Paper 30: Superior Improvements in Knee Pain and Function with a Novel Synthetic Medial Meniscus Replacement Prosthesis Compared to Non-surgical Care in Subjects with Knee Pain Following Partial Meniscectomy: Three-year Results from Two Prospective US Clinical Trials

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Objectives: Results from 2 FDA-regulated clinical trials demonstrate superiority of a synthetic medial meniscus prosthesis to non-surgical care in treating persistent or recurrent knee pain following previous partial meniscectomy.

Arthroscopic partial meniscectomy (APM) is the most common surgical treatment for symptomatic, irreparable meniscal tears that do not improve with non-surgical care. For many patients, APM is associated with improvements in knee pain and function, but a subset of patients report persistent or recurrent knee pain 1-2 years after APM surgery. Current treatment options for post-APM knee pain are limited, especially for patients considered too young for knee replacement. The polymeric medial meniscus prosthesis (NUsurface®, Active Implants, Memphis TN) mimics the biomechanical function of the natural medial meniscus and provides relief from pain and improved function in subjects with knee pain following APM. The meniscus prosthesis met the primary endpoint of superiority over non-surgical care at 2 years. The current hypothesis was that investigational subjects maintained superior improvements in knee-related pain, function, and quality of life, compared to non-surgical subjects, through 3 years of follow-up.

Methods: 242 subjects (176 investigational, 66 control) treated in 2 prospective, concurrent clinical trials in the U.S., and pooled for analysis: a randomized controlled superiority trial (RCT) comparing the investigational device (investigational group) to non-surgical care (control), and a single-arm, prosthesis-only trial. Subjects had persistent knee pain and one or more previous partial meniscectomies at least 6 months before trial entry. Subject follow-up visits at 1.5 months, 6 months, 1, 2 and 3 year. Patient-reported knee pain, function, and quality of life were assessed using the Knee Injury and Osteoarthritis Outcome Score (KOOS). Treatment cessation was defined as any investigational subject who discontinued the per-protocol treatment by permanent prosthesis removal, or control subjects undergoing any surgical procedure on the index knee. Investigational subjects who underwent subsequent surgical procedures on index knees (e.g. prosthesis exchange) remained in the trial. The investigational and control cohorts analyzed were compared at each time point using a two tailed t-test. All baseline cohort comparisons of demographics were not statistically different ($p>0.05$).

Results: The magnitude of improvement from baseline to 3 years was statistically superior in the investigational cohort, compared to the control cohort for all 6 KOOS subscales (Figure 1), including the primary outcomes of KOOS Overall and KOOS Pain (Figure 1A, B). Improvement in KOOS Overall and KOOS Pain for the investigational and control cohorts at 3 years were 26.4 vs 10.4 points, and 26.9 vs 15.4 points, respectively (Figure 1). These data show a statistically significant improvement, exceeding a clinically meaningful improvement of ≥20 points versus controls as early as 6 months (20.0 vs 9.2 pts), continuing through the 3-year timepoint. Controls experienced a 35% decline in KOOS Overall improvement between the 2-year and 3-year

timepoint (15.9 vs 10.4). Accountability of patients not available or yet reaching the 3-year follow-up time period are reflected in Table 1. Treatment cessation through 3 years was 31% greater in the control cohort than the investigational cohort (15.0% vs. 19.6%).

Conclusions: Three-year results demonstrate statistically superior relief from post-APM knee pain and function compared to non-surgical care alone. At 3 years, the magnitude of change from baseline to 3 years significantly favored the investigational device compared to control treatments. Investigational subjects discontinued treatment at a far lower rate compared to control subjects. Investigational subjects who underwent a device exchange or repositioning procedure were able to continue therapy benefit with the medial meniscus prosthesis. In all KOOS subscales, the investigational subjects experienced superior improvements and outcomes at 3 years compared to non-surgical care subjects.

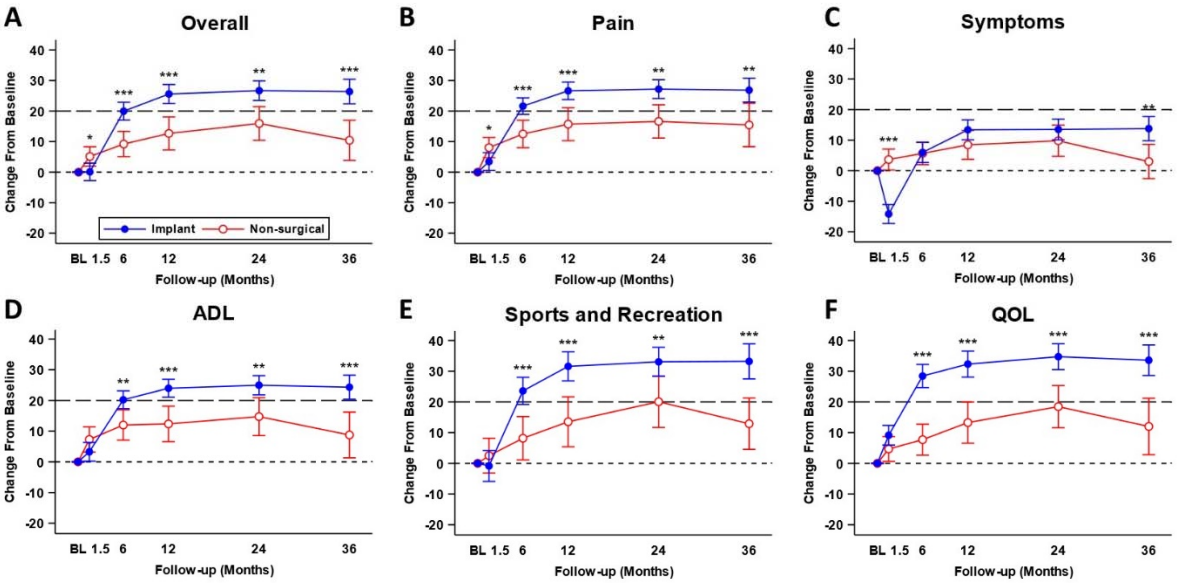

Figure 1. Magnitude of improvement in KOOS Overall (A), Pain (B), Symptoms (C), Activities of Daily Living (ADL; D), Sports and Recreation (E), and Quality of Life (QOL; F) from baseline (BL) to each follow-up time point.

Subjects	Investigational	Non-Surgical Control	TOTAL
Baseline	176	66	242
6 weeks	166 (94%)	62 (94%)	228 (94%)
6 months	167 (95%)	56 (85%)	223 (92%)
1 year	165 (94%)	46 (70%)	211 (87%)
2 year	153 (87%)	43 (65%)	196 (81%)
3 year	117 (67%)	25 (38%)	142 (59%)

Table 1 *Numbers are patients available to complete the KOOS questionnaire; Numbers in parentheses are percentages of the baseline population.*

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