



Retrospective Study

A RETROSPECTIVE MULTICENTRIC STUDY OF 56 PATIENTS TREATED WITH 92 PTERYGOID IMPLANTS FOR PARTIAL/FULL ARCH IMPLANT SUPPORTED FIXED REHABILITATION: IMPLANT AND PROSTHESIS SUCCESS RATE

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ABSTRACT

In the case of severe atrophic patients, the search for native bone can be extended beyond the anatomical limits of the oral cavity. So remote anchorage solutions could involve the pterygomaxillary complex composed of the maxillary tuberosity, the pyramidal process of the palatine bone and the pterygoid pillar. Pterygoid implants are typically placed in this zone to rehabilitate patients affected by severe maxillary atrophy. This study's aim consists of the surgical and prosthetic success rate evaluation concerning the pterygoid implants placed to support fixed partial or full arch rehabilitation without a cantilever. All team members designed and conceived this retrospective multicenter study (performed in three different clinical offices) to evaluate the reliability and predictability of this anatomically guided surgical technique without immediate loading. The study was successful with 100 per cent surgical success and all torque values ≥ 45 N/cm considered as a threshold value. The series comprised 56 people who underwent 92 procedures. The male-to-female ratio

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was close to one (27 men, 29 women). The mean age ($\pm$ SD) was 64.0 ± 9.3 years (range 41-85 years). Only one prosthetic failure was recorded in a woman aged 67 years receiving a full arch pterygoid implant. Pterygoid implants supported by fixed rehabilitation represent a reliable strategic solution for treating severe atrophic posterior maxilla.

KEYWORDS: *pterygoid implants; cantilever free, insertion torque, fixed rehabilitation, atrophic maxilla, graftless surgery*

INTRODUCTION

Osseointegrated implantology represents a reliable treatment solution to solve edentulism in jaws (1) in daily clinical practice. Insufficient bone amount and closeness to important anatomical landmarks could prevent implant placement. Each anatomical area is characterized by features and limitations (bone quality and quantity, nerve course, maxillary sinus cavity), which certainly conditioned/impacted this surgical procedure.

Among all, the atrophic posterior maxilla represents a critical and demanding area in the patient's rehabilitation through the insertion of integrated bone implants (2, 3) since it often lacks both in height and in thickness, thus preventing the placement of implants without adjunctive strategies (4).

The presence of the maxillary sinus, an inadequate bone in terms of quality or amount, a large fatty marrow space or the rare presence of cortical bone covering the alveolus represent some of the critical aspects that surgeons could meet during the surgical approach. Regenerative techniques such as maxillary sinus elevation, block grafts, or Customized Bone Regeneration allow bypassing these anatomical criticalities, even if they are not free from long healing periods or donor site morbidity (5-8). In implant surgery, it is mandatory to minimize patients' morbidity, especially if implant patients are getting older. Consequently, therapeutic, surgical procedures must be tailored to them and their ingrained features, systemic diseases, pharmacological therapies, and functional sinus impairment due to sinus lift augmentation (9). According to the current guidelines, daily clinical practice should consider the most cost-effective treatment equal to clinical efficacy.

Although surgical reliability is well documented, there is still disagreement on clinical and prosthetic primacy techniques. Some suggest it could be a good practice to go beyond these critical issues, using shorter and wider diameter implants to reach a high bone implant surface contact (10, 11). Furthermore, biomechanical considerations such as the intense chewing forces acting in the atrophic posterior maxilla should not be forgotten. Ideally, a prosthetic cantilever should be avoided for this aspect (12): several complications could occur, such as screw and framework fracture, marginal bone loss or implant osteointegration loss.

In the case of severe atrophic patients, the search for native bone can be extended beyond the anatomical limits of the oral cavity. So remote anchorage solutions could involve the pterygomaxillary complex composed of the maxillary tuberosity, the pyramidal process of the palatine bone and the pterygoid pillar. Pterygoid implants are typically placed in this zone to rehabilitate patients affected by severe maxillary atrophy (13).

Bone availability in the maxillary tuberosity is highly variable and is based mainly on the adjacent maxillary sinus pneumatization amount. In 1989, Tulasne (14) introduced implant placement in the pterygoid region to overcome anatomical limitations due to atrophic alveolar bone.

The pterygoid implant entails the fixture penetrating three specific osseous structures: maxillary tuberosity, the pyramidal process of the palatine bone and pterygoid pillar, and if it reaches osteointegration successfully, it offers support and stability to the final cantilever-free prosthesis. It significantly differs from tuberosity implant usually placed in the tuberosity region (mainly composed of 3 or 4 types of cancellous bone at the most distal portion of the maxillary alveolar process) and rarely with an angulation above 10 degrees. The pterygoid implants are usually placed with an angulation of 30 – 60 degrees relative to the horizontal maxillary plane, and they could offer support in partial and full arch prosthetic fixed rehabilitation. This anchorage satisfies surgeons and patients due to the time-consuming surgical strategy and favourable cost-benefit ratio.

The aim of this study consists of the surgical and prosthetic success rate evaluation concerning the pterygoid implants placed (with a minimum torque of 45 Ncm) to support fixed partial or full arch rehabilitation without a cantilever. Its proposal consolidates the literature evidence with our shared experience, whose data were analyzed and interpreted according to a characteristic descriptive statistical analysis.

MATERIAL AND METHODS

Study design

All team members designed and conceived this retrospective multicenter study with an enrolled sample of 92 pterygoid implants to evaluate the reliability and predictability of this anatomically guided surgical technique (Noris Medical PteriFit™) with a 1-year follow-up. It was performed in three different clinical offices:

1. Dr Tealdo Tiziano Clinical Office, Alba, Italy;
2. Dr Bevilacqua Marco Clinical Office, Boves, Italy;
3. Dr Alberti Christian Clinical Office, Rosà, Italy.

Only one type of pterygoid implant (Noris Medical PteriFit™) was employed not to introduce further variables. All the patients previously visited after a CBCT 3D scan (Gendex GXDP-700 S) showed clinical and radiological signs of hopeless dentition and severe atrophy. After computer-assisted surgery planning (DTX Studio Clinic software, Nobel Biocare), the implant placement was defined in the pterygoid region. The study was conducted according to the Helsinki Declaration of 1975 principles and revised in 2000 for biomedical research involving human subjects.



Fig. 1a. Initial case of the atrophic patient in the maxillary arch.

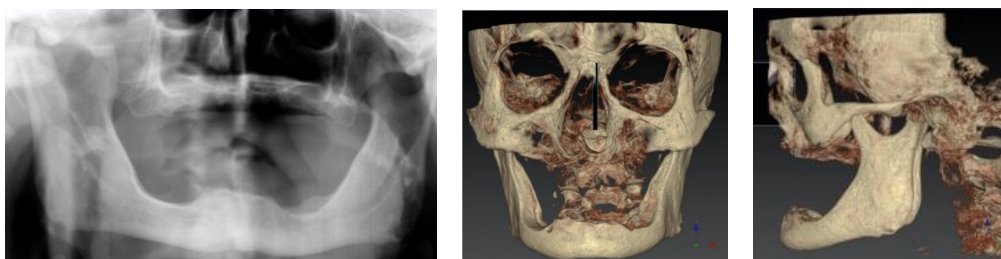


Fig. 1b. 2D radiological images and 3D reconstruction of the same atrophic patient.

Since the authors analyzed preexisting and no identifiable data of patients, who were all informed about the nature of the data treatment and their written consent was obtained prior to participation.

Pterygoid rehabilitation protocol

All the patients enrolled in this study had to meet the inclusion criteria or good general health, no contraindications to implant placement or insufficient pterygoid bone amount (Fig. 1a, 1b, Fig. 2). All patients had at least 1 year of follow-up after the prosthesis delivery.

The surgical protocol applied to all the enrolled patients (January 2021 to February 2022) consisted of raising a full-thickness flap to expose the pterygomaxillary synostosis and performing the osteotomy for implant placement according to the manufacturer's guidelines. The implant site



Fig. 2. Initial case of the patient from the occlusal point of view.

preparation sequence included a marking drill, the subsequent passage of a manual osteotome with a 2mm tip to define the implant insertion axis, the use of a 2.3mm diameter twist drill at approximately 1000 RPM, a second 2.8 mm diameter twist drill along the entire working length. The implant insertion was manually performed using a dedicated straight screwdriver.

Manual insertion did not allow the implant insertion torque to be objectively quantified; therefore, a torque wrench was fitted to accept the achievement of a torque of 45 Ncm or greater. Unstable pterygoid implants were immediately removed, and the osteotomy was filled with a hemostatic gelatin sponge (Spongostan -Ethicon). Since the Noris Medical PteriFit TM is soft-tissue level fixture, part of the stained neck of the implant was purposely left with extra bone to contract the relationship with the soft tissues in the tuber area.

The axis of the implants was corrected during the surgery by connecting a pre-angled conical abutment at 30Ncm. Before suturing the flap, a healing cup at 10 Ncm was connected above the stump to achieve non-submerged healing. The one-stage solution offers to screw a 5 mm healing cap on the pterygoid implant immediately after the surgery without any risk of interference with the opposite teeth, as interference during mastication with the chewing forces could prejudice the primary stability, and a surgical failure may occur. Thus, it could be recommended to cover the head of the pterygoid implant with the flap after the implant placement (two-stage) (Fig. 3-5).

After a minimum period of 3 months without prosthetic load, the pterygoid implants were registered with the pick-up and open tray technique for the definitive rehabilitation, which envisaged their union with other implants inserted in the same period.

A specific quick-setting plaster (BF plaster - Dentaltorino, Italy) was used as impression material for fixed full arch rehabilitation. In the case of partial rehabilitation, in addition to the impression plaster to solidify the implants together, silicone was also used for the remaining fixed dental elements. The final prosthetic frameworks were tightened by a

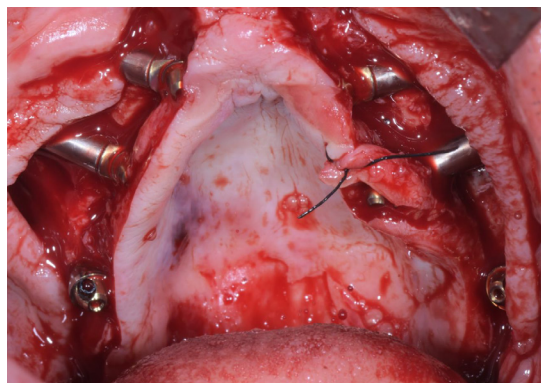


Fig. 3. Intra-operative picture after implant insertion and Multi Unit Abutment (MUA) connection on different kind of implants.



Fig. 4. Intraoral picture after a healing period of 4 months.



Fig. 5. Frontal aspect of the provisional prosthesis delivery.

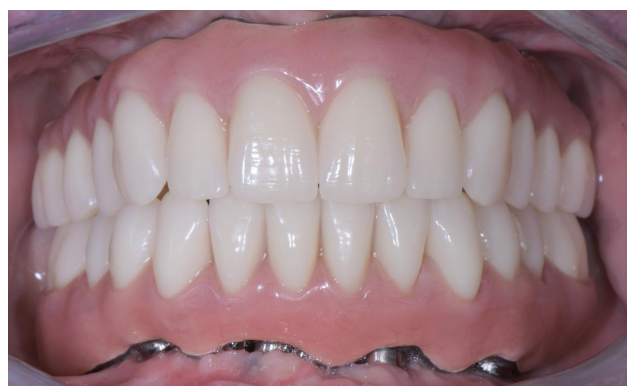


Fig. 6. Frontal aspect of the final prosthesis delivery supported by the pterygoid implants.

motor with a torque of 25Ncm on the pterygoid implants Unigrip™ connection (Fig. 6, 7).

Study variables

This kind of implant differs from conventional dental implants according to their extra-oral anchorage. For this reason, all the Authors considered only two outcome variables for this study: surgical and prosthetic success rate. Concerning the surgical success rate, only the pterygoid implants that reached a minimum of 45 Ncm insertion torque were considered and maintained in the pterygoid bone (otherwise, they were immediately removed during the surgical phase). The study was successful with 100 per cent surgical success and all torque values ≥ 45 N/cm. The evaluated criteria to meet the prosthetic success rate were overall stability, comfort, function and patient acceptance. This last concept means that after prosthesis delivery, patients met satisfaction in chewing and phonetics without any excessive encumbrance or symptom. All the patients' feedback was collected and recorded during the follow-up dates planned after the prosthesis delivery.

Predictor variables

The following determinant or predictor variable was addressed in this study:

- demographic factors (gender, age) (Fig. 8);
- dental factors (size, length, diameter, MUA angle, torque insertion, surgical date, one or two-stage, number of implants, nasal implants, zygoma implants, partial/full arch rehabilitation, prosthesis delivery) (Fig. 9).

RESULTS

Population under study

The series comprised 56 people who underwent 92 procedures. The male-to-female ratio was close to one (27 men, 29 women). The mean age ($\pm$ SD) was 64.0 ± 9.3 years (range 41-85 years). The primary endpoint was torque.

Surgical technique

The two-stage approach was used in nearly all patients. The one-stage approach was used in just one patient, a woman aged 74 years receiving a full arch pterygoid implant. Zygomatic implants were done in 15 patients (27%), and nasal implants in 10 (19%). Five patients had both zygomatic and nasal implants.

Variable angulation was never considered. A full arch was used in most subjects ($39/56=70\%$), while a partial arch was used in less than one-third ($17/56 = 30\%$).

Patients in the series received 5.6 ± 1.4 implants overall (mean $\pm$ SD) (range 2-8). Patients receiving partial arch had an



Fig. 7. A final Orthopantomography exam after the delivery of the final prosthesis.

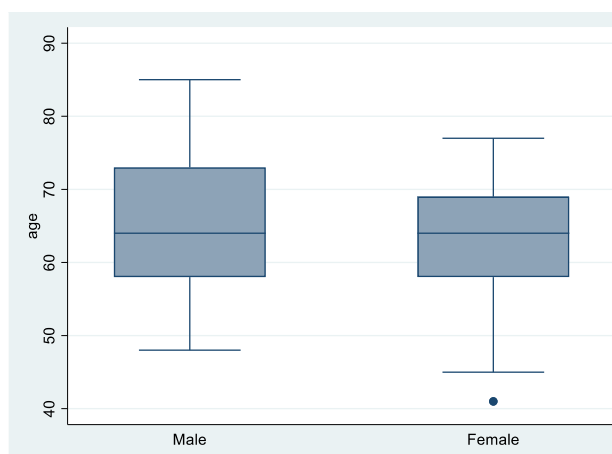


Fig. 8. Distribution of the age range between the genders.

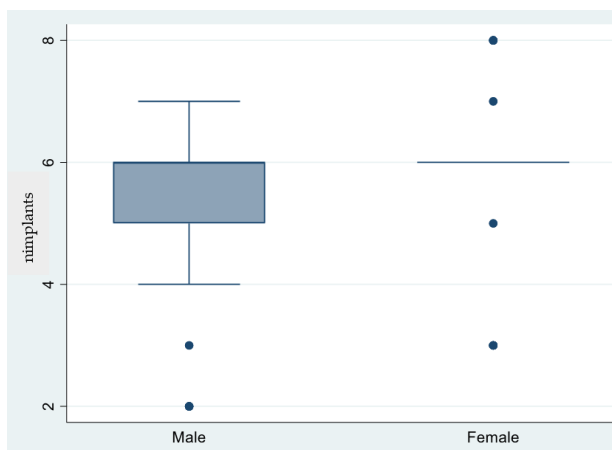


Fig. 9. Graph describing the distribution of the number of implants over genders (male/female).

average of 4.3 ± 1.9 implants (median 4, range 2-8), while patients receiving full arch had an average of 6.1 ± 0.7 implants (median 6, range 5-8). Notably, two-thirds of the latter group (26/39) received 6 implants. The length of pterygoid implants ranges from 16 to 28 mm (median value 20.78 mm).

Surgical outcomes

The study succeeded with 100% surgical success and all torque values ≥ 45 N/cm. Only one prosthetic failure was recorded in a woman aged 67 years receiving a full arch pterygoid implant.

DISCUSSION

In the case of severe atrophic posterior maxilla, the search for extraoral implant anchorages could represent a reliable strategy to restore and rehabilitate patients and prevent other alternative regenerative treatments (7, 15); in fact, the pterygoid implants play a crucial role in the reaching of extra oral bony pillar (rescue implants).

This retrospective study shows a success with 100 per cent surgical success and with all torque values ≥ 45 N/cm, even if other authors reported lower success rates for pterygoid implants (ranging from 80% to 99%) (10-16, 17). However, the surgical success rate we have observed should not mislead us into thinking it is a simple technique. This surgical approach requires operative skills and learning curves. The surgeon should recur to an accurate previous CBCT scan evaluation.

Clinicians should always consider that numerous vascular structures such as maxillary artery, descending palatine artery and pterygoid venous plexus can be detected in this area. Only with a detailed observation of pre-clinical CBCT can the placement of pterygoid implants be relatively safely planned. Up to now, three surgical techniques exist concerning pterygoid implant placement (18). The first is a free-hand surgical technique: we use this to plan and manage the pterygoid region. After a CBCT examination of the area to determine the correct axe insertion of the pterygoid implant, we expose the pterygoid-maxillary synostosis to access and approach the area. The surgeon can alternatively fold up a guided surgery, particularly a static fully guided implant placement (option #2) or a dynamic guided implant placement (option #3). For the static guide surgery, it is very important to consider the opening of the patient's mouth due to the encumbrance of the template and the dedicated drills (19); either technique requires continuous application and a constant learning curve to reach a well-established surgical skill.

This type of retrospective study requires a descriptive statistical analysis: the primary endpoint was the insertion torque; a value equal to or above 45 Ncm was the initial parameter considered. The authors want to underline the important prognostic value of the insertion torque (≥ 45 N/cm) on the surgical success rate. The primary stability is not always reachable during surgery. Whenever the insertion torque cannot satisfy the minimum of 45 Ncm, it is recommended removing the implant to place another in another surgery date. An eventual prosthetic connection with nasal implants (10%) or zygomatic implants (27%) does not seem to play a prognostic decisive role. Even if these pterygoid implants differ from conventional intra-oral dental implants, they show a common feature: the importance of primary stability.

Furthermore, the length of pterygoid implants should be enough to allow these fixtures to engage the pterygoid process of the sphenoid bone. In the present study, implants of length ranging from 16 to 28 mm were used (median value 20.78 mm). The length of these implants is very closely related to primary stability and long-term success, as reported in the literature (16-20). Paying attention to all the surrounding anatomical determinants is mandatory in this situation.

It is possible to perform the one-stage surgery (5 mm height for the healing cap) only in safe conditions: at least 5 mm distance from the antagonist teeth. In case of interference during mastication, the chewing forces could prejudice the primary stability, and a surgical failure may occur. Compared to previous studies (20, 21), all the authors decided to redefine the clinical reliability of some parameters, such as:

- angulation of pterygoid implants: it was initially evaluated on an orthopantomography exam. In our opinion, a Cephalometric evaluation could be more indicated to estimate angulation than an Opt evaluation; it gives only an interpretation of the angulation: but would expose patients to further radiological exposure.
- bone loss: the pterygoid region represents a deep area for anchorage. All the authors consider estimating effective bone loss affecting pterygoid implants very challenging. To the best of our knowledge, the literature does not offer

solid support for scientific evidence on the calculation of bone loss around these implants. These are, unfortunately, empirical evaluations (21);

- bleeding on probing (BoP): in this deep posterior area, the mucosal tunnel is deeper, and a possible BoP is not a necessary sign of inflammation. Therefore, we cannot consider this biological parameter as reliable as dental implants; If we consider this procedure from a prosthetic and biomechanical point of view, unscrewing and cantilever should be prevented.

The unscrewing may occur if the screw is not tightened with a torque wrench (20 Ncm).

The mobility of the Multi Unit Abutment (MUA) resulting from unscrewing can induce bleeding, suppuration and tenderness and impact the function and satisfaction of the patient. Finally, the cantilever may play an unfavourable role in the overloading and consequent bone loss around the implants (20).

The bone loss was assessed in other studies (22, 23) comparing Opt exams scanned after 1 year of prosthetic loading. We argue that this calculation method is only interpretative but not scientifically reproducible and repeatable.

The postoperative healing phase of each patient did not have any particular signs or events worthy of note: bleeding could occur due to veins of the pterygoid muscles. These events could be stopped with the pterygoid implant placement. Patient acceptance of the distal prosthetic framework was high.

This retrospective study has only one prosthetic failure due to a partial fracture of the framework. As reported in Literature (24), our population under study confirmed high satisfaction with the fixed prostheses. No phonetic problems or speaking problems were referred. Correct and daily hygiene maintenance is mandatory to avoid high levels of plaque index, tissue hyperplasia or mucosal inflammation.

CONCLUSIONS

Fixed maxillary rehabilitations supported by Pterygoid implants represent an alternative reliable treatment solution for atrophic patients in the posterior maxilla; this anchorage allows the time reduction in the surgical procedure and the prosthesis restoration and favourably impacts the quality of the patient's life. This retrospective study met a surgical success of 100% with all torque values ≥ 45 N/cm. Furthermore, these rehabilitation techniques are integrated with the digital flow up from the initial previsualization diagnostic phase, where the patient has real indications of final expectations.

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Conflict of Interest Statement:

All the Authors declare no conflict of interest.

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