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The Clinical Outcomes of 234 Spiral Family Implants

Matteo Danza, MD; Ophir Fromovich, DMD; Riccardo Guidi, DDS; Francesco Carinci, MD

Abstract

Aim: Spiral family implants (SFIs) are a new type of implant fixture with a conical internal helix and a variable thread design. The aim of this retrospective study was to evaluate the clinical outcomes of a series of SFIs.

Methods and Materials: A total of 234 SFIs were placed in 86 patients (55 females and 31 males, median age 53 years) during the period between May 2004 and November 2007. The mean follow-up was 13 months. Several host, surgery, and implant-related factors were investigated, and the Kaplan Meier algorithm and the Cox regression were used to detect variables associated with the clinical outcome.

Results: Only nine out of 234 implants were lost (i.e., survival rate (SVR) of 96.2%) and no differences were detected among the studied variables.

Conclusion: SFIs have a high SVR similar to those reported in previous studies on different implant types.

Clinical Significance: SFIs demonstrated a very high primary stability which offers the potential for use of a specific implant device for immediate loading. However, additional studies are necessary to verify their outcome on the medium/long period.

Keywords: Kaplan Meier algorithm, Cox regression analysis, CRA, dental implant

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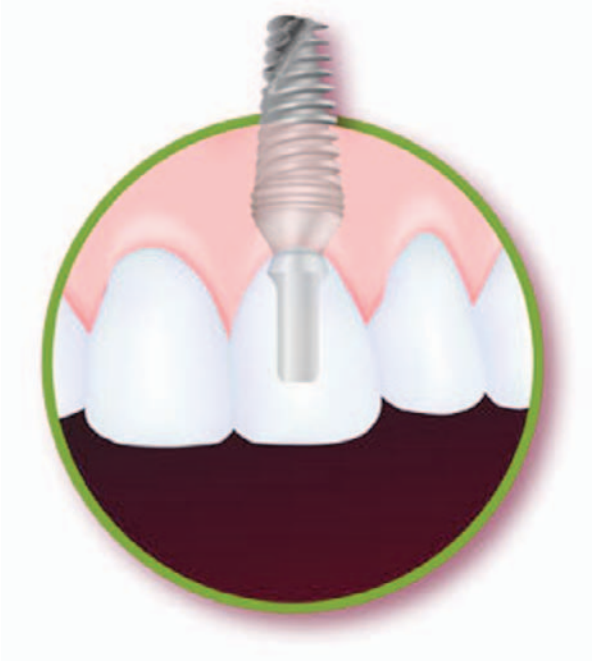
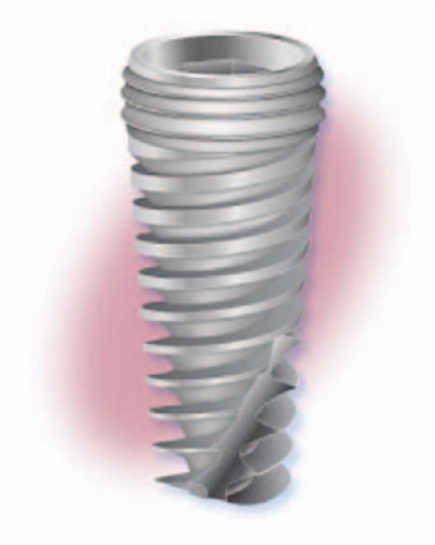


Introduction

A spiral implant is a conical internal helix implant with a variable thread design that offers the clinician the characteristics of self-drilling, self-tapping, and self-bone condensing. These properties 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. The location and orientation of an implant can be altered even after initial insertion without trauma



to the surrounding tissues. Its advantages are particularly obvious in compromised situations with minimal amount of bone and/or low bone density available, when achieving high stabilization in freshly extracted sites is critical, and in the presence of 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 feature is very useful in situations of close proximity to anatomical structures such as the mandibular nerve canal, the maxillary sinus, or the nasal cavity.

SFIs consist of two types of implants: the Spiral Implant (SPI) and the Spiral Flare Bevel (SFB). The SFB has a reverse conical head that allows an increased volume of crestal bone to form around the implant neck, which facilitates closer placement of adjacent implants without compromising healthy tissues and provides an esthetic outcome.

Although SFIs have been available for the last ten years, no clinical reports about them were found in the literature. Therefore, the aim of this retrospective study was to evaluate the clinical outcomes of a series of SFIs.

Methods and Materials

Subjects

During the period between May 2004 and November 2007, 86 patients (55 females and 31 males) with a median age of 53 years received 234 SFIs (Alpha Bio LTD, Petah-Tikva, Israel). The final post-surgical evaluation was performed in December 2007, with a mean follow-up of 13 months.

Subjects were screened according to standard inclusion criteria:[1-3]

- Controlled oral hygiene
- Absence of any mucosal lesions in the oral cavity
- Patient agreement to participate in a post-operative evaluation program

Exclusion criteria were as follows:

- Bruxism
- Smoking more than 20 cigarettes/day
- Localized radiation therapy of the oral cavity
- Antitumor chemotherapy
- Presence of liver, blood, and kidney diseases
- Immunosupressed patients
- Active corticosteroid therapy
- Pregnant women
- Inflammatory and autoimmune diseases of the oral cavity
- Poor oral hygiene

Data Collection

Pre-surgical radiographic examinations were done with the use of orthopantomograph and CT scans and again during the follow-up period. In addition to the radiographic findings, the following parameters were also recorded:[4]

- Absence of persisting pain or dysesthesia
- Absence of peri-implant infection with suppuration
- absence of mobility
- 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 follow-up years.

Implants

A total of 234 SFIs (40 SPI and 194 SFB) were inserted in 86 patients: 88 (37.6 %) in the mandible and 146 (62.4 %) in the maxilla. The diameters and lengths of the SFIs inserted are shown in Table 1.

Implants were inserted to replace 50 incisors (21.4 %), 26 cuspids (11.1 %), 91 premolars (38.9 %), and 67 molars (28.6 %). One hundred one fixtures were inserted in post-extraction sockets and the remaining 133 in healed bone; 129 (55.1%) were immediately loaded.

Table 1. The sizes and numbers of the 234 SFIs inserted in the 86 subjects.

Implant Diameter	Number Inserted	Percentage of 234 SFIs
3.75 mm	24	10.74%
4.20 mm	112	49.9%
5.00 mm	65	27.8%
6.00 mm	33	11.6%
Implant Length	**Number**	**Percentage of 234 SFIs**
<13 mm	94	40.2%
13 mm	76	32.5%
16 mm	64	27.3%

Surgical and Prosthetic Technique

All patients underwent the same surgical protocol. An antimicrobial prophylaxis was administered using 500 mg Amoxycillin twice daily for five days starting one hour before surgery. Local anesthesia was induced by infiltration with articaine/epinephrine and post-surgical analgesic treatment was performed with 100 mg Nimesulid twice daily for five days. Oral hygiene instructions were provided.

After making a crestal incision a mucoperiosteal flap was elevated. In several cases a mucotomy was performed. Implants were inserted according to the procedures recommended by the manufacturer. The implant platform was positioned at the alveolar crest level. Sutures, if used, were removed 14 days after surgery. In case of delayed loading, the provisional prosthesis was provided after 24 weeks from implant insertion and in all cases the final restoration was usually delivered within an additional eight weeks following surgery. The number of prosthetic units (i.e., implant/crown ratio) was about 0.8. Fifty-one (21.8%) implants were inserted in patients with totally edentulous jaws. The antagonists were natural teeth and prosthetic crowns in 115 (49.1%) and 119 (50.9%) cases, respectively. Implants bore fixed and removable restorations in 219 (93.6%) and 12 (5.1%) cases respectively. Three implants were lost before prosthetic rehabilitation. All patients participated in a strict hygiene recall program (Figures 1-6).

Figure 1. A spiral family implant.

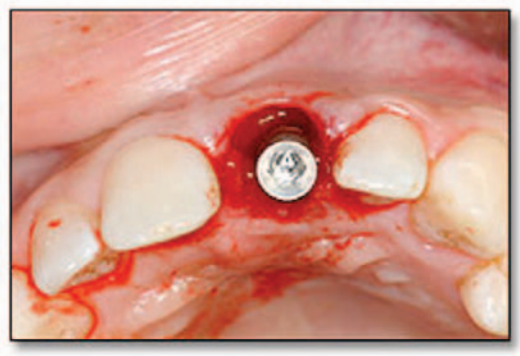


Figure 2. Post-extractive implant inserted to replace a central incisor.

Statistical Analysis

Disease-specific survival curves were calculated according to the product-limit method (Kaplan-Meier algorithm).[5] Time zero was defined as the date of the implant insertion. Implants, which are

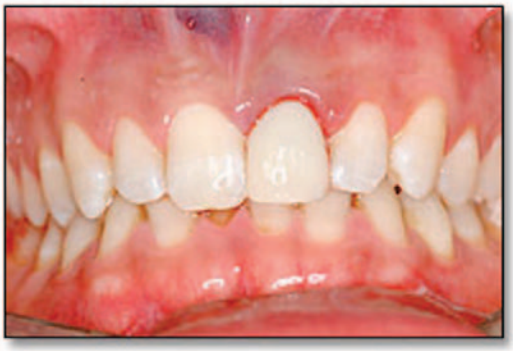


Figure 3. The immediate provisional prosthetic result.

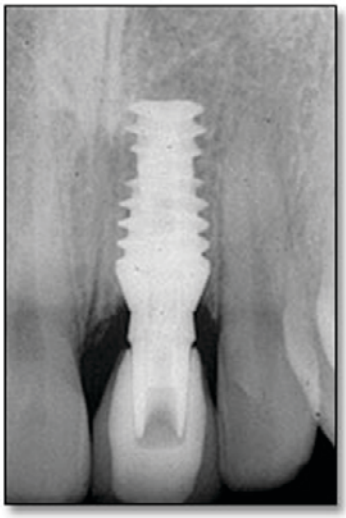


Figure 4. The immediate periapical control (showing a gap between the provisional restoration and the abutment).

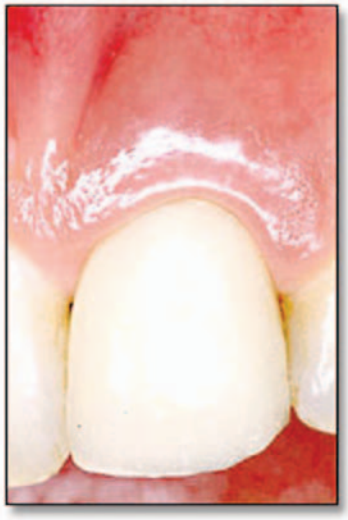


Figure 5. The final prosthetic rehabilitation.

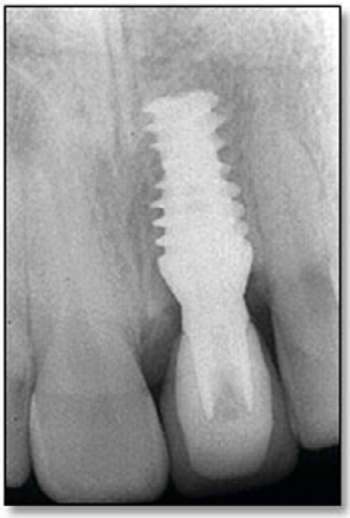


Figure 6. The twelve months periapical control.

still in place, were included in the total number at risk of loss only up to the time of their last follow-up. Therefore, the survival rate only changed when implant loss occurred. The calculated survival rate was the maximum estimate of the true survival curve. Log rank testing was used to compare survival curves, generated by stratifications for a variable of interest.

The Cox regression analysis (CRA) was then applied to determine the single contribution of covariates on the SVR. The CRA compares survival data while taking into account the statistical value of independent variables, such as age and sex, on whether or not an event (i.e., implant loss) is likely to occur. If the associated probability was less than 5% ($p<.05$), the difference was considered statistically significant. In the process of doing the regression analysis, odds ratio and 95% confidence bounds were calculated. Confidence bounds did not have to include the value 1.[6] Use of a stepwise CRA facilitated the detection of the variables most associated with implant survival.

Results

Nine of the 234 implants were lost (five in the post-operative period, i.e., within one month) and Table 2 describes their characteristics.

The investigated variables were implant length, diameter, and subtype; age and gender of patients; upper/lower jaw, site, and post-extractive/healed bone; type of prosthesis, number of prosthetic units (NPU), type of edentulism, and type of antagonist element.

Table 2. Failed implants.

Implant Diameter	Implant Length	Graft Site	Implant Site	Implant Type	Months	Prothesis	Immediate Loading
3.75	16.0	Maxilla	11	SPI	1	Fixed	No
3.75	16.0	Maxilla	13	SPI	1	None	No
4.20	13.0	Mandible	34	SPI	1	Fixed	Yes
6.00	11.5	Maxilla	25	SPI	41	Fixed	No
4.20	10.0	Maxilla	25	SFB	15	None	No
5.00	16.0	Maxilla	21	SFB	1	None	No
5.00	11.5	Maxilla	16	SFB	18	Fixed	Yes
5.00	10.0	Maxilla	25	SFB	11	Overdenture	Yes
4.20	11.5	Mandible	46	SFB	7	Fixed	No

Note: Implant site is identified by the tooth number (FDI) replaced.

Table 3. Kaplan Meier algorithm output.

Variable	Log Rank	df	p value
Imp-type	2.86	1	.0909
Imp-length	1.59	2	.4509
Imp-diameter	2.66	3	.4478
Imp-site	0.16	3	.9844
Mandible/maxilla	0.68	1	.4080
Post-extractive	3.63	1	.0567
Prosthesis	3.40	1	.0651
NPU	0.88	3	.8300
Endentulness	0.60	1	.4403
Antagonist	0.02	1	.8778
Immediate loading	5.62	1	.0178

df = degree of freedom, **Imp** = implant, **NPU** = number of prosthetic units.

Table 4. CRA output.

Variable	df	p value	Exp (B)	95% CI for Exp (B)	
				Lower	Upper
Age	1	.7638	1.0126	.9330	1.0991
Gender	1	.2697	.2007	.0116	3.4757
Immediate loading	1	.3777	.3363	.0299	3.7867
Post-extractive	1	.5472	1.8167	.2601	12.6893
Prosthesis	1	.0835	19.1613	.6764	542.7729

df = degree of freedom, **Imp** = implant, **NPU** = number of prosthetic units.

In univariate analysis, type of loading was statistically significant (see Table 3, Kaplan Meier algorithm, Log rank = 5.62, df = 1, p = .0178), whereas the type of prosthetic restoration and post-extractive site reached a borderline value (Log rank = 3.4, df = 1, p = .0651, and Log rank = 3.63, df = 1, p = .0567, respectively). Implant type does not have an impact on SVR.

In multivariate analysis, none of the studied variables has a statistical impact on the clinical outcome (Table 4).

Discussion

Identification of guidelines for SVR is a main goal of the recent literature. Several variables can influence the clinical outcome and are generally grouped as factors related to the following:[7]

- The surgical event
- The characteristics of the host
- Implant characteristics
- Occlusal characteristics

Surgery-related factors consist of such variables as excessive surgical trauma as a result of thermal injury[8], bone preparation,[9] as well as lack of drill sharpness and poor design.[10] Bone quality and quantity are the most important host-related factors,[11-14] while design,[15-17] surface coating,[12,15,18] diameter and length[14] are the most important implant-related factors. Finally, quality and quantity of force[19,20] and prosthetic design[21-23] are the variables of interest among the occlusion-related factors. All these variables are a matter of scientific investigation since they may affect the clinical outcome.

The present study reports a series of 234 SFIs with only nine implants lost during a mean follow-up of 13 months (SVR = 96.2%). Although the short observation period, the SVR is comparable to those of different implant types.[1-3] In general, length and diameter are considered relevant implant-related factors.[1-3] However, implant length, diameter, and subtype (i.e., SPI vs. SFB) were not critical factors that influence the SVR.

Bone quality is believed to be one of the strongest predictors of outcome. Bone quality is higher in the mandible (especially the interforaminal region) than in the maxilla and may account for the high SVR of immediately loaded implants inserted into the mandible reported in the literature.[24,25] Implant immediate loading is an example of a critical procedure in implantology. In the present study, no differences were detected with regard to implant site (i.e., incisor, cuspid, premolar, molar, or jaw location). The same was true of post-extraction vs. healed bone site implantations. These data suggest SFIs can be successfully used in critical sites.

Among the occlusal-related factors, no differences were detected with regard to the number of prosthetic units (NPUs).Three groups were considered with regard to the NPU: NPU less than 0.5; NPU equal to or higher than 0.5 but less than 1, and NPU equal to 1. Additional occlusal-related factors such as the type of edentulism (total vs. partial), type of antagonist element (prosthetic vs. natural tooth), type of prosthetic restoration (removable vs. fixed), and type of loading (immediate vs. delayed) were considered. This finding was of particular interest as the two compared groups were statistically balanced (129 vs. 105 cases). This means an SFI can be successfully used in immediate loading without any additional prosthetic procedure needed to augment implant stability.[26]

Conclusion

SFIs have a high SVR similar to those reported for different implant types. Additional studies with a longer observation period are needed to verify the effectiveness of SFIs over time.

Clinical Significance

SFIs demonstrated a very high primary stability that offers the potential for use of a specific implant device for immediate loading. However, additional studies are necessary to verify their outcome on the medium/long period.

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