

Real-World Experience and Patient Satisfaction with Local Osteo-Enhancement Procedure (LOEP): An Open Label Study in Patients with High Fracture Risk

Jo De Schepper, MD; Koen Bulterys; Jonathan Shaul, PhD

Purpose: Our objective was to evaluate the safety and patient satisfaction of the percutaneous local osteo-enhancement procedure (LOEP) using a resorbable calcium-based implant material (AGN1) in bone voids in the hips of patients with osteopenia or osteoporosis.

Methods: This was a retrospective, open-label, single-surgeon study of 43 adults with osteopenia or osteoporosis receiving AGN1 LOEP treatment of their proximal femurs (N = 50 hips). Informed consent was obtained from all participants. Evaluations consisted of medical record review, including radiographs, pain and functional assessments, and a participant experience questionnaire. All subjects met at least one criterion for high or very high fracture risk based on bone mineral density (BMD) T-scores, fracture history, and fracture risk assessment (FRAX®) scores.

Results: Postoperative dual-energy X-ray absorptiometry (DXA) scans performed on average 397 ± 216 days after LOEP indicated that mean femoral neck and total hip BMD increased 25% and 28%, respectively (Fig 1). Participants reported high satisfaction scores average 81.3 ± 25.3 (maximum = 100). In 25 of the 26 evaluable radiographs gathered during medical review, AGN1 resorption and regional bone formation were evident. 21 adverse events (AE) were recorded, eight of which were classified as serious adverse events (SAE). Eight adverse events related to the device or procedure were observed in a total of 43 participants (18.6%). These events were categorized as mild and related to wound complications (pain, bruising, seroma) or implant material leakage. Four of the eight events were device related and consisted of discomfort, localized pain, and material leakage.

Conclusion: This real-world study supports the safety and patient satisfaction of AGN1 LOEP for treating bone voids associated with osteopenia and osteoporosis in the hip.

