Regenexx-SD Knee Candidacy Data

April 2014

Data Sources:

This document describes the impact of several demographic and medical factors on the knee outcomes after Regenexx treatment. The findings in this document are mainly based on the Regenexx-SD and Regenexx-AD data. Knee outcomes included four clinical scales: the Lower Extremity Functional Scale (LEFS), International Knee Documentation Committee (IKDC), Visual Analog Scale (VAS) and a Likert scale of percentage improvement. The range of clinical scales were 0-80 for LEFS, 0-100 for IKDC, 0-10 for VAS and -100 to 100 for the Likert scale of percentage improvement.

Findings:

- **Gender:**

  Female patients were more likely to report functional and symptomatic improvement on the lower extremity functional and VAS scales compared to the male patients.
  Improvement was defined as nine points increase on the LEFS and two points decrease on VAS scales scale. For female, the odds ratios were 3.4 for LEFS improvement and 2.6 for VAS improvement compared to the male control. This effect was noticed with the lower baseline functioning level (LEFS ≥45) and the higher baseline pain level (VAS ≥5). The effect was not evident in patients who presented with higher baseline LEFS level (LEFS between 46 to 70) or lower baseline VAS level (VAS less than 5). The retrospective study included osteoarthritis patients who were treated with Regenexx-SD and Regenexx-AD procedures. The analysis was adjusted for procedure type, age, BMI and disease severity.

- **Age:**

  In the current data, there is no correlation with age and knee outcomes.
  In retrospective analysis of Regenexx-SD and AD patients, age was divided into three groups: ≤50 years, 51-60 years and >60 years. Having the younger age (≤50 years) as a control group, the differences in outcomes were not statistically significant.

- **BMI:**

  In the current data, there is no correlation with BMI and knee outcomes.
  Higher BMI groups showed an increased likelihood of LEFS improvement in a subset of 111 patients but this finding was not replicable in other subsets.

- **Disease severity:**

  In the current data, there is no clear correlation with disease severity and knee outcomes.
  KL2 grades were more likely to report 50% improvement or higher compared to KL3-4 grade (odds ratio= 2.2). KL1 grade had odds ratio of 1.7 for reporting 50% improvement or higher but it was not statistically significant. Disease severity was not associated with LEFS and VAS outcomes.

- **Unilateral vs. Bilateral Procedures:**

  Pain improvement was more prominent in the unilateral procedures compared to the bilateral procedures.
  Based on a regression model that took into account age, BMI, gender, severity, the adjusted mean for post-treatment VAS was 2.6 for unilateral procedures compared to 3.2 for bilateral procedures. We did not observe the same effect on the LEFS and Likert scale of percentage improvement.

- **Number of joints involved:**

  Based on the baseline health questionnaire data, patients who had fewer number of joints involved reported greater functional and symptomatic improvement.

31 patients with less than three painful joints were compared to 16 patients who had three or more joints involved. The first group (<3 joints) reported 17 points increase on LEFS, 26 points increase on the IKDC, 2.4 points drop on VAS and average of 58% improvement on the Likert scale. These findings were compared to -0.6 change on LEFS, 4 points increase on IKDC, 0.4 drop on VAS and average of 19% improvement on the Likert scale for the second group (≥3 joints involved). This analysis was not adjusted for other factors.

- **Type of complaint and disease specifics:**

  Based on the baseline health questionnaire data, patients who presented with limping reported better response to treatment.
  This group of patients (N=20) reported averages of 20 point increase on LEFS and 28 points increase on IKDC respectively. The control group (N=19) reported 0.6 increase on LEFS and 9 points increase on IKDC.

- **Drugs and supplements:**

  Based on the baseline health questionnaire data, there were no obvious trends favoring specific drugs or supplements except for glucosamine and chondroitin which were associated with better outcomes.
  A group of 27 patients who received glucosamine, chondroitin, or both were compared to control group of 32 patients who did not receive these supplements. The glucosamine/chondroitin group reported means of 14 points increase on LEFS, 25 points increase on IKDC, 2.8 points decrease on VAS, and 64% improvement on the Likert scale. The control group reported means of 10 points increase on LEFS, 14 points increase on IKDC, 1.2 decreases on VAS and 34% improvement on the Likert scale. This analysis was not adjusted for age, BMI, gender, severity or treatment type.

- **Second Procedure:**

  Patients who received Regenexx-SD treatment for their knees and repeated the procedure within one year reported 16-20% increase on the Likert scale of percentage improvement.
  The most prominent increase was observed after repeating the procedure within 6-11 months after the first procedure. The mean of this group gained 16% improvement (out of 100 points) while the median gained 20 points (n=8). Lesser improvements were seen when the procedure was repeated between 2-5 months (n=13). When the entire group of patients who repeated within 1 year is considered (n=21), the mean

improvement was 50% to 59% (StdDev 25-28, range 8-100). The median improvement for all patients was from 50% to 65%.

Note:

The gender, age, BMI and disease severity findings are the results of retrospective clinical study that included 840 Regenexx-SD and Regenexx-AD patients. Patients were followed up for 1 to 36 months post-procedure. The health questionnaire data included 59 patients who completed the survey at the baseline and were followed up for 1 to 6 months. Seven of these were treated with Regenexx-C. This dataset was analyzed separately.