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Clinical trial

CLINICAL OUTCOME OF SPIRAL IMPLANTS INSERTED IN THE MOLAR REGION

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ABSTRACT

In the last decade, spiral implants were introduced in the market as a new tool for oral rehabilitation. A retrospective study has been planned to verify this system's effectiveness in replacing missing molars. A series of 67 implants inserted to replace molars were analyzed. Several variables related to the patient, such as anatomic site, implant, and surgery, were investigated. Implant failure and peri-implant bone resorption were 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, 67 fixtures were inserted to replace missing molars. Forty-six were inserted in females and 21 males with a median age of 51 (max-min 32-80, STD = 14 years). Two failed (i.e., survival rate SVR =97%), and 9 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 = 86.56%). The mean follow-up was 14 months (max-min 1-41, STD = 9 months). Among the studied variables, none reached a significant statistical value. SVR and SCR were 97% and 86.56% in our series, respectively. Statistical analysis demonstrated that no studied variable impacted survival (i.e., lost implants) and clinical success (i.e., crestal bone resorption). Spiral implants are reliable devices to replace molars.

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

INTRODUCTION

Researchers have always studied new types of implants to improve the quality of implant-prosthetic rehabilitations. A new type of implant is a spiral implant (SI) with a conical internal helix and 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 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

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to the surrounding tissues. The advantages of SI are undeniable in compromised situations with minimal bone and low bone density, achieving high stabilization in freshly extracted sites and thin sinus floors without prior bone augmentation. 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.

The spiral implants are composed of 2 types of implants, the SI and the spiral flare bevel (SFB). The latter has a reverse conical head that allows for an increased volume of crestal bone around the implant neck, accounting for additional benefits, such as a closer placement of adjacent implants without compromising health tissues and esthetic outcome.

The effectiveness of SI and SFB was demonstrated in several clinical situations. However, we decided to perform a retrospective study because no reports specifically focus on the clinical outcomes of SI inserted in molars sites.

MATERIALS AND METHODS

Study design/sample

To address the research purpose, the investigators designed a retrospective cohort study of patients treated with spiral implants (Alpha Bio LTD, Petah-Tikva, Israel) as previously reported (1-3). The study population comprised 67 patients (46 female and 21 male, median age 51 years, min 32 - max 80) 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 6 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 6 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), implant (length and diameter), surgical (CT-planned surgery, post-extractive, immediate loading) and prosthetic (type of prosthesis, number of prosthetic units, edentulness, 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 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/year during the following years (4).

Data collection methods and summary of operative methods

Before surgery, radiographic examinations were done using orthopantomography and CT scans. Computer-guided surgery was performed as described elsewhere (5, 6).

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's 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. We were not allowed to perform a second CT because of the number of X-rays delivered. The measurement was rounded off to the nearest 0.1 mm.

A periapical radiograph was impressed using 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 (7, 8).

All patients underwent the same surgical protocol. Antimicrobial prophylaxis was administered with 500 mg Amoxycillin 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 (Fig. 1, 2).

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 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» (9). Stepwise Cox analysis allowed us to detect the variables most associated with implant survival and/or clinical success.

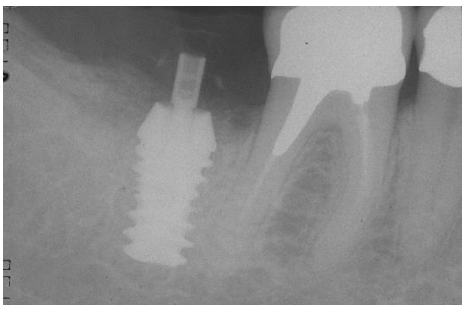

Fig. 1. *Periapical radiograph performed immediately after implant placement to replace a molar in the mandible.*

RESULTS

From June 2010 to June 2014, 234 spiral implants were inserted in patients. Specifically, 67 fixtures were inserted to replace missing molars. Forty-six were inserted in females and 21 males with a median age of 51 (max-min 32-80, STD = 14 years). Twenty-nine were in post-extractive sites and 28 in native bone. Flapless surgery was performed in 25 cases. Computer-guided surgery was done in one case. Thirty were placed in the maxilla and 37 in the mandible. Thirty-eight were immediately loaded. All had fixed prostheses. Two failed (i.e., survival rate SVR =97%), and 9 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 = 86,56%). The mean follow-up was 14 months (max-min 1-41, STD = 9 months). Implant lengths 6, 8, 10, 11.5 and 13 in 1, 1, 16, 24 and 25 cases,

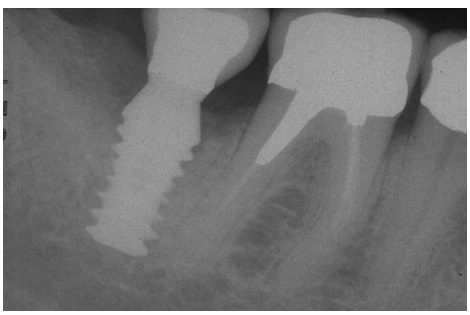

Fig. 2. *A second periapical impression was performed at the end of the period of follow-up.*

respectively. Implant diameter was 3.75, 4.2, 5 and 6 mm in 4, 15, 24, and 24 cases, respectively. Among the studied variables, none reached a significant statistical value (Table I).

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

Variables	Degree of Freedom	Sig.	Exp(B)
Male/Female	1	.293	1.020
Post-extractive/Native site	1	.811	1.112
Flapped / Flapless	1	.690	1.186
Computer Guided Surgery	1	.993	.000
Mandible/Mandible	1	.182	1.878
Implant Type (SPI/SFB)	1	.106	.281
Immediate/Delayed Loading	1	.238	.594
Number of Prosthetic Units	1	.271	.449
Type of Edentulous	1	.985	.000

DISCUSSION

New studies are necessary to demonstrate the high success of SI. Investigators have studied several aspects of the surgical and prosthetic protocol of SI, discovering the relative importance of each variable and their influence on osseointegration, such as anatomic site (upper/lower jaws), the implant (length and diameter), surgical (CT-planned surgery, post-extractive, immediate loading) and prosthetic (type of prosthesis, number of prosthetic units, etc.). However, the guidelines of SI for the long-term SVR (i.e., total implants still in place at the end of the follow-up) and SCR (the absence of persisting peri-implant bone resorption greater than 1,5 mm during the first year of loading and 0,2 mm/years during the following years) are the principal goals to achieve a good clinical outcome of SI.

All variables that influence the result of SI are grouped as factors related to surgery, host, implant, and occlusion-related factors (10-14). Surgery-related factors comprise several variables, such as excess surgical trauma, bone thermal injury, and insufficient irrigation during SI insertion. The host-related factors are the quantity and quality of bone. The most important implant-related factors are surface coating, design, length, and diameter of SI. The intensity of force and type of prosthetic restoration are the variables of interest among the occlusion-related factors. All these variables may affect the clinical outcome of SI (10-14).

Flapless implant surgery of SI has been suggested as one possible treatment option for enhancing implant esthetics because it is easy to perform and is beneficial for patient morbidity (15). However, by performing this blind procedure, one should be aware of the risk of deviating SI and that accurate positioning of each implant is extremely important for fixed restorations (16). Using radiographic images is necessary to evaluate the surgical site of placing SI underneath the soft tissue, and CT images provide an accurate 3D picture of the surgical field (17-21). In addition, several authors have advocated using drill guides (22-24) to link the virtual preoperative treatment plan based on the CT images to the situation encountered during surgery. CT-planned and free-hand surgery have shown no differences in clinical outcomes.

Few articles focus on implants inserted in molar sites. Annibali et al. (25) reported a series of patients treated consecutively for first molar replacement according to unconventional (immediate = Group 1, early = Group 2) or conventional (late = Group 3) surgical protocols. The authors concluded that short-term implant survival and success rates and marginal bone loss values for immediate, early, and conventional implants appear similar for maxillary and mandibular first molar sites.

SVR and SCR were 97% and 86.56% in our series, respectively. Statistical analysis demonstrated that none of the studied variables impacted survival (i.e., lost implants) and clinical success (i.e., crestal bone resorption). Spiral implants

are reliable devices to replace molars.

No statistical difference was detected about anatomic sites (mandible vs maxillae) or surgery-related factors (i.e., surgeon, flapless surgery, CT- planned, and post-extractive sites).

CONCLUSIONS

In conclusion, spiral implants are reliable for complex cases of oral rehabilitation. They have a high SVR and SCR, which means stable results over time. Flapless and CT-planned surgery does not significantly increase the clinical outcome in implant rehabilitation.

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