

## **Regenerating Bone Using Biomimetic Hematoma Delivering rhBMP-2: Preliminary Clinical Assessment of Safety and Efficacy**

*Vaida Glatt, PhD; Stephen M. Quinnan, MD; Kevin Tetsworth, MD, FIOTA*

**Purpose:** We sought to determine the clinical safety and efficacy of a Biomimetic Hematoma (BH), closely resembling the microarchitecture of naturally healing fracture hematoma while acting as a carrier to deliver low doses of human recombinant bone morphogenetic protein-2 (rhBMP-2) for treatment of complex bone injuries.

**Methods:** From August 2022 through January 2024, 43 treatments (in 29 patients) of nonunions and bone defects treated with BH delivering rhBMP-2 at 2 tertiary referral centers were studied. Demographic information, clinical factors, size of defect, indication for treatment, volume of BH used, intraoperative adverse reactions, local inflammatory reactions (cellulitis, drainage, or wound dehiscence), surgical site infection, and efficacy were evaluated.

**Results:** The mean age of these patients was  $52.1 \pm 20.5$  years. The distribution of Gustilo-Anderson type for these patients treated with BH included 40% closed injuries, 0% Type 1 (T1) open, 7% T2 open, 53% T3 open. Of the patients treated, 27% received treatment because of aseptic nonunion, 20% for sequelae from septic nonunion, 33% for a segmental defect, 13% for subsegmental defect, and 7% for other reasons. Anatomic sites treated included the humerus (33%), ulna (7%), femur (40%), and tibia (20%). The average volume of bone defect treated was 18.5 cc. The average volume of BH created intraoperatively was 39.0 cc. There were no intraoperative adverse reactions, and no postoperative local inflammatory reactions (cellulitis, wound dehiscence) or surgical site infections were identified. Radiographic images demonstrated healed bone after 1- year follow-up in all cases.

**Conclusion:** Preliminary data suggest the BH is currently the only clinically used carrier able to effectively deliver reduced doses of rhBMP-2 with high efficiency, rapidly and robustly initiating the bone repair cascade to successfully reconstruct complex bone injuries without side effects. The use of BH delivering rh-BMP2 in this series was not associated with intraoperative adverse reactions, postoperative local inflammatory reactions, or wound complications. While further studies with respect to its clinical efficacy are ongoing, this novel approach nevertheless has tremendous potential as a favorable treatment option for bone defects, open fractures, and recalcitrant nonunions.