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Fixation properties of a biodegradable "free-form" osteosynthesis plate with screws with cut-off screw heads: Biomechanical evaluation over 26 weeks

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Objective. The aim of this study was to compare the postoperative fixation properties of a biodegradable osteosynthesis "free-form" plate achieved with countersunk screws with those provided by screws with cut-off screw heads.
Study design. Acrylic pipes were fixed together to simulate fracture fixation for tensile testing. Additional plates were fixed to a polyurethane block with a single screw for plate-screw pullout testing. Specimens were incubated in phosphate buffer solution at 37°C, and testing was conducted at various time points during hydrolytic degradation of 26 weeks. In both tests the specimens were loaded at a speed of 5 mm/min until failure. The yield load, maximum load, and stiffness were recorded, and failure mode was visually determined.
Results. Both countersunk screws and screws with cut-off screw heads provided similar plate fixation properties over degradation time.
Conclusion. According to these results, fixation of the biodegradable osteosynthesis free-form plate with screws with cut-off screw heads seems to be feasible. **(Oral Surg Oral Med Oral Pathol Oral Radiol Endod 2009;107:462-468)**

The use of biodegradable plates and screws is a well known alternative to titanium in the osteosynthesis of maxillofacial fractures.[1-9] Biodegradable implants have previously been demonstrated to be suitable for use in the midface, the craniofacial area, mandibular fractures, and orthognathic surgery.[1-31] Furthermore, the loss of stability after a period of about 6 months leads to an indication of biodegradables in pediatric fractures.[7-9,13-14,20,32] The design of the plates and screws is similar to that of titanium, but usually they need to be thicker to achieve the same stability. The thickness of the plates has been criticized by some surgeons complaining that the plates are too bulky compared with titanium miniplates. Excessively bulky plates (e.g., with a thickness of 3 mm) and protruding screw heads of the first-generation biodegradable systems have been reported to increase the risk of postoperative tissue reactions.[33] Accordingly, thinner plates and low-profile screws are now preferred and developed.

Recently, a new type of a biodegradable plating system (Inion FreedomPlate; Inion, Tampere, Finland) was introduced to provide low-profile fixation compared with conventional metal and biodegradable plates.[34] The 1.4-mm thick plate does not have ready-made screw holes but only several pilot holes allowing fluid flow through the plate, and the freedom to drill holes through the desired pilot holes in the desired direction (angulation). This technique allows optimal screw positioning in relation to fracture line(s).[34] For low-profile seating of the screw head, either the screw

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Table I. The study groups

Study group	*Plate*	*Screw*
Tensile test		
1	Inion FreedomPlate, 20 × 65 mm*	4 × Inion 2.0 × 10 mm screws, heads countersunk into the plate
2	Inion FreedomPlate, 20 × 65 mm*	4 × Inion 2.0 × 10 mm screws, screw heads cut off
Plate-screw pull-out test		
1	Inion FreedomPlate, 20 × 65 mm†	1 × Inion 2.0 × 10 mm screw, head countersunk into the plate
2	Inion FreedomPlate, 20 × 65 mm†	1 × Inion 2.0 × 10 mm screws, screw heads cut off

*Cut to the size of 28 × 7 mm.
†Cut to the size of 20 × 20 mm.

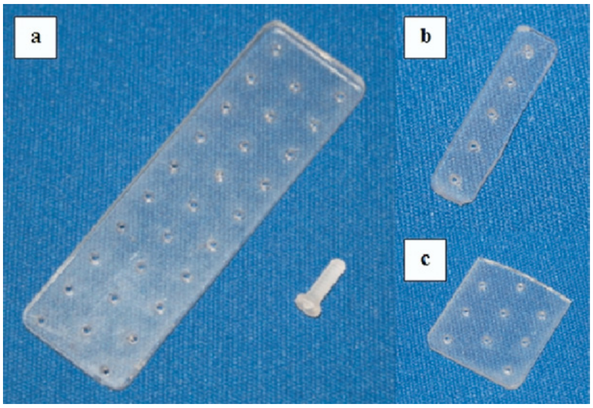

Fig. 1. **a,** Intact Inion FreedomPlate (20 × 65 mm) and Inion 2.0 × 10 mm screw; **b,** cut plate sample for tensile test (28 × 7 mm); and **c,** cut plate sample for plate-screw pullout test (20 × 20 mm).

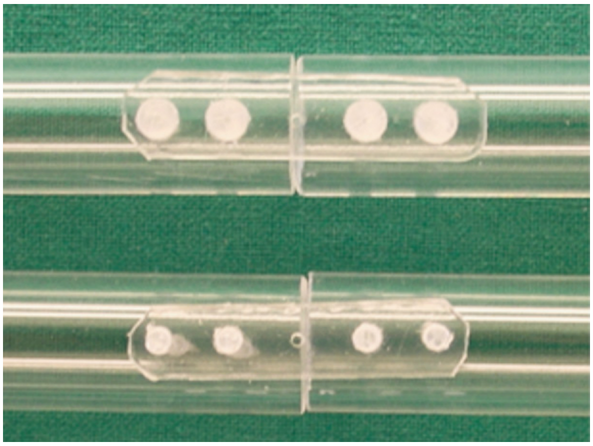

Fig. 2. Free-form plate sample for tensile test fixed with countersunk screws (**top**) and fixed with screws with cut-off screw heads (**bottom**).

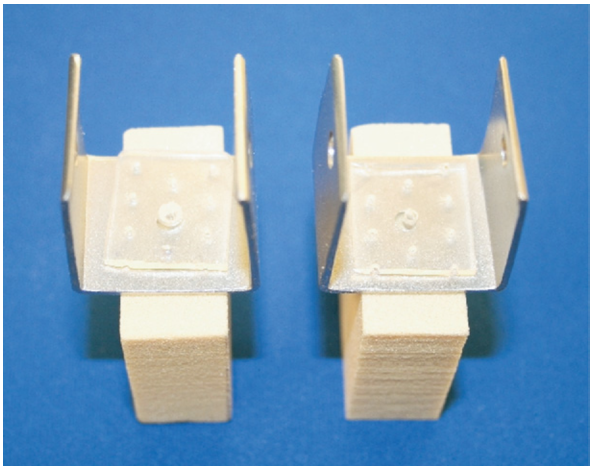

Fig. 3. Free-form plate sample for plate-screw pullout test fixed with countersunk screw (**left**) and fixed with screw with cut-off screw head (**right**).

heads can be countersunk into the plate as in conventional fixation or the screw heads can be cut off along the plate surface after screw insertion. Screw head removal is possible when threads are created with a bone tap instrument through the plate. By tapping through the plate, a kind of "locking plate" is created. In addition, after heating in a warm water bath, the free-form plate can be cut to the desired size and shape and easily contoured to match the contours of the bone surface.

According to the manufacturer, the thickness of the plate is sufficient to provide an adequate portion of threaded material for interlock between the plate and the tight threaded screws to provide sufficient fixation strength of the plate. Väänänen et al.[34] have previously demonstrated that the free-form plate fixed either with countersunk screws or with screws with cut-off screw heads provides similar initial fixation properties to the previously clinically used biodegradable plate fixed with conventional screw fixation.[35] However, because biodegradable implants lose their mechanical strength over time, determination of their strength retention properties is important.

Therefore, the aim of the present study was to compare the fixation properties of the biodegradable osteosynthesis free-form plate achieved with conventional countersunk screws with those provided by screws with cut-off screw heads over time.

MATERIALS AND METHODS

The study groups were: 1) free-form plates fixed with countersunk screws; and 2) free-form plates fixed with screws with cut-off screw heads (Table I). To create the

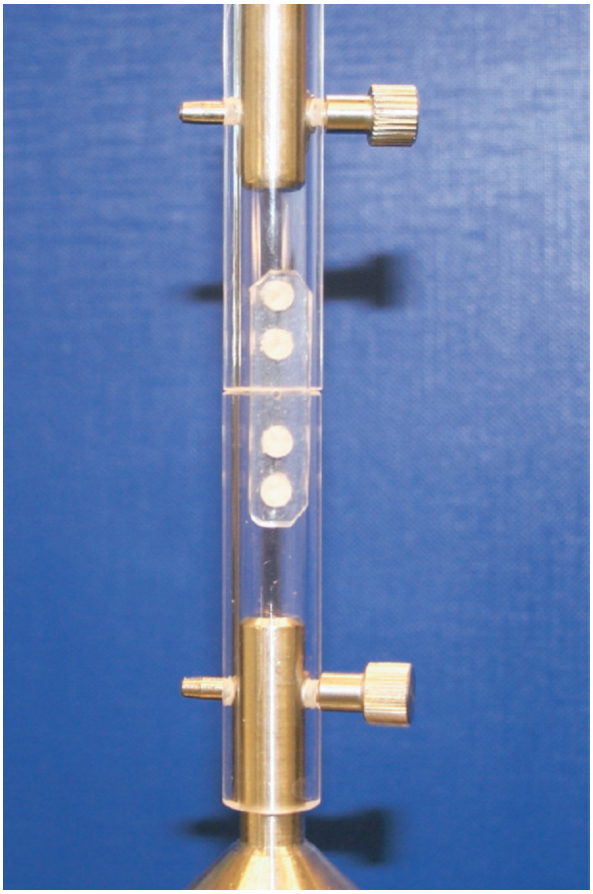

Fig. 4. Test set-up for the tensile test. Note that the actual tests were carried out in water at 37°C.

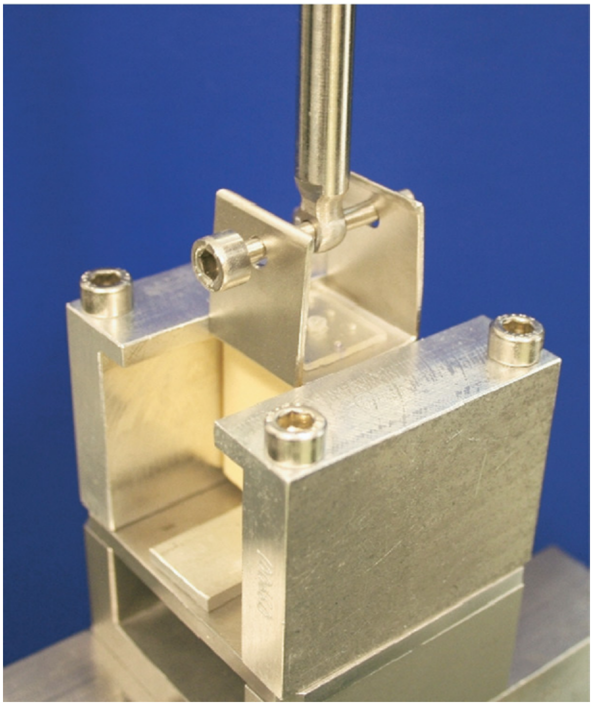

Fig. 5. Test set-up for the plate-screw pullout test. Note that the actual tests were carried out in water at 37°C.

worst-case scenario for the fixations tested, the smallest diameter screw (i.e., 2.0 mm) available for use with the investigated free-form plate was used (Fig. 1, *a*).

According to the manufacturer's instructions for use, the plates were immersed in a warm water bath at 70°C for 1 min before use, and immediately after rejuvenation the plates were cut to the size of the test samples. All fixations were carried out with product-specific instruments and according to the procedures recommended by the manufacturer.

Tensile testing was carried out according to the protocol of Väänänen et al.[34] The plate sample for tensile test was cut to the size of 28 × 7 mm (Fig. 1, *b*) and contoured to match the shape of the acrylic pipe simulating bone in this study. The acrylic pipes had an outer diameter of 13 mm and an inner diameter of 9 mm. Two pipes were joined with a plate and screws to simulate plate fixation of a standard, transverse osteotomy. A gap of 1 mm was left between the pipe ends for worst-case scenario conditions (corresponding to a clinical situation where no close contact between or perfect alignment of bone fragments is achieved). The screw length of 10 mm provides a monocortical fixation in the tensile test set-up used. Each plate sample for tensile test was fixed with 4 screws (2 on each side of the osteotomy line; Fig. 2).

In addition to the tensile test, plate-screw pullout testing was carried out to further study the plate-screw interlocking strength. In the previous study of Väänänen et al.,[34] cantilever bending test was carried out in addition to the tensile tests. The failure mode in the cantilever bending test was always plate bending. Therefore, the plate-screw pullout testing was conducted instead of the cantilever bending test in the present study to focus the investigations on the interlocking strength between the plate and the screw. The plate sample for plate-screw pullout test was cut to the size of 20 × 20 mm (Fig. 1, *c*). The plate was then fixed to a 30 pcf solid polyurethane foam block (Sawbones; Pacific Research Laboratories, Vacon, WA) together with a metallic test fixture by a single screw (Fig. 3). Testing of single screw fixation in the worst-case direction, i.e., with loading applied parallel to the long axis of the screw, provided worst-case scenario test conditions for evaluation of the plate-screw interlocking strength.

In study group 1 of both tests, each screw hole was drilled through a pilot hole of the plate and the under-

Table II. Results (mean ± SD) from the tensile tests over time

Parameter	*Study group*	*0 week*	*6 weeks*	*9 weeks*	*12 weeks*	*20 weeks*	*26 weeks*
Yield load (N)	1	86 ± 13	96 ± 13	92 ± 3	93 ± 8	66 ± 3	*
	2	90 ± 12	101 ± 5	99 ± 9	88 ± 8	71 ± 7	*
Maximum load (N)	1	109 ± 19	108 ± 15	102 ± 14	107 ± 14	69 ± 3	*
	2	113 ± 7	112 ± 9	112 ± 7	96 ± 7	74 ± 7	*
Stiffness (N/mm)	1	119 ± 17	137 ± 13	136 ± 12	123 ± 5	105 ± 13	*
	2	131 ± 6	143 ± 9	142 ± 15	120 ± 10	116 ± 6	*

*Samples had lost their mechanical strength and could not be tested.

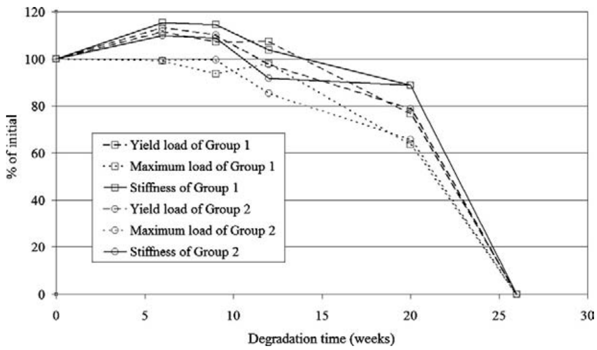

Fig. 6. Relative changes in tensile test quantities over time.

lying acrylic pipe or the foam block, and a countersink instrument was used to prepare the hole entrance on the plate for low-profile seating of the screw head. Then threads were created to the hole manually with a bone tap instrument, and finally a screw was inserted into the threaded hole. In study group 2 of both tests, threaded drill holes were created in the same way but without countersinking. Without countersinking, the tapping also created threads to the plate, enabling interlocking between the screw and the plate. After screw insertion, the head of the screw was cut off along the surface of the plate.

After insertion of screws, the samples were incubated in phosphate buffer solution (pH 7.4 ± 0.2) at 37°C and testing was conducted after 0 (i.e., 24 h), 6, 9, 12, 20, and 26 weeks of hydrolytic degradation. At each time point a total of 5 identical samples from each group were tested.

The testing was carried out in water at 37°C using the Z020/TH2A 2000 materials test machine (Zwick and Co., Ulm, Germany). In the tensile test, the acrylic pipes were connected to the testing machine with specially designed jigs (Fig. 4) and the sample was loaded in a direction parallel to the long axis of the acrylic pipe at a constant speed of 5 mm/min until failure of fixation. In the plate-screw pullout test, the sample was rigidly fixed to the testing machine (Fig. 5) and loaded in a direction parallel to the long axis of the screw at a constant speed of 5 mm/min until failure of fixation. The yield load (N), maximum load (N), and stiffness (N/mm) were recorded, and the mode of failure was visually determined.

Difference between groups 1 and 2 in both tests at each testing time point was determined by using a paired Student *t* test. A P value of $<.05$ was considered to be statistically significant.

RESULTS

The results of the tensile test are shown in Table II and Fig. 6. No significant difference was found between the groups in any of the parameters at any time point in the tensile test. In the tensile test, all fixations at all time points failed by screws' shaft breakage.

The results of the plate-screw pullout test are shown in Table III and Fig. 7. No significant difference was found between the groups in any parameters at any time point in the plate-screw pullout test. In group 1 of the plate-screw pullout test, 1 sample at 6 weeks failed by screw pullout from the foam, but the rest of the samples at all time points failed by screw shaft breakage. In group 2, all fixations failed by screw shaft breakage.

All samples in both tests had lost their mechanical strength by 26 weeks and could no longer be tested.

DISCUSSION

The results of this study show that the screws with cut-off screw heads provide postoperative fixation strength of the biodegradable osteosynthesis free-form plate equivalent conventional countersunk screws during 26 weeks of hydrolytic degradation. No statistically significant differences were found between the groups in any parameters at any time point in the tensile or plate-screw pullout tests.

Fractures typically heal in 6 weeks. After 6 weeks of hydrolytic degradation in both groups, >99% and >88% of the initial tensile and plate-screw pullout strengths, respectively, remained (Figs. 6 and 7). Moreover, after 12 weeks in both groups, >85% and >60% of the initial tensile and plate-screw pullout strengths remained. Accordingly, with both fixation techniques the strength retention rate appeared to be adequate for a normal fracture healing period. In addition, consider-

Table III. Results (mean ± SD) from the plate-screw pullout tests over time

Parameter	*Study group*	*0 week*	*6 weeks*	*9 weeks*	*12 weeks*	*20 weeks*	*26 weeks*
Yield load (N)	1	71 ± 1	63 ± 5	48 ± 15	43 ± 19	23 ± 10	*
	2	73 ± 4	68 ± 6	58 ± 5	50 ± 3	13 ± 1	*
Maximum load (N)	1	73 ± 1	66 ± 7	51 ± 15	50 ± 9	23 ± 10	*
	2	77 ± 3	71 ± 7	61 ± 6	53 ± 4	14 ± 1	*
Stiffness (N/mm)	1	127 ± 7	130 ± 14	110 ± 20	105 ± 27	67 ± 27	*
	2	129 ± 13	133 ± 5	105 ± 9	100 ± 8	60 ± 8	*

*Samples had lost their mechanical strength and could not be tested.

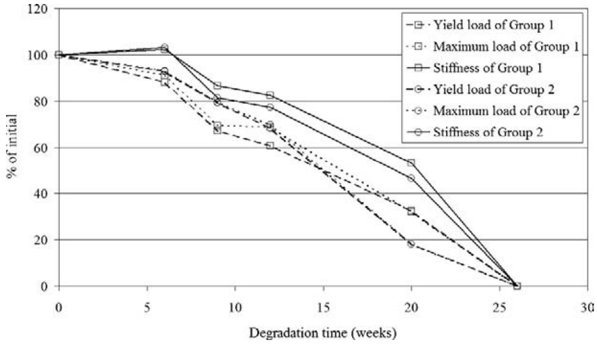

Fig. 7. Relative changes in plate-screw pullout test quantities over time.

ing that both fixation types had lost their mechanical strength and stability by 26 weeks, the biodegradable free-form osteosynthesis plate tested is less likely to restrict growth in pediatric patients than conventional metal implants.

In most previously published biomechanical studies on biodegradable implants, only their initial properties have been investigated.[4,12,15,17,34,36-42] However, considering that the mechanical properties of biodegradable implants usually decrease over time, it is important to determine the strength retention rate of the new biodegradable fixation methods before they are used clinically. In the present study, the fixation properties of the biodegradable implants were studied in hydrolytic conditions at body temperature for up to 26 weeks, covering the postoperative window for normal fracture healing. Previously, if biodegradable implants were investigated under hydrolytic degradation conditions, usually only the implant material or pure mechanical properties of the implant rather than the stability of a complete implant fixation construct were tested.[28,43-49] In some studies, degradation has been evaluated in in vivo conditions.[10-11,16,25,30,46,50-54] Although in vivo conditions may provide very realistic degradation conditions for biodegradable implants, it is extremely difficult to quantify or control loads and loading conditions in animal models or to determine and compare the fixation properties of implant constructs.

In the present study, homogeneous carrier materials were used to substitute human bone. Although use of real bone would have been optimal, cadaver bones could not be used because the specimens would not have tolerated incubation at 37°C for 26 weeks without decomposing. Therefore, and to ensure that the test results obtained reflect the actual fixation properties of the implant constructs rather than properties of the carrier material, surrogate materials known to tolerate hydrolytic conditions without weakening had to be used. Furthermore, by using homogeneous carrier material instead of cadaver bone, potential bias due to the effect of variation in bone quality (a well known limitation of biomechanical testing with cadaver bones) could be avoided.

To achieve sufficient stability, the first biodegradable plates and screws were designed to be thicker than the corresponding metal implants.[23,26-29,41,43,55-59] The thickness of the plates resulted in complaints about the bulkiness of the material. The novel concept of cutting off the screw heads after screw insertion is tempting, because it results in a lower-profile plate-screw construct than the conventional countersunk screw fixation where the inserted screws usually lead to somewhat increased thickness of the plate-screw system. When biodegradable implants are used, the screw heads can be removed after screw insertion because even if implant removal is needed later, the screw heads are not needed, because the screw shaft can simply be drilled out (if the implant has not have degraded by the time of the secondary procedure).

The principle of having numerous small pilot holes instead of ready-made screw holes on the plate enables placement of the screws where desired and simultaneous use of screws with different diameters (2.0-3.1 mm). In the present study, the screws with the smallest diameter were used for worst-case scenario testing. Considering that all of the samples in the tensile test and all expect 1 of the samples in the plate-screw pullout test failed due to screw shaft breakage, the use of larger-diameter screws is likely to provide better fixation strengths than those measured in the present study. In addition, the failure mode (i.e., screw shaft breakage) of the plate-screw pull-out test (in which the load is applied directly to the plate-screw interface) indicates that the plate-screw interlock is not the weakest point of the fixation even with screws with cut-off screw heads. Furthermore, the fact that the failure mode did not change over time indicates that the strength and stability of the plate-screw interlock are also retained after surgery.

In conclusion, in this 26-week hydrolytic degradation study, the free-form plate fixation with screws with cut-off screw heads was found to provide postoperative fixation properties similar to conventional fixation with countersunk screws. The strength retention of both fixation techniques can be considered to be adequate for fracture fixation. The results of this study justify further clinical research with these devices and methods of fixation.

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