

Self-reinforced biodegradable
poly-70L/30DL-lactide 고정장치를
이용한 LeFort I 골절제술 후
상악골의 위치 안정성 평가

연세대학교 대학원

치 의 학 과

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이 논문을 석사학위논문으로 제출함

2012 년 12 월

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김봉철의 석사 학위논문을 인준함

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감사의 글

본 논문이 완성되기까지 늘 바쁘신 가운데서도 열정과 관심을 가지고 부족한 저를 지도해 주신 정영수 교수님께 깊은 감사를 드립니다. 또한 많은 조언과 가르침으로 논문을 세심하게 심사해주신 김형준 교수님과 이기준 교수님께도 머리 숙여 감사 드립니다. 그리고 구강악안면외과 수련기간 동안 많은 가르침을 주신 이의웅 교수님, 이충국 교수님, 박형식 교수님, 차인호 교수님, 강정완 교수님, 이상휘 교수님, 남용 교수님께도 감사의 말씀을 전합니다.

그리고 구강악안면외과 수련기간 동안 함께하며 힘이 되어준 동기들인 변성수, 정희동, 최영달에게 고마움을 전합니다. 또한 보람된 수련기간을 보낼 수 있도록 해주신 의국 선배님들과 후배들에게도 감사의 말을 전합니다.

늘 아낌없는 사랑과 관심을 보여주신 양가 부모님께도 감사의 말씀을 드립니다. 그리고 남편을 믿고 이해해 준 아내 김미희와 밝은 웃음으로 힘을 준 딸 시원이에게 깊은 사랑과 고마운 마음을 전합니다. 마지막으로 이 모든 것을 인도해주신 하나님의 은혜에 감사드립니다.

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국문요약

Self-reinforced biodegradable poly-70L/30DL-lactide

고정장치를 이용한 LeFort I 골절제술 후 상악골의 위치 안정성 평가

본 연구는 self-reinforced biodegradable poly-70L/30DL-lactide miniplates 와 screws 를 이용한 LeFort I 골절제술 후 상악골의 위치 안정성을 평가하고자 하였다. Self-reinforced biodegradable poly-70L/30DL-lactide miniplates 와 screws 를 이용한 LeFort I 골절제술 및 내측고정을 시행한 19 명의 환자들을 임상 및 방사선학적으로 평가하였다. 상악 위치의 변화를 수술 후 1 주일, 1, 3, 6 개월 그리고/또는 1 년에 측모 두부규격 방사선사진을 촬영하여 측정하였다. Self-reinforced biodegradable poly-70L/30DL-lactide miniplates 및 screws 와 관련된 합병증은 술후 촬영한 방사선 사진과 의무 기록으로 평가하였다. 통계 분석을 위해 mixed model analysis for repeated measures 법을 사용하였으며 다음과 같은 결론을 얻었다.

1. 상악골의 위치는 수술 후 모든 기간에서 통계적으로 유의한 변화 없이 안정적으로 유지되었다.

2. 수술 후 모든 기간에서 self-reinforced biodegradable poly-70L/30DL-lactide miniplates 및 screws와 관련된 합병증은 없었다.

이상의 결과로 self-reinforced biodegradable poly-70L/30DL-lactide miniplates와 screws를 이용한 LeFort I 골절제술 후 내측 고정법은 수술 후 상악골의 위치를 안정적으로 유지시킬 수 있는 방법이라고 생각된다.

핵심되는 말 : self-reinforced biodegradable poly-70L/30DL-lactide miniplates and screws, 악교정수술, LeFort I 골절제술, 수술 후 변화

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I . Introduction

Internal fixation with titanium plates and screws for stabilization of osteotomized bone segments¹ has been the standard² in orthognathic surgery. The mechanical properties of titanium including strength, easy handling, no dimensional change^{3,4}, minimal scatter on computerized tomography scanning, and compatibility with plain radiography and magnetic resonance imaging⁵ have won its widespread acceptance as the standard.

However, there are several disadvantages to the use of titanium fixation, including interference with radiation therapy, migration of the material, growth restriction, palpability, and thermal

sensitivity^{4,6,7}. Moreover, titanium devices remaining in situ may induce pain, sinusitis, chronic headache, and infection^{8,9}. Thus, the removal of titanium plates after osteosynthesis is recommended¹⁰. This may require general anesthesia and is associated with additional surgical discomfort, risks, and cost^{3,11}. From a socioeconomic as well as a patient-care point of view, it would be preferable to avoid this additional surgical procedure³.

The use of a biodegradable osteosynthesis material is an attractive alternative for providing stability. The strength of the original biodegradable plates was poor, and intermaxillary fixation was required to support these devices¹. However, self-reinforced 70L/30DL polylactic acid was introduced as a new material for maxillofacial surgery. These plates and screws are radiolucent, easily adaptable with forceps at room temperature, and maintain the desired position without requiring a heating device^{7,8}. Several studies have shown that biodegradable fixation devices offer similar stability to titanium in fixation for orthognathic surgery and do not impose an increase in morbidity^{2,7,8,12-16}.

The long-term results of the stability and morbidity of self-reinforced biodegradable poly-70L/30DL-lactide miniplates and screws in maxillary repositioning have not been reported. The aims of this study

were to evaluate 1) the stability of Le Fort I with rigid internal fixation using self-reinforced biodegradable poly-70L/30DL-lactide miniplates and screws and 2) the morbidity of these devices in the postoperative course.

II. Materials and Methods

1. Subjects and Materials

Nineteen patients (9 men and 10 women) with a mean age of 22.2 yr had bimaxillary orthognathic surgery using self-reinforced biodegradable poly-70L/30DL-lactide miniplates in the Department of Oral and Maxillofacial Surgery at the Hospital of Yonsei University Health System, South Korea, between 2005 and 2006. Other procedures that occurred concurrently are shown in [Table 1](#). A single surgeon (Y.-S.J.) performed all operative procedures, using the same technique for all patients.

Rigid internal fixation with a self-reinforced biodegradable poly-70L/30DL-lactide (BioSorb FX; CONMED LINVATEC Biomaterials, Utica, NY) was used to stabilize the maxilla after Le Fort I osteotomy. After drilling and tapping, 4 L-shaped plates with monocortical 2.0-mm-diameter bone screws were placed in the canine fossa and zygomatic buttress bilaterally([Fig 1](#)). All patients were treated with routine antibiotic prophylaxis consisting of intravenous cephalosporin, or clindamycin administered at induction of anesthesia and repeated every 12 hours until day of discharge, for about 5 days.

Table 1. Other operation combined with LeFort I osteotomy

Name of operation	Number of patients
Bilateral sagittal split osteotomy (BSSO)	
advancement	2
setback	2
Bilateral vertical ramus osteotomy (BVRO)	14
Sagittal split osteotomy, Rt. and Vertical ramus osteotomy, Lt.	1

NOTE. Mandibular surgery consists of main ramus operation (sagittal split osteotomy and/or vertical ramus osteotomy) and adjunctive operation (genioplasty and/or anterior subapical osteotomy). In sagittal split osteotomy and adjunctive operation, internal fixation was done with biodegradable poly-70L/30DL-lactide miniplates and screws. In BVRO, no internal fixation was done.



Fig. 1. Clinical view of maxilla showing rigid fixation after Le Fort I osteotomy using 4 plates with monocortical bone screws 2.0 mm in diameter placed in the canine fossa and zygomatic buttress.

Preoperative, 1 week, 1 mo, 3 mo, 6 mo, and/or a maximum of 1 yr postoperative lateral cephalograms were used to compare hard tissue changes after bimaxillary orthognathic surgery in all 19 patients. Complications at the operation area were documented by reviewing the medical records. Before surgery, the patients were given information regarding the advantages and disadvantages of the biodegradable plates,

including the medical expenses and complications involved. Informed consent for using self-reinforced biodegradable miniplates and screws was obtained from the patients. Because the patients were going to have the procedure and radiographs as part of the standard postoperative protocol, this study was exempt from Institutional Review Board full review.

2. Analytic method

Delaire's architectural and structural analysis¹⁷ was used for evaluation of hard tissue changes after maxillary repositioning. The reference points and lines used included the following:

1. M: the junction of the nasofrontal, maxillofrontal, and maxillonasal sutures
2. Clp: apex of the posterior clinoid process
3. OP (posterior occipital point): the junction of the occipital bone and C3
4. C3 (superior line of the cranial base): line connecting M and Clp
5. FM (fronto-maxillary point): the point slightly posterior to M on the cranial baseline C3, where the frontal process of the maxilla articulates with the lacrimal bone

6. CF1 (craniofacial balance): the line that traced passing through FM, rectangular to C3

7. ANS: anterior nasal spine

8. NP: anterior border of nasopalatine canal

The measurements analyzed were as follows (Fig 2).

1. VNP: Vertical position of the NP: the distance from C3 to NP

2. VANS: Vertical position of the ANS: the distance from C3 to ANS

3. HNP: Horizontal position of the NP: the distance from CF1 to NP

4. HANS: Horizontal position of the ANS: the distance from CF1 to ANS

Reference lines and points on each of the lateral cephalometric films were traced on 0.07-mm acetate sheets with a 0.3-mm lead pencil. All measurements were performed by the same individual with a caliper that was accurate to 0.01 mm. To ensure the precision of tracing and measurements, the vertical position of NP (VNP) and HANS in all preoperative samples were traced and measured 4 times. The paired *t* test was undertaken to evaluate the difference in the measurements.

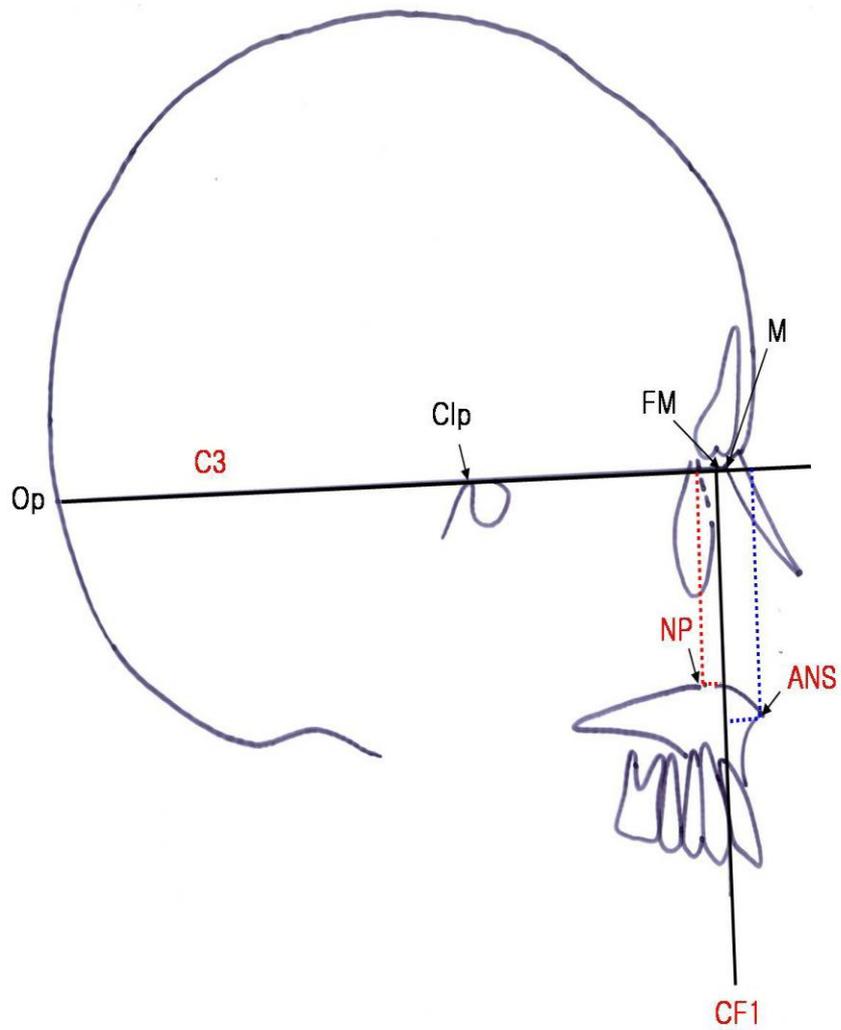


Fig. 2. Reference landmarks and planes used in this study are illustrated

The measures of vertical and horizontal maxillary position were subjected to the mixed model analysis for repeated measures in all postoperative intervals. The statistical program used for this study was SAS package for Windows version 9.1 (SAS Institute Inc, Cary, NC).

III. Results

1. Analysis of measurement values by tracing

There was no statistically significant difference in the repeated measures ($P > .05$) indicating that the measurements were accurate.

The changes in maxillary position from immediate postoperative to 1 yr are given in 6 intervals (Table 2). Horizontal changes include anterior movement at NP (0.04 ± 0.02 mm) and at ANS (0.13 ± 0.09 mm) up to 1 yr postoperation. Vertical changes did not show a tendency of unidirectional movement. For the amount of largest movement in each category, VANS horizontal position of NP (HNP) and HANS showed it from immediately after operation to 6 mo (0.08, 0.09, and 0.29 mm, respectively). VNP showed the biggest movement (-0.09 mm) from 3 mo after operation to 6 mo.

By frequencies up to 1 yr postoperation, 66.7% of subjects represented changes within 0.3 mm; 16.7% were over 0.3 mm but within 0.5 mm, and the other 16.7% were more than 0.5 mm. However, the largest variation of these subjects was within 0.6 mm. All of these changes were clinically and statistically insignificant.

Table 2. The amount of maxillary positional change by LeFort I osteotomy

Period	VNP			VANS			HNP			HANS		
	Mean	SD	P value	Mean	SD	P value	Mean	SD	P value	Mean	SD	P value
immediate to 1M (n=19)	-0.02	0.04	0.99	0.05	0.14	0.98	0.01	0.07	0.99	0.12	0.07	0.29
1M to 3M (n=19)	0.07	0.06	0.82	-0.03	0.11	0.99	0.05	0.02	0.87	0.16	0.06	0.09
3M to 6M (n=19)	-0.09	0.05	0.67	0.06	0.08	0.98	0.03	0.03	0.98	0	0.02	0.99
immediate to 6M (n=19)	-0.04	0.12	0.98	0.08	0.22	0.92	0.09	0.04	0.41	0.29	0.08	0.09
6M to 1Y (n=12)	0.01	0.01	0.99	-0.04	0.03	0.93	0.06	0.01	0.96	0.17	0.02	0.1
immediate to 1Y (n=12)	0.03	0.05	0.99	-0.03	0.16	0.99	0.04	0.02	0.93	0.13	0.09	0.65

(scale : mm)

Abbreviations: HANS, horizontal position of ANS; HNP, horizontal position of NP; VANS, vertical position of ANS; VNP, vertical position of NP

All data $P > .05$, mixed model analysis for repeated measures

2. Safety of self-reinforced biodegradable poly-70L/30DL-lactide miniplates and screws

There was no abnormal swelling, discharge, local inflammation, infection, or wound dehiscence in patients who had self-reinforced biodegradable poly-70L/30DL-lactide miniplates and screws. Osteotomy segment failure or mobility was not seen on a clinical examination in any of the patients during the follow-up period. All the patients had a stable occlusion in early follow-up visits and elastics were placed to guide occlusion. In addition, mouth opening and jaw movement recovered to normal range within 1 mo after operation.

IV. Discussion

Replacement of titanium plates and screws with those that have similar properties and can be absorbed by the human body has been extensively evaluated. Kallela et al¹⁶ reported mandibular advancement with bilateral sagittal split osteotomy (BSSO) and biodegradable self-reinforced poly-L-lactide (SR-PLLA) screws for fixation. They found the net backward relapse was 15% at pogonion and 17% at B point. Ferretti et al¹⁵ compared skeletal stability after BSSO advancement fixed with titanium or biodegradable bicortical screws. Their results showed that BSSO stabilized with poly-L-lactic/polyglycolic acid copolymer screws relapsed 0.83 mm compared with 0.25 mm for titanium fixation. However, these changes were statistically and clinically insignificant. Ueki et al¹² concluded that the change in condylar angle after BSSO and fixation with a titanium plate is greater than that after BSSO and fixation with an SR-PLLA plate, but skeletal stability related to the occlusion was similar for the 2 fixation methods. These results showed that for BSSO advancement of less than 6 mm, biodegradable device fixation was a viable alternative to titanium in mandibular surgery.

However, the stability of Le Fort I osteotomy with biodegradable fixation has been the subject of only a few studies. Haers and Sailer⁸ presented data up to 6 weeks for 10 patients with biodegradable self-reinforced poly-L/DL-lactide plate and screw fixation in bimaxillary orthognathic surgery. Turvey et al¹⁷ described that maintenance of adequate strength to permit jaw movement for 3 mo, as is afforded with this polymer, permits initial bone healing. Our study documented stability of biodegradable plate fixation for Le Fort I osteotomy at 6 mo to a year.

Several investigators found that after fixation with biodegradable devices, the maxilla had postoperative mobility^{2,7,13,14}. Turvey et al noticed stabilization of the maxilla with self-reinforced poly L/DL-lactide plates and screws was associated with greater mobility of the segments during the postoperative phase than with titanium systems⁷. Cheung et al² also detected mobility of the osteotomy segments at the second postoperative week. However, this was anecdotal with no quantitative measurements such as the amount of maxillary position change, method of measurement, and period of observation. Additionally, they included patients who had segmental osteotomy^{2,7}. Norholt et al¹⁴, using PLLA/PGA plates, showed a statistically significant difference in

vertical maxillary position after 6 weeks. The maxilla moved superiorly over time (mean change of 0.6 mm). Ueki et al¹³ reported significant differences between titanium and PLLA groups in time course changes for the vertical component at A point after Le Fort I osteotomy and BSSO, and the vertical component of PNS after Le Fort I osteotomy in both combinations with BSSO and vertical ramus osteotomy (VRO).

In the present study, changes in maxillary position were -0.03 to 0.13 mm up to 1 yr after operation. This small amount of positional change may be due to recommendations for a soft diet for at least 1 mo after the operation, and intermaxillary fixation for 12 days. Additionally, our surgical treatment objective included maxillary impaction and/or advancement but did not include vertical lengthening. This may also contribute to the stability of maxillary position in our patients. There were no statistically significant changes in our measurements ($P > .05$) at any time interval, resulting in a well-maintained maxillary position. Therefore, self-reinforced biodegradable poly-70L/30DL-lactide miniplates and screws were strong enough to permit initial bone healing.

Reported complications with biodegradable plates include loosening of screws, wound dehiscence, and plate exposure². Infection rates with biodegradable plates vary from study to study and were generally quite

low, ranging from 1.82% to 10%^{2,8,18,19}. Similar to our findings, Ferretti et al¹⁵ reported no infection related to the use of the biodegradable plate and screw fixation. The large difference between the infection rates is probably due to the small sample size of patients. With a small sample, an increase in 1 patient would produce a significant overall percentage change². Variation in infection rates between studies may not be the result of the material but rather the patient' s hygiene habits and other factors.

We had no patients with mobile segments, which is different from that reported by Turvey et al and Cheung et al^{2,7}.

V. Conclusion

Our experience with self-reinforced biodegradable poly-70L/30DL-lactide miniplates and screws for maxillary repositioning after Le Fort I osteotomy has been described. All patients showed satisfactory wound healing without any complications. The plates allowed for bony union and there was no mobility of bone segment. Although our study assessed only 1-piece Le Fort I osteotomy and the sample size was small, our experience showed the efficiency of self-reinforced biodegradable poly-70L/30DL-lactide miniplates and screws for maxillary repositioning.

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Abstract

Stability of maxillary position after LeFort I osteotomy using self-reinforced biodegradable poly-70L/30DL-lactide miniplates and screws

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The purpose of this study was to evaluate the stability of Le Fort I osteotomy using self-reinforced biodegradable poly-70L/30DL-lactide miniplates and screws.

Nineteen patients who had Le Fort I osteotomy and internal fixation using self-reinforced biodegradable poly-70L/30DL-lactide miniplates and screws were evaluated both radiographically and clinically. Changes in maxillary position after operation were documented 1 week, 1, 3, 6 mo, and/or 1-yr postoperatively with lateral cephalometric tracings.

Complications of the self-reinforced biodegradable poly-70L/30DL-lactide miniplates and screws were evaluated by follow-up roentgenograms and clinical observation. A mixed model analysis for repeated measures was used for statistical analysis. A retrospective study was conducted based on the results and the results are follows.

1. Maxillary position was stable after operation with no change between time points ($P > .05$).

2. There were no complications with the self-reinforced biodegradable poly-70L/30DL-lactide miniplates and screws.

In conclusion, Internal fixation of the maxilla after Le Fort I osteotomy with self-reinforced biodegradable poly-70L/30DL-lactide miniplates and screws is a reliable method for maintaining the postoperative maxillary position after Le Fort I osteotomy.

Key words : Self-reinforced biodegradable poly-70L/30DL-lactide miniplates and screws, Orthognathic surgery, LeFort I osteotomy, Postoperative change