족관절 골절에서 생체흡수성 판과 나사못으로 고정 후 지연성 이물질 반응
- 증례 보고 -

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족관절 골절에서 생체흡수성 판과 나사못으로 고정 후 지연성 이물질 반응을 보인 환자를 경험하였기 때문에 보고하고자 한다. 아울러 생체흡수성 판과 나사못을 이용하여 고정술 시 지연성 이물질 반응의 발생 가능성을 대해 고려하고 수술 후 최소 2년간 추시 관찰할 것을 추천하고자 한다.

색인 단어: 족관절 골절, 생체흡수성, 이물질 반응

L-lactide, D-lactide and trimethylene carbonate 등의 중합체로 구성되어 있는 생체흡수성 판과 나사못이 현재 사용되고 있다. 최근 이러한 생체흡수성 판과 나사못을 이용한 족관절 골절의 치료에서 지연성 이물질 반응이 발생하였다는 보고가 국내외에 있었으나 국내에는 없었다. 족관절 골절에서 생체흡수성 판과 나사못을 이용하여 고정술 후 발생한 지연성 이물질 반응을 보인 환자를 경험하였기에 보고하고자 한다. 아울러 생체흡수성 판과 나사못을 이용하여 고정술 시 지연성 이물질 반응의 발생 가능성을 대해 고려하고 수술 후 최소 2년간 추시 관찰할 것을 추천하고자 한다.

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Delayed Foreign-body Reaction of Ankle Fracture Treated with a Biodegradable Plate and Screws
− A Case Report −

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Biodegradable implants made of co-polymers composed of L-lactide, D-lactide, and trimethylene carbonate were used in the present case. To our knowledge, only one reported tissue reaction has been associated with ankle fracture treated with third-generation implants internationally and none yet domestically. We report a delayed foreign-body reaction of ankle fracture treated with a third-generation biodegradable plate and screws. We suggest that ankle fracture patients treated with biodegradable implants should be advised of this possible complication and should be followed for at least 2 years.

Key Words: Ankle fracture, Biodegradable, Foreign-body reaction

First-generation bioabsorbable implants consisting mainly of polyglycolic acid appeared in the 1990s. They displayed rapid degradation and high rates of subsequent inflammatory reactions1). Second-generation implants consisted of poly-L-lactide and showed substantial improvements in degradation rates and foreign-body reactions1). Third-generation implants composed of trimethylene carbonate, L-lactide, and D, L-lactide displayed improved degradation rates and reduced foreign-body reactions2).
strength and slow degradation rates (2~4 years)\textsuperscript{5-7}). These were designed to overcome the problems of rapidly diminishing strength and frequent foreign-body reactions\textsuperscript{5-7}). However, the prolonged degradation rate of new implants has raised another concern. One of the major concerns is whether these materials actually diminish adverse soft tissue reactions or the reactions simply are postponed to a later time. These bioabsorbable implants have been studied extensively in vitro and in animal models\textsuperscript{5,7)}, but only few short-term studies were conducted in humans\textsuperscript{5,9)). To our knowledge, only one reported tissue reaction have been associated with ankle fracture treated with Third-generation implants internationally\textsuperscript{9}) and not yet domestically. We report delayed foreign-body reaction of ankle fracture treated with Third-generation bioabsorbable plate and screws.

**CASE REPORT**

A 21-year-old male soldier sustained a closed, left lateral malleolar fracture when he slipped during soccer game in March 2010. He had no known systemic diseases and reported no allergy. One week after the injury, he underwent open reduction and internal fixation with a biodegradable plate and screws (Inion OPTSTM, Inion Oy, Tampere, Finland) by other orthopedic surgeon (Fig. 1). The postoperative course was unremarkable. In February 2011, eleven months after the procedure, the patient noted a gradually enlarging soft-tissue mass adjacent to the previous surgical scar.

**Fig. 2.** The patient noted a gradually enlarging soft-tissue mass adjacent to the previous surgical scar.

**Fig. 3.** (A) On radiographs, the fracture had healed but osteolytic change had occurred.

(B) Magnetic resonance imaging showed a healed lateral malleolar fracture accompanied by an oval mass with an accumulation of fluid in the sinus formation.

**Fig. 1.** (A) Preoperative radiograph showing a lateral malleolar fracture.

(B) Radiograph made one week after open reduction and internal fixation with biodegradable implants.

(C) Biodegradable plate and screws (Inion OPTSTM, Inion Oy, Tampere, Finland).
Fig. 4. (A) Intraoperative clinical photographs showing a collection of fluid accompanied by several fragments of whitish material. (B) Granulomatous tissue and foreign-body fragments.

Fig. 5. (A) Photomicrograph showing some variably shaped, hyaline foreign-body material with a rhomboid shape (H&E stain, ×100). (B) Photomicrograph showing fragments surrounded by a foreign-body reaction with mononuclear cells, foamy histiocytes, foreign body-type multinucleated giant cells, and granulation tissue in the stroma (H&E stain, ×400).

DISCUSSION

All biodegradable implants induce a subclinical but histopathologically recognizable non-specific foreign body type of tissue response. According to Rokkanen et al., this seems to be a phenomenon inherent in the degradation and absorption processes of these polymers in the tissues. This can be regarded normal as long as it does not cause any clinical symptoms. The process of
biodegradation of a polymer implant begins with the polymer chains being broken into smaller fragments by hydrolysis. The molecular weight of the implant decreases first. Thereafter, the mechanical strength of the implant decreases, allowing subsequent mechanical fragmentation and absorption of the implant to begin. Actual mass loss of the implant then occurs through the release of soluble degradation products, phagocytosis by macrophages and histiocytes, intracellular degradation, and finally, metabolic elimination through citric acid (Krebs) cycle to carbon dioxide and water occur, which are expelled from the body via respiration and urine. Regarding the phagocytic and clearing capacity of the tissues, the most demanding phase is the decomposition stage, when the gross geometry of the implant is rapidly lost. At this time, the production rate of polymeric debris particles may exceed the critical limits of tissue tolerance. This may occur especially if there is poor vascularity at the implantation site or if there is only a thin soft tissue layer covering the implants like when implants are placed on the lateral malleolus. Local accumulation of released monomers may lower the local pH of the tissue, which may in turn lead to increased osmotic pressure resulting in a temporary local sterile fluid accumulation. The patient notices this reaction as swelling which can be painful if severe. However, such soft tissue reactions do not usually impair bone healing because with the currently used materials they are unlikely to occur during the first 6 months after implantation.

The biodegradable implants used in the present study are made of co-polymers composed of L-lactide, D-lactide and trimethylene carbonate. The plates are 1.2 mm thick and the 2.8~3.1 mm diameters screws have flat low-profile heads. The co-polymer material has been found in sheep to become soft in 6 months to 1 year and to degrade completely by 24 months without any harmful inflammatory or foreign body reactions. However, in the recent study, subcutaneous implant-degradation related soft tissue reactions were found in four patients (three mild and painless, and one more severe reaction, i.e., 2~8% occurrence rate) 8~18 months postoperatively. In Korea, we first present a patient with delayed foreign-body reaction 11 months postoperatively, Cho et al previously investigated the suitability of the Third-generation biodegradable implants for the treatment of ankle fracture. In their study, 20 patient were treated with a biodegradable plate and screws (Inion OTPSTM) and no foreign-body reaction was observed after a mean 5.6-months follow-up. We think the follow-up period of their study was too short.

We suggest modern absorbable implants with slow degradation rates have not eliminated the problem of foreign-body reactions but simply postponed the occurrence of reactions. So ankle fracture patients treated with biodegradable implants should be advised of this possible complication that is foreign-body reaction and should be followed for at least 2 years, possibly longer.

REFERENCES