BonyPid™: Osteoconductive and antimicrobial outcome in patients with Gustilo III open fractures: Six months follow up results

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INTRODUCTION: Gustilo type III open fractures are associated with high infection rates in spite of instituting a standard of care (SOC) consisting of intravenous antibiotics, irrigation and debridement (I&D), and delayed wound closure. Locally-delivered antibiotic has been proven to assist in reducing infection in open fractures. The aims of this study are to determine the effectiveness and safety of BonyPid™, a new implantable and biodegradable antibacterial bone void filer in initiating bone growth and preventing bacterial infections in open fractures.

METHODS: The osteoconductive antibacterial BonyPid™ used is a synthetic bone void filler (comprised of ≤1 mm β-tricalcium phosphate granules) coated by a thin layer (≤20 µm) of PolyPid nanotechnology formulation. Upon implantation, the coating releases doxycycline at a constant rate for a predetermined period of 30 days. One BonyPid™ vial of 10 grams contains 65 mg of formulated doxycycline. After approval, sixteen subjects with Gustilo type III open tibia fractures, were implanted with the BonyPid™ immediately on the first surgical intervention (I&D), followed by external fixation and systemic antibiotic treatment. Patients had periodic laboratory, bacteriology and radiology follow-up of 6 months.

RESULTS: Immediate soft wound closure was done in 6 (38%) subjects following implantation. Out of 10 remaining subjects, 3 needed soleus muscle transfer-skin grafting and 7 required delayed primary closure; by skin grafting (5) or suturing (2). Early callus formation seen at 8-12 weeks post-surgery, followed by bone healing seen from 16 weeks onwards. No infections were developed at the target fracture site. . Only one BonyPid™ implantation was needed with no subsequent I&D in the target tibia fracture. Safety of implantation was remarkable, with only one deep infection at a fibular open fracture without BonyPid™ implantation. One BonyPid™ related adverse event caused delay in skin healing due to excessive granules in the superficial soft tissues.

Fig. 1: 49Y. Male, Gustilo IIIB, 1.5 Hrs. post injury

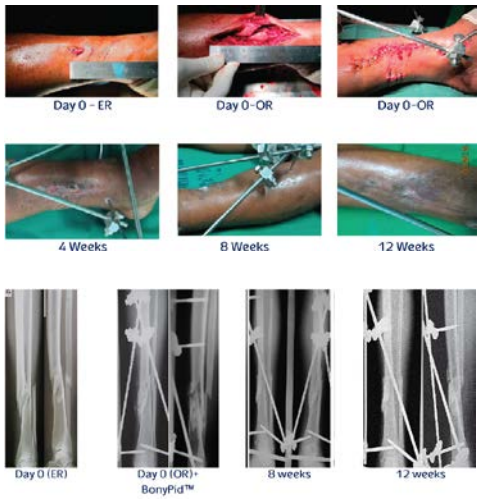
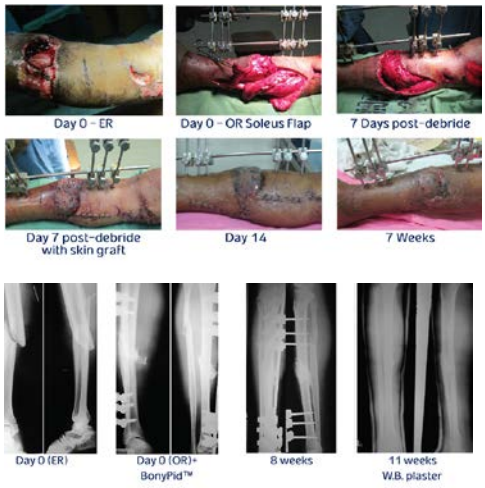


Fig. 2: 30Y. Male, Gustilo IIIB, 132 Hrs. post injury



DISCUSSION & CONCLUSIONS: BoniPid™ is a synthetic bone void filler coated with a new and unique nano-technology that delivered antibiotic, therefor can be applicable locally into contaminated bone voids.

BonyPid™ was found to be highly effective in promoting early callus formation, resulting in early bone healing of contaminated severe open-bone fractures. BonyPid™ is safe for immediate implantation into contaminated bone voids. Results support that BoniPid™ provides an effective way for treating open fractures.