*European Journal of Musculoskeletal Diseases*
ISSN 2038-4106/2016

*Original article*

# SPIRAL IMPLANTS FOR REHABILITATION OF AESTHETIC ZONE: A RETROSPECTIVE STUDY

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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 the effectiveness of this system to replace missing incisors. A series of 50 implants inserted to replace incisors 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, 50 fixtures were inserted to replace missing incisors. Twenty-four were inserted in females and 26 in males with a median age of 55 (max-min 29-77, STD = 14 years). Two failed (i.e., survival rate SVR =96%), and 5 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%). Among the studied variables, none reached a significant statistical value. In the present report, the SVR and SCR were 96% and 90%, respectively. Statistical analysis demonstrated that no studied variable impacts the survival (i.e., lost implants) and clinical success (i.e., crestal bone resorption), so spiral implants effectively restore the aesthetic zone of upper and lower jaws.

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

Received: 10 November 2015
Accepted: 12 January 2016

ISSN: 2038-4106
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## INTRODUCTION

Implant replacement in the aesthetic zone (aesthetic implant replacement - AIR) of upper and lower jaws has been a hot topic for several years. In 2007, some case reports of AIRs were published. Holst et al. (1) described a case of AIR of a non-restorable central incisor using forced orthodontic eruption, immediate AIR, and an all-ceramic restoration. Chu et al. (2) reported using immediate AIR to replace a periodontally involved misaligned lateral incisor. Paolantoni, et al. (3) described a case of AIR of a central incisor. In 2008, Peñarrocha et al. (4) described a series of 10 AIR in lateral incisor sites, all of which were subjected to immediate rehabilitation with provisional acrylic resin crowns in non-occlusal loading. One implant failed 3 weeks after AIR because of acute local trauma. The other nine AIRs remained functional within the mouth, with standard clinical and radiological characteristics after a minimum follow-up period of 12 months. The authors concluded that immediate AIR in maxillary lateral incisors offers an esthetic solution, eliminates the need for a removable provisional restoration, and avoids implant failures associated with excess cement or screw loosening.

Moreover, in the case of extractions, immediate AIR and provisionalization in maxillary lateral incisors can effectively optimize the peri-implant esthetic results by maintaining the existing hard and soft tissue architecture of the replaced tooth, thereby reducing the possibility of bone resorption caused by bacteria (5). In 2009, Degidi et al. (6) compared the bone loss pattern and soft tissue healing of immediate AIR versus one-stage loaded 3.0mm diameter implants in cases involving a single missing lateral maxillary incisor. Sixty patients with a missing lateral incisor in the maxilla were randomized to one of the treatments: 30 patients in the immediate AIR group and 30 in the one-stage group. All AIRs were placed in healed sites and had to be inserted with a torque >25 Ncm. The AIR in the immediate restoration group were fitted with a non-occluding temporary crown on the day of surgery. Both AIR groups received rehabilitation 6 months after surgery. Probing depth, bleeding on probing, and bone loss of AIRs were assessed at 6, 12, 24, and 36 months follow-up periods. Sixty 3.0mm diameter implants were placed. All AIRs were clinically stable at the 6-month follow-up.

No statistically significant differences were observed for bleeding on probing or plaque index. No implant fractures occurred. At the 36-month follow-up, no statistically significant difference was detected between the two procedures of AIR. Thus, the authors concluded that in the AIR of a single missing lateral maxillary incisor, no statistically significant difference was assessed between immediate and one-stage AIR about bone loss and probing depth. Implants with 3 millimetres of diameter proved to be a predictable treatment option.

Here we evaluate a series of spiral implants (Alpha Bio LTD, Petah-Tikva, Israel) to verify their effectiveness of AIR of upper and lower jaws.

## 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 (7-9). The study population comprised 50 patients (24 female and 26 male, median age 54 years, min 21 - 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, 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 the survival rate (i.e., SVR), which is 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 (10).

*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 (11, 12).

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. Unfortunately, we were not allowed to perform a second CT because of the number of X-rays delivered. Therefore, the measurement was rounded off to the nearest 0.1 mm (Fig. 1, 2).

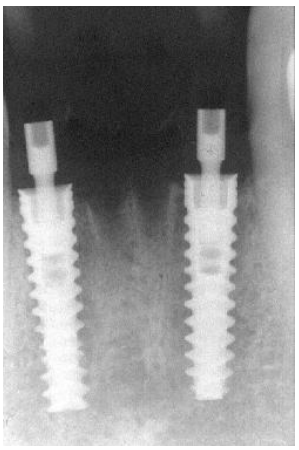

**Fig.1.** *Periapical radiograph performed immediately after implant placement in the incisor lower jaw area.*

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 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. In addition, 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 (13).

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 gender, 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% ($p<.05$). During the regression analysis, the odds ratio and 95% confidence bounds were calculated. Confidence bounds did not have to include the value «1» (14). Stepwise Cox analysis allowed us to detect the variables most associated with implant survival and/or clinical success.

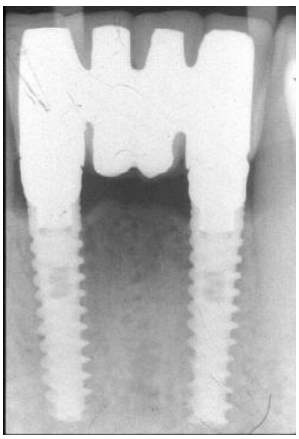

**Fig. 2.** *A second periapical impression was performed at the end of the period of follow up.*

## RESULTS

From June 2010 to June 2014, 234 spiral implants were inserted in patients. Specifically, 50 fixtures were inserted to replace missing incisors. Twenty-four were inserted in females and 26 in males with a median age of 55 (max-min 29-77, STD = 14 years). Twenty-one were in post-extractive sites and 21 in native bone. Flapless surgery was performed in 25 cases. Computer-guided surgery was done in 6 cases.

Thirty-three were placed in the maxilla and 17 in the mandible. Thirty-two were immediately loaded. Thirty-one had a fixed prosthesis. Two failed (i.e., survival rate SVR =96%), and 5 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%). The mean follow-up was 18 months (max-min 1-41, STD = 10 months). Implant length was 11.5, 13 and 16 mm in 2, 15, and 33 cases, respectively. Implant diameter was 3.75, 4.2, 5 and 6 mm in 7, 30, 12, and one case, respectively, and diameter ranged from 10 to 16 mm and from 3.75 to 6.0 mm, 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 | .892 | .877 |
| Post-extractive/Native site | 1 | .098 | 5.428 |
| Flapped / Flapless | 1 | .366 | .503 |
| Computer Guided Surgery | 1 | .976 | .000 |
| Mandible/Mandible | 1 | .084 | 5.703 |
| Implant Type (SPI/SFB) | 1 | .485 | .484 |
| Immediate/Delayed Loading | 1 | .853 | 1.208 |
| Number of Prosthetic Units | 1 | .238 | .187 |
| Type of Edentulous | 1 | .750 | 1.304 |

## DISCUSSION

In 2011, Turkyilmaz et al. (15) described the AIR of a maxillary peg-shaped lateral incisor with the placement of an immediate AIR and a provisional restoration following a minimally invasive extraction to preserve anterior esthetics. Extraction sites in the anterior maxilla can present restorative challenges regarding esthetics. Additionally, resistance to wearing a temporary removable partial denture during healing makes immediate AIR an appealing alternative to patients.

AIR into fresh extraction sockets using no flap elevation has become more popular recently because of advantages such as less bleeding, less swelling, and the preservation of existing soft tissue contours. For example, a 20-year-old woman with a peg-shaped maxillary left lateral incisor was treated using an AIR placed into the fresh extraction socket using a flapless approach and immediate provisional crown fabrication. Flapless AIR helps to preserve site morphology by protecting and supporting existing hard and soft tissues while minimizing surgical trauma to the adjacent tissues. In addition, by using a previously fabricated acrylic index, a provisional acrylic crown was fabricated on the AIR and delivered to the patient on the same day during the extraction visit. Thus, the authors concluded that flapless AIR into fresh extraction sockets and placement of immediate provisional crowns in cases involving the maxillary anterior region represents a viable treatment option when aesthetics are a priority.

The AIR preserves optimum gingival contours, and papillary height may be a viable option compared with fixed partial dentures. In 2012, Sekine et al. (16) reported a 67-year-old female with a maxillary central incisor root fracture who underwent AIR immediately after extraction to shorten the treatment period. The prosthetic rehabilitation was placed on the implant after a 4-month healing period. A review performed 5 years after the AIR loading revealed no clinical problems. Thus, they concluded that the treatment time was shortened effectively by the flapless immediate post-extraction AIR procedure. In addition, immediate post-extraction AIR based on proper examination and diagnosis would reduce patient burden.

Previously, we investigated the reliability of spiral implants in various clinical situations (7-9). Spiral implants should be very effective for AIR also. Spiral implants show a conical internal helix and a variable thread design that confers the characteristic of self-drilling, self-tapping, and self-bone condensing. These proprieties offer better control during AIR and high initial stabilization even in poor-quality bone. A small-diameter drilling results in reduced trauma and minimal bone loss during AIR. Spiral implants' (SPI) location and orientation can be altered even after initial insertion without trauma to the surrounding tissues. The advantages of SPI are particularly obvious in compromised situations where there is a minimal amount of 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 the SPI allows it to be inserted into sites prepared to a reduced depth. This ability becomes useful in situations of proximity to anatomical structures such as the mandibular nerve canal or the maxillary sinus and nasal cavity. The spiral family implants are composed of 2 types of implants, the spiral implants and the spiral flare bevel. This type of implant has a reverse conical head that allows for an increased volume of crestal bone around the implant neck. That accounts for additional benefits such as a closer placement of adjacent implants without compromising tissue health and aesthetic outcome.

## CONCLUSIONS

In the present report, the SVR and SCR were 96% and 90%, respectively. Furthermore, statistical analysis demonstrated that no studied variable impacts the survival (i.e., lost implants) and clinical success (i.e., crestal bone resorption), so SPI effectively restores the aesthetic zone of upper and lower jaws.

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