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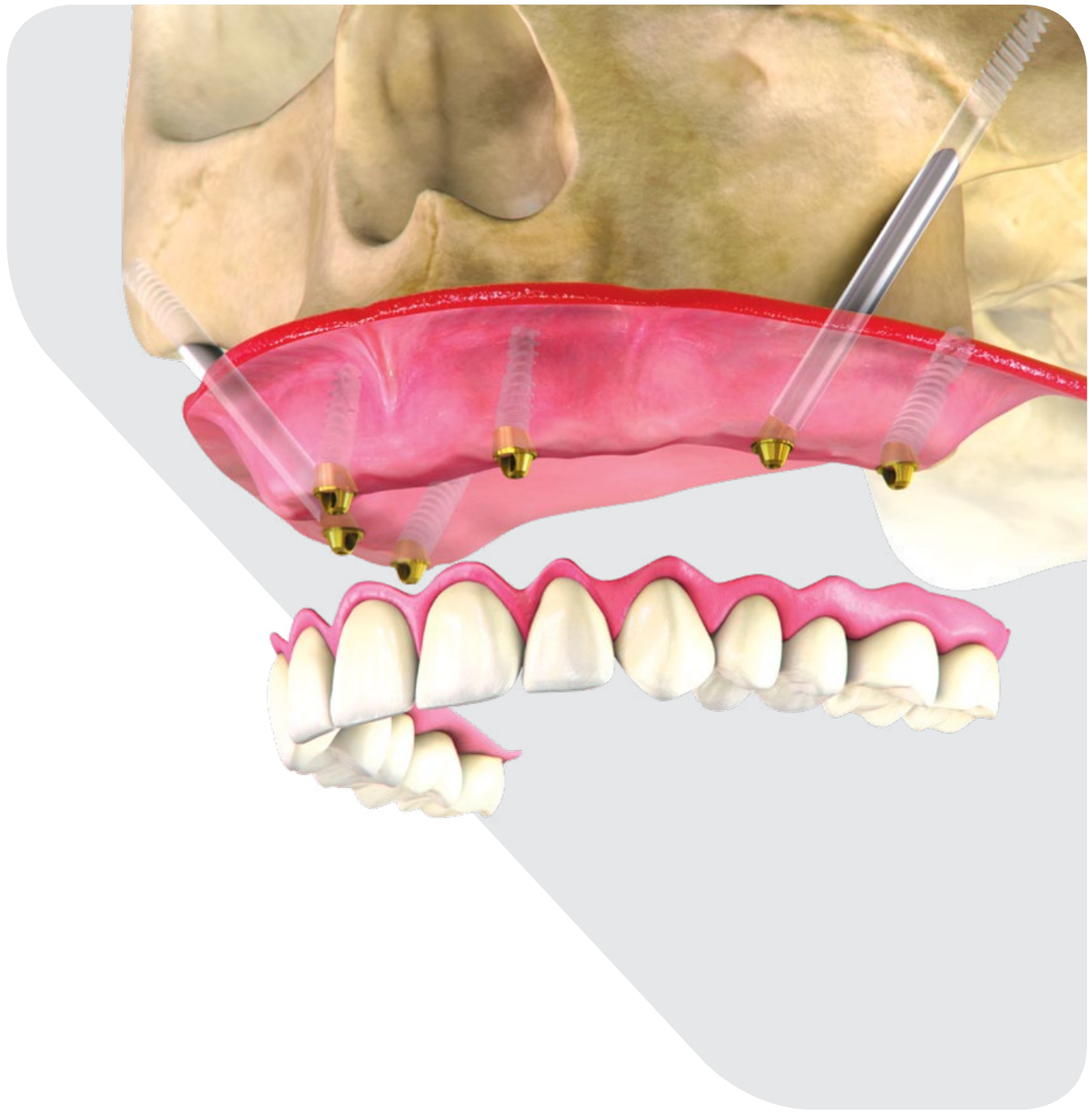

Zygomatic Implants

Maxillary resection for cancer, zygomatic implants insertion, and palatal repair as single-stage procedure: report of three cases

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Abstract

Background: Oronasal/antral communication, loss of teeth and/or tooth-supporting bone, and facial contour deformity may occur as a consequence of maxillectomy for cancer. As a result, speaking, chewing, swallowing, and appearance are variably affected. The restoration is focused on rebuilding the oronasal wall, using either flaps (local or free) for primary closure, either prosthetic obturator. Postoperative radiotherapy surely postpones every dental procedure aimed to set fixed devices, often makes it difficult and risky, even unfeasible. Regular prosthesis, tooth-bearing obturator, and endosseous implants (in native and/or transplanted bone) are used in order to complete dental rehabilitation. Zygomatic implantology (ZI) is a valid, usually delayed, multi-staged procedure, either after having primarily closed the oronasal/antral communication or after left it untreated or amended with obturator.

The present paper is an early report of a relatively new, one-stage approach for rehabilitation of patients after tumour resection, with palatal repair with loco-regional flaps and zygomatic implant insertion: supposed advantages are concentration of surgical procedures, reduced time of rehabilitation, and lowered patient discomfort.

Cases presentation: We report three patients who underwent alveolo-maxillary resection for cancer and had the resulting oroantral communication directly closed with loco-regional flaps. Simultaneous zygomatic implant insertion was added, in view of granting the optimal dental rehabilitation.

Conclusions: All surgical procedures were successful in terms of oroantral separation and implant survival. One patient had the fixed dental restoration just after 3 months, and the others had to receive postoperative radiotherapy; thus, rehabilitation timing was longer, as expected. We think this approach could improve the outcome in selected patients.

Key words: Maxillectomy, Zygomatic implant, Tumour resection, Maxillofacial, Carcinoma, Maxillary reconstruction.

Backgrounds

Major defects following maxillectomy for cancer include oronasal/antral communication, loss of teeth and/or tooth-supporting bone, and facial contour deformity.

As a result, speaking, chewing, swallowing, and appearance are variably affected. Priority of restoration is focused on rebuilding the oronasal wall, by means either of flaps (local or free), either prosthetic obturator.

Dental rehabilitation might follow by means of regular prosthesis, toothbearing obturator, and endosseous implants (in native and/or transplanted bone). Zygomatic implantology (ZI) has been first mentioned by Aparicio et al. in 1993 [1], then proposed by Brånemark [2] in order to overcome bone availability after maxillectomy.

Commonly, this option is offered as delayed procedure after tumour resection. Later, ZI has been employed in non-neoplastic, severely atrophic maxilla [3–11].

The present paper is an early report of a relatively new, one-stage approach providing for tumour resection, palatal repair with loco-regional flaps, and zygomatic implant insertion in three patients. Advantages are concentration of surgical procedures, reduced time of rehabilitation, and patient discomfort.

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Case presentation

Three patients have been operated on for malignant neoplasms affecting the maxilla at the Legnano Hospital, Italy, and at the Humanitas San Pio X, Italy.
Written informed consent was obtained from each patient, and the study protocol conformed to the ethical guidelines of the World Medical Association Declaration of Helsinki—Ethical Principles for Medical Research Involving Human Subjects. Surgical plan was based on tumour resection, palatal repair, and zygomatic implant insertion in view of fixed dental rehabilitation.
CT scan for zygomatic bone evaluation was part of working up. No virtual planning of resection or of implant insertion was considered, and fixture placement was performed under direct vision, enhanced by simple resin guide simulating the resected dental arch.
All patients were dentate (natively or after fixed restoration) and resulted partially dentate after tumour resection, so fitting class IIA defect classification, according to Pellegrino et al.
[12]. Osteotomies were achieved with saw, burs, and piezosurgery. Frozen sections were obtained in order to demonstrate clean margins.

The zygomatic bone was adequately exposed. Implants from Noris Medical Ltd. (Nesher, Israel) were chosen. The working, threaded part of the implant is 13 mm long, while the remaining, fully smooth shaft has 4-mm diameter and variable length. In all, length ranges from 35 to 57.5 mm. Implant drilling was performed using both straight and angled handpieces.
The fixtures were placed at 35 rpm for the 2/3 of the apical and manually for the most coronal 1/3 working part. Palatal-alveolar repair was attained with soft tissue, local flaps: these were also wrapped around the implants. In order to obtain a durable watertight seal between oral and nasal antral cavities, implant uncovering and loading were planned to be deferred by 3 months.

CT scans and/or panoramic radiograph were taken to monitor implant healing.
Screw-retained fixed prosthesis was considered for teeth replacement.

Patient no. 1

A 76-year-old gentleman suffering from lichenoid mucositis was operated on for verrucous carcinoma of the vestibular attached gingiva in the areas of 22 and 23, in 2013. The tooth 24 was missing, having been extracted elsewhere years before. Clear margins were obtained, and healing was uneventful.
Then, the patient regularly attended follow-up examinations: on April 2015, a white, creamy discharge was noted from the gingiva covering the 24 socket. The gingiva was opened and the socket debrided. Histologic examination of the removed material was consistent with verrucous carcinoma. CT scan showed a radiolucent area involving the socket of 24 and the surrounding bone (Fig. 1). The neoplasm was staged T4 N0. The patient underwent partial maxillectomy involving the antral floor, the alveolar bone, and teeth 23 to 25. The tooth 26 had abnormal mobility, hence was extracted.
Two zygomatic implants (40 and 42.5 mm, respectively) were placed into the malar bone.
The buccal fat pad was harvested and moved to both repair the oroantral communication and wrap the implants (Fig. 2). The buccal mucosa was advanced over the buccal fat pad and implants and closed with single sutures.
CT scan was taken after surgery (Fig. 3). Time was allowed for soft tissue healing, and after 3 months implants were uncovered, 45° abutments placed and a fixed, screw-retained prosthesis ended the rehabilitation (Fig. 4).
To reduce direct loading on zygomatic fixtures, the prosthetic device was splinted mesially to 22 and distally to 27. After 1 year, the dental prosthetic restoration was unscrewed and zygomatic implant stability successfully checked (Fig. 5).

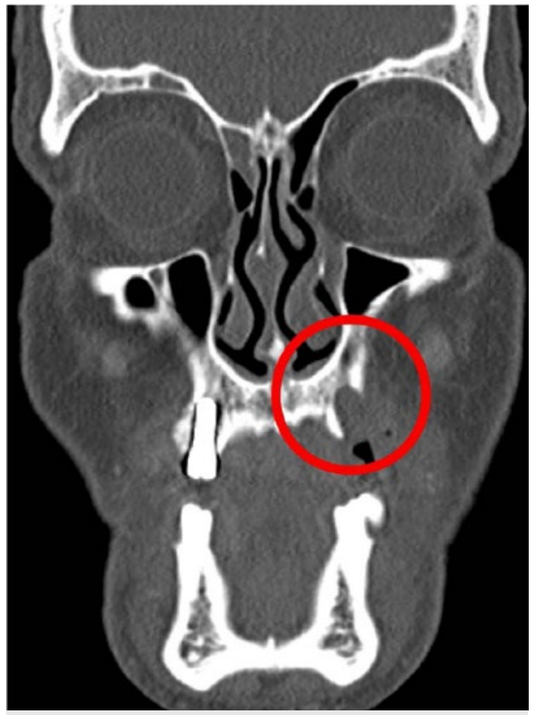

Figure 1
Pt no. 1. CT scan showing a radiolucent area involving the socket of tooth 24 and the surrounding bone.

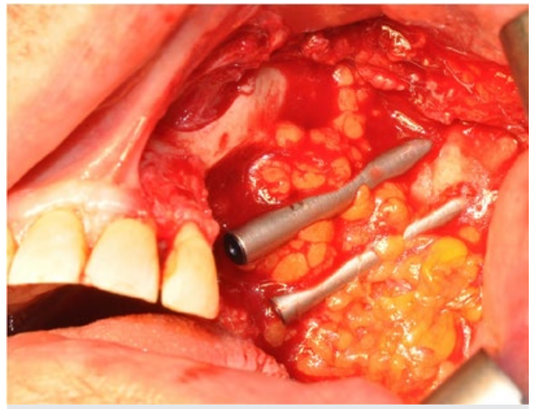

Figure 2
Pt no. 1. The buccal fat pad harvested and moved in order to repair the oroantral communication and to wrap the zygomatic implants

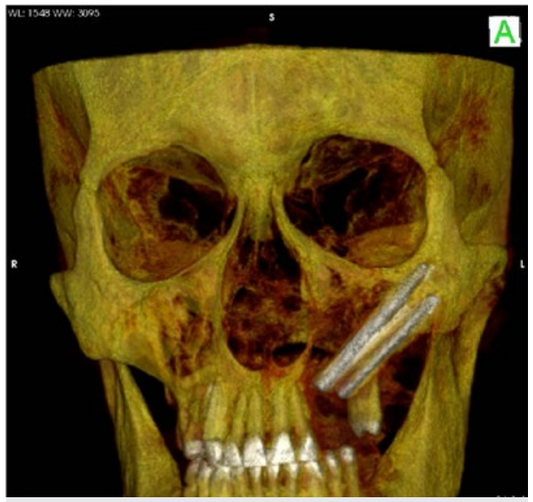

Figure 3
Pt no. 1. CT scan reconstruction showing zygomatic implant placement after maxillectomy

Patient no. 2

A 43-year-old lady bearing an adenoid cystic carcinoma of the left maxilla was referred for treatment. Clinical and radiologic examination leaded us to stage the tumour T4 N0 (Figs. 6 and 7). The patient underwent left extended maxillectomy (Fig. 8).
A prefabricated occlusal replica (Fig. 9) allowed the most correct insertion of two zygomatic implants (40 and 42.5 mm, respectively). Then, the left temporalis muscle flap was entirely raised and rotated to fill the defect and to wrap the implants (Fig. 10). The fascial side was stitched to the mucosal margins in order to separate the sino-nasal cavity from the oral one (Fig. 11). The postoperative period was uneventful, and care had been taken in order to contrast trismus since the surgery.
The final pathologic report alerted against perineural invasion, and some spotted margins close to the tumour. These data, together with the tumour nature and extension at presentation, led to address the patient to receive a full course of adrotherapy. Regrettably, the latter treatment carried some important sequelae (radionecrosis in the pterygoid region and trismus, mostly antalgic) that forced to delay dental rehabilitation. However, hyperbaric oxygen therapy and sequestrectomy granted the complete healing of radionecrosis and trismus improvement: implant stability was checked during this in-office surgery and appeared fully satisfactory, so did CT scan imaging. Pathologic examination did not reveal any relapsing disease.

Patient no. 3

A 65-year-old gentleman suffering from squamous cell carcinoma of the upper gingiva underwent right partial maxillectomy (Fig. 12). The lesion showed have arisen around three endosseous implants placed years before in the teeth 13, 14, and 15 areas. The CT scan did not demonstrate frank bone involvement, neither neck node extension (Fig. 13) nor distant metastases.
Consequently, a large oroantral communication derived

Figure 4
Pt no. 1. The final screw-retained prosthesis placed after 3 months

Figure 5
Pt no. 1. X-ray follow-up examination showing the final dental prosthetic rehabilitation

from tumour ablation (that had to include the three implants); the fat pad flap preoperatively planned was judged adequate after harvesting and actually used to close the defect. Compromised teeth 11 and 21 were also extracted and immediately replaced by two standard implants. A third standard, tilted implant was posed in the 13 area.
Finally, one zygomatic implant was inserted in order to emerge in the 16 area (Fig. 14).
Postoperative course was complicated by limited suture dehiscence, without oroantral fistula, and spontaneous healing was then reached adopting a conservative treatment (Figs. 15 and 16). Pathologic examination demonstrated clear margins in the sinus mucosa, but bone invasion upstaged the patient from cT2 to pT4, and then, adjuvant radiotherapy was advised. Soft tissues were allowed to recover from radiation upshots and the prosthetic timing was subsequently scheduled.

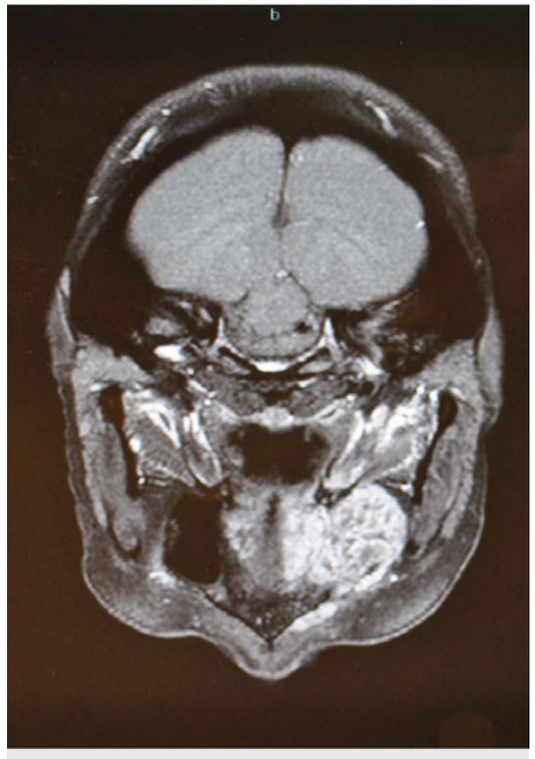

Figure 6
Pt no. 2. Transverse plane of the preoperative CT scan showing a radiopaque mass of the left maxilla

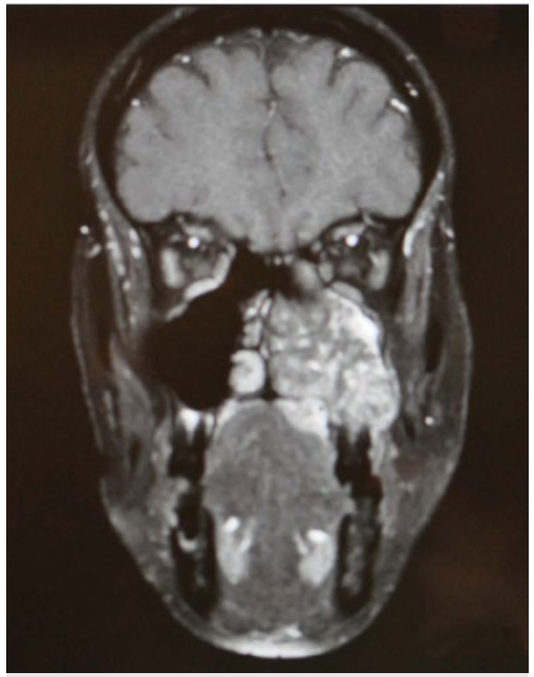

Figure 7
Pt no. 2. Coronal plane of the preoperative CT scan showing a radiopaque mass of the left maxilla

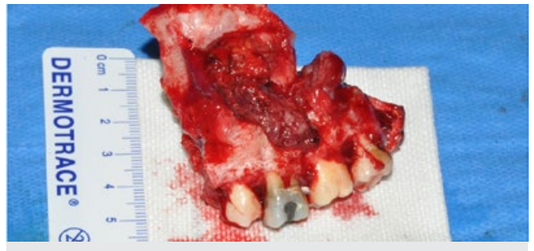

Figure 8
Pt no. 2. The extended portion of the left maxilla removed after maxillectomy

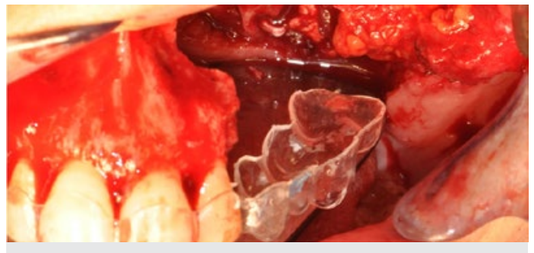

Figure 9
Pt no. 2. The prefabricated occlusal replica used for correct zygomatic implant emergence planning

Discussion

Neoplasms of the maxilla often require extensive surgery and adjuvant treatments: as a consequence, quality of life might result as heavily impaired.

Reconstructive surgery (immediate or delayed) allows anatomic and basic functionality restoration following maxillary tumour resection. Actually, the most important goal has to be achieved—as earlier as possible— is the repair of the natural barrier between oral and nasal/ antral cavities: options include free or local flaps and obturator.

Free flaps may either be harvested as single component, or as soft tissue and bone complex. Among the latter, fibula, iliac crest, and scapula are the most popular, with personal preference for the fibula flap. These composite auto-transplants allow both restoration of the oronasal/antral barrier and bone support for implants. Disease-related indications for composite free flaps include repair of large defects (2/3 of the palato-alveolar complex) and 3-D maxillary reconstruction. Their use implies large consumption of resources, yet patients' survival is quite rewarding [13].
In contrast, local and regional flaps are less demanding, but their use is restricted to more limited palato-alveolar defects (up to the midline). The temporalis muscle is the workhorse for repairing such defects, while buccal fat pad has room in case of minor oronasal/antral communications [14]. When needed, adequate bone support may be set by secondary bone grafting.

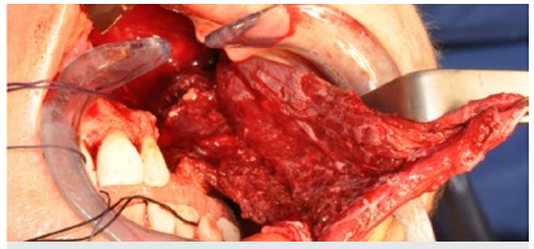

Figure 10
Pt no. 2. The left temporalis muscle raised and rotated in order to fill the defect and to wrap the zygomatic implants

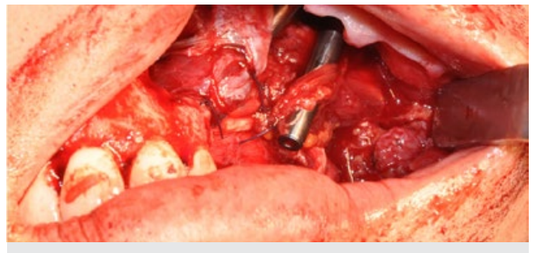

Figure 11
Pt no. 2. The fascial side of the left temporalis muscle stitched to the mucosal margin to separate the sino-nasal cavity from the oral one

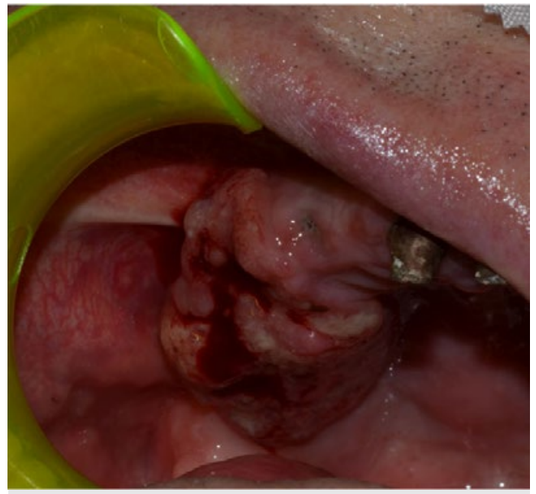

Figure 12
Pt no. 2. Coronal plane of the preoperative CT scan showing a radiopaque mass of the left maxilla

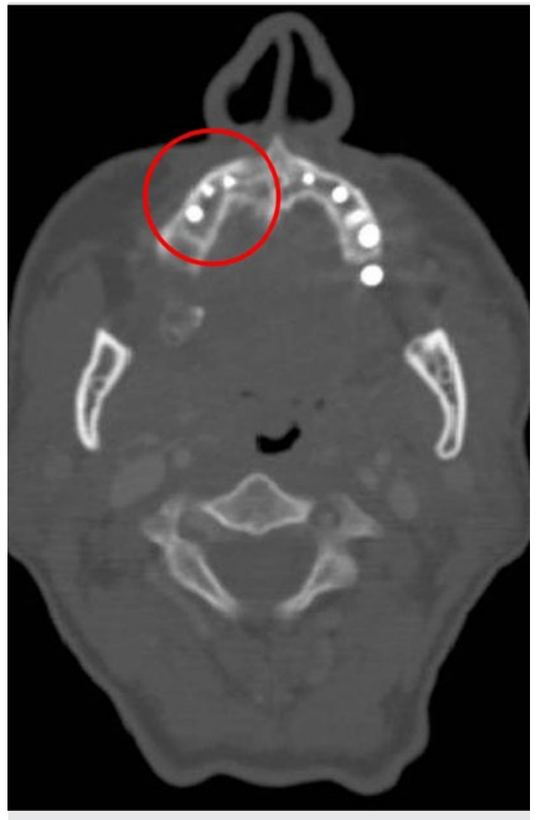

Figure 13
Pt no. 3. Preoperative CT scan

Finally, prosthetic obturator is recommended when the above solutions cannot be available or are contraindicated: it requires adequate anchoring (residual dentition, standard implants, deep vestibular sulcus) and continuous servicing.

In our opinion, primary closure by flaps should be preferred over prosthetic obturator, as this approach makes the patients more comfortable and prosthesisfree, immediately and during his/her daily activity. Indeed, in all three patients, local flaps have performed well and led to successful immediate closure of the oroantral communication following tumour ablation.
Seok et al. [14] advocate the application of 4-hexylresorcinol in order to accelerate and improve re-epithelialization.

Common belief stresses that follow-up in patients wearing obturator would be easier and safer than that in patients having surgical closure of the palate. In fact, possible local recurrence of the tumour could be detected early, yet benefit in survival of such a policy has not definitively proved. Moreover, modern imaging techniques could be at least as effective as inspection in revealing possible relapse at an early stage.

Nevertheless, some patients are or become more demanding about full or maximum recovery of the finest activities linked to chewing, phonation, deglutition, and aesthetics: in these cases, dental rehabilitation through implant-supported prosthesis might greatly help, the fixture(s) being usually inserted in native or grafted bone. Zygomatic implants could overcome the possible problem of lacking or poor-quality bone [2, 5, 12, 15–22]. In such patients, ZI is usually a delayed, multi-staged procedure, either after having primarily closed the oronasal/ antral communication [12, 17, 19], either after left it untreated or amended with obturator [5, 16, 18]: the overall time from tumour treatment and final dental rehabilitation might require 1 year or more. Intuitively, interest has arisen in shortening this gap and we planned to move toward this direction.

The relatively innovative aspect of the present paper deals with the idea of challenging three different tasks in a single-stage procedure: resection of the tumour, closure of the oronasal/antral communication, and insertion of the zygomatic implants finalized to a fixed restoration.
In few words, we tried to reach the best cost/benefit ratio.

Indeed, Pellegrino et al. [12] should be credited for the first reported case, even if not clearly evident from their paper (personal communication from Prof. C. Marchetti). The authors also proposed a new classification of rehabilitation-orientated maxillary defects: in our opinion, it deserves attention because of its clarity and effectiveness in orientating therapeutic options.

We were able to complete the above plan within the expected period of 3 months in patient no. 1, whose outcome is optimal after 1 year.

Supplementary advantage of ZI at the time of tumour resection is to give implants sufficient time to become osseointegrated before prospective radiotherapy course,

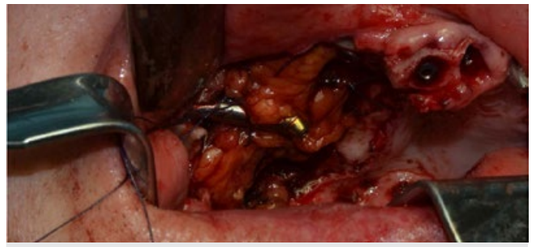

Figure 14
Pt no. 3. The zygomatic implant emerging in area of tooth 16 and surrounded by the buccal fat pad

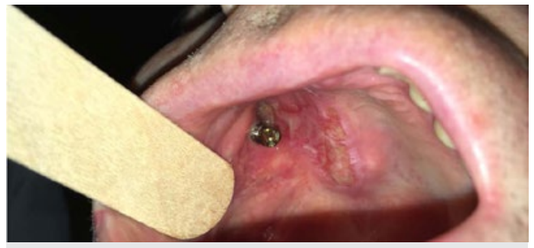

Figure 15
Pt no. 3. Intraoral view after 1 month

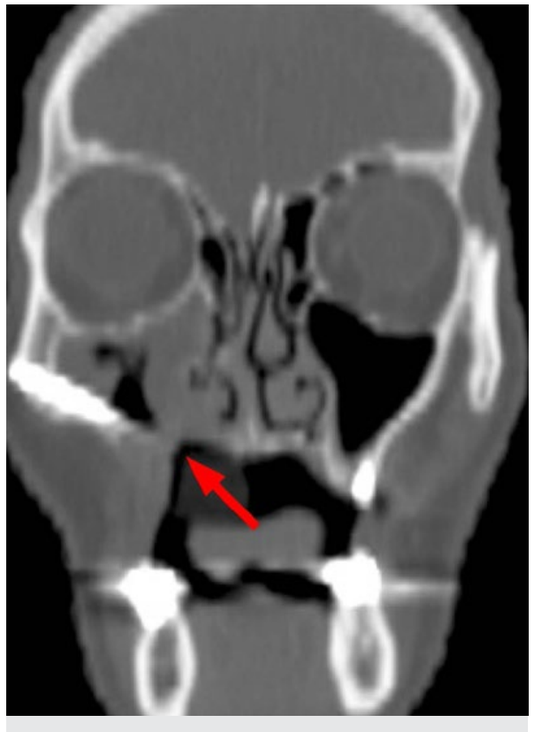

Figure 16
Pt no. 3. CT scan showing the optimal ZI insertion and the newly formed oroantral barrier

then avoiding or minimizing its well-known negative impact on healing [23]. Actually, patient nos. 2 and 3 took some benefits from this policy.

In addition, applying a maxillary prosthesis in the early stages minimizes contraction of facial soft tissues [16].

We performed ZI under direct vision, enhanced by resin guide pointing landmarks. The procedure was somewhat easier than ZI in simply atrophic patients, as the resected bone allowed more room to vision and manipulation.
On the other hand, the prepared flaps and the residual dentition could make things a bit more difficult than usual situations. Some authors advocate either general [24] or specific computer-aided surgery [12, 25], or surgical navigation [15, 26], for accurate, safe zygomatic implant installation. Undoubtedly, these are effective apparatuses, whose limitations are availability and operating costs. The pilot hole technique [27] and piezosurgery could offer similar advantages—at least in terms of safety—with lower costs.

Zygomatic implants are most suitable for immediate loading in reason of the high torque usually necessary for their insertion and consequent outstanding primary stability. However, we privileged the delayed loading to achieve and maintain an adequate seal between oral and nasal/antral cavities.

Long-term results of ZI are quite satisfactory. Brånemark [2] reported a 97% success rate in a series of 184 zygomatic implants inserted in 81 patients.
Aparicio et al. [10] conducted a large review of zygomatic implant survival: success rates ranged 94.4 to 100%. Recently, Chrcanovic et al. [11] extended the analysis over 4556 zygomatic implants in 2161 patients: they found a noteworthy 12-year cumulative survival rate of 95.21%.

Despite the prosthetic aspects of the proposed technique are somewhat beyond the paper scope, some considerations appear obliged. Screw-retained, metal-core dental prostheses are popular, manageable devices allowing easy removal for fixture inspection and cleaning. An interesting point is that in patient no. 1, the interdental and inter-arch obligations lead to a double-cantilevered dental restoration, entailing a possible overload: to mitigate it prudently, mesial (to 23) and distal (to 27) splinting were conceived. Indeed, implant stability was preserved, as checked at regular clinical and X-ray follow-up examinations (Fig. 5).

Within reason, delayed ZI insertion in regard of radiotherapy and/or primary ablative surgery would have been more hazardous and difficult, if not impossible. In turn, fixed dental restoration would have been more demanding, more lasting, suboptimal, even not feasible. Concisely, immediate insertion of ZI at the ablative tumour time could be considered as a biological investment.

Conclusions

In selected cases, maxillary resection, zygomatic implant(s) placement, and palato-alveolar repair through local flaps can be conducted as same-stage procedure. Advantages would include the following:

- Immediate closure of the oronasal communication
- Quick return to normal or near-normal feeding and phonation
- Wide access to bony segment receiving zygomatic implants
- Unnecessary bone grafting Short surgery time
- Reduced number of substantial interventions
- Short time-to-rehabilitation
- Reduced financial impact
- Valid functional results
- Excellent long-term performance of ZI

We intend to propose this approach and wish the results will be confirmed in large series.

Abbreviations
Pt: Patient; ZI: Zygomatic implantology

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Authors' contributions
PS ideated the approach, performed the surgery, took care of the patients, collected the data, and wrote the manuscript. FG planned and performed or assisted with the implant surgery.

AM, LR, FC, and AB assisted with the surgery and took care of the patients. EG helped in the data collection, documentation, and editorial assistance. UG did the critical review. All authors read and approved the final manuscript.

Competing interests
The authors declare that they have no competing interests.

Consent for publication
All patients have agreed and signed the consent for publication.

Ethics approval and consent to participate
Written informed consent was obtained from each patient, and the study protocol conformed to the ethical guidelines of the World Medical Association Declaration of Helsinki—Ethical Principles for Medical Research Involving Human Subjects.

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A New Surgical And Technical Approach In Zygomatic Implantology

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SUMMARY

Purpose: Different surgical approaches for zygomatic implantology using new designed implants are reported. Material and methods. The surgical technique is described and two cases reported. The zygomatic fixture has a complete extrasinus path in order to preserve the sinus membrane and to avoid any post-surgical sinus sequelae. Results. The surgical procedure allows an optimal position of the implant and consequently an ideal emergence of the fixture on the alveolar crest.

Conclusion: The surgical procedures and the zygomatic implant design reduce remarkably the serious post-operative sequelae due to the intrasinus path of the zygomatic fixtures.

Key words: zygomatic implantology, atrophic maxilla, immediate loading.

Introduction

During the last two decades, the placement of zygomatic implants, usually inserted through the maxillary sinus and apically stabilized in the zygomatic bone, has proven to be an effective option in the management of severe atrophic edentulous maxilla (1-4). Zygomatic implants are an useful option in atrophic jaws to avoid bone grafting plus standard implants insertion (5-52, 112-114).

The installation of zygomatic implants was firstly introduced by Brånemark et al. in 1998 in order to rehabilitate the masticatory and the aesthetic functions in severe atrophied maxilla caused by trauma, congenital conditions, tumour resections or increased sinus pneumatisation (53). Given the high success rate reported in literature for ZIs placement, this surgical technique can be considered as a valid alternative to bone augmentation and invasive surgery to restore function and improve the aesthetic result for patients with atrophic edentulous maxilla (2, 53- 57). Zygomatic implants, in fact, were subsequently used to rehabilitate severe atrophic upper jaws, classes V and VI, according to Cawood and Howell classification of edentulous jaws (58). At the beginning 1970 Linkow presented a surgical technique to rehabilitate extremely atrophic maxillae placing smooth implant (diameter 2 mm) apically inserted in the zygomatic bone (59).

New procedures and improvements have been developed since the description of the classical surgical technique in 1998 (53). Stella and Warner introduced the "sinus slot approach" in 2000, a zygomatic implantation method that minimize the presence of the zygomatic implant through the sinus, improving the emergence orientation of the implant, because it allows a more vertical angle of the fixtures than the original technique (60, 115). In 2013 Aparicio (61) et al. proposed a surgical technique based on the relationship between the zygomatic/alveolar crest complex and the various anatomy guided zygomatic implants pathways (ZAGA) (61).

Extremely absolute contraindications to the placement of zygomatic implants are acute sinus infections, maxillary or zygomatic bone pathologies and underlying uncontrolled or malignant systemic disorders. Relative contraindications are chronic infections of the maxillary sinus and smoking more than 20 cigarettes a day. Zygomatic implants placement in patients that use bisphosphonates is to this day debated. A maxillary sinus with any pathology should preferably be treated before or during surgical procedures (56).

The surgical intervention for zygomatic implant placement, with currently systematic devices offered on the market, results to be remarkably challenging and arduous and it frequently requires the use of general anesthesia. The post surgical sequelae described in the literature (61, 62, 116), such as rhinosinusitis, sinusitis, paresthesia, oroantral fistula, mucositis and perimplant soft tissue dehiscences, represent to this day a critical and significant limit to the implementation of the zygomatic implant surgery and the extensive regular practice of this procedure. The surgical system we present below was firstly introduced and described by Dr. Balan Igal D.M.D (ISR) and produced by Noris Medical, and it represents an important evolution and improvement of the previous techniques and systems both in the technical-operative procedures and in the eradication of the critical post operative sequelae due to the intrasinus path of the zygomatic fixtures.

Materials and methods

The surgical technique used for zygomatic implants placement considers the use of implant with a specific design: Noris Medical Zygomatic implant has an unthreaded long body ending with a particularly aggressive thread at the apical part of the implant The zygomatic implant is anchored in the zygomatic bone with the conical threaded apical segment: the resulting torque, by virtue of the apically threaded 12.5 millimetres, is extremely high. The implant is placed following the procedures of the extramaxillary protocol, which is a successive modification of the traditional Brånemark technique. In the extramaxillary approach a bypass of the maxillary sinus is made in order to prevent any damage to the sinus membrane and to avoid post surgical sinus sequelae. The implant prosthetic platform is therefore shifted buccally to a more appropriate position of the emergence close to the alveolar crest, a less bulky restoration and a better designed prosthesis. A special design of the drills have been made in order to allow the clinician to create a clean and safe tunnel preparation with minimal risk of damaging the membrane. An angled Multi-Unit abutment from 17° to 60° will then provide the correction of the emerging angle needed.

The operative technique we are now describing has the purpose to decrease and avoid post surgical possible complications derived from the sinus path of the zygomatic implant, as rhinitis and sinusitis, difficult and uncomfortable prosthetic restorations consequent to the palatal emergence of the abutments, and extensive problems with the intraoral perimplant soft tissue, as mucositis.

For the surgical approach a slightly incision is made in the maxillary alveolar crest extending from the first molar right region to the left one, paying attention not to injure the emergence of the descending palatine artery that, due to anatomical evolution of the atrophic maxilla, may arise in the alveolar crest.

Two posterior vestibular releasing incisions are made bilaterally considering the emergence of Stensen's duct not to produce any accidental injuries, and a median releasing incision is made below the nasal spine

Afterward a mucoperiosteal flap is raised simultaneously bilaterally along the whole incision or in two separate stages, according to the different anesthetic approach chosen for the intervention (general anesthesia or deep narcosis).

The mucoperiosteal flap reflection can be performed in two different ways depending on the surgical procedure implicated: the placement of only two zygomatic implants, or a quad-zygomatic surgery.

In the surgical case of two zygomatic implants placement, the mucoperiosteal flap is raised in order to expose the alveolar crest, the anterolateral wall of the maxillary sinus, and the origin of the zygomatic arch where the masseter muscle tendon is inserted; the mucoperiosteal flap of the paranasal region is raised medially to the emergence of the infraorbital nerve.

The infraorbital foramen is the posterior limit of the mucoperiosteal reflection and of the visible bone and it is exceeded only in case of special needs to reach the zygomatic notch and totally expose the outer surface of the malar region, area dedicated to the implant site preparation. In fact, normally the perception of the bone cutter spill is acquired from the fingertips through the thickness of the overlying skin on the malar bone.

In case of quad-zygoma surgery, the bone region exposed after the mucoperiosteal flap reflection is wider, and it reaches the lower orbital rim. The infraorbital foramen is localized and isolated both medially and distally, the emergence of the infraorbital nerve is meticulously ensured and protected during the entire surgical phases as the anterior zygomatic implant should be positioned at a safe distance from the aforementioned nerve.

The implant site preparation is performed with drills and burs mounted on a contro-angled handpiece. This expedient allows the posterior zygomatic implant positioning distal to the region of the maxillary second premolar easier. The end point of the anterior zygomatic implant will be close to the maxillary canine region bilaterally on the lowermost point of the alveolar crest.

After the mucoperiosteal flap is reflected, the surgical procedure minimum provides one or two corticotomies of the anterolateral wall of the sinus performed with a round diamond bur (4mm in diameter) in order to determine one or two marking points (Figures 1, 2).

The holes made through the bone with the round diamond bur, in order to set the correct place of the zygomatic implant, are then connected to the intraoral emergence of the zygomatic implant earlier determined using zygomatic burs for groove preparation. These burs have a not working tip and a diamond cilindric body of three different levels of grit (fine, medium, coarse) (Figure 3).

The conical not working tip of the bur is inserted in the marking point which provides a valid point of support and fulcrum for the subsequent bone preparation in the premolar and in the distal canine region, passing from the coarser to the finer bur.

The bur will be further deepen with a tangential movement of go and come for two-thirds of its diameter.

This procedure correctly performed respects the integrity of the Schneiderian membrane. In order not to lacerate the sinus mucosa during following actions, a gentle inward shift of the Small Schneiderian membrane with a sinus periosteal should be carried out (Figure 4).

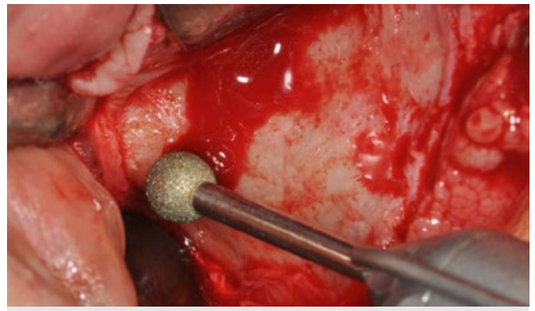

Figure 1
The 4 mm diameter round bur used to determine the initial marking point.

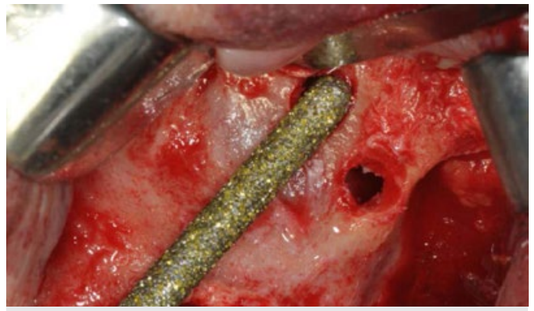

Figure 3
The anterolateral sinus wall is prepared with the coarse zygomatic bur: the not working tip is inserted in the marking point and the working diamond cylindrical body prepares the bone.

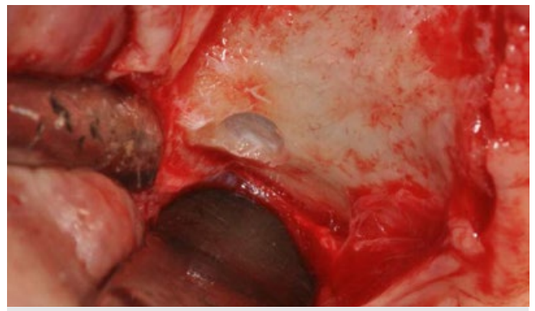

Figure 2
The marking point performed on the sinus wall.

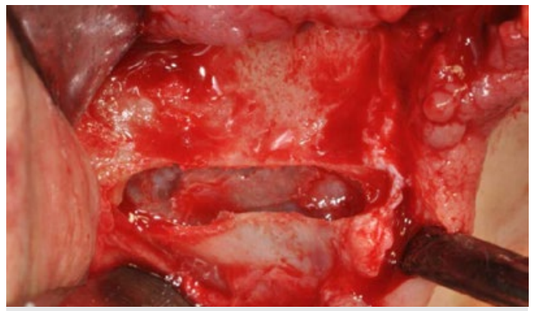

Figure 4
The sinus slot is performed and a gentle inward shift of the Schneiderian membrane is made.

Small accidental injuries and lacerations of the sinus mucosa in the region of the zygomatic recess are easily fixed and not significant in terms of sinusitis sequelae; on the contrary, those produced in the region of the alveolar crest, where the end of the zygomatic implant should be, must be solved also using resorbable membranes

The zygomatic bone preparation, where the apex of the zygomatic implant will be placed and anchored, is performed with a sequence of drills with the final conical cutting tip 2.5 cm long and 2-3.2mm in diameter in apex (Figure 5).

The smooth body of the drill has the same diameter of the antrostomy previously carried out. This slot in the sinus wall reproduces a true apical surgical preparation guide for the drills and it prevents dangerous and unsafe errors due to the excessive movements caused by the length of the drills used. It avoids the deviation of the drill from the planned direction.

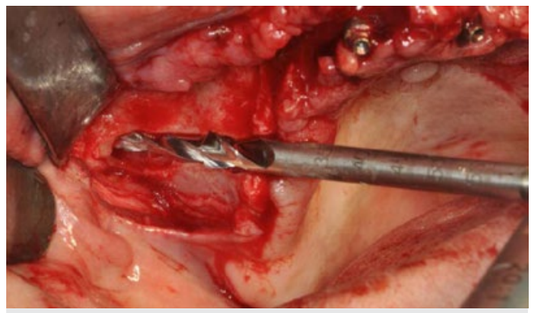

Figure 5
A sequence of drills with the final cutting tip 2.5 cm long and 2-3.2, mm in diameter in apex is used for the zygomatic bone preparation.

The first drill must totally penetrate the zygomatic bone and come out through the external cortical layer. It's important to fell with a finger through the skin of the periorbital region the cutting apex of the drill coming out from the zygomatic arch, laterally on the malar bone.

The preparation of the zygomatic implant site continues with the sequence of drills.

A depth indicator is then used to decide the correct length of the zygomatic fixture. The tip of the depth gauge is located on the external cortical zygomatic bone.

The diameter of the final hole on the zygomatic arch carried out by the drills is approximately 2.2 mm in diameter, much lower than the final circumferential size of the implant (3.2 mm). This difference avoids the risk of emergence of the end of the zygoma fixture from the bone during malar screwing when searching primary stability.

Generally we firstly perform the preparation of the anterior zygomatic implant, which is the more complicated and dangerous one, and subsequently we complete the preparation of the distal fixture tilting the drills in relation to the residual bone available, the most posterior and vertical as possible, so that the apexes are convergent, but do not interfere between them.

The implant is positioned with an extraoral screwdriver, if the anatomy is favourable, or with the usual operations of screwing that we use in all types of endosseous implants (Figure 6).

The emergence of the fixture must be in the optimal site from a prosthetic point of view, on the alveolar crest. The angled abutment position is checked in order to obtain an ideal emergence of the prosthetic abutment, and it's screwed.

The coverage of the region with Bichat fat pad or resorbable membranes is performed in those cases that present particular conditions of vestibular maxillary concavity and therefore it is not usually and frequently carried out (Figure 7).

The resorbable suture completes the surgical intervention.

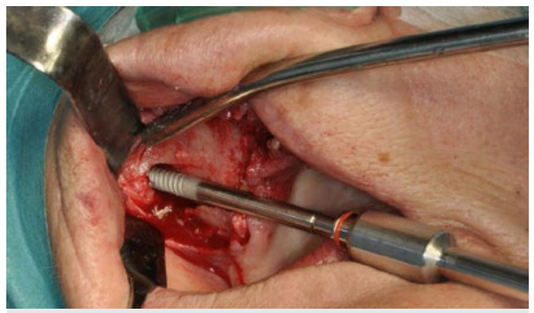

Figure 6
The zygomatic implant is positioned with an extraoral screwdriver.

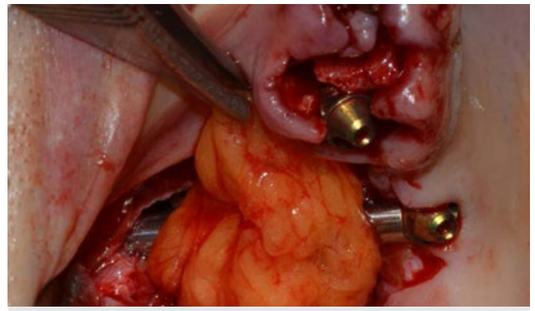

Figure 7
The Bichat fat pad used to cover the zygomatic implant.

Clinical case 1

A 59-year-old Caucasian male patient with partial edentulous maxilla required a fixed prosthetic rehabilitation with zygomatic implants. He had no history of pathologies that could contraindicate surgery.

Panoramic radiography and CT were examined to evaluate the bone volume of the maxilla and of the zygomas and to eliminate the risk of undiagnosed pathologies.

The surgery procedures were performed under general anesthesia with endotracheal intubation reinforced with local infiltration of anesthesia with vasoconstrictor. Three upper incisors were extracted and two zygomatic implants and four normal implants were placed (Figure 8).

Clinical case 2

A 51-year-old Caucasian female patient with total edentulous maxilla needed prosthetic rehabil itation. The patient refused grafting procedures prior to implant placement, as onlay bone grafting and/or sinus lift. It was decided to perform a quad-zygoma implant rehabilitation.

Pre op. radiographic examination, included orthopantomograms and computed tomography, were evaluated. An advanced vertical and horizontal bone loss of the alveolar ridge was revealed and there was no evidence of other patho - logies that could exclude surgery.

The operation was executed under general anesthesia with nasotracheal intubation and local injection of anesthesia with vasoconstrictor. Four zygomatic implants were placed (Figure 9).

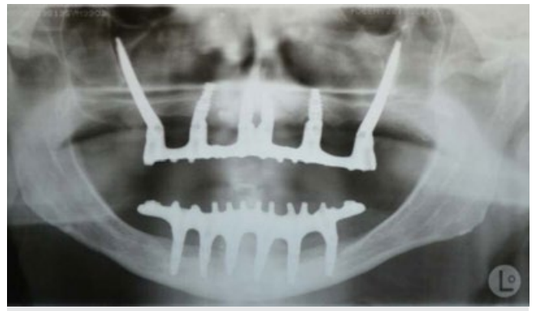

Figure 8
Post surgery orthopantomograms of clinical case 1.

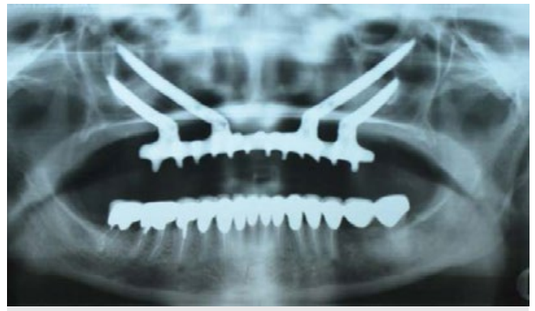

Figure 9
Post surgery radiographic examination of clinical case 2.

Discussion

A functional occlusal prosthetic rehabilitation of severely resorbed edentulous maxilla with conventional implant-supported dental bridges constitutes a difficult therapeutic challenge. Tooth extractions, use of dentures and the presence of extensive maxillary sinus often result in a lack of bone volume. Therefore there are many obstacles and limitations to the final result that can be achieved using bone-anchored fixed prostheses in all those patients with advanced atrophic maxilla. Recurrently the residual alveolar bone is too small for placement and osseointegration of dental implants (63). For more than three decades, bone grafting prior to, or simultaneously with, implant placement, has become routine in oral rehabilitation. Several bone augmentation techniques (maxillary sinus floor augmentation, onlay bone grafting...) have been described in literature with the common goal of increasing the volume of the residual bone in order to place implants and rehabilitate the masticatory function and speech with fixed prosthesis (54, 64-67). However all bone grafting procedures are resource demanding and require long treatment and healing periods, such as Le Fort I osteotomies or revascularized flaps. High risk for morbidity is present because of harvesting of bone grafts, and the failure rates are more than in nongrafted situations (68). Many efforts have been made to pursue alternatives to major bone grafting procedures and to achieve a valid osseointegrated implant anchorage exploiting the residual native bone. The need of bone grafting may be replaced and bypassed by the use of remaining existing anchorage bone sites in the maxillary tuberosities, pterygoid plates or zygomatic bone. Some Authors suggested the pterigomaxillary suture as an alternative location for implant placement, but the risk of vascular damage is very high because of the path of the descending maxillary artery (69-71). Other Authors proposed the use of tilted implants and/or short implants to use the residual bone and to avoid any sinus lift procedures (64).

Brånemark et al. firstly introduced the use of zygomatic bone for anchorage of zygomatic fixtures (53).
This surgical technique was presented for rehabilitating patients with extremely resorbed maxilla and wide-ranging maxillary defects due to tumor resections, congenital defects, traumatic events. The use of zygomatic implants reduced the time of treatment and the number of surgical operations. The surgical approach consists of a similar Le Fort I vestibular incision between the first molar region with vertical releasing incisions. Subsequently a mucoperiosteal flap is raised in order to expose the hard palate and the alveolar crest, the zygomatic complex, the lateral wall of the maxillary sinus, the infraorbital nerve. A bone window is opened at the uppermost lateral aspect of the maxillary sinus wall and the sinus membrane is prudently reflected in the sinus cavity. The site for the implant placement in the maxillary sinus and on the palatal side of the alveolar crest is then prepared with a series of drills. Unfortunately this surgical procedure often causes problems related to the intrasinus path of the zygomatic implant and patient discomfort and difficulties with hygiene procedures and speech due to the bulky dental bridge at the palatal aspect.

Since Brånemark, new procedures and improvements have been made.

In 2000 Stella and Warner (60) introduced “the sinus slot approach”. This operative technique allows a more vertical placement of the zygomatic implant and consequently a better buccal emergence of the implant. The crestal incision is less extensive than that of Brånemark: it’s made from one tuberosity to the contralateral one, vertical releasing incisions are made. The raising of the mucoperiosteal flap allows a good visibility of the region and the palatal mucosa is reflected only to expose the alveolar ridge. Two bur holes are made, the first on the superior extent of the contour of the zygomatic buttress, and the second one on the alveolar ridge. Afterward a slot connects the holes and it results in a small antrostomy in order to have a correct orientation of the drills used for zygomatic implants placement. The sinus mucosa is preserved and the implant can be directly seen during all the surgical procedures. A greater bone to implant contact is obtained. The presence of the zygomatic implant through the sinus is minimize and postoperative edema and ecchymosis are reduced. The patient discomfort decreases because of the improvements of the implant emergence, which results more buccally than the original technique.

Aparicio (61) et al. in 2013 proposed a more anatomically and more prosthetically driven approach called “the zygomatic anatomy guided approach” (ZAGA). This surgical technique focuses on interindividual anatomical differences between patients. No initial window or slot is needed to be prepared on the lateral wall of the maxillary sinus because the preparation of the zygomatic implant site is guided by the anatomy of the edentulous maxilla. The procedure, in order to determine the placement of the fixture, is different from the previously described techniques.
Firstly, the correct emergence of the zygomatic implant on the alveolar ridge is established in order to obtain an optimal prosthetic outcome. Then, the apical entrance of the implant in the zygomatic bone is decided according to the number and to the length of implants required, and to the anatomy of the area. Thirdly, the implant pathway is identified after connecting the two points: the direction of the final preparation of the site is guided. The final path of the implant body may definitely depends on the anatomy of the patient, and it may vary from a totally intrasinus placement to a totally extrasinus one.

The surgical technique we have above described introduces new expedients and precautions in order to decrease and avoid post-surgical possible complications. The innovative design of the zygomatic implant is different from the first proposed and used by other Authors: the implant has an unthreaded long body ending with a particularly aggressive threaded apical segment. The risk of peri-implantitis is so decreased that is of paramount importance in two-stage implantology (13, 14, 16, 72-111, 117).

The zygomatic fixture has a complete extrasinus path in order to preserve the sinus membrane and to avoid any post-surgical sinus sequelae.
The surgical procedure allows an optimal position of the implant and consequently an ideal emergence of the fixture on the alveolar crest. The correction of the emerging angle needed is provided thanks to angled Multi Unit Abutments from 17 to 60°.

Those developments and improvements both of the surgical procedures and the zygomatic implant design reduce the serious post-operative sequelae remarkably due to the intrasinus path of the zygomatic fixtures.

Acknowledgments

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Treatment of severe atrophic maxilla with zygomatic implants: a case series

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SUMMARY

Treatment of severe maxillary atrophy with implants has achieved important successes in recent years. The limit of implant insertion is related to inadequate bone quantity (i.e. height and width). Alveolar bone grafting, sinus lifting and major grafting via Le Fort I osteotomy have used in the past to restore bone volume prior of implant insertion. However successes do not always occur and a second stage surgery is necessary in most cases.
Immediate loading cannot be performed in all grafted bone. In recent years a new treatment approach has been proposed by using zygomatic implants. This new technique can provide a better stability to the prosthesis and less morbidity for patient. Here a cases series of eighteen patients rehabilitated with zygomatic together with standard implants and immediate loading is reported.

Key words: zygomatic implants, bone atrophy, severe resorbed maxilla, implant dentistry, bone.

Introduction

Treatment of severe maxillary atrophy with implants has achieved important successes in recent years (1, 2). The limit of implant rehabilitation is represented by inadequate bone height and width for which the treatment of severe atrophy shows still difficulties from the surgical and functional point of view (3-11).
The severe atrophy of both maxilla and mandible causes further difficulties related to an inverse relationship between two jaws. Therefore, the correction of improper relationship of the bony bases is more complicated than a simple alveolar atrophy.
When an edentulous maxilla is reabsorbed, the retention area of the total denture becomes narrower and shorter, since the anterior surface moves superiorly and dorsally, creating a form of the alveolar bone crest similar to a knife blade. The resorption of the edentulous maxilla determines a progressive loss of bone height, thus reducing the volume of bone available for fixture placement and decreasing the bone quality, consequently increasing the risk of implant failure. When these phenomena happen, the vertical resorption of alveolar bone increases the inter- arch space. As the projection of the maxilla decreases in the sagittal plane, the spatial relationship between the maxilla and mandible changes, thus creating a pseudo-prognathism. This discrepancy between the two jaws creates problems both in the rehabilitation with removable or fixed prostheses. The jaws are resorbed till the muscle insertion causes a dislocation of the prosthesis and inhibit an adequate insertion of the implants. The combination of the loss of sagittal projection of the maxilla and a decrease in vertical height, results in a collapse of the soft tissues of the lower third of the face, therefore the patient experiences an aged expression, and the quantity of residual bone is unfavourable to the retention of the denture. Various processes have been designed to increase the volume of the alveolar ridges and allow an adequate reconstruction of the dentition.
Orthodontic surgical techniques have just been developed to restore the jaws in a correct skeletal position when a malocclusion occurs in dentate patients. The same procedures, such as the maxillary Le Fort I osteotomy, can be used in edentulous patients to correct the discrepancies between the jaws and restore an implant-supported dentition.
Bone grafting procedures are frequently used to increase bone volume and place the implants in the same surgical time (12, 13). Sinus lifting and alveolar bone grafting are minor and well knowntechniques in oral surgery.

In recent years a new treatment has been proposed with zygomatic implants. This new technique can provide a better stability to the prosthesis and less morbidity for patient. Here a series of 18 patients treated with zygomatic implant in combination with standard fixture (Noris Medical, Israel) are reported and clinical outcome discussed.

Materials and methods

A series of eighteen patients with severe atrophy of maxilla were admitted at the Balan Clinic (Kiryat Yam, Israel) in the period between August and December 2013. There were 10 females and 8 males with a median age of 62 (min-max 36-86) all with general advanced periodontitis, most with complete edentulness.
Half of patients had good general health and none was pregnant. Three patients had hypothyroidism, five have diabetes, one was affected by prostate cancer and one by cervical cancer.
The protocol is similar to that previously reported (14).

The surgery was performed under local anaesthesia with intravenous conscious sedation after antibiotic prophylaxis with amoxicillin and clavulanic acid (2 g) two hours before surgery.

Pre-operative medication protocol

One hour prior to dental surgery: 1 g Augmentin (amoxicillin and clavulanate potassium) for patients who are allergic to penicillin - 600 mg Dalacin (clindamycin); 12 mg dexamethasone (not for diabetics); 20 mg vaben (oxazepam); 100 mg Otarex (hydroxyzine hydrochloride); 2 tab narocin 275 mg (naproxen); 1 cap Losec 20 mg (omeprazole); probiotic.

Surgical protocol (Figures 1-6)

A palatal incision is made in the maxillary crest with a bilateral vertical posterior releasing incisions (like Le Fort I exposure). A muco-periosteal flap was reflected to expose the alveolar crest, the piriform opening, the central and posterior part of the zygomatic complex, the infraorbital nerve emergence and the lateral wall of the maxillary sinus. The retractor was then placed to separate the cheek, to guide the osteotomy and to protect the soft tissue from drilling. The compression of the infraorbital nerve with retractor must be avoided as well as the invasion of the orbit. Implant sites were prepared and guided positioning of the pterygoid and standard implants.
Corticotomy of the anterolateral wall of the maxillary sinus was done. The antrostomy was performed with a diamond ball drill with a progressive diameter preserving and slightly detaching the sinus membrane.
Following the inclination predisposed by the slot, the zygomatic implant beds were prepared under visual control using progressive-diameter drills with extra-oral access and alveolar zygomatic arch direction.
Then zygomatic implants (Noris Medical, Israel) were then screwed manually. Afterwards standard implants were inserted in premaxilla.
The definitive prosthesis was screwed using preformed abutments. Haemostasis control was followed by suturing of the surgical field.

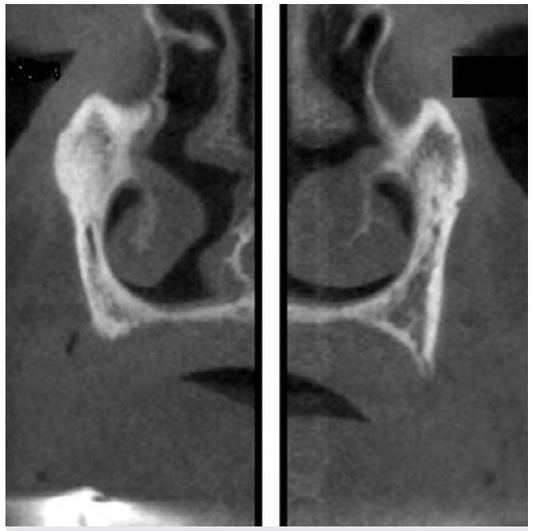

Figure 1
Right and left CT showing the pre-surgical maxillary atrophy.

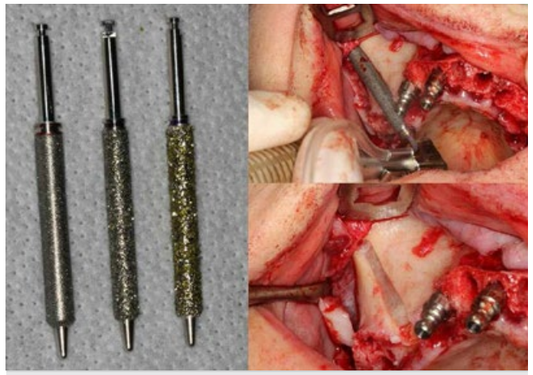

Figure 2
Drills and surgical preparation of the grooves for implant placement in the lateral wall of maxillary sinus.

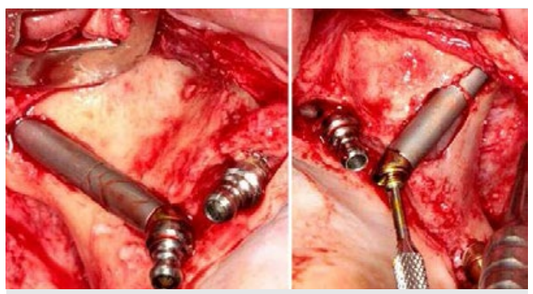

Figure 3
Right and left zygomatic implants inserted.

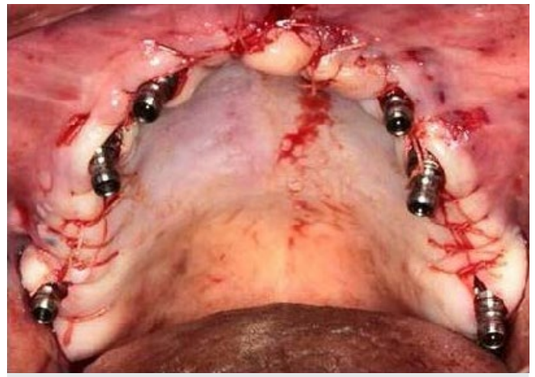

Figure 4
The operation field at the end of suture stitching.

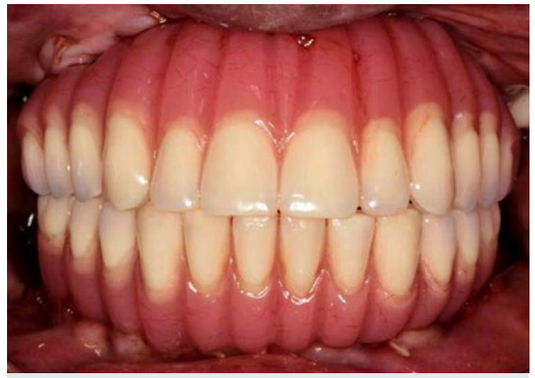

Figure 5
Fixed dentures in place.

Post-operative medication protocol

Antibiotics: Moxypen (amoxicillin) 500 mg 3 times a day/ Augmentin 500/875 3 or 2 times a day/ Dalacin 300 mg 3 times a day, for 7 days; 0.12% chlorhexidine rinse for a month; 400 mg ibuprofen every 4 hours, if needed; dexamethasone, starting with 12 mg daily and reducing 2 mg each following day, Botox (dilute according to manufacturer's instructions, divide to 6 doses, inject to the Masseter muscle in 3 points along the muscle, in each side).

By using the above mentioned technique a total of 29 zygomatic implants were inserted in the second pre-molar area of upper (left and/or right) maxilla. Additional 99 standard implants were inserted to restore the upper jaw (mean 5.5 implants per patient).

All patients agree to follow a strict oral hygiene protocol and recall. The post-operative period was uneventful and no soft tissue down-growth to interfere with the bone healing. The rehabilitation was successfully completed on all the implants with no adverse event reported by the patient.

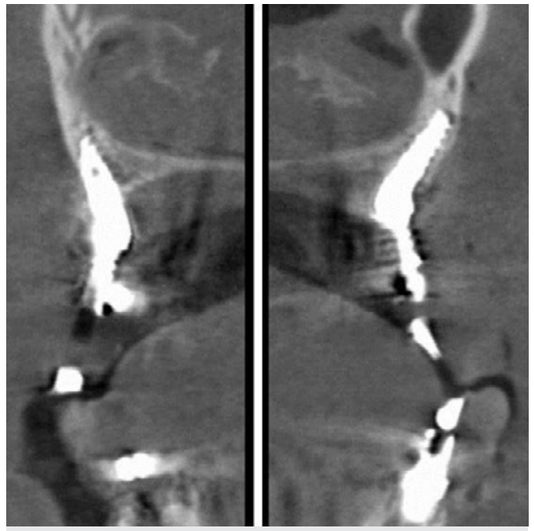

Figure 6
Right and left CT showing zygomatic implants.

Results

There were 10 females and 8 males with a median completed on all the implants with no adverse event reported by the patient. age of 62 (min-max 36-86). Half of them have a systemic diseases or major illness.
A total of 29 zygomatic implants (Noris Medical, Italy) was inserted. In six cases ZI were single and place only in one side of upper maxilla. No one implant were lost after 12 months of follow-up. Provisional prosthesis was delivered the same day of surgery and patients have a great improvement in their quality of life.

Discussion

Maxillary atrophy is a hot topic of current implantology. Several different options were proposed over time, starting from simpli alveolar grats and sinus lifting to Le Fort I osteotomy combined with inlay bone block.

Zygomatic implants, introduced by Branemark in 1997 for the prosthetic rehabilitation of patients with serious and extended defects of the jaws caused by post-oncological resections, trauma or congenital malformations, have proven over the years a valid alternative in the treatment of atrophy of the jaws, presenting high success rates (96% in 10 years) (15). The technique used in our study, implies the insertion of implants in the frontal portion of zygomatic bone, and the residual alveolar-basal bone as anchorage of standard implants, decreasing the biological cost of surgery, and improving the postoperative morbidity and the healing time. In the majority of cases, it is possible a rehabilitation of the maxilla with a denture, with 2 zygomatic implants in adjunction to traditional implantology of the pre-maxilla. Besides the success rate of zygomatic implants is above 80%, peri-implantitis may occurs in zygomatic rehabilitations also (16-21). Peri-implantitis and periodontal disease spring from bacterial infection that activates a cytokines cascade leading to inflammation and bone loss (22-25). In addiction, the patient-related susceptibility is a critical factor for disease onset.
So, every factor favouring oral biofilm formation (poor oral hygiene), host defence capability (smoking habit, excessive alcohol consumption, genetic traits, history of periodontitis, use of bisphosphonates), might favour developing of peri-implantis and periodontal disease in zygomatic implants, which diagnosis and treatment require dentist's engagement (26, 27).

Recently zygomatic implant solution has become popular since patients ask for therapies that offer a good final result while at the same time reduce costs, healing time and the temporary inability to work, as is the case of major grafting surgeries. So this procedure, that avoid big surgical field both for collecting and grafting bone, reduces the morbidity of treatment especiallyif one consider the advanced age of patients that request this treatment or type of pathology that determines the surgical indications such post-traumatic sequelae, post-oncological resections and severe malformations. In addition, bone grafting usually requires some time before fixtures and prosthesis can be loaded with consequent discomfort and limitation to social life.

In the recent literature there are few studies describing zygomatic implants to restore severe atrophic maxilla based on a large case series. Early publications on zygomatic implants were presented as case reports (28-38).

By considering our large case series, it became evident that the reconstruction of an atrophic jaw with zygomatic implants provide a good fine prosthetic solution while reduce the disadvantages related to a major surgery. In fact, it not only allow an immediate loading prosthetic rehabilitation but also restore the correct maxillary relationships and improve the aesthetics of the face. Among the most important advantages in using zygomatic implants are a more retentive denture-bearing ridge and a correct relationship between the two jaws The use of zygomatic implants prevents problems related to potential bone resorption which usually happen after grafting.

In conclusion, oral rehabilitation of the maxilla with zygomatic implants can be used in selected patients, significantly shortened the time of rehabilitation with a reduction of adverse effects.

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Surface Treatment of Dental Implants

Comparison of Implant Stability Quotient of sand blasted large-grit acid etched (SLA) & biological calcium phosphate surface treated (RBM) dental implants using Resonance Frequency Analysis - A Parallel Arm Double Blinded Randomized Controlled Trial

ABSTRACT

Background: Sand blasted large-grit aluminum oxide acid etched (SLA) and biological calcium phosphate surface treated Resorbable Blast Medium (RBM) mechanism leads to wettability of surfaces of dental implants which helps in osseointegration. The present study was conducted to discern the Implant Stability Quotient (ISQ) of SLA and RBM chemically modified dental implants.

Materials & Methods: The present study was conducted on 34 patients (males- 16, females- 18) of age ranged 18-54 years. Dental implants (Tuff Noris Medical) treated with SLA (Group I) and RBM (Group II) were inserted in patients using standardized clinical protocols. Resonance Frequency Analysis (RFA) was done immediately after implant insertion, after 1 week, 2 weeks, 6 weeks, 8 weeks and 12 weeks to discern the ISQ and hence predict the implant stability.

Results: Age group 18-30 and 31-54 years had 17 patients each. There was no absolute reported case of peri-implantitis or dental implant failure. Maximum mean RFA value in Group I was 85.6 and minimum was 43.2. In group II, maximum mean RFA value was 87.4 and minimum 31.8.
Conclusion: There is fastest osseointegration in implants with RBM group than with SLE surfaces. ISQ was higher than 80 in both groups which indicate higher implant stability.

Clinical Significance: It can be observed that surface treatment of dental implants shows higher implant -bone osseointegration.

Key words: Dental implant, Osseointegration, Implant Stability Quotient.

Introduction

Dental implants are being used aggressively in world. Dental implants of numerous companies are available to us.1 The success of any dental implant is based on its ability to show osseointegration. Various factors are responsible for survival of dental implant. It is divided into host related factors and dental implant related.[2] Host related factors include systemic conditions and local factors.[3] Literature revealed that acid etched or sandblasted implant offer high osseointegration in comparison to machined implants. Dental implant related factors are considered more important before inserting dental implants. Chemical modified Sand blasted large-grit aluminum oxide acid etched (SLA) and biological calcium phosphate surface treated Resorbable Blast Medium (RBM) mechanism leads to wettability of surfaces of dental implants which helps in osseointegration.[4,5] It has been seen that hydroxylation of oxide layer improves the wettability of titanium oxide surface and absorption of proteins on surface of dental implants by increasing interaction between water and implant surfaces.[6]

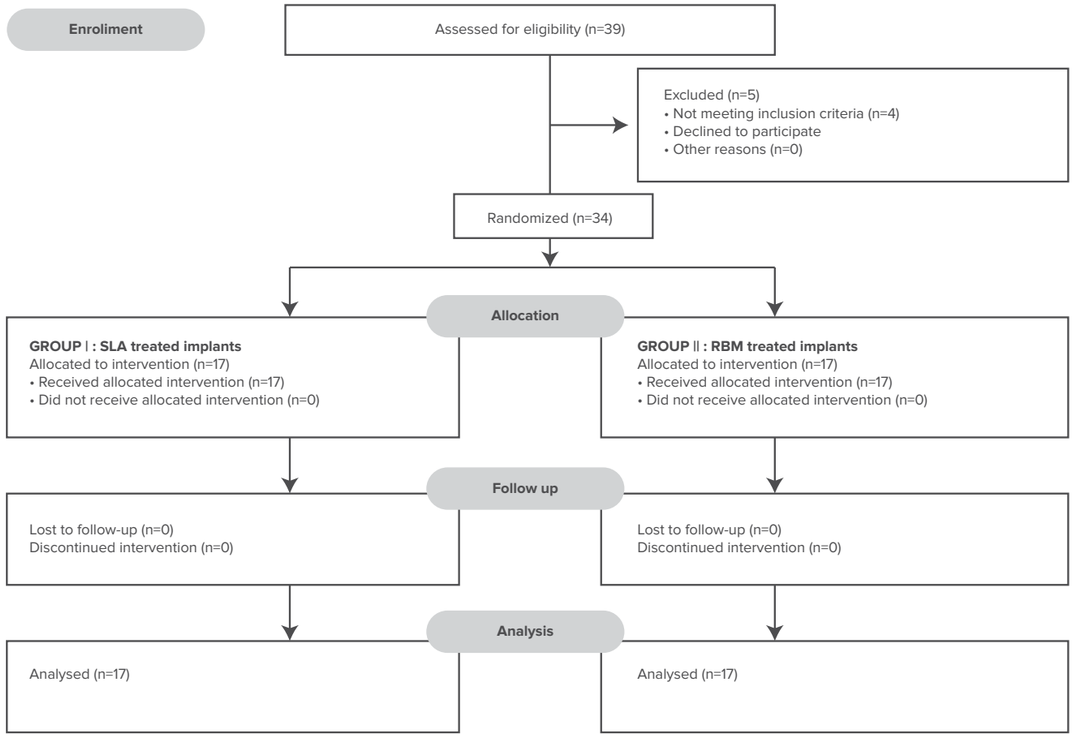
Resonance Frequency Analysis (RFA) is the method of checking the stability or osseointegration of dental implants. It is represented as Implant Stability Quotient (ISQ). RFA helps in judging the level of osseointegration after insertion of implant or during healing period. This guides dentist to place prosthetic part after obtaining high ISQ value.7 The method is done by sending magnetic pulses to a small metal rod temporarily attached to the implant. As the rod vibrates, the probe reads its resonance frequency and translates it into an ISQ value. SLA implants have similar microstructure and roughness surface.[8]
The present study was conducted in the department of Prosthodontics to determine the ISQ of SLA and RBM chemically modified dental implants.

Materials & Methods

The present study was conducted in the Mumbai, India (Aesthetic Smiles Dental Clinic). It comprised of a convenience sample of 34 patients (males- 16, females- 18) of age ranged 18-54 years who were a part of the regular pool of patients at the study setting.
All patients were informed regarding the study and written consent was obtained from all those recruited. This randomized controlled clinical trial was a parallel arm double blinded study, with the patient and the statistician unaware of the allotment.
The patients were allocated in the two arms of the trial with an allocation ratio of 1:1. Thus, each group comprised of 17 participants each who fulfilled the inclusion and exclusion criteria. Tuff Noris Dental implants (Noris Medical Pvt. Ltd) treated with SLA (Group I) and RBM (Group II) were inserted in patients using standardized clinical protocols. All implants were placed in the mandibular region (having D1/ D2 type of bone quality) to maintain uniformity.
Patients without systemic diseases and edentulous area in posterior mandible were included while patients with insufficient bone height, systemic diseases and pregnant women were excluded. In all patients, bone height was, measured with intraoral radiographs and bone height above 8mm was considered. Patients suffering from Type II Diabetes Mellitus were not taken in the purview of the study. Patients with bone height < 8mm and those unwilling to give written informed consent were not considered in the study.
In all patients assessment was performed with clinical examination, intraoral radiographic examination and CT scan of the implant site.

In all patients, implants with 10 mm height and 4.20 mm width were inserted. The ISQ was measured by a single standardized calibrated machine (Mega ISQ Implant Stability System, Megagen, Korea). RFA was done immediately after implant insertion, after 1 week, 2 weeks, 6 weeks, 8 weeks and 12 weeks.
Each of the readings were verified three times and the mean value was recorded during each visit. Results thus obtained were subjected to statistical analysis using SPSS Software (Version 19.0, IBM USA) That distribution of the variables were normal, as discerned by the Shapiro Wilk's test.
Parametric test of independent unpaired Student t-test was used for intergroup comparison and Repeated Measures Analysis of variance (ANOVA) followed by post-hoc Bonferroni correction was performed to compare the groups over the scheduled study period intervals.
Descriptive statistics and Chi Square test was used for association. Alpha error was set at 5% which corresponded to a p-value of less than 0.05 yielding statistically significant results.

CONSORT Flow Diagram



Results

Age group 18-30 years had 8 males and 7 females, 31-40 years had 6 males and 9 females and 41-54 years had 2 males and 2 females (Table I). The difference was non- significant (P> 0.05).
The maximum mean RFA value in group I was 85.6 and minimum was 43.2. In group II, maximum mean RFA value was 87.4 and minimum 31.8. Graph I elucidates the RFA values of the two groups at the specified time intervals. Table II depicts the intergroup comparison between the intervention groups. There was a statistically significant difference between the RFA values recorded in the SLA and RBM groups in the first, sixth, eight and twelfth week.

Mauchly's test of sphericity displayed a statistically significant result, pointing towards a jeopardized F-ratio value interpretation in both the groups. Hence, the Epsilon test statistic was performed to discern further departure from the degree of sphericity.
Since epsilon was >0.75, the Huynh- Fieldt correction was applied. The multivariate statistic Wilks' Lamda yielded a statistically significant result for both the groups. (Tables III and IV).

Pairwise comparisons were performed by the repeated measures ANOVA Bonferroni correction post-hoc test. The within group differences showed statistically significant results (P< 0.05) (Table V). Graph II shows that torque value in group I was 34.2 and in group II was 36.4. The difference was non- significant (P> 0.05).

Tables

Table I: Association between Age & gender distribution of participants.

Age group (years)	Males	Females	P value
18-30	8	7	0.5
31-40	6	9	
41-54	2	2	

Chi Square test. (p<0.05 indicates statistical significance)

Table II : Intergroup comparison of RFA values .

Time duration	Resonance Frequency Analysis (RFA) value		P value
	Group I (SLA)	Group II (RBM)	
Immediate post- op (0 weeks)	43.2	31.8	0.23
One Week	50.4	51.5	0.003*
Two Weeks	53.7	55.3	0.06
Six Weeks	46.5	54.6	0.001*
Eight Weeks	77.1	81.5	0.001*
Twelve Weeks	85.6	87.4	0.001*

Unpaired Student t-Test. (p<0.05 indicates statistical significance)

Table III : Mauchly's Test of Sphericity.

Within subjects effect (Design Intercept)	Mauchly's W	p-value	Epsilon		
			Greenhouse-Geisser	Huynh- Feldt	Lower bound
Group I (Time)	0.487	0.002*	0.663	0.675	0.510
Group II (Time)	0.412	0.001*	0.597	0.688	0.523

Indicates Statistical Significance (p<0.05)

Table IV : Multivariate Tests

Effect	Value	F- Value	p-value
Group I (Time) Wilks' Lambda	0.471	23.612	<0.001*
Group II (Time) Wilks' Lambda	0.419	24.021	<0.001*

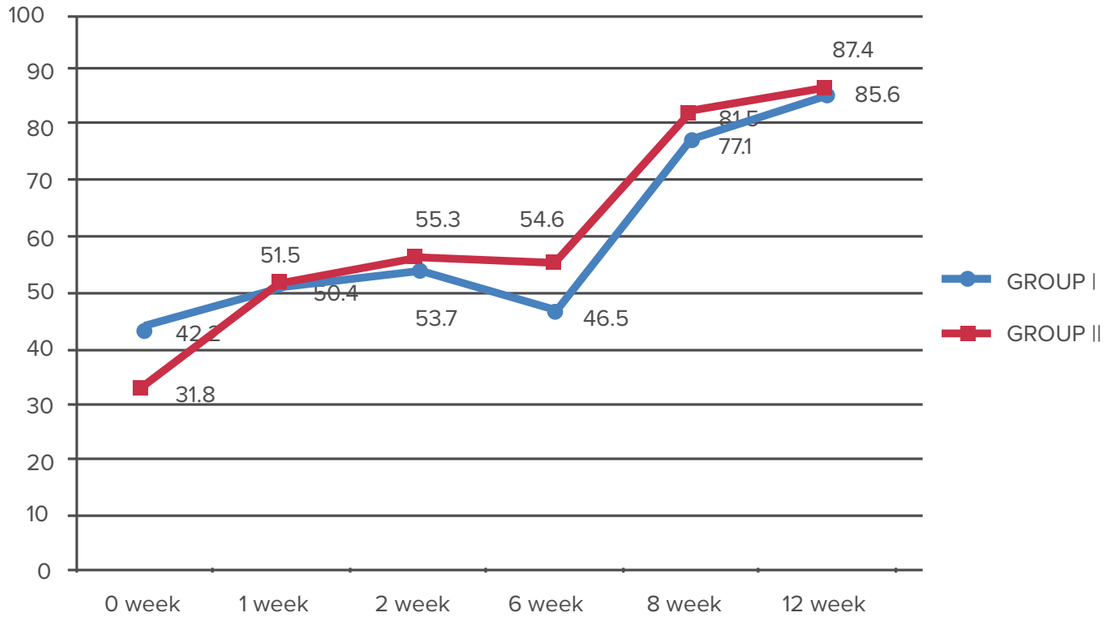
*Indicates Statistical Significance (p<0.05)

Table V : Pairwise Comparisons

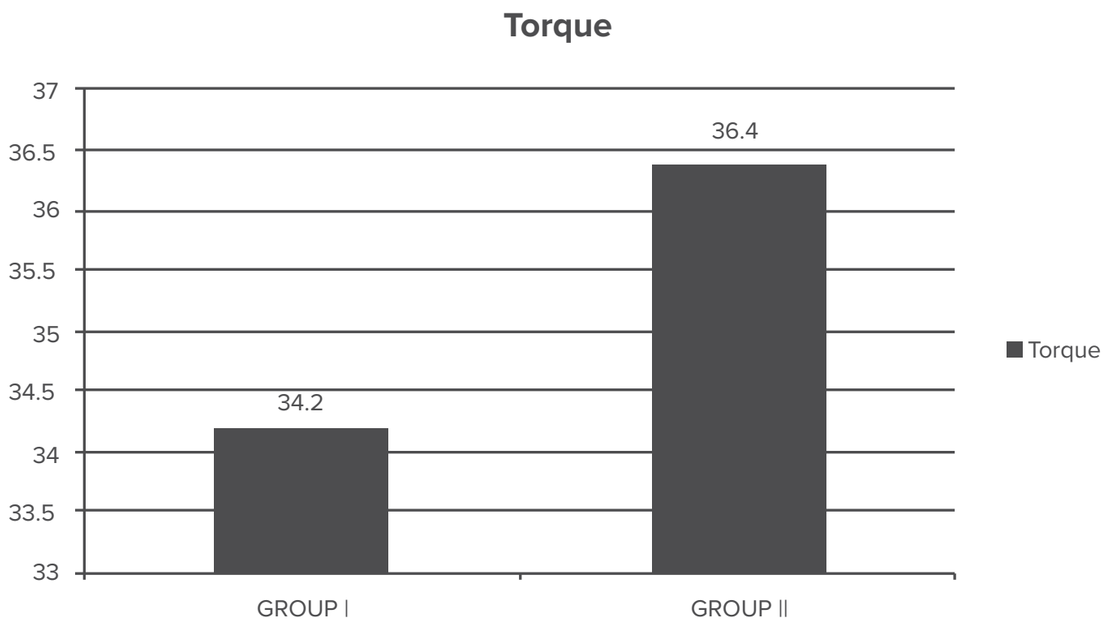
	GROUP I (SLA)			GROUP II (RBM)		
		Mean Difference	p-value		Mean Difference	p-value
Immediate post- op (0 weeks)	1 Week	-7.2	<0.001*	1 Week	-19.7	<0.001*
	2 Weeks	-10.5		2 Weeks	-23.5	
	6 Weeks	-3.3		6 Weeks	-22.8	
	8 Weeks	-33.9		8 Weeks	-49.7	
	12 Weeks	-42.4		12 Weeks	-55.6	
1 Week	Immediate post- op (0 weeks)	7.2	<0.001*	Immediate post- op (0 weeks)	19.7	<0.001*
	2 Weeks	-3.3		2 Weeks	-3.8	
	6 Weeks	3.9		6 Weeks	-3.1	
	8 Weeks	-26.7		8 Weeks	-30.0	
	12 Weeks	-35.2		12 Weeks	-35.9	
2 Weeks	Immediate post- op (0 weeks)	10.5	<0.001*	Immediate post- op (0 weeks)	23.5	<0.001*
	2 Weeks	3.3		2 Weeks	3.8	
	6 Weeks	7.2		6 Weeks	0.7	
	8 Weeks	-23.4		8 Weeks	-26.2	
	12 Weeks	-31.9		12 Weeks	-32.1	
6 Weeks	Immediate post- op (0 weeks)	3.3	<0.001*	Immediate post- op (0 weeks)	22.8	<0.001*
	2 Weeks	-3.9		2 Weeks	3.1	
	6 Weeks	-7.2		6 Weeks	-0.7	
	8 Weeks	-30.6		8 Weeks	-26.9	
	12 Weeks	-39.1		12 Weeks	-32.8	
8 Weeks	Immediate post- op (0 weeks)	33.9	<0.001*	Immediate post- op (0 weeks)	49.7	<0.001*
	2 Weeks	26.7		2 Weeks	30.0	
	6 Weeks	23.4		6 Weeks	26.2	
	8 Weeks	30.6		8 Weeks	26.9	
	12 Weeks	-8.5		12 Weeks	-5.9	
12 Weeks	Immediate post- op (0 weeks)	42.4	<0.001*	Immediate post- op (0 weeks)	55.6	<0.001*
	2 Weeks	35.2		2 Weeks	35.9	
	6 Weeks	31.9		6 Weeks	32.1	
	8 Weeks	39.1		8 Weeks	32.8	
	12 Weeks	8.5		12 Weeks	5.9	

Post-hoc Bonferroni correction based on estimated marginal means.
***Indicates Statistical Significance (p<0.05)**

Graph I : Resonance Frequency Analysis in both groups



Graph II Torque during implant placement in both groups



Discussion

The success of dental implant is affected by various factors. The general and oral health of the patient, presence of systemic diseases, diabetes mellitus, osteoporosis, bleeding disorders etc. determine the future outcome of dental implant therapy.[9]
The diameter, length, site and design of dental implant also affects the stability of dental implant. The quality of bone affects the osseointegration process. Implant placed at D1 and D2 bones are more likely to show better osseointegration as compared to D3 and D4 bone.[10]

In present study we compared ISQ of two similar design implants but treated with Sand blasted large-grit aluminum oxide acid etched (SLA) and biological calcium phosphate surface treated Resorbable Blast Medium (RBM) mechanism. Sim CP et al[11] in their study evaluated the factors such as length of dental implant, quality of bone and instrument positioning on RFA. They suggested that ISQ is affected by bone quality and implant length. Implant placed in D1 and D2 bone is highly stable and shows better osseointegration.

Atieh et al[12] revealed that RFA greatly determines the success and failure rate of dental implants. This technique may be used in healing period to assess the stability of dental implant. Bone deposition at the interface of implant- bone can be evaluated by increasing ISQ.
In present study we found that in case of group I, minimum mean ISQ was 43.2 and maximum was 85.6. In case of group II, maximum value was 87.4 and minimum was 31.8. Our results are in agreement with the results of Han et al[13] who found lowest ISQ as 55 and highest as 85. Ersanli et al[14] observed highest ISQ value in type I and II bone than type III and IV bone.

It was observed that ISQ level at all weeks in both groups increased significantly with the progression of time. This may be due to difference in primary and secondary stability between weeks.
At initial weeks, low ISQ may indicate loss of primary stability and increase in value indicates secondary stability. Simunek et al[15] in their study concluded that during early healing of immediately loaded implant, there is minimum stability at 3rd and 4th weeks. Similarly, in our study, it was quite lower at both weeks as compared to subsequent weeks in both groups.

We observed that the ISQ value increased significantly from 4th week to 12th weeks and at the end both the groups. Gahona et al[16] in their study evaluated ISQ of dental implants placed in maxilla and mandible. This comprised of 29 implants in mandibular arch and 31 in maxillary arch. It was seen that in implants with ISQ more than 60, there was successful osseointegration than those less than 60. Similarly, better osseointegration was observed in implants with torque insertion 35 or above.

We observed that torque value in group I was 34.2 and in group II was 36.4. Sarfaraz et al[17] conducted a study on 37 patients. ISQ was measured in 3rd, 7th, 11th and 15th week. Author evaluated RFA, ISQ and insertion torque value. There was positive correlation between ISQ and ITV.

Bornstein et al[18] in their study assessed the ISQ in 3 years prospective study. A comparison was done between acid-etched surface implant and chemically modified sandblasted implant. They suggested that hydrophilic implants have 2 times faster and better osseointegration. SLA implants had ability to be loaded in 3 weeks than 7-8 weeks.
Rocuzzo et al[19] in their study demonstrated that SLA implants can be best placed at 3rd week especially in maxillary posterior teeth region. Maxillary posterior region has type III or IV bone which shows higher implant failure rates. However, surfaced modified dental implants are effectively placed in this bone with higher survival rate. In present study, we used SLA and RBM chemically modified dental implants. Active surface treatment of dental implants makes it efficient for osseointegration even in bone with poor density.

Kokovic V et al[20] in their study of immediate vs. early loading of SLA implants in the posterior mandibular region suggested that ISQ >70 is the indicator of higher implant stability. In both groups, we observed ISQ above 80 which is predictor of implant success.
Park et al[21] in their study on rabbit tibia found a correlation between ISQ and BIC after 4 weeks of healing. We observed that stability increased with time in both groups. Chambrone et al[22] suggested that surface treated implants may more effectively inserted in poor quality bone and one can expect better results in such cases.

The shortcoming of the study is that small sample was utilized for the study. Long term follow up was not done in present study. Only maxillary posterior region was considered whereas in cases of other parts of jaw bones could have resulted in different findings. Other causes of implant failure such as poor oral hygeine, smoking etc might be the reason for poor osseointegration.

Conclusion

There is fastest osseointegration in implants with RBM surfaces than with SLA surfaces. ISQ was higher than 80 in both groups which indicate higher implant stability. However large scale studies are required to substantiate the results obtained in this study.

Clinical Significance

Surface treatment of dental implants offers higher implant bone osseointegration.

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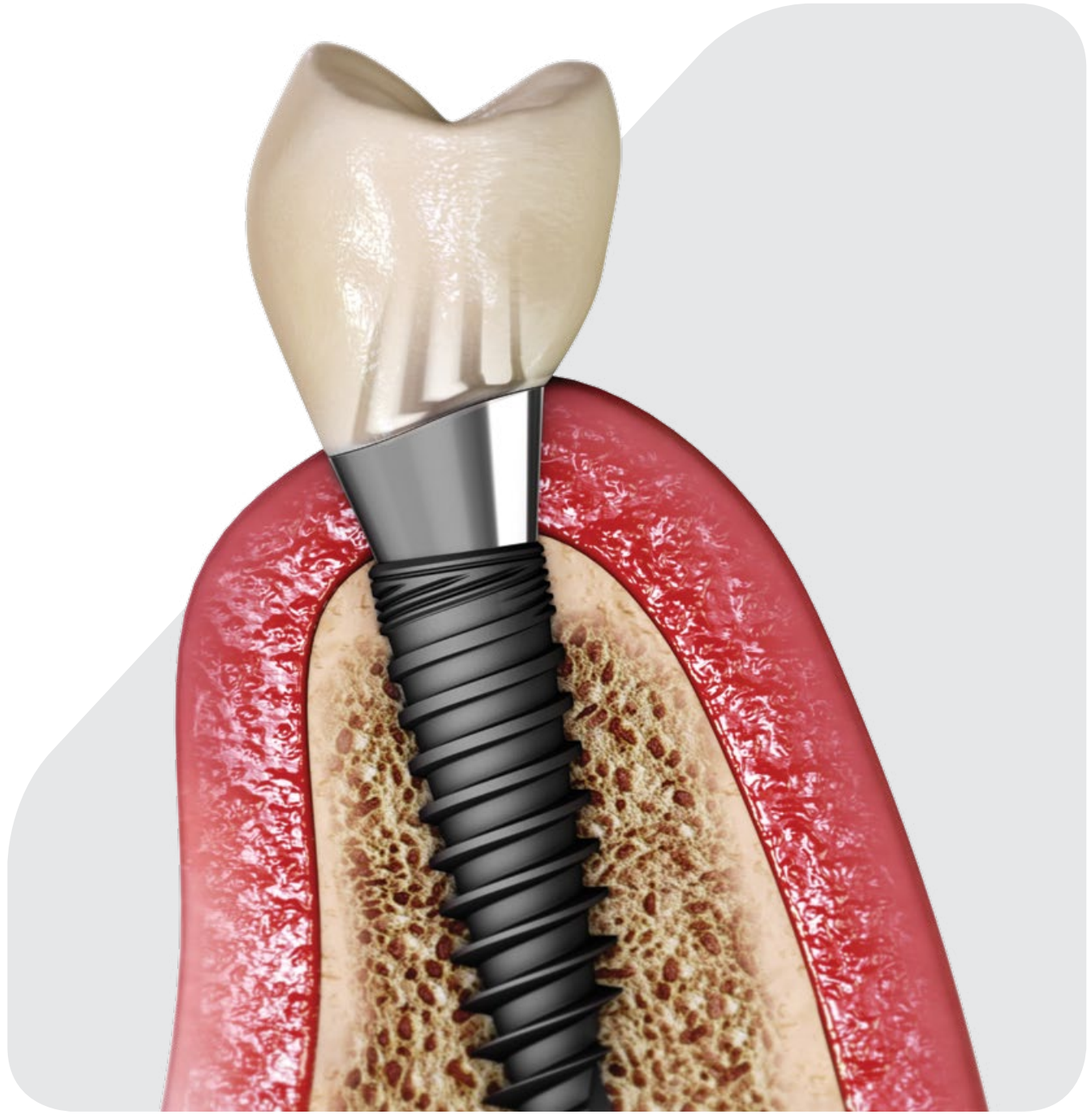
Prevention of Peri-implantitis



A New System of Implant Abutment Connection: How to Improve a Two Piece Implant System Sealing

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SUMMARY

Purpose. Implant dentistry has become one of the most successful dentistry techniques for replacing missing teeth. The success rate of implant dentistry is above 80%. However, peri-implantitis is a later complication of implant dentistry that if untreated, can lead to implant loss. One of the hypotized causes of peri-implantis is the bacterial leakage at the level of implant-abutment connection. Bacterial leakage is favored to the presence of a micro gap at the implant-abutment interface, allowing microorganisms to penetrate and colonize the inner part of the implant leading to biofilm accumulation and consequently to peri-implantitis development.

Materials and methods: To identify the capability of the implant to protect the internal space from the external environment, the passage of genetically modified Escherichia coli across implant-abutment interface was evaluated. Implants were immerged in a bacterial culture for twenty-four hours and then bacteria amount was measured inside implant-abutment interface with Real-time PCR.

Results: Bacteria were detected inside all studied implants, with a median percentage of 9%.

Conclusions: The reported results are better to those of previous studies carried out on different implant systems. Until now, none implant-abutment system has been proven to seal the gap between implant and abutment.

Key words: implant-abutment connection, implant dentistry, bacterial leakage, peri-implantitis, bone resorption.

Introduction

Implant dentistry has become one of the most successful dentistry techniques for replacing missing teeth. The success rate of implant dentistry is above 80% (1-16) and implant placement requires an adequate quantity and quality of bone (17-25).

However, peri-implantitis is a later complication of implant dentistry, that if untreated can lead to implant loss.

One of the hypotized causes of peri-implantiis is the bacterial leakage at the level of implantabutment interface. Bacterial leakage is favored by the presence of a micro gap at the implantabutment interface level, allowing microorganisms to penetrate and colonize the inner part of the implant leading to biofilm accumulation and consequently to peri-implantitis development (26, 27). Peri-implantitis is associated with a significantly higher inflammatory cell infiltration and bone loss (28). Prevention of microbial leakage at the level of implant-abutment interface is the main aim for the construction of a new two-piece implant systems (TPISs) to avoid inflammation in peri-implant tissues.

The aim of our study is to value the microbial leakage at implant-abutment interface of a new TPIS (Noris Medical Dental Implants System, Israel).

Tuff two-piece implant system

Tuff implant (Noris Medical Dental Implants System, Israel) is a new TPIS, which, with its three thread zones, has been designed according to the anatomy of the bone structure. The lower V-shape thread zone is for self-tapping. The middle zone has a square thread design, used especially for compressing cancellous bone, and helping achieving BIC (Bone-Implant Contact). The micro thread design on the upper zone adds stability and reduces crestal bone loss. Mono implants are specifically indicated for replacing maxillary lateral incisors and mandibular central and lateral incisors. They are cleared for immediate, non-occlusal provisionalization in singletooth restorations. Multiple unit restorations should be splinted together and may be used immediately, when clinically appropriate.

The Noris Medical Dental TPIS includes different types and sizes of dental implants made of medical grade Titanium Alloy and undergo a unique surface treatment.

Noris Medical TPIS are used for rehabilitating completely or partially edentulous patients. The rehabilitation on the implants includes a number of options: single crown, a number of connected crowns and partial or full dentures that are connected to Noris Medical TPIS using abutments. Quantity and quality of bone that are suitable for performing implants are an essential condition. This data is gathered during the planning stage by making appropriate radiographs (panoramic and computer tomography) of the implantation site. Anatomic areas near the implantation site such as: blood vessels, nerves, maxillary sinus and nasal cavity must be identified in order to prevent their damage. The performance of surgical procedures is subject to the patient's systemic condition.

The Noris Medical Dental TPIS employs internal hex connection designed to provide assembly facility while minimizing micro movements of the implant/abutment connection. The implants material composition is: TI 6AL 4V - ELI. The Noris Medical TPIS surface is RBM treated. RBM (Resorbable Blast Media) Surface Technology is a surface treatment processed by blasting the implant with a soluble calcium phosphate material, creating a macro surface roughness, using of biocompatible Calcium Phosphate blasting media. Calcium Phosphates are easily dissolved by gentle solvents like alcohol, leaving well textured surface completely free of contaminants.

Noris Medical Dental TPIS is intended to replace missing tooth/teeth in either jaw for supporting prosthetic devices that may aid in restoring the patient's chewing function. The procedure can be accomplished in a one-stage or twostage surgical operation. All implants are appropriate for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

Materials and methods

Implant preparation

In order to size up the ability of the implant to isolate the heart of the device from the external environment, we evaluated the passage of modified E. coli across the joint of the implant. The peculiarity of these bacteria is that they contain synthetic DNA target sequences in their plasmid. In detail, the plasmid contains two sequence specific for two bacterial species (P. gingivalis and T. forsythia) and two genes for antibiotic selection (Kanamycin and Ampicillin).

Bacteria were cultured in lysogeny broth (LB) containing both Kanamycin and Ampicillin (at a final concentration of 50ug/ml) at 37°C for 12-18h in a shacking incubator. Four Tuff implants (Noris Medical®, Israel) were used in this study (Figure 1). Few microliters of LB with antibiotics were put inside the implants. The implants and the abutment are screwed with a torque of 35 Ncm. Few microliters of this culture were used to "contaminate" fresh LB with antibiotics contained in a microcentrifuge tube together with the implant. Tubes were then let at 37°C for 48h in a heater, in order to allow bacterial growth and their hypothetical passage within the implant. Inside the implant, instead, we just put LB and antibiotics without bacteria.

To be sure that there were no contaminations, a negative control containing only LB and antibiotics, was prepared.

Forty-eight hours later, implants were opened and samples were collected by dipping a paper probe in both the sites containing LB (external and internal to the implant) for each implant, and in the negative control too.

DNA extraction

Once collected, paper probe were put on a new microcentrifuge tube and processed for bacterial DNA extraction, by using the GenEluteTM Bacterial Genomic DNA Kit (Sigma-Aldrich, St., St. Louis, MO, USA), following the manufacturing procedures. Briefly, samples were incubated with lysozyme and, subsequently with proteinase K to isolate DNA. Once extracted, DNA was purified by spin-column method.

Real-time polymerase chain reaction

Bacterial quantification was performed by Real-Time Polymerase Chain Reaction using the absolute quantification with the standard curve method.

Primers and probes oligonucleotides for P. gingivalis and T. forsythia were designed basing on 16S rRNA gene sequences of the Human Oral Microbiome Database (HOMD 16S rRNA Ref- Seq Version 10.1).
For the quantitative analysis, plasmid (Eurofin MWG Operon, Ebersberg Germany) containing the specific DNA target sequence was employed as standard.

All reactions were performed in duplex, in 20ul final volumes, with 2X TaqMan Universal PCR master mix (Applied Biosystems, Foster City, CA, USA) and 50nM concentration of each primers and 200nM of the probes. Amplifications were carried out by using the ABI PRISM 7500 (Applied Bio systems, Foster City, CA, USA).

Statistical analysis

To evaluate if the difference in viability among outside and inside the implant was statistically significant, we applied Student's t-test on average bacteria quantification at each time point.

Figure 1
Tuff Implant and abutment by Noris Medica

Results

Bacteria quantification is reported in Table 1. In all the tested implants, bacteria were found in the inner side, with a median percentage of 9%. The analysis revealed that in both cases (internally and externally), bacteria grew for the first 48 hours but subsequently they started to dye, probably as a consequence of nutrient consumption.
Moreover, the difference between outer and inner bacteria concentration was statistically significant at each time point.

Table 1 : Absolute quantification of P. gingivalis and T. forsythia, outside and inside the implant. Implant permeability is expressed as percent rate of the internal vs external bacteria quantity.

Implant	Bacteria	Bacteria quantity	Implant	Bacteria	Bacteria quantity	Passage of bacteria from outside to inside the implant (%)
1 OUTSIDE	P. gingivalis	3581973	1 INSIDE	P. gingivalis	697785	19%
	T. forsythia	3304664		T. forsythia	708424	21%
2 OUTSIDE	P. gingivalis	7195087	2 INSIDE	P. gingivalis	396791	6%
	T. forsythia	6789549		T. forsythia	400960	6%
3 OUTSIDE	P. gingivalis	4579415	3 INSIDE	P. gingivalis	1082464	24%
	T. forsythia	4582728		T. forsythia	1084939	24%
4 OUTSIDE	P. gingivalis	2820289	4 INSIDE	P. gingivalis	89335	3%
	T. forsythia	2720166		T. forsythia	98433	4%
5 OUTSIDE	P. gingivalis	1351250	5 INSIDE	P. gingivalis	198973	15%
	T. forsythia	1372971		T. forsythia	203651	15%
6 OUTSIDE	P. gingivalis	2877517	6 INSIDE	P. gingivalis	88918	3%
	T. forsythia	2452891		T. forsythia	100066	4%
7 OUTSIDE	P. gingivalis	1124582	7 INSIDE	P. gingivalis	142005	13%
	T. forsythia	1150407		T. forsythia	145277	13%
8 OUTSIDE	P. gingivalis	1150527	8 INSIDE	P. gingivalis	101557	9%
	T. forsythia	1112707		T. forsythia	128467	12%
9 OUTSIDE	P. gingivalis	8131886	9 INSIDE	P. gingivalis	101248	1%
	T. forsythia	7506339		T. forsythia	111292	1%
10 OUTSIDE	P. gingivalis	2836594	10 INSIDE	P. gingivalis	243945	9%
	T. forsythia	2614350		T. forsythia	252896	10%
11 OUTSIDE	P. gingivalis	1792653	11 INSIDE	P. gingivalis	100353	6%
	T. forsythia	1700109		T. forsythia	101758	6%
12 OUTSIDE	P. gingivalis	1310796	12 INSIDE	P. gingivalis	110644	8%
	T. forsythia	1173590		T. forsythia	112948	10%
Negative Control OUTSIDE	P. gingivalis	0	Negative Control INSIDE	P. gingivalis	0	0
	T. forsythia	0		T. forsythia	0	0
	Media Outside			Media Inside		
	PorG	3229381	PorG	Media Inside	279502	9%
	TanF	3040039	TanF	Media Inside	287426	9%

Discussion

Bacterial leakage at implant-abutment connection is the main cause of peri-implantitis. The current TPISs cannot completely prevent microleakage and consequent bacterial colonization of the inner part of the implants.
Although efforts have been made to reduce this TPISs limitation, several investigations have shown that bacterial oral leakage along the implantabutment interface may constitute a potential risk of inflammation of the supporting tissues, compromising the long-term success of the treatment with TPISs.
A diversity of data regarding the leakage and consequent bacterial penetration along the gaps and cavities into the TIPSs, as a consequence of poor adaptation of components, has been reported in some in vitro studies (26-37).

Other studies demonstrated microbial penetration of the TPISs micro gap of fixtures with an external hex design (29, 30). Some studies (31, 32) have investigated bacterial leakage of TPISs in order to find an efficient bacterial seal system.
With the TPISs, the abutment is retained in the fixture with mechanical methods, favoring an inflammatory process in peri-implant tissues.
Microbial colonization of the TPISs may have consequences as bone resorption. Some in vitro studies has demonstrated the passage of fluid into and out of TPISs. Our results are better to those reported in the English literature (33, 34). Aloise et al. found that the frequency of bacterial leakage was 20% of the TPIS of Bicon© and Ankylos® systems (27).
Implant internal contamination evidently shows that the presence of gap in TPISs may represent a bacterial passage from the external medium (35).
TPISs do not prevent microbiological leakage in the inner part of implant-abutment interface (36).
In any case, the peri-implantitis is associated with gram- negative bacteria similar to those that cause periodontal disease (37).
The peri-implantitis, such as periodontal disease, is the result of the bacterial insult and the subsequent host response, in fact some studies have shown that bacterial species of periodontal disease are very similar to those that cause peri-implantitis (38).
Blocking the passage of bacteria, in a TPIS is essential to prevent periimplantitis, in fact the presence of a cavity near to bone may influence in the development of peri-implant inflammation and bone resorption.
An intense inflammatory cell infiltrate may be the cause of a significant bone resorption in a TPIS, on the contrary one-piece implants showed a minimal inflammation and bone loss around peri-implant tissues.
Some studies demonstrated that the presence of a micro gap significantly influence hard and soft tissues around an implant, so few literature data are available about the differences in the microbial penetration in TPISs with different connection designs.
The design of the implant-abutment junction may have an impact on the amount of bacterial penetration in the internal part of dental implants of a TPIS system.

Conclusions

The reported results are similar to previous work. Noris Medical Dental Implants System showed bacterial leakage better respect others implant systems (9 versus 20% of Bicon© and Ankylos® systems).
In spite of the limits of our study, none TPIS has been demonstrated to perfectly close the gap between implant and abutment.

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A Comparative Evaluation of Height of Interdental Papilla around Noris Tuff TT and Nobel Active Dental Implants placed in Maxillary Anterior Region

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ABSTRACT

Background: Interdental papilla height is important as esthetic factor for dental implant success. The present study was conducted to compare the amount of soft tissues around Noris Tuff TT and Nobel Active dental implant systems. Materials & Methods: The present study was conducted on 28 patients (males- 13, females- 15) who received 32 dental implants in maxillary anterior region.Group I patients received Nobel Active dental implants and Group II patients received Noris Tuff TT dental implants. In all patients, interdental papilla was evaluated using JEMT index. The amount of bone loss in both groups was evaluated using paired and unpaired t-test.

Results: The amount of bone loss around dental implants in both groups did not show significant difference (P> 0.05). There was nonsignificant correlation between bone loss and papilla index in both groups (P> 0.05) Conclusion: The amount of interdental bone loss and papilla profile in the maxillary anterior region around Noris Tuff TT when compared to that around Nobel Active dental implants was non-significant.

Clinical significance: The preservation of interdental papilla is of paramount importance for the successful dental implant therapy.

Key words: Bone loss, Noris Tuff TT implants, Nobel Active implants, Interdental papilla, JEMT index.

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Introduction

Maxillary anterior region is common site for tooth loss. The causes may be trauma, cysts or tumors etc. The prime most reason to replace missing anterior teeth is esthetics and functions. Dental implants are considered options for replacing single tooth. This treatment modality has advantages over Fixed Partial Denture (FPD) or Removable Partial Denture (RPD). There is no need to prepare adjacent teeth as in cases of FPD. The clasps of RPD may lead to trauma to tooth as well as to soft tissues. Thus dental implants are useful in restoring function and esthetics.[1]

Studies have revealed high success rate of 95% over 10 years for dental implants. The process of osseointegration promotes union of dental implant with bone, ensuring better attachment and success rate. Apart from it, the soft tissues around dental implant play an important role in NIong term survival. Interdental papilla and labial gingiva add beauty to dental implants.[2,3]

Factors such as periodontitis, over contoured restoration, flossing technique, improper alignment prosthetic part of M dental implant and abnormal tooth morphology may affect interdental papilla. The level of bone around dental implant and adjacent teeth determines the future outcome of treatment. Therefore, the height of interdental papilla may be regarded as deciding parameter for successful implant therapy. Literature has shown that there is variation in height of interdental papilla on distal and mesial side of dental implant.4 The present study was conducted to compare the amount of soft tissues around Nobel Active and Noris Tuff TT dental implant system.

Materials & Methods

The present three years retrospective study was conducted in a Mumbai, India (Aesthetic Smiles Dental Clinic). EC approval was obtained from an Independent Review Board. A non-probability convenience sample comprising of 28 patients (Males- 13, Females- 15) who received 32 dental implants in the maxillary anteriorregion was fixes as the study sample.
Inclusion criteria were patients with dental implant in maxillary anterior region in last three years, no systemic diseases, non- smokers, pocket depth <3mm and no bone loss. Patients with poor quality radiographs, uncooperative, pregnant women, patients with systemic diseases and on steroid therapy or those unwilling to give written informed consent were excluded from the study.

All the subjects recruited for the study were informed regarding the same and written consent was obtained. The patients were divided into 2 groups. Group I patients comprised of those who received Nobel Active dental implants (Nobel Biocare) and Group II patients received Noris Tuff TT dental implants (Noris Medical Pvt. Ltd.). The reason why these two implant systems were chosen in the purview of the study, among the pool of various other systems available can be attributed to the fact that these two systems have similar external geometry of thread design.

All the dental implant were inserted by same clinical team comprising of a faciomaxillary surgeon (NA) and periodontist (RA) following standardized operating surgical protocols. The prosthetic part was prepared by the same technician (R.R. Dental Lab).
Following the dental implant insertion, Intraoral Periapical Radiographs (IOPAR) were taken with the same calibrated machine following the paralleling technique using size 2 x- ray films.
The patients were recalled periodically in accordance to the Merin's classification of patient scheduling and radiographs of the same site were obtained after 2 years.

Upper edge of the implant shoulder in initial radiograph and the distance between abutment and implant was regarded as reference line. In initial radiographs, the distance from the contact point of the implant and bone to the reference line and the distance from the CEJ of the adjacent tooth to the contact point of the crestal bone and tooth were measured. In follow up radiographs, the distance from the contact point of the crestal bone and implant to the reference line and the distance from the CEJ of the adjacent tooth to the contact point of the crestal bone and tooth were measured. The distance from the contact point of the implant restoration and the adjacent tooth to the crestal bone was also calculated.

JEMT index (Figure 1) was used to measure presence of interdental papilla between implant and adjacent teeth in follow up period (after 2 years). All the measurements were performed by two independent clinicians following astute training of the examiners (RA and VK). Cohen's Kappa (unweighted) statistic yielded a strong level of agreement (0.90) between the two examiners. The mean of their values was considered to further overcome interobserver bias. A digital Vernier caliper was used for measurements in mm.

Papilla index (PI) grading was used. Score 0 depicted no papilla in the interproximal space, score 1 was presence of less than 50% of the papillaheight, score 2 had presence of at least 50% of the papillaheight but not all the interproximal space, score 3 showed the papilla completely fills the interproximalspace and is coordinated by the adjacent papillaewith a favorable gingival contour and score 4 had the hyperplasic papillae that covers toomuch of the single implant restoration and/or the adjacenttooth, with unfavorable gingival contour was used.

The data was compiled in Microsoft Excel spreadsheet and subjected to necessary statistical analysis. The normality of the data was assessed using Shapiro-Wilk test and the data was found amenable to parametric inferential statistics.
Intergroup comparisons were analyzed using the paired t-test and the intragroup comparisons were judged using the Student's t-test.The level of significance (α) was seta-priori, at 5% (p< 0.05) with the power of the study(1 – β) at 80%.

Results

The results are elaborated in Table I and III.Group I, mean distances from the implant shoulder to the crestal bone on mesial side was 1.22 mm initially and 1.8 mm after 2 years. On distal side, it was 0.82 initially and 2.3 mm after 2 years. In group II, mean distances from the implant shoulder to the crestal bone on mesial side was 1.8 mm initially and 3.1 mm after 2 years.
On distal side, it was 1.6 mm initially and 2.2 mm after 2 years. The difference was significantly (P< 0.05) on distal side in group I. The mean distance between the CEJ of the adjacent tooth and the crestal bone in group I initially on mesial side was 2 mm and 2.6 mm after 2 years, on distal side it was 2.2 mm initially and 2.4 mm after 2 years.
In group II, it was 2.1 mm initially and 2.5 mm after 2 years on mesial side. It was 2.5 mm initially and 2.7 mm after 2 years on distal side. The difference was non-significant (P> 0.05) (Graph I). Mean bone loss adjacent to implant shoulder in group I was 1.34 mm and 0.72 mm in group II. The difference was non- significant (P>0.05).

Figure 1: Jemt T. Int J Periodontics Restorative Dent. 1997 Aug;17(4):326-33

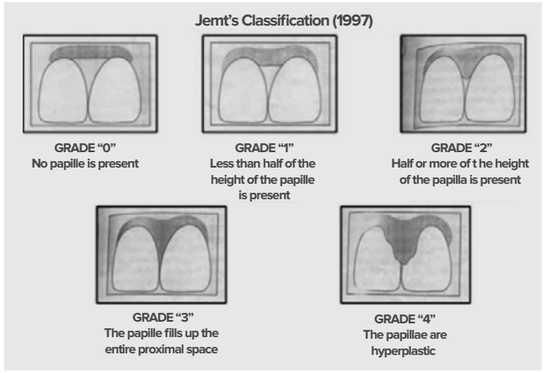


Table I : Intragroup comparison of mean distances (mm) from the implant shoulder to the crestal bone

Group I (Nobel Active)	Mesial	1.22	1.8	0.5
	Distal	0.82	2.3	0.01*
Group II (Noris Tuff)	Mesial	1.8	3.1	0.08
	Distal	1.6	2.2	0.1

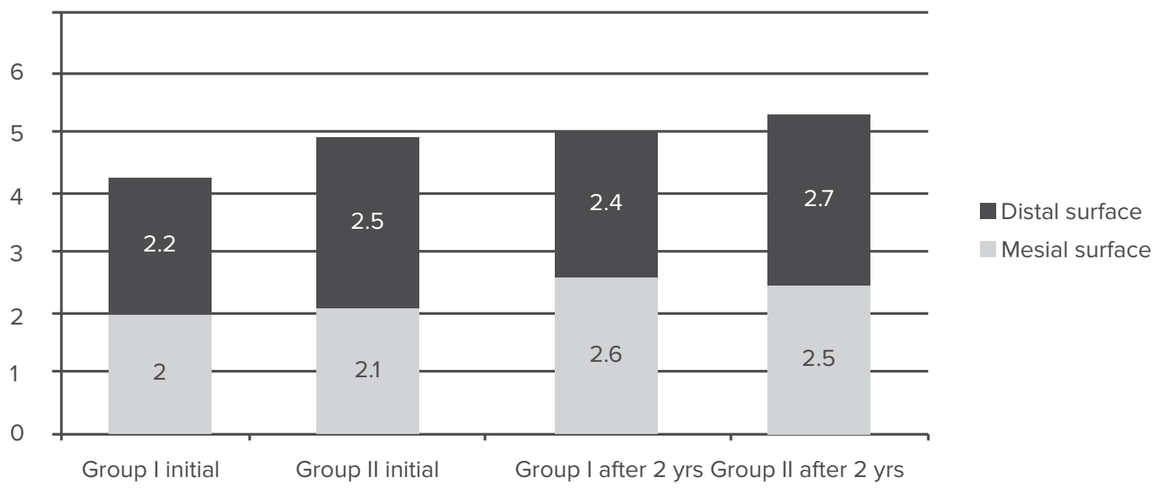
Paired t-test. * Indicates Statistical Significance. (p> 0.05)

Table II : Intergroup comparison of mean distances (mm) from the implant shoulder to the crestal bone

	Interdental papilla height (mm)	Group I (Nobel Active)	Group II (Noris Tuff)	P value
Initial IOPAR	Mesial	1.22	1.8	0.2
	Distal	0.82	1.6	0.3
2 Years	Mesial	1.8	3.1	0.5
	Distal	2.3	2.2	0.07

Unpaired Student t-test.

Graph I: Comparison of the mean distance between the CEJ of the adjacent tooth and the crestal bone



Discussion

Teeth are lost due to various reasons such as a result of trauma, dental caries, and periodontitis or due to orthodontic reasons. Dental implant therapy is widely used nowadays.
The higher survival rate is one of the reasons for its popularity. The successful implant therapy is based on its ability to restore esthetics as well as functions.[5] It should mimic the natural teeth and perform all required functions such as eating, biting, chewing etc. Maxillary anterior tooth region is favorable site for dental implant. The presence of sufficient bone height in this region favours dental implant therapy. Moreover, maxillary anterior region shows type I bone which is suitable for dental implants. Dental implants in maxillary anterior region are less subjected to occlusal forces. The height of interdental papilla also determines the dental implant success rate.[6] Many studies have been conducted which evaluate factors affecting bone loss around dental implants. Very few studies have been performed so far which shows importance of dental papilla as key factor in deciding outcome of dental implants.[7,8] Considering this, the present study was conducted to compare the amount of soft tissues around Nobel Active and Noris Tuff TT dental implant systems.

Chang M et al[9] in their study revealed that interdental papilla formation is greatly depends on distance between dental implant and natural teeth and anatomy of adjacent teeth. Grunder U[10] suggested that bone level around dental implant determines the presence of interdental papilla between implant and natural teeth.

In present study we included 28 patients of both genders having 32 dental implants. All were the cases of maxillary anterior region. We used Nobel Active dental implants in group I and Noris Tuff TT dental implants in group II. We observed that the mean distances from the implant shoulder to the crestal bone was 1.22 mm initially which become 1.8 mm after 2 years in group I on mesial side. It was 0.82 initially and 2.3 mm after 2 years on distal side. Similarly, the mean distance from the implant shoulder to the crestal bone was 1.8 mm initially and 3.1 mm after 2 years on mesial side and 1.6 mm initially and 2.2 mm after 2 years on distal side. Our results are in accordance to the study of Henriksson K et al.[11] In their study, the height of interdental papilla around dental implants was compared.

In present study, there was no significant bone loss in either of dental implant systems. Our results are in tandem with the study by Bratuet al[12] who performed a prospective study to evaluate the level of bone loss around micro- threaded dental implants and found that there was significantly less bone loss in dental implants having micro- threads. Studies have demonstrated that micro- threaded dental implants tend to deliver stress at crestal bone. It was found that rough dental implants with micro- threads are helpful in maintaining crestal bone level as compared to non threaded dental implants.[13,14]

We observed that on mesial side the mean distance between the CEJ of the adjacent tooth and the crestal bone was 2 mm initially and 2.6 mm after 2 years whereas on distal side it was 2.2 mm initially and 2.4 mm after 2 years in group I.
In group II, it was 2.1 mm initially and 2.5 mm after 2 years on mesial side. It was 2.5 mm initially and 2.7 mm after 2 years on distal side. However, the difference in both groups found to be non- significant. Kan JY et al[15] in their study on 6 dental implant system found that interdental papilla are greatly affected by the around of crestal bone level in adjacent teeth.

Choquet et al[16] in their study assessed the level of interdental papilla around single maxillary anterior dental implant both clinically as well as radiographically. Authors found that in cases where there was >6mm distance between alveolar crest and contact point, the interdental papilla was seen in all cases whereas when it was <5mm, only half of cases showed interdental papilla.

Ozdemir et al[17] in their study included 33 immediate dental implants and adjacent implants.
The level of interdental papilla height was measured using Pink esthetic score at 1 week, 1 month and 4 months. Authors concluded that immediate dental implants and loading are effective in maintaining soft tissue health such as interdental papilla.

Similarly, the study by Mankoo et a[18] in their 2-7 years follow up study on 10 dental implants placed in esthetic zone suggested the role of labial tissue thickness and tissue biotype in dental implant therapy in maxillary anterior region.

The limitation of the study was small sample size. Only Noble Active and Noris Tuff TT types of dental implants were included. Further studies are warranted to elucidate fortified results in different study settings and populations. Keeping the congruency of the gingival biotype and studies depicting survival analysis data could prove to be a cornerstone in research within this paradigm and vista.

Conclusion

Authors found relation between presence of papilla and the distance of the contact point ofthe implant restoration and the adjacent tooth to thecrestal bone. The amount of bone loss in both groups was not significant.

Clinical Significance

The preservation of interdental papilla is of paramount importance for predictable results and successful dental implant therapy.

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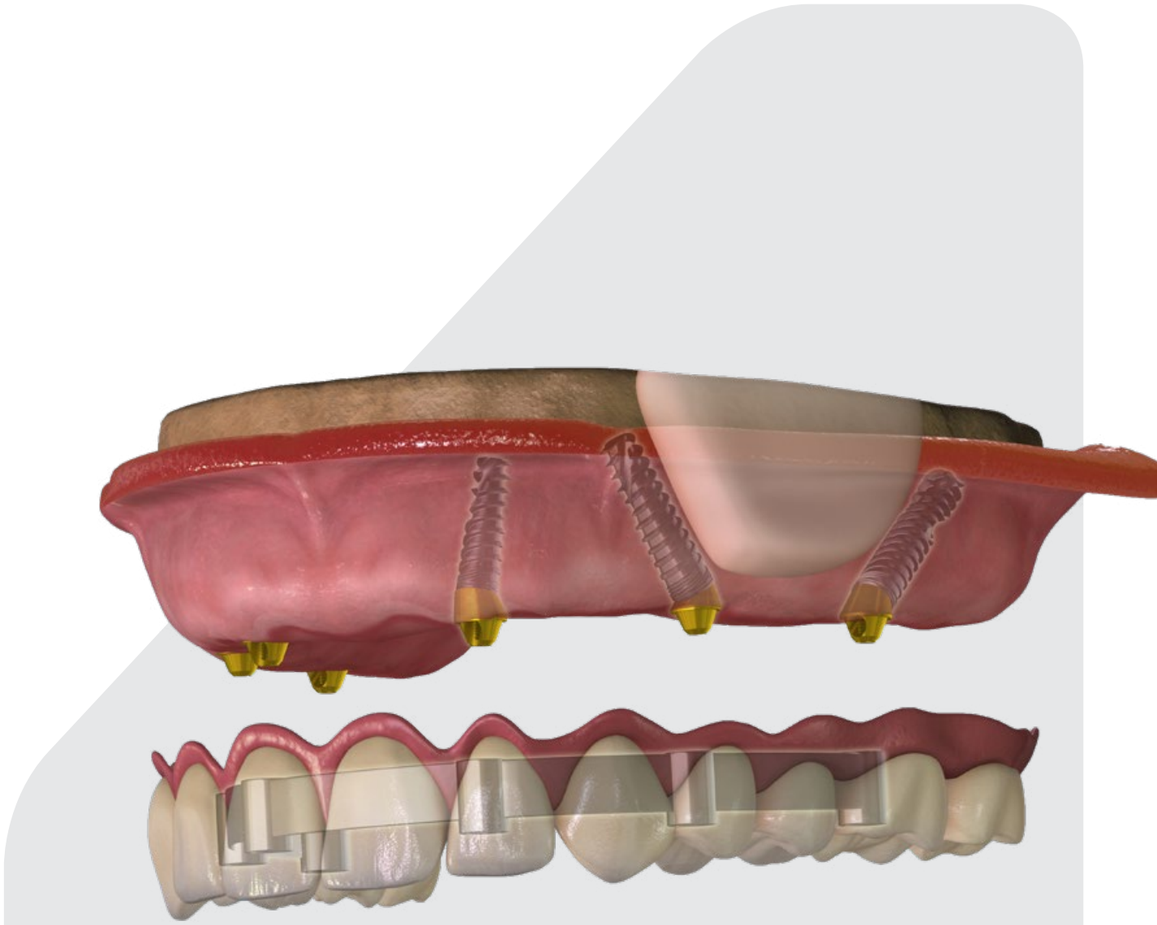
Clinical Challenges



A NEW SPIRAL DENTAL IMPLANT: A TOOL FOR ORAL REHABILITATION OF DIFFICULT CASES

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SUMMARY

Spiral dental implant (SDI) is an implant with a conical internal helix that confers the characteristic of self-drilling, self-tapping, and self-bone condensing. These proprieties offer better control during insertion of SDI giving a high primary stabilization, even in poor quality bone. A shorter diameter of SDI results in reduced drilling during insertion and consequently less trauma and minimal bone loss. To address the research purpose, the investigators designed a retrospective cohort study. The study population was composed of 25 patients, 11 males and 14 females that have been treated by Dr. Balan with 187 SDI positioned in mandible and into maxilla bone. The implants were placed during the years 2013 to 2014 in Dr. Balan clinic.
All patients underwent the same surgical protocol. Several variables are investigated: demographic (age and gender), anatomic (upper/lower jaws and tooth site), implant (length and diameter and type) variables, edentulism (partial or total), and comorbid status of health (i.e.: hypothyroidism, parodontitis, hypertension, diabetes, presence of cancer, heart disease, hepatitis and rheumatologic disease). Pearson Chi-Square test was used to investigate variables and p < 0.05 was considered statistically significant.
Statistically it has been shown that females have a higher possibility of unsuccessful respect of male, with a “p value” of 0.014.
Another important impact factor for success of implant insertion has been represented by concomitants pathologies: cancer represents the most negative high factor risk with a percentage of unsuccessful of 50%, followed by heart disease (15%), and diabetes (3.7%).
SDIs are reliable tools for difficult cases of oral rehabilitation. They have a higher success and survival rate, which means stable results over time. No differences were detected among SDI lengths, implant/crown ratio. In addition, the insertion of SDIs in banked bone can be performed without adverse effects. Finally, flapless and computer tomography-planned surgery does not significantly increase the clinical outcome of SDIs in complex rehabilitation. Cancer represents the most important variable to consider when a patient wants to do oral rehabilitation because of its high risk of unsuccessful.

Key words: implant dentistry, spiral implants, bone, helix design, survival rate.

Introduction

Spiral dental implant (SDI) is a conical internal helix implant with a variable thread design that confers the characteristic of self-drilling, self-tapping, and self-bone condensing (1-3). These proprieties offer better control during insertion of SDI giving a high primary stabilization, even in poor quality bone. A shorter diameter of SDI results in reduced drilling during insertion and consequently less trauma and minimal bone loss. Position and orientation of SDI can be changed even after initial insertion without trauma to the alveolar bone tissues. These properties of SDI are particularly useful in case of bone atrophy, in low bone density, or in freshly extracted sites and thin sinus floors elevation without prior bone augmen-tation. Implant placement requires an adequate quantity and quality of bone (4-12). The selfdrilling capability of the SDI allows it to be inserted into sites with reduced depth. This characteristic of SDI is very useful for implant surgeon when implant must be inserted in proximity to anatomic structures such as the mandibular nerve canal or the maxillary sinus and nose cavity.

Some studies have proven the SDIs to be highly successful (13-16). However, to achieve this predictable success, a specific protocol for SDI should be followed. Researches have challenged several aspects of this specific protocol, and their investigations found the relative importance of helix design on osseointegration. Therefore, the identification of guidelines for the long-term success (i.e., total implants still in place at the end of the follow- up, good clinical, radiologic, and aesthetic outcome) has been to achieve good clinical outcome (17-20).

Many variables may influence the clinical outcome of SDI: surgery protocol, bone quality and quantity, helix design, and occlusion (21-25). Surgery-related factors comprise several variables such as an excess surgical trauma like flap, bone thermal injury, and irrigation. Bone quality and quantity are the most important host-related factors, while helix design, surface coating, and length are the strongest implant-related factors. Finally prosthetic restoration and occlusion-related factors may affect the clinical outcome.

Surgery-related factors

Flapless implant surgery is easy to perform since the helix design allows a simpler penetration into bone of SDI. With this blind procedure, the surgeon may run the risk to deviate SDI. The use of radiographic images is necessary to evaluate the surgical site underneath the soft tissue, and computer tomography images provide an accurate 3D picture of the surgical field. In addition, several Authors have advocated the use of drill guides for SDI insertion to link the virtual preoperative treatment plan based on the computer tomography images to the situation encountered during surgery (18, 19).

Bone quality and quantity

Bone quality and quantity, a host-related factor, is believed to be the strongest predictor of outcome in SDIs. Some studies have reported that most of the immediately loaded implants are placed in anatomic sites with bone quality D1 or D2 (16, 17, 26). No differences were detected between implants inserted in native and grafted bone. Some papers on clinical outcome of SDIs reported no statistical difference with regard to anatomic sites (mandible vs maxilla or tooth site) or surgery-related factors (i.e., surgeon, flapless surgery, computed tomography- planned, and post extraction sites).

Prosthetic-related variables

Several prosthetic-related variables were reported: loading time, situation of antagonist arch, and implant/crown ratio; this variable was statistically significant with a worse outcome for full arches loading few implants.
Several reports have appeared in the last decade and good medium-term success rate of SDIs has been reported. The effectiveness of these types of SDI was demonstrated in several clinical situations (25).

However, because there are no reports about survival rate of SDI we therefore decide to perform a retrospective study on 187 SDIs.

Materials and methods

Study design/sample

To address the research purpose, the investigators designed a retrospective cohort study. The study population was composed of 25 patients, 11 males and 14 females that have been treated by Dr. Balan with 187 SDI positioned in mandible and into maxilla bone. The implants were placed during the years 2013 to 2014 in Dr. Balan clinic.

Subjects were screened according to the following inclusion criteria: controlled oral hygiene, the absence of any lesions in the oral cavity; in addition, the patients had to agree to participate in a post-operative check-up program.

The exclusion criteria were as follows: bruxism, smoking more than 20 cigarettes day and consumption of more than 2 glass of wine per day, localized radiation therapy of the oral cavity, blood and kidney diseases.

Pre-operative medication protocol

An antimicrobial prophylaxis was administered with 500 mg amoxycillin twice daily for 5 days One hour prior to dental surgery: 1g Augmentin (amoxicillin and clavulanate potassium) for patients who are allergic to penicillin - 600 mg Dalacin (clindamycin); 12 mg dexamethasone (not for diabetics); 20 mg Vaben (oxazepam); 100 mg Otarex (hydroxyzine hydrochloride); 2 tab Narocin 275 mg (naproxen); 1 cap Losec 20 mg (omeprazole); Probiotic.

Implant surgery

All patients underwent the same surgical protocol. Local anesthesia was induced by infiltration with articaine/epinephrine and post-surgical analgesic treatment was performed with 100 mg nimesulid twice daily for 3 days. Oral hygiene instructions were provided.

After a crestal incision a mucoperiosteal flap was elevated. Implants were inserted according to the procedures recommended. The implant platform was positioned at the alveolar crest level. Sutures were removed 14 days after surgery.

The provisional prosthesis is delivered on the same day of the operation and the final restoration was usually delivered within an additional 6 months. All patients were included in a strict hygiene recall.

Post-operative medication protocol

Antibiotics: Moxypen (amoxicillin) 500 mg 3 times a day/ Augmentin 500/875 3 or 2 times a day/Dalacin 300 mg 3 times a day, for 7 days; 0.12% Chlorhexidine rinse for a month; 400 mg Ibuprofen every 4 hours, if needed; Dexamethasone, starting with 12 mg daily and reducing 2 mg each following day, botox (dilute according to manufacturer’s instructions, divide to 6 doses, inject to the masseter muscle in 3 points along the muscle, in each side).

Variables

Several variables are investigated: demographic (age and gender), anatomic (upper/lower jaws and tooth site), implant (length and diameter and type) variables, edentulism (partial or total), comorbid status of health (i.e.: hypothyroidism, parodontitis, hypertension, diabetes, presence of cancer, heart disease, hepatitis and rheumatologic disease.

Primary and secondary predictors of clinical outcome were used. The primary predictor is the presence/absence of the implant at the end of the observation period. It is defined as survival rate (i.e., SVR) that is the total number of implants still in place at the end of the follow-up period. The second predictor of outcome was the periimplant bone resorption. It is defined as implant success rate (SCR and it is evaluated according to the absence of persisting peri-implant bone resorption greater than 1.5 mm during the first year of loading and 0.2 mm per year during the following years (24).

Data collection methods and summary of operative methods

Before surgery, radiographic examinations were done with the use of orthopantomography (Figure 1).

In each patient, peri-implant crestal bone levels were evaluated by the calibrated examination of orthopantomography X-rays. Measurements were recorded after surgery (Figure 2) and at the end of the follow-up period (Figure 3). The measurements were carried out mesially and distally to each implant, calculating the distance between the implant' platform and the most coronal point of contact between the bone and theimplant. The bone level recorded just after the surgical insertion of the implant was the reference point for the following measurements.
The measurement was rounded off to the nearest 0.1 mm. A peak Scale Loupe with a magnifying factor of seven times and a scale graduated in 0.1 mm was used.

The difference between the implant-abutment junction and the bone crestal level was defined as the Implant Abutment Junction (IAJ) and calculated at the time of operation and during follow- up.
The delta IAJ is the difference between the IAJ at the last check-up and the IAJ recorded just after the operation. Delta IAJ medians were stratified according to the variables of interest.

Peri-implant probing was not performed because controversy still exists regarding the correlation between probing depth and implant success rates (24, 25).

Data analysis

Pearson Chi-Square test was used to investigate variables and $p < 0.05$ was considered statistically significant.

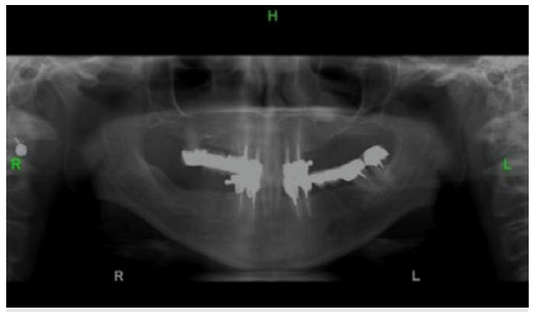

Figure 1
Pre-operative Rx opt.

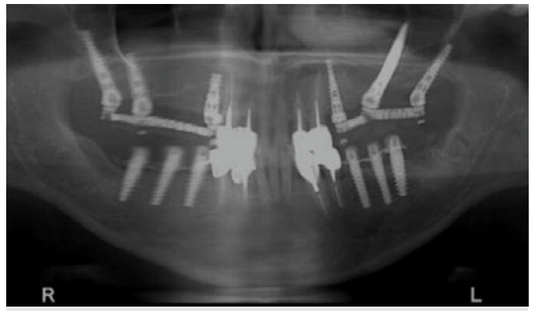

Figure 2
Rx opt in the immediate post-operative (t0).

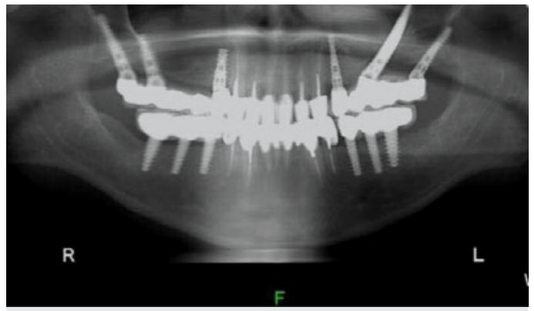

Figure 3
Rx opt after 11 months of follow-up.

Results

Twenty-five patients, 11 males and 14 females, treated by Dr. Balan with 187 SDI with a medium age of 58.4 years have the inclusion criteria and were enrolled in the present study. Informed written consent approved by the local Ethics Committee was obtained from patients to use their data for research purposes. The mean post loading follow-up was 8.7±2.5 months. One hundred and ten implants (58.8%) were inserted in females, 77 (41.2%) in males. A total of 187 implants was inserted into 25 patients: 73 (39.0%) into the mandible and 114 (61%) into the maxilla.

There were 187 NORIS Medical Ltd dental Implant system (Israel):166 Tuff 21 Cortical. They were inserted because of atrophy of the bone in 97 cases (51.9%), periodontitis in 78 cases (41.7 %) and 12 (6.4%) in post extraction for caries.

Implant length and diameter ranged from 8 mm to 16 mm (standard was 11.5 mm) and from 3.75 mm to 6.0 mm, (standard was considered 3.75 mm) respectively.
There were 40 standard length fixtures (i.e. 11.5 mm), 33 short and 114 long implants. There were 79 standard diameter fixtures (i.e. 3.75 mm) and 108 wide implants. Implants were inserted to replace 51 incisors, 26 cuspids, 49 premolars and 61 molars.

One hundred and fifty-three implants were inserted in totally edentulous patients, and 34 in partially edentulous patients.

Considering the presence of comorbidity, the most percentage of SDI were inserted in healthy patients (58.8%), while 27 (14.4%) implants were inserted in diabetic patients, 19 (10.2%) in patients with heart disease, 21 (11.2 %) in hypothyroid, and finally 10 (5.3%) in patients with cancer. Seventy-three (39%) implants were inserted in mandibular bone. One hundred and fourteen (61%) implants were inserted in maxilla bone. No implant was lost in the post-operative period. Every variable has been studied with Pearson Chi-Square test, to investigate which of these can compromise the successful rate of the insertion of SDI.

Statistically it has been shown that females have a higher possibility of unsuccessful respect of males, with a "p value" of 0.014. Another important impact factor for success of implant insertion has been represented by concomitants pathologies: cancer represents the most negative high factor risk with a percentage of unsuccessful of 50%, followed by heart disease (15%), and diabetes (3.7%).

Discussion

Primary implant stability and bone density are variables considered essential to achieve predictable osseointegration and long-term clinical survival of SDIs. For osseointegration of SDI, not only adequate bone quantity is required, but adequate density is also needed. The initial bone density not only provides mechanical immobilization of the SDI during healing, but also permits distribution and transmission of stresses from the prosthesis to the implant bone interface.
The mechanical distribution of stress occurs primarily where bone is in contact with the SDI (16-18, 26).
One study demonstrated that when maximum stress concentration occurs in cortical bone, it is located in the area of contact with the thread of helix, and when the maximumstress concentration occurs in trabecular bone, it occurs around the apex of the helix (25).
Besides the success rate of SDIs is above 80%, peri-implantitis may occur in oral rehabilitations of difficult cases also. Peri-implantitis and periodontal disease spring from bacterial infection that activates a cytokines cascade leading to inflammation and bone loss (27-31).

In addiction, the patient-related susceptibility is a critical factor for disease onset. So, every factor favouring oral biofilm formation (poor oral hygiene), host defence capability (smoking habit, excessive alcohol consumption, genetic traits, history of periodontitis, oral mucosal lesions and prosthetics), might favour developing of peri implantis and periodontal disease in SDIs, which diagnosis and treatment require dentist's engagement (32-39).

Conclusion

In conclusion, SDIs are reliable tools for difficult cases of oral rehabilitation. They have a higher success and survival rate, which means stable results over time. No differences were detected among SDI lengths, implant/crown ratio.
In addition, the insertion of SDIs in banked bone can be performed without adverse effects. Finally, flapless and computer tomography-planned surgery does not significantly increase the clinical outcome of SDIs in complex rehabilitation. Considering risks factors above all health status and female sex seems to be mandatory for the success of SDI. Nowadays we should keep in touch that cancer represents the most important variable to consider when patients wants to do oral rehabilitation because of its high risk of unsuccessful.

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