

The Regenerative Clinic Ltd.

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Six month VAS and OHS Results of Patients treated with Lipogem® Treatment at The Regenerative Clinic UK

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At The Regenerative Clinic, we have treated 26 hip joints, which now are six months following Lipogem® treatment. The data gathered and analysed here is for this group. We have assessed patients' responses at 3 months and 6 months following their treatment. Our findings show that 17 out of 26 patients have had a dramatic response of up to 83% reduction in pain, while just 9 have not responded; this means that 66% of our hip patients have seen an improvement in their functional outcomes and in their pain scores. ¹

The methodology used to determine patient's pain levels is the Visual Analogue Scale (VAS).ⁱⁱ On average, patients come to us with a VAS pain levels of 52. Patients then fall into two groups; those that respond and those that do not respond. In those that respond we have found that, 6 months after treatment, their average pain scale falls to just 9 out of 100. This represents over 80% reduction in pain.

The 9 patients who did not respond had a mean VAS score of 47 prior to treatment, slightly less than the overall group average. The rather small number within this subgroup makes attaching significance to this difference with the response group difficult. After treatment, the non-responsive patients' average scores increased to 60 and have remained at this level for 6 months. It is likely that this is due to the natural progression of the

disease in these arthritic hips. Arthritis is a progressive condition with deterioration of symptoms over time.

Another method which we use to measure the functional outcome of our Lipogem® treatment is the Oxford Hip Score (OHS). iv This is a questionnaire which assesses how the arthritis of the hip is affecting the function of the patient, and to make judgements about the severity of their symptoms. The OHS places each patient on a scale from 0 (a poor OHS score) to 48 (an excellent OHS score). The average OHS of the patients we have treated is approximately 28. In the group that have responded to the Lipogem® injections, their OHS has improved from 28 to 43. This represents a return to an almost normal level of function for the majority of people. The group that has not responded, who had a functional score of 30 before treatment, have been reported to have maintained a very similar score (an avg. score of 37) six months later.

Our results show that the majority of patients treated with hip arthritis have seen positive responses, with a dramatic reduction in pain and a considerable improvement in functionality.^{vi}

In the non-response group of patients, there are group who have lost the ball and socket shape of the hip joint which dramatically reduces the likelihood of the biologics working. Whilst these patients were advised that the Lipogem® treatment would not be a suitable treatment considering the level of mechanical degradation, this was still their preferred option. Likewise, despite being advised against the procedure, two patients had a severe phobia of surgery and therefore would not consider any other type of intervention.



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The Regenerative Clinic Six Month Hip Score Outcome

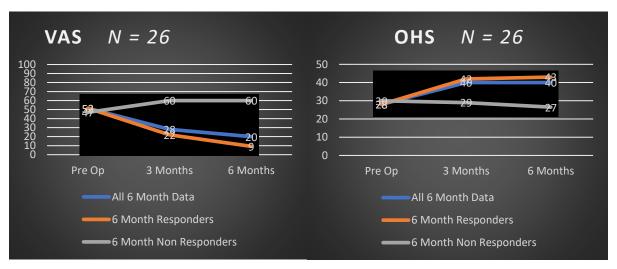
26 hips treated

66% Response rate

Comments: Responders show continued improvements according to OKS: consistent for up to 6 months

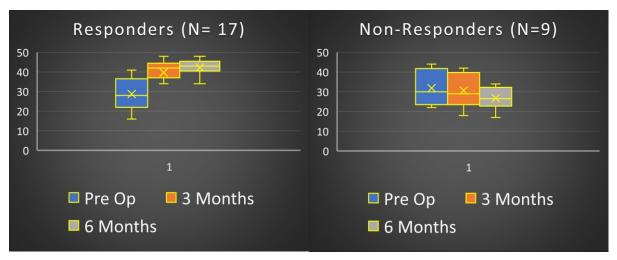
Visual Analog Score

Graph 1.1



Oxford Hip Score

Graph 1.2





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¹ See Graph 1.1 Above with 6 month Visual Analog Scale (VAS) accumulated May 2019 by R&D Copyright The Regenerative Clinic 2019.

ⁱⁱ See Graph 1.1 Above with 6 month Visual Analog Scale (VAS) accumulated May 2019 by R&D Copyright The Regenerative Clinic 2019.

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^{iv} See Graph 1.2 Above with 6 month Oxford Hip Score (OHS) accumulated May 2019 by R&D Copyright The Regenerative Clinic 2019.

^v See Graph 1.2 Above with 6 month Oxford Hip Score (OHS) accumulated May 2019 by R&D Copyright The Regenerative Clinic 2019.

vi See Graph 1.2 Above with 6 month Oxford Hip Score (OHS) accumulated May 2019 by R&D Copyright The Regenerative Clinic 2019.