Prospective Randomised Clinical Trial Evaluating the Effects of Two Different Implant Collar Designs on Peri-Implant Healing and Functional Osseointegration after 25 Years

ClinicalTrials.gov Identifier: NCT03862482.
University of Montreal Ethics Committee Certificate No. CERC-19-015-P (Approved May 02, 2019).

Prospective Randomised Clinical Trial Evaluating the Effects of Two Different Implant Collar Designs on Peri-Implant Healing and Functional Osseointegration after 25 Years

ClinicalTrials.gov Identifier: NCT03862482.
University of Montreal Ethics Committee Certificate No. CERC-19-015-P.

Objectives: Evaluate the effects of two different machined-collar lengths and designs on peri-implant healing.

Material and Methods: An implant with a microtextured surface and 3.6mm-long internal-connection machined collar was compared to two implants that had an identical 1.2mm-long external-connection machined collar, but one had the microtextured surface while the other's was machined. Participants received the three implants, with microgap at the crest, alternately at five sites between mental foramen, and a full-arch prosthesis. Peri-implant bone levels were measured after 23 to 26 years of function. Keratinized gingiva height, plaque, probing depth, bleeding, and purulence were also evaluated. Descriptive and mixed models for repeated-measures analyses were used, with Bonferroni correction for pairwise comparisons.

Material and Methods

Participants, and implant description

Between 1993 and 1996, 58 of 60 eligible participants were recruited into a prospective, randomized clinical trial. This trial had been peer reviewed, had received ethical approval, and had taken place at the Université de Montréal's Faculty of Dental Medicine and its affiliated hospital dental department (SMH Scientific Research Committee Certificate No. PROJECT-90-01). The present article documents data collected at the 25-year (24.6 ± 0.19 years, mean ± SE) follow-up of this within-subject trial (University of Montreal Ethics Committee Certificate No. CERC-19-015-P, ClinicalTrials.gov Identifier: NCT03862482). All study procedures were performed in accordance with the Helsinki Declaration and its later amendments, and all participants signed informed consent documents prior to inclusion into this study.

Standard Brånemark System®, Swede-Vent® and Screw-Vent® two-piece, platform-matched implants had a parallel-wall fixture/screw macro structure, with pitch height (0.6 mm) and flange angle (60 degrees) starting below their collar. (Binon, et al., 1992; De Bruyn, et al., 1992; Helsingen, & Lyberg, 1994; Niznick, 1989; Wennerberg, et al., 1993). Swede-Vent® was a clone of the Brånemark® macro design (Binon, et al., 1992; Helsingen, & Lyberg, 1994). It had an

identical 1.2mm-long external-connection machined collar requiring countersinking to place its fixture/collar border 1.2mm below, 0.6mm-long centrally located external connection above, and wider implant/abutment interface platform at the alveolar crest (De Bruyn, et al., 1992; Helsingen & Lyberg, 1994; Wennerberg, et al., 1993). Brånemark® and Swede-Vent® received a two-piece, platform-matched, parallel-wall abutment/screw unit. While the Brånemark® fixture surface was machined, Swede-Vent's® was acid etched to a 1-3µm-pitted surface. Although Swede-Vent® and Screw-Vent® fixtures were identically acid etched by the same manufacturer, Screw-Vent's® narrower 3.6mm-long machined collar did not require countersinking to place its fixture/collar border below and implant/abutment interface platform at the crest. In addition, Screw-Vent's® internal-connection, friction-fit collar design accepted a platform-matched, one-piece abutment/screw unit (De Bruyn, et al., 1992; Niznick, 1989).

Initial study design, surgical and prosthetic treatments

A statistician prepared a sampling design that included three configuration diagrams. Each diagram identified five implants of the three types, and showed how one of each type was to be placed in a cyclical, side-by-side, rotating fashion at five sites between mental foramen. In this way, an equal number of each implant type was to be placed at each of the five sites, and an equal number of participants received three of the five implants to the left or right of the midline. Configuration diagrams also documented each implant's length. Allocation concealment by the project coordinator then allowed 20 participants to receive Configuration 1, 19 had Configuration 2, and 19 had Configuration 3. Configuration diagram (but not number) was stored inside each chart, and only shown to the operating team at the time of surgery. The same surgeon (A.J.C.) placed all implants, in a submerged fashion, with MG at the crest. Implants were 3.75mm in diameter, but the project coordinator determined implant length based on pre-operative radiographic measurements of available bone height. After approximately six months, the same surgeon exposed all implants, removed cover screws, and placed healing/prosthetic abutments. Complete seating of abutments onto implant platforms was confirmed with radiographs. Each participant received a conventional complete removable maxillary prosthesis and a fixed implant-supported mandibular prosthesis with bilateral posterior cantilever sections. Acrylic-resin teeth were processed over a casted, silver-palladium alloy framework. Gold prosthetic screws for Brånemark® and Swede-Vent® implants, and titanium screws for Screw-Vent® implants anchored the mandibular prostheses to the abutments. Participants followed an oral/implant hygiene regimen of daily mouthwash rinses, and gentle flossing and brushing with provided hygiene kits. Follow-ups occurred at one year, two years, 15 to 20 years, and 23 to 26 years

following prostheses attachment. Twenty-two participants (41.5%, age 71.1 ± 1.2 years, 11 women, 110 implants) were enrolled in the present study

Clinical and radiographic evaluation

At the 23- to 26-year recall, prosthodontists (H.C. and G.G.) ascertained the presence of any fractured or mobile prosthetic component. Following this assessment, the prosthodontists removed the prostheses, and abutment mobility was evaluated. Prosthesis and abutment mobility were evaluated by exerting manual pressure alternately on the handles of two instruments, each placed on opposite sides, and were recorded as absent (0) or present (1). Because abutment screws are tightened to 35N/cm of pressure using an instrument during prosthesis insertion, abutments should not be retrievable by finger pressure alone. Consequently, an attempt was also made to untighten each of the non-mobile abutments with finger pressure. If the abutment screw was retrievable, then the abutment was considered to be loose, even in the absence of visual mobility. Two calibrated examiners then performed the follow-up clinical (periodontist R.D.) and radiographic (M.B.) examinations, with abutments in place. All examiners were unaware of implant configurations. The dichotomous/binary plaque index (dPI) was used to document the absence (0) or presence (1) of plaque on the mesial, distal, buccal and lingual implant/abutment surfaces (Galgut, 1999). A ColorVue UNC12 Hu-Friedy probe was then used to measure (mm) the keratinized gingiva height on the buccal and lingual implant/abutment surfaces, and probing depth on the mesial, distal, buccal and lingual implant/abutment surfaces. Intra-examiner agreement for 46 sites regarding keratinized gingiva height and 100 sites for probing depth showed that 100% and 99% of measurements differed by 1mm or less, respectively. Following probing, the dichotomous/binary bleeding index (dBI) documented the absence (0) or presence (1) of bleeding at each peri-implant site on the mesial, distal, buccal and lingual implant/abutment surfaces. (Galgut, 1999). Absence (0) or presence (1) of purulence was also documented.

After having assured the stability of all abutments, radiographic evaluation of quantitative peri-implant bone healing was performed with the conventional peri-apical technique, using a standardized equipment and measurement protocol (Camarda, et al., 2018). Five peri-apical radiographs per participant were taken and numbered according to the implant site, 1 being the first on the subject's left, 5 the last on the right, and were stored in plastic film holders. In order to compare and calibrate conventional peri-apical radiology with phosphor-plate technology, the Digora System™ (Digora Optime™ , Sporedex Dental Co., Tuusula, Finland) was also used with the standardized equipment to take peri-apical radiographs on 95 implant/abutment units (Bhasharan, et al., 2005). Following calibration, the distance between the first-bone-to-implant-

contact-point and the crestal-microgap (fBIC-MG) was measured (mm) at the mesial and distal aspects of each implant/abutment unit using a Schei ruler under X10 magnification on the conventional films. Adobe Photoshop® (Adobe System Incorporated, San Jose, CA, USA) was used to measure fBIC-MG on the digital radiographs acquired with phosphor-plate technology. After having taken the radiographs, all abutments were removed and cleaned, and prosthesis/framework structures were cleaned and polished. Abutments and prosthesis/framework structures were then re-inserted using recommended instrument torque. Intraclass Correlation Coefficient (ICC, two-way mixed-effect model) assessed inter-examiner and intra-examiner reliability of bone level measurement on 20 radiographs. The reliability was excellent, with an inter-examiner ICC of 0.94 and an intra-examiner ICC of 1.00. The Dahlberg measurement error was 0.38mm.

Statistical methods

Assessment was initially based on intention-to-treat. Based on a previous study (Camarda, et al., 2018), the effect size for the difference in bone level change between implant groups was expected to be 0.95. A sample size of 16 participants would, therefore, ensure an 80% power to reject the null hypothesis, if it was indeed false at a two-sided Bonferroni-adjusted α level of 0.017 (to adjust for pairwise comparisons between implant groups), using a repeated measures ANOVA. Absence or presence of prosthesis, abutment, and implant mobility was analyzed with the Fisher's exact test. The mean keratinized gingiva height (mm), probing depth (mm), and percentage of sites with dPI, dBI and purulence were calculated for each implant. Shapiro-Wilk test was used to assess the normality of data distribution. These values were then analyzed with nonparametric ANOVA-type statistic for repeated measures within subject, with implant type, site and configuration as independent variables (Brunner, et al., 2002). Quantitative bone healing was analyzed with mixed models for repeated measures within subject, with implant type, site and configuration as independent variables, and implant length as covariate. The lengths of the different implant types were compared with a Kruskal-Wallis test. Confidence Interval (CI) was established at two-sided 95% Confidence Level (CL). The level of significance was set at $p < 0.05$ and Bonferroni correction was applied for pairwise comparisons. ICC (two-way, mixed-effect model) and Bland-Altman limits of agreement (Bland, & Altman, 1986) were used to analyze comparison of mean fBIC-MG values between conventional peri-apical radiology and phosphor-plate technology. All statistical analyses were performed using IBM SPSS Statistics for Windows® Version 25 (IBM Co., Armonk, NY, USA), and SAS 9.4 (SAS Institute, Cary, NC, USA).