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*Retrospective study*

## **CLINICAL OUTCOMES OF SPIRAL IMPLANTS INSERTED TO REPLACE CUSPIDS: A RETROSPECTIVE STUDY**

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### **ABSTRACT**

In the last decade, spiral implants were introduced as a new tool for oral rehabilitation. A retrospective study has been planned to verify the effectiveness of this system in replacing cuspids. A series of 26 spiral implants inserted to replace cuspids were analyzed. Several variables related to a patient, anatomic site, implant, and surgery were investigated. Implant failure and peri-implant bone resorption were considered predictors of clinical outcome. Cox regression was then performed to detect statistically associated variables with the clinical outcome. From June 2010 to June 2014, 234 spiral implants were inserted in patients. Specifically, 26 fixtures were inserted to replace missing cuspids. Fifteen were inserted in females and 11 in males with a median age of 55 (max-min 29-77, STD = 14 years). One failed (i.e., survival rate SVR =96%). The mean follow-up was 16 months (max-min 1-41, STD = 10 months). Among the studied variables, none reached a significant statistical value. In the present report, the SVR and SCR were 96% and 88.46%, respectively. Statistical analysis demonstrated that no studied variable impacts the survival (i.e., lost implants) and clinical success (i.e., crestal bone resorption), so SPI is a reliable device to replace cuspid.

**KEYWORDS:** *spiral, implant, fixture, bone, remodeling, resorption, ridge, alveolar*

### **INTRODUCTION**

Few papers were published on implant-prosthetic rehabilitations (IPRs) inserted in the canine site, despite the esthetic

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playing an important role in rehabilitating the frontal zone. Of the many factors that influence the outcome of the IPRs to replace cuspids, the principal ones are 1) the bone and soft-tissue deficiencies, 2) the timing of implant insertion and 3) the management of regenerative procedures (1). Furthermore, IPR in the esthetic area is influenced by other outcomes, such as the correct three-dimensional position of the implant between the cuspid area and the abutment and the crown morphology regarding implant position (2). Immediate IPR can be a successful procedure in terms of aesthetics, but it is related to the surgeon's ability. Immediate IPR is less traumatic as fewer surgical procedures are involved, so patients prefer this clinical approach for better comfort (3). The diagnostic phase is very important: bone and soft tissue characteristics must be considered; skeletal growth, hard and soft tissue parameters, and the morphology of the roots adjacent to the edentulous area should be taken into consideration also (4). The correct position of the IPR should follow the guidelines; in particular, the abutment morphologies play a role in the vestibular/palatal position of the IPR (4).

For IPR in the canine site, we considered a new type of implant: spiral implant. A spiral implant (SI) is a new implant with a conical internal helix and a variable thread design that confers the characteristic of self-drilling, self-tapping, and self-bone condensing (5-7). These proprieties offer better control during SI insertion and high initial stabilization, even in poor-quality bone; small-diameter drilling of SI results in reduced trauma and minimal bone loss. The location and orientation of SI can be altered even after initial insertion without trauma to the surrounding tissues. The advantages of SI are particularly obvious in esthetic sites with minimal bone and low bone density, achieving high stabilization in freshly extracted sites. The self-drilling capability of SI allows it to be inserted into sites that have been prepared to a reduced depth. This ability of SI becomes very useful in situations of proximity to anatomic structures such as the mandibular nerve canal or the maxillary sinus and nasal cavity.

Because few reports have been published about implants inserted in cuspids, we conducted a retrospective study on 26 spiral implants (Alpha Bio LTD, Petah-Tikva, Israel) inserted in canine sites.

## MATERIALS AND METHODS

### *Study design/sample*

To address the research purpose, the investigators designed a retrospective cohort study. The study population comprised 26 patients (15 female and 11 male, median age 55 years, min 29 - max 77) for evaluation and implant treatment between June 2010 and June 2014.

Subjects were screened according to the following inclusion criteria: controlled oral hygiene, the absence of any lesions in the oral cavity, sufficient residual bone volume to receive implants of 3.75 mm in diameter and 10 mm in length; in addition, the patients had to agree to participate in a post-operative check-up program.

The exclusion criteria were as follows: insufficient bone volume to receive implants of 3.75 mm in diameter and 10 mm in length, bruxism, smoking more than 20 cigarettes/day and excessive consumption of alcohol (i.e., more than 2 glasses of wine per day), localized radiation therapy of the oral cavity, antitumor chemotherapy, liver, blood and kidney diseases, immune-suppressed patients, patients taking corticosteroids, pregnant women, inflammatory and autoimmune diseases of the oral cavity.

### *Variables*

Several variables are investigated: demographic (age and gender), anatomic (upper/lower jaws, tooth site), implant (type, length, and diameter), surgical (CT-planned surgery, post-extractive, immediate loading) and prosthetic (type of prosthesis, number of prosthetic units, edentulousness, dentition in the antagonist arch) variables.

Primary and secondary predictors of clinical outcome are 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), the total number of implants still in place at the end of the follow-up period.

The second predictor of outcome is peri-implant bone resorption. It is defined as implant success rate (SCR) and 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/year during the following years (8).

### *Data collection methods and summary of operative methods*

Before surgery, radiographic examinations were done using orthopantomograph and CT scans. Computer-guided surgery was performed as described elsewhere (9, 10).

Peri-implant crestal bone levels were evaluated in each patient by calibrating periapical X-rays. Measurements were recorded before, after, and at the end of the follow-up period. 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.

A second CT could not be performed due to the amount of X-rays delivered. The measurement was rounded off to the nearest 0.1 mm. A periapical radiograph was impressed utilizing a customized Rinn holder device. This device was necessary to maintain the X-ray cone perpendicular to a film pieced parallel to the long axis of the implant. The endoral X-rays were taken using a long X-ray tube at 70 Kw of power, performed with a computer system, and saved in an uncompressed TIFF format for classification. Each file was processed with the Windows XP Professional operating system using Photoshop 7.0 and shown on a 17" SXGA TFT LCD with an NVIDIA GÈ Force FX GO 5600, 64 MB video card.

Each image was modified using the fit-on-screen function (maximized screen), and the necessary adjustments in contrast, brightness and magnification were made. The measurements were taken at the highest level of resolution possible through the "grid and ruler" program options using various metric scales. Knowing the known dimensions of the implant and having located various points of reference on the profiles of the x-rayed fixtures (edge of the platform, bone crestal level, total length of the implant), it was possible to take linear measurements on the computer and thus execute a proportional metric calculation comparing the known dimensions of the implant's geometric design with those of the examined x-ray images; this made it possible to establish the distance from the mesial and distal edges of the implant platform to the point of bone-implant contact plus the visible crown (expressed in tenths of a millimetre) as an expression of marginal bone resorption. The proportional calculation of the measurements also made it possible to establish, where present, any distortion in the X-ray images for further screening, thereby reducing the margin of error of the analysis to a minimum.

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 after the operation. Delta IAJ medians were stratified according to the variables of interest. Peri-implant probing was not performed because a controversy exists regarding the correlation between probing depth and implant success rates (11).

All patients underwent the same surgical protocol. Antimicrobial prophylaxis was administered with 500 mg Amoxicillin twice daily for 5 days starting 1 hour before surgery. Local anaesthesia 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 placing the surgical guide, mucotomy was performed, bone drilled, and implants inserted as previously planned with CT-guided protocol. No surgical guide was used for "free-hand" inserted implants. The implant platform was positioned at the alveolar crest level, and provisional restoration was immediately delivered or after 3 months (in 2 stages of surgery). After 8 weeks, the final restoration was usually delivered. All patients were included in a strict hygiene recall.

### *Data analysis*

Cox regression analysis was applied to determine the single contribution of covariates on the survival/success rate. Cox regression analysis compares survival/success data while considering the statistical value of independent variables, such as age and sex, on whether or not an event (i.e. implant loss, crestal bone resorption value overcome) is likely to occur. The difference was considered statistically significant if the associated probability was less than 5% ( $p < .05$ ). The odds ratio and 95% confidence bounds were calculated during the regression analysis. Confidence bounds did not have to include the value «1» (12). Stepwise Cox analysis allowed us to detect the variables most associated with implant survival and/or clinical success.

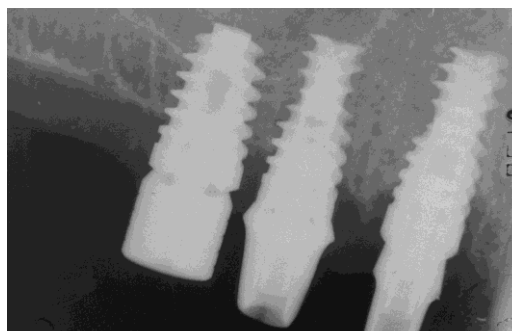
**RESULTS**

From June 2010 to June 2014, 234 spiral implants were inserted in patients. Specifically, 26 fixtures were inserted to replace missing cuspids. Fifteen were inserted in females and 11 in males with a median age of 55 (max-min 29-77, STD=14 years). Twelve were in post-extractive sites, and 14 were in native bone. Flapless surgery was performed in 10 cases. Computer-guided surgery was done in 6 cases. Nineteen were placed in the maxilla and 7 in the mandible. Seventeen were immediately loaded. All had fixed prostheses. One failed (i.e., survival rate SVR=96%), and 3 had a crestal bone resorption higher than 1.5 mm in the first year and an additional 0.2 mm in each following year of follow-up. (i.e., success rate SCR=88.46). The mean follow-up was 16 months (max-min 1-41, STD = 10 months) (Fig. 1, 2).

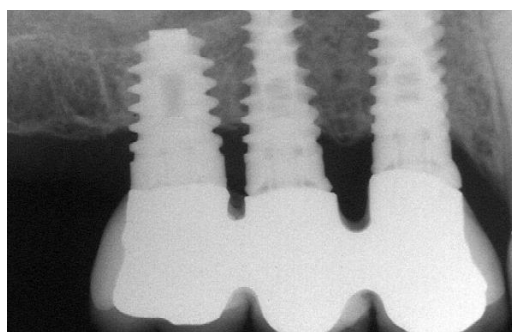
Implant lengths 10, 11.5, 13 and 16 mm in 2, 1, 13 and 10 cases, respectively. Implant diameter was 3.75, 4.2, 5 and 6 mm in 3, 14, 8 and 1 cases, respectively. Among the studied variables, none reached a significant statistical value (Table I).

**DISCUSSION**

Few articles focus on implants inserted in the canine site (13-16). Some recent papers studied prosthetic restorations. In a report about IPRs for replacing canines, Sailer et al. (13) analyzed if customized zirconium abutments and prosthetic rehabilitation exhibit the same survival rates in the canine and posterior regions as titanium abutments. Twenty-two patients with 40 IPRs in the posterior region were included, and the implant sites were randomly assigned to 20 customized zirconium and 20 customized titanium abutments. All IPRs were fabricated in all-ceramic and metal-ceramic materials. Probing pocket depth, plaque index, and bleeding on probing were assessed and compared with the natural teeth (control). The survival rate for IRPs and abutments was 100%. No technical or biological problems were observed at the test and control sites. Two crowns



**Fig. 1.** *Periapical radiograph performed immediately after implant placement to replace a cuspid in the maxilla.*



**Fig. 2.** *A second periapical x-ray was performed at the end of the period of follow up.*

**Table I.** *Statistical output of Cox regression analysis.*

Variable	Degree of Freedom	Sig.	Exp (B)
Male/Female	1	.772	.000
Post-extractive/Native site	1	.753	14099568571596.158
Flapped / Flapless	1	.949	.899
Computer Guided Surgery	1	.853	.000
Mandible/Mandible	1	.770	1635066962386.072
Implant Type (SPI/SFB)	1	.764	128918416724235104.000
Immediate/Delayed Loading	1	.781	6256382053987044.000
Number of Prosthetic Units	1	.368	10.816
Type of Edentulous	1	.769	1810410595678.683

supported by titanium abutments were chipped. No difference in probing pocket depth, plaque index, and bleeding on probing was observed between the two groups. The authors concluded that IPRs with zirconium abutments exhibited the same survival outcome at one year as IPRs with titanium abutments.

Zembic et al. (14) tested whether IPRs with zirconium abutments exhibit the same survival and technical/biological outcome as IPRs with titanium abutments. Twenty-two patients receiving 40 single-tooth IPRs in the canine and posterior regions were included. The implant sites were randomly assigned to 20 zirconium and 20 titanium abutments. All-ceramic and metal-ceramic crowns were fabricated. Probing pocket depth, plaque index, and bleeding on probing were assessed at abutments (test) and analogous contralateral teeth (control). Standardized radiographs of the IPRs were made, and the bone level was measured regarding the implant shoulder on the mesial and distal sides. No abutment fracture or IPR loss was observed. Hence, both exhibited 100% survival. Two metal ceramic crowns supported by titanium abutments were chipped. No difference was observed in the biological outcome of IPRs with zirconium and titanium abutments: probing pocket depth, plaque index, and bleeding on probing were similar in both groups. Furthermore, the bone level was similar at IPRs supporting zirconium and titanium abutments. Thus, the authors concluded that at 3 years, IPRs zirconium and titanium abutments exhibited the same survival and technical, biological, and esthetical outcomes.

In 2011, Turkyilmaz and Shapiro (15) reported a clinical case in which a primary maxillary canine with mobility and root resorption was replaced successfully with an immediate IPR inserted into the fresh extraction socket.

Finally, in 2012 Carinci (16) reported a series of one-piece implants inserted to replace cuspids. Nineteen patients (10 females and 9 males) with a median age of 62 years (range, 43-80) were admitted at the Dental Clinic, University of Chieti (Italy), for evaluation and implant treatment, by one surgeon between January and December 2010. The survival rate (SVR) and success rate (SCR) were 96.8% and 100%, respectively. Statistical analysis demonstrated that no studied variable impacted the survival (i.e., lost implants) and clinical success (i.e., crestal bone resorption), thus showing that one-piece implants are reliable devices for oral rehabilitation in the cuspid sites.

## CONCLUSIONS

The SVR and SCR were 96% and 88.46% in our series, respectively. Statistical analyses demonstrated that no studied variable impacted survival (i.e., lost implants) and clinical success (i.e., crestal bone resorption), so IPRs are reliable devices to replace cuspids.

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