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**Preliminary In Vivo Investigation of the Biodegradability of a Novel Elastomer Material for Bone Regeneration**

A novel elastomer material (poly-glycerol sebate, PGS) so-called "Biorubber" is being tested in a bony environment. The **purpose** of this pilot study is to assess the biodegradability and the bone formation of the novel polymer material using microcomputed tomography (micro-CT) imaging analysis, histological analysis and histomorphometric analysis. The **specific hypothesis** of this investigation was that this novel elastomer material (poly-glycerol sebate, PGS) when placed in a bony defect will poses biodegradable properties that will lead to bone formation.

**Materials & methods:** 32 female Sprague-Dawley rats were anesthetized with an intramuscular injection combination of Ketamine hydrochloride (Ketalar) and Xylazin chloride (Rompun). Two symmetrical, circular full thickness non-critical size (Non-CSD) bone defects (bilateral craniotomy defects) were surgically created in the parietal bones. The first defect was filled with PGS supplied in 2 different porosities (50% and 60%) creating thus 2 test groups. The second defect was left empty and was used as a control. The test and control groups were randomly allocated in regards to the filling material.

At set times of post implantation the cranial bones were harvested to assess the biodegradability and biocompatibility of the PGS. Four rats from each of the 2 test groups were sacrificed at 1 (total n=8), 2 (n=8), 3 (n=8), and 4 (n=8) weeks for sample harvesting. A Micro-CT scan analysis was performed to three dimensionally analyze the healing of the bone defects. To further assess the biodegradability and the normal bone formation a histological and histomorphometric analysis is being performed.

**Results:** We anticipate the biocompatibility and biodegradability capabilities of PGS (Biorubber) as preliminary data.

**Conclusion:** An elastomer material (Biorubber) that would demonstrate biodegradable and biocompatible properties could improve Guided Bone Regeneration by acting as:

• A porous scaffold which could be three-dimensionally pre-shaped according to the recipient's site
• Carrier of specific cells and molecules (precursors, growth factors, etc)
• Biodegradable barrier membrane
• Osteoconductive material

**Key Words**: Tissue Engineering, Bone regeneration, poly-glycerol sebate - PGS, Biorubber, biodegradable, bony environment,non critical defect.