

A Retrospective study in Comparison of Skeletal Stability and Pharyngeal Airway
Changes in Mandibular Prognathism after correction with Mandibular Setback Surgery
using Two Different Types of Osteofixation Materials



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การศึกษาย้อนหลังเปรียบเทียบเสถียรภาพของโครงกระดูกและการเปลี่ยนแปลงของทางเดินหายใจใน
ผู้ป่วยที่มีขากระดูกไกรกลางยื่น
หลังการผ่าตัดถอยขากระดูกไกรกลางด้วยการใช้วัสดุยึดติดกระดูก สองประเภท



วิทยานิพนธ์นี้เป็นส่วนหนึ่งของการศึกษาตามหลักสูตรปริญญาวิทยาศาสตรมหาบัณฑิต
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พูนิน เตต :

การศึกษาย้อนหลังเปรียบเทียบเสถียรภาพของโครงกระดูกและการเปลี่ยนแปลงของทางเดินหายใจในผู้ป่วยที่มีขากรรไกรล่างยื่น หลังการผ่าตัดดัดอวัยวะขากรรไกรล่างด้วยการใช้วัสดุยึดติดกระดูก สองประเภท. (A Retrospective study in Comparison of Skeletal Stability and Pharyngeal Airway Changes in Mandibular Prognathism after correction with Mandibular Setback Surgery using Two Different Types of Osteofixation Materials) อ.ที่ปรึกษาหลัก : อ.ทพญ. ดร.บุศนา คະບຸສຍ໌

ว ี ติ ฎ ุ ป รั ะ ส ัง ค ์ :

การศึกษานี้เปรียบเทียบความคงตัวของโครงกระดูกและการเปลี่ยนแปลงของทางเดินหายใจบริเวณคอดอยหลังจากการผ่าตัดดัดอวัยวะขากรรไกรล่างที่ยึดกระดูกด้วยไททาเนียมและวัสดุที่สามารถละลายตัวได้

วัสดุและวิธีการ: สุ่มเลือกผู้ป่วย 28 รายที่ได้รับการผ่าตัดดัดอวัยวะขากรรไกรล่างแบบ bilateral sagittal split ramus osteotomy (BSSRO) ที่ยึดกระดูกด้วยไททาเนียมและวัสดุที่สามารถละลายตัวได้ ทำการวิเคราะห์ภาพรังสีกระดูกสันหลังด้านข้างก่อนการผ่าตัด (T0) สัปดาห์ที่ 1 หลังการผ่าตัด (T1) 3-6 เดือนหลังการผ่าตัด (T2) และ 1 ปีหลังการผ่าตัด (T3) โดยศึกษาความเสถียรของโครงกระดูกโดยการวัดแนวนอน (BX) การวัดแนวตั้ง (BY) และการวัดมุม (SNB และ Mandibular Plane Angle; MPA) และศึกษาการเปลี่ยนแปลงของทางเดินหายใจบริเวณคอดอยโดยการวัดช่องว่างบริเวณจมูก (NOP), ลิ้นไก่ (UOP), ลิ้น (TOP) และฝาปิดกล่องเสียง (EOP)

ผลลัพธ์: ไม่มีความแตกต่างกันของระยะการดัดอวัยวะขากรรไกรล่างทั้งในไททาเนียม (6.61 ± 3.96 มม.) และวัสดุยึดกระดูกที่สามารถละลายตัวได้ (5.08 ± 3.21 มม.) พบการเปลี่ยนแปลงมุม MPA ที่มีนัยสำคัญทั้งในไททาเนียมและวัสดุยึดกระดูกที่สามารถละลายตัวได้ในช่วง 3-6 เดือนหลังการผ่าตัด โดยมุม MPA ยังคงแสดงการเปลี่ยนแปลงที่มีนัยสำคัญในวัสดุยึดกระดูกที่สามารถละลายตัวได้ ในช่วง 1 ปีหลังการผ่าตัด (2.29 ± 0.59 ; $p\text{-value}=0.006$) นอกจากนี้พบว่า วัสดุยึดกระดูกที่สามารถละลายตัวได้มีการเปลี่ยนแปลงบริเวณ EOP อย่างมีนัยสำคัญ (-1.21 ± 0.3 มม.; $p\text{-value}=0.02$) ที่ 3-6 เดือนหลังการผ่าตัด จากนั้นจึงไม่มีการเปลี่ยนแปลงอย่างมีนัยสำคัญที่ 1 ปีหลังการผ่าตัด

สรุป : การศึกษาครั้งนี้แสดงให้เห็นว่า วัสดุยึดกระดูกที่สามารถละลายตัวได้นั้นมีคุณสมบัติเทียบได้กับไททาเนียมในแง่ความคงตัวของทางเดินหายใจบริเวณคอดอยในระยะยาว แต่มีแนวโน้มที่จะเกิดการเปลี่ยนแปลงของกระดูกโดยเฉพาะมุม MPA

สาขาวิชา ศัลยศาสตร์ช่องปากและแม็กซิลโลเฟเชียล ลายมือชื่อนิสิต

ยล

ปีการศึกษา 2564 ลายมือชื่อ อ.ที่ปรึกษาหลัก

6370031332 : MAJOR ORAL AND MAXILLOFACIAL SURGERY

KEYWORD: Titanium, Resorbable plate and screws, BSSRO, Stability, Pharyngeal airway

Phu Hnin Thet : A Retrospective study in Comparison of Skeletal Stability and Pharyngeal Airway Changes in Mandibular Prognathism after correction with Mandibular Setback Surgery using Two Different Types of Osteofixation Materials.
Advisor: Dr. BOOSANA KABOOSAYA, D.D.S., Ph.D.

Objectives: This study compared the skeletal stability and pharyngeal airway changes after mandibular setback procedure using the titanium and resorbable plate and screws fixation.

Materials and Methods: 28 patients with mandibular prognathism being treated with bilateral sagittal split ramus osteotomy (BSSRO) were randomly selected from titanium and resorbable fixations. Analyses of lateral cephalometric x-rays were performed according to preoperative (T0), 1st week post-surgery (T1), 3-6 months post-surgery (T2) and 1-year post-surgery (T3). The horizontal measurement (BX), vertical measurement (BY), and angle measurement (SNB and Mandibular Plane Angle; MPA) were studied for skeletal stability. The pharyngeal airway changes were observed by nasopharynx (NOP), uvula (UOP), tongue (TOP) and epiglottis (EOP).

Results: There were no significant difference of mandibular setback in titanium (6.61 ± 3.97 mm.) and resorbable groups (5.08 ± 3.21 mm.). Significant MPA changes were found in both titanium and resorbable groups in 3-6 months post-surgery, but MPA still expressed significant changes in the resorbable group in 1-year post-surgery (2.29 ± 0.59 ; p -value=0.006). The resorbable group was found significant EOP changes (-1.21 ± 0.3 mm; p -value=0.02) in 3-6 months post-surgery, then gradually returned to no significant changes in 1-year post-surgery.

Conclusion: This study could be demonstrated that osteofixation with resorbable plates and screws was comparable to titanium in long-term pharyngeal airway dimension, but

Field of Study: Oral and Maxillofacial Surgery Student's Signature

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จุฬาลงกรณ์มหาวิทยาลัย
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1. INTRODUCTION

1.1 Background and Rationale

The desire of both orthodontists and maxillofacial surgeons to remedy the deformities of the maxillomandibular complex was an old urge since the 19th century. When jaw deformity with or without occlusal discrepancy was beyond the orthodontic treatment limits, the corrective surgery has been considered. The first known orthognathic surgery was the anterior mandibular subapical osteotomy and setback procedure using the intraoral approach by American Surgeon Simon P. Hullihen in 1849 (1). Since then, the evolution of surgical techniques for the correction of dentofacial skeletal deformities has been developed.

The advantages of rigid internal fixation had a major influence not only on patients but also on the surgeons performing the surgery. An internal fixation with metal plates and screws provided less morbidity, more comfort and shorter hospital stayed for the patients because the requirement for intermaxillary fixation (IMF) was markedly reduced (2). It also provided an earlier return of masticatory function, better patient's satisfaction, and significant improvement in oral health-related quality of life.

Titanium plates and screws have been considered as the gold standard for internal fixation in the field of oral and maxillofacial surgery, such as trauma management, orthognathic surgery, maxillofacial oncology and reconstruction. Although titanium osteosynthesis system was highly recommended for its excellent biocompatibility, good mechanical and chemical properties, it also has several potential drawbacks, including screw or plate migration, growth restriction, radiographic obstruction, subsequent imaging distortion, and physiologic or psychological need for removal with second surgery (3-5). Those limitations of

titanium plates and screws had led to the innovation of biologically resorbable osteofixation materials for the purpose of osteofixation.

Bioabsorbable materials have several advantages over metallic based materials, which were reduced stress-shielding effect, absence of metal corrosion, no interference with a radiological evaluation due to their radiolucent properties, easily bendable with forceps at the room temperature and maintained the desired position without requiring a heating device, and did not disturb growth potential (4-7). Meanwhile, the surgeon's primary concern was postoperative skeletal stability, which was achieved by using bioabsorbable plates and screws.

Mandibular setback played an important role in skeletal relapse tendency due to upper airway, soft palate and tongue changes (8). An increase in muscle tension because of stretching of the suprahyoid musculature might be related to skeletal relapse was postulated. The stability after mandibular setback procedures remained the third most problematic issue among orthognathic surgery, especially during the first post-surgical year (9). Previous studies reported that pharyngeal airway was significantly reduced after mandibular setback surgery, and depletion was maintained over the long term (10, -11). Several cephalometric studies have been carried out to compare the mandibular stability obtained by titanium and resorbable materials with different material designs (12), or the same osteofixation technique (13-16).

However, no article investigated skeletal stability and pharyngeal airway changes in mandibular setback surgery using two different types of osteofixation materials. This study aimed to compare the cephalometric analysis of skeletal stability of the mandible and resultant airway changes evaluation, achieved using resorbable plates and screws compared with gold standard titanium.

1.2 Research Question

Are the skeletal stability and pharyngeal airway positional changes maintained by the bioabsorbable plates and screws fixation the same as that of titanium plates and screws fixation?

1.3 Research Objectives

1. To compare the skeletal stability after mandibular setback procedure between using the bioabsorbable plate and screws fixation and titanium plate and screws fixation
2. To analyze the long-term pharyngeal airway changes after mandibular setback procedure between using the bioabsorbable plate and screws fixation and titanium plate and screws fixation

1.4 Research Hypothesis

Skeletal stability and pharyngeal airway positional changes after mandibular setback procedure using bioabsorbable plates and screws fixation are maintained the same as that in using titanium plates and screws fixation

1.5 Benefit of our study

This is the first study analyzing the oropharyngeal complex and comparing the skeletal stability provided by monocortical bioabsorbable plate and screws fixation in mandibular setback procedure and the cases fixed by gold standard monocortical titanium plate and screws in terms of cephalometric analysis. The results from this study provided evidence-based information related to skeletal stability and the long-term pharyngeal airway changes that might help in determining the usage of bioabsorbable plates and screws instead of titanium plates and screws in the future.

1.6 Limitations of our study

A few numbers of patients with resorbable plate and screws were available (14 patients).

1.7 Conceptual framework

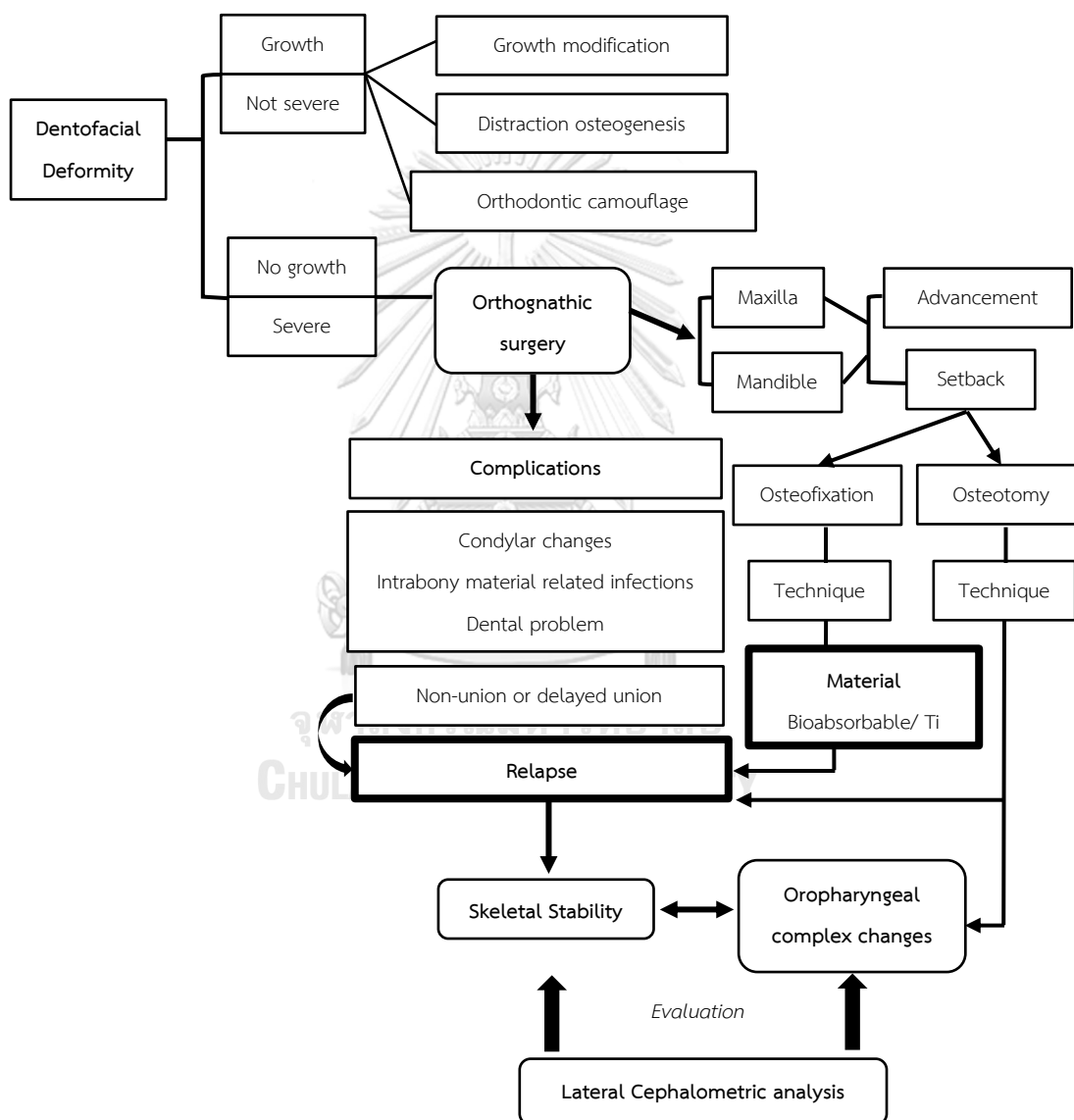


Figure 1. Conceptual framework of this research study

2. LITERATURE REVIEWS

2.1 Dentofacial Skeletal Deformities

The term dentofacial skeletal deformity was stated by Posnick JC (17) as a significant deviation from the normal proportions of the maxillomandibular complex that negatively affects the relationship of the teeth within the arch as well as the relationships of the arches with one another. The etiology of dentofacial skeletal deformities may be congenital, developmental, or acquired (traumatic) conditions. Disturbances in the normal growth pattern of various facial skeleton elements dismantle the anatomic proportions of the face resulting in aesthetic and functional impairments (18).

The prevalence and types of dentofacial skeletal deformities, especially mandibular prognathism, may vary among different racial groups and nationalities (19-22). Boeck et al. (19) reported that the most prevalent skeletal deformity in Brazilian patients was Class III skeletal malocclusion, with a higher incidence of asymmetry. Olkun et al. (20) pointed out that most Turkish patients with dentofacial deformity had Class III skeletal type. Similarly, Class III facial skeletal pattern was the most prevalent dentofacial deformity in Chinese and Caucasians (21). Ruslin et al. (22) also concluded that the mandibular prognathism with an open bite was the most common dentofacial deformity in South East Asian patients.

With dentofacial deformity, individuals have negative effects in functions such as malocclusion, breathing, chewing, swallowing, speaking and lip closure or posture. Dentofacial deformity not only adversely affects the anatomical structures like temporomandibular joints, periodontium, teeth but also causes the disturbances in the socio-psychological health status of the one being due to low self-esteem and decreased level of confidence (17).

There were generally four dentofacial deformities treatment options according to the severity of malocclusion; growth modification, orthodontic treatment to compensate the jaw discrepancies, distraction osteogenesis and orthognathic surgery (23). In the absence of growth, beyond the limit of growth modification treatment, orthodontic treatment alone was not enough to improve the function and to obtain the desired esthetic appearance (23). Thereby, orthognathic surgery has become the most feasible option to correct the dentofacial deformity for the optimal results.

2.2 Orthognathic Surgery

Orthognathic surgery may be defined as repositioning the maxilla and/or mandible and/or their segments through a surgical approach to enhance the dentofacial function and appearance (in a stable manner) and health-related quality of life (24). The first mandibular osteotomy was performed by Hullihen in 1897 (24-26). After almost 50 years before, Blair (27) performed the first mandibular body osteotomy to correct of horizontal mandibular excess through an extraoral approach (17, 24, 26).

In the 1940s and 50s, the transition from an extraoral towards a complete intraoral approach for the mandibular ramus osteotomy had occurred (24). To obtain a broad bone-contacting surface for promoting stable bony union and avoid mandibular canal trauma, in 1953, Obwegeser (24, 28) performed sagittal split ramus osteotomy (SSRO) through an intraoral approach with better aesthetic outcomes. Further modifications were made to improve Obwegeser's SSRO by Dal Pont (29) in 1961, Hunsuck (1968) (30), and Epker (1977) (31) with the emphasis on decreasing relapse, promoting healing and minimizing complications (Figure 2) (24, 32).

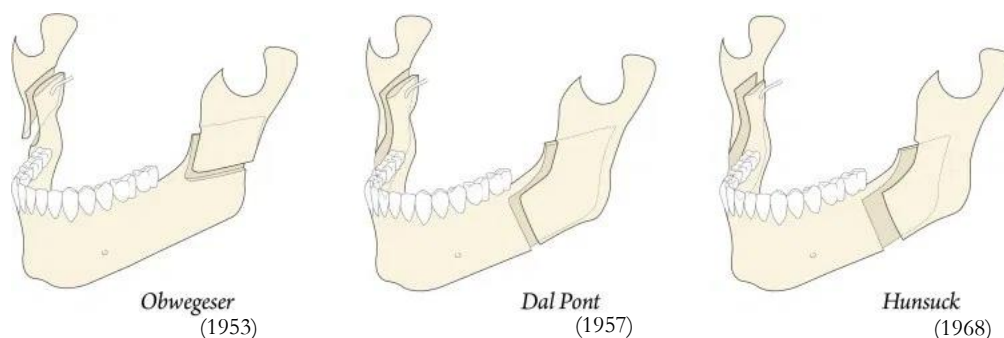


Figure 2. Modifications of BSSRO technique

Hunsuck (1968) modified the Obwegeser's sagittal split procedure by ending the medial horizontal osteotomy to just behind the lingula. In this technique, the potential for bleeding from the accidental cutting of the vessels posterior to the ramus was reduced (24, 26, 28, 32). In 1977, Epker advocated further refinements to the Hunsuck approach by suggesting a minimal soft tissue dissection on both sides of the ramus. As the proximal segment was not necessary to be repositioned, periosteum and masseter muscles should not be reflected from the mandibular ramus laterally and also pterygomasseteric sling should be remained attached to the posteroinferior border of the mandible.

By doing so, the vascular supply to the proximal segment was preserved and thus eliminated the occurrence of postoperative swelling, hemorrhage, nerve injury, bone resorption and loss of the gonial angle (24, 26, 32). After all of these modifications, the SSRO procedure has become a versatile technique for the correction of many dentofacial deformities. Using bilateral sagittal split ramus osteotomy (BSSRO), the mandible advancement, setback, rotation and closing of the open bite cases are possible to achieve better aesthetic outcomes with less chance of postoperative complications like nerve injury.

2.3 Internal Fixation

Restoring normal jaw function and improving facial appearance with long-term stability were the major goals of orthognathic surgery (22). After positioning the various elements of the dentofacial skeleton, it was important to maintain them in the planned surgical position during the healing process. Along with developing surgical techniques of osteotomy, types of fixation methods and materials used to stabilize the distal and proximal bone segments have also been improved. The main objectives of internal fixation usage after BSSRO were to facilitate rapid bone healing, initiate mandibular function as soon as possible and minimize relapse (33, 34). Plate and screws application in orthognathic surgery also promoted patient safety because the airway can be easily secured in the critical postoperative phase after extubation (25).

Two major internal fixation methods have been used in orthognathic surgery in recent years; monocortical and bicortical plate and screws (33-35). Plate fixation with monocortical screws provided some benefits over bicortical screws such as reducing the occurrence of inferior alveolar nerve injury, avoidance of visible scars on the face or neck or through trans-cutaneous drilling, and prevention of mandibular condyles rotation (35). No statistically significant differences in postsurgical skeletal stability between monocortical osteosynthesis and bicortical osteosynthesis after BSSRO had also been reported (33-35).

2.4 Titanium Plate and Screws

Osteofixation with metal plate and screws have been used widely in the reconstructive treatment in traumatology, orthognathic surgery and maxillofacial oncology. Stainless steel materials had been used before titanium alloys has been replaced in the 1990s due to the superior corrosion resistance, lower stiffness,

enhanced diagnostic imaging compatibility (40% less magnetic resonance imaging interference than stainless steel) (36) and its biocompatibility (5, 37).

Several authors have reported about the drawbacks of titanium osteosynthesis, including infection (37-40), palpability (38-40), thermal sensitivity, screw loosening (38), artifact in imaging, interference with radiotherapy (41), and growth disturbances (42, 43). Titanium plate and screws have to be removed when it becomes symptomatic. Generally, the two main reasons for removal were removal due to plate related complications (infection or hardware failure) and removal due to subjective discomfort (palpability, sensitivity to cold, patient's discomfort about having foreign objects in the body) (4, 5, 38). Kuhlefeldt et al. (38) and Bhatt et al. (40) reported about the elective removal of asymptomatic titanium plates and screws due to the patient's request. The requirement of second-time surgery for plate removal is time- and cost-consuming for the patient (3).

2.5 Resorbable Plate and Screws

The first bioabsorbable materials used for internal fixation of maxillofacial skeletal fractures was in 1971 (4, 44). In the field of orthognathic surgery, its use was first reported in 1998 (45). Since then, oral and maxillofacial surgeons are increasingly using bioabsorbable materials due to their biologically absorbable properties, eliminating the potential need for a subsequent operation to remove metal devices.

Bioabsorbable signified not only biodegradation but also the presence of osteoconduction stimulation. The ideal bioabsorbable material should have enough support for bone healing, restore adequate intrinsic bone strength, copolymers should not cause local or systemic side effects, the size must be small and must be applicable at the various maxillofacial bone sites and resorb completely once the healing process was finished (46, 47).

The benefits of bioabsorbable fixation materials included an absence of metal particles accumulation and metal corrosion in tissues, no disturbance in radiographs due to their radiolucent properties and prevention of osteoporosis by its low stress-shielding effect due to initial bearing of a smaller load and gradual transferring of the functional load to the healing bone during degradation process (6, 44, 48). Usage of the bioabsorbable plate and screws fixation in pediatric patients had been reported that there were no growth disturbances (47). The most significant benefit of the bioabsorbable plate and screws was the obviation of the need for a patient to undergo a second-stage removal surgery.

Generally, there are two sequential phases in the degradation process of bioabsorbable materials: the hydrolysis phase and the metabolic phase. As soon as the material was implanted, the hydrolytic degradation of poly-L-lactic acid (PLA) and polyglycolic acid (PGA) occurs by the diffusion of water molecules into the polymer chains resulting in separated smaller polymer fragments which are glycolic acid and lactic acid monomers. They are phagocytized by macrophages and transported into the liver for the metabolic phase. They enter the Krebs citric acid cycle and produce carbon dioxide (CO_2) and water (H_2O) as the end products. The main route of breakdown products elimination is through respiration and, to a lesser extent, in urine and feces (Figure 3) (49, 50).

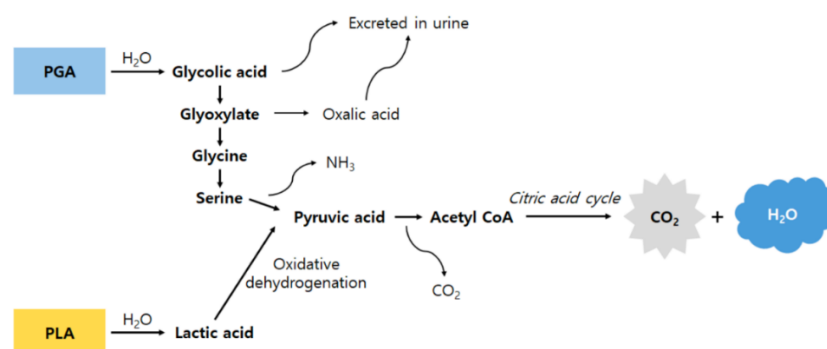


Figure 3. Diagram describing the degradation process of PGA and PLA polymers and copolymers

The rate of the degradation process is influenced by the bioabsorbable copolymer's crystallinity, porosity, and molecular weight. If the degradation process is rapid and the host cannot remove acidic metabolites, the local tissue pH will be decreased. The acidic environment is unfavorable for the healing process and thus leads to local tissue inflammatory reactions (51). The combination of copolymers has been designed to adjust the resorption time and maintain the desired strength of the bioabsorbable materials (Table 1).

Table 1. Commercially available bioabsorbable internal fixation system

| Product | Manufacturer | Composition (%) | Resorption time |
|----------------------------|-----------------------------|--------------------------------|-----------------|
| LactoSorb | Walter Lorenz Surgical Inc. | PLLA (82); PGA (18) | 6-12 months |
| Rapidsorb | DePuy Synthes | PLLA (85); PGA (15) | 12 months |
| PolyMax RAPID | Synthes | PLLA (85); PGA (15) | 12 months |
| ResorbX | KLS martin | PLLA (50); PDLLA (50) | 12-30 months |
| Macropore | Medtronic | PLLA (70); PDLLA (30) | 1-3 years |
| Bionx | Bionx Implants Inc. | PLLA (70); PDLLA (30) | 1-2 years |
| BiosorbFX | Bionix Implants | PLLA (70); PDLLA (30) | 2-3 years |
| PolyMax | Synthes | PLLA (70); PDLLA (30) | 2 years |
| Resomer | Evonik | PLLA (70); PDLLA (30) | 2-3 years |
| Resorbable fixation system | Synthes | PLLA (70); PDLLA (30) | 1-6 years |
| Delta System | Stryker-Leibinger | PLLA (85); PDLLA (5); PGA (10) | 1.5-3 years |
| OsteotransMx | Takiron | u-HA (30-40); PLLA (60-70) | 4.5-5.5 years |
| Inion CPS | Inion Inc. | PLLA; PDLLA; TMC | 1-2 years |

PLLA, poly-L-lactic acid; PGA, polyglycolic acid; PDLLA, poly-DL-lactic acid; u-HA, unsintered hydroxyapatite; TMC, trimethylene carbonate.

2.6 Stability and Relapse

According to Proffit's hierarchy of post-surgical stability (Figure 4), mandibular setback procedures remained the third most problematic procedure among other orthognathic surgeries (9). After isolated mandibular setback procedure, 40-50% of patients experienced 2-4 mm of post-surgical change, and more than 4 mm of change in 20% (52).

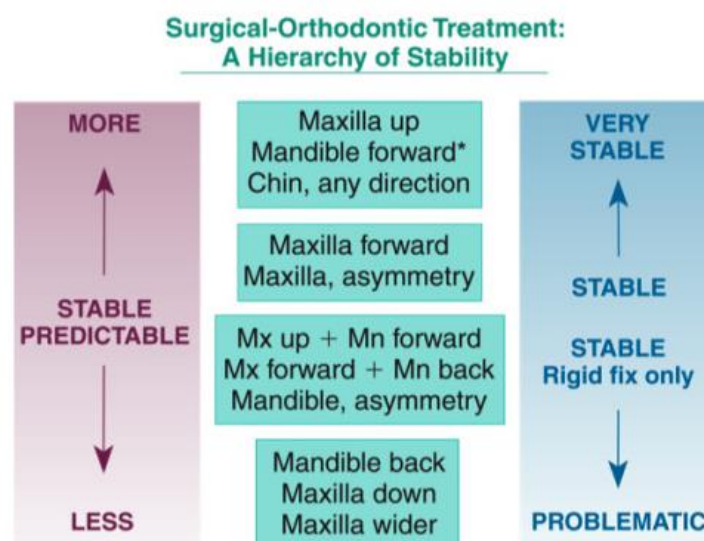


Figure 4. Proffit's Hierarchy of predictability and stability for orthognathic surgical procedure

Stability can be described as the maintenance of the skeletal and associated dental components in the surgically placed new position over time. Failure to maintain stability will lead to relapse. If the mean of skeletal components' position after surgery has changed more than 2mm, it was considered a clinically significant relapse. Most of the relapse occurred during the first 6 months after surgery (53-55). Both horizontal and vertical measurements should be evaluated to analyze the relapse of mandibular surgery (56).

Factors influencing the stability of BSSRO could be generally categorized into surgical factor, patient factor and orthodontic factor. Surgical factors included

magnitude and direction of skeletal movement, proper seating of condyles and method of bone fixation. For the patient factors, gender and age of the patient (remaining growth and remodeling), pre-surgical skeletal pattern (high mandibular plane angle with mandibular hypoplasia), soft tissue and muscle tension (tongue, suprahyoid muscles) and temporomandibular joint impairment were involved. In addition, pre-and post-surgical orthodontic alignment and change of occlusal plane also played a role in postoperative stability (8, 57).

Skeletal stability and skeletal changes after orthognathic surgery can be assessed in 2-dimensional measurements using posteroanterior cephalograms, panoramic radiographs, and lateral cephalograms. Lateral cephalometric radiographs remained a useful imaging method to evaluate the hard and soft tissues of craniomaxillofacial regions, as well as the pharyngeal airway (58). Cephalometric analysis for skeletal stability should be made on bony structures because of inconsistency in locating the soft tissue points (59, 60). Most studies investigated the skeletal relapse after mandibular setback surgery using B-point, menton and pogonion as the reference landmarks on the mandible (12-14, 16, 35).

2.7 Changes in Pharyngeal airway after Mandibular setback procedure

In mandibular setback surgery, along with the posterior positioning of the osteotomized mandible (distal segment), posterior displacement of the tongue, suprahyoid muscles attaching to the mandible and hyoid bone resulted in the narrowing of the pharyngeal airway space immediately after the surgery (61). Postoperative positional changes of the hyoid bone might affect the skeletal stability and the pharyngeal airway morphology by disturbing the balance within the head and neck musculature (62).

Several studies reported the changes in the pharyngeal airway after mandibular setback surgery (61-64). Eggensperger et al. (62) concluded that then

narrowing of the upper and middle pharyngeal airways seemed to continue for a long time (12 years observation period) after surgery while the narrowed lower pharyngeal airway remained unchanged from the postoperative first year. In contrast, Choi et al. (64) reported that the narrowed pharyngeal airway immediately after mandibular setback surgery gradually increased in anteroposterior dimension within postoperative 6 months but not to the full recovery condition. It could be inferred that the amount of mandibular setback significantly affected the airway changes.

2.8 Osteofixation and Stability

Many studies had been done to analyze the postoperative skeletal stability after mandibular setback surgery using different types of osteofixation. Park et al. (12) investigated the long-term stability of bioabsorbable mesh and titanium miniplate by observing point B on lateral cephalograms. It was concluded that applying bioabsorbable mesh and screws fixation after mandibular setback with BSSRO provided better stability in the horizontal plane than titanium miniplate and screws.

Meanwhile, Paeng et al. (14) and Harada et al. (16) studied about skeletal stability provided by bicortical resorbable and titanium screws. The former researcher observed the horizontal relapse with B point and vertical relapse with menton while the latter with B point and pogonion in both horizontal and vertical aspects. Both studies concluded that the presence of greater relapse tendency during first 6 months after surgery in resorbable bicortical screws due to the lower physical strength than titanium materials.

The directions of rotation of proximal and distal segments were also made in linear measurement analysis. Increased relapse tendency for clockwise rotation of distal segments had been reported in resorbable bicortical screws primarily if more counterclockwise rotation during surgery was conducted (13).

It has still been questioned about the stability supported by the resorbable plate and screws in mandibular setback procedure, which was the main concern by maxillofacial surgeons after orthognathic surgery. As far as our knowledge, there has been no study comparing the skeletal stability after correction of the prognathic mandible with BSSRO using monocortical titanium and bioabsorbable miniplate and screws in terms of both cephalometric analysis and related pharyngeal airway changes evaluation.



3. MATERIAL AND METHODS

3.1 Research Methodology Framework

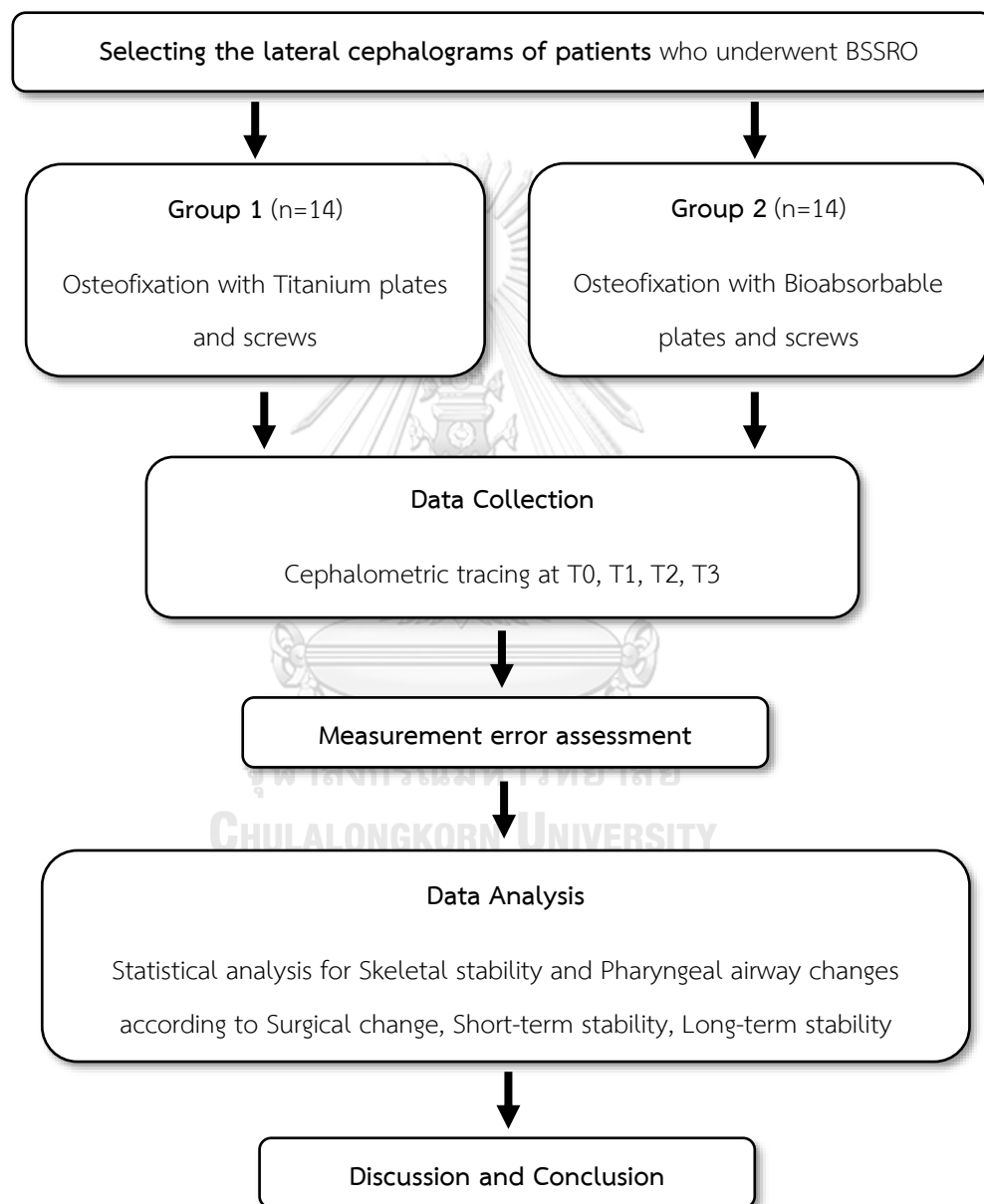


Figure 5. Study flowchart design for this study

3.2 Study Design

This is a retrospective study using the lateral cephalometric radiographs of mandibular prognathic patients.

3.3 Ethical Consideration

Our research was approved by The Human Research Ethical Committee of the Faculty of Dentistry, Chulalongkorn University, Bangkok, Thailand (HREC-DCU 2021-026) on July 9, 2021. (Letter No. 031/2021)

3.4 Materials

3.4(a) Subjects

Patients included in this study underwent the mandibular setback surgery by BSSRO surgical technique, fixed with 2 titanium or resorbable plate and screws on each side of the mandible at the Department of Oral and Maxillofacial Surgery, Faculty of Dentistry, Chulalongkorn University, Thailand between December 2015 and November 2018. Lateral cephalometric radiographs of those patients were randomly collected.

3.4(b) Inclusion Criteria

(determined from lateral cephalometric analysis of the radiographic images)

1. Mandibular prognathism with or without facial asymmetry
2. Adult patients (aged > 18 years)
3. Patients who received orthodontic treatment accompanied with orthognathic surgery

4. Patients who received only mandibular setback surgery using modified Epker technique (31) and pterygomasseteric sling was completely stripped
5. Patients who received rigid intermaxillary fixation for 2 weeks postoperatively

3.4(c) Exclusion Criteria

1. Patients with craniofacial syndromes such as cleft lip and palate, hemifacial microsomia (Goldenhar syndrome), Crouzon's syndrome, and Treacher Collin syndrome
2. Evidence of previous maxillofacial trauma
3. Patients who received bimaxillary surgery or Le Fort I osteotomy
4. Patients who received genioplasty

3.4(d) Sample size calculation

The output of the sample size calculation was referred to Oba et al. (13) using G Power 3.1 for testing two groups (t-tests, Means: Wilcoxon-Mann-Whitney test (two groups), two tails) (Figure 4). The sample size was 26, and then plus 15 % of compensation for dropout. Thus, the total number size was 30.

Mean in group 1 (μ_1) = 2.61, SD. In group 1 (σ_1) = 0.49

Mean in group 2 (μ_2) = 1.79, SD. In group 2 (σ_2) = 0.69

Effect size = 1.37, Ratio (r) = 1.00, Alpha (σ) = 0.05, Power (1- β) = 0.9

Sample size: Group 1 (n_1) = 13. Group 2 (n_2) = 13

Plus 15 % of compensation for dropout \sim 4

Total sample size = 26+4 = 30

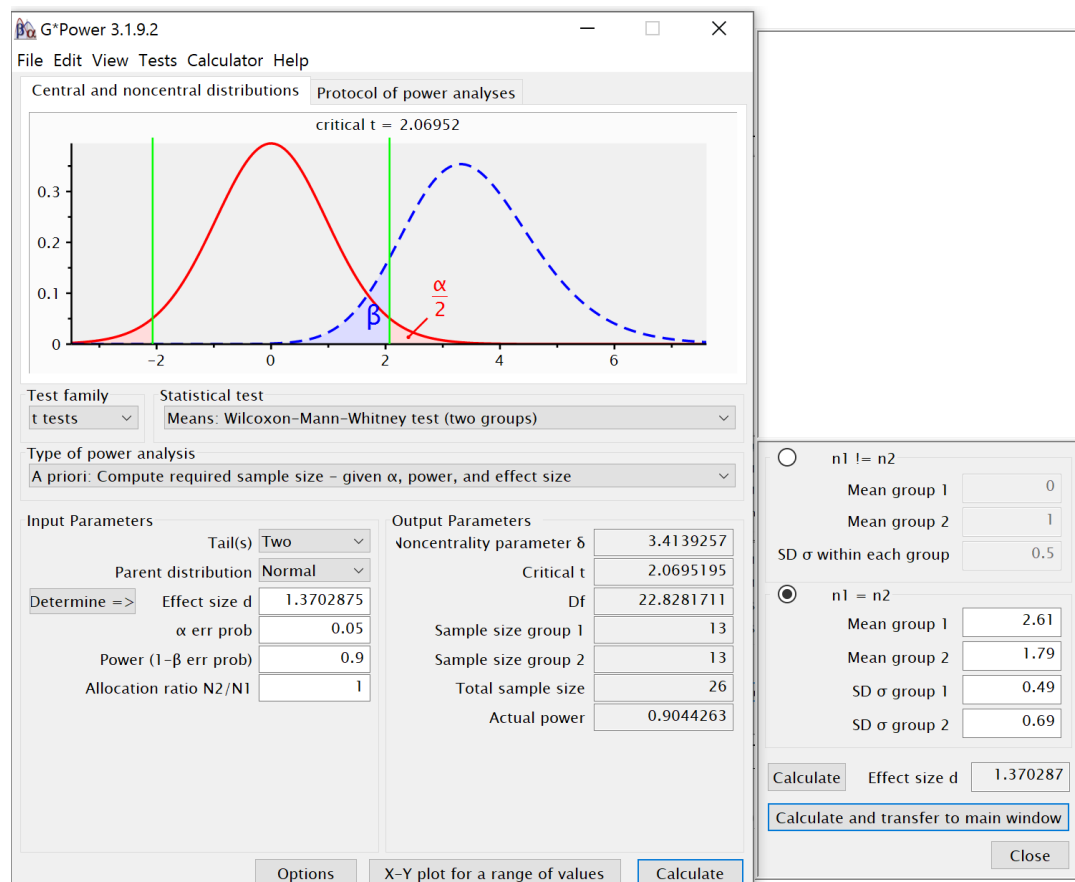


Figure 6. Sample size calculation using G Power 3.1 for testing two groups (t-tests, Means: Wilcoxon-Mann-Whitney test (two groups), two tails)

3.5 Methods

According to the inclusive and exclusive criteria, the lateral cephalometric radiographs were randomly retrospective picked-up and evaluated by 1 investigator with conventional cephalometric tracing method on acetate paper concerning the planned timeline for analysis and recorded onto each patient's record form.

Timeline for Cephalometric analysis:

- T0 Before surgery
- T1 Within 1 week post-surgery
- T2 Within 3-6 months post-surgery
- T3 After 1 year post-surgery

The hospital number, age, gender and amount of mandibular setback (difference of BX_{T1} and BX_{T0}) were recorded from all patients. Cephalometric landmarks for skeletal stability evaluation were chosen similar to those in the study by Hsu et al. (35) (Figure 7-8, Table 2-3) and for pharyngeal airway evaluation, parameters were chosen according to the study previously reported by Cheng JH et al. (65) (Figure 9, Table 4-5).

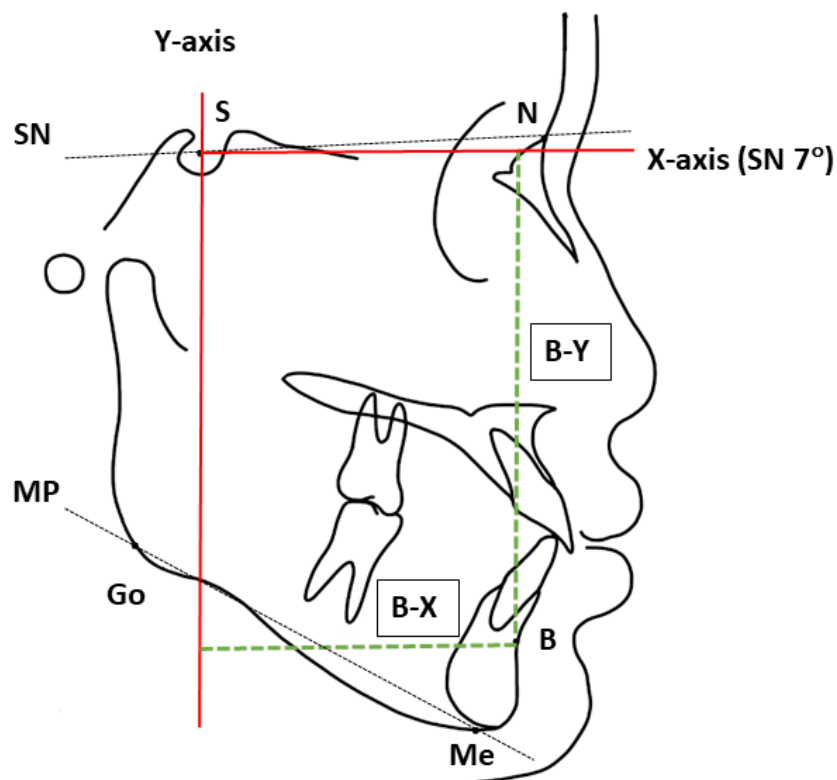


Figure 7. Cephalometric points and linear measurement for skeletal stability evaluation

Table 2. Description of cephalometric reference points and line for skeletal stability evaluation

| Reference | Description |
|--------------------|---|
| Point | |
| Sella (S) | Center of sella turcica |
| Nasion (N) | Most anterior point on the frontal nasal suture in the midsagittal plane |
| Point B | The innermost point on the contour of the mandible between the incisor and the bony chin |
| Menton (Me) | The most inferior point on the mandibular symphysis in the midline |
| Gonion (Go) | The point on the curvature of the angle of the mandible located by bisecting the angle formed by the lines tangent to the posterior ramus and the inferior border of the mandible |
| Line | |
| SN | Connecting of point S and point N |
| X-axis | Indicated 7° below SN |
| Y-axis | Perpendicular with X-axis through S |
| MP | Connecting of point Go and point Me |

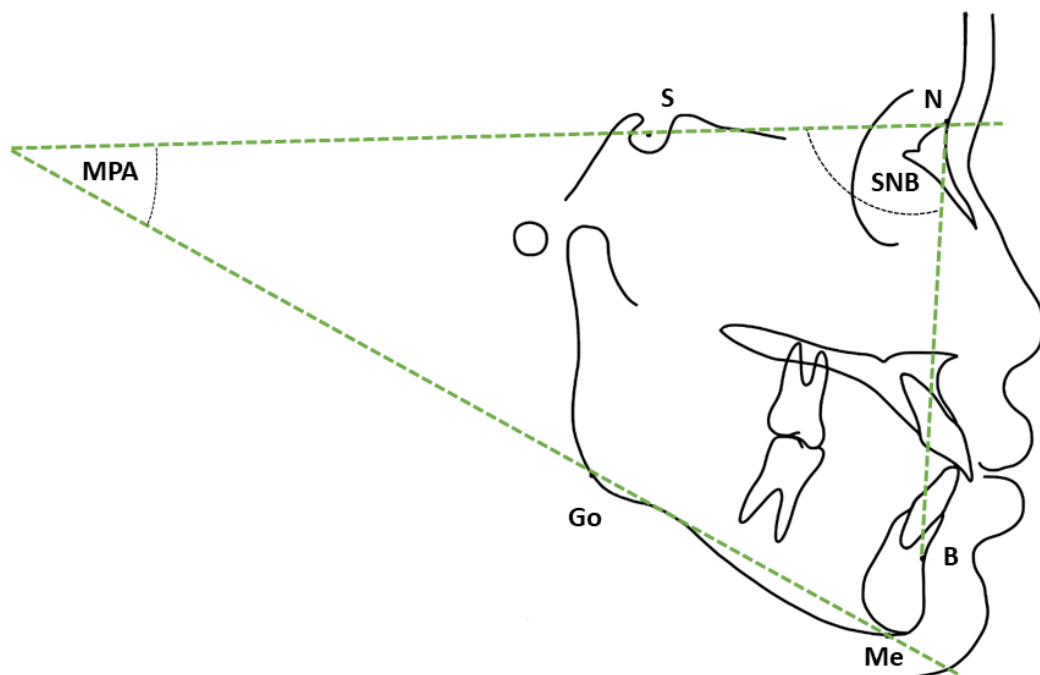


Figure 8. Angular measurement for skeletal stability

Table 3. Description of cephalometric parameters for skeletal stability evaluation

| Parameters | Description | |
|------------------------|------------------------------|--|
| Horizontal measurement | B-X | Perpendicular line from point B to Y-axis |
| Vertical measurement | B-Y | Perpendicular line from point B to X-axis |
| Angular measurement | SNB | Angle between SN line and a line drawn through N and point B |
| | Mandibular plane angle (MPA) | Angle between SN line and MP line |

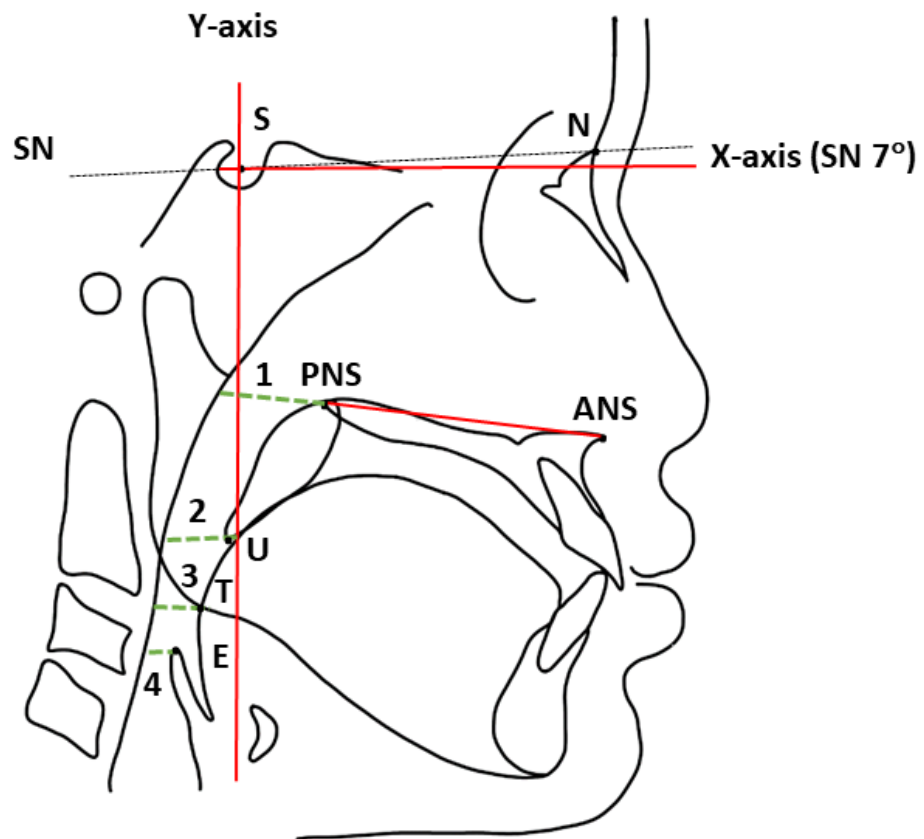


Figure 9. Lateral cephalometric parameters for pharyngeal airway evaluation

Table 4. Description of cephalometric reference points and line for pharyngeal evaluation

| Reference | Description |
|-----------------------------|---|
| Point | |
| Sella (S) | Center of sella turcica |
| Nasion (N) | Most anterior point on the frontal nasal suture in the midsagittal plane |
| Anterior nasal spine (ANS) | A point projection at the anterior extremity of the intermaxillary suture |
| Posterior nasal spine (PNS) | A point formed by medial ends of the horizontal processes of the palatine bones at the posterior of hard palate |
| Uvula (U) | Tip of uvula |
| Tongue (T) | Posterior tongue |
| Epiglottis (E) | Tip of epiglottis |
| Line | |
| SN | Connecting of point S and point N |
| X-axis | Indicated 7° below SN |
| Y-axis | Perpendicular with X-axis through S |
| ANS-PNS | Connecting of point ANS and point PNS (ANS-PNS plane) |

Table 5. Description of cephalometric parameters for pharyngeal airway evaluation

| Parameters | Description |
|-------------------------------------|--|
| Nasopharyngeal airway (NOP; 1) | Distance between PNS along ANS-PNS plane intersecting the pharyngeal wall |
| Uvula-pharyngeal wall (UOP; 2) | Distance between the tip of uvula (perpendicular to Y-axis) to the pharyngeal wall |
| Tongue-pharyngeal wall (TOP; 3) | Shortest distance between posterior tongue to the pharyngeal wall |
| Epiglottis-pharyngeal wall (EOP; 4) | Distance between epiglottis (parallel to X-axis) to the pharyngeal wall |

The conventional manual cephalometric tracing method was used in this study and prepared as followed. On INFINITT Radiologists PACS software, lateral cephalometric radiographs were saved into JPEG format possessing 300 dpi resolution images. Image files were imported into Microsoft Office Publisher software and the images' sizes were calibrated according to the dimensions of the original printed lateral cephalometric radiographic films. After setting up, the images were printed onto 85 grams of A4 paper and then 0.003 inches thick acetate tracing papers (G&H Orthodontics) were adapted on each of the printed A4 papers. 0.5 mm 2B lead mechanical pencil and eraser were used in tracing landmarks and outlines (Figure 10). Linear and angular measurements were collected by using a millimeter ruler and protractor with the help of the nearest 0.5 mm and 0.5 degrees, respectively. All measurements were recorded in a Microsoft Excel spreadsheet.

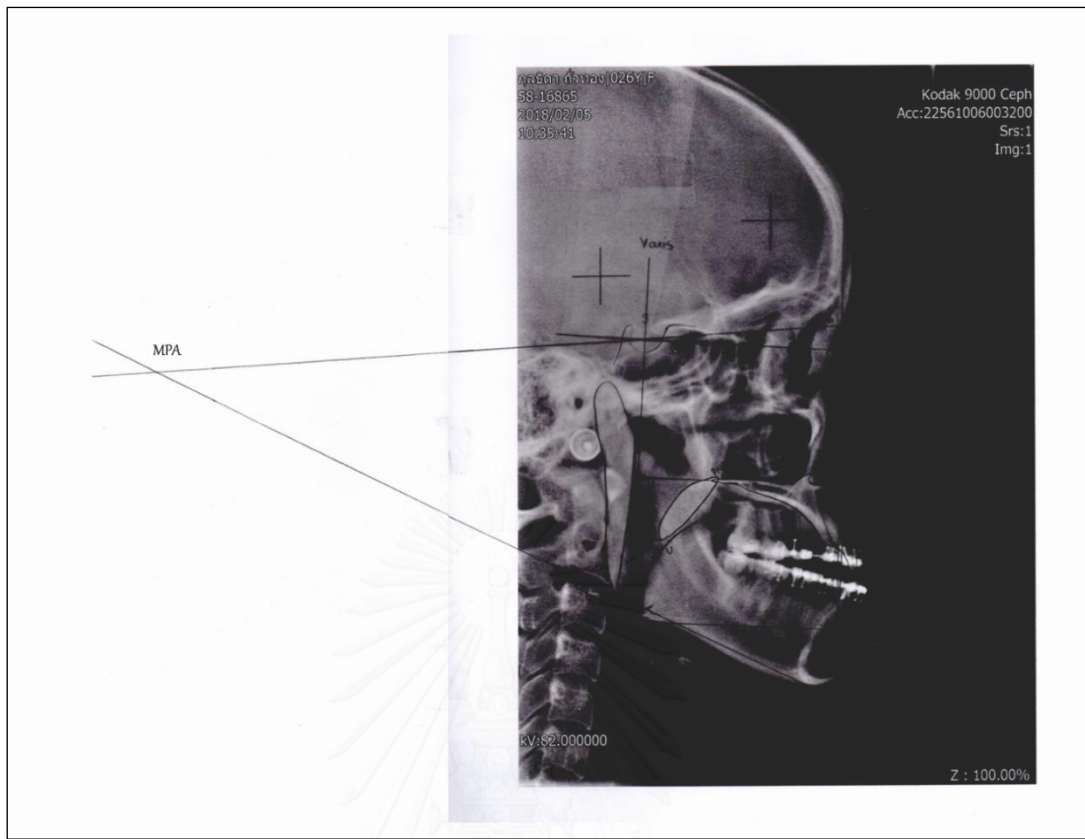


Figure 10. Photo scanned of conventional manual tracing in this study

For the skeletal stability evaluation, examinations of B point in linear measurement (mm) to horizontal and vertical reference lines were performed. Horizontal measurement (B-X) indicated the anteroposterior position of the mandible and vertical measurement (B-Y) indicated the vertical position of the mandible. Angular measurements were performed using SNB and MPA (Mandibular plane angle). For the pharyngeal airway evaluation, examinations of 4 airway lengths; nasopharyngeal airway (NOP), uvula-pharyngeal wall (UOP), tongue-pharyngeal wall (TOP), and epiglottis-pharyngeal wall (EOP) were made.

Comparisons between different timelines were studied according to;

- Between T1 and T0 (T1-T0) indicated a surgical change
- Between T2 and T1 (T2-T1) indicated a short-term stability
- Between T3 and T1 (T3-T1) indicated a long-term stability

A comparison of surgical change, a short-term stability and a long-term stability by all the measurement (B-X, B-Y, SNB, MPA, NOP, UOP, TOP, and EOP) were made between titanium and bioabsorbable groups.

3.6 Measurement error analysis

The accidental error of measurements was assessed by randomly selected the 5 titanium patients and 5 resorbable patients (total 40 lateral cephalograms) which were approximately 36% of total sample size. All the parameters were retraced and re-measured for a second time by the same examiner on the 10th day after the first measurement to ensure the intra-examiner accuracy (15). The intraclass correlation coefficient test based on 95% confident interval was applied.

3.7 Statistical Analysis

All data were analyzed by using the statistical software IBM SPSS version 26.0 (IBM Co., NY, USA). The normality of the data distribution was assessed by the Shapiro-Wilk test ($n < 50$). Nonparametric tests were chosen to analyze the parameters because the normality was not obtained in the data showing movement between periods assessed. The differences in age and amount of setback between titanium and resorbable groups were analyzed by Mann Whitney U test. Fisher's Exact test was used for determining the association between gender and type of osteofixation usage. The initial measurement (T0) of all parameters were compared between titanium and resorbable group by using the Mann-Whitney U test. To analyze each parameter during surgical changes (T1-T0), short-term stability (T2-T1) and long-term stability (T3-T1) of the same patients in both groups (titanium, resorbable), Wilcoxon Signed Ranked test was used. The results were analyzed at a maximum level of significance of 5% which means that the values with a *p-value* less than 0.05 rejected the null hypothesis that there were no significant changes between the

preoperative and postoperative periods (T1-T0) and between the two postoperative periods (T2-T1, T3-T1) for each measurement in both groups (titanium, resorbable). Intraclass correlation coefficient was used to determine the intra-examiner variance.



4. RESULTS

The intra-class correlation coefficients for intra-rater repeatability of skeletal and pharyngeal airway parameters ranged from 0.905 to 0.994, indicating excellent reliability (Table 6).

Table 6. Intraclass correlation coefficient test for assessing intra-examiner accuracy

| Parameters | Intraclass Correlation | 95% Confidence Interval | |
|------------|------------------------|-------------------------|-------------|
| | | Lower Bound | Upper Bound |
| BX | 0.994 | 0.989 | 0.997 |
| BY | 0.991 | 0.982 | 0.995 |
| SNB | 0.980 | 0.946 | 0.991 |
| MPA | 0.990 | 0.982 | 0.995 |
| NOP | 0.905 | 0.821 | 0.950 |
| UOP | 0.974 | 0.950 | 0.986 |
| TOP | 0.986 | 0.973 | 0.992 |
| EOP | 0.994 | 0.989 | 0.997 |

Regarding our inclusion and exclusion criteria, 14 patients of titanium and 14 patients of resorbable groups were included. The demographic data (age, amount of setback, gender) were described in Table 7. The age, gender, and setback amount between the 2 groups did not show statistically significant differences. At the pre-surgical stage (T0), there were no statistically significant differences between titanium and resorbable groups in all parameters (skeletal and pharyngeal) (Table 8).

Table 7. Patient characteristic data (age, gender, amount of setback) of Titanium and Resorbable groups

(^a*p*-value by Mann-Whitney U test, ^b*p*-value by Fisher's Exact test, significant at *p* value < 0.05)

| | Titanium group (n=14) | Resorbable group (n=14) | <i>p</i> -value |
|------------------------------------|--------------------------|----------------------------|--------------------|
| Age (Mean±SD; year) | 26.79±4.17 | 25.29±4.08 | 0.369 ^a |
| Gender (Male/Female) | 4/10 | 3/11 | 1.000 ^b |
| Amount of setback (Mean±SD; mm) | 6.61±3.97 | 5.36±3.26 | 0.357 ^a |

SD = Standard deviation, mm = Millimeter

Table 8. Comparison of initial cephalometric analyses (T0) between titanium and resorbable groups

(*p*-value by Mann-Whitney U Test, significant at *p*-value < 0.05)

| | Titanium group (n=13) | Resorbable group (n=13) | <i>p</i> -value |
|------------------------------|--------------------------|----------------------------|-----------------|
| Parameters (mm) | Mean±SD | Mean±SD | |
| Skeletal parameters | | | |
| BX | 73±7.25 | 68.82±8.79 | 0.260 |
| BY | 91.57±5.85 | 92.61±6.33 | 0.549 |
| SNB | 86.93±3.48 | 84.50±3.99 | 0.127 |
| MPA | 33.07±5.17 | 36.64±5.96 | 0.093 |
| Pharyngeal parameters | | | |
| NOP | 24.14±3.83 | 23.79±3.49 | 0.817 |
| UOP | 11.46±2.55 | 9.82±1.78 | 0.058 |
| TOP | 12.96±3.68 | 11.14±3.98 | 0.127 |
| EOP | 7.71±2.68 | 7.43±2.54 | 1.000 |

SD = Standard deviation, mm = Millimeter

After the mandibular setback surgery (T1-T0), BX was significantly moved posteriorly in both groups. BY also showed a significant change of vertical reduction in the titanium group, but the difference was not significant in the resorbable group. In angular changes, SNB was significantly decreased in both groups (p -value < 0.01), while statistically significant changes were not seen in MPA. In pharyngeal airway changes, all of the pharyngeal airway parameters revealed no significant differences in both groups (Table 9).

At short-term stability (T2-T1), BX moved to a horizontally anterior position in both groups; however, the statistically significant change was only detected in the resorbable group. Vertical reduction of BY was also found in both groups, but the changes were not statistically significant. Regarding the angular changes, titanium group showed statistically significant differences in SNB. Meanwhile, MPA showed statistically significant differences in both groups. All pharyngeal parameters moved in the horizontal dimension, but no statistical significance except a significant reduction of EOP was only seen in the resorbable group (Table 9).

Significant changes were only apparent at long-term stability (T3-T1) in B-X of the titanium group and in angular measurements. While SNB was increased in the titanium group, the resorbable group had MPA widening. Statistically significant changes were not found in other parameters, such as linear changes in B-Y and pharyngeal airway changes (Table 9). There were no significant pharyngeal airway changes after the mandibular setback procedure in both titanium and resorbable groups.

Table 9. Comparison of surgical changes (T1-T0), 3-6 months post-surgery (T2-T1), and 1-year post-surgery (T3-T1) between titanium and resorbable groups (*p-value* by Wilcoxon Signed Ranks Test, *significant at *p-value* < 0.05, ** significant at *p-value* < 0.01)

| | | Surgical changes (T1-T0) | | 3-6 months post-surgery (T2-T1) | | 1-year post-surgery (T3-T1) | |
|------------------------------|----------------|-----------------------------|-------------|------------------------------------|-------------|--------------------------------|-------------|
| | | Titanium | Resorbable | Titanium | Resorbable | Titanium | Resorbable |
| Skeletal parameters | | | | | | | |
| BX | Diff | -6.607±3.97 | -5.357±3.26 | 0.786±1.46 | 1.179±1.50 | 1.264±1.77 | 1.071±2.23 |
| | <i>p-value</i> | 0.001** | 0.001** | 0.073 | 0.012* | 0.035* | 0.102 |
| BY | Diff | -1.464±2.01 | -0.121±2.41 | -0.793±2.41 | -0.293±2.81 | -0.979±1.99 | -1.357±3.93 |
| | <i>p-value</i> | 0.012* | 0.893 | 0.262 | 0.694 | 0.083 | 0.505 |
| SNB | Diff | -4±2.38 | -2.871±2.77 | 0.643±0.97 | 0.621±1.50 | 0.823±1.05 | 0.621±1.72 |
| | <i>p-value</i> | 0.001** | 0.004** | 0.034* | 0.123 | 0.011* | 0.192 |
| MPA | Diff | -0.143±1.96 | 0.471±1.84 | 0.857±1.43 | 2.093±2.14 | 0.25±1.11 | 2.286±2.28 |
| | <i>p-value</i> | 0.832 | 0.246 | 0.039* | 0.006** | 0.407 | 0.006** |
| Pharyngeal parameters | | | | | | | |
| NOP | Diff | -0.036±2.03 | -0.107±3.13 | 0.286±1.49 | -0.607±1.86 | 0.464±2.48 | 0.857±2.16 |
| | <i>p-value</i> | 0.719 | 0.725 | 0.473 | 0.243 | 0.562 | 0.219 |
| UOP | Diff | -0.964±2.84 | 0.143±2.57 | -0.286±3.4 | -1.164±2.2 | -0.286±3.77 | -1.036±2.16 |
| | <i>p-value</i> | 0.132 | 0.972 | 0.806 | 0.073 | 0.861 | 0.097 |
| TOP | Diff | -1.357±3.21 | -1.107±2.82 | 0.036±2.94 | -0.393±2.07 | 0.143±3.99 | 0±2.56 |
| | <i>p-value</i> | 0.157 | 0.171 | 0.680 | 0.504 | 0.255 | 0.888 |
| EOP | Diff | -0.071±3.59 | 0.036±1.46 | -0.893±3.55 | -1.214±1.54 | -0.857±4.12 | -0.321±2.31 |
| | <i>p-value</i> | 0.779 | 1.000 | 0.642 | 0.02* | 0.789 | 0.753 |

“ - ” indicated the movement to left (posterior) or upward

5. DISCUSSION AND CONCLUSION

5.1 Discussion

As the titanium plate and screws were considered as a gold standard in oral and maxillofacial osteofixation procedures, the surgeons preferred using them to provide proven postoperative stability and good biocompatibility. Many clinical studies have been conducted on the improved skeletal stability of resorbable plates and screws, but no previous studies mention pharyngeal airway changes. This retrospective study highlighted the stability of the resorbable osteofixation system in orthognathic surgery, which could be used as a reliable alternative to the titanium system, especially for the era of oral and maxillofacial surgeries in which secondary operation for plate removal is not favored.

In this study, a total of 28 patients were included. The age, gender, and amount of setback were not statistically significant between titanium and resorbable groups. The horizontal relapse was analyzed with B point and vertical relapse with Me point. All of the patients' skeletal characteristics and pharyngeal airway measurements before surgery also did not show any significant differences between titanium and resorbable plate and screws.

In this study, the skeletal relapses; the horizontal relapse was analyzed with B point and vertical relapse with Me point, were observed after surgery. Especially, the B-X significantly moved forward from the surgically planned position in resorbable group in first 3-6 months, while the titanium group significantly moved forward from the surgically planned position in 1 year post-surgery. These similar results were also shown in several studies. Paeng et al. (14) observed the horizontal relapse with B point and vertical relapse with Menton. Harada et al. (16) observed the horizontal relapse with B point and vertical relapse with Pogonion. Both studies concluded that greater relapse tendency during the first 6 months after surgery in resorbable

bicortical screws. While Landes et al. (66) observed the horizontal relapse with B point and vertical relapse with Gonial angle and found higher relapse in titanium group (the mean follow-up was 24 ± 22 months). Additionally, Park YW et al. (67) observed the horizontal and vertical relapse with B point and demonstrated inferior long-term skeletal stability (2-year postoperative) in titanium compared with resorbable fixation.

Our study found SNB angle changes (immediate to 1-year postoperative) 0.82 ± 0.3 in titanium group and 0.62 ± 0.02 in resorbable group. Rao et al. (68) also correspondingly found constant SNB angle changes (0.8-1.2) in titanium plate and screw fixation through 1-year follow-up. Skeletal changes were noticed significantly in cephalometry but was clinically insignificant. Admitting the use of plates and screws to provide rigid skeletal fixation, the minor movements of the fragments can occur during bone remodeling. If it was not clinically significant, the extra intervention was not necessary.

Park et al. (12) explained the mandibular plane angle change at 6 months post-surgery that seem to indicate complex results of segmental remodeling, adaptive change of temporomandibular joints (proximal segment), and postoperative orthodontics. A recent article found significant mandibular plane angle (MPA) changes in both titanium and resorbable groups in short-term stability, but MPA expressed significantly different in the only resorbable group 1-year post-surgery. Likewise, the previous study (14) proposed that the resorbable fixation showed lesser stable results vertically and more open bite tendency than the titanium. These findings indicated that the resorbable plate and screws provide less vertical stability than titanium, leading to an open bite tendency in long-term measurement. It was suggested that when resorbable plates and screws were used, elastic traction (14) or intermaxillary fixation (69) may be necessary to stabilize the bony segments in the early postoperative period.

When the bilateral sagittal split osteotomy (BSSRO) was performed to correct mandibular prognathism, the anatomical structures at the tongue base that were attached to the mandible and form part of the upper airway were also re-positioned. An upper airway of the immediate mandibular setback procedure was expected to be reduced, but long-term airway changes remained controversial. Enacar et al. (70) revealed that reduction of the hypopharyngeal airway after mandibular setback could be permanent. Meanwhile, On et al. (71) stated that the narrowing of the oropharynx recovered to 2.0 mm. at 6 months after surgery. The recovery airway space might be affected by the re-position of the hyoid bone to return to its preoperative position though it never regained its original (72).

However, previous studies have investigated upper airway changes in the titanium system. This recent article was the first report considering upper airway changes in resorbable fixation compared to titanium. Preoperatively, no significant differences in all pharyngeal airway dimensions were observed between titanium and resorbable fixations. NOP, UOP and TOP did not exhibit significant differences in surgical changes, 3-6 months post-surgery and 1-year post-surgery, both titanium and resorbable groups. Remarkably, the resorbable group was discovered to have significant EOP changes within 3-6 months post-surgery, then gradually returned to no changes in 1-year post-surgery. This finding was consistent with the previous study that the airway dimension changes following mandibular setback surgery recovered during short-term follow-up and maintained during the long-term follow-up (73).

Eppley (4) described the author's 10-year experience in using resorbable plates and screws in selected orthognathic cases, as well as a comprehensive review of related material. He stated that the surgical technique for resorbable plates and screws was insignificant between maxilla and mandible in dentofacial deformities as a deviation from normal facial proportions and dental relationships. Nevertheless, the exclusion criteria for using this resorbable material included a cleft or craniofacial

deformity condition, when the maxilla needed to be segmentized, the maxilla advancement required more than 5mm, and the mandibular advancement required more than 15 mm. Shand and Heggie (74) also summarized that the surgical technique and case selection have a vital role in the clinical success of resorbable fixation in orthognathic surgery.

The most significant benefit of the bioabsorbable plate and screws was the obviation of the need for a patient to undergo a second-stage removal surgery (75, 76). The other benefits of bioabsorbable fixation materials included an absence of metal particles accumulation and metal corrosion in tissues, and no disturbance in radiographs due to their radiolucent properties. Resorbable materials could provide prevention of osteoporosis by their low stress-shielding effect due to the initial bearing of a smaller load and gradual transferring of the functional load to the healing bone during the degradation process (4, 48). Furthermore, usage of the bioabsorbable plate and screws fixation in patients requiring routine CT or MRI imaging to follow tumor status or pediatric patients had been reported that there were no growth disturbances (47).

Despite the potential advantages, it was essential to note that resorbable plates and screws fixation systems were more expensive than conventional titanium systems, the most significant deterrent to its wider use. The absorbable type was also a more complicated fixation and a more technique sensitive. Heat adaptation was required to be bent and shaped to the bone surface because each polymer's glass transition temperature was specified. Below setting temperature, the polymers were stiff and brittle, whereas, above setting temperature, they behaved like a rubber (77). Placement of resorbable screws required pre-tapping of the drilled hole led to increased operating time (78).

According to Maurus et al. (2004), among 3 basically utilized biodegradable polymers, polyglycolic acid (PGA) was found to produce more acidic breakdown

products than polylactic acid (PLA) or polydioxanone (PDS), which have led to inflammatory reactions to the surrounding tissues as it degrades rapidly via the hydrolytic process. Altering the ratio of PGA to PLA has a beneficial effect on the degradation rates and mechanical properties of bioabsorbable materials. PLA-PGA copolymers degrade more rapidly than L-PLA or DL-PLA, which do not have rapid degradation properties, and it also does not release acidic breakdown products as in pure PGA (51).

Adverse tissue reactions to degradation products without severe side effects had been reported in the study by Landes et al. in 2006. 5% of poly(70L-lactide-co-30DL-lactide) copolymer (P(L/DL)LA) patients produced uninfected intraoral fistulas draining lactide debris at postoperative 3 months (76). The postoperative infection rate was seen at 1.82% in resorbable plates and screws compared to 1.53% in titanium. Interestingly, infection in the resorbable group was diagnosed later at the 6 weeks to 6 months post-surgery. In contrast, the titanium group was diagnosed earlier at 2 weeks to 3 months post-surgery (78). On the contrary, the clinical problems (signs of infection) or wound discomfort were not found in our study up to 33 months follow-up period in patients fixed with resorbable plates and screws.

There were some limitations in this study. Insufficient participants have been encountered because the resorbable fixation price was more expensive than titanium. The resorbable plates used in this study were osteotrans-Mx system, a high strength, bioresorbable, and bioactive composite material composed of poly L-lactide acid (PLLA) and unsintered hydroxyapatite (u-HA). However, this study did not include other commercial resorbable plate systems to compare. Additional studies are required to determine the long-term changes in the skeletal and pharyngeal airway space.

5.2 Conclusion

The use of resorbable plates and screws may not have a negative impact on the long-term pharyngeal stability after mandibular setback surgery, which was comparable to the gold-standard titanium. However, the resorbable plates and screws showed more skeletal horizontal change than the titanium during short-term stability and revealed more mandibular plane angle changes. These results suggested that although resorbable plates and screws were the clinically successful outcome, these patients may need long-term follow-up to confirm clinical presentation.

5.3 Further study

Further evaluation of the long-term effects of these orthognathic surgical procedures in a larger study population is necessary to perform and extended period of stability observations should be considered for better evidence-based results. The pharyngeal airway assessment should also be performed based on volume rather than anteroposterior measurements for better prediction as the airway is in the shape of cylinder.

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STATISTIC OUTPUT

Table 1. Comparison in age and amount of setback between titanium and resorbable group

| | Group | N | Mean | Std. Deviation | Std. Error Mean |
|-------------|------------|----|-------|----------------|-----------------|
| Age | Ti | 14 | 26.79 | 4.173 | 1.115 |
| | Resorbable | 14 | 25.29 | 4.084 | 1.092 |
| Setback(mm) | Ti | 14 | 6.61 | 3.967 | 1.060 |
| | Resorbable | 14 | 5.36 | 3.261 | 0.871 |

| | Age | Setback(mm) |
|--------------------------------|-------------------|-------------------|
| Mann-Whitney U | 78.500 | 78.000 |
| Wilcoxon W | 183.500 | 183.000 |
| Z | -.899 | -.921 |
| Asymp. Sig. (2-tailed) | .369 | .357 |
| Exact Sig. [2*(1-tailed Sig.)] | .376 ^b | .376 ^b |

a. Grouping Variable: Group

b. Not corrected for ties.

Table 2. Comparison in gender distribution between titanium and resorbable group**Group * Gender Crosstabulation**

Count

| | | Gender | | Total |
|-------|------------|--------|--------|-------|
| | | Male | Female | |
| Group | Ti | 4 | 10 | 14 |
| | Resorbable | 3 | 11 | 14 |
| Total | | 7 | 21 | 28 |

**Chi-Square Tests**

| | Value | df | Asymp. Sig. (2-sided) | Exact Sig. (2- sided) | Exact Sig. (1- sided) |
|------------------------------------|-------------------|----|--------------------------|--------------------------|--------------------------|
| Pearson Chi-Square | .190 ^a | 1 | .663 | 1.000 | .500 |
| Continuity Correction ^b | .000 | 1 | 1.000 | | |
| Likelihood Ratio | .191 | 1 | .662 | | |
| Fisher's Exact Test | | | | 1.000 | .500 |
| Linear-by-Linear Association | .184 | 1 | .668 | | |
| N of Valid Cases | 28 | | | | |

a. 2 cells (50.0%) have expected count less than 5. The minimum expected count is 3.00.

b. Computed only for a 2x2 table

Table 3. Comparison in Initial measurement of all parameters between titanium and resorbable group

Group Statistics

| Group | | N | Mean | Std. Deviation |
|------------|-------|----|---------|----------------|
| Ti | BxT0 | 14 | 73.0000 | 7.24569 |
| | ByT0 | 14 | 91.5714 | 5.85352 |
| | SNBT0 | 14 | 86.9286 | 3.47993 |
| | MPAT0 | 14 | 33.0714 | 5.17337 |
| | NOPT0 | 14 | 24.1429 | 3.82516 |
| | UOPT0 | 14 | 11.4643 | 2.55301 |
| | TOPT0 | 14 | 12.9643 | 3.67666 |
| | EOPT0 | 14 | 7.7143 | 2.67980 |
| Resorbable | BxT0 | 14 | 68.8214 | 8.79599 |
| | ByT0 | 14 | 92.6071 | 6.33421 |
| | SNBT0 | 14 | 84.5000 | 3.98555 |
| | MPAT0 | 14 | 36.6357 | 5.96498 |
| | NOPT0 | 14 | 23.7857 | 3.49017 |
| | UOPT0 | 14 | 9.8214 | 1.78247 |
| | TOPT0 | 14 | 11.1429 | 3.98279 |
| | EOPT0 | 14 | 7.4286 | 2.54087 |

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Test Statistics

| | Bx T0 | By T0 | SNB T0 | MPA T0 | NOP T0 | UOP T0 | TOP T0 | EOP T0 |
|--------------------------------|-------------------|-------------------|-------------------|-------------------|-------------------|-------------------|-------------------|--------------------|
| Mann-Whitney U | 73.500 | 85.000 | 65.000 | 61.500 | 93.000 | 57.000 | 65.000 | 98.000 |
| Wilcoxon W | 178.500 | 190.000 | 170.000 | 166.500 | 198.000 | 162.000 | 170.000 | 203.000 |
| Z | -1.128 | -.599 | -1.525 | -1.680 | -.231 | -1.895 | -1.527 | .000 |
| Asymp. Sig. (2-tailed) | .260 | .549 | .127 | .093 | .817 | .058 | .127 | 1.000 |
| Exact Sig. [2*(1-tailed Sig.)] | .265 ^b | .571 ^b | .137 ^b | .094 ^b | .839 ^b | .062 ^b | .137 ^b | 1.000 ^b |

a. Grouping Variable: Ti or Re

b. Not corrected for ties

Table 4. Comparison in BX in each group (Titanium, Resorbable)

Descriptive Statistics

| Group | N | Mean | Std. Deviation | Minimum | Maximum | |
|------------|------|------|----------------|---------|---------|-------|
| Ti | BxT0 | 14 | 73.0000 | 7.24569 | 61.50 | 85.00 |
| | BxT1 | 14 | 66.3929 | 6.77433 | 55.50 | 78.00 |
| | BxT2 | 14 | 67.1786 | 6.32336 | 57.50 | 79.00 |
| | BxT3 | 14 | 67.6571 | 7.61069 | 58.50 | 82.00 |
| Resorbable | BxT0 | 14 | 68.8214 | 8.79599 | 50.50 | 82.00 |
| | BxT1 | 14 | 63.4643 | 8.40207 | 44.00 | 74.00 |
| | BxT2 | 14 | 64.6429 | 8.57418 | 46.00 | 75.50 |
| | BxT3 | 14 | 64.5357 | 8.83059 | 44.00 | 75.00 |

| Group | | BxT1 - BxT0 | BxT2 - BxT1 | BxT3 - BxT1 |
|------------|------------------------|---------------------|---------------------|---------------------|
| Ti | Z | -3.299 ^b | -1.792 ^c | -2.111 ^c |
| | Asymp. Sig. (2-tailed) | .001 | .073 | .035 |
| Resorbable | Z | -3.237 ^b | -2.509 ^c | -1.636 ^c |
| | Asymp. Sig. (2-tailed) | .001 | .012 | .102 |

a. Wilcoxon Signed Ranks Test

b. Based on positive ranks.

c. Based on negative ranks.

Table 5. Comparison of BY in each group (Titanium, Resorbable)

| Group | | N | Mean | Std. Deviation | Minimum | Maximum |
|------------|------|----|---------|----------------|---------|---------|
| Ti | ByT0 | 14 | 91.5714 | 5.85352 | 80.00 | 102.00 |
| | ByT1 | 14 | 90.1071 | 6.66269 | 78.00 | 102.00 |
| | ByT2 | 14 | 89.3143 | 7.25777 | 79.40 | 103.00 |
| | ByT3 | 14 | 89.1286 | 5.62076 | 79.00 | 99.00 |
| Resorbable | ByT0 | 14 | 92.6071 | 6.33421 | 81.50 | 104.00 |
| | ByT1 | 14 | 92.4857 | 6.30346 | 83.00 | 102.00 |
| | ByT2 | 14 | 92.1929 | 7.06328 | 79.20 | 104.00 |
| | ByT3 | 14 | 91.1286 | 8.59879 | 73.00 | 104.50 |

| Group | | ByT1 - ByT0 | ByT2 - ByT1 | ByT3 - ByT1 |
|------------|------------------------|---------------------|---------------------|---------------------|
| Ti | Z | -2.504 ^b | -1.122 ^b | -1.736 ^b |
| | Asymp. Sig. (2-tailed) | .012 | .262 | .083 |
| Resorbable | Z | -.134 ^b | .393 ^c | -.666 ^b |
| | Asymp. Sig. (2-tailed) | .893 | .694 | .505 |

a. Wilcoxon Signed Ranks Test

b. Based on positive ranks.

c. The sum of negative ranks equals the sum of positive ranks.

d. Based on negative ranks.

Table 6. Comparison in SNB in each group (Titanium, Resorbable)

Descriptive Statistics

| Group | N | Mean | Std. Deviation | Minimum | Maximum | |
|------------|-------|------|----------------|---------|---------|-------|
| Ti | SNBT0 | 14 | 86.9286 | 3.47993 | 82.00 | 93.00 |
| | SNBT1 | 14 | 82.9286 | 2.90793 | 78.00 | 88.00 |
| | SNBT2 | 14 | 83.5714 | 2.98623 | 79.00 | 89.00 |
| | SNBT3 | 14 | 83.7514 | 3.20799 | 78.00 | 89.50 |
| Resorbable | SNBT0 | 14 | 84.5000 | 3.98555 | 77.00 | 93.00 |
| | SNBT1 | 14 | 81.6286 | 3.67432 | 74.00 | 86.00 |
| | SNBT2 | 14 | 82.2500 | 3.51234 | 75.00 | 87.50 |
| | SNBT3 | 14 | 82.2500 | 3.69381 | 74.50 | 89.00 |

| Group | | SNBT1 - SNBT0 | SNBT2 - SNBT1 | SNBT3 - SNBT1 |
|------------|------------------------|---------------------|---------------------|---------------------|
| Ti | Z | -3.298 ^b | -2.126 ^c | -2.549 ^c |
| | Asymp. Sig. (2-tailed) | .001 | .034 | .011 |
| Resorbable | Z | -2.867 ^b | -1.544 ^c | -1.305 ^c |
| | Asymp. Sig. (2-tailed) | .004 | .123 | .192 |

a. Wilcoxon Signed Ranks Test

b. Based on positive ranks.

c. Based on negative ranks.

Table 7. Comparison in MPA in each group (Titanium, Resorbable)

Descriptive Statistics

| Group | N | Mean | Std. Deviation | Minimum | Maximum | |
|------------|-------|------|----------------|---------|---------|-------|
| Ti | MPAT0 | 14 | 33.0714 | 5.17337 | 25.00 | 41.00 |
| | MPAT1 | 14 | 32.9286 | 5.47672 | 24.00 | 42.50 |
| | MPAT2 | 14 | 33.7857 | 5.19509 | 27.50 | 43.50 |
| | MPAT3 | 14 | 33.1786 | 5.63399 | 24.50 | 43.90 |
| Resorbable | MPAT0 | 14 | 36.6357 | 5.96498 | 24.90 | 46.00 |
| | MPAT1 | 14 | 37.1071 | 5.85458 | 27.00 | 46.50 |
| | MPAT2 | 14 | 39.2000 | 6.29273 | 26.80 | 50.00 |
| | MPAT3 | 14 | 39.3929 | 6.44258 | 27.50 | 50.00 |

| Group | | MPAT1 - MPAT0 | MPAT2 - MPAT1 | MPAT3 - MPAT1 |
|------------|------------------------|---------------------|---------------------|---------------------|
| Ti | Z | -.212 ^b | -2.068 ^c | -.828 ^c |
| | Asymp. Sig. (2-tailed) | .832 | .039 | .407 |
| Resorbable | Z | -1.160 ^c | -2.763 ^c | -2.735 ^c |
| | Asymp. Sig. (2-tailed) | .246 | .006 | .006 |

- a. Wilcoxon Signed Ranks Test
- b. Based on positive ranks.
- c. Based on negative ranks.
- d. The sum of negative ranks equals the sum of positive ranks.

Table 8. Comparison in NOP in each group (Titanium, Resorbable)

Descriptive Statistics

| Group | N | Mean | Std. Deviation | Minimum | Maximum | |
|------------|-------|------|----------------|---------|---------|-------|
| Ti | NOPT0 | 14 | 24.1429 | 3.82516 | 19.00 | 31.00 |
| | NOPT1 | 14 | 24.1786 | 3.85610 | 18.00 | 30.00 |
| | NOPT2 | 14 | 24.4643 | 3.99261 | 17.00 | 30.00 |
| | NOPT3 | 14 | 24.6429 | 3.58109 | 19.00 | 30.00 |
| Resorbable | NOPT0 | 14 | 23.7857 | 3.49017 | 18.00 | 29.00 |
| | NOPT1 | 14 | 23.8929 | 3.07708 | 18.00 | 28.00 |
| | NOPT2 | 14 | 23.2857 | 2.83328 | 18.00 | 29.00 |
| | NOPT3 | 14 | 24.7500 | 2.65844 | 19.50 | 28.00 |

| Group | | NOPT1 - NOPT0 | NOPT2 - NOPT1 | NOPT3 - NOPT1 |
|------------|------------------------|--------------------|---------------------|---------------------|
| Ti | Z | -.360 ^b | -.718 ^c | -.579 ^c |
| | Asymp. Sig. (2-tailed) | .719 | .473 | .562 |
| Resorbable | Z | -.352 ^c | -1.167 ^b | -1.230 ^c |
| | Asymp. Sig. (2-tailed) | .725 | .243 | .219 |

a. Wilcoxon Signed Ranks Test

b. Based on positive ranks.

c. Based on negative ranks.

Table 9. Comparison in UOP in each group (Titanium, Resorbable)

Descriptive Statistics

| Group | N | Mean | Std. Deviation | Minimum | Maximum | |
|------------|-------|------|----------------|---------|---------|-------|
| Ti | UOPT0 | 14 | 11.4643 | 2.55301 | 7.00 | 15.00 |
| | UOPT1 | 14 | 10.5000 | 3.93700 | 5.50 | 18.50 |
| | UOPT2 | 14 | 10.2143 | 2.12779 | 7.50 | 16.00 |
| | UOPT3 | 14 | 10.2143 | 2.49395 | 7.00 | 15.00 |
| Resorbable | UOPT0 | 14 | 9.8214 | 1.78247 | 5.50 | 12.00 |
| | UOPT1 | 14 | 9.9643 | 2.54547 | 6.00 | 15.00 |
| | UOPT2 | 14 | 8.8000 | 1.93112 | 6.00 | 12.00 |
| | UOPT3 | 14 | 8.9286 | 2.24343 | 6.00 | 14.00 |

| Group | | UOPT1 - UOPT0 | UOPT2 - UOPT1 | UOPT3 - UOPT1 |
|------------|------------------------|---------------------|---------------------|---------------------|
| Ti | Z | -1.504 ^b | -.245 ^c | -.175 ^c |
| | Asymp. Sig. (2-tailed) | .132 | .806 | .861 |
| Resorbable | Z | -.035 ^c | -1.796 ^b | -1.661 ^b |
| | Asymp. Sig. (2-tailed) | .972 | .073 | .097 |

a. Wilcoxon Signed Ranks Test

b. Based on positive ranks.

c. Based on negative ranks.

Table 10. Comparison in TOP in each group (Titanium, Resorbable)

| | | Descriptive Statistics | | | | |
|------------|-------|------------------------|---------|----------------|---------|---------|
| Group | | N | Mean | Std. Deviation | Minimum | Maximum |
| Ti | TOPT0 | 14 | 12.9643 | 3.67666 | 8.50 | 23.00 |
| | TOPT1 | 14 | 11.6071 | 3.95250 | 7.00 | 19.00 |
| | TOPT2 | 14 | 11.6429 | 2.42922 | 9.00 | 16.00 |
| | TOPT3 | 14 | 11.7500 | 3.58281 | 6.50 | 20.00 |
| Resorbable | TOPT0 | 14 | 11.1429 | 3.98279 | 3.50 | 21.00 |
| | TOPT1 | 14 | 10.0357 | 3.12843 | 5.50 | 17.00 |
| | TOPT2 | 14 | 9.6429 | 3.03460 | 5.00 | 17.00 |
| | TOPT3 | 14 | 10.0357 | 2.91854 | 6.00 | 17.00 |

| Group | | TOPT1 - TOPT0 | TOPT2 - TOPT1 | TOPT3 - TOPT1 |
|------------|------------------------|---------------------|--------------------|---------------------|
| Ti | Z | -1.416 ^b | -.412 ^c | -1.139 ^c |
| | Asymp. Sig. (2-tailed) | .157 | .680 | .255 |
| Resorbable | Z | -1.369 ^b | -.669 ^b | -.141 ^c |
| | Asymp. Sig. (2-tailed) | .171 | .504 | .888 |

a. Wilcoxon Signed Ranks Test

b. Based on positive ranks.

c. Based on negative ranks.

Table 11. Comparison in EOP in each group (Titanium, Resorbable)

Descriptive Statistics

| Group | N | Mean | Std. Deviation | Minimum | Maximum | |
|------------|-------|------|----------------|----------|---------|-------|
| Ti | EOPT0 | 14 | 7.7143 | 2.67980 | 4.50 | 13.00 |
| | EOPT1 | 14 | 7.7857 | 4.25493 | 3.00 | 19.00 |
| | EOPT2 | 14 | 6.8929 | 1.88291 | 3.50 | 11.00 |
| | EOPT3 | 14 | 6.9286 | 2.05555 | 4.00 | 12.00 |
| Resorbable | EOPT0 | 14 | 7.4286 | 2.54087 | 3.00 | 13.00 |
| | EOPT1 | 14 | 7.4643 | 2.34081 | 3.00 | 11.00 |
| | EOPT2 | 14 | 6.2500 | 2.04516 | 3.00 | 11.00 |
| | EOPT3 | 14 | 7.1429 | 2.381235 | 3.50 | 11.00 |

| Group | | EOPT1 - EOPT0 | EOPT2 - EOPT1 | EOPT3 - EOPT1 |
|------------|------------------------|--------------------|---------------------|--------------------|
| Ti | Z | -.280 ^b | -.465 ^c | -.268 ^c |
| | Asymp. Sig. (2-tailed) | .779 | .642 | .789 |
| Resorbable | Z | -.000 ^c | -2.329 ^b | -.315 ^b |
| | Asymp. Sig. (2-tailed) | 1.000 | .020 | .753 |

a. Wilcoxon Signed Ranks Test

b. Based on positive ranks.

c. Based on negative ranks.

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