Biomechanical Comparison of Four Methods of Fixation of a Polymeric Cranial Cruciate Ligament in the Canine Femur and Tibia

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Abstract

Objective The aim of this study was to compare the biomechanical properties of four different methods of artificial cranial cruciate ligament fixation in canine cadaveric tibias and femurs.

Methods Femurs and tibias from skeletally mature large breed canine cadavers were assigned into four fixation groups: group 1, 4.5-mm interference screw (IS); group 2, 4.5-mm IS and 4.0-mm screw and spiked washer (SW); group 3, 5.0-mm IS; group 4, 5.0-mm IS + SW.

Results The mean ultimate load was significantly greater for femur fixations than for tibias, when a SW was added, and for 5.0-mm IS compared with 4.5-mm sizes. There was also a significant interaction between SW and IS size. A SW significantly increased stiffness, a 5.0-mm IS in femurs provided more stiffness than 4.5-mm IS and was greater than 5.0-mm IS in tibias. In tibias, a 4.5-mm IS was stiffer than a 5.0-mm IS and a 4.5 IS + SW had greater stiffness than a 5.0-mm IS + SW. Groups 1 to 3 and tibias in group 4 failed by artificial ligament pullout. Nine femurs in group 4 failed by fracture, 5 by artificial ligament pullout, and 1 by artificial ligament tearing.

Clinical Significance A 5.0-mm IS + SW provided superior artificial ligament fixation strength in femurs and tibias compared with a 4.5-mm IS without SW. Overall, artificial ligament fixation with 5.0-mm IS in femurs had the mechanical characteristics that most closely matched those reported in normal canine cranial cruciate ligaments.

Keywords
- biomechanics
- cruciate ligament repair techniques
- ligaments
- canine
- interference screw

Introduction

Cranial cruciate ligament rupture is the most common cause of canine pelvic limb lameness and it causes joint instability, pain and inflammation.[1] A gold standard for the treatment of cranial cruciate ligament disease does not exist which likely represents the complexity of this condition and our lack of complete understanding of its pathophysiology. Current surgical treatment techniques can be categorized into extracapsular stabilization, intracapsular reconstruction and tibial osteotomy. Techniques which utilize intracapsular grafts placed in the anatomic footprints of the native ligament are the most common method of surgical treatment for human anterior cruciate ligament injury.[2] A similar intracapsular graft procedure could

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offer several potential benefits over currently used techniques in dogs including a lack of requirement for osteotomy with extensive internal fixation, broader applications for minimally invasive surgical techniques and the restoration of more normal stifle kinematics which might positively impact both patient function and osteoarthritis progression.[3] However, intracapsular graft techniques, while previously described, are very rarely used in canine stifles.[4,5] The small number of reported clinical cases and outcome studies, the technical challenges and the lengthy autograft preparation times required are all likely to be partly responsible for their lack of popularity in veterinary surgery.[6] In dogs, a graft would not only be challenged by less-controlled postoperative patient weight bearing and cranial tibial thrust and internal tibial rotation generation but also the often less than favourable joint environment present with cranial cruciate ligament disease. As such, any intracapsular graft would not only need to have immediate mechanical properties similar or superior to the recipient's native cranial cruciate ligament but its fixation would also need to be to maintained while it becomes incorporated into the patient's bone during the initial postoperative period.

In comparison to an autograft, an artificial ligament could offer the benefits of being readily available without graft preparation time, produce no donor site morbidity and be at full strength immediately because there would not be any requirement for ligamentization. Regardless, even an artificial ligament implant with ideal mechanical properties is still initially dependent on the strength and stability of its fixation to the patient's bone and, despite numerous described fixation techniques described for allo- and autografts, the graft-to-bone fixation would be expected to be the weakest part of the construct.[7–10]

The present study evaluated the effect of four different fixation methods on bone tunnel ultimate loads (fixation strength) and fixation stiffness of a composite polymeric ligament in canine femurs and tibias. We hypothesized that fixation strength would be greater for an artificial ligament secured with an interference screw (IS) and a screw and washer compared with one fixed with an IS alone. These data were collected prior to completion and publication of the prospective clinical trial evaluation of the artificial ligament described hereafter.[11]

Materials and Methods

Specimen Preparation

Femurs and tibias were harvested from skeletally mature (2–6 years of age) dogs (22–45kg body weight) that were humanely euthanized for reasons unrelated to this study. All stifles were grossly free of any signs of osteoarthritis and cranial cruciate ligament disease. The specimens were stripped of soft tissues with the origins and insertions of the cranial cruciate ligaments preserved, wrapped in 0.9% saline-soaked paper towels and stored at −40°C. Both femurs and tibias were assigned into four fixation groups: group 1, 4.5-mm titanium IS (Securos; Fiskdale, Massachusetts, United States) (4.5 IS); group 2, 4.5-mm IS and 4.0-mm self-tapping stainless steel cortical screw and a 14-mm spiked washer (SW) (Securos; Fiskdale, Massachusetts, United States) (4.5 IS + SW); group 3, 5.0-mm IS (5.0 IS); group 4, 5.0-mm IS and SW (Securos; Fiskdale, Massachusetts, United States) (5.0 IS + SW). Six femurs and tibias were tested in groups 1 and 2, 5 femurs and tibias in the group 3 and 5 tibias and 15 femurs in group 4. Fifteen femurs in total were tested because nine failed prior to test completion as described hereafter in the results. Groups 1 and 2 were prepared by the second author (BB) and groups 3 and 4 were prepared by the first author (MB).

Artificial Ligament Implant

The artificial ligament was a composite polymeric device consisting of a porous multifilamentous high tenacity polyester core contained within a braided polytetrafluoroethylene sheath. (Avalon Medical; Stillwater, Minnesota, United States) The two components were mechanically joined using metric 4 polyester suture with a tapered plastic sheath applied to each end to aid in passing the implant through bone tunnels. Both ends of the artificial ligament had 4 cm of cross-stitching with the same suture to prevent the linearly arranged core fibres from separating around the screw posts and SW. All of the artificial ligaments tested were 34 cm in total length and 6 mm in diameter.

Ligament Fixation

The cadaveric specimens were thawed at room temperature for 24 hours prior to artificial ligament placement and testing. Specimens were prepared and artificial ligaments placed in similar fashion to that previously described *in vivo*.[11] The tibial tunnels were created by placing a 2.0-mm drill bit in the cranial cruciate ligament insertion and advancing it in a proximal to distal direction exiting approximately halfway between the medial collateral ligament and the cranial aspect of the tibial metaphysis. A 4.5 mm cannulated drill bit was placed over the drill bit to create the bone tunnel. The artificial ligament was placed through the tunnel and secured with a 16 to 24 mm long 4.5- or 5.0-mm IS inserted distal to proximal until approximately flush with the *cis* cortex in groups without a SW. Screw length was determined such as to ensure the entire bone tunnel was filled.

In groups with a SW, a 2.5-mm drill bit was advanced through the tibia 2 cm distal to the IS tunnel opening. A corresponding 5-mm slit was created with a number 11 scalpel blade in the cross-stitched portion of the artificial ligament parallel to its core filaments and the screw shaft placed through it. The artificial ligament was grasped with large needle holders and held under firm hand tension, while the SW affixed it to the tibia.

The femoral tunnels were created in similar fashion in a distal to proximal direction through the cranial cruciate ligament origin exiting the lateral femur condyle in line with the proximal aspect of the trochlear groove. In contrast to the tibial constructs, SW placement in femoral constructs preceded the IS placement. Following SW placement, 20 to 30-mm long IS were inserted proximal to distal with the artificial ligament held under tension. The order in which IS and SW were placed in the femur and tibia was to replicate the placement *in vivo*.[11]

Biomechanical Testing

Each femur and tibia was secured to the servohydraulic test frame (858 Bionix: MTS Corp, Eden Prairie, Minnesota, United States) with two 3/16" transfixation pins between two metal plates and the artificial ligaments were oriented vertically and in line with the actuator. The artificial ligaments were secured between serrated metal clamps 2 cm from emergence of the bone tunnels (to standardize the test orientation) and ink marked at the edge of each clamp as a reference for determining grip slippage. Each specimen was preloaded to 5N and held at 5N for 60 seconds. Testing was conducted under displacement control at 20 mm/min with continuous, real-time recording of load and displacement. Mode of failure was recorded after observation of the failed specimens. Loss of fixation was defined as more than 5 mm of exposed artificial ligament slippage from the fixation. Structural stiffness was measured as the force per millimetre of extension measured from the slope of the linear portion of the load-deformation curve. A manual process using a 0.2% offset line parallel to the linear portion of the curve was utilized to consistently determine significant deviation from linearity. The ultimate load was determined as the point of maximum load along the load-deformation curve, indicating failure of the construct. This point consistently occurred after of more than 5-mm displacement. Specimens were preloaded to 5N and held at that level for 60 seconds prior to loading so the toe region of the curve was not visualized. This was a deliberate decision so that we could focus on the interface and fixation strength of the various constructs.

Statistical Analysis

Statistical analysis consisted of performing three-factor analysis of variance for both ultimate load and stiffness with the factors being bone type, IS size and SW usage. All statistical testing was considered significant at $p \leq 0.05$. Analysis was performed using SAS Version 9.4 software (SAS Institute Inc., Cary, North Carolina, United States).

Results

Ultimately, six femurs were tested to completion in groups 1, 2 and 4, and five femurs for group 3. Six tibias were tested to completion for groups 1 and 2 and five tibias for groups 3 and 4. All the femurs and tibias in groups 1 to 3 and all of the tibias in group 4 failed by slippage of the artificial ligament from the bone tunnels. Nine femoral constructs in group 4 failed by fracture at the level of the transfixation pins, five failed by slippage of the artificial ligament from the bone tunnels and one failed by artificial ligament tearing at the plastic sheath near the metal grips. The nine fractured femoral constructs and the one torn artificial ligament in group 4 were not included in the statistical analysis because their failure did not allow for complete evaluation of the fixation strength.

There were significant differences in the mean ultimate load between bone types. Overall, fixation strength in femurs was stronger than in tibias. Supplementing the IS with the SW produced greater fixation strength than the IS alone. The 5.0-mm IS also produced greater fixation strength than the smaller 4.5-mm screws with and without the SW condition (►**Table 1**). There was also a significant interaction between the SW condition and IS size, indicating the effects of the two factors on ultimate load were not additive. The difference in ultimate load between groups 3 and 4 was greater than the difference in ultimate load between groups 1 and 2, which indicates that the SW has a greater effect on ultimate load in conjunction with the larger IS than it does in conjunction with the smaller IS.

In the femoral constructs, the 5.0-mm IS resulted in greater stiffness than the 4.5-mm screws. In the tibia constructs, the stiffness was greater with the 4.5-mm IS compared with the 5.0-mm IS. Overall, use of a SW provided a significant increase in stiffness. The means and standard deviations for each factor and interaction are reported in ►**Table 1**.

Discussion

Graft fixation techniques are generally categorized as extra- or intratunnel and dozens of different implants and combinations thereof have been described in the human literature.[12] In the present study, the combination of 5.0-mm IS + SW produced the highest bone to artificial ligament fixation strength irrespective of bone type compared with other fixation combinations. Additionally, a larger diameter IS significantly improved fixation strength in femurs independent of a SW and in tibias when combined with a SW. This finding is consistent with a previous study which determined that increasing the diameter of the IS by 1 mm over the tunnel diameter significantly increased fixation strength.[13] By contrast, the addition of a SW decreased fixation stiffness in femurs and, to a lesser extent, in tibias. The differences in stiffness may have been due to variation in bone density at the level of artificial ligament fixation and differences in artificial ligament tensioning and screw insertion torque.[7–10] While the combination of supplementary and intratunnel fixation did provide the greatest artificial ligament fixation strength, our finding of decreased stiffness caused us to reject our hypothesis.

The mechanical properties of the normal canine cranial cruciate ligament vary considerably among breeds. Ultimate loads of 1389 to 2130 N and stiffness of 148 N/mm and 306 N/mm were reported when comparing the cranial cruciate ligament of the Rottweiler and Greyhound respectively; these values varied with the direction in which the load was applied and the degree of stifle flexion tested.[14] The *in vivo* loading of the canine cranial cruciate ligament under normal walking conditions has been calculated at 10 to 25% of the ultimate load.[15] Accordingly, any artificial ligament-bone fixation should be able to resist a load of between 139 and 612 N to prevent fixation loss. In the present study, only the use of a 5.0 IS $\pm$ SW in femurs and + SW in tibias provided artificial ligament ultimate load above 612 N. The mean ultimate load values for the remaining groups ranged between 139 N and 612 N suggesting that these fixations may be more prone to slippage. Based on the aforementioned normal cranial cruciate ligament mechanical characteristics, a 5.0 IS alone provided the most balanced artificial ligament fixation in femurs with a mean ultimate load of 647 N and a

Table 1 Summary of the means and standard deviation for each factor and interaction evaluated

Effect level	Bone type	SW usage	IS size (mm)	Ultimate load (*N*)		Stiffness (N/mm)	
				Mean	SD	Mean	SD
Main effects	Femur			617.5*	373.6	133.3	60.4
	Tibia			458.2*	3078.0	130.6	59.2
		No		414.0*	168.7	158.7*	62.0
		Yes		661.7*	432.6	105.2*	42.4
			4.5	352.5*	145.4	131.7	41.3
			5	760.3*	390.7	132.2	76.5
Two-way interactions	Femur	No		525.8	154.4	172.4	60.8
	Femur	Yes		709.1	500.8	94.2	24.3
	Tibia	No		302.2	91.7	145.1	63.1
	Tibia	Yes		614.3	370.4	116.2	54.0
	Femur		4.5	395.7	187.4	117.8 *	35.8
	Femur		5	883.6	372.1	151.9 *	79.0
	Tibia		4.5	309.3	71.0	145.7*	43.1
	Tibia		5	637.0	387.3	112.5*	72.4
		No	4.5	366.1*	118.3	133.7*	42.0
		No	5	471.5*	206.3	188.8*	70.7
		Yes	4.5	338.8*	172.7	129.8[8]	42.4
		Yes	5	1049.1*	307.2	75.7*	15.0
Three-way interaction	Femur	No	4.5	424.8	137.1	129.2	44.2
	Femur	No	5	647.0	49.5	224.2	25.5
	Femur	Yes	4.5	366.5	237.5	106.3	23.4
	Femur	Yes	5	1120.2	411.31	79.6	17.3
	Tibia	No	4.5	307.3	60.7	138.2	43.2
	Tibia	No	5	296.0	127.8	153.4	86.4
	Tibia	Yes	4.5	311.2	86.0	153.2	45.6
	Tibia	Yes	5	978.0	174.8	71.7	13.0

Abbreviations: IS, interference screw; SD, standard deviation; SW, spiked washer.
*Significant at $p < 0.05$.

stiffness of 224.2 N/mm. By contrast only 5.0 IS + SW fixation produced adequate ultimate load values in tibias but lacked appropriate stiffness characteristics. Interestingly, loss of tibial fixation is the more common place for graft slippage in humans.[10]

Limitations of our study include those inherent in *in vitro* studies and the problems of making clinical correlations from such study results. The femurs and tibias tested were without the supporting structures present in an intact stifle so what influence they might have on artificial ligament fixation properties is unknown. Additionally, we assessed quasistatic ultimate load versus cyclic loading, the latter of which may better reflect a clinical situation and would allow for better evaluation of artificial ligament abrasion, a previously reported common cause of implant failure.[16] Also, no formal randomization method was used to group the bones, rather they were collected throughout the study duration and assigned to the test group that required completion at that time. It is possible that a lack of randomization could have introduced some unknown bias into our results. Additional variability may also have been introduced by the fact that the four groups were not created by a single individual. Cadaveric bones also vary in structural properties between individuals, whereas using a more homogenous testing material with similar properties to bone might have decreased some variability. As such, pre-testing radiographs of the bones to detect any underlying pathology not grossly apparent may also have helped limit further variability. Lastly, the use of hand versus a standardized tensiometer for tensioning the artificial ligament could have introduced some variability as could a lack of standardized tunnel length and angle. However, the hand tensioning and bone tunnel creation techniques were as used previously during *in vivo* placement and the authors were attempting to replicate such an application.[11]

In conclusion, a combination of a 5.0 IS + SW provided superior strength of artificial ligament fixation in both femurs and tibias compared with a smaller diameter IS and not using a SW. In femurs, use of a 5.0 IS alone had the mechanical characteristics that most closely matched those reported in normal canine cranial cruciate ligaments. By contrast, no single method of the tibia fixation we evaluated satisfied both ultimate load and stiffness requirements. While this artificial ligament technique has previously been determined to be an unsuitable alternative to currently used surgical techniques for the treatment of canine cranial cruciate ligament disease, the findings from the present study may be pertinent to other types of intracapsular graft fixation procedures.[11]

Author Contribution

Matthew D. Barnhart contributed to conception of study, study design, acquisition of data and data analysis and interpretation. Brian W. Bufkin and Alan S. Litsky contributed to acquisition of data and data analysis and interpretation. All authors drafted, revised and approved the submitted manuscript.

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Conflict of Interest

Matthew D. Barnhart receives royalties from the sales of some Securos products. Brian W. Bufkin reports personal fees from Securos, outside the submitted work. Alan S. Litsky declares no current conflicts of interest.

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