Journal of Cranio-Maxillo-Facial Surgery (2010) **38**, 517–521

doi:10.1016/j.jcms.2010.02.013, available online at http://www.sciencedirect.com

Pullout strength of a biodegradable free form osteosynthesis plate

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SUMMARY. **The Inion® Free Form Plate is a newly designed biodegradable plate. After drilling through the plate and tapping, a biodegradable screw can be inserted, followed by removal of the screw head. As an alternative a countersink screw can be used. Aim of the study was to compare the mechanical properties of the 1.4 mm Free Form Plate with the 2.0 mm conventional shaped plate. Mechanical testing of the plate pullout strength was conducted for the Inion® Free Form Plate fixed with an Inion OTPS™ 2.0 × 20 mm Screw. In addition, the failure mode was reported. Overlapping confidence levels were found with regard to the yield load, first peak load and maximum load, when comparing the Free Form Plate and the conventional 4-hole plate. The Free Form Plate fixed with a screw with head and countersink showed the highest stability at maximum load. The results of the mechanical stability testing showed no significant differences between the tested plates. The main failure mode was a failure of the screw shaft. The results of the current investigation imply that the 1.4 mm Free Form Plate could be used as an alternative to the 2.0 mm conventional shaped plate. © 2010 European Association for Cranio-Maxillo-Facial Surgery**

Keywords: **biodegradable materials, osteosynthesis, mechanical testings, pullout strength, polylactide**

INTRODUCTION

Biodegradable osteosynthesis materials are well-established in maxillofacial surgery (*Tams* et al., 2001; *Yerit* et al., 2005a, b), being well-documented by numerous publications in the last decade (*Haers* et al., 1998; *Bahr* et al., 1999; *Kallela*, 1999a, b; *Enislidis* et al., 2005; *Eckelt* et al., 2007). They have been used for craniofacial and pediatric fractures (*Shetty* et al., 1997; *Gosain* et al., 1998; *Yerit* et al., 2005a, b), midfacial fractures (*Bahr* et al., 1999; *Bell* and *Kindsfater*, 2006), mandibular fractures (*Tormala* et al., 1987; *Bos et al.*, 1989; *Gerlach*, 1993; *Tams* et al., 1999, 2001; *Hasirci* et al., 2000; *Wiltfang* et al., 2000; *Yerit* et al., 2002; *Ylikontiola* et al., 2003; *Bell* and *Kindsfater*, 2006; *Rasse* et al., 2007) and orthognathic surgery (*Suuronen* et al., 1992a, b, 1997; *Maurer* et al., 2002). Many patients still undergo the removal of titanium plates because of temperature sensitivity, palpation of the plates or the unacceptability of an incorporated foreign-body. The advantage of biodegradable materials is the degradation of the material over a period of 12–24 months. Until now, biodegradable materials have had to be thicker than titanium to achieve the same mechanical stability (*Ferguson* et al., 1996a, b; *Maurer* et al., 2001; *Leinonen* et al., 2003). This has resulted in surgeons' and patients' complaints regarding the bulkiness of the material especially in the first six postoperative months. Therefore, research on biodegradable osteosynthesis materials should focus on the reduction of the materials size when compared to titanium plates. When considering the Inion® System, the 2.0 mm biodegradable plates are indicated for use in the midface (*Wood*, 2005). The stability of the 2.0 mm system is comparable with conventional 1.5 mm titanium systems (*Wood*, 2005). Recently, a new plate design has been introduced: The Inion® Free Form Plate (Fig. 1) is a plate which has a thickness of 1.4 mm. The plate has no prefabricated holes, only pilot holes to guide the drill. It is also possible to drill through the plate in a position without a pilot hole. After drilling there are two ways of inserting a screw: 1. Inserting a conventional screw with a countersink and 2. Inserting a screw after tapping the hole and then cutting off the screws head.

The 1.4 mm Free Form Plate was designed to achieve the same mechanical stability as the 2.0 mm conventional plates. The aim of the study was to evaluate the mechanical pullout strength of the 1.4 mm Free Form Plate when compared to the 2.0 mm conventional plate.

MATERIAL AND METHODS

Two different sizes of the Inion® Free Form Plate are manufactured. One of which is 65 mm and the other

100 mm long. The width of the plates is 20 mm and the thickness 1.4 mm. The diameter of the pilot holes is 1 mm. The distance between the adjacent pilot holes is 6.5 mm and the displacement between the pilot hole columns is 3.25 mm (Fig. 1). The manufacturing process consists of extrusion, compression molding and laser cutting. The plates are designed to allow for them to be cut and shaped to the desired form during use. Only the pilot holes which are going to be used are drilled and tapped for screws (holes can also be drilled and tapped at other positions on the plate if needed). Countersinks for the screw heads can be created on the surface of the plate or, alternatively, the screw heads can be removed after screw insertion.

In this study, two different types of fixation for the Inion® Free Form Plate were created and tested. The first fixation of the plate was created by drilling and tapping the pilot hole and cutting off the screw head on the surface of the plate after screw insertion. The second fixation of the plate was created by drilling the pilot hole and creating a countersink for the screw head on the surface of the plate. In these cases of countersink fixation the screw head was not cut and the plate was not tapped. The mechanical testing of plate pullout strength was conducted using the plate secured with an Inion OTPS™ 2.0 × 20 mm Screw.

The testing was generally conducted by following the guidelines of the FDA draft: *Guidance Document for Testing Biodegradable Polymer Implant Devices* and ISO 15814, ASTM F543 and ASTM F1839-standards.

After water bath treatment (one minute at 70 °C) the test sample plate was created by cutting the Inion® Free Form Plate to an approximate size of 20 mm × 20 mm. The pilot hole, located in the middle of the test sample, was drilled and tapped or drilled and countersunk for the screw. The appropriate hole was also drilled and tapped in an underlying foam block (20 mm × 40 mm × 45 mm). Finally the test sample was fixed to the foam block and test jig by one Inion OTPS™ Screw as shown in Figs. 2 and 3. When the hole in the test sample plate was tapped, the screw head was cut off after insertion on the surface of the plate by cutting forceps. When the countersink was created on the plate, the screw head was not cut off after insertion (Fig. 2).

Water bath treatment (1 min at 55 °C) was conducted for the Inion OTPS™ 2.0 mm System extended 4 Hole Plates, according to the manufacturers' guidelines for the product line. The appropriate hole was drilled and tapped in the foam block (20 mm × 40 mm × 45 mm) through the hole of the plate. Finally the plate was fixed to the foam block and test jig by one Inion OTPS™ Screw as shown in Fig. 2. The screw head was not cut off after insertion and a countersink was not created on the plate.

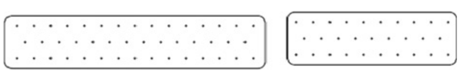

Fig. 1 – The Inion® Free Form Plate, 20 × 100 mm, on the left and the Inion® Free Form Plate, 20 × 65 mm, on the right. Notice that pictures are not in real scale.

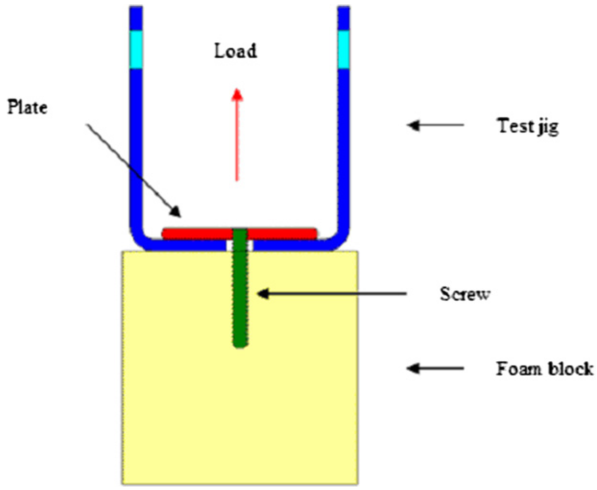

Fig. 2 – The schematic drawing of the test setup of the Inion® Free Form Plate test sample fixed with screw, foam block and test jigs. The direction of the load is shown with a red arrow.

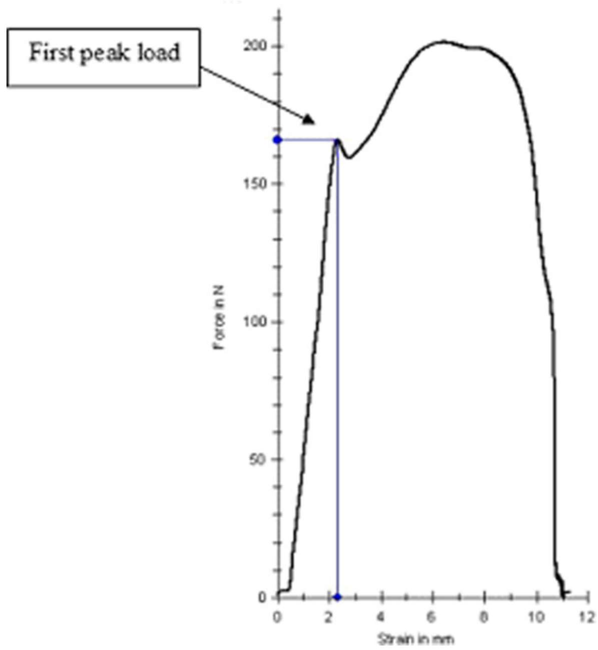

Fig. 3 – Determination of the first peak load from the stress–strain curve.

The test setup (i.e., test jig) decreases the effective length (i.e., the part of the screw which is inside the foam block) of the screw threads approximately 1.5 mm in comparison to the clinical situation (Fig. 2).

Prior to testing the sample plate, the screw attached to the foam block and the test jig were all conditioned in ionized water at 37 °C for 24 h.

The plate pullout testing was performed in water at 37 °C. The foam blocks were connected to the material testing machine by specially designed test jigs. Once connected the plate was loaded (pullup) with a constant speed of 5 mm/min until failure of the fixation. The yield load (N), first peak load (N), maximum load (N), corresponding strains (mm), stiffness (N/mm) and the failure mode of fixation were determined and recorded. The first peak load was determined from the stress–strain curve as shown in Fig. 3. A total of four of each plate–screw combinations were tested. Standard errors have been calculated using the standard normal approximation for estimating proportions: $\sqrt{\frac{p(1-p)}{n}}$ (*Tormala* et al., 1987). Data analysis was carried out with SPSS 7.5 (SPSS Inc.).

The mechanical test (plate pullout) was judged to be successful if there were equivalent or better (95 % confidence level) first peak loads (N) in plate pullout test for both fixations (i.e., headless screw and countersunk screw) of the Inion® Free Form Plate with 2.0 × 20 mm screw when compared to the fixation of the Inion OTPS™ 2.0 mm System extended 4 Hole Plate with 2.0 × 20 mm screw.

RESULTS

Table 1 summarizes the results of the plate pullout test of the Inion® Free Form Plate 2.0 mm headless screw and 2.0 mm screw with head and countersink in comparison to the Inion OTPS™ 2.0 mm System extended 4 Hole Plate with 2.0 mm screws. Based on the calculated 95% confidence levels, the confidence intervals of the measurements of the Inion® Free Form Plate with both 2.0 mm screws overlap in comparison to the confidence intervals of the measurements of the Inion OTPS™ extended 4 Hole Plate with the 2.0 mm screw. Overall the first peak loads of the Inion® Free Form Plate with both 2.0 mm screws are the same as the first peak load of the Inion OTPS™ extended 4 Hole Plate with 2.0 mm screw in the plate pullout test.

The failure mode (Table 2) for the Inion® Free Form Plate with the 2.0 mm headless screw was a failure of the plate–screw interface. The failure modes for the Inion® Free Form Plate with the 2.0 mm screw with head and countersink and for the Inion OTPS™ extended 4 Hole Plate with the 2.0 mm screw were failures of the screw shafts. Table 2 shows the strain at yield load. The confidence levels of the Free Form Plates and the 4-hole plate overlap, indicating no significant difference in the strain between the tested plates.

Looking at first peak load, overlapping confidence intervals were found between the Free Form Plate results with the headless screws and the 4-hole plate, while the Free Form Plate with a screw with head and countersink showed significantly higher pullout strength.

Regarding the strain at first peak load (Table 1), overlapping confidence intervals were found. Evaluation of the maximum load (Table 1) shows that the Free Form

Table 1 – Results of the mechanical testings of the Free Form plate

Investigated parameters	Screw	Ave.	Stdev.	95% Confidence level
Yield load (N)	Headless	58.89	4.73	53.27–64.50
	Head and countersink	67.94	11.68	56.59–79.39
	Normal	70.69	9.33	61.55–79.83
Strain (mm) at yield load	Headless	0.74	0.22	0.52–0.95
	Head and countersink	0.70	0.08	0.63–0.77
	Normal	0.60	0.05	0.55–0.65
First peak load (N)	Headless	65.24	6.70	58.67–71.80
	Head and countersink	77.04	1.87	75.21–78.27
	Normal	73.30	9.51	63.98–82.61
Strain (mm) at first peak load	Headless	0.89	0.21	0.69–1.09
	Head and countersink	0.88	0.12	0.76–0.99
	Normal	0.66	0.05	0.61–0.71
Maximum load (N)	Headless	65.24	6.70	58.67–71.80
	Head and countersink	77.04	1.87	75.21–78.87
	Normal	73.59	9.22	64.44–82,53
Strain (mm) at maximum load	Headless	0.89	0.21	0.69–1.09
	Head and countersink	0.88	1.12	0.76–0.99
	Normal	0.69	0.05	0.64–0.74
Stiffness	Headless	87.21	18.65	68.93–105.48
	Head and countersink	99.68	12.71	87.23–112.14
	Normal	122.53	11.43	111.33–133.74

Table 2 – Failure modes of the tested plates

Sample	Screw	1	2	3	4
Inion® Free Form Plate	Headless	**	***	**	**
Inion® Free Form Plate	With head and countersink	***	***	***	***
Inion® OTPS™ 4 Hole Plate	Normal	***	***	***	***

*Screw-pullout, **failure of plate–screw interface, ***failure of screw shaft.

Plate with head and countersink had a significantly higher value than the Free Form Plate with the headless screw. The confidence levels of both Free Form Plates overlapped with the 4-hole plates' confidence level. The strain at maximum load (Table 1) shows overlapping confidence levels in all three plates.

The evaluation of the stiffness (Table 1) shows overlapping confidence levels between both Free Form Plates and a significantly higher stiffness of the 4-hole plate.

The evaluation of the failure mode (Table 2) shows that the Free Form Plate with the headless screws showed a failure of the screw shaft in one screw (screw 2) while the other screws showed a failure of plate—screw interface. The failure modes of the Free Form Plate with countersunk screw heads and the 4-hole plate were failures of the screw shafts in all cases.

DISCUSSION

Biodegradable plates have to be thicker than titanium plates to achieve the same stability as titanium (*Tormala* et al., 1987; *Wittenberg* et al., 1991; *Suuronen* et al., 1992a, b, 1998; *Tormala*, 1992; *Ferguson* et al., 1996a, b; *Shetty* et al., 1997; *Maurer* et al., 2001; *Leinonen* et al., 2003).

In the case of the Inion® biodegradable osteosynthesis system the OTPS™ 2.0 mm System shows equivalent stability to conventional 1.5 mm titanium systems (*Wood*, 2005), leading to the indication for midfacial fractures (*Bahr* et al., 1999; *Bell* and *Kindsfater*, 2006). Many maxillofacial surgeons working with biodegradable osteosynthesis systems have been unhappy with the bulkiness of the plates, especially in the infraorbital region. Therefore new plate designs should aim to reduce the thickness of the biodegradable plates to be comparable with titanium plates used in the same anatomical areas. The current investigation shows that the principle of tapping through the plate leads to an increase of stability of the plate—screw interface. The results of the mechanical testings show that the confidence levels of the Free Form Plates, either fixed with a screw with head and countersink or with a headless screw, show the same stability as the conventional 2.0 mm plate. These results are comparable at yield load, first peak load and maximum load. Considering the maximum load, the Free Form Plate fixed with a screw with head and countersink showed the highest mechanical stability followed by the conventional 2.0 mm 4-hole plate and the Free Form Plate with the headless screw. Evaluation of the stiffness shows that the conventional 4-hole plate demonstrates the highest stiffness followed by the two Free Form plates. Comparison of the confidence interval of strain at yield, first peak and maximum load also shows overlapping confidence levels. These results can be explained by the fact that the strain depends on the diameter of the screws used but not on the shape and thickness of the plate.

This test setup reduces the length of the screw about 1.5 mm compared to the clinical situation. There was no screw-pullout from the foam block detected. Therefore, the test setup has no influence on the screw—foam interface and the results could be considered comparable to the clinical situation. The principle of tapping the biodegradable plate before inserting the screw leads creates a kind of "locking system" between plate and screw, which is already well-known in titanium plates. This locking system could be one explanation for the high stability of the 1.4 mm biodegradable Free Form Plate.

Extrapolating the results to the clinical situation, the Free Form Plate allows holes to be drilled only in the necessary positions which reduces the number of empty holes weakening the plates' stability. Improved stability of the Free Form Plate is postulated, because the ideal size could be cut from the Free Form Plate. Such an ideally adapted plate should lead to increased three-dimensional stability compared to the conventional prefabricated biodegradable plates.

CONCLUSION

The results of the current investigation suggest that the 1.4 mm Free Form Plate could be used as an alternative to the 2.0 mm conventional shaped plate. Further studies need to be performed to confirm the current results in a clinical setting.

CONFLICT OF INTEREST

Any financial and personal relationships with other people or organizations that could inappropriately influence (bias) the work are disclosed by all authors: Siegfried Jank, Petteri Väänänen, Frank R. Kloss, Janne T. Nurmi, Juha-Pekka Nuutinen, Sanna Jakonen, Harri Happonen.

Funding source: The material testings were performed in the laboratories of Inion Oy in Finland. The following authors were employees of Inion Oy when the study was performed: Sanna Jakonen, Harri Happonen.

References

Bahr W, Stricker A, Gutwald R, Wellens E: Biodegradable osteosynthesis material for stabilization of midface fractures: experimental investigation in sheep. J Craniomaxillofac Surg 27: 51—57, 1999

Bell B, Kindsfater CS: The use of biodegradable plates and screws to stabilize facial fractures. J Oral Maxillofac Surg 64: 31—39, 2006

Bos RR, Rozema FR, Boering G, Nijenhuis AJ, Pennings AJ, Verwey AB: Bio-absorbable plates and screws for internal fixation of mandibular fractures. A study in six dogs. Int J Oral Maxillofac Surg 18: 365—369, 1989

Eckelt U, Nitsche M, Müller A, Pilling E, Pinzer T, Roesner D: Ultrasound aided pin fixation of biodegradable osteosynthetic materials in cranioplasty for infants with craniosynostosis. J Craniomaxillofac Surg 35: 218—221, 2007

Enislidis G, Kaan Y, Wittwer G, Köhnke R, Schragl S, Ewers R: Self-reinforced biodegradable plates and screws for fixation of zygomatic fractures. J Craniomaxillofac Surg 33: 95—102, 2005

Ferguson SJ, Wyss UP, Pichora DR: Finite element stress analysis of a hybrid fracture fixation plate. Med Eng Phys 18: 241—250, 1996a

Ferguson S, Wahl D, Gogolewski S: Enhancement of the mechanical properties of polylactides by solid-state extrusion. II. Poly(L-lactide), poly(L/D-lactide), and poly(L/DL-lactide). J Biomed Mater Res 30: 543—551, 1996b

Gerlach KL: In-vivo and clinical evaluations of poly(L-lactide) plates and screws for use in maxillofacial traumatology. Clin Mater 13: 21—28, 1993

Gosain A, Song L, Crrao M, Pintar F: Biomechanical evaluation of titanium, biodegradable late and screw, and cyanoacrylate glue

fixation systems in craniofacial surgery. Plast Reconstr Surg 101: 282–291, 1998
Haers PE, Suuronen R, Lindqvist C, Sailer H: Biodegradable polylactide plates and screws in orthognathic surgery: technical note. J Craniomaxillofac Surg 26: 87–91, 1998
Hasirci V, Lewandrowski KU, Bondre SP, Gresser JD, Trantolo DJ, Wise DL: High strength bioresorbable bone plates: preparation mechanical properties and in vitro analysis. Biomed Mater Eng 10: 10–29, 2000
Kallela I, Iizuka T, Salo A, Lindqvist C: Lag-screw fixation of anterior mandibular fractures using biodegradable polylactide screws: a preliminary report. J Oral Maxillofac Surg 57: 113–118, 1999a
Kallela I, Tulam RM, Hietanen J, Pohjonen T, Suuronen R, Lindqvist C: Fixation of mandibular body osteotomies using biodegradable amorphous self-reinforced (70L:30DL) polylactide or metal lag screws: an experimental study in sheep. J Craniomaxillofac Surg 27: 124–133, 1999b
Leinonen S, Tiainen J, Kellomaki M, Tormala P, Waris T, Ninkovic M, Ashammaki N: Holding power of bioabsorbable self-reinforced poly-L/DL-lactide 70/30 tacks and miniscrews in human cadaver bone. J Craniofac Surg 14: 171–175, 2003
Maurer P, Schubert S, Holweg S: Finite element analysis of a tandem screw configuration in sagittal split oseotomy using biodegradable osteosynthesis screws. Int J Adult Orthodon Orthognath Surg 16: 300–304, 2001
Maurer P, Holweg S, Knoll WD, Schubert J: Study by finite element method of the mechanical stress of selected biodegradable osteosynthesis screws in sagittal ramus osteotomy. Br J Oral Maxillofac Surg 40: 76–83, 2002
Rasse M, Moser D, Zahl C, Gerlach KL, Eckelt U, Loukota R: Resorbable poly(D, L)lactide plates and screws for osteosynthesis of condylar neck fractures in sheep. Br J Oral Maxillofac Surg 45: 35–40, 2007
Shetty V, Caputo AA, Kelso I: Torsion–axial force characteristics of SR-PLLA screws. J Craniomaxillofac Surg 25: 19–23, 1997
Suuronen R, Pohjonen T, Vasenius J, Vainionpaa S: Comparison of absorbable self-reinforced multilayer poly-L-lactide and metallic plates fort he fixation of mandibular body osteotomies: an experimental study in sheep. J Oral Maxillofac Surg 50: 255–262, 1992a
Suuronen R, Laine P, Sarkiala E, Pohjonen T, Lindqvist C: Sagittal split osteotomy fixed with biodegradable, self-reinforced poly-L-lactide screws. A pilot study in sheep. Int J Oral Maxillofac Surg 21: 303–308, 1992b
Suuronen R, Manninen MJ, Pohjonen T, Laitinen O, Lindqvist C: Mandibular osteotomy fixed with biodegradable plates and screws: an animal study. Br J Oral Maxillofac Surg 35: 341–348, 1997
Suuronen R, Pohjonen T, Hietanen J, Lindqvist C: A 5-year in vitro and in vivo study of the biodegradation of polylactide plates. J Oral Maxillofac Surg 56: 604–614, 1998
Tams J, Otten B, van Loon JP, Bos RR: A computer study of fracture mobility and strain on biodegradable plates used for fixation of mandibular fractures. J Oral Maxillofac Surg 57: 978–981, 1999
Tams J, Loon JP, Otten B, Bos R: A computer study of biodegradable plates for internal fixation of mandibular angle fractures. J Oral Maxillofac Surg 59: 404–407, 2001
Tormala P, Vainionpaa S, Kilpikari J, Rokkanen P: The effects of fibre reinforcement and gold plating on the flexural and tensile strength of PGA/PLA copolymer materials in vitro. Biomaterials 8: 42–45, 1987
Tormala P: Biodegradable self-reinforced composite materials; manufacturing structure and mechanical properties. Clin Mater 10: 29–34, 1992
Wiltfang J, Merten HA, Schultze-Mosgau S, Schrell U, Wenzel D, Kessler P: Biodegradable miniplates (LactoSorb): long-term results in infant minipigs and clinical results. J Craniofac Surg 11: 239–243, 2000
Wittenberg JM, Wittenberg RH, Hipp JA: Biomechanical properties of resorbable poly-L-lactide plates and screws: a comparison with traditional systems. J Oral Maxillofac Surg 49: 512–516, 1991
Wood GD: Inion biodegradable plates: the first century. Br J Oral Maxillofac Surg 44: 38–41, 2005
Yerit KC, Enislidis G, Schopper C, Turhani D, Wanschitz F, Wagner A, Watzinger F, Ewers R: Fixation of mandibular fractures with biodegradable plates and screws. Oral Surg Oral Med Oral Pathol Oral Radiol Endod 94: 294–300, 2002
Yerit K, Hainich S, Enislidis G, Turhani D, Klug C, Wittwer G, Öckher M, Undt G, Kermer C, Watzinger F, Ewers R: Biodegradable fixation of mandibular fractures in children: stability and early results. Oral Surg Oral Med Oral Pathol Oral Radiol Endod 100: 17–24, 2005a
Yerit KC, Hainich S, Turhani D, Klug C, Wittwer G, Ockher M, Ploder O, Undt G, Baumann A, Ewers R: Stability of biodegradable implants in treatment of mandibular fractures. Plast Reconstr Surg 115: 1863–1870, 2005b
Ylikontiola L, Sundqvist K, Sandor G, Törmälä P, Ashammakhi N: Self-reinforced bioresorbable poly-L/DL-Lactide [SR-P(L/DL)LA 70/30 miniplates and miniscrews are reliable for fixation of anterior mandibular fractures: a pilot study. Oral Surg Oral Med Oral Pathol Oral Radiol Endod 97: 312–317, 2003

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Paper received 8 December 2009
Accepted 10 February 2010