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ORIGINAL ARTICLE - RESEARCH

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Ex vivo biomechanical comparison of four Center of Rotation Angulation Based Leveling Osteotomy fixation methods

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Abstract

Objective: To compare the strength of four constructs used to secure an osteotomy in a Center of Rotation Angulation (CORA)-Based Leveling Osteotomy (CBLO) in an ex vivo model.

Study design: Ex vivo study.

Sample population: Thirty-two canine tibiae from 17 skeletally mature cadavers weighing between 18 and 33.2 kg.

Methods: Thirty-two paired tibiae with patella and patellar tendon were collected. Each tibia was randomly allocated to a construct group: plate and pin (Plate), plate with countersink compression screw (HCS), plate with tension band (TB), or plate with HCS and TB (HCSTB). Samples were loaded by distraction until failure. The stiffness, yield load, and ultimate load were compared between each fixation method.

Results: No difference in stiffness of the constructs was detected between groups ($p = .6937$). Yield load for the HCSTB group (1211.06 N) was greater than the TB group (1016.41 N), the HCS group (907.20 N), and the Plate group (787.73 N) ($p = .0069$). The ultimate load for the HCSTB group (1387.82 N) was greater than the TB group (1076.36 N), HCS group (926.62 N), and the Plate group (774.35 N) ($p = .0004$).

Conclusions: CBLO fixation augmented with a TB and HCS provided a stronger construct that withstood a greater yield load and ultimate load than either augmentation strategy alone.

Clinical significance: Augmenting a CBLO fixation with a TB and a HCS can provide increased construct strength.

1 | INTRODUCTION

Center of rotation and angulation (CORA)-based leveling osteotomy (CBLO) is one of the available osteotomy procedures performed to address cranial cruciate ligament rupture.[1]

A benefit to the CBLO compared to a tibial plateau leveling osteotomy (TPLO), is a larger proximal tibial segment that allows for ancillary stifle stabilization methods. Current recommendations for CBLO fixation involve use of a bone plate and a headless compression screw (HCS). Recently, the suggestion has been made to further augment the fixation with the addition of a tension band (TB) in conjunction with the bone plate and HCS.[2] There have been no previous biomechanical evaluations of the stability of the CBLO fixation methods. It is unknown if similar biomechanical stability could be achieved in a CBLO construct secured by a plate alone, or a plate and tension band. This information would be valuable to aid the surgeon in limiting the number of implants used to only those required to achieve similar stability to avoid excess surgical implant cost, minimize surgical time, and minimize surgical trauma.

The objective of this study was to compare the biomechanical properties (stiffness, ultimate load, and yield load) of four constructs used to secure an osteotomy following a CBLO in an ex vivo model and identify mode of failure for each fixation method. We hypothesized that the CBLO plate with headless compression screw and tension band would provide the strongest construct.

2 | MATERIALS AND METHODS

2.1 | Cadaveric samples

Tibiae with patella and patellar tendons were collected from canines euthanized at a local humane society for reasons unrelated to this study. Study inclusion criteria were a body weight of 18-35 kg to and radiographically confirmed skeletal maturity. Tibiae with open physes or osseous abnormalities noted on preoperative planning radiographs were excluded. An alphabetic label was assigned to each limb as each sample became available. Prior to completing any procedures, each alphabetic label was randomized to a construct group (Figure 1); CBLO plate and pin (Plate), CBLO plate with headless compression screw (HCS), CBLO plate with tension band (TB), or CBLO plate with HCS and TB (HCSTB) using a computer-generated randomization program (randomizer.org). Cadavers were frozen at −20°C until they were ready to be tested. Cadavers were thawed at room temperature for 6 to 24 h, and tibiae were harvested, stripped of soft tissues other than the patellar ligament and patella, and tested within 48 h of being removed from the freezer. When samples were not actively being prepared or tested, they were wrapped in saline moistened towels at 4°C.

2.2 | Application of fixation method

Preoperative radiographs were taken to determine the CORA, appropriate blade size, tibial plateau angle, and appropriate location for the osteotomy as previously described.[3] The primary author planned and performed all procedures. All implants used in this study were manufactured by the same company (Veterinary Orthopedic Implants, St. Augustine, Florida). A CBLO was performed, and a fixation was applied according to assigned treatment group. An oscillating saw with a crescentic blade was used to create a bi-radial osteotomy in the proximal tibia centered on the CORA. The proximal tibia was rotated to decrease the TPA to 9 to 12° and align the proximal and distal weight bearing axis of the tibia as described by Raske et al.[3] A 1.6 mm (0.062″) anti-rotational pin was placed at the level of insertion of the patellar tendon to maintain reduction while the osteotomy was secured via one of the four previously listed methods.

The CBLO plates were secured with five 3.5 mm locking screws and one 3.5 mm cortical screw placed in compression. In the indicated treatment groups, a 4.5 mm cannulated HCS was placed across the osteotomy at the level of the insertion of the patellar tendon in a cranioproximal to caudodistal orientation such that it exited the caudomedial cortex of the tibia, as described by Raske et al.[3] When a TB was a component of the fixation, it was placed after the plate and HCS were secured.

The anti-rotational pin was cut flush with the tibia after the construct was completed in the Plate group. In the HCS group, this pin was used as the guide pin for placement of the HCS. In the TB group, an additional 1.6 mm (0.062″) pin was driven parallel to the anti-rotational pin, and both pins served as the proximal fixation point of the TB. In the HCSTB group, the anti-rotation pin served as the guide for the HCS, and two

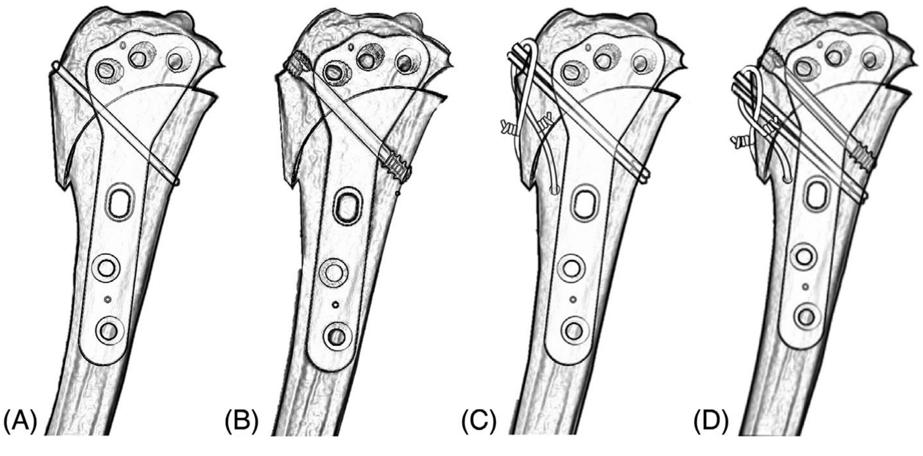

FIGURE 1 Digital sketches of each construct group. (A) Plate and pin construct. (B) Headless compression screw (HCS) construct. (C) Tension band (TB) construct. (D) Headless compression screw with tension band (HCSTB) construct

separate 1.6 mm pins were placed parallel to and approximately 5 mm distal to the HCS. The distal anchor point of the TB was a bone tunnel created by driving a 1.6 mm pin in a medial to lateral fashion, immediately cranial to the CBLO plate, and approximately equidistant to the osteotomy compared to the proximal fixation points. Tension bands were constructed from 18-gauge orthopedic wire with a twist knot on each side of the figure eight, twisted until palpably tight as would occur in a clinical scenario.

2.3 | Testing

The distal tibiae were potted in a 1.5″ diameter PCV pipe with poly methyl methacrylate (PMMA) to facilitate placement in a jig. A clamp was used to secure the patella and patellar tendon, such that the apex of the patella was included in the clamp. The jig was configured to hold the tibia and patellar tendon at 135° to simulate the mid-stance weight bearing angle of the patellar ligament in dogs (Figure 2).[4]

Vertical distraction force was applied to the patella and patellar tendon via a universal testing machine (Model MTI K2, Measurement Technology Inc., Marietta, GA). A preload of 20 N was applied, and the construct was then loaded at a displacement rate of 20 mm/min until failure of the construct was observed. Stiffness (N/mm) was defined as the slope of the linear portion of the load–displacement curve. Yield load was defined using an offset method of 1.5 mm displacement for samples that had plastic deformation prior to failure.[5,6] For samples with no plastic deformation prior to failure (those that underwent acute failure), the yield load was defined as the ultimate load. Ultimate load (N) was the maximum load applied during a test. Mode of failure was recorded for each specimen. Data was inadvertently lost for two samples by accidentally over writing the information collected from these samples. These samples were replaced in alphabetic order by the next available sample that had not already been assigned a treatment group.

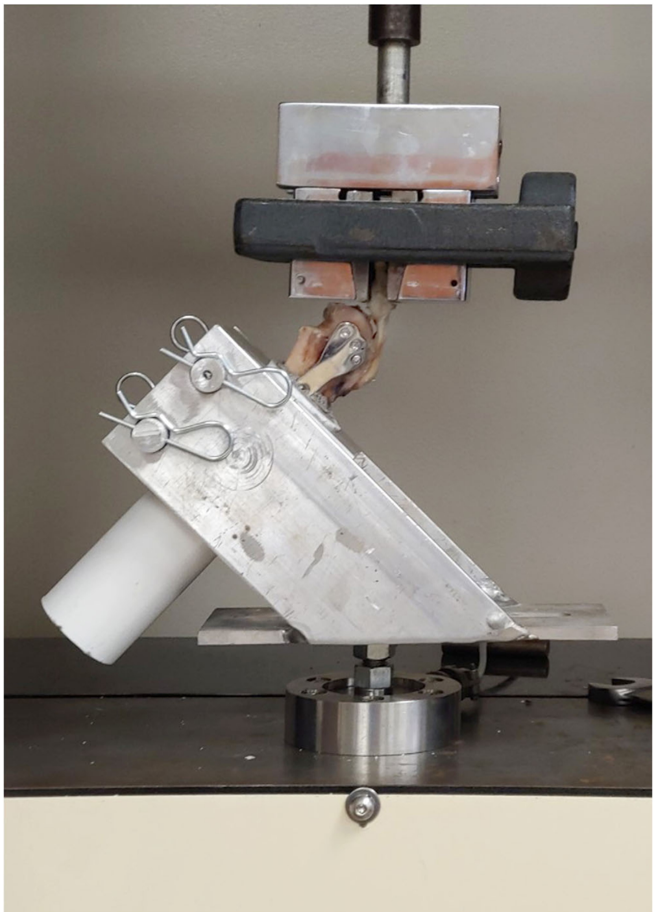

FIGURE 2 Testing apparatus, including the potted tibia loaded in jig, attached to the load cell prior to testing

2.4 | Statistical analysis

Using data from a similar biomechanical study,[4] it was determined that eight samples per group would be adequate to achieve a power of 0.80 and alpha of 0.05. To calculate the sample size, an estimate of the standard deviation of the mean load at failure for the phase I TPLO group using G*Power 3.1 software.[7] Assuming an alpha level of 0.05, power of 0.80, and a two-tail test, it was estimated a sample size of 8 tibias per treatment group would allow the detection of a difference of 500 N or greater between groups.

The effect of construct on stiffness, yield load, and ultimate load were assessed separately by linear models using the mixed procedure of SAS for Windows v9.4 (SAS Institute Inc., Cary, North Carolina). Tibias were considered independent when randomly allocating constructs rather than blocking by dog. Body weight was considered the most important dog specific factor and was, therefore, included as a covariate in the models. If the construct by weight interaction was not significant, the interaction was dropped from the model and re-assessed with construct and weight as explanatory variables. Differences in least squares means were used to make pairwise comparisons between constructs using a Tukey adjustment to account for multiple comparisons. Visual assessment of the residuals was used to determine whether the assumptions of normality and homoscedasticity were met. The level of significance was set at an alpha of 0.05.

3 | RESULTS

Data were collected from 32 tibiae from 17 mixed breed dogs (Table 1 and Figure 3). Yield load was higher for the HCSTB group when compared to the HCS group ($p = .0311$), and

TABLE 1 Least squares mean (95% confidence interval) for stiffness, yield load, and ultimate load for each construct group

Biomechanical properties by construct group

	Stiffness, *N*/mm	Yield load, *N*	Ultimate load, *N*
Plate	117^{a} (98.1–136.4)	788^{a} (639.5–936.0)	774^{a} (608.4–940.3)
HCS	117^{a} (99.9–135.5)	907^{a} (769.6–1044.9)	927^{a} (772.6–1080.7)
TB	109^{a} (90.8–128.6)	1016^{ab} (870.2–1162.6)	1076^{a} (912.8–1240.0)
HCSTB	125^{a} (105.7–145.0)	1212^{b} (1059.9–1363.3)	1388^{b} (1218.1–1557.6)

Note: Means within a column that share the same letter superscript are not significantly different ($p > .05$). Abbreviations: HCS, headless compression screw group; HCSTB, headless compression screw and tension band group; Plate, bone plate and pin; TB, tension band group.

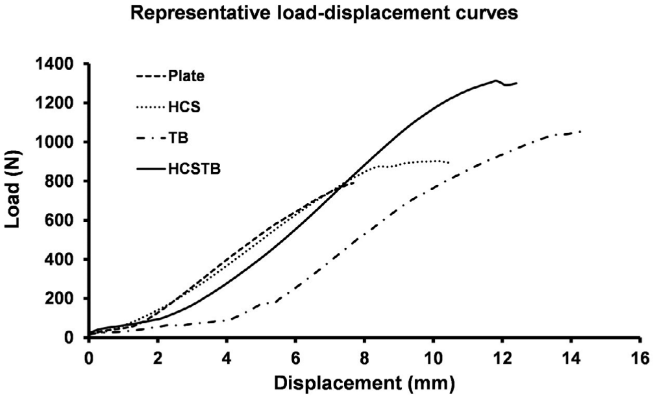

FIGURE 3 Typical load deformation curves of each construct group

the HCSTB group the Plate group ($p = 0.0042$). Ultimate load was also higher for the HCSTB group when compared to the HCS group ($p = .0025$) and to the HCS group ($p = .0025$), the HCSTB group to the Plate group ($p = .0002$), and the HCSTB group to the TB group ($p = .0456$).

There were no differences in yield load for: HCS vs plate, HCS vs TB, HCSTB vs TB, and Plate vs TB ($p = .6004$, $p = .6869$, $p = .2334$, and $p = 0.1459$, respectively). There were no differences in ultimate load for: HCS vs Plate, HCS vs TB, and Plate vs TB ($p = .4952$, $p = .5351$, $p = .0661$, respectively). Body weight of the dog did not have an effect on construct stiffness ($p = .6681$), ultimate load ($p = .6793$), and yield load ($p = .9991$). There was no difference detected in construct stiffness between fixation methods ($p = .6937$).

All HCS constructs failed by fracture through the HCS hole. All Plate constructs failed by displacement of the tibial tuberosity followed by fracture through the most cranial screw hole in the proximal tibia. All TB constructs failed by progressive stretching of the TB, widening of the osteotomy cranially, and subsequent fracture through the most cranial screw hole in the proximal tibia. All HCSTB constructs failed by progressive stretching of the TB, widening of the osteotomy cranially, and subsequent fracture through the HCS hole.

4 | DISCUSSION

In this study, the ultimate load of the HCSTB was greater than those of the HCS, TB, and Plate groups, while the yield load of the HCSTB was greater than the HCS, and Plate groups, but not different than the TB group. The stiffness was not different among groups. Body weight of the animal was accounted for in our statistical model and did not differ between groups.

Stiffness is defined as the extent to which an object resists deformation in response to an applied force. Interestingly, there was no difference in stiffness between the construct groups. The load displacement curve for each sample has a variable "toe region" (Figure 3). The "toe region" of the curve likely reflects the elongation of the patellar tendon as load was applied by the testing apparatus. A preload of 20 N was applied to each sample. The time between preload and application of our testing forces was not measured as a part of the study but is estimated to be <1 min in each case. This time may have allowed a variable degree of stress relaxation of each tendon prior to the test force being applied. The patellar tendon and patella were included in the jig's clamp to the level of the patellar apex for each sample. However, the working length of the patellar tendon (between the clamp and the tibial tuberosity) subjectively varied between samples, and likely corresponded to the body weight of the dog. It is possible that longer patellar tendons allow for greater displacement prior to becoming fully stretched and transmitting the load to the bone. Although not objectively measured by our study, subjective real-time observations indicated that the tibial tuberosity did not undergo significant displacement during the "toe region" of the curve. This suggests that displacement on the curves account for both the displacement that occurs at the level of the patellar tendon as it is stretched, as well as changes occurring at the level of the bone and implants. Given this information, displacement from these curves alone should not be used to determine a point of clinical failure. This could be considered a limitation of this study, however measuring displacement at the level of the osteotomy, or determining a point of clinical failure was not an outcome established at the outset of the study. The following data points were not radiographically documented on every specimen and may be considered a limitation of this study: actual postoperative TPA, and size of tibial crest available for implants. Given that the CBLO procedures performed were consistent with that of clinical cases the authors' feel that the TPA values are.

The true magnitude of the force created by the quadriceps mechanism on the tibial tuberosity in a normal dog is unknown. However, using three-dimensional biomechanical modeling of the canine pelvic limb, Shahar and Banks-Sills estimated the force of the quadriceps muscles during the stance phase of the walk as up to 94.8% of body weight.[8] Our samples were from dogs weighing 18 to 35 kg. Applying this model, our samples would be expected to experience approximately between 170 and 325 N from the quadriceps muscles. All samples in our study withstood at least 542 N. This suggests that all four construct types would adequately resist the peak distractive forces generated by the quadriceps mechanism on the tibial tuberosity postoperatively; however, clinical cases suggest that fixation by CBLO plate alone risks catastrophic failure. It has been assumed that an HCS is required to oppose the forces of the quadriceps muscles and avoid catastrophic failure in a CBLO construct. Interestingly, the HCS was not different than the TB, or Plate constructs in terms of yield load or ultimate load. The HCSTB construct was superior in terms of both yield and ultimate load. The definition of clinical failure for these implants has not been established and data regarding frequency or mode of failure of each fixation method in clinical cases are not available. This study suggests that the HSCTB construct would provide the strongest construct.

Postoperative TPA shift is a reported complication of the CBLO.[3,9–12] This complication is attributed to the pull of the quadriceps mechanism on the tibial tuberosity during muscle contraction. However, Johnson et al. reported no change in TPA in 49 cases of CBLO fixation with HCS and TB.[2] It is possible that the early bony healing observed in that study led to a shorter window of vulnerability to this complication. In vivo, the pull of the quadriceps mechanism is cyclic, and that cyclic force would cause cyclic fatigue of the implants used to secure the osteotomy. Pin and wire constructs, such as a tension band, would be expected to be more susceptible to plastic deformation from this dynamic loading than screws or plates would.[13] The ex vivo nature of our model did not allow us to capture and compare TPA shift among the fixation groups.

Mode of failure was consistent within groups but varied between each group. Ultimately, all constructs failed by fracture of the bone through the most cranial screw hole in the proximal tibial segment. In cases of the constructs that included a HCS (HCSTB and HCS groups), this was through the HCS hole, and those without an HCS (TB and Plate groups) failure was through the most cranial and proximal screw associated with the plate. This seems logical as both types of screw implant represent a relatively large defect in a small section of bone. The Plate group showed progressive proximal displacement of the tibial tuberosity, and subsequently fractured at the most cranial screw in the proximal tibia. Similarly, the TB group showed progressive stretching of the TB and displacement of the tibial tuberosity until subsequent fracture at the most cranial screw in the proximal tibia. These modes of failure are also logical, as the pins are much smaller and smooth, which allowed the bone to slide along the pins as the tibial tuberosity became progressively displaced. No construct failed at the level of the patellar tendon, indicating that the limiting factor to resisting the distractive pull on the patellar tendon was the construct, not the tendon itself.

A limitation of this ex vivo model may be that it does not account for all forces experienced by the postoperative patient in the convalescent period, such as cyclic fatigue or physiologic loading. However, the authors believe the model replicates the pull of the quadriceps mechanism on the patellar tendon and effectively tests the ability of the implants to resist the load on the proximal tibia generated by the quadriceps.

In conclusion, the HCSTB fixation method confers clear biomechanical advantage in terms of yield load and ultimate load. Future studies could consider evaluating frequency and mode of implant failure in clinical CBLO cases, the degree of compression achieved with each fixation method, and surgical time required for application of each fixation method.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

AUTHOR CONTRIBUTIONS

Whitney M., VMD contributed to study design, data acquisition, data analysis, data interpretation, as well as drafting initial and revising final work. James R. Butler, DVM, MS, DACVS-SA contributed to study design, data analysis, data interpretation, and revising final work. David L. Dycus, DVM, MS, DACVS-SA contributed to study design and revision of final work. Landon B. Teer contributed to data acquisition, data analysis, and revision of final work. Steve H. Elder, PhD contributed to study design, data acquisition, data interpretation and revision of final work. Lauren B. Priddy, PhD contributed to study design, data acquisition, data interpretation, and revision of final work. Robert W. Wills, MS, DVM, PhD, DACVPM contributed to study design, data interpretation and revision of final work.

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