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BASIC RESEARCH

Loosely Implanted Cementless Stems May Become Rotationally Stable After Loading

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Abstract

Background Experimental studies have suggested that initial micromotion of cementless components may lead to failure of osteointegration. Roentgen stereophotogrammetric analyses have shown durable implant fixation can be achieved long-term even when initial instability exists, as evidenced by subsidence. However improved implant stability as a result of subsidence, before osteointegration, has not been shown biomechanically.

Questions/purposes We asked whether insertionally loose cementless tapered femoral stems show (1) less rotational stability (more toggle); (2) more subsidence; and (3) reduced ability to resist torsion (lower initial construct stiffness), lower torque at failure, and greater rotation to failure in comparison to well-fixed cementless tapered femoral stems.

Methods Ten matched pairs of cadaveric femurs were implanted with well-fixed and loose cementless tapered stems. The loose stem construct was obtained by appropriately broaching the femur but afterwards inserting a stem one size smaller than that broached. Femoral stem rotational stability of implanted femurs was tested by measuring the angular rotation (ie, toggle) required to produce a torque of 2 N-m at 0 N, 250 N, and 500 N vertical load in 25° adduction simulating single-legged stance. Subsidence was measured as vertical movement during the toggle tests. Then at 500 N initial vertical load, femoral stems were externally rotated to failure. The construct stiffness between 5 and 40 N-m was determined to assess ability to resist torsion. The torque and rotation to failure were recorded to compare failure characteristics. Groups were compared using mixed model ANOVA followed by Tukey–Kramer post hoc pairwise comparison for toggle and subsidence tests and by Student's paired t-tests for stiffness, torque at failure, and rotation to failure tests.

Results Loose tapered cementless stems were less stable (ie, more toggle) than well-fixed at 0 N of load ($p < 0.0001$), but no difference was detectable in toggle between loose and well-fixed stems at 250 N ($p = 0.7019$) and 500 N ($p = 0.9970$). Loose tapered cementless stems showed significant subsidence at 250 N ($p < 0.0001$) and 500 N ($p < 0.0001$), which was not found in the well-fixed stems at 250 N ($p = 0.8813$) and 500 N ($p = 0.1621$). Torsional stiffness was lower for loose stems as compared with well-fixed stems ($p = 0.0033$). No difference in torque at failure ($p = 0.7568$) or rotation to failure ($p = 0.2629$) was detected between loose and well-fixed stems.

Conclusions In this study, we observed that insertionally loose cementless stems have the ability to subside and become rotationally stable with loading. They did not

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exhibit a lower torque or rotation to failure in comparison to well-fixed stems when under simulated single-legged stance.
Clinical Relevance Secondary rotational stabilization may prevent insertionally loose tapered stems from producing a stress pattern that predisposes to early postoperative periprosthetic fracture around loose cemented stems.

Introduction

Cementless femoral stems have become the standard option in THA in the United States [3]. Cementless stems allow for biological fixation and, in one randomized controlled trial with 20 years followup, were shown to have a better survival rate as compared with cemented stems [5]. However, the relative merits and disadvantages of cemented and cementless fixation of prosthetic components in THA continue to be debated, with meta-analyses failing to show the superiority of one over the other [1, 15].

Cementless stems rely on intial stable fixation by press fit before osteointegration occurs. Although experimental studies have suggested that initial implant micromotion may lead to fibrous ingrowth, failure of osteointegration, and early loosening [11, 17], roentgen stereophotogrammetric analyses of in vivo cementless hip stems have shown that durable implant fixation can be achieved in the long term despite having initial instability that was demonstrable by subsidence [12, 13]. In a study of 240 THAs, 29% of tapered cementless stems showed initial migration of at least 1 mm during the first 2 years after implantation followed by secondary stabilization [13]. Rotational stability of the femoral stem is a commonly tested parameter during implantation of cementless femoral stems [10]. It is not known, however, if loose stems attain rotational stability with subsidence.

In addition to the potential for lack of osteointegration, another concern with a cementless stem that is loose at implantation is periprosthetic fracture. The reported incidence of periprosthetic femoral fractures around cementless stems in primary THAs has been as much as 2.6% to 5.6% in some series [18–20]. The early periprosthetic fracture rate with cementless femoral fixation is several times greater when compared with cemented femoral fixation [2]. There has been some evidence of an increasing incidence of early postoperative femoral fractures with cementless femoral stems [4].

A loose cemented stem is a known risk factor for periprosthetic fracture [9, 14]. The Swedish hip registry noted that 70% of periprosthetic femoral fractures around cemented stems were associated with preexisting femoral component loosening [14]. This was supported by a biomechanical study that showed that loose cemented femoral stems fracture at a lower torque as compared with well-fixed femoral stems when torsional forces were applied [9]. This is believed to be attributable to an altered strain pattern experienced by the femur with a loose stem. When a torsional force is applied to a loose stem, the stress experienced by the femur is likely to be greater as the force is concentrated on a smaller contact area where the loose stem contacts the femur.

We questioned whether femurs containing cementless stems that are loose at implantation experience the same mechanics as those with a loose cemented stem and thereby carry a higher risk of early postoperative periprosthetic fracture. Alternatively, these stems may subside and attain rotational stability, mitigating or avoiding the stress pattern that predisposes the construct to fracture. Accordingly, we examined the rotational stability and subsidence of vertically loaded loose cementless stems in a cadaveric model. The objectives were to determine whether insertionally loose cementless tapered femoral stems show (1) less rotational stability (more toggle); (2) more subsidence; and (3) reduced ability to resist torsion (lower initial construct stiffness), lower torque at failure, and greater rotation to failure in comparison to well-fixed cementless tapered femoral stems.

Materials and Methods

Specimens and Preparation

Ten matched pairs of cadaveric femurs (from six men and four women) harvested from fresh frozen thighs (age range, 54–85 years; mean, 67.4 years), were planned for the study. Donors had no known history of bony lesion, malignancy, or metabolic bone disease. The femoral neck bone mineral density estimated by dual energy x-ray absorptiometry ranged from 0.50 to 1.17 gm/cm^2 using Hologic® QDR-4500A (Hologic® Inc, Waltham, MA, USA). The mean neck bone mineral density for femurs tested with well-fixed and loose stems was 0.78 ± 0.20 gm/cm^2 and 0.78 ± 0.22 gm/cm^2, respectively; this difference was not statistically significant ($p = 0.69$). The fresh frozen thighs were stored at −20° C in airtight bags until testing. Each specimen was thawed at room temperature and cleared of soft tissues and then was prepared in a standard manner for accepting an FDA-approved anatomic tapered femoral stem (ABG$^{\text{TM}}$II; Stryker Inc, Mahwah, NJ, USA).

A femoral neck osteotomy was marked approximately 15 mm from the lesser trochanter using a template and performed with an oscillating saw. Each specimen then was serially reamed and broached until the broach was rotationally stable to a torque of 60 inch-pounds force (in-lbf) applied by a torque wrench through the broach handle [10]. Osteotomy of the femurs then was performed at a standard distance of 30 cm from the tip of the greater trochanter. The distal end of the specimen was fixed in a 45-mm long section of 2-inch polyvinyl chloride piping with two 1/8-inch transfixing pins and the polyvinyl chloride pipe was filled with polymethylmethacrylate. One femur of each pair was implanted with a stem corresponding to the last broach to create a well-fixed femoral stem, whereas the contralateral femur was implanted with a stem one size smaller than the last broach to create a loose femoral stem. A calcar split developed in one osteoporotic femur at the time of stem insertion and the entire pair was excluded, leaving nine pairs of femurs (from five men and four women; age range, 54–85 years; mean, 69 years) for the analysis.

Loading and Testing

The specimens were mounted on a biaxial servohydraulic testing machine (Instron® 1321; Instron® Corp, Canton, MA, USA) retrofitted with a digital control and data acquisition system (TestStar™II system; MTS® Systems, Eden Prairie, MN, USA). The specimen was mounted at an adduction angle of 25° and loaded vertically up to 500 N to simulate single-legged stance [6, 7, 21]. The center of rotation of the assembly passed through the proximal end of the prosthetic neck, approximating the center of the femoral head (Fig. 1). The specimen was controlled to 0 N vertical load initially. The toggle of the specimen was defined as the rotation necessary to produce 2 N-m torque in either direction, based on a previous study of cemented stems [9]. Three times each, specimens were rotated at 0.5° per second in both directions until 2 N-m was achieved to yield three values of the range of angular motion. Toggle was determined as ½ of the average of these three values and was recorded as a measure of rotational stability of the stem. Vertical displacement (change in vertical distance between the two holding points of the actuator) during toggling also was recorded as a correlative measure of prosthetic subsidence. The specimen then was subjected to successive vertical loads of 250 N and 500 N and the toggle at each magnitude of vertical load measured as before. The mean toggle of the stem with 500 N of vertical load was used to determine the central starting position of the stem in failure testing. With an initial load of 500 N, the femur was rotated at 90° per second to simulate external rotation of a planted foot [9]. The torque (N-m) was plotted against angular rotation (degrees) and the point at which the torque recorded a sharp decline was noted as the point of failure. The torque at failure and rotation to failure were noted. Stiffness of the construct was measured by the slope of the linear portion of the curve from 5 to 40 N-m.

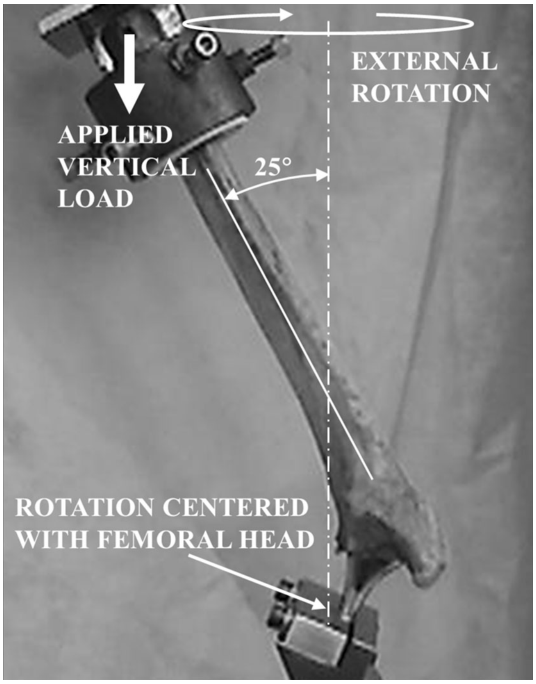

Fig. 1 The experimental setup shows a femur placed in 25° adduction to the direction of vertical loading and center of rotation passing through the estimated center of the femoral head.

Statistical Analysis

Toggle and subsidence data acquired for the loose and well-fixed stems under the three vertical loads (0, 250, and 500 N) were analyzed by mixed model ANOVA followed by Tukey–Kramer post hoc pairwise comparisons. Construct stiffness, torque at failure, and rotation to failure were compared using paired Student's t-tests. SAS® analysis software (SAS® Institute, Cary, NC, USA) was used for all analyses. Probability values less than 0.05 were considered significant.

Results

The mean toggle for the loose stems was greater than that of the well-fixed stems at 0 N load ($p < 0.0001$) (Fig. 2), whereas no difference was detected between well-fixed and loose stems in the mean toggle at 250 N ($p = 0.7019$) or 500 N ($p = 0.9970$). Load and construct type had a crossed effect on toggle ($p < 0.0001$) such that, for loose stems relative to toggle at 0 N of load, toggle decreased as load

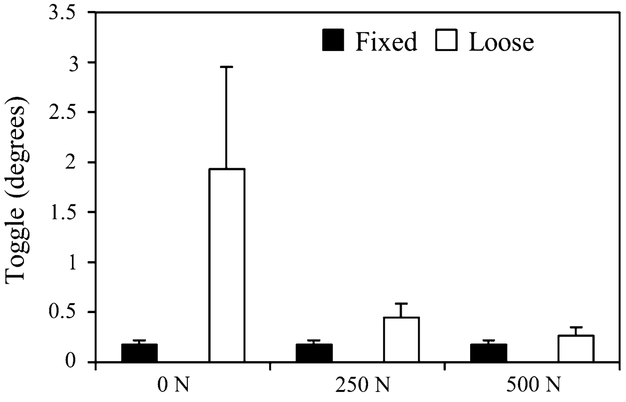

Fig. 2 Rotational stability of loose and well-fixed tapered cementless femoral stems at different levels of vertical load is illustrated. The error bars represent SD across specimens.

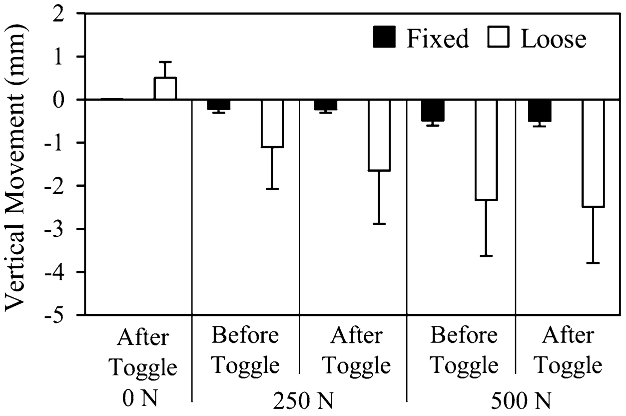

Fig. 3 The effect of vertical loading on subsidence of loose and well-fixed tapered cementless femoral stems is shown. A bar exists for the fixed stems at 0 N but the value is effectively 0. The error bars represent SD across specimens.

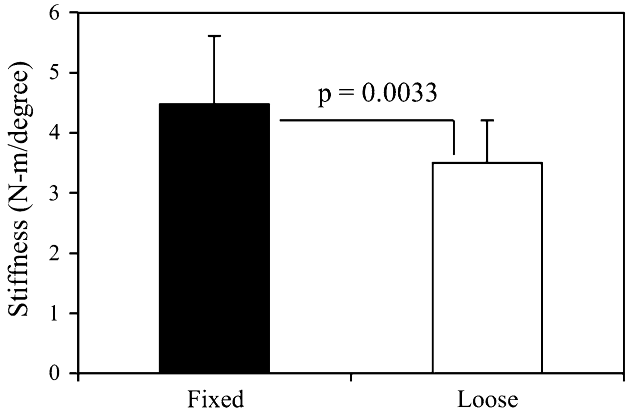

Fig. 4 Stiffness of the construct from 5 N-m to 40 N-m of torque for loose stems was lower as compared with well-fixed tapered cementless femoral stems. The error bars represent SD across specimens.

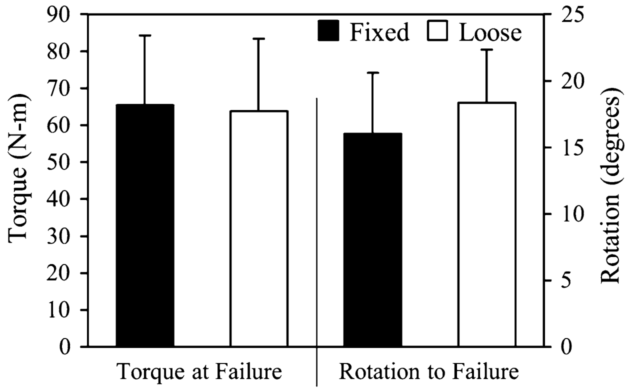

Fig. 5 Torque at failure and rotation to failure for loose and well-fixed tapered cementless femoral stems were not significantly different. The error bars represent SD across specimens.

increased ($p < 0.0001$ for 250 N and 500 N) but not for increasing load in the well-fixed stems ($p > 0.999$). No difference was detected between toggle of loose stems at 250 N and 500 N of load ($p = 0.9229$).

Vertical movement, indicating subsidence, increased relative to 0 N of vertical load for loose stems at 250 N ($p < 0.0001$) and 500 N ($p < 0.0001$) of load with the subsidence at 500 N also being greater than at 250 N ($p < 0.0001$) (Fig. 3). In contrast, the well-fixed stems did not show subsidence relative to 0 N of vertical load at 250 N ($p = 0.8813$) or 500 N ($p = 0.1621$). No difference was detected in subsidence during toggle testing between loose and well-fixed stems at 0 N ($p = 0.8086$), but loose stems had greater subsidence than well-fixed stems at 250 N and 500 N ($p < 0.0001$).

The well-fixed stems had greater stiffness as compared with the loose stems ($p = 0.0033$) (Fig. 4). However, no difference was detected between loose and well-fixed stems for the torque at failure ($p = 0.7568$, power = 5%) (Fig. 5) or the rotation to failure ($p = 0.2629$). The pattern of fracture was spiral in all cases consistent with Vancouver Type B2 fractures. The lateral cortex and greater trochanter were fractured in all but three specimens. There was no apparent difference in fracture pattern between the loose and well-fixed stems.

Discussion

A cementless stem implanted with inadequate stability may be at greater risk of early loosening [7, 11]. Another potential concern with loose stems is that of periprosthetic femoral fracture secondary to altered stress concentration [6]. We explored whether cementless stems that are loose at implantation are rotationally unstable under vertical loading conditions and therefore potentially predisposed to early periprosthetic femoral fracture. Our results revealed that insertionally loose tapered stems exhibit more toggle initially but subside with vertical loading resulting in less toggle. Although having lower construct stiffness as compared with well-fixed stems, the loose stems did not exhibit a lower torque at failure or rotation to failure when under simulated single-legged stance loading.

These results should be interpreted within the limitations of the study. First, the effect of a single static load was examined, whereas the in vivo forces on the femur are more varied and repetitive. It is impossible to replicate all in vivo forces in an in vitro experimental setup. In this study, we were interested in femoral stem stability during the early recovery period after THA. Therefore, we decided to focus on lower static loads as might be experienced during the early postoperative period, rather than the higher cyclic loads experienced during gait. A vertical load of 500 N with femur held in 25° adduction has been used in previous studies and is considered representative of single-legged stance [6, 7, 21]. We therefore selected this substantiated loading condition and 250 N to see if the effects of vertical loading were graded. We applied a torsional force to failure because Vancouver Type B2 periprosthetic femoral fractures are known to exhibit a characteristic spiral pattern [8]. Second, the addition of a vertical load to a femur loaded at 25° adduction is likely to have added a bending force in addition to the torsion applied. However, as the loose and well-fixed stems were loaded in the same manner, the resulting comparative values should measure the difference between the two groups. Third, only one type of stem was examined, namely an anatomic tapered collarless stem, and the results may not be applicable to other stem geometries. Fourth, a loose construct was created by inserting a stem one size smaller than a well-fixed broach. In clinical practice, a loose stem would likely result from failure to broach until rotational and vertical stability are truly achieved. We had to broach up to the appropriate size for a well-fixed stem to determine the size of the stem that would be loose at implantation. Fifth, during testing, the measurement of subsidence from actuator movement could be subject to small inaccuracies from bending of the construct. However, because loose and well-fixed stems were tested in an identical fashion, differences between the groups are unlikely to have been influenced by this. Finally, a post hoc power analysis revealed low power for the comparisons in which statistical significance was not detected (approximately 5% for toggle and axial comparisons, approximately 6% for torque at failure, approximately 16% for rotation to failure) and suggested that more than 50 pairs of femurs would be required to achieve 80% power for failure parameters and more than 100 pairs of femurs would be needed for axial and toggle data. Testing of such large numbers of femurs is not practical and would not change conclusions of the study if the current means and SDs stayed near their current values.

Our findings indicate that, with vertical loading, insertionally loose cementless tapered stems exhibit less toggle and therefore tend to be rotationally more stable than one might expect intraoperatively for a loose stem. Although rotational stability is a commonly tested parameter to intraoperatively judge the press fit of a cementless femoral stem, it may change with further loading of the stem. The fact that toggle was significantly different between loose and well-fixed stems at 0 N load supports the experimental method used to prepare the loose and well-fixed stems.

Insertionally loose cementless stems subsided substantially in the femoral canal with vertical loading, while well-fixed stems did not. A previous roentgen stereophotogrammetric analysis study involving 155 hips showed that 45 stems subsided more than 1 mm during the first 2 years after implantation. Of these, 33 stems stabilized after a mean subsidence of 2 mm during the first 2 years [13]. The mean axial movement in our study at 2.49 mm for the loose stems was comparable to this level of subsidence. Our results indicate that loose stems subside and attain rotational stability comparable to well-fixed stems with vertical load and support the concept of secondary stabilization of tapered collarless cementless stems. Clinical [14] and in vitro biomechanical [9] studies have shown a greater fracture risk with loose cemented stems compared with well-fixed cemented stems. Cemented stems usually cannot subside as a result of geometric differences and presence of the cement mantle, and thus do not gain secondary stabilization.

The torque at failure and rotation to failure for the cementless tapered femoral stems in our study were not found to be significantly different between loose and well-fixed stems, although the femurs with loose stems showed a lower stiffness compared with those with well-fixed stems. Although a lower stiffness has been observed to increase risk of periprosthetic fracture in prior models [9, 16], this was not observed in our study. The tendency to subside and attain secondary rotational stability likely prevents a loose tapered stem from acting as a risk factor for periprosthetic fracture despite a lower stiffness for the femurs with loose stems under lower torques. Thus, we speculate that insertionally loose cementless tapered stems may not be at greater risk of early postoperative periprosthetic fracture compared with well-fixed cementless tapered stems.

This experimental model was intended to reproduce conditions that occur during the initial placement of a cementless femoral stem. The results of our study suggest that periprosthetic fractures are unlikely the result of femoral components that are placed with residual torsional instability (ie, loose) if subsidence is allowed. It may be the result of unidentified fractures that initiated during insertion of the component.

Our study showed that tapered collarless cementless stems, which are loose at implantation, have the ability to subside and become rotationally stable in the femoral canal. Our work illustrates the mechanical aspects that allow for stabilization of an insertionally loose tapered cementless stem; our results should not be taken to interpret that all insertionally loose stems become stable with loading. Secondary rotational stabilization may prevent loose tapered stems from producing a stress pattern that predisposes to periprosthetic fracture around loose cemented stems.

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