Journal of Cranio-Maxillo-Facial Surgery xxx (2018) 1–6

Contents lists available at ScienceDirect

Journal of Cranio-Maxillo-Facial Surgery

journal homepage: www.jcmfs.com

Enhanced radiographic visualization of resorbable foils for orbital floor reconstruction: A proof of principle

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ARTICLE INFO

Article history:
Paper received 27 February 2018
Accepted 24 May 2018
Available online xxx

Keywords:
Orbital floor fracture
Reconstruction
Resorbable foil
Radiopaque

ABSTRACT

Purpose: Despite the advantages and broad applications of alloplastic resorbable implants, postoperative radiological control is challenging due to its radiolucency. The aim of the present study was to evaluate the radiographic visibility of newly developed materials for orbital floor reconstruction.

Materials and Methods: The radiographic visibility of four different material combinations consisting of poly-(L-lactic acid)/poly-glycolic acid (PLLA/PGA) or poly(D,L-lactic acid) (PDLLA) enriched with magnesium (Mg), hydroxyapatite (HA) or β-tricalcium phosphate (β-TCP) with various layers of thicknesses (0.3, 0.6, and 1 mm), surgically placed above the orbital floor of a human head specimen, was evaluated using computed tomography (CT) and cone beam computed tomography (CBCT). The visibility was rated on a scale of 0–10 in CT/CBCT and by Hounsfield Units in CT for each subject.

Results: All of the materials were clearly detectable in CT scans. Visibility was significantly higher ($p < 0.001$) in the standard soft tissue window (mean score: 7.3, ranging from 2 to 10) in comparison to the standard bone window (mean score: 5.2, ranging from 1 to 10). In CBCT (mean score: 3.3, ranging from 0 to 7), there was significantly lower but still sufficient visibility of the materials compared to the CT soft tissue window ($p < 0.001$) and CT bone window ($p < 0.001$). Comparing the different materials' visibility among the group of same layer thicknesses with each other, in the majority of cases, PDLLA enriched with β-TCP appeared to be most visible in both CT and CBCT.

Conclusion: The incorporation of radiopaque elements to PLLA/PGA and PDLLA polymers is a promising strategy to improve their visibility in CT and CBCT. Our data suggest that the reconstruction of the orbital floor with these new materials could provide an advantageous postoperative radiographic control.

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1. Introduction

Orbital floor fractures are commonly seen in patients with midface trauma (Salentijn et al., 2013). Typical symptoms include enophthalmos, diplopia, hypoesthesia of the second trigeminal branch, and limitations of ocular motility (Bartoli et al., 2015). Although the exact surgical indications and timing remain controversial (Chen and Chen, 2010; Dubois et al., 2015), certain clinical and radiological findings require (immediate) orbital reconstruction. Therefore, a multitude of different materials exist including autologous bone grafts, (patient specific) titan implants, and (resorbable) alloplastic materials, each with distinct advantages and disadvantages.

The ideal implant material must meet a variety of requirements: biocompatible, non-carcinogenic, non-allergenic, radiopaque, and strong enough to sufficiently support the orbital contents. If alloplastic, it should be cost-effective and capable of sterilization. Resorbable implants should completely resorb without a formation of harmful degradation products. The implant should be available in large quantities, and cutting, adjusting and fixing it to the orbital floor should not be complicated (Potter et al., 2012). Until today,

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https://doi.org/10.1016/j.jcms.2018.05.045
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Please cite this article in press as: Doll C, et al., Enhanced radiographic visualization of resorbable foils for orbital floor reconstruction: A proof of principle, Journal of Cranio-Maxillo-Facial Surgery (2018), https://doi.org/10.1016/j.jcms.2018.05.045

none of the available materials has met all these criteria simultaneously; hence, there is no general guideline as to which of these materials should be used for orbital reconstruction (Baino, 2011). Although autografts have been traditionally considered the "gold standard," they give rise to various problems and difficulties, including the limited availability, the need for extra surgery, and, therefore, a higher risk of donor site morbidity (Baino, 2011). Patient-specific implants based on titanium or ceramic to precisely restore the orbital anatomy are becoming increasingly popular. Although initial studies are promising (Boyette et al., 2015), long-term results are still lacking. There are several disadvantages: the fabrication is time consuming (at least 5–7 days) and comparably expensive. Since it is a foreign body, there is a risk of infection, even years after insertion, as observed, e.g., in patient-specific titanium cranioplasties (Williams et al., 2015). In case of secondary trauma, there might be a higher risk of injury due to the rigid foreign body.

Many surgeons are using resorbable alloplastic materials such as Ethisorb™ (Ethicon, Norderstedt, Germany) patches or PDS™ (Ethicon, Norderstedt, Germany) foils for the orbital floor reconstruction, especially in smaller defects (Jank et al., 2003; Blake et al., 2011; Gerressen et al., 2012; Beck-Broichsitter et al., 2015). Resorbable synthetic materials, in contrast to autografts, exhibit unlimited availability and provide more control over absorption kinetics. Both Ethisorb™ patches and PDS™ foils are easily tailored and adapted to the anatomical details during the operation. Despite these advantages, postoperative radiological evaluation of the surgical outcome is difficult due to radiolucency. To overcome these limitations, new resorbable plates enriched with radiopaque substances have been developed in cooperation with the KLS Martin Group (Tuttlingen, Germany). The polymer matrix of these new foils consist of one of the following materials: poly(D,L-lactic acid) (PDLLA) or a combination of poly-(L-lactic acid) (PLLA) and polyglycolic acid (PGA). Several studies have demonstrated the suitability of PLLA/PGA and PDLLA (alone or combined to P(L/DL)LA) for orbital floor repair (Enislidis et al., 1997; Hollier et al., 2001; Persons and Wong, 2002; Al-Sukhun et al., 2006; Lieger et al., 2010; Lin et al., 2014; Tabakovic et al., 2015; Young et al., 2017). The substances used to enrich these foils include magnesium (Mg), hydroxyapatite (HA), and β-tricalcium phosphate (β-TCP).

The aim of the present study was to evaluate the radiographic visibility of these new materials being surgically inserted above the orbital floor of a human head specimen on computed tomography (CT) and cone beam computed tomography (CBCT).

2. Materials and Methods

2.1. Materials

In this study, the radiographic visibility of four different material combinations (PLLA/PGA or PDLLA enriched with Mg, HA, or β-TCP) with various layer thicknesses (0.3, 0.6, and 1 mm) was evaluated (Table 1). These materials were developed in close collaboration with the KLS Martin Group (Tuttlingen, Germany).

Table 1
Study objects with material composition.

Study object	Material composition	Thickness (mm)
1	PLLA/PGA; 85:15 + ≈ 10% Mg	1.0
2	PDLLA (PLLA:PDLA; 50:50) + ≈ 10% Mg	0.3, 0.6, 1.0
3	PDLLA (PLLA:PDLA; 50:50) + ≈ 18% HA	0.3, 0.6, 1.0
4	PDLLA (PLLA:PDLA; 50:50) + ≈ 20% β-TCP	0.3, 0.6, 1.0

PDLLA: poly(D,L-lactic acid); PLLA: poly-(L-lactic acid); PGA: poly-glycolic acid; Mg: magnesium; HA: hydroxyapatite; β-TCP: β-tricalcium phosphate.

The polymer matrix was composed of either PDLLA or PLLA/PGA. Several studies have demonstrated the suitability of PLLA/PGA implants for orbital floor repair (Enislidis et al., 1997; Hollier et al., 2001; Persons and Wong, 2002; Lin et al., 2014). Also for PDLLA, used either alone (Tabakovic et al., 2015) or within poly-L/DL-lactide (P(L/DL)LA) (Al-Sukhun et al., 2006; Lieger et al., 2010; Young et al., 2017), there are promising results for orbital floor reconstruction. The radiopaque substances, which were used for enriching the alloplastic resorbable plates, were HA, Mg and β-TCP (Biovision, Germany).

The newly developed foils examined in this study are moldable by warming in hot water. Fig. 1 displays the adaptability of study object no. 4 (40 × 30 mm) well. Once heated up to a temperature of approximately 65 °C–75 °C, an individual shape according to the defect and the orbital anatomy can be formed giving the typical s-form (Fig. 1). After cooling down (approx. 10-second window), the plates remain (dimensionally) stable regaining their original stability and rigidity.

Titanium mesh (0.3 mm; M-4432; Medartis, Basel, Switzerland) was used as the positive control; PDS™ (0.15 mm; ZX7; Ethicon, Norderstedt, Germany) and Ethisorb™ patch (0.6 mm; ZVP203; Ethicon, Norderstedt, Germany) were used as negative controls. All of these materials/products are widely used for orbital floor reconstruction (Jank et al., 2003; Baino, 2011; Blake et al., 2011; Gerressen et al., 2012; Beck-Broichsitter et al., 2015).

Radiographic visibility was evaluated by using a human head specimen, which was obtained by the Center for Anatomy, Charité – Universitätsmedizin Berlin. Meeting the requirements of a double-blind study, the tested substances and the material compositions were not known to either the team who performed the experimental procedure or the evaluators who analyzed the radiographic footage.

a

b

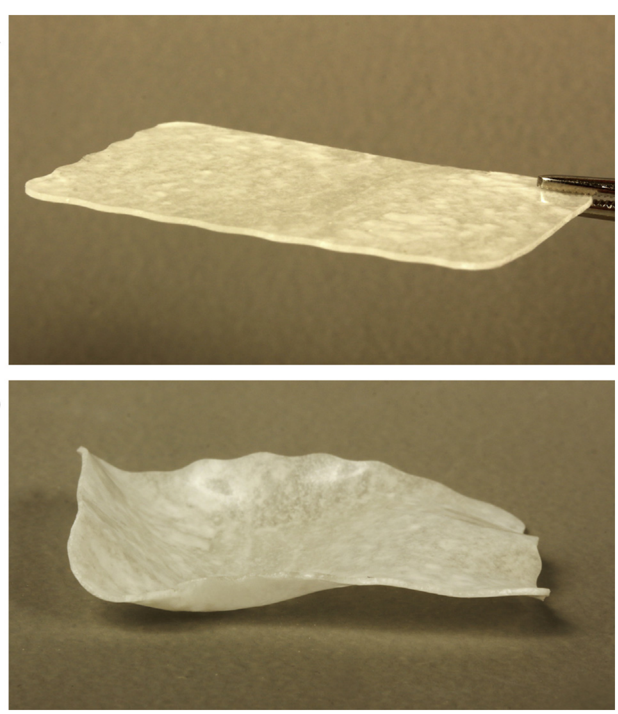

Fig. 1. Picture of study object no. 4 (0.6 mm) in a plane condition (A) and the typical S-shape of the orbital floor (B).

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