# Clinical Compendium MTF Allograft Tendons for ACLR

PEER-REVIEWED CLINICAL REFERENCES
WHITE PAPERS
POSTER PRESENTATIONS



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**Revision Rates After Anterior Cruciate Ligament** Reconstruction Using Bone-Patellar Tendon-Bone

Allograft or Autograft in a Population 25 Years Old

and Younger

Author:

Eric J. Sanders, B.S.

Source: Arthroscopy. 2014 Apr;30(4):483-91. doi: 10.1016/j.arthro.2013.12.022.

**Key Takeaways:** 

#### STUDY OBJECTIVE

To compare clinical outcomes and revision rates for anterior cruciate ligament (ACL) reconstructions using bone-patellar tendon-bone (BPTB) allografts versus BPTB autografts in a population of patients aged 25 years and younger.

#### **METHODS**

- 81 patients were enrolled (28 allografts and 53 autografts)
- Patients were given the choice between allograft and autograft
- All Allografts were sourced by MTF
- Minimum follow-up was 24 months

- The allograft group showed a 7.1% failure rate and autograft showed a 9.4% failure rate
- Using a patient-choice ACL graft selection program after appropriate counseling and using graft specific rehabilitation programs, not chemically processed or irradiated BPTB allograft reconstructions have no greater failure rate than autografts in patients aged 25 years and younger at a minimum 2-year follow-up

Author:

**Analysis of Outcomes of Anterior Cruciate Ligament** 

Repair With 5-Year Follow-up: Allograft Versus Autograft

and Beth P. Smith, Ph.D.

Source:

**Key Takeaways:** 

#### STUDY OBJECTIVE

To prospectively compare outcomes of primary anterior cruciate ligament (ACL) reconstruction with either Achilles tendon allograft with soft-tissue fixation or standard bone patellar tendon-bone autograft with interference screw fixation.

#### **METHODS**

- 159 patients (41 allografts, 118 autografts) were included in the study
- Patients were evaluated preoperatively and postoperatively at 1 to 2 weeks, 6 weeks, 3 months, 6 months, and then annually for 5 years
- All Allografts were sourced by MTF

- At five-year follow-up both groups achieved similar long-term outcomes
- Allograft patients reported less pain than autograft patients at 1 and 6 weeks after surgery
- Allograft patients reported better function than autograft patients at 1 week, 3 months, and 1 year, and fewer activity limitations throughout the follow-up period



Failure rate of Achilles tendon allograft in primary anterior cruciate ligament reconstruction

Richard Lowe, M.D.

Source:

**Key Takeaways:** 

#### STUDY OBJECTIVE

This study was performed to determine the failure rate of patients undergoing primary anterior cruciate ligament (ACL) reconstruction with an Achilles tendon allograft by a single surgeon with the same surgical technique, graft fixation, and postoperative rehabilitation. The Achilles tendon allograft was obtained from a single source.

#### **METHODS**

- 144 patients were followed up at a mean of 40 months and a minimum of 24 months
- The results of those 144 allograft patients were compared against historic autograft results as a control
- Evaluation included a questionnaire at serial follow-up visits, physical examination, and return to play
- All Allografts were sourced by MTF

- The failure rate for Allograft was 5.6%. This is comparable to historic autograft failure rates which range from 5%-13%
- A X<sup>2</sup> contingency test was performed comparing patients aged 25 years or younger and those aged over 25 years with a resulting P value of 0.5811. No statistically significant difference between the groups of failures was seen

**Anterior Cruciate Ligament Reconstruction Using** 

Title: Patellar Tendon Allograft: An Age-Dependent Outcome

**Evaluation** 

Author: F. Alan Barber, M.D., Jorge Aziz-Jacobo, M.D., and Fernando Barrera

Oro, M.D.

Source: Arthroscopy. Vol 26, No 4 (April), 2010: pp 488-493. Doi:10.1016/j.

arthro.2009.08.022

**Key Takeaways:** • There was no clinical difference when using allograft in patients over or under

40 years old

#### STUDY OBJECTIVE

To compare the outcomes of a consecutive series of non revision bone–patellar tendon–bone (BPTB) allograft anterior cruciate ligament (ACL) reconstructions in patients aged 40 years or older and patients aged younger than 40 years.

#### **METHODS**

- 32 patients were followed up at a mean of 40 months and a minimum of 24 months
- Preoperative and postoperative outcome assessments included Cincinnati, Lysholm, and Tegner scores and International Knee Documentation Committee (IKDC) activity scores. Lachman test, pivot-shift test, and KT arthrometer (MEDmetric, San Diego, CA) measurements were obtained at a minimum of 24 months after surgery

#### **RESULTS**

 The outcomes of BPTB allograft ACL reconstructions were not different both subjectively and objectively for patients aged 40 years or older and patients aged younger than 40 years. BPTB allograft ACL reconstruction provides consistent results for patients of all age groups



Allograft Compared with Autograft Infection Rates in Primary Anterior Cruciate Ligament Reconstruction

David D. Greenberg, Michael Robertson, Santaram Vallurupalli, Richard Author:

A. White and William C. Allen

Source: J Bone Joint Surg Am. 92:2402-2408

**Key Takeaways:** 

for ACLR

#### STUDY OBJECTIVE

The purpose of this study was to compare infection rates between procedures using allograft or autograft tissue in primary anterior cruciate ligament (ACL) reconstruction.

#### **METHODS**

- 221 autograft patients and 640 allograft patients were included in this study
- A combined prospective and retrospective multicenter cohort study was performed over a three-year period
- Graft selection was determined by the individual surgeon
- Inclusion and exclusion criteria were equivalent for the two groups (allograft and autograft tissue) Our primary outcome was intra-articular infection following anterior cruciate ligament reconstruction

- The rate of superficial infections in the entire study group was 2.32%. We did not identify a significant difference in the rate of superficial infections between autograft and allograft reconstruction in our study group
- While the theoretical risk of disease transmission inherent with allograft tissue cannot be eliminated, we found no increased clinical risk of infection with the use of allograft tissue compared with autologous tissue for primary anterior cruciate ligament reconstruction

Anterior Laxity, Slippage, and Recovery of Function in

the First Year After Tibialis Allograft Anterior Cruciate

**Ligament Reconstruction** 

Author: Conrad K. Smith, PhD, Stephen M. Howell, yz MD, and

Maury L. Hull, PhD

Source: AJSM, published on October 7, 2010 as doi:10.1177/0363546510378652

Key Takeaways: • There was no increase in anterior laxity or slippage at 1 year when using MTF allografi

#### **STUDY OBJECTIVE**

When slippage-resistant fixation is used with a soft tissue graft, early recovery of function does not result in a clinically important increase in anterior laxity and slippage.

#### **METHODS**

- Nineteen subjects were treated with a single-tunnel, single-looped, MTF tibialis allograft with slippage-resistant, cortical fixation
- An examiner, different from the treating surgeon, used stereophotogrammetric analysis to compute
  the increase in anterior laxity at a 150 N anterior force and slippage between the day of surgery and
  each monthly follow-up interval, and determined recovery of function and motion

#### **RESULTS**

• Early recovery of function after ACL reconstruction with an MTF soft tissue allograft did not result in a clinically important increase in anterior laxity and slippage at 1 year



Title: Anterior Cruciate Ligament Reconstruction in the Multicenter ACL Revision Study (MARS) Cohort

**Author:** The MARS Group

**Source:** Am J Sports Med 2014 42: 2301 as DOI: 10.1177/0363546514549005

**Key Takeaways:** • This stud

• This study demonstrates that MTF allografts can have a 95% success rate in revision

anterior cruciate ligament (ACL) reconstruction

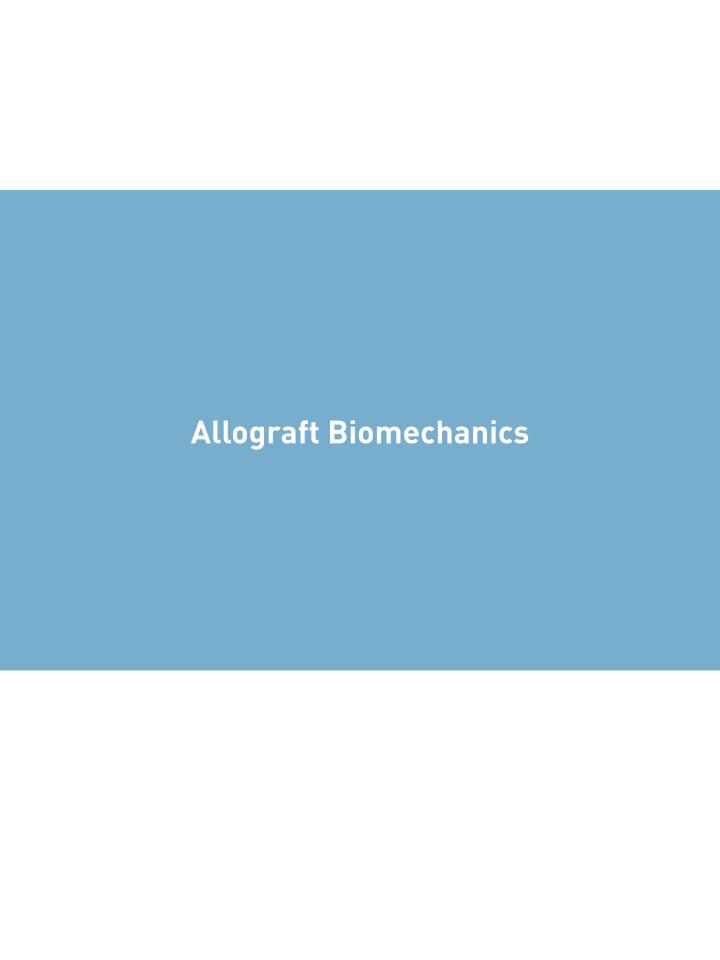
#### **STUDY OBJECTIVE**

The purpose of this study was to compare revision rates of Allograft and Autograft to see if autograft would result in decreased failure rates 2 years after revision ACL reconstruction.

#### **METHODS**

- 1205 patients were enrolled in the study; half of the patients received an autograft and half received an allograft for their reconstruction. All surgeries were performed by members of the AOSSM
- The study used only MTF tissue and all patients were followed up with at 2 years post operation

- The Autograft group had a 97.8% Success rate (520 out of 542)
- The Allograft group had a 95.6% Success rate (516 out of 540)



**Evaluation of Mechanical Properties of Allograft Patellar** 

Tendons as a Function of Age and Gender

Author:

Archer, LPN

Source: MTF White Paper

**Key Takeaways:** 

#### STUDY OBJECTIVE

The purpose of this study was to evaluate the effect of donor age and gender on the mechanical properties of patellar tendon allograft tissue.

#### **METHODS**

- All grafts were supplied by MTF
- 87 patellar tendon allografts were tested
- Donor ages were 16 69 years old
- Each graft was placed on an Instron Mechanical Tester and loaded to failure at 80mm/minute

- One way ANOVA testing showed there was no statistical difference in mechanical strength between age groups 16-29, 30-39, 40-49, 50-59 and 60-69
- The differences between male or female donors were not statistically significant

Title: The Effect of Donor Age on Structural and Mechanical

**Properties of Allograft Tendons** 

Author: Katherine R. Swank, BA, Anthony W. Behn, MS, and Jason L. Dragoo, MD

Source: Am J Sports Med 2015 43: 453 originally published online November 17, 2014. DOI: 10.1177/0363546514557246

**Key Takeaways:** • After evaluating the mechanical strength of tibialis grafts using donor age as a variable,

#### **STUDY OBJECTIVE**

The hypothesis of this study is that donor age will significantly influence the structural and mechanical properties of tibialis posterior allograft tendons.

#### **METHODS**

- 550 allograft posterior tibialis tendons were examined
- Linear stiffness, ultimate tensile force, ultimate displacement, tensile modulus, ultimate tensile strength, and ultimate tensile strain were calculated
- 6 age groups were tested: 15-29, 30-39, 40-49, 50-59, 60-69, and 70-79
- Welch analyses of variance with Games-Howell post hoc tests were performed to facilitate comparisons among age groups

- Posterior tibialis tendons from all age groups displayed structural properties superior to the native anterior cruciate ligament
- The age of the donor will not likely affect the suitability of a graft for use in surgical reconstruction



A Biomechanical Comparison of Three Lower Extremity Tendons for Ligamentous Reconstruction About the Knee

Author:

Source: Arthroscopy. 2003 Dec;19(10):1091-6

#### STUDY OBJECTIVE

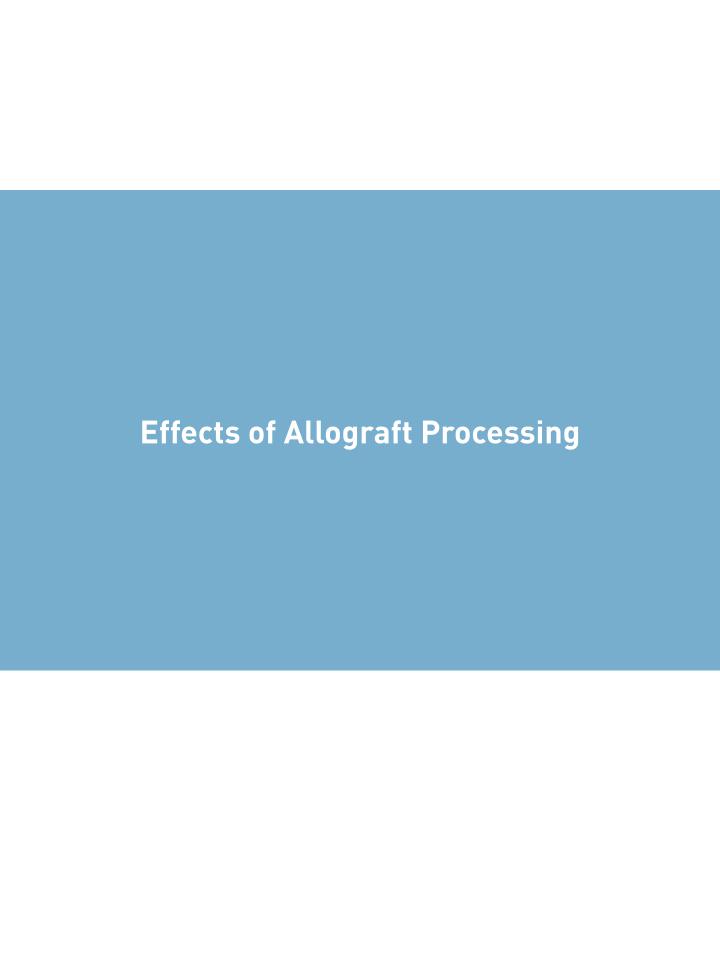
**Key Takeaways:** 

The purpose of this study was to evaluate 3 previously unreported allograft tendons for use in knee surgery: anterior tibialis, posterior tibialis and peroneus longus.

#### **METHODS**

- Sixteen fresh-frozen cadaveric lower limbs were used for testing
- All specimens were tested in a custom-designed hydraulic testing machine using dry ice clamps
- · Stiffness, modulus of elasticity, and stress and strain at failure were calculated

- The anterior tibialis, posterior tibialis, and peroneus longus tendons showed excellent biomechanical properties when compared with historical data evaluating other graft sources
- Good biomechanical properties observed for the TA, TP, and PL were noted in specimens despite an average age of 78.3 years



Revision Risk After Allograft Anterior Cruciate Ligament

Reconstruction: Association With Graft Processing Techniques, Patient Characteristics, and Graft Type

Tejwani SG, Chen J, Funahashi TT, Maletis GB, Love R Author:

AAOS presentation 2015. Pending publication in AJSM in 2015 Source:

**Key Takeaways:** 

#### STUDY OBJECTIVE

The purpose of this study was to examine the association of graft processing techniques, patient characteristics, and graft type with risk of revision surgery after allograft ACLR.

#### **METHODS**

- 5,968 primary anterior cruciate ligament reconstructions with allograft were included in the study
- Allograft processing, donor age and graft type were assessed as potential risk factors for revision while adjusting for patient age, gender and BMI using a logistic analysis models

- In the largest known study examining outcomes after primary allograft anterior cruciate ligament reconstruction (ACLR), the following were associated with higher risk of clinical failure and a subsequent revision surgery
  - BioCleanse® graft processing
  - Allograft irradiated with over 1.8Mrad
  - Younger patient age
  - · BPTB allogaft
- Surgeons should be aware that vendor-specific graft processing methods as well as patient age and graft type have implications on revision risk after allograft ACLR

Increased Risk of Revision After ACLR With Soft Tissue

Allograft Compared to Hamstring Autograft

Author: Maletis G, Chen J, Inacio M, Love R, Funahasi T

**Source:** *ISAKOS presentation 2015* 

**Key Takeaways:** 

Soft tissue allografts processed with BioCleanse or irradiated with over 1.8Mrad show
increased failure rates when compared to autograft. Allografts with no processing or
less than 1.8Mrad did not have a significantly different risk of revision compared to
autograft. More highly processed tissue leads to a higher risk of revision at earlier

#### STUDY OBJECTIVE

To compare revision rates with soft tissue using tissue type and processing methods as factors

#### **METHODS**

- Using a survival analysis, results were compared between 5707 Autograft and 3751 Allografts and the following processing parameters were taken into consideration,
- Irradiation <1.8 Mrad or > 1.8 Mrad
- Chemical Processing via Allowash, Allotrue and BioCleanse
- Sterilely procured non-processed tissue

- BioCleanse processed grafts had a 3.0x higher risk of revision compared to hamstring autograft
- Autograft had a 3.5% Cumulative failure at 3 years
- Sterilely procured non-processed tissue and less than 1.8Mrad without chemicals had a 2% and 3% cumulative failure rate
- Grafts processed with over 1.8Mrad had a 6.8% cumulative failure rate at 3 years



Nonirradiated Versus Irradiated Achilles Allograft In Vivo **Failure Comparison** 

Author:

Meister, MD, Peter Indelicato, MD

The American Journal of Sports Medicine, Vol. 35, No. 10. DOI: Source:

10.1177/0363546507302926

**Key Takeaways:** 

#### STUDY OBJECTIVE

The purpose of this study was to explore if allografts irradiated at 2.0-2.5Mrad would have an increased failure rate compared to non-irradiated allografts.

#### **METHODS**

- A group of 42 patients that received non-irradiated grafts were compared to a group of 33 patients that received irradiated grafts at 6 months
- Both groups used the same surgical technique and rehab protocols

- At 6 months, a significant difference in failure rates was noted between the two groups
- Surgeons should be aware that vendor-specific graft processing methods as well as patient age and graft type have implications on revision risk after allograft ACLR
- The irradiated group had a 11 in 33 (33%) failure rate
- The non-irradiated group had a 1 in 42 (2.4%) failure rate

Outcomes and Revision Rate After Bone–Patellar Tendon–

Bone Allograft Versus Autograft Anterior Cruciate

Ligament Reconstruction in Patients Aged 18 Years or

**Younger With Closed Physes** 

Henry B. Ellis, M.D., Lauren M. Matheny, B.A., Karen K. Briggs, M.P.H.,

Andrew T. Pennock, M.D., and J. Richard Steadman, M.D.

Arthroscopy: The Journal of Arthroscopic and Related Surgery, Vol 28, No Source: 12 (December 2) 2012, and 1825

12 (December), 2012: pp 1819-1825

**Key Takeaways:** • There was a 15 times higher failure rate using RTI and Allosource allografts compared

to autograft

#### STUDY OBJECTIVE

The purpose of this study was to compare revision rates and outcomes after anterior cruciate ligament (ACL) reconstruction with bone–patellar tendon–bone (BPTB) autografts versus BPTB allografts in patients aged 18 years or younger with closed physes

#### **METHODS**

- 59 patients received an autograft
- 20 patients received an RTI or Allosource allograft
- Outcome measures included Lysholm score, Tegner activity scale, and patient satisfaction (0, very unsatisfied; 10, very satisfied). Failures were defined as cases requiring ACL revision surgery

- The autograft group had a 3% failure rate (2 of 59)
- The allograft group had a 35% failure rate (7 of 20)



Effect of Hydrogen Peroxide Treatment on the

Biomechanical and Biochemical Properties of Soft Tissue

**Allografts** 

Author:

Source: MTF White paper

Key Takeaways:

#### STUDY OBJECTIVE

The object of this study was to see if  $H_2O_2$  had any effect on biomechanical and biochemical properties of soft tissue allografts.

#### **METHODS**

- Six allografts were processed and put through 3% and 6%  $H_2O_2$  soak for 30 and 120 minutes
- Six allografts were processed aseptically and rinsed with water without  $H_2O_2$ . These grafts served as the control
- All allografts were mechanically tested to observe creep, stiffness, maximum load and ultimate stress
- All allografts were also biochemically tested for collagenase digestion and native collagen I ELISA

- The grafts treated with  $H_2O_2$  had a significant reduction in Collagen I and a significant reduction in resistance to enzyme degradation
- The grafts treated with  $H_2O_2$  had a significant reduction in stiffness and ultimate stress

Mechanical Properties of Tendon Allografts Following Low-Dose Radiation Exposure Prior to Processing

Author: Jeffrey Cartmell, Ph.D., Lead Scientist, MTF

**Source:** White Paper

**Key Takeaways:** • The use of low dose

 The use of low dose pre-treatment for allograft tendons has no measureable effect on an allografts machanical proportion.

#### STUDY OBJECTIVE

Determine that Pre-Treatment of allograft tendons with low-dose (1.5Mrad) gamma radiation has no measurable effect upon baseline mechanical properties of human gracilis tendon and bone-patellar tendon - bone (BPTB) grafts compared to donor-matched, non-gamma irradiated controls.

#### **METHODS**

- Gracilis and bone-patellar tendon-bone (BPTB) were used for testing
- The grafts were placed into a pre-treatment (1.5Mrad) group and a control group (non-irradiated)
- All grafts went through the normal MTF process and storage methods
- Gracilis grafts were tested using Cryogenic grips and the BPTB grafts were tested using PMMA for fixation
- All grafts were tested for peak stress, peak load and creep

#### **RESULTS**

 Pre-Treatment of allograft tendons with low-dose (1.5Mrad) gamma radiation has no measurable effect on mechanical properties



A Meta-analysis of Patellar Tendon Autograft Versus Patellar Tendon Allograft in Anterior Cruciate Ligament Reconstruction

**Author:** and Diane L. Dahm, M.D.

2008. pp. 292-298

**Key Takeaways:** 

#### STUDY OBJECTIVE

A meta-analysis to examine the differences between Allograft and Autograft for Patellar Tendon grafts

#### **METHODS**

- 548 studies were reviewed, 6 of which met the inclusion criteria
- Studies needed to include 2-year follow-up
- Summary odds ratios, confidence intervals, and P values were calculated

#### **RESULTS**

· ACL reconstruction with BPTB autograft was favored over BPTB allograft for graft rupture and hop test parameters. However, when irradiated and chemically processed grafts were excluded, results were not significantly different between allograft and autograft

## **Summary of MTF Clinical Studies**

| STUDY                                                                                                                                                                                            | RESULTS                                                                                 |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| Barber et. al. – Arthroscopy 2014 Revision Rates After Anterior Cruciate Ligament Reconstruction Using Bone Patellar Tendon Bone Allograft or Autograft in a Population 25 Years Old and Younger | 7% Failure rate for MTF Allograft.<br>9% Failure rate for Autograft.                    |
| Poehling et. al., Curl et. al – Arthroscopy 2005 Analysis of Outcomes of Anterior Cruciate Ligament Repair With 5-Year Follow-up: Allograft Versus Autograft                                     | 5-year follow-up.<br>No difference MTF Allograft<br>vs. Autograft.                      |
| Shah et. al., Lowe et. al – Arthroscopy 2010  Failure Rate of Achilles Tendon Allograft in Primary Anterior  Cruciate Ligament Reconstruction                                                    | MTF Allograft 5.6% failure rate.<br>Historic autograph control 5%-13%<br>failure rates. |
| Barber et. al., Aziz-Jacobo et. al – Arthroscopy 2010 Anterior Cruciate Ligament Reconstruction Using Patellar Tendon Allograft: An Age-Dependent Outcome Evaluation                             | 2-year follow-up. Patients over/under 40 years old had similar outcomes.                |
| Greenberg et. al. – JBJS 2010 Allograft Compared with Autograft Infection Rates in Primary Anterior Cruciate Ligament Reconstruction                                                             | No increased clinical risk of infection with MTF Allograft vs. Autograft.               |
| Howell et. al AJSM 2010 Anterior Laxity, Slippage, and Recovery of Function in the First Year After Tibialis Allograft Anterior Cruciate Ligament Reconstruction                                 | No clinically significant increase in anterior laxity and slippage at one year.         |
| MARS study group – AJSM 2014                                                                                                                                                                     | MTF allograft 95.6% Success rate. Autograft 97.8% Success rate.                         |



### **Summary of Allograft Mechanical Studies**

| STUDY                                                                                                                                         | RESULTS                                                                                                                                                                                                                |
|-----------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Gatt et al. – White Paper Evaluation of Mechanical Properties of Allograft Patellar Tendons as a Function of Age and Gender                   | BPTB Allografts from donors up to the age 69 have acceptable mechanical properties needed for surgery.                                                                                                                 |
| Dragoo et. al – Arthroscopy 2014  The Effect of Donor Age on Structural and Mechanical Properties of Allograft Tendons                        | The age of the donor will not likely affect the suitability of a graft for use in surgical reconstruction.                                                                                                             |
| Pearsall et. al. –Arthroscopy 2003  A Biomechanical Comparison of Three Lower Extremity Tendons for Ligamentous Reconstruction About the Knee | The anterior tibialis, posterior tibialis, and peroneus longus tendons showed excellent biomechanical properties when compared with historical data evaluating other graft sources such as Semitendinosus or Gracilis. |

### **Summary of Allograft Processing Studies**

| STUDY                                                                                                                                                                                                                                    | RESULTS                                                                                                                                                                                                             |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Tejwani et al., Maletis et. al. – AAOS Presentation 2015</b> Revision Risk After Allograft Anterior Cruciate Ligament Reconstruction: Association With Graft Processing Techniques, Patient Characteristics, and Graft Type           | Grafts processed with BioCleanse or over 1.8Mrad had a statistically significant negative effect on revision risk.  Donor age did not effect revision risk.                                                         |
| Maletis et. al – ISAKOS Presentation 2015 Increased Risk of Revision After ACLR With Soft Tissue Allograft Compared to Hamstring Autograft                                                                                               | Aseptically processed tissue and tissue processed with less than 1.8Mrad did not increase revision compared to autograft.  Tissue processed using BioCleanse or over 1.8Mrad significantly increased revision risk. |
| Rappé et. al. –AJSM 2007<br>Nonirradiated Versus Irradiated Achilles Allograft In Vivo Failure<br>Comparison                                                                                                                             | Grafts treated with 2.0-2.5Mrad had a 33% failure rate.  Aseptically processed grafts had a 2.4% failure rate.                                                                                                      |
| Ellis.et al, Steadman et. al.— Arthroscopy 2012 Outcomes and Revision Rate After Bone—Patellar Tendon— Bone Allograft Versus Autograft Anterior Cruciate Ligament Reconstruction in Patients Aged 18 Years or Younger With Closed Physes | Grafts processed by RTI and Allosource had a 35% failure rate. Autograft had a 3% failure rate.                                                                                                                     |
| MTF White Paper Effect of Hydrogen Peroxide Treatment on the Biomechanical and Biochemical Properties of Soft Tissue Allografts                                                                                                          | Grafts processed with hydrogen peroxide had decreased stiffness, ultimate stress and resistance to enzyme degradation.                                                                                              |
| Cartmell, J. – White Paper  Mechanical Properties of Tendon Allografts Following Low-Dose Radiation Exposure Prior to Processing                                                                                                         | MTF pre-treated grafts did not effect mechanical properties of an allograft.                                                                                                                                        |
| Krych et. al AJSM 2010  A Meta-analysis of Patellar Tendon Autograft Versus Patellar Tendon Allograft in Anterior Cruciate Ligament Reconstruction                                                                                       | Allografts are equivalent to autografts if they aren't processed with chemicals or terminal irradiation.                                                                                                            |



## If you have any questions, we'd love to hear from you!

### **MTF Sports Medicine**

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