The use of bioabsorbable poly-L-lactide acid miniplate and screw (FIXSORB®-MX) for bone fixation in mandibular fracture: cases report

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Abstract

Objective: This report aims to elucidate the degree of degradation of bioabsorbable poly-L-lactide acid (PLLA) devices and the influence of these materials on the surrounding tissues in the human body.

Methods: Two patients with fractured mandibles underwent treatment using a biodegradable fixation system. In the first case, the plates and screws were removed along with extraction of an impacted wisdom tooth at 6 months after surgery, and in the second case, the same procedure was performed 12 months after surgery. Changes in

the physical properties of the materials and histologic alterations in the periosteum and bone associated with the bioabsorbable plates were assessed.

Results: The materials demonstrated adequate degradation in the human body, and skeletal stability proved sufficient for the duration of mandibular bone healing without complications after surgery.

Conclusion: On the basis these findings, it can be concluded that PLLA implants are useful for the fixation of human mandibular fractures.

Keywords: Bioabsorbable poly-L-lactide acid materials, Mandibular fracture

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Introduction

Owing to the stability and safety of bioabsorbable materials, clinical applications of these materials in humans have advanced in recent years.¹⁻⁹ On the other hand, the use of conventional metal bonding materials is accompanied by various issues such as elution of the metal elements, accumulation in the organs, sustained mechanical stimulation, and suppression of growth when used in children, the metals are often removed as early as possible immediately after bone healing has occurred.⁶⁻⁹

The biodegradable material poly-L-lactide (PLLA) is eventually broken down into water and carbon dioxide following hydrolysis in the human body.¹⁻³ Therefore, it has the advantage of suppressing the frequency of occurrence of various adverse events.

Herein, we investigated the degree of degradation of PLLA and the influence of this material in the surrounding tissue in two trauma cases.

Case Report Case 1

An 18-year-old male came to our hospital with a chief complaint of malocclusion due to a traffic accident [table 1](#). An oral examination showed malocclusion with displacement of the distal portion of tooth 33 and a lacerated wound on the gingiva in the region of the fracture. A panoramic radiograph revealed that the site of the fracture

was located at the body and left angle of the mandible (32-33): an impacted molar (38) was observed above the fracture line [figure 1A](#). No deviation in occlusion was observed until 3 months after surgery, and abnormal findings were not noted in the vicinity of the fixed miniplate. Furthermore, no deviation of bone fragment at the bone junction or expansion of the hole in the bone (where the screw was fixed) was observed in the radiographs 6 months postsurgery [figure 1B](#).

The patient underwent open reduction under general anaesthesia using PLLA materials. At 6 months following surgery, the plates and screws in the left angle portion were removed along with the extraction of the impacted 38 after obtaining informed consent from the patient [figure 2](#). Changes in the following physical properties of the removed materials were investigated at Takiron Co., Ltd., Osaka, Japan: viscosity-average molecular weight ($\times 10^4$), bending strength (N), torsion strength (N·cm), melting point (°C), and degree of crystallinity (%). Histologic alterations in the periosteum and bone associated with the bioabsorbable plates were assessed.

Macroscopic findings of excised PLLA materials at this time included loss of elasticity of the plate, even though it retained its prototype, along with the loosening of all four screws, three of which had tears in the middle [figure 3](#). The physical properties of the excised PLLA materials were as follows: the

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Table 1 Patient characteristics

	Case 1	Case 2
Gender	Male	Male
Age (years)	18	20
Cause of injured	traffic accident	fighting
Fracture site	mandibular body+left angle	mandibular body+left angle
Procedure	open reduction	open reduction
Materials	mini plate x3: length 28.0, thickness 1.5	mini plate x2: length 28.0, thickness 1.5 mini plate x1: length 34.0, thickness 1.5
(FIXSORB [®] MX)		
length (mm)	mini screw x12 : length 8.0	mini screw x12 : length 8.0
thickness (mm)	: core diameter Φ2.2	: core diameter Φ2.2
diameter (mm)	: threed diameter Φ1.7	: threed diameter Φ1.7
Intermaxillary fixation	2 weeks	2 weeks
Period of removed PLLA	6 months	6 months

Table 2 The result of physical properties of removed PLLA plate

	New materials	Post-op 6 months	Post-op 12 months
Viscosity-average	20.0~25.0	5.6	1.0
Molecular weight (x10 ⁴)			
Bending strength(N)	30.0	12.6	-
Melting point (°C)	175.0~180.5	179.4	171.6
Degree of crystallinity (%)	40.0~50.0	66.2	82.5

Table 3 The result of physical properties of removed PLLA screw

	New materials	Post-op 6 months	Post-op 12 months
Viscosity-average	20.0~25.0	4.8	4.7
Molecular weight (x10 ⁴)			
Torsion strength(N·cm)	7.0	4.8	0.2
Melting point (°C)	175.0~180.5	179.3	178.8
Degree of crystallinity (%)	40.0~50.0	70.8	67.5

average molecular weight of the extracted plate and screw were reduced from approximately 250.000 to 56.000 and 48.000, respectively; bending and torque strengths were decreased from initial values of 30.0 N and 7.0 N·cm to 12.6 N and 4.8 N·cm retrospectively; the melting point showed little change even after removal. Additionally, the degree of crystallinity was 70.8% for the screw and 66.2% for the plate, which was higher than the initial value of 45.0% [table 2](#) and [3](#). Histopathological findings included a well-maintained trabeculae with no abnormal findings in the periosteum and bone tissues [figures 4](#) and [5](#).

Case 2

A 20-year-old male presented at our hospital with a chief complaint of malocclusion caused by fighting [table 1](#). An oral examination revealed crossbite with movement of the distal portion of 43. A panoramic radiograph showed that the fracture site was located at the body (43-44) and the left angle of the mandible with an impacted 38 [figure 1A](#). During the period until surgical removal of the plate and screw, clinical findings were stable [figure 1B](#).

The patient underwent open reduction under general anaesthesia using PLLA materials. Twelve months later, the plates and screws in the left angle portion were removed along with the extraction of the impacted 38, as described in case 1 [figure 2](#).

Macroscopic findings of the excised PLLA at 12 months after surgery revealed that the plate and screws had become cloudy without retaining the prototype [figure 3](#). At the time of extraction, the materials were brittle and in a very vulnerable state. The physical properties of the excised PLLA materials were as follows: average molecular weights

Figure 1 A. Panoramic radiograph of fracture before operation. The arrows show fracture line, B. Panoramic radiograph after operation

Figure 2 Intraoperative view

Figure 3 Removed PLLA plate & screw
*The screw used for measurement

of the extracted plate and screw were reduced from approximately 250.000 to 10.000 and 47.000, respectively: torque strength had decreased from approximately 7.0 N·cm to 0.2 N·cm, whereas, bending strength was undetectable as plate decomposition progressed: melting point was slightly

Figure 4 Pathological findings of periosteum at surroundings of PLLA plate. (H&E x200)

Figure 5 Pathological findings of cortex bone at surroundings of PLLA plate. (H&E x200)

decreased in the extracted the plate: the crystallinities of the plate and screw were higher than the initial values [table 2](#) and [3](#). Histopathologically, no abnormal findings were noted [figures 4](#) and [5](#).

Discussion

PLLA materials must possess properties, such as improved mechanical strength and adequate absorption, with no harmful effects on the human body.¹⁻⁹ Although the initial strength of PLLA is said to be similar to that of the cortical bone, it faces the possibility of decomposition immediately after implantation in the living body.¹⁻³ Therefore, it is important to maintain the strength of the material in the body during bone healing.¹⁻⁹ In the two cases presented herein, occlusion was normal, and no dislocation, diastasis or nonunion was observed implying that the strength required for fixation was maintained throughout the period.

It is believed that measurements of reduction in weight, molecular weight and strength as a means to investigate the rate of decomposition and absorption are reliable.¹⁻³ In vivo and in vitro studies have shown a 10% loss in the bending strength of PLLA rods 8 weeks after implantation, and a 40% loss after 12 weeks of implantation. Furthermore, development of transect cracks were noted after 20 weeks with complete loss of the measured strength.¹⁻³ Generally, it takes 2 to 3 years for complete absorption depending on factors such

as, the site of implantation, the molecular weight, crystallinity, and size and the surface condition, following which full replacement of the bone is achieved.¹⁻³ Noguchi et al.⁴ confirmed the survival of the plate morphology in a patient who underwent reconstruction of the frontal morphology 1.3 years after craniofacial plastic surgery using a PLLA plate and a screw. In accordance with the results reported by Noguchi et al.,⁴ the molecular weight and the strength of the materials extracted from the two cases in the current study also demonstrated a decrease. Furthermore, in the present report, the crystallinities of both the plate and the screw were increased when compared with their initial values during decomposition. This may be attributed to the difference in decomposition rates between the crystalline portion and the amorphous portion of the material.¹⁻³ The decomposition proceeds more rapidly in the amorphous portion therefore, the proportion occupied by the crystalline part of the polymer is relatively higher.

Ayhan, et al.⁵ assessed the histologic alterations in the dura mater and brain tissue associated with bioabsorbable plates in Sprague-Dawley rats. They observed fibrous encapsulations around the plates accompanied by foreign body giant cell reactions and calcifications. They also reported that neurologic and histologic effects of bioabsorbable plates on neural tissue may be considered as negligible during the early postoperative period. In the present case studies, the histologic effects of PLLA materials on the periosteum and cortex were considered to be within normal limits at 6 and 12 months after treatment. However, late noninfectious inflammatory tissue responses have been observed as a form of delayed foreign body reaction,^{4,7,10} indicating the need for follow-up observations in the future.

Conclusion

On the basis these results, the PLLA materials underwent adequate degradation in the human body, and the skeletal stability required for mandibular bone healing after surgery was sufficient without the occurrence of any complications.

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Conflict of Interest

The authors report no conflict of interest.

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