by machining and wire cutting.

The rigid polyurethane foam was used for the pull-out test, which is generally known to be suitable for the mechanical tests of bone screws and medical devices [2]. Fig. 3 shows the used cubical polyurethane block (40mm×40mm×40mm) with a drilled hole at the center with a diameter of 12mm and a depth of 30mm.

In performing the pull-out test, first the polyurethane block was fixed on the pull-out tester(Instron 4206, Instron Inc., USA). A stainless steel wire of 1.2mm in diameter and 260mm in length was hooked at the link of the fixation device (section C of Fig. 1) and the ACL anchor with the hooked wire was inserted into the polyurethane block. Then the opposite end of the stainless steel wire was fixed to the tester and the pull-out test was performed. Fig. 4 shows the polyurethane block and the anchor installed on the tester.

The direction of pull-out load (*P* in Fig. 1) was made parallel to the longitudinal axis of the polyurethane block hole in order to simulate the worst case scenario [3, 14, 15, 23, 26]. All the pull-out tests were performed at a velocity of 5mm/min until the anchor failed, and the pull-out load, stiffness and slippage were measured.

The biggest load that the anchor can resist was selected as the pull-out load. Fig. 5 shows the variation of the maximum pull-out load versus the ring thickness. The stiffness of the anchor to secure knee stability represents the linear area of the load/displacement diagram obtained from the pull-out test. The slippage of the anchor is an important factor to show the initial stability in early postoperative period. As for the amount of slippage, we chose the displacement at 500N of the pull-out load. The load is reported as the tensile strength that can satisfy accelerated rehabilitation after ACL reconstruction [13].

To investigate the statistical significance of the pull-out load, stiffness and slippage according to the variations in the expansion angle and thickness of the ring section, we performed the Kruskal-Wallis H-test and Mann-Whitney U-test. The statistical processing software used was the SPSS 10.0 (SPSS Inc., Chicago, IL, USA). The results were considered to have statistical significance if the *p* value was less than 0.05.

IV. RESULTS AND DISCUSSIONS

For the ACL anchor heated at 800℃, the hardness and the elastic modulus were about 1.2 times higher than those of the non-treated Ti6Al4V. This heat treatment of the Ti6Al4V led to the formation of porous surface. The morphological and chemical changes of the surfaces were mostly due to Ti oxides formed with the residual oxygen in the chamber [27].

Fig. 5 shows the variations of the pull-out load versus the

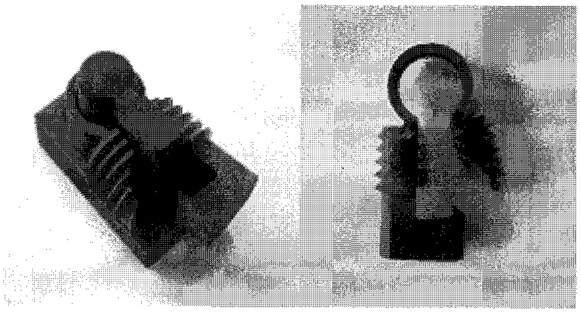

Fig. 2. The jig for heat treatment and the photograph of the ACL anchor after heat treatment.

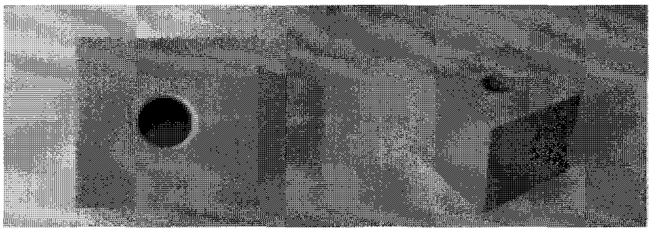

Fig. 3. The polyurethane block for the pull-out test.

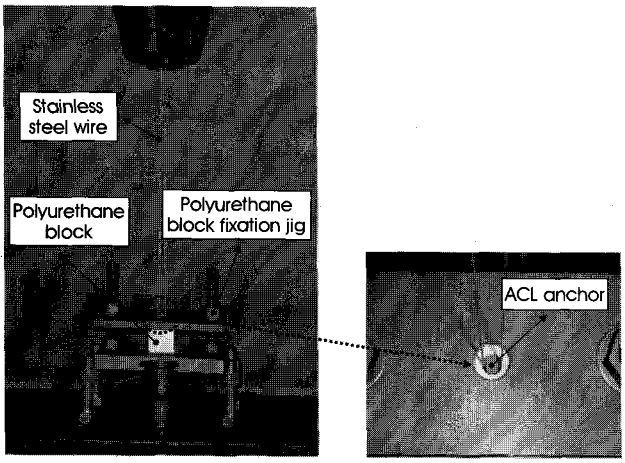

Fig. 4. The pull-out test machine (Instron 4206, Instron Inc., USA).

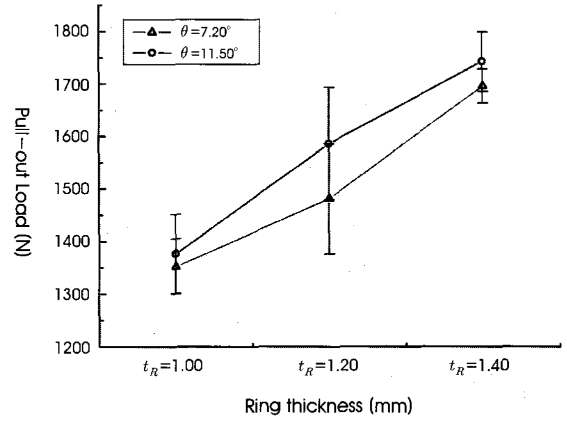

Fig. 5. The pull-out load of the ACL anchor groups versus the ring thickness.

thickness of the ring section for the expansion angles of 7.2° and 11.5°. The pull-out load of the ACL anchors significantly increased as the thicknesses of the ring section were increased, having a similar trend for both expansion angles. All of the groups of the ACL anchors showed about 2.5 times higher values of the pull-out load than that of the minimum load (500N) required for the "accelerated rehabilitation". The maximum pull-out load of about 1840N occurred in group F.

The stiffness variation of the anchor versus the ring thickness in Fig. 6 showed similar trend of the pull-out load variation. The stiffness differences in the same ring thickness according to the expansion angle were dominant as compared to those of the pull-out load. The maximum value of the stiffness was about 330N/mm (at $\theta = 11.5°$ and $t_R = 1.4$mm in Group F) and the minimum value was about 128N/mm (at $\theta = 7.2°$ and $t_R = 1.0$mm in Group A). Table 2 shows the comparison between the results of To et al. [19] and the present stiffness values of the ACL anchor. To et al. reported the stiffness values obtained from three types of commercialized fixation devices for the femoral side using the spring-in-series analysis method [19]. The stiffness values of Group A and Group F of the newly designed ACL anchor were about 5 and 13 times higher than those of the button and suture loop type, and the anchor and suture loop type, respectively.

Fig. 7 shows the slippages measured at the pull-out load of 500N. The slippages decreased as the expansion angles and the thicknesses of the ring section increased. The slippages for both expansion angles had a steep decrease as the thickness increased from 1.0mm to 1.2mm and a gradual decrease in slippage was obtained as the thickness was increased from 1.2mm to 1.4mm. Therefore in the point of view of the slippage, the thickness of the ring section of more than 1.2mm did not give a dominant effect to minimize the slippage.

The Kruskal-Wallis H-test was performed to investigate the statistical significance of the pull-out load, stiffness and slippage according to the variation in the expansion angle and

Table 2. The stiffness values of the ACL anchor in comparison with the results of To et al. [19].

Fixation Method		Stiffness (N/mm)
To et al.	Post with bone graft	575 ± 117
	Button and suture loop	24 ± 2
	Anchor and suture loop	26 ± 2
ACL anchor	Group A (θ= 7.2°, t_R = 1.0mm)	128.1 ± 12.4
	Group B (θ= 11.5°, t_R = 1.4mm)	330.6 ± 5.6

Table 3. Statistical comparisons of the biomechanical properties of ACL anchor groups.

Properties / Groups	Pull−out Load (N)	Stiffness (N/mm)	Slippage (mm)
θ= 7.2° Groups (Group A, B, C)	0.002	0.002	0.047
θ= 11.5° Groups (Group D, E, F)	0.002	0.009	0.002

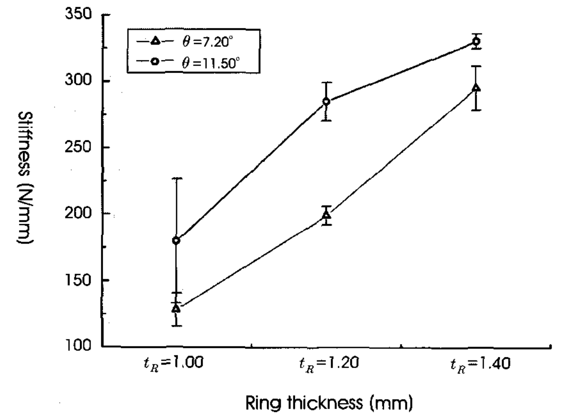

Fig. 6. The stiffness of the ACL anchor groups versus the ring thickness.

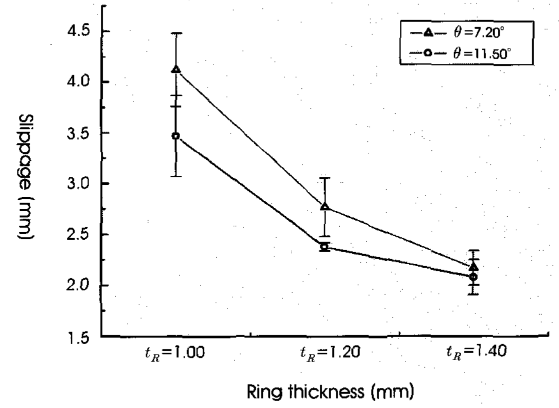

Fig. 7. The slippage of the ACL anchor groups versus the ring thickness.

thickness of the ACL anchor ring section [7, 12, 16, 24]. Table 3 shows the results which determined whether the variation of t_R value at two different angles caused the significant difference of the pull-out load, stiffness and slippage of the groups. While Table 4 shows the result of the Mann-Whitney U-test [7, 12, 16, 24], which determined if the variations of θ value at three different thicknesses caused the significant difference of the pull-out load, stiffness and slippage of the groups. The results were considered to have statistical significance if the p value was less than 0.05.

From Kruskal-Wallis H-test in Table 3, the variations of t_R of the anchor for both values of θ appeared to cause significant differences in the pull-out load, stiffness and slippage ($p < 0.05$). However, from the Mann-Whitney U-test in Table 4, it revealed that the variations of θ of the anchor for each value of t_R appeared to cause significant differences in the stiffness and slippage ($p < 0.05$) but not in the pull-out load, where only in the case of $t_R = 1.2$mm, there was significant differences.

The main properties of the anchor showed to have generally better values as the design parameters were increased. However at higher values of θ and t_R, it may require stronger force to grab the anchor using a surgical instrument and at this higher force, it has the possibility to lose the function of the anchor, if the stress incurred in the central area of the ring section goes beyond the yield strength of the heat treated Ti material. Furthermore, excessive expansion force can also cause bone necrosis or depression by stress concentration on the bone area contacting with the wedge of the anchor.

Accordingly, when designing a self-expansion type of this ACL anchor, based on the results of our study, we propose the values for the design parameters as $t_R = 1.2$mm and $\theta = 7.2°$ to resist sufficiently against the pull-out force of 500N for "accelerated rehabilitation" and to maintain high stiffness and relatively low slippage after an ACL reconstruction.

V. CONCLUSIONS

In this paper, the self-expansion type anterior cruciate ligament fixation device was proposed. The device provided graft fixation force by maintaining contact with the femur tunnel through its elastic force after ACL reconstruction. The device consisted of the ring section providing the elastic force, the wedge section to keep contact with the bone tunnel wall and the link for suspending the graft. In order to study the influence of the expansion angle and the thickness of the ring section of the main design parameters on the biomechanical properties of the anchor, we made 30 samples of the anchor which were the combinations of the expansion angle and the thickness of the ring section having the values of 7.2° and 11.5°, and 1.0mm, 1.2mm and 1.4mm, respectively. The samples were inserted into the polyurethane foam block and a pull-out test was performed. Maximum fixation force, stiffness and

Table 4. Statistical comparisons of the biomechanical properties of ACL anchor groups.

Groups \ Properties	Pull-out Load (N)	Stiffness (N/mm)	Slippage (mm)
t_R = 1.0mm Groups (Group A, D)	0.754*	0.009	0.012
t_R = 1.2mm Groups (Group B, E)	0.047	0.009	0.016
t_R = 1.4mm Groups (Group C, F)	0.117*	0.009	0.015

slippage of the ACL anchor were measured using the pull-out test machine.

The main properties of the anchor showed to have generally better values as the design parameters were increased. All of the groups of the ACL anchors showed about 2.5 times higher values of the pull-out load than that of the minimum load (500N) required for the "accelerated rehabilitation". The stiffness values of Group A and Group F of the newly designed ACL anchor were about 5 and 13 times higher than those of the button and suture loop type, and the anchor and suture loop type, respectively (in Table 2). In the slippage of the ACL anchor, the thickness of the ring section of more than 1.2mm did not give a dominant effect to minimize the slippage.

To investigate the statistical significance of the pull-out load, stiffness and slippage according to the variations in the expansion angle and thickness of the ring section, we performed the Kruskal-Wallis H-test and Mann-Whitney U-test. From the tests, the variation of the thickness of the ring section showed to give significant effects in the pull-out load, stiffness and slippage of the anchor. While the variation of the expansion angle showed to give significant effects in the stiffness and slippage. But in the pull-out load, only at the case of t_R = 1.2mm was there a significant effect.

From the present results, the optimum values obtained for the design were at t_R = 1.2mm and $\theta = 7.2°$ to give the best effect for "accelerated rehabilitation" at the pull-out load of 500N with lower instance of slippage while maintaining high stiffness.

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