

Comparison between Titanium and Biodegradable Miniplates in Mandibular Fractures

하악골 골절 치료시 티타늄 miniplate와 생물분해성
miniplate의 사용에 대한 비교 연구

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국문초록

하악골 골절 치료시 티타늄 miniplate와 생물분해성 miniplate의 사용에 대한 비교 연구

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본 연구의 목적은 임상에서 하악골 골절의 고정에 사용되는 흡수성 고정판과 티타늄 금속판의 임상적 및 방사선학적 비교를 통해 흡수성 고정판의 임상적 유용성을 평가하는 데 있다.

총 환자는 91명이었으며 12개월간의 추적기간 중 합병증이 나타난 환자는 4명(4.41%)으로 흡수성 고정판은 4.26%, 티타늄 금속판은 4.56%로 티타늄 금속판이 약간 높은 것으로 나타났으나 유의할 만한 차이는 없었다. 4예 중 감염이 3예, 티타늄 금속판의 파절이 1예였고 모두 우각부에서 발생하였다. 감염된 3예는 항생 소염요법 및 절개 배농술로 치유되었으며 금속판이 파절된 예는 파절된 금속판을 제거하고 재고정을 시행하였다. 이처럼 낮은 합병증 발생율을 보인 점과 추적기간 중 모든 증례에서 양호한 골유합을 보인 점은 분쇄골절과 같은 복잡한 골절을 제외하고 단순골절 증례에만 적용한 것이 그 이유라고 생각된다. 따라서 추후에 단순골절 뿐만 아니라 분쇄골절이나 다른 안면부 골절에 대한 연구가 필요할 것으로 생각된다.

술 후 12개월의 추적기간 동안 흡수성 고정판을 티타늄 금속판과 비교했을 때 임상 결과 및 방사선학적 결과, 단순한 감염 외에 부정유합이나 비유합, 골괴사 등의 합병증이 없었고 정확한 골유합을 관찰할 수 있었으며 따라서 하악골 골절에 있어 흡수성 고정장치를 이용한 고정은 임상적으로 티타늄 금속판의 단점을 보완해 주는 대체 수단으로 유용하게 사용할 수 있을 것으로 생각된다.

I . Introduction

Mandible is bound to the skull with bilateral joints, and it is the only facial bone that has a skeletal structure for mobility. It has the shape of a bow which is protruded externally. Due to these anatomical characteristics, the mandibular fracture has the second highest occurring incidents next to nasal fractures of the total cases of maxillofacial bone fractures.¹ Besides, mandible is responsible for such functions as respiration, sensation, phonation, occlusion and mastication. It constitutes the inferior part of the face and therefore plays a significant role in maintaining aesthetic functions as a measure of assessing the degree of overall countenance, symmetry and protrusion. In order to prevent the deformity of outward appearance and to minimize the functional disability, the accurate reduction and stable fixation are mandatory in cases in which the mandibular fracture occurred due to the damage of facial area. Also in these cases, a prompt recovery must be achieved without any complications. In particular, because the fragments from mandibular fracture are exerted by the biomechanical force whose magnitude is very great, the stable fixation between the fragments is needed.^{1,2}

The treatment of mandibular fracture is made based on the closed reduction or open reduction depending on the site and type of fracture. With open reduction and fixation, such a good treatment outcome that the complete reduction and correction can be achieved and the healing period can be shortened can be obtained. Open reduction and fixation using a metal plate and a screw made it possible to perform the rigid internal fixation of bone fragments. Thus, this led to the direct bone union and produced a good prognosis following the surgery. Most of the metal plates are composed of biocompatible metals, and they are used to reconstruct the defects in the head-and-neck area without any notable adverse effects. In patients in the growth period, however, the solid fixation using a metal plate has disclosed the disadvantages that it restricts the growth of skull and facial bones; it causes the bone

deformity, the release of a screw and the resulting failure of bone union when it does not have an accurate contact with the bone surface; and it produces the necessity of the secondary surgery for the removal of a metal plate.^{3,4} Therefore, to date, studies have been conducted to examine the absorbable fixation plate manufactured using polymer and a fixation screw that can maintain the strength during the bone healing process and can compensate the disadvantages of a metal plate by being gradually absorbed without any disorder of bone healing and foreign body reaction within the body following the completion of bone healing.⁵⁻⁷ However, a bioabsorbable fixation plate is weaker compared to metal plates such as titanium and its possibility of developing the adverse effects to the body remains problematic when absorbed.⁸

Given this background, we compared the clinical outcomes which were obtained from patients in whom titanium metal plate and bioabsorbable fixation plate were used for the reduction of various mandibular fractures. Then, we attempted to evaluate the postoperative stability and efficiency of bioabsorbable fixation plate with a review of literatures.

II. Patients and Methods

This study was conducted in 91 patients (65 males and 26 females) with mandibular fracture who visited and then underwent open reduction at department of oral and maxillofacial surgery of Chosun University Hospital between May 2005 and August 2007. Age distribution of these patients ranged from 11 to 69 years, in which the mean age was 28.4 years. Our patients consisted of 34 cases of symphysis fracture, 23 cases of mandibular angle fracture, 13 cases of symphysis fracture accompanied by mandibular condylar fracture and 21 cases of the concurrent presence of mandibular angle fracture and symphysis fracture. Patients with comminuted fracture and those who concurrently had other types of fracture were excluded from the analysis. The number of patients who underwent open reduction with an absorbable fixation plate was 47. The number of patients who underwent open reduction with a titanium metal plate was 44.

Prior to the surgery, patients were given the information regarding the advantages and disadvantages of absorbable and non-absorbable fixation plate, medical expense and complications. In patients who submitted a written informed consent for the surgery using an absorbable metal plate, a resorbable plate was used. Pediatric patients in the growth period were given the application of an absorbable fixation plate. Other patients underwent open reduction using a titanium metal plate. An absorbable fixation plate used here was self-reinforced P(L/DL)LA copolymer BioSorb FX (Linvatec Biomaterials Ltd, Tampere, Finland), and a metal plate was a Titanium miniplate (SYNTHES[®], Solothurn, Switzerland).

SURGICAL METHODS

All the patients underwent intermaxillary fixation using arch bar. Based on Champy' s theory,⁹ the reduction and fixation of mandible were performed. All the surgeries were performed via an intraoral approach.

The fracture site was exposed and the displaced bone fragments were reduced to their anatomical location. One fixation plate was used for the mandibular angle and two were used for the median area. In cases of mandibular angle fracture in which the variation of bone fragments was severe, the open reduction was performed using a trocar. According to manufacturer's instructions, a fixation plate and a screw were used. An absorbable fixation plate underwent drilling and pre-tapping prior to its use.

Postoperative intermaxillary fixation was performed for 0 to 15 days (mean period: 7.6 days) based on the occlusal status and the presence of condylar fracture. All the patients were given liquid diet for 2–3 weeks, and thus the variation of bone fragments was minimized.

CLINICAL AND RADIOLOGIC EVALUATION

Patients were divided into two groups: the group in which titanium metal plate was used and the group in which an absorbable fixation plate was used. Then, based on the clinical records and radiologic findings of patients, the fracture site, age and sex of patients and the period of intermaxillary fixation were all reviewed. Besides, a radiologic assessment was performed preoperatively, immediately after surgery, on month 1, month 3, month 6 and month 12. Thus, the pattern of bone fracture healing was monitored. The occurrence of complications was evaluated using clinical assessment.

III. Results

Titanium metal plate was applied in a total of 43 patients (33 cases of the use in the median area and 23 cases in the mandibular angle). An absorbable fixation plate was applied to a total of 48 patients (35 cases of the use in the median area and 21 cases in the mandibular angle) (Table 1). The postoperative complications include three cases of infection and the fracture of a fixation plate, and the overall incidence of complications was 4.41%. Of them, the complications developed in an absorbable fixation plate were infections in all cases; incidence was 4.26% (2 cases). Complications associated with titanium metal plates were seen in two cases (4.56%), which include one case of infection and another case of fracture of metal plate (Table 2). Complications at each site include three cases of infection in the mandibular angle and one case of the fracture of a fixation plate. This showed that all the complications were developed in the mandibular angle. The incidence of complications was 9.09% (Table 3).

Table 1. CLASSIFICATION ACCORDING TO THE FRACTURE SITE

	Symphysis only	Angle only	Symphysis + Condyle	Symphysis + Angle	Total
Biodegradable plate	21	12	5	9	47
Titanium plate	13	11	8	12	44
Total	34	23	13	21	91

Table 2. COMPLICATION ACCORDING TO TYPE OF PLATE

	Infection	Plate fracture	Total
Biodegradable plate	2	0	2(4.26%)
Titanium plate	1	1	2(4.56%)
Total	3	1	4(4.41%)

Table 3. COMPLICATION ACCORDING TO FRACTURE SITE

	Infection	Plate fracture	Total
Symphysis	0	0	0(0%)
Angle	3	1	4(9.09%)

In all cases in which titanium metal plate and an absorbable fixation plate were applied, non-union or malunion were observed on radiography during the follow-up period. In all cases in which titanium metal plate was applied, no screw loosening was noted. In cases in which an absorbable fixation plate was applied, the bone fracture line and the indentation due to drilling were observed immediately after surgery on radiography. Six months later, radiography results revealed that the bone fracture line was absent and the bone union was present.

IV. Discussion

Equipments that are used to minimize the complications by fixing the bone fragments following the fracture or osteotomy and to induce solid bone union by the stabilized fixation have persistently been developed.

Requirements for bone fixation device include (1) the strength and rigidity to such a sufficient extent as to induce the bone union, (2) no foreign body reaction or infection within the body, (3) no interference with the bone union, (4) an inability to be palpated or visualized and (5) the spontaneous absorption.⁴ An extraoral fixation device has also been used. A metal plate manufactured with a stainless steel has mainly been used. In recent years, a biocompatible metal plate made of titanium has been universally used. Bioabsorbable plates can be selectively used for internal fixation in mandibular fractures, with the advantage that they do not need to be removed.

A metal plate made of a stainless steel or titanium has such advantages as the availability of solid fixation, shortened surgical time and the convenience of surgical procedure. In cases in which this metal plate is not accurately contacted to the bone surface, however, the deformity of bone can also be developed even because of the solidity of a metal plate. In cases in which the skin is thin, the following disadvantages can be disclosed: (1) the palpability or exposability, (2) the sensitivity to temperature, (3) metal allergy, (4) secondary infection or bone resorption and (5) the possibility of interfering the postoperative radiologic assessments. In addition, it has the great strength and can maintain the bone union persistently. Accordingly, the metal plate can restrict the growth of bone in patients in the growth period. Furthermore, it is also disadvantageous in that the secondary surgery is required for the removal of a metal plate following the bone union.^{10,11} Therefore, the necessity of an absorbable bone fixator has been proposed.

Kulkarni et al.¹² first performed an experiment associated with it.

Since then, studies about an absorbable bone fixator using polymers such as PLA (polylactic acid), polyglycolic acid (PGA) have been actively conducted. Cutright and Hunsuck¹³ reported that the bone union was successfully performed using poly-L-lactic acid (PLLA) in the treatment of monkey with a traumatic ocular fracture. However, foreign body reaction and osteolysis occurred in association with PLA and PGA. To resolve these complications, the polymer has been developed using the polymer and co-polymer of PLA and PGA. Ferretti and Reyneke¹⁴ conducted a clinical trial and reported that there was no significant difference in a long-term stability between self-reinforced P(L/DL)LA co-polymer and non-absorbable screw.

At the present, PLGA co-polymer or P(L/DL)LA copolymer has become universally and commercially available. An absorbable plate, which was used in this study, is a self-reinforced P(L/DL)LA co-polymer. It is advantageous in that it can maintain the solid rigidity even at room temperature unlike other types of a fixation plate that must be applied by the heating using a heating unit within a few seconds. Unlike the general types of metal plates, however, it requires pretapping. In cases in which the tapping was not sufficiently performed or a fixation screw was inserted with an excessive force, a screw head can be isolated before it is completely inserted.¹⁵ The dynamic strength is maintained during a maximum period of 3–4 months. An absorbable plate is gradually absorbed within the body across 2–3 years. Therefore, from the point of view that an absorbable plate must be absorbed between six months and one year during which the bone union is completed, this can interfere with the growth of pediatric patients in the growth period. Also in this study, in cases in which an absorbable fixation plate was applied, the indentation due to the drilling was detected on radiography taken 12 months later. This indicates that an absorbable fixation screw was not absorbed and was then left at the site of surgery.

Wittwer et al¹⁶ reported that there was no significant difference between biodegradable osteosynthesis materials or between biodegradable

materials and titanium fixation with respect to fracture healing and postoperative complications. In this study, there was no significant difference between biodegradable materials and titanium fixation with respect to fracture healing and postoperative complications.

Postoperative complications were of a minor nature and resolved spontaneously or after local therapy.¹⁶ Generally, in cases of mandibular fracture in which titanium metal plate was used, the incidence of complications has been reported to be 7–13.3%.^{17–19} Smoking habits may play a significant role in the incidence of complications with biodegradable materials.¹⁶ Delayed infection (osteomyelitis) developed in a symphysis fracture can be treated by saucerization and antibiotics.²⁰

In this study, complications occurred in 4.41% of total patients, whose incidence was 4.56% in patients who used titanium metal plates and 4.26% in those who used an absorbable fixation plates. But this difference did not reach a statistical significance. In cases of mandibular condylar fractures in which the third molar was extracted synchronously, all the complications occurred at an incidence of 9.09%. Presumably, the reason that the incidence of complications was low in this study might be that an absorbable fixation plate was restrictively applied to the simple cases of mandibular fracture except for comminuted fracture. Complications include three cases of infection and one case of the fracture of fixation plate.

In this study, infection occurred within one month. For the treatments, all cases underwent the antibiotic therapy. In two cases in which an absorbable fixation plate was used, the incision and drainage were performed. The removal of fixation plate was not performed at the site of infection. Infection was cured within 5–7 days. In one case in which a fixation plate was fractured, in such a condition that the intermaxillary fixation was not performed postoperatively, patients voluntarily took solid foods and did not manage the surgical site postoperatively. In this case, the fractured titanium metal plate was removed and the re-fixation was performed for mandibular angle using a trocar. Besides, in

cases of the mandibular condylar fracture, the strength of fixation was weaker and the suture site was easily split as compared with other areas. These cases were highly vulnerable to the postoperative infection.²¹ Also in this study, all the complications occurred in the mandibular angle. While the extraction was performed synchronously, the extraction socket played a role as a dead space. Presumably, this might lead to the development of infection.

In a research paper which reported cases in which the infection occurred after more than 12 months, the fixation plate causes an inflammation while it has the mobility within the mucosa during the process of the absorption of absorbable fixation plates following the completion of bone union. In cases in which the adjacent tissue did not sufficiently absorb an absorbable fixation plate while it is absorbed because it was commonly placed right inferior to the oral mucosa. In these cases, the delayed infection or fistula might occur. Accordingly, a great care must be taken for 2–3 years until the absorption is completed.²¹

Besides, in a research paper which reported that the swelling was developed after more than 12 months relapsed postoperatively, the dissolved fixation plate may thicken the adjacent soft tissue because of the incomplete absorption or the increased amount of dissolved material may be suddenly secreted due to such factors as the impact. This excessively increases the clearance rate for dissolved materials that the adjacent can tolerate, and it eventually leads to the occurrence of swelling.²² Delayed adverse effects may therefore occur in patients who used an absorbable fixation plate. A cautious monitoring of clinical course is needed in these patients. Furthermore, an assessment of long-term prognosis is also needed.

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저작물 이용 허락서

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	영어 : Comparison between Titanium and Biodegradable Miniplates in Mandibular Fractures				

본인이 저작한 위의 저작물에 대하여 다음과 같은 조건아래 조선대학교가 저작물을 이용할 수 있도록 허락하고 동의합니다.

- 다 음 -

1. 저작물의 DB구축 및 인터넷을 포함한 정보통신망에의 공개를 위한 저작물의 복제, 기억장치에의 저장, 전송 등을 허락함
2. 위의 목적을 위하여 필요한 범위 내에서의 편집·형식상의 변경을 허락함. 다만, 저작물의 내용변경은 금지함.
3. 배포·전송된 저작물의 영리적 목적을 위한 복제, 저장, 전송 등은 금지함.
4. 저작물에 대한 이용기간은 5년으로 하고, 기간종료 3개월 이내에 별도의 의사 표시가 없을 경우에는 저작물의 이용기간을 계속 연장함.
5. 해당 저작물의 저작권을 타인에게 양도하거나 또는 출판을 허락을 하였을 경우에는 1개월 이내에 대학에 이를 통보함.
6. 조선대학교는 저작물의 이용허락 이후 해당 저작물로 인하여 발생하는 타인에 의한 권리 침해에 대하여 일체의 법적 책임을 지지 않음
7. 소속대학의 협정기관에 저작물의 제공 및 인터넷 등 정보통신망을 이용한 저작물의 전송·출력을 허락함.

동의여부 : 동의(○) 반대()

2009 년 2 월 일

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