Improved Pain and Function Scores After Implantable Shock Absorber in Post-Meniscectomy Subjects

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Disclosures

I (and/or my co-authors) have something to disclose.

All relevant financial relationships have been mitigated.

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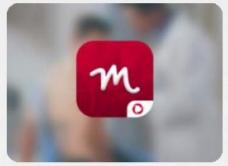

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The Clinical Problem

- 850k meniscectomies/yr in US[1, 2]
- Greater risk of developing OA post-meniscectomy[3, 4, 5]

Up to 25% of patients develop post-meniscectomy pain and OA, likely due to overloaded condition of knee[6, 7, 8]

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Potential Solution: A Revolutionary Solution for Mild-to-Moderate OA

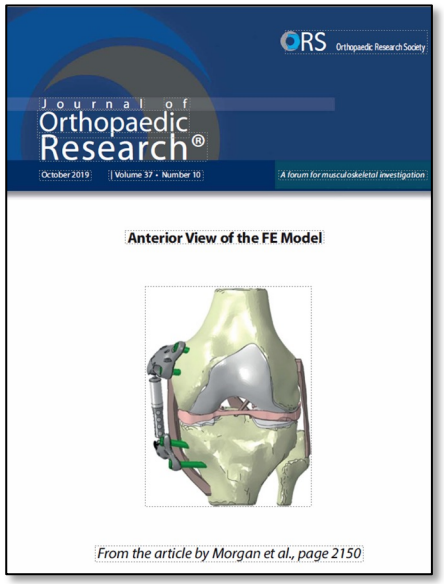
The World's 1st Implantable Shock Absorber

Breakthrough Technology

- Reduces load and pain
- Outside the knee joint
- Preserves the entire knee
- Minimally invasive

MISHA™
KNEE SYSTEM

Potential Solution: Reduces Peak Loads by 30%



Effects of a Medial Knee Unloading Implant on Tibiofemoral Joint Mechanics During Walking

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Received 1 November 2018; accepted 14 May 2019
Published online in Wiley Online Library (wileyonlinelibrary.com). DOI 10.1002/jor.24379

ABSTRACT: The Atlas™ unicompartmental knee system is a second-generation extra-articular unloading implant for patients with mild to moderate medial knee osteoarthritis. The technology acts to reduce a portion of the weight-bearing load exerted on the medial knee during physical activity thereby, reducing the mechanical stress imposed on a degenerative joint. The purpose of the present study was to evaluate the effects of the Atlas™ on tibiofemoral joint mechanics during walking. A computer-aided design assembly of the Atlas™ was virtually implanted on the medial aspect of a previously validated finite element tibiofemoral joint model. Data for knee joint forces and moments from an anthropometrically matched male were applied to the model to quasi-statically simulate the stance phase of gait. Predictions of tibiofemoral joint mechanics were computed pre- and post-virtual implantation of the Atlas™. Compressive force in the medial tibiofemoral compartment was reduced by a mean of 53%, resulting in the decrement of mean cartilage–cartilage and cartilage–meniscus von Mises stress by 31% and 32%, respectively. The Atlas™ was not predicted to transfer net loading to the lateral compartment. The tibiofemoral joint model exhibited less internal–external rotation and anterior–posterior translation post-Atlas™, indicating a change in the kinematic environment of the knee. From a biomechanical perspective, extra-articular joint unloading may serve as a treatment option for patients recalcitrant to conservative care. Evaluation of mechanical changes in the tibiofemoral joint demonstrate the potential treatment mechanism of the Atlas™, in accordance with the available clinical data. © 2019 Orthopaedic Research Society. Published by Wiley Periodicals, Inc. J Orthop Res 37:2149–2156, 2019

Keywords: knee; Atlas™ unicompartmental knee system; extra-articular joint unloading; finite element analysis

Study Objective

- Assess the pain and functional outcomes of ISA use at 24 months in OA subjects with a prior history of meniscectomy as compared to those with intact menisci

Materials and Methods

81 subjects prospectively enrolled

Eligible subjects were age 25-65 with medial knee OA refractory to non-surgical treatments

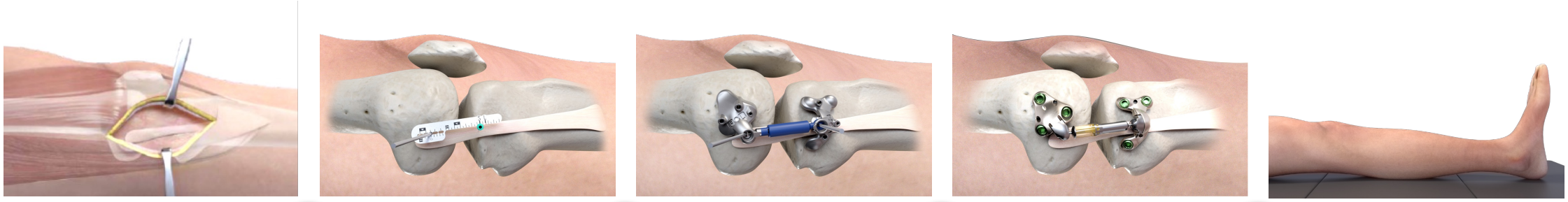
Knee pain ≥ 40 out of 100

Subjects' history of medial meniscectomy was noted

Post-hoc analysis, two groups, one with and one without previous medial meniscectomy, were formed

Surgical Technique

Aligns with Standard Orthopedic Practices



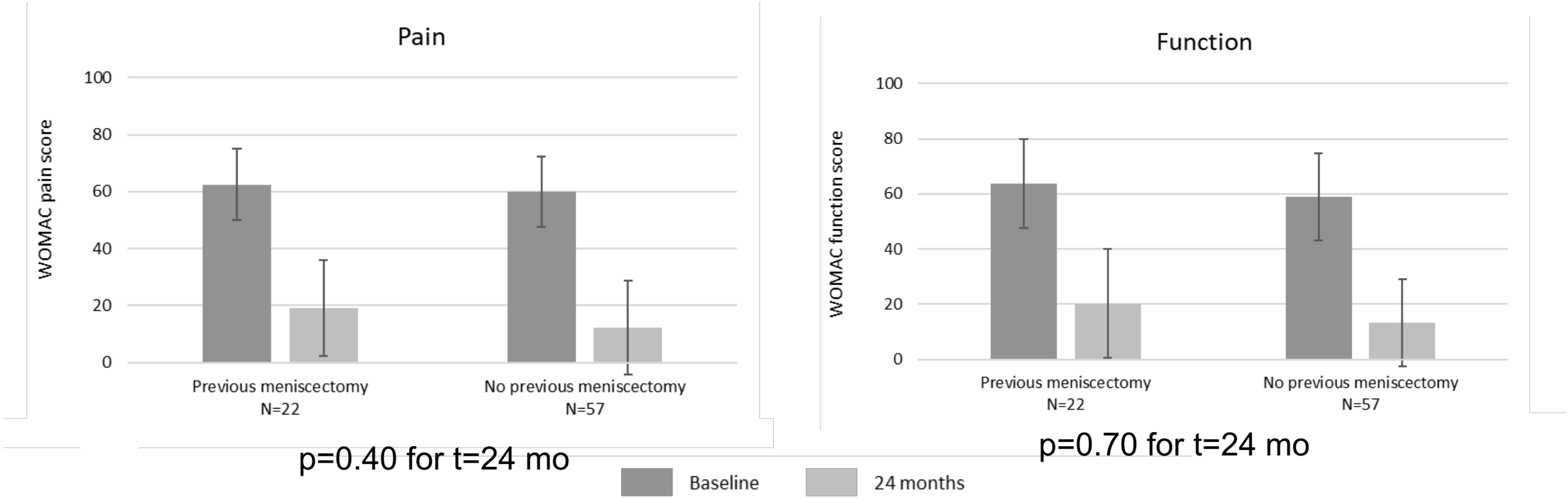
Expose › Target › Trial › Secure › Close

Repeatable, low risk procedure with consistent results

Results – Similar Demographics

	Subjects with medial meniscectomy		Subjects without medial meniscectomy		P value
	N, of 23 (%)	Mean (SD)	N, of 58 (%)	Mean (SD)	
Sex					
Female	5 (21.7%)		27 (46.6%)		
Male	18 (78.3%)		31 (53.4%)		0.0394
Age (years)		50.9 (± 8.2) range: 33 - 62		51.4 (± 7.6) range: 33 - 64	0.7972
BMI (kg/m^2)		28.9 (± 3.2) range: 21.4 -34.1		28.1 (± 3.5) range: 21.7 -34.7	0.3672
Medical history					
Duration of OA symptoms (months)		55.6 (± 49.0)		51.7 (± 56.7)	0.7732
KL Grade		2.6 (± 0.8) range: 1 - 4		2.4 (± 0.9) range: 1 - 4	0.4171
Knee alignment angle (degrees)		-4.3 (± 2.2) range: -9.3 – -0.6		-4.6 (± 2.6) range: -11.1 – 1.1	0.6280
Flexion contracture (degrees)		3.3 (± 1.53) range: 2.0 – 5.0		1.5 (± 0.71) range: 1.0 – 2.0	< 0.0001

Results – Patients With or Without Meniscectomy Reported Improvement



None of the subjects with meniscectomy subsequently underwent arthroplasty in the 24 months after ISA implantation. One subject in the non-meniscectomy group underwent a conversion to unicompartmental knee arthroplasty (UKA) due to progression of OA. The rate of study safety events were comparable between groups (p=0.21) with three subjects having discomfort, infection, kinesiophobia, and pain in the mensiectomy group and fifteen subjects having anesthesia complications, discomfort, infection, nerve injury, pain and scar formation in the non-meniscectomy group.

Conclusions

At 24 months follow-up, the ISA provided significant improvement on WOMAC pain and function for subjects with prior meniscectomy and knee OA that is comparable to the improvement for subjects without history of meniscectomy.

Subjects with meniscectomy no greater rate of adverse events than non-meniscectomy subjects.

Significance of the Findings

- The ISA represents an effective treatment with an attractive safety profile for subjects with symptomatic OA in post-meniscectomy knees.