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A prospective randomized comparison of two distinct allogenic tissue constructs for anterior cruciate ligament reconstruction

Michael B Rose, Christopher Domes, Mehwish Farooqi, Dennis C Crawford *

Department of Orthopedic Surgery and Rehabilitation, Oregon Health and Science University, 3181 S.W. Sam Jackson Park Road, Portland, OR 97239-3098, United States

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ABSTRACT

Background: Conduct a prospective randomized study to compare clinical outcomes of anterior cruciate ligament (ACL) reconstruction using quadrupled hamstring tendon (HT) allograft or doubled tibialis anterior (TA) allograft. Limited level 1 data exist comparing outcomes of different soft tissue allograft constructs for ACL reconstruction. We hypothesized no difference would exist in the patient reported outcomes (PRO), arthrometric testing, or rate of re-rupture between the two constructs.

Methods: Ninety eight subjects undergoing primary ACL reconstruction were randomized to HT ($n = 47$) or TA ($n = 51$) allograft. Subjects completed validated (PRO) measures pre-operatively, and six months and two years post-operatively. Arthrometric testing was performed at six months to assess integrity of the reconstruction.

Results: Fifty-eight percent of subjects (57/98) completed a two-year follow up. Allograft re-tear rates were similar between groups (6.2% HT vs. 4.0% TA, respectively, $p = 1.0$). The relative risk of re-tear in the HT group was 1.5 compared to the TA group ($p = 0.7$). The TA group improved significantly more on the physical portion of the VR-12 ($p = 0.046$) and Lysholm score ($p = 0.014$) compared to the HT group. There was no difference in the change from baseline for the other PRO scores at two years.

Conclusions: Our data indicate no difference in graft failure rate and similar improvement from baseline in most PRO scores between treatment groups after two years. Based on these findings, TA allograft appears to provide a reliable and satisfactory option for patients who elect to undergo allograft ACL reconstruction.

1. Introduction

Current treatment options for surgical reconstruction of the anterior cruciate ligament (ACL) are numerous. The choice of reconstruction technique is dependent on surgeon experience and numerous patient specific factors, in balance with considerations to cost and efficacy [1–3]. While bone patella tendon bone (BPTB) autograft may be considered the historic "gold standard", the use of allograft tissues for ACL reconstruction has increased over the last 20 years [1]. Estimates suggest that 20 to 40% of ACL reconstructions are now performed using allogenic graft sources [4–6]. Advantages for allograft may include shorter surgical and anesthesia times, fewer complications, reduced morbidity at the harvest site, lower incidence of post-operative arthrofibrosis, faster immediate post-operative recovery, and less post-operative pain [1,2,7]. Drawbacks include potentially higher rates of re-rupture, limited availability, delayed healing and ligamentization compared to autografts, risks of disease transmission, and higher cost [3,8–11].

* Corresponding author at: 3181 S.W. Sam Jackson Park Road, Portland, OR 97239-3098, United States.
E-mail address: crawfden@ohsu.edu (D.C. Crawford).

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Comparison between the two types of grafts is still the focus of much research. Limited prospective clinical outcomes data exist directly comparing the available allograft tissues, in particular soft tissue grafts [7,12–17]. Unfortunately, prior studies assessing soft tissue allografts have mostly included hamstring grafts and an assortment of tissue processing methods [6,16,17]. It is understood that allograft processing plays a major role in graft mechanical and biologic properties, with cryopreservation, proprietary chemical washes, level of irradiation, and donor age among other factors affecting the allogenic tissue integrity [18].

In general, more recent studies suggest that the type of allograft selected makes little difference in outcomes [12,15]. In vitro, BPTB, Achilles tendon, tibialis anterior (TA), and hamstring tendon (HT) allografts have similar biomechanical properties including ultimate tensile stress and failure strain [19,20]. Our group was specifically interested in TA allografts due to a widely cited publication suggesting a remarkably high risk of re-rupture and rate of reoperation for TA allografts [21]. However, consistent with our prior clinical experience, no other studies of TA allografts have found similar rates of failure and several long term follow-up studies have shown good clinical outcomes with re-rupture rates ranging from six to 14% [22–24]. Additionally, a more recent prospective study showed no statistically significant differences in arthrometry, mean International Knee Documentation Committee (IKDC) subjective knee evaluation scores, or rate of re-operation when comparing TA allografts and HT autografts [14].

1.1. Purpose and hypothesis

The purpose of this study was to address the void in the literature comparing commonly used soft tissue allografts. Therefore, we conducted a prospective randomized study to compare clinical outcomes of ACL reconstruction using quadrupled HT allograft or doubled TA allograft. We hypothesized that no difference would exist in the rate of re-rupture between HT and TA groups. Secondary outcomes included differences in arthrometric testing and patient reported outcomes data between the two allograft constructs.

2. Methods

Institutional ethics review approval was obtained and the study was registered with clinicaltrials.gov (NCT01148784) before enrollment began. All patients aged 18 to 70 years who presented to the principal investigator's clinic for a primary ACL tear during the open enrollment period were considered for the study. Patients underwent a pre-operative history and physical exam as well as magnetic resonance imaging (MRI) to confirm the diagnosis of an ACL tear. To be eligible, the patient's ACL injury had to be the primary limitation to activities of daily living and the patients must have been willing and medically able to undergo surgical repair of their injured knee. Patients were excluded if they had multiple ligamentous injuries to the knee (posterior cruciate ligament, posterolateral corner), advanced knee arthritis, any associated fracture around the knee, or uncorrected instability of the ACL on the contralateral knee. Patients were not excluded if they had previous minor ipsilateral arthroscopic knee surgery (e.g. chondroplasty, meniscectomy or repair), although ACL revision surgery was an exclusion criterion. Patients meeting study criteria were then counseled about the differences between autograft and allograft reconstruction. If the patient chose to undergo allograft reconstruction of their ACL, they were invited to participate in the study. A total of 102 subjects were consented for the study by a physician's assistant or research assistant at a separate pre-operative appointment. Subjects were randomized via block randomization (sealed envelope) to either HT or TA allograft at the time of surgery. Two subjects who were consented and randomized were found intra-operatively to have strained but intact ACLs (negative pivot shift) and were withdrawn from study participation. Therefore, 100 subjects underwent reconstruction of their ACL tears with either doubled TA allograft or quadrupled HT allograft. Two subjects who were randomized and received TA allografts did not complete all baseline PRO data and therefore were excluded from the final data analysis (Figure 1).

2.1. Surgical technique

All allografts were fresh frozen, low level gamma irradiated (less than 20 kGy), treated with a proprietary detergent (Allowash©, LifeNet Health, Virginia Beach, VA) and were a minimum of 7.0 mm diameter when bundled (Community Tissue Services©, Kettering, OH). Subjects then underwent standard ACL reconstruction as outpatients in one academic hospital ambulatory surgical center setting by a single attending surgeon (DC). General anesthesia was used with the addition of a continuous infusion femoral nerve block catheter (0.2% Ropivicaine), which was left in place for 72 h. All reconstructions were performed with a trans-tibial femoral anatomic single tunnel technique. The allografts were prepared with interlocking stitch sutures (#2 Ticron) at the tendon extremes, leaving at least 18 mm of non-stitched intra-articular and intra-osseous graft tissue and doubled. Grafts were pre-tensioned to 10 N before fixation with an endobutton (Smith & Nephew©, Andover, MA) on the femoral cortex and a “bio-interference” screw with sheath (DePuy Mitek©, Raynham, MA) in the tibial metaphysis (sized to nearest 0.5 mm). Post-operatively, subjects were prescribed and instructed on a standard progressive ACL rehabilitation protocol with progression dependent on achieving functional milestones (Table 1). This included immediate crutch-assisted weight bearing as tolerated on the operative extremity with a knee immobilizer for protection only during the period of quadriceps inhibition (approximately four days) while the nerve block remained in effect. Routine follow-up was conducted at two and six weeks as well as three, six, 12 and 24 months post-operatively. Subjects were allowed to return to sport after all goals of physical therapy had been met (Table 1). Subjects were not routinely braced for sport after rehabilitation was complete. Upon request, subjects were made aware of the intervention (allograft type) they received after completing 2-year follow-up.

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