

The Regenerative Clinic Ltd.

18-22 Queen Anne Street
London, W1G 8HU
t: +44 (0)330 223 3332
f: +44 (0)330 223 3325 #
e: info@theregenerativeclinic.co.uk
www.theregenerativeclinic.co.uk

One Year Knee Outcome VAS and OKS Results of Patients treated with Lipogem® Treatment at The Regenerative Clinic UK.

Author: Mr. Nima Heidari; Consultant Foot, Ankle and Limb Reconstruction Surgeon MBBS, MSc, FRCS (Tr&Orth)

The Regenerative Clinic have used Lipogems® to treat knee arthritis for almost two years. Over this time, our clinic has successfully collected data on the patients that have been treated. Significantly, we now have one-year, post-procedure follow-up data for 42 patients that suffered from arthritis in their knee joint/s.

The Regenerative Clinic have an expert research team that measure patient responses to the Lipogems® treatment in two distinct ways: Using a Visual Analogue Scale (VAS) and the Oxford Knee Score (OKS). These are both validated ways of objectively measuring the outcomes of our treatments.

The VAS measures the level of the patient's pain between 0-100; 0 = no pain and 100 = max imaginable pain.

The OKS measures the functionality of the joint between 0-48; 0 = no function at all and 48 = best possible functionality

We measured these outcomes at various time points following the treatment. We start collecting data pre-procedure and continue to follow up with the patient at 3 months, 6 months, 12 months post-procedure.

The results of the VAS of 42 patients treated show that 35 patients (i.e. 83%) have responded to our treatment. This means that, by the 12-month mark after the procedure, their degree of pain is less than the pain that they had prior to the treatment. On average, patients come to us with a pain score of 75. This has improved to a score in the region between 20-30. This equates to an improvement of over 60%. It is important to note that there are individuals who have not responded to the Lipogems® treatment. Although they may have initially had a reduction in pain in the initial 3-6 months, this was not maintained at the 1-year mark. The reasons for this are not entirely clear and may be multifactorial, which is why we are still

continuously collect data from every patient that has the Lipogems® procedure.

In terms of the OKS results, we found a similar rate of response as the VAS results. 33 patients responded, which equates to 79%. 2 people did not complete the OKS scores, but these 2 were responders on the VAS data. We found that on average patients came to us with an OKS below 20 and by the 1-year mark this increased to approximately 35. These results are comparable with having a total knee replacement, but without any complication which are associated with surgery.

7 of the participants OKS scores remained constant throughout (i.e. their mean OKS remained between 20-25, where it started out from), thus no change in symptoms was witnessed in this group.

The deterioration that can be seen on the graph is presumably due to the natural progression of the arthritis disease and has no correlation to the Lipogem® treatment.

The severity of arthritis on x-ray's can be graded using the Kellgren-Lawrence system of radiological classification. We found that most patients that we have treated, presented with the most severe grading of arthritis on their x-ray's. The response witnessed in these patients has shown to be similar to those who have less severe forms of arthritis. It can be inferred from this information that the vast majority of patients have actually responded to the treatment. For example, in our grade IV group, which concerns the patients presenting with the most severe arthritis, we have treated 25 individuals. Of these, only 2 have not responded to Lipogems®.

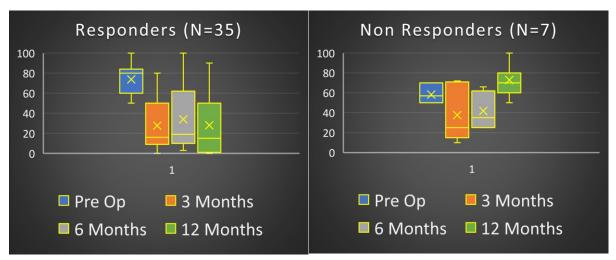
In conclusion, our results demonstrate that over 80% of patients have responded to their Lipogems® treatment for arthritic knees. This response has been dramatic and equivalent to those who opt for a total knee replacement. Significantly, the patients that opted for Lipogems® saw the same results without the complications and risks of having operative surgery

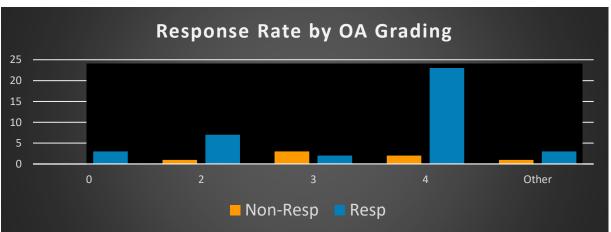


One Year Knee Score Outcome 42 knee treated; 80% Response rate

Comments: Responders show continued improvements according to OKS: consistent for up to One Year.

Visual Analog Score Graph 1.1





Oxford Knee Score

Graph 1.2

