Spiral Implants Bearing Full-Arch Rehabilitation: Analysis of Clinical Outcome

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A spiral implant (SPI) is a conical internal helix implant with a variable thread design which confers the characteristic of self drilling, self tapping, and self bone condensing. The effectiveness of this type of implant has been reported in several clinical situations. However, because there are no reports that specifically focus on one of the biggest challenges in oral rehabilitation, that is, full arch rehabilitation, it was decided to perform a retrospective study. The study population was composed of 23 patients (12 women and 11 men, median age 57 years) for evaluation and implant treatment between January 2005 and June 2009. Two-hundred six spiral family implants (SFIs) were inserted with a mean postloading follow-up of 23 months. Several variables were investigated: demographic (age and gender), anatomic (maxilla and mandible, tooth site), implant (type, length, and diameter), surgical (surgeon, postextractive, flapless technique, grafts), and prosthetic (implant/crown ratio, dentition in the antagonist arch, type of loading, and computerized tomography [CT] planning) variables. Implant loss and peri-implant bone resorption were evaluated. Univariate and multivariate tests were performed. Survival and success rates were 97.1% and 82.5%, respectively. Only implant length and implant/crown ratio showed statistical significance in determining a better clinical outcome. In conclusion, SFIs are a reliable tool for the most difficult cases of oral rehabilitation. No differences were detected among implant type. Length and implant/crown ratio can influence the crestal bone resorption with better result for longer fixtures and a higher implant/crown ratio. In addition, banked bone derived from living donors can be used to restore alveolar ridge augmentation without adverse effects. Finally, flapless and CT-planned surgery did not significantly increase the clinical outcome in most complex rehabilitation.

Key Words: spiral implant, full arch, CT-planned, banked bone, oral rehabilitation

INTRODUCTION

A spiral implant (SPI) is a conical internal helix implant with a variable thread design that confers the characteristic of self drilling, self tapping, and

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self bone condensing.[1–3] These proprieties offer better control during insertion and high initial stabilization, even in poor quality bone. Small diameter drilling results in reduced trauma and minimal bone loss. Location and orientation of implant can be altered even after initial insertion without trauma to the surrounding tissues. Its advantages are particularly obvious in compromised situations where there is 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 implant allows it to be inserted into sites that have been prepared to a reduced depth. This ability becomes very useful in situations of close proximity to anatomic structures such as the mandibular nerve canal or the maxillary sinus and nose cavity.

The spiral family implants (SFIs) are composed of 2 types of implants, the SPI 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 that accounts for some additional benefits, that is, as a closer placement of adjacent implants without compromising health tissues and esthetic outcome.

The effectiveness of these types of implants was demonstrated in several clinical situations.[1–3] However, because there are no reports that specifically focus on one of the biggest challenges in oral rehabilitation, that is, the full arch rehabilitation, we therefore decide to perform a retrospective study on 206 SFIs bearing full arches.

Materials and Methods

Study design/sample

To address the research purpose, the investigators designed a retrospective cohort study. The study population was composed of 23 patients (12 women and 11 men, median age 57 years) for evaluation and implant treatment between January 2005 and June 2009. Informed written consent approved by the local ethics committee was obtained from patients for research purposes.

Subjects were screened according to the following inclusion criteria: controlled oral hygiene and the absence of any lesions in the oral cavity. The patients also had to agree to participate in a postoperative check-up program.

The exclusion criteria were as follows: smoking more than 20 cigarettes per day; excessive consumption of alcohol (ie, more than 2 glasses of wine per day); localized radiation therapy of the oral cavity; antitumor chemotherapy; liver, blood, or kidney diseases; immunosuppressed patients; patients taking corticosteroids; pregnant women; and inflammatory or autoimmune diseases of the oral cavity.

Computer planned implantology

The protocol was previously reported.[4] In summary, the method is based on the transfer of geometric and mathematical values relative to implants 3-dimensional (3D) position obtained by computerized tomography (CT) and elaborated with a computer program (Implant 3D Software Media-Lab Co, La Spezia, Italy) to the custom model by means of a 3D parallelometer called Ray-Set apparatus (Biaggini Medical Devices, La Spezia, Italy). The Ray-Set apparatus transfers data from the virtual to the real dimension, and it allows verifying the planned rehabilitation on the model.

Bone grafts

Four patients underwent the grafting procedure, all of which were performed with inlay technique in the maxilla after a Le Fort I osteotomy. Autologous iliac crest bone was used in 1 case, whereas fresh-frozen bone derived from healthy donors (who underwent to hip substitution) was used in the remaining 3 cases. Bone specimens were prepared, tested, and stored as previously reported.[5]

Variables

Several variables were investigated: demographic (age and gender), anatomic (maxilla and mandible, tooth site), implant (type, length, and diameter), surgical (surgeon, postextractive, flapless technique, grafts), and prosthetic (implant/crown ratio, dentition in the antagonist arch, type of loading, and CT planning) variables.

Primary and secondary predictors of clinical outcome were used. The primary predictor was the presence or absence of the implant at the end of the observation period. It was defined as survival rate (SVR) that was 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 was defined as implant success rate (SCR), and it was 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/y during the following years.[6]

Data collection methods and summary of operative methods

Panoramic radiographs and CT scans were taken before surgery.

In each patient, peri-implant crestal bone levels were evaluated by the calibrated examination of periapical radiographs. Measurements were recorded before surgery, after surgery, 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 scan was not performed because of the quantity of X rays delivered. The measurement was rounded off to the nearest 0.1 mm. A periapical radiograph was impressed by means of 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 radiographs were taken using a long X-ray tube at 70 Kw of power, and performed with a computer system (Gendex, KaVo ITALIA Srl, Genova, Italia) and saved in an uncompressed TIFF format for classification. Each file was processed with the Windows XP Professional operating system using Photoshop 7.0 (Adobe, San Jose, Calif), and shown on a 17-inch SXGA TFT LCD display with a NVIDIA GÈ Force FX GO 5600, 64 MB video card (Acer Aspire 1703SM-2.6, San Jose, Calif). Knowing the known dimensions of the implant, it was possible to establish the distance from the mesial and distal edges of the implant platform to the point of bone-implant contact (expressed in tenths of a millimeter).

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.[7,8]

All patients underwent the same surgical protocol. An antimicrobial prophylaxis was administered with 500 mg amoxicillin twice daily for 5 days starting 1 hour before surgery. Local anesthesia was induced by infiltration with articaine/epinephrine, and postsurgical analgesic treatment was performed with 100 mg nimesulide twice daily for 3 days. Oral hygiene instructions were provided.

After placing the surgical guide, mucotomy was performed (in flapless cases), bone

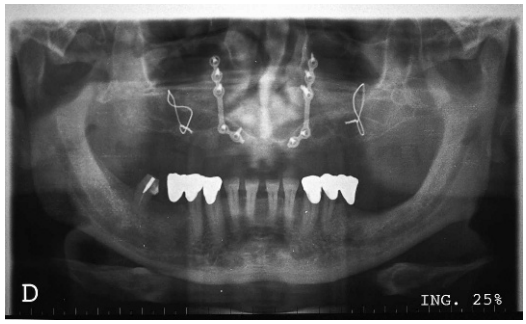

Figure 1. Orthopantomography showing the inlay bone graft inserted into Le Fort I osteotomy.

drilled and implants inserted as previously planned with CT-planned protocol (in CT-planned cases). No surgical guide was used for "free-hand" inserted implants. The implant platform was positioned at the alveolar crest level and provisional restoration was delivered immediately. After 8 weeks, the final restoration was delivered (Figures 1 through 4). The implant/crown ratio ranged from 0.4 to 0.8. All patients were included in a strict hygiene recall.

Data analysis

Disease-specific survival curves were calculated according to the product-limit method (Kaplan-Meier algorithm).[9] Log-rank testing was used to compare survival/success curves, generated by stratifications for a variable of interest.

Cox regression analysis was then applied to determine the single contribution of covariates on the survival/success rate.[10]

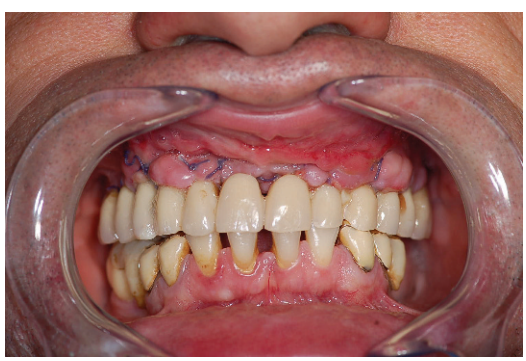

Figure 2. The immediate postsurgical provisional rehabilitation.

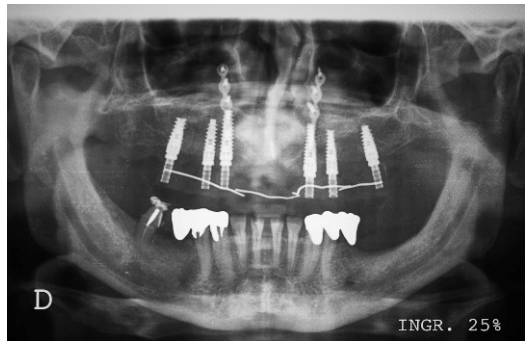

Figure 3. Postimplant orthopantomography.

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

Results

Twenty-three patients (12 women and 11 men, median age 57 years) were enrolled in the present study. They had 206 fixtures. Among the patients 4 were grafted and received 30 implants, whereas 9 had a CT-planned implantology and 91 fixtures inserted. Informed written consent approved by the local ethics committee was obtained from patients to use their data for research purposes. The mean postloading follow-up was 23 months (minimum 6 months, maximum 51 months).

A total of 206 SFIs (3D Alpha-Biomedical Srl, Pescara, Italy) were inserted: 147 (71.4%) into the maxillae and 59 (28.6%) into the mandible. There were 129 SFB implants, 73 SPIs, and 4 short spiral implants. Implant length and diameter ranged from 8 to 16 mm and from 3.75 to 6.0 mm, respectively. Short

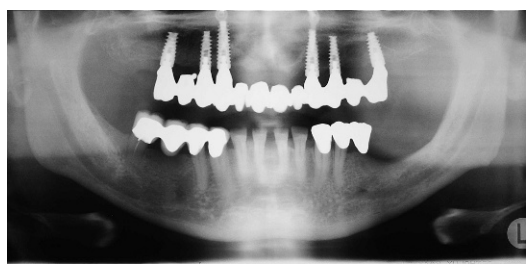

Figure 4. Orthopantomography with the final rehabilitation performed at the end of follow-up.

TABLE 1

Kaplan-Meier algorithm output by using the lost implants (ie, implant survival rate [SVR])*

Variable	Log Rank	*df*	*P* Value
Implant type	9.13	2	.0104
Implant length	11.04	2	.0040
Implant diameter	7.20	2	.0273
Implant site	4.81	3	.1864
Postextractive	0.55	1	.4578
Flapless	0.33	1	.5685
Immediate loading	0.16	1	.6876
Surgeon	1.71	1	.1905
Implant/crown ratio	19.08	5	.0019
Graft	20.25	1	.0001
Upper/lower jaw	4.92	1	.0266
Antagonist arch	2.38	3	.4977
CT-planned	1.84	1	.1747

**df* indicates degree of freedom.

TABLE 2

Kaplan-Meier algorithm output by using higher bone resorption around implant neck (ie, implant success rate [SCR])*

Variable	Log Rank	*df*	*P* Value
Implant type	9.93	2	.0070
Implant length	13.88	2	.0010
Implant diameter	20.80	2	.0001
Implant site	5.71	3	.1264
Postextractive	9.57	1	.0020
Flapless	0.10	1	.7528
Immediate loading	1.04	1	.3088
Surgeon	7.57	1	.0059
Implant/crown ratio	28.41	1	.0001
Graft	17.66	1	.0001
Upper/lower jaw	2.33	1	.1268
Antagonist arch	1.80	3	.6150
CT-planned	1.31	1	.2528

**df* indicates degree of freedom.

(ie, <13 mm), standard (ie, =13 mm), and long (ie, >13 mm) fixtures totaled 69, 76, and 61, respectively. Narrow (ie, <3.75 mm), standard (ie, =3.75 mm), and wide (ie, >3.75 mm) fixtures totaled 5, 89, and 112, respectively. Implants were inserted to replace 53 incisors, 44 cuspids, 68 premolars, and 41 molars. Seventy-seven patients had flapless surgery, and immediate loading with fixed prosthetic restorations was performed in all cases but one. Eighty-one implants were placed in postextractive sockets; the mean implant/crown ratio was 0.6, ranging from 0.4 to 0.8; the antagonist was a natural tooth or crown (ie, natural pillars) in 69 cases, fixtures (ie, metal pillars) in 58 cases, mixed pillars (ie, teeth and implants) in 26 cases, and total or partial removable dentures in the remaining 53 cases.

Six implants were lost. The overall SVR was 97.1%. Univariate analyses demonstrated that graft, upper/lower jaws, implant length, diameter, and type and implant/crown ratio could have an impact on clinical outcome (Table 1). However, multivariate analyses did not detect any differences among variables selected by the log-rank test.

The peri-implant mean bone resorption was 1.2 mm in the observation period (mean value 23 months). Among the 200 implants still in place at the end of follow-up, 35 had greater bone resorption and thus were considered failed in terms of clinical success (ie, SCR). The SCR was 82.5%. By using the SCR, the log-rank test was statistically significant for surgeon; postextractive site; graft; implant length, diameter, and type; and implant/crown ratio (Table 2). Subsequently, Cox analyses confirmed that implant length and implant/crown ratio have a significant impact on the clinical outcome (Table 3) with a worse outcome for short implants and lower implant/crown ratio. Short implants have a mean peri-implant bone loss (ie, delta IAJ) of 1.5 mm, whereas standard plus long fixtures have a mean delta IAJ of 1.1 mm. Full arches with implant/crown ratio of 0.4 have a mean delta IAJ of 1.4 mm, whereas full arches with an implant/crown ratio of 0.5 or higher have a mean delta IAJ of 1.2 mm.

DISCUSSION

Seventy studies have proven the concept of osseointegration to be highly successful. However, to achieve this predictable SVR, a strict protocol should be followed. Researches have challenged several aspects of this rigorous protocol, and their investigations

TABLE 3
Cox regression output*

Variable	*df*	*P* Value	Exp(B)	95% CI for Exp(B)	
				Lower	Upper
Age	1	.6420	1.0089	.9718	1.0474
Gender	1	.8903	1.0713	.4027	2.8499
Implant type	1	.2743	1.7676	.6365	4.9086
Implant length	1	.0005	.4144	.2516	.6826
Implant diameter	1	.2721	.6076	.2498	1.4782
Postextractive	1	.0709	.4326	.1742	1.0741
Surgeon	1	.1197	7.0279	.6026	81.9641
Implant/crown ratio	1	.0171	85.8250	2.2083	3335.5301
Graft	1	.4481	2.7769	.1984	38.8558

**df* indicates degree of freedom.

found the relative importance of each variable with respect to their influence on osseointegration—incision design, sterile protocol, timing of surgery, timing of loading—are but a few examples. Therefore, the identification of guidelines for the long-term SVR (ie, total implants still in place at the end of the follow-up) and SCR (ie, good clinical, radiologic, and esthetic outcome) have been and still are the main goals to achieve good clinical outcome.

All variables that influence the final result are grouped as factors related to (1) surgery, (2) host, (3) implant, and (4) occlusion.[11–15] 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 design, surface coating, and length are the strongest implant-related factors. Finally, quality and quantity of force and type of prosthetic restoration are the variables of interest among the occlusion-related factors. All these variables are substance for scientific investigations because they may affect the clinical outcome.[11–15]

Regarding immediate loading (IL) for full-arch rehabilitation in completely edentulous mandible, several reports have appeared in the last decade and good medium-term SVR and SCR with IL surgical procedures have been reported.[16–22] Starting with a few implants immediately loaded with a bar overdenture in the mandible,[23] the concept of IL evolved to loading multiple implants in both the maxilla[24–27] and mandible.[20,22]

The reported number of implants for completely edentulous mandible rehabilitation ranged from 3[16,23] to 10,[17] the provisional restoration was performed the same day (proper immediate loading)[19] or within 3 days (early loading),[18,21] and the recommended minimum implant length was 10 mm.[18] The SVR ranged from 85% of early publications[16] to over 99% in the recent literature.[20,22] Only few reports have large series with a medium-term follow-up,[20–22] but only one describes the true IL.[20] Because we believe that more studies produced by independent groups are needed before the reproducibility of the method is clearly established, we decided to perform a retrospective study. Here, a large series of 206 implants with only 6 fixtures lost during a mean postloading follow-up of 23 months (SVR = 97.1%) is reported. Because no statistical differences were detected among the studied variables by using the SVR, no or reduced crestal bone resorption was considered an indicator of SCR to evaluate the effect of host, surgery, and implants on clinical outcome.

In general, length (Tables 1 and 3), surface (Table 1), and diameter (Table 3) are considered to be relevant implant-related factors. Tarnow

et al[17] proposed to use implants longer than 10 mm in case of IL. In our series, a different SCR according to length was found (Table 3) with a better outcome with regard to reduced crestal bone loss over time for standard and longer (ie, length $\geq$ 13 mm) fixtures.

No statistical difference was detected with regard to anatomic sites (mandible vs maxillae or tooth site) or surgery-related factors (ie, surgeon, flapless surgery, CT-planned, and postextractive sites).

Flapless implant surgery has been suggested as one possible treatment option for enhancement of implant esthetics because it is easy to perform and is beneficial for patient morbidity.[28] However, by performing this blind procedure, one should be aware of the risk to deviate implants and that accurate positioning of each implant is extremely important for fixed restorations.[22,29] The use of radiographic images is necessary to evaluate the surgical site underneath the soft tissue, and CT images provide an accurate 3D picture of the surgical field.[30–34] In addition, several authors have advocated the use of drill guides[32,35–37] to link the virtual preoperative treatment plan based on the CT images to the situation encountered during surgery. Here, no differences were detected between CT-planned and free-hand surgery.[4]

Bone quality, a host-related factor, is believed to be the strongest predictor of outcome in immediate loading. Misch[38] has reported that most of the immediately loaded implants are placed in anatomic sites with bone quality D1 or D2. Here, 4 patients were grafted and 3 of them with banked bone. No differences were detected between implants inserted in native and grafted bone. These results are similar to those reported from banked bone derived from cadaver.[39–41] Here we proved that femur homograft derived from living donors is a valuable material for grafting jaw: the homograft is cheap, is available in programmed amounts, avoids a second operation field, and is safer than the homograft derived from cadaver.

Finally, several prosthetic-related variables were investigated: loading time, situation of antagonist arch, and implant/crown ratio. This last was statistically significant with a worse outcome for full arches loading few implants.

Conclusion

In conclusion, SFIs are a reliable tool for difficult cases of oral rehabilitation. They have a higher SVR and SCR, which means stable results over time. No differences were detected among implant type. Length and implant/crown ratio can influence the crestal bone resorption with better results for longer fixtures and a higher implant/crown ratio. In addition, banked bone derived from living donors can be used to restore alveolar ridge augmentation without adverse effects. Finally, flapless and CT-planned surgery does not significantly increase the clinical outcome in complex rehabilitation.

Abbreviations

CT: computerized tomography
IAJ: implant abutment junction
IL: immediate loading
SCR: success rate
SFB: spiral flare bevel
SFIs: spiral family implants
SPI: spiral implant
SVR: survival rate

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