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 self-drilling 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 pre-operative 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 peri-implant 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 the implant. 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

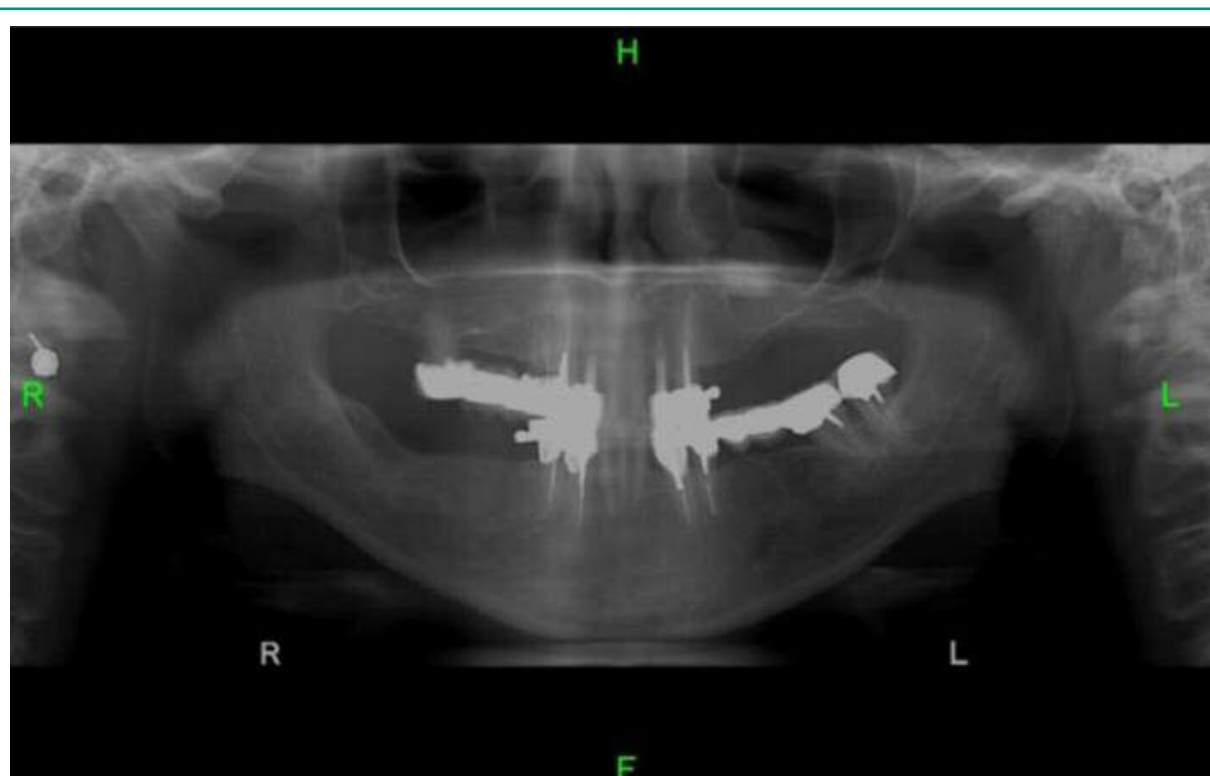Pearson Chi-Square test was used to investigate variables and $p < 0.05$ was considered statistically significant.
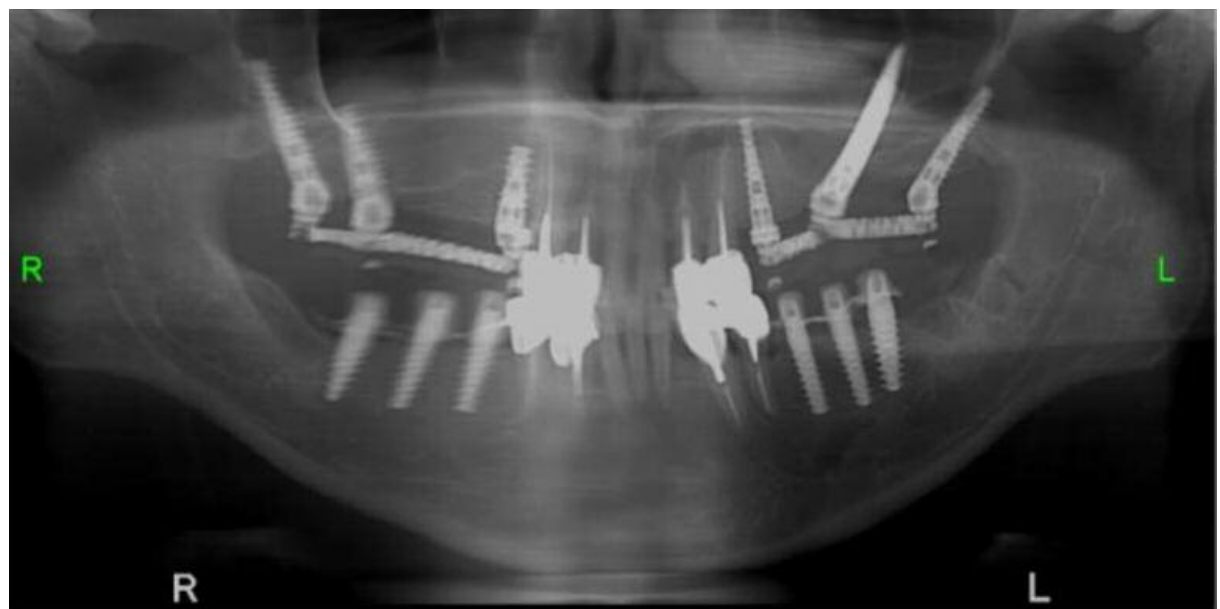

Figure 1
Pre-operative Rx opt.

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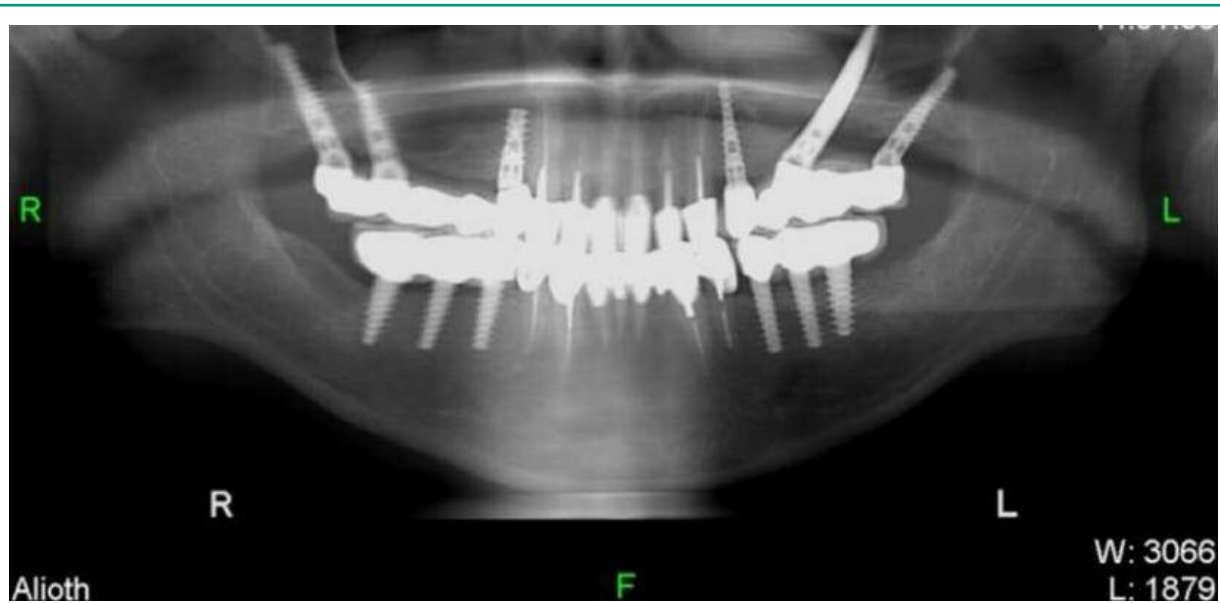Rx opt in the immediate post-operative (t0).

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 medi- um 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 maximum stress 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.

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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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