Evaluation of Polyetheretherketone (PEEK) Versus Titanium Patient Specific Plates for Fixation in Computer-Guided Advancement Genioplasty

Introduction

The chin has a major role in the profile and the whole esthetics of the face, affecting the individual's psychology and social acceptance [1]. The need for surgical intervention to alter the size and shape of the bony chin associated with changes of the surrounding soft tissues, which is known as "Genioplasty" was developed since the isolated chin deformities represent about 15% of all dentofacial deformities. Genioplasty was first described by Hofer who performed osteotomy anteriorly at the lower border of the mandible via a submental incision, followed by Trauner and Obwegeser via labial sulcular incision [1,2].

Advancement genioplasty is the corrective procedure of the anteroposterior chin deficiency. Traditionally, the planning of genioplasty was done using analysis of clinical photos and lateral cephalograms, relying on the personal experiences and visual assessments of the surgeon to control the three-dimensional (3D) movements of the distal bone segment during the surgery resulting in variable outcomes that could impair the surgical results [3,4].

Recently, the introduction of virtual surgical planning (VSP) along with 3D radiographic technology in orthognathic surgery allowed the surgeon to produce surgical guides based on preoperative VSP to simulate this plan precisely into the operating room. These guides transfer the planned osteotomy site and direction during surgery and accurately move the bony segments into the desired positions as planned. VSP has additional benefits including optimal planning accuracy and reliability, reduced possibilities of vital structure injury, less surgical time, achievement of the predictable stable functional and aesthetic with better clinical outcome [5,6].

Regarding the fixation, rigid bone fixation with plate and screws are more commonly used because of their reliability, rapid and easy application [7]. Fixation of the repositioned distal bone segment using titanium plates is commonly used because titanium is considered as the gold standard material of plates. However, recently polyetheretherketone (PEEK) is considered as an acceptable material for reconstruction because of its mechanical properties and it could be used as an alternative to titanium due to its biocompatibility, inertness, non-toxicity, high fatigue resistance, and ability to initiate osseointegration [8,9].

Nowadays, PEEK is popular and commonly used in cranioplasty and spine surgeries because of its high reliable biocompatibility, excellent corrosion resistance, lack of allergic reactions, the possibility of sterilization without loss of mechanical properties, permeability to X-ray beam allowing CT examination, and the absence of artifacts during MRI. Most importantly its energy-absorbing properties and modulus of elasticity which closely resemble the bone more than titanium. Therefore, PEEK represents an ideal alloplastic material and has been successfully used [9].

However, a finite element analysis study of PEEK supported the possibility of its use as a material for reconstruction plate [10]. This study compared titanium and PEEK by forming the same standard design of reconstruction plate, proving the validity of using PEEK as a material for reconstruction plate used in fracture of the angle of the mandible and the results showed that the mechanical properties of the PEEK are more close to the bone and in consequence increasing the static safety factor of the plate and improving the fatigue strength criteria. Thus, supporting the rationality of using PEEK as a material of reconstruction plate [10].

To our knowledge, this is the first clinical report of using patient specific PEEK plates in the fixation of computer-guided advancement genioplasty and

evaluate it clinically and radiographically in comparison to patient specific titanium plates.

Aim of the Study

The aim of this comparative analysis study was to compare polyetheretherketone (PEEK) and titanium patient specific plates for fixation in computer-guided advancement genioplasty clinically and radiographically.

Patients and Method

Subjects

This study was designed and performed in the departments of Oral and Maxillofacial Surgery in Faculty of Dental Medicine for Girls, Al-Azhar University and Ahmed Maher Teaching Hospital. After having ethical approval from the Research Ethics Committee with code ORSUR-108-2-L, the selection of the patients was based on these inclusion criteria (1) Patients who are indicated to advancement genioplasty. (2) Patients with completed growth. (3) Physically and psychologically able to tolerate surgical procedures. While the exclusion criteria were (1) Presence of any medical conditions that contraindicate the surgical procedure. (2) Any medical condition that compromises the healing and surgical outcome.

Grouping of Patients

This study included fourteen patients indicated for advancement genioplasty. They were randomly assigned into two groups.

- Group A included seven patients who were treated by computer guided advancement genioplasty using patient specific titanium plates considered as a control group.

- Group B involved seven patients who were treated by computer guided advancement genioplasty using patient specific PEEK plates considered as a study group.

The full treatment plan, surgical procedure and possible complications were explained and discussed with the patients, and an informed consent form was signed as well. All surgeries were performed under general anesthesia through nasotracheal intubation. Local anesthesia solution containing 1% lidocaine and 1:100,000 epinephrine is infiltrated along the proposed incision line and dissection area.

The incision was performed in the labial mucosa (anterior region of mandible), at least 10 to 15mm of mucosa attached to the gingiva. The incision was designed to be more superior in the region of canine. Care must be taken not to extend the incision too far posteriorly to avoid the mental nerve where it exits from the mental foramen, and to identify the branches of the mental nerve which are often visible. Then the incision is then completed down to the bone.

Clinical Procedures

After documenting past medical and dental history, patients were examined clinically and radiographically with Computed Tomography (CT) scan to confirm the need for advancement genioplasty. Then the virtual surgical planning (VSP) started by transferring the resulting Digital Imaging and Communications in Medicine (DICOM) data of CT to ProPlan CMF software (Materialise NV, Leuven, Belgium) to perform the osteotomy and the repositioning of the genial bone segment

Then exported the VSP data in the form of Stereolithography into 3-matic software (Materialise NV, Leuven, Belgium) to design the surgical cutting and repositioning surgical guide and the plate as well in the form of STL files. Then

the resulting STL data was transmitted to a 3D printing machine to fabricate the surgical guide and to a milling machine for the plate production of both groups [1,3,11]. All patients underwent standard advancement genioplasty [12,13,14] and were fixed with either titanium or PEEK patient specific plates.

Postoperative Evaluation

1- Clinical evaluation
   - Extraoral: Signs of hematoma, infection or inflammation of the skin also any neurological affection of mental nerve.
   - Intraoral: Signs of infection or any soft tissue dehiscence or plate exposure.
2- Radiographic evaluation
   - Discrepancy evaluation (Linear measurements) between immediate (Within the first postoperative week) and six months postoperative CT by comparing the position of hard tissue menton (Me) and hard tissue pogonion (Pg) on CT to assess the vertical and horizontal changes respectively.
   - Superimposition of the immediate and six months postoperative using 3-matic software (Materialise) software to measure the linear discrepancy and to create a color map [15].
3- Cost evaluation
   - A comparison between the costs of the cutting and repositioning guides in addition to the patient specific plates were calculated for each patient in both groups in Egyptian pounds.
4- Patient satisfaction evaluation
   - Patient satisfaction with the aesthetic results was evaluated using a 5-point Likert scale postoperatively (1 is very dissatisfied, 2 dissatisfied, 3 neither dissatisfied nor satisfied, 4 satisfied, 5 is very satisfied).
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Statistical Analysis

The results were represented from normality tests (Kolmogorov-Smirnov and Shapiro-Wilk) conducted on multiple groups (Vertical movement, Vertical discrepancy, Horizontal movement, Horizontal discrepancy) and materials (Ti and PEEK) to assess whether the data follows a normal distribution. Based on these results, all datasets (Across groups A and B) are normally distributed according to both the Kolmogorov-Smirnov and Shapiro-Wilk tests. This supports the assumption of normality, which is often a prerequisite for parametric statistical tests.

Consent

I declare and acknowledge that I agree to perform the operation and to all modifications that may occur during the operation according to the necessity, as well as the anesthesia, whether general or local, or any type of anesthesia that serves this purpose.

I also agree to perform advancement genioplasty and fixation of the chin bone with patient specific plates (titanium or polyetheretherketone).

This is my consent of this without any responsibility on the part of the surgeon and anesthesiologist at the hospital

Name:

ID:

Adress: