Attrax Putty versus Autograft in eXtreme Lateral Interbody Fusion (XLIF): A Prospective Randomized Single-Center Evaluation of Radiographic, Safety, and Clinical Outcomes

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Introduction: Spinal fusion with autologous bone graft is a frequently performed surgical treatment to establish a bony fusion despite its limitations in the quantity available and complications associated with the harvesting procedure. These drawbacks of autografting have driven the development of numerous alternatives including synthetic ceramics. As demonstrated in pre-clinical studies, AttraX Putty is a synthetic bone material composed of tricalcium phosphate (TCP) granules that can be used to promote spinal fusions. The objective of this prospective, randomized, single-center study (conducted in Brazil) is to evaluate the clinical success of Attrax Putty as a bone graft substitute for autograft in eXtreme Lateral Interbody Fusion (XLIF) procedures. **Materials & Methods:** 45 adult subjects were consecutively enrolled and randomized into a single-level XLIF procedure using either Attrax Putty or iliac crest bone graft (ICBG) autograft (30 and 15 subjects, respectively). At the time of study completion, 29 (96.7%) and 14 (93.3%) subjects were available with 24-month follow-up data in the Attrax Putty and autograft groups, respectively. Radiographic outcomes were measured using the Lenke grade by a qualified, independent assessor. Additional clinical outcomes included patient reported back and worst leg pain scores, as well as disability scores (Oswestry disability index (ODI)). Patient complications (safety) were identified and reported throughout the course of the study. **Results:** Of the 45 subjects enrolled in this study, 23 (51.1%) subjects were female, and the mean age was 57 years. The majority of subjects had estimated blood loss <100 mL (86.7% and 80.0% in Attrax Putty and autograft groups, respectively; $p>0.05$). Mean total operative time was 76.6 minutes and 76.3 minutes and the mean length of hospital stay was 1.4 days and 1.6 days for Attrax Putty and autograft groups, respectively (all, $p>0.05$). Complications were observed for 9 (30.0%) subjects in Attrax Putty group and 8 (53.3%) subjects in autograft group ($p=0.128$). Of the 20 complications (17 subjects) reported in this study, 5 were XLIF procedure-related in Attrax Putty group and 6 in the autograft group. For the Attrax Putty group, mean ODI, mean back pain, and mean worst leg pain significantly improved at the 24-month follow-up by 97.0% (39.9 to 1.2), 78.1% (7.3 to 1.6), and 80.4% (5.1 to 1.0), respectively. For the autograft group, mean ODI, mean back pain, and mean worst leg pain significantly improved during the same time period by 77.2% (35.9 to 8.2), 75.4% (6.1 to 1.5), and 86.4% (6.6 to 0.9), respectively (all time points between groups, $p>0.05$). The fusion rates for both AttraX Putty and autograft groups at the 24-month follow-up were 96.4% and 100%, respectively. **Conclusion:** The results of this prospective, randomized study support the use of Attrax Putty as a standalone bone graft substitute for autograft in single-level XLIF surgery. The clinical performance and safety outcomes reported here are consistent with published evidence on

Attrax Putty. Improvements in patient-reported back pain, leg pain, and disability outcomes were comparable between the Attrax Putty and autograft groups.