근위골절술을 위한 Staple 설계

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A Newly Designed Miniplate Staple for High Tibial Osteotomy

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Abstract

A biomechanical study was made to demonstrate the superior mechanical performance of the newly designed Miniplate staple to the conventional Coventry staple in high tibial osteotomy(HTO). Using twenty fresh porcine tibiae, the fixational strengh of the two different types of staple in HTO was compared. To minimize the error due to the specimen-to-specimen individuality, the bone mineral density of the tibiae was measured with a bone densitometry(Dual photon absorptionometer,Luner,USA) and those with 0.8 ~ 1.2 gm/cm^2 at the proximal tibia was used in the biomechanical test. Testing was performed on a material testing system (Autogram ET-5,Shimatzu,Japan) with aid of a commercial data processor (IBM 80386/ ASYST). Using two differant loading modes ,'pull-out' and 'push-out', the maximum resistant force required to release the staple from the substrate bone was recorded. In the pull-out test, ten non-osteotomized specimens were used and the staple was pull out by subjecting an axial tension on the head of the staple inserted. While in the pull-out test where ten tibiae osteotomized in the usual way of HTO were used, the staple was not directly loaded. In this testing, as a mimic condition of the natural knee, the distal part of the specimen tibia was pushed horizontally in order for the staple to be pulled out while the proximal tibia was fixed. The pull-out strength of Coventry staple and miniplate staple were found to be 27.88 ± 5.12 kgf and 182.47 ± 32.75 kgf, respectively. The push-out strength of Coventry staple and miniplate staple were 18.40 ± 4.47 kgf and 119.95 ± 19.06 kgf, respectively. The result revealed that miniplate staple had the pull-out/ push-out strength at least fivetimes higher than Coventry staple.

Based on the measured data, it was believed that the newly designed miniplate staple could provide much better postoperative fixation in HTO. The postoerative application of long leg casting may not be needed after HTO surgery.

Keyword : Knee, Osteoarthritis, High tibial osteotomy, Miniplate staple

INTRODUCTION

Though there are the many factors causing the degenerative arthritis at the knee, the major cause of the disease is known to be the abnormal loading on the joint surface due to the physiological change. It was in 1958 that Jackson introduced the high tibial osteotomy treatment for the osteoarthritis at the knee. Since then, the high tibial osteotomy has been widely used to treat the case when the knee joint has either eversive or inversive deformition and the symptom is confined to one side of the knee joint, and the effectiveness of the high tibial osteotomy has been claimed by many authors.[2,6,7,8,11,12] The goal of the high tibial osteotomy is to reduce the pain and to stop the progress of the disease by rectifying the abnormal angular position between femur and tibia resulting from the degenerative change of articular cartilage at the knee. [2,8,10,14]

The Coventry staple has been used widely to fix the bones during high tibial osteotomy since Coventry first used in 1960. However, its holding power being rather weak, patients need six week plasterization and rehospitalization to undergo physical therapy to obtain smooth knee joint movement. The Miniplate staple was designed to remove these shortcomings by the authors and made by Johnson & Johnson Orthopaedics in New Nilton, UK.

Biomechanical testing was conducted to show the superior mechanical performance of the Miniplate staple to the conventional Coventry staple using porcine tibiae. In the tests, the staples were inserted into the porcine tibiae which were osteotomized in the usual procedure of the high tibial osteotomy, and the fixational strength of the two types of staples was measured using the physiologically mimic loading conditions including pull-out test and push-out test. The results of the comparison between the biological stabilities of the two staples are reported in this paper.

TEST SPECIMEN AND TEST PROCEDURE

1. Test specimen

(1). Tibiae used for the test.

The test animals used were over 5 months old porker (Yorkshire) weighing over 90kg and had no previous history of disease. They were transported to the laboratory immediately after they were butchered at a local slaughterhouse and kept at a temperature under -72°C in a refrigerator in a bonebank until the test. The bone mineral density of the proximal tibia of every specimens where osteotomy would be performed was measured (Dual photon absorptionmetry, Lunar, USA), and only the bones with the density between 0.8 ~ 1.2 gm/cm^2 were selected for the test to minimize the error due to the bone strength of each specimen resulting from the difference of age, sex and the growth extent of the testing animal.

(2). Staples

1). Coventry staple (Zimmer, USA),
.Material: Stainless steel
.Dimension: Length: 17/32 inch.
: Width: 15/16 inch.
: Offset: 3/16 inch.

2).Miniplate staple (Johnson & Johnson Orthopaedics, New Milton, UK).
.Material: ASTM F-90, Co-Cr Alloy
.Dimension: Length: 40 mm
: Width: 3 mm
: Offset: 5 mm

2. Test Procedure

(1). Specimen preparation

The porcine tibiae kept in a refrigerator under -72oC to maintain freshness were thawed at room temperature two hours before the test. The fibula and the soft tissues not affecting the mechanical stability of the specimens were removed so that there remained no obstacles around the test area. The total height of the specimen was made upto 120 cm by cutting the distal part of the tibia for the easy mounting of the specimen.

A). Specimen preparation for the pull-out test.

In order to measure the simple holding power of the staple under axial pull-out force, the tibiae which were not osteotomized were selected and tested either 1) with a Coventry staple inserted laterally 1.5 ~ 2 cm below from the tibial plateau plane(Group I, 5ea) or 2) with a Miniplate staple inserted and reinforced with two cortical screws of 3.5 mm in diameter (Group II, 5ea). The specimen were mounted on a Material Testing Systems(MTS; Autograph ET-5, Shimatzu, Japan) after the 70 mm of the distal part of the specimen were made to have a rectangular cross-section by using resin for the easy clampinmg. In order to avoid the undesirable reinforcement by the mounting material-resin, the staple and its surrounding area were covered with enough paraffin to prevent the testing area from the contamination of the resin.

B). The specimen preparation for the push-out test.

The specimens were osteotomized along the plane parallel to the tibial plateau with an oscillating saw 25 cm below from the top of the tibia in order to provide the same condition as the high tibial osteotomy conducted to the human. The two types of staples were inserted into the 10 porcine tibiae in the same manner as those used on the human tibiae. To minimize the difference due to the specimen-to-specimen individuality, the left tibia and the right tibia of an animal were inserted with different types of staples. The tibiae were divided into two groups depending on the types of staples used. Therefore,the left and the right tibiae of an animal belonged to different groups. The Group I consisting of 5 tibiae were subject to the Coventry staples and the Group II consisting of 5 tibiae were inserted by Miniplate staples.

Since in the case of the Miniplate staples of Group II, the reinforcement of the staple fixation was actually achieved with two cortical screws, it would be very important how the screws were inserted. Using the two screw holes designed originally at the lower part of the staple, two cortical screws of 3.5 mm in diameter were inserted anterior-distally upto the distal end of the cortex respectively. For each specimen, the diection of screw insertion was radiographically checked before it was mounted in resin.

C). Radiographical Checkup.

The X-ray photographs of the specimen prepared by the procedure in A) and B) were taken to determine the insertion depth, position, and the direction of the staples and those with improper position or direction of osteotomy for the test were discarded.

D). Specimen fixation.

To facilitate the specimen mounting on the MTS and to prevent the clamping force transmitted to the bone, the bone was mounted with the ends made to be parallelpiped of 60x60x70 mm in size using resin. The entrance of the screw and the screw itself were covered with enough paraffin before the resin was poured into the vessel. To avoid the unnecessary strenthening of the fixation due to the contamination of resin (especially on the entrance region), resin was filled up to 1 cm under the staple entrance. Also, before mounting, a 10 cm long nail was inserted horizontally into the tibial body to avoid undesirable rotation of the tibial body against the surrounding resin.

E). Test.

a). Test I (Pull out test)

The specimen was placed horizontally on the fixed cross-head of the MTS and clamped by its mounted part with a specially-designed jig to give the axial tension to the staple easily. (Fig.1) The moving cross-head of the MTS moved vertically at the speed of 1 mm/min until the staple was pulled out of the bone completely. For the whole period of the testing, the load-displacement curve was recorded numerically. The pull-out strength of a specimen was determined as the the maximum force on the load-displacement curve for the specimen tested. (Table 1)

b). Test II (Push-out test).

The specimen was fixed at the stationary end of the MTS in the same way as the Test I, but the loading scheme was totally different. Using a fixture, the proximal part of the specimen was clamped and pushed laterally by the moving end of the MTS. (Fig.1) The distal and the proximal part of the specimen would eventually be separated, because the load increased due to the pressure of the moving cross-head and the staple would be pushed out. The speed of the moving cross-head was 1 mm/min and the load and displacement were continuously recorded until the staple was completely separated from the bone. The maximum load on the load-displacement curve was defined as the push-out strength of the tested staple and its value was recorded. (Table 2)

RESULTS

A). Test I, Pull-out strength.

The average pull-out strength of the Coventry staple and that of the Miniplate staple measured at the proximal tibiae without the osteotomy were 27.88 ± 5.12 kg and 182.47 ± 32.75 kg respectively, and the Miniplate staples showed 6.54 time higher strength than the Coventry staples (Table 1).

Table 1. Pull strength of Coventry vs. Miniplate staple.

	Coventry	Miniplate staple
	22.875	116.120
	16.000	129.000
	17.875	109.250
	18.000	123.370
	17.250	123.000
Mean	27.88±5.12	187.47±32.75

(Unit:Kgf)

B). Test II, Push-out strength.

The average push-out strength of the Coventry staple and that of Miniplate staples tested with the osteotomy conducted under the same condition as those of the high tibial osteotomy conducted on the human were 18.40±4.47 kgf and 119.95±19.06 kgf respectively. The push-out strength of the Miniplate staple turned out to be 6.52 times higher than that of the Coventry staples (Table 2).

Table 2. Push-out strength of Coventry vs. Miniplate staple.

	Coventry	Minuiplate staple
	23.750	196.25
	25.000	223.75
	28.875	bone fractured
	bone fractured	158.00
	33.875	181.875
mean	18.40±4.47	119.950±19.06

(Unit:Kgf)

DISCUSSION

Osteoarthritis, also known as degenerative arthritis or degenerative joint disease, is found among the middle ages or elder patients. It usually occurs at the weight-bearing joints, induces the pain with the degenerative change and gradually progresses, eventually resulting in the decrease of the range-of-motion, joint stiffness, and joint deformation. Even though the primary cause of the osteoarthritis has not been found yet, it is widely believed that it occurs as the articular surface is continuously stressed. It is reported that variety of factors, such as the progress of the inflammation, metabolic abnormality, and biomechanical factors, affects the occurrence of the osteoarthritis. [4,15,16,17,18,19] The cause of the pain, the main symptom of the osteoarthritis, is known not to be the deformity due to the disease of the cartilage or minisci but to be the micro-fracture of subcondral trabeculae underneath articular cartilage which makes the blood flow in end-arterial teminals of the tibia impeded and results in the tumor in epiphyseal area. [1,2,5,9]

Coventry and his followers conducted high tibial osteotomy to reduce the pain by correcting the abnormal arignment of the mechanical axis between femur and tibia, since it is believed that the inversive deformation resulting from the degenerative loss of articular cartilage in the knee leads to the joint instability and more loss of the cartilage due to the repetitive overloading in the joint increases the inversive deformation which then accompanies the degenerative change. [2,3,5,6,9,13]

The high tibial osteotomy moves some of the weight from the overstressed subcondral trabeculae at

the medial area to those at the lateral area by correcting the abnormal angle between the femur and tibia, which can leads to the reduction of the pain and the prevention of the progressive degeneration of articular cartilage.

Coventry and his followers used the Coventry staples for the postoperative fixation of the proximal tibial osteotomy. The patients were allowed to move their knee when the clear radiographical evidence of the bone weldment showed, which usually took six weeks after the plasterization of the lower limb. When the patients were able to do the movement, they were allowed to walk with the aid of a clutch and to apply partial load to the operated leg. It was until 12 weeks after that they were allowed to apply full weight load to the leg.

The authors had also used the Coventry staples for the high tibial osteotomy. However, the patients complained the uncomfortableness due to the plaster fixztion. Especially for the relatively young patients under 65 years old, the disadvantage of this surgical procedure was serious, because it accompanied by the social industry lost as well as extra economic loss due

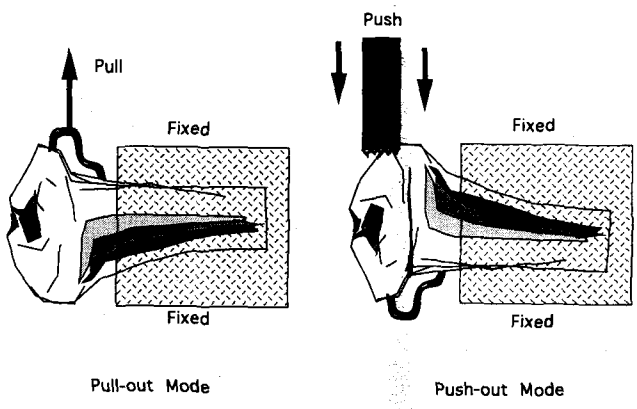

Figure 1: Experimental Set-up

to the need of the rehospitalization. It is believed that the Miniplate staple with stronger fixation strength can reduce many of these problems. The authors believe that the use of plaster fixation can be removed and the quicker rehabilitation is possible by using the Miniplate staple for the correctional high tibial osteotomy on the degenerative joint arthritis patients based on the results of this biomechanical investigation that the Miniplate staple has much higher fixational strength than Coventry staples.

CONCLUSION

The authors conducted the biomechanical tests using tibiae of the grown-up swine to examine the difference of the fixational strength between the Coventry staple which was used traditionally for the high tibial osteotomy and the newly designed Miniplate staple, and we derived the following conclusions.

1. The average pull-out strength of the Miniplate staples was 6.54 times higher than that of the Coventry staples.

2. The average push-out strength of the Miniplate staples was 6.52 times higher than that of the Coventry staples.

From the above results, it is concluded that the clinical application of the Miniplate staple into the high tibial osteotomy may result in;

1) The rehabilitation period can be reduced substantially, 2) The early knee joint movement can be possible without the post-operative plasterization of the lower limb since it has about six times higher fixational strength that the Coventry staples.

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