Journal of Cranio-Maxillo-Facial Surgery 42 (2014) 930–942

Contents lists available at ScienceDirect

Journal of Cranio-Maxillo-Facial Surgery

journal homepage: www.jcmfs.com

Segmental stability in orthognathic surgery: Hydroxyapatite/Poly-L-lactide osteoconductive composite versus titanium miniplate osteosyntheses

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ARTICLE INFO

Article history:
Paper received 13 May 2013
Accepted 3 January 2014

Keywords:
Hydroxyapatite
Osteoconductive osteosynthesis
Orthognathic surgery
Bioabsorbable osteosyntheses

ABSTRACT

Hydroxyapatite was included into F-u-HA/PLLA (unsintered hydroxyapatite – Poly L-lactide) composite osteosynthesis material for its documented osteoconductive capacity. This study investigates segmental retention capacities and outcome stability using F-u-HA/PLLA composite osteosyntheses in orthognathic surgery.

Of fifty patients in total, 25 patients were osteofixated with F-u-HA/PLLA osteoconductive bioabsorbable osteosyntheses and compared to a group of 25 patients treated with titanium miniplates. The F-u-HA/PLLA group included 14 maxillary advancements, 4 setbacks, 13 impactions, 5 elongations at A-point; the titanium group included 20 maxillary advancements, 2 setbacks, 11 impactions and 11 elongations. In the mandible the F-u-HA/PLLA group included 13 advancements at B-point, 11 setbacks, 16 clockwise rotations and 8 counterclockwise rotations at the Gonial angle (Ar-Go-Gn); the titanium group included 9 mandibular advancements, 5 setbacks, 8 clockwise rotations and 6 counterclockwise rotations at Ar-Go-Gn.

Segmental stability and relapse were assessed comparing preoperative, postoperative and follow-up roentgen cephalometrics at 22 ± 11 months on average in F-u-HA/PLLA cases, 24 ± 22 months on average in the titanium group.

All absolute operative movements were nonsignificant in the F-u-HA/PLLA cases compared to the titanium osteosynthesis cases. Relapses were nonsignificant but there was greater vertical relapse in maxillary impactions with titanium osteosyntheses.

Throughout this study, F-u-HA/PLLA composite osteosyntheses appeared as stable as titanium miniplates. It can therefore be concluded, although from a limited number of patients, that the investigated osteoconductive osteosynthesis can be used in a similar way to titanium miniplates in orthognathic surgery. Compared to earlier studies using other bioabsorbable polymers in the literature, F-u-HA/PLLA proved to be more stable in segmental retention.

1. Introduction

The standard osteofixation in orthognathic surgery over the past 25 years has been titanium osteosyntheses. Although many previous reports have shown resorbable osteosyntheses to yield comparable results regarding stability and relapse (Van Sickels et al., 1986; Pistner, 1992; Louis et al., 1993; Hoffman et al., 1994; Hoffman and Moloney, 1995; Haers and Sailer, 1998; Pistner, 1999; Mobarak et al., 2001; Landes and Ballon, 2006; Landes et al., 2007; Stockmann et al., 2010; Turvey et al., 2011; Ballon et al. 2012), resorbable osteosyntheses are not widely used. Meanwhile resorbable osteosynthesis technology is evolving to bioabsorbability and osteoconductive osteosyntheses with new material compositions, different and improved in-situ behaviour.

For its osteoconductive properties, Hydroxyapatite (HA) was incorporated into a recent bioabsorbable osteosynthesis system (Shikinami and Okuno, 1999; Shikinami et al., 2005). The resulting

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http://dx.doi.org/10.1016/j.jcms.2014.01.013

composite F-u-HA/PLLA (forged unsintered hydroxyapatite – Poly L-lactide) showed improved initial strength, bioabsorbability, osteoconductivity and bone-bonding capacity when compared to PLLA-only devices. This was reported by the developers to be the result of extrusion and compression moulding during fabrication, leaving PLLA as a matrix for embedded unsintered HA particles of 30–40 weight fractions (Shikinami and Okuno, 1999).

Previous laboratory experimentation demonstrated higher mechanical strengths when compared to similar products of earlier making: bending strengths (S_b) of 270 MPa, higher than for cortical bone, and modulus (E_b) of 12 GPa, almost equivalent to cortical bone. The previously determinated impact strength (Si) was about two times the value of polycarbonate (166 kJ/m^2). Immediate change in molecular weight upon phosphate buffer immersion, when u-HA contents of 30–50 % were used, S_b changed with decremental curves for M_v (viscosity average molecular weight). S_b retained over 200 MPa for up to 24 weeks necessary and sufficient for bone union. According to the developer the high u-HA content permitted, immediate hydrolysis through the whole body of the implant and had no major time gap to the onset of hydrolysis as in PLLA (Shikinami and Okuno, 1999). Moreover HA crystals deposited on the surfaces after 3 to 6d and generously covered the surface after 7d immersion. This observation suggested bone-bonding capacity. From the raw material, production of mini-screws and plates used here and of other bone fixation devices was enabled, which are to be further developed for broader and more specific applications with more specifically dedicated designs (Shikinami and Okuno, 2001).

Following biocompatibility and biodegradation studies in animal models and clinical testing in pilot groups, this study evaluates segmental stabilization capacity of the designs currently available for orthognathic surgery (Suzuki et al., 2004; Shikinami et al., 2005; Hasegawa et al., 2006; Ueki et al., 2006).

2. Patients, materials and methods

This retrospective study compares F-u-HA/PLLA (forged unsintered hydroxyapatite – Poly L-lactide; Osteotrans MX®, Takiron, Osaka, Japan) with standard titanium miniplates (2.0 mm Standard Würzburg Miniplate system®; Stryker-Leibinger, Tuttlingen, Germany) regarding segment stability in orthognathic surgery.

Identical to previous studies, patients were asked prior to the operation for their preferred material. This was approved by our IRB, the declaration of Helsinki was followed. All patients were operated according to ISO 9001:2008 standard.

All included patients were not randomized or homogenized regarding repositioning distances for ethical reasons: Randomization of operative movements would have eventually sacrificed individual demands and thus could have incurred inferior functional and aesthetic results. Moreover randomization to homogeneous pairs regarding all performed maxillary and mandible movements requires a patient number most services such as ours are unable to provide.

2.1. Inclusion and exclusion criteria

All patients with Angle class II, III or open bite were included.

Patients with cleft lip and palate were not excluded from the study, as previous studies by the authors had shown, patients with cleft lip and palate do not have higher relapse rates than non-cleft patients (Ballon et al. 2012). In addition many studies have shown mandibular surgery in combination with maxillary surgery does not affect maxillary stability (Fish and Epker, 1987; Hennes et al., 1988; Law et al., 1989; Proffit et al., 1996; Van Sickels and Richardson, 1996; Bothur et al., 1998). Therefore monomaxillary/monognathic and bimaxillary/bignathic procedures have been included. All ages were included.

Exclusion: absence of dysgnathia, or a dysgnathia that required dentofacial orthopaedics only to be satisfactorily treated, and patient unwillingness for operation. Patients with laterognathia or marked asymmetries have not been included in the study, as their craniofacial conformation is unreliable to judge on lateral cephalograms.

Altogether 50 patients (25 in the F-u-HA/PLLA group; 25 in the titanium group) suffering from dysgnathia that required either combined orthodontic therapy with monognathic or bignathic operative repositioning have been assessed throughout this study.

2.2. Operative technique

Osteotrans MX plates can be cold-bent, basically in the same way as titanium plates; only slower bending speed and less force should be applied. The maximum possible bending angle at room temperature is 40° (degrees), otherwise preshaped bent plates as used in this evaluation for maxillary advancements, or a heating basin can be used. Osteotrans MX osteosyntheses were used with 1.0 mm-strength L-plates for maxillary fixation with 4 × 4 screws 6 mm long of 2 mm diameter for each plate. Maxillary L-plates with 2.5 mm, 5 mm and 7.5 mm preshaped steps are available for maxillary advancement and these need only minor individualization intraoperatively. After drilling of the screw holes, a tapper cut the threads prior to screw insertion. Screw fractures were rare, but when they occurred, a new hole was drilled through the fractured screw and a new replacement screw was inserted.

Altogether $n = 16$ screws, 6 mm long and of 2 mm diameter were used for maxillary fixation. In maxillary elongation as well as maxillary and mandibular advancement, only the osteosyntheses bridged the resulting osseous gap and no bone grafts were applied for reinforcement.

Mandibular osteosyntheses with Osteotrans MX were accomplished with two straight 1.4 mm strength 4-hole plates, one on each ascending ramus, fixed with 4 × 8 mm monocortical screws, two screws in each segment proximal and distal (Ueki et al., 2006). Fig. 1 shows a 3D CT-reconstruction of an operated cleft lip and

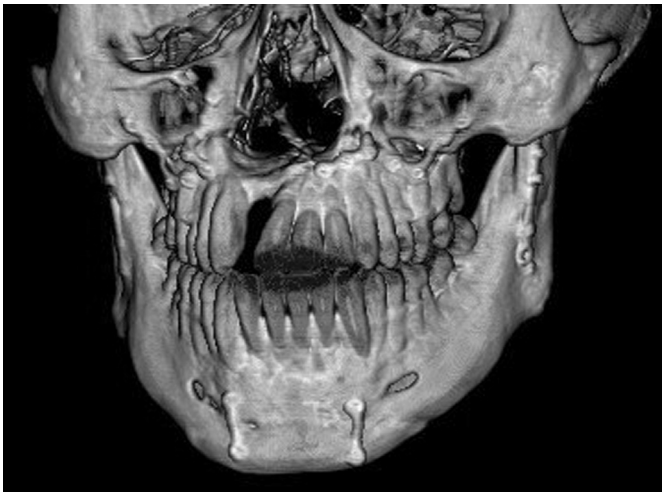

Fig. 1. 3-D-reconstructed computed tomography, 2 years after bignathic osteotomy and repositioning using Osteotrans Mx fixation in a cleft-lip and palate patient. Having received a 2-piece maxillary advancement, mandibular setback and chin plasty, the plate's residuals can still be recognized as bone osteoconduction occurs into the implanted material (Shikinami and Okuno, 1999), which was also shown in an exemplar patient biopsy (Fig. 5).