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Original Article

CLINICAL OUTCOMES OF SPIRAL FIXTURES INSERTED IN PREMOLAR AREA: A PRELIMINARY 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 to replace missing premolars. A series of 91 spiral implants inserted to replace premolars were analyzed. Several variables related to the 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, 91 fixtures were inserted to replace missing premolars. Sixty were inserted in females and 31 in males with a median age of 53 (max-min 16-89, STD = 14 years). Four failed (i.e., survival rate SVR =96%). The mean follow-up was 14 months (max-min 1-41, STD = 14 months). Among the studied variables, flapless surgery and computer-guided surgery have better outcomes. In the present report, the SVR and SCR were 96% and 90.1%, respectively.

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

INTRODUCTION

Primary stability is the first objective to achieve osseointegration (OI) and facilitate the immediate loading protocol (1). Moreover, implant surface modifications have a significant role in reaching the success of osseointegration (2). The

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original Branemark concept of OI (3) advocated a two-stage surgical procedure: 1) insertion of the implant into the bone after raising a soft tissue flap and 2) subsequently repositioning the flap to cover the implant during healing. After a healing period, a second surgical intervention is necessary. A new flap is raised, and a transmucosal abutment is screwed onto the implant to allow the prosthetic connection (4). However, the two-stage procedure, with a submerged healing period, may not be strictly necessary. Implants can be placed with an immediate prosthetic loading protocol with high success rates (SCRs) without compromising OI (5). Moreover, immediate implant placement in extraction sites may preserve the alveolar bone height and width and allow optimal soft tissue function (4).

Spiral implant

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 (6-8). 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 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.

Because spiral implants (Alpha Bio LTD, Petah-Tikva, Israel) have been on the market for the last 10 years and no reports are available on implants inserted in the premolar area, we decided to perform a retrospective study.

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 (6-8). The study population comprised 91 patients (60 female and 31 male, median age 53 years, min 16 - max 89) 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, 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 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 (9).

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 (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'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 through 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, 12).

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.

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% ($p<.05$). During the regression analysis, the odds ratio and 95% confidence bounds were calculated. Confidence bounds did not have to include the value «1» (13). 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, 91 fixtures were inserted to replace missing premolars. Sixty were inserted in females and 31 in males with a median age of 53 (max-min 16-89, STD = 14 years). Fifty-tree were in post-extractive sites and 38 in native bone. Flapless surgery was performed in 37 cases. Computer-guided surgery was done in 7 cases. Sixty-four were placed in the maxilla and 77 in the mandible. Fifty-two were immediately loaded. All had fixed prostheses. Four failed (i.e., survival rate SVR =96%), 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 = 90.1%). The mean follow-up was 14 months (max-min 1-41, STD = 14 months). Implant length was 10, 11.5, 13, and 16 in 16, 22, 32 and 21 cases, respectively. Implant diameter was 3.75, 4.2, 5 and 6 mm in 10, 53, 21 and 7 cases, respectively (Fig. 1, 2).

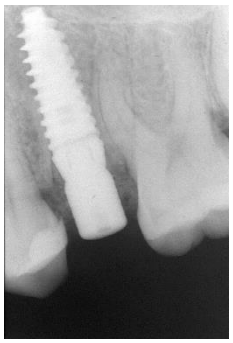

Fig.1. *Periapical radiograph performed immediately after implant placement to replace a premolar in maxilla.*

Among the studied variables, flapless surgery and computer-guided surgery determined a statistically significant better outcome (Table I).

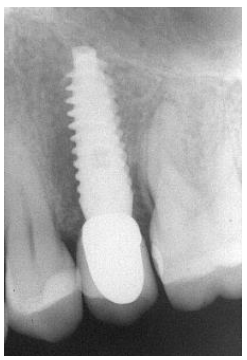

Fig. 2. *A second periapical x-ray was performed at the end of the period of follow-up.*

DISCUSSION

There are few specific reports which focus on premolar rehabilitation. In 2008, Swart and van Niekerk (14) reported a case of premolar implant-prosthetic rehabilitation with a one-piece implant. In 2011, Kolhatkar et al. (15) described an insertion of an implant after maxillary premolar extraction with simultaneous abfraction of the sinus floor using two-piece implants. The authors presented five premolars implant-prosthetic rehabilitation after extraction with simultaneous abfraction of the sinus floor using osteotomes. All premolars were extracted traumatically, sockets carefully debrided and checked for integrity of the walls, and after osteotomy, a particulate of bone graft was placed in the osteotomy and used for sinus floor elevation. After sufficient elevation, the implant was inserted with a particulate bone when indicated. All implant-prosthetic rehabilitation was performed after a minimum healing period of 6 months, and the bone surrounded the final restorations from the apical portion to the most coronal thread. The implant-prosthetic rehabilitated premolars healed without complications and were in function for periods ranging from 6 to 12 months.

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

Variabiles	Degree of Freedom	Sig.	Exp(B)
Male/Female	1	.527	1.289
Post-extractive/Native site	1	.297	1.404
Flapped / Flapless	1	.001	.313
Computer Guided Surgery	1	.020	.141
Mandible/Mandible	1	.592	1.203
Implant Type (SPI/SFB)	1	.123	.449
Immediate/Delayed Loading	1	.975	.987
Number of Prosthetic Units	1	.291	.429
Type of Edentulous	1	.556	1.362

The authors concluded that post-extractive immediate implant insertion with simultaneous osteotome sinus floor elevation was advantageous for premolar replacement. In addition, the described approach can significantly reduce the treatment time for implant-prosthetic rehabilitation in premolars close to sinus proximity, allowing the operator to place implants of the desired length.

CONCLUSIONS

We demonstrated that SVR and SCR were 96% and 90.1%, respectively. Statistical analysis demonstrated that flapless and computer-guided surgery determine a statistically significant better outcome regarding survival (i.e., lost implants) and clinical success (i.e., crestal bone resorption). Spiral implants are effective in substituting premolars.

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