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Long-term randomized clinical trial evaluating the effects of fixture surface acid-etching and machined collar design on bone healing

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Objectives: An implant with an acid-etched fixture surface and internal-hex collar may achieve greater osseointegration. The goal of this research was to study the effects on long-term bone healing of fixture surface acid-etching and machined collar design. **Method and Materials:** Three two-part implant types were compared: standard Brånemark (with an external-hex 1.2 mm long machined flat collar), Swede-Vent (a copy of the Brånemark design, with an identical collar but a fixture surface acid-etched to 1 to 3 µm), and Screw-Vent (with a fixture surface acid-etched identically to that of Swede-Vent, but a longer internal-hex machined flat collar that did not require countersinking). Fifty-eight subjects each received the three types in alternate fashion at five sites between mental foramen, and a fixed full-arch prosthesis. Abutment-implant interface/microgap (MG) was placed at the crest, and first bone-to-implant contact point-to microgap (fBIC-MG) was measured at mesial and distal sides of each implant. Mean fBIC-MG values were compared after 15 to 20 years of function. Statistical analysis was based on the mixed linear model with the level of significance set at $P < .05$ and Bonferroni correction for pairwise comparisons. **Results:** Brånemark had less mean marginal bone loss (−1.08 mm, standard error [SE] 0.20) compared with Swede-Vent (−1.28 mm, SE 0.20), but pairwise comparisons showed that the difference was not statistically significant (mean difference of 0.20 mm, $P = .662$). Screw-Vent had the greatest loss (−1.92 mm, SE 0.20), and pairwise comparisons showed that the difference was statistically significant compared with Brånemark and Swede-Vent (difference ≥ 0.64 mm, $P < .001$). **Conclusion:** According to accepted standards for osseointegration, all three implant types achieved very acceptable long-term results. However, while Brånemark had the least bone loss, the implant with the acid-etched fixture surface and longer internal-hex collar design had the greatest loss. Within the confines of this study, shorter collar length of 1.2 mm may be more important to limit long-term bone loss with microgap placed at the crest. *(Quintessence Int 2018;49:733–743; doi: 10.3290/j.qi.a41013)*

Key words: acid-etched fixture, machined collar design, prospective study

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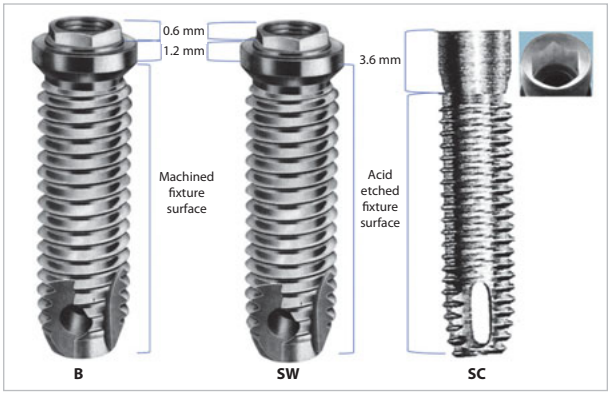


Fig 1 Implant types: B, Brånemark, 3.75 mm width, machined fixture surface, 1.2 mm long external-hex machined flat collar; SW, Swede-Vent, 3.75 mm width, fixture surface uniformly acid-etched to 1–3 µm, 1.2 mm long external-hex machined flat collar; SC, Screw-Vent, 3.75 mm width, fixture surface identically acid-etched to that of Swede-Vent by the same manufacturer, 3.6 mm long internal-hex machined flat collar.

Osseointegration was clinically introduced in 1965, and benchmark criteria of implant success, including maximal bone loss of 1.2 mm after the first year of function followed by not more than 0.1 mm loss annually, were established.[1-5] Since then, interest in more rapid osseointegration and greater bone preservation has led to an increased study of implant surface preparation and sterilization techniques, microscopic texturing, and macroscopic design.[6-20] Microscopically, a fixture surface acid-etched to 1 to 2 µm resulted in more rapid osseointegration.[19] Macroscopically, the standard two-piece external-hex abutment-screw unit eventually loosened after only half of the initial tightening force was applied.[21] Consequently, when the abutment-implant interface microgap was placed at the crest, a widened gap appeared within 3 months of function, resulting in microleakage and bacterial detection at the abutment screw apex.[22] These bacteria had been identified in pockets around failing implants.[23] As a result, new implant designs were introduced that could increase resistance to forces at the crestal microgap, limiting abutment movement and bone loss.[24-27] One such implant (Screw-Vent, Core-Vent) had a screw-shaped fixture surface uniformly acid-etched to enhance osseointegration, a longer internal-hex interlocking machined flat collar that did not require countersinking, and increased resistance to functional forces at the crestal microgap according to the manufacturer.[27] However, one clinical study had reported greater short-term bone loss with this implant compared to the standard machined Brånemark implant.[26] The authors suggested that Screw-Vent's greater bone loss could have been due to its longer collar, and advocated long-term clinical studies regarding this issue. Therefore, the present study first evaluated the possibility that an acid-etched fixture surface could more favorably influence long-term bone healing by comparing the machined external-hex Brånemark fixture to a copy (Swede-Vent) whose fixture was acid-etched. Since Screw-Vent's fixture was identically acid-etched compared to that of Swede-Vent by the same manufacturer, this allowed discussion of the effect of long-term bone healing of the two different machined flat collar designs (shorter identical external-hex for Brånemark and Swede-Vent, and longer internal-hex for Screw-Vent), with microgap placed at the crest.

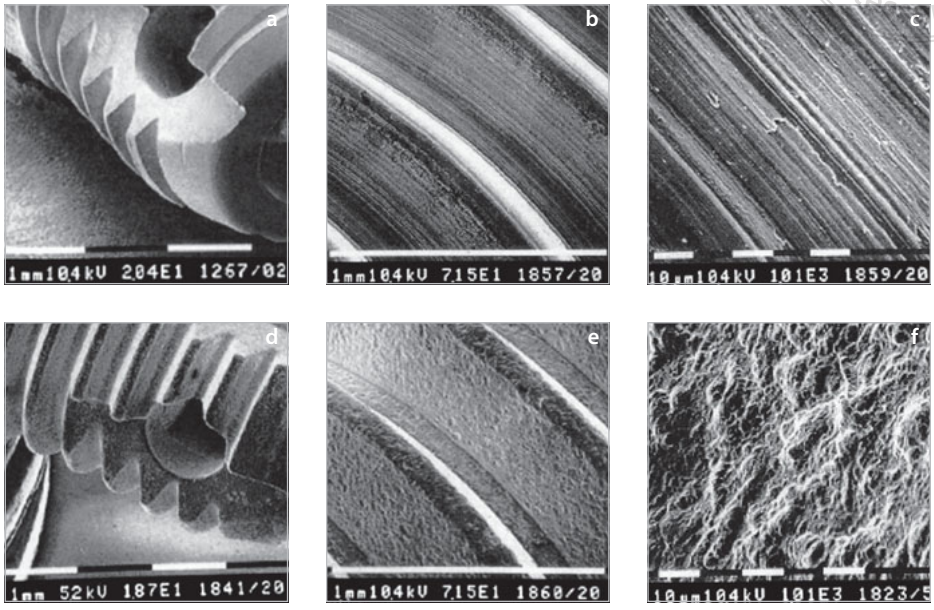
METHOD AND MATERIALS

Subjects

Age-eligible subjects were assessed between 1990 and 1992 for recruitment into this clinical trial, which was peer reviewed, had received ethical approval, and was to take place at a university dental faculty and affiliated hospital department. Following clinical examination, including panoramic and cephalometric radiographs, 60 subjects (30 women) were selected and signed a written informed consent.

Implant types

Standard Brånemark System (Nobelpharma), Swede-Vent (Core-Vent), and Screw-Vent (Core-Vent) two-part platform-matched implants had a parallel-wall fixture screw design, with pitch height (0.6 mm) and flange angle (60 degrees) starting below their machined flat collar (Fig 1).[15,26,27]. Swede-Vent was a copy of the Brånemark design,[8,20,26] with an identical 1.2 mm long external-hex collar requiring countersinking to seat its fixture/collar border 1.2 mm below, 0.6 mm long centrally located



Figs 2a to 2f Implant types: *(a)* low magnification (× 18), *(b)* low magnification (× 72), *(c)* high magnification (× 1,010) scanning electron micrographs of Brånemark implant; *(d)* low magnification (× 18), *(e)* low magnification (× 72), *(f)* high magnification (× 1,010) scanning electron micrographs of Swede-Vent implant. Reproduced from Helsingen and Lyberg[20] with permission from Quintessence Publishing.

external-hex above, and wider shoulder at the alveolar crest. Both received a two-piece platform-matched parallel-wall abutment-screw unit. However, while Brånemark's fixture surface was machined (Ra value 0.53 µm[15]), Swede-Vent's was acid-etched resulting in peaks and valleys measuring 1 to 3 µm (Fig 2).[27] Swede-Vent and Screw-Vent fixtures were identically acid etched by the same manufacturer, but Screw-Vent had a narrower 3.6 mm long collar that did not require countersinking to seat its fixture/collar border below and shoulder at the crest. This collar resulted in a beveled interlocking internal-hex connection with its platform-matched one-piece abutment-screw unit.[26,27] Collar lengths were confirmed on a sample of each implant type by a person (A1) who was not part of the research team using Grifhold ×10 magnification scale loupe with integrated ruler at 0.2 mm, and Storz gauge stainless steel calipers.

Study design, and surgical and prosthodontic treatment

A statistician who was not part of the research team prepared a sampling design that included three configurations. Each configuration contained five implants of the three types, thereby allowing an equal number of each implant type to be placed in a cyclical side-by-side rotating fashion at each of five sites between mental foramen. Consequently, 100 implants of each of the three types were to be placed, for a total of 300. However, two participants opted out before the start of the study so that 58 (30 women) received 290 implants, and each participant acted as their own control. Allocation concealment then allowed 20 participants to receive configuration 1, 19 configuration 2, and 19 configuration 3 (Tables 1 to 3). Configuration diagram (but not number) identifying the implant type and length to be placed at each site was stored inside each chart, and only shown to the operating team at surgery.

Following elevation of mucoperiosteal flap, protection of mental foramen contents, and alveolar crest reduction when indicated, a submerged surgical protocol was followed by the same surgeon who placed all implants with fixture/collar border below and microgap (MG) at the crest. Only external irrigation was used, as recommended by one of the study's external reviewers and the scientific literature.[29] Manual anchorage of each implant at the last 2 mm assured mechanical stability, and at least 1 mm of bone thickness remained buccally and lingually. While all implants placed measured 3.75 mm in width, their length was determined by the project coordinator, based on preoperative radio-

Table 1 Baseline demographic and clinical characteristics for each configuration

	Configuration 1 (n = 20)	Configuration 2 (n = 19)	Configuration 3 (n = 19)
Age (mean, SE)	45.3 years, 1.2	45.5 years, 1.3	44.8 years, 1.4
Gender* (no. women, %)	10, 50.0%	10, 52.6%	10, 52.6%
Smoking status	Nonsmoking	Nonsmoking	Nonsmoking
Race* (no. white)	20	19	19
Medical history	No systemic disease	No systemic disease	No systemic disease
Dental history	Maxillary and mandibular complete removable prostheses for at least 1 year, No TMJ abnormalities; Class I inter-maxillary relationship; Mandibular type 2 and/or 3 bone quality[28]	Maxillary and mandibular complete removable prostheses for at least 1 year; No TMJ abnormalities; Class I inter-maxillary relationship; Mandibular type 2 and/or 3 bone quality[28]	Maxillary and mandibular complete removable prostheses for at least 1 year; No TMJ abnormalities; Class I inter-maxillary relationship; Mandibular type 2 and/or 3 bone quality[28]

*According to American Psychological Association, Washington, DC.[30] TMJ, temporomandibular joint.

Table 2 Fifty-eight participants each received one of three configuration numbers

	Subject's right				Subject's left	
Configuration	Site 5	Site 4	Site 3	Site 2	Site 1	Total (no. subjects)
1	B	SW	SC	B	SW	20
2	SW	SC	B	SW	SC	19
3	SC	B	SW	SC	B	19
Total						58

Table 3 Fifty-eight participants received 290 implants of three types at five different sites

	No. of implants			
Site	SW	B	SC	Total
1	20	19	19	58
2	19	20	19	58
3	19	18	21	58
4	19	20	19	58
5	20	20	18	58
Total	97	97	96	290

graphic measurement of available bone height. An equal number of subjects received three of the five implants to the left or right of the midline. Cover screws were attached and mucoperiosteal flap sutured. Each subject received 1 million units of penicillin G, or 250 mg of erythromycin if allergic to penicillin, intravenously at surgery, and the same antibiotic was taken orally with the postoperative analgesic. Subjects were instructed to consume a liquid/soft diet, rinse their mouths gently two to three times per day, and not wear either denture. Sutures were removed 10 days after surgery, and prostheses were adjusted using a soft tissue conditioner material (Coe-Soft, GC America), and inserted. All subjects were reevaluated regularly for comfort, soft tissue health, and prosthesis stability. Approximately 6 months after surgery the same surgeon exposed all implants, removed cover screws, and placed transepithelial abutment-screw units. Radiographs were taken to assure complete seating of abutments onto implant platforms.

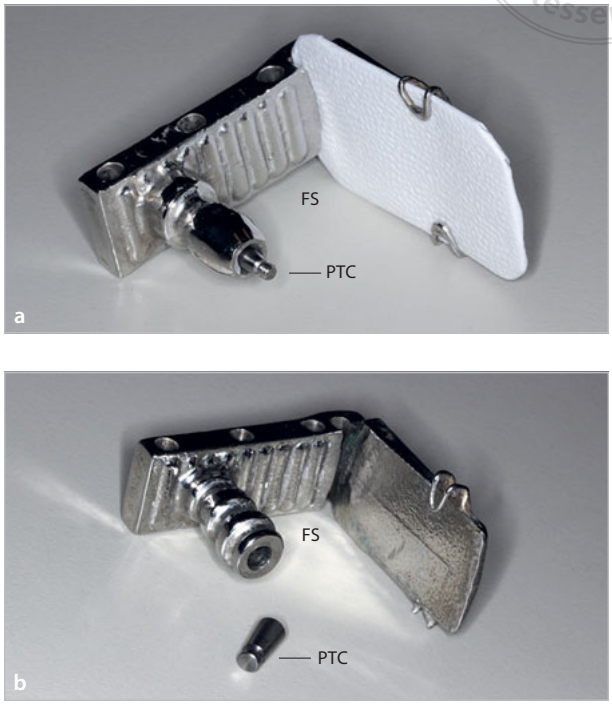
Each subject then received a full-arch removable maxillary and fixed mandibular prosthesis with bilateral posterior cantilever sections.[31] Treatment was supervised by an experienced prosthodontist/laboratory implant team, assuring standardized restorative procedures that included seating of stable framework and balanced distribution of occlusal forces. Acrylic resin teeth were used and metallic framework was anchored to abutments using gold prosthetic screws for Brånemark and Swede-Vent, and titanium screws for Screw-Vent. Subjects followed an oral/implant hygiene regi-

men of daily mouthwash rinses, and gentle flossing and brushing of abutments with furnished hygiene kits. Prostheses and abutments were removed on follow-up visits, cleaned with nonabrasive materials, placed in an ultrasound bath, reinserted, and tightened.

Radiographic technique and measurement protocol

Panoramic and cephalometric radiographs were taken prior to removal of prosthesis/framework structures. Following removal of structures, visual examination and an applied pressure of 35 Ncm to all abutments confirmed osseointegration. A prefabricated metallic positioning transfer cylinder, one for identical Brånemark and Swede-Vent abutments or one for Screw-Vent, was screwed into the appropriate abutment, as shown in preliminary research (Berbari R, personal communication, 1992). A prefabricated metallic film support, one for Brånemark and Swede-Vent or one for Screw-Vent, was then securely anchored onto the appropriate cylinder and a periapical radiograph was taken using standardized long-cone technique (Fig 3). The metallic film support counteracted the strong resistance of the thick soft tissues of the floor of the mouth, as discussed by De Bruyn et al.[26] This radiographic technique assured film placement with minimal bending, reproduction of correct angulation and distance between each implant and film, and standardization between persons taking radiographs at different intervals. Five radiographs per subject were taken and numbered according to implant position, 1 being the first on the subject's left, 5 the last on the right, and were stored in plastic film holders. All prosthesis/framework structures and abutments were cleaned and reinserted after having taken the radiographs. Collar length of each implant type was measured directly on radiographs randomly selected from a subject's chart, and compared to those previously made by the same person (A1) directly on a sample of each implant type.

The trial maintained separation between teams that had delivered clinical treatment and the examiners performing bone level measurements. First bone-to-implant contact point-to microgap (fBIC-MG) measurements were made on mesial and distal sides of each abutment-implant unit. Mean fBIC-MG values were then calculated and compared. All short-term fBIC-MG measurements after 12 and 24 months of function had been performed by one examiner (T1) using the measurement protocol developed for this study, as shown in preliminary research (Chen C, personal communication, 1997). In order to evaluate this examiner's reliability, a different examiner (E2) retrieved a statistically significant sample number of charts, and using the same measurement protocol repeated measurements on the original periapical radiographs taken after 12 months of function. Using the same materials, radiographic technique, and measurement protocol, E2 then performed measurements on periapical radiographs taken at the 15- to 20-year period. Inter-examiner and intra-examiner (E2) measurement reliability were evaluated. Intra-examiner reliability was evaluated using measurements repeated 3- to 4-days after initial recordings.



Figs 3a and 3b Periapical radiographic material. Prefabricated metallic positioning transfer cylinder (PTC) and metallic film support (FS) for identical Brånemark and Swede-Vent *(a)* and Screw-Vent *(b)* abutments.

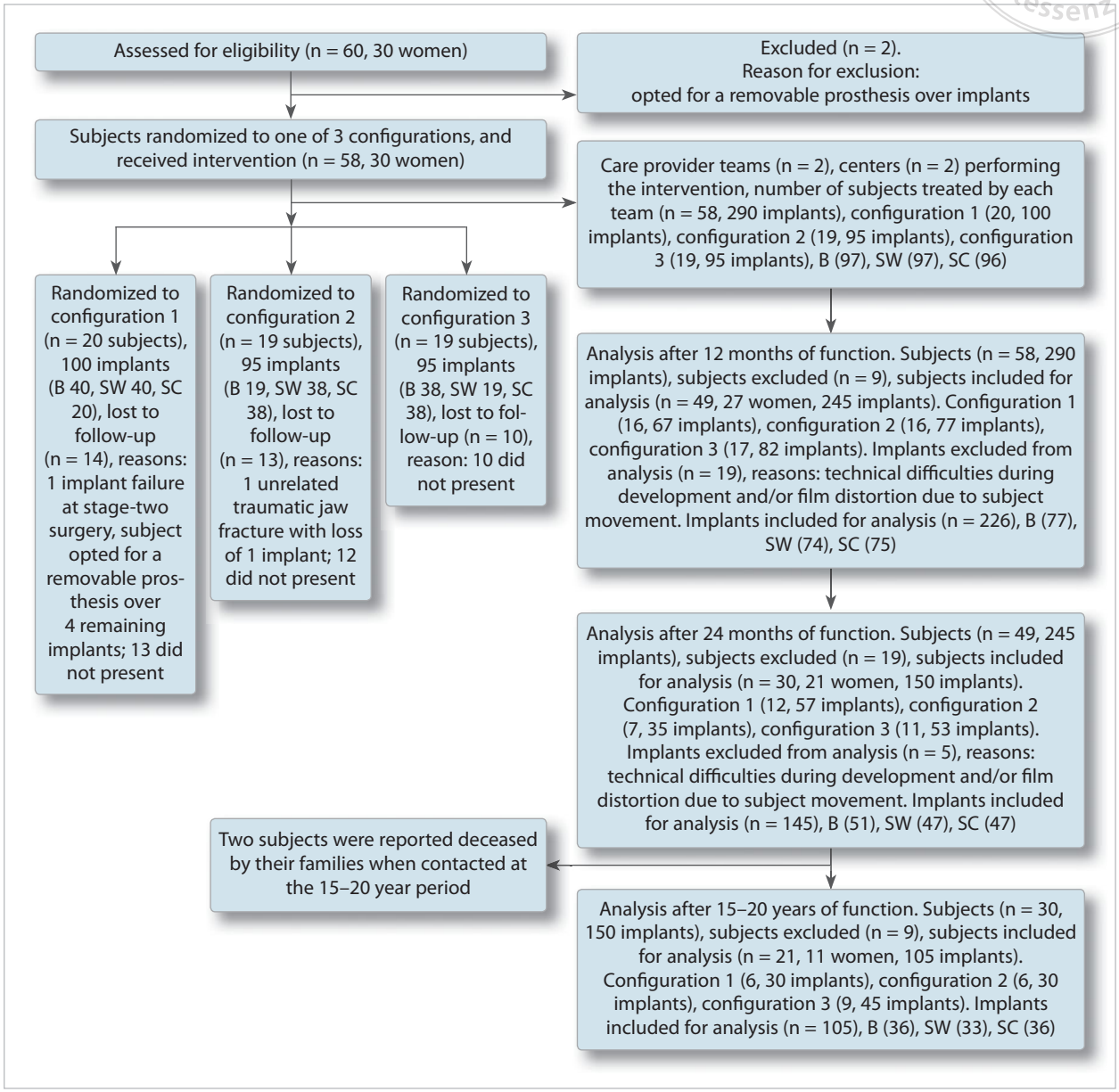


Fig 4 Flow diagram of the study.

Implant and soft tissue evaluation

Subjects had been seen every 6 months for 24 months after prostheses insertion. Clinical examination at the 15- to 20-year recall period included visual assessment of fixed prosthesis, abutment, and implant mobility. Mobility between two instruments was recorded as absent or present. Peri-abutment soft tissue health was evaluated using Gingival Index (GI), and mean GI was calculated.[23,32,33] Using a Hu-Friedy PH6 Colorvue Probe Model CE0410, peri-implant depth probing was performed at midfacial, midlingual, mesial, and distal surfaces. Angulation and pressure were not controlled.

Statistical methods

Assessment was based on intention to treat. Inter-examiner and intra-examiner measurement reliability

were assessed using intraclass correlation coefficient (ICC) and Bland-Altman repeatability (BAR). Statistical analysis was based on the mixed linear model that included fixed effects of time, implant position, implant configuration, implant type (and implant length as a covariate effect). Position and time were repeated within participants. A *P* value of < .05 was considered significant and Bonferroni correction was used for pairwise comparisons. Shapiro-Wilk test was applied to verify that data were following normal distribution. Confidence interval (CI) was established at two-sided 95% confidence level. All statistical analyses were performed using IBM SPSS Statistics for Windows, version 23.0.

RESULTS

Sixty age-eligible edentulous subjects were recruited into this within subject clinical trial. Two subjects voluntarily opted out so that 58 (mean age 45.29 years, 30 women) were each randomly allocated to one of three implant configurations, and a total of 290 implants were placed. One non-osseointegrated implant was removed at stage-two surgery. This subject opted for a removable prosthesis on the remaining four implants, resulting in 57 subjects receiving intended surgical and prosthodontic treatment. Thereafter, one subject had an accidental fall sustaining a mandibular fracture with implant loss, and was removed from the study. As a result, 56 subjects (280 implants) remained, attended clinic visits at 6-month intervals for 24 months, and were recalled at the 15- to 20-year period. Fifty-three of the 56 subjects were included in the follow-up, 49 after 12 months, 30 after 24 months, and 21 between 15 and 20 years (Fig 4). Mean fBIC-MG values were calculated, recorded, and compared. Inter-examiner reliability was high (ICC 0.96, BAR 0.58), and intra-examiner reliability was very high (ICC 0.99, BAR 0.15).

While mean bone loss was not significantly different between 1 and 2 years (*P* = .145), and between 2 and 15 to 20 years (*P* = .284), there was significantly greater bone loss between 1 year and 15 to 20 years (*P* = .004). Implant position and implant configuration were not statistically significant for mean bone loss (*P* = .224 and .241, respectively). Since the relationship between implant length and mean bone loss was significant regardless of implant type, implant length was included in the mixed linear model as a covariate effect with longer implants having greater bone loss (Fig 5). Separate analyses evaluating differences in mean bone loss between implant types were also performed at all three intervals (Table 4).

At the 15- to 20-year interval, 28 (50%, 140 implants) of the 56 subjects who underwent treatment were contacted, 26 (130 implants) were untraceable and two (10 implants) were reported deceased by their families. On initial contact, these subjects stated that their prostheses were functioning well, and that there were no problems with the implants according to their treating dental practitioners. Four (20 implants) reserved their right not to present to follow-up, and one (five implants) was in the process of moving across the country. Of the remaining 23 subjects (115 implants) examined, two (10 implants) had had their original abutments changed to accommodate a removable prosthesis, not due to implant failure but at subjects' requests. In order to respect the original protocol only implants restored with a fixed prosthesis were included in the analysis. Consequently, 21 subjects (38%, 105 implants, mean age 64 years, 11 women) were evaluated. Eleven subjects had had their fixed prosthesis replaced once, one subject twice, one subject three times, and eight subjects presented with their original prosthesis. There was no mobility of all fixed prostheses on visual examination, and all implants remained osseointegrated. Mean GI was 0.8 for Brånemark and Swede-Vent, and 0.7 for Screw-Vent. Mean probing depths for all implants combined were 1.93 mm midfacially, 2.55 mm midlingually, 2.52 mm mesially, and 2.74 mm distally. Implant length regardless of implant type was statistically significant for mean bone loss (*P* = .002); however, implant configuration (*P* = .879) and implant position (*P* = .075) were not. Implant type was also statistically significant for mean bone loss (*P* < .001). Brånemark had the least bone loss (–1.08 mm, standard error [SE] 0.20) compared with

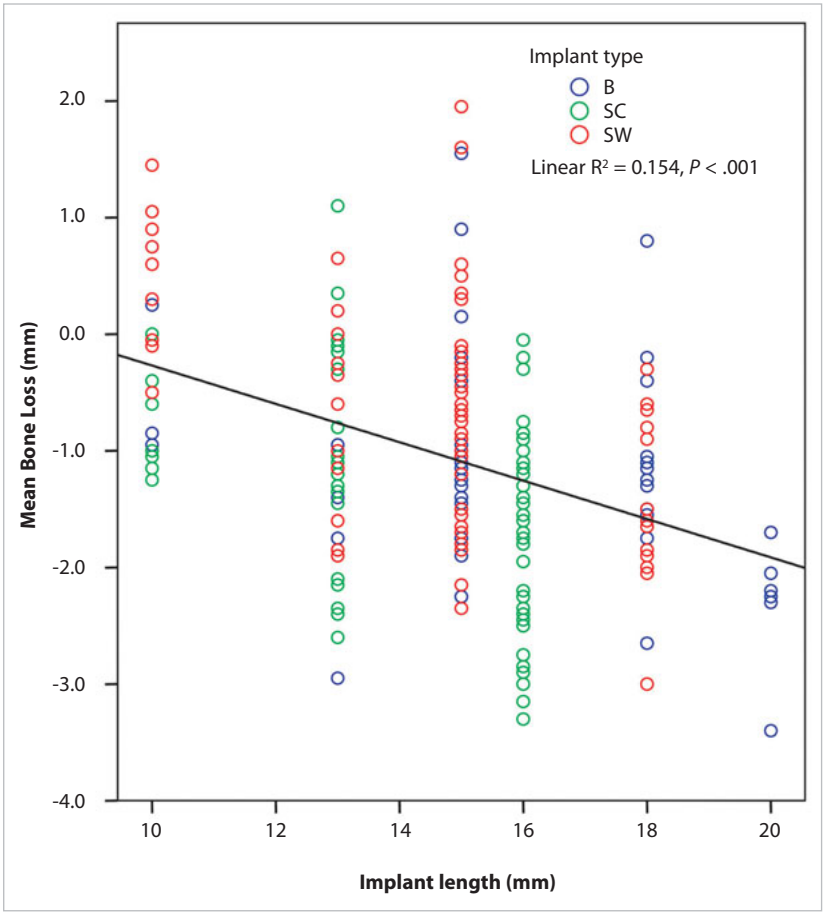


Fig 5 Scatter plot showing the relationship between implant length and bone loss after 12 months.

Swede-Vent (−1.28 mm, SE 0.20), but pairwise comparisons showed that the difference was not statistically significant (mean difference of 0.20 mm, $P = .662$). Screw-Vent had the significantly greatest loss (−1.92 mm, SE 0.20), compared to Brånemark and Swede-Vent (difference ≥ 0.64 mm, $P < .001$). A life-table analysis was performed (Table 5).

DISCUSSION

While variable bone healing results had been obtained with implants whose fixture surfaces were microtextured using additive techniques,[34,35] acid-etch subtractive techniques of the time had achieved better results compared to the standard machined fixture, and are still used in dental and orthopedic implantology research.[9-19,36-44] However, one short-term clinical study had reported comparable bone healing between Swede-Vent and the standard machined Brånemark implant, but greater bone loss with Screw-Vent compared to both Brånemark and Swede-Vent.[26] Swede-Vent and Screw-Vent were two new two-part screw-shaped parallel wall implants at the time, with fixture surfaces identically acid-etched to 1 to 3 µm by the same manufacturer. Swede-Vent was a copy of the Brånemark design, with an identical 1.2 mm long machined external-hex flat collar. Screw-Vent's narrower significantly longer machined internal-hex flat collar did not require countersinking and increased resistance to functional forces at crestal microgap, features which should have preserved more bone according to the manufacturer. Since both implants had fixtures that were identically acid-etched, the authors suggested that Screw-Vent's greater bone loss could

Table 4 Mean bone change, estimated with the mixed linear model (mean ± SE, 95% CI)

Time (y after prosthesis attachment)	B	SC	SW	Mean difference (95% CI)	*P**
1	−1.00 ± 0.12 (−1.23,−0.77)	−1.39 ± 0.12 (−1.62,−1.16)	−0.71 ± 0.11 (−0.94,−0.48)	B-SC: 0.39 (0.09, 0.69)	.006
				B-SW: −0.29 (−0.59, 0.01)	.059
				SC-SW: −0.68 (−0.98, −0.39)	< .001
2	−0.99 ± 0.13 (−1.26,−0.72)	−1.55 ± 0.13 (−1.82,−1.28)	−0.82 ± 0.14 (−1.09,−0.55)	B-SC: 0.56 (0.26, 0.85)	< .001
				B-SW: −0.17 (−0.47, 0.13)	.495
				SC-SW: −0.73 (−1.02, −0.43)	< .001
15	−1.08 ± 0.20 (−1.49,−0.67)	−1.92 ± 0.20 (−2.33,−1.51)	−1.28 ± 0.20 (−1.69,−0.87)	B-SC: 0.83 (0.45, 1.22)	< .001
				B-SW: 0.20 (−0.19, 0.59)	.662
				SC-SW: −0.64 (−1.01, −0.26)	< .001

*Bonferroni adjusted *P* values are shown.

Table 5 Life-table analysis of functional implants

Interval (y)	Number entering interval	Number withdrawn during interval*	Number exposed to risk†	Number of failures	Interval survival rate (%)	Cumulative survival rate (%)
0	290	30	275,000	2	99	99
1	258	67	224,500	0	100	99
2	191	86	148,000	0	100	99
15–20	105	105	52,500	0	100	99

*Number of implants with observation periods shorter than the particular time interval.
†Number of cases entering the respective interval, minus half the number of cases lost or censored in the respective interval.

have been due to its longer collar. Therefore, the goal of the present study was to evaluate the long-term effects on marginal bone healing of fixture surface texture and machined collar design by comparing these three implant types.

In order to limit extraneous variables that may have led to alternative explanations for long-term bone loss, all implants were placed with fixture/collar border below and microgap at the crest, in types 2 and 3 mandibular bone of healthy nonsmoking edentulous subjects, and were restored with a fixed full-arch prosthesis. Configuration allocation allowed an equal number of each implant type to be placed alternately per site, per subject, so that subjects acted as their own control. Implant configuration and implant site were not statistically significant for mean bone loss, but implant type was significant. The present result with the Brånemark implant approached that of another prospective study that evaluated this same implant after 15 years of function with fixed full-arch mandibular prostheses.[45,46] Long-term cumulative survival rate was 99%, and mean bone loss for all implants combined in the study was −1.43 mm (SE 0.18, CI −1.80 to −1.05). Mean bone losses of −1.3 mm after 13.4 years, and −0.24 mm, −0.48 mm, and −0.75 mm after 5 years have been reported.[47,48] Since Brånemark had the least long-term bone loss, the fixture surface microtexturing technique evaluated did not result in significantly greater bone preservation. Other long-term clinical studies have reported statistically comparable results between machined and microtextured implants.[49,50] Screw-Vent's microtextured fixture and internal-hex collar design should have preserved more bone. However, Screw-Vent had the statistically significant greatest long-term

bone loss compared to Brånemark and Swede-Vent, confirming the short-term clinical results of De Bruyn et al.[26] In the present study, the implant designs with the identical shorter 1.2 mm machined collar (Brånemark and Swede-Vent) had the statistically significant least long-term marginal bone loss, while the design with the longer collar (Screw-Vent) had the significantly greatest loss. Brånemark is still available, but as Mk III RP (Nobel Biocare) with an oxidized surface and an even shorter 0.75 mm machined flat collar.[51,52] Screw-Vent Dental Implant System (Zimmer Biomet) is still available with a microtextured surface but a 1.5 mm long machined flat collar.[53,54] Swede-Vent is no longer available.

Since there had been no significant difference in mean bone loss between the 12 and 24 month intervals for all implant types, a steady-state had occurred. In such cases it was proposed that if follow-up were to be assured with experienced clinicians, then the need for radiology could be based more on clinical necessity and patient benefit than on periodicity.[55-57] In the present study, clinical follow-up between the 2 year and 15- to 20-year intervals generally occurred in the private practice setting. While justifiable, this may have been a disadvantage for the research team. Although 53 (265 implants) of the 56 (280 implants) subjects participated in the follow-up, due to attrition 21 (105 implants) were seen at the 15- to 20-year recall period. However, this is compensated for, to an extent, by the within-subject study design and limitation of confounding variables.

CONCLUSION

Although newer completely different implant products are now available, according to accepted standards for osseointegration the three implant designs studied achieved very acceptable long-term bone healing with microgap at the crest. However, the implants with the shorter identical 1.2 mm machined collar achieved significantly less bone loss. Similar long-term studies are required to support or refute this conclusion.

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