〈Regular Article〉

Evaluation of the appropriate reaming diameter during initial fixation of a cementless hip prosthesis

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ABSTRACT **Background**: Press-fit fixation is important technical factor to achieve initial stability of a cementless acetabular cup for good clinical results of total hip arthroplasty. However, appropriate reaming diameter during initial fixation is unclear. Therefore, this study aimed to evaluate the optimal reaming diameter using simulated bones and cementless cups.

Methods: Three types of simulated bones with different degrees of hardness were used (10 pcf, 20 pcf, 30 pcf, pcf = 16.02 kg/m^3). Acetabular models were created by reaming the simulated bone into a hemisphere, and the reaming diameters were 48 mm, 49 mm, and 50 mm.The 50 mm diameter acetabular cup was fixed to simulated bones with a compressive load of 16,000 N at a rate of 12 mm/min. The testing machine was attached to a cup fixed to the simulated bone, and a pull-out test, rotation test, and lever-out test were performed. To evaluate the initial gap, ink was applied to the cup surface during the pull-out test, and the contact between the bone and cup was visually evaluated after pull-out.

Results: The pull-out load of the 20 and 30 pcf simulated bones was significantly lower at a reaming diameter of 50 mm that those at reaming diameters of both 48 and 49 mm ($P < 0.05$). The rotational torque of the 20 and 30 pcf simulated bones was significantly lower at a reaming diameter of 50 mm that those at reaming diameters of both 48 mm and 49 mm ($P < 0.05$). The lever-out moment of the 20 and 30 pcf simulated bones was significantly lower at a reaming diameter of 50 mm than those at reaming diameters of both 48 mm and 49 mm ($P < 0.05$).

Contact between the 30 pcf simulated bone and the cup at a reaming diameter of 48 mm was mainly at the edge of the cup; contact at the center of the cup was poor.

Conclusions: We performed mechanical tests using simulated bones and evaluated the initial fixation of the cup according to the bone reaming diameter. We recommend under-reaming by 1 mm in all cases to optimize both initial fixation capacity and contact between acetabular cup and bone.

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Key words：Cementless cup, Pressfit, Under reaming

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INTRODUCTION

In recent years, the medium- to long-term outcome of hip arthroplasty has improved due to advancement in technology and implants. Presently, start of rehabilitation is essential in the early postoperative period, and better long-term outcomes is required due to increase the life expectancy of patients. Proper placement and fixation of implants is therefore needed to meet these demands. Currently, cement fixation and cementless fixation are two ways by which an artificial joint implant can be fixed. Cement-fixed implants have excellent initial fixation and are the conventional method of fixation. However, slack between bone, cement, and implants inevitably emerges postoperatively with time; in particular, loosening in the acetabular cup is a common problem. Studies have reported that the 20-year survival rate with the loosening of the cement cup as the endpoint is merely 50.9% or 63%, and longer-term results are even poorer[1, 2].

Cementless implants, however, can be biologically fixed, forming a tight bond between the bone and implant surface due to osteogenesis, after achieving reliable initial fixation by press-fit fixation via under-reaming (reaming 1-2 mm smaller than the cup diameter and then driving the cup into the implant). In theory, cementless implants are expected to provide permanent fixation without loosening but there are few long-term studies on cementless THA. Study have reported that the mid-to long term (range 7-14 years) survival rate with the revision of the cup as the endpoint is 11%[3]. One issue with cementless implants is that titanium alloy, the main raw material in cementless implants, has good bone affinity but a low capacity for osteoinduction. Therefore, extensive direct contact between the bone and implant is essential for obtaining biological fixation[4]. If the reaming diameter is substantially smaller than the cup diameter, the bone and cup come into contact only at the edge, creating an initial gap between the cup surface and the bone, and alignment will not be adequate. However, if the contact between the cup and bone is prioritized and the reaming diameter is increased to avoid this, the stability of initial fixation will be reduced. Reaming needs to be carried out so that these two opposing outcomes are well balanced. Here, we report on our study of the optimal reaming size using simulated bones and cementless cups.

TARGET AND METHOD

The cementless cup used was a hemispherical Nakashima THA cup (manufactured by Teijin Nakashima Medical Co., Ltd.) with an outer diameter of 50 mm and a surface processed into a fiber mesh (FM) shape using titanium alloy. Three types of simulated bones with different degrees of hardness (solid rigid polyurethane foam block #1522-01 10 pcf, solid rigid polyurethane foam block #1522-03 20 pcf, solid rigid polyurethane foam block #1522-04 30 pcf, SAWBONES, pcf = 16.02 kg/m^3) were used. SAWBONES was used as the substrate to simulate the quality of cancellous bone[5]. The simulated bone made of 10 pcf polyurethane was classified as poor bone; 20 pcf polyurethane, normal bone; and 30 pcf polyurethane, good bone. Simulated acetabular cavities were prepared in the polyurethane foam block using hemispherical reamers of precision machinery. Acetabular models were created by reaming the simulated bone into a hemisphere by machining, and the reaming diameters were 48 mm (2 mm undersize), 49 mm (1 mm undersize), and 50 mm (same size). The cup was impacted into the foam using a material-testing machine (Shimadzu Corporation, EHF-EV050k1-020-0A) with a compressive force of 16,000 N and a compressive speed of 12 mm/min to ensure seating of the cup in the foam bone prior to testing.

Since the 10 pcf simulated bone reached its peak load before the applied load reached 16,000 N, its indentation load was set to its peak load instead.

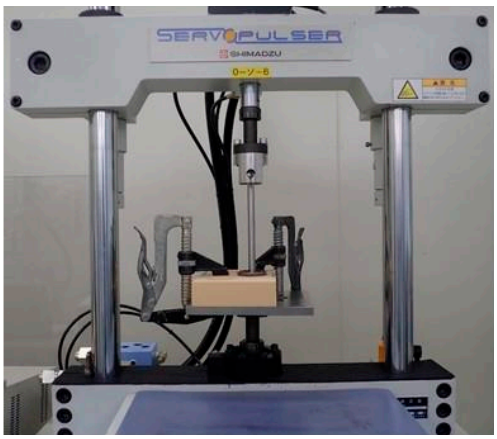

Fig. 1A. Photo of pull-out test apparatus

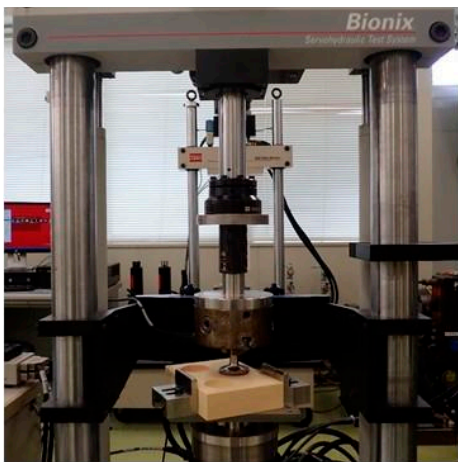

Fig. 2A. Photo of rotation test apparatus

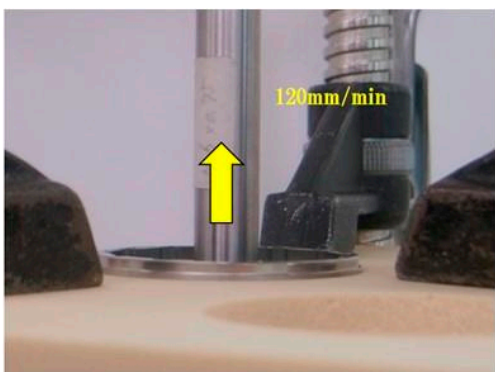

Fig. 1B. Close up photo of pull-out test apparatus

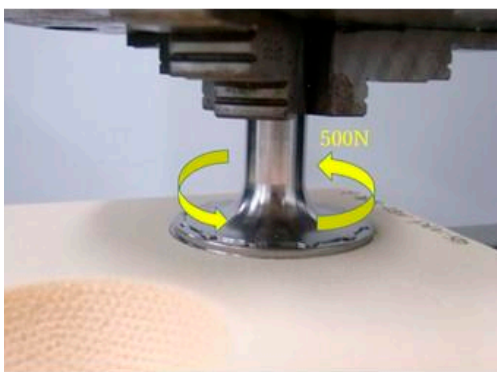

Fig. 2B. Close up photo of rotation test apparatus

The testing machine was attached to a cup fixed to the simulated bone, and a pull-out test, rotation test, and lever-out test were performed.

The pull-out test (Fig. 1A and B, using EHF-LV010k1-A04, Shimadzu Corporation) was performed by applying a pull-out load at a rate of 12 mm/min, and the maximum pull-out load was estimated by measuring the maximum value at the time of pull-out.

The rotation test (Fig. 2A and B, using Mini Bionix, MTS Japan) was performed by rotating the bone at a rate of 0.2 rpm while applying a load of 500 N in the vertical direction and measuring the maximum torque at which the cup was displaced.

In the lever-out test (Fig. 3A and B, using EHF-LV010k1-A04, Shimadzu Corporation), a load was applied in the vertical direction at a rate of 12 mm/min, and the maximum lever-out load was approximated as the load at the time the cup was displaced. The lever-out moment was calculated by multiplying the maximum lever-out load by the moment distance (52.184 mm) (Fig. 4). Each test was performed three times and values averaged. To evaluate the initial gap, ink was applied to the cup surface during the pull-out test, and the contact between the bone and cup was visually evaluated after pull-out. The conditions for each test were reference based on past reported[6, 7].

All statistical analyses were performed with EZR[8], which is for R. More precisely, it is a

modified version of R commander designed to add statistical functions frequently used in biostatistics. Tukey method was used for multiple comparisons. A level of $p < 0.05$ was considered statistically significant.

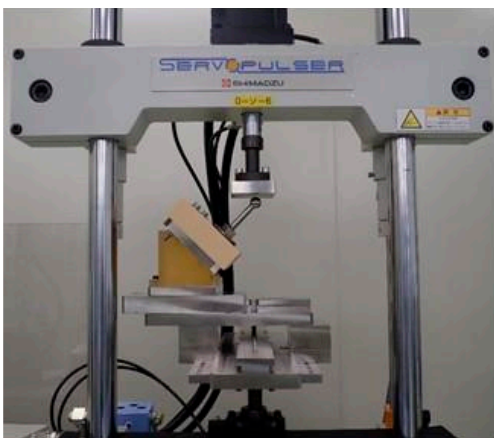

Fig. 3A. Photo of lever-out test apparatus

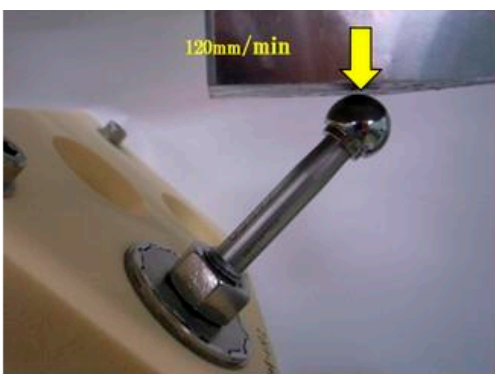

Fig. 3B. Close up photo of lever-out test apparatus

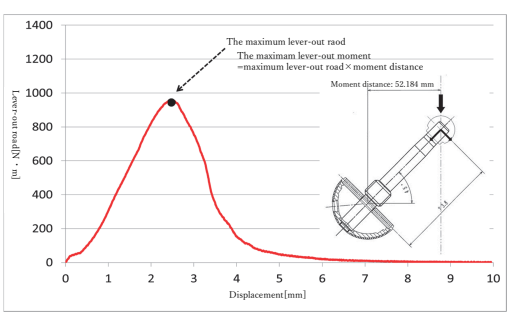

Fig. 4. Calculation of maximum lever-out moment

RESULTS

Pull-out test (Fig. 5)

The maximum pull-out load on the 10 pcf simulated bone was 441 N at a reaming diameter of 48 mm, 530 N at a reaming diameter of 49 mm, and 418 N at a diameter of 50 mm. In the 20 pcf simulated bone, the maximum pull-out load was 1,194 N at a reaming diameter of 48 mm, 1,098 N at a reaming diameter of 49 mm, and 305 N at a reaming diameter of 50 mm. In the 30 pcf simulated bone, the maximum pull-out load was 2,380 N at a reaming diameter of 48 mm, 2,249 N at a reaming diameter of 49 mm, and 641 N at a reaming diameter of 50 mm. The pull-out load of the 20 and 30 pcf simulated bones was significantly lower at a reaming diameter of 50 mm that those at reaming diameters of both 48 and 49 mm ($P < 0.05$).

Rotation test (Fig. 6)

In the 10 pcf simulated bone, the maximum torque was 41, 42, and 35 N/m at reaming diameters of 48, 49, and 50 mm, respectively. In the 20 pcf simulated bone, the maximum torque was 82, 89, and 43 N/m at reaming diameters of 48, 49, and 50 mm, respectively. In the 30 pcf simulated bone, the maximum torque was 146, 141, and 60

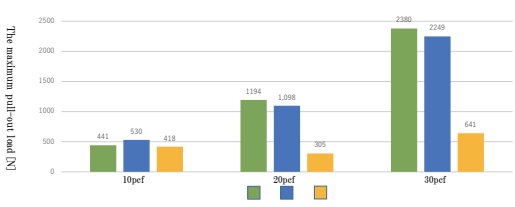

Fig. 5. Results of pull-out test

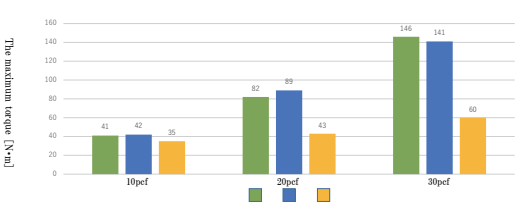

Fig. 6. Results of rotation test

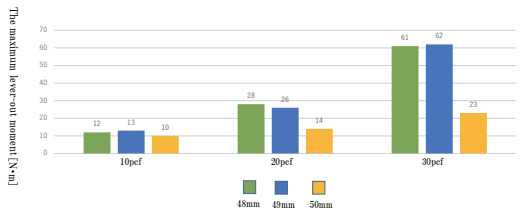

Fig. 7. Results of lever-out test

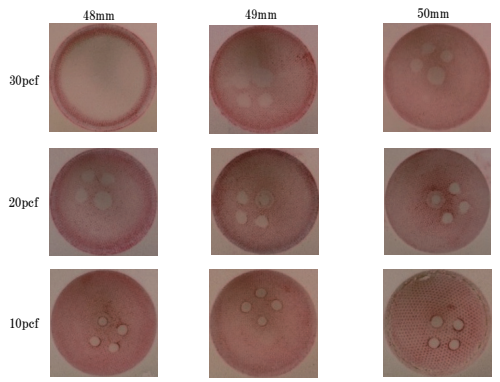

Fig. 8. Contact between simulated bone and cup

N/m at reaming diameters of 48, 49, and 50 mm, respectively.

The rotational torque of the 20 and 30 pcf simulated bones was significantly lower at a reaming diameter of 50 mm that those at reaming diameters of both 48 mm and 49 mm ($P < 0.05$).

Lever-out test (Fig. 7)

In the 10 pcf simulated bone, the maximum lever-out moment was 12, 13, and 10 N/m at reaming diameters of 48, 49, and 50 mm, respectively. In the 20 pcf simulated bone, the maximum lever-out moment was 28, 26, and 14 N/m at reaming diameters of 48, 49, and 50 mm, respectively. In the 30 pcf simulated bone, the maximum lever-out moment was 61, 62, and 23 N/m at reaming diameters of 48, 49, and 50 mm, respectively.

The lever-out moment of the 20 and 30 pcf simulated bones was significantly lower at a reaming diameter of 50 mm than those at reaming diameters of both 48 mm and 49 mm ($P < 0.05$).

Contact between the simulated bone and cup (Fig. 8)

Both the 10 pcf (assumed to be an osteoporotic bone) and 20 pcf (normal) simulated bones were in contact with the entire cup at all reaming diameters. However, contact between the 30 pcf simulated bone and the cup at a reaming diameter of 48 mm (2 mm undersize) was mainly at the edge of the cup; contact at the center of the cup was poor (Fig. 8).

DISCUSSION

In recent years, patients who have undergone total hip arthroplasty (THA) are required to initiate rehabilitation in the early stages of recovery. This requires initial fixation that is strong enough to withstand a weight-bearing gait for patients immediately after surgery. Although cement fixation is superior to cementless fixation in initial fixation, there are concerns about its long-term effectiveness, which has led to an increased use of cementless implants in recent years. However, in THA procedures, acetabular cups are known to involve fixation failure 3 times as often compared to femoral stems. In particular, loosening in the acetabular cup has been cited as a cause for cup replacement[9, 10]. In a previous report on the acetabular reaming diameter and initial fixation of the cup, Kaneko *et al*[11]. recommended under-reaming by 2 mm based on mechanical studies and clinical performance. Adler *et al*[12]. in contrast, recommended under-reaming by 2 mm for low-density bones and 1 mm for high-density bones based on mechanical tests, while Curtis *et al*[13]. recommend under-reaming by 2-3 mm based on mechanical tests conducted using donated bodies and reported that 4 mm under-reaming may pose a risk of acetabular fracture. Therefore, there is still no consensus on the appropriate reaming diameter. In addition, these have mainly been examined using mechanical tests for initial fixation, and no reports have directly

examined the bone-cup contact to assess its impact on biological fixation. In our study, the 20 and 30 pcf simulated bones with a reaming diameter of 50 mm (same diameter as the implant) demonstrated significantly poorer results than under-reamed bones in all the tests. Although the 10 pcf simulated under-reamed bone tended to show high fixation in the pull-out and rotation tests, there was no statistically significant difference in these results. It is presumed that there was no significant difference because of the low strength of the simulated bone. There were no significant differences between bones reamed at 48 mm (2 mm undersized) and those reamed at 49 mm (1 mm undersized) in any of the tests, which suggests that they are neither superior nor inferior regarding initial fixation. The theoretical rotation torque (T) applied during walking can be expressed by the formula: bone head radius (R) × coefficient of friction × load, and if the maximum rotation torque measured in the experiment is less than this value, there is a risk that the cup will be displaced while walking. The friction on the sliding surface is affected by the properties of the synovial fluid, and the coefficient of friction of the sliding surface of the bone head is reportedly between 0.1 and 0.18[14]. Bergmann stated that the maximum value of the force applied to the femoral head during normal gait is four times the body weight[15]. We provided further leeway in our study by assuming that the bone head must be able to withstand a load of six times the body weight. This suggests that a minimum of 15.5 N/m of rotational resistance torque is required for safety. This theoretical value was exceeded under all conditions in the rotation tests we conducted; therefore, we believe that the rotational resistance required for walking was met under all conditions.

In addition, we evaluated the contact between the cup and simulated bone after the pull-out test. Both the 10 pcf (assumed to be an osteoporotic bone) and 20 pcf (normal) simulated bones were in contact with the entire cup at all reaming diameters. However, when the 30 pcf (hard) bone was reamed at a diameter of 48 mm (2 mm undersized), the contact between the simulated bone and the cup took place mainly at the edge of the cup, and there was almost no contact with the cup surface. This suggests that in hard bone, under-reaming by 2 mm or more leads to the emergence of an initial gap. A reaming diameter of 49 mm (1 mm undersize) had the same initial fixing capacity as that of 48 mm (2 mm undersized), and the contact between the cup and simulated bone was also good. Therefore, taking into account both the initial fixation capacity and biological fixation, we recommend undersized reaming by 1 mm for all bone densities to provide good contact between the bone and cup.

Limitations of this study include the use of Sawbones instead of human bone, which have differences in quality. In addition, hip dysplasia is the common cause of THA in Japan but this study has not examined bone defect in the acetabulum.

Examination using defect bone model will be required.

CONCLUSION

We performed mechanical tests using simulated bones and evaluated the initial fixation of the cup according to the bone reaming diameter. We recommend under-reaming by 1 mm in all cases to optimize both initial fixation capacity and biological fixation.

CONFLICT OF INTEREST

For this study, part of the research was conducted by concluding a commissioned research with Teijin Nakashima Medical Co, Ltd .

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