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

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A B S T R A C T

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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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).

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palate patient after a bignathic procedure and additional chin plasty (using Osteotrans MX doubled two hole plates with 8 mm screws for the chin plasty). Figs. 2 and 3 show maxillary and mandible osteosyntheses intraoperatively.

The titanium group received titanium osteosyntheses of 2.0 mm strength: 4 L-plates with each 4 × 4 screws, all 6 by 2 mm for the maxillary fixation and 2 mm strength straight 4-hole plates for the mandible with 4 × 6 mm long screws, two screws to each segment. In all elongations and advancements, osteosyntheses only bridged the osseous discontinuity gaps and no bone grafts were used for reinforcement.

Operative positioning was planned on lateral cephalograms by evaluation of photographs and plaster models, individually positioned within an articulator (SAM II®, ADS, Munich, Germany). According to the planning, intraoperative positioning splints were manufactured by the surgeons within a model surgery prior to operation. Two splints were used for bignathic surgery and one for single jaw surgery (Landes and Sader, 2011).

No rigid wire fixation was ever used. Instead, from the second postoperative day on, elastic bands were placed over the final splint and guided occlusion was maintained for 3 weeks.

Postoperatively patients were placed on a soft diet for 6 weeks; from the seventh week on to the twelfth week, all foods not requiring heavy mastication were allowed.

2.3. Cephalogram analysis

All patients received preoperative, postoperative and follow-up radiographs. Lateral cephalograms were used in all cases. All X-rays were taken with the identical X-ray equipment (Philips, The Netherlands). Preoperative X-rays were taken no longer than 3 months preoperatively. Postoperative cephalograms were taken after the splint had set into occlusion completely within the first week after operation. Follow-up was scheduled 12 months after operation. All radiologic examinations were done in conjunction with a clinical examination.

Cephalometric analyses compared the preoperative craniofacial conformation to the postoperative and the follow-up (Burstone et al., 1978). Fig. 4 shows a series of all three cephalograms with their respective cephalometric measurements. All cephalograms were analysed using computer-supported dedicated analysis program (Onyx Ceph®, Image Instruments, Chemnitz). Tracing by mouse-clicks were performed on scanned lateral cephalograms.

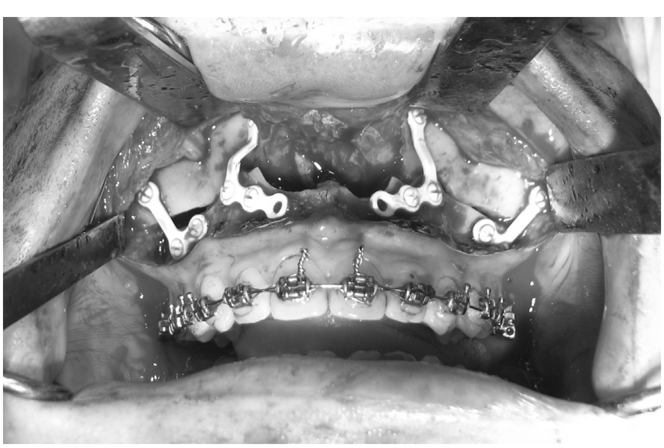

Fig. 2. Maxillary intrusion and advancement. The paranasal and lateral osteosyntheses at the infrazygomatic crest can be seen similar to the titanium osteosynthesis technique. The third hole within the prebent plates paranasally could be left empty if two screws were adequately tight.

Fig. 3. Right mandibular angle after advancement and counterclockwise rotation. The gap has not been bridged, the 1.4 mm strength plates bear the whole torque and load fixated to the bone with 8 by 2 mm screws.

The second author, who was not performing the operations and was therefore not biased, performed all cephalometry. Within a random selection of scans, ten percent of patients were traced for assessment of interobserver error also by the first author. Intraobserver error was ascertained by reassessment of the 10% random selected cephalograms by the first and the second author with one week interval.

Effective maxillary horizontal movement was measured at A-point. A point was drawn perpendicular to the facial horizontal, Nasion and the distance between the two perpendiculars on the facial horizontal measured, resulting in the relative change in millimetre distance preoperatively versus postoperatively and finally postoperatively versus follow-up.

Effective vertical maxillary movement was assessed as the distance between the Anterior Nasal Spine (ANS) and Nasion in millimetres parallel to the facial vertical. The relative change in millimetre distance preoperatively versus postoperatively and finally postoperatively versus follow-up was noted.

Effective horizontal mandibular movement was measured between B-point and Nasion in millimetres perpendicular to the facial horizontal, synonymously to the measurement of A-point.

Effective vertical mandibular movement was measured as the angle Articulare-Gonion-Gnathion in degrees preoperatively versus postoperatively versus follow-up. No vertical assessment was performed in B-point as vertical B-point position can shift secondary to maxillary vertical elongation or impaction.

Effective relapse was therefore measured between postoperative and follow-up cephalograms as the difference found between the postoperative situation and follow-up.

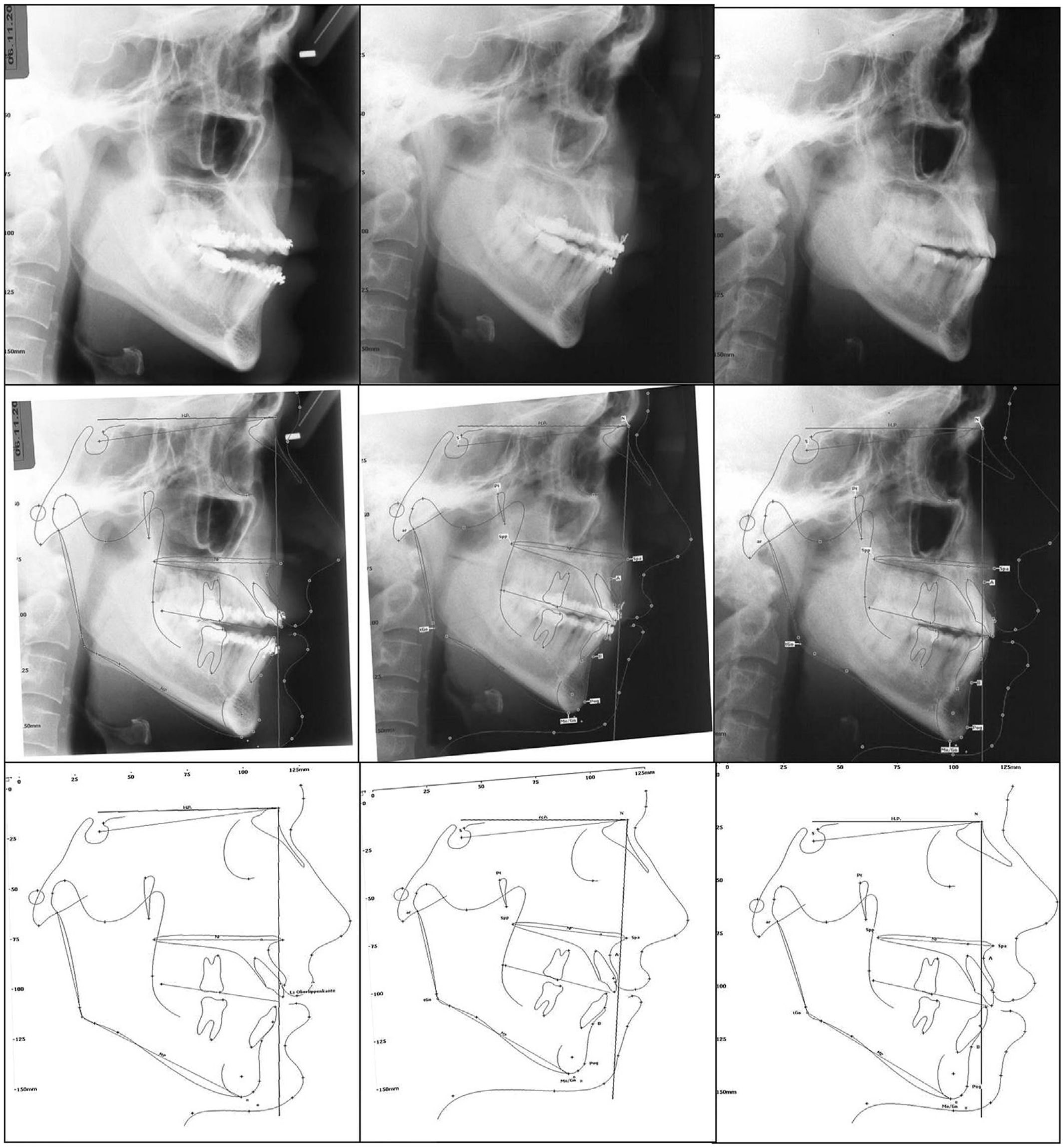

Fig. 4. The upper row shows the change between preoperative, postoperative and follow-up on lateral cephalograms in an open bite case. The middle row shows the superimposition of the landmarks on the lateral cephalograms in preoperative, postoperative and follow-up situation. The lower row shows the cephalometric analysis solely. It is obvious, that the dental relation changes from a slight overcompensation postoperative to an Angle class I with 2 mm overbite and overjet in the follow-up cephalogram.

2.4. Statistical analyses

Spreadsheet analysis was performed with SPSS (Statistical Package Social Science® 16.0 SPSS Company, Chicago, IL.). As statistical method the independent *T*-test (level for significance $p < 0.05$) was used.

A biopsy was permitted in one patient by our IRB, as local bone augmentation for dental implant insertion made local removal of the F-u-HA/PLLA material necessary and the patient agreed. Fig. 5 depicts this follow-up biopsy in a patient.

3. Results

3.1. General group data

All 50 patients were operated on between 2008 and 2009. The patient's decision was mostly for bioabsorbable osteosyntheses as published earlier (Ballon et al., 2012). However, due to availability, not all patients could be offered bioabsorbable osteosyntheses at their date of operation and therefore 25 patients finally received titanium osteosyntheses.

The 25 patients of the F-u-HA/PLLA group had ages ranging from 14 to 56 years (mean 29 ± 13.3); 11 male and 14 female patients have been operated. Twelve patients had Angle class II, 13 had Angle class III. 17 patients received bignathic surgery, 1 received a Le Fort I osteotomy only and 7 mere BSSO.

Within the titanium group, ages ranged from 15 to 42 years (mean: 24 ± 8.1); 11 male and 14 female patients have been operated. There of 8 patients had Angle class II, 17 had Angle class III; 11 patients received bignathic surgery, 11 received a Le Fort I osteotomy only, 3 merely BSSO.

3.2. General patient data

Patient baseline data (e.g., age, sex, diagnosis, operative movements) are given in Table 1 for the F-u-HA/PLLA group and in

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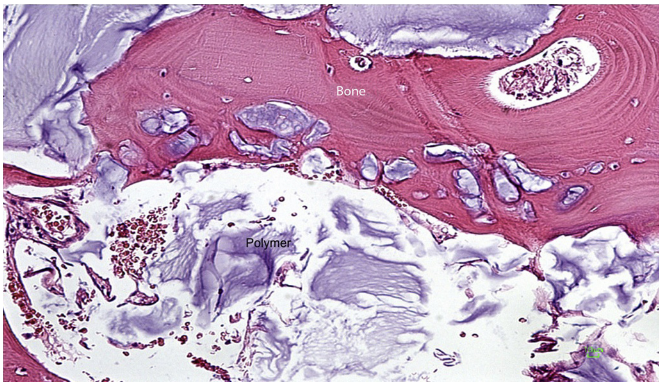

Fig. 5. An exemplar patient's histology explanted at a secondary operation after 24 months for implant placement of an exemplar explanted material, showing sound bone ingrowth into the F-u-HA/PLLA material without interpositioned connective tissue. This finding explains the long-term residues seen on the 3D-CT in Fig. 1.

Table 2 for the titanium group respectively. The operative procedures, values and significances in the maxilla are given in Tables 3 and 4 subdivided into advancement, setback, impaction and elongation. The procedures in the mandible are given in Tables 5 and 6 subdivided into advancement, setback, clockwise-rotation and counter-clockwise-rotation at the Gonial angle. Within the F-u-HA/PLLA group, the mean radiological follow-up was 22 ± 11 months (7–59 months), in the titanium group mean follow-up was 24 ± 22 months (6–80 months).

3.3. Measurements

In both examiners (individual and interindividual standard measurement error), the mean point setting deviation was 1 mm around a centre point within the 10% cephalograms that have been re-examined. This correlates with the findings of Proffit et al. (2007).

3.4. Intraoperative management

Due to long experience using resorbable osteosynthesis materials in our facility, no extra time was necessary to learn the handling of the bioabsorbable F-u-HA/PLLA screws and plates. Compared to the time needed for bending of the titanium plates, no extra time was required in comparison to the bending and adaptation of the bioabsorbable materials. The rate of broken screws was 5 percent.

3.5. Operative procedures and implant numbers

Altogether 120 osteoconductive plates and 124 titanium plates were used.

The F-u-HA/PLLA group included 14 maxillary advancements at A-point, 4 setbacks, 12 impactions and 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 and 11 setbacks, 16 clockwise rotations and 8 counterclockwise rotations at Ar-Go-Gn.

The titanium group included 9 mandible advancements, 5 setbacks, 8 clockwise rotations and 6 counterclockwise rotations at Ar-Go-Gn.

Total patient number may vary between single groups, patients with movements in more than one direction scored in different groups.

Table 3 shows horizontal maxillary advancement and elongation with relapse. The results show nonsignificant operative repositioning, the titanium group movements tend to be bigger. Relapses are equal and nonsignificant. Titanium osteosyntheses tend to show stronger horizontal retention than F-u-HA/PLLA osteosyntheses, yet without significance within the given case numbers of $N = 14$ for F-u-HA/PLLA osteosyntheses and $n = 20$ for titanium osteosyntheses.

Vertical maxillary elongation has been performed with a tendency (nonsignificant) to bigger operative maxillary elongation in the titanium osteosynthesis group. Titanium osteosynthesis group shows a nonsignificant tendency to higher relapse $n = 11$ vs. $n = 5$ F-u-HA/PLLA cases.

Table 4 shows horizontal maxillary setback and impaction and relapses. Horizontal setback is comparable for both osteosyntheses groups (F-u-HA/PLLA $n = 4$, titanium $n = 2$) showing similar relapses. Regarding vertical movement, the titanium group ($n = 11$) had bigger movements than the F-u-HA/PLLA group ($n = 12$), and titanium shows significantly higher relapse ($p = 0.012$).

Table 5 shows horizontal mandibular advancement and relapse for advancement and clockwise rotation at the Gonial angle. The titanium plates show higher horizontal advancement and also higher relapse without significances in $n = 9$ control and $n = 13$ study cases.

Gonial angle enlargement is bigger in the titanium group, while both osteosynthesis systems show comparable relapses, all without significance ($n = 8$ control vs. $n = 16$ study cases).

Table 6 shows horizontal mandibular setback and relapse for setback and counterclockwise rotation i.e., decrease of the Gonial angle. Setback shows higher movements in the titanium group ($n = 11$) but with less non-significant relapse than the F-u-HA/PLLA cases ($n = 5$).

Gonial angle narrowing or diminution is bigger in the titanium group, while both osteosynthesis systems show comparable high relapses, all without significance ($n = 8$ control vs. $n = 6$ study cases).

Comparing clinical parameters, both groups suffered the same adverse effects like postoperative swelling or paraesthesia. These effects were non-specific for the plating systems used. In the F-u-HA/PLLA osteosynthesis group, no foreign body granuloma occurred throughout this study.

The biopsy in Fig. 5 documents bone union between Osteotrans Mx and local bone. No connective tissue is formed between growing bone and polymer as well as the Hydroxyapatite lies in direct continuity with the growing bone.

4. Discussion

Kiely et al. (2006) and Turvey et al. (2002, 2006) reported an overwhelming majority of their patients asking for resorbable osteosynthesis, when given the choice, comparable with our experience (Ballon et al., 2011), therefore resorbable or bioabsorbable osteosyntheses can be considered very popular among orthognathic surgery patients. A literature overview showed the increasing frequency of published articles in this regard: comparing the years 1998–2013 in three-year classes, see Fig. 6, increasing numbers of articles are found in the PubMed, Cochrane and Google scholar databases. While in the period 1998–2000 four articles were found, between 2010 and 2012 eleven articles were found. These were authored by 13 from 1998 to 2000 and by 51 authors in 2010–2012. The manuscripts and authors came from 5 countries and 6 centres in 1998–2000 and from 13 countries and 23 centres 2010–2012. Although merely indicating the number of published clinical trials involving resorbable polymer osteosyntheses in orthognathic surgery, as a secondary indicator the published data

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Table 1
Study group: Raw patient data, measurements in mm except for vertical mandibular movement which is Gonial angle narrowing of augmentation given in degrees.

Pat. No.	Diagnosis	Direction of movement	Plate system	Sex	Years of age at operation	Radiographic follow-up [months]	Clinical follow-up [months]	Horizontal movement of maxilla [mm]	Horizontal relapse of maxilla [mm]	Vertical movement of maxilla [mm]	Vertical relapse of maxilla [mm]	Horizontal movement of mandible [mm]	Horizontal relapse of mandible [mm]	Vertical movement of mandible [deg]	Vertical relapse of mandible [deg]
1	Class II, deep bite	Le Fort I advancement, impaction and mandibular advancement, CCW	F-u-HA-PLLA	F	17	19	19	3.9	**0.5**	0.2	**1.6**	2.4	**1.8**	13.4	**6.1**
2	Class III	Le Fort I advancement, impaction and mandibular setback, CW	F-u-HA-PLLA	M	21	29	29	10.9	**11.9**	2.2	**3.3**	1.8	**11.1**	2.2	**2.2**
3	Class III, genioplasty	Le Fort I advancement, elongation and mandibular advancement, CCW	F-u-HA-PLLA	F	17	23	23	7.6	**5.9**	3.2	**2.7**	4.0	**8.4**	0.5	**2.0**
4	Class II, long face, gummy smile	Le Fort I advancement, elongation and mandibular advancement, CCW	F-u-HA-PLLA	M	18	33	33	5.5	**3.4**	3.1	**2.1**	16.2	**0.3**	6.7	**8.7**
5	Class III	Le Fort I advancement, impaction and mandibular setback, CCW	F-u-HA-PLLA	F	41	32	32	2.2	**4.9**	6.5	**2.0**	3.5	**8.7**	7.0	**4.1**
6	Class III, open bite	Le Fort I advancement, impaction and mandibular setback, CCW	F-u-HA-PLLA	F	14	12	12	0.9	**0.7**	0.8	**1.6**	7.9	**8.3**	1.2	**1.2**
7	Class III, genioplasty	Mandibular setback, CCW	F-u-HA-PLLA	F	23	12	12					1.0	**0.9**	0.4	**0.1**
8	Class III	Le Fort I advancement, impaction	F-u-HA-PLLA	F	48	21	21	4.6	**3.7**	5.0	**1.7**				
9	Class II	Mandibular advancement, CCW	F-u-HA-PLLA	F	23	32	32					0.2	**4.2**	1.1	**3.3**
10	Class III, genioplasty	Le Fort I setback, elongation and mandibular setback, CCW	F-u-HA-PLLA	M	20	29	29	2.7	**1.0**	0.5	**2.9**	12.5	**4.0**	9.0	**10.6**
11	Class II	Mandibular advancement, CCW	F-u-HA-PLLA	M	42	14	14					5.1	**1.7**	7.0	**1.3**
12	Class III	Mandibular setback, CW	F-u-HA-PLLA	F	40	7	7					1.1	**3.6**	13.5	**0.7**
13	Class III, open bite	Le Fort I advancement, elongation and mandibular setback, CW	F-u-HA-PLLA	M	18	11	11	2.7	**1.1**	2.0	**1.2**	3.8	**0.2**	6.7	**1.2**
14	Class III	Le Fort I advancement, elongation and mandibular setback, CW	F-u-HA-PLLA	F	16	14	14	5.0	**5**	2.8	**1.0**	12.6	**3.9**	0.1	**0.0**
15	Class II	Mandibular advancement, CCW	F-u-HA-PLLA	F	25	32	32					0.3	**6.7**	6.3	**8.3**
16	Class II, deep bite	Mandibular advancement, CCW	F-u-HA-PLLA	F	56	33	33					0.9	**1.6**	1.1	**1.5**
17	Class III	Le Fort I advancement, impaction and mandibular setback, CW	F-u-HA-PLLA	M	19	15	15	3.4	**7.2**	6.0	**2.3**	3.7	**7.0**	2.6	**4.5**
18	Class III, genioplasty	Le Fort I advancement, impaction and mandibular advancement, CCW	F-u-HA-PLLA	F	35	12	12	8.1	**7.9**	6.9	**3.0**	4.1	**4.1**	4.5	**4.5**
19	Class II	Mandibular advancement, CCW	F-u-HA-PLLA	M	46	15	15					0.6	**1.9**	10.2	**11.9**
20	Class III, open bite	Le Fort I setback, impaction and mandibular setback, CW	F-u-HA-PLLA	F	23	17	17	6.4	**10.0**	14.2	**2.3**	7.3	**11.0**	0.6	**0.4**
21	Class II	Le Fort I advancement, impaction and mandibular advancement, CCW	F-u-HA-PLLA	M	53	12	12	2.6	**2.3**	0.6	**1.0**	7.2	**1.5**	11.2	**2.6**
22	Class II	Le Fort I advancement, impaction and mandibular advancement, CW	F-u-HA-PLLA	F	45	29	29	4.9	**0.7**	3.7	**0.7**	3.3	**0.8**	2.7	**11.6**
23	Class II	Le Fort I setback, impaction and mandibular advancement, CCW	F-u-HA-PLLA	M	18	17	94	0.2	**0.7**	4.3	**0.5**	6.4	**3.6**	7.3	**1.2**

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24	Class II, mandibular retrognathia	Le Fort I setback, impaction and mandibular setback, CCW, genioplasty	F-u-HA-PLLA	M	30	27	29	14.4	**6.2**	8.9	**2.3**	0.9	**8.2**	4.7	**4.1**
25	Class II, open bite	Le Fort I advancement, impaction and mandibular advancement, CW, genioplasty	F-u-HA-PLLA	M	16	59	61	3.5	**1.0**	6.6	**0.0**	9.6	**2.1**	8.9	**2.3**

Two-tailed T-test (level for significance $p < 0.05$) have been represented in bold.

provide a clear international availability, prominence and attention and a third effect of more frequent use may carefully be postulated at least regarding patients included in clinical trials.

Only a proportion of these consider general feasibility with segment retention stability. F-u-HA/PLLA osteosyntheses in the present group will become compared to the published reports of earlier resorbable, not bioabsorbable or osteoconductive osteosyntheses. These earlier resorbable implants do not have the osteoconductive and bone-bonding capacities the used F-u-HA/PLLA implants do possess (Shikinami and Okuno 1999). Osteotrans Mx has been developed from Fixsorb® PLLA (Takiron Osaka, Japan) implants and the hydroxyapatite particles are distributed in a PLLA matrix similar to the earlier implants. Table 7 shows studies with comparable settings regarding only minor differences in cephalometric analyses: preoperative versus postoperative and one-year follow-up segmental stability (not six weeks or four years etc., as these results cannot be compared). Largely different cephalometry routines also cannot become compared on Table 7 (Turvey et al., 2002, 2006; Kiely et al., 2006; Ueki et al., 2006), although the authors of the articles in question stated generally comparable results to their titanium osteosyntheses control groups. Multicentre studies could not be found. Therefore comparable groups using similar assessment techniques are used for comparison in Table 7 (using the facial horizontal as reference line), with an emphasis on recent resorbable/bioabsorbable osteosyntheses results. Previous studies using earlier resorbable osteosyntheses have shown relapses may occur up to 1 year postoperatively (Haers and Sailer, 1998; Kiely et al., 2006; Landes and Ballon, 2006; Landes et al., 2007; Stockmann et al., 2010; Moure et al., 2012). All later changes are a result of postoperative myofunctional and orthodontic influence or growth in young patients (Proffit et al., 2007). Therefore this study covers the critical postoperative time interval, although typically for clinical assessment in patients, the envisaged follow-up time was finally longer. This was due to patient's individual schedules and geographical mobility.

According to the results in the present study, the F-u-HA/PLLA group tended to nonsignificant smaller operative **maxillary advancement**, bringing about relapses comparable to the titanium group with no significances. Consistent with other studies evaluating bioabsorbable osteosyntheses, no significant difference in this study's group's instability and case numbers were found (Haers and Sailer, 1998; Kiely et al., 2006; Landes and Ballon, 2006; Landes et al., 2007; Moure et al., 2012). Therefore within the limited number of patients, F-u-HA/PLLA osteosyntheses can be counted equally stable to titanium plates regarding maxillary advancements.

Maxillary elongations are generally susceptible to relapse and less stable than maxillary advancements and impaction regardless of method of fixation (Proffit et al., 1991; Baker et al., 1992; Louis et al., 1993; Gosain et al., 1998; Bailey et al., 2004; Ueki et al., 2006; Proffit et al., 2007; Ballon et al., 2012; Moure et al., 2012). Within the present and compared studies, no bone reinforcements i.e., transplants have been placed in the osteotomy gaps and the osteosyntheses absorbed the complete bite forces. Proffit et al. (2007) report relapses of 2–4 mm in 50% and over 4 mm in 20%. In the present evaluation, study as control group show high relapses, without significant differences. Compared to previous studies on resorbable osteosyntheses by the authors (Landes et al., 2006, 2007; Ballon et al., 2012), relapse rates for elongation are also high, while in the present study operative elongation movement was smaller. Albeit a small number of cases ($n = 5$) these results have to be interpreted with caution, yet other recent studies had similar small case numbers and similarly high relapses (Moure et al., 2012: $n = 8$).

Table 2
Control group: Raw patient data, measurements in mm except for vertical mandibular movement which is Gonial angle decrease or increase given in degrees.

Pat. No.	Diagnosis	Direction of movement	Plate system	Sex	Years of age at operation	Radiographic follow-up [months]	Clinical follow-up [months]	Horizontal movement of maxilla [mm]	Horizontal relapse of maxilla [mm]	Vertical movement of maxilla [mm]	Vertical relapse of maxilla [mm]	Horizontal movement of mandible [mm]	Horizontal relapse of mandible [mm]	Vertical movement of mandible [deg]	Vertical relapse of mandible [deg]
1	Class II	Mandibular advancement, CW	Titanium	F	29	19	56					7.6	**32.9**	5.9	**2.3**
2	Class III	Le Fort I advancement, elongation and mandibular advancement, CW, genioplasty	Titanium	F	38	12	98	0.3	**0.9**	7.3	**0.8**	10.8	**0.7**	3.4	**4.3**
3	Class II	Le Fort I advancement, impaction and mandibular advancement, CCW	Titanium	M	27	34	91	1.3	**0.8**	1.5	**3.2**	2.0	**2.5**	2.3	**5.2**
4	Class III, cleft lip and palate	Le Fort I advancement, impaction	Titanium	M	19	8	80	7.9	**6.7**	0.9	**0.3**				
5	Class III	Le Fort I advancement, elongation and mandibular setback, CCW	Titanium	F	28	27	75	2.3	**6.5**	3.0	**15.1**	13.7	**9.7**	3.9	**2.3**
6	Class III, cleft lip and palate	Le Fort I advancement, impaction	Titanium	M	19	17	86	2.4	**2.0**	10.6	**5.3**				
7	Class III	Le Fort I advancement, elongation	Titanium	M	19	6	105	5.0	**2.6**	4.9	**1.1**				
8	Class II, open bite	Le Fort I setback, impaction	Titanium	F	16	22	90	3.7	**3.6**	8.6	**6.6**				
9	Class III	Le Fort I advancement, impaction	Titanium	M	27	9	98	2.4	**3.4**	5.3	**3.1**				
10	Class II, deep bite	Mandibular advancement, CW	Titanium	M	16	10	13					1.2	**3.8**	7.1	**4.0**
11	Class II	Le Fort I advancement, impaction, mandibular advancement, CW	Titanium	F	20	23	57	1.8	**3.4**	0.1	**7.4**	1.2	**11.1**	4.7	**7.9**
12	Class III	Le Fort I advancement, impaction	Titanium	F	16	54	61	22.4	**8.5**	14.3	**10.1**				
13	Class III, cleft lip and palate	Le Fort I advancement, elongation	Titanium	F	16	12	85	2.1	**0.0**	2.7	**4.3**				
14	Class III	Le Fort I advancement, impaction	Titanium	M	16	11	78	10.7	**1.1**	0.6	**4.6**				
15	Class III	Le Fort I advancement, elongation and mandibular setback, CCW	Titanium	F	27	9	85	4.4	**4.0**	1.6	**2.4**	4.9	**0.7**	6.8	**2.4**
16	Extreme class III, acromegaly	Le Fort I advancement, elongation and mandibular setback, CCW genioplasty	Titanium	M	38	6	63	11.3	**6.9**	36.9	**19**	9.7	**0.4**	14.8	**2.7**
17	Class II, open bite	Le Fort I setback, elongation and mandibular setback, CCW	Titanium	F	33	7	12	7.0	**6.0**	11.0	**7.1**	8.9	**1.5**	0.9	**14.9**
18	Class III	Le Fort I advancement, impaction and mandibular advancement, CW, genioplasty	Titanium	F	26	7	49	24.3	**4.3**	0.2	**7.5**	21.7	**8.3**	9.5	**0.8**

19	Class III	Le Fort I advancement, impaction and mandibular advancement, CW	Titanium	F	33	18	82	5.4	**3.9**	2.3	**2.5**	11.3	**4.2**	5.4	**0.3**
20	Severe class II	Le Fort I advancement, elongation and mandibular advancement, CW	Titanium	F	42	13	83	1.4	**4.9**	4.8	**1.9**	4.9	**9.7**	9.0	**3.4**
21	Class III, cleft lip and palate	Le Fort I advancement, elongation	Titanium	F	17	48	92	0.7	**11.6**	0.8	**17.2**				
22	Class II, posttraumatic open bite	Mandibular advancement, CW	Titanium	M	29	8	63					5.0	**5.3**	14.7	**10.4**
23	Class III, facial scoliosis	Le Fort I advancement, elongation	Titanium	M	18	72	137	4.2	**4.5**	10.5	**10.7**				
24	Class III	Le Fort I advancement, elongation and mandibular setback, CCW, genioplasty	Titanium	F	20	61	64	5.9	**0.8**	1.1	**1.5**	4.6	**4.1**	4.6	**1.8**
25	Class III	Le Fort I advancement, impaction	Titanium	M	15	80	83	4.5	**0.0**	42.8	**0.3**				

Two-tailed *T*-test (level for significance $p < 0.05$) have been represented in bold.

Table 3
Evaluation of the cephalometric analysis in the Le Fort I level. Horizontal advancement, relapse for advancement and vertical elongation and relapse for elongation.

		N	Mean	Std. deviation	Sig. (2-tailed)
HMA	F-u-HA-PLLA	14	4.56	2.71	**0.442**
	Titanium plates	20	6.04	6.66	
HRA	F-u-HA-PLLA	14	3.82	3.47	**0.987**
	Titanium plates	20	3.84	3.06	
VMA	F-u-HA-PLLA	5	2.32	1.12	**0.339**
	Titanium plates	11	3.25	1.95	
VRA	F-u-HA-PLLA	5	1.98	0.86	**0.647**
	Titanium plates	11	2.88	4.19	

Two-tailed *T*-test (level for significance $p < 0.05$) have been represented in bold.
Explanation of abbreviations: HMA: Horizontal Movement at A-Point, HRA: Horizontal Relapse at A-Point, VMA: Vertical Movement at A-Point, VRA: Vertical Relapse at A-Point, HMB: Horizontal Movement at B-Point, HRB: Horizontal Relapse at B-Point, VMB: Vertical Movement at B-Point i.e., clockwise or counterclockwise rotation operative movement with appending decrease or increase of the Gonial angle. VRB: Vertical Relapse at B-Point i.e., clockwise or counterclockwise rotation relapse with appending decrease or increase of the Gonial angle.

In **maxillary setback** both groups have small case numbers comparable for operative movement and relapse with no significant differences. The relapse is higher after bigger setbacks than in previous studies, yet relatively comparable (Landes et al., 2007; Ballon et al., 2012).

In the **vertical maxillary intrusion** F-u-HA/PLLA showed significantly higher stability with less relapse. This movement direction is described as highly stable in the literature, yet generally bigger operative movements provoke higher relapses (Araujo et al., 2001; Bailey et al., 2004; Kiely et al., 2006; Proffit et al., 2007). The significantly higher relapse rate in titanium is surprising, may have been caused by insufficient reduction of the nasal septum or the posterior maxillary sinus wall, may be due to the case number and requires further control in bigger study groups. Abeltins et al. (2011) likewise report significant vertical relapse on one-year follow-up.

In **mandible advancement** the titanium group had bigger movement and relapse than the F-u-HA/PLLA group. The F-u-HA/PLLA group showed less relapse yet with smaller operative movement. While anterior positioning of the mandible is a movement with high stability also in resorbable osteosyntheses (Turvey et al., 2006; Proffit et al., 2007; Stockmann et al., 2010; Moure et al., 2012), the results show no significant differences between study and control groups.

Regarding **mandibular setback** the results are different. While the movement in the titanium group ($n = 5$) is bigger, the osteoconductive osteosyntheses show higher relapses ($n = 11$). Other authors and our earlier trial report difficulties with relapses in setbacks of the mandible using titanium as well as resorbable osteosyntheses (Bailey et al., 2004; Proffit et al., 2007; Ballon et al.,

Table 4
Evaluation of the cephalometric analysis in the Le Fort I level. Horizontal setback and relapse for setback, vertical impaction and relapse for impaction. Abbreviations are explained in legend to Table 3.

		N	Mean	Std. deviation	Sig. (2-tailed)
HMA	F-u-HA-PLLA	4	5.93	6.20	**0.910**
	Titanium	2	5.35	2.33	
HRA	F-u-HA-PLLA	4	4.48	4.47	**0.929**
	Titanium	2	4.80	1.70	
VMA	F-u-HA-PLLA	12	5.08	4.04	**0.462**
	Titanium	11	7.93	12.52	
VRA	F-u-HA-PLLA	12	1.72	1.01	**0.012**
	Titanium	11	4.63	3.11	

Two-tailed *T*-test (level for significance $p < 0.05$) have been represented in bold.

Table 5
Evaluation of the cephalometric analysis in BSSO. Horizontal advancement and relapse for advancement, clockwise rotation i.e., enlargement of the Gonial angle. Abbreviations are explained in legend to Table 3.

		N	Mean	Std. deviation	Sig. (2-tailed)
HMB	F-u-HA-PLLA	13	4.64	4.51	**0.273**
	Titanium plates	9	7.30	6.61	
HRB	F-u-HA-PLLA	13	2.98	2.37	**0.117**
	Titanium plates	9	8.72	9.69	
VMB	F-u-HA-PLLA	16	5.73	4.07	**0.317**
	Titanium plates	8	7.46	3.58	
VRB	F-u-HA-PLLA	16	4.47	3.64	**0.851**
	Titanium plates	8	4.18	3.45	

Two-tailed *T*-test (level for significance $p < 0.05$) have been represented in bold.

2012; Proffit et al., 2012). Using 2 Osteotrans Mx plates on each ascending ramus may give higher stability to the mandibular segments above all in setbacks analogue to Ueki et al. (2006), yet setback from the literature evidence remains the more unstable mandibular movement independent of osteosynthesis type.

The mandibular vertical movement in B-point cannot be reliably estimated, as maxillary vertical movement and secondary mandibular rotation influence it. Therefore, the authors use the Gonial angle, which is more exact (Landes and Ballon, 2006). The measurements and results for **clockwise and counterclockwise rotation** have to be interpreted with caution, as relapses are high compared to the operative movements similar to earlier reports where angular diminution and counterclockwise rotation were reported to be very unstable (Proffit et al., 1991, 2007, 2012; Paeng et al., 2012). The influence of proximal segment rotation has been addressed repeatedly (Proffit et al., 2012; Yang and Hwang, 2013) as a contributing factor for relapse. Methods of additionally stabilizing the proximal segment rotation and Gonial angle have not shown higher stability (Ueki et al., 2013).

At the present time, with the given number of patients in this study absolute operative movements were nonsignificant in the F-u-HA/PLLA cases compared to the titanium osteosynthesis cases. Relapses were nonsignificant but bigger vertical maxillary relapse with titanium osteosyntheses in maxillary impactions, relapses in the study group occurred without significance. Still, this study's resorbable and control groups were not matched in magnitude and direction of surgical movement. Therefore possible differences or lack of differences between the groups regarding instability may be attributable to the differences in the surgical movement. In contrast, free patient decision to be in the study or control group did not cause statistically different operative movement distribution; therefore, the influence of free patient decision should be nonsignificant (e.g., patients with significantly larger operative movements did not prefer titanium osteofixations). We attempted to account for these differences by calculating the instability in the percentage of surgical movement. Because of the problem of measurement standard error and overinterpretation of small movements, relative movements have to be interpreted with care. Statistical tests could have been designed to compare instability between the study and control groups accounting for differences in surgical movement.

One possible approach would have been to perform an analysis of covariance adjusting for preoperative versus postoperative changes. An alternative approach could have been be to assign a threshold creating two or three categories of surgical movements (e.g., minimal, moderate, and large) and then look at differences between these subgroups. Finally, another method was a nonparametric analysis of covariance. Although it might have been possible to develop such a test, the groups were so small that the result most likely would not have been valid (Landes et al., 2007). Therefore absolute instability is reported and compared, and the results of this study should be interpreted with caution because the groups were not matched for magnitude or direction of movement, age, sex, and so forth (Landes and Ballon, 2006).

In bioabsorbable fixations such as titanium, a hierarchy of stability was encountered in this study's cases, similar to that in

Table 6
Evaluation of the cephalometric analysis in BSSO. Horizontal setback and relapse for setback, counter-clockwise rotation i.e., decrease of the Gonial angle. Abbreviations are explained in legend to Table 3.

		N	Mean	Std. deviation	Sig. (2-tailed)
HMB	F-u-HA-PLLA	11	5.10	4.37	**0.173**
	Titanium plates	5	8.36	3.77	
HRB	F-u-HA-PLLA	11	6.08	3.78	**0.194**
	Titanium plates	5	3.28	3.87	
VMB	F-u-HA-PLLA	8	3.66	4.47	**0.470**
	Titanium plates	6	5.55	4.96	
VRB	F-u-HA-PLLA	8	3.60	4.23	**0.614**
	Titanium plates	6	4.88	5.05	

Two-tailed *T*-test (level for significance $p < 0.05$) have been represented in bold.

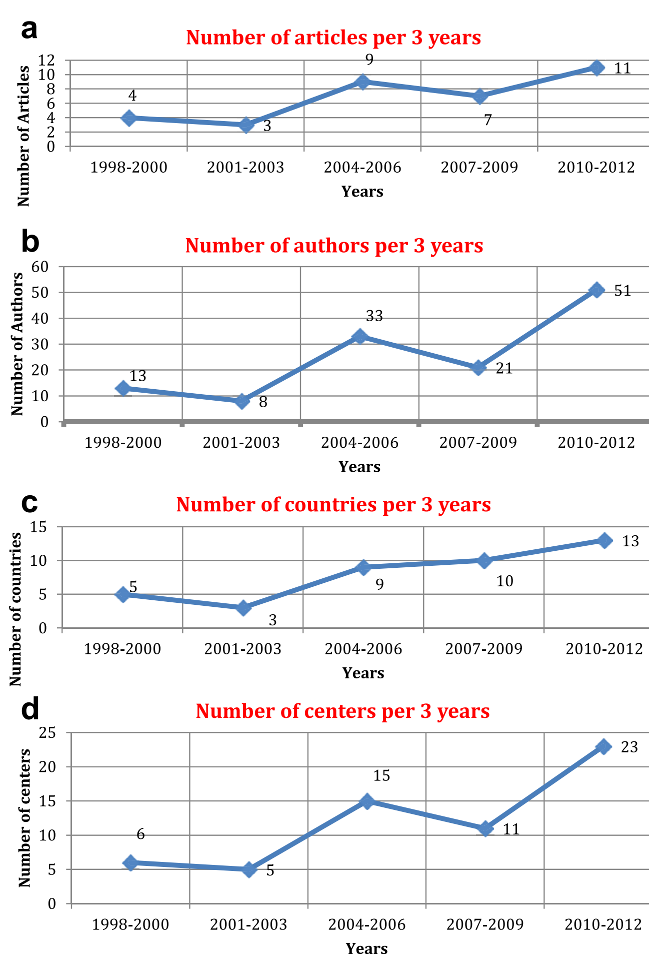

Fig. 6. The frequency of published articles in PubMed, Cochrane and Google scholar distributed from 1998 to 2013 in three-year periods shows a clear increase as indication of increasing frequency of clinical studies performed, authors, institutions and countries involved. a) is the two-word string result for: "orthognathic surgery and resorbable osteosynthesis or resorbable osteofixation or bioresorbable osteosynthesis" and the number of encountered articles; b) the number of associated authors; c) the number of countries of article origin and d) the number of centres involved as (co) authors.

Table 7
Synopsis of movement and mean relapse in mm of maxillary advancement and setback, maxillary elongation, maxillary intrusion, mandibular advancement and mandibular setback with miniplates, monocortical screw fixation (rigid internal fixation) or resorbable fixation in the literature. To keep data comprehensible, merely BSSO mandible osteotomies were listed.

Authors	Year	Osteosynthesis system	Number of patients	Bone grafts	MMF (weeks)	**Maxillary advancement**	Follow-up relapse	**Maxillary setback**	Follow-up relapse	**Intrusion**	Follow-up relapse	**Elongation**	Follow-up relapse	**Mandibular advancement**	Follow-up relapse	**Mandibular setback**	Follow-up relapse
Van Sickels et al.	1986	Rigid internal fixation	19	No	Wire (6)									**5.5**	0.4		
Louis et al.	1993	Rigid internal fixation	20	No	No	**9**	0.9										
Hoffman et al.	1994	Rigid internal fixation	15	No	Elastics	**6**	0.6										
Hoffman and Moloney	1995	Rigid internal fixation	15	No	Elastics (4)	**9**	0.6					**1.3**	0.3	**12.7**	0.2		
Haers and Sailer	1998	(P(L/DL)LA) plates and screws	10	Yes	Elastics	**2.9**	0.1			**1.8**	4	**2.3**	0.6	**2.8**	1.2	**4**	1.1
Mobarak et al.	2001	Titanium miniplates and three bicortical screws (one above, two below the mandibular canal)	80	n.s.	n.s.									**6.9**	1.3		
Arpornmaeklong et al.	2003	Rigid internal fixation	29	No	Elastics (4)	**2.6**	0.2										
Landes and Ballon	2006	P(L/DL)LA plates and monocortical screws	30	No	Elastics (4)	**3.5**	2.3	**2.8**	2.3	**1.9**	2.1	**4.2**	3.8	**4.6**	4.9	**7.5**	3.0
Landes and Ballon	2006	Titanium miniplates and monocortical screws	30	No	Elastics (4)	**5.4**	2.4	**1.9**	2.5	**3.3**	2.2	**3.7**	3.1	**6.3**	5.1	**7.2**	1.7
Landes et al.	2007	PLGA plates and monocortical screws	15	No	Elastics (4)	**2.5**	1.2	**2.2**	1.8	**1.0**	1.1	**6.5**	2.0	**5.5**	2.6	**11.2**	2.7
Landes et al.	2007	Titanium miniplates and monocortical screws	30	No	Elastics (4)	**5.4**	2.4	**1.9**	2.5	**3.3**	2.2	**3.7**	3.1	**6.3**	5.1	**7.2**	1.7
Abeltins et al.	2011	Titanium miniplates and monocortical screws	21	No	Elastics (2)	**5.6**	0.1			**1.4**	0.8					**5.4**	1.4
Moure et al.	2012	P(L/DL)LA self-reinforced plates and monocortical screws	30	No	Wire (1–2)	**3.3**	0.8			**3.11**	1.1	**0.4**	1.5			**6.1**	2.2
Ballon et al.	2012	P(L/DL)LA-TMC plates and monocortical screws	41	No	Elastics (4)	**2.7**	1.8	**3.5**	2	**3.1**	2.7	**5.2**	2.7	**4.9**	3.7	**9.3**	4.9
Ballon et al.	2012	Titanium miniplates and monocortical screws	43	No	Elastics (4)	**4.3**	1.5	**3.7**	1.7	**3.3**	1.4	**3**	1.4	**4.1**	2.1	**8.6**	1.5
This study	2013	F-uHA-PLLA plates and monocortical screws	25	No	Elastics (2–6)	**4.6**	3.8	**5.9**	4.5	**5.1**	1.7	**2.3**	2	**4.6**	3	**5**	6.1
This study	2013	Titanium miniplates and monocortical screws	25	No	Elastics (2–6)	**6**	3.8	**5.4**	4.8	**7.9**	4.6	**3.3**	2.9	**7.3**	8.7	**8.4**	3.3

Two-tailed *T*-test (level for significance $p < 0.05$) have been represented in bold.

previous reports, with maxillary elongation being the most unstable displacement for both osteosyntheses and mandibular setback being the most unstable mandibular displacement for the study group and mandibular advancement for the controls.

The difference in instability percentages may also be attributed to slightly different cephalometric routines, insecurity of landmark definition, different operative movements, thicker postoperative interocclusal wafers (approximately 2–3 mm high), operative overcorrection according to the surgeon's preference, and differences in follow-up (postoperative orthodontics, soft tissue characteristics and muscle tonicity, Abeltins et al., 2011). Last of all, there was imprecision in cephalometry (i.e., head positioning, landmark definition) on lateral cephalograms, as the applied standard examination method does not become balanced therefrom. Frontal cephalograms were deferred, as these are even more sensitive to head position and may be potentially incorrect. The author's clinical impression, shared by other authors, was that resorbable plates allowed faster occlusal settling (Turvey et al., 2002; Eppley, 2007; Landes and Ballon, 2006) and had a greater adaptive capacity for delayed adjustments in jaw position and condylar positioning, yet bigger initial rigidity of jaw position than earlier amorphous copolymers (Landes and Ballon, 2006).

Regarding adverse effects, no plate specific adverse effects like foreign body reactions occurred. Other material compositions with faster resorption or absorption rate have shown 6% mild foreign body granuloma (Landes et al., 2006; Turvey et al., 2011).

Osteotrans Mx was not the first resorbable/osteoconductive osteosynthesis system used in our facility, the surgeons were well acquainted to the operative use of the plates and screws that by themselves are more brittle than titanium and have to be bent slowly. No heating basin is required any more for bending of plates over the surface up to 40°, not over the edge and no extra operation time was needed due to the material.

5. Conclusion

As in previous reports using resorbable osteosyntheses (Turvey et al., 2002; Eppley, 2007; Landes et al., 2007; Stockmann et al., 2010), their successor *osteoconductive* osteosyntheses can be used comparable to titanium miniplate osteosyntheses as documented within this study's follow-up results. Maxillary advancement, intrusion, setback and mandibular advancement show stable results. With the limitation of small case numbers included, the use for these repositioning movements can be recommended. Maxillary elongation and mandibular setback show adequate results, yet have to be handled with caution as although nonsignificant, relapses were accentuated within this study and other earlier studies by several authors using also titanium (Bailey et al., 2004; Proffit et al., 2007; Stockmann et al., 2010; Ballon et al., 2012; Proffit et al., 2012). Here longer intermaxillary fixation, double osteosyntheses or bigger plate diameters should be considered.

Conflict of interest statement

Recruitment, patient treatment and data assembly were performed independently without any funding. Later on for the writing of the manuscript, the manufacturer Takiron (Osaka, Japan) provided independent funding.

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References

Abeltins A, Jakobsone G, Urtane I, Bigestans A: The stability of bilateral sagittal ramus osteotomy and vertical ramus osteotomy after bimaxillary correction of class III malocclusion. J Craniomaxillofac Surg 39: 583–587, 2011
Araujo MM, Waite PD, Lemons JE: Strength analysis of Le Fort I osteotomy fixation: titanium versus resorbable plates. J Oral Maxillofac Surg 59: 1034–1039, 2001
Arpornmaeklong P, Shand JM, Heggie AA: Stability of combined Le Fort I maxillary advancement and mandibular reduction. Aust Orthod J 19: 57–66, 2003
Bailey LJ, Cevidanes LH, Proffit WR: Stability and predictability of orthognathic surgery. Am J Orthod Dentofacial Orthop 126: 273–277, 2004
Baker DL, Stoelinga PJW, Blijdorp PA, Brouns JJ: Long-term stability after inferior maxillary repositioning by miniplate fixation. Int J Oral Maxillofac Surg 21: 320, 1992
Ballon A, Laudemann K, Sader R, Landes CA: Patients' preoperative expectations and postoperative satisfaction of dysgnathic patients operated on with resorbable osteosyntheses. J Craniofac Surg 22: 730–734, 2011
Ballon A, Laudemann K, Sader R, Landes CA: Segmental stability of resorbable P(L/DL)LA-TMC osteosynthesis versus titanium miniplates in orthognathic surgery. J Craniomaxillofac Surg 40: e408–414, 2012
Bothur S, Blomqvist JE, Isaksson S: Stability of Le Fort I osteotomy with advanced: a comparison of single maxillary surgery and two-jaw procedure. J Oral Maxillofac Surg 56: 1029, 1998
Burstone CJ, James RB, Legan H, Murphy GA, Norton LA: Cephalometrics for orthognathic surgery. J Oral Surg 36: 269–277, 1978
Eppley BL: Bioabsorbable plate and screw fixation in orthognathic surgery. J Craniofac Surg 18: 818–825, 2007
Fish LC, Epker BN: Prevention of relapse in surgical-orthodontic treatment. Part 2: maxillary superior repositioning. J Clin Orthod 21: 33–47, 1987
Gosain AK, Song L, Corrao MA, Pintar FA: Biomechanical evaluation of titanium, biodegradable plate and screw, and cyanoacrylate glue fixation systems in craniofacial surgery. Plast Reconstr Surg 101: 582–591, 1998
Haers PE, Sailer HF: Biodegradable self-reinforced poly-L/DL-lactide screws and plates in bimaxillary orthognathic surgery: short term skeletal stability and material related failures. J Craniomaxillofac Surg 26: 363–372, 1998
Hasegawa S, Ishii S, Tamura J, Furukawa T, Neo M, Matsusue Y, et al: A 5–7 year in vivo study of high-strength hydroxyapatite/poly(L-lactide) composite rods for the internal fixation of bone fractures. Biomaterials 27: 1327–1332, 2006
Hennes JA, Wallen TR, Bloomquist DS, Crouch DL: Stability of simultaneous mobilization of the maxilla and mandible utilizing internal rigid fixation. Int J Adult Orthodon Orthognath Surg 3: 127, 1988
Hoffman GR, Moloney FB, Effeney DJ: The stability of facial advancement surgery in the management of combined mid and lower dento-facial deficiency. J Craniomaxillofac Surg 22: 86–94, 1994
Hoffman GR, Moloney FB: The stability of facial osteotomies: 4. Maxillary and mandibular (with or without chin) advancement with rigid internal fixation. Aust Dent J 40: 365–371, 1995
Kiely KD, Wendfeldt KS, Johnson BE, Haskell BS, Edwards RC: One-year postoperative stability of LeFort I osteotomies with biodegradable fixation: a retrospective analysis of skeletal relapse. Am J Orthod Dentofacial Orthop 130: 310–316, 2006
Law JH, Rotskoff KS, Smith RJ: Stability following combined maxillary and mandibular osteotomies treated with rigid internal fixation. J Oral Maxillofac Surg 47: 128, 1989
Landes CA, Ballon A, Roth C: In-patient versus in vitro degradation of P(L/DL)LA and PLGA. J Biomed Mater Res B Appl Biomater 76: 403–411, 2006
Landes CA, Ballon A: Skeletal stability in bimaxillary orthognathic surgery: P(L/DL) LA-resorbable versus titanium osteofixation. Plast Reconstr Surg 118: 703–721, 2006
Landes CA, Ballon A, Sader R: Segment stability in bimaxillary orthognathic surgery after resorbable Poly (L-lactide-co-glycolide) versus titanium osteosyntheses. J Craniofac Surg 18: 1216–1229, 2007
Landes CA, Sader R: Dysgnathiechirurgie. In: Sander NS, Martin F, Ehrenfeld (eds), Zahn-Mund-Kiefer-Heilkunde – Kieferorthopädie. Stuttgart: Thieme, 400–439, 2011
Louis PJ, Waite PD, Austin RB: Long-term skeletal stability after rigid fixation of Le Fort 1 osteotomies with advancements. Int J Oral Maxillofac Surg 22: 82–86, 1993
Mobarak KA, Espeland L, Krogstad O, Lyberg T: Mandibular advancement surgery in high-angle and low-angle class II patients: different long-term skeletal responses. Am J Orthod Dentofacial Orthop 119: 368–381, 2001
Moure C, Qassemyar Q, Dunaud O, Neiva C, Testelin S, Devauchelle B: Skeletal stability and morbidity with self-reinforced P (L/DL) LA resorbable osteosynthesis in bimaxillary orthognathic surgery. J Craniomaxillofac Surg 40: 55–60, 2012
Paeng JY, Hong J, Kim CS, Kim MJ: Comparative study of skeletal stability between bicortical resorbable and titanium screw fixation after sagittal split ramus osteotomy for mandibular prognathism. J Craniomaxillofac Surg 40: 660–664, 2012
Pistner H: Osteosynthese mit Blinddübeln und Platten aus biodegradierbarem Block-Poly(L-Lactid). München: Akademischer Verlag, 1992
Pistner H: Osteosynthese mit resorbierbaren Materialien: Entwicklung einer Schraube vom Werkstoff bis zur klinischen Anwendung. Reinbek: Einhorn-Presse Verlag, 1999

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Proffit WR, Phillips C, Dann 4th C, Turvey TA: Stability after surgical-orthodontic correction of skeletal Class III malocclusion. 2. Maxillary advancement. Int J Adult Orthodon Orthognath Surg 6: 71–80, 1991

Proffit WR, Turvey TA, Phillips C: Orthognathic surgery: a hierarchy of stability. Int J Adult Orthodon Orthognath Surg 11: 191, 1996

Proffit WR, Turvey TA, Phillips C: The hierarchy of stability and predictability in orthognathic surgery with rigid fixation: an update and extension. Head Face Med 3: 21, 2007

Proffit WR, Phillips C, Turvey TA: Stability after mandibular setback: mandible-only versus 2-jaw surgery. J Oral Maxillofac Surg 70: e408–414, 2012

Shikinami Y, Okuno M: Bioresorbable devices made of forged composites of hydroxyapatite (HA) particles and poly-L-lactide (PLLA): part I. Basic characteristics. Biomaterials 20: 859–877, 1999

Shikinami Y, Okuno M: Bioresorbable devices made of forged composites of hydroxyapatite (HA) particles and poly-L-lactide (PLLA): part II: practical properties of miniscrews and miniplates. Biomaterials 22: 3179–3211, 2001

Shikinami Y, Matsusue Y, Nakamura T: The complete process of bioresorption and bone replacement using devices made of forged composites of raw hydroxylapatite particles/poly l-lactide (F-u-HA/PLLA). Biomaterials 26: 5542–5551, 2005

Stockmann P, Böhm H, Driemel O, Mühling J, Pistner H: Resorbable versus titanium osteosynthesis devices in bilateral sagittal split ramus osteotomy of the mandible – the results of a two centre randomised clinical study with an eight-year follow-up. J Craniomaxillofac Surg 38: 522–528, 2010

Suzuki T, Kawamura H, Kasahara T, Nagasaka H: Resorbable poly-l-lactide plates and screws for the treatment of mandibular condylar process fractures: a clinical and radiologic follow-up study. J Oral Maxillofac Surg 62: 919–924, 2004

Turvey TA, Bell RB, Tejera TJ, Proffit WR: The use of self-reinforced biodegradable bone plates and screws in orthognathic surgery. J Oral Maxillofac Surg 60: 59–65, 2002

Turvey TA, Bell RB, Phillips C, Proffit WR: Self-reinforced biodegradable screw fixation compared with titanium screw fixation in mandibular advancement. J Oral Maxillofac Surg 64: 40–46, 2006

Turvey TA, Proffit WP, Phillips C: Biodegradable fixation for craniomaxillofacial surgery: a 10-year experience involving 761 operations and 745 patients. Int J Oral Maxillofac Surg 40: 244–249, 2011

Ueki K, Marukawa K, Shimada M, Nakagawa K, Alam S, Yamamoto E: Maxillary stability following Le Fort I osteotomy in combination with sagittal split ramus osteotomy and intraoral vertical ramus osteotomy: a comparative study between titanium miniplate and poly-L-lactic acid plate. J Oral Maxillofac Surg 64: 74–80, 2006

Ueki K, Okabe K, Marukawa K, Mukozawa A, Moroi A, Miyazaki M, et al: Skeletal stability after mandibular setback surgery: comparison between the hybrid technique for fixation and the conventional plate fixation using an absorbable plate and screws. J Craniomaxillofac Surg, 2013 Jul 6. pii: S1010-5182(13)00160-1. http://dx.doi.org/10.1016/j.jcms.2013.06.001. [Epub ahead of print]

Van Sickels JE, Larsen AJ, Thrash WJ: Relapse after rigid fixation of mandibular advancement. J Oral Maxillofac Surg 44: 698–702, 1986

Van Sickels JE, Richardson DA: Stability of orthognathic surgery: a review of rigid fixation. Br J Oral Maxillofac Surg 34: 279, 1996

Yang HJ, Hwang SJ: Contributing factors to intraoperative clockwise rotation of the proximal segment as a relapse factor after mandibular setback with sagittal split ramus osteotomy. J Craniomaxillofac Surg, 2013 Jul 4. pii: S1010-5182(13)00168-6. http://dx.doi.org/10.1016/j.jcms.2013.05.034. [Epub ahead of print] PMID: 23830770

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