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Mechanical testing of cephalomedullary nail lag screws after the addition of hydroxyapatite substitutes

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Abstract

Objective: To compare the effects of 3 implant designs, with and without hydroxyapatite reinforcement, on push/pull-out strength and rotational torque.

Methods: Three implant designs (Gamma 3, INTERTAN, and PFNA-II) were selected for comparison. A hydroxyapatite cylinder (NEOBRACE) was used to reinforce the interface between the femoral head and the lag screw. Maximum push-out strength, maximum pull-out strength, and peak rotational torque were measured in cellular blocks mimicking osteoporotic cancellous bone, with and without NEOBRACE.

Results: In the push-out test, INTERTAN produced a significantly higher push-out strength in osteoporotic bone density cellular blocks than the other lag screws and blades ($P < .05$). With the addition of NEOBRACE, push-out strength was significantly higher for INTERTAN and PFNA-II ($P < .05$) than for the non-NEOBRACE group. In the pull-out test, INTERTAN produced a significantly higher pull-out strength in the osteoporotic bone density cellular blocks than did the other lag screws and blades ($P < .05$). With the addition of NEOBRACE, the pull-out strengths of INTERTAN and Gamma 3 versus those of the non-NEOBRACE group significantly increased ($P < .05$). In the rotational torque test, INTERTAN produced significantly greater rotational torque in the osteoporotic cellular blocks than the other lag screws and blades ($P < .05$). The addition of NEOBRACE resulted in a significant increase in rotational torque only for INTERTAN ($P < .05$).

Conclusion: The use of NEOBRACE supported an increase in push/pull-out strength and rotational torque, especially in systems with a relatively increased bone or implant interface area.

Level of Evidence: Level V

Keywords: bone substitute, bone/implant interface, femoral nail failure prevention, intertrochanteric fracture fixation, push/pull-out strength, rotational torque, synthetic bone augmentation

1. Introduction

During the treatment of an intertrochanteric hip fracture, implant selection, fracture reduction, implant placement, and postoperative mobilization can be controlled by the surgeon; however, the fracture type and bone quality are not controllable. The perioperative complication rate of intertrochanteric hip fractures is 4% to18%.[1] The primary mechanism of failure for cephalomedullary nails is lag screw cut-out, defined as a protrusion of the implant outside the femoral head on any radiographic view. Previous studies suggest osteoporosis, unstable fractures, inadequate reduction, and poor lag screw positioning as predictors of the cut-out.[2–4] One reason for postoperative mechanical failure is loss of proper fracture reduction after intraoperative implant fixation. Rotation between the lag screw and femoral head can result in cut-out, cut-through, and back-out.[1,2] We hypothesized that postoperative failure would be preventable through secure fixation using a proper short femoral nail design combined with synthetic bone to support and augment the osteoporotic bone.

It is unknown which implant design elicits the greatest push-out, pull-out strength, and rotational torque in osteoporotic bone, and whether it is possible to strengthen the femoral head and screw interface by adding hydroxyapatite (HA) synthetic bone. Therefore, in the present in vitro study, we compared the effects of 3 implant designs, with and without HA reinforcement, on push/pull-out strength, and rotational torque.

2. Materials and methods

Based on compression classification,[5] 3 implant designs were selected for comparison. The compression types were as follows:

The NEOBRACE implant used in this study was provided by Coors Tek.

The authors have no conflicts of interest to disclose.

The datasets generated and/or analyzed during the current study are available and can be obtained from the corresponding author on reasonable request.

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Implant	Gamma3 with U lag	INTERTAN	PFNA-II
Class	Dynamic compression	Linear compression integrated	Impaction

Figure 1. Compression-type implant. Dynamic compression: Gamma 3 nail with U-lag (Stryker, Mahwah, New Jersey), integrated linear compression (INTERTAN; Smith & Nephew, Memphis, Tennessee), and impaction (PFNA-II; Depuy Synthes, West Chester, Pennsylvania).

dynamic compression: Gamma 3 nail with U-lag (Stryker, Mahwah, New Jersey); integrated linear compression: INTERTAN (Smith & Nephew, Memphis, Tennessee); and impaction: PFNA-II (Depuy Synthes, West Chester, Pennsylvania) (Fig. 1). The diameters of the lag screw and blade of each implant design were as follows: Gamma 3, 10.3 mm; U-lag, 12.5 mm; INTERTAN lag screw, 11.0 mm and compression screw, 7.0 mm (integrated, 15.25 mm); PFNA-II blade, 10.3 mm.

A 100% HA cylinder NEOBRACE (CoorsTek, Tokyo, Japan), consisting of a 75% ± 3% porous structure with macropores of 50 to 300 μm that are fully interconnected by openings ~40 μm in diameter with a design that allows easy breakage of the HA substitute in the femoral head when the lag screw is inserted (Fig. 2), was used to reinforce the interface between the femoral head and the lag screw. Compressive strength is higher than 8 MPa, and sintering temperature is 1200°C. It was inserted through a guide wire with a pusher. NEOBRACE breaks uniformly and interacts with the lag screw (Fig. 3). Because HA is not fully absorbed in vivo, a long-term anchoring effect and osteoconduction of the bone at the lag screw/femoral head interface is expected in osteoporotic bone.[6] We conducted push/pull-out strength and rotational torque tests according to the testing method outlined by Suhm et al.[7] Ten cellular rigid polyurethane foam (#1522-10-10 PCF, Sawbones: Density: 0.16 g/cc; yield strength: 2.3 MPa), which has a cell size that is closer to that of human cancellous bone and is most commonly used for testing subsidence, press-fit devices, and cement augmentation, was chosen for all push-out, pull-out, and rotational torque tests to provide consistent test results mimicking osteoporotic bone (average yield strength of osteoporotic bone: 2.5 MPa).[8,9]

2.1. Push-out test

Push-out strength was measured using 3 short femoral nail designs in a PCF cellular block mimicking osteoporotic cancellous bone,[8] with and without NEOBRACE. A desktop-type precision universal testing machine, Autograph AG-1 (Shimadzu Corporation, Tokyo, Japan), was used to evaluate the push-out strength of the screw.

A 3.2-mm-diameter guide pin was inserted in the cellular block and reamed to a depth of 75 mm, which is the average distance from the tip of the lag screw to the nail/lag screw junction in Japanese patients. Pull-out strength between the lag screw and the femoral head cancellous bone was evaluated. A lag screw/blade was inserted into the predrilled screw hole. By compressing the end of the lag screw/blade, the tip of the lag screw/blade was pushed out.

As shown in the schematic diagram, by compressing the end of the lag screw/blade, the tip of the lag screw/blade was pushed out at a speed of 1 mm/min. Push-out strength was increased until the fixation between the lag screw/blade and the cellular block failed (Fig. 4). The maximum push-out strength for each condition was recorded (the average of 3 measurements).

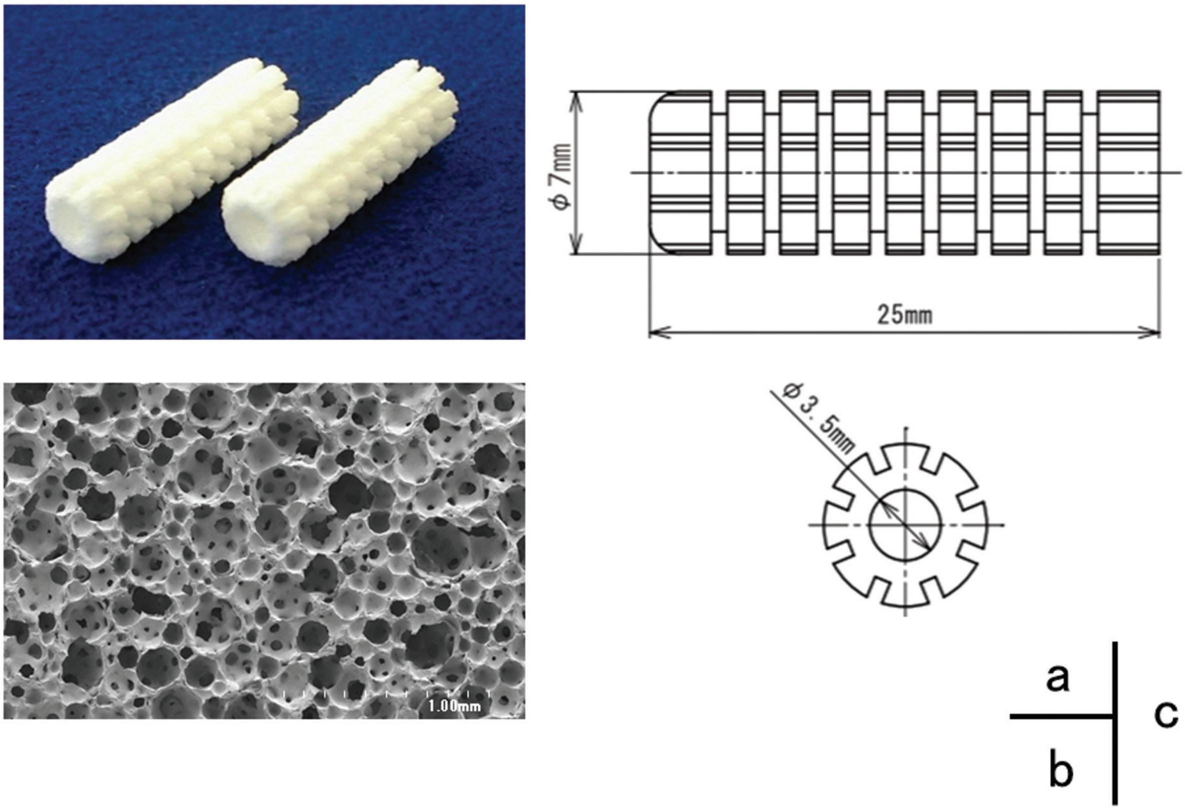

Figure 2. NEOBRACE implant (photograph courtesy of CoorsTek, Tokyo, Japan). (a) NEOBRACE implant design, (b) NEOBRACE porous structure, and (c) NEOBRACE specification.

2.2. Pull-out test

Pull-out strength was measured with 3 different short femoral nail designs in a cellular block mimicking osteoporotic cancellous bone, with and without NEOBRACE. A desktop-type precision universal testing machine, Autograph AG-1, was used to evaluate the pull-out strength of the screw.

A 3.2-mm-diameter guide pin was inserted in the cellular block and reamed to a depth of 75 mm, which is the average distance

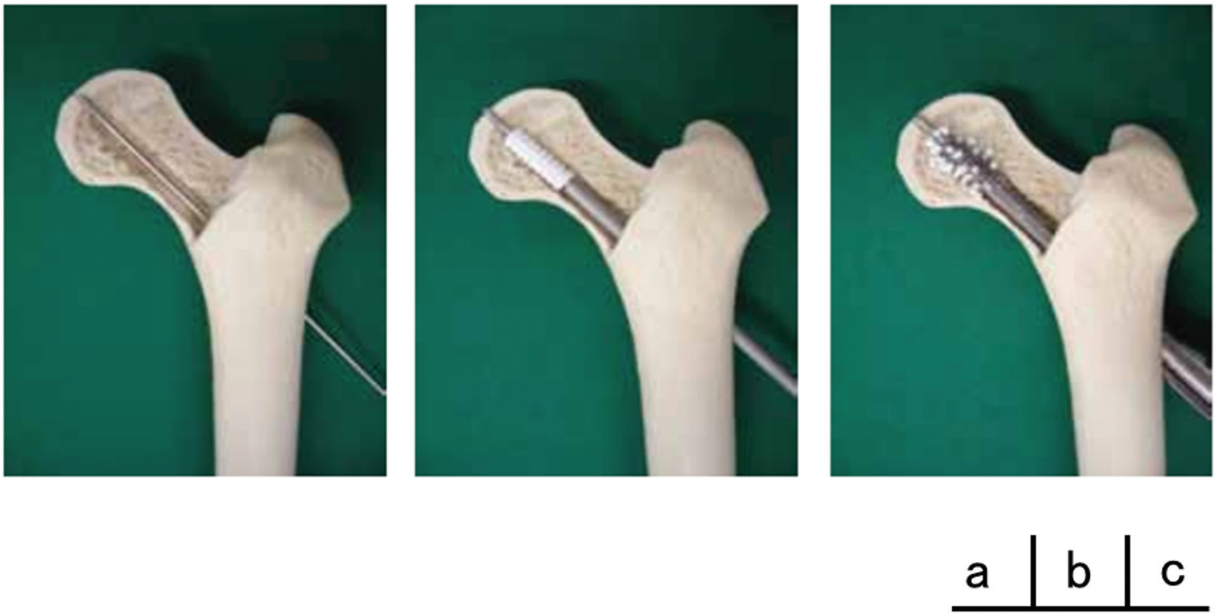

Figure 3. NEOBRACE surgical technique. (a) Insertion of a ϕ3.2-mm guide wire, (b) NEOBRACE placed in the femoral head through the guide wire with a pusher, and (c) NEOBRACE broken in granules by inserting the lag screw.

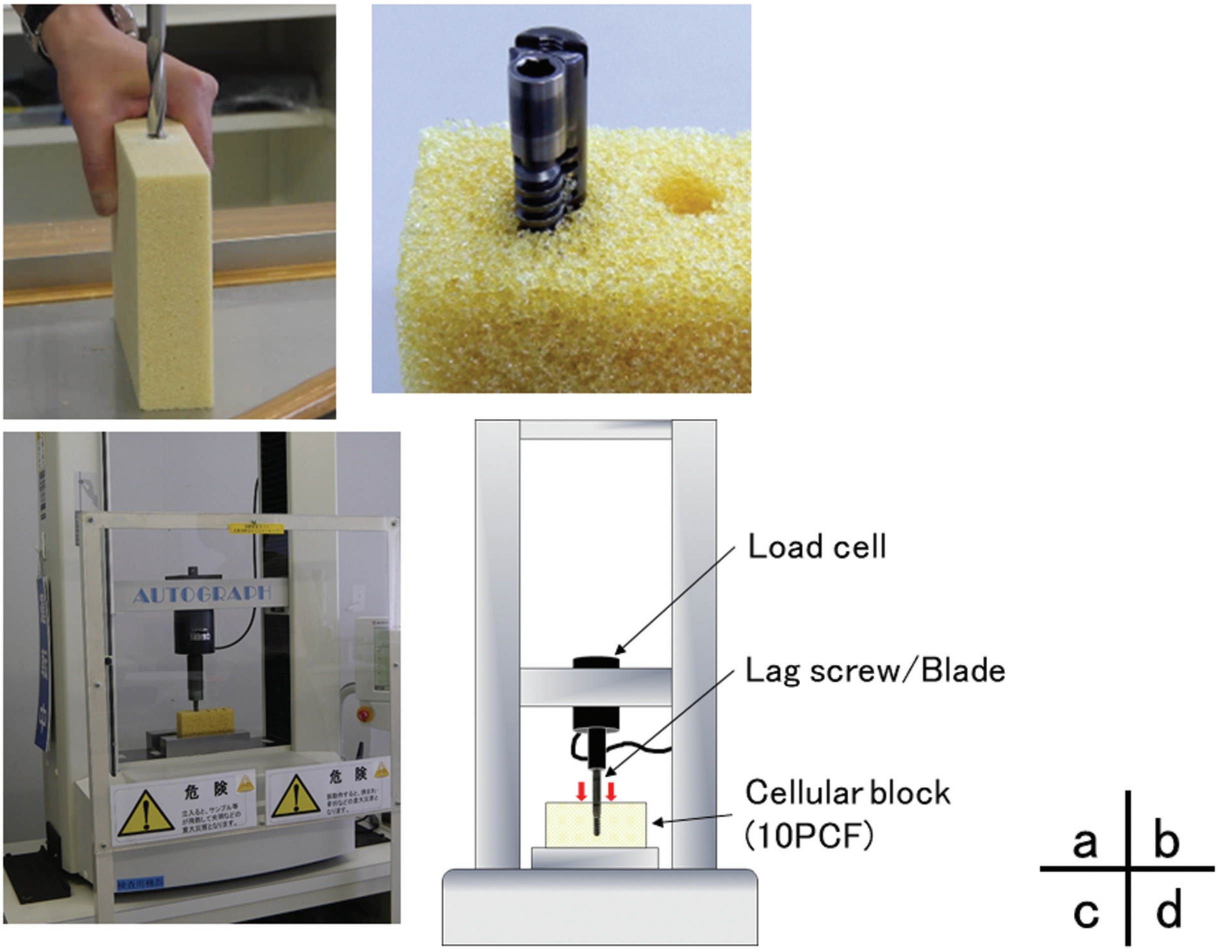

Figure 4. Push-out test setup. (a) A 3.2-mm diameter guide pin was inserted in the cellular block and reamed to a depth of 75 mm, (b) A lag screw/blade was inserted into the predrilled screw hole, (c) Desktop-type precision universal testing machine, Autograph AG-1, and (d) as shown in the schematic diagram, by compressing the end of the lag screw/blade, the tip of the lag screw/blade was pushed out at a speed of 1 mm/min. The maximum push-out strength for the 5-mm strain was recorded.

from the tip of the lag screw to the nail in Japanese patients. Pull-out strength between the lag screw and the femoral head cancellous bone was evaluated. A lag screw/blade attached to the metal plate of the machine was inserted into the predrilled screw hole. By compressing the cellular block, the lag screw/blade was pulled out.

As shown in the schematic diagram, by compressing the cellular block, the lag screw/blade was pulled out at a speed of 1 mm/min. Pull-out strength was increased until the fixation between the lag screw/blade and the cellular block failed (Fig. 5). The maximum pull-out strength in a 5-mm strain for each condition was recorded (the average of 3 measurements).

2.3. Rotational torque test

Rotational torque was also measured with 3 different short femoral nail designs in a cellular block mimicking osteoporotic cancellous bone, with and without NEOBRACE. A Torsion Testing Machine, TTM-3000 (Shimadzu Corporation, Japan), was used to measure the rotational torque.

As with the measurements for push/pull-out, the lag screw/blade was inserted into the cellular block. Each cellular block was fixed with a metal plate. By rotating the device firmly fixed to the base of the lag screw/blade, the tip of the lag screw/blade was rotated in the cellular block (Fig. 6). The maximum rotational torque (Nm) for each condition was recorded (the average of 3 measurements).

2.4. Statistical analysis

For statistical comparisons between the 2 groups, we used the Student *t* test. P values $<.05$ were considered to indicate statistically significant differences. Data are presented as mean ± standard deviation. Statistical analysis was performed using IBM Statistical Package for the Social Sciences version 22.0 (IBM Corporation, Chicago, Illinois).

3. Results

3.1. Push-out test

Push-out testing in the cellular block with osteoporotic bone density yielded the highest push-out strength for INTERTAN (1302 ± 18.7 N), followed by Gamma 3 (777 ± 17.9 N) and PFNA-II (437 ± 16.1 N) (Fig. 7). The push-out strength obtained with INTERTAN was significantly higher than that obtained with the other lag screws and blades ($P < .05$). Blocks with added NEOBRACE produced the highest push-out strength with INTERTAN (1536 ± 26.5 N), followed by Gamma 3 (847 ± 40.0 N) and PFNA-II (676 ± 7.4 N). When NEOBRACE was added to

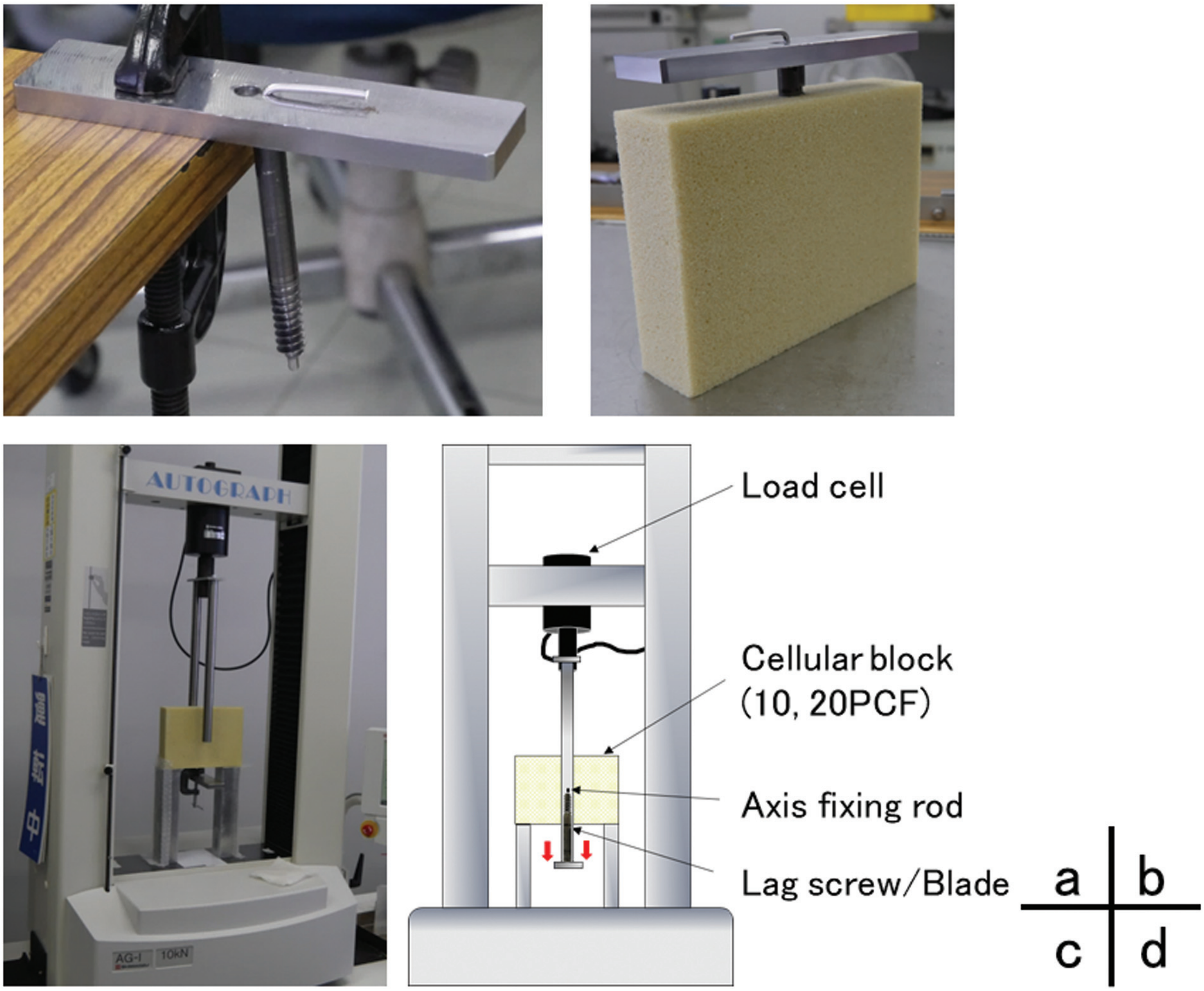

Figure 5. Pull-out test setup. (a) A lag screw/blade was attached to the metal plate, (b) A lag screw/blade was inserted in the drilled screw hole, (c) Desktop-type precision universal testing machine, Autograph AG-1, and (d) as shown in the schematic diagram, by compressing the cellular block, the lag screw/blade was pulled out at a speed of 1 mm/min. The maximum pull-out strength was recorded.

the blocks, INTERTAN yielded a significantly higher push-out strength than did the other lag screws and blades ($P < .05$). Compared with the non-NEOBRACE group, INTERTAN and PFNA-II showed a significant increase in push-out strength when NEOBRACE was added to the blocks ($P < .05$).

3.2. Pull-out test

Pull-out testing in cellular blocks with osteoporotic bone density yielded the highest values for INTERTAN (806 ± 45.7 N), followed by Gamma 3 (471 ± 18.5 N) and PFNA-II (363 ± 23.6 N) (Fig. 8). INTERTAN resulted in a significantly higher pull-out strength in the osteoporotic bone density cellular blocks than did the other lag screws and blades ($P < .05$). Blocks with added NEOBRACE produced higher values with INTERTAN (1028 ± 74.4 N), followed by Gamma 3 (560 ± 21.5 N) and PFNA-II (328 ± 4.5 N). With NEOBRACE addition, the pull-out strength in the osteoporotic bone density cellular blocks was significantly higher for INTERTAN than for the other lag screws and blades ($P < .05$). With NEOBRACE addition, INTERTAN and Gamma 3 showed a significant increase in pull-out strength ($P < .05$) relative to that in the non-NEOBRACE group.

3.3. Rotational torque test

Rotational torque test values in cellular blocks with osteoporotic bone density were highest for INTERTAN (11.07 ± 0.45 Nm), followed by PFNA-II (3.42 ± 0.45 Nm) and Gamma 3 (2.84 ± 0.13 Nm) (Fig. 9). INTERTAN produced significantly greater rotational torque in the osteoporotic cellular blocks than did the other lag screws and blades ($P < 0.05$). With the addition of NEOBRACE, the values were highest for INTERTAN (12.77 ± 0.87 Nm), followed by PFNA-II (3.99 ± 0.50 Nm) and Gamma 3 (3.41 ± 0.34 Nm). INTERTAN produced significantly greater rotational torque in osteoporotic cellular blocks with the addition of NEOBRACE than did the other lag screws and blades ($P < .05$). When NEOBRACE was added to the blocks, only INTERTAN showed a significant increase in rotational torque ($P < .05$) relative to that in the non-NEOBRACE group.

4. Discussion

We quantified the fixation strength between a screw or blade implant and a cancellous cellular block mimicking osteoporotic bone by measuring the peak push/pull-out strength and rotational torque to prevent postoperative failure after treatment

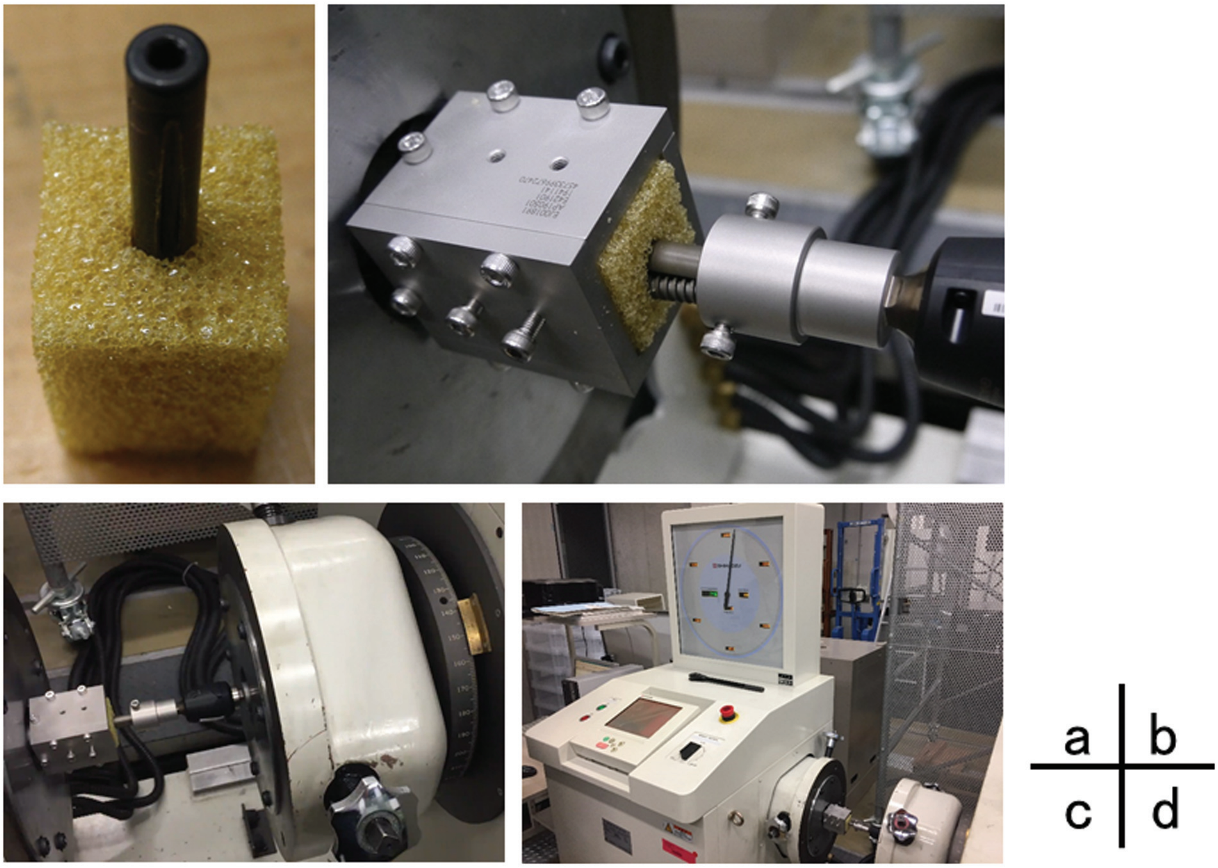

Figure 6. Rotational test setup. (a) A lag screw/blade was inserted into the drilled screw hole, (b) the cellular block was fixed with a metal plate (c), and (d) Torsion Testing Machine, TTM-3000. By rotating the device, which was firmly fixed to the base of the lag screw/blade, the tip of the lag screw/blade was rotated in the cellular block. Peak torque was recorded.

of intertrochanteric hip fractures. We also evaluated the effect of HA bone substitute (NEOBRACE) augmentation for the fixation of the femoral head and lag screw/blade interfaces. Push/pull-out strength and rotational torque testing were conducted on 3 representative implant designs that are most often used to treat intertrochanteric hip fractures. INTERTAN integrated screw showed significantly higher push/pull-out strength in the osteoporotic cellular blocks. Moreover, the push-out strength increased when NEOBRACE was added to the blocks; while it was significantly increased for the dual screw (INTERTAN) and blade-type (PFNA-II) designs ($P < .05$), the single-screw design (Gamma 3) did not show a significant difference.

These findings may be explained by the superior fixation of the dual screw design compared to that of the blade design,[1] larger screw surface, and design of the thread angle and length. Stern et al[10] compared the cut-out rate of 362 short femoral nail cases and found that the blade-type had a significantly higher cut-out rate. Their report supports our findings of reduced push/pull-out strength with the blade-type implant design.

Investigations into lag screw and blade stability using polyurethane blocks have previously been published. Al-Munajjed evaluated the rotational stability and pull-out strength of blade-type and screw implants,[1] while Sermon et al[11] studied the rotational stability and pull-out strength of the blade when used in conjunction with bone cement. Hayashi et al[12] reported a comparison between blade and screw techniques and demonstrated superior rotational stability of the blade. Santoni et al and Yu et al reported similar results to those of our study, showing superior resistance of the INTERTAN against reduction loss due to reduced femoral head rotation.[13,14]

In our study, pull-out strength increased when NEOBRACE was used, and the single and dual screw designs showed an advantage over the blade design. Rotational torque also increased when NEOBRACE was used, and the dual screw design was superior to the single-screw and blade designs in this respect. NEOBRACE tended to enhance fixation with the larger surface interface of the thread design implants.

Rotational stability and pull-out strength with the addition of bone cement in the PFNA-II blade were reported to strengthen femoral head and blade fixation.[8] It has also been reported that the use of bone cement to fill the femoral head in hip nail revision surgery involving a PFNA-II blade showed higher pull-out strength and rotational torque than without the use of bone cement.[15] However, because bone cement may leak into the fracture site and joint, it is not recommended for use in revision surgery of cut-out and cut-through cases, although it may be used carefully in blade back-out cases. Regarding the disadvantages of bone cement, NEOBRACE granulates, when crushed, are less likely to leak into the joint than paste-type bone cement. NEOBRACE with HA does not interfere with bone union even if it leaks into the fracture site. This feature enables NEOBRACE to be utilized in all osteoporotic patients with necessity. Yee et al[16] reported that 10.7% of osteoporotic patients with TraumaCem V+ indication could not utilize NEOBRACE because of guidewire perforation into the hip joint (6.4%), and cement injection failure was reported due to high injection

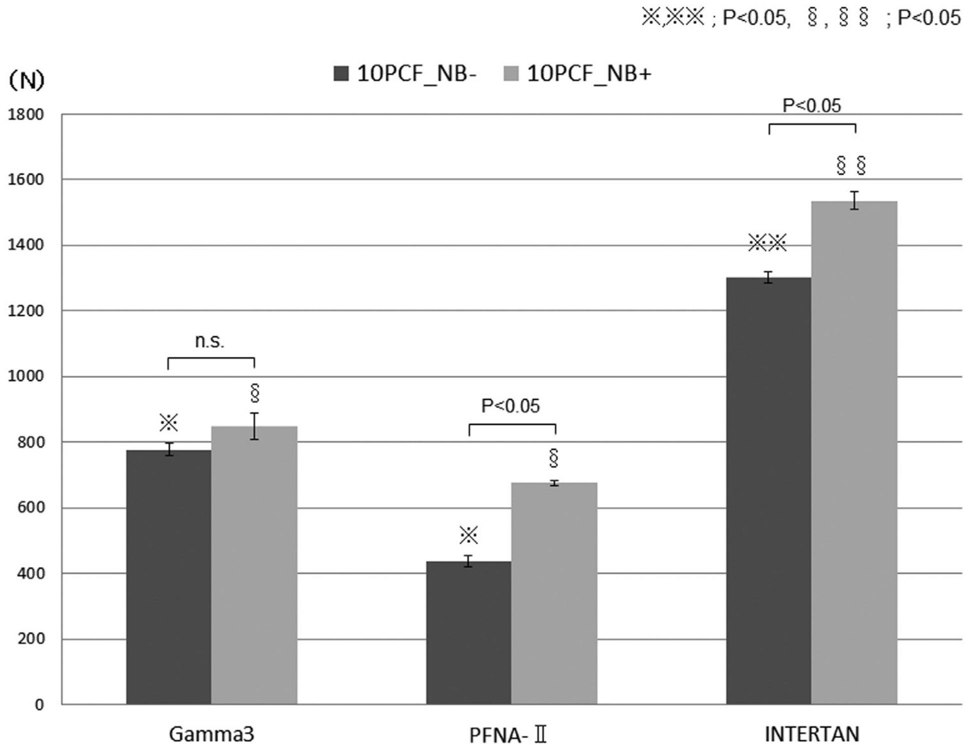

Figure 7. Push-out test. INTERTAN provided a statistically higher push-out strength in osteoporotic bone density cellular blocks than did the other lag screws and blades (※,§; $P < .05$). INTERTAN provided a significantly higher push-out strength in osteoporotic bone density cellular blocks with the addition of NEOBRACE than did the other lag screws and blades (※,§; $P < .05$). With NEOBRACE addition, the push-out strengths of INTERTAN and PFNA-II increased significantly ($P < .05$) compared with those of the non-NEOBRACE groups (10PCF_NB−; osteoporotic bone density cellular block, 10PCF_NB+; osteoporotic bone density cellular block with NEOBRACE).

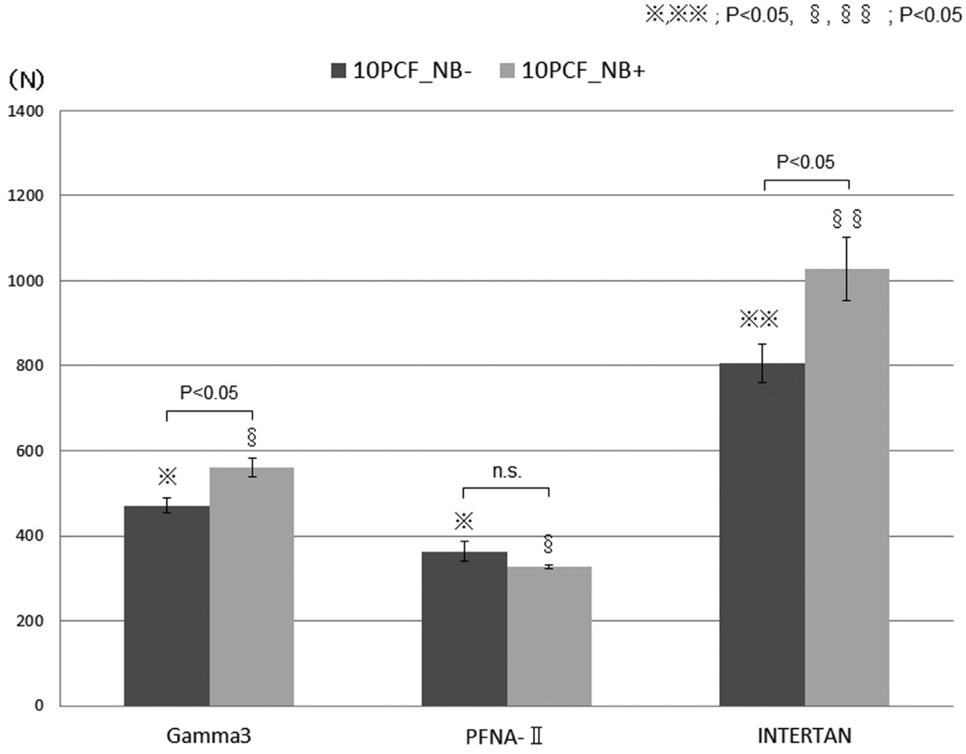

Figure 8. Pull-out test. INTERTAN provided a statistically higher pull-out strength for osteoporotic bone density cellular blocks than did the other lag screws and blades (※,§; $P < .05$). INTERTAN provided a statistically higher pull-out strength in osteoporotic bone density cellular blocks with the addition of NEOBRACE than did the other lag screws and blades (※,§; $P < .05$). With NEOBRACE addition, the pull-out strength of INTERTAN and Gamma 3 increased significantly ($P < .05$) compared with that of the non-NEOBRACE groups (10PCF_NB−; osteoporotic bone density cellular block, 10PCF_NB+; osteoporotic bone density cellular block with NEOBRACE).

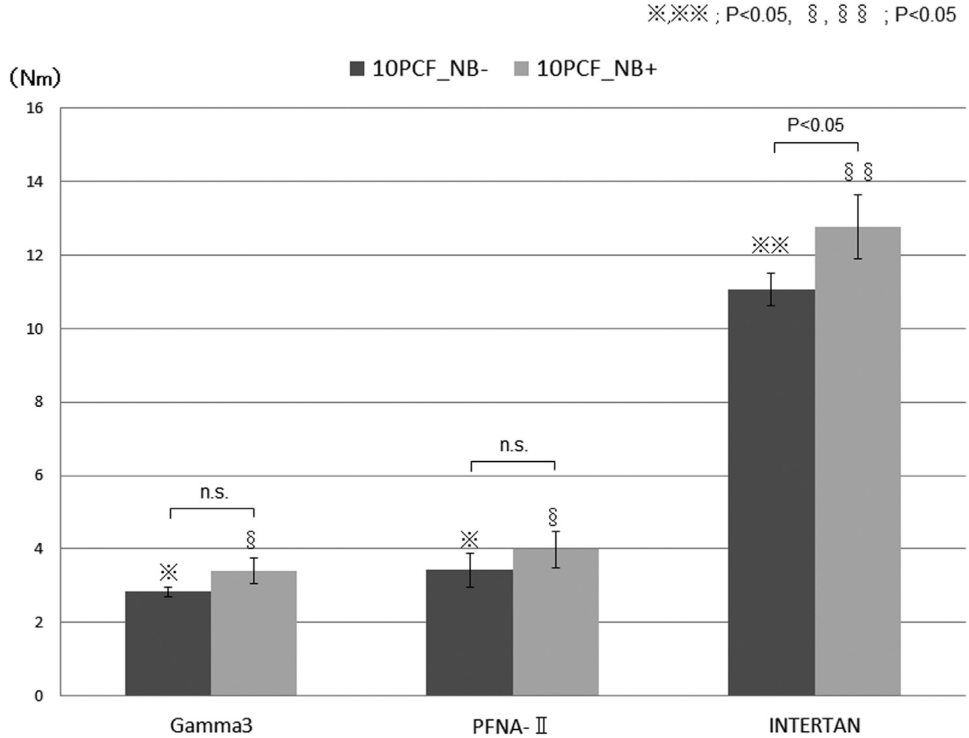

Figure 9. Rotational torque test. INTERTAN produced a significantly greater rotational torque in the osteoporotic cellular blocks than did the other lag screws and blades (※,§; $P < .05$). With the addition of NEOBRACE, INTERTAN produced significantly greater rotational torque in the osteoporotic cellular blocks than did the other lag screws and blades (※,§; $P < .05$). With NEOBRACE addition, only INTERTAN showed a significant increase in rotational torque ($P < .05$) (10PCF_NB−; osteoporotic bone density cellular block, 10PCF_NB+; osteoporotic bone density cellular block with NEOBRACE).

resistance (4.3%). In addition, additional preparation, injection, and cement setting time of a maximum of 30 minutes are required with paste-type bone cement.[17] NEOBRACE does not require the same setting time as other substitutes like cement, and there is no risk of adverse reactions to bone cement (significantly higher blood pressure drop and vasoactive intervention[18]). Moreover, there is no need to use a contrast agent to confirm cement leakage in the hip joint and fracture site. A limitation of this study was the use of cellular blocks instead of human bone with the consideration that the use of an augment could reduce cut-out. However, the higher strengths of INTERTAN alone versus Gamma 3 and PFNA-II achieved in the tests could provide evidence supporting the superior performance of INTERTAN. Other limitations were that the effects of reduction and implant placement were not assessed in this study. A cadaveric study might be helpful to validate our findings. Furthermore, the clinical benefits of NEOBRACE addition in patients with osteoporotic intertrochanteric hip fractures should be evaluated.

5. Conclusions

In this study, push/pull-out and rotational torque tests were conducted using cellular blocks mimicking osteoporotic bone. We found that INTERTAN yielded the highest values among the tested devices. For all the tested fixation strengths, INTERTAN was significantly better than Gamma 3 and PFNA-II. Addition of NEOBRACE improved the fixation of all 3 devices (Gamma 3 single lag screw: significantly higher pull-out strength, PFNA-II single blade: significantly higher push-out strength, INTERTAN Integrated Screw: significantly higher push/pull-out and rotational torque); however, even with the augmentation, both Gamma 3 and PFNA-II achieved strengths lower than those of INTERTAN alone. Overall, although the use of NEOBRACE enhanced push/pull-out strength and rotational torque, especially in systems with a relatively increased bone or implant interface area, this adjunctive technique seemed to have a limited effect relative to the choice of implant. Further studies on human patients are necessary.

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