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Biomechanical Characteristics of an Implant Used to Secure Semitendinosus–Gracilis Tendon Grafts in a Canine Model of Extra-Articular Anterior Cruciate Ligament Reconstruction

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Abstract

Objective—To compare initial femoral fixation properties of a new implant, Graftgrab (GG), with 2 established methods of extra-articular femoral graft fixation, spiked washers (SW) and bone staples (ST).

Study Design—Experimental in vitro cohort study.

Methods—Canine semitendinosus–gracilis tendon grafts were passed through bone tunnels and fixed to the lateral surface of femoral condyles with spiked washers, bone staples, or new implant prototypes. The fixations were tested to failure with a single-cycle load at a rate of 50 mm/min. Failure and yield strength, stiffness, energy, and elongation were determined from load–displacement curves and failure modes were recorded.

Results—The graft failed midsubstance in 4 SW, 4 ST, and 1 GG fixations. In 3 SW, 3 ST, and 1 GG specimens, the graft slipped from the fixation. The graft ruptured at the clip (3) and the intra-articular (2) surface of the bone tunnel in the remaining GG specimens. There were no significant differences between fixation groups in femoral tunnel length, femoral width, or the mechanical properties evaluated.

Conclusions—The initial in vitro mechanical properties of the new fixation implant are comparable with those of spiked washers and bone staples.

Clinical Relevance—The initial mechanical performance of the new implant tested in this study was similar to those of comparable, established implants. The new implant is novel and may be useful for human anterior and veterinary cranial cruciate ligament graft reconstruction fixation.

INTRODUCTION

The bone–patellar bone and semitendinosus–gracilis grafts are 2 of the most widely used anterior cruciate ligament (ACL) reconstruction grafts in human patients.^{1,2} Various implants are available for graft fixation to the lateral aspect of the femoral condyle. Endo-Button (Acufex Microsurgical Inc., Mansfield, MA), spiked washers, and bone staples are 3 implants used to secure ACL reconstruction grafts to bone around the femoral bone tunnel.² Optimal fixation of an ACL graft requires sufficient initial strength to avoid fixation failure,

sufficient stiffness to restore knee stability, anatomic fixation to minimize graft motion within the tunnel, and resistance against slippage to avoid loosening in the immediate postoperative period.³

Graft elongation behavior during implantation contributes to anteroposterior knee translation and is detrimental to long-term knee stability and graft tensile properties.⁴ Loss of initial graft tension is inevitable when using current fixation methods and contributes to problems associated with joint instability.^{5,6} Loss of initial intra-articular graft tension occurs during application of spiked washers and bone staples for tibial graft fixation⁵ but even greater loss occurs during application of femoral fixation implants, which allow more initial lengthening than the tibial implants.^{3,7} Tension loss during implant fixation varies widely even with careful surgical technique.⁵ An implant that allows graft fixation with minimal further action after graft tensioning may counteract some of the factors that contribute to tension loss.

We reasoned that an implant seated in the extra-articular side of the femoral bone tunnel that had a simple mechanism for anchoring the graft immediately after tensioning would minimize the likelihood of graft tension loss. Accordingly, we developed an implant that allows graft fixation in a single motion after graft tensioning (Fig 1). To evaluate the fixation characteristics of this implant we compared it against 2 established methods of extra-articular graft fixation: spiked washers and bone staples. Our intent was to determine if initial fixation strength of this implant was comparable with that of established implants before further testing and design refinement.

MATERIALS AND METHODS

Implant Description

The implant named Graftgrab (GG) has a stainless-steel base (diameter, 13.5 mm; maximum height, 2.7 mm) with a central hole (4.5 mm diameter; Fig 1). A 2.7-mm-long sleeve (5.5 mm outer diameter, 4.5 mm inner diameter) and tapered spikes (2 mm long) extend from the medial surface of the implant into the femoral tunnel and bone, respectively. There is a channel from the center to the perimeter of the implant to position the graft for attachment once it is pulled through the hole. An acetal copolymer clip with a hinge on one side and a clasp on the other crosses this channel to fit securely into notches in the implant base. The clip has a serrated central surface with 2 central serrations that protrude further into the channel and 2 shorter peripheral serrations that secure the graft without impeding clip closure. The geometry of the clip was designed to hold grafts of uniform size and facilitate clasping into the base.

Constructs

Hind limbs of 11 hounds (~ 2 years old; mean $\pm$ SEM weight, 25.6 ± 0.65 kg) euthanatized for unrelated reasons were collected immediately after death and frozen at -20°C . Specimens were thawed on the day of testing and randomly assigned to 1 of 3 fixation groups ($n = 7/\text{fixation}$): SW, screw and spiked washer; ST, bone staples; GG, Graftgrab (Fig 1).

Stifles were disarticulated and grafts were prepared from the combined tendinous insertion of the gracilis and semitendinosus muscles and cranial tibialis fascia on the medial aspect of each tibia.⁸ Briefly, the tendons were dissected free of their muscular origins maintaining the combined bony insertion. The insertion was elevated and the attached dense connective tissue and muscle fascia of the cranial tibialis muscle were dissected free of bony and muscular attachments to a length of ~ 7 cm. Tissue was trimmed to a width of 1.5 cm and twisted from the distal end to a final graft diameter of ~ 4.5 mm and a length of 7 cm. A

Chinese finger trap of #1 polyglactin 910 was placed around the length of each graft,⁹ and the combined bony insertion was transected. Grafts were passed through a 4.4 mm diameter stainless-steel tube to ensure diameter consistency.

All soft tissue was removed from the femurs which were sectioned 6 cm proximal to the distal articular surface and sagittally equidistant between trochlear ridges. An aiming device was used to guide a 4.5 mm drill bit from the intra-articular origin of the cranial cruciate ligament (CrCL) to the center of the lateral aspect of each femoral condyle at an angle of $\sim 45^\circ$ to the long axis of the femur. The femoral width just proximal to the condyle and the tunnel length were measured with a Vernier caliper (McMaster-Carr, Chicago, IL) and depth gauge (Synthes, Monument, CO), respectively. Constructs were assembled by 1 investigator. Grafts were pulled through the tunnel to a length of 1.5 cm beyond the lateral femoral surface in all groups (Fig 2).

SW

A 3.2 mm pilot hole was drilled 5 mm caudal to the bone tunnel in the SW group. The graft was secured to the femur (Fig 3) with a 13 mm diameter stainless-steel spiked bone washer (IMEX Veterinary Inc., Longview, TX) and 4.5 mm diameter, 22 mm long, self-tapping cortical screw (Synthes). The graft was wrapped around the screw which was inserted through the washer and into the pilot hole. The washer was held firmly against the graft as the screw was tightened.

ST

The graft was secured to the femur just proximal and cranial to the lateral fabella using a belt-buckle technique with two 7×7 mm bone staples (Fig 4) from a powered metaphyseal stapler (Stapilizer; 3M, St. Paul, MN).⁸ A staple was placed over the graft ~ 5 mm caudal to the bone tunnel, the graft was folded over the staple in an cranial direction, and another staple was placed over the graft between the bone tunnel and the first staple.

GG

The base of the implant was tapped into place with an osteotomy mallet. After the graft was passed through the femoral tunnel and implant sleeve, the hinge side of the clip was placed in the base, and the graft was secured by closing the clip over it (Fig 5).

Biomechanical Testing

Femoral sections were mounted on a testing fixture attached to the load cell of a materials test system (Model 319.10 A/T system, MTS Systems Corporation, Eden Prairie, MN). The intra-articular surface of each specimen faced the direction of the actuator, and the long axis of the bone tunnel was aligned with the direction of load application. All specimens were moistened with saline (0.9% NaCl) solution spray during testing. The free ends of the grafts were gripped with a specially designed cryoclamp (Fig 6). The clamp was designed with a dry ice reservoir to freeze the gripped portion of the grafts. There was a 25 mm length of graft between the clamp and the intra-articular edge of the bone tunnel. A 1 N preload was applied, and specimens were evaluated with a load to failure at 50 mm/min after 10 preconditioning cycles of 15% strain at 0.5 Hz. Load and displacement data sampled at 60 Hz from the MTS were used to generate load displacement curves.

Yield and failure load, strain energy, elongation, and the stiffness of each implant/graft construct were determined graphically. Failure load was the load at the point of graft rupture. Yield load was the load where the load displacement curve first deviates from a straight line, indicating plastic deformation. Yield and failure strain energy were defined as the total area under the curve at the yield and failure points, respectively. Stiffness was

calculated as the change in load over the change in displacement in the elastic portion of the load–displacement curves. Yield and failure elongation were the grip to grip displacements measured at yield and failure, respectively. Each test was recorded with a digital camcorder, and failure mode was confirmed after testing.

Data Analysis

Comparison of mechanical properties, tunnel length, and condylar width between groups was determined by 1-way ANOVA (GraphPad Prism v4.0, GraphPad Software Inc., San Diego, CA). Significance was set at $P < .05$. When comparisons were not significant, the difference (δ) between groups necessary to detect a significant difference was calculated.¹⁰ Results are reported as mean $\pm$ SEM.

RESULTS

Grafts failed midsubstance in 4 SW, 4 ST, and 1 GG fixations. In 3 SW, 3 ST, and 1 GG specimens, the graft slipped from the fixation. The graft ruptured at the clip (3) and the intra-articular (2) surface of the bone tunnel in the remaining GG specimens. There were no significant differences between fixation groups in femoral tunnel length, femoral width, or the mechanical properties evaluated (Table 1).

DISCUSSION

Implant Design

We designed this implant to achieve graft fixation to the femur in a single motion after tensioning the graft. The GG implant has a low profile and is free of sharp surfaces that may potentially cause graft damage. Designed to facilitate implant alignment, the central sleeve counteracts translational forces preventing implant motion and should also prevent acute or cyclic damage to the graft at the bone tunnel edge. The spikes extending from the implant base are for rotational stability. The position of the implant against the bone is maintained by inherent graft tension, so bone necrosis because of pressure is unlikely.

The implant can be created in any size, and multiple clip sizes and configurations can be fabricated to facilitate stable fixation without unnecessary graft compression. Insertion and use of the implant does not require special equipment and it can be used with arthrotomy or arthroscopy. Incorporation of bioabsorbable components or a comparable bioabsorbable implant should be possible.

Bony incorporation of a soft-tissue graft in the bone tunnel is required for survival of the tissue.¹¹ Graft incorporation, healing quality, and strength of the graft–bone interface are augmented by optimizing the fit between the graft and the bone tunnel and maximizing the length of graft within the tunnel.¹² The sleeve that extends from the GG base into the bone tunnel is designed to serve a protective and stabilizing function. In these femoral specimens, the sleeve covered 12–13% of the length of bone tunnel. It is likely that the sleeve will inhibit graft incorporation in that location, so this potential effect will need to be investigated and the design modified accordingly.

Study Design Considerations

Canine CrCL grafts were harvested and prepared by established methods.⁸ Because initial graft strength is not affected by rotation, graft rotation may be used to address graft–tunnel mismatch.¹³ Rotating the free end of the graft increases its diameter to achieve a better fit within the bone tunnel. We used graft rotation to achieve a final diameter of ~ 4.5 mm (confirmed by use of a 4.4 mm stainless-steel sizing tube) to achieve graft size consistency

between groups. We minimized variation in tunnel length and femoral condylar width between constructs (Table 1); however, there was significant variation in mechanical properties between constructs, reducing the overall power of the study. Wide standard deviations are not uncommon for investigations of this nature.²

Differences in failure mode may have contributed to large variations in failure load and strain energy observed for GG constructs. It is also possible that clip design was a factor when failure occurred at that level. Despite this, mean values for failure, yield, elongation, and strain energies were relatively similar between groups. Whereas it is difficult to compare values between studies, the initial mechanical properties of the implant/graft constructs were similar to comparable canine soft tissue fixation studies,^{14–16} supporting our observations.

Graft Fixation Considerations

Graft elongation after implantation is one of the critical factors that affect long-term outcome of knee stability. Loss of initial graft tension is seemingly unavoidable using current graft fixation techniques,^{4–6} and may result from inability to tension the graft optimally because of bone tunnel friction, loss of tension during insertion of the device used to secure the graft to the femur, and subsequent slippage at the fixation site.⁵ Graft slippage at the fixation site occurred in all 3 construct types but less often with GG. The sleeve component of GG may have caused increased bone tunnel friction compared with the other 2 fixations. The comparison techniques (spiked washer and screw insertion, staple insertion) require substantially more manipulation than clip closure so seemingly there should be less likelihood of slippage when securing the graft with the clip. However, a comparative assessment of initial graft tension loss is needed to definitively conclude that GG would have this specific advantage.

Fixation is the weakest point of graft reconstruction in the immediate postoperative period, so knowledge of fixation properties is essential for any implant designed for this purpose.³ Further, the importance of implant/graft construct stiffness has been well established, and a high stiffness construct requires substantially less initial tension to achieve the same joint stability as a low-stiffness construct.⁶ We attempted to control those variables that can influence stiffness and found no differences between construct types. For this initial evaluation we compared the mechanical properties of these graft–femoral fixation techniques by single cycle uniaxial distraction to failure. More comprehensive evaluation will require assessment of cyclic loading behavior and in situ mechanical properties.

We found that the initial mechanical performance of a new bone implant designed to secure a tendinous or ligamentous graft to the canine femur was similar to comparable, established implants (spiked washer and screw; staples). Further evaluation is needed to determine the fatigue and graft tensioning characteristics of this prototype implant, which may be a useful for femoral CrCL (or ACL) graft reconstruction fixation after additional optimization.

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Fig 1.

Schematic of a prototype fixation implant (Graftgrab; GG). The stainless-steel base of the new implant has a round, tapered lateral surface with a central hole (H). A sleeve (S) and tapered spikes (black arrows) extend from the inner surface of the implant. There is a channel (C) from the center to the perimeter of the implant to position the graft for attachment once it is pulled through the sleeve. An acetal copolymer clip with a hinge (Hi) on one side and a clasp (Cl) on the other crosses the channel to fit securely into notches in the implant base (black arrow heads). The clip has a serrated central surface with 2 central prongs (gray arrow heads) that protrude further into the channel and 2 shorter peripheral prongs (gray arrows) that secure the graft without impeding clip closure.

Fig 2.
Tendinous reconstruction graft (black arrow) extending from the femoral bone tunnel. The cranial aspect of the lateral condyle is to the right (C).

Fig 3.
Tendinous reconstruction graft secured to the lateral aspect of the femoral condyle with a spiked washer and screw. The cranial aspect of the lateral condyle is to the right (C).

Fig 4.

Tendinous reconstruction graft secured to the lateral aspect of the femoral condyle with 2 bone staples. A staple (arrow head) was placed over the graft caudal to the bone tunnel. The graft was folded over the staple in a cranial direction, and another staple (arrow) was placed over the graft between the bone tunnel and the first staple. The cranial aspect of the lateral condyle is to the right (C).

Fig 5.
Tendinous reconstruction graft secured to the lateral aspect of the femoral condyle with a prototype implant (Graftgrab; GG). The cranial aspect of the lateral condyle is to the right (C).

Fig 6. Femoral section mounted on a testing fixture attached to the load cell of a materials test system (white arrow). The intra-articular surface of the specimen faces the direction of the actuator, and the long axis of the bone tunnel is aligned with the direction of load application. The free end of the graft (black arrow) is gripped with a cryoclamp.

Mean ($\pm$ SEM) Mechanical Properties of 3 Implants (Spiked Washer and Screw [SW]; Bone Staple [ST]; Prototype Implant [Graftgrab, GG]) for Fixation of Semitendinosus–Gracilis Muscle Tendons Grafts to the Lateral Aspect of the Canine Femur for Cranial Cruciate Ligament Reconstruction

Table 1

Variable	SW	ST	GG	P	δ (%)
Failure load (N)	110.1 $\pm$ 9.3	123.8 $\pm$ 9.1	137.9 $\pm$ 20.3	0.39	30
Failure elongation (mm)	23.2 $\pm$ 2.6	25.6 $\pm$ 2.7	28.9 $\pm$ 3.1	0.36	21
Yield load (N)	82.8 $\pm$ 7.2	105.4 $\pm$ 3.1	94.5 $\pm$ 18.4	0.40	35
Yield elongation (mm)	15.7 $\pm$ 2.1	20.0 $\pm$ 2.2	17.0 $\pm$ 2.1	0.37	34
Stiffness (N/mm)	8.2 $\pm$ 1.6	7.8 $\pm$ 1.0	7.4 $\pm$ 0.8	0.90	41
Yield strain energy (J)	0.55 $\pm$ 0.13	0.87 $\pm$ 0.13	0.76 $\pm$ 0.25	0.46	65
Failure strain energy (J)	1.38 $\pm$ 0.36	1.72 $\pm$ 0.33	1.95 $\pm$ 0.38	0.53	60
Femoral condyle width (mm)	24.3 $\pm$ 1.1	24.0 $\pm$ 0.61	26.9 $\pm$ 1.1	0.07	10
Femoral tunnel length (mm)	19.7 $\pm$ 0.07	19.8 $\pm$ 0.03	19.8 $\pm$ 0.06	0.25	0.71

Fixation was tested in single cycle uniaxial distraction (50mm/min) to failure.

δ =differences between populations necessary for significance at power=0.80.