

Effects of Unloader Bracing in Clinical Outcome and Articular Cartilage Physiology Following Microfracture of Isolated Chondral Defects

Statistical Analysis Plan
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The primary endpoints were change in three MRI outcomes at 24 months: T2 relaxation times, repair region volume, and repair region thickness. Secondary endpoints included the KOOS sub-scores, the VR-12 score, the Lysholm score, and the Tegner score. For the primary and secondary endpoints, differences in the groups for T2 relaxation time, repair region volume, and repair region thickness and clinical outcomes were examined using multilevel, repeated measures linear regression models. A Bonferroni correction was used to adjust for multiple comparisons. The adjusted p-value was .008. We aimed to assess whether the data provided evidence of superiority of the off-loading brace in recovery after microfracture surgery.

Subgroup analyses examining correlations between questionnaire items and brace data were conducted with analyses limited to patients in the off-loading brace group. The number of days the brace was worn, the average number of minutes per day that the brace was worn, and the total number of minutes the brace was worn were calculated for patients in the off-loading brace group. Correlations were also examined between either the questionnaire items at each time point or the change from baseline to each time point in relationship to the total number of days the brace was worn or the total number of minutes the brace was worn over all days. Similarly, correlations were assessed between the MRI data at each time point and the change from baseline to each time point and the total amount of time the brace was worn. Data were analyzed using R and Rstudio (R Core Team, 2018; Rstudio Team, 2016). No interim analyses were performed.