Disclaimer: The following information is fictional and is only intended for the purpose of illustrating key concepts for results data entry in the Protocol Registration and Results System (PRS).

Units Other Than Participants Study Example

(A Study of Ghostsply® Dental Implants vs. Crestene® Dental Implants)

METHODS

Study Design

This was an unblinded, prospective, randomized, self-controlled study designed to compare the effectiveness of two dental implant systems in a split-mouth randomized design. Participants were enrolled from four research sites in the United States: the UCSF School of Dentistry (San Francisco, CA), University of Colorado School of Dental Medicine (Aurora, CO), University of Maryland School of Dentistry (Baltimore, MD), and University of Minnesota School of Dentistry (Minneapolis, MN). In this study, titanium Ghostsply® implants were compared to ceramic Crestene® implants 1 year after placement in 30 patients with comparable bilateral edentulous sites. The overall hypothesis tested was that the clinical performance of Ghostsply® implants, as measured by change in marginal bone level (also referred to as “marginal bone adaptation”) and bleeding upon probing of the implants, would be superior to that of Crestene® implants. Subjects were randomly assigned to receive no more than three Ghostsply® implants in the left or the right mandible side and no more than three Crestene® implants in the opposite mandible side. Clinical measures and radiographic changes were recorded 1 year post surgery by the same operator. Both types of implants were inserted strictly according to the manufacturer’s directions and American Dental Association Seal of Acceptance Program guidelines.

Eligibility Criteria

The inclusion criteria were as follows: male or female participants, at least 18 years of age, with written informed consent, sufficient oral hygiene, sufficient width and height of bone to place implants, and comparable bilateral edentulous areas. Individuals were excluded from participating in the study for the following reasons: inflammation/disorder or infection in the area of the implant site, a need for bone or soft-tissue augmentation in the planned implant areas before surgery, systemic metabolic disorder, prescription medications that would compromise postoperative healing, an allergy to dental medications or materials, pregnancy or lactation, or the inability or unwillingness to return for a follow-up visit after 12 months.

Statistical Analysis

The significance of the change in marginal bone level at the 12-month follow-up visit was determined by a two-sided t-test (a comparison between study arms) and paired two-sided t-tests (comparisons within study arms). A chi-squared test was used to evaluate the significance of the difference between the two treatments in the percentage of implant sites with bleeding upon probing. The null hypothesis was that there would be no difference between the two implants or between the time points, and the threshold for statistical significance was $p = 0.05$.

RESULTS

Study Patients

Thirty patients were screened for eligibility between September 9, 2017, and January 15, 2018. Of those, three did not meet the inclusion criteria, and one declined to participate. A total of 26 patients (17 males and 9 females, 21 to 75 years of age) met the inclusion criteria and were enrolled. All 26 participants received implants of both types, according to the randomization scheme described in the Study Design section. Two participants with six implants, in total, were lost to follow-up; 24 participants completed the study and were analyzed (see figure 1). The study length was 12 months, and the last patient's last visit was on January 27, 2019. Demographic characteristics and baseline measurements were collected for participants randomized to intervention (see table 1).

Figure 1. Recruitment, enrollment, and progression of the study population

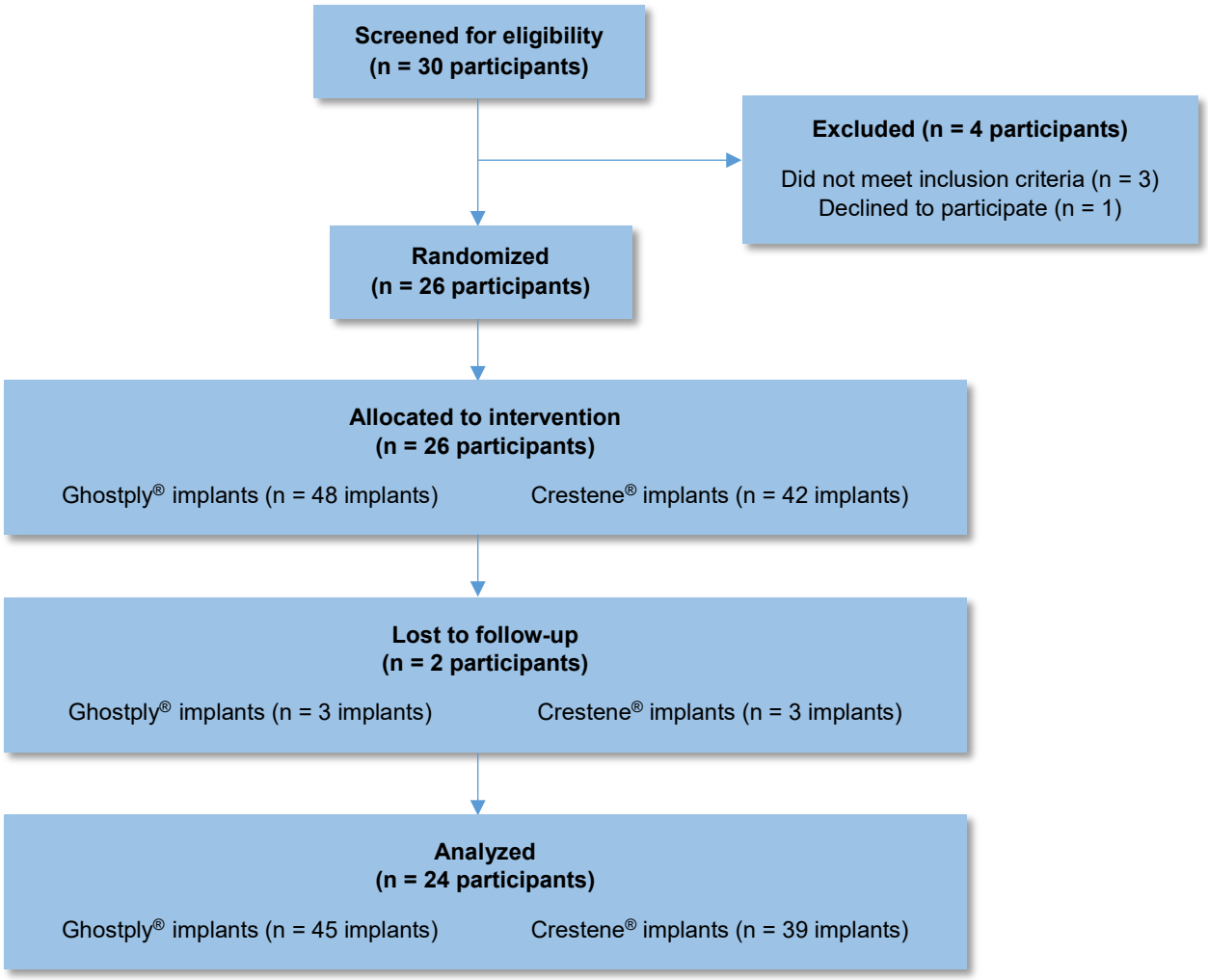

Table 1. Demographic Characteristics and Baseline Measurements of Study Participants

Demographic Characteristic or Baseline Measurement	Study Participants (n = 26)
Age (years) *Median (full range)*	55 (21 to 75)
Age (participants) *<= 18 years* *> 18 years and < 65 years* *>= 65 years*	 0 25 1
Sex (participants) *Male* *Female*	 17 9
Region of Enrollment (participants) *United States*	 26
Implantation Site Type (implants) *Ghostsply® (n = 48)* *Prior edentulism** *Extraction* *Crestene® (n = 42)* *Prior edentulism** *Extraction*	 19 29 16 26

***** Missing teeth

OUTCOMES

Primary Endpoint

The primary endpoint was the change in marginal bone level, 12 months after surgery, in participants who completed the 12-month follow-up visit (per protocol analysis; see table 2). Marginal bone level was expressed as the distance from the implant reference point to the most coronal bone-to-implant contact on the mesial and distal sides of the implant. Change in marginal bone level, also referred to as "bone adaptation," was calculated by subtracting the value, in millimeters, at the 12-month follow-up visit from the value obtained at implant placement. Positive values indicate bone gain, and negative values indicate bone loss. A marginal bone loss that does not exceed 1 mm after 1 year and 0.2 mm each year after is widely considered consistent with successful treatment.

There was no significant difference in bone loss between the Ghostsply® Implants and Crestene® Implants arms. Although bone loss experienced with the Crestene® implants was significant over the 12-month evaluation period, and bone loss experienced with the Ghostsply® implants approached significance over the same time period, the amount of bone loss in both study arms was consistent with treatment success.

Table 2. Primary Endpoint, Per Protocol Analysis: Change in Marginal Bone Level at the 12-Month Follow-up Visit

	Ghostsply® Implants			Crestene® Implants			Treatment Difference	
	24 participants	45 implants	P-value†	24 participants	39 implants	P-value†	Net mean difference‡	P-value§
Marginal bone level (mm)	Mean (SD)			Mean (SD)			Mean (SD)	
Baseline	10.2 (0.69)			9.6 (0.53)				
Change at 12 months*	-0.25 (0.92)		0.08	-0.46 (0.93)		0.004	0.212 (0.21)	0.3

* Change at 12 months = Value at baseline – Value at 12 months
† Paired two-sided t-test
‡ Net mean difference = Ghostsply® implant change at 12 months – Crestene® implant change at 12 months
§ Two-sided t-test

Secondary Endpoint

The secondary endpoint was the percentage of implant sites with bleeding on probing (BOP) at 12 months (per protocol analysis; see table 3). BOP is a measure of gingival inflammation and tissue destruction. Bleeding sites were identified by gently probing the base of the implant site and assigning a score of 0 (no bleeding) or 1 (bleeding). The number of implant sites that bled was divided by the total number of implants and expressed as a percentage.

Table 3. Secondary Endpoint, Per Protocol Analysis: Percentage of Implant Sites with BOP at 12 Months

	Ghostsply® Implants		Crestene® Implants		P-value*
	24 participants	45 implants	24 participants	39 implants	
Percentage of implant sites with BOP	% BOP (# implants)		% BOP (# implants)		
12 months	24.4 (11)		30.8 (12)		0.52

* Chi-squared test

Adverse Events

Data on all serious and non-serious Adverse Events experienced by participants were collected over 12 months, irrespective of the event's relation to the dental implants. Adverse Events were collected by non-systematic assessment, using terms from the Systematized Nomenclature of Medicine – Clinical Terms (SNOMED CT), of participants who received at least one implant. There were no Serious Adverse Events. A total of 13 participants reported non-serious Adverse Events; of these, 7 participants reported Adverse Events localized at a Ghostsply® implant site, and 4 participants reported Adverse Events localized at a Crestene® implant site. One participant who received the Ghostsply® implants in the right mandible side reported an ear-popping sensation in the right ear. Eight participants reported pain; of these,

one participant reported pain on both sides, two participants reported pain only on the side with the Crestene® implants, and five participants reported pain only on the side with the Ghostsply® implants. One participant had a tooth abscess on the side with the Crestene® implants. Three participants reported nausea, and one participant reported an upper respiratory tract infection.