1998

Tensile Properties of the Autogenous Quadruple-Stranded Semitendinosus-Gracilis Graft Used for Reconstruction of the Anterior Cruciate Ligament

James E. Swanton
University of North Dakota

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TENSILE PROPERTIES OF THE AUTOGENOUS QUADRUPLE-STRANDED SEMITENDINOSUS-GRACILIS GRAFT USED FOR RECONSTRUCTION OF THE ANTERIOR CRUCIATE LIGAMENT

by

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Bachelor of Science, University of Wyoming, 1993
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University of North Dakota, 1997

An Independent Study
Submitted to the Graduate Faculty of the
Department of Physical Therapy
School of Medicine and Health Sciences
University of North Dakota
in partial fulfillment of the requirements
for the degree of
Master of Physical Therapy

Grand Forks, North Dakota
May 1998
This Independent Study, submitted by James E. Swanton in partial fulfillment of the requirements for the degree of Master of Physical Therapy from the University of North Dakota, has been read by the Faculty Preceptor, Advisor, and Chairperson of Physical Therapy under whom the work has been done and is hereby approved.

(David Kelly)
(Faculty Preceptor)

(Gregg M. Mahl)
(Graduate School Advisor)

(Thomas M.)
(Chairperson, Physical Therapy)
PERMISSION

Title
Tensile Properties of the Autogenous Quadruple-Stranded Semitendinosus-Gracilis Graft Used For Reconstruction of the Anterior Cruciate Ligament

Department
Physical Therapy

Degree
Master of Physical Therapy

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Signature

Date
12/15/97
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ACKNOWLEDGEMENTS

I must thank a number of people, for without them this project would not have been possible. First and foremost, thanks to Dr. Philip Q. Johnson whose enthusiasm, patience, and funding made this study a reality. Second, thanks to my preceptor Dave Relling and the entire UND-PT staff for your continual guidance over the past three years. A very special thanks to “my mentor” whose endless passion for the field of physical therapy continues to inspire me, as well as many others.

My family deserves more than a mere ‘acknowledgement’ for their unending prayers, encouragement, and support given throughout my life. Thank you for always being there. I dedicate this paper to you!

And finally, thanks to my special classmates who allowed me to lead them as their class president for three years. I won’t forget you...
ABSTRACT

The purpose of this study was to further enhance the knowledge of autogenous tissues around the knee which are used for reconstruction of the anterior cruciate ligament (ACL). Ten fresh-frozen cadaveric knee specimens were used to conduct this experiment. The semitendinosus and gracilis tendons, as well as the bone-patellar tendon-bone complex, were excised and prepared for testing. The semitendinosus and gracilis tendons were doubled and fashioned into a quadruple-stranded graft. The tissue units were then individually fixated in a tensile testing apparatus and tested to failure. Descriptive statistics were used to analyze and compare our data with similar studies to determine which graft best imitates the tensile strength of the biological ACL. Results of this study will add to the orthopaedic body of knowledge concerned with the determination of which knee autograft is optimal for reconstruction of an ACL-deficient knee.
CHAPTER I
INTRODUCTION

Tensile properties of the human anterior cruciate ligament (ACL) have been studied for years; however, few published articles exist which characterize its strength and stiffness behaviors. Even fewer studies exist which describe the tensile strengths of grafts used for replacement of an ACL-deficient knee. Intra-articular reconstructions of the ACL using either the central one-third of the patellar tendon or the pes anserine tendons have clinically proven to be the most successful types of grafts used.\textsuperscript{1,2,3,4} While there is literature to illustrate the average strengths of these cadaveric bone-patellar tendon-bone grafts, as well as the semitendinosus and gracilis tendon grafts as single units, it is believed that only one study exists which measures the tensile strength of a quadruple-stranded (double-looped) semitendinosus-gracilis (STG) graft to be used for reconstruction of the ACL.\textsuperscript{5}
The use of tendons as ligament substitutes historically reveals that these tissues were chosen for a large combination of reasons: ease of translation, close proximity to the injured joint, size and relative strength, expendability of their biological function, viability after transfer, and avoidance of immune reactions seen with allograft and synthetic materials. Furthermore, the similarities between tendons and ligaments excised from fresh cadaveric specimens have grossly been observed to be biologically similar. Their gross anatomical features seem to be more important from a functional standpoint than is their microscopic structure. Pragmatically, these observations would suggest that tendons could in fact mechanically perform as ligamentous substitutes. It has also been generally accepted that both tissues are histologically similar as well, such that they can be classified as “dense, regularly arranged connective tissues.” Therefore, most literature would classify the two tissues interchangeably. A study by Amiel et al substantiates this claim as they demonstrated histological similarities between ligaments and tendons in rabbits showing “thick, closely packed, collagenous bundles oriented parallel to the longitudinal axis of each structure.” Both structures were supplied with a small number of blood vessels.
Also, cells were aligned in rows between the bundles of collagenous fibers and were both elongated along the same axis as the direction of their biological function. However, further research indicates that human ligaments and tendons are not morphologically or biologically identical, but the positive traits that exist for using an autograft tendon for replacement of the ACL far outweigh the choice of introducing a foreign graft into the body.\textsuperscript{8,6} Whether it be patellar or hamstring, the use of intra-articular tendons for reconstruction of an ACL-deficient knee are the most popular grafts used today.

Since tendons have shown beneficial results as ligament substitutes (termed ‘ligamentization’), many biological tissues have been tested in an attempt to determine which tendinous structure(s) would serve as the best replacement graft. While some grafts have proven long-term success to function in a useful manner, other grafts remain unpredictable as they tend to elongate under low forces or remain weak in the knee, thus providing inadequate ligamentous support. In a landmark study, Noyes et al\textsuperscript{9} measured the initial mechanical properties of the normal ACL and commonly used autograft structures from a young-adult donor population (26 ± 6 years old). Of the ninety autograft tissues tested, the 14 mm-wide
central one-third bone-patellar tendon-bone unit was found to be the strongest replacement with an average ultimate failure strength of 168% (2900 ± 260 N) of the normal ACL (1725 ± 269 N).

Conversely, ultimate failure loads of the semitendinosus and gracilis tendons, measuring 70% (1216 ± 50 N) and 49% (838 ± 30 N) of the normal ACL respectively, were reported. Stiffness values, or the resistance to deformation, between the bone-patellar tendon-bone and STG tissues were also significantly different. The central one-third patellar tendon was approximately four times stiffer than that of the normal ACL, with a measure of 685.2 ± 85.6 KN/m. On the other hand, both of the hamstring tendon grafts closely mimicked the stiffness of the normal ACL (182 ± 33 KN/m), producing an averaged 1:1 ratio with measures of 186.1 ± 9.2 KN/m for the semitendinosus tendon and 170.9 ± 11 KN/m for the gracilis tendon.

Results from the Noyes et al9 study have often been used by advocates who claim that because of its incredible strength, the patellar tendon should be considered the "gold standard" for intra-articular reconstruction of the ACL. But one should not assume that the use of a high strength graft will ensure consistent
postoperative success. Due to its high degree of stiffness, several long-term studies have shown that the patellar tendon graft may be too rigid, thus leading to additional pathology. Reported complications associated with the use of patellar tendon autografts include lack of terminal knee extension, anterior knee pain (patellofemoral), donor site pain, patellar tendinitis, patellofemoral crepitus, patellar fractures, knee stiffness, quadriceps muscle atrophy and weakness, increased incidence of infrapatellar contracture syndrome, and arthrofibrosis.

Because of these numerous accounts of morbidity following the use of the patellar tendon graft, the search for an alternative graft has recently been of great interest. Several studies have established that hamstring grafts are adequate ACL replacements. Also, recent studies by Aglietti et al and Marder et al failed to show statistically significant differences in knee stability and functional outcomes between central-third bone-patellar tendon-bone grafts and quadruple-stranded hamstring tendon grafts.

Based on the research of Noyes et al, both Marder et al and Larson have hypothesized that proportionately doubling the
semitendinosus and gracilis tendons could possibly double the tensile strength of the combined grafts, at least in the section of the graft with the largest cross sectional area. Although no in vivo biomechanical experiments have been conducted, data by Steiner et al\textsuperscript{5} demonstrates that doubling a hamstring tendon graft does in fact double the ultimate failure load without increasing its stiffness value. If further substantiated, this data would seem to support the belief that the mechanical properties of the quadruple-stranded STG graft are adequate to provide a more acceptable replacement for the human ACL.

Clearly, further studies measuring hysteresis properties of tendons are needed to determine the exact effect that doubling a tendon will have on maximum load to failure and stiffness, as well as the effect of combining tissues together, such as a quadruple-stranded STG graft. This study will look at the tensile strengths of sutured quadruple-stranded (double-looped) STG grafts from cadaveric specimens. Because of the differing stiffness characteristics, it is hypothesized that the hamstring graft will prove to be as strong or stronger than the biological ACL, thus providing an
adequate and more forgiving graft compared to the rigid bone-patellar tendon-bone graft.
CHAPTER II

MATERIALS & METHODS

Specimen History

Fresh-frozen human cadaveric knees stored at -20° C were obtained from the donor banks of Anatomical Service, Inc. in Rosemont, Ill. A total of 10 specimens were procured from five donors, ranging in age from 46 - 64 years old, of which four were male and one female. Causes of death ranged from lung cancer to a gastrointestinal bleed (Table 1).

Graft Preparation

The specimens were thawed at room temperature for 24 hours prior to excision of the tissues. Following standard universal precautions during handling of the cadaveric tissues, the semitendinosus and gracilis tendons were each exposed through an oblique incision over the posteromedial capsule and pes anserinus. The tendons of the semitendinosus and gracilis were identified, then
**TABLE 1**

History of Specimen Donors

<table>
<thead>
<tr>
<th>AGE</th>
<th>GENDER</th>
<th>CAUSE OF DEATH</th>
</tr>
</thead>
<tbody>
<tr>
<td>46</td>
<td>M</td>
<td>Gastrointestinal Bleed</td>
</tr>
<tr>
<td>56</td>
<td>M</td>
<td>Lung Cancer</td>
</tr>
<tr>
<td>60</td>
<td>M</td>
<td>Metastatic Cancer</td>
</tr>
<tr>
<td>62</td>
<td>M</td>
<td>Lung Cancer</td>
</tr>
<tr>
<td>64</td>
<td>F</td>
<td>Small Cell Lung Cancer</td>
</tr>
</tbody>
</table>
harvested separately using a tendon stripper (Orthopedic Systems, Inc., Union City, Calif). Dissected from their musculotendinous junctions, the tendons were pulled out of the knee and released at their tibial insertions, producing two free 25-30 cm-long tendon grafts (average length is 30 cm for men and 28 cm for women).14

Preparation of the quadruple-stranded STG graft was simplified by using a graft tension board (Acufex Microsurgical, Inc., Mansfield, Mass). Two small, smooth hooks on each end of the board firmly secured each of the tendon ends and provided a stable working surface. Remaining muscle fibers on the proximal ends of the tendons were gently removed with a scalpel. Aligned side-by-side, the semitendinosus and gracilis tendons were folded together to produce a four-stranded graft. The natural loop, formed by folding the tendons in half, was attached over a hook on one end of the graft preparation board. The four free ends were then secured with a running baseball whip stitch using No. 2 nonabsorbable suture and attached to the other end of the preparation board. Secured between the two attachments, a pre-load of 20 lbs of tension was taken up within the graft for 25 minutes (Figure 1). With the graft in place between the attachments, tension distributed throughout the
Figure 1. Quadruple-stranded semitendinosus-gracilis ACL graft in graft tension board.
graft eliminated the need to use other clamps to secure the graft.
The tendons were then sutured together using a continuous baseball
whip stitch with No. 2 nonabsorbable suture.

The quadruple-stranded STG graft, as it would be used for
reconstruction of an ACL-deficient knee, was now complete.
However, in order to provide an adequate gripping surface to test the
graft’s tensile strength, an artificial loop was fashioned and secured
to the four-stranded end. A nylon tendon leader (Acufex
Microsurgical, Inc., Mansfield, Mass) (Figure 2) was used to create
this loop. With the graft’s natural loop attached over a hook on the
preparation board, one end of the braided nylon tendon leader was
retracted and inserted over the four-stranded end of the graft and
stitched using a No. 5 nonabsorbable suture (Ethibond®, Ethicon®,
Inc.) with a running, interlocking stitch. A single loop was then
created with the remaining end of the tendon leader by folding it
back and securing it to the opposite end of the leader with the No. 5
suture. To ensure a tight attachment, the artificial looped end was
additionally anchored by suturing the tendon leader 10 to 15 times
(depending upon graft size), followed by 10 circumferential wraps,
Figure 2. Nylon tendon leader.
sutured one final time, then tied off. Figure 3 illustrates the quadruple-stranded graft with the addition of the nylon loop.

**Tensile Testing**

With 1 cm-wide threaded J-hooks inserted through each looped end, the STG grafts were individually loaded into the clamps of the Mach 89390 tensile testing apparatus (Tinius Olsen Testing Machine Company, Willow Grove, Pa) (Figure 4) with the artificial loop inserted superiorly (Figure 5). The widths and lengths of the specimens were measured with each specimen under a small pre-load of 4 Newtons (N), such as that performed in a previous study. Readings were measured with a Digimatic handheld digital caliper (Mitutuyo Corporation, Japan). Lengths of the STG grafts were measured from hook-graft attachment to hook-graft attachment (Figure 6).

Following two pre-load cycles of 4 N, (Figure 7a) each specimen was loaded to failure at a displacement rate of 20 cm/min (Figure 7b). Tensile strength readings were displayed in pounds of force.
Figure 3. Quadruple-stranded STG graft with artificial nylon loop.
Figure 4. Tinius Olsen Tensile Testing Machine.
Figure 5. ACL graft with artificial loop loaded superiorly.
Figure 6. Length measurement between hook-graft attachment to hook-graft attachment.
Figure 7. a, Graft after preload of 4 N; b, Graft loaded to failure.
Mode of failure was observed and recorded as either: 1) tendon midsubstance failure, or 2) failure throughout the tendon leader.

**Data Analysis**

Descriptive statistics were used to report the tensile testing results of the STG grafts. Means and standard deviations were computed for the entire sample to demonstrate the average hysteresis and variability for the quadruple-stranded STG graft.
CHAPTER III

RESULTS

While determining the best possible way to measure the strengths of the soft-tissue grafts, two grafts were lost during testing, decreasing sample size to eight (Table 2). A maximal tensile strength mean of 653.6 N was obtained (SD = 161.65 N). Values obtained from the Noyes et al\(^9\) study were used in determining the differing strengths between the native ACL and our grafts. Tensile testing results showed that the average maximum strength of our quadruple-stranded STG grafts were roughly 39 % ± 6 % of the biological ACL values obtained by Noyes et al.\(^9\)
TABLE 2

Maximum Tensile Strengths of the Quadruple-Stranded Semitendinosus-Gracilis ACL Replacement Graft

<table>
<thead>
<tr>
<th>SPECIMEN AGE</th>
<th>KNEE TESTED</th>
<th>GRAFT LENGTH (mm)</th>
<th>MAXIMUM TENSILE STRENGTH (N)</th>
</tr>
</thead>
<tbody>
<tr>
<td>46 R</td>
<td>161.4</td>
<td>849.6</td>
<td></td>
</tr>
<tr>
<td>46 L</td>
<td>159.25</td>
<td>818.4</td>
<td></td>
</tr>
<tr>
<td>56 R</td>
<td>138.97</td>
<td>796.2</td>
<td></td>
</tr>
<tr>
<td>56 L</td>
<td>170.11</td>
<td>671.76</td>
<td></td>
</tr>
<tr>
<td>60* R</td>
<td>93.36</td>
<td>NDO</td>
<td></td>
</tr>
<tr>
<td>60* L</td>
<td>193.64</td>
<td>NDO</td>
<td></td>
</tr>
<tr>
<td>62 R</td>
<td>134.31</td>
<td>502.6</td>
<td></td>
</tr>
<tr>
<td>62 L</td>
<td>139.7</td>
<td>604.9</td>
<td></td>
</tr>
<tr>
<td>64 R</td>
<td>152.2</td>
<td>591.6</td>
<td></td>
</tr>
<tr>
<td>64 L</td>
<td>148.6</td>
<td>393.7</td>
<td></td>
</tr>
</tbody>
</table>

* NDO = No Data Obtained

* Accurate values for these two specimen grafts were lost due to testing malfunction.
CHAPTER IV
DISCUSSION

This study presents the tensile strength values of the quadruple-stranded (double-looped) human semitendinosus-gracilis ACL autograft. Whereas many researchers have tested the strength of a single semitendinosus tendon or gracilis tendon, or both together, only Steiner and associates\(^5\) have tested the two tendons doubled as a four-stranded graft. Table 3 illustrates our findings as compared to previous researchers. Although modes of testing varied greatly between groups, some correlations can be noted. The results from our quadruple-stranded graft parallel results found in recent studies. Rowden et al\(^1\) and Steiner et al\(^5\) each reported quadruple-stranded graft strengths of \(612 \pm 73\) N and \(573 \pm 109\) N, respectively. The Rowden group tested quadruple-stranded semitendinosus tendons while Steiner and associates tested quadruple-stranded STG tendons, much like our hamstring graft. Even though testing
### TABLE 3

Maximum Tensile Strengths of the Human Anterior Cruciate Ligament and Autogenous Replacement Grafts

<table>
<thead>
<tr>
<th>RESEARCHER</th>
<th>STRUCTURE</th>
<th>MAXIMUM LOAD (N)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Noyes et al(^9)</td>
<td>ACL</td>
<td>1725 ± 269</td>
</tr>
<tr>
<td></td>
<td>ST</td>
<td>1216 ± 50</td>
</tr>
<tr>
<td></td>
<td>G</td>
<td>838 ± 30</td>
</tr>
<tr>
<td></td>
<td>PT</td>
<td>2900 ± 260</td>
</tr>
<tr>
<td>Steiner et al(^5)</td>
<td>ACL</td>
<td>800 ± 469</td>
</tr>
<tr>
<td></td>
<td>STG</td>
<td>335 ± 87</td>
</tr>
<tr>
<td></td>
<td>QSTG</td>
<td>573 ± 109</td>
</tr>
<tr>
<td></td>
<td>PT</td>
<td>674 ± 206</td>
</tr>
<tr>
<td>Woo et al(^15)</td>
<td>ACL</td>
<td>2160 ± 157(^a)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1503 ± 83(^b)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>658 ± 129(^c)</td>
</tr>
<tr>
<td>Rowden et al(^1)</td>
<td>ACL</td>
<td>2195 ± 427</td>
</tr>
<tr>
<td></td>
<td>QST</td>
<td>612 ± 73</td>
</tr>
<tr>
<td></td>
<td>PT</td>
<td>416 ± 66</td>
</tr>
<tr>
<td>Swanton</td>
<td>QSTG</td>
<td>653.6 ± 161.65</td>
</tr>
</tbody>
</table>

\(^a\) = younger donors (age 22 - 35)  
\(^b\) = middle-aged donors (40 - 50)  
\(^c\) = older donors (60 - 97)

**STRUCTURE KEY:**

ACL = Native anterior cruciate ligament  
ST = Single semitendinosus  
G = Single gracilis  
PT = Patellar tendon complex  
STG = Semitendinosus-gracilis  
QSTG = Quadruple-stranded semitendinosus-gracilis  
QST = Quadruple-stranded semitendinosus
techniques were completely different between the groups, similar values were obtained.

The strength results from our study, and these other two studies, are low compared to the ACL data established by Noyes et al\textsuperscript{9}. Since the ACL is the structure we're striving to simulate, it would appear that our STG graft would be inadequate based on these strength values. However, upon further inspection, a comparison of our results with the two previously mentioned studies\textsuperscript{5,1} identifies a trend among tensile strength and donor age.

Whereas the Noyes group\textsuperscript{9} and Woo et al\textsuperscript{15} measured ACL strength values from young samples (26 ± 6 years old and 22 - 35 years old, respectively), donor ages from the Steiner et al\textsuperscript{5} and Rowden et al\textsuperscript{1} studies were older at 69.5 years old (range, 48 - 79 years) and 42 years old or less, respectively. These 'older' samples compare to our mean donor age of 57 (ages 46 - 64 years old). Furthermore, Woo et al\textsuperscript{15} measured an older sample of donors (aged 60 - 97) and reported ACL strength values of 658 ± 129 N, a near 1 : 1 ratio with our results. Therefore, there appears to be an inverse
relationship between aging and the tensile strength values of soft tissues.

The results of our low strength values paralleling recent studies pose many questions concerning the discrepancies of tensile strength values reported among the researchers. Several possible reasons for our lower values become evident upon further investigation of our cadaveric specimens, including the effects of donor age, cryopreservation and thawing, terminal cancer, and chemotherapeutic agents.

As previously mentioned, donor age of our specimens averaged 57 years old, distinguishing them into a category of 'older individuals.' Although one study found that increased donor age (17 to 54 years) does not affect the tensile strength properties of the BPTB complex,\textsuperscript{10} many other authors note severe age-related changes in dense fibrous tissues.\textsuperscript{16,17} Collagen constitutes a large portion of the organic make-up of tendons and ligaments. Because of its great mechanical stability, collagen provides tendons and ligaments with their unique and characteristic strength and flexibility.\textsuperscript{17} The properties of collagen are closely related to the
quantity and quality of the cross-links found within the collagen molecules.\textsuperscript{17} As muscles develop throughout the first two decades of life, the number and quality of the collagenous cross-links increases, thus resulting in increased tensile strength within the muscle.\textsuperscript{18,19,20} As aging progresses, collagen production levels off with respect to its mechanical properties, and tensile strength and tissue stiffness begin to decrease.\textsuperscript{20,21,22} As a result, a gradual decline in the mechanical properties of tendons ensues, possibly causing decreased strength, stiffness, and ability to withstand deformation.

One particular study focused on the structural properties of the human femur-ACL-tibia complex from three age groups as it directly relates to a progressive decline in tensile strength with increasing age.\textsuperscript{15} The decrease in maximum load to failure was shown to occur rapidly between the third decade of life (twenty-two to thirty-five years) and middle age (forty to fifty years). After middle age, maximum load to failure of the ligament complexes continued to decrease even further in older individuals (sixty to ninety-seven years) as the ligaments failed at less than one-third of the ultimate tensile load of the younger age group. Another source reports the
tensile strength of skeletal muscle (rectus abdominis) as it relates to aging rate. Results illustrate an 8% strength decline in the 30 to 39 age group and a 24% decline in the 60 to 79 age group. These findings are compared to the 20 to 29 age group, which was considered to be the standard testing group. However, the greatest strength was found to occur in the 10 to 19 year old age group. These findings, as related to this study, show a direct correlation between the effects of donor age and tensile strength of human tendons and ligaments.

The second possible reason for our low strength findings involves that of cryopreservation and the thawing of human soft tissue. Several studies have compared the properties of tendons and ligaments after storage by freezing, but conflicting results have been reported. One study reported that freezing and thawing had a “strong effect in decreasing the immunological antigenicity of tendon cells . . . and damages or denatures the histocompatibility antigens on their surface.” But while the study confirmed that the effects of freezing and thawing killed tendon cells, it also showed that the collagen bundles in the tendon remained normal. This would suggest that the tensile strength properties should remain relatively
unchanged. Another study measured the tensile strengths of the fresh bone-ligament medial collateral ligament (MCL) unit from rabbits. One group of MCLs were frozen at -20°C for three months, while the other group of MCLs were promptly excised and tested. In both groups, the effects of drying were strictly minimized. In this study, Woo and his colleagues discovered that freezing does significantly decrease the area of hysteresis during the process of pre-loading the tissues prior to failure, but did not appear to affect the tissue’s mechanical properties. Our specimen samples may have been tainted during testing as some of the grafts were frozen and thawed up to four times. Although strict care was taken to prevent sample dehydration between testing sessions, it was evident that the effects of the multiple freezing and thawing episodes did in fact change the gross appearance and texture of the specimens.

Our third concern includes the deleterious effects that terminal cancer can have on the human body. Although it is not known how long each of our specimen donors battled their respective bouts with cancer, it’s hypothesized that the effects of cancer, coupled with their older age, signifies a deconditioned physical state. The positive effects of exercise and activity level as it relates to increased muscle
mass, adaptation, and increased vitality have been well
documented.\textsuperscript{17} This variable may have affected the biomechanical
properties of the donors. For example, if the donor sample in this
study were healthier or more active throughout their older years
than samples used in previous studies, we would expect increased
mechanical property values. On the other hand, if our grafts did in
fact come from a donor sample with more sedentary lifestyles,
reduced mechanical properties would be expected when compared to
other studies such as that of Woo and associates\textsuperscript{15} from the younger
donor population. It should be noted that our youngest donor (age
46), the only donor not to die from cancer, yielded the strongest
tensile strength values. Although still not in the desired strength
realm of the biological ACL at $1725 \pm 269$ N, the noncancerous graft
produced the strongest graft with an average maximal tensile
strength of 834 N compared to an average strength of 593.5 N for the
remaining grafts. Even though it stands alone, the noncancerous
graft average of 834 N compares to ACL strength values established
by Steiner et al\textsuperscript{5} at $800 \pm 469$ N. Also, the noncancerous graft had a
higher strength value than the patellar tendon grafts reported by
both Rowden et al\textsuperscript{1} and Steiner et al\textsuperscript{5} at $416 \pm 66$ N and $674 \pm 206$ N,
respectively. As mentioned earlier, these results would seem beneficial considering the fact that the stiffness properties of the STG graft mimic that of the native ACL, whereas the BPTB units are approximately four times stiffer.\textsuperscript{5,9}

And the fourth possible difference for our resulting low strength values involves the detrimental effects of chemotherapeutic agents on cartilage. Although the exact chemotherapeutic drugs used on our donors are unknown, studies show the degradative changes in articular cartilage analogous to those seen in osteoarthritic cartilages.\textsuperscript{25} Chemotherapeutic drugs produce severe morphological and biochemical changes in cartilage, resulting in several dangerous consequences. The most worthy consequence as it relates to this study was a decreased resistance to stress and an increased susceptibility to cartilage degeneration. As far as the possibility of the chemotherapeutic agents having an effect on collagen content, it appears that it remains unchanged regardless of age.\textsuperscript{25} This is seemingly beneficial since the semitendinosus and gracilis tendons
are 99.0% and 96.8% collagen\textsuperscript{8}, as expressed by a percentage of tissue dry weight.

Although tensile strength results appear to significantly differ among the researchers, we believe that the strength results from our grafts are extremely valuable. More importantly, our strength values suggest intertester reliability based on the results from the Steiner et al\textsuperscript{5}, Rowden et al\textsuperscript{1}, and Woo et al\textsuperscript{15} studies (see Table 3).

One of the most exciting factors surrounding this particular study was developing a method for testing the tensile strength of soft tissue. Never before has a study measured the tensile strength of a soft tissue without the use of a graft-to-bone fixation or preparations using methyImethacrylate cement. For the first time we were able to measure soft-tissue strength with the simple aid of a nylon tendon leader. Fashioned into a loop and sutured to the graft, the tendon leader seems to have proven to be a beneficial and reliable method for testing tissues without a bone-tendon-bone complex (such as the patellar tendon unit) for fixation.

Also, although not the primary focus of this study, the stiffness characteristics of the quadruple-stranded STG grafts are extremely important in the advocacy of their use as an ACL replacement. As
mentioned before, Noyes et al\textsuperscript{9} established that single semitendinosus and gracilis tendons each have a stiffness that is nearly equal to the biological ACL. And when doubled, their stiffness characteristics do not change.\textsuperscript{5} Conversely, the patellar tendon is nearly four times as stiff as the native ACL.\textsuperscript{9} This relationship between strength and stiffness characteristics must be considered when deciding which structures will make the best ACL substitute.
Limitations of Study

Many limitations arose throughout the course of performing this study as a result of experimental trial-and-error and equipment malfunction. In particular, the study's limitations were as follows: 1) inability to adequately test the BPTB grafts, 2) failure of the primary testing apparatus, 3) unknown tensile strength of the tendon leader, and 4) direction and speed of the force exerted.

Unfortunately, we were unable to successfully test the tensile strengths of the donor BPTB complexes, which would have provided a helpful correlation between our results and previous studies. We made an attempt to test the BPTB grafts from each donor. Ten grafts were procured with the tibial and femoral bone plugs measuring 8 - 10 mm in width and 3 cm in length. The entire graft measured approximately 10 cm in length. However, the bone plugs of each graft had to be narrowed from their original width to 6 - 7 mm in order to fit into the grips of the testing apparatus (Figure 8). Aluminum plates were fixated to both sides of the BPTB plugs with epoxy. These plates each measured 0.5 mm in width and were used
Figure 8. BPTB ACL graft loaded in grips of testing apparatus.
to secure the bone grafts within the jaws of the testing apparatus (Figure 9). The result of narrowing the bone plugs decreased the grafts' strength capacity and caused each to fail by avulsion at the bone-tendon junction. An average maximal load of only 68.05 N was recorded, an extremely lower value than the 2900 ± 260 N reported by Noyes et al.9 Certainly it would have been beneficial to obtain usable data from the BPTB grafts. Since each set of grafts came from the same donors, it would have been useful to compare the BPTB grafts with the STG grafts. As a result, each STG graft was at least eight times stronger than the weaker BPTB graft obtained from the same donor specimen.

The second limitation of the study involved the malfunction of the original testing apparatus (MTS Systems Corporation, Minneapolis, Minn) (Figure 10) midway through testing of the BPTB grafts. This primary machine was a computer-controlled testing system which provided load-elongation curves, and more importantly the stiffness values of the tissues. Failure of this machine's motor forced us to interrupt testing and make arrangements to use another equally reliable machine. The decision was made to use an older machine (Tinius Olsen Testing Machine
Figure 9. BPTB graft with aluminum plate fixation.
Figure 10. MTS Q-Test Tensile Testing Machine.
Company, Willow Grove, Pa) (see Figure 4) since it was recently inspected and demonstrated a reliability rating of 0.09 % error.

Unequipped with state-of-the-art computer aids, the ancillary machine was limited to recording tensile strength values in pounds of force by way of a large scale (Figure 11). Exerting a longitudinal pull through each graft at a displacement rate of 20 cm/min, the machine enabled us to successfully test all of the STG grafts with comparable results.

The inability to discover the tensile strength value of the tendon leader used for fashioning the loop on the STG graft represents our third limitation. Research and phone calls to the manufacturing company unfortunately could not determine reliable data (or estimates) concerning the strength of the braided nylon tendon leader. We attempted to test its strength by fashioning a sutured loop on each side of the tendon leader, attaching it to the J-hooks, then exerting the same pull as with the STG grafts. The tendon leader subsequently frayed and failed at the suture site during each trial as the integrity of the weave was obviously damaged by the shearing forces created by the sutures. However, since all of the STG grafts failed throughout the tendon’s
Figure 11. Tinius Olsen Tensile Measuring Scale.
midsubstance, it is believed that the tendon leader is adequately strong and is a reliable testing aid.

The final significant limitation of our study was the limiting factor of the machine's direction and speed of force throughout the graft. Clearly, it is near impossible to experimentally replicate the exact angles and velocities of forces exerted throughout the knee during injury and subsequent rupture of the ACL. The machine used was capable of exerting a longitudinal force through the graft at a maximal speed of 20 cm/min. It should be noted however that this study mimicked the rate of displacement of that used in previous tensile testing studies.15

Suggestions for Future Studies

In order to make this study stronger and more reliable, four items should be noted. First, the detrimental effects of freezing and thawing the tissues should be reduced to one time, or eliminated all together. An optimal situation would be to immediately test fresh autopsied donors, thus negating the possibility of tissue dehydration. Second, young, disease-free donors (age twenty to thirty-five) should
be chosen and tested to observe the strengths of healthy individuals. This age group would also be the most reliable and significant group to test as this is one of the most common age groups for ACL reconstruction due to an increased participation in high-risk sports.\textsuperscript{26,27} Third, a testing apparatus should be chosen which can incorporate multiplanar settings, increase displacement speeds, and measure stiffness values. The option of setting the grip angles will allow the graft to be oriented in any chosen position, thus better mimicking an actual preselected knee angle for failure. The displacement rate for failure of the graft should also be increased far beyond 20 cm/min to simulate similar forces throughout the knee during injury. Further studies will need to be performed to determine a comparable value. Also, a machine must be used which can adequately measure the grafts’ stiffness values so they can be compared to the current and previous studies. And finally, a larger sample size of young knees comparing the BPTB complex, native ACL, and quadruple-stranded graft should be tested to obtain the most reliable results possible.
CHAPTER V

CONCLUSION

As a general observation, results from our study reveal significantly lower tensile strength values of the quadruple-stranded (double-looped) semitendinosus-gracilis ACL autograft as was originally hypothesized. However, even though limitations and setbacks were experienced, we still believe this study to be of significant worth to any researcher concerned with the tensile testing of soft tissues. Through the use of our newly invented technique for testing the tensile strength of soft-tissues, we believe that the strength of any soft-tissue can be reliably tested.

Although considerably lower than the values posed by the Noyes group, our strength values are comparable to other studies. Analyzing the results from our older donor samples, our strength values correspond with the older samples from previous works. Our grafts yielded better strengths than those of similar grafts.
established by the Steiner\textsuperscript{5} and Rowden\textsuperscript{1} groups. Also, our average strength closely matched the ACL value set forth by Woo et al\textsuperscript{15} from an older sample.

It would seem that the use of a nylon tendon leader fashioned into a loop and anchored to the graft appears to be an adequate aid for testing these types of tissues. Compared to methods used in previous studies, our method for soft-tissue testing is not only reproducible, but reliable. Comparison of our results with other studies\textsuperscript{5,1,15} suggests a definitive association among the groups.

In light of the vast orthopaedic surgical advances made over the last decade, replacing a ruptured ACL continues to be a very complex surgical procedure with a number of significant factors. Not only must the surgeon choose the most adequate graft, but postoperative success also depends upon meticulous surgical technique, proper adjustments of graft tension, correct fixation, and a well-executed rehabilitation program. Despite all of these factors, choice of the 'best' graft continues to be the popular topic among the orthopaedic profession. This study will add to the orthopaedic body of knowledge concerned with the tensile strength properties of the quadruple-stranded STG graft used for reconstruction of an
ACL-deficient knee. Further studies measuring hysteresis and appropriate mechanical properties must continue to be of importance, as well as longitudinal studies comparing the STG graft with the BPTB complex, in order to clearly establish which graft is the most acceptable ACL replacement.
APPENDIX

Institutional Review Board Approvals
**EXPEDITED REVIEW REQUESTED UNDER ITEM _X_ (NUMBER[S]) OF HHS REGULATIONS**

**EXEMPT REVIEW REQUESTED UNDER ITEM ___ (NUMBER[S]) OF HHS REGULATIONS**

UNIVERSITY OF NORTH DAKOTA
HUMAN SUBJECTS REVIEW FORM
FOR NEW PROJECTS OR PROCEDURAL REVISIONS TO APPROVED
PROJECTS INVOLVING HUMAN SUBJECTS

PRINCIPAL INVESTIGATOR: James E. Swanton
TELEPHONE: (701) 746-6209 DATE: 02.21.97

ADDRESS TO WHICH NOTICE OF APPROVAL SHOULD BE SENT: 609 Princeton Park; Grand Forks, ND 58203

SCHOOL/COLLEGE: UND-School of Med DEPARTMENT: Physical Therapy PROPOSED PROJECT DATES: 4/10/97

PROJECT TITLE: Tensile Strengths of Autogenous Knee Tendons Used For Reconstruction of the Anterior Cruciate Ligament

FUNDING AGENCIES (IF APPLICABLE): Philip O. Johnson, M.D., P.C.

TYPE OF PROJECT:

X NEW PROJECT ___ CONTINUATION ___ RENEWAL ___ THESIS RESEARCH _X_ STUDENT RESEARCH PROJECT

CHANGE IN PROCEDURE FOR A PREVIOUSLY APPROVED PROJECT

DISSERTATION/THESIS ADVISER, OR STUDENT ADVISER: Dave Relling, P.T.

PROPOSED PROJECT: ___ INVOLVES NEW DRUGS (IND) ___ INVOLVES NON-APPROVED USE OF DRUG

X INVOLVES A COOPERATING INSTITUTION

IF ANY OF YOUR SUBJECTS FALL IN ANY OF THE FOLLOWING CLASSIFICATIONS, PLEASE INDICATE THE CLASSIFICATION(S):

_ MINORS (<18 YEARS) _ PREGNANT WOMEN _ MENTALLY DISABLED _ FETUSES _ MENTALLY RETARDED

_ PRISONERS _ ABORTUSES _ UND STUDENTS (>18 YEARS)

IF YOUR PROJECT INVOLVES ANY HUMAN TISSUE, BODY FLUIDS, PATHOLOGICAL SPECIMENS, DONATED ORGANS, FETAL MATERIAL, OR PLACENTAL MATERIALS, CHECK HERE _X_

1. ABSTRACT: (LIMIT TO 200 WORDS OR LESS AND INCLUDE JUSTIFICATION OR NECESSITY FOR USING HUMAN SUBJECTS.

The purpose of this study is to further enhance the knowledge of autogenous tissues around the knee which are used in anterior cruciate ligament (ACL) reconstruction. Six to ten fresh-frozen cadaveric knee specimens will be used to conduct this experiment. Before testing, each knee specimen will be removed from the freezer, thawed while protected by a plastic and aluminum foil wrap, and dissected to harvest the test tissues. From the knees, bone-patellar tendon-bone, semitendinosus, and gracilis tendons will be excised and prepared for testing. All tissues will be cut into the same length, width, and thickness as that used for ACL reconstruction procedures. The tissue units will then be individually fixed in the Instron machine, an instrument used to test tensile strength properties, and tested to failure. All tissues will be kept moist with saline solution during dissection, area measurement, and testing. After testing, all cadaveric specimens will be incinerated at the UND School of Medicine and Health Sciences Anatomy Department. The data will be statistically analyzed to determine which graft best imitates the tensile strength of the biological ACL. Results from this study will add to the orthopedic body of knowledge concerned with the determination of which autograft is optimal for reconstruction of the ACL.
February 19, 1997

University of North Dakota
IRB Board
Grand Forks, ND 58201

Dear Board Members:

Jim Swanton and I are currently in the preliminary stages of a research project that is going to be investigating the ultimate tensile strength of composite tissues around the knee that we use currently for anterior cruciate ligament reconstruction. This study will be funded by myself and enlist the help of people at the Engineering Department at North Dakota State University for utilizing the Instron Tensile Strength Machine. We will be taking cadaver tissue, preparing that for tensile strength measurements and then recording the ultimate failure of tensile strength for these composite tissues to be then reported in peer review journals. The statistics will be done for statistical relevance concerning the tensile strength of these materials as well.

If there is any further questions that need to be answered, please feel free to contact me.

Sincerely Yours,

Philip O. Johnson, M.D., P.C.

PQJ/crb
Dict. 2-18-97
March 27, 1997

TO WHOM IT MAY CONCERN:

I received my doctoral degree at The University of Wisconsin-Madison. I did my post-doctoral research and was promoted to Research Associate at The Biomechanics Laboratory, Department of Orthopedics, Mayo Clinic/Mayo Foundation. I am currently a tenure-track Assistant Professor at The Department of Mechanical Engineering and Applied Mechanics, North Dakota State University. I have published articles in refereed Journals and conference proceedings, and have been awarded national, competitive grants for biomedical engineering research.

I will be glad to participate in the research project entitled, "Tensile Strengths of Autogenous Knee Tendons Used for Reconstruction of the Anterior Cruciate Ligament." Mr. James E. Swanton, a graduate student under the direction of Dr. Philip Johnson, will be conducting this research as partial fulfillment for his Master degree in Physical Therapy for the School of Medicine and Science at The University of North Dakota.

It is believe that the results from this study will not only advance our understanding of the biomechanical functions of the anterior cruciate ligament, but will also provide important clinical information for surgical treatments of knee injury. I would be interested in participating in this research, and will provide bioengineering input for this study. We have a facility that can accommodate this research. The fee involving the use of material testing machine, design/fabricate loading apparatus and technician time is subject to department/university policy.

Please do not hesitate to contact me if you have any questions.

Sincerely,

James Jim-Shown Stone, Ph.D.
Assistant Professor

cc: Mr. James E. Swanton, UND
    Dr. Philip Johnson, UND
    Dr. Robert Pieri, Chair, MEAM, NDSU
    Dr. Otto Helweg, Dean, CEA, NDSU
PLEASE NOTE: Only information pertinent to your request to utilize human subjects in your project or activity should be included on this form. Where appropriate attach sections from your proposal (if seeking outside funding).

2. PROTOCOL: (Describe procedures to which humans will be subjected. Use additional pages if necessary.)

Six to ten fresh-frozen cadaveric knees, from mid-femur to mid-tibia, will be purchased from the Anatomy and Service Company in Rosemont, Illinois. Tendons will be harvested from these cadaveric specimens, including the central-third bone-patellar tendon-bone complex, semitendinosus, and gracilis, and used for the purposes of this experiment. The anterior cruciate ligament (ACL) will also be excised from each specimen and used in the study. Other demographic information such as gender, age, and cause of death will not be known until after purchase of the specimens. The supplying company maintains confidentiality of specimens beyond the demographic data mentioned above; however, any demographic data collected will be kept for three years after completion of this study then stored to maintain donor confidentiality in accordance with IRB guidelines.

Donor specimens will be thawed, excised, and prepared according to standard procedures followed when these grafts are used in ACL reconstruction. During the testing procedure, universal precautions emphasizing a sterile environment will be practiced by the researchers to negate the risk of disease transmission. Each tissue will be the same length, width, and thickness used during ACL reconstruction procedures. The semitendinosus and gracilis tendons will be doubled and sutured together using the appropriate surgical thread to create a four-stranded graft.

The Instron machine will be used to evaluate hysteresis properties of the excised tissues. All tissues will be Identically anchored in the Instron apparatus and subjected to mechanical stress until tissue failure occurs. Specimens will be loaded to failure in tension at a displacement rate of 100 per cent of the initial length of the specimen per second, which will permit an identical strain rate for all specimens. Force, in Newtons, will be measured using the Instron. Photographs will be taken of the test procedure at three intervals: pre-test, during test, and failure. Testing will be administered at the North Dakota State University Department of Mechanical Engineering and Applied Mechanics under the supervision of Dr. Jim Stone, NDSU Mechanical Engineering Assistant Professor.

Care will be taken during the experiment to store all discarded and used tissues according to waste containment policies. Following completion of the experiment, all of the cadaveric specimens will be incinerated by the University of North Dakota School of Medicine and Health Sciences Anatomy Department using standard incineration procedures. Tensile strength results will be statistically analyzed to determine which tissue specimens best imitate the tensile properties of the biological ACL.
3. BENEFITS: (Describe the benefits to the individual or society.)

Results from this study will further enhance orthopedic knowledge of autogenous tissues used for reconstruction of the anterior cruciate ligament (ACL). With this knowledge, surgeons will be able to improve their choice of graft selection when replacing the ACL and subsequently decrease the incidence of post-operative pathologies associated with this surgery. We anticipate that the double-thickness semitendinosus-gracilis graft will closely approximate the biological ACL.

4. RISKS: (Describe the risks to the subject and precautions that will be taken to minimize them. The concept of risk goes beyond physical risk and includes risks to the subject's dignity and self-respect, as well as psychological, emotional or behavioral risk. If data are collected which could prove harmful or embarrassing to the subject if associated with him or her, then describe the methods to be used to insure the confidentiality of data obtained, including plans for final disposition or destruction, debriefing procedures, etc.)

No risks to the subjects exist due to the fact that they are no longer living. Also, personal information of the cadaveric specimens will not be included in the study. Information regarding age, gender, and cause may be added to the study if made available.

A minor risk to the researchers exists due to the potential of disease transmission. To negate this risk, universal precautions emphasizing a sterile environment will be utilized by all personnel involved with the actual testing of the cadaveric specimens.
5. CONSENT FORM: A copy of the CONSENT FORM to be signed by the subject (if applicable) and/or any statement to be read to the subject should be attached to this form. If no CONSENT FORM is to be used, document the procedures to be used to assure that infringement upon the subject's rights will not occur.

Describe where signed consent forms will be kept and for what period of time.

In accordance with IRB guidelines, all study results and demographic data collected from the cadaveric specimens will be stored in the student advisor's office for a period of three years after which they will be destroyed.

6. For FULL IRB REVIEW forward a signed original and thirteen (13) copies of this completed form, and where applicable, thirteen (13) copies of the proposed consent form, questionnaires, etc. and any supporting documentation to:

Office of Research & Program Development
University of North Dakota
Grand Forks, North Dakota 58202-7134

On campus, mail to: Office of Research & Program Development, Box 7134, or drop it off at Room 105 Twamley Hall.

For EXEMPT or EXPEDITED REVIEW forward a signed original and a copy of the consent form, questionnaires, etc. and any supporting documentation to one of the addresses above.

The policies and procedures on Use of Human Subjects of the University of North Dakota apply to all activities involving use of Human Subjects performed by personnel conducting such activities under the auspices of the University. No activities are to be initiated without prior review and approval as prescribed by the University's policies and procedures governing the use of human subjects.

SIGNATURES:

Principal Investigator

Project Director or Student Adviser

Training or Center Grant Director

Date

Date

Date

(Revised 3/1996)
REPORT OF ACTION: EXEMPT/EXPEDITED REVIEW
University of North Dakota Institutional Review Board

DATE: May 12, 1997  PROJECT NUMBER: IRB-9705-266

NAME: James E. Swanton  DEPARTMENT/COLLEGE: Physical Therapy

PROJECT TITLE: Tensile Strengths of Autogenous Knee Tendons Used for Reconstruction of the Anterior Cruciate Ligament

The above referenced project was reviewed by a designated member for the University's Institutional Review Board on May 13, 1997 and the following action was taken:

☑ Project approved. EXPEDITED REVIEW NO. 8
☐ Project approved. EXEMPT CATEGORY NO. _____________. No periodic review scheduled unless so stated in the Remarks Section.
☐ Project approved pending receipt of corrections/additions. These corrections/additions should be submitted to ORPD for review and approval. This study may NOT be started until final IRB approval has been received. (See Remarks Section for further information.)
☐ Project approval deferred. This study may not be started until final IRB approval has been received. (See Remarks Section for further information.)
☐ Project denied. (See Remarks Section for further information.)

REMARKS: Any changes in protocol or adverse occurrences in the course of the research project must be reported immediately to the IRB Chairperson or ORPD.

cc: D. Relling, Adviser
Dean, Medical School

Signature of Designated IRB Member
UND's Institutional Review Board

If the proposed project (clinical medical) is to be part of a research activity funded by a Federal Agency, a special assurance statement or a completed 310 Form may be required. Contact ORPD to obtain the required documents.

(3/96)
REQUEST FOR IRB REVIEW
(Expedited or Full Board Review)

North Dakota State University policy requires that all research involving human subjects, whether funded by an external organization or not, must comply with regulations for human subject research established by the U.S. Department of Health and Human Services and described in the Code of Federal Regulations 45 CFR 46. That means that projects involving human subjects have IRB approval prior to project initiation. This form should be used for requesting IRB review in either the expedited or full review categories. The "Request for Exempt Status" form should be used for requesting IRB certification of exempt projects.

Expedited Review

Research activities involving no more than minimal risk and in which the only involvement of human subjects will be in one or more of the categories described on the attached sheet titled "Research Activities Which May Be Reviewed by Expedited Review Procedures" may qualify for expedited review. Under the expedited review procedure, a project is reviewed by the Executive Director and at least one other IRB member. If a reviewer has concerns about a project, the Executive Director will attempt to resolve the concerns through communication with the investigator. If a reviewer's concerns cannot be resolved to his or her satisfaction, the protocol must be referred to the full Board for review at a convened meeting. The required format for submitting a request for expedited review is explained on the reverse side of this form. Expedited review normally takes about two weeks. Research that will be federally funded cannot be approved by the expedited review procedure. It must be reviewed by the full Board.

Full Board Review

Research projects that do not qualify for exempt certification or expedited review must be reviewed by the full Board at a convened meeting. IRB meetings are scheduled for the second Tuesday of each month. Projects to be reviewed by full Board review must be submitted to the IRB Office no later than two weeks prior to the next scheduled meeting. The required format for submitting a request for full Board review is explained on the reverse side of this form.

Please complete the following:
Investigator's name and Department: James E. Swanton, Dr. Jim Stone, Mechanical Eng.
609 Princeton Park; Grand Forks, ND 58203 (701) 746-6209

Address where you want to receive IRB correspondence:  
Project title: "Tensile Strengths of Autogenous Knee Tendons Used for Reconstructions of the ACL"

Dave Relling, M.S., P.T.
Faculty advisor's name (please type or print)  
Investigator's signature  
Date 4/16/97

For IRB Office use:
Date received: APR 21, 1997
Protocol #: EN 97033

Approval signature:  
Date: 4/22/97

August 2, 1994
Co-Investigator:  
Date: 4/22/97
James J. Stone, Ph.D., Mechanical Engineering
April 22, 1997

James Swanton
University of North Dakota
609 Princeton Park
Grand Forks, ND 58203

Re: Request for IRB Review: “Tensile Strengths of Autogenous Knee Tendons
Used for Reconstruction of the ACL” #EN97033

Project Approval Date: April 22, 1997
Approval Period: April 22, 1997 to April 22, 1998
Annual Report Due Date: March 1, 1998

Dear Mr. Swanton:

Your project has been reviewed by the NDSU IRB and has been granted IRB approval in concurrence with the IRB review and approval by the University of North Dakota. A copy of your request form with the IRB approval signature is enclosed for your records. For NDSU record-keeping purposes, Dr. James Stone of the NDSU Mechanical Engineering Department will be listed as a co-investigator in this project.

IRB approval of this project is for one year. If the project will continue beyond the above expiration date, you must submit an annual report by the annual report due date indicated above in order to ensure continuity of approval beyond the expiration date. Approval of the report will result in IRB approval of the project for a second year. We will send you (and/or Dr. Stone) a reminder letter approximately one month before the above annual report due date. It is then your responsibility to submit the report on time to prevent expiration of your IRB approval.

If you decide to make any changes to the protocol, you must notify this office (on the Change in Protocol request form) before the change is implemented, to receive IRB approval for the changed portion of the project.

When your project is completed, a final project report is required so that our records on the file can be inactivated. Federal regulations require that IRB records on a protocol be retained for three years following project completion. Both the annual report and the final report should be submitted according to instructions on the "Annual Update/Project Completion" form.

Thank you for cooperating with NDSU IRB policies, and best wishes for a successful study.

Sincerely,

Kay Sizer
IRB Executive Director

cc: Dr. James Stone, NDSU Mechanical Engineering

NDSU is an equal opportunity institution.
THE GRADUATE SCHOOL
UNIVERSITY OF NORTH DAKOTA OUTLINE

(Check One)
Outline of Independent Study: X Thesis Dissertation Project Design

Student: James E. Swanton Date: 10/14/97

Proposed Title: Tensile Properties of the Autogenous Double-Looped Semitendinosus-Gracilis Graft Used for Reconstruction of the Anterior Cruciate Ligament

Anticipated Date of Graduation: 5/10/98

Description of the nature of the study, procedure or methodology to be followed, and the proposed results:

Description/Nature of Study:
Tensile properties of the human anterior cruciate ligament (ACL) have been studied for years; however, few published articles exist which characterize its strength and stiffness behaviors. Furthermore, even fewer studies exist which describe the tensile strengths of grafts used for replacement of an ACL-deficient knee. Continuing controversy exists concerning which graft best imitates the biological ACL. This study will concentrate on the tensile strength properties of a hamstring graft which is used for ACL reconstruction.

Procedure/Methodology:
Ten fresh-frozen cadaveric knees, from mid-femur to mid-tibia, will be purchased from the Anatomy and Service Company in Rosemont, Illinois. Tendons will be harvested from these cadaveric specimens, including the central-third bone-patellar tendon-bone complex, semitendinosus, and gracilis, and used for the purposes of this experiment.

Donor specimens will be thawed, excised, and prepared according to standard procedures followed when these grafts are used in ACL reconstruction. Each tissue will be the same length, width, and thickness used during ACL reconstruction procedures. The semitendinosus and gracilis tendons will be doubled and sutured together using the appropriate thread to create a four-stranded graft. An Instron machine will be used to evaluate the hysteresis properties of the excised tissues. During the testing procedure, strict sterility protocols will be practiced by the researchers to negate the risk of disease transmission.

All tissues will be identically anchored in the Instron apparatus and subjected to mechanical stress until tissue failure occurs. Care will be taken during the experiment to store all discarded and used tissues according to waste containment policies. Following completion of the experiment, all of the cadaveric specimens will be incinerated by the UND School of Medicine and Health Sciences Anatomy Department using standard incineration procedures. Tensile strength results will be statistically analyzed to determine which tissue specimens best imitate the tensile properties of the biological ACL.

Proposed Results:
Results from this study will further enhance the orthopedic knowledge of autogenous tissues used for reconstruction of the ACL. With this knowledge, surgeons will be able to improve their choice of graft selection when replacing the ACL and subsequently decrease the incidence of post-operative pathologies associated with this injury. It is anticipated that the double-thickness semitendinosus-gracilis graft will closely approximate the tensile strength properties of the biological ACL.

Signatures of approval as specified in the "Degree Requirements" section of the Graduate Bulletin:

[Signature]

THIS OUTLINE MUST BE FILED IN THE GRADUATE SCHOOL BEFORE ADVANCEMENT TO CANDIDACY.
REFERENCES


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