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Segmental stability of resorbable P(L/DL)LA-TMC osteosynthesis versus titanium miniplates in orthognatic surgery☆

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A B S T R A C T

After two decades of the use of resorbable miniplates, new polymer compositions for resorbable osteosynthesis are still being developed to make the handling and outcome of operations even more predictable and give higher stability to the repositioned segments. This study investigates a new resorbable osteosynthesis system in orthognathic patients.

50 patients were treated with P(L/DL)LA-TMC resorbable osteosynthesis and compared to a group of 50 patients treated with titanium miniplates. Segmental stability and relapse were measured comparing preoperative, postoperative and follow-up lateral cephalograms.

Throughout this study, resorbables appeared to be as stable as titanium miniplates except in maxillary elongation and mandibular setback. Here, the titanium miniplates showed significantly higher stability than resorbable plates.

P(L/DL)LA-TMC osteosynthesis seem to have less strength against compressive forces after maxillary elongation and they are less resistant to the forces the tongue exerts, pressing against the mandible after setback. It can therefore be concluded that the resorbable osteosynthesis can be used in the same situations as titanium miniplates except in maxillary elongation and mandibular setback.

1. Introduction

Titanium osteosyntheses have been the standard osteofixation devices for orthognathic surgery for about 25 years now. Many reports have shown that resorbable osteosynthesis give comparable results regarding stability and relapse, but they are still not in general use in many departments. As resorbable osteosynthesis' technology is evolving, new resorbable material compositions and improved performance are intended and achieved (Landes and Ballon, 2006a, b). New osteofixation materials need to be evaluated against the current standard. This study compares a recent resorbable osteosynthesis system of P(L/DL)LA-TMC (Poly L/DL Lactide–Trimethylene-Carbonateas) a copolymer (INION CPS) with standard titanium miniplates with regards to segment stability in orthognathic surgery.

2. Patients and methods

The patients in this study were not randomized or paired, but were asked for their treatment preference and treated accordingly. This was because the individual demands and expectations of patients may not have been me, or perceived to have been met, which could have led to suboptimal functional or aesthetic outcomes. Some of the patients declined treatment with P(L79/DL15)LA-TMC. Permission was obtained from the University Medical Center Ethical Board for the treatment with INION resorbable osteosynthesis.

From 2002 on, all patients were operated after ISO 9001:2001 certification and the declaration of Helsinki was strictly followed.

All patients in the INION CPS group signed a detailed informed consent for the use of the resorbable osteosyntheses.

84 patients were enrolled in this study (41 in the study group; 43 in the control group). Patients with cleft lip and palate were excluded from the study; others with systemic or general diseases were not excluded.

Patients were divided into a P(L/DL)LA-TMC group which used INION CPS (amorphous injection molded copolymer of P(L/DL) LA-TMC copolymers (Poly L/DL Lactid-Trimethylenecarbonate),

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Manufacturer: INION OY, Tampere, Finland), 2.0 mm for maxillary and 2.5 mm for mandibular osteosyntheses and a control group who received standard titanium osteosyntheses (2.0 mm Standard Würzburg Miniplattesystem; Stryker-Leibinger, Tuttlingen, Germany).

2.1. Study group

Among the 41 Patients in the INION CPS group there were 20 male and 21 female patients whose ages ranged from 16 to 46 years (mean 24). Ten patients had Angle class II, 31 had Angle class III. 38 patients received bimaxillary surgery, three received a Le Fort I osteotomy, none had a BSSO alone.

2.2. Controls

This group consisted of 22 male and 21 female patients with a range from 16 to 57 (mean: 25). Nine patients had Angle class II, 34 had Angle class III. 24 patients received bimaxillary surgery, 15 received only a Le Fort I osteotomy, four BSSO alone.

2.3. Operative technique

Resorbable maxillary osteosynthesis was performed with four resorbable, 2.0 mm 4-hole L-plates, fixed with 6 mm screws (Figs. 1 and 2). The standard procedure used two plates in the paranasal region and two on the infrazygomatic crest, fixed with two screws to each segment.

Resorbable mandibular osteosynthesis was accomplished with one straight 2.5 mm 4-hole plate on each ascending ramus, fixed with 6 mm monocortical screws, two in each segment (proximal and distal) (Fig. 3). In elongation and advancement, straight plates with a step were used to bridge the gap and no bone grafts were used for reinforcement.

Maxillary titanium osteosynthesis was performed with 2.0 mm four L-plates, each 4-hole plate being, fixed with 6 mm screws. The standard procedure used two plates in the paranasal region and two on the infrazygomatic crest fixed with two screws to each

Fig. 1. Intraoperative photograph. Fixation of an INION CPS plate on the right zygomatic crest. A mechanically delivery system (Tacker) is used in this case.

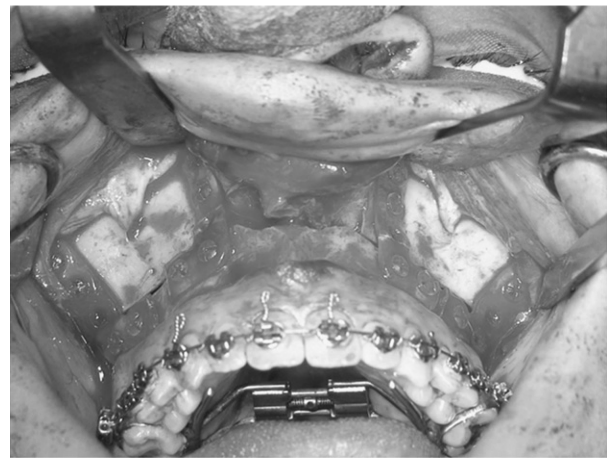

Fig. 2. The picture shows the fixation of a Le fort I osteotomy after impaction and slight advancement. The maxillary bone has been fixated with four L-shape 5-hole plates. Upper and lower segment have been fixated with two 6 mm screws in each segment while the middle hole bridges the osteotomy gap.

Fig. 3. Fixation of the right mandibular ramus after Obwegeser osteotomy and mandibular angle rotation. One straight 4-hole plates with bridge fixates the osteotomy site with two 8 mm screws in the proximal and distal segment. A slight torque has been prebent to have the plate fit in the ideal position.

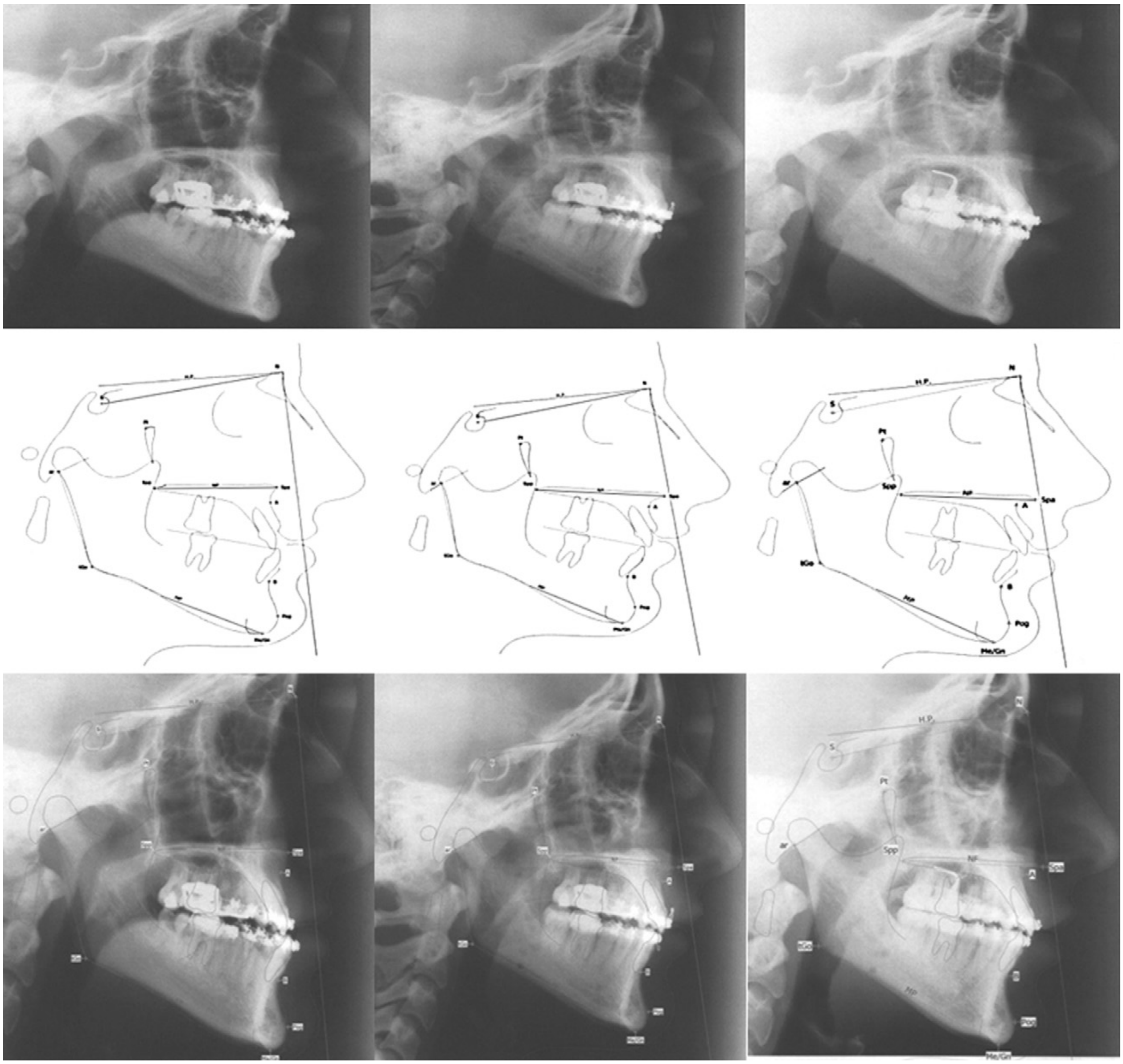

Fig. 4. The upper row of cephalograms shows the change between preoperative, postoperative and follow-up situation in an Angle class III case. The middle row shows the cephalometric analysis, the lower row the superimposition of the marks on the lateral cephalograms. It is obvious that between the postoperative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

segment. Mandibular titanium osteosynthesis was accomplished with one 2.0 mm straight 4-hole plate on each ascending ramus, fixed with 6 mm monocortical screws, two in each segment. In elongation and advancement straight plates with connecting bar were used to bridge the gap and no bone grafts were used for reinforcement.

Operative positioning was planned on lateral cephalograms, evaluation of photographs and plaster models. According to the planning, intraoperative plastic positioning wafers were manufactured by the operators in model surgery. Two splints were used for bimaxillary surgery and one for single jaw surgery.

Postoperatively, patients were put on a soft diet for 6 weeks; from the seventh to the twelfth week, all foods that did not require hard mastication were allowed.

No rigid wire fixation was used. Instead, from the second postoperative day elastic bands were used for guided occlusion with an occlusal splint for 2–6 weeks.

Table 1
Evaluation of the cephalometric analysis in the Le Fort I level. Horizontal movement and relapse for advancement, vertical movement and relapse for elongation.

		N	Mean	Standard deviation	Sig. (2-tailed)
HMA	INION CPS	26	2,70	1,94	0,010
	Titanminiplatte	29	4,28	2,37	
HRA	INION CPS	26	1,84	1,69	0,558
	Titanminiplatte	29	1,59	1,48	
VMA	INION CPS	21	5,22	4,05	0,039
	Titanminiplatte	19	2,92	2,64	
VRA	INION CPS	21	2,68	2,65	0,073
	Titanminiplatte	19	1,39	1,55	

HMA: Horizontal Movement at A-Point; HRA: Horizontal Relapse at A-Point; VMA: Vertical Movement at A-Point; VRA: Vertical Relapse at A-Point

2.4. Radiographic examinations

All patients had preoperative, postoperative and follow-up X-rays. A lateral cephalogram was used in all cases. All X-rays were done with the same X-ray apparatus. Preoperative X-rays were taken no earlier than 3 months prior to operation. Postoperative X-rays were taken immediately when the splint and guided occlusion were in place after operation (between second postoperative day and second week) and follow-up was intended to be taken 12 months after surgery. In the study group, mean radiological follow-up was 13 months (7–27 months), in controls mean follow up was 35 months (6–113 months). Previous studies (Kiely et al., 2006; Landes and Ballon, 2006a, b; Landes et al., 2007) have shown that relapses occur up to 1–1.5 years. All changes after that point result from postoperative orthodontic changes or, in younger patients, are secondary to postoperative growth (Proffit et al., 2007).

All radiological controls were in conjunction with a clinical examination. Cephalometric analysis compared the pre- and postoperative craniofacial changes (Burstone et al., 1978) and the follow-up. All cephalometry was performed using Onyx Ceph®, (Image Instruments, Chemnitz) and tracings were marked on scanned lateral cephalograms. Figure 4 shows the process. All measurement was done by one experienced examiner to calculate the absolute measurement error. Ten percent of a random selection of scans was traced by a second surgeon for assessment of the intraobeserver error. In both examiners the mean point setting deviation was 1 mm around a centerpoint.

Effective maxillary horizontal movement was measured at A-point to Nasion between pre- and postoperative cephalograms in millimeters; effective relapse was measured between postoperative and follow-up cephalograms. Effective vertical maxillary movement was assessed between ANS (Anterior Nasal Spine) and Nasion in millimeters.

Effective horizontal mandibular movement was measured between B-point and Nasion in millimeters, effective vertical mandibular movement was measured as angle between Articulare-Gonion-Gnathion in degrees (see Landes and Ballon, 2006a, b for methodology).

2.5. Operative procedures

Altogether 212 resorbable plates and 240 titanium plates were used.

The study group included 26 maxillary advancements at, 14 setbacks, 18 impactions and 21 elongations. The control group included 29 maxillary advancements, 10 setbacks, 20 impactions and 19 elongations.

In the mandible the study group included 11 advancements, 27 setbacks, 20 clockwise rotations and 14 counterclockwise rotations. The control group included 17 mandibular advancements, 11 setbacks, 15 clockwise rotations and 13 counterclockwise rotations.

The number of patients varies between single groups and the overall total because patients with movements in more than one direction were counted twice for different groups.

2.6. Intraoperative management

Because we had long experience in the use of resorbable osteosynthesis materials in our facility, it took no extra time to learn the handling with screws and plates. Compared to the time needed for bending of the titanium plates, no extra time was required in comparison to the bending of the resorbables. The plates are activated in a 55° water bath and can then be bent for approximately 10–15 s. The procedure was repeated up to three times if necessary.

Table 2
Evaluation of the cephalometric analysis in the Le Fort I level. Horizontal movement and relapse for setback, vertical movement and relapse for impaction.

		N	Mean	Standard deviation	Sig. (2-tailed)
HMA	INION CPS	14	3,46	2,63	0,811
	Titanminiplatte	10	3,70	2,10	
HRA	INION CPS	13	2,02	1,89	0,679
	Titanminiplatte	10	1,70	1,64	
VMA	INION CPS	18	3,13	2,25	0,852
	Titanminiplatte	20	3,25	1,55	
VRA	INION CPS	18	2,67	2,08	0,033
	Titanminiplatte	20	1,40	1,42	

HMA: Horizontal Movement at A-Point; HRA: Horizontal Relapse at A-Point; VMA: Vertical Movement at A-Point; VRA: Vertical Relapse at A-Point

Table 3
Evaluation of the cephalometric analysis in BSSO. Horizontal movement and relapse for advancement, vertical movement and relapse for clockwise rotation.

		N	Mean	Standard deviation	Sig. (2-tailed)
HMB	INION CPS	11	4,89	3,67	0,520
	Titanminiplatte	17	4,09	2,84	
HRB	INION CPS	11	3,65	3,39	0,171
	Titanminiplatte	17	2,09	1,43	
VMB	INION CPS	20	7,75	6,18	0,426
	Titanminiplatte	15	9,57	7,13	
VRB	INION CPS	20	4,55	3,52	0,030
	Titanminiplatte	15	10,63	9,47	

HMB: Horizontal Movement at B-Point; HRB: Horizontal Relapse at B-Point; VMB: Vertical Movement at B-Point; VRB: Vertical Relapse at B-Point

Table 4
Evaluation of the cephalometric analysis in BSSO. Horizontal movement and relapse for setback, vertical movement and relapse for counter-clockwise rotation.

		N	Mean	Standard deviation	Sig. (2-tailed)
HMB	INION CPS	27	9,31	5,46	0,688
	Titanminiplatte	11	8,55	4,85	
HRB	INION CPS	27	4,86	2,87	0,000
	Titanminiplatte	11	1,05	1,31	
VMB	INION CPS	14	4,79	3,09	0,358
	Titanminiplatte	13	6,50	6,06	
VRB	INION CPS	14	6,36	4,86	0,544
	Titanminiplatte	13	5,00	6,53	

HMB: Horizontal Movement at B-Point; HRB: Horizontal Relapse at B-Point; VMB: Vertical Movement at B-Point; VRB: Vertical Relapse at B-Point

The rate of broken screws was two percent. When they occurred, a new hole was drilled through the fractured screw and a new replacement screw was inserted.

2.7. Statistical analyses

Spreadsheet analyses were performed with SPSS (statistical Package Social Science 16.0 SPSS Company, Chicago, Il.). As statistical method the Shapiro-Wilks and independent *T*-test (level for significance $p < 0.05$) was used.

3. Results

The operative procedures in the maxilla are given in Tables 1 and 2 subdivided into advancement, setback, impaction and elongation. The procedures in the mandible are given in Tables 3 and 4 subdivided into advancement, setback, clockwise-rotation and counter-clockwise-rotation in Gonial angle.

Table 1 shows horizontal maxillary movement and relapse in advancement and elongation. The table shows a significantly

Table 5
Movement, short and long term mean relapse in mm of maxillary advancement, elongation, intrusion, mandibular advancement and mandibular setback with wire fixation, miniplates, monocortical screw fixation (rigid internal fixation) or resorbable fixation.

Authors		Fixation	Number of patients	Bone graft	MMF (weeks)	**Maxillary advancement**	Postoperative relapse	1 year follow-up relapse
Van Sickels et al.	1986	Rigid internal fixation	19	No	Wire (6)			
Hiranaka and Kelly	1987	Wire osteofixation	4	Yes	Wire (6)	**3.3**	0.3	
Skoczylas et al.	1988	Wire osteofixation	15	No	Wire (6)	**1.5**	0.15	
Proffit et al.	1991/92	Wire osteofixation	21	Yes	Wire (6)	**4.4**	0.1	
Louis et al.	1993	Rigid internal fixation	20	No	No	**9**		0.9
Hoffman et al.	1994	Rigid internal fixation	15	No	Elastics	**6**	0.03	0.6
Hoffmann and Moloney	1995	Rigid internal fixation	15	No	Elastics (4)	**9**		0.6
Haers and Sailer	1998	(P(L/DL)LA) plates and screws	10	Yes	Elastics	**2.9**	0.1	
Mobarak et al.	2000	Rigid internal fixation (3 bicortical fixation screws)	80	n. s.	n.s.			
Arpornmaeklong et al.	2003	Rigid internal fixation	29	No	Elastics (4)	**2.6**		
Landes and Ballon	2005	P(L/DL)LA plates and screws	19	No	Elastics (4)	**3.5**		0.2
This study	2010	P(L/DL)LA-TMC plates and screws	41	No	Elastics (4)	**2.7**		1.8
This study	2010	Titanium plates and screws	43	No	Elastics (4)	**4.3**		1.5

higher horizontal movement for the titanium plates ($p = 0.01$) whereas the relapses are nearly equal. Thus, titanium plates appear to be stronger than the resorbables.

In the vertical direction in elongation the INION CPS group shows a significantly higher movement ($p = 0.039$) but no significantly higher relapse ($p = 0.073$). This indicates more stability for the resorbables.

Table 2 shows horizontal maxillary movement and relapse in setback and impaction.

Horizontal movement is comparable for both groups and both plating systems show a similar relapse rate. The vertical *movement* is comparable between groups whereas the INION CPS group shows a significantly higher *relapse* rate ($p = 0.033$)

Table 3 shows horizontal mandibular movement and relapse for advancement and clockwise rotation. Horizontal movement and relapse are comparable. Vertical movement is comparable, but titanium osteosynthesis shows a significantly higher relapse ($p = 0.03$).

Table 4 shows horizontal mandibular movement and relapse for setback and counterclockwise rotation. Setback is comparable between both groups but the INION CPS group showed a significantly higher relapse ($p = 0.00$). Vertical movement is comparable as well as the vertical relapse.

Comparing clinical parameters, both groups suffered the same adverse effects such as swelling or paraesthesia. These effects are non-specific for a plating system. In the INION CPS group, no foreign body granuloma occurred throughout this study. The slow resorption of the INION CPS osteosynthesis over 2 years may be the background of these findings.

Thus this was not the first resorbable osteosynthesis system used in our facility and the surgeons where accustomed to the operative process when using resorbable plates. There was no difference in the mean duration of the operation between the groups.

Individual and interindividual standard measurement error, while setting the tracings on the lateral cephalograms, was 1 mm around a central point. This is within the general error described by Proffit (Proffit et al., 2007).

4. Discussion

According to the results shown above, the INION CPS group had a larger *maxillary advancement* with a relapse equal to the study group. As higher movements have higher relapses (Kiely et al., 2006), this would suggest that the titanium plates are more stable in advancements. This is also supported within other studies (Proffit et al., 1991c; Araujo et al., 2001; Bailey et al., 2004). According to Araujo, titanium plates show more long-term stability through elastic response, although maxillary advancement is the second stable category of three described by Bailey (Bailey et al., 2004).

Maxillary elongations are generally problematic for relapse, because they are less stable than other directions (Proffit et al., 1991c; Gosain et al., 1998; Bailey et al., 2004). In our study, no bone reinforcements have been placed in the osteotomy gaps and the plates had to withstand the whole load. Relapse of 2–4 mm in 50% and over 4 mm in 20% of a study group are described by Proffit (Proffit et al., 2007). In this study, the study group had higher movements than the controls (4.9 mm–1.3 mm) with more relapse then the control group (2.9 mm–1.3 mm). This would suggest that the resorbables are less stable than the titanium plates. Resorbables had the larger movements, which may have led to the higher relapse rate. In an earlier study from the authors with other resorbable osteosynthesis systems no significant instability was found between resorbables and titanium plates (Landes and Ballon, 2006a, b; Landes et al., 2007).

The clinical follow-up revealed a phenomenon within the study group: the impression that after 1 week, the maxilla elongated a bit only to re-impact after 4–6 weeks. If the postoperative X-ray controls took place in the elongation period, the follow-ups are in the time when re-impaction had taken place. This leads to the false conclusion, that initially more elongation occurred and then a larger relapse was seen. This, was just a clinical impression, elongation may have been due to the elasticity of the resorbables, while intermaxillary guided occlusion was maintained by elastic bands. For accuracy, X-rays were taken immediately after the operation without intermaxillary guided occlusion.

In *maxillary setback* both groups had the same movement and relapse. These findings correspond with the findings of other studies (Kiely et al., 2006; Landes and Ballon, 2006a, b; Landes et al., 2007) that describe setbacks as a stable movement.

In the vertical dimension, both groups were impacted equally. The resorbables showed significantly more relapse here than the controls. As movement in this direction is described as highly stable (Bailey et al., 2004; Proffit et al., 2007) and the relapse is in the limits of the measurement error (1 mm), no importance was given to these results.

In *mandibular advancement* operative movement and relapse were comparable. These results correspond with the results by

Intrusion	Postoperative relapse	1 year follow-up relapse	Elongation	Postoperative relapse	1 year follow-up relapse	Mandibular advancement	Postoperative relapse	1 year follow-up relapse	Mandibular setback	Postoperative relapse	1 year follow-up relapse
						5.5		0.4			
3.5	0.6					**9.8**	2.1				
2.9	0.6					**5.1**	0.9		**9**	2.3	
			2	1.3					**4.6**		4.2
			1.3	0.3		**12.7**	0.2				
1.8	4		**2.3**	0.6		**2.8**	1.2		**4**	1.1	
									6.9		1.3
4.3						**10.7**					
1.9		0.2	**4.2**		2.0	**4.6**		2	**7.5**		1.2
3.1		2.7	**5.2**		2.7	**4.9**		3.7	**9.3**		4.9
3.3		1.4	**3**		1.4	**4.1**		2.1	**8.6**		1.5

other authors (Landes and Ballon, 2006a, b; Landes et al., 2006; Proffit et al., 2007). Anterior positioning of the mandible is a movement with generally high stability.

Regarding *mandibular setback* the results are different. While the movement is comparable (9.9 mm–8 mm), the resorbables show a significantly higher relapse (4.6 mm–1.4 mm). This direction has been described as highly stable (Turvey et al., 2002) from some authors. Others describe relapses in setbacks of the mandible (Bailey et al., 2004; Proffit et al., 2007). One possible factor may have been that the position of the tongue is moved backwards in the more dorsal position. Therewith the tongue presses against the mandible, forcing it into a more anterior position (Kim et al., 2009). In previous studies by the authors into resorbable systems (Landes and Ballon, 2006a, b; Landes et al., 2007) no difference in relapse was found between resorbable and titanium plates. Thus, one INION CPS osteosynthesis plate on each side may be not stable enough to prevent a relapse in mandibular setback. Another possible answer could be that the relapse is based on the postoperative settling of the mandibular condyles, which in our patients have been positioned accurately intraoperatively by ultrasonographic control.

The measurements for clockwise and counterclockwise rotation have to be interpreted with care. Through overexposure in the cephalometric X-rays, the mandibular angle cannot always be traced in the ideal position. It is even more difficult to reproduce the tracings on all three cephalograms. As in others studies, there are many ways for interpretation. While in this study titanium plates are less stable than the resorbables in clockwise rotation, they are of equal stability in counterclockwise rotation. Kim et al. (Kim et al., 2009) showed high relapse rates with clockwise rotation for resorbable plates while titanium plates are more stable. Previous studies showed stable results for both directions (Landes and Ballon, 2006a, b; Landes et al., 2007). As a general statement for rotational movement, we conclude that rotations in the mandibular angle are difficult to measure on the one hand and on the other, advancement and setback bring more influence to the results in the mandible than they do in the maxilla due to the submandibular muscles and the hyoid bone. These factors are difficult to measure and they are not yet fully understood. Further studies are encouraged to bring more definite results.

5. Conclusion

Like previous studies (Landes and Ballon, 2006a, b; Eppley, 2007; Landes et al., 2007) resorbable osteosynthesis systems can be used in the most movement directions and are comparable to titanium miniplates regarding stability. These differences in this study can be interpreted in different ways. Many studies (Proffit et al., 1991a, b; Eppley, 2007; Proffit et al., 2007; Goncalves et al., 2008) describe only one or two directions in mainly healthy patients, so the results are easier to interpret. These groups do not compare with the group in this study. Some of them had major general diseases or/and had bimaxillary surgery and were evaluated in six sagittal directions. The outcome is then much more difficult to predict and relapse may occur more often. Modern orthognathic surgery cannot be reduced to only one or two directions and a separate analysis of the movements is less significant.

Is it then reasonable to compare all these studies? Table 5 gives an overview of some of the literature on this issue (Arpornmaeklong et al., 2003; Haers and Sailer, 1998; Hiranaka and Kelly, 1987; Hoffman and Moloney, 1995; Hoffman et al., 1994; Landes and Ballon, 2006a, b; Louis et al., 1993; Mobarak et al., 2001; Proffit et al., 1991a, b; Skoczylas et al., 1988; Van Sickels et al., 1986)

A general answer is difficult and the problems are too complex to reduce them only to the plating system. It can be concluded that resorbable INION CPS osteosynthesis can be used as an alternative to titanium osteosynthesis, bearing in mind the higher relapse in maxillary elongation and mandibular setback. Longer postoperative intermaxillary retention may be used as well as overcorrection to compensate the higher relapse rate in these movements or the use of additional plates on each side may have to be considered.

5.1. Clinical consequences

Resorbable INION CPS osteosynthesis can be used with equivalent outcomes to titanium miniplates except in maxillary elongation and mandibular setback. Overcompensation and longer intermaxillary retention are needed in these directions and the ascending ramus should be double-plated on each side while performing mandibular setback.

Conflict of interest

The authors had full freedom of investigation and there were no potential conflicts of interest. There was no grant support for this study.

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