INTRODUCTION

Over the past three decades, significant advances have been made in 3-D computer assisted orthognathic surgery. The advent of computer-aided surgical simulation (CASS) and Virtual Surgical Planning (VSP) in the early 2000s, revolutionized orthognathic surgical planning, obviating the need for traditional model surgery and subsequently streamlining the planning process. In the most recent decade, patient specific implants (PSI) fabricated using 3-D printing technology have emerged as the next step in the technological advancements in orthognathic surgery, beginning with the first documented use of PSI described by Philippe in 2013.\(^1\) While evidence for PSIs remains relatively limited given how recently this technology has been developed, numerous studies have proven that PSIs not only are a viable option for orthognathic surgery, but can improve the accuracy of transferring the virtual surgical plan into the operating room.

PATIENT SPECIFIC IMPLANTS FOR ORTHOGNATHIC SURGERY

HISTORY

While traditional model surgery has been used reliably for decades for fabrication of interocclusal splints for repositioning of the jaws during orthognathic surgery, it can be a labor-intensive process that is subject to cumulative error that can accumulate during the diagnostic and planning process. Furthermore, traditional model surgery has limitations in certain complex dentofacial deformities and semi adjustable articulators.
are imperfect representations of the maxillomandibular unit.\textsuperscript{6}

With the advent of CASS and Virtual Surgical Planning (Medical Modeling/3D Systems, Golden, Colorado) in the early 2000s, a paradigm shift occurred within the world of orthognathic surgical planning.\textsuperscript{5}

Several studies by Xia et al., and Resnick et al., have shown that the utilization of CASS/VSP results in both time and cost savings.\textsuperscript{7,8} Further supporting their findings, a study performed by Wrzosek et al., suggested pairing VSP technology with more modern dental technologies such as intraoral scanners allows for the elimination of impression taking, face bow mounting, and model preparation, which can reduce preparation time by 91\% (approximately 6.78 hours) within their study.\textsuperscript{9}

VSP with its advantages in both accuracy and efficiency essentially supplanted traditional model surgery as the most popular modality for orthognathic surgical planning. The digital workflow has been refined throughout the last two decades, and now allows surgeons to plan cases accurately with only a cone beam CT (CBCT).\textsuperscript{5} While VSP has been used for decades to produce occlusal splints/wafers for orthognathic surgery, the next step in the technological progression is the production of patient specific custom surgical cutting guides and implants based off the virtual surgical plan. (Figure 1)

In 2010, the US Food and Drug Administration (FDA) approved the first 3D-printed titanium implant thus paving the way for patient specific implants. In 2013, Philippe performed the first orthognathic surgery using custom made titanium osteosynthesis plates for repositioning of an edentulous maxilla.\textsuperscript{1} In 2015, Mazzoni et al.,\textsuperscript{2} and Gander et al.,\textsuperscript{3} reported successful maxillary surgeries using custom surgical guides and custom plates based off of 3-D planning software.

**ADVANTAGES**

The advantages of PSIs in orthognathic surgery are significant. Most importantly, PSIs help precisely transfer the surgical plan directly to the patient while also allowing for time savings due to the elimination of steps during surgery that would otherwise be required.

Most of the PSIs described in the literature are maxillary patient specific implants designed to allow surgeons to reposition the maxilla irrespective of the mandibular
position. Multiple studies have shown that these maxillary PSIs are accurate enough to eliminate the need for occlusal wafer splints altogether \(^2\text{-}^4\) although many advocate for the continued use of wafer splints as a reliable back-up in the event there is an intraoperative problem with the PSI such as a poor adaptation to the bone. Growing evidence within the literature supports the notion that this waferless/splintless orthognathic surgery using custom bone plates is just as accurate if not more accurate than orthognathic surgery using occlusal wafer splints.\(^2\text{-}^4\)

CASS/VSP also allows for the fabrication of patient-specific guides and cutting jigs, which can facilitate the accurate execution of the ideal surgical plan. Patient-specific guides allow for osteotomies to be placed precisely with the use of cutting channels. This predetermined placement of osteotomies not only helps with transference of the surgical plan to the patient but also can eliminate time spent removing bony interferences following downfracture of the maxilla. For example, in the case of a maxillary impaction, multiple cutting channels within the surgical guide can allow the surgeon to resect the precise amount of bone in the anterior maxilla to allow for the desired vertical repositioning of the maxilla. This is a more efficient method than the traditional “cut and check” approach, which sometimes requires the surgeon to check and adjust the vertical position of the maxilla multiple times. Furthermore, predictive screw placement using the surgical guide provides significant advantages aside from accurate positioning of the maxilla. Predetermined placement of screw holes based on the surgical guide can allow for screw placement in areas of ideal bony thickness and avoidance of tooth roots during fixation. (Figure 2)

*Figure 2. Image taken from bone thickness analysis performed during virtual pre-surgical planning. VSP and CASS allows surgeons and engineers to design fixation plates with screw holes placed in areas of ideal bone thickness.*

Patient specific implants designed using virtual surgical planning allows for significant time savings not only in preoperative planning but also in the operating room. Both the patient specific guide and custom fabricated plate facilitate the intraoperative surgical workflow by streamlining or eliminating several steps within the surgery. Although checking the fit of the guide and securing it into place takes additional time, this time saved throughout the rest of the surgery more than compensates for this additional step. Once the guide is in place, the precisely placed ostetomies can save significant time especially in the context of maxillary impactions as previously described, and furthermore, the predictive screw holes allow the surgeon to drill all of the screw holes in a much more efficient way. The custom fixation plate itself also facilitates the surgery by allowing for easy positioning
of the maxilla. As the predetermined vertical/horizontal changes are already built into the plate, there is no need to painstakingly stabilize the maxilla during fixation. The surgeon simply aligns the predetermined screw holes to the plate and the fixation screws can be placed in quick succession. This precise predetermined positioning built into the plate eliminates the need for an external reference with a Kirschner wire to determine vertical positioning of the maxilla and as well as the need to wire the patient into an intermediate splint based on the position of the mandible. Finally, the use of PSIs saves the time spent bending the two to four fixation plates traditionally used in a LeFort osteotomy. Mazzoni et al.,\(^1\) found that despite the fact that osteotomy times were longer with waferless repositioning, overall surgical times were faster due to time savings in plate bending and actual maxillary positioning. As mentioned previously, the stiffness and accuracy of the PSI plates could allow for the elimination of post-operative surgical splints.

Although there is an absence of quantitative evidence directly comparing operative times using PSIs for orthognathic surgery versus more traditional techniques, a recent survey of oral and maxillofacial surgeons in the UK showed that 61% believed that waferless surgery reduced the surgical time.\(^11\) Furthermore, Li et al., reported a mean operating time of only 160 minutes using a waferless technique for bimaxillary surgery in their study.\(^12\) (Figures 3, 4)

**ACCURACY**

Several studies have even shown accuracy of patient specific maxillary implants for orthognathic surgery even without surgical wafer splints.\(^2\)-\(^4\) The first study to measure the accuracy of these computer generated
surgical guides and plates was published in 2017 by Heufelder et al.\textsuperscript{4} They demonstrated that the guides were particularly accurate in the transverse and vertical dimensions with median linear deviations of 0.3 mm and 0.33 mm respectively from the virtually determined position. They found that while slightly less accurate, anterior-posterior positioning was still quite precise with a median linear deviation of 0.7 mm. A recent study by Jones et al. studying the comparing the accuracy of maxillary positioning during bimaxillary surgery comparing custom fabricated splints vs. PSIs concluded that PSIs allowed for greater control of the post-operative maxillary position than splints.\textsuperscript{10}

**STABILITY**

Preliminary studies comparing the postoperative stability of patient specific custom plates against standard miniplate fixation have shown no significant differences in the maxillary stability fixation.\textsuperscript{13} An in-vitro study by Stokbro et al., comparing stabilities of patient specific custom fixation plates and manually adapted stock plates, proved that in terms of compressive strength, patient specific custom fixation plates are actually stronger and can withstand stronger compressive forces. The authors posit that this increased strength is for a variety of reasons including the fact that PSI fixation plates are thicker, more rigid, and placed in areas of ideal bone thickness, and are not subject to weakening effects from bending the plates.\textsuperscript{14} PSIs with their increased rigidity can render the use of a palatal or occlusal splint unnecessary in cases of maxillary expansion. Splints are known to impair phonation, create a hygiene challenge to patients, and must be removed several weeks after surgery.

**DISADVANTAGES**

While patient specific implants offer obvious advantages over more traditional approaches, they are not without some drawbacks. From the surgical perspective, the main disadvantage of patient specific implants for orthognathic surgery is the limited ability to alter the plan intraoperatively. Any deviation from the predetermined surgical plan essentially means that the custom cutting guides and fixation plates must be scrapped in most cases as alterations are difficult. For this reason, some still advocate for fabrication of occlusal wafers as a backup option should the necessity of alterations to the operative plan arise. Furthermore, while custom guides and fixation plates are made to fit precisely, errors can accumulate if the guide is not properly seated/fixated or if the predictive screw holes are drilled without paying specific attention to the angulation of the predetermined screw hole. For this reason, some surgeons prefer to use single-body surgical guides/plates as these are inherently easier to index.

While there may be significant healthcare cost savings due to decreased intraoperative time, there is an increased cost in the fabrication of the patient specific guides and implants. One vendor frequently used by the authors estimates the average cost of stock plates with traditional VSP and splints at $5,000 per case, while a PSI case including cutting guides and splints (available as a backup) at $11,000 per case. Furthermore, there is an increased
lead time, sometimes requiring 10-15 business days, in the fabrication of custom guides and implants although efficient surgical scheduling should make this additional manufacturing time a non-issue for surgeons. (Figure 5)

Figure 5. Before (A) and after (B) photos of the above patient with unilateral condylar hyperplasia treated with a surgery-first approach with patient specific implants and postoperative orthodontic treatment with clear aligners.

MAXILLARY VS. MANDIBULAR CUSTOM PLATES

Currently, most literature regarding PSIs for orthognathic surgery involve the use of maxillary PSIs. However, PSIs can be fabricated for use in mandibular surgery as well. Suojanen and colleagues evaluated their use in patients who underwent mandibular advancement via bilateral sagittal split osteotomies (BSSO). While their findings showed success in most patients, they found the fit of the implants was relatively less predictable than their maxillary counterparts. The authors postulated that this relative inaccuracy is likely a result of the unpredictability in seating of the condylar segment into the glenoid fossa as well as less predictability in the actual split of the mandible.15 Heufelder et al., also described how the of uncertainty of the condylar position during the pre-operative CT would pose problems when attempting to perform waferless positioning of the mandible.4

However, in a different study, Suojanen et al., found that there were no differences in infection rates, reoperation rates, or soft tissue complications using patient specific miniplates for BSSO fixation with up to 3-years of follow up.16

While PSIs for BSSOs may be less predictable relative to those used in maxillary surgery, PSIs still offer significant utility in other mandibular orthognathic procedures such as genioplasties and Inverted-L osteotomies. Farrell et al., describe a technique using patient specific cutting guides and fixation plates to perform an inverted L osteotomy for patients requiring large counterclockwise rotations of the maxillomandibular complex through intraoral access only.17 Apart from the increased accuracy of both the osteotomies and fixation during the procedure, the PSIs allow a surgery that was traditionally performed via extraoral and intraoral approaches to be performed
entirely intraorally. This avoids an extraoral scar, prevents cross contamination between intra and extraoral wounds, and streamlines the intraoperative workflow.

PSIs for genioplasties offer similar advantages to those afforded by maxillary PSIs. Custom made cutting guides allow for both precise placement of the osteotomies well as predictive screw placement. Positioning of the free segment is also made simpler with custom fixation plates as the planned movement is already built into the plate similar to custom fixation plates in the maxilla. (Figure 6)

(Figure 6. Postoperative panorex of the previously shown case performed using a maxillary patient specific implant to accurately reposition the maxilla.)

**FUTURE APPLICATIONS**

While PSIs fabricated using CASS technology already represent the next step forward in orthognathic surgery, the potential applications for this technology have likely not been fully explored. One particular scenario in which the authors believe there is particular utility for PSIs is in cases where a “surgery first” is used. Nagasaka et al., in 2009, described a “surgery first” approach essentially eliminating the traditional pre-surgical orthodontic period needed for decompensation, dental alignment, and arch alignment. Orthognathic surgery is performed first in an effort to result in a postoperative malocclusion that can be treated with traditional orthodontics. In select cases, this approach can afford numerous benefits such as reduced treatment time due to the obviation of the pre-surgical orthodontic period as well as physiologic increases in bony remodeling and subsequent tooth movement, commonly referred to as the regional acceleratory phenomenon (RAP). Furthermore, there are psychological benefits to performing surgery first as there is an earlier re-establishment of facial aesthetic harmony and elimination of pre-surgical decompensation which often leads to a more obvious dentofacial deformity. In the authors’ experience, the facilitated workflow from patient specific implants can greatly help in these cases, especially as it can be difficult to achieve a stable occlusion intraoperatively.

**CONCLUSION**

Modern orthognathic surgery has evolved significantly since the times of pioneering surgeons such as Hugo Obwegeser and William Bell. Just as the emergence of CASS/VSP technology marked a tremendous leap forward in the early and mid 2000s, PSIs could potentially represent the next great step forward in the field of orthognathic surgery. The advantages afforded by PSIs in transferring the plan from the virtual world to the operating room while also offering significant time savings outweigh their perceived drawbacks. With continued advancements in surgical technologies and techniques including intraoral scanning, virtual 3-D planning,
and patient specific implants with an increased emphasis on surgery first approaches, orthognathic surgery in the future may be a faster, simpler, and more accurate process than was envisioned by past generations of oral and maxillofacial surgeons.

REFERENCES


