Units Other Than Participants Study Example (With Results)

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).

ClinicalTrials.gov Identifier: NCT00055620

Recruitment Status: Completed
First Posted: September 9, 2017
Results First Posted: September 22, 2019
Last Update Posted: September 22, 2019

Sponsor:

PRS Results Training

Information provided by (Responsible Party):

PRS Results Training

Study Description

Brief Summary:

This is a randomized split-mouth study of the comparative effectiveness of two dental implants: titanium Ghostsply® implants vs. ceramic Crestene® implants. The primary aim is to evaluate the change in marginal bone level. The secondary aim is to evaluate bleeding upon probing of the implants.

Condition or disease	Intervention/treatment	Phase
Partial Edentulism	Device: Ghostsply® Dental Implant Device: Crestene® Dental Implant	Not Applicable

Detailed Description:

This is an unblinded, prospective, randomized, self-controlled study designed to compare the effectiveness of two dental implant systems in a split-mouth randomized design. In this study, titanium Ghostsply® implants will be compared to ceramic Crestene® implants 1 year after placement in patients with comparable bilateral edentulous sites. The overall hypothesis is 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, will be superior to that of Crestene® implants. Subjects will be 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 will be recorded 1 year post surgery by the same operator. Both types of implants will be inserted strictly according to the manufacturer's directions and American Dental Association Seal of Acceptance Program guidelines.

Study Design

Study Type:	Interventional
Actual Enrollment:	26 participants
Allocation:	Randomized
Intervention Model:	Parallel Assignment
Masking:	None (Open Label)
Primary Purpose:	Treatment
Official Title:	A Study of Ghostsply® Dental Implants vs. Crestene® Dental Implants
Actual Study Start Date:	September 9, 2017
Actual Primary Completion Date:	January 27, 2019
Actual Study Completion Date:	January 27, 2019

Arms and Interventions

Arm	Intervention/treatment
Experimental: Ghostsply® Dental Implants In a split-mouth design, subjects were randomly assigned to receive no more than three Ghostsply® implants in the left or the right mandible side.	Device: Ghostsply® Dental Implant Titanium dental implant
Experimental: Crestene® Dental Implants In a split-mouth design, subjects were randomly assigned to receive no more than three Crestene® implants in the mandible side opposite the Ghostsply® implants.	Device: Crestene® Dental Implant Ceramic dental implant

Outcome Measures

Primary Outcome Measure:

1. Change in Marginal Bone Level at the 12-Month Follow-up Visit [Time Frame: Baseline, 12 months]

   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 (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.

Secondary Outcome Measure:

1. Number (%) of Implant Sites With Bleeding on Probing [Time Frame: 12 months]

   Bleeding on probing (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). Percentage of BOP = 100% * (total implant sites that bled) / (total number of implants).

Eligibility Criteria

Ages Eligible for Study: 18 Years and older (Adult, Older Adult)
Sexes Eligible for Study: Both
Accepts Healthy Volunteers: Yes

Criteria

Inclusion Criteria:

- Sufficient oral hygiene
- Sufficient width and height of bone to place implants
- Comparable bilateral edentulous areas

Exclusion Criteria:

- Inflammation/disorder or infection in the area of the implant site
- Need for bone or soft-tissue augmentation in the planned implant areas before surgery
- Systemic metabolic disorder
- Prescription medications that would compromise postoperative healing
- Allergy to dental medications or materials
- Pregnancy or lactation
- Inability or unwillingness to return for a follow-up visit after 12 months

Contacts and Locations

Locations

United States, California

UCSF School of Dentistry

San Francisco, California, United States, 94143

United States, Colorado

University of Colorado School of Dental Medicine

Aurora, Colorado, United States, 80045

United States, Maryland

University of Maryland School of Dentistry

Baltimore, Maryland, United States, 21201

United States, Minnesota

University of Minnesota School of Dentistry

Minneapolis, Minnesota, United States, 55455

Study Documents (Full-Text)

Documents provided by PRS Results Training

Study Protocol and Statistical Analysis Plan [PDF] July 1, 2017

More Information

Responsible Party:	PRS Results Training
ClinicalTrials.gov Identifier:	NCT00055620
Other Study ID Numbers:	TTTUnitsOtherThanParticipantsR
First Posted:	September 9, 2017
Results First Posted:	September 22, 2019
Last Update Posted:	September 22, 2019
Last Verified:	August 2019

Human Subjects Protection Review Board Status:	Approved
Studies a U.S. FDA-regulated Drug Product:	No
Studies a U.S. FDA-regulated Device Product:	No

Study Results

Study Type	Interventional
Study Design	Allocation: Randomized; Intervention Model: Parallel Assignment; Masking: None (Open Label); Primary Purpose: Treatment
Condition	Partial Edentulism
Interventions	Device: Ghostsply® Dental Implant Device: Crestene® Dental Implant
Enrollment	26

Participant Flow

Recruitment Details	Participants were recruited from four locations in the United States.
Pre-assignment Details	A total of 30 patients were screened. Of those, 26 met the inclusion criteria and were enrolled.

Arm/Group Title	Ghostsply® Implants	Crestene® Implants
Arm/Group Description	Titanium Ghostsply® implants were randomly assigned to the left or the right mandible side in a split-mouth randomized design.	Ceramic Crestene® implants were randomly assigned to the left or the right mandible side in a split-mouth randomized design.

Period Title: **Overall Study**

Type Units Assigned: Implants	Number of participants	Number of units (implants)	Number of participants	Number of units (implants)
Started	26	48	26	42
Completed	24	45	24	39
Not Completed	2	3	2	3
Reason Not Completed				
Lost to Follow-up	2		2	

Baseline Characteristics

Arm/Group Title		Ghostsply® Implants	Crestene® Implants	Total
Arm/Group Description		Titanium Ghostsply® implants were randomly assigned to the left or the right mandible side in a split-mouth randomized design.	Ceramic Crestene® implants were randomly assigned to the left or the right mandible side in a split-mouth randomized design.	Total of all reporting groups
Overall Number of Baseline Participants		26	26	26
Overall Number of Units Analyzed Type of Units Analyzed: implants		48	42	90
Baseline Analysis Population Description		[Not Specified]		
Age, Continuous Median (Full Range) Unit of Measure: years				
	Number Analyzed	26 participants	26 participants	26 participants
		55 (21 to 75)	55 (21 to 75)	55 (21 to 75)
Age, Customized Measure Type: Number Unit of Measure: participants	Number Analyzed	26 participants	26 participants	26 participants
<=18 years		0	0	0
Between 18 and 65 years		25	25	25
>=65 years		1	1	1

Sex/Gender, Customized Measure Type: Number Unit of measure: participants	Number Analyzed	26 participants	26 participants	26 participants
Female		9	9	9
Male		17	17	17
Race and Ethnicity Not Collected [1] Measure Type: Count of Participants Unit of measure: participants	Number Analyzed	0 participants	0 participants	0 participants
		0	0	0
		[1] Measure Analysis Population Description: Race and Ethnicity were not collected from any participant.		
Region of Enrollment Measure Type: Number Unit of measure: participants				
United States	Number Analyzed	26 participants	26 participants	26 participants
		26 100%	26 100%	26 100%

Implantation Site Type Count of Units Unit of measure: implants				
	Number Analyzed	48 implants	42 implants	90 implants
	Prior Edentulism (missing tooth)	19 39.58%	16 38.1%	35 38.89%
	Extraction	29 60.42%	26 61.9%	55 61.11%

Outcome Measures

1. Primary Outcome

Title	Change in Marginal Bone Level at the 12-Month Follow-up Visit
Description	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 (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.
Time Frame	Baseline, 12 months

Outcome Measure Data

Analysis Population Description
Per Protocol population, defined as participants completing the 12-month follow-up visit

Arm/Group Title	Ghostsply® Implants	Crestene® Implants
Arm/Group Description:	Titanium Ghostsply® implants were randomly assigned to the left or the right mandible side in a split-mouth randomized design.	Ceramic Crestene® implants were randomly assigned to the left or the right mandible side in a split-mouth randomized design.
Overall Number of Participants Analyzed	24	24
Overall Number of Units Analyzed Type of Units Analyzed: implants	45	39
Mean (Standard Deviation) Unit of Measure: millimeters (mm)		
Baseline Marginal Bone Level	10.2 (0.69)	9.6 (0.53)
Change at 12 months	-0.25 (0.92)	-0.46 (0.93)

Statistical Analysis 1

Statistical Analysis Overview	Comparison Group Selection	Ghostsply® Implants, Crestene® Implants
	Comments	The null hypothesis was that the change from baseline to 12 months in the marginal bone level for the Ghostsply® implants would be no different than the change from baseline to 12 months for the Crestene® implants.
	Type of Statistical Test	Superiority
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.3
	Comments	The threshold for statistical significance was p = 0.05.
	Method	t-test, 2 sided
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Mean Difference (Net)
	Estimated value	0.212
	Parameter Dispersion	Type: Standard Deviation Value: 0.21
	Estimation Comments	Difference = Ghostsply® implants minus Crestene® implants

Statistical Analysis 2

Statistical Analysis Overview	Comparison Group Selection	Ghostsply® Implants
	Comments	The null hypothesis was that there would be no change from baseline to 12 months in the marginal bone level.
	Type of Statistical Test	Other
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.08
	Comments	Paired; the threshold for statistical significance was p = 0.05.
	Method	t-test, 2 sided
	Comments	[Not specified]

Statistical Analysis 3

Statistical Analysis Overview	Comparison Group Selection	Crestene® Implants
	Comments	The null hypothesis was that there would be no change from baseline to 12 months in the marginal bone level.
	Type of Statistical Test	Other
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.004
	Comments	Paired; the threshold for statistical significance was p = 0.05.
	Method	t-test, 2 sided
	Comments	[Not specified]

2. Secondary Outcome

Title	Number (%) of Implant Sites With Bleeding on Probing
Description	Bleeding on probing (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). Percentage of BOP = 100% * (total implant sites that bled) / (total number of implants).
Time Frame	12 months

Outcome Measure Data

Analysis Population Description
Per Protocol population, defined as participants completing the 12-month follow-up visit

Arm/Group Title	Ghostsply® Implants	Crestene® Implants
Arm/Group Description:	Titanium Ghostsply® implants were randomly assigned to the left or the right mandible side in a split-mouth randomized design.	Ceramic Crestene® implants were randomly assigned to the left or the right mandible side in a split-mouth randomized design.
Overall Number of Participants Analyzed	24	24
Overall Number of Units Analyzed Type of Units Analyzed: implants	45	39
Count of Units Unit of Measure: implants	11 24.44%	12 30.77%

Statistical Analysis 1

Statistical Analysis Overview	Comparison Group Selection	Ghostsply® Implants, Crestene® Implants
	Comments	The null hypothesis was that there would be no difference between the two interventions in the percentage of implant sites with BOP at 12 months.
	Type of Statistical Test	Superiority
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.52
	Comments	The threshold for statistical significance was p = 0.05.
	Method	Chi-squared
	Comments	[Not specified]

Adverse Events

Time Frame	Up to 12 months after implant surgery
Adverse Event Reporting Description	Data on all serious and non-serious Adverse Events experienced by participants were collected, irrespective of the event's relation to the dental implants. Participants with systemic Adverse Events were not considered at risk for these events in the Ghostsply® Implants and Crestene® Implants arms since those arms were limited to the analysis of localized events.
Source Vocabulary Name for Table Default	SNOMED CT
Collection Approach for Table Default	Non-systematic Assessment

Arm/Group Title	Ghostsply® Implants	Crestene® Implants	All Study Participants
Arm/Group Description	Adverse Events localized to the mouth side with Ghostsply® implants	Adverse Events localized to the mouth side with Crestene® implants	All Adverse Events, including those that affected participants as a whole (systemic events)

All-Cause Mortality

	Ghostsply® Implants	**Crestene® Implants**	**All Study Participants**
	Affected / at Risk (%)	Affected / at Risk (%)	Affected / at Risk (%)
Total	0/26 (0%)	0/26 (0%)	0/26 (0%)

Serious Adverse Events

	Ghostsply® Implants	**Crestene® Implants**	**All Study Participants**
	Affected / at Risk (%)	Affected / at Risk (%)	Affected / at Risk (%)
Total	0/26 (0%)	0/26 (0%)	0/26 (0%)

Other (Not Including Serious) Adverse Events

Frequency Threshold for Reporting Other Adverse Events	0%		
	Ghostsply® Implants	**Crestene® Implants**	**All Study Participants**
	Affected / at Risk (%)	Affected / at Risk (%)	Affected / at Risk (%)
Total	7/26 (26.92%)	4/26 (15.38%)	13/26 (50%)
Ear and labyrinth disorders			
Ear-Popping Sensation * 1 [1]	1/26 (3.85%)	0/26 (0%)	1/26 (3.85%)
Gastrointestinal disorders			
Nausea * 1	0/0	0/0	3/26 (11.54%)
Infections and infestations			
Tooth Abscess * 1	0/26 (0%)	1/26 (3.85%)	1/26 (3.85%)
Respiratory, thoracic and mediastinal disorders			
Upper Respiratory Tract Infection * 1	0/0	0/0	1/26 (3.85%)
Surgical and medical procedures			
Pain * 1	6/26 (23.08%)	3/26 (11.54%)	8/26 (30.77%)

1 Term from vocabulary, SNOMED CT

* Indicates events were collected by non-systematic assessment

[1] Ear-popping sensation was on the side with the Ghostsply® implants

Limitations and Caveats

[Not Specified]

More Information

Certain Agreements

Principal Investigators are NOT employed by the organization sponsoring the study.

There is NOT an agreement between the Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

Results Point of Contact

Name/Title:	PRS Training Lead
Organization:	PRS Results Training
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Responsible Party:	PRS Results Training
ClinicalTrials.gov Identifier:	NCT00055620
Other Study ID Numbers:	TTTUnitsOtherThanParticipantsR
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