

First Clinical Use of a Novel Plasma-Based Biomaterial to Augment the Healing of Open Tibia Fractures

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Purpose: This study was designed to examine the performance of a novel blood plasma-based bone putty for augmenting the treatment of open tibia fractures (Gustilo types II, IIIA, IIIB). The putty was manufactured from pooled blood plasma (Carmell Therapeutics, Pittsburgh, PA) and contains a concentration of both plasma and platelet-derived regenerative factors. Based on clinical reports of the use of autologous platelet-rich plasma (PRP) to treat injuries, we anticipated that the putty would accelerate the healing of both the bone fractures as well as surrounding soft tissues.

Methods: This was a two-arm, randomized controlled study including 20 treatment patients and 10 controls. Follow-up examinations, including radiographs and clinical assessments, occurred at 14, 30, 60, 90, 180, and 365 days. The product was provided in a delivery syringe containing 3 cm³ of putty contained in a double-pouched, sterile box that was stored at room temperature. The putty was placed at the site of the fracture during open fracture reduction and mechanical stabilization.

Results: Both treatment and control groups were well balanced with a mean age of 35 years. 79% were type IIIA and IIIB injuries, 67% were active smokers, and 70% received external fixation. No adverse events related to the use of the putty were noted. The use of the putty significantly reduced infections through the first 90 days ($P = 0.002$), accelerated bone bridging at 90 and 180 days, and provided more rapid wound closure at 30 days. In the subset of patients with IIIA/IIIB injuries, the putty group demonstrated more significantly reduced infections ($P = 0.0007$), with accelerated bone healing and wound closure approaching statistical significance. There were also statistically fewer adverse events with the putty (42.1%) compared to controls (80.0%).

Conclusion: The study was a challenging one to demonstrate efficacy given the small sample size, the majority of type IIIA/IIIB injuries, the use of external fixation known to have a relatively high incidence of pin tract infection, and the relatively high percentage of smokers. The putty performed as expected, promoting the more rapid healing of the bone fractures and wounds. The rather dramatic reduction in infections, however, was unanticipated and is most likely related to the recruitment of the innate immune system to the site of the injury over several weeks as these plasma-based materials degrade. A larger, statistically powered study is planned. The potential for using a concentration of natural plasma and platelet-derived regenerative factors to augment the healing of traumatic injuries, however, makes this first-in-human study particularly relevant and exciting.

- The FDA has not cleared this drug and/or medical device for the use described in this presentation (i.e., the drug or medical device is being discussed for an "off label" use). For full information, refer to page 600.