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ADULT HUMAN MESENCHYMAL STEM CELLS DELIVERED VIA INTRA-ARTICULAR INJECTION TO THE KNEE FOLLOWING PARTIAL MEDIAL MENISCECTOMY http://dx.doi.org/10.2106/JBJS.M.00058

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Inclusion criteria Age of 18 to 60 years, inclusive

Indicated for partial medial meniscectomy

Normal axial alignment (presentation of standing alignment without gross varus or valgus deviation)

Stable knee; previous ligament reconstruction acceptable if stable

Intact articular cartilage in the posterior meniscal weight-bearing zone of the operative joint Meniscectomy in which at least 50% of the medial meniscus was excised. Excised portion must include at least half of the circumferential arc of the meniscus (e.g., the posterior half)

Willingness to follow postoperative rehabilitation

Willingness to participate in the study-required follow-up of 2 years post meniscectomy

Ability to understand and willingness to sign the consent form

Exclusion criteria Confirmed ACL or other support-structure damage during partial medial meniscectomy

Grade 3 or 4 articular cartilage damage in the medial compartment of the operative joint Hyaluronic acid or corticosteroid injections to the knee within the preceding 3 months

Diffuse synovitis at the time of arthroscopy

Inflammatory arthritis

Current use of oral steroid, such as methotrexate therapy

Pregnancy or lactation

Alcohol or substance abuse within 6 months of study entry

Active tobacco product use

Positive test result for human immunodeficiency virus (HIV)
Positive test result for hepatitis (history of hepatitis A allowed)

Indwelling pacemaker Cerebral aneurysm clips

Electrical indwelling device, such as bone stimulator Indwelling magnets as tissue expander for future implants

Ear, eye, or penile implant with avian components Known allergies to avian, bovine, or porcine protein

Any medical condition that, in the opinion of the clinical investigator, rendered the patient's

participation in the study unsuitable

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	Vehicle Control (N = 20)	Group A $50 \times 10^6$ hMSCs (N = 20)	Group B $150 \times 10^6$ hMSCs (N = 20)	Total (N = 60)
Participants* (no. [%])				
Randomized	20 (100)	20 (100)	20 (100)	60 (100)
Treated	19 (95)	18 (90)	18 (90)	55 (92)
Completed	19 (95)	17 (85)	18 (90)	54 (90)
Discontinued	3 (15)†	3 (15)‡	2 (10)§	8 (13)
Age (yr)				
Mean $\pm$ SD	$47.8 \pm 8.00$	$44.6 \pm 9.82$	$45.6 \pm 12.42$	46.0 ±10.16
Median	49.5	46.5	48.5	48.5
Min, max	24, 60	24, 57	18, 60	18, 60
Sex (no. [%])				
Male	13 (65)	11 (55)	14 (70)	38 (63)
Height (cm)				
Mean ± SD	$176.3 \pm 11.89$	$172.0 \pm 9.02$	$174.2 \pm 11.19$	$174.2 \pm 10.7$
Median	178.9	171.8	175.6	174.0
Min, max	153.2, 198.1	157.0, 185.4	152.4, 193.0	152.4, 198.1
Weight (kg)				
Mean ± SD	$84.1 \pm 17.29$	$88.0 \pm 21.42$	$89.0 \pm 22.61$	87.0 ± 20.33
Median	85.1	90.4	90.1	87.9
Min, max	49.5, 120.3	45.4, 128.0	51.3, 145.7	45.4, 145.7
BMI $(kg/m^2)$				
Mean ± SD	$26.89 \pm 4.049$	$29.86 \pm 7.943$	$29.09 \pm 5.909$	$28.61 \pm 6.201$
Median	26.72	27.53	28.36	27.51
Min, max	19.1, 34.7	18.0, 45.3	21.2, 45.5	18.0, 45.5
Prior ACL reconstruction on study knee (no. [%])	0	0	1 (5)	1 (2)
Prior surgery on study knee (no. [%])	0	1 (5)	2 (10)	3 (5)
Prior knee surgery on either knee (no. [%])	2 (10)	4 (20)	6 (30)	12 (20)

<sup>\*</sup>Treated = patients who were randomized and received the investigational agent (IA). Completed = patients who were randomized, received the IA, and underwent MRI through six months. †Discontinued due to withdrawal of consent; one patient moved. †Discontinued due to withdrawal of consent; one patient not treated due to physician decision (postoperative complication). §Discontinued; one patient due to withdrawal of consent, and one due to error.

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	Vehicle Control	Group A $50 \times 10^6$ hMSCs	Group B 150 $\times$ 10 $^6$ hMSCs
Overall			
No. of patients	19	17	18
6 wk	31.7	38.9	26.5
6 mo	33.6	39.4	35.3
1 yr	40.0	39.1	40.8
2 yr	38.7	48.4	40.0
Osteoarthritis			
No. of patients	7	11	12
6 wk	17.0	35.6	31.6
6 mo	22.3	35.4	39.9
1 yr	26.1	37.3	47.6
2 yr	19.4	46.7	43.5
More severe osteoarthritis			
No. of patients	4	4	5
6 wk	12.5	33.5	43.2
6 mo	13.3	30.5	37.0
1 yr	19.5	25.5	55.7
2 yr	18.3	47.5	52.4

<sup>\*</sup>Values presented as the mean. Knee pain assessed with use of a 100-mm VAS.