An Evaluation of Poly(L-Lactic Acid) Plate and Screw System for Fixation of Mandible Fracture in Rabbit Model

Subin Park1,2, Kyohwa Kang2, Hyojin Park3, Jongsoon Park4, Suhak Heo4,5, Hong Kim5, Young Bin Choy1,6, and Chan Yeong Heo2,7

1Department of Biomedical Engineering, Seoul National University College of Medicine, Seoul, 110-799 Korea
2Department of Plastic Surgery, Seoul National University Bundang Hospital, Bundang, Sungnamgu, Kyunggido 116 Korea
3Department of Pathology, Seoul National University Bundang Hospital, Bundang, Sungnamgu, Kyunggido 116 Korea
4Department of Safety and Health, Hoseo University and Glotech Co., Ltd. R & D center, Asan, 336-851 Korea
5Department of Biochemistry, College of Medicine, Soonchunhyang University, Cheonan, 330-090 Korea
6Interdisciplinary Program in Bioengineering, College of Engineering and Institute of Medical & Biological Engineering, Medical Research Center, Seoul National University, Seoul, 152-742 Korea
7Department of Plastic Surgery and Reconstructive Surgery, College of Medicine, Seoul National University, Seoul, Korea

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Abstract: Bioabsorbable plates and screws for bone fixation system have been used owing to many advantages over conventional metallic devices. This study investigated the effects and safety of recently developed modifiable bioabsorbable plate and screw made of 100% poly(L-lactic acid) in the healing process of mandible fracture in a rabbit model. In vitro extract test for cytotoxicity and bacterial reverse mutation test for genotoxicity were carried out. Any cytotoxicity caused by extract from experiment sample was not observed. In genotoxicity test, increase in the number of revertants was not observed. As an in vivo test, plates and screws were used for rigid fixation of experimental mandible fracture in twenty rabbits. Tissue specimens with plate were taken from the rabbits after 4, 6, 8, 10 weeks and histological analysis was studied. After 4 weeks, the plate was covered by connective tissue and severe chronic active inflammation in soft tissue was observed. After 6 weeks, absorbed part in plate and new bone formation around periostium and decrease in inflammation were detected. After 10 weeks, new bone formation was observed in all samples and the thickness of bone increased. The remodeling was not complete yet. This study demonstrates that recently developed biodegradable plate and screw system made of poly(L-lactic acid) was effective in mandible fracture regions known as high load-bearing areas. This indicates that bioabsorbable poly(L-lactic acid) plates and screws are available for most of bone fractures, although the adjustment process and long-term follow-up study are necessary for clinical application.

Key words: bioabsorbable plate and screw, poly(L-lactic acid), bone fracture healing, mandible fracture, osteotomy

1. Introduction

Currently, traditional titanium systems have been used for the treatment of facial fracture. This system has many advantages such as the reduction of healing time and the convenience in operation process. However, concerns about infection, exposure, transcranial migration, and growth restriction when using metal devices were noted by studies.1 Schnidt et al (1998) reported that 11% of Le Fort I osteotomy patients had secondary removal of plates due to infection and plate exposure.2 Another study from Glasgow reported that in the cases of the 16 orthognathic patients had to have their plates removed, 9 removals were due to infection, 4 due to pain, 1 due to denture discomfort, and 2 due to palpability.3 In the field of orthopedics, it has been reported that the rigid metallic plate fixation system can be obstacles for rapid formation of a primary callus.4

To overcome these problems with the conventional metallic system, a variety of bioabsorbable materials have been developed for the treatment of bone fracture. Plate and screw internal fixation techniques for fracture healing had been boosted with the development of new biocompatible materials.5 Poly(L-lactic acid) is the most widely used of this kind due to its good biocompatibility and feasibility.6-13 Studies
reported the tissue reaction and disappearance rate of polylactic acid (PLA) and successful application in different clinical situations, including maxillofacial fracture, orthognathic surgery, and pediatric surgery.\(^{14}\)

The aim of this study is to evaluate the effects and safety of recently developed modifiable bio-absorbable plate and screw system for treating mandible fracture with rabbit models. The success of this system in mandible region, which is known for its ability of bearing high-load, might be manifest proof for the usefulness of bioabsorbable plates and screws.

2. Material and Methods

2.1 Mechanical Properties of the Biodegradable Plates and Screw

Plates and screws used in this study were made of 100% polylactic acid (PLA). The fixation system consists of plates (31\times4.5\times0.5\text{ mm}) and screws of length 7.46\times1.4 (Fig 2). The ultimate strength of plates was determined to be 41.8 N/cm\(^2\) in bending test according to ASTM F2502 rule. This value is similar to the value of synthetic plate which is conventional titanium plate (Table 1). The results of extract test from PLA plates and screw are given in Table 2.

\begin{table}[h]
\centering
\begin{tabular}{|c|c|c|c|c|c|c|}
\hline
\textbf{Measurement} & \textbf{Result} & \textbf{Standard} \\
\hline
Morphology & Transparent & No alien material & Transparent & No alien material \\
\hline
pH & 1.47 & \leq 1.5 \\
\hline
Absorption spectrum in ultraviolet rays & 0.0061 & \leq 0.1 \\
\hline
K\text{MnO} reducing agent & 0.3 mL & \leq 2.0 mL \\
\hline
Evaporation residue & 0.1 mg & \leq 1.0 mg \\
\hline
Heavy metal & No darker than control & No darker than control \\
\hline
\end{tabular}
\end{table}

2.2 In Vitro Study

As a biocompatibility test, genotoxicity test and in vitro-cytotoxicity test were carried out by Korea Testing & Research Institute. The former one is Bacterial Reverse Mutation Test according to International Organization for Standardization 10993: Biological Evaluation of Medical Devices, Part 3: Tests for Genotoxicity, Carcinogenicity and Reproductive Toxicity. The latter one is extract test according to International Organization for Standardization 10993: Biological Evaluation of Medical Devices, Part 5: Tests for Cytotoxicity: in vitro Methods (ISO 10993-5).

2.2.1 Genotoxicity Test

The treatment of extract was carried out by pre-incubation method. In sterilized tube, 100 \text{ µL} of extract from plates and screws, S-9 mix 0.5 mL, medium 0.1 mL were mixed and centrifuged at 120 rpm, 37°C for 20min. 2 mL of top agar was inoculated, mixed and poured immediately to minimal glucose...