

Multicenter Study on the Use of Biosorb Osteofixation Devices in 165 Cranial and Maxillofacial Cases: A Multicenter Report

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Bioabsorbable osteofixation devices were developed to avoid problems associated with metals. Bioabsorbable devices are mostly made of the polymers polylactide (PLA), polyglycolide (PGA) and their copolymers (PLGA and P(L/DL)LA). Using the technique of self-reinforcement of bioabsorbable materials, it is possible to manufacture osteofixation devices with ultra high strength. Self-reinforced (SR) polyglycolide-co-polylactide (SR-PLGA) 80/20 was selected to make devices (Biosorb™ PDX) for this study because of its favorable degradation characteristics. The aim of this study was to evaluate the efficacy of using SR-PLGA (Biosorb™) plates and screws in the fixation of osteotomies in craniomaxillofacial (CMF) surgery. In a prospective study, 165 patients (161 children and 4 adults) were operated on in four EU centers (Paris, Innsbruck, London and Oulu) from May 1st, 1998 to January 31st, 2002. Indications included correction of dyssynostotic deformities (n=159), reconstruction of bone defects following trauma (n=2), tumor removal (n=2), and treatment of encephalocele (n=2). Plates used were 0.8, 1 or 1.2 mm thick and screws had an outer (thread) diameter of 1.5 or 2 mm and a length of 4, 6 or 8 mm. Tacks had an outer diameter of 1.5 or 2 mm and a length of 4 or 6 mm. Intraoperatively the devices were easy to handle and apply and provided stable fixation apart from two cases. Postoperative complications occurred in 12 cases (7.3%), comprising infection (n=6), bone resorption (n=4), diabetes insipidus (n=1), delayed skin wound healing/skin slough (n=2), and liquorrhea (n=1). Accordingly, SR-PLGA 80/20 (Biosorb) plates and screws can be used safely and with favorable outcome in corrective cranioplasties, especially in infants and young children.

Keywords

Bioabsorbable, biosorb, bone, fixation, polylactide, polyglycolide, self-reinforced

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