



UNIVERSITY
OF TAMPERE

This document has been downloaded from
TamPub – The Institutional Repository of University of Tampere

 *Publisher's version* <http://urn.fi/URN:NBN:fi:uta-201602171224>

Author(s): Sihvonen, Raine; Paavola, Mika; Malmivaara, Antti; Itälä, Ari;
Joukainen, Antti; Nurmi, Heikki; Kalske, Juha; Järvinen, Teppo;
Nyrhinen, Jukka; Järvelä, Timo; Järvinen, Tero; Lehtinen, Janne;
Raivio, Marko; Karhunen, Janne; Tukiainen, Sikri; Kröger, Heikki;
Äärimaa, Ville

Title: Arthroscopic partial meniscectomy versus sham surgery for a
degenerative meniscal tear.

Year: 2013

Journal
Title: New England Journal of Medicine

Vol and
number: 369 : 26

Pages: 2515-2524

ISSN: 0028-4793

Discipline: Surgery, anesthesiology, intensive care, radiology

School
/Other: School of Medicine

Unit:

Item Type: Journal Article

Language: en

DOI: <http://dx.doi.org/10.1056/NEJMoa1305189>.

URN: URN:NBN:fi:uta-201602171224

URL: <http://dx.doi.org/10.1056/NEJMoa1305189>

All material supplied via TamPub is protected by copyright and other intellectual property rights, and duplication or sale of all part of any of the repository collections is not permitted, except that material may be duplicated by you for your research use or educational purposes in electronic or print form. You must obtain permission for any other use. Electronic or print copies may not be offered, whether for sale or otherwise to anyone who is not an authorized user.

ORIGINAL ARTICLE

Arthroscopic Partial Meniscectomy versus Sham Surgery for a Degenerative Meniscal Tear

Raine Sihvonen, M.D., Mika Paavola, M.D., Ph.D., Antti Malmivaara, M.D., Ph.D., Ari Itälä, M.D., Ph.D., Antti Joukainen, M.D., Ph.D., Heikki Nurmi, M.D., Juha Kalske, M.D., and Teppo L.N. Järvinen, M.D., Ph.D.,
for the Finnish Degenerative Meniscal Lesion Study (FIDELITY) Group

ABSTRACT

BACKGROUND

Arthroscopic partial meniscectomy is one of the most common orthopedic procedures, yet rigorous evidence of its efficacy is lacking.

METHODS

We conducted a multicenter, randomized, double-blind, sham-controlled trial in 146 patients 35 to 65 years of age who had knee symptoms consistent with a degenerative medial meniscus tear and no knee osteoarthritis. Patients were randomly assigned to arthroscopic partial meniscectomy or sham surgery. The primary outcomes were changes in the Lysholm and Western Ontario Meniscal Evaluation Tool (WOMET) scores (each ranging from 0 to 100, with lower scores indicating more severe symptoms) and in knee pain after exercise (rated on a scale from 0 to 10, with 0 denoting no pain) at 12 months after the procedure.

RESULTS

In the intention-to-treat analysis, there were no significant between-group differences in the change from baseline to 12 months in any primary outcome. The mean changes (improvements) in the primary outcome measures were as follows: Lysholm score, 21.7 points in the partial-meniscectomy group as compared with 23.3 points in the sham-surgery group (between-group difference, -1.6 points; 95% confidence interval [CI], -7.2 to 4.0); WOMET score, 24.6 and 27.1 points, respectively (between-group difference, -2.5 points; 95% CI, -9.2 to 4.1); and score for knee pain after exercise, 3.1 and 3.3 points, respectively (between-group difference, -0.1 ; 95% CI, -0.9 to 0.7). There were no significant differences between groups in the number of patients who required subsequent knee surgery (two in the partial-meniscectomy group and five in the sham-surgery group) or serious adverse events (one and zero, respectively).

CONCLUSIONS

In this trial involving patients without knee osteoarthritis but with symptoms of a degenerative medial meniscus tear, the outcomes after arthroscopic partial meniscectomy were no better than those after a sham surgical procedure. (Funded by the Sigrid Juselius Foundation and others; ClinicalTrials.gov number, NCT00549172.)

From the Department of Orthopedics and Traumatology, Hatanpää City Hospital, Tampere (R.S.), the Department of Orthopedics and Traumatology, Helsinki University Central Hospital and University of Helsinki (M.P., J.K., T.L.N.J.), and the National Institute for Health and Welfare, Center for Health and Social Economics (A.M.), Helsinki, the Department of Orthopedics and Traumatology, University of Turku, Turku (A.I.), the Department of Orthopedics, Traumatology, and Hand Surgery, Kuopio University Hospital, Kuopio (A.J.), and the Department of Orthopedics and Traumatology, Central Finland Central Hospital, Jyväskylä (H.N.) — all in Finland. Address reprint requests to Dr. Järvinen at the Department of Orthopedics and Traumatology, Helsinki University Central Hospital/Töölö Hospital, Topeliuksenkatu 5, P.O. Box 266, 00029 HUS, Helsinki, Finland, or at teppo.jarvinen@helsinki.fi.

*A list of additional members of the FIDELITY Group is provided in the Supplementary Appendix, available at NEJM.org.

N Engl J Med 2013;369:2515-24.

DOI: 10.1056/NEJMoa1305189

Copyright © 2013 Massachusetts Medical Society

ARTHROSCOPIC PARTIAL MENISCECTOMY is the most common orthopedic procedure performed in the United States.¹ The aim of the procedure is to relieve symptoms attributed to a meniscal tear by removing torn meniscal fragments and trimming the meniscus back to a stable rim. Most treated meniscal tears are associated with degenerative knee disease, which can range from mild chondral changes not visible on a radiograph to established knee osteoarthritis.^{2,3} The number of arthroscopic surgical procedures performed to treat established knee osteoarthritis, with or without a concomitant meniscal lesion, has decreased dramatically in the past 15 years.^{4,5} This trend has been attributed to two controlled trials^{6,7} showing a lack of efficacy of arthroscopic surgery. However, the number of arthroscopic partial meniscectomies performed has concurrently increased by 50%.⁴ Approximately 700,000 arthroscopic partial meniscectomies are performed annually in the United States alone,¹ with annual direct medical costs estimated at \$4 billion. A recent randomized trial⁸ showed that arthroscopic partial meniscectomy combined with physical therapy provides no better relief of symptoms than physical therapy alone in patients with a meniscal tear and knee osteoarthritis. We conducted a multicenter, randomized, double-blind, sham-controlled trial to assess the efficacy of arthroscopic partial meniscectomy in patients who have a degenerative tear of the medial meniscus without knee osteoarthritis.

written informed consent. On entering the study, patients were unequivocally informed that they might undergo sham surgery and that they would be allowed to consider crossing over to the other procedure (arthroscopic partial meniscectomy) 6 months or later after the sham procedure if they did not have adequate relief of symptoms.

PARTICIPANTS

We enrolled patients 35 to 65 years of age who had knee pain (for >3 months) that was unresponsive to conventional conservative treatment and had clinical findings consistent with a tear of the medial meniscus (Fig. 1). Patients with an obvious traumatic onset of symptoms or with knee osteoarthritis as defined with the use of clinical criteria (American College of Rheumatology)¹⁰ or radiographic criteria (Kellgren–Lawrence grade >1)¹¹ were excluded. On the Kellgren–Lawrence scale, grade 0 denotes no abnormalities, grade 1 minor degenerative changes (doubtful narrowing of the joint space and possible osteophytic lipping), and grade 2 knee osteoarthritis (definite narrowing of the joint line or an osteophyte). Preoperative magnetic resonance imaging (MRI) was performed to confirm the presence of a medial meniscus tear, but the eligibility of the patients was ultimately determined by arthroscopic examination. Detailed inclusion and exclusion criteria are provided in Table S1 in the Supplementary Appendix, available at NEJM.org.

METHODS

TRIAL DESIGN

We conducted this parallel-group study at five orthopedic clinics in Finland during the period from December 2007 through January 2013. Details of the trial design and methods have been published elsewhere.⁹ The patients, the people who collected and analyzed the data, and the authors were unaware of the study-group assignments. The protocol was approved by the institutional review board of the Pirkanmaa Hospital District. The first and last authors vouch for the accuracy and completeness of the reported data and analyses and for adherence of the study to this article, available with the full text of this article at NEJM.org.

The study was conducted in accordance with the Declaration of Helsinki. All patients gave

DIAGNOSTIC ARTHROSCOPY

Arthroscopic examination of the knee was first performed in all patients with the use of standard anterolateral and anteromedial portals and a 4-mm arthroscope. The orthopedic surgeon evaluated the medial, lateral, and patellofemoral joint compartments and graded the intraarticular pathologic changes (Table S2 in the Supplementary Appendix).^{12,13}

RANDOMIZATION

During the diagnostic arthroscopic procedure, if a patient was confirmed to be eligible for the trial, the surgeon asked a research nurse to open an envelope containing the study-group assignment (arthroscopic partial meniscectomy or sham surgery) and reveal it to the surgeon; the assignment was not revealed to the patient. The sequentially numbered, opaque, sealed envelopes

were prepared by a statistician with no involvement in the clinical care of patients in the trial. Randomization was performed in a 1:1 ratio with a block size of 4 (known only to the statistician). The randomization sequence involved stratification according to study site, age (35 to 50 or 51 to 65 years of age), sex, and the absence or presence of minor degenerative changes on a radiograph (Kellgren–Lawrence grade 0 or 1, respectively).¹¹ Only the orthopedic surgeon and other staff in the operating room were made aware of the group assignment, and they did not participate in further treatment or follow-up of the patient.

OPERATIVE AND POSTOPERATIVE PROCEDURES

During the arthroscopic partial meniscectomy, the damaged and loose parts of the meniscus were removed with the use of arthroscopic instruments (a mechanized shaver and meniscal punches) until solid meniscal tissue was reached. The meniscus was then probed to ensure that all loose and weak fragments and unstable meniscus had been successfully resected, with preservation of as much of the meniscus as possible. No other surgical procedure was performed.

For the sham surgery, a standard arthroscopic partial meniscectomy was simulated. To mimic the sensations and sounds of a true arthroscopic partial meniscectomy, the surgeon asked for all instruments, manipulated the knee as if an arthroscopic partial meniscectomy was being performed, pushed a mechanized shaver (without the blade) firmly against the patella (outside the knee), and used suction. The patient was also kept in the operating room for the amount of time required to perform an actual arthroscopic partial meniscectomy.

No medication was instilled into the knee during arthroscopy. All procedures were standardized and recorded on video. In both the partial-meniscectomy group and the sham-surgery group, postoperative care was delivered according to a standardized protocol specifying that all patients receive the same walking aids and instructions for the same graduated exercise program (Fig. S1 in the Supplementary Appendix). Patients were instructed to take over-the-counter analgesic agents as required.

OUTCOME MEASURES

Initially, our two primary outcomes were knee pain after exercise (during the preceding week)

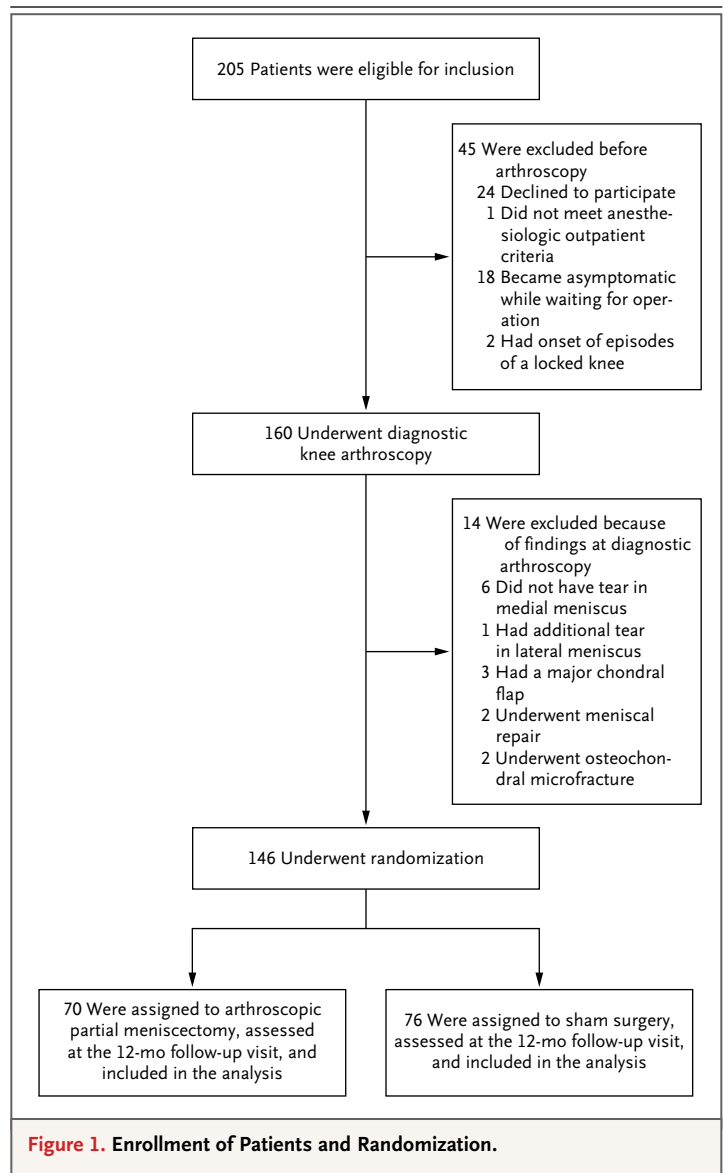


Figure 1. Enrollment of Patients and Randomization.

and the Lysholm knee score at 12 months after surgery. Knee pain was assessed on an 11-point scale ranging from 0 (no pain) to 10 (extreme pain). The Lysholm knee score is a validated,¹⁴ condition-specific outcome measure.¹⁵ After the Western Ontario Meniscal Evaluation Tool (WOMET),¹⁶ a meniscus-specific health-related quality-of-life instrument, was validated for patients with a degenerative meniscal tear,¹⁷ this measure was added as our third primary outcome (before any data analysis). The Lysholm and WOMET scores each range from 0 to 100, with 0 indicating the most severe symptoms and 100 an absence of symptoms. Secondary out-

comes included the score for knee pain after exercise and the Lysholm and WOMET score measured at 2 and 6 months after surgery; knee pain at rest, measured at 12 months; and the score on 15D, a generic health-related quality-of-life instrument made up of 15 dimensions and scored on a scale of 0 (death) to 1 (full health), also measured at 12 months.¹⁸

Questionnaires were administered at baseline and at 2, 6, and 12 months after surgery. The follow-up questionnaires included a separate section on adverse events, defined as untoward medical occurrences that may or may not have had a causal relationship with the treatment administered. Adverse events were classified as serious if they necessitated hospitalization or prolonged inpatient hospital care, or if they were life-threatening or resulted in death. For the 12-month follow-up questionnaire, the patients also responded to the following four questions: Is your knee better than before the intervention? Are you satisfied with your knee at present? Would you choose to be operated on again if you were asked to make the decision now? Which procedure do you think you underwent? Responses to the first two questions were given on a 5-point Likert scale; the response to the third question was “yes” or “no.”

STATISTICAL ANALYSIS

We powered the study to detect a minimal clinically important improvement in the Lysholm and WOMET scores (improvements of at least 11.5 and 15.5 points, respectively) and in the score for knee pain after exercise (improvement of at least 2.0 points) between the partial-meniscectomy and sham-surgery groups.⁹ The estimates of minimal clinically important improvement were based on the difference we noted in our prospective cohort of 377 patients with a degenerative meniscal injury who had undergone arthroscopic partial meniscectomy.⁹ For the study to have 80% power to show a clinically meaningful advantage of arthroscopic partial meniscectomy over sham surgery, under the assumption of a two-sided type 1 error rate of 5%, the required sample sizes were 40, 54, and 40 participants per group for the Lysholm score, the WOMET score, and the score for knee pain after exercise, respectively. Anticipating a loss to follow-up of at least 20%, we planned to recruit 70 patients per group.

The trial was designed to ascertain whether arthroscopic partial meniscectomy is superior to

sham surgery, at 12 months after the procedure, with regard to the three primary outcomes. Baseline characteristics were analyzed with the use of descriptive statistics. For the primary analysis, the change in each score (mean and 95% confidence interval) from baseline to 12 months was compared between the two study groups. This analysis was also performed after adjustment for the baseline score and for the stratifying variables used for randomization. Secondary analyses included between-group comparisons of the change in the 15D score and in the score for knee pain at rest, as well as comparisons of the frequencies of patients who reported satisfaction or subjective improvement, who had serious adverse events, or whose treatment assignment was revealed within 12 months after surgery (who required subsequent knee surgery). Analyses of the primary outcomes were also performed at 2 and 6 months, but these analyses were intended only to illustrate the trajectory of the treatment response.

Because knee osteoarthritis has been associated with poor outcomes after knee arthroscopy,¹⁹ our only prespecified subgroup analysis was performed with patients stratified according to the extent of radiographically assessed degenerative changes (Kellgren–Lawrence grade 0 [no degeneration] vs. grade 1 [minor degenerative changes]). A Student's t-test and nonparametric test were used to compare continuous variables (normally distributed and not normally distributed, respectively) between the groups, and Fisher's exact test was used with binomial and categorical variables. Univariate analysis was used to test for interaction in the subgroup analysis. All statistical analyses were performed on an intention-to-treat basis; no per-protocol analysis was performed, because the frequency of crossover was low. A P value of 0.05 was considered to indicate statistical significance. SPSS Statistics, version 20 (IBM), was used for all statistical analyses.

The writing committee developed and recorded two interpretations of the results on the basis of a blinded review of the primary outcome data (treatment A compared with treatment B), one assuming that treatment A was arthroscopic partial meniscectomy, and the other assuming that treatment A was sham surgery. Only after the committee members had agreed that there would be no further changes in the interpretation was the randomization code broken, the correct interpretation chosen, and the manuscript finalized (see the Supplementary Appendix).²⁰

RESULTS

CHARACTERISTICS OF THE PATIENTS

Of the 205 patients who were eligible for enrollment, 59 were excluded; Figure 1 shows the reasons for exclusion. A total of 146 patients underwent randomization; 70 were assigned to undergo arthroscopic partial meniscectomy, and 76 were assigned to undergo sham surgery. The baseline characteristics of the two groups were similar (Table 1, and Table S2 in the Supplementary Appendix). The patients who declined to participate were similar to those who underwent randomization with respect to age, sex, and body-mass index, and all underwent arthroscopic partial meniscectomy. There was no loss to follow-up.

PRIMARY OUTCOMES

Although marked improvement from baseline to 12 months was seen in the three primary outcomes in both study groups (Fig. 2 and Table 2), there were no significant between-group differences in the change from baseline to 12 months in any of these measures. The mean between-group difference in improvement in the Lysholm knee score was -1.6 points (95% confidence interval [CI], -7.2 to 4.0), that in the WOMET score was -2.5 points (95% CI, -9.2 to 4.1), and that in the score for knee pain after exercise was -0.1 points (95% CI, -0.9 to 0.7) (Table 2). These results did not materially change after adjustment for baseline scores and stratifying variables used for randomization (Table S3 in the Supplementary Appendix).

SECONDARY AND OTHER OUTCOMES

No significant between-group differences were found in any of the secondary outcomes, in the frequency of the need for subsequent knee surgery, or in the frequency of serious adverse events (Table 2, and Table S4 in the Supplementary Appendix). Also, in the prespecified subgroup analysis, no significant between-group differences were found in the primary outcomes at 12 months when the study groups were stratified according to the Kellgren–Lawrence grade, and there were no significant interactions by grade (Table S5 in the Supplementary Appendix). In an additional, post hoc subgroup analysis, we likewise found no significant benefit of arthroscopic partial meniscectomy over sham surgery among patients who reported a sudden onset of symptoms (Table S6 in the Supplementary Appendix).

Two patients in the partial-meniscectomy group

and five patients in the sham-surgery group reported persistent symptoms after surgery that were sufficiently severe to lead to revealing of the study-group assignment (at an average of 8 months after the index operation) and to consequent additional surgery. Of the two patients who underwent additional knee surgery after arthroscopic partial meniscectomy, one had a total knee replacement 10 months after the index procedure because of MRI-verified aseptic necrosis of the medial femoral condyle, and the other underwent a second resection of the meniscus 5 months after the index procedure because of a recurrence of symptoms.

Patients in the sham-surgery group were not significantly more likely than patients in the partial-meniscectomy group to guess that they had undergone a sham procedure (47% and 38%, respectively; $P=0.39$).

DISCUSSION

This multicenter, randomized, sham-controlled trial involving patients with a degenerative medial meniscus tear showed that arthroscopic partial meniscectomy was not superior to sham surgery, with regard to outcomes assessed during a 12-month follow-up period. Although both groups had significant improvement in all primary outcomes, the patients assigned to arthroscopic partial meniscectomy had no greater improvement than those assigned to sham surgery.

We are aware of one previous randomized, sham-controlled trial of arthroscopic treatment for degenerative knee disease.⁶ In patients with established knee osteoarthritis, arthroscopic lavage or débridement did not result in better outcomes than a sham procedure (skin incisions only). In a subsequent trial that did not involve a sham control, arthroscopic surgery coupled with optimized physical and medical therapy showed no significant benefit over optimized physical and medical therapy alone.⁷ In previous trials assessing the benefit of arthroscopic partial meniscectomy in the treatment of a degenerative meniscal tear in patients with varying degrees of knee osteoarthritis,^{8,21,22} arthroscopic surgery and exercise therapy were not superior to exercise therapy alone.

Whereas these earlier trials assessed whether arthroscopic surgery confers a benefit in ordinary health care settings (i.e., they were effectiveness trials involving patients with typical

Table 1. Baseline Characteristics of the Patients According to Study Group.*

Characteristic	Partial Meniscectomy (N=70)	Sham Surgery (N=76)
Age — yr	52±7	52±7
Male sex — no. (%)	42 (60)	47 (62)
Weight — kg	81±14	83±15
Height — cm	173±8	173±9
Body-mass index†	26.9±4.0	27.9±4.0
Duration of medial knee pain — mo		
Median	10	10
Range	3–50	3–47
Onset of symptoms — no. (%)		
Gradual	48 (69)	48 (63)
After exercise or hard work	12 (17)	14 (18)
Suddenly or after twisting	10 (14)	14 (18)
Kellgren–Lawrence grade — no. (%)‡		
0	35 (50)	36 (47)
1	35 (50)	40 (53)
Symptoms of catching or locking — no. (%)	32 (46)	37 (49)
Positive result of McMurray test — no. (%)§	16 (23)	15 (20)
Pain provoked by forced flexion, causing compression, at the medial tibiofemoral joint line — no. (%)	50 (71)	59 (78)
Pain provoked by palpation at the medial tibiofemoral joint line — no. (%)	63 (90)	74 (97)
Lysholm knee score¶	60.2±14.7	60.1±14.6
WOMET score	56.4±17.3	52.8±18.1
Score for knee pain**		
After exercise	5.8±2.0	6.1±2.0
At rest	4.1±2.3	4.4±2.4
15D score††	0.90±0.06	0.89±0.06

* Plus–minus values are means ±SD. There were no significant differences in the baseline characteristics between the two treatment groups.

† The body-mass index is the weight in kilograms divided by the square of the height in meters.

‡ The Kellgren–Lawrence scale is a radiographic classification of the severity of knee osteoarthritis. Grade 0 denotes no abnormalities, and grade 1 minor degenerative changes (doubtful narrowing of the joint space or possible osteophytic lipping).

§ Results of a McMurray test are positive if a “click” over the medial tibiofemoral joint line is felt by the examiner during flexion and extension of the knee under varus stress.

¶ The Lysholm knee score is based on an eight-item questionnaire designed to evaluate knee function and symptoms in activities of daily living. Scores range from 0 to 100; higher scores indicate less severe symptoms.

|| The Western Ontario Meniscal Evaluation Tool (WOMET) contains 16 items addressing three domains: 9 items addressing physical symptoms; 4 items addressing disabilities with regard to sports, recreation, work, and lifestyle; and 3 items addressing emotions. The score indicates the percentage of a normal score; therefore, 100 is the best possible score, and 0 is the worst possible score.

** Knee pain after exercise and at rest (during the preceding week) was assessed on a rating scale of 0 to 10, with 0 denoting no pain and 10 denoting extreme pain.

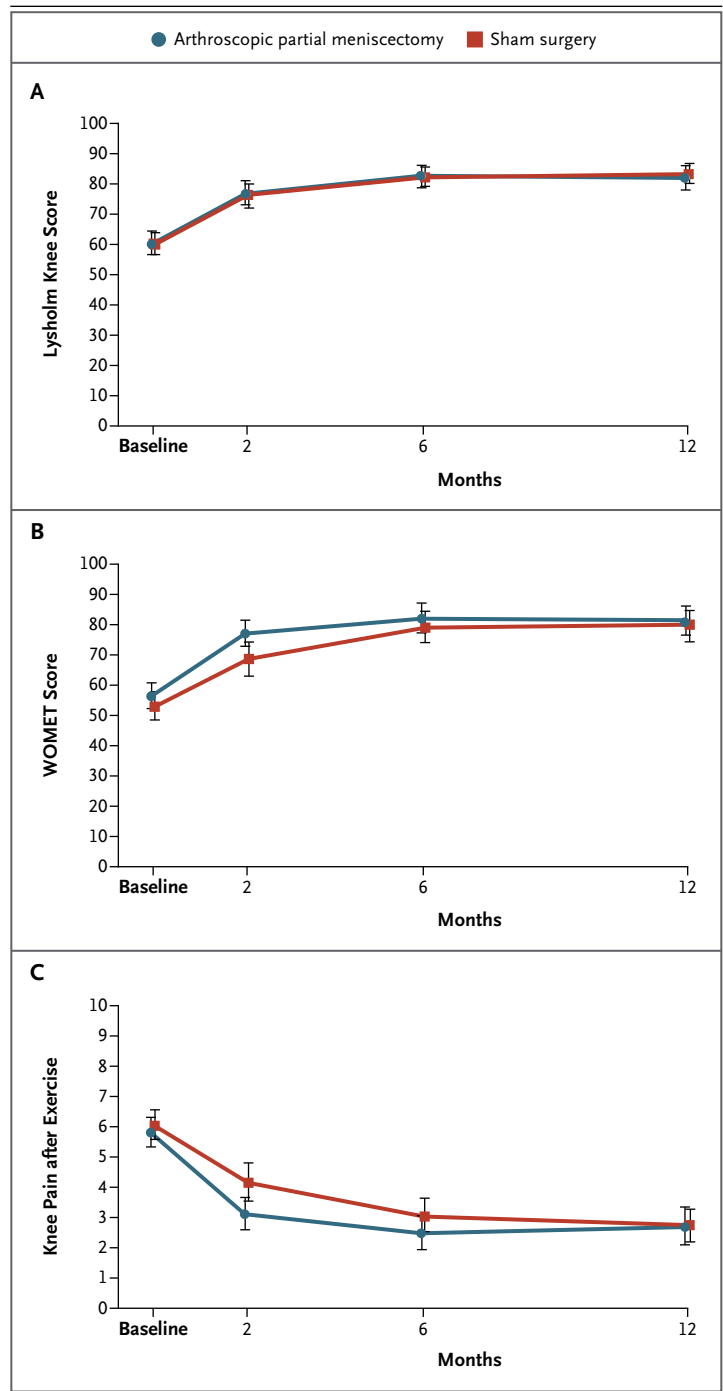
†† The 15D instrument is a generic health-related quality-of-life instrument comprising 15 dimensions. The maximum 15D score is 1 (full health), and the minimum score is 0 (death).

Figure 2. Primary Outcomes in the Partial-Meniscectomy Group and the Sham-Surgery Group.

Lysholm knee scores (Panel A), Western Ontario Meniscal Evaluation Tool (WOMET) scores (Panel B), and scores for knee pain after exercise (Panel C) over the 12-month follow-up period are shown. Lysholm knee scores and WOMET scores range from 0 to 100, with lower scores indicating more severe symptoms; scores for knee pain after exercise range from 0 to 10, with higher scores indicating more severe pain. I bars denote 95% confidence intervals. A single value was missing for one patient in the sham-surgery group at the 6-month follow-up and for one patient in the partial-meniscectomy group at the 12-month follow-up; these values were not imputed.

degenerative knee disease and varying degrees of knee osteoarthritis),^{6-8,21,22} we assessed whether arthroscopic partial meniscectomy is effective under “ideal” circumstances.^{9,23} Accordingly, we selected patients who would be expected to benefit from arthroscopic partial meniscectomy — those with a degenerative tear of the medial meniscus^{24,25} and no osteoarthritis¹⁹ — and the surgeons performing the operations were highly experienced. The use of a sham-surgery control, with study-group assignments concealed from patients as well as from those collecting data and analyzing outcomes, further increased the rigor of our trial. Because the act of performing surgery itself has a profound placebo effect,^{6,26,27} a true treatment effect is impossible to distinguish from nonspecific (placebo) effects without a sham comparison group.²⁸ Such bias is a particular concern in trials with subjective end points.²⁹ The proportion of patients who guessed that they had undergone a sham procedure was similar in the two groups, which indicates that the study-group assignments were concealed effectively and probably also contributed to the low treatment conversion rate (7% [5 of 76 patients]) in the sham-surgery group.

Some limitations of our trial warrant discussion. Our results are directly applicable only to patients with nontraumatic degenerative medial meniscus tears, because a traumatic onset of the condition was an exclusion criterion. However, results of a post hoc subgroup analysis limited to patients who had a sudden onset of symptoms likewise showed no significant benefit of arthroscopic partial meniscectomy over sham surgery, although the sample for this analysis was small. It is possible that some enrolled patients



had knee osteoarthritis that was not apparent with the use of the clinical¹⁰ and radiological¹¹ criteria we used for diagnosis, but our approach to diagnosing osteoarthritis was consistent with earlier controlled trials^{6,7} and with clinical practice. The observed 95% confidence intervals around

Table 2. Primary and Secondary Outcomes at 12 Months after Arthroscopy.*

Outcome	Partial Meniscectomy (N = 70)	Sham Surgery (N = 76)	Improvement from Baseline	Between-Group Difference, Partial Meniscectomy vs. Sham Surgery†
			Partial Meniscectomy	Sham Surgery
Primary outcome — mean (95% CI)				
Lysholm knee score	82.2 (78.4 to 85.9)	83.4 (80.3 to 86.5)	21.7 (17.6 to 25.8)	23.3 (19.5 to 27.2)
WOMET score	81.0 (76.1 to 85.9)	79.9 (75.1 to 84.7)	24.6 (19.7 to 29.4)	27.1 (22.4 to 31.8)
Score for knee pain after exercise	2.7 (2.1 to 3.3)	2.9 (2.3 to 3.4)	3.1 (2.5 to 3.8)	3.3 (2.8 to 3.8)
Secondary outcome — mean (95% CI)				
15D score	0.94 (0.92 to 0.95)	0.92 (0.90 to 0.93)	0.03 (0.02 to 0.04)	0.03 (0.01 to 0.04)
Score for knee pain at rest	1.6 (1.0 to 2.1)	1.9 (1.4 to 2.5)	2.5 (1.8 to 3.2)	2.5 (1.8 to 3.1)
Patients reporting satisfaction — no. (%)‡	54 (77.1)	53 (69.7)		
Patients reporting improvement — no. (%)§	62 (88.6)	63 (82.9)		
Patients willing to repeat the procedure — no. (%)¶	65 (92.9)	73 (96.1)		
Patients for whom study-group assignment was revealed — no. (%)	2 (2.9)	5 (6.6)		
Patients who underwent additional arthroscopy — no. (%)	1 (1.4)	4 (5.3)		
Patients who subsequently underwent high tibial osteotomy or total knee replacement — no. (%)	1 (1.4)	1 (1.3)		
Patients with a serious adverse event — no. (%)**	1 (1.4)	0		

* There were no significant differences between the groups in any of the outcomes.

† Values may not equal the differences in score between the study groups because of rounding.

‡ Patients' global assessment of satisfaction at 12 months after arthroscopy was elicited with the question, "How satisfied are you with your knee at present?" Responses were given on a 5-point Likert scale. "Very satisfied" and "Satisfied" were categorized as satisfied, and "Neither satisfied nor dissatisfied," "Dissatisfied," and "Very dissatisfied" were categorized as dissatisfied.

§ Patients' assessment of improvement was elicited with the standard Patient Global Impression of Change question, "How do you rate your knee now, 12 months after arthroscopy?" Responses were given on a 5-point Likert scale. "Much better" and "Better" were considered to indicate improvement, and "Unchanged," "Worse," and "Much worse" were considered to indicate no improvement.

¶ At the 12-month follow-up visit, the patients responded to a question eliciting whether, after having gone through the surgery and 12 months of follow-up, they would be willing to repeat the process if asked to make the decision again.

|| Study-group assignments were revealed when persistent symptoms resulted in any subsequent knee surgery.

** The only observed serious adverse reaction was a deep infection of the index knee 4 months after surgery and 1 week after a dental procedure, leading to joint irrigation.

the between-group differences indicate that a clinically significant benefit of arthroscopic partial meniscectomy was unlikely.

The patients enrolled in our trial reported medial-joint-line symptoms that are commonly attributed to a meniscal tear. Arthroscopic partial meniscectomy is typically advocated for patients with these symptoms in whom a tear is confirmed by MRI, particularly those without concomitant knee osteoarthritis.³⁰ However, increasing evidence suggests that a degenerative meniscal tear may be an early sign of knee osteoarthritis rather than a separate clinical problem requiring meniscal intervention.^{2,31-33} For example, one study showed no significant association between the presence of meniscal damage and the development of frequent knee pain in middle-aged and older adults, once the co-occurrence of osteoarthritis at baseline was taken into account.³⁴

Previous cohort studies have suggested that progression of osteoarthritis may be more rapid in persons who have undergone arthroscopic partial meniscectomy^{35,36}; it is uncertain

whether this is an effect of the surgery.³⁷ Long-term follow-up of patients in the present trial and in other trials^{8,38} is needed to address this question.

In conclusion, the results of this randomized, sham-controlled trial show that arthroscopic partial medial meniscectomy provides no significant benefit over sham surgery in patients with a degenerative meniscal tear and no knee osteoarthritis. These results argue against the current practice of performing arthroscopic partial meniscectomy in patients with a degenerative meniscal tear.

Supported by grants from the Sigrid Juselius Foundation, the Competitive Research Fund of Pirkanmaa Hospital District, and the Academy of Finland.

Disclosure forms provided by the authors are available with the full text of this article at NEJM.org.

We thank Heini Huhtala and Seppo Sarna for their help with the statistical analyses; Gordon Guyatt for his help with blinded data interpretation; research coordinator Pirjo Toivonen for her role in the implementation of the trial; research nurses Saara-Maija Hinkkanen, Marja-Liisa Sutinen, Pekka Karppi, Johanna Koivistoinen, and Sari Karesvuori for their assistance; Kari Tikkinen and Ghassan Alami for their critical comments on the manuscript; and Virginia Mattila for linguistic expertise and language revisions.

REFERENCES

- Cullen KA, Hall MJ, Golosinskiy A. Ambulatory surgery in the United States, 2006. *Natl Health Stat Rep* 2009;11:1-25.
- Englund M, Guermazi A, Gale D, et al. Incidental meniscal findings on knee MRI in middle-aged and elderly persons. *N Engl J Med* 2008;359:1108-15.
- Metcalfe MH, Barrett GR. Prospective evaluation of 1485 meniscal tear patterns in patients with stable knees. *Am J Sports Med* 2004;32:675-80.
- Kim S, Bosque J, Meehan JP, Jamali A, Marder R. Increase in outpatient knee arthroscopy in the United States: a comparison of National Surveys of Ambulatory Surgery, 1996 and 2006. *J Bone Joint Surg Am* 2011;93:994-1000.
- Holmes R, Moschetti W, Martin B, Tomek I, Finlayson S. Effect of evidence and changes in reimbursement on the rate of arthroscopy for osteoarthritis. *Am J Sports Med* 2013;41:1039-43.
- Moseley JB, O'Malley K, Petersen NJ, et al. A controlled trial of arthroscopic surgery for osteoarthritis of the knee. *N Engl J Med* 2002;347:81-8.
- Kirkley A, Birmingham TB, Litchfield RB, et al. A randomized trial of arthroscopic surgery for osteoarthritis of the knee. *N Engl J Med* 2008;359:1097-107. [Erratum, *N Engl J Med* 2009;361:2004.]
- Katz JN, Brophy RH, Chaisson CE, et al. Surgery versus physical therapy for a meniscal tear and osteoarthritis. *N Engl J Med* 2013;368:1675-84.
- Sihvonen R, Paavola M, Malmivaara A, Järvinen TL. Finnish Degenerative Meniscal Lesion Study (FIDELITY): a protocol for a randomised, placebo surgery controlled trial on the efficacy of arthroscopic partial meniscectomy for patients with degenerative meniscus injury with a novel 'RCT within-a-cohort' study design. *BMJ Open* 2013;3(3):e002510.
- Altman R, Asch E, Bloch D, et al. Development of criteria for the classification and reporting of osteoarthritis: classification of osteoarthritis of the knee. *Arthritis Rheum* 1986;29:1039-49.
- Kellgren JH, Lawrence JS. Radiological assessment of osteoarthrosis. *Ann Rheum Dis* 1957;16:494-502.
- Brittberg M, Winalski CS. Evaluation of cartilage injuries and repair. *J Bone Joint Surg Am* 2003;85-A:Suppl 2:58-69.
- Cooper DE, Arnoczky SP, Warren RF. Meniscal repair. *Clin Sports Med* 1991;10:529-48.
- Briggs KK, Kocher MS, Rodkey WG, Steadman JR. Reliability, validity, and responsiveness of the Lysholm knee score and Tegner activity scale for patients with meniscal injury of the knee. *J Bone Joint Surg Am* 2006;88:698-705.
- Tegner Y, Lysholm J. Rating systems in the evaluation of knee ligament injuries. *Clin Orthop Relat Res* 1985;198:43-9.
- Kirkley A, Griffin S, Whelan D. The development and validation of a quality of life-measurement tool for patients with meniscal pathology: the Western Ontario Meniscal Evaluation Tool (WOMET). *Clin J Sport Med* 2007;17:349-56.
- Sihvonen R, Järvelä T, Aho H, Järvinen TL. Validation of the Western Ontario Meniscal Evaluation Tool (WOMET) for patients with a degenerative meniscal tear: a meniscal pathology-specific quality-of-life index. *J Bone Joint Surg Am* 2012;94(10):e65.
- Sintonen H. The 15D instrument of health-related quality of life: properties and applications. *Ann Med* 2001;33:328-36.
- Fabricant PD, Rosenberger PH, Jokl P, Ickovics JR. Predictors of short-term recovery differ from those of long-term outcome after arthroscopic partial meniscectomy. *Arthroscopy* 2008;24:769-78.
- Järvinen TLN, Sihvonen R, Bhandari M, et al. Blinded interpretation of study results can feasibly and effectively diminish interpretation bias. *J Clin Epidemiol* (in press).
- Herrlin SV, Wange PO, Lapidus G, Hällander M, Werner S, Weidenhielm L. Is arthroscopic surgery beneficial in treating non-traumatic, degenerative medial

- meniscal tears? A five year follow-up. *Knee Surg Sports Traumatol Arthrosc* 2013;21:358-64.
22. Yim JH, Seon JK, Song EK, et al. A comparative study of meniscectomy and non-operative treatment for degenerative horizontal tears of the medial meniscus. *Am J Sports Med* 2013;41:1565-70.
23. Haynes B. Can it work? Does it work? Is it worth it? The testing of healthcare interventions is evolving. *BMJ* 1999;319:652-3.
24. Hede A, Larsen E, Sandberg H. Partial versus total meniscectomy: a prospective, randomised study with long-term follow-up. *J Bone Joint Surg Br* 1992;74:118-21.
25. Chatain F, Adeleine P, Chambat P, Neyret P. A comparative study of medial versus lateral arthroscopic partial meniscectomy on stable knees: 10-year minimum follow-up. *Arthroscopy* 2003;19:842-9.
26. Buchbinder R, Osborne RH, Ebeling PR, et al. A randomized trial of vertebroplasty for painful osteoporotic vertebral fractures. *N Engl J Med* 2009;361:557-68.
27. Kallmes DF, Comstock BA, Heagerty PJ, et al. A randomized trial of vertebroplasty for osteoporotic spinal fractures. *N Engl J Med* 2009;361:569-79. [Erratum, *N Engl J Med* 2012;366:970.]
28. Buchbinder R. Meniscectomy in patients with knee osteoarthritis and a meniscal tear? *N Engl J Med* 2013;368:1740-1.
29. Finnis DG, Kaptchuk TJ, Miller F, Benedetti F. Biological, clinical, and ethical advances of placebo effects. *Lancet* 2010;375:686-95.
30. Lyman S, Oh LS, Reinhardt KR, et al. Surgical decision making for arthroscopic partial meniscectomy in patients aged over 40 years. *Arthroscopy* 2012;28(4):492.e1-501.e1.
31. Bhattacharyya T, Gale D, Dewire P, et al. The clinical importance of meniscal tears demonstrated by magnetic resonance imaging in osteoarthritis of the knee. *J Bone Joint Surg Am* 2003;85-A:4-9.
32. Ding C, Martel-Pelletier J, Pelletier JP, et al. Meniscal tear as an osteoarthritis risk factor in a largely non-osteoarthritic cohort: a cross-sectional study. *J Rheumatol* 2007;34:776-84.
33. Englund M, Guermazi A, Roemer FW, et al. Meniscal tear in knees without surgery and the development of radiographic osteoarthritis among middle-aged and elderly persons: the Multicenter Osteoarthritis Study. *Arthritis Rheum* 2009;60:831-9.
34. Englund M, Niu J, Guermazi A, et al. Effect of meniscal damage on the development of frequent knee pain, aching, or stiffness. *Arthritis Rheum* 2007;56:4048-54.
35. Roos EM, Ostenberg A, Roos H, Ekdahl C, Lohmander LS. Long-term outcome of meniscectomy: symptoms, function, and performance tests in patients with or without radiographic osteoarthritis compared to matched controls. *Osteoarthritis Cartilage* 2001;9:316-24.
36. Englund M, Lohmander LS. Risk factors for symptomatic knee osteoarthritis fifteen to twenty-two years after meniscectomy. *Arthritis Rheum* 2004;50:2811-9.
37. Katz JN, Martin SD. Meniscus — friend or foe: epidemiologic observations and surgical implications. *Arthritis Rheum* 2009;60:633-5.
38. Hare KB, Lohmander LS, Christensen R, Roos EM. Arthroscopic partial meniscectomy in middle-aged patients with mild or no knee osteoarthritis: a protocol for a double-blind, randomized sham-controlled multi-centre trial. *BMC Musculoskelet Disord* 2013;14:71.

Copyright © 2013 Massachusetts Medical Society.

SPECIALTIES AND TOPICS AT NEJM.ORG

Specialty pages at the *Journal's* website (NEJM.org) feature articles in cardiology, endocrinology, genetics, infectious disease, nephrology, pediatrics, and many other medical specialties. These pages, along with collections of articles on clinical and nonclinical topics, offer links to interactive and multimedia content and feature recently published articles as well as material from the NEJM archive (1812–1989).