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ANTERIOR CRUCIATE LIGAMENT RECONSTRUCTION:

WHICH GRAFT IS BEST TO PREVENT RE-TEAR?

A MASTER'S PROJECT
SUBMITTED TO THE GRADUATE FACULTY
GRADUATE SCHOOL
BETHEL UNIVERSITY

BY
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IN PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR
THE DEGREE OF
MASTERS OF SCIENCE IN PHYSICIAN ASSISTANTS

AUGUST 2016

BETHEL UNIVERSITY

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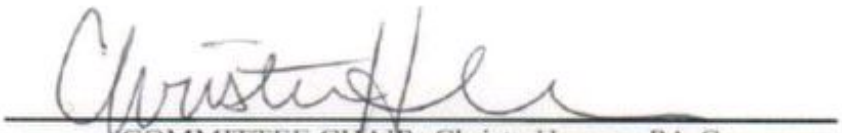
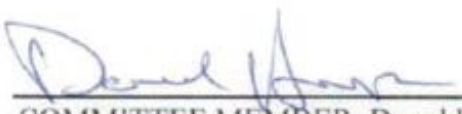
GRADUATE RESEARCH APPROVAL



COMMITTEE CHAIR; Christy Hanson, PA-C



COMMITTEE MEMBER; Donald Hopper, PhD, ACSM-RCEP

ABSTRACT

The three most widely used graft choices currently employed in anterior cruciate ligament (ACL) repair are: patellar tendon autograft, hamstring tendon autograft, and cadaver tendon allograft. The purpose of this study is to examine the efficacy of each of these 3 graft choices (patellar tendon autograft, hamstring tendon autograft, and cadaver tendon allograft) and determine which graft is less prone to re-tear. The study was implemented using a quantitative design process. The patient data was obtained and analyzed via Facebook survey. All identifying patient information was removed. Patients were included based on whether or not their ACL reconstruction was performed using patellar tendon autograft, hamstring tendon autograft, or cadaver tendon allograft. Although ACL reconstruction remains one of the most widely performed procedures, there is no definitive answer as to which type of repair is more preferential in regards to preventing re-tear. This study found that there is not a significant difference in the three most commonly used grafts in ACL reconstruction among this population of participants in regards to postoperative re-tear.

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INTRODUCTION

Background

The anterior cruciate ligament (ACL) runs diagonally through the middle of the human knee connecting the femur to the anterior tibial plateau. It provides rotational stability to the knee and prevents the tibia from sliding out in front of the femur (ACL Injuries, 2014). The ACL is one of two cruciate ligaments located within the knee joint, the other being the posterior cruciate ligament (PCL). Within the knee joint, these ligaments cross each other to form an "X." Their respective names are derived from whether they attach to the anterior or posterior side of the tibia (Saladin, 1998). Together, these ligaments are responsible for controlling the flexion and extension of the knee (ACL Injuries, 2014).

The ACL may be injured in several ways. Mechanism of injury include, but are not limited to: stopping suddenly, rapidly changing direction, decreasing acceleration while running, landing from a jump incorrectly, or via direct contact or collision (ACL Injuries, 2014). Symptoms of a tear include: loss of full range of motion, tenderness along the joint line, discomfort while walking, and pain with swelling (ACL Injuries, 2014). The gold standard diagnosis of an ACL tear is arthroscopy (Siegel, 2012). However, due to invasiveness of the procedure and for purposes of more rapid detection, magnetic resonance imaging (MRI) Scan is more frequently used with a specificity of 95% and a sensitivity of 86%, in diagnosing ACL injuries (Siegel, 2012). Even without these diagnostic procedures, most providers are able to correctly diagnose an ACL tear based on a thorough history and physical examination of the knee (ACL Injuries, 2014).

ACL reconstruction restores functional stability to the knee, protecting the meniscal cartilages from cumulative future damage. Successful ACL reconstruction can enable patients to return to full active exercise, sporting activities and activities of daily living (McDermott, 2013).

Graft types can be broadly divided into two basic categories: autograft and allograft. An autograft reconstruction involves harvesting tissue from one part of the patient's body and implanting it into another area. An allograft reconstruction involves harvesting tissue from one human and transplanting it into another human host (McDermott, 2013). Within these two categories, the graft choices are further refined according to each category. Autograft reconstruction provides two options: patellar tendon or hamstring tendon (McDermott, 2013). Allograft reconstruction also provides two options: achilles tendon or quadriceps tendon. These two allograft options are sometimes grouped together as one category, simply referred to as tendon allografts (McDermott, 2013).

A patellar tendon autograft is considered to be one of the strongest grafts currently employed based upon the bone blocks present at either end of the graft (McDermott, 2013). These bone blocks allow for very solid, immediate fixation (McDermott, 2013). A patellar tendon autograft is also associated with a rapid rate of biological healing and incorporation into the repaired tissues, allowing for a more expedient return to full athletic participation and resumption of normal activities of daily living (ADLs) (McDermott, 2013). For these reasons, patellar tendon autograft remains one of the most frequently performed types of ACL reconstruction (McDermott, 2013). In addition to being one of the most painful post-operative grafts, other disadvantages of a patellar tendon graft include an extra incision where the graft is harvested, increased incidence of patellar tendonitis, patella fracture, patellar tendon pain and

discomfort while kneeling, and increased difficulty with rehabilitation/activation of the quadriceps tendon (McDermott, 2013).

Hamstring autografts are associated with the lowest amount of postoperative pain (Lowe, 2014). Additionally, they require only one incision site, result in an easier rehabilitation and activation of the quadriceps tendon post-operatively, and has a faster return rate to normal activities of daily living when compared to the patellar autograft (Lowe, 2014). Disadvantages of a hamstring autograft may include a permanent reduction in hamstring strength on the side of the harvest, saphenous nerve damage near the site of the harvest which can result in numbness at the anterior side of the proximal tibial area thus resulting in a slower return to sporting activities and normal activities of daily living, and a weaker initial fixation at the site of repair (Lowe, 2014).

Benefits of using a cadaver allograft include no harvest morbidity, the most expedient return among graft choices to activities of daily living and sporting activities, a smaller incision on the medial tibia, and the least postoperative pain (Lowe, 2014). Disadvantages to a cadaver allograft repair include a higher risk of contamination and infection than autograft tendons, higher expense, delayed graft incorporation and failure, and a decrease in availability of cadaver allografts. (Mckee, 2012).

Minimal data exists to currently indicate which type of repair is associated with the lowest occurrence of re-tear. The purpose of this study to determine which type of ACL repair (patellar tendon autograft, hamstring tendon autograft or cadaver tendon allograft) is the best option to prevent re-tear. By providing data regarding which types of repair are associated with a

higher risk of re-tear, both patients and providers will be able to make a more informed decision regarding the optimal treatment option.

Problem Statement

The anterior cruciate ligament is the most commonly injured ligament in the knee (Friedberg, 2014). Between 100,000 and 200,000 ACL ruptures occur per year in the United States (Friedberg, 2014). With ruptures affecting roughly 1 in every 3,500 people, and a high recurring rupture potential, it is important to understand treatment efficacy (Friedberg, 2014). An abundance of literature exists regarding differing grafts used in ACL reconstruction, however most findings regarding re-tear are insignificant and the conclusive data is based off of minimal evidence (Pastides, 2014). Current data has shown distinct differences between reconstructive graft choices, but it is still clear that no single graft has been deemed the "best" graft (Pastides, 2014). In addition, extensive variation exists in the decisions made by surgeons due to the lack of irrefutable evidence as to which reconstructive graft choice is best. With anterior cruciate ligament rupture rates increasing, it is pertinent to acquire significant data as to which reconstructive graft is best to prevent recurrence.

Purpose

The purpose of this study is to perform a quantitative assessment of the three types of anterior cruciate ligament reconstructive grafts (patellar tendon autograft, hamstring tendon autograft or cadaver allograft) with respect to re-tear post-operatively.

Significance of the Problem

Identifying an ACL reconstruction graft with the highest survival rate is crucial to determining the graft most likely to prevent re-tear. There is currently no significant data that

shows a single reconstruction graft (patellar tendon autograft, hamstring tendon autograft, or cadaver allograft) that is least likely to re-tear. The graft choice for ACL reconstruction is often determined by each individual physician based on their own preferences. This can create a problem where physicians choose the graft that they are most comfortable using and not the best graft for the individual patient. Thus, more information and research needs to be conducted to determine the best type of graft for each patient to prevent re-tear. Additional information and research will improve the ability of healthcare providers to choose the best graft for their patient's ACL reconstructions in order to prevent re-tear.

In addition, current data does not provide any conclusive or agreeing information for providers. The studies comparing various ACL reconstructive grafts are inconclusive and have not found any significant differences in regards to re-tear. It is important for physicians to be able to recommend the best graft option for their patients based on current evidence.

Research Questions

The following research questions will be explored in this study through a quantitative approach:

1) Is there a significant difference in the rate to re-tear between the three different graft types used (patellar tendon autograft, hamstring tendon autograft and cadaver tendon allograft) in ACL reconstructive surgery?

2) Which type of graft has the strongest relationship with preventing re-tear post-operatively?

Variable Definitions

The following terms will be addressed within the study: ACL re-tear in this study is considered to be a full tear of the ACL as determined by an MRI that had previously been successfully repaired through ACL reconstruction surgery using a patellar tendon autograft, hamstring tendon autograft or cadaver allograft.

LITERATURE REVIEW

Introduction

Anterior cruciate ligament (ACL) reconstructive surgery is one of the most common elective orthopedic procedures performed (Lyman, Linklater, Pinczewski, Salmon, Roe & Russell, 2007). In the United States alone, over 102,000 ACL reconstructions were performed in 1996 (Lyman et al., 2007). Yet, despite the frequency of ACL reconstructions performed, there remains significant disagreement among surgeons as to which outcomes are the most preferred regarding ligament graft choice (Lyman et al., 2007). For this reason, additional studies are required to determine which type of graft is truly optimal to prevent re-tear. Throughout this literature review, current studies performed on graft choice and graft comparison will be discussed.

A study done in 2014 reviewed the graft choice for ACL reconstruction (Pastides, Sarraf, Shaerf, Willis-Owen, 2014). This analytical study concentrated on the reasons for the wide variation in graft choice among physicians and how current research available is backed by minimal evidence. The results of this study found no significant differences between the patellar tendon autograft, hamstring tendon autograft, cadaver allograft, and synthetic grafts used in ACL reconstruction. Thus, the study concluded that there is no clear-cut "best" graft for everyone. Surgeons need to understand the unique characteristics of each type of graft in order to choose the appropriate graft for each individual patient based upon their requirements (Pastides, Sarraf, Shaerf, Willis-Owen, 2014).

In 2011, Csintalan, Fithian, Granan, Inacio, Maletis, Maria, Paxton and Tadashi performed a cross-sectional study that focused on the important factors associated with graft

selection. This study questioned whether a surgeon's experience was the most important factor associated with graft selection. The study evaluated 9,849 ACL reconstruction procedures, by 214 surgeons, in 42 different locations throughout the United States (Csintalan, Fithian, Granan, Inacio, Maletis, Maria, Paxton, Tadashi, 2011). The high volume of procedures analyzed and the sample of surgeons allowed the study findings to be generalized to the community. The results revealed that throughout the country, the allograft was the most commonly used graft, followed by the hamstring autograft, and then the patellar tendon autograft. When comparing these statistics with possible factors for graft choice, the study found that there were diverse and insignificant patterns associated with graft selection (Csintalan, Fithian, Granan, Inacio, Maletis, Maria, Paxton, Tadashi, 2011). In conclusion, multiple variables including gender, age, race, facility and surgeon characteristics, are associated with graft selection.

Comparison of Patellar Tendon and Hamstring Tendon Autografts in ACL Reconstruction

Despite the multitude of studies, graft choice for ACL reconstruction is an ongoing debate. The controversy stems from the lack of clinical studies that adequately support one graft over another. In the past, the patellar tendon autograft graft has been the most commonly used, but in recent years the number of hamstring tendon autografts being used for ACL reconstruction has been increasing. Today, the two most widely used grafts in ACL reconstruction are the patellar tendon and the hamstring tendon autograft (Lind, Pedersen, Rahr-Wagner, Thillemann, 2014). Many studies are finding that the patellar tendon and hamstring tendon autograft selections have insignificant differences overall (Harilainen, Jansson, Linko, Sandelin, 2003).

In a controlled, prospective trial conducted at St. Vincent's Hospital in Sydney, Australia by physicians Linklater, Lyman, Pinczewski, Roe, Russell, and Salmon, a 10-year comparison of

ACL reconstruction was studied between hamstring tendon and patellar tendon autografts (2007). The study began in January 1993 and ended in January 2003. The goal was to provide a comparison to better determine the effects of graft choice on the clinical outcome of ACL reconstruction. The authors believed that studying the long-term implications of patellar tendon autografts and hamstring tendon autografts would lead to fewer discrepancies in determining which graft choice was best (Linklater et al., 2007). A focus was placed on patient selection, surgical technique, rehabilitation and independent assessment pre and post surgically (Lyman et al., 2007).

The study population consisted of patients who met the inclusion criteria that included a need for ACL reconstruction, who desired to return to sports with pivoting, cutting or sidestepping or who had experienced continued episodes of instability despite conservative treatments involving physiotherapy (Lyman et al., 2007). Additionally, all patients studied exhibited a failed Lachman and pivot shift test during preoperative clinical examination (Lyman et al., 2007).

A total of 180 patients (95 men and 85 women) were collectively studied (Lyman et al., 2007). These patients were then divided into two groups, those that received a patellar tendon autograft (90) and those that received hamstring autograft (90) (Lyman et al., 2007). The median age of patients that received a patellar tendon autograft was 25, while the median age of those that received a hamstring tendon autograft was 24 (Lyman et al., 2007). Data was collected on each group of patients annually for 5 years, and then again at 7 and 10 years respectively (Lyman et al., 2007).

The surgical technique used involved the use of the ipsilateral middle third patellar

tendon, or 4-strand gracilis, and semitendinosus tendon grafts (Lyman et al., 2007). Within the patellar tendon group, a tunnel size of 1 mm greater than bone block size was used, with a range of 8 to 11 mm (Lyman et al., 2007). The hamstring tendon group used a tunnel size that equaled the cross-sectional diameter of the graft with a range of 6 to 9 mm (Lyman et al., 2007). Both patient groups were enrolled in a similar rehabilitation program post operatively with the same group of physical therapists (Lyman et al., 2007). Physical therapy involving quadriceps and hamstring muscle contraction began immediately following surgery (Lyman et al., 2007). No brace was used post operatively in either patient group, and weight bearing with assistance was strongly encouraged (Lyman et al., 2007). All patients were encouraged to reach full extension by day 14, to begin jogging by week 6, and to return to competitive sports 6 months' post-operatively (Lyman et al., 2007).

The results concluded that at 10 years post operation, no significant difference was present among graft rupture rates. Full knee joint function was reported in 97% of patients (Lyman et al., 2007). However, the patellar tendon group experienced 20 contralateral ACL ruptures in comparison to the hamstring tendon group who experienced 9 ruptures (Lyman et al., 2007). In both groups, graft rupture was associated with instrumented laxity >2 mm at 2 years. Additionally, the patellar tendon group experienced harvest site symptoms such as kneeling pain and pain with strenuous activities more frequently than the hamstring tendon group. Those who received patellar tendon reconstruction experienced an increased prevalence of radiographic osteoarthritis in comparison to hamstring tendon reconstruction, thus supporting the hamstring tendon as a better graft choice (Lyman et al., 2007).

This study suggests hamstring tendon reconstructions are the most desirable based on

decreased harvest-site symptoms, and radiographic osteoarthritis (Lyman et al., 2007). However, what is missing from this study is an evaluation or comparative study on the third available graft, a tendon allograft. Therefore, further studies are needed before hamstring tendon ACL reconstruction can be deemed the superior graft choice.

A different randomized study compared the patellar tendon and hamstring tendon grafts in ACL reconstruction. Population size included 150 patients with a mean age of 26 years old (Hanus, Havlas, Kautzner, Kos, Trc, 2014). A Tegner Lysholm knee score and stability was used to evaluate each participant one to two years after ACL reconstructive surgery. An identical rehabilitation protocol was used on all participants. Analysis of collected data revealed statistically insignificant results. Participants who received the hamstring graft had significantly less anterior knee pain in the first six months postoperatively. However, overall, the Lysholm scores and stability between the patellar and hamstring grafts were not significantly different (Hanus, Havlas, Kautzner, Kos, Trc, 2014). Thus, the study found that neither patellar tendon grafts or hamstring tendon grafts showed a higher tendency toward graft failure within the first two years post-operatively.

A more recent study was conducted in April 2014. The study was a meta-analysis of 1,443 patients at least five years postoperative from patellar tendon autograft or hamstring tendon autograft ACL reconstruction surgery (Chen, Chen, Chen, Lai, Li, Liu, Xie, Xiao, Yang, Zhu, 2014). The objective of the study was to compare the two types of grafts at a minimum of five years postoperative, analyzing factors including preinjury activity level, Lachman test, pivot shift test, anterior knee pain, kneeling pain, extension and flexion loss, graft failure and radiographic outcomes. The methods of this study consisted of a systematic search of published

literature of randomized controlled trials and prospective cohort studies. (Chen, Chen, Chen, Lai, Li, Liu, Xie, Xiao, Yang, Zhu, 2014).

The results of the meta-analysis revealed no significant difference between the patellar tendon autograft or the hamstring tendon autograft in terms of the international knee documentation scores, return to preinjury activity, Lachman test, pivot shift test, extension deficit, flexion deficit and graft failure. However, statistical evidence did suggest that hamstring tendon autografts have better outcomes in terms of anterior knee pain, and kneeling pain. In addition, radiographic findings showed evidence that the incidence of osteoarthritis was significantly higher in those who received patellar tendon grafts in comparison to those who received hamstring tendon grafts during ACL reconstruction (Chen, Chen, Chen, Lai, Li, Liu, Xie, Xiao, Yang, Zhu, 2014). This study showed that overall, there are no significant differences between the patellar tendon and hamstring tendon graft choices in ACL reconstruction, but revealed long-term benefits of choosing the hamstring tendon graft over the patellar tendon graft.

A similar study was performed by Chan DS, Dainty KN, Mohtadi NGH, and Whelan DB in 2011, and revealed additional statistical differences between the patellar tendon autograft and the hamstring tendon autograft in ACL reconstruction. This study compiled nineteen trials, for a total of 1,597 middle-aged adults who had ACL reconstruction surgery with either patellar or hamstring tendon autografts. The pooled data showed no statistically significant differences between the two graft choices in regard to functional assessment (single leg hop test), return to activity, Tegner and Lysholm scores, interventions for re-rupture, international knee committee scores, and subjective measures outcome (Chan, Dainty, Mohtadi, Whelan, 2011). This study had inadequate long-term results, therefore making one unable to compare long-term knee

function and incidence of osteoarthritis in the patellar and hamstring tendon autografts. In contrast to the previous meta-analysis, this study found that the tests for static stability, including the instrumental, Lachman, and pivot shift tests, consistently showed significantly higher scores in the patients with patellar tendon reconstruction (Chan, Dainty, Mohtadi, Whelan, 2011). In conclusion, this study demonstrated that the patellar tendon and hamstring tendon autograft choices in ACL reconstruction are statistically similar in many aspects, except for knee stability, in which case the patellar tendon autograft demonstrates better results.

Comparison of Autografts versus Allograft in ACL Reconstruction

One concern about ACL reconstruction arises from the controversy that exists between multiple postoperative outcomes of different reconstruction grafts (Bravman, Kraeutler, McCarty, 2013). Functional results, complications, knee stability and patient satisfaction are at the root of comparison of ACL reconstructive grafts. (Bravman, Kraeutler, McCarty, 2013)

In a meta-analysis of 5,182 patients conducted by Bravman, McCarty and Kraeutler, patellar tendon autografts were compared to patellar tendon allografts in effort to statistically define differences between the two graft options. The analysis found that of 11 outcomes assessed, 6 significantly favored patellar tendon autografts for ACL reconstruction (Bravman, Kraeutler, McCarty, 2013). These outcome tests indicate that patellar tendon autografts have a lower rate of re-injury, lower level of knee laxity, better jumping function, and overall, greater satisfaction (Bravman, Kraeutler, McCarty, 2013). In comparison, 4 of 11 outcome tests significantly favored patellar tendon allografts, and suggest that the allograft is best for return to preinjury activity level, pivoting function and lower levels of anterior knee pain (Bravman, Kraeutler, McCarty, 2013). Although the analysis illustrates disparities among patellar tendon

autografts and patellar tendon allografts, it fails to establish a definitive conclusion as to which graft is best for ACL reconstruction. In addition, the study notes a need for additional research tailored to patient decision making concerning graft choice. (Bravman, Kraeutler, McCarty, 2013).

A similar systematic review was conducted by Foster, Kaye, Ryan, Silvestri and Wolfe, and involved 31 studies. The study questioned whether or not the graft source was a significant factor in the outcome of patients who underwent ACL reconstruction. An assessment of autograft versus allograft reconstruction was conducted and showed very few statistically significant differences between autograft and allograft tissues. (Foster, Kaye, Ryan, Silvestri, Wolf, 2010). Evaluation of short-term and long-term studies involving autografts show different postoperative trends, thus questioning the reliability of the data (Foster, Kaye, Ryan, Silvestri, Wolf, 2010). Definitive problems regarding allografts revolve around disease transmission and graft rejection, but lack the functional outcome evidence needed to determine the most beneficial ACL reconstruction graft (Foster, Kaye, Ryan, Silvestri, Wolf, 2010). Overall, the study could not identify an individual superior graft type due to an absence of statistically significant evidence (Foster, Kaye, Ryan, Silvestri, Wolf, 2010).

In addition, a study of revision rates in patellar tendon autograft and allografts in ACL reconstruction was completed by researchers Foster, Mandala, Mehtha and Petsche, and showed conclusive results. The study involved 173 patellar tendon ACL reconstructions, 142 patellar autograft and 31 patellar allograft reconstructions, all performed by a single surgeon (Foster, Mandela, Mehta, Petsche, 2006). The data was collected over a six-year period, from January 2000 to December 2006 with a mean patient follow up of 49 months (Foster, Mandela, Mehta,

Petsche, 2006). All patients who were a part of the study participated in the same rehabilitation program. Activity was introduced 4 months postoperatively, and full return to sports occurred at 6 months after passing a strength assessment test (Foster, Mandela, Mehta, Petsche, 2006). The study concluded that revision rates were 0.7% in patellar tendon autografts in comparison to 9.7% in patellar tendon allografts. Also concluded, was that in non-ruptured, non-revised grafts the international knee documentation committee scores were higher for autografts at 98.3 versus 95.2 in the allograft group (Foster, Mandela, Mehta, Petsche, 2006). Overall, 45%, 14 of the 31 allografts used in ACL reconstruction were irradiated (Foster, Mandela, Mehta, Petsche, 2006). However, no difference in revision rates were found when the irradiated grafts were excluded from the data (Foster, Mandela, Mehta, Petsche, 2006).

Among concerns for the use of allografts in ACL reconstruction is the increased length of time it takes for the graft to re-vascularize and remodel in comparison to an autograft (Foster, Mandela, Mehta, Petsche, 2006). Literature states that this factor may cause the allograft to have weaker structure, thus possibly leading to higher rupture rates (Foster, Mandela, Mehta, Petsche, 2006). Despite this evidence, allografts are still a popular option in effort to avoid peri-operative morbidity linked with the harvesting of autograft tissue and due to faster return to full function (Foster, Mandela, Mehta, Petsche, 2006). This study demonstrates that allografts have a higher failure rate in ACL reconstruction in contrast to autografts.

Summary

The current literature shows a large variance in knowledge surrounding ACL reconstruction and demonstrates the need for additional evidence-based research involving ACL reconstruction and the graft choices available. The studies, as highlighted earlier, focus on

varying graft choices, but do not provide a definitive answer about the superiority of one graft over another. This suggests that altering study design and focusing on one variable may be beneficial in determining which ACL reconstruction graft is superior. In this study, the focus will be placed on determining which ACL reconstruction graft choice (patellar tendon autograft, hamstring tendon autograft or cadaver tendon allograft) is truly optimal to prevent re-tear.

METHODOLOGY

Introduction

Anterior cruciate ligament (ACL) injury has an annual incidence of more than 200,000 cases with roughly 100,000 of these resulting in reconstruction. Despite this staggering figure, there is currently no definitive analysis to indicate which type of ACL reconstruction graft, patellar tendon autograft, hamstring tendon autograft or cadaver tendon allograft, is associated with the lowest occurrence of re-tear. The purpose of this research study is to examine the efficacy of the 3 most widely used graft choices and determine which graft is least prone to re-tear. The following research question is designed to address the purpose of this study:

1) Is there a significant difference in the rate to re-tear between the three different graft types used (patellar tendon autograft, hamstring tendon autograft and cadaver tendon allograft) in ACL reconstructive surgery?

In order to implement this approach, a survey was used and distributed electronically through Facebook. The purpose of this chapter is to further describe the research methodology employed. This description includes a discussion of the following sections: study design, study subject variables, population, validity and reliability, procedures, data analysis and limitations.

Study Design

This research project obtained data from a structured survey through Survey Monkey in order to analyze which anterior cruciate ligament reconstruction graft is best to prevent re-tear after surgical repair. The survey was delivered and shared through the researchers' Facebook accounts. Participants were required to be 18 years or older to participate. The survey asked voluntary participants questions regarding their ACL repair, including graft choice, date of repair,

and outcomes. Data involving anterior cruciate ligament reconstruction using patellar tendon autografts, hamstring tendon autografts and cadaver tendon allografts was collected and analyzed. Distribution of this survey as a means for data collection allowed for an extensive, diverse population size to be studied.

Study Subject Variables

This study compiled information on three different independent variables and tested whether they affected a single dependent variable. The independent variables are the three types of possible ACL reconstructive grafts, including patellar tendon autografts, hamstring tendon autografts and cadaver tendon allografts. The dependent variable is the frequency of re-tear based on research findings.

Population

The survey was offered and shared through Facebook to voluntary participants. The survey was public, allowing anyone who came across the survey to take it by clicking the hyperlink to Survey Monkey. It was shared by the authors of this study to their Facebook friends. This population was selected based on convenience, as well as variability in gender, race, age and education levels. The participants were required to be 18 years or older to take the survey. The survey collected data from participants who have undergone ACL reconstruction using patellar tendon autografts, hamstring tendon autografts or cadaver tendon allografts. The surgeon and surgical technique were not considered in this research. Identifying factors such as patient name, address, date of birth and social security number were not asked or obtained in this study. There was no contact between the researchers and the participants involved in this study. All survey participants were required to view an informed consent prior to taking the survey. Data

collection took place over Facebook for one month, beginning February 13, 2016 to March 13, 2016, with a total of 94 survey responses collected.

Validity & Reliability

Data was collected from completed surveys that were distributed via Facebook. The survey obtained objective information from individuals who have undergone ACL reconstructive surgery. This study did not include qualitative or subjective data. It is assumed that the data was obtained from individuals who have been cared for by various orthopedic surgeons from numerous healthcare systems, thus the information can be generalized to all medical orthopedic centers. There is the potential that over time there will be new surgical techniques or preferred graft choices that may out date this study in the future. The statistical analysis was reviewed by Donald Hopper, PhD, ACSM-RCEP to ensure that statistical tests were completed accurately.

Procedure

During February 13, 2016 to March 13, 2016, a seven question survey was accessible to the authors of this study's Facebook friends via a hyperlink to Survey Monkey. A cover letter was viewed prior to accessing the survey. The survey was shared multiple times from February 13th to March 13th via Facebook to increase response rates. At least 30 surveys were intended to be received based on expectations. Surveys collected after March 13th, 2016 were not included in the data analysis.

Statistical Analysis

Following the collection of participant data, information was compiled and statistically calculated using MedCalc. The statistical analysis was conducted by the authors of this study

under the direction of Donald Hopper, PhD, ACSM-RCEP. A statistical comparison of the three graft types (patellar tendon autograft, hamstring tendon autograft and cadaver tendon allograft) was performed using Kaplan-Meier survival analysis, to assess for a statistical difference in time or rate to graft re-tear. All data is stored with the Bethel University Research Coordinator for security purposes.

Limitations

The following are limitations that the researchers believe to be possible weaknesses of this study, that were out of the researchers' control:

1. The research data was obtained through Facebook; thus it will not include information from individuals who do not have a Facebook profile.
2. The survey was distributed by the study's authors; thus only having reached a certain Facebook population.
3. There was a lack of personal contact with the survey population, which may have decreased the response rate compared to having in-person contact.
4. The participants of this survey were assumed to be from all age groups above the age of 18. Thus, some data may contain outdated surgical techniques and strategies that are not used anymore today.
5. The surgeon and surgical technique were not considered in this study.
6. All data collected and analyzed was self-reported and is not from a medical database, therefore information may be inaccurate.

The delimitations of this study are boundaries that have been set to ensure focus is kept on the independent variable, ACL re-tear. This study did not take into consideration other

independent variables that may have impacted the result of re-tear, including; patient adherence of wearing a knee brace, post-operative physical therapy patient participation, time of recovery, or time of return to activity.

Conclusion

The next chapter analyzes the results of the data collected from the survey. It contains a statistical analysis of the data to determine if there is a significant difference between graft choice and time to re-tear. The following chapter five discusses the relevant conclusions of the study and the possible follow-up research questions that may result from this study.

RESULTS

Data Collection

Data was collected from 94 survey participants who answered the web-based survey in regards to ACL reconstruction with graft repair. Of the 94 participants, 84 responses fit inclusion criteria and were analyzed. Participant surveys eliminated from data analysis met the exclusion criteria listed below in table 1.

Exclusion Criteria
Age <18
Incomplete survey
Participants who did not tear their ACL
Time to graft re-tear exceeding 5 years (60 months)
ACL reconstructions performed before the year 2000

Table 1. Summary of participant exclusion criteria

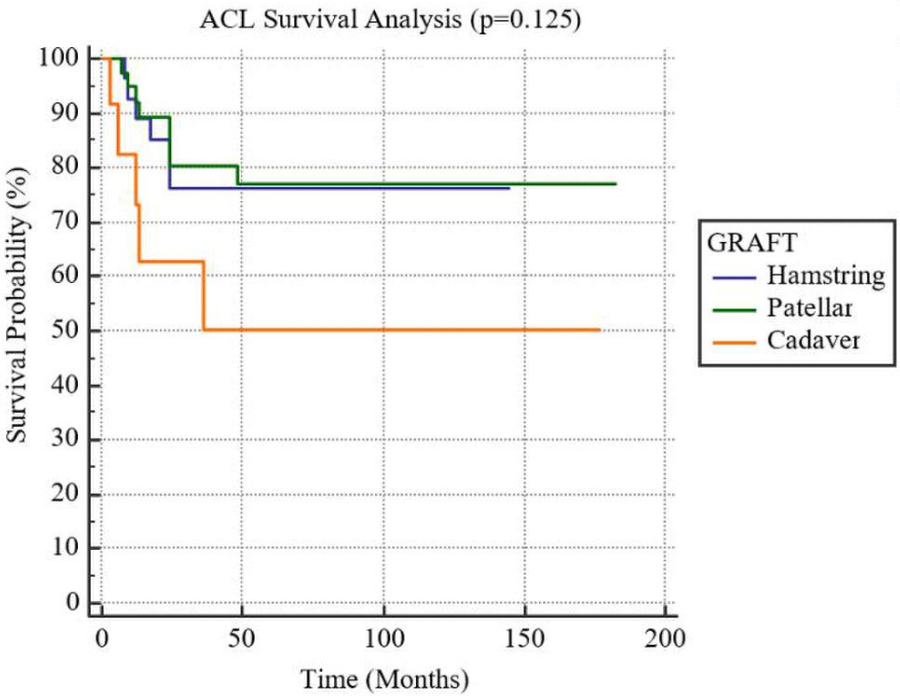
Graphs 1 and 2 shown below represent sample sizes of initial ACL reconstruction graft choice and re-tear occurrence. Of the population, 47.6% of participants underwent initial repair with patellar tendon autograft, 36.9% with hamstring tendon autograft, and the remaining 14.3%

with cadaver tendon allograft. ACL graft re-tear occurred in 23.8% of the studied population.

Graph 1. Total ACL reconstructions versus the number of graft re-tears among the population of participants
Graph 2. Specific graft used in the population of participants and the re-tear rates of each graft choice

Data Analysis

A Kaplan Meier estimate was performed using the program MedCalc, which analyzed graft survival over a period of 60 months. Survival rates of three graft types, patellar tendon autograft, hamstring tendon autograft and cadaver tendon allograft were compared. A log-rank statistical test was used to determine if there was a statistically significant difference, at any point in time, between the probability of ACL graft re-tear among the three graft types. Graph 3 and table 2 below show the survival analysis curve and the statistical analysis of the values across the curve. The p value, generated using the log-rank analysis, was 0.1255, supporting the null hypothesis and indicating that this study did not show a statistically significant difference among the survival of the three different ACL reconstruction grafts.



Statistical Comparison of Survival Curves			
	Chi-Square	DF	Significance
.og Rank (Mantel-Cox)	4.1503	2	p=0.1255

Statistical Significance is indicated if the P Value is

Graph 3. ACL survival analysis comparison of the three graft choices; Patellar, hamstring and cadaver
Table 2. Statistical comparison of the survival curve of the three grafts; Patellar, hamstring and cadaver

Although a statistically significant difference was not found, one must consider the logistics of the statistical test used. The Kaplan Meier analysis includes censored observations, thus surviving ACL grafts at the time of data analysis were involved in the generated results. This aspect comes into play when interpreting the survival analysis graph. The graph demonstrates a steep drop in the survival probability of the cadaver graft at a time of roughly 25 months. The lack of statistical significance may be correlated to the fact that not enough time has transpired for all subjects to reach the termination point of 25 months, where the cadaver graft appears to fail or result in re-tear. Therefore, the study lacks longevity in regards to the population of participants with cadaver repair.

DISCUSSION

The goal of this study was to determine if there was a significant difference between three different ACL reconstruction grafts (patellar tendon autograft, hamstring tendon autograft and cadaver tendon allograft) with respect to graft re-tear post-operatively. The statistical analysis reviewed in Chapter 4 calculated the survival probability as a means of comparing the three grafts studied. These results were used to evaluate and determine whether or not there is a significant difference among ACL reconstruction grafts in regards to graft re-tear after ACL reconstruction.

Study Conclusions

The data discussed above revealed that there is no significant difference between the three graft choices, (patellar tendon autografts, hamstring tendon autografts, or cadaver allografts) in regards to the population of participants. The survival rate was calculated for each of the three grafts based on the time to re-tear from the data collected via internet surveys. The three graft's survival probabilities were compared and revealed no significant difference.

Although the study did not definitively answer the research question posed, it did reveal a disparity between the two autografts, patellar and hamstring, in comparison to the cadaver allograft. The data indicates that those who underwent ACL reconstruction using the cadaver allograft had a decreased length in survival and a higher re-tear rate at a time frame of less than 25 months. The data is insignificant however, because not all studied participants who underwent ACL reconstruction with a cadaver allograft have reached 25 months' post-reconstruction. Thus implying that if participants were re-evaluated at a later date, once more time expires, with no change in graft outcome, there may be a significant difference between the graft choices.

Limitations

There are several limitations within this study. The first major limitation is the limited population size; surveys were distributed via Facebook and only a certain population was reached. Another limitation of this research project was the lack of participant's medical knowledge. This study assumed that each participant accurately answered the questions in the survey to the best of their knowledge, but error must be considered as the data provided was not verified. Also, this study did not allow for any personal contact with the participants, thus goals of the study were not emphasized and questions that may have arose during the completion of the survey were not answered. Lastly, there was no follow up with the participants after they completed the survey.

Implications and Recommendations for Further Research

Further research is needed to distinguish the benefits and negative outcomes of the three most commonly used ACL reconstruction graft choices, patellar tendon autograft, hamstring tendon autograft and cadaver tendon allograft. Additional data and information would be beneficial for orthopedic healthcare providers so they are better equipped to give accurate recommendations to patients undergoing ACL reconstructive surgery. More informative data on the various grafts would also help providers determine the best graft for each individual patient based on their specific needs.

Additional studies with larger population sizes are needed to determine if there are significant differences among the commonly used graft choices in ACL reconstruction. Future research projects could analyze the survival rate in regards to re-tear on a larger scale to determine if there is a significance. Also, added research could be done to repeat this survey with the same

group of participants in 5 years and then again in 10 years to see if the percentage of participants with re-tears has increased. This may produce significant results in the future.

Another option for future studies would be to choose a different dependent variable when comparing the graft choices such as patient adherence of wearing a knee brace, post-operative participation in physical therapy, time of recovery, or time of return to activity. This would give patients and providers more specific information about each graft option.

This study utilized internet connections via Facebook to accumulate data for analysis and graft comparison. Another method to study the differences between the grafts could involve obtaining patient data from an official orthopedic center and analyzing the success rates of grafts used among their own patients. This method of study may result in more accurate and reliable results but may needed additional time and funding.

Conclusion

Overall, the purpose of this study was to examine the efficacy of the three most common graft choices in ACL reconstruction (patellar tendon autograft, hamstring tendon autograft, and cadaver allograft) in regards to which graft is more preferential to preventing re-tear. A statistical quantitative analysis was performed using 84 participant responses from the distributed Facebook survey and assessed personal history of ACL reconstruction and repair with one of the studied grafts. The data and statistical analysis revealed that there is no significant difference between the three graft choices (patellar tendon autograft, hamstring tendon autograft, and cadaver allograft) in regards to re-tear among this population.

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APPENDIX A: INFORMED CONSENT

Physician Assistant Anterior Cruciate Ligament Reconstruction Survey

February 13 - March 13, 2016

Dear Participant:

You are invited to participate in a research study being conducted by graduate students from the Bethel University Physician Assistant Program. The study is designed to collect information to assess which ACL reconstruction graft (patellar tendon autograft, hamstring tendon autograft and cadaver allograft) is best to prevent retear.

You will be asked to complete an electronic survey. Your participation in this study is voluntary and you may refuse to participate at any time. At a maximum, the survey should only take five minutes to complete.

This survey has been approved by the Institutional Review Board of Bethel University. There are no risks associated with participating in this study beyond those encountered in everyday life. The survey collects no identifying information of any respondent. All responses will be anonymous and reported only as a collective combined total.

If you have any questions regarding the survey or this research project in general, please contact the research faculty chair, Professor Christina Hanson at (c-hanson@bethel.edu). If you have any questions concerning your rights as a research participant, please contact the IRB of Bethel University at Bethel University Institutional Review Board, P.O. Box 2322, 3900 Bethel Drive, St. Paul, MN 55112.

By continuing with the survey, you are indicating your consent to participate in the study. While you will not experience any direct benefits from participation, information collected in this study may benefit the profession of physician assistants in the future by better understanding their role in ACL reconstructive surgery. Your participation is appreciated.

Please click on the survey link below and provide us with your feedback no later than February 29, 2016.

https://www.surveymonkey.com/r/M2Q5Z2W

Thank you,

Katie Eslinger, Noelle Kreofsky & Brittany Kapala

APPENDIX B: SURVEY QUESTIONNAIRE

1. Have you ever torn your ACL (Anterior Cruciate Ligament)? YES NO

IF YOU ANSWERED NO TO QUESTION #1 PLEASE END THE SURVEY HERE.

2. Did you have your ACL repaired by a surgeon? YES NO

IF YOU ANSWERED NO TO QUESTION #2 PLEASE END THE SURVEY HERE

3. Which graft choice was used to repair your ACL?

    a. Patellar tendon
    b. Hamstring tendon
    c. Cadaver tendon
    d. Other

4. What was the date of your ACL reconstruction repair (month & year)? _____

5. Since your repair have you retorn your ACL? YES NO

IF YOU ANSWERED NO TO QUESTION #4 PLEASE STOP THE SURVEY HERE

6. How long after your ACL reconstruction did this retear occur? _____

7. Did you repair your ACL again after tearing the graft? YES NO

APPENDIX C: IRB Approval

Level 3 IRB Approval Inbox x

Wallace Boeve <w-boeve@bethel.edu> Feb 13

to me, Katherine, Noelle, Christy, Peter, Lisa

February 13, 2016

Brittany, Katie, & Noelle;

As granted by the Bethel University Human Subjects committee as the program director, I write this letter to you in approval of Level 3 Bethel IRB of your project entitled: "Anterior Cruciate Ligament Reconstruction: Which Graft is Best to Prevent Retear?" This approval is good for one year from today's date. You may proceed with data collection and analysis. Please let me know if you have any questions."

Sincerely;

Wallace Boeve, EdD, PA-C
Program Director
Physician Assistant Program
Bethel University
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651 308-1398 cell
651 635-1013 office
651 635-8039 fax
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CC: Bethel IRB Chair
Faculty Chair Advisor
PA Program Research Coordinator

APPENDIX D: DATA ANALYSIS

Data Summary					
	Number of events [a]		Number censored [b]		
Graft Type	N	%	N	%	Total sample size
Hamstring	7	22.58	24	77.42	31
Patellar	8	19.51	33	80.49	41
Cadaver	5	41.67	7	58.33	12
Overall	19	22.89	64	77.11	83

Mean Survival			
Graft Type	Mean	Standard Error	95% Confidence Interval for the Mean
Hamstring	114.372	10.995	92.821 to 135.923
Patellar	145.793	11.616	123.025 to 168.561
Cadaver	96.793	26.202	45.438 to 148.149
Overall	138.282	8.85	120.935 to 155.628