Reduction of Pullout Strength Caused by Reinsertion of 3.5-mm Cortical Screws

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Introduction: Osteosynthesis of the tibia, tibial plafond, and calcaneus is commonly performed with plates and 3.5-mm self-tapping cortical screws. Screw insertion and reinsertion within the same hole in the bone may occur during surgery. Therefore, the purpose of this study was to evaluate the pullout strength of 3.5-mm self-tapping screws with up to 5 re-insertions in the diaphysis of the tibia, metaphysis of the distal tibia, calcaneus, and a polyurethane synthetic bone model.

Methods: Screws were inserted into a synthetic bone model and 5 pairs of human cadaveric diaphyseal tibiae, distal tibiae, and calcanei. The bone was predrilled, and then 3.5-mm cortical self-tapping 316 L stainless steel screws with a washer were inserted bicortically. Screws were inserted from 1 to 5 times at each location. The screws were grasped and subjected to 5-mm/min tensional force via the biaxial material testing systems machine. Statistical significance was determined using a paired 2-tailed *t* test.

Results: There was a significant difference in the pullout strength of the tibial diaphysis (1710 ± 550 N), tibial metaphysis (471 ± 266 N), and calcaneus (238 ± 90 N; $P < 0.01$). The tibial diaphysis pullout strength was 1710 ± 550 N for one insertion differing significantly relative to the groups with 4 (average 1030 ± 543 N, $P = 0.004$) or 5 (average 364 ± 209 N, $P < 0.001$) insertions. The tibial metaphyseal pullout strength for the single insertion group was 471 ± 266 N and differed significantly relative to the 3 ($P = 0.026$), 4 ($P = 0.044$), and 5 ($P = 0.042$) insertion groups. The calcaneal pullout strength for the single insertion group was 238 ± 90 N with a significant difference of the 1, 3, and 4, versus the 5 insertion group ($P = 0.027$, 0.040, and 0.033, respectively). The synthetic bone model pullout strength decreased significantly from the one insertion group relative to all other insertion groups (group 1, 1167 ± 263 N; group 2, 768 ± 199 N; group 3, 694 ± 295 N; group 4, 662 ± 356 N; and group 5, 154 ± 183 N; $P < 0.02$).

Conclusions: There is a significant decrease in relative pullout strength of 3.5-mm self-tapping cortical screws when comparing the tibial diaphysis, tibial metaphysis, and calcaneus. There is also a significant decrease in 3.5-mm self-tapping screw pullout strength after repeated reinsertions in the synthetic bone model, mid-shaft tibia, metaphyseal tibia, and calcaneus. We recommend that during osteosynthesis, careful screw insertion, and minimal reinsertion be performed.

Key Words: screw pullout strength, screws, stainless steal screws, self-tapping screws, biomechanics, osteoporosis, cadaveric study, fracture, osteosynthesis

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INTRODUCTION

Osteosynthesis is commonly performed with plates and 3.5-mm self-tapping screws.[1–16] During the insertion of screws, there may be errors in screw placement technique.[17] It has been our experience that screw reinsertion within the same hole in the bone can happen for reasons such as performing a re-reduction of fractured fragments, changing screw lengths, and manipulating plate position. One previous porcine rib study illustrated no difference in the pullout strength of reinserted screws.[18] However, the porcine rib is a flat bone that is not mechanically or clinically similar to human tubular diaphyseal bone such as the tibia or the metaphyseal area of the tibial plafond and calcaneus. Therefore, we proposed a biomechanical study to evaluate the effect of screw reinsertion on pullout strength of 3.5-mm self-tapping screws. Up to 5 reinsertions in the diaphysis of the tibia, metaphysis of the distal tibia, calcaneus, and a polyurethane synthetic bone model were tested.

MATERIALS AND METHODS

Synthetic Bone Model

Screws were inserted into a synthetic bone model (Pacific Research Labs, Vashon, WA) to a thread depth of 39.5 mm, leaving the screw heads proud 10 mm to engage the pulling apparatus and the screw tip at least 2 mm past the opposite side of the polyurethane. The polyurethane foam selected for testing had a density of 0.32 g/cm^3, compressive strength of 8.4 megapascals (MPa) compressive modulus of 210 MPa, tensile strength of 5.6 MPa, tensile modulus of

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284 MPa, shear strength of 4.3 MPa, and shear modulus of 49 MPa, values close to cancellous bones.[17,19] According to ASTM F-1839-08, "standard specification for rigid polyurethane foam for use as a standard material for testing orthpaedic devices and instruments" states that: "The uniformity and consistent properties of rigid polyurethane foam make it an ideal material for comparative testing of bones screws and other medical devices and instruments.[20]"

Cadaveric Specimens

Five pairs of fresh frozen and then thawed distal tibiae, ankles, and feet were dissected of all soft tissues the same day as biomechanical testing. The specimens were potted in rigid Polymethylmethacrylate at the proximal tibia and held in place on the material testing machine base (material testing systems (MTS) 858 Mini Bionix, MTS GmbH, Berlin, Germany). Screws with washers were inserted into the tibial shaft, tibial metaphysis, and calcaneus. The specimens were rigidly held to prevent motion using clamps on either side of the screw that was being pulled out (Fig. 1).

Anatomic Sites

There were 3 anatomic sites used for experimentation. All screws were placed bicortically with the tip of the screw at least 2 mm past the opposite cortex. Tibial diaphyseal cortical screws were placed at least 8 cm proximal to the tibial plafond. Screws were inserted in standard arbeitsgemeinschaft für osteosynthesefragen (AO) fashion from lateral to medial parallel to the lateral face of the tibia at the mid-face location. Distal tibia metaphyseal screws were placed anterior to posterior 1 cm proximal to the distal tibia articular surface and not farther then 3 cm from the articular surface. There were 2 rows of screws. One row of 3 screws 1 cm from the ankle joint surface and the second row of screws 8 mm proximal to the distal row. Calcaneal screws were inserted from lateral to medial in hexagonal patterns at least 1 cm from the posterior and distal ends of the calcaneus. The screw reinsertion number location was rotated so that there were variable but consistent screw locations among specimens. That is, because there were 5 pairs of cadaver specimens (10 specimens in all), each screw location was used twice for each reinsertion group. All screws were placed using standard operative techniques at 8 mm intervals as described previously.[18]

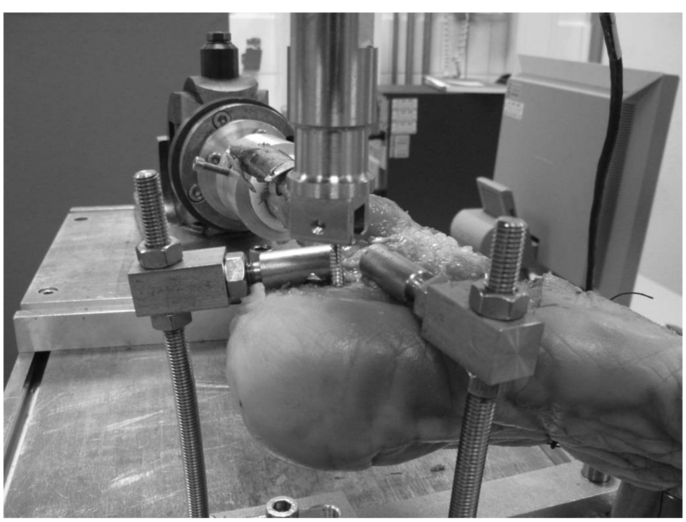


FIGURE 1. Photograph depicting a specimen securely potted into a clamp and held by jig to avoid movement.

Screw Insertion

All holes for screw insertion were predrilled with a 2.5-mm drill bit. Screws [3.5 mm cortical self-tapping 316 L stainless steel Synthes (Paoli, PA) with a washer] were inserted using a 2.5-mm hexagonal screwdriver by a fellowship trained orthopaedic traumatologist. Each inserted screw was placed so that the distal tip was proud at least 2 mm. Washers were used to allow for distribution of force on the screw head, self centering, and multiaxial vector pull along the custom made capturing device as described previously.[17]

Experimental Groups

There were 5 groups in each anatomical site and synthetic bone (Fig. 2). Each group consisted of 10 specimens. Each specimen had 1 screw inserted as described below. All of the groups used 3.5-mm cortical self-tapping screws.

Group 1 had screws inserted once and then tested for pullout strength. Group 2 had screws inserted once, removed, and then reinserted and then tested for pullout strength. Group 3 had screws inserted once, removed, and then reinserted 2 times and then tested for pullout strength (total of 3 insertions). Group 4 had screws inserted once, removed, and then reinserted 3 times and then tested for pullout strength (total of 4 insertions). Group 5 had screws inserted once, removed, and then reinserted 4 times and then tested for pullout strength (total of 5 insertions). All screws were placed free hand by a fellowship-trained orthopaedic traumatologist to mimic surgical insertion. The screw lengths were at least 2 mm longer than the total width of the bone or synthetic model.

Mechanical Testing

The specimens and synthetic bone were secured to the servohydraulic material tester table. The screw washers were grasped and subjected to increased uniaxial tensional force at a constant rate via the biaxial materials testing system machine at a rate of 5 mm/min.[17]

Statistical Analysis

Means and standard deviation were calculated. Statistical significance was determined using t test (2-tailed, paired). A value of $P < 0.05$ was considered significant. Each specimen's contralateral side was used as a control. We also compared the pullout strength of the group with initial insertion (no reinsertion) in each anatomical site to the other anatomical sites. A priori power analysis was performed with G*Power 3.1.2 software to compute required sample size with given effect size of 1.3, alpha error probability of 0.05, power of 0.95 with 2-tailed t test resulting in actual power of 0.954 and of total sample size of 10 needed.

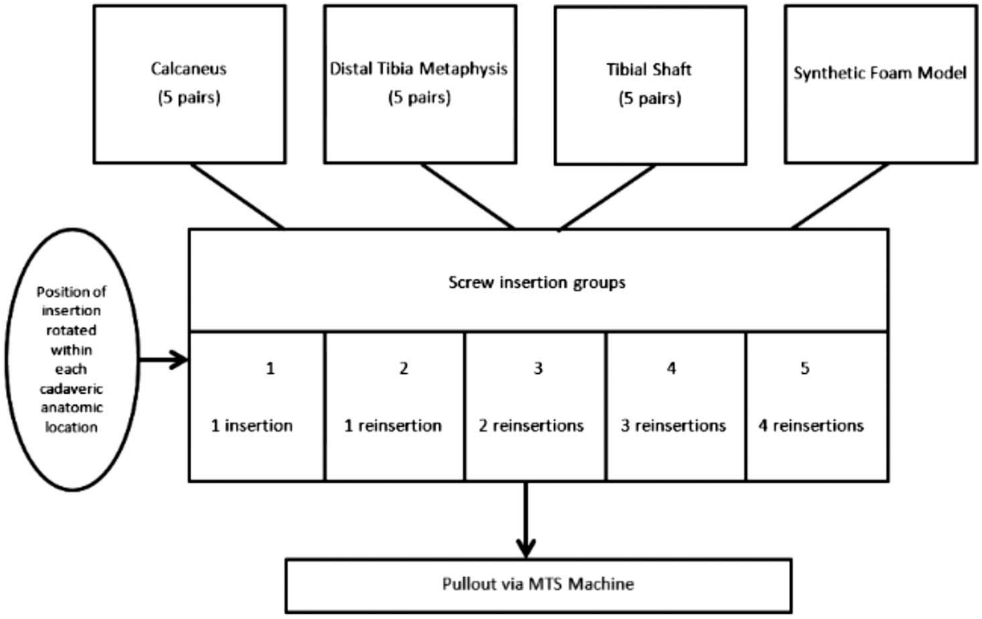


FIGURE 2. Flow diagram illustrating the experimental groups (see Methods).

RESULTS

A total of 180 3.5-mm self-tapping cortical screws were utilized for pullout testing. Failure occurred in the screw to bone interface in all cases. There was local failure around the screw with acute loss of fixation in all specimens.

Synthetic Bone Model

The synthetic bone model had 6 rows of screws with insertion of 1 to 5 times for a total of 30 screws. The screws failed at the screw to synthetic bone model interface. There was local collapse of the polyurethane foam surrounding the screw threads. There was no gross propagation of the screw hole at failure more than 2 mm in any direction. Pullout strength testing of the synthetic bone model of the 3.5 cortical self-tapping cortical screws was variable depending on the number of insertions (Fig. 3). The average pullout strength for the single insertion group was 1167 ± 263 N with coefficient of variation (CV) of 0.23. There was a significant decrease in pullout strength from the 1 insertion group relative to all of the other insertion groups. There was also a marked increase in the CV (average 154 ± 183 N, CV 1.2) and significant decrease pullout strength between the 5 insertions group and all other groups.

Comparing Anatomic Sites

There was a significant difference in the pullout strength of the tibia diaphysis (1710 ± 550 N, CV 0.32), tibia metaphysis (471 ± 266 N, CV 0.56), and calcaneus (238 ± 90 N, CV 0.38) with 1, 2, 3, and 4 screw insertions when comparing each of the anatomic locations. There was no significant difference in pullout strength between the tibial metaphysis and calcaneus or the tibial diaphysis and tibial metaphysis after the fifth screw insertion.

Tibial Diaphysis

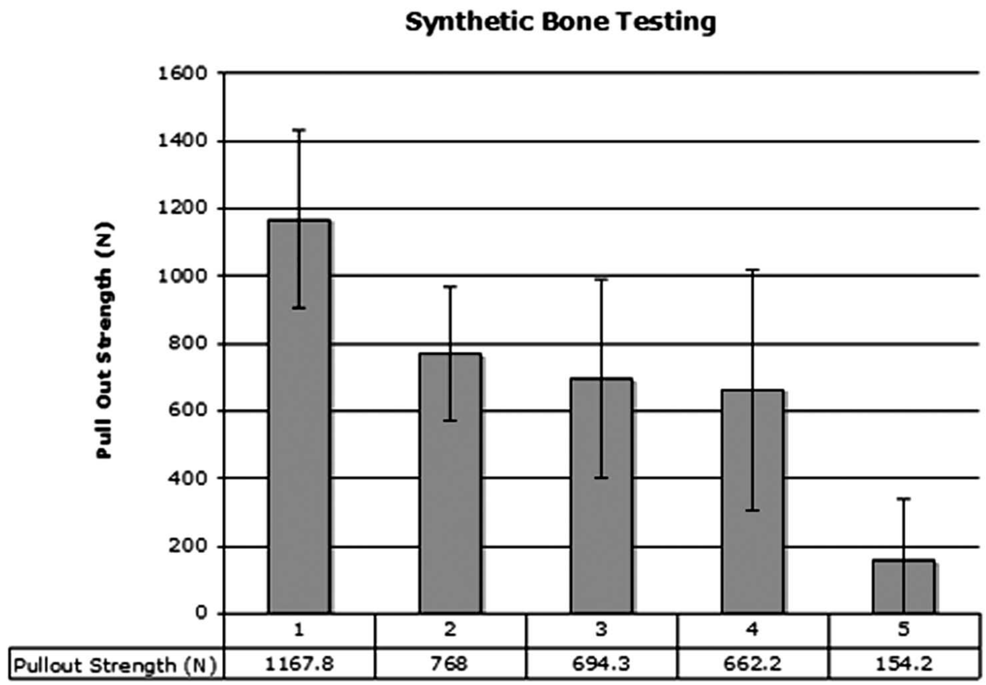
There were 5 pairs of tibial diaphyseal bone used for testing screw pullout strength with a total of 50 screws tested. The failure mechanism was catastrophic failure at the bone screw interface with local splintering of the bone. There was propagation of the fractured bone that was no more than 3 mm in any specimen. The average pullout strength of all screws regardless of number of insertions was 1160 ± 643 N. Pullout strength testing of the tibial diaphysis was variable depending on the number of insertions (Fig. 4). The average pullout strength for the single insertion group was 1710 ± 550 N. There was a significant difference between the single screw insertion group versus the groups with 4 (average 1030 ± 543 N, CV = 0.53 $P = 0.004$) or 5 (average 364 ± 209 N, CV = .574, $P < 0.001$) insertions.

Tibial Metaphysis

There were 5 pairs of tibial metaphysis bones used for testing screw pullout strength with a total of 50 screws tested. The failure mechanism was catastrophic failure at the bone screw interface without local splintering of the bone. There was no propagation of the fractured bone more than 2 mm in any specimen. The average pullout strength of all screws regardless of number of insertions was 393 ± 223 N. Pullout strength testing of the tibial metaphysis was variable depending on the number of insertions. The average pullout strength for the single insertion group was 471 ± 266 N (Fig. 5). There was a significant difference of the single insertion group relative to the 3 ($P = 0.025$), 4 ($P = 0.044$), and 5 ($P = 0.036$) insertion groups. There was also a significant difference between the 2 and 5 insertions groups ($P = 0.042$). However, there was no significant difference between any of the other screw insertion groups.

Calcaneus

There were 5 pairs of calcaneus bones used for testing screw pullout strength with a total of 50 screws tested. The failure mechanism was catastrophic failure at the bone screw interface without local splintering of the bone. There was no propagation of the fractured bone more than 1 mm in any



Number of Screw Insertions	P value Pullout 1 vs	P value Pullout 2 vs	P value Pullout 3 vs	P value Pullout 4 vs
2	0.014			
3	0.015	0.62		
4	0.024	0.55	0.87	
5	<0.001	<0.001	0.004	0.014

FIGURE 3. Pullout strength of 3.5-mm self-tapping screws in a synthetic bone model relative to the number of screw insertions with table outlining number of screws insertions and their relative *P* values when compared with each other.

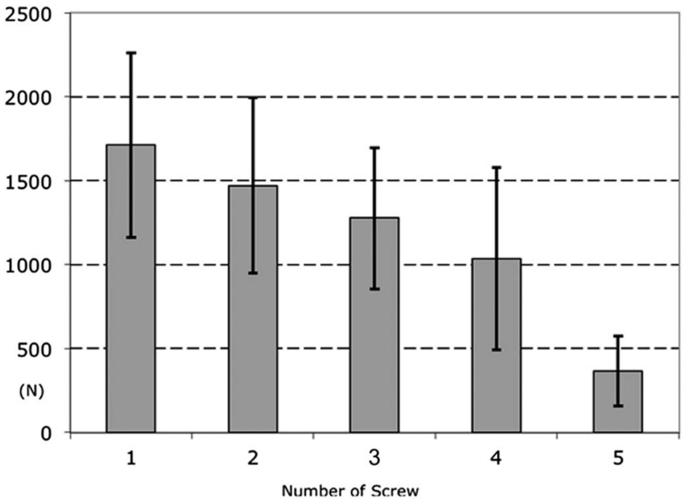
specimen. The average pullout strength of all screws regardless of number of insertions was 230 ± 113 N. Pullout strength testing of the calcaneus was variable depending on the number of insertions (Fig. 5). The average pullout strength for the single insertion group was 238 ± 90 N. There was a significant difference between the 1, 3, and 4 screw insertion groups versus the 5 insertion group (P = 0.027, 0.040, and 0.033, respectively).

DISCUSSION

Reinsertion of screws during fracture fixation is commonly performed in our experience. This study illustrates that significant loss of pullout strength occurs after the second reinsertion (third insertion) of a 3.5-mm cortical screw in the same predrilled hole in metaphyseal bone. Screw reinsertion in diaphyseal bone also showed a significant decrease in pullout strength during the fourth screw insertions.

There have been several authors that previously evaluated the pullout strength of screws during different conditions.[17,18,21–25] Only one study evaluated the effect of repeated insertion of one to 3 times.[18] The authors studied 3.5 mm pretapped screws in the porcine rib and found that there were no differences in pullout strength when repeatedly reinserting the screws up to 3 times.[18] This model is in the flat bone porcine model with thin cortices and would have a different geometry than the mid-shaft tibia, metaphyseal tibia, or calcaneus. In another study that investigated the pullout strength of screws in the canine femoral model, the authors assert in the discussion that self-tapping screws inserted into the same hole up to 12 times at 80 percent of their torque out value had the same push out resistance.[25]

This study found significant differences when reinserting the 3.5-mm self-tapping screws in the synthetic bone model and in the tibial diaphysis. Because pullout strength of a screw is related to both the bone density and the screw design, we chose to use 3.5-mm self-tapping cortical screw in



Number of Screw Insertions	P value Pullout 1 vs	P value Pullout 2 vs	P value Pullout 3 vs	P value Pullout 4 vs
2	0.22			
3	0.061	0.10		
4	0.019	0.033	0.087	
5	< 0.001	< 0.001	< 0.001	0.006

FIGURE 4. Pullout strength testing of 3.5-mm cortical screws in the tibial diaphysis relative to number of screw insertions with table of associated *P* values when comparing the pullout strength of number of screw insertions in each group.

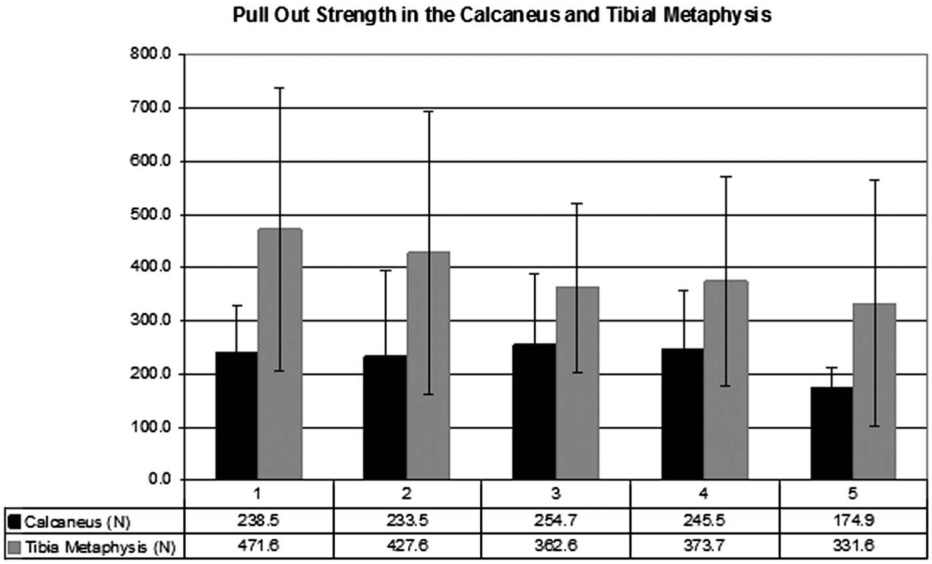
all tested locations to be more consistent between groups. Evaluation of the synthetic bone illustrated that there is a significant decrease in pullout strength from the first insertion to all other reinsertions. Because the density of the synthetic bone is uniform, we expected it to emulate homogeneous metaphyseal bone. We chose metaphyseal emulating synthetic material to imitate a density of bone that is between tibial diaphysis and metaphyseal bone. The advantage of using synthetic bone was in having decreased coefficient of variability of the first insertion group. However, the pullout strength variability increased with subsequent insertion to the point of being comparable to the cadaveric specimens. This finding illustrates that the variability in pullout strength is a result of insertion technique coupled with a lower density material. In cadaveric tibial metaphyseal bone, a significant decrease in pullout strength was seen from the third reinsertion and beyond. This study also found that there was a significant difference between the first insertion and fifth insertion in all anatomic locations. However, this finding in not be clinically relevant in most cases because five reinsertions are a rare occurrence. In cases where there are repeated insertions of a 3.5-mm cortical screw into the same hole, we suggest changing to a different location if possible. The difference in results between our study and the previous studies can be explained by the difference in bone models and by the insertion technique. In the previous studies, a special jig was devised to insert the screws. However, in our study, we tried to simulate the clinical situation by inserting each screw in a free-hand manner by a fellowship trained orthopaedic traumatologist. Technical factors that lead to differences in pullout strength can be attributed to slight changes in the angle of insertion and removal of the screw, causing stripping of the bone threads and change in bone hole morphology.

Screws inserted in different locations in the body have differences in screw pullout strength due to variable bone density and architecture. We found that the diaphyseal bone of the tibia has more than 3-fold increase in pullout strength relative to the metaphyseal tibia and more than 7-fold increase pullout strength relative to the calcaneus. The metaphysis of the tibia has a 2-fold increase in pullout strength relative to the calcaneus.

There are factors that influence the failure of fixation not tested in this study. These factors include insertion torque, bone density, screw length within the bone, and screw design. Previously, screw design has been shown to affect screw insertion torque but not pullout strength.[26] However, the influence of reinsertion of screws on insertion torque has not been studied previously and may be the subject of future research.

This study has some limitations. The local bone density within each specimen may not be consistent. We tried to minimize this limitation by utilizing 5 pairs of specimens and a synthetic bone model. We also tried to address this problem by placing screws in the metaphysis of the tibia equidistant from the ankle joint surface. Another limitation of this study is that there are only 10 screws at each anatomic location (5 pairs). When placing screws in the mid-tibia or distal tibial metaphysis, there was enough of a difference in pullout strength to achieve significance. However, in the calcaneus, we could not illustrate differences in pullout strength between the first though fourth reinsertions. This may be due to the fact that the differences in pullout strength are small, the standard deviation is large, and as the bone density decreases, the overall pullout strength decreases. The phenomenon of decreased bone density with increased standard deviation of pullout strength in cadaveric bone has been described previously and is a limitation of this study as applied to the distal tibia and calcaneus.[21] Moreover, although all screws were placed bicortically, different bone diameter and length of screw within the cadaver tissue dictated different screw lengths within the bone. As a result, this may have influenced the ultimate pullout strength and its standard deviation. Another limitation of the study could have been the technique of insertion of the screws. Because the screws were placed by the surgeon and not via a mechanical apparatus, there may have been inconsistency in screw insertion technique. Therefore, we may have had an increase in pullout strength standard deviation from specimen to specimen if the insertion of the screws was performed by hand and not by an apparatus. However, we chose this technique to simulate the intraoperative situation where the surgeon is placing the screw into the bone by hand and without an apparatus.

In summary, this study demonstrated significant decrease in 3.5-mm self-tapping screw pullout strength with reinsertions in the same predrilled hole. This effect was more pronounced



Tibial Metaphyseal Number of Screw Insertions	P value Pullout 1 vs	P value Pullout 2 vs	P value Pullout 3 vs	P value Pullout 4 vs
2	0.17			
3	0.025	0.17		
4	0.044	0.12	0.40	
5	0.036	0.042	0.33	0.11

Calcaneal Number of Screw Insertions	P value Pullout 1 vs	P value Pullout 2 vs	P value Pullout 3 vs	P value Pullout 4 vs
2	0.44			
3	0.33	0.21		
4	0.41	0.35	0.40	
5	0.026	0.16	0.040	0.033

FIGURE 5. Pullout strength testing of 3.5-mm cortical screws in the distal tibial metaphysis and calcaneus relative to number of screw insertions with table of associated *P* values when comparing the pullout strength of number of screw insertions in each group.

in high-density bone. This study also illustrates that avoidance of more than 2 reinsertions in the distal tibial metaphysis could minimize an iatrogenic decrease in pullout strength of screws.

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