

Original

**Effectiveness of Initial Fixation of a Grasping Pin
for Proximal Femoral Fractures**

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Abstract : We developed a grasping pin with a hook for osteosynthesis of proximal femoral fractures and compared its performance with that of a lag screw. Cyclic compressive tests were performed to simulate cut-outs, and quasi-static torsion tests were conducted to simulate rotational displacement in polyurethane model bones and femoral heads collected after hip replacement surgery, and cadaveric femoral heads. In the polyurethane model bones and femoral head collected after hip replacement surgery, implant displacement was increased in the cut-out simulation test in both the grasping pin group and lag screw group, deformation was less in the grasping pin group than in the lag screw group. In polyurethane bones and cadaveric bones, the grasping pins showed higher rotational resistance compared with the lag screws in the quasi-static torsion test because of the high compression force generated during implantation. In contrast, in the collected femoral head after hip replacement surgery model, the lag screws destroyed bone tissue, the lag screw group exhibited a higher rotational resistance and a lower risk of rotational displacement than the grasping pin model. The depth of cadaveric femoral heads was 60 mm compared with 30 mm for femoral heads obtained after surgery; therefore, the pins could be completely inserted up to the octagonal portion in the cadaveric bones, resulting in higher rotational resistance.

Key words : proximal femoral fracture, rotational deformity, cut-out, grasping pin

Introduction

The hip joint is important for ambulation. It comprises a ball-shaped femoral head and an acetabular socket and exhibits a wide range of motion and adequate load-bearing strength. However, the incidence of hip joint diseases such as coxarthrosis and rheumatoid arthritis is increasing with an increase in the elderly population. In particular, an increase in proximal femoral fractures and arthropathy associated with osteoporosis in the lower limbs has been observed.

Trochanteric fractures are divided into two types and four groups according to Evans' classification: type 1 fractures, which extend from the trochanter minor to the trochanter major of the

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proximal trochanter ; and type 2 fractures or reverse obliquity fractures, where the main fracture line runs laterally and distally from the proximal trochanter minor. Type 1 fractures can be subdivided into groups 1 and 2, categorized as stable fractures, and groups 3 and 4, categorized as unstable fractures.

Osteosynthesis is used to treat trochanteric fractures so that patients can begin rehabilitation soon after surgery, and advances in the repair of trochanteric fractures have improved the prognosis after osteosynthesis with various implants. Bone union in osteoporotic bone is usually achieved by maintaining the medial circumflex artery at the extra-articular site ; however, complications such as cut-outs of the bone, dislocation or loosening of implants, or secondary deformations after implantation can occur.

Currently, surgical intervention using a short femoral nail with a lag screw is considered less invasive than osteosynthesis. It is quick and straightforward and is the standard procedure for elderly patients. This treatment promotes early rehabilitation and potentially allows the patient to return to the same level of daily activities exhibited before surgery¹⁾.

In this study, we inserted a prototype grasping pin instead of a conventional lag screw in the femoral head and investigated the effects of mechanical changes and fixation forces. Polyurethane model bones, femoral heads extracted during prosthetic replacement and cadaveric bones were used as test materials. Mechanical testing involved repeated compressive and quasi-static torsion tests to compare the mechanical properties of lag screws and grasping pins. Cyclic compressive loading tests were conducted to simulate cut-out complications and quasi-static torsion tests were conducted to simulate rotational displacement of the pins and screws.

Materials and Methods

Lag screws

A short femoral nail (Gamma 3 Trochanteric Nail 180 ; Stryker, Germany) was used in this study²⁾. Fig. 1-1 and 1-2 show the lag screw shape. The screws were manufactured from a titanium alloy and were 110 mm long with a 10.5-mm outer diameter.

Grasping pins

Fig. 1-3 shows the grasping pin that we developed. The pins were designed to prevent the cut-out phenomena and rotational displacement and were constructed from a titanium alloy (Ti-6Al-4V). They were pyramid-shaped at the 35-mm proximal tip and octagonal in shape at the 65-mm distal end. The opposite side measured 10.5 mm, the opposite length 11.0 mm, and the total length 100 mm. After tapping the grasping pin into place, three hooks could be opened from the tip by rotating the internal screws. Unlike the lag screws, the pins did not require rotational insertion. Therefore, intraoperative rotational displacement could be prevented.

Bone compaction

Bone compaction is the compression force generated when the implant is inserted. This force improves fixation and bone union. Screw grooves were observed in the insertion hole after

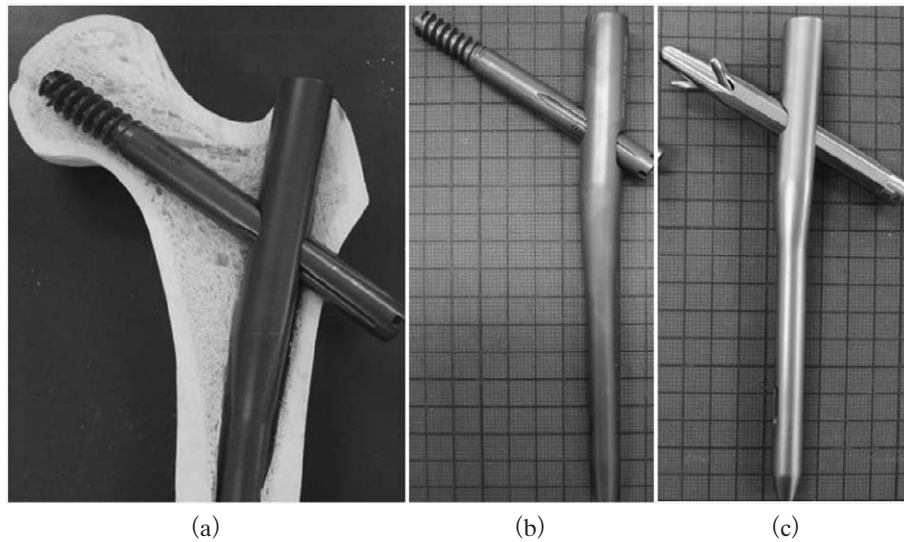


Fig. 1-1. Insertion with a short femoral nail (a), lag screw (b), grasping pin (c)

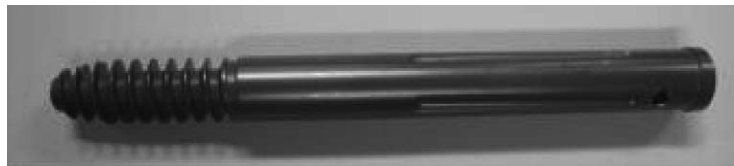


Fig. 1-2. Lag screw

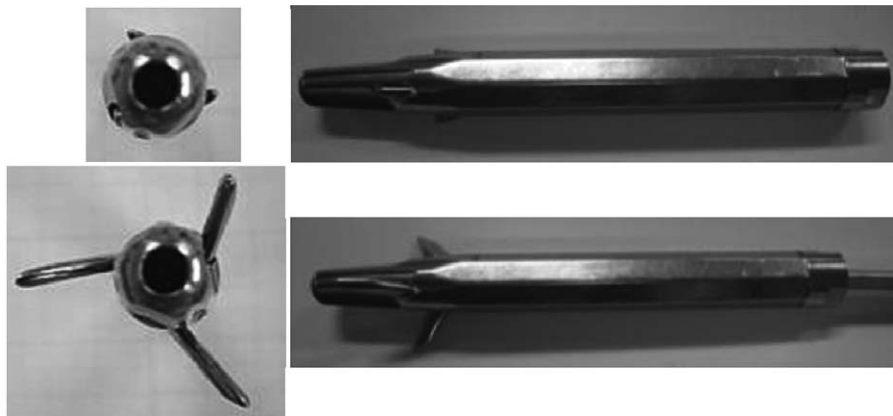


Fig. 1-3. Grasping pin

removal of the lag screw, but there were no signs of compression. In contrast, examination of the insertion hole after removal of the grasping pin showed that the spongy bone was compressed by the tapping insertion of the device.

Bone Materials

Polyurethane model bone (rigid polyurethane foam)

Two types of polyurethane model bone (SawbonesTM) are available : a high-density solid type

Table 1 Material properties of polyurethane model bone

| Model | density | compression | | Cell size |
|----------------|-----------------------|-------------|---------|-----------|
| | | Strength | modulus | |
| | (mg/cm ³) | (MPa) | (MPa) | (mm) |
| Solid | 80 | 0.6 | 16 | — |
| Cellular #7.5 | 120 | 1.4 | 12.4 | 0.5-2.5 |
| Cellular #12.5 | 200 | 3.9 | 47.5 | 0.5-1.5 |

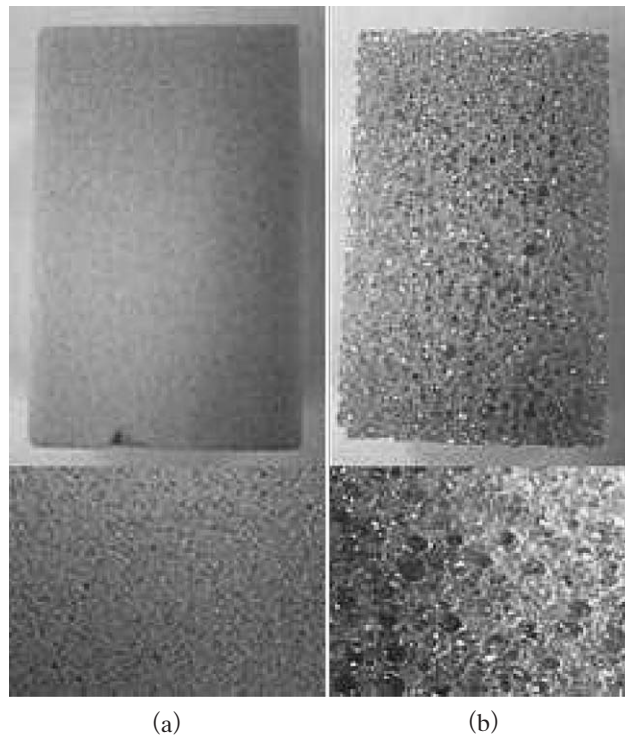


Fig. 1-4. Polyurethane model bone, solid type (a) and cellular type (b)

(filling density, 96.0% ~ 99.9%) and a cellular type with a loose structure and many voids (void size, 0.5 ~ 2.5 mm). In this study, both types were used to model the femur. Compared with the solid type, the cellular type is more similar to normal human cancellous bone. Table 1 lists the materials used in this study. Fig. 1-4 shows the morphologies of the model bones.

The mechanical tests in our study were conducted by using cellular rigid polyurethane foam #12.5 (200 mg/cm³), processed into bullet-shaped polyurethane model bones. Reproducible processing of the bone samples was performed with the use of a guide pin. Concentric holes or implantations were created in the samples, which were then fixed in a dedicated bullet-type metal shell (radius, 20 mm ; cylinder length, 40 mm ; Fig. 1-5).



Fig. 1-5. Model bone and metal shell for fixation

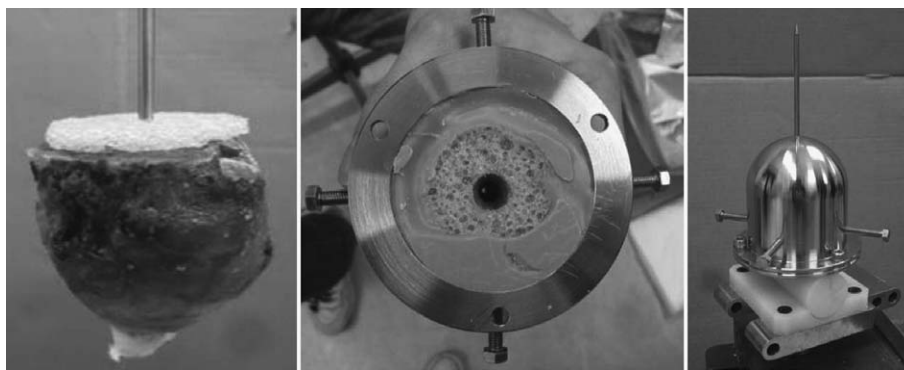


Fig. 1-6. Extracted femoral head and metal shell

Femoral heads

The same tests were performed using femoral heads for a more clinically relevant evaluation. Femoral heads were extracted during the hip replacement surgery thought due to be under the same condition. Cancellous bone should be located in the same position when fixing the femoral heads; therefore, polyurethane model bone spacers were added if the femoral head samples were small. The femoral heads were fixed and embedded in the dedicated bullet-type metal shells by using autopolymer resin (Ostron-II, GC Corporation, Tokyo, Japan ; Fig. 1-6).

Implant placement

The implants were inserted into the polyurethane model bones, which mimicked spongy bone, and the femoral heads described above.

The implant insertion holes were created in a stepwise manner in the polyurethane model bones composed of solid rigid polyurethane #7.5 (160 mg/cm³). {3.4 [JP]} A small hole measuring 20 mm in length and 5 mm in diameter was created, followed by a large hole measuring 20 mm in length and 7 mm in diameter. The total insertion depth was 40 mm (Fig. 1-9).

For the lag screws in the femoral heads, the small hole measured 20 mm in length and 5 mm in diameter, whereas the large hole measured 10 mm in length and 7 mm in diameter. The total insertion depth was 30 mm. The small hole for the grasping pin measured 20 mm in length and

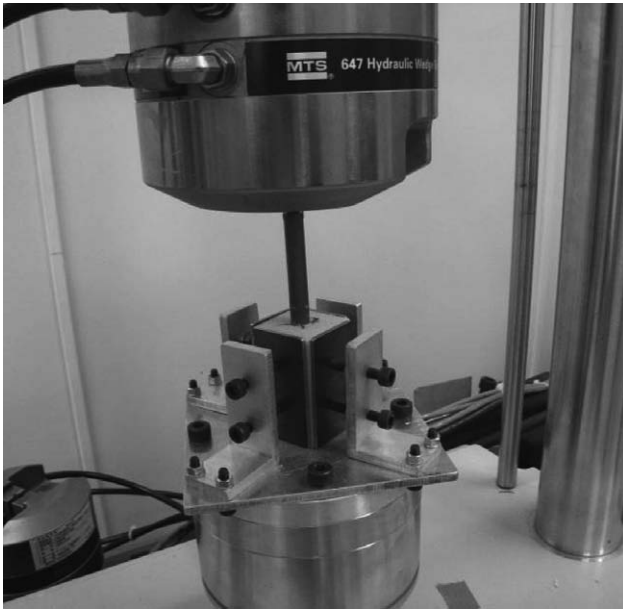


Fig. 1-9. Quasi-static torsion test with a 2-control material tester (material : model bone)



Fig. 1-10. Quasi-static torsion test with a 2-control material tester (material : femoral head)

5 mm in diameter, whereas the large hole measured 10 mm in length and 8 mm in diameter. The total insertion depth was 30 mm. The maximum insertion depth was restricted to 30 mm because of the sizes of the collected femoral heads. Cadaveric femoral heads were used to investigate an insertion depth of 60 mm. Both the femoral heads collected after hip replacement surgery and the cadaveric femoral heads were fixed and embedded in metal vessels by using anhydrite (New Plastone, GC Corporation, Tokyo ; Fig. 1-10).

Compression tests

Each sample in the metal shell was fixed at a 140° inclination to simulate load bearing-induced anatomical changes in the body (Fig. 1-7). Repeated compression tests were conducted using a two-axis biomaterial tester (Mini-Bionix, MTS Systems Corporation, Minneapolis, MN, USA). The relationship between load and dislocation in the vertical direction was investigated (Fig. 1-8).

The polyurethane model bone samples were compressed 20,000 times (5 Hz) at 1.2 kN ($r = 0.1$). The force was maintained at 660 N ($r = 0.5$) at every 1000th event. Dislocation in the vertical direction was measured. The tests were conducted twice for each type of implant. The femoral head samples were compressed 10,000 times (5 Hz) at 1.0 kN ($r = 0.1$), followed by 10,000 times (5 Hz) at 1.2 kN ($r = 0.1$). The force was maintained at 550 N at every 1000th event. Dislocation in the vertical direction was measured. Two independent tests were performed for each type of implant.

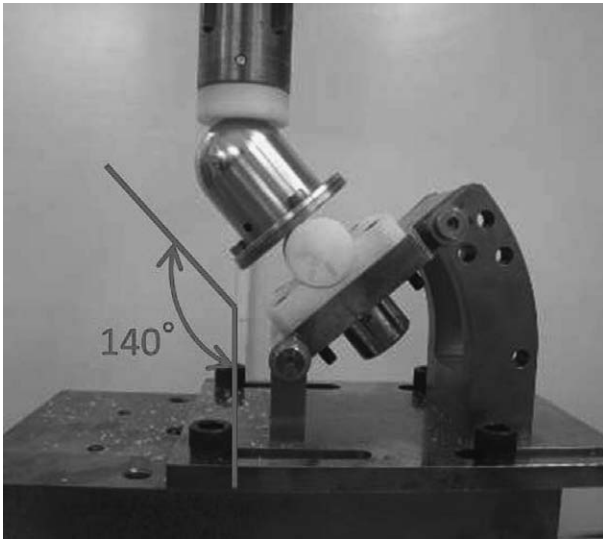


Fig. 1-7. Jig assembly



Fig. 1-8. Repeated compression test with a 2-axis biomaterial tester

Quasi-static torsion tests

Quasi-static torsion tests using the lag screws and grasping pins were performed to simulate rotational deformities. The rotational resistances were measured and mechanical fixation was investigated. The samples were rotated at a twist angular velocity of $72^\circ/\text{min}$ by using a 2-control biomaterial tester (Mini-Bionix, MTS Systems Corporation, Eden Prairie, mn). The maximum angle was 140° . The relationship between the twist angles and rotational resistance ($\text{N} \cdot \text{m}$) was investigated. Torsional rigidity ($\text{N} \cdot \text{m}/\text{deg}$) was temporarily set on the basis of the rotational resistance-twist angle curve obtained from tests using the polyurethane model bones; for this calculation, the torsional rigidity was estimated from the colinear approximation of the incline of the above curve from 1° to 5° . Curves were calculated for both femoral heads collected after hip replacement surgery and cadaveric femoral heads.

Results

Cyclic Compressive Loading Tests

Polyurethane model bones

Fig. 2-1 shows the displacement–frequency curves derived from cyclic compressive loading tests comparing the lag screws and grasping pins in polyurethane model bones. Fig. 2-2 shows the cross-sectional areas of loosening after the cyclic loading test. No implant fracture was observed after testing. The displacement differed by 2.5% in the initial stages, and subsequently increased with similar differences between the two types of implant (Fig. 2-1).

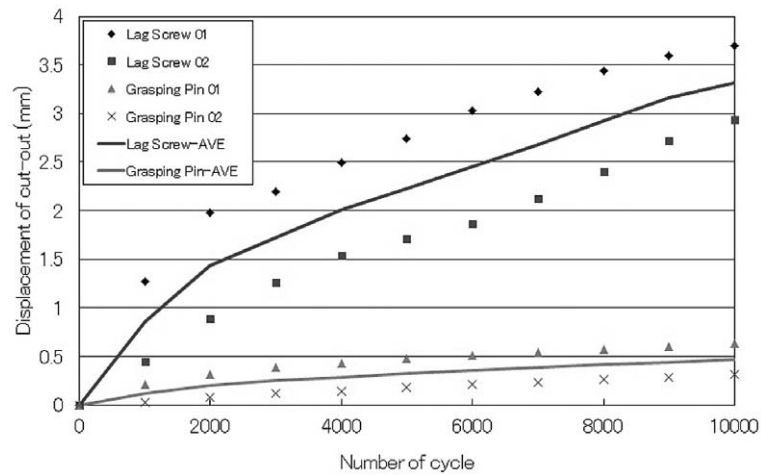


Fig. 2-1. Displacement-frequency curve after cyclic loading test
(material : Cellular#12.5)

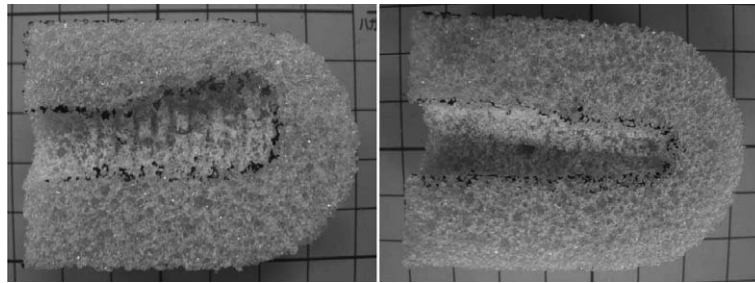


Fig. 2-2. Cross-sectional area of loosening after cyclic loading test
(Left : lag screw ; Right : grasping pin)
(material : Cellular#12.5)

Femoral heads

Fig. 2-3 shows the displacement–frequency curve for differences in cyclic compressive loading between the lag screws and grasping pins in the femoral heads. The results showed a slight increase in displacement of the femoral heads on cyclic loading on both tests of grasping pins and the lag screw. Fig. 2-4 shows the cross-sectional areas of loosening after the cyclic loading test. No cut-outs or implant fractures were observed.

Quasi-Static Torsion Tests

Polyurethane model bones

Fig. 2-5 shows rotational resistance–twist angle curves for grasping pins and lag screws in Solid #5 model bone. The lag screws showed no rotational resistance, whereas the grasping pins showed high rotational resistance even with no hook. The rotational resistance of the grasping pins increased as the level of hook protrusion increased (Fig. 2-5). The curve for Cellular #7.5 model bone was similar to that observed for Solid #5 model bone (Fig. 2-6). Fluctuations in rotational resistance were evident because of the porosity of the cellular material. Temporary torsional rigidity ($\text{N} \cdot \text{m}/\text{deg}$) calculated at various hook protrusion levels did not increase as

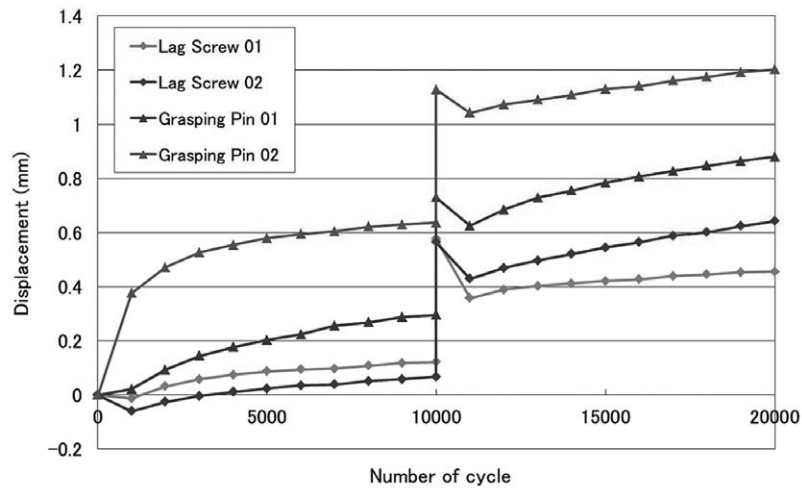


Fig. 2-3. Displacement-frequency curve (material : femoral head)



Fig. 2-4. Cross-sectional images of after-test samples
(Left : lag screw ; Right : grasping pin)
(material : femoral head)

hook protrusion increased. The grasping pins showed higher torsional rigidity compared with the lag screw.

Cadaveric femoral heads

With regard to cadaveric femoral heads, the initial rotational resistance of the grasping pins was twice that of the lag screws according to the rotational resistance–twist angle curve (Fig. 2-7). The grasping pins showed a high rotational resistance in the cadaveric bones; the hook did not rotate and cut the samples. Fig. 2-10 shows a cadaveric femoral head after insertion of a grasping pin.

Discussion

Proximal femoral osteosynthesis implants should have sufficient fixation to resist cyclic compressive loading and rotational torque. An adequately fixed implant does not cause rotational deformities or cut-out phenomena after osteosynthesis. Most current implants are of the screw-type

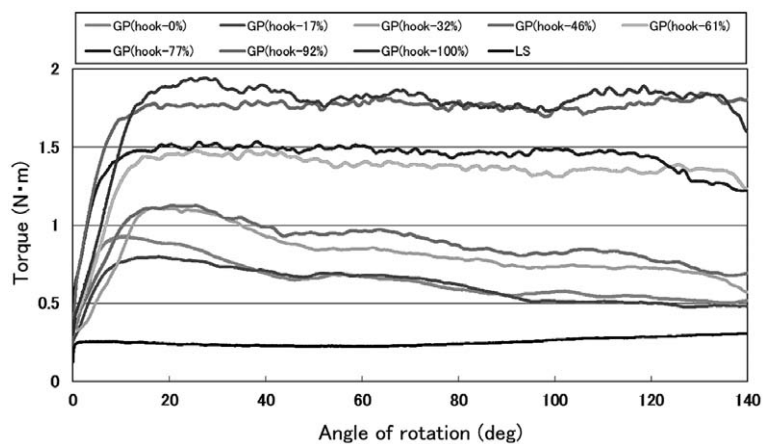


Fig. 2-5. Rotation resistance-twist angle curve (material : Solid#5)

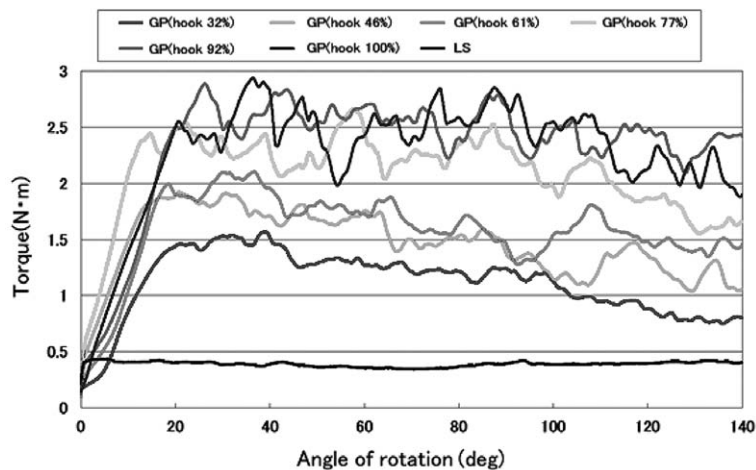
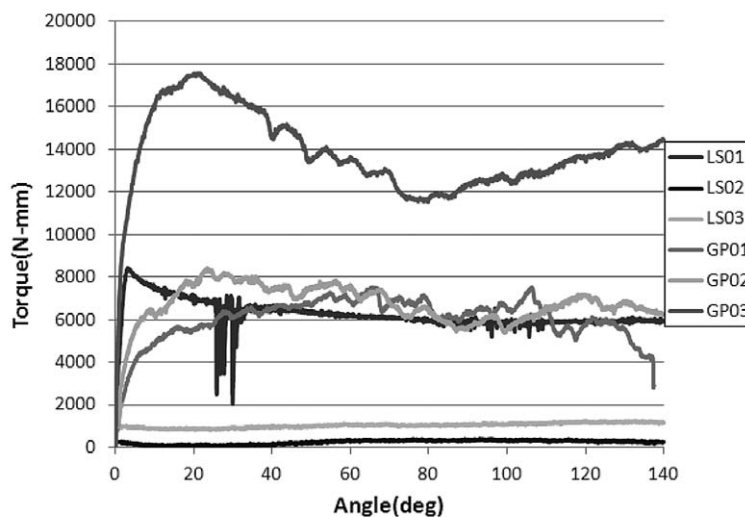


Fig. 2-6. Rotation resistance-twist angle curve (material : Cellular#7.5)

Fig. 2-7. Rotation resistance-twist angle curve
(material : cadaveric femoral head)

variety, which generates rotational force and may destroy bone tissue because of screw rotation, leading to cut-out or rotational deformities.

This study demonstrates the efficacy of the grasping pin that we developed to avoid rotational deformity and cyclic compressive loading. In the case of lag screw, the displacement in the vertical direction increased in the cyclic loading test compared with grasping pins. The grasping pins exhibited less cut-out compared with the lag screws. The displacement differed by approximately 2.5% at the initial stages, and the subsequent increases showed similar trends for both implant types. The quantitative tests using the model bones were reproducible (Fig. 2-1). Clear signs of cut-out were observed in the cross-sectional images of the lag screw samples after testing. The grasping pins did not show any signs of cut-out. The cut-out resulting from lag screw insertion was consistent with clinical cut-out complications. Therefore, this test was considered to be a useful comparative analytical tool.

Dislocation was observed in all tests. The grasping pins showed more dislocation compared with the lag screws; however, the maximum dislocation (1.2 mm) was minor (Fig. 2-3). No cut-out was observed on a cross-sectional image of the sample after testing. Repeated compression tests on the polyurethane model bones showed no cut-out and similar resistance with both types of implant^{3,4)}. Less dislocation was observed in the femoral head samples (Fig. 2-3) than in the polyurethane model bones (Fig. 2-1). This difference suggests that implant fixation may depend strongly on the fluid filling the tissue or the trabecular alignment. Fixation in the model bones did not simulate the clinical conditions.

Repeated compression tests were performed to simulate cut-out complications under physiological loading conditions. The grasping pins showed higher cut-out resistance in the model bone samples compared with the lag screw, and showed no cut-out in the femoral head samples. These resistances were similar to those reported under clinical conditions^{5,6)}. In both types of model bone (Solid #5 and Cellular #7.5), the grasping pins showed higher rotational resistance compared with the lag screws, and this result was independent of the twist angles (Figs. 2-5 and 2-6). A high value was obtained even when the hook protrusion was zero. The lag screws showed almost no rotational resistance, and rotation of the threads twisted and destroyed the internal bone structure. The grasping pins generated a high compression force and fixation as a result of their octagonal shape and the tapping action required for insertion into the bone. The rotational resistance of the pins increased as hook protrusion increased. In the case of the cadaveric femoral heads, the rotational resistance generated by the grasping pins was higher than that generated by the lag screws in the initial stage of insertion (Fig. 2-7). The pins generated a higher compression force and greater fixation than that generated by the lag screw. Full insertion of the pin meant that rotational resistance was generated by the entire pin and that the integrity of the bone tissue was maintained. This was in contrast to the results obtained with the lag screw. The cadaveric femoral heads were associated with higher rotational resistance than that of the model bones and femoral heads collected after hip replacement surgery. The grasping pins showed markedly higher resistance in the cadaveric femoral heads than in the model bones. As discussed above for cut-out resistance, the dependence of the rotational resis-

tance on the microstructure of the bone tissue suggests that implant fixation might be dependent on fluid filling the tissue or trabecular alignment. The initial rotational resistance increased from zero in the femoral heads because the depth of insertion was insufficient to reach the octagonal portion of the grasping pins. Normal initial resistance was obtained when the pin was inserted to a sufficient depth in the cadaveric femoral heads.

In conclusion, the lag screw showed almost zero rotational resistance in the model bone samples. The grasping pins showed higher resistance than the lag screws, with or without hook protrusion. The resistance increased proportionally as the hook protrusion increased. The rotational resistance of the lag screws in the femoral head samples was markedly higher than that in the model bones. The grasping pins showed almost zero resistance. The increase in resistance was dependent on the twist angle. This test was not considered to be an appropriate analytical method because the insertion depth was too shallow compared with the situation in actual trochanteric fractures. The rotational resistance of the grasping pins in the cadaveric femoral head samples was twice that of the lag screws. These results are considered applicable because the insertion depth was comparable to that used in trochanteric fractures⁷⁾.

Conflict of interest

The authors have declared no conflict of interest.

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