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BonoFill – A Novel Treatment for Maxillofacial Bone Tissue Regeneration

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Over recent years, we have developed a three-dimensional, high-density bone graft designed to overcome the limitations associated with current bone reconstruction treatments. The graft, named BonoFill™, is generated from the patients' adipose tissue-derived cells, and consists of a heterogeneous cell population, providing superior osteinductive properties and promoting graft integration and *de novo* bone formation. Produced in Bonus Biogroup's GMP-certified clean room facility, BonoFill™ represents a potent therapeutic modality for bone repair.

A phase 1/2 open label first-in-human clinical study was performed to evaluate the safety and efficacy of BonoFill™ as a bone graft for reconstructing maxillofacial bone tissue in two clinical indications:

- Bone augmentation
- Bone grafting

Eleven eligible male and female subjects aged 49-65 years were enrolled and underwent the BonoFill™ treatment. Clinical follow-up was performed throughout a period of 20-27 months and included X-rays, CT scans and biopsies collected from the transplantation site. The study was conducted in MY Medical Center, Israel, under regulatory approval and in compliance with the ICH-GCP guidelines.

Results of the study demonstrate that BonoFill™ promoted fast and high quality bone tissue regeneration without complications. There was no chronic bone infection (Osteomyelitis), no significant changes in complete blood count (CBC) and in the subject's general health.

The newly-generated bone was of high density and provided stable support for dental implants. To conclude, BonoFill™ is a promising novel solution for bone repair, which will be further studied in additional clinical settings.

Biography

Ephraim Tzur is a senior periodontal surgeon specializing in implant surgery and cranio-maxillofacial rehabilitation and is the former Director of the Oral & Maxillofacial Surgery Unit at Assaf Harofeh Medical Center, Israel. He earned his medical degree from Hadassah University School and is board certified by the Israeli Board of Dental Surgeons. Dr. Tzur is a member of the Israeli and American Oral and Maxillofacial Surgeons. He has over 30 years of experience in all aspects of reconstruction and rehabilitation of hard and soft tissue defects of the oral cavity, jaws and facial structures. He is actively involved in dent-alveolar surgery, orthogenetic surgery for the treatment of congenital and developmental deformities, reconstruction of disease and trauma-induced defects and in dental implantology for the regeneration and restoration of the jawbones.

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