Introduction: Traditionally, pedicle screws have been designed with a single pitch thread. These designs are conventionally optimized for insertion within either the cortical or cancellous bone. However, screw insertion usually results in the shaft residing in both cortical and cancellous bone. A pedicle screw possessing a dual-threaded design could then potentially provide better fixation than a single-threaded design by taking advantage of both vertebral bone densities. The hypothesis for this study was that a dual-threaded pedicle screw would exhibit superior mechanical characteristics to a single-threaded design.

Materials and Methods: A bovine calf model from T11 to L4 was employed to reduce the effects of specimen variability. For each vertebral body, a dual-threaded (DT) and single-threaded (ST) screw (Figure 1) was inserted into each pedicle in a randomized fashion. Insertion torques and extraction torques were measured for bilateral insertions using a calibrated torque wrench. The remaining screws were subjected to mechanical testing. Six vertebral bodies were assigned to static tensile testing, resulting in perpendicular pull-out of the screw with respect to the screw insertion axis. A total of 12 additional vertebral bodies were subjected to toggle fatigue in a similar configuration to the static test. These vertebral bodies were subsequently tested in either straight pull-out or perpendicular pull-out. Static tests were conducted at 25 mm/min with data acquisition at 20 Hz. Toggle testing consisted of sinusoidal loading between ±340 N to 2600 cycles at 0.5 Hz. Fatigue load and displacement data was collected at 100-cycle intervals.

For insertion, extraction, and static testing, a Student’s t-test was used to infer statistical differences in mechanical performance between the two screw designs. For toggle fatigue tests, the total deflection at each 100-cycle interval was computed for each screw type and subsequently averaged. The resulting average deflection at each interval was then subjected to a non-linear regression to compute mean deflection versus the number of cycles applied.

Results: Insertion and Extraction Torques:
Mean peak insertion torques for the DT and ST screws were 5.88 Nm and 3.69 Nm, respectively. The mean peak extraction torque for the DT screw was 4.30 Nm, as compared to the mean peak ST screw extraction torque of 2.61 Nm. For both insertion and extraction torques, the DT screws possessed significantly higher mean values (P<0.05).

Static Testing:
No statistical differences (P>0.05) were detected between the DT and ST screw designs for maximum load to failure in either the pre-toggled or post-toggled test sets.

Toggle Fatigue Testing:
The non-linear analyses of each screw type resulted in an exponential fit with r² values and half-lives of 0.995 at 1375±74 cycles and 0.99 at 1235±93 cycles for the ST and DT screws, respectively. The fitted curves possessed a similar growth to approximately 1505 cycles. At this point, the ST curve increased at a greater rate than the DT curve, indicative of greater toggle for the ST screw (Figure 2).

Discussion: While the static tests did not elucidate differences in pull-out strength between the two screw designs, the toggle fatigue testing revealed that beyond approximately 1500 cycles the DT screw displayed a reduction in toggle deflection rate and subsequently a decreased net deflection. It has been proposed that the average individual will perform approximately 5,000 post-op gait (or toggle) cycles in the first two weeks.1 Using this data and the fact that a patient undergoing surgery would not completely fuse in the first three months, a difference of 50% in deflection would occur at 12,100 cycles, or 4-5 weeks post-operative. The effects upon healing and fusion rate using a dual-threaded screw design at this point are unknown. However, assuming that a less toggling rod-screw construct would lead to an increased fusion rate, the fatigue data presented in this study suggest that the dual-threaded design could aid in a more stable construct.

The new dual-threaded screw design possessed significantly greater (59%) insertion torques and extraction torques (64%). No statistical differences were evident between the screws in static pull-out. However, the DT screw did provide improved toggle resistance. Future in vitro studies could utilize human cadaver models, which generally possess lower bone densities and smaller cortical walls than bovine vertebrae. These changes in vertebral properties could enhance the advantages of the DT screw and represent a more realistic population of surgical patients. Ultimately, though, clinical data with respect to fusion rate will provide the definitive clinical validation for this design.