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석사학위논문

Comparative study between
resorbable and non-resorbable
plate in orthognathic surgery

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악교정 환자에서의 흡수성판과 비흡수성판의 비교 연구

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이 논문을 치의학 석사학위신청 논문으로 제출함.

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조선대학교 대학원

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악교정 환자에서의 흡수성판과 비흡수성판의 비교 연구

안 유 석

지도교수 : 김 수 관

조선대학교 치의학과

구강악안면외과학 전공

본 연구의 목적은 악교정 수술을 시행 시에 티타늄 고정판과 흡수성 고정판을 이용하여 고정하고, 이러한 두 형태의 고정 방법에 따른 술 후 회귀 성향과 술 후 부작용 등을 조사하여 임상적 유의성을 비교하는 데 있다.

하악전돌증 환자에서 고정에 사용된 재료에 따라 악교정 수술 후 발생할 수 있는 차이점을 비교하고자 2006년부터 2007년까지 조선대학교와 분당 서울대병원에 내원하여 악교정 수술을 시행 받은 환자 272명을 대상으로 조사한 결과 다음과 같은 결론을 얻을 수 있었다.

1. 269명(98.89%)에서 성공을 보였고 재발(surgical relapse)을 보여 재수술을 시행한 환자는 3명이었다.
2. titanium plate를 사용한 환자의 경우 152명중 13명(8.6%)에서 합병증이 발생하였고, resorbable plate를 사용한 120명 중 22명(18.3%)에서 합병증이 발생하였다.
3. 술 후 합병증으로는 술 후 개교합, 감염, TMD(temporomandibular joint dysfunction), 술 후 회귀 성향 등이 발생하였다.

그 합병증들이 각 재료의 특징으로 인해 발생할 수 있지만 단순히 재료의 물리적성질로만 발생한다고 결론을 내리기는 옳지 않다고 생각된다.

4. 흡수성 고정판은 티타늄 고정판의 강도에는 미치지 못하나 제거 수술이 필요 없고 만족할만한 강도를 지녀 임상적 적용에 있어 적응증이 되는 경우 티타늄 고정판을 대체할 만한 재료라 사료된다.

I. Introduction

Since the concept of rigid internal fixation using a compression screw, this rigid internal fixation has been used as one of the most universal treatment modalities for sagittal split ramus osteotomy of mandible (SSRO).^{1,2} The aims of this rigid fixation are to provide the stability for the site of osteotomy, to promote the bone healing, to make the early movement of jaw bones possible, to reduce the patient discomfort, and to diminish the risk of postoperative re-entry.

In the treatment using titanium fixation plate, however, the postoperative release of titanium into the body has been reported. There is still a controversy as to the necessity of the removal of released titanium.^{2,3} It causes the distortion and unclarity of images on radiography. There are many cases in which titanium fixation plate must be removed following the completion of postoperative healing.^{4,5} According to this, surgeries using absorbable materials have recently been performed in the field of maxillofacial surgery. Orthognathic surgery is one of the represented areas.

An absorbable fixation plate has been actively examined in various fields. An absorbable fixation plate (BioSorb FX, Linvatec Biomaterials Ltd, Tampere, Finland), which is used in the current study, has the characteristics that it can be

bend without heating in the same manner as titanium fixation plate. Haers and Sailer managed ten consecutive cases using biodegradable self reinforced poly L/DL lactide plates and screws. Class II patients and Class III patients were mixed with the sample. A cephalometric analysis was performed to evaluate the stability of a skull. Six weeks postoperatively, all the jaw bones were clinically stable. In all groups (n=10), the mean maxillary growth was 2.9 mm at point A and the mean postoperative relapse was 0.0 mm. The mean vertical surgical displacement was inferiorly directed at point A, which showed a value of 1.8 mm and a relapse of 0.4 mm. These authors postulated that biodegradable self reinforced poly L/DL lactide plates and screws produced a predictable, short term stability of skull compared to the gold standard treatment modality, titanium plates and screws.

It has been reported, however, that an absorbable fixation plate has a weaker strength than titanium and it has been reported to produce the in vivo adverse effects. Therefore, it has cautiously been used until now. Still, many studies⁷⁻⁹ are conducted to examine an absorbable fixation plate. According to this, comparative studies have been conducted to examine the postoperative stability, re-entry and adverse effects in a clinical setting. Unlike the Western countries, however, a comparative study about the postoperative outcomes of fixation method would be more important in a Korean clinical setting

where the Angle III group was prevalently present.

Given the above background, we used titanium fixation plate and an absorbable fixation plate for orthognathic surgery and compared the trend of postoperative re-entry and the postoperative complications between the two methods. Thus, we placed the aims of the current study in a comparison of clinical significance.

II. Patients and Methods

In the current study, 272 patients who visited Chosun University Hospital and Bundang Seoul National University Hospital between 2006 and 2007 and then underwent orthognathic surgery were enrolled. These patients consisted of 126 males and 146 females, whose mean age was 23 years, and they were divided into two groups based on the fixation method for surgery.

Surgical modalities in the current study included LeFort I osteotomy + BSSRO + genioplasty, LeFort I osteotomy + BSSRO, BSSRO + genioplasty and BSSRO.

SURGICAL METHODS

Surgery was performed based on the conventional method. Bone fragments were fixed using titanium plate in group I and fixed using an absorbable fixation plate (BioSorb FX, Linvatec Biomaterials Ltd, Tampere, Finland), in group II.

According to manufacturer's instructions, resorbable plate was adjusted using a plate bender. A screw hole was formed using a drill. The tapping was performed using a self-tapping driver. In addition, the fixation was performed using a resorbable screw.

Following the orthognathic surgery, patients were instructed to visit on a regular basis and received a check up for the

occurrence of complications. The site of osteotomy was fixed using a non resorbable plate in group I (n=152) and fixed using a resorbable plate in group II (n=120).

In a comparison of complications between the two groups, we excluded those whose high incidence result was not different between the use of a non resorbable plate and that of a resorbable one, e.g., nerve damage, following the orthognathic surgery. We examined the complications that could be compared in patients who underwent surgery using other types of materials. Postoperative complications included the postoperative anterior open bite, infection, temporomandibular joint dysfunction (TMD) and postoperative relapse, whose incidence was examined.

III. Results

In 272 patients who underwent orthognathic surgery at Chosun University Hospital and Pundang Seoul National University Hospital between 2006 and 2007, the current study was conducted. This showed that the surgical outcome was successful in 269 patients (98.89%), but the revision surgery due to surgical relapse was performed in three patients. Of 152 patients who used titanium plate, 13 (8.6%) developed complications. Of 120 patients who used a resorbable plate, 22 (18.3%) developed complications (Table 1). A greater degree of postoperative open bite and relapse trend were observed in cases using an absorbable fixation plate. The postoperative infection occurred in patients who used an absorbable fixation plate (Table 2).

Table 1. CLINICAL DATA OF APPLICATION OF PLATE IN ORTHOGNATHIC SURGERY

	No. of patients	Success	Re-operation	Complication
Titanium (2006)	86	86	0	7
Resorbable plate (2006)	61	58	3	12
Titanium (2007)	66	66	0	6
Resorbable plate (2007)	59	59	0	10
Total	272	269	3	35

Table 2. CLINICAL DATA OF COMPLICATION TYPE AFTER ORTHOGNATHIC SURGERY

	Anterior open bite	Infection	TMD	Surgical relapse
Titanium plate	3	0	10	0
Resorbable plate	7	5	7	3

TMD: temporomandibular joint dysfunction.

IV. Discussion

Sagittal split ramus osteotomy of mandible (SSRO) causes various complications. In addition to the common type of postsurgical complications, including infection and hemorrhage, sensory disturbance due to the inferior alveolar nerve injury, temporomandibular joint dysfunction (TMD) and relapse may be complicated.¹⁰⁻¹² In the current study, however, only the anterior open bite, postoperative infection, TMD and postoperative relapse were examined to make a comparison of a resorbable fixation plate and a non-resorbable one. Particularly, the relapse due to the transferral of bone fragments has become of interest. There is still a great controversy as to the relapse rate and its causes. The relapse was defined as the anterior displacement of more than 1.5 mm from normal occlusion of maxillary teeth following the surgical treatment of mandibular prognathism, as described by Peppersack.¹³ The trend of relapse following orthognathic surgery using sagittal split ramus osteotomy of mandible (SSRO) has been reported to vary depending on the authors or study design; it has been reported to range between 6% and 70%.¹⁴⁻¹⁶

It has been reported that the relapse trend is affected by various factors including the preoperative orthodontic therapy, the accuracy of osteotomy, the amount of movement, the tension of attached muscles, the change of location of mandibular

condyle, the fixation of bone fragments and the postoperative stabilization of occlusion. Of them, the pattern of bone attachments in the proximal and distal area has been the most significant factor that affected the relapse trend. This is due to the interactions of masticatory muscle in the related areas. In some previous studies, attempts have been made to minimize the activity of these masticatory muscles. Representatively, Wessberg et al¹⁷ attempted to prevent the relapse trend using suprahyoid myotomy, but these authors also did not explain the correlation between the suprahyoid myotomy and the relapse trend in detail. As described here, many controversial opinions exist regarding the cause of relapse. Many reports have also been made regarding the method of intraoperative fixation. Many authors^{18,19} have reported about the methods using a miniplate, rather than a screw, via an intraoral route to fix the bone fragments. These methods make it easy to attach a miniplate between the bone fragments, therefore they can minimize the change of the location of mandibular condyle and the compression of inferior alveolar nerve. The above authors also reported that these methods can provide a sufficient degree of fixation methods for decreasing the postoperative trend of relapse. According to Watzke et al,¹⁶ however, the fixation method using a screw can provide the comfort for patients by reducing the period for intermaxillary fixation, although there was no significant difference in a long term

stability between the fixation method using a screw and that using a wire.

To date, osteosynthesis from rigid internal fixation has been considered a standard regimen for the orthognathic surgery performed to adjust the skeletal segment position in response to the factors that can postoperatively cause malocclusion and relapse in the field of orthognathic surgery. As mentioned earlier, however, the necessity for the removal of a metal plate may be presented because of the psychological and other factors following the complete fixation of bone segments. Besides, various complications have been reported in cases using titanium metal plate. These complications include the deposition of titanium ion in the adjacent lymph nodes²⁰⁻²² or the soft tissue covering the metal plate, thermal conductivity, maxillary sinusitis, the discomfort on palpation^{23,24} allergic hypersensitivity,²⁵ and chemical carcinogenesis.²⁶ Accordingly, many studies have been conducted to identify the materials that can be used in substitution for titanium metal plate.

An absorbable fixation plate was developed to resolve these problems. At earlier times, an absorbable fixation plate had the advantage of prompt absorbption. With the addition to this advantage, the strength was maintained and the absorption was delayed using poly L lactic acid (PLLA). Still, however, the early strength is weak. To enhance this strength, PLLA/PGA composite field was applied. The application enhanced the

strength and delayed the absorption. In recent years, PLLA/PGA composite field has been used as an absorbable fixation plate in a clinical setting.

An absorbable fixation plate (BioSorb FX, Linvatec Biomaterials Ltd, Tampere, Finland), which was used in the current study, consisted of PDLLA (70L:30DL polymer), the copolymer of L lactic acid and D lactic acid. Its mechanical strength is maintained during a maximum period of 22 weeks. The degree of absorption can be predicted; it is absorbed after 24 to 30 months. Based on the thickness, it is divided into a 1.5-mm, a 2.0-mm and a 2.4-mm fixation plate. A 1.5-mm fixation plate can be applied to craniofacial surgery for pediatric patients, the orthognathic surgery of the maxilla and the midfacial 1/3 of maxillofacial trauma. A 2.0-mm fixation plate can be applied to the craniofacial surgery for adult patients, the orthognathic surgery for midface, genioplasty and sagittal split osteotomy of the ramus. A 2.4-mm fixation plate can be applied to the extensive trauma developed in the maxilla and mandible.

Wittwer et al.²⁷ 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. Bos et al.²⁸ reported fixation using resorbable poly(L-lactide) (PLLA) plates and screws gives good stability over a sufficiently long period to enable undisturbed fracture healing. Harada et al.²⁹

conducted a study to examine the relapse seen in patients who underwent orthognathic surgery, and reported that LA screw showed no statistically significant results compared to titanium plate. Furthermore, these authors noted that LA screw produced an excellent outcome in the treatment of facial bone fracture.

However, a resorbable plate discloses the disadvantages. To put this in another way, small fragments formed after it was hydrolyzed within the body are phagocytosized by macrophages and giant cells, and they are absorbed within the body. During this process, the degraded products are not sufficiently absorbed due to the partially prompt absorption in the local tissue. Meanwhile, postoperative complications such as swelling or fistula occur in many cases. The underlying bone is also absorbed.³⁰ PDLA which was manufactured to compensate these disadvantages maintain the mechanical strength for about 3-4 months and has an absorption period of 2-3 years. Besides, the absorption undergoes two phase process. During the absorption process, PDLA has a sufficient period of adaptation for the absorption. Accordingly, PDLA is advantageous in minimizing the risk of developing infection due to absorbable materials.³¹

In this study, the treatment success was observed in 269 patients (98.89%) and the surgical relapse leading to revision surgery was seen in three patients. In addition, the complications

were developed in 8.6% (3/152) of patients who used titanium plate and 18.3% (22/120) of those who used a resorbable plate. Postoperative complications include the postoperative open bite, infection, TMD and the postoperative relapse. These complications might originate from the characteristics of each material, but it cannot be concluded that the complications are correlated with the physical property of each material.

In the current study, as shown in Table 2, the postoperative infection occurred in patients who used an absorbable fixation plate. Considering the absorption period of an absorbable fixation plate which was used in the current study, the above results might be associated with other factors such as the oral hygiene status of patients and intraoperative infection.

In addition to the fixation methods, the location of proximal bone fragments greatly affects the postoperative stability. As the proximal segment is intraoperatively rotated to the posterior and inferior direction, the pterygomasseteric sling is extended. This is known to greatly affect the relapse trend and anterior open bite. In cases in which the proximal segment was rotated as described herein, the elevator muscle has a tendency to return to its preoperative length if the fixation between the bone fragments is unstable. Finally, the distal segment is rotated to the posterior and inferior direction using the molar as a leverage and thereby shows the anterior open bite as well as the relapse trend that the horizontal angle of lower

mandibular margin. It is our opinion that the above phenomena can easily occur particularly in cases involving a weak absorbable fixation plate.

According to Shand and Heggie,³² at least three screws must be used to fix each bone fragment and thereby to prevent the anterior open bite which was mentioned above in cases using an absorbable fixation plate. Commercially available form of absorbable fixation plate, used at the present, improved profile of physical property, however, it cannot be stated that the anterior open bite or postoperative relapse occur due to an insufficient extent of strength as previously described. This may be supported by many reports that stated that the amount of relapse was proportional to the degree of horizontal displacement due to orthognathic surgery. Kobayashi et al.³³ noted that more than 10 mm displacement could be considered a significant relapse trend because the degree of horizontal retraction was proportional to the relapse amount in patients with mandibular prognathism. Besides, Franco et al.³⁴ maintained that the amount of mandibular setback was the single variable that is correlated with the relapse in cases in which only the mandible was surgically managed.

Accordingly in the current study, a greater degree of postoperative open bite and relapse trend were observed in cases using an absorbable fixation plate. However, more careful approaches are needed to examine these phenomena in which

multiple factors are involved in a complex pattern. An absorbable fixation plate has a strength which is not equivalent to titanium fixation plate, but it does not need removal surgery and has the satisfactory degree of strength. It can therefore be inferred that an absorbable fixation plate will be useful in substitution for titanium fixation plate in indicated patients.

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저작물 이용 허락서

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논문제목	한글: 악교정 환자에서의 흡수성판과 비흡수성판의 비교 연구 영문: Comparative study between resorbable and non resorbable plate in orthognathic surgery				

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 의사표시가 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() 조건부 동의() 반대()

2009년 2월 일

저작자: 안 유 석 (서명 또는 인)

조선대학교 총장 귀하