M any veterinary orthopedic procedures require the use of screws placed into cancellous bone for osteosynthesis. Such procedures may involve epiphyseal and metaphyseal regions (eg, the femoral head, femoral condyles, and proximal and distal portions of the tibia) or be a component of fixation applications in juvenile bone, the pelvis, and vertebrae. These placed screws are subject to complex multiaxial cyclic loading, which may lead to screw loosening.1–6 Screw loosening may result in secondary loss of reduction, leading to delayed union, malunion, nonunion, and implant failure with screw pullout.1–9 The design of cancellous bone screws, with a greater thread depth and decreased cross-sectional thickness of the threads, allows for compression of the trabeculae during insertion of the screw. This compression leads to an increase in the holding strength as the holes in the trabeculae are filled with compressed bone, resulting in hypertrophy and realignment of the trabeculae in line with the force.10–12

The axial pullout strength of screws, defined as the tensile force needed to extract the intact screw from the bone or other materials, is determined by the ability of the bone to equilibrate tension in the screw core with a cylindrical surface of shearing stress corresponding to the outer diameter of the screw threads.8,9,13–16 Primary factors affecting pullout strength are the quality and shear strength of the bone, major diameter of the screw, and the length of engagement of the thread.8,13,17 These primary factors affect load transfer at the thread-bone interface and determine the mean shear stress in the surrounding bone. However, because the shear force is not uniform, the geometry of the interface is also affected by local reaction forces and structural stresses due to secondary factors including thread profile, pilot hole dimensions, and tapping.12–15,18,19

In general, insertion of a non–self-tapping bone screw requires drilling a pilot hole that is slightly (0.1 mm) larger than the core diameter of the screw. However, the Arbeitsgemeinschaft für Osteosynthese-Fragen (AO) and manufacturer recommendation for insertion of 4.0-mm cancellous screws is to drill a pilot hole that is 2.5 mm in diameter (ie, approx 25% greater than the core diameter [1.9 mm] of the screw).20 Pi-

Effect of pilot hole diameter and tapping on insertion torque and axial pullout strength of 4.0-mm cancellous bone screws

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Objective—To evaluate the effects of pilot hole diameter and tapping on insertion torque and axial pullout strength of 4.0-mm cancellous bone screws in a synthetic canine cancellous bone substitute.

Sample—75 synthetic cancellous bone blocks (15 blocks/group).

Procedures—For groups 1 through 5, screw size-pilot hole diameter combinations were 3.5-2.5 mm (cortical screws), 4.0-2.5 mm, 4.0-2.5 mm, 4.0-2.0 mm, and 4.0-2.0 mm, respectively. Holes were tapped in groups 1, 2, and 4 only (tap diameter, 3.5, 4.0, and 4.0 mm, respectively). One 70-mm-long screw was inserted into each block; in a servohydraulic materials testing machine, the screw was extracted (rate, 5 mm/min) until failure. Mean group values of maximum insertion torque, axial pullout strength, yield strength, and stiffness were determined.

Results—Mean maximum insertion torque differed significantly among the 5 groups; the group 5 value was greatest, followed by group 3, 4, 2, and 1 values. Group 3, 4, and 5 axial pullout strengths were similar and significantly greater than the group 2 value; all values were significantly greater than that for group 1. Group 5 and 4 yield strengths were similar and significantly greater than the group 3, 2, and 1 values. Stiffness in group 3 was similar to group 4 and 2 values but significantly greater than the group 5 value; all values were significantly greater than that for group 1.

Conclusions and Clinical Relevance—These synthetic cancellous bone model findings suggested that tapping a 2.0-mm-diameter pilot hole when placing a 4.0-mm screw is the optimal insertion technique. (Am J Vet Res 2011;72:1660–1665)
lot holes that are too small create increased insertion torque, which may lead to screw failure, inaccurate screw insertion, or fracture of the surrounding bone.\textsuperscript{10} Drilling a larger pilot hole effectively reduces insertion torque at the expense of thread depth and available trabecular bone for the cancellous screw to compress, resulting in decreased holding strength.\textsuperscript{10,18} Although several studies\textsuperscript{10,18,21} have revealed that decreasing pilot hole size results in increased pullout strength, other studies\textsuperscript{12,22–24} did not find a significant increase in pullout strength as a result of reducing pilot hole size.

Pilot hole size also affects insertion torque. The goal of screw insertion is to convert applied torque into tension. Applied torque can be divided into the torque needed to cut threads, torque needed to overcome thread friction, and useful torque.\textsuperscript{16} Increasing the pilot hole size may result in too little thread being cut into the bone, thereby decreasing holding strength.\textsuperscript{12} Conversely, insertion of a screw into a smaller pilot hole may lead to increasing levels of torque, resulting in plastic deformation and mechanical failure of the bone or screw.\textsuperscript{18,21} Tapping of the pilot hole decreases insertion torque by eliminating the thread cutting torque requirement, providing thread channels, and decreasing heat generated at the distal end of the screw and also limiting deformations such as microfractures in the surrounding bone.\textsuperscript{18,21,22,23,26} However, studies\textsuperscript{22,31,32} on the effects of pilot hole tapping on axial pullout strength in biological and synthetic material have shown variable results.

The purpose of the study reported here was to evaluate the effects of pilot hole diameter and tapping on insertion torque and axial pullout strength of 4.0-mm cancellous bone screws in a synthetic canine cancellous bone substitute. A group of 3.5-mm cortical bone screws inserted in standard fashion was included to demonstrate the mechanical performance of 3.5-mm screws in a cancellous bone model, confirm the predicted lower axial pullout strength of cortical screws in this model, and provide another group for comparison with the 4.0-mm screw groups (groups 2 through 5). Group 2 had a screw size, pilot hole diameter, and tap diameter of 4.0, 2.5, and 4.0 mm, respectively. Group 3 had a screw size and pilot hole diameter of 4.0 and 2.5 mm, respectively, and no tap. Group 4 had a screw size, pilot hole diameter, and tap diameter of 4.0, 2.0, and 4.0 mm, respectively. Group 5 had a screw size and pilot hole diameter of 4.0 and 2.0 mm, respectively, and no tap. All blocks were prepared by a single investigator (KARK).

Each block was inserted into a custom-designed centering jig to facilitate accurate centering and perpendicular placement of the drill holes. A drill press\textsuperscript{1} set at 700 revolutions/min, which simulated a standard surgical drill,\textsuperscript{4} was used to drill the pilot holes in all bone blocks. A new drill bit\textsuperscript{1} was used for each group of blocks. All drill holes in the tapped groups were tapped by hand with a new tap\textsuperscript{1} for each group of blocks. In each block, one 70-mm-long screw\textsuperscript{1} was inserted, by hand, by use of a torque-recording screwdriver\textsuperscript{1} until 2 threads exited the trans surface.\textsuperscript{32} The torque was recorded at the end of each hand rotation for each screw in each block in each group; mean maximum insertion torque for each group was determined by calculating the mean of the maximum torque measurements for all screw-block units in the group.

Each screw-block unit was mounted to the load cell of a servohydraulic materials testing machine\textsuperscript{4} with a custom-made jig base and distraction bar designed to ensure only axial pull on the screw (Figure 1). A preload of approximately 1 N was applied to each screw prior to the start of the test. The screws were extracted by use of displacement control at a rate of 5 mm/min according to published standards until failure.\textsuperscript{33} Load and displacement data were collected at 10 Hz by use of commercial software.\textsuperscript{1} Failure was defined as the shearing of a column of polyurethane foam by the screw, failure of the polyurethane foam block, or mechanical failure of the screw. Axial pullout strength was determined from the load-displacement data as the point of maximum load during the test. The yield point was determined by use of the 0.1% slope offset criteria applied to the linear region of the load-displacement curve.\textsuperscript{34} A least squares mean linear regression line with an $R^2$ value $\geq 0.9$ was determined in the linear region of the curve. Data points were added to the regression line in the yield region of the curve until the $R^2$ value decreased by $\geq 0.1$; the final point added was considered the yield point (ie, the point at which the slope decreased by a standard amount of $\geq 0.1$). Stiffness was calculated as the slope of the initial least squares mean linear regression line.

**Materials and Methods**

Synthetic cancellous bone blocks (40 X 130 X 180 mm) composed of synthetic rigid polyurethane foam\textsuperscript{a} (density, 0.32 g/cm$^3$) were cut by use of a table saw\textsuperscript{b} and power miter box\textsuperscript{c} into smaller (30 X 30 X 40-mm) blocks to fit the testing apparatus. The blocks were randomly assigned to 1 of 5 groups (15 blocks/group). For each group, the screw size and type, pilot hole diameter, and tap size (when applicable) varied. Group 1 had a screw size, pilot hole diameter, and tap diameter of 3.5, 2.5, and 3.5 mm, respectively; these screws were cortical screws and were evaluated to demonstrate the mechanical performance of 3.5-mm screws in the cancellous bone model, confirm the predicted lower axial pullout strength of cortical screws in the model, and provide another group for comparison with the 4.0-mm screw groups (groups 2 through 5). Group 2 had a screw size, pilot hole diameter, and tap diameter of 4.0, 2.5, and 4.0 mm, respectively. Group 3 had a screw size and pilot hole diameter of 4.0 and 2.5 mm, respectively, and no tap. Group 4 had a screw size, pilot hole diameter, and tap diameter of 4.0, 2.0, and 4.0 mm, respectively. Group 5 had a screw size and pilot hole diameter of 4.0 and 2.0 mm, respectively, and no tap. All blocks were prepared by a single investigator (KARK).

Each block was inserted into a custom-designed centering jig to facilitate accurate centering and perpendicular placement of the drill holes. A drill press\textsuperscript{1} set at 700 revolutions/min, which simulated a standard surgical drill,\textsuperscript{4} was used to drill the pilot holes in all bone blocks. A new drill bit\textsuperscript{1} was used for each group of blocks. All drill holes in the tapped groups were tapped by hand with a new tap\textsuperscript{1} for each group of blocks. In each block, one 70-mm-long screw\textsuperscript{1} was inserted, by hand, by use of a torque-recording screwdriver\textsuperscript{1} until 2 threads exited the trans surface.\textsuperscript{32} The torque was recorded at the end of each hand rotation for each screw in each block in each group; mean maximum insertion torque for each group was determined by calculating the mean of the maximum torque measurements for all screw-block units in the group.

Each screw-block unit was mounted to the load cell of a servohydraulic materials testing machine\textsuperscript{4} with a custom-made jig base and distraction bar designed to ensure only axial pull on the screw (Figure 1). A preload of approximately 1 N was applied to each screw prior to the start of the test. The screws were extracte...
procedure. Values of \( P < 0.05 \) were considered significant for all hypothesis tests.\(^{35} \)

**Results**

Mode of failure for all constructs was shearing of a column of polyurethane foam. No screws or blocks failed during screw insertion or pullout. The mean maximum insertion torque, axial pullout strength, yield strength, and stiffness for each group were calculated and compared (Table 1).

Maximum insertion torque was significantly \( (P < 0.001) \) different among all groups. Group 5 had the greatest maximum insertion torque, followed in descending order by groups 3, 4, 2, and 1. Insertion torque profiles were similar to those previously reported.\(^{11} \)

![Figure 1](image-url)

**Table 1**—Mean ± SD maximum insertion torque, axial pullout strength, yield strength, and stiffness for bone screws inserted into blocks of a synthetic canine cancellous bone substitute.

<table>
<thead>
<tr>
<th>Group (n = 15 screw-block units/group)</th>
<th>Maximum insertion torque (Nm)</th>
<th>Axial pullout strength (N)</th>
<th>Yield strength (N)</th>
<th>Stiffness (N/mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>0.21 ± 0.05(^*)</td>
<td>1,373.02 ± 67.7(^a)</td>
<td>1,165.48 ± 64.5(^a)</td>
<td>2,259.9 ± 83.8(^a)</td>
</tr>
<tr>
<td>2</td>
<td>0.56 ± 0.1(^a)</td>
<td>1,660.9 ± 97.7(^b)</td>
<td>1,181.95 ± 93(^b)</td>
<td>2,573.62 ± 118.4(^b)</td>
</tr>
<tr>
<td>3</td>
<td>0.74 ± 0.08(^c)</td>
<td>1,799.6 ± 102.7(^c)</td>
<td>1,222.29 ± 80.5(^c)</td>
<td>2,613.55 ± 156.7(^c)</td>
</tr>
<tr>
<td>4</td>
<td>0.67 ± 0.04(^d)</td>
<td>1,754.4 ± 48.7(^d)</td>
<td>1,308.26 ± 69.9(^d)</td>
<td>2,575.6 ± 67.9(^d)</td>
</tr>
<tr>
<td>5</td>
<td>0.93 ± 0.03(^e)</td>
<td>1,767 ± 30.9(^e)</td>
<td>1,338.15 ± 104.7(^e)</td>
<td>2,505.45 ± 190.6(^e)</td>
</tr>
</tbody>
</table>

One screw was inserted into each block by use of a torque-recording screwdriver. Cortical bone screws were used in group 1, and cancellous bone screws were used in groups 2 to 5. Group 1 had a screw size, pilot hole diameter, and tap diameter of 3.5, 2.5, and 3.5 mm, respectively. Group 2 had a screw size, pilot hole diameter, and tap diameter of 4.0, 2.5, and 4.0 mm, respectively. Group 3 had a screw size and pilot hole diameter of 4.0 and 2.5 mm, respectively, and no tap. Group 4 had a screw size, pilot hole diameter, and tap diameter of 4.0, 2.0, and 4.0 mm, respectively. Group 5 had a screw size and pilot hole diameter of 4.0 and 2.0 mm, respectively, and no tap. Each screw was extracted (rate, 5 mm/min) until failure in a servohydraulic materials testing machine.

\(^*\) Within a column, values with different superscript letters are significantly \( P < 0.05 \) different.

with the greatest torques occurring as the screw penetrated the trans surface of the synthetic bone block.

Groups 3, 4, and 5 had significantly \( (P < 0.001) \) higher values for axial pullout strength than groups 1 and 2. Groups 2 through 5 had significantly \( (P < 0.001) \) greater axial pullout strength, compared with findings for group 1.

Yield strengths in groups 4 and 5 were significantly \( (P < 0.001) \) higher than the values in groups 1, 2, and 3. Stiffness in group 3 was similar to group 4 and 2 values but significantly \( (P = 0.017) \) greater than the group 5 value; all values were significantly \( (P < 0.001) \) greater than that for group 1.

**Discussion**

The Arbeitsgemeinschaft für Osteosynthesefragen (AO) and screw manufacturers recommend drilling a 2.5-mm-diameter pilot hole and preparation with a 4.0-mm-diameter tap prior to insertion of a 4.0-mm screw in cancellous bone. Because screw pullout is a potential mode of failure for screws placed in cancellous bone, maximizing the holding strength of the screws and minimizing insertion factors such as torque reduce the chance for screw or bone failure and are important to maximize the stability of osteosynthesis. Bone is a nonlinear, viscoelastic, anisotropic, and heterogeneous material that has the ability to adapt continually to metabolic and environmental changes in vivo. As a result, it can be difficult to analyze mechanically.\(^ {1,4,36} \) To gain statistically relevant data, large numbers of cadaveric samples are needed because of differences in size, shape, age, bone mineral density, preservation techniques, and anatomic variations, even among matched bone pairs from the same animal.\(^ {36,37} \) Thus, cadaveric bone cannot be considered a uniform test medium.\(^ {4} \) In addition, acquisition, handling, and transport of cadaveric specimens can involve considerable financial, ethical, and biohazard issues.

Synthetic bone blocks, representative of cancellous bone, have been accepted as a substitute for cadaveric bone to provide a uniform testing material and control for the inherent variations in composition and mineral density when reproducibility of experiments is required.\(^ {4,8,36–39} \) Compared with can-
cancellous bone, polyurethane foam is microstructurally similar in terms of volume fraction, trabecular spacing, trabecular number, and connectivity density; and its mechanical properties such as compressive modulus, compressive strength, and pullout strength compare favorably. The density of polyurethane foam (0.32 g/cm³) and the similarity of its structural and material properties to those of canine cancellous bone have been previously validated. The material properties of more sophisticated bone models, such as third-generation composites with synthetic cortices, have also correlated well with those of cadaveric bone. The size of the synthetic bone blocks used in the present study was chosen to mimic a clinical situation, such as the proximal tibial metaphysis in a medium- to large-breed dog. Although bone cortices likely play a role in increasing axial pullout strength in the epiphysis or metaphysis in vivo, synthetic cortices were not used in the present study to eliminate any contribution of the cortices to cancellous holding strength. In most instances, strength of fixation is dependent on the combined strength of the cancellous bone and the cortical bone. However, it has been shown in human cadaveric bones with cortices < 1.5 mm in thickness that cortical thickness has no significant influence on axial pullout strength. The long thread engagement length in the model used in the present study also diminishes the contribution of cortices to pullout indices. Therefore, it is unlikely that addition of cortices to the model would significantly affect axial pullout strength or yield strength; however, this supposition would need to be confirmed via mechanical testing. Insertion torques would likely be increased by the addition of cortices, especially in the tapped groups. However, in the tapped groups, pilot hole preparation should reduce or eliminate the thread-cutting requirement and therefore should not significantly increase insertion torque.

Clinically, the screws applied in groups 1 through 4 in the present study are commonly used for osteosynthesis in areas of predominantly cancellous bone. The group of 3.5-mm cortical bone screws inserted in standard fashion (group 1) was included in the study to demonstrate the mechanical performance of 3.5-mm screws in this cancellous bone model, confirm the predicted lower axial pullout strength of cortical screws in the model, and provide another group for comparison with the 4.0-mm screw groups. Predictably, the screws inserted in the group 1 blocks performed poorly in the synthetic canine cancellous bone substitute.

In the present study, the screws were tapped and inserted by hand to mimic clinical situations. New drill bits and taps were used for each group of blocks to eliminate potential errors caused by dulling of drills or taps. Insertion torques recorded during testing were all lower than the torque reported to result in screw failure. All the constructs yielded force-displacement curves and modes of failure typical of axial pullout tests.

Axial pullout strength is related to the primary factors of thread geometry and material shear strength according to the following formula:

\[ F_p = S \cdot A_p = (S \cdot L \cdot \pi \cdot D_{major}) \cdot TSF \]

where \( F_p \) is the predicted shear failure force (N), \( S \) is the ultimate shear stress (MPa), \( A_p \) is the thread area (mm²), \( L \) is the length of thread engagement in material (mm), \( D_{major} \) is the major diameter of the screw (mm), and \( TSF \) is thread shape factor (0.5 + 0.57735 \cdot \text{thread depth (mm)/thread pitch (mm)}). Thread depth (mm) is \( D_{minor} - D_{major} \)/2, where \( D_{minor} \) is the minor (root or core) diameter (mm) of the screw.

This equation would predict that, in a homogenous material with a fixed length of axial thread engagement, axial pullout strength would be dependent primarily on the major diameter of the screw, the thread depth, and the thread pitch. An increase in the major diameter and thread pitch, such as that achieved by use of a cancellous screw instead of a cortical screw, should result in greater axial pullout strength. Furthermore, increasing the effective thread depth by decreasing pilot hole diameter should also increase axial pullout strength.

Consistent with this equation, the present study revealed significantly greater axial pullout strength and yield strength of 4.0-mm cancellous screws in the synthetic canine cancellous bone substitute used, regardless of pilot hole preparation, compared with insertion of 3.5-mm cortical bone screws. The study results also indicated that the axial pullout strengths of 4.0-mm screws inserted into 2.0-mm-diameter tapped or untapped pilot holes and 4.0-mm screws inserted into untapped 2.5-mm-diameter pilot holes were greater than that of 4.0-mm screws inserted into tapped 2.5-mm-diameter pilot holes. Drilling the larger 2.5-mm-diameter pilot hole results in the removal of more material, such that when the hole is tapped with a 4.0-mm-diameter tap, less bone is available for compression, thereby decreasing axial pullout strength. It has also been suggested that, clinically, tapping of the pilot hole beyond the initial cortex is unnecessary for insertion of cancellous screws into soft bone. Indeed, insertion of 4.0-mm cancellous screws into untapped 2.5-mm-diameter holes is commonly practiced. This idea is reflected in the data obtained in the present study, in that the axial pullout strengths of 4.0-mm screws inserted into untapped 2.5-mm-diameter holes were not significantly different from the values for 4.0-mm screws inserted into tapped or untapped 2.5-mm-diameter holes. However, insertion torque was significantly greater for 4.0-mm screws inserted into the untapped 2.5-mm-diameter holes than those inserted into the tapped 2.0-mm-diameter holes. Minimization of insertion torque is important to maximize torque conversion to tension and to decrease microdamage to the surrounding bone, which could result in screw loosening or failure of the bone. YIELD strength corresponds to the elastic limit of a material. Loads applied in excess of the yield strength result in irreversible material failure and, consequently, loss of pullout strength, especially with subsequent cycles of loading. The yield strength corresponds to the end of the linear part of the load-deformation curve and represents the point at which the screw-bone interface starts to fail. As a result, this value is more clinically relevant than axial pullout strength. In the present study, yield strength was significantly greater for 4.0-mm screws inserted into tapped or untapped...
2.0-mm-diameter pilot holes than for screws in all other constructs. However, 4.0-mm screws placed into untapped 2.0-mm-diameter pilot holes also had significantly higher insertion torque than did the screws in the other constructs. Although no screws or blocks failed during insertion, insertion of a 4.0-mm screw into an untapped 2.0-mm-diameter pilot hole or an untapped 2.5-mm-diameter pilot hole was subjectively more difficult than were screw insertions in the other constructs. This was especially true of the 4.0-mm screws inserted into untapped 2.0-mm-diameter holes. Insertion of 4.0-mm screws into either untapped 2.0-mm-diameter pilot holes or untapped 2.5-mm-diameter pilot holes resulted in greater hand fatigue and visible deformation of the screws, compared with findings for the other constructs. As stated earlier, this increased insertion torque would likely result in increased microfracturing of the surrounding bone and reduce the amount of torque available for axial compression. Furthermore, as suggested previously, the presence of bone cortices would likely amplify this effect, potentially resulting in failure of the screw or bone. However, this supposition is beyond the scope of the study, and research involving a composite bone model or cadaveric bone would be necessary to evaluate this further. Tapping of the 2.0-mm-diameter pilot holes with a 4.0-mm-diameter tap did not significantly reduce axial pullout strength or yield strength in the present study; thus, tapping reduced the insertion torque without affecting pullout or yield strength. These findings are consistent with other reported findings of a reduction in insertion torque with tapping.16,22,29,32

Stiffness data represent the material properties of a test material and a screw–test material composite.4 The stiffness is determined when the screw is being driven through the test material and therefore represents a value beyond the point of what would be considered clinical failure. It would be expected that all the constructs in the present study would have had similar stiffness values. Interestingly, group 1 stiffness was significantly less than values in the other groups. Group 3 stiffness was significantly greater than that in group 5, but values in groups 2 and 4 were not significantly different from the values in groups 3 and 5. In the case of group 1, this difference was likely due to the fact the screw–test material construct was, in fact, less stiff than the other constructs given the poor performance of the 3.5-mm screws in cancellous bone as predicted by the axial pullout strength equation. The difference between stiffnesses in groups 3 and 5 was possibly due to test material damage as a result of the higher torques less than that associated with the insertion of screw in an untapped 2.5-mm-diameter pilot hole, which is commonly practiced, nor did it exceed reported values for screw failure. Because yield point is the most clinically relevant variable, the results of the present study have suggested that use of a tapped 2.0-mm-diameter pilot hole should be considered when placing a 4.0-mm screw in cancellous bone.

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