Potential Market for New Meniscus Repair Strategies

Evaluation of the MOON Cohort

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ABSTRACT: This study aimed to determine the incidence of meniscal tears and describe the tear morphology and selected treatment in patients undergoing anterior cruciate ligament (ACL) reconstruction. We also will discuss the potential market for future tissue engineering aimed at preserving meniscal function. A multicenter cohort of 1014 patients undergoing ACL reconstruction between January 2002 and December 2003 was evaluated. Data on patient demographics, presence of a meniscus tear at time of ACL reconstruction, tear morphology, and meniscal treatment were collected prospectively. Meniscal tears were categorized into 3 potential tissue engineering treatment strategies: all-biologic repair, advanced repair, and scaffold replacement. Of the knees, 36% had medial meniscal tears and 44% had lateral meniscal tears. Longitudinal tears were the most common tear morphology. The most frequent treatment method was partial meniscectomy. Thirty percent of medial meniscal tears and 10% of lateral meniscal tears are eligible for all-biologic repair; 35% of medial meniscal tears and 35% of lateral meniscal tears are eligible for an advanced repair technique; and 35% of medial meniscal tears and 55% of lateral meniscal tears are eligible for scaffold replacement. Although meniscal preservation is generally accepted in the treatment of meniscal tears, most tears in this cohort were not repairable, despite contemporary methods. The results of this cohort will hopefully stimulate and focus future research and development of new tissue engineering strategies for meniscus repair.

[*J Knee Surg*. 2009;21:180-186.]

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INTRODUCTION

The knee menisci are important structures that preserve a pain-free functional knee. The main function of the meniscus is to support and distribute loads across the knee, thus decreasing the weight-bearing stress delivered to the articular surface.[22,35,52] The medial meniscus has also been demonstrated to provide restraint to anterior tibial translation in the anterior cruciate ligament (ACL)-deficient knee.[52] Meniscal tears disrupt structural integrity and alter meniscal function. In 1948, Fairbank[21] reported on a series of meniscal tears and the deleterious effects of total meniscectomy on articular cartilage. In his long-term radiographic follow-up study, he documented "ridge formation, narrowing of the joint space, and flattening of the femoral condyle" following open meniscectomy. Despite this and previous work characterizing early evidence of potential meniscal healing by King,[30] total meniscectomy was the standard operative treatment for a torn meniscus until the 1970s.

As biomechanical and clinical studies documented the significance of the knee menisci, a shift from total meniscectomy to meniscal preservation surgery became a primary goal of treatment. Loss of the meniscus alters the pattern of load transmission in the knee, resulting in higher peak stress and greater stress concentration in the articular cartilage.[6,23,33] Contemporary treatment methods used in addressing meniscal tears include "benign neglect," partial excision, repair, or allograft replacement. Treatment choice is based on tear morphology, proximity to the meniscal blood supply, length of tear, stability of the meniscus, presence of meniscal degeneration, and ligamentous stability of the knee. Over the past 2 decades, contemporary meniscal repair techniques have evolved to include arthroscopic inside-out repair,[9,13,26,27,42] arthroscopic outside-in repair,[38,40,53] arthroscopic all-inside repair,[7,10,37] and open repair.[12,17,19]

Meniscal tears are common, and surgeons often have limited options, which are dictated by the tear morphology and location. Meniscal tears are frequently associated with ACL disruptions. The American Orthopaedic Society for Sports Medicine (AOSSM) and industry sources estimate that 200,000 ACL reconstructions are performed annually in the United States. It has been hypothesized that long-term results of ACL reconstruction are predicted by the meniscal tears and treatment.[44,45] Therefore, there is significant potential value to new tissue engineering and surgical techniques aimed at preserving meniscal function.

Several tissue engineering strategies have the potential to restore meniscal function to torn menisci.* These include all biological repair techniques, techniques to enhance the ability to repair tears in the avascular zone, and scaffolds to replace excised portions of the meniscus. Biological repair may allow meniscal repair without the use of implants or accessory incisions that are currently used in meniscal repair techniques. Advanced repair strategies using tissue engineering may promote the healing rate of meniscal repairs in the avascular zone, allowing repair of meniscus tears currently treated by excision. Biological scaffolds may provide a mechanism for tissue regeneration and cellular repopulation of currently irreparable menisci, thus preserving meniscus function in knees treated with excision.

The potential national market for these new options has not been previously established in a large multicenter prospective cohort where interrater agreement has been established for meniscus tear type and treatment. Meniscal tear types and their current treatments must be carefully determined to characterize this potential. Therefore, the purpose of this study was to determine the incidence of meniscal tears and describe meniscal tear morphology and current treatments from the Multicenter Orthopaedic Outcomes Network (MOON) prospective cohort of relatively young patients undergoing ACL reconstruction. We will also demonstrate the potential profound influence new innovations could have on meniscal preservation and, subsequently, patient outcomes after ACL reconstruction. The information gained is important to provide reliable population estimates of meniscus tears and treatment that is generalizable to the U.S. market to stimulate academic centers and industry to focus resources to improve meniscal tear treatment. We hypothesize that in this relatively young population undergoing ACL reconstruction, the majority of meniscal tears currently require partial meniscectomy, and this cohort will demonstrate a large potential market that exists for tissue engineering aimed at preserving meniscal function.

METHODS

Between January 2002 and December 2003, 1014 consecutive ACL reconstructions were performed and prospectively followed by 9 sports medicine fellowship-trained orthopedists from 6 orthopedic centers. Participating centers are all part of the Multicenter Orthopaedic Outcomes Network (MOON), and include Washington University (St Louis, Mo), the Hospital for Special Surgery (New York, NY), the University of Iowa Hospitals and Clinics (Iowa City, Iowa), the Cleveland Clinic Foundation (Cleveland, Ohio), the Ohio State Sports Medicine Clinic (Columbus, Ohio), and Vanderbilt University Sports Medicine (Nashville, Tenn). Institutional Review Board approval was obtained at each participating center.

Of the patients who underwent ACL reconstruction during this time, 99% agreed to participate in this study. Anterior cruciate ligament reconstruction was performed with arthroscopic-assisted, endoscopic, or rear-entry techniques, primarily with either autogenous bone-patellar tendon-bone or hamstring grafts. Approximately 10% of the ACL reconstructions were defined as revisions. The only exclusion criteria were knees that underwent multiligament knee reconstruction, including associated pos-

5, 14, 15, 25, 31, 32, 39, 41, 47, 49-51, 54

TABLE 1

FREQUENCY OF OBSERVED MEDIAL MENISCUS TEARS, TEAR TYPES, AND TREATMENT METHOD

		Treatment		
Type of Tear	**Total (N = 1014)[a]**	**Repair**	**Benign Neglect**	**Excision**
Bucket handle	52 (5%)	14	0	38
Longitudinal	170 (17%)	91	44	29
Complex	93 (9%)	1	1	86
Oblique	28 (3%)	4	3	21
Radial	10 (1%)	0	2	8
Horizontal	11 (1%)	0	0	10

[a] Of the 1014 knees undergoing anterior cruciate ligament reconstruction, 364 medial meniscus tears were identified. Missing data results in some treatments not totaling the number of tears.

terior cruciate ligament tear or a grade III collateral ligament injury.

Patient demographic information was obtained, including age at time of surgery, gender, and time from injury to ACL reconstruction. At the time of ACL reconstruction, the surgeon completed a detailed knee examination under anesthesia, including the "normal" contralateral knee, and detailed operative arthroscopic assessment and treatment of meniscus and articular cartilage injuries. Data were uniformly entered by the operating surgeon, with 98% compliance of the cases performed. Data were compiled from all of the participating centers and recorded into the MOON database. A more detailed description of the surgeon documentation is detailed in previous studies.[20,48]

Meniscal tears were classified according to tear morphology and location. Tears were classified as longitudinal, oblique, radial, horizontal, bucket handle, or complex. Meniscal treatment at the time of ACL reconstruction was also documented. Consistency between surgeons from this research group concerning classification of tear type and selected treatment is based on the previously established excellent interrater agreement of the MOON surgeons.[20] In procedures involving meniscal repair, it was performed by either the arthroscopic-assisted inside-out or the all-inside technique. Meniscal repair was performed for reparable longitudinal or bucket handle tears in the peripheral one-third of the meniscus. Meniscal tears were left untreated if the tear was <10 mm in length and stable to probing. Partial meniscectomy was performed for unstable tears >10 mm in length in the avascular zone, tears including a discoid meniscus, oblique, radial, complex tears, or tears with a significant portion of degeneration.

Tears were then categorized into 1 of the following 3 potential tissue engineering strategies:

- All-biological repair.
- Advanced repair in the avascular zone.
- Scaffold replacement.

The all-biological repair group (eliminating the need for sutures or implants) included reparable bucket handle and longitudinal tears in the vascular zone. The advanced repair group included all irreparable bucket handle and longitudinal tears in the avascular zone. Tears classified into the scaffold replacement group included irreparable complex, oblique, radial, and horizontal tears.

The total number of tears categorized into each group, as well as the relative percentage of the total number of tears represented, was calculated. We then determined the potential influence on the U.S. market by multiplying the following data points: estimated number of ACL reconstruction performed in the United States, the percentage of ACL reconstructions with meniscus tears (medial or lateral), and the representative percent of each tissue engineering strategy (all-biologic, advanced repair, scaffold). The resultant number represents the estimated number of meniscal tears that could be effectively treated with a new treatment strategy.

RESULTS

The study population consisted of 1014 patients, with a total of 1014 ACL reconstructions during the period from January 2002 to December 2003. Patients' median age at the time of surgery was 24 years (12-24 years, 51.5%; 25-34 years, 22.5%; >34 years, 26%). The cohort comprised 51% men and 49% women.

Three hundred sixty-four medial meniscus tears were identified, which represented 36% of the reconstructions (Table 1). Tear type and treatment rendered are noted in Table 1. Four hundred forty-two lateral meniscus tears were identified, which represented 44% of the total reconstructions (Table 2). Tear type and treatment rendered are noted in Table 2.

In this ACL reconstruction population, longitudinal tears were the most commonly observed tear morphology in both the medial and lateral meniscus. The most frequent treatment method was partial meniscectomy. Sixty-nine

TABLE 2

Frequency of Observed Lateral Meniscus Tears, Tear Types, and Treatment Method

		Treatment		
Type of Tear	Total (N = 1014)[a]	Repair	Benign Neglect	Excision
Bucket handle	23 (2%)	6	0	17
Longitudinal	148 (15%)	37	71	33
Complex	115 (11%)	1	3	109
Oblique	90 (9%)	5	14	71
Radial	55 (5%)	0	2	53
Horizontal	11 (1%)	2	2	7

[a] Of the 1014 knees undergoing anterior cruciate ligament reconstruction, 442 lateral meniscus tears were identified. Missing data results in some treatments not totaling the number of tears.

percent of the medial meniscus tears and 88% percent of the lateral meniscus tears were not reparable by contemporary techniques or were left alone (benign neglect). Fifty (14%) of the 352 medial meniscal tears and 92 (21%) of the 433 lateral meniscal tears were treated with benign neglect. Treatment data from 12 medial meniscal and 9 lateral meniscal tears was missing (21 of 806, 2.6%).

The medial and lateral meniscus tears were further classified into 3 categories for consideration of future advanced treatment options:

- All-biological repair.
- Advanced repair in the avascular zone.
- Scaffold replacement.

This classification was based on tear morphology, location in vascular zone, and repairability (Tables 3 and 4). One hundred five (30%) of the 352 medial meniscal tears were reparable bucket-handle or longitudinal tears and were categorized to the biological repair group. One hundred twenty-two (35%) of the medial meniscus tears were irreparable bucket handle or longitudinal tears and were categorized to the advanced repair technique group (this also includes other tear types treated with repair or benign neglect). One hundred twenty-five (35%) were irreparable complex, oblique, radial, or horizontal medial meniscal tears treated with partial excision and were categorized to the scaffold replacement group. Forty-three lateral meniscus tears (10%) were reparable bucket handle or longitudinal tears and were categorized in the all-biological repair group. One hundred fifty lateral meniscus tears (35%) were irreparable bucket handle or longitudinal tears and were categorized in the advanced repair technique group (this also includes other tear types treated with repair or benign neglect). Two-hundred forty (55%) were irreparable complex, oblique, radial, or horizontal lateral meniscal tears treated with partial excision and were categorized in the scaffold replacement group.

The potential influence on the U.S. market is summarized in Tables 3, 4, and 5.

DISCUSSION

The results of this study demonstrate two points: First, despite the known emphasis on meniscal preservation, the majority of meniscus tears observed at the time of ACL reconstruction are treated with partial meniscectomy. The surgeon's current treatment algorithm is dictated by the tear morphology (type), proximity to meniscus blood supply, length and stability of tear, and presence of degeneration. Most of these factors are out of the control of the surgeon, as the meniscus tear pattern is determined at the time of injury to the ACL. In addition, treatment is biased by a surgeon's training and experience level, as well as confidence in and technical skill at performing meniscal repair techniques. Thus, 55% of medial meniscus tears and 67% of lateral meniscus tears currently are treated with partial meniscectomy based on the lack of vascular supply or tear pattern. Second, based on an estimated 200,000 ACL reconstructions performed annually, a relatively large potential market (approximately 160,000) exists for tissue engineering strategies to replace repairs done with implants (approximately 30,000), advance the repairs to avascular zone (approximately 56,000), and use scaffold replacements (approximately 74,000). The prospective patient cohort selected for this study is an excellent model for this meniscal evaluation for many reasons. Meniscus tears are common injuries associated with ACL disruptions. Most reparable meniscal tears occur in the second or third decades of life and most are associated with ACL disruption.[43] Most patients <40 years diagnosed with an ACL tear undergo reconstruction to allow return to their active lifestyle. Patients in this age group generally have normal articular cartilage and, thus, meniscal preservation may have the highest yield to prevent early degenerative joint disease. Therefore, this young population is the ideal target population for aggressive attempts at meniscal preservation.

TABLE 3

POTENTIAL UNITED STATES MARKET FOR MEDIAL MENISCUS TREATMENT [a]

Future Treatment	Total (n = 352)	Annual Market
Biological repair	105 (30%)	21,600
Advanced repair	122 (35%)	25,200
Scaffold replacement	125 (35%)	25,200

[a] Of approximately 200,000 anterior cruciate ligament reconstructions performed annually in the United States, 36% of knees will have an associated medial meniscal tear.

TABLE 4

POTENTIAL UNITED STATES MARKET FOR LATERAL MENISCUS TREATMENT [a]

Future Treatment	Total (n = 433)	Annual Market
Biological repair	43 (10%)	8800
Advanced repair	150 (35%)	30,800
Scaffold replacement	240 (55%)	48,400

[a] Of approximately 200,000 anterior cruciate ligament reconstructions performed annually in the United States, 44% of knees will have an associated lateral meniscal tear.

TABLE 5

POTENTIAL UNITED STATES MARKET FOR MENISCUS TREATMENT IN PATIENTS UNDERGOING ANTERIOR CRUCIATE LIGAMENT RECONSTRUCTION

Future Treatment	Annual Market
Biological repair	30,400
Advanced repair	56,000
Scaffold replacement	73,600

In our cohort of 1014 ACL reconstructions, we found that meniscal tears were common injuries, similar to previous studies.[8,46,48] We found that 36% of the knees had medial meniscal tears and 44% of the knees had lateral meniscal tears. In an entirely different cohort of more than 300 ACL reconstructions, Spindler et al[48] noted 43% of the knees had medial meniscus tears and 51% of the knees had lateral meniscus tears. Bellabarba et al[8] performed a meta-analysis and reported the overall incidence of meniscal tears in the ACL-deficient knee. They reported that overall, 41% to 82% of knees with acute ACL injuries had meniscal tears and that 58% to 100% of knees with chronic ACL deficiency had meniscal tears. Smith and Barrett[46] have also previously published their respective data on meniscal tear patterns in ACL-deficient knees.

Of note, in our series, only 31% of medial meniscal tears and 12% of lateral meniscal tears were reparable at the time of ACL reconstruction. Repairs were primarily done for bucket handle and longitudinal tears within the vascular zone (ie, peripheral one-third). Previous studies have demonstrated the high rates of successful meniscal repair in association with ACL reconstruction, with successful outcomes rates in the 85% to 90% range.[11,16,18,27,29] The data from these outcome studies help support the argument that more aggressive attempts at repair may be indicated in conjunction with reconstruction of the ACL. There are many supporting data to suggest that meniscal integrity may be the key factor in the long-term outcomes of ACL reconstruction. Aglietti et al[1] found that patients undergoing partial meniscectomy at the time of ACL reconstruction had more pain and more degenerative radiographic changes than did patients undergoing meniscus repair or patients without meniscal injury at 55 months follow-up. Shelbourne and Gray[45] reported improved KT-1000 scores with intact meniscus versus patients treated with partial meniscectomy and lower subjective knee outcome scores in patients who underwent partial meniscectomy at 7 years. Lynch et al[34] found that patients undergoing partial or total meniscectomy at the time of ACL reconstruction led to an incidence of Fairbank's changes 22 times that of the control group (no meniscal tear), and 7 times that with meniscus repair. Anderson et al[2] similarly reported that the absence of meniscal injury had a high correlation with normal radiographs at final follow-up. Jomha et al[28] evaluated the long-term osteoarthritic changes in ACL-reconstructed knees and found that acute ACL reconstruction with meniscal preservation led to the lowest incidence of degenerative changes.

However, intermediate-term 5-year multivariable modeling results by Spindler et al[48] did not support the findings of the above series. They found no association between outcomes and either the occurrence or the form of treatment of a meniscal tear or chondromalacia of the articular cartilage. Shelbourne and Carr[44] have also reported a retrospective evaluation of bucket handle tears in ACL reconstructions and found that outcomes from repair were not superior to those treated with partial excision. However, longer follow-up of these cohorts may demonstrate different findings.

Perhaps a much larger market exists for tissue engineering strategies to preserve meniscus function. Garrett et al[24] have recently reported the data collected by the American Board of Orthopaedic Surgery for surgeons preparing for their oral examination. Partial excision of the medial or lateral meniscus of the knee (*Current Procedural Terminology* code 29881) is the most common procedure in this group. Thus, in addition to the tears that are associated with ACL injuries, there are thousands of tears not associated with ACL reconstruction that may also benefit from new tissue engineering strategies.

In an effort to improve the potential healing response of meniscal tears and expand the indications of "reparable" menisci, a variety of repair techniques, repair augmentation techniques, and biologic scaffolds have been attempted and reported in both human and animal models.* Augmentation of healing has been attempted with the creation of vascular access channels, trephination, abrasion, insertion of fibrin clot at the repair site, and synovial flaps.[3-5,27,36] A review of these enhancement techniques was recently performed by McAndrews and Arnoczky.[36] The goal of these enhancement techniques is to optimize the healing bed of the meniscus by stimulating vascular ingrowth and release of local growth factors. Attempts of implanting biological scaffolds and tissue engineered cellular repair are also reported in the literature, with encouraging results.[14,15,39,41,49,50,54]

There are several strengths of this study. First, the data from this cohort were collected in a prospective manner. Second, the MOON cohort has a sufficient sample size from which to make accurate conclusions and provide meaningful generalizability to ACL reconstructions nationwide. There are two potential weaknesses of this study. First, some data were missing from the database—Treatment data from 12 medial meniscal and 9 lateral meniscal tears were missing. The potential source of this error is likely that the surgeon noted and categorized the tear but did not enter the treatment method into the database. Due to the large sample size, the authors think this small percentage of missing data does not affect the outcomes or conclusions of the study. A second potential weakness is that this is a multicenter investigation, in which tear identification and morphology data, as well as selected treatment, can potentially be inconsistent from classification and treatment by different surgeons. However, we think any potential problems are addressed by the high surgeon compliance in the data collection and nearly 100% patient participation. More important, surgeons participating in the MOON consortium have previously demonstrated and published their high interrater agreement on meniscal tear identification and anticipated treatment.[20]

CONCLUSION

The majority of meniscus tears observed at the time of ACL reconstruction are still treated by partial meniscectomy (55% medial meniscectomy, 67% lateral meniscectomy). A relatively large potential market (approximately 160,000) exists for functional tissue engineering strategies to preserve meniscus function through scaffolds (approximately 74,000), advancing repairs to avascular zone (approximately 56,000), and performing all-biologic repairs without implants (approximately 30,000). We hope that many of these options will be available in the future.

**3-5, 14, 15, 25, 31, 32, 36, 39, 41, 47, 49-51, 54*

ACKNOWLEDGEMENTS

The authors thank William Renfrew for data analysis, Lynn Cain for editorial assistance, and Allison Beatty, research coordinator of the project. The described project was supported in part by the Vanderbilt Sports Medicine Research Fund; National Institutes of Health grants #R01AR053684-01A1 (to Dr Spindler) and #5K23 AR052392-02 (to Dr Dunn), both from the National Institute of Arthritis and Musculoskeletal and Skin Diseases; unrestricted educational gifts from both Aircast, Inc (Vista, Calif), and Smith & Nephew (Andover, Mass); a National Football League Charities medical grant; and a Pfizer Scholars Grant in Clinical Epidemiology (to Dr Dunn).

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