Efficacy and Cost of Maxillary Patient-Specific Implants in Orthognathic Surgery: A Review of Three Patient Cases

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Abstract

INTRODUCTION: Patient-specific implants (PSIs) are accurate, efficient alternatives to traditional plate fixation. They are well-suited for use in procedures that require the utmost accuracy, stability, and efficiency. Although PSIs have demonstrated such qualities in craniomaxillofacial reconstruction, they have so far found limited utilization elsewhere.

CASE PRESENTATION: We explored the departmental protocol for Lefort 1 PSI orthognathic surgery at a high-volume, tertiary referral center. Three cases were selected that matched predetermined criteria, which included treatment by the same surgical team, concurrent Lefort 1 osteotomy and bilateral sagittal split osteotomy, Angle’s type 3 malocclusion, lack of interdental osteotomies, and American Society of Anesthesiologists classification 2 or less without metabolic or osseous diseases. The operative outcomes from these patients were then compared to similar cases also meeting the same criteria and conducted within the same time period.

CONCLUSION: The use of PSI in Lefort 1 osteotomy is associated with anatomically sound designs that could contribute to postoperative stability of the jaws. They also have not shown increased rates of complications such as infection, dehiscence, or relapse at 6 weeks postoperatively but may in fact decrease the operative duration. These findings are consistent with the results gleaned from literature on the use of PSI in craniomaxillofacial reconstruction.

Introduction

Orthognathic surgery is a well-accepted and safe modality for the treatment of a variety of maxillomandibular discrepancies. In the past, planning for orthognathic surgery required complex and time-consuming surgical simulations on handmade stone models; these simulations were also prone to error and operator fatigue. Today, much of the planning is conducted virtually, which renders the treatment process more affordable, accurate, and simple.

Similarly, patient-specific implants (PSIs) have been associated with accurate, efficient reconstruction of the skull in the aftermath of craniomaxillofacial trauma or pathologic ablation. These implants would often come in the form of titanium plates to allow adequate function, contour, and biocompatibility. Studies have shown that 3-dimensionally designed PSIs demonstrate accuracy equal to, if not greater...
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than, hand-bent titanium plates, with the added benefits of reduced surgery time and possibly shortened recovery period.\textsuperscript{4,5}

Recent studies have indicated that PSIs may also be a viable option in orthognathic surgery, especially in surgeries of the maxilla. PSIs were associated with improvements in fidelity of hardware shapes to preexisting patient anatomy during Le Fort 1 osteotomy.\textsuperscript{6–8} When used in nonsyndromic patients, PSI fixation also demonstrated similar stability and complication rates, in terms of infection and dehiscence, to traditional mini-plate fixation.\textsuperscript{9,10}

Here, we describe a departmental PSI protocol at a high-volume, regional orthognathic referral center. We present a streamlined treatment approach and outline postoperative comparisons of the PSI modality to traditional orthognathic surgery. For a timeline of the key events, see Table 1.

Case Narrative

Three PSI patient cases from 2020 were included in this study. Inclusion criteria included 1) age range of 18 to 35 years; 2) treatment by the same surgical team (the authors); 3) concurrent LeFort 1 osteotomy and bilateral sagittal split osteotomy; 4) Angle’s type 3 malocclusion; 5) lack of interdental osteotomies; 6) American Society of Anesthesiologists classification 2 or less without metabolic or osseous diseases; and 7) male gender. None of the patients presented with obesity or obstructive sleep apnea.

Virtual surgical planning (VSP) and PSI production were done according to cone beam computed tomography (CBCT) and intraoral scan of each maxillomandibular complex. VSP determined the osteotomy sites, degree of maxillary advancements and mandibular setbacks, as well as the number and location of maxillary plate screws according to cortical thickness. Mandibular setbacks were planned at 5 mm or less to minimize the chance of sleep-disordered breathing.\textsuperscript{11,12} Two side-specific titanium Facial ID\textsuperscript{®} PSIs were designed (Stryker Corp, Kalamzoo, MI) for the fixation of the maxilla in a thickness of 1.0 mm. Each PSI consisted of 3 relatively straight titanium struts in a roughly U-shaped formation, which avoids the thin areas of the anterior maxillary sinus walls, with 3 or

<table>
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<th>Table 1: Timeline</th>
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<td>ADA = American Society of Anesthesiologists; BSSO = bilateral sagittal split osteotomy.</td>
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more screw fixation points each on the medial vertical strut along the nasomaxillary buttress, the horizontal strut along the alveolar buttress, and the lateral vertical strut along the zygomaticomaxillary buttress (Figure 1). This design was intended to distribute the forces of occlusion and muscular traction along the main weight-bearing portions of the skull. An anatomical, bone-borne titanium surgical guide (3D Systems Inc, Rock Hill, SC) was also produced that spanned the anterior walls of both maxillary sinuses and temporarily secured with 2 screws. It incorporated two 1.5-mm-wide horizontal osteotomy slots, each spanning from the piriform rim approximately 1 cm superior to the nasal floor to the lateral maxilla approximately 1 cm inferior to the zygomatic arch. Bone hooks were devised around the edges of the guide to engage the inferior piriform rim and the anterior zygomatic arch (Figure 2). This guide serves as a cutting and marking guide to predict the placement of the predetermined screw osteotomies.

The patients underwent surgery with PSI in the maxilla only. After application of the titanium surgical guide, the LeFort 1 osteotomy was conducted in standard fashion, and all predicted bony interferences were reduced. The mobilized and reduced LeFort 1 segment was fixated to the rest of the midface using a PSI on each side. Maxillary fixation was performed based on predrilled screw osteotomies without maxillomandiublar fixation (MMF) or seating of the temporomandibular joint complex. The bilateral sagittal split osteotomies were completed and the mandibular segment secured via MMF for application of the mandibular plates. Upon completion, the MMF was released and the patient placed in guiding elastics.

Patients were admitted for overnight surveillance and then followed biweekly for a minimum of 6 weeks with CBCT imaging conducted at 2 weeks postoperation. Patients were instructed to undertake a non-chewing diet for 6 weeks. Any complications, including dehiscence, infection, and relapse, were noted.
Results

The preoperative overjet for the 3 patients (A, B, and C) were −10 mm, −2 mm, and −9 mm, respectively, with an average of −7 mm. The operating times from the first incision to the conclusion of the final suture were 172, 152, and 125 minutes, also respectively, with a mean of 149 minutes (Table 2). All demonstrated no complications at 6 weeks, and postoperative imaging demonstrated appropriate placement of the hardware and bony segments. No relapses were noted at 6 weeks, and each patient remained satisfied with their postoperative presentation.

The records of the 3 individuals who underwent treatment with occlusal splints and hand-bent plates were also accessed. These individuals met the same inclusion criteria, as well as additional stipulations, so that, when compared to their paired PSI patients, their surgeries were conducted within approximately 2 weeks. The mean operative time for the traditional surgery group (TG) was longer, at more than 177 minutes (p = 0.0115). The average age of the TG group was 21 years, compared to 24 years for the PSI surgery group (PG). The average overjet of the TG group was comparable to the PG group at −9 mm (p = 0.69). For all patients, the open bite and maxillary/mandibular midline discrepancies were minimal at 2 mm or less with no discernable maxillary cant. All were also fully dentate with at least 6 teeth in each quadrant. A general consent was received from each patient to utilize anonymized clinical data for academic and educational purposes.
Discussion

PSIs are well-established treatment modalities for the reconstruction of the facial skeleton, and their use in orthognathic surgery has begun to gain acceptance. Although data on orthognathic patients are somewhat limited by the recent implementation of PSIs, several studies have attested to the reproducibility, ease, and low complication rates of PSIs in nonsyndromic craniofacial patients.\textsuperscript{6–9,13,14} PSIs allow placement of screws along predetermined stable bony landmarks of the midface, reducing operator error and dependence on ideal seating of the bilateral condyles.\textsuperscript{8} Our surgical guide design sought to further increase this accuracy by incorporating hooks for the piriform aperture and zygomatic buttress for a more secure fit and verification. PSI postsurgical stability is enhanced by the cross-stabilization of a uni-design that spans the nasomaxillary and zygomaticomaxillary pillars.

A search of the MEDLINE English literature for keywords “custom” OR “customized” OR “specific” AND “implants” AND “orthognathic” did not yield data regarding the time efficacy of PSIs as of late 2020. The PSI modality may confer benefits to orthognathic surgery and, in our experience, does not lead to an increased rate of complications, including relapse. Trained VSP engineers can increase integrity of the osseous movements by incorporating thicker plates akin to those of reconstruction plates. These engineers can also help avoid the thinner areas of the maxillary sinus wall, which could compromise the engagement and stability of the screws. Surgeons can avoid plate fatigue, which is associated with traditional plate bending. In addition, PSIs could reduce reliance on single-use acrylic occlusal splints, which may deform, are difficult to decontaminate, and do not degrade well in the environment.

Unsurprisingly, our PSI protocol may also confer operative time benefits over traditional plates. Comparison of the TG and PG via paired $t$-testing showed a 28-minute benefit ($p = 0.0115$), which translates to approximately $2500 savings in operating room personnel costs alone (in 2020 US dollars).\textsuperscript{15,16} A comparison of all our TG and PG orthognathic patients, without accounting for similarities in age and gender, also showed an 11-minute benefit to PSI surgery, even though PSIs were more frequently utilized in complex segmental maxillary osteotomies. These benefits are likely much greater when considering the additional, non-personnel costs associated with operating room usage. In fact, a 2018 meta-analysis showed that complication rates increased by approximately 14% for every 30 additional minutes under anesthesia.\textsuperscript{17}

Conclusion

The added CBCT-based planning and customization of maxillary PSIs may be conducive to successes in orthognathic surgery. Comparisons in well-paired large cohorts may further demonstrate the value of this new technology and the proposed alternative way of executing this type of surgery.

Table 2: Patient demographics. Capitalized letters denote patients who underwent surgery with PSI, and lowercase letters denote patients who underwent traditional surgery.

<table>
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<tr>
<th></th>
<th>Age</th>
<th>Occlusion Class</th>
<th>Op Time</th>
<th>Overjet</th>
<th>Overbite</th>
<th>Max Midline</th>
<th>Mand Midline</th>
<th>Incisal Show</th>
<th>Max Cant</th>
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<tbody>
<tr>
<td>A</td>
<td>21</td>
<td>3</td>
<td>172</td>
<td>$-10\text{ mm}$</td>
<td>$-1\text{ mm}$</td>
<td>Coincident</td>
<td>Coincident</td>
<td>3 mm</td>
<td>None</td>
</tr>
<tr>
<td>B</td>
<td>20</td>
<td>3</td>
<td>152</td>
<td>$-2\text{ mm}$</td>
<td>0 mm</td>
<td>Coincident</td>
<td>Coincident</td>
<td>1 mm</td>
<td>None</td>
</tr>
<tr>
<td>C</td>
<td>31</td>
<td>3</td>
<td>125</td>
<td>$-9\text{ mm}$</td>
<td>$-1\text{ mm}$</td>
<td>Coincident</td>
<td>1 mm left</td>
<td>3 mm</td>
<td>None</td>
</tr>
<tr>
<td>a</td>
<td>20</td>
<td>3</td>
<td>197</td>
<td>$-5\text{ mm}$</td>
<td>1 mm</td>
<td>Coincident</td>
<td>Coincident</td>
<td>0 mm</td>
<td>None</td>
</tr>
<tr>
<td>b</td>
<td>18</td>
<td>3</td>
<td>187</td>
<td>$-12\text{ mm}$</td>
<td>$-2\text{ mm}$</td>
<td>Coincident</td>
<td>1 mm right</td>
<td>2 mm</td>
<td>None</td>
</tr>
<tr>
<td>c</td>
<td>25</td>
<td>3</td>
<td>148</td>
<td>$-10\text{ mm}$</td>
<td>2 mm</td>
<td>Coincident</td>
<td>2 mm right</td>
<td>3 mm</td>
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REFERENCES


