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Comparison of the long-term skeletal stability between a biodegradable and a titanium fixation system following BSSO advancement — A cohort study based on a multicenter randomised controlled trial

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Abstract

Biodegradable fixation systems could reduce or eliminate the problems associated with removal of titanium plates. A multicenter randomised controlled trial (RCT) was performed in the Netherlands from December 2006-July 2009, and originally 230 injured and orthognatic patients were included. The patients were randomly assigned to either a titanium control group (KLS Martin) or to a biodegradable test group (Inion CPS). The aim of the present study was to compare the long-term skeletal stability of advancement bilateral sagittal split osteotomies (BSSO) of a biodegradable system and a titanium system. Only patients from the original RCT who were at least 18 years old and who had a BSSO advancement osteotomy were included. Those who had simultaneous Le Fort I osteotomy or genioplasty were excluded. Analysis of skeletal stability was made by digital tracing of lateral cephalograms.

Long-term skeletal stability in BSSO advancement did not differ significantly between patients treated with biodegradable plates and screws and those treated with titanium plates and screws. Given the comparable amount of relapse, the general use of Inion CPS in the treatment of BSSO advancement should not be discouraged. On the basis of other properties a total picture of the clinical use can be obtained; the short-term stability, the intraoperative switches, the number of plates removed and cost-effectiveness.

Trial registration of original RCT: http://www.controlled-trials.com; ISRCTN 44212338.

Keywords: Inion; KLS Martin; relapse; treatment outcome; surgical fixation devices; oral surgery.

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Introduction

Titanium osteosynthesis is regarded as the gold standard of fixation systems in maxillofacial surgery.[1–3] The titanium is removed at a second operation after the bone has healed in 5%-40% of cases.[4,5] Biodegradable osteosynthesis has been developed to reduce or even eliminate the problems associated with the removal of titanium plates. Fewer operations for removal implies less discomfort for patients. It may also benefit society, as fewer removal operations will put less pressure on the capacity of the healthcare system, and provide patients with continuing employment. There is an ongoing search for the ideal fixation system.

The present study is part of a current research project. The results 8 weeks postoperatively have been described in detail elsewhere.[1] When it was possible to apply the biodegradable plates and screws, bone healing (short-term stability) did not seem to be inferior to titanium plates and screws. However, in cases where the application of the biodegradable system failed, this resulted in an intraoperative switch to titanium.[2]

The aim of the present study was to establish the long-term skeletal stability of a biodegradable system as a potential alternative to titanium for fixation of advancement bilateral sagittal split osteotomies (BSSO).

Material and Methods

Design of the study

This prospective cohort study was derived from a randomised controlled trial (RCT) published by Buijs et al.[1] and has been described according to the STROBE statement (http://www.strobe-statement.org/).

Group studied

In the cohort study only patients from the original RCT who had had a BSSO advancement osteotomy were included, and who were at least 18 years old. Patients who had a simultaneous genioplasty or a Le Fort I osteotomy were excluded. In the original RCT we studied 230 patients who required treatment of trauma and orthognathic conditions. They were treated from December 2006 to July 2009 at 4 different departments of Oral and Maxillofacial Surgery in the Netherlands. The inclusion and exclusion criteria of the original trial are summarised in Table 1. All patients provided informed consent before enrollment, and to publication of the study. Details of the randomisation procedure have been described elsewhere.[1] The study was approved by the Medical Ethics Committees of the participating hospitals.

Interventions

In the original RCT patients were assigned to a titanium control group (KLS Martin, Gebrüder Martin GmbH & Co. Tuttlingen, Germany) or to a biodegradable test group (Inion CPS, Inion Ltd. Tampere, Finland). The mandibular osteotomies were fixed with 2.5 mm biodegradable, or 2.0 mm titanium, plates and screws (Fig. 1). The patients had no rigid maxillomandibular fixation but only soft guiding elastics postoperatively, and they were instructed to take a soft diet for 5 weeks. All patients had orthodontic treatment before and after operation. All patients had a surgical splint to achieve proper occlusion.

Table 1
Inclusion and exclusion criteria of the original prospective multicenter random control trial.

Inclusion criteria:
Patients listed for a Le Fort I fracture, or one or more (maximum 2) mandibular fracture(s), or a fracture of the zygoma, or a combination
Patients listed for a Le Fort I osteotomy, or bilateral sagittal split osteotomy, or both
Patients or parents (or other responsible people if necessary) who gave signed informed consent
Exclusion criteria:
Patients who were younger than 18 years old (trauma), or patients who were younger than 14 years (osteotomies)
Patients presented with extremely comminuted fractures of the facial skeleton
Patients who had had compromised bone healing in the past
Patients who were pregnant
Patients who could/would not participate in a 1-year follow-up (reasons);
Patients who would not agree to random assignment to one of the treatment groups, or one of the methods or treatment given
Patients who were diagnosed with a psychiatric disorder by a psychiatrist
Patients who had had operations for cleft lip and palate in the past
Patients whose reduction and fixation of the fracture was delayed for more than 7 days after the trauma
Patients whose general health or medication could affect bone healing, in the opinion of the oral and maxillofacial surgeon.

Outcome measures

The most important outcome variable in the current study was the skeletal stability (by measuring the relapse) 2 years after operation with biodegradable or titanium plates and screws. Relapse is the difference between certain cephalo-

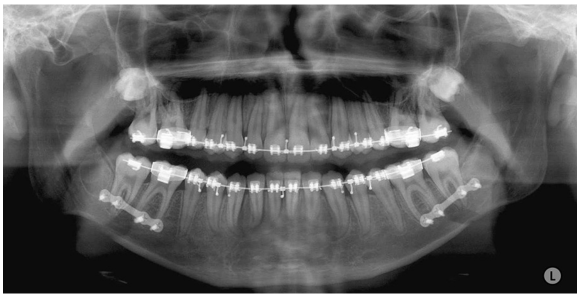

Figure 1. Orthopantomogram showing the position of the plates and screws in a patient who had titanium fixation of bilateral sagittal split osteotomy. Biodegradable plates and screws in "biodegradable" cases were placed in a similar manner, but would not be visible on the radiograph.

metric variables measured at the final follow-up visit (T2) and directly postoperatively (T1). According to Joss and Vassalli points B and Pg were chosen as the most important variables to indicate relapse.[6] This was analysed by digitally tracing the lateral cephalograms. Extra analyses were made to find out if there was a difference in relapse between the biodegradable and titanium group in advancements (reduction of overjet) of 8 mm or less and advancements of more than 8 mm. The cut-off point of 8 mm was chosen according to Ferretti and Reyneke, and Will and West.[7,8]

In addition, the relations between the amount of relapse (mm) and other variables that possibly influenced this (the predictive variables) were studied for points B and Pg. The following possible predictive variables were included: female sex, age, difference in the amount of advancement between the position of point B (or Pg) directly postoperatively (T1) and at baseline (T0) (mm), the mandibular length (the distance between Articulare midpoint (Arm) and Menton (Me) at T0 (mm)), the length of the body of the mandible (the distance between Gonion (Go) and Menton (Me) at T0 (mm)), and the angle between the mandibular plane (Steiner) and SN-line at T0 (^{o}).

The last preoperative cephalogram (titanium taken after a mean of 84 days compared with biodegradable 90 days) was selected as T0. The second cephalogram (T1) was taken at the first postoperative outpatient visit (both titanium and biodegradable 8 days), and the third one 2 years later (T2) (titanium taken after a mean of 27 months compared with biodegradable 25 months).

Cephalometric analysis

All digital lateral cephalograms were made using each participating hospital's own cephalostat with the mandible in the most retruded position (centric relation) and the lips relaxed. The "mirror position" was used to get a reproducible position of the head.

A predefined trace-protocol (Table 2, Fig. 2, Appendix A) was designed[9] and all tracings were made using Viewbox 3.1.1.14 (dHal software. Kifissia, Greece). Seventeen landmarks were identified on the lateral cephalograms. Vertical distances were measured (mm) from the landmark perpendicular to SN; horizontal distances from the landmark perpendicular to SN-perp (line perpendicular to SN through S). First, all cephalograms were converted to lifesize values using the "centimetre-indication" incorporated in each cephalogram. Next, for sagittal and vertical measurements, the 3 cephalograms were superimposed on the anterior contour of the sella turcica and the line sella-nasion (SN).[10] To reduce the error of measurement further, the coordinates of sella and nasion were, after superimposition, transferred from the baseline to the follow-up cephalograms to obtain exactly the same coordinates on all 3 cephalograms. To calculate interobserver reliability, all baseline cephalograms were traced by 2 different observers (NBvB and BDAB). Next, all cephalograms were traced by one observer (NBvB).

Statistical analysis

Inclusion of the 230 patients was based on power analysis using the primary outcome measure "bone healing after 8 weeks" that has been described elsewhere.[1] We used SPSS Statistics for Windows (version 20.0, IBM Corp. Armonk NY) to analyse the data.

To assess interobserver reliability of the tracings, the intraclass correlation coefficient (ICC) was calculated for each variable. An ICC of less than 0.4 was considered poor, ICC of 0.4-0.75 was considered fair to good, and that of over 0.75 was considered excellent.[11]

For the continuous cephalometric measures, "between groups" effect sizes are reported as Cohen's *d*, based on the mean difference between the groups divided by the SD of the control group (titanium). Cohen's *d* effect sizes are interpreted as small (0.2), medium (0.5), or large (over 0.8).[12] Cohen's *d* was calculated only when analysis showed a significant difference in relapse (or advancement) between the groups.

Inspection (by eye) and the Kolmogorov-Smirnov test showed that all continous data had a normal distribution, so we calculated the mean (SD) of the continous variables and analysed them using the independent samples *t* test. Dichotomous variables were analysed using the chi squared test.

To identify variables predictive of relapse we tested factors with the potential to have an influence by a univariate linear regression analysis. To ensure broad inclusion of possible determinants, α was set at 0.15 for the univariate analyses. All significant variables were then analysed by multiple regression. Female sex, as a predictive variable for relapse, was tested using an independent samples *t* test.[13] Probabilities of less than 0.05 were accepted as significant.

Results

Patients

Of the original 230 randomised patients, 149 completed the 2 year postoperative follow up.[3] Patients with fractures (n = 6), Le Fort I osteotomies (n = 11), bimaxillary operations (n = 34), simultaneous genioplasty (n = 14), BSSO setbacks (n = 6), age <18 years (n = 5), lateral cephalograms not taken at all 3 time intervals (n = 16), or who had lateral cephalograms of poor quality or not taken in centric relation (n = 20), were excluded from the analysis of relapse. This resulted in an analysis of 15 patients in the biodegradable group, and 22 in the titanium group.

Baseline measurements

Neither age nor sex differed significantly between the 2 groups (Table 3).

Table 2
Cephalometric variables point B and point Pg.

Variable	ICC[*] (95%CI) Baseline	Titanium (n = 22) Baseline[†] (T0)	Bio (n = 15) Baseline[†] (T0)	Difference (95%CI) *p*-value[‡]	Titanium (n = 22) Advancement[†] (T1-T0)	Bio (n = 15) Advancement[†] (T1-T0)	Difference (95%CI) *p*-value[‡] [Cohen's *d*]	Titanium (n = 22) Relapse[†] (T2-T1)	Bio (n = 15) Relapse[†] (T2-T1)	Difference (95%CI) P-value[‡] [Cohen's *d*]
Total group										
Point B-hor; shortest distance from point B to line SN-perp through S (mm)	0.95 (0.90–0.97)	45.4 (5.7)	44.6 (6.4)	0.8 (−3.3 to 4.8) p = 0.71	4.2 (2.2)	3.2 (1.6)	1.0 (−0.2 to 2.3) p = 0.11	−0.3 (2.3)	−0.03 (1.7)	−0.3 (−1.7 to 1.1) p = 0.71
Point B-ver; shortest distance from point B to line SN (mm)	0.98 (0.94–0.99)	88.7 (7.6)	93.0 (8.5)	−4.3 (−9.8 to 1.1) p = 0.12	3.2 (2.4)	4.8 (1.8)	−1.6 (−3.1 to −0.2) p = 0.03 [0.69]	−0.9 (1.6)	−1.1 (1.5)	0.2 (−0.9 to 1.2) p = 0.41
Point Pg-hor; shortest distance from point Pg to line SN-perp through S (mm)	0.96 (0.92–0.98)	44.2 (6.3)	44.3 (7.5)	−0.1 (−4.7 to 4.5) p = 0.97	4.1 (2.6)	2.3 (2.2)	1.8 (0.1 to 3.5) p = 0.04 [0.68]	−0.3 (2.6)	−0.1 (2.0)	−0.2 (−1.8 to 1.4) p = 0.45
Point Pg-ver; shortest distance from point Pg to line SN (mm)	0.98 (0.94–0.99)	105.3 (8.4)	109.2 (7.8)	−3.9 (−9.5 to 1.6) p = 0.16	3.2 (1.7)	4.3 (1.9)	−1.1 (−2.3 to 0.1) p = 0.07	−0.6 (1.7)	−1.7 (1.5)	1.1 (<0.001 to 2.2) p = 0.05
Advancements ≤8mm[¶]										
Point B-hor; shortest distance from point B to line SN-perp through S (mm)	See above	45.8 (5.7)	44.6 (6.4)	1.2 (−3.0 to 5.4) p = 0.57	4.0 (2.1)	3.2 (1.6)	0.8 (−0.6 to 2.1) p = 0.25	−0.3 (2.4)	−0.03 (1.7)	−0.3 (−1.8 to 1.2) p = 0.69
Point B-ver; shortest distance from point B to line SN (mm)	See above	89.0 (7.9)	93.0 (8.5)	−4.0 (−9.7 to 1.7) p = 0.16	3.0 (2.3)	4.9 (1.8)	−1.9 (−3.3 to −0.4) p = 0.02 [0.83]	−0.9 (1.6)	−1.1 (1.5)	0.2 (−0.6 to 1.5) p = 0.43
Point Pg-hor; shortest distance from point Pg to line SN-perp through S (mm)	See above	44.5 (6.4)	44.3 (7.5)	0.2 (−4.6 to 5.0) p = 0.94	3.9 (2.6)	2.3 (2.2)	1.6 (−0.2 to 3.2) p = 0.08	−0.3 (2.7)	−0.1 (2.0)	−0.2 (−1.9 to 1.5) p = 0.81
Point Pg-ver; shortest distance from point Pg to line SN (mm)	See above	105.5 (8.8)	109.2 (7.8)	−3.7 (−9.6 to 2.1) p = 0.20	3.2 (1.8)	4.4 (1.9)	−1.2 (−2.4 to 0.1) p = 0.07	−0.7 (1.8)	−1.7 (1.5)	1.0 (−0.1 to 2.2) p = 0.07

[*] ICC = interclass correlation coefficient: <0.4 was considered poor, 0.4 to 0.75 was considered fair to good, and >0.75 was considered excellent.

[†] Mean (SD). Minus values imply a backward movement in the horizontal plane or an upward movement in the vertical plane. Plus values imply a forward movement in the horizontal plane or a downward movement in the vertical plane.

[‡] Inspection (eyeball) and the Kolmogorov-Smirnov tests showed a normal distribution for all continuous data, so differences between the two groups were analysed using the independent samples *t* test. For differences in advancement a regression to the mean analysis for baseline was done only when there was a significant difference between the groups at baseline. For differences in relapse between the groups a regression to the mean analysis for baseline or for advancement was done only when there was a significant difference between the groups in baseline or in advancement, respectively. When both baseline and advancement differed significantly between the groups, then regression was done only for advancement. Cohen's *d* was given only when $p < 0.05$. Cohen's *d* effect sizes are interpreted as small (0.20), medium (0.50), or large (>0.80). As far as differences between the groups are concerned: minus values imply bigger dimensions or a greater displacement during operation in the biodegradable group, or more relapse in the titanium group (and vice versa). As far as values within the groups are concerned: plus values imply an advancement, and minus values imply a relapse.

[¶] We did not analyse advancements of more than 8 mm, because there were only 2 patients in the titanium group and no patients in the biodegradable group with a lateral cephalogram of good quality or in centric relation.

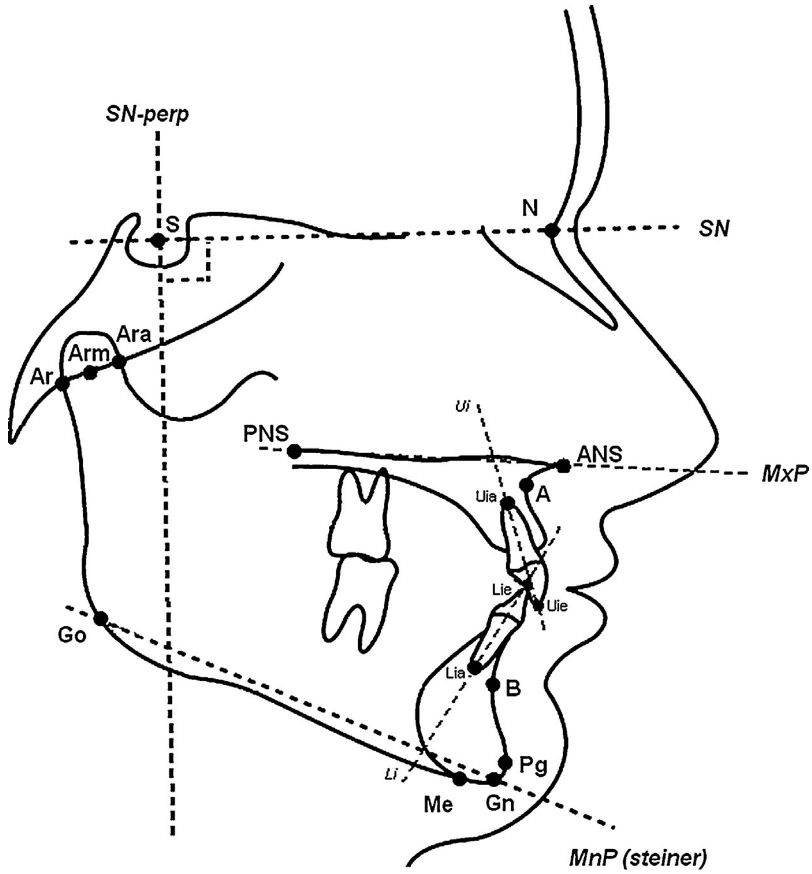

Figure 2. Cephalometric landmarks and reference lines traced on lateral cephalograms.
The following 17 reference points were identified on lateral cephalograms: A (point A: the deepest midline concavity on the anterior maxilla), ans (anterior nasal spine: the tip of the median, sharp bony process of the maxilla at the lower margin of the anterior nasal opening), Ara (anterior articulare: the point of intersection of the inferior cranial base surface and the averaged anterior surfaces of the mandibular condyles), Arm (articulare midpoint: the midpoint of the line between Ara–Ar), Ar (articulare; the point of intersection of the inferior cranial base surface and the averaged posterior surfaces of the mandibular condyles), B (point B: the deepest midline concavity on the mandibular symphysis), Gn (gnathion: the most anteriorinferior point on the contour on the bony chin symphysis, calculated by bisecting the angle formed by the mandibular plane and a line through pogonion and nasion), Go (gonion: the constructed point of the intersection of the ramus plane and the tangent to the body of the mandible), Lia (lower incisor apex), Lie (lower incisor edge: the incisal tip of the mandibular central incisor), Me (menton: the intersection of the bony inferior symphysis with the inferior margin of the mandibular body), N (nasion: the most anterior point on the frontonasal suture), Pg (pogonion: the most anterior point on the contour of the bony chin determined by a tangent through nasion), pns (posterior nasal spine: the intersection of a continuation of the anterior wall of the pterygopalatine fossa and the floor of the nose, marking the dorsal limit of the maxilla), S (sella; the midpoint of the pituitary fossa), Uia (upper incisor apex), Uie (upper incisor edge: the incisal tip of the maxillary central incisor).
The following 6 reference lines were identified on lateral cephalograms: Li (lower incisor line: the line through the lower incisor apex and the lower incisor incisal edge), MnP (mandibular plane according to Steiner: the line through gonion and gnathion), MxP (maxillary plane: the line through the posterior nasal spine (pns) and the anterior nasal spine (ans)), SN (sella-nasion line: the line through sella and nasion), SN-perp (SN-perpendicular: the line through Sella (S) perpendicular on line SN), Ui (upper incisor line: the line through the upper incisor apex and the upper incisor incisal edge).
Vertical distances were measured (mm) from the landmark perpendicular to SN; horizontal distances were measured (mm) from the landmark perpendicular to SN-perp.

Reliability

There was "excellent" agreement between the examiners for all cephalometric variables (Table 2, Appendix A), except for ANB (angle), for which agreement was "fair to good".

Outcome measures

Relapse of biodegradable and titanium fixation: The mean (SD) horizontal relapse at point B for the biodegradable group was 0.03 (1.7) mm, and 0.3 (2.3) mm for the titanium group (mean difference −0.3 mm (95%CI −1.7 to 1.1); *t* −0.37, df = 35, p = 0.71) (Table 2). The mean (SD) vertical relapse at point B was 1.1 (1.5) mm for the biodegradable group, and 0.9 (1.6) mm for the titanium group (mean difference 0.2 mm (95%CI −0.9 to 1.2); *t* 0.34, df = 35, p = 0.41).

The mean (SD) horizontal relapse at point Pg for the biodegradable group was 0.1 (2.0) mm, and 0.3 (2.6) mm for the titanium group (mean difference −0.2 (95%CI −1.8 to 1.4); *t* −0.23, df = 35, p = 0.45). The vertical relapse at point Pg for the biodegradable group was 1.7 (1.5) mm, and 0.6 (1.7) mm for the titanium group (mean difference 1.1 mm (95%CI <0.001 to 2.2); *t* 2.0, df = 35, p = 0.05).

Table 3
Baseline characteristics. Data are number of observations, unless otherwise stated.

	Titanium (n = 22)	Biodegradable (n = 15)	P value/mean difference (95%CI)
Baseline characteristics:			
Sex:			
Male	6	7	p = 0.30
Female	16	8	
Mean (SD) age (years):	35 (11)	35 (12)	−0.4* (−8.3 to 7.5)
Range	19–59	18–59	p = 0.91
Subgroups:			
Advancement ≤8 mm †	n = 20	n = 15	
Sex:			
Male	6	7	p = 0.48
Female	14	8	
Mean (SD) age (years):	34 (12)	35 (12)	−0.5 (−8.8 to 7.7)
Range	19–59	18–59	p = 0.90
Advancement >8mm†	n = 2	n = 0	
Sex:			
Male	-	-	-
Female	2	-	
Mean age (years):	36	-	-
Range	20–41	-	

* The minus sign indicates that the age in the biodegradable group is higher.
† The cut-off point of 8 mm was chosen according to the criteria of Ferretti and Reyneke.[20] Advancements of more than 9 to 10 mm are considered particularly unstable,[8] and a reduction in overjet during operation of 7 mm is about the upper limit of the average advancement.

There were no significant differences between the 2 groups in variables that might predict relapse in the base of the skull, the maxilla, the intermaxillary relations, and facial height (Appendix A). Analyses of BSSO advancements of 8 mm or less showed no significant difference in relapse between patients treated with the biodegradable or the titanium system (Table 2). We did not analyse advancements of more than 8 mm because there were too few patients.

Variables that might predict relapse: The horizontal amount of advancement at point B was significantly associated with more horizontal relapse at point B in the univariate regression analysis (regression coefficient (B) −0.4 (95%CI −0.8 to −0.1); t = −2.8, df = 36, p = 0.008). The same applied to the horizontal relapse at point Pg (B = −0.4 (95%CI −0.7 to −0.1; t = −2.9, df = 36, p = 0.007)), the vertical relapse at point B (B = −0.3 (95%CI −0.5 to −0.1); t = −3.2, df = 36, p = 0.002) and the vertical relapse at point Pg (B = −0.5 (95%CI −0.7 to −0.2); t = −3.5, df = 36, p = 0.001) (Table 4). Age, female sex, length of mandible, length of the body of the mandible, and the angle of the mandibular plane were not significantly associated with more horizontal and vertical relapse at points B and Pg.

Alpha was set at 0.15 for the univariate analyses, so we made a multiple linear regression analysis for the horizontal relapse at point B for the combination of the predictor variables "female sex" and "horizontal advancement at point B". In this analysis only the horizontal amount of advancement at point B was significantly associated with more horizontal relapse at point B (B = −0.4 (95%CI −0.7 to −0.1); t = −2.3, df = 36, p = 0.03). The same was true for the horizontal (B = −0.4 (95%CI −0.7 to −0.05); t = −2.3, df = 36, p = 0.03) amount of relapse at point Pg, showing that only the amount of advancement was significantly associated with more relapse. In this regression analysis predictive variables were a combination of "female sex" and "horizontal advancement".

Discussion

There were no significant differences in the amount of relapse at points B and Pg after BSSO advancement between patients treated with biodegradable plates and screws from Inion CPS and titanium plates and screws from KLS Martin. This applied to the total group of patients, as well as for advancements of 8 mm or less. We did not analyse larger advancements because we did not have enough patients.

We found that the amount of horizontal advancement at points B and Pg was a predictive variable for the amount of horizontal relapse at points B and Pg, respectively. The same was true for the vertical dimensions at these 2 points. We could not identify age, female sex, length of the mandible, length of the mandibular body, and angle of the mandibular plane as variables that predicted relapse.

Many authors have used different reference lines to measure relapse: surrogate Frankfurter Horizontal (FH) plane,[14–17] the FH plane,[18,19] or the line SN,[7,20] which could explain the differences between studies. In a systematic review on stability after BSSO advancement, Joss and Vassalli identified only one eligible prospective controlled trial that compared biodegradable osteosynthesis with titanium.[6] Ferretti and Reyneke used the same reference line (line SN) as we did.[7] They used a different biodegradable material

Table 4
Predictive variables for relapse (n = 37 in each group for relapse point).

Description	Relapse point B-horizontal Regression coefficient (B) (95%CI) *p*-value	Relapse point B-vertical Regression coefficient (B) (95%CI) *p*-value	Relapse point Pg-horizontal Regression coefficient (B) (95%CI) *p*-value	Relapse point Pg-vertical Regression coefficient (B) (95%CI) *p*-value
Age (years)	0.03 (−0.03 to 0.1) p = 0.27	−0.02 (−0.1 to 0.03) p = 0.39	0.05 (−0.02 to 0.1) p = 0.19	−0.03 (−0.1 to 0.03) p = 0.31
Amount of advancement (difference between T1 and T0)				
Point B-horizontal	−0.4 (−0.8 to −0.1) p = 0.008*	-	-	-
Point B-vertical	-	−0.3 (−0.5 to −0.1) p = 0.002	-	-
Point Pg-horizontal	-	-	−0.4 (−0.7 to −0.1) p = 0.007†	-
Point Pg-vertical	-	-	-	−0.5 (−0.7 to −0.2) p = 0.001
Mandibular length (arm-Me at T0)	0.03 (−0.1 to 0.1) p = 0.53	−0.01 (−0.1 to 0.1) p = 0.87	0.02 (−0.1 to 0.1) p = 0.72	−0.002 (−0.1 to 0.1) p = 0.97
Body length (Go-Me at T0)	0.01 (−0.1 to 0.1) p = 0.94	−0.02 (−0.1 to 0.1) p = 0.71	0.01 (−0.1 to 0.2) p = 0.93	−0.03 (−0.1 to 0.1) p = 0.58
Mandibular plane angle (MnP-SN)‡	−0.03 (−0.1 to 0.1) p = 0.65	0.03 (−0.1 to 0.1) p = 0.44	−0.04 (−0.2 to 0.1) p = 0.58	0.07 (−0.03 to 0.2) p = 0.15
Sex (mean (SD)):				
Female (n = 24)	−0.6 (2.0)	−0.9 (1.2)	−0.6 (2.3)	−0.9 (1.3)
Male (n = 13)	0.7 (1.9)	−1.2 (2.0)	0.7 (2.2)	−1.3 (2.3)
Mean difference relapse (95%CI)	−1.3 (−2.7 to 0.5) p = 0.06*	0.3 (−0.8 to 1.4) p = 0.59	−1.3 (−2.9 to 0.3) p = 0.10†	0.4 (−0.8 to 1.6) p = 0.55

* "α was set at 0.15 for the univariate analyses as described in the methods section, so a multiple linear regression analysis was made for the horizontal relapse of point B for the combination of the predictor variables 'female sex' and 'horizontal advancement of point B'. In this analysis only the horizontal amount of advancement of point B was statistically associated with more horizontal relapse of point B (B = −0.4 (95% CI −0.7 to −0.1); p = 0.03).

† A multiple linear regression analysis was made for the horizontal relapse of point Pg for the combination of the predictor variables 'female sex' and 'horizontal advancement of point Pg'. In this analysis only the horizontal amount of advancement of point Pg was statistically associated with more horizontal relapse of point Pg (B = −0.4 (95%CI −0.7 to −0.05); p = 0.03).

‡ MnP is the mandibular plane according to Steiner: the line through gonion and gnathion.

(Lactosorb) and bicortical screws instead of a plate with monocortical screws as we did. They reported no significant difference in stability at point B (Lactosorb 0.83 (1.25) mm compared with titanium 0.25 (1.38) mm). This is within the same range as the relapse that we measured, but their follow-up was only 1 year. They concluded that Lactosorb screws were a viable alternative to titanium screws for the fixation of BSSO advancements.

Ballon et al. compared 84 non-randomised orthognathic patients treated with plates and screws from Inion CPS or with titanium from Stryker-Leibinger.[21] They reported similar advancement to us for the BSSO advancement group. Horizontal (as well as vertical) relapse at point B for both groups was far more pronounced (Inion 3.65 mm, and titanium 2.09 mm). They used a different reference line (surrogate FH) to measure relapse, the follow-up period for the titanium group was longer (mean follow-up 35 months compared with 28 months in our study), and many of their patients required bimaxillary operations.

Joss and Vassalli[6] found that the amount of advancement was the factor with the strongest influence on relapse after BSSO advancement; the greater the advancement, the larger the relapse. We found the same.

As far as we know Ballon et al. published the only study on long-term stability after treatment with Inion CPS in BSSO advancements. Our study therefore adds definite scientific evidence to the available published reports. There is a certain degree of inaccuracy in defining cephalometric points on cephalograms in general, but our interobserver reliability indicates that our method was accurate.

We conclude that the postoperative skeletal stability 2 years after BSSO advancement did not differ significantly between patients treated with biodegradable plates and screws from Inion CPS and titanium plates and screws from KLS Martin. Given the comparable amount of relapse, the general use of Inion CPS in the treatment of BSSO advancement need not be discouraged. On the basis of other properties, a total picture of the clinical use can be obtained; the short-term stability,[1] the intraoperative switches,[2] the number of plates that required removal,[3] and the cost-effectiveness (will be reported in the near future).

Conflict of interest

We have no conflicts of interest.

Ethics statement, and confirmation of patients' permission

The protocol was approved by the Medical Ethics Committees of the participating hospitals, and all patients provided informed consent to publication of the work.

Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at http://dx.doi.org/10.1016/j.bjoms.2014.06.014.

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