

Matrix-Induced Autologous Chondrocyte Implant vs. Microfracture: Prospective, Randomized Trial in European Patients, 2-Year Follow Up

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Summary:

Clinical results of the SUMMIT phase 3 trial demonstrate that matrix-induced autologous chondrocyte implant (MACI) provides clinically superior pain relief and functional improvement when compared with microfracture for the treatment of symptomatic articular cartilage defects of the knee.

Abstract:

Introduction:

The primary objective of the SUMMIT (Superiority of Matrix-induced autologous chondrocyte implant versus Microfracture for Treatment of symptomatic articular cartilage defects; NCT00719576) trial was to demonstrate superior pain relief and functional improvement with the matrix-induced autologous chondrocyte implant (MACI) compared with microfracture for treating symptomatic articular cartilage defects of the knee.

Method:

The SUMMIT phase 3 trial enrolled patients at 16 European sites in a prospective, randomized, controlled clinical trial. Patients were aged 18-55 years; had at least 1 symptomatic focal articular cartilage defect (Outerbridge grade III or IV; 3 or more cm²) of the femoral condyles and/or trochlea; and had a baseline moderate to severe Knee Injury and Osteoarthritis Outcome Score (KOOS) pain score of at least 55. Patients with osteoarthritis (Kellgren-Lawrence grade 3 or 4) were excluded. The co-primary efficacy endpoint was defined as the change from baseline to 2 years for the KOOS pain and function (sports and recreational activities) subscales. Clinical efficacy endpoints were evaluated at baseline and throughout the study at 6-month intervals up to 2 years. The remaining 3 KOOS subscales were recorded as secondary endpoints.

Results:

A total of 144 patients were enrolled and treated (72 per treatment arm); 95% (137/144) completed the full 2 years of the study. At baseline, patients had a mean age of 33.8 years and 51% were male; the mean lesion size was 4.8 cm². Mean changes from baseline to 2 years for KOOS pain and KOOS function subscales were 45.5 and 46.0, respectively, for patients treated with the MACI implant, while those treated with microfracture were 35.2 and 35.8. At 2 years, the MACI implant clinical outcome was significantly better than microfracture for the co-primary endpoints of the KOOS pain and KOOS function subscales ($P=0.001$). Significantly better scores for the KOOS subscales for function—activities of daily living ($P<0.001$), quality of life ($P=0.029$) and symptoms ($P<0.001$)—were also observed for patients treated with the MACI implant than with the microfracture procedure. Compared with the microfracture group at 2 years, the MACI group had significantly improved Modified Cincinnati scores ($P=0.002$), but had similar scores for the International Knee Documentation Committee Subjective Knee Form (IKDC) scores

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($P=0.069$). Treatment failure rates were lower than expected; 2 patients treated with microfracture were deemed treatment failures, while no patients treated with the MACI implant failed treatment. The incidence of adverse events was comparable between the treatment groups at 2 years and no unexpected safety findings were reported.

Discussion and Conclusion:

The SUMMIT clinical trial is the most comprehensive Good Clinical Practice-conducted, prospective, multicenter, randomized, controlled study of cell-based cartilage repair to date. Clinical results from this trial demonstrate that the MACI implant provides superior pain relief and functional improvement when compared with microfracture in the treatment of symptomatic articular cartilage defects of the knee based on significantly better outcomes for various patient-reported efficacy endpoints.