How pilot-hole size affects bone-screw pullout strength in human cadaveric cancellous bone

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Objective: Screw failure of cancellous bone screws is not uncommon. To compare the effect of varying pilot-hole size on pullout strength of cancellous bone screws in human cadaveric bone, we designed and performed a biomechanical study to allow quantitative analysis. **Methods:** Three pairs of distal femurs and 4 pairs of proximal tibias from embalmed human cadavers were stabilized in a mould, and the bone cortex was overdrilled. Four sites in a linear transverse plane were randomly assigned, anatomically matched with the paired bone and drilled with either pilot-hole size 3.2 mm or 2.5 mm. The cancellous screw (Synthes noncannulated 4.5-mm shaft, 6.5-mm external diameter) was guided into the pilot hole and pulled on by a test frame (Instron 8874 biaxial servo-hydraulic test frame) with increasing force to the point of failure, and the forces at which failure resulted were compared. **Results:** A comparison of 25 anatomically paired sites with a 2-tailed paired t test and Wilcoxon matched-pairs signed rank test indicated significantly stronger pullout strength (p = 0.047 and p = 0.047) of the 2.5-mm compared with the 3.2-mm pilot hole. Subanalysis of the 4 studied locations indicated that 3 supported the above findings and 1 supported a reverse trend. **Conclusions:** Generally, cancellous screws demonstrated a significantly (p < 0.05) stronger hold using a smaller size pilot hole than the recommended standard diameter. All locations except the inner lateral site supported this finding.

Objectif : Il n'est pas rare que les vis d'os spongieux fassent défaut. En vue de comparer l'effet qu'ont divers diamètres de trou sur la résistance à l'arrachement de vis d'os spongieux dans des os de cadavres humains, nous avons créé et effectué une étude biomécanique permettant la réalisation d'une analyse quantitative. **Méthodes :** Trois paires de fémurs distaux et quatre paires de tibias proximaux provenant de cadavres humains embaumés ont été stabilisés dans un moule, puis on a foré les trous dans la portion corticale des os. On a réparti aléatoirement quatre sites dans un plan transverse linéaire, qui étaient jumelés anatomiquement avec l'os correspondant, et dans lesquels on a foré des trous d'essai dont le diamètre s'établissait soit à 3,2 mm, soit à 2,5 mm. Les vis d'os spongieux (tige Synthes sans canule de 4,5 mm, diamètre externe de 6,5 mm) ont été introduites dans les trous d'essai puis soumises, au moyen d'un corps d'épreuve (corps d'épreuve servo-hydraulique biaxial Instron 8874), à une force croissante jusqu'à ce qu'on parvienne au point d'arraachement. On a ensuite comparé les forces qui étaient exercées lorsque l'arrachement est survenu. **Résultats :** La comparaison de 25 sites jumelés anatomiquement au moyen du test t jumelé bilatéral et du test de Wilcoxon pour observations appariées a indiqué que le trou d'essai de 2,5 mm permettait une résistance à la rupture considérablement supérieure à celle du trou d'essai de 3,2 mm (p = 0,047 et p = 0,047). Dans la sous-analyse des quatre sites étudiés, les constatations présentées ci-dessus se sont confirmées dans trois sites, tandis que la tendance contraire a été observée dans un site. **Conclusions :** En général, les vis d'os spongieux démontraient une stabilité considérablement supérieure (p < 0,05) dans les cas où l'on avait pratiqué un trou d'essai de diamètre inférieur à l'étalon recommandé. À l'exception du site latéral interne, cette constatation était soutenue dans tous les sites.

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Cancellous bone screws are commonly used for fixation of fractures.[1,2] These screws are designed to have deep threads with a large outer diameter and thin core to increase holding power in the fine trabecular bone of the metaphysis and epiphysis.[1,3,4] Fully threaded screws are used to fasten plates in metaphyseal and epiphyseal bone, whereas partially threaded screws are used as lag screws for fragmented bone.[1] The high loads to which these screws can be subjected may lead to screw failure and pullout.[4] The risk of screw failure challenges orthopedic surgeons to obtain the optimal hold when inserting screws in cancellous bone.

Cortical bone has greater mineral density than trabecular bone, which directly correlates with screw pullout strength.[5–8] Previous research indicates that the greatest pullout resistance is obtained when the inserted screw's threads contact both the cortex through which it was inserted and the opposite cortex (bicortical purchase), creating an increase of 6 times in pullout strength.[1,9] Although bicortical purchase is the optimal hold, it is not always possible, leaving unicortical or (in the worst case) only cancellous bone purchase.

According to the AO/ASIF (Arbeitsgemeinschaft für Osteosynthesefragen/Association for the Study of Internal Fixation) technique manual, cancellous screw use requires a pilot hole to be drilled before inserting the screw.[1] A pilot hole is drilled to create a path to guide the cancellous screw and to ease its insertion.[10] A pilot hole that is too small creates increased resistance to screw insertion that may result in screw fracture, inaccurate screw insertion or fracture of surrounding bone.[1,11,12] Pilot holes that are too large decrease contact with the screw's threads, thereby decreasing pullout strength.[12] The AO/ASIF technique manual recommends that a pilot hole of 3.2 mm be drilled for a cancellous screw of 6.5-mm external, 4.5-mm shaft and 3.0-mm core diameter.[1]

The holding strength of a screw in bone correlates directly with quality of bone,[5] increased outer diameter of the threads relative to the scale of the fracture,[13–16] increased length of threads with screw purchase,[13–16] and being parallel to the trabecular pattern.[5,13] The compression of the trabeculae together during insertion of the cancellous screws leads to an increased holding strength by filling the holes of the trabeculae with compressed bone.[1,10] Assuming that the use of a decreased pilot-hole size allows more trabeculae to be compressed and fill the trabecular holes, pullout strength should increase as a result.

Many studies have compared elements of bone screws and alluded to the effects of varying pilot-hole size.[10,11,17–20] To our knowledge, no research has been published that has experimented with varying pilot-hole sizes in human cadaver bone. Synthetic bone is often selected for research because there is low intra- and interspecimen variability, the cost is low, and it can be easily obtained and stored.[2] The polyurethane foam of synthetic bone is a homogeneous material with a uniform matrix pattern that is unlike the true trabecular pattern of bone.[10] Studies in synthetic bone were unable to prove a statistically significant benefit of reducing pilot-hole size.[10,19]

The purpose of this study was to determine if a smaller pilot hole than the standard recommended size would offer greater pullout strength. This study used human cadaveric bone, as recommended by Oketenoglu and colleagues,[10] instead of synthetic bone, and determined if there was a statistically significant difference that has not yet been found in similar research of varying pilot-hole sizes studied in synthetic bone. This hypothesis was based on the supposition that a smaller sized pilot hole allows more compression of trabeculae and fill between the holes.[10,16]

Methods

Seven pairs of bone were harvested from 4 human cadavers embalmed in potassium acetate dissolved in water, formaldehyde, phenol, Dettol, glycerin and 95% ethyl alcohol. The sex and ages in years of the cadavers at the time of death were: male, 62 years; male, 75 years; female, 78 years; and male, 82 years. Soft tissues were removed, and 4 pairs of tibias and 3 pairs of femurs were labelled and kept moist. They were held in sealed occlusive containers at 4°C in a refrigerating unit until studied. The anterior surface of proximal tibias and distal femurs was used to study the cancellous bone in the metaphysis.

The femurs and tibias were sawn in half through the transverse plane. Each anatomic pair (e.g., left and right proximal tibia) was held in an aluminum frame. Then 70°C Cerrobend (Cerro Metal Co., Bellefonte, Penn.) (a bismuth alloy that melts at 70°C) was poured around the bone and quickly solidified by cooling to 4°C with a water cooling bath. The diaphyseal shaft of the bone was submersed in the Cerrobend, and the anterior metaphyseal surface remained exposed. A holding screw was inserted through the diaphysis to allow the bone to be held in position for approximately 5 minutes until the Cerrobend had set (Fig. 1).

Four locations were selected for pilot-hole sites in a line along the metaphysis, approximately 2 cm from the lateral and medial cortex and with approximately 1.5 cm between each site. The mounting apparatus holding the bones was clamped on a drill press. The drill press was used to overdrill the cortex and drill the pilot holes. A 9-mm diameter drill was used to overdrill the cortex to expose the underlying cancellous bone in each location. Overdrilling ensured the cortex would not influence the pullout strength of the cancellous bone. A coin was tossed to randomly assign the pilot hole to be drilled in each site on one bone. In one bone, after 2 holes of the same diameter were selected, the remaining sites were automatically assigned to the other diameter to ensure an equal sample size. The anatomically paired bone had the alternate pilot hole drilled in the anatomically matched location (e.g., if the left tibia's most lateral pilot hole was randomly assigned a 3.2-mm diameter, the right tibia's most lateral pilot hole was assigned a 2.5-mm diameter). The bones used had an anterior–posterior width of less than 40 mm, and pilot holes were drilled to a depth of 30 mm below the overdrilled cortex.

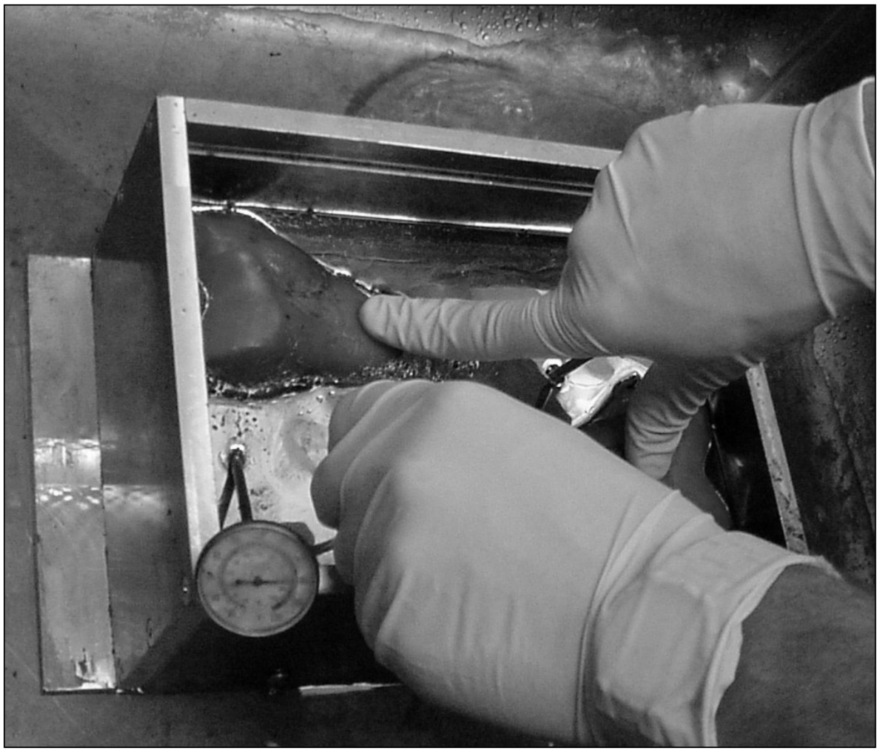

FIG. 1. Pair of distal femurs held in the aluminum frame containing 70°C Cerrobend (Cerro Metal Co.) with the anterior metaphysis exposed while cooling in a water bath to set the Cerrobend.

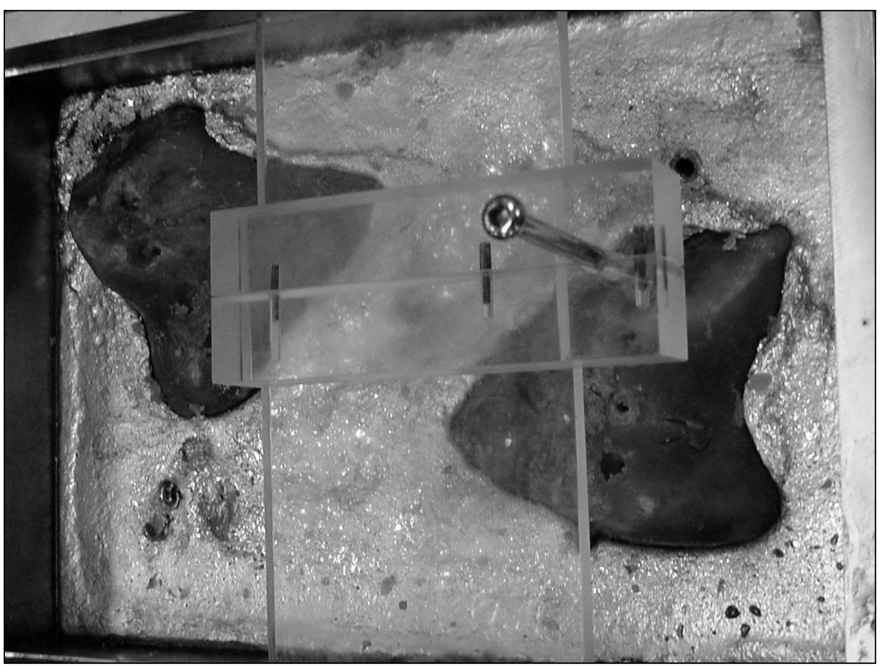

FIG. 2. Pair of distal femurs set in Cerrobend with the pilot holes drilled and a screw in position to be inserted in the same plane as the servohydraulic test frame pulls the screw until failure.

The cancellous screw used in this study was a 6.5-mm cancellous screw (noncannulated, 115-mm long, partially threaded 16-mm threads, 4.5-mm shaft, 6.5-mm external diameter and 3.0-mm internal diameter; Synthes, Monument, Colo.). A clear plastic guide was designed and placed on the surface of the aluminum mounting system. The guide was engineered to ensure that each screw was inserted in the same plane as the pilot hole was drilled and the screw pulled out (Fig. 2). The screw was inserted into 20 mm of cancellous bone, below the overdrilled cortex. After pullout, the bone fragments were cleaned from between the screw's threads, and the screw was inserted into the next pilot hole. The same researcher inserted all of the screws. This method of screw insertion allowed the effect of varying the pilot hole to be studied without the influence of screw purchase in opposing cortex or trabeculae not pre-drilled.

The mounted bone was secured to the base of the test frame allowing movement in 2 horizontal planes so the exact position could be achieved. A designed jig was secured to the test frame and lowered into position to firmly encase the head of the screw. The pulling force on the screw rose under load control at a constant ramp of 10.0 N, starting at 0.0 N until failure of the screw to withstand the applied force, at which point the supporting trabeculae sheared and the screw was rapidly removed from the bone. Data recorded from the 7 pairs of bone, each with 4 anatomically pilot hole trial locations, were analyzed by 2-tailed paired t test and Wilcoxon matched-pairs signed rank tests to determine significance ($p < 0.05$ was considered significant).

Results

In 25 anatomically matched pairs, the servohydraulic test frame ramped until failure occurred. At failure, the screw was sheared from the bone, pulling the trabeculae compressed between the screw's threads from its surrounding trabeculae. In 3 tests, screw extraction was not properly recorded because of failure to start the recording of data, insecure mounting of the aluminum bone to the test frame and improper programmin of the material testing system's ramping force.

Data from the trials in both the femur and tibia were collapsed into a single group and organized by locations as follows: extreme lateral, inner lateral, inner medial and extreme medial. The maximum load values achieved before failure were anaylzed to compare the effects on the 2.5-mm and 3.2-mm diameter pilot holes.

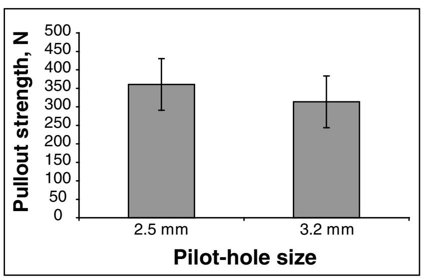

FIG. 3. Mean pullout strength from all trials in the distal femur and proximal tibia (360.6 N for the 2.5-mm-diameter hole and 313.5 N for the 3.2-mm-diameter hole). Error bars indicate the standard errors of the means.

Comparison of the pullout strength for all anatomically matched pairs by 2-tailed paired t test and Wilcoxon matched-pairs signed rank test indicated a significant ($p = 0.047$ and $p = 0.047$) difference (Fig. 3). The standard error of the means for the 2.5-mm pilot-hole sites was 73.8 N and for the 3.2-mm pilot hole sites was 67.4 N. The difference between the 2 means was 47.1 N (95% confidence interval [CI] 0.53–93.7 N).

The effect of a 2.5-mm compared to 3.2-mm pilot hole on pullout strength for each of the 4 locations was analyzed with a Wilcoxon matched-pairs signed rank test (Table 1). Results indicated a significant ($p = 0.027$) difference at the extreme lateral location; there was no significant difference for the other 3 locations (Table 1). Pullout strength at the extreme lateral, inner medial and extreme medial locations challenge the findings in the literature that a 3.2-mm pilot hole provides stronger pullout strength than the 2.5-mm pilot hole. Pullout strengths at the inner lateral location support a reversed trend, in which the 3.2-mm pilot hole provides stronger pullout strength than the 2.5-mm pilot hole.

Comparison of pullout strengths in the tibia relative to the femur with a Wilcoxon signed rank test revealed no significant difference between the 2 groups ($p = 0.75$). Trials in the femur and tibia demonstrated pullout strength means of 381.2 N and 312.7 N and standard error means of 87.5 N and 49.2 N, respectively.

Extreme lateral and medial pullout strengths were compared with pullout strengths of the inner lateral and medial positions for both the tibia and femur. The extreme lateral and medial locations mean was 502.4 N and standard error mean was 83.54 N. The inner lateral and medial locations mean was 156.5 N and standard error mean was 24.27 N. Analysis of the pullout strengths at the extreme compared with inner locations with a Wilcoxon signed rank test indicated a significant difference ($p < 0.001$); a t test also indicated a significant difference ($p < 0.001$).

Discussion

The standard recommendation when using a 6.5-mm cancellous screw is to drill a 3.2-mm diameter pilot hole before inserting the screw.[1] The proven effect of compressing the trabeculae during insertion of the cancellous screws, leading to increased holding strength by filling the holes of the trabeculae with compressed bone,[1,10] incited the hypothesis that a decreased pilot hole would create increased pullout strength of the cancellous screw. This hypothesis was accepted ($p = 0.047$) by our data comparing 25 anatomically matched sites of 2.5-mm with 3.2-mm diameter pilot holes. Analysis of all locations (extreme medial, inner medial, inner lateral, extreme lateral) as a single group indicates a statistically sig-

Table 1

Pullout strengths for the distal femur and proximal tibia analyzed by location*

	Location; pilot-hole size, mm							
	Extreme lateral		Inner lateral		Inner medial		Extreme medial	
Pullout strength	2.5	3.2	2.5	3.2	2.5	3.2	2.5	3.2
Mean pullout strength, N	582.1	418.8	107.4	163.8	188.2	160.5	528.5	493.3
Standard deviation, N	249.4	215.8	26.1	54.9	165.2	157.3	579.3	594.0
Range, N	285.7–908.7	202.3–751.7	74.7–138.5	104.1–251.3	79.6–516.2	55.1–477.0	158.1–1649.4	104.1–1644.5
p value†	0.027‡		0.075§		0.080‡		0.075‡	

*Six pairs studied at each location
†Wilcoxon matched-pairs signed rank test
‡Based on positive ranks.
§Based on negative ranks.

nificant generalized approach favouring a 2.5-mm pilot hole's association with an increased pullout strength. This trend was not statistically significant at every location, and a reverse trend was found at 1 of the 4 locations (inner lateral).

The significant increase in holding strength resulting from the reduction of pilot-hole size demonstrated in this study, as opposed to the previous research, may be attributed to the use of human cadaver bone. This study's findings differ from those of previous research in synthetic bone.[2,4,10,11,16,19–21] Synthetic material cannot replicate the true trabecular structure and therefore cannot demonstrate the benefits of compressing the trabeculae.[10] In addition to differences between synthetic and cadaver bone, there are further changes that affect screws inserted to living bone.

The beneficial effect of compressing the cancellous bone's trabeculae has been proven to have a greater effect in vivo by causing hypertrophy and realignment of the trabeculae in line with the force.[18,22] This suggests that a reduced pilot-hole size could result in more compression causing further hypertrophy and realignment, resulting in increased pullout strength. We could not study these beneficial effects in this cadaveric study, but they would likely further support the greater strength provided by a smaller pilot hole.

The pullout strengths in the condylar region were 3.2 times greater than those found in the intercondylar cancellous bone, a statistically significant difference ($p < 0.001$). These results may have resulted from variations in bone density within specimens. Supporting Wolff's law, research has concluded that varus or valgus deformity in the knee can result in increased bone density and strength on the side that is more compressed.[23–25] The cadavers in this study were not assessed for varus or valgus demormities, and additionally dual photon and dual energy x-ray absorptinometry was not done to analyze the specimens. Without such data, we cannot determine the cause of variations among locations. This study focused on comparison between the 3.2-mm and 2.5-mm pilot hole for a 6.5-mm cancellous screw, and in doing so anatomically paired each trial to account for variations among cadavers and among locations.

Location affected both the magnitude of pullout strength and the effect of the pilot-hole size. Indicated in Table 1 is a trend of decreasing magnitude of pullout strength of the most beneficial pilot-hole size causing a decrease in benefit of the 2.5-mm relative to the 3.2-mm pilot hole. The greatest mean pullout strength of either pilot hole at each location decreases from greatest at the extreme lateral position to the extreme medial, inner medial and inner lateral locations. Analysis with the Wilcoxon matched-pairs signed rank test indicated the same descending order of locations, with a trend of greatest influence ($p = 0.025$) for the 2.5-mm pilot hole to benefit the pullout strength, to a reversed trend of the 3.2-mm pilot hole insignificantly ($p = 0.08$) providing greatest pullout strength. These trends imply that the cancellous bone is capable of producing greater pullout strength and benefited most from the smaller pilot-hole size. It is possible that the intercondylar trabeculae are fractured by the reduced pilot-hole size, resulting in a decreased pullout strength, as opposed to the condylar trabeculae which may be compressed by the smaller pilot-hole size, resulting in increased pullout strength. Researchers have thought that not tapping cancellous bone provides greater pullout strength because compression of the trabeculae causes greater holding power.[1,4] The benefits this compression has in trabeculae may not be uniform owing to the varying properties of trabeculae that allow a greater chance of fracture with compression.

It should be noted there are large variations in the standard error means and standard deviations throughout this study. These large variations may be attributed to differences among cadavers. Similar large variations were found among the properties of bone in previous studies of stress, strain and pullout strength.[26] Bone density research found larger variations in the intercondylar region than in the condyles, which may support the reverse trend in this study favouring a 3.2-mm pilot hole in the inner lateral location.[24]

This study has a number of possible limitations: first, limited access to bone decreased the number of pilot holes that could be compared. Limited availability of cadaver bone restricted the variation of pilot holes to the standard 3.2 mm and the smaller 2.5 mm. Second, the bone was subjected to 70°C temperatures for approximately 5 minutes. This temperature could have altered the bone's composition. We attempted to control the temperature's effect by exposing all pairs of bone to the same temperature for the same amount of time. Third, anterior–posterior insertion of the screws may not replicate the common planes of insertion in the knee of lateral–medial or medial–lateral. This could have an impact, as the alignment of the screw relative to the trabeculae contributes to its holding power. Although analysis with a Wilcoxon signed rank test supports no significant difference ($p = 0.75$) between the proximal tibia and distal femur pullout strength trials, there are likely differences in the trabeculae of these bones that contribute to variation in our data. Finally, the preservatives in which the cadavers were stored may have altered the trabeculae. Aldehyde has been shown to increase collagen crosslinks but not alter bone's mineral structure; formalin has been shown to have little, if any, effect on the mechanical properties of bone; and glycerine, 95% ethyl alcohol, phenol and water have not been shown to have a significant effect.[27,28] Since the literature does not support the challenge that preservatives would significantly alter the bone's structure, they likely had little effect.

Further research on varying pilot-hole size should be done to find the optimal size. This study simply showed that the standard recommended size of 3.2 mm is not the optimal size, and we cannot tell if an even smaller or perhaps larger pilot hole would be optimal. Additional research into the effect of varying pilot-hole size with in vivo animal bone would allow the current results in human cadaveric bone to be verified. Ultimately, additional research is needed to identify which pilot-hole size is optimal for each screw size.

Competing interests: None declared.

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