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Experimental and clinical studies

Yuji NAKANISHI, M.D. , Tatsuo NAKAJIMA, M.D. , Yohko YOSHIMURA, M.D. ,  
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# Improved Poly-L-Lactic Acid Mini-Plate and Screws for Cranio-Maxillofacial Surgery : Experimental and clinical studies

Yuji NAKANISHI, M.D.\*, Tatsuo NAKAJIMA, M.D.\*\*, Yohko YOSHIMURA, M.D.\*\*\*,  
Kaoru TAKAMI, M.D.\*\*\* and Jun UKAI, M.D.\*\*\*

*\*Department of Plastic and Reconstructive Surgery, Ise Keio Hospital, Keio University, Ise, 516-0041  
(Head : Assist. prof. Yuji Nakanishi)*

*\*\*Department of Plastic and Reconstructive Surgery, School of Medicine, Keio University, Tokyo, 160-8582  
(Head : Prof. Tatsuo Nakajima)*

*\*\*\*Department of Plastic and Reconstructive Surgery, School of Medicine, Fujita Health University, Toyoake, 470-1192  
(Head : Prof. Yohko Yoshimura)*

## Abstract

Poly-L-lactic acid has become a popular bioabsorbable material in the field of plastic surgery. Though PLLA plates have previously been reported, they generally had a high molecular weight and were difficult to absorb. Therefore, we developed a system with a low molecular weight that is both easy to absorb and strong. Improved mini-plates and screws were used to treat experimental skull fractures in rabbits. Fracture healing and plate and screw absorption were investigated using gross inspection and microscopy. Male Japanese white rabbits (n=15) weighing approx 3 kg were used. After the outer table of the skull was elevated, it was repositioned and fixed with a miniplate and screws. At 3, 6, 9, 12, and 24 months after fixation, the plate was exposed. Tissue specimens were removed and examined using light and electron microscopy. The plates and screws were used in cranio-maxillofacial surgery from January 1995, these mini-plates and screws were used in 45 cases. All patients had an uneventful postoperative course. There were no complications. Polylactic acid mini-plates may eventually replace metallic hardware in these applications.

**Key Words :** biodegradable material, fracture fixation, fracture healing, Poly-L-lactic acid mini-plate and screw, facial fracture

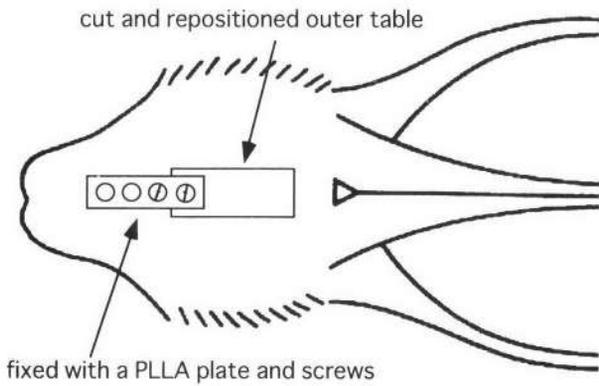
## INTRODUCTION

Bioabsorbable materials were introduced in the 1960's when sutures made of polyglycolic acid came into use. Since then, bioabsorbable materials in a variety of shapes have been developed and applied clinically, including mesh used to reinforce the chest and abdominal walls and pins used to buttress the ribs. The strength of the material was directly proportional, while the absorption time was inversely proportional, to the molecular weight. We prepared a strong readily-absorbable mini-plate with a low molecular weight by extruding polylactic acid. The effects of this mini-plate on

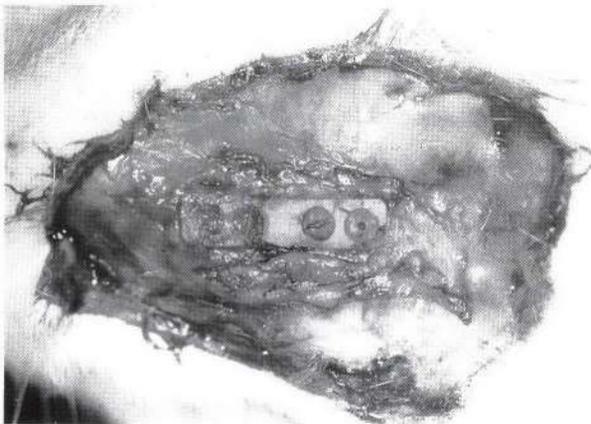
fracture healing were examined in animals. The device was then applied clinically in the field of cranio-maxillofacial surgery.

## MATERIALS AND METHODS

Poly-L-lactic acid (PLLA) rods were manufactured with an extruder using a PLLA polymer ( $M_w=3.0-5.0 \times 10^5$ ). The rods were initially drawn using several deformation ratios and temperatures. High-strength PLLA rods were shaped into mini-plates and screws ( $M_w=2.0 \times 10^5$ ) using a deformation ratio of 2.5. The length of the plate was 20 mm, the height was 2 mm, and the width was 5 mm. The screws had a thread diameter of 2.7 mm



**Fig. 1** Schematic showing the repositioned outer table fixed with a poly-L-lactic acid plate and screws.



**Fig. 3** Photograph at 6 months after fixation showing the opaque plate with evidence of degradation. There are few findings suggestive of absorption.

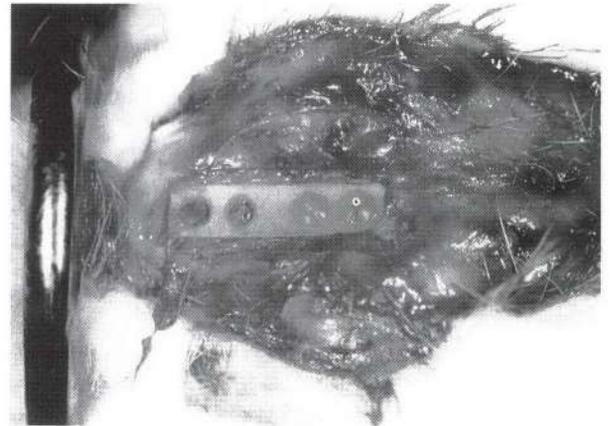
and a height of 7 mm. Both plates and screws were made from the same clinical materials.

Male Japanese white rabbits (n=15) weighing approx 3 kg were used. After the outer table of the skull was incised and elevated, it was repositioned and fixed with a PLLA mini-plate and screws (**Fig. 1**). At 3 (n=3), 6 (n=3), 9 (n=3), 12 (n=3), and 24 (n=3) months after fixation, the plate was exposed and the surrounding tissue was inspected macroscopically. Tissue specimens were then removed, cut vertically into sections, and stained with hematoxylin-eosin (light microscopy) or uranyl acetate and lead (electron microscopy).

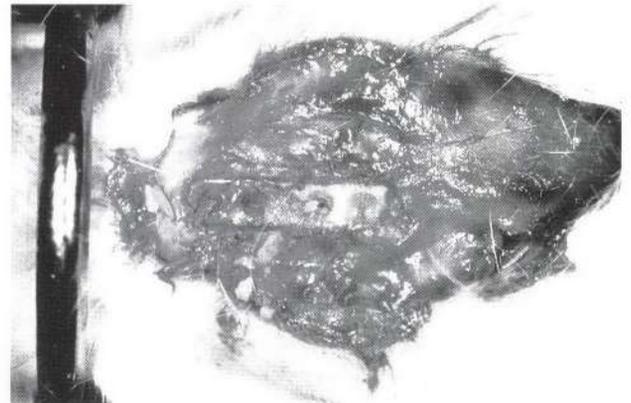
### RESULTS

#### Macroscopic examination

At 3 months, the PLLA mini-plates were densely adherent to the bone and good union of the fractures was noted. The plate surface was more



**Fig. 2** Photograph at 3 months after fixation showing the opaque plate that exhibited no change in hardness. Favorable osteosynthesis is noted at the fracture site. The plate is firmly adherent to the bone.

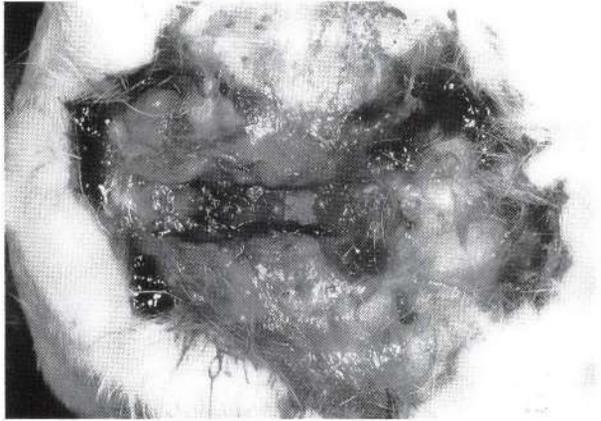


**Fig. 4** Photograph at 9 months after fixation showing progressive degradation and the beginning of absorption.

opaque than before operation. There were no changes in shape (**Fig. 2**). At 6 months, the surface of the plate was opaque and degradation was apparent, but there were few findings suggestive of absorption (**Fig. 3**). At 9 months, the changes in the plate shape suggested that degradation was progressing and that absorption had begun (**Fig. 4**). At 12 months, the plate was transparent and gelatinous. The plates and screws broke easily (**Fig. 5**). At 24 months, there was almost complete degradation, although a small amount of material remained and absorption was not judged to be complete (**Fig. 6**).

#### Microscopic examination

Histologic examination at 3 months showed good union at the fracture site without inflammatory cell infiltration (**Fig. 7**). A small amount of degradation and absorption were apparent at 6 months.



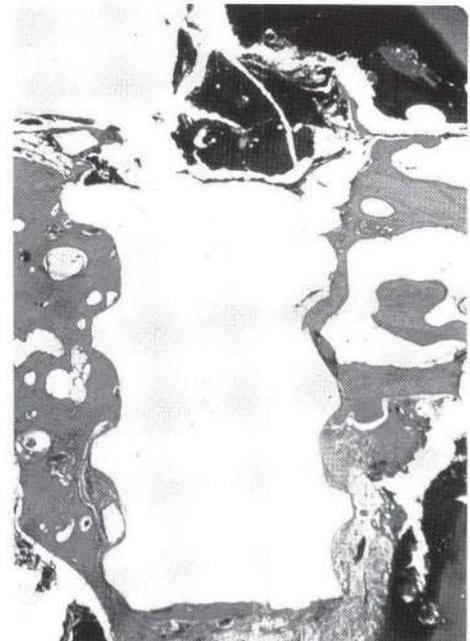
**Fig. 5** Photograph at 12 months after fixation showing the transparent gelatinous plate.



**Fig. 6** Photograph at 24 months after fixation showing almost complete degradation. Absorption is not complete.



**Fig. 7** Photomicrograph at 3 months after fixation showing a good union at the fracture site without inflammatory cell infiltration (Hematoxylin-eosin stain,  $\times 8$ ).



**Fig. 8** Photomicrograph at 6 months after fixation showing a small amount of degradation and absorption (Hematoxylin-eosin,  $\times 8$ ).

The plates and screws were in direct contact with the bone without evidence of inflammation (**Fig. 8**). At 9 months, fibrous tissue was seen invading the plates. Degradation and absorption were evident at the upper and lower ends of the screws. Bone filled the spaces left by the absorbed material (**Fig. 9**). At 12 months, the plates were not recognizable on histologic examination. The degradation and absorption of the screws was more advanced and a greater amount of bone formation was noted (**Fig. 10**). At 24 months, the plates had undergone complete degradation. There was considerable progress in the degradation of the screws. At high magnifications, foam cells were seen occupying the spaces left by the dissolving screws, in preparation for phagocytosis (**Fig. 11a~c**).

Scanning electron microscopy at 3 months revealed the formation of small pores within the

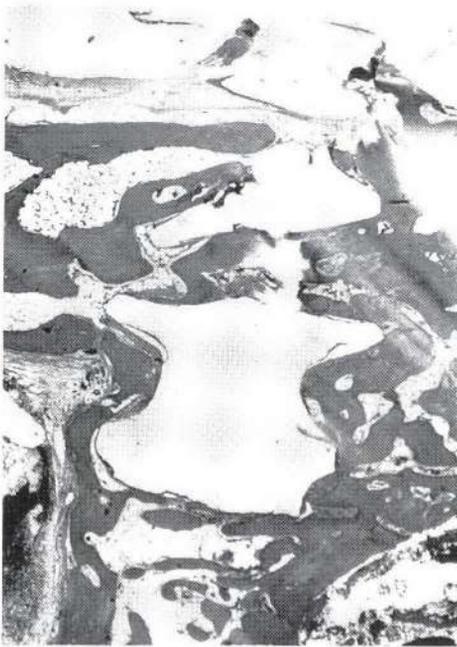
The plate is in direct contact with the bone, without evidence of inflammation.

plate due to the hydrolysis (**Fig. 12**). At 12 months, electron microscopy revealed degradation and small residual fragments of the PLLA plates (**Fig. 13**).

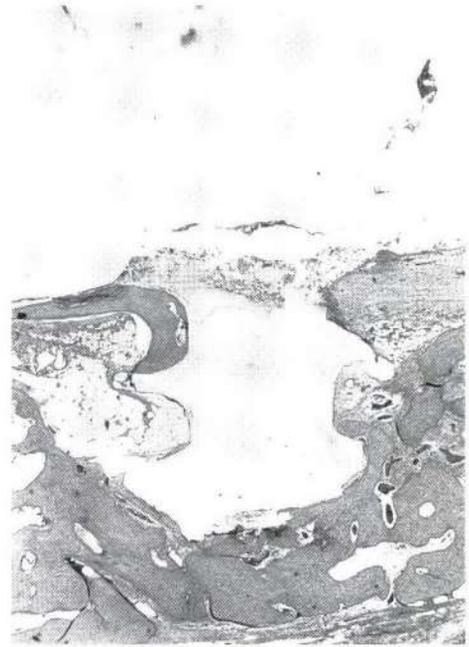
### CLINICAL APPLICATION

Prior to clinical application, the optimum shape and specifications of the PLLA plates were investigated.

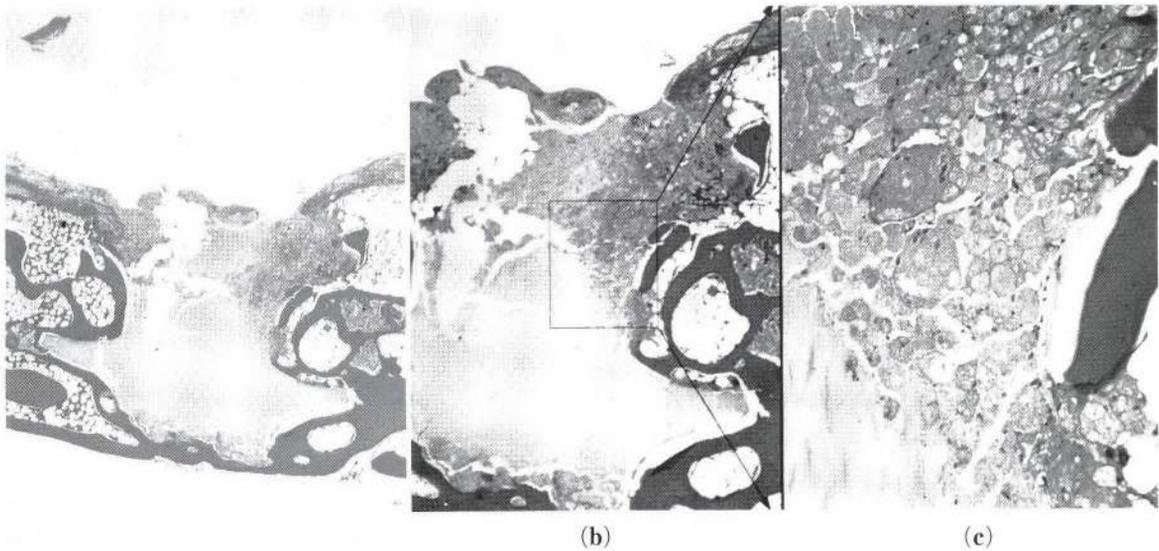
At first, a simple, flat plate was designed. Use of the screws required tapping with a drill. To encour-



**Fig. 9** Photomicrograph at 9 months after fixation showing fibrous tissue invading rifts in the plate (Hematoxylin-eosin,  $\times 8$ ). Degradation and absorption are noted at both ends of the screw. Bone fills the spaces left by the absorbed material.



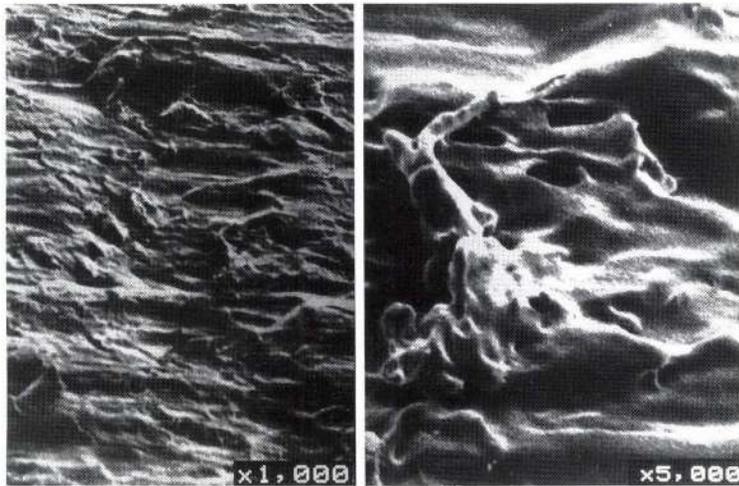
**Fig. 10** Photomicrograph at 12 months after fixation showing no evidence of the plate (Hematoxylin-eosin,  $\times 8$ ). Degradation and absorption were noted.



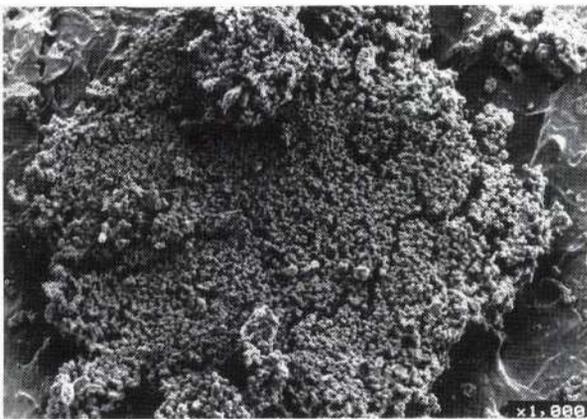
**Fig. 11** Photomicrograph at 24 months after fixation (Hematoxylin-eosin,). (a) The plate has undergone complete degradation. There is considerable degradation of the screw ( $\times 8$ ). (b) ( $\times 50$ ). (c) The spaces in the dissolved screw are occupied by foam cells ( $\times 200$ ).

age widespread use, a screw with standard threads was subsequently constructed. Based on the requirements for bending strength, the extension rate (deformation rate) for both the plates and

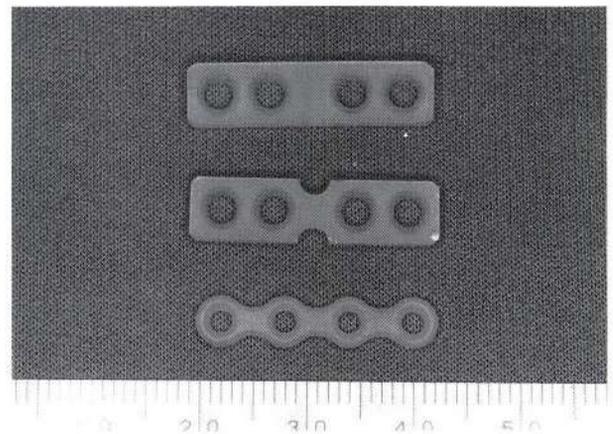
screws was set at 2.5 times. Since it was difficult to bend the original plate laterally, the central portion was made thinner. Further refinements then were made to allow the plates to conform to the three-



**Fig. 12** Scanning electron micrograph at 3 months after fixation showing the formation of small pores within the plate due to hydrolysis.



**Fig. 13** Scanning electron micrograph at 12 months after fixation showing degradation and small fragments of the plate.



**Fig. 14** Photographs showing the innovative changes in the shape of the Poly-L-lactic acid mini-plate (above). The original plate was difficult to bend to conform to the three-dimensional structure of the face. Then the central portion was made thinner to allow for bending (middle). The final design of plate and screw. The plate was made to allow it to conform to the three-dimensional facial skeleton (below).

dimensional structure of the face (**Fig 14**). These plates and screws were used clinically in 45 patients from January 1995. The longest follow up was 5 years. All patients gave written, informed consent and this study was performed in accordance with the Helsinki Declaration revised in 1989. There were no major complications and the postoperative recovery was uneventful in all patients.

### CASE REPORTS

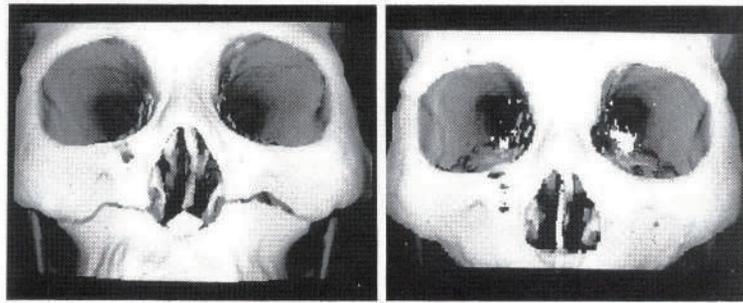
**Case 1 :** A 21-year-old woman who sustained a Le-Fort I fracture in a traffic accident underwent open reduction. The maxillary buttress was fixed with four PLLA mini-plates and screws. Three-dimensional computed tomography showed good results and the results at 4 years were satisfactory

(**Fig. 15**).

**Case 2 :** A 28-year-old man underwent treatment for a post-traumatic deformity of the zygoma. Osteotomy of the zygoma and augmentation of the orbital floor with apatite ceramics was performed. Fixation of the osteotomy site was accomplished with one PLLA mini-plate along the lateral and one mini-plate along the inferior orbital rim. At 3 years, the results were satisfactory (**Fig. 16**).

### DISCUSSION

After bioabsorbable fibers were introduced for

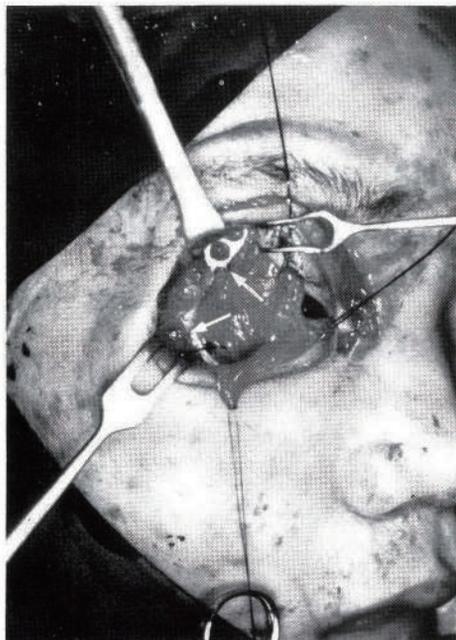


(a)



(b)

**Fig. 15** Case 1 : A 21-year-old woman with a Le-Fort I fracture. (a) Three-dimensional computed tomography before (left) and 12 months after (right) fixation. (b) Clinical photographs before (left) and 4 years after (right) the fixation.



(a)



(b)

**Fig. 16** Case 2 : A 28-year-old man with a deformity of the right zygoma. (a) Intraoperative photograph showing a poly-L-lactic acid mini-plate along the inferior orbital rim, and one along the lateral orbital rim. (b) Photographs before (left) and 3 years after (right) fixation.

use as surgical suture, a variety of bioabsorbable polymers have been developed and used in thoracic and orthopedic surgery. However, since polyglycolic acid degrades rapidly, it does not provide adequate fixation at sites where some degree of strength must be maintained. The polylactic acid plate has been gradually refined since 1972 when Cutright used it for the repair of orbital floor fractures in monkeys<sup>4)</sup>. In cranio-maxillofacial surgery, the metal miniplate has been used since 1978<sup>3)</sup>.

Poly-lactic acid is rapidly hydrolyzed after the period of bone fixation, without disturbing bone growth. It has been used to fix fractures of the zygoma<sup>2)</sup> and the mandible<sup>9)</sup>. We have reported previously on the use of the PLLA plate as a strut for surgical elevation of the sternum in funnel chest<sup>6)</sup>.

The most important advance in extending the clinical applications of the plate to cranio-maxillofacial surgery has been the decrease in the molecular weight without a corresponding decrease in strength, which was obtained by increasing the potential of absorption. This polylactic acid mini-plate, which is prepared by special extrusion, exhibits superior strength and degradation properties compared to plates prepared by conventional extension. When PLLA is extended 4 to 8 times, its bending strength increases 2.5 to 3 times. Our mini-plate is made using PLLA extended 2.5 times because the bending strength more closely resembles that of human cortical bone (20 kgf/mm<sup>2</sup>). Furthermore, excessive extension produces large gaps between the molecules, resulting in extreme friability.

Since January 1995, the PLLA mini-plates were used to fix facial fractures in 11 patients<sup>7)</sup>. No definite conclusions can be drawn yet concerning the 5-year follow-up. However, Bergsma<sup>1)</sup> have reported a patient in whom a PLLA mini-plate became swollen during the course of degradation<sup>1)</sup>. They concluded that these mini-plates should be used with caution. In a previous study, we have shown that PLLA mini-plates are absorbed more slowly than expected<sup>8)</sup>. The speed of absorption is probably influenced by the site of implantation, the blood flow to the surrounding tissues, the molecular weight of the material, the extension ratio, and the

plate size.

At present, the clinical use of PLLA or PL/DLLA (poly-L/DL-lactide)<sup>5)</sup> mini-plates should be limited to cranio-maxillofacial surgery because of the rich regional blood supply<sup>5)</sup>. During the reduction and fixation of multiple facial fractures that require many mini-plates, due attention must be paid to the complications that might develop if absorption is not rapid.

The development of materials with superior absorption and fixation properties will speed the replacement of metal mini-plates and screws.

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*Yuji NAKANISHI, M.D.*

*Department of Plastic and Reconstructive Surgery, Ise Keio Hospital, Keio University*

*2-7-28 Tokiwa, Ise, Mie, 516-0041*

*E-mail : nakanice@keio-hosp.mie.jp*

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