A 5-Year Prospective Clinical Study of Submerged and Nonsubmerged Paragon System Implants in the Edentulous Mandible

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Purpose: The aim of this investigation was to evaluate the clinical outcome of two different surgical protocols in the edentulous mandible: submerged and nonsubmerged. Further, the Paragon dental implant with a titanium plasma-sprayed surface was evaluated. ***Materials and Methods:*** Twenty-nine consecutively treated patients with 168 implants supporting fixed prostheses were included. All but 3 patients were provided 6 implants, placed via nonsubmerged healing on one side and submerged healing on the other. Data were collected from patient records and radiographs. Twenty-four patients participated in the 5-year clinical follow-up examination. ***Results:*** After 5 years, all patients still had their mandibular fixed prostheses in function. Cumulative survival rates were 100% for prostheses and 99.4% for implants. However, 3 implants fractured in 1 patient. One submerged implant was lost before loading but no further implants were lost during follow-up. The radiographic bone loss was small for all implants with a mean of 0.14 mm (standard deviation [SD]: 0.37) at 1 year and 0.42 mm (SD: 0.48) at 5 years for nonsubmerged implants and 0.17 mm (SD: 0.32) at 1 year and 0.51 mm (SD: 0.33) at 5 years for submerged implants. Nineteen implants (including the 3 that fractured) presented annual bone loss exceeding 0.2 mm after the first year, yielding a cumulative success rate of 86.2% after 5 years. ***Conclusion:*** Single-stage surgery was shown to have the same predictability as two-stage surgery in the anterior edentulous mandible. Paragon implants with a titanium plasma-sprayed surface showed a fracture rate of 2.2% and a success rate of 86.2% after 5 years. *Int J Prosthodont 2010;23:231–238.*

Osseointegrated dental implants made of commercially pure titanium have been used successfully for more than 35 years for the replacement of missing teeth.[1–3] The original Brånemark concept prescribed two-stage surgery with a submerged healing period of 3 months in the mandible and 6 months in the maxilla. The predictable outcome of this two-stage insertion technique has been established in several studies.[4–9] More recent studies have shown that osseointegration can be achieved with equally promising results using single-stage surgery in both edentulous and partially edentulous arches.[10–16] However, divergent results have been presented.[17,18] The use of single-stage surgery has gained more and more interest since it reduces surgical intervention, thus reducing surgical time and patient discomfort, and produces healed and healthy peri-implant mucosa at the time of prosthetic rehabilitation. Few prospective clinical studies have been published comparing the two different surgical approaches in the same patient.[19,20] Some studies on single-stage surgery use exclusion criteria such as bruxism and heavy smoking.[11,16,17,20,21] These patients are sometimes included in studies on completely edentulous mandibles using the two-stage technique, which thereby makes it difficult to compare results from different studies.[6,21] Consequently, randomized controlled trials are best suited to evaluate different interventions.[22]

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The present study was designed to evaluate single-stage and two-stage surgery in the same patient using a split-mouth technique and Paragon dental implants (DBA Paragon) in the edentulous mandible. The hypothesis was that there would be no difference in results between the two surgical methods concerning implant survival and bone loss. An additional aim was to evaluate the Paragon dental implant system.

Materials and Methods

The study population consisted of patients consecutively referred to the Department of Prosthetic Dentistry, Public Dental Health Service, Uppsala, Sweden, between April 1998 and October 1999 for treatment with a full-arch implant-supported fixed prosthesis (ISFP). A total of 29 patients (16 men, 13 women) with a mean age of 65 years met the inclusion criteria and received a total of 168 implants. The only exclusion criterion was poor general health. General health was assessed according to the American Society of Anesthesiologist classification, and under-compensated patients (ASA III) were not entered into the study[23] (to avoid dropouts). Ten of the included patients were smokers; 2 were heavy smokers (> 15 cigarettes/day). Before commencing the study, ethical approval was obtained from the regional ethical committee. All patients received oral and written information about the study and those who agreed to participate gave their written consent.

Surgical Procedures

Twenty-six patients received six Paragon implants each and three patients received four implants each. The reason for inserting only four implants was because of anatomical restrictions preventing the placement of six implants; since implants were to be evaluated pairwise, the placement of five implants was not an option. All implants were 3.75-mm-diameter screw-shaped implants with a titanium plasma-sprayed surface treatment (TPS). Patients were randomly assigned (by drawing cards) to receive a two-stage procedure with submerged healing on one side of the mandible and single-stage surgery and nonsubmerged healing on the opposite side, and the implants were inserted accordingly. One hour prior to surgery, patients received premedication: one single dose of 3 g amoxicillin (Imacillin, AstraZeneca) and oral sedation with diazepam 0.2 mg/kg (Stesolid, Alpharma). All surgeries were performed under local anesthesia according to the standard protocols for the respective technique[2,17] by one of two credentialed oral surgical specialists with extensive experience in implant surgery. Bone quantity and quality was recorded at the time of implant placement according to Lekholm and Zarb.[24]

Implant sites were prepared using standard drills with a final twist drill of 3.0-mm diameter. Healing abutments (0.75- or 2.0-mm long) were connected on the nonsubmerged implants. During the primary healing period, chemical plaque control was recommended via rinsing with a 0.1% chlorhexidine solution twice daily for 1 week. Sutures were removed after 7 to 10 days. Two patients did not accept wearing a removable complete prosthesis during the healing period. Stage-two surgery and healing abutment connection was performed on submerged implants 3 to 4 months after placement.

Prosthetic Procedures

Prosthetic treatment was performed by one of three credentialed prosthodontic specialists. The mandibular dentures were adjusted and provided with a soft relining material (CoeSoft, GC America) 1 to 2 weeks after implant placement. The relining material was normally replaced once a month during the healing period. One to 2 weeks after stage-two surgery, 2-mm-long standard abutments were connected on all but five implants, where shorter abutments were used, and tightened in accordance with the manufacturer's instructions. Impressions were made using impression copings, custom-made trays, and polyether impression material (Impregum NF, 3M ESPE). Prosthetic treatment followed a routine protocol at the specialist clinic.

All patients received a full-arch ISFP provided with distal cantilevers ranging from 9 to 21 mm (mean: 14.7 mm) with no significant differences between the sides. The prostheses were fabricated in type III gold alloy (C3 gold, KAR Sjödings) with acrylic resin teeth (SR Vivodent, Ivoclar Vivadent) cured to the framework using acrylic resin (ProBase Hot, Ivoclar Vivadent). Twenty-seven prostheses were provided with 12 acrylic teeth and 2 were provided with only 10 teeth due to a short interforaminal distance. Fourteen patients had an ISFP in the maxilla, while 10 had natural teeth or fixed partial dentures. The remaining 5 were edentulous or partially edentulous and wore a removable denture.

Follow-up

In accordance with study protocol, the prostheses were removed at yearly checkups and the stability of the retaining and abutment screws were recorded. The screws were tested for stability by applying a 15-Ncm tightening force with a torque wrench, and if rotation of more than a quarter of a turn was possible, the screws were classified as loose. The technique was previously described by Ekfeldt and colleagues.[25] Baseline evaluations included registration of the peri-implant soft tissue, oral hygiene, occlusal conditions, and stability of

Table 1 Life Table Analysis of Implants Placed and Lost During 5 Years and the Number of Patients Examined and Lost to Follow-up

Period	Placed/examined		Failed		Lost to follow-up		CSR	
	Prostheses (n = 29)	Implants (n = 168)	Prostheses	Implants	Prostheses	Implants	Prostheses (%)	Implants (%)
1st surgery	–	168	–	1	–	–	–	99.4
Loaded	29	168	–	–	–	–	100	99.4
1 y	27	156	–	–	2	12	100	99.4
2 y	25	144	–	–	2	12	100	99.4
3 y	24	138	–	–	1	6	100	99.4
4 y	24	138	–	–	–	–	100	99.4
5 y	24	138	–	–	–	–	100	99.4

CSR = cumulative survival rate.

the prostheses and individual implants. These were repeated after 6 months, 12 months, and at subsequent yearly checkups throughout follow-up. In some cases, additional visits to a dental hygienist were performed to improve oral hygiene. Radiographic examination was performed when the prostheses were delivered and at subsequent 12- and 60-month follow-ups. Radiographic examinations were performed at the department of oral radiology using standardized periapical radiographs with the paralleling technique. However, in two patients, this was not possible and panoramic radiographs were used instead. At the 5-year checkup, all prostheses were removed and the stability of the individual abutments and implants was tested clinically for immobility, in accordance with the success criteria proposed by Albrektsson and coworkers.[26]

The 5-year follow-up examinations and rereading of all radiographs were performed by an independent prosthodontist not involved in any of the treatments. A Peak scale loupe with a magnifying factor of ×7 and a scale graded in 0.1-mm increments was used, the bone level was assessed to the closest 0.3 mm in relation to the implant-abutment junction at the mesial and distal surface of the implant, and the mean of the mesial and distal measurements was used.[27] Only patients with standardized periapical radiographs were included in the statistical analyses for bone loss.

All evaluations (clinical and radiographic) were blinded. The evaluations included an interview (which covered issues such as type and number of drugs used daily, general health, smoking habits, temporomandibular disorder symptoms, and discomfort associated with the manufacturing and use of the implant-supported prosthesis), in addition to general records and a clinical examination.

Clinical examination included registration of the peri-implant mucosa and stability of the prosthesis, retaining screws, and implants.

Table 2 Number and Lengths of Submerged and Nonsubmerged Implants

Implant length	Submerged	Nonsubmerged	Total
10 mm	2	2	4
13 mm	13	20	33
16 mm	69	62	131
Total	84	84	168

Statistical Analysis

Conventional descriptive statistics were used for descriptive purposes. A paired Student *t* test was used to evaluate bone level changes at the implants placed according to submerged and nonsubmerged procedures. One-way analysis of variance was used to evaluate bone loss at implants with or without attached peri-implant mucosa (healthy or not). All statistical analyses were done using SPSS version 15.0 (SPSS). The significance level was set at $P < .05$.

Results

Twenty-four of the original 29 patients were followed over the entire study period; 3 patients died and 2 patients could not attend the 5-year follow-up due to severe illness (Table 1). Two deaths occurred during the first year of follow-up and baseline radiographs were not obtained for 1 of those patients; 1-year registrations are missing for both. The number and lengths of the implants placed with the single-stage and two-stage procedures are presented in Table 2. Unscheduled visits were registered for 3 patients during the first year, 5 patients during the second year, 3 patients during the third year, and 1 patient during the fourth year for a variety of complications; no unscheduled visits occurred during the fifth year.

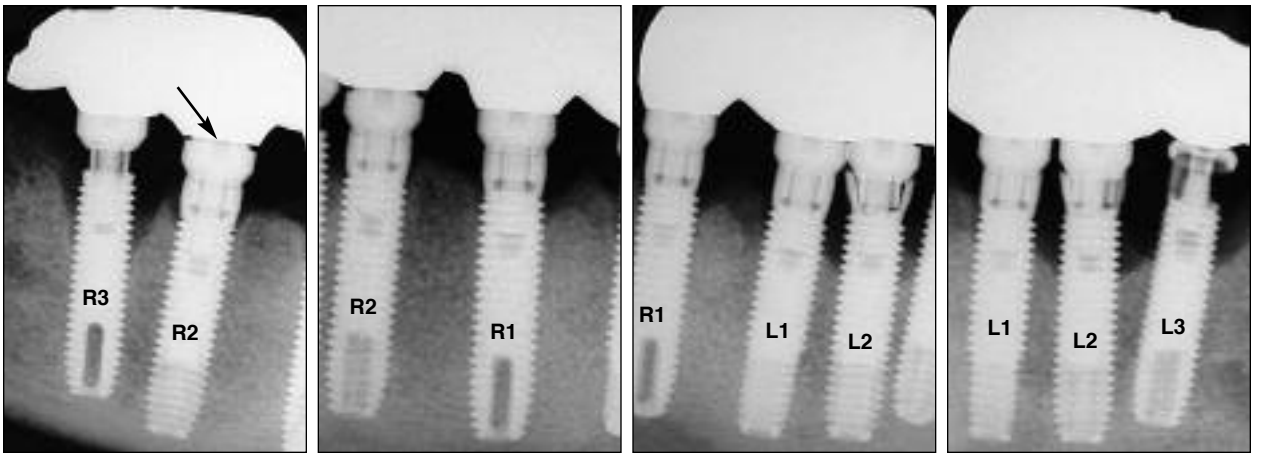

Fig 1 Radiographs of a fixed prosthesis displaying a gap at the prosthesis-abutment junction of implant R2 *(arrow)* and fractured implants R3, L2, and L3 in combination with extensive bone loss at three implants. R3 = right distal implant; L2 = left intermediate implant; L3 = left distal implant.

Surgical Complications

At the time of surgery, three implants displayed poor stability and were rotationally mobile; five implants exhibited bone deficiencies at some of the coronal threads of the implants. However, none of these implants failed during the healing phase and they were all included in the study.

Implant Loss and Fractures

One submerged implant was lost before loading and was replaced with a new implant, according to the two-stage procedure, prior to prosthesis placement. No further implant losses were recorded during the follow-up and no implants were registered as mobile at the 5-year follow-up (Table 1).

One patient presented three fractured implants at the 5-year follow-up. In spite of this, the prosthesis was still registered as stable (Fig 1). The first implant fracture occurred after 3 years of function and the other two after 4 years.

Bone Loss

Twenty-four patients were available for the 5-year follow-up examination. Of these, 23 had periapical radiographs of good quality, but in 1 patient, baseline radiographs were missing. Bone levels registered at baseline and the 1- and 5-year follow-ups are presented in Table 3. Bone loss during the first year was low for nonsubmerged and submerged implants, with a mean bone loss of 0.14 mm (standard deviation [SD]: 0.37) and 0.17 mm (SD: 0.32), respectively. The mean bone loss from the 1-year checkup to the 5-year follow-up was 0.30 mm (SD: 0.61) in the nonsubmerged and 0.24 mm (SD: 0.35) in the submerged group, with no statistically significant differences in bone loss between the groups. Bone loss is presented in Table 4. Nineteen implants presented a bone loss of 0.9 mm or more from the 1-year to the 5-year follow-up. There was a statistically significant difference in bone loss from baseline to the 5-year follow-up between implants with attached peri-implant mucosa (mean: 0.35 mm) and those with nonattached mucosa (mean: 1 mm, $P < .001$). However, the number of implants with nonattached peri-implant mucosa was small (n = 31). No statistically significant differences were seen in bone loss between implants with peri-implant mucosa registered as healthy or not, male and female, implants with good fit or misfit of the prostheses, or implants with registered rotational mobility at implant placement and implants with good stability initially. On the other hand, there was a tendency towards a statistically significant difference *(*$P = .064$) in bone loss in smokers after the first year to the 5-year follow-up, with a mean of 0.37 mm (SD: 0.67) compared to 0.18 mm (SD: 0.46) in the nonsmokers.

Prosthetic Complications

Ten of the 28 ISFPs with available radiographs presented minor gaps at the framework-abutment junction at one (n = 7) or more (n = 3) abutments. Of these, 3 prostheses were removed and adjusted during the first year; 7 prostheses presented minor misfit at one framework-abutment junction at the 5-year examination. Fifteen (52%) patients encountered no complications.

Table 3 Mean Marginal Bone Level (mm) in Relation to the Implant Reference Point at Baseline and After 1 and 5 Years of Follow-up According to Placement Procedure

	Baseline			1 y			5 y		
Placement procedure	n	Mean	SD	n	Mean	SD	n	Mean	SD
Submerged	26	2.89	0.67	25	3.07	0.81	24	3.55	0.96
Nonsubmerged	26	3.00	0.37	25	3.15	0.56	24	3.51	1.03
Total	26	2.95	0.44	25	3.11	0.57	24	3.53	0.92

SD = standard deviation.

Table 4 Frequency Distribution of Marginal Bone Loss Throughout the 5-Year Follow-up

	Baseline–1 y				1 y–5 y				Baseline–5 y			
	Submerged n = 69		Nonsubmerged n = 69		Submerged n = 66		Nonsubmerged n = 66		Submerged n = 66		Nonsubmerged n = 66	
Bone loss (mm)	n	%	n	%	n	%	n	%	n	%	n	%
0	57	82.6	59	85.5	45	68.2	48	72.3	41	62.1	48	72.7
> 0–0.6	7	10.1	7	10.1	10	15.2	5	7.6	5	7.6	2	3.0
> 0.6–1.2	3	4.3	2	2.9	8	12.1	7	10.6	11	16.7	5	7.6
> 1.2–1.8	2	2.9	1	1.4	3	4.5	2	3.0	4	6.1	6	9.1
> 1.8–2.4	–	–	–	–	–	–	3	4.5	2	3.0	3	4.5
> 2.4–3.0	–	–	–	–	–	–	1	1.5	–	–	–	–
> 3.0	–	–	–	–	–	–	–	–	3	4.5	2	3.0

Table 5 No. of Patients and Complications Registered During Follow-up

		No. of complications					
Complications	No. of patients	1	2	3	4	5	Total (%)*
Loose prosthesis	4	3	–	1	–	–	6 (13.8)
Loose retaining screw	6	3	–	2	–	1	14 (20.7)
Fracture of retaining screw	3	1	1	–	–	1	8 (10.3)
Loose abutment screw	6	6	–	–	–	–	6 (20.7)
Fracture of abutment screw	1	1	–	–	–	–	1 (3.4)
Fracture of implant	1	–	–	1	–	–	3 (3.4)
Shortening of framework	2	2	–	–	–	–	2 (6.9)

*Some patients experienced multiple complications during the follow-up.

All complications encountered throughout the study period are shown in Table 5. Six patients experienced problems with loose or fractured retaining screws and in 3 of these patients, the problem was recurrent. As a result, 2 patients had one bilateral cantilever unit removed. Both prostheses were adjusted within the second year of service; 1 of these patients presented implant fractures at the 5-year follow-up. Loose abutment screws were registered in 4 patients; 1 of them also presented fractures of the abutment and prosthetic screws. All but 1 of the patients presenting loose abutment or retaining screws had ISFPs (n = 5) or natural dentition (n = 3) in the maxilla. Some of the registered prosthetic complications did not result in additional visits; most loose abutment screws were registered and taken care of at the annual checkups and not registered or reported by the patients.

Soft Tissue Reactions

Most implants were surrounded by attached peri-implant mucosa, but a minor proportion of the implants had nonattached peri-implant mucosa on one or both sides (n = 31). There were no implants with suppuration at the 5-year checkup and in most cases, the peri-implant mucosa was registered as healthy whether attached or not. Peri-implant mucositis was diagnosed at the annual follow-up in three patients.

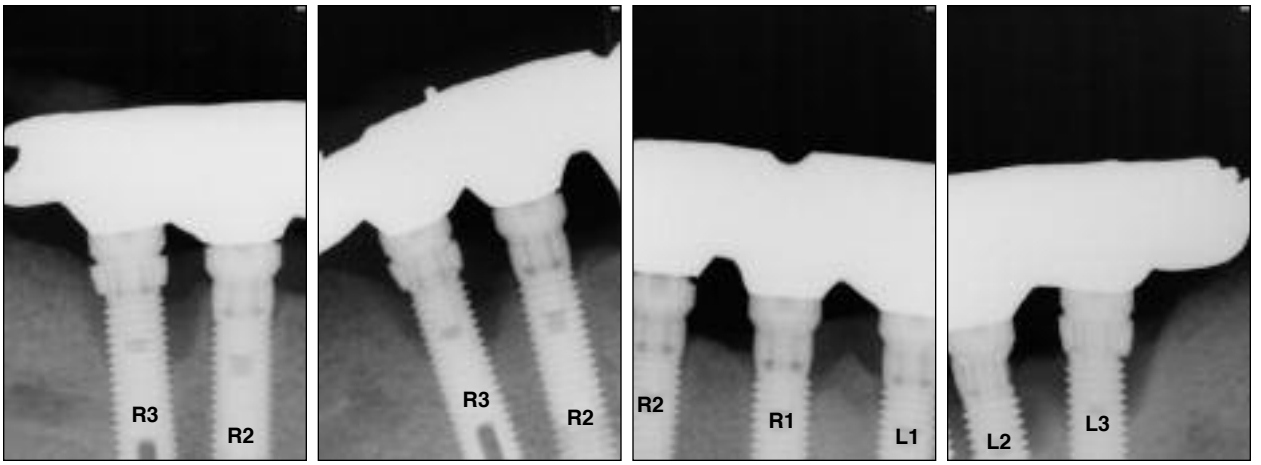

Fig 2 Seven-year follow-up radiographs of patient in Fig 1 with customized titanium cylinders at implants R3 and L3. Note: the gap is still present at implant R2.

Discussion

Patients not attending the follow-up had either died (n = 3) or declined to participate due to severe illness (n = 2), suggesting that no bias was introduced by the dropout rate (17%).

With only one implant lost before loading and no further implants lost up to the 5-year evaluation, the survival rate of implants compares favorably to most studies.[2,4,7,28] However, three fractured implants (2.2%) in one patient is a rare event today. A systematic review reported an implant fracture rate of 0.4% after 5 years.[29] Whether the implant fractures were a result of overloading the prosthesis or a result of the implant design in combination with high occlusal loads could not be established. Yet, this patient was one of the two patients who experienced recurrent problems with retaining screw loosening and screw fractures; subsequently, the cantilevers were reduced to 7 mm bilaterally. Since the patient was not interested in having the implants removed and replaced, a semipermanent repair using customized titanium "abutments" was performed to increase the supporting function of the implants. The prosthesis has now been in service for more than 3 years since the fractures (Fig 2). However, this emphasizes the need for longer follow-up periods when new implants are introduced to the market, since no implant fracture was recorded before the 3-year follow-up.

In the present study, the mean bone loss from baseline to the 5-year follow-up was 0.47 mm (SD: 0.70), which compares well with other studies.[6,7,27,30] Most implants (62% of submerged and 73% of nonsubmerged) presented no bone loss from baseline to the 5-year follow-up. Nevertheless, 13.8% of implants displayed bone loss greater than 0.8 mm during the 4-year period after the first year, which exceeds earlier reports (reporting 2% to 8% of implants having an annual bone loss exceeding 0.2 mm after the first year).[14,27,30,31] In the present study, no correlation was found between bone loss and prostheses with misfit or loosening and fracture of the retaining screws. The only patient that presented fractures of both abutment and retaining screws presented no bone loss during the follow-up. These results concur with those presented by Kallus and Bessing[32] and Jemt et al,[33] who reported no differences in implant or bone loss in patients with good or poor fit of the prostheses. Further, prostheses having cantilevers of more than 15 mm presented no increase in bone loss, neither did patients with ISFPs in both arches. This might indicate that high occlusal loads per se do not result in bone loss.

In the present study, smokers presented a somewhat higher annual bone loss after the first year than nonsmokers. However, the difference was not statistically significant, possibly due to a small study population. An increase in bone loss in smokers was also reported by Lindquist and coworkers[6] and Strietzel et al[34] in a review article concluding that smoking is a significant risk factor for dental implant therapy. Yet, in the present study, some smokers presented no bone loss during the 5-year follow-up, indicating that other factors may contribute to bone loss.

Some patients presented poor oral hygiene. Due to the small sample size, no statistically significant differences could be observed between smokers and nonsmokers with different levels of oral hygiene. However, the mean bone loss was somewhat higher in patients presenting poor oral hygiene, irrespective of if they were smokers or not, and concurs with the results presented by Lindquist and colleagues.[6]

In the radiographs, a minor gap at one of the framework-abutment junctions was registered in 7 of the 24 clinically examined prostheses. Verification was made by visible plaque accumulation on the mating surfaces of the abutments, despite the fact that all prosthetic treatment was performed by credentialed prosthodontists in a specialist clinic. This concurs with other reports on vertical misfit registered in cast frameworks for implant-supported prostheses both in laboratory and clinical studies.[19,32,33,35] Ericsson et al[19] reported that plaque accumulation registered on one or more of the mating surfaces in 4 of 11 prostheses; Al-Fadda et al[35] reported that 3 of 9 cast frameworks presented a mean vertical distortion of more than 100 µm, indicating that some of the individual framework-abutment junctions presented a vertical gap in excess of this. These results confirm the recognized problem with achieving good fit of cast frameworks for implant-supported prostheses. Whether the distortion in the frameworks in the present study was introduced in the frameworks due to improper placement of impression copings or mounting of abutment analogs when pouring the impression could not be ascertained.

In the present study, the screw resistance test was used to discriminate the fit of the prostheses according to routine protocol at the clinic. The screw resistance test alone or in combination with radiographs is commonly used to verify proper seating of implant-supported prostheses. Different explanations for the failure to detect the vertical misfit in some of the prostheses in the present study exist; either the prosthodontists were not sensitive enough, the mechanical properties of the framework or abutment and the prosthetic screws made it difficult to recognize the misfit, or a combination of these. However, the results in the present study and other follow-up studies performed in specialist clinics indicate that misfits may go undetected even if the screw resistance test is used.[19,32,33]

The loose abutment screws registered in four patients (one prosthesis with misfit) could be a result of the unscrewing of the retaining screws when the prostheses were removed at the yearly checkups,[25] a result of loading during function or inferior implant component quality. Six patients (two with prostheses with minor misfit) presented loose retaining screws; two of these had recurrent problems and the cantilevers were reduced. Complications with loose and fractured abutment and prosthetic screws were more frequent in patients having implant-supported prostheses in both arches but were not statistically significant, indicating that high occlusal loads may influence the stability of screw joints. In the present study, the distal cantilevers were 13 to 17 mm in most cases, and the few exceptions with longer cantilevers did not present complications. However, loose retaining and abutment screws have been reported in other studies, some related to framework misfit and some not.[19,25,30,33] In total, four (17%) patients presented loose prostheses during follow-up (two patients with ISFPs in both arches, one patient with a complete removable denture, and one patient with a natural dentition in the maxilla), which is higher than that reported in other studies.[7,30,33]

Peri-implant soft tissue complications were rare and no statistically significant difference was seen between implants placed with the submerged or nonsubmerged method. One patient with a systemic disease (polycythemia vera) presented recurrent problems with peri-implant mucosal swelling and inflammation around the implants, so the hyperplastic peri-implant mucosa was surgically corrected on several occasions. This patient's bone loss at individual implants ranged from 0.0 to 4.0 mm at the 5-year follow-up.

Conclusions

Within the limitations of this study, the following conclusions can be made:

- Implant placement according to single-stage surgery has the same predictability as two-stage surgery.
- The percentage of implant fractures (2.2%) and implants with a continuous bone loss exceeding 0.2 mm annually after the first year (13.8%) was higher for Paragon implants than reported in other 5-year follow-up studies.
- Paragon implants surrounded by nonattached peri-implant mucosa presented more bone loss than implants with attached peri-implant mucosa.

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