STATISTICAL REPORTING AND ANALYSIS PLAN

A Randomized, Open-Label, Clinical Study to Evaluate a Methodology to Assess Food Occlusion Efficacy of a Denture Adhesive in Healthy, Edentulous Subjects

Protocol Number: 208397

Phase: 2

Document History

Document	Version Date	Summary of Changes (New analysis or Change in planned analysis)
Final Analysis Plan	14-Dec-2017	Not applicable (N/A)

Amendments incorporate all revisions to date.

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Abbreviation

Abbreviation	Term
AE	Adverse Event
DRM	Data Review Meeting
CI	Confidence Interval
CSR	Clinical Study Report
ITT	Intent-To-Treat
MedDRA	Medical Dictionary for Regulatory Activities
OST	Oral Soft Tissue
PP	Per-Protocol
PT	Preferred Term
SAE	Serious Adverse Event
SD	Standard Deviation
SE	Standard Error
SOC	System Organ Class
TEAE	Treatment Emergent Adverse Event
USA	United State of America

The purpose of this Statistical Reporting and Analysis Plan is to describe the planned analyses and outputs to be included in the Clinical Study Report (CSR) for Protocol 208397.

1 Summary of Key Protocol Information

The aim of this study is to establish a reliable methodology that is able to characterize the performance of the adhesive in terms of reducing food ingress in a food occlusion methodology where subjects are asked to eat peanuts in a controlled manner and the mass of peanut particles under the denture, post peanut consumption, is measured and compared.

This study will be conducted in subjects with complete maxillary and mandibular dentures.

This study will be conducted at Salus Research in the United States of America (USA).

1.1 Study Design

This study is a single centre, controlled, open label, randomized, three-treatment, three-period, cross-over design in subjects with full upper and full lower dentures. Each treatment period will consist of one day of testing with at least two days between adjacent treatment visits.

All the study procedures (as defined in protocol) will be repeated in a crossover manner. There will be 2-30 days between treatment visits to allow for recovery from the mastication procedures.

At the screening visit, following an Oral Soft Tissue (OST) examination, each subject's dentures (upper and lower) will be cleaned then assessed for retention and stability using the Kapur Index (Olshan Modification) and whether they are well made. Only those subjects with dentures (both upper and lower) that satisfy both of these criteria will undergo the food migration adequacy assessment to provide evidence of adequate peanut particle migration under the dentures after chewing a portion of peanuts. A visual observation and rating of location and extent of peanut particle migration adequacy must indicate > 0 on a 0 - 3 scale. Subjects meeting all the inclusion criteria with no exclusions will then be randomised at Visit 2.

On each test day (Visits 2-4) subjects will undergo an OST examination and have their dentures cleaned. Treatment (or no treatment as per the randomization schedule) will then be applied as per the application instructions and the dentures worn by the subject. Then, 60±5 minutes after inserting their dentures each subject will be given a standardized portion of

peanuts to consume, following a prescribed chewing and swallowing method. Whilst chewing the peanuts subjects will record the number of denture dislodgements that occur during the chewing procedure. After this, subjects will rinse their mouth with water. The examiner will then remove the lower denture and any peanut particles or adhesive remaining on the mandibular ridge will be removed using gauze. The examiner will then remove the upper denture and any peanut particles or adhesive remaining on the palate will be removed using new gauze. The subject will then complete a questionnaire on efficacy and a further OST examination will be performed.

1.2 Study Objectives

The study objectives are as follows:

Objectives	Endpoints
Primary Objective	**Primary Endpoint**
• To evaluate the mass of peanut particles that migrate under the dentures during a food occlusion methodology when denture adhesive is applied per continuous strips pattern and when no adhesive is used.	• Mass of peanuts under combined maxillary and mandibular dentures.
Exploratory Objectives	**Exploratory Endpoints**
• To evaluate the mass of peanut particles that migrate under the dentures during a food occlusion methodology when denture adhesive is applied per continuous strips pattern and when no adhesive is used.	• Mass of peanuts under combined maxillary and mandibular dentures.
• To evaluate the mass of peanut particles that migrate under the maxillary and mandibular dentures during a food occlusion methodology when denture adhesive is applied per conventional pattern, continuous strips pattern and when no adhesive is used.	• Mass of peanuts under maxillary dentures. • Mass of peanuts under mandibular dentures.
• To evaluate subject responses to questions during a food occlusion	• Subject completed questionnaire.

Objectives	Endpoints
methodology when denture adhesive is applied per conventional pattern, continuous strips pattern and when no adhesive is used.	
• To explore the performance of a marketed denture adhesive when applied per conventional pattern to no adhesive use for subjects in the low and high Kapur-Olshan subgroups.	• Mass of peanuts under combined maxillary and mandibular dentures in each subgroup (low and high Kapur-Olshan scores).
• To explore the relationship between the numbers of subject-reported denture dislodgements when denture adhesive is applied per conventional pattern, continuous strips pattern and when no adhesive is used.	• The number of subject reported denture dislodgements during chewing.
Safety	
• To assess the tolerability of marketed denture adhesive (Super Poligrip Free).	• Treatment emergent adverse events.

This study is a method development study and therefore there is no formal success criterion.

1.3 Treatments

The detail of three treatments used in this cross-over study is as follows:

	Test Product (Conventional Application)	**Test Product (Continuous Strip Application)**	**Negative Control**
	Super Poligrip Free Denture Adhesive Cream (USA Marketplace)	Super Poligrip Free Denture Adhesive Cream (USA Marketplace)	No Adhesive
Product Formulation Code	CCI [redacted]	CCI [redacted]	N/A
Dose	1.6 gram (g) of adhesive applied as 1.0g for maxillary denture and 0.6g for	1.6g of adhesive applied as 1.0g for maxillary denture and 0.6g for mandibular	N/A

	Test Product (Conventional Application)	Test Product (Continuous Strip Application)	Negative Control
	mandibular denture.	denture.	
Route of Administration	Applied to the denture which is placed in mouth	Applied to the denture which is placed in mouth	N/A
Dose Instructions	As per the product application instructions	As per the product application instructions	N/A

A single, common adhesive will be used (Super Poligrip Free) with a common dose (1.6g) for both application methods. The adhesive will be extruded from a pre-dosed syringe following the application instructions. Super Poligrip Free has been selected as the adhesive in this study as it is a currently marketed product and is considered a representative denture adhesive. 1.6g of adhesive per treatment will be applied to each subject's dentures, an amount consistent with that used in previous studies and will therefore facilitate comparison of data from this study with previous work. This dose will be split as 1.00±0.05g for the maxillary and 0.60± 0.05g for the mandibular dentures in accordance with consumer's normal distribution of adhesive.

A no adhesive negative control treatment has been chosen to provide a continual reference point to allow interpretation of the results and to facilitate comparison of the results from this study with previous work, and is representative of a significant number of denture wearers who currently do not use an adhesive.

1.4 Sample Size Calculation

Since this is an exploratory methodology development study, no formal sample size calculation was conducted. CCI [redacted]

Therefore, approximately 48 (maximum 50) healthy subjects with both maxillary and mandibular full dentures will be enrolled in this study. Subject recruitment will be controlled to ensure 50±10% of the subjects will be in each of the low and high Kapur-Olshan groups

[the low Kapur-Olshan group is defined as a composite Kapur-Olshan score of 6-14 (clinically fair and good dentures) and the high Kapur-Olshan score as 15-18 (clinically very good dentures)].

2 Planned Analyses

2.1 Interim Analysis

No interim analysis is planned.

2.2 Final Analyses

The final planned primary analyses will be performed after the completion of the following sequential steps:

1. All subjects have completed the study as defined in the protocol.
2. All required database cleaning activities have been completed and database has been locked.

3 Considerations for Data Analyses and Data Handling Conventions

3.1 Baseline Definition

A baseline definition is not required for this trial as no baseline measurements are performed or required for the summaries and analysis.

3.2 Subgroups/Stratifications

The subgroups defined in this study are as follows:

Low Kapur-Olshan group: Defined as a composite Kapur-Olshan score of 6-14 (clinically fair and good dentures) at screening.

High Kapur-Olshan group: Defined as a composite Kapur-Olshan score of 15-18 (clinically very good dentures) at screening.

Exploratory analysis will be performed on the above defined subgroups.

Stratification factors are not defined in this study.

3.3 Centers Pools

Since this is single center study, pooling of center is not applicable.

3.4 Timepoints and Visit Windows

The timepoints and visits for this study are defined in the section "Schedule of Activities" of the protocol. Any deviation from the study schedule will be reviewed on case-by-case basis to determine whether the data should be excluded from the Per-Protocol (PP) population. A time window non-compliance listing will be produced for the Data Review Meeting (DRM).

4 Data Analysis

Data analysis will be performed by inVentiv Health Clinical. The statistical analysis software used will be SAS version 9.4 (Studio) or higher.

Prior to database closure a DRM will be conducted in which various aspects of the trial will be discussed and agreed.

In this study the date and time of start of treatment will be the date and time when dentures were inserted.

Unless otherwise described below, all listings will be produced for all randomized subjects.

4.1 Populations for Analysis

4.1.1 Subject Disposition

Screen failures will be defined as subjects who do not satisfy either of the inclusion or exclusion criteria and are not subsequently randomized. A summary table for number of subjects screened, number of screen failure subjects with reasons why not randomized (Table 14.1.1.1) will be presented. The percentage will be based on total number of screened subjects.

Subject disposition will also be summarized as the number and percentage of subjects in each of the defined analysis population, who complete the study, who discontinue the study and reason for discontinuation (Table 14.1.1.1). The summary table will be presented by treatment group and for all combined treatment group (Overall). The percentage will be based on total number of subjects randomized in each treatment and overall.

The subject disposition table by treatment sequence, period (Table 14.1.1.2) will also be presented. In this summary table, the number and percentage of subjects starting and completing each period with reason for not completing any of the periods will be presented. The percentage will be computed using the number of subjects starting each period as a denominator.

Subject disposition including the critical demographic data (age, sex, race), screening date, treatment start date, date of completion or withdrawal, subject status (completer, Yes/No) and the specific reason for discontinuation, will be listed in Listing 16.2.1.1 by treatment sequence for randomized subject and non-randomized subjects (Listing 16.2.1.2) separately.

4.1.2 Protocol Deviations

Major protocol deviations (including deviations related to study inclusion/exclusion criteria, conduct of the trial, patient management or patient assessment) will be summarized and listed.

Protocol deviations will be tracked by the study team throughout the conduct of the study. Data will be reviewed at the DRM prior to closure of the database to ensure all important deviations are captured and categorised.

Major deviations of the protocol procedures identified as liable to influence the outcomes of the study may include, but will not be necessarily limited to the following:

- Inclusion/Exclusion criteria
- Treatment non-compliance
- Treatment administration error
- Use of prohibited medications before and during the study which is deemed to affect the assessment of efficacy.
- Deviations likely to affect study outcomes.

Minor deviations will be identified as those not classified as major deviations.

More details on protocol deviations can be found in the Protocol Deviation Management Plan (PDMP) of this study.

The number and percentage of subjects with any major protocol deviations and with each type of major protocol deviations will be presented by treatment (Table 14.1.2) and listed in Listing 16.2.2.1. Any minor protocol deviations will be listed similarly (Listing 16.2.2.2).

4.1.3 Analysis Populations

The analysis population defined in this study as follows:

Population	Definition / Criteria	Analyses Evaluated
Safety Population	• All randomized subjects. • Receive at least one dose of study treatment during the study.	Safety
Intent-To-Treat (ITT) Population	• All randomized subjects. • Received at least one dose of study treatment during the study. • Consumed peanuts and have at least one mass of peanuts from both upper and lower dentures.	Efficacy
PP Population	• Subset of ITT population. • All subjects who are assessed as sufficiently compliant with study procedures and restrictions. • Subjects with major protocol deviations will be excluded. Depending on the nature of the major protocol deviation and impact on the efficacy variable (s), subjects will be either completely excluded from PP population or only partially excluded from the PP analyses. This will be determined on a case-by-case basis.	Efficacy

NOTES :

- Please refer to Attachment 1: List of Data Displays which details the population to be used for each displays being generated.

The primary population for assessment of efficacy will be the ITT population. A PP analysis will be performed only if 10% or more of ITT subjects are excluded from PP population.

Exclusion of any data from the analyses will be determined during a DRM prior to database lock. Subjects completely excluded from any analysis population will be listed (Listing 16.2.3.1).

4.2 Subject Demographics and Other Baseline Characteristics

4.2.1 Demographic Characteristics

Descriptive statistics [number of subjects (n), mean, standard deviation (SD), median, minimum and maximum values] for continuous variables and frequency count (n) and percentages (%) for all categorical variables will be presented.

The continuous variable includes age (in years) and categorical variables include sex, race and ethnicity. This data will be summarized descriptively for all subjects in Safety (Table 14.1.4.1) and ITT (Table 14.1.4.2) population by overall and will be listed (Listing 16.2.4.1).

Number and percentage of subjects in individual Kapur-Olshan retention and stability index sum score and group (Low and High) will be presented for all subjects in Safety (Table 14.1.4.1) and ITT (Table 14.1.4.2) population by overall. The listing of evaluation of well fit denture will be provided (Listing 16.2.4.2).

The current denture age (years) will be summarized descriptively for all subjects in Safety (Table 14.1.4.1) and ITT (Table 14.1.4.2) population by overall and complete denture history will be listed (Listing 16.2.4.3).

No formal statistical analysis will be performed for this data.

4.2.2 General Medical History

Medical history and current medical conditions will be listed in Listing 16.2.4.4, with start date and end date or ongoing.

4.3 Treatments (Study Product, Rescue Medication, other Concomitant Therapies, Compliance)

4.3.1 Study Product Compliance and Exposure

In this study single, common adhesive Super Poligrip Free will be used. 1.6g adhesive per treatment will be applied to each subject's dentures. This dose will be split as 1.00±0.05g for maxillary and 0.60±0.05g for mandibular dentures in accordance with consumer's normal distribution of adhesive.

The weight of adhesive applied to the dentures will be summarized descriptively (n, mean, SD, median, minimum and maximum) by treatment group and for lower, upper and combined

dentures (Table 14.2.1) on all subjects in ITT population. In the combined dentures the sum of weight of adhesive applied to lower and upper dentures will be obtained. The study product compliance data will be listed in Listing 16.2.5.1 on all randomized subjects.

4.3.2 Prior and Concomitant Medication

Prior or concomitant medication taken by or administered to a subject will be recorded in the case report form. The prior and concomitant medications will be coded using an internal validated medication dictionary, GSKDrug.

Prior medications are defined as the medications started and stopped before first administration of study treatment (dentures were inserted). If the stop date is unknown or incomplete and medication cannot be considered as stopped prior to first administration of study treatment then the medication will be considered as concomitant medication.

Concomitant medications are defined as the medication started before the first administration of study treatment (dentures were inserted) and continued in the study or medication taken between the date of first dose and last dose of study treatment.

In this crossover study, the concomitant medication will be assigned to the treatment group based on the treatment being received at that date. Medication with date and time between the periods will be assigned to the treatment received in the previous period. Medications with a date after last treatment or the end of the study will be assigned to the treatment taken in the last period. In case the medication is taken during washout period, then it will be assigned to the most recent treatment period prior to washout.

Unknown dates will not be imputed, however if the start date is unknown, then it will be assumed to concomitant medication for all periods, unless the partial start date or stop date indicates differently.

Prior and concomitant medications/non-drug therapies will be listed by subject, with preferred term, indication, dose, dose form, frequency, route, start date, end date or ongoing and start day relative to first dose of study drug (Listing 16.2.5.2 and Listing 16.2.5.3).

4.4 Analysis of Efficacy

4.4.1 Primary Endpoint

4.4.1.1 Primary Endpoint Definition

The primary endpoint is defined as the combined mass of peanuts under maxillary and mandibular dentures.

4.4.1.2 Statistical Hypothesis, Model, and Method of Analysis

Food occlusion will be measured by weight of peanut particles (mass of retrieved peanuts in grams). Analysis will be performed on combined values (maxillary and mandibular dentures) of food occlusion.

Descriptive statistics (number of subjects, number of missing data, raw means, SD, standard errors [SE], median, minimum and maximum values) of combined masses of peanuts recovered from mandibular and maxillary dentures and their associated gauzes will be provided by treatment group (Table 14.2.2.1) for all subjects in ITT population.

The bar chart to display mean (±SE) of mass of peanuts recovered in each treatment group from mandibular (Figure 14.2.2), maxillary (Figure 14.2.3) and combined (Figure 14.2.1) dentures will be presented.

No formal statistical analysis as a primary analysis will be performed on this endpoint.

4.4.1.3 Supportive Analyses

If there is more than 10% difference in the overall number of subjects between PP and ITT populations, a summary of the primary efficacy variable will be presented for all subjects in the PP population (Table 14.2.2.2).

4.4.2 Secondary Efficacy Variables

In this study secondary efficacy variables are not defined.

4.4.3 Handling of Missing Values/Censoring/Discontinuations

Missing data will not be replaced or imputed. Dropouts will be included in analyses up to the point of discontinuation.

4.5 Analysis of Exploratory Objectives

4.5.1 Exploratory Endpoints Definition

The exploratory endpoints defined in this study are as follows:

- Mass of peanuts under maxillary dentures.
- Mass of peanuts under mandibular dentures.
- Subject completed questionnaire.
- Mass of peanuts under combined maxillary and mandibular dentures in each subgroup (low and high Kapur-Olshan scores).
- The number of denture dislodgements reported by subjects during chewing.

4.5.2 Statistical Hypothesis, Model, and Method of Analysis

Descriptive statistics (number of subjects, number of missing data, raw means, SD, SE, minimum and maximum values) for the mass of peanuts recovered from mandibular and maxillary dentures will be provided by treatment group (Table 14.2.3).

For the subjects' response to questionnaires, descriptive statistics (number of subjects, number of missing data and percentages), mean score and SE of the response will be provided for each question by treatment group (Table 14.2.4).

Descriptive statistics (number of subjects, number of missing data, raw means, SD, SE, median, minimum and maximum values) for combined mass of peanuts recovered from mandibular and maxillary dentures will be provided by treatment group in low and high Kapur-Olshan groups of subjects (Table 14.2.5).

The number of denture dislodgements reported by subjects during chewing will be summarized descriptively (number of subjects, number of missing data, raw means, SD, SE, median, minimum and maximum values) by treatment group (Table 14.2.6). The bar chart to display mean (±SE) of number of denture dislodgments during chewing in each treatment group (Figure 14.2.4) will be presented.

Mass of peanuts will also be plotted against the number of dislodgements by all treatment groups in one plot (Figure 14.2.5.1) and by each treatment group in separate plots (Figures 14.2.5.2, 14.2.5.3, 14.2.5.4).

4.6 Additional Analysis

Adjusted means for mass of peanuts recovered from mandibular, maxillary (Table 16.1.9.2.1) and combined (Table 16.1.9.1.1) dentures, along with 95% confidence interval (CI) will also be reported by treatment group. These will be derived from a mixed model with period and treatment as fixed effects and subject as a random effect. The pair-wise comparisons will be performed and corresponding treatment differences, SE and 95% CI will be presented for all patients in ITT population. No p-value will be reported.

Using the same model as above, a subgroup analysis will be also conducted in low and high Kapur-Olshan groups of subjects. Adjusted means of combined masses of peanuts recovered from mandibular and maxillary denture, along with 95% CI will be presented by treatment groups for each sub-group (Table 16.1.9.3.1) for all patients in ITT population.

These results will be reported in the statistical appendix as part of CSR.

The assumptions underlying the mixed model will be examined using appropriate statistical method and if necessary, a suitable transformation of data or alternative non-parametric method based on ranks will be applied to obtain the inferential statistics. Hodges-Lehmann estimates of median of differences and Hodges-Lehmann 95% confidence intervals will be calculated.

4.7 Analysis of Safety

Safety analysis will be performed on all subjects in safety population, unless specified otherwise.

4.7.1 Adverse Events and Serious Adverse Events

Adverse events (AE) recorded during the study will be mapped to a system organ class (SOC) and preferred term (PT) using the current medical dictionary for regulatory activities (MedDRA).

Prior to database lock all AEs will be reviewed by the Clinical Research Director (or designee) and categorized as either oral or non-oral.

Treatment emergent adverse events (TEAEs) are defined as new AEs that occur on or after the date/time of the first supervised use of the randomized treatment (dentures were inserted). Events with an onset date/time prior to first use of a treatment (in period 1) will be considered as non-treatment emergent.

In this crossover trial, events will be assigned to the treatment group based on the treatment being received at the onset of the event. TEAEs with an onset date time between treatments visits will be assigned the treatment received in the previous period. TEAEs with an onset after last treatment or the end of the study will be assigned to the treatment taken in the last period. If an emergent AE continues to another treatment period, the AE will be considered emergent in the period in which it started.

The following summary tables and listings will be presented by treatment group:

- Table of TEAEs by oral/non-oral and PT (Table 14.3.1.1.2)
- Table of TEAEs by SOC and PT (Table 14.3.1.1.1)
- Table of TEAEs related to study treatment by oral/non-oral and PT (Table 14.3.1.2)
- Listing of all AEs (including all subjects: Listing 16.2.7.1.1 for all randomized subjects; Listing 16.2.7.1.2 for non-randomized subjects)
- Listing of death (Listing 14.3.2.1)
- Listing of non-fatal serious AEs (Listing 14.3.2.2)
- Listing of TEAEs leading to withdrawal (Listing 14.3.2.3)
- Listing of TEAEs classified as oral (Listing 14.3.2.4)

4.7.2 Other Safety Variables

All incidents captured in the study will be listed (Listing 16.2.7.2). Oral soft issue data will be listed (Listing 16.2.7.3).

5 Changes to the Protocol Defined Statistical Analysis Plan

The changes from the originally planned statistical analysis specified in the protocol are outlined in Table 1.

Table 1 Changes to Protocol Defined Analysis Plan

Protocol	Reporting & Analysis Plan	
Statistical Analysis section	**Statistical Analysis Plan**	**Rationale for Changes**
• **10.2.1 Definition of Analysis Population** **ITT Population** The primary population for efficacy assessment will be intent-to-treat (ITT) population, defined as all subjects who are randomised, receive the study treatment at least once and provide at least one assessment of efficacy **PP Population** The PP population includes all subjects who fully comply with all study procedures and restrictions	• **4.1.3 Analysis Population** **ITT Population** • All randomized subjects. • Receive at least one dose of study treatment during the study. • Consumed peanuts and have at least one mass of peanuts from both upper and lower dentures. **PP Population** • Subset of ITT population. • All subjects who are assessed as sufficiently compliant with study procedures and restrictions. • Subjects with major protocol deviations will be excluded. Depending on the nature of the major protocol deviation and impact on the efficacy variable (s), subjects will be either completely excluded from PP population or only partially excluded from the PP analyses. This will be determined	The definitions of ITT and PP population in protocol were generalized. The definitions have been clarified and are now more study specific.

Protocol	Reporting & Analysis Plan	
Statistical Analysis section	**Statistical Analysis Plan**	**Rationale for Changes**
	on a case-by-case basis.	

Attachment 1: List of Data Displays

Study 208397_List of Outputs .xlsx

6 Appendix 1: Template for Tables, Figures and Listings

The following provides some specifications for the tables, listings and figures.

The treatment labels for the column heading will be as follow:

- Conventional Application
- Continuous Strip Application
- No Adhesive

The sequence group labels and ordering will be as follows:

- A-B-C
- A-C-B
- B-A-C
- B-C-A
- C-A-B
- C-B-A

The treatment comparison will be in below order:

- Conventional Application vs No Adhesive
- Continuous Strip Application vs No Adhesive
- Conventional Application vs Continuous Strip Application

Protocol 208397 Program Run Date: DDMMMYYYY

Table 14.1.1.1
Subject Disposition by Treatment Group
All Screened Subjects

Study Population: All Screened Subjects (N=XXX)

	Conventional Application n (%)	Continuous Strip Application n (%)	No Adhesive n (%)	Overall n (%)
TOTAL SUBJECTS SCREENED				xxx
SUBJECTS NOT RANDOMIZED*				xxx (xx.x)
DID NOT MEET STUDY CRITERIA				xxx (xx.x)
ADVERSE EVENT				xxx (xx.x)
---				---
SUBJECT RANDOMIZED				xxx
SUBJECTS STARTED TREATMENT**	xxx	xxx	xxx	xxx
COMPLETED***	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
DID NOT COMPLETE***	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
DID NOT MEET STUDY CRITERIA	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
ADVERSE EVENT	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
LOST TO FOLLOW-UP	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
PROTOCOL VIOLATION	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
WITHDRAWAL OF CONSENT	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
OTHER	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
SAFETY POPULATION				xxx (xx.x)
ITT POPULATION				xxx (xx.x)
PP POPULATION				xxx (xx.x)

* Percentages are based on number of screened subjects.
** Subjects included in a given column if they started that treatment period.
*** Percentages are based on number of subjects that started each treatment.
Percentage of subjects in each study population is calculated using number of subjects randomized as the denominator.

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Program: xxxxxx.sas Source: Filename

Programming Note: *This table will list all reasons for subjects not being randomized.*

Protocol 208397 Program Run Date: DDMMMYYYY

Table 14.1.1.2
Subject Disposition by Treatment Sequence
All Screened Subjects

Study Population: All Screened Subjects (N=xxx)

	A-B-C n (%)	A-C-B n (%)	B-A-C n (%)	B-C-A n (%)	C-A-B n (%)	C-B-A n (%)	Overall n (%)
TOTAL SUBJECTS SCREENED							xxx
SUBJECTS NOT RANDOMIZED*							xxx (xx.x)
DID NOT MEET STUDY CRITERIA							xxx (xx.x)

SUBJECTS RANDOMIZED	xxx	xxx	xxx	xxx	xxx	xxx	xxx
STARTED PERIOD 1	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
COMPLETED PERIOD 1**	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
DID NOT COMPLETE PERIOD 1**	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
ADVERSE EVENT	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
LOST TO FOLLOW-UP	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)

SAFETY POPULATION	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
ITT POPULATION	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
PP POPULATION	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)

* Percentages are based on number of screened subjects.
** Percentages are based on number of randomized subjects in each treatment sequence.
A = Conventional Application; B = Continuous Strip Application; C = No Adhesive.

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Programming Note: *This table will list all reason for not completing the study period and will continue for all other study period.*

Protocol 208397 Program Run Date: DDMMYYYY

Table 14.1.2
Incidence of Major Protocol Deviations
All Randomized Subjects

Study Population: All Randomized Subjects (N=xxx)

	Conventional Application n (%)	Continuous Strip Application n (%)	No Adhesive n (%)	Overall n (%)
SUBJECTS WITH AT LEAST ONE MAJOR PROTOCOL DEVIATION	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
MAJOR PROTOCOL DEVIATIONS NOT LEADING TO EXCLUSION FROM PP POPULATION	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
DEVIATION REASON 1	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)

MAJOR PROTOCOL DEVIATIONS LEADING TO EXCLUSION FROM PP POPULATION	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
EXCLUDING ALL				
DEVIATION REASON 1	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)

EXCLUDING STUDY PERIOD 1				
DEVIATION REASON 1	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)

EXCLUDING STUDY PERIOD 2				
DEVIATION REASON 1	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)

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Table 14.1.4.1
Demographic and Baseline Characteristics
Safety Population

Study Population: Safety Population (N=xxx)

	Overall (N = xxx)
SEX n (%)	
MALE	xxx (xx.x)
FEMALE	xxx (xx.x)
RACE n (%)	
AFRICAN AMERICAN/AFRICAN HERITAGE	xxx (xx.x)
AMERICAN INDIAN OR ALASKAN NATIVE	xxx (xx.x)

ETHNICITY n (%)	
HISPANIC OR LATINO	xxx (xx.x)
NOT HISPANIC OR LATINO	xxx (xx.x)
AGE (YEARS)	
n	xx
MEAN	xx.x
SD	xx.xx
MEDIAN	xx.x
MINIMUM	xx
MAXIMUM	xx
CURRENT DENTURE AGE (YEARS)	
n	xx
MEAN	xx.xx
SD	xx.xxx
MEDIAN	xx.xx
MINIMUM	xx.x
MAXIMUM	xx.x
KAPUR-OLSHAN SUBGROUP n (%)	
LOW (SCORE 6-14)	xxx (xx.x)
6	xxx (xx.x)
7	xxx (xx.x)

HIGH (SCORE 15-18)	xxx (xx.x)
15	xxx (xx.x)
16	xxx (xx.x)

Programming Note: *The categories for all the races will be displayed. Similar table will be generated for ITT population.*

All individual score of Kapur-Olshan groups will be summarized.

Protocol 208397 Program Run Date: DDMMMYYYY

Table 14.2.1
Study Product Compliance
Intent-to-Treat Population

Study Population: Intent-to-Treat Population (N=XXX)

	Statistics	Conventional Application (N = XXX)	Continuous Strip Application (N = XXX)
WEIGHT (g) OF ADHESIVE			
LOWER	n	XXX	XXX
	MEAN	X.XXX	X.XXX
	SD	X.XXXX	X.XXXX
	MEDIAN	X.XXX	X.XXX
	MINIMUM	X.XX	X.XX
	MAXIMUM	X.XX	X.XX
UPPER	n	XXX	XXX
	MEAN	X.XXX	X.XXX
	SD	X.XXXX	X.XXXX
	MEDIAN	X.XXX	X.XXX
	MINIMUM	X.XX	X.XX
	MAXIMUM	X.XX	X.XX
COMBINED (LOWER + UPPER)	n	XXX	XXX
	MEAN	X.XXX	X.XXX
	SD	X.XXXX	X.XXXX
	MEDIAN	X.XXX	X.XXX
	MINIMUM	X.XX	X.XX
	MAXIMUM	X.XX	X.XX

Protocol 208397 Program Run Date: DDMMMYYYY

Table 14.2.2.1
Summary of Mass of Peanut Particles under Combined Dentures
Intent-to-Treat Population

Study Population: Intent-to-Treat Population (N=XXX)

	Conventional Application (N = XXX)	Continuous Strip Application (N = XXX)	No Adhesive (N = XXX)
WEIGHT OF PEANUTS (g)			
n	XX	XX	XX
MISSING	XX	XX	XX
MEAN	XX.XX	XX.XX	XX.XX
SD	XX.XXX	XX.XXX	XX.XXX
SE	XX.XXX	XX.XXX	XX.XXX
MEDIAN	XX.XX	XX.XX	XX.XX
MINIMUM	XX.X	XX.X	XX.X
MAXIMUM	XX.X	XX.X	XX.X

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Programming Note: *Similar table will be generated for Combined Dentures in PP Population. Also similar table will be generated for Maxillary and Mandibular Dentures in ITT population.*

Protocol 208397 Program Run Date: DDMMMYYYY

Table 16.1.9.1.1
Statistical Analysis of Mass of Peanut Particles under Combined Dentures
Intent-to-Treat Population

Study Population: Intent-to-Treat Population (N=XXX)

	Conventional Application (N = XXX)	Continuous Strip Application (N = XXX)	No Adhesive (N = XXX)
WEIGHT OF PEANUTS (g)			
ADJUSTED MEAN [1]	XX.XX	XX.XX	XX.XX
STANDARD ERROR [2]	XX.XXX	XX.XXX	XX.XXX
95% CI	XX.XX, XX.XX	XX.XX, XX.XX	XX.XX, XX.XX

COMPARISONS BETWEEN TREATMENTS	DIFFERENCE (SE) [1,3]	95% CI
CONVENTIONAL APPLICATION Vs. NO ADHESIVE	X.XX (X.XXX)	XX.XX, XX.XX
CONTINUOUS STRIP APPLICATION Vs. NO ADHESIVE	X.XX (X.XXX)	XX.XX, XX.XX
CONVENTIONAL APPLICATION Vs. CONTINUOUS STRIP APPLICATION	X.XX (X.XXX)	XX.XX, XX.XX

[1] Analysis was performed using ANOVA model with weight of the peanut particle (food occlusion) as response variable, treatment and period as fixed effect, and subject as random effect.

[2] Within-subject standard error for adjusted mean.

[3] Difference is first named treatment minus second named treatment is such that a negative difference favors the first named treatment.

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Programming Note: *Similar table will be generated for Maxillary and Mandibular Dentures in ITT population.*

Protocol 208397 Program Run Date: DDMMMYYYY

Table 14.2.4
Subject's Response to the Questionnaire
Intent-to-Treat Population

Study Population: Intent-to-Treat Population (N = XXX)

	Conventional Application (N = XXX)	Continuous Strip Application (N = XXX)	No Adhesive (N = XXX)
NUMBER OF SUBJECTS AWARE ABOUT THE PEANUTS UNDER DENTURES*	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
AMOUNT OF PEANUT PARTICLES UNDER DENTURES**			
1 [NONE]	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
2	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
3			
---			
10 [NUMEROUS]	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
MISSING	XXX	XXX	XXX
MEAN SCORE (SE)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
IRRITATION OF PEANUTS UNDER DENTURES**			
1 [NOT AT ALL IRRITATING]	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
2	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
3			
---			
10 [EXTREMELY IRRITATING]	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
MISSING	XXX	XXX	XXX
MEAN SCORE (SE)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
BOTHERED BY THE PEANUTS UNDER DENTURES**			
1 [NOT AT ALL BOTHERED]	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
2	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
3			
---			
10 [EXTREMELY BOTHERED]	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
MISSING	XXX	XXX	XXX
MEAN SCORE (SE)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)

	Conventional Application (N = XXX)	Continuous Strip Application (N = XXX)	No Adhesive (N = XXX)

* Percentage is based on number of subjects in each treatment group.
** Percentage is based on number of subjects who were aware about the peanuts under dentures in each treatment group.

Protocol 208397 Program Run Date: DDMMMYYYY

Table 14.2.5
Summary of Mass of Peanut Particles under Combined Dentures by Kapur-Olshan Subgroups
Intent-to-Treat Population

Study Population: Intent-to-Treat Population (N = XXX)

Subgroup		Conventional Application (N = XXX)	Continuous Strip Application (N = XXX)	No Adhesive (N = XXX)
Low (6-14)	WEIGHT OF PEANUTS (g)			
	n	XX	XX	XX
	MISSING	XX	XX	XX
	MEAN	XX.XX	XX.XX	XX.XX
	SD	XX.XXX	XX.XXX	XX.XXX
	SE	XX.XXX	XX.XXX	XX.XXX
	MEDIAN	XX.XX	XX.XX	XX.XX
	MINIMUM	XX.X	XX.X	XX.X
	MAXIMUM	XX.X	XX.X	XX.X
High (15-18)	WEIGHT OF PEANUTS (g)			
	n	XX	XX	XX
	MISSING	XX	XX	XX
	MEAN	XX.XX	XX.XX	XX.XX
	SD	XX.XXX	XX.XXX	XX.XXX
	SE	XX.XXX	XX.XXX	XX.XXX
	MEDIAN	XX.XX	XX.XX	XX.XX
	MINIMUM	XX.X	XX.X	XX.X
	MAXIMUM	XX.X	XX.X	XX.X

Protocol 208397 Program Run Date: DDMMMYYYY

Table 16.1.9.3.1
Statistical Analysis of Mass of Peanut Particles under Combined Dentures by Kapur-Olshan Subgroups
Intent-to-Treat Population

Study Population: Intent-to-Treat Population (N = XXX)

Subgroup		Conventional Application (N = XXX)	Continuous Strip Application (N = XXX)	No Adhesive (N = XXX)
Low (6-14)	WEIGHT OF PEANUTS (g)			
	ADJUSTED MEAN [1]	XX.XX	XX.XX	XX.XX
	STANDARD ERROR [2]	XX.XXX	XX.XXX	XX.XXX
	95% CI	XX.XX, XX.XX	XX.XX, XX.XX	XX.XX, XX.XX
	COMPARISONS BETWEEN TREATMENTS	DIFFERENCE (SE) [1,3]	95% CI	
	CONVENTIONAL APPLICATION Vs. NO ADHESIVE	X.XX (X.XXX)	XX.XX, XX.XX	
	CONTINUOUS STRIP APPLICATION Vs. NO ADHESIVE	X.XX (X.XXX)	XX.XX, XX.XX	
	CONVENTIONAL APPLICATION Vs. CONTINUOUS STRIP APPLICATION	X.XX (X.XXX)	XX.XX, XX.XX	
High (15-18)	WEIGHT OF PEANUTS (g)			
	ADJUSTED MEAN [1]	XX.XX	XX.XX	XX.XX
	STANDARD ERROR [2]	XX.XXX	XX.XXX	XX.XXX
	95% CI	XX.XX, XX.XX	XX.XX, XX.XX	XX.XX, XX.XX
	COMPARISONS BETWEEN TREATMENTS	DIFFERENCE (SE) [1,3]	95% CI	
	CONVENTIONAL APPLICATION Vs. NO ADHESIVE	X.XX (X.XXX)	XX.XX, XX.XX	
	CONTINUOUS STRIP APPLICATION Vs. NO ADHESIVE	X.XX (X.XXX)	XX.XX, XX.XX	
	CONVENTIONAL APPLICATION Vs. CONTINUOUS STRIP APPLICATION	X.XX (X.XXX)	XX.XX, XX.XX	

[1] Analysis was performed using ANOVA model with weight of the peanut particles (food occlusion) as response variable, treatment and period as fixed effect, and subject as random effect.

[2] Within-subject standard error for adjusted mean.

[3] Difference is first named treatment minus second named treatment is such that a negative difference favors the first named treatment.

Protocol 208397 Program Run Date: DDMMMYYYY

Table 14.2.6
Subject Reported Denture Dislodgements During Chewing
Intent-to-Treat Population

Study Population: Intent-to-Treat Population (N = XXX)

	Conventional Application (N = XXX)	Continuous Strip Application (N = XXX)	No Adhesive (N = XXX)
Denture Dislodgements			
n	XX	XX	XX
MISSING	XX	XX	XX
MEAN	XX.XX	XX.XX	XX.XX
SD	XX.XXX	XX.XXX	XX.XXX
SE	XX.XXX	XX.XXX	XX.XXX
MEDIAN	XX.XX	XX.XX	XX.XX
MINIMUM	XX.X	XX.X	XX.X
MAXIMUM	XX.X	XX.X	XX.X
Denture Dislodgements [n (%)]*			
1	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)
2	XXX (XX.X)	XXX (XX.X)	XXX (XX.X)

MISSING	XX	XX	XX

* Percentage will be based on number of subjects in each treatment group.

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Table 14.3.1.1.1
Treatment Emergent Adverse Event by SOC and Preferred Term
Safety Population

Study Population: Safety Population (N=XXX)

System Organ Class Preferred Term	Conventional Application (N = XXX)		Continuous Strip Application (N = XXX)		No Adhesive (N = XXX)		Overall (N = XXX)	
	n (%)	nAE	n (%)	nAE	n (%)	nAE	n (%)	nAE
NUMBER OF SUBJECTS WITH AT LEAST ONE AE	XX (XX.X)	XX	XX (XX.X)	XX	XX (XX.X)	XX	XX (XX.X)	XX
NUMBER OF SUBJECTS WITH NO AE	XX (XX.X)		XX (XX.X)		XX (XX.X)		XX (XX.X)	
SOC 1	XX (XX.X)	XX	XX (XX.X)	XX	XX (XX.X)	XX	XX (XX.X)	XX
PT 1	XX (XX.X)	XX	XX (XX.X)	XX	XX (XX.X)	XX	XX (XX.X)	XX
PT 2	XX (XX.X)	XX	XX (XX.X)	XX	XX (XX.X)	XX	XX (XX.X)	XX

SOC 2	XX (XX.X)	XX	XX (XX.X)	XX	XX (XX.X)	XX	XX (XX.X)	XX
PT 1	XX (XX.X)	XX	XX (XX.X)	XX	XX (XX.X)	XX	XX (XX.X)	XX
PT 2	XX (XX.X)	XX	XX (XX.X)	XX	XX (XX.X)	XX	XX (XX.X)	XX

---								

n (%) = Number (percent) of subjects; nAE = Number of adverse events.

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Table 14.3.1.1.2
Treatment Emergent Adverse Event by Oral/Non-Oral and Preferred Term
Safety Population

Study Population: Safety Population (N=XXX)

Oral/Non-Oral Preferred Term	Conventional Application (N = XXX)		Continuous Strip Application (N = XXX)		No Adhesive (N = XXX)		Overall (N = XXX)	
	n (%)	nAE	n (%)	nAE	n (%)	nAE	n (%)	nAE
NUMBER OF SUBJECTS WITH AT LEAST ONE AE	XX (XX.X)	XX	XX (XX.X)	XX	XX (XX.X)	XX	XX (XX.X)	XX
NUMBER OF SUBJECTS WITH NO AE	XX (XX.X)		XX (XX.X)		XX (XX.X)		XX (XX.X)	
ORAL	XX (XX.X)	XX	XX (XX.X)	XX	XX (XX.X)	XX	XX (XX.X)	XX
PT 1	XX (XX.X)	XX	XX (XX.X)	XX	XX (XX.X)	XX	XX (XX.X)	XX
PT 2	XX (XX.X)	XX	XX (XX.X)	XX	XX (XX.X)	XX	XX (XX.X)	XX

NON-ORAL	XX (XX.X)	XX	XX (XX.X)	XX	XX (XX.X)	XX	XX (XX.X)	XX
PT 1	XX (XX.X)	XX	XX (XX.X)	XX	XX (XX.X)	XX	XX (XX.X)	XX
PT 2	XX (XX.X)	XX	XX (XX.X)	XX	XX (XX.X)	XX	XX (XX.X)	XX

---								

n (%) = Number (percent) of subjects; nAE = Number of adverse events.

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Programming Note: *Similar table will be generated for treatment related TEAEs.*

Protocol 208397 Program Run Date: DDMMYYYY

Listing 16.1.7
Randomization Information
All Randomized Subjects

Subject Number	Age/Sex/Race[1]	Randomization Number	Treatment Sequence [2]	Date of Randomization
XXXXXX	XX/F/A1	xxxx	A-B-C	DDMMMYYYY

---

[1] Age in years; Sex: F = Female, M = Male; Race: A1 = African American/African Heritage, A2 = American Indian Or Alaskan Native,A3 = Asian-Central/South Asian Heritage, A4 = Asian-East Asian Heritage, A5 = Asian-Japanese Heritage, A6 = Asian-South East Asian Heritage, N = Native Hawaiian Or Other Pacific Islander, W1 = White-Arabic/North African Heritage, W2 = White - White/Caucasian/European Heritage, MT = Multiple Races.
[2] A = Conventional Application; B = Continuous Strip Application; C = No Adhesive.

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Listing 16.2.1.1
Subject Disposition
All Randomized Subjects

Treatment Sequence: A-B-C

Subject Number	Age/Sex/Race[1]	Screening Date	Treatment	Treatment Start Date[3]	Completed the Study?	Date of Completion or Withdrawal	Period of Withdrawal	Primary Reason for Withdrawal	Further Details[4]
XXXXXX	XX/F/A1	DDMMMYYYY	A	DDMMMYYYY	Yes				
			B	DDMMMYYYY					
			C	DDMMMYYYY		DDMMMYYYY			
XXXXXX	XX/F/A6	DDMMMYYYY	A	DDMMMYYYY	No		XX	Other	XXXXXX
			B	DDMMMYYYY		DDMMMYYYY			

---

[1] Age in years; Sex: F = Female, M = Male; Race: A1 = African American/African Heritage, A2 = American Indian Or Alaskan Native,A3 = Asian-Central/South Asian Heritage, A4 = Asian-East Asian Heritage, A5 = Asian-Japanese Heritage, A6 = Asian-South East Asian Heritage, N = Native Hawaiian Or Other Pacific Islander, W1 = White-Arabic/North African Heritage, W2 = White - White/Caucasian/European Heritage, MT = Multiple Races.
[2] A = Conventional Application; B = Continuous Strip Application; C = No Adhesive.
[3] Treatment start date is equivalent to date of denture insertion.
[4] Further details of reasons for withdrawal.

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Listing 16.2.1.2
Subject Disposition
All Non-Randomized Subjects

Subject Number	Age/Sex/Race[1]	Screening Date	Reason for Screen Failure	Further Details[2]
XXXXXX	XX/F/A1	DDMMMYYYY	XXXXXX	XXXXXX
---				

[1] Age in years; Sex: F = Female, M = Male; Race: A1 = African American/African Heritage, A2 = American Indian Or Alaskan Native,A3 = Asian-Central/South Asian Heritage, A4 = Asian-East Asian Heritage, A5 = Asian-Japanese Heritage, A6 = Asian-South East Asian Heritage, N = Native Hawaiian Or Other Pacific Islander, W1 = White-Arabic/North African Heritage, W2 = White - White/Caucasian/European Heritage, MT = Multiple Races.
[2] Further details of reasons for screen failure.

Program: xxxxxx.sas Source: Filename

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Listing 16.2.2.1
Major Protocol Deviations
All Randomized Subjects

Treatment Sequence: A-B-C

Subject	Age/Sex/Race [1]	Period(s) Excluded from PP Population	Deviation Reason
XXXXXX	PPD	All	PPD
XXXXXX		Period 1 only	
XXXXXX		From Period 2	

[1] Age in years; Sex: F = Female, M = Male; Race: A1 = African American/African Heritage, A2 = American Indian Or Alaskan Native,A3 = Asian-Central/South Asian Heritage, A4 = Asian-East Asian Heritage, A5 = Asian-Japanese Heritage, A6 = Asian-South East Asian Heritage, N = Native Hawaiian Or Other Pacific Islander, W1 = White-Arabic/North African Heritage, W2 = White - White/Caucasian/European Heritage, MT = Multiple Races.
A = Conventional Application; B = Continuous Strip Application; C = No Adhesive.

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Program: xxxxxx.sas Source: Filename

Programming Note: *This listing is based on some of the details in the population definition document.*

Protocol 208397 Program Run Date: DDMMYYYY

Listing 16.2.2.2
Minor Protocol Deviations
All Randomized Subjects

Treatment Sequence: A-B-C

Subject Number	Age/Sex/Race [1]	Deviation Sequence	Date of Deviation	Deviation Type	Deviation Description
XXXXXX	XX/F/A1	1	PPD	XXXXXX	XXXXXX

---

[1] Age in years; Sex: F = Female, M = Male; Race: A1 = African American/African Heritage, A2 = American Indian Or Alaskan Native,A3 = Asian-Central/South Asian Heritage, A4 = Asian-East Asian Heritage, A5 = Asian-Japanese Heritage, A6 = Asian-South East Asian Heritage, N = Native Hawaiian Or Other Pacific Islander, W1 = White-Arabic/North African Heritage, W2 = White - White/Caucasian/European Heritage, MT = Multiple Races.
A = Conventional Application; B = Continuous Strip Application; C = No Adhesive.

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Listing 16.2.3.1
Exclusions from Analysis Populations
All Randomized Subjects

Treatment Sequence: A-B-C

Subject Number	Age/Sex/Race[1]	Safety Population	ITT Population	PP population
XXXXXX	XX/F/A1	YES	YES	YES
---				

[1] Age in years; Sex: F = Female, M = Male; Race: A1 = African American/African Heritage, A2 = American Indian Or Alaskan Native,A3 = Asian-Central/South Asian Heritage, A4 = Asian-East Asian Heritage, A5 = Asian-Japanese Heritage, A6 = Asian-South East Asian Heritage, N = Native Hawaiian Or Other Pacific Islander, W1 = White-Arabic/North African Heritage, W2 = White - White/Caucasian/European Heritage, MT = Multiple Races.
A = Conventional Application; B = Continuous Strip Application; C = No Adhesive.

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Listing 16.2.4.1
Demographic Characteristics
All Randomized Subjects

Treatment Sequence: A-B-C

Subject Number	Age (years)	Sex	Race	Ethnicity
XXXXXX	XX	Female	African American/African Heritage	Hispanic or Latino
XXXXXX	XX	Male	African American/African Heritage	Hispanic or Latino

A = Conventional Application; B = Continuous Strip Application; C = No Adhesive.

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Listing 16.2.4.2
Evaluation of Well Fit Dentures
All Randomized Subjects

Treatment Sequence: A-B-C

Subject Number	Age/Sex/Race[1]	Upper Denture		Lower Denture		Sum Score Retention and Stability	Kapur-Olshan Group [4]
		Retention[2]	Stability[3]	Retention[2]	Stability[3]		
XXXXXX	XX/F/A1	1	2	3	1	XX	Low
XXXXXX	XX/F/A1	4	4	5	2	XX	High

[1] Age in years; Sex: F = Female, M = Male; Race: A1 = African American/African Heritage, A2 = American Indian Or Alaskan Native, A3 = Asian-Central/South Asian Heritage, A4 = Asian-East Asian Heritage, A5 = Asian-Japanese Heritage, A6 = Asian-South East Asian Heritage, N = Native Hawaiian Or Other Pacific Islander, W1 = White-Arabic/North African Heritage, W2 = White - White/Caucasian/European Heritage, MT = Multiple Races.
A = Conventional Application; B = Continuous Strip Application; C = No Adhesive.
[2] 0 = No retention - when the denture is seated in place, it displaces itself, 1 = Poor retention - denture offers slight resistance to vertical pull and little or no resistance to lateral force, 2 = Fair retention - denture offers moderate resistance to vertical pull and little or no resistance to lateral forces, 3 = Good retention - denture offers moderate resistance to vertical pull and lateral force, 4 = Very good retention - denture offers very good resistance to vertical pull and lateral force, 5 = Excellent retention - denture offers excellent resistance to vertical pull and lateral force.
[3] 0 = No stability - when denture base has extreme rocking under pressure, 1 = Poor stability - when denture base has moderate rocking on its supporting structures under pressure, 2 = Fair stability - when denture base has slight rocking on its supporting structures under pressure, 3 = Good stability - when denture base has very slight rocking on its supporting structures under pressure, 4 = Excellent stability - when denture base offers no rocking on its supporting structures under pressure.
[4] Low – score of 6-14; High = score of 15-18.

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Listing 16.2.4.3
Denture History
All Randomized Subjects

Treatment Sequence: A-B-C

Subject Number	Age/Sex/ Race[1]	Denture	Duration of Denture Use (Years)/ Current Denture Age (Years)	Denture Relined?/ If Yes, How Many Times	Use of Dentures While Sleeping?	Recent Changes in Denture Fit?	Secure Dentures Adhesive Use?	Denture Satisfaction	Food Under Dentures?
XXXXXX	XX/F/A1	Lower	XX.X / XX.X	Yes, XX	No	Yes	Yes	Completely Satisfied	No
		Upper	XX.X / XX.X	No	No	Yes	Yes	Completely Satisfied	No

---

[1] Age in years; Sex: F = Female, M = Male; Race: A1 = African American/African Heritage, A2 = American Indian Or Alaskan Native,A3 = Asian-Central/South Asian Heritage, A4 = Asian-East Asian Heritage, A5 = Asian-Japanese Heritage, A6 = Asian-South East Asian Heritage, N = Native Hawaiian Or Other Pacific Islander, W1 = White-Arabic/North African Heritage, W2 = White - White/Caucasian/European Heritage, MT = Multiple Races.
A = Conventional Application; B = Continuous Strip Application; C = No Adhesive.

Protocol 208397 Program Run Date: DDMMYYYY

Listing 16.2.4.4
Medical History and Current Medical Conditions
All Randomized Subjects

Treatment Sequence: A-B-C

Subject Number	Age/Sex/Race[1]	Any Medical History?	Medical Condition	Start Date	End Date or Ongoing
XXXXXX	XX/F/A1	Yes	XXXXXX	DDMMMYYYY	DDMMMYYYY
XXXXXX	XX/M/A6	Yes	XXXXXX	DDMMMYYYY	Ongoing

[1] Age in years; Sex: F = Female, M = Male; Race: A1 = African American/African Heritage, A2 = American Indian Or Alaskan Native,A3 = Asian-Central/South Asian Heritage, A4 = Asian-East Asian Heritage, A5 = Asian-Japanese Heritage, A6 = Asian-South East Asian Heritage, N = Native Hawaiian Or Other Pacific Islander, W1 = White-Arabic/North African Heritage, W2 = White - White/Caucasian/European Heritage, MT = Multiple Races.
A = Conventional Application; B = Continuous Strip Application; C = No Adhesive.

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Listing 16.2.5.1
Study Drug Administration and Compliance
All Randomized Subjects

Treatment Sequence: A-B-C

Subject Number	Age/Sex/Race[1]	Treatment	Was the Adhesive Applied?	Weight of Adhesive (g)		
				Upper Denture	Lower Denture	Combined Dentures
XXXXXX	XX/F/A1	A	Yes	X.XX	X.XX	XX.XX
		B	Yes	X.XX	X.XX	XX.XX
XXXXXX	XX/M/A6		No			
---						

[1] Age in years; Sex: F = Female, M = Male; Race: A1 = African American/African Heritage, A2 = American Indian Or Alaskan Native,A3 = Asian-Central/South Asian Heritage, A4 = Asian-East Asian Heritage, A5 = Asian-Japanese Heritage, A6 = Asian-South East Asian Heritage, N = Native Hawaiian Or Other Pacific Islander, W1 = White-Arabic/North African Heritage, W2 = White - White/Caucasian/European Heritage, MT = Multiple Races.
A = Conventional Application; B = Continuous Strip Application; C = No Adhesive.

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Listing 16.2.5.2
Prior Medications
All Randomized Subjects

Treatment Sequence: A-B-C

Subject Number	Age/Sex/Race[1]	Drug Name [GSK Drug Synonym]	Reason for Medication	Route of Admin.	Dose per Admin. (Unit)	Frequency	Start Date (Study Day[2])	End Date/ Ongoing
XXXXXX	XX/M/A6	XXXXXX [XXXXXX]	XXXXXX	XXXXXX	XXXXXX (xx)	XXXXXX	DDMMMYYYY (XX)	Ongoing
XXXXXX	XX/M/A6	XXXXXX [XXXXXX]	XXXXXX	XXXXXX	XXXXXX (xx)	XXXXXX	DDMMMYYYY (XX)	DDMMMYYYY

[1] Age in years; Sex: F = Female, M = Male; Race: A1 = African American/African Heritage, A2 = American Indian Or Alaskan Native,A3 = Asian-Central/South Asian Heritage, A4 = Asian-East Asian Heritage, A5 = Asian-Japanese Heritage, A6 = Asian-South East Asian Heritage, N = Native Hawaiian Or Other Pacific Islander, W1 = White-Arabic/North African Heritage, W2 = White - White/Caucasian/European Heritage, MT = Multiple Races.
[2] Study day is relative to the date of first dose of treatment.
A = Conventional Application; B = Continuous Strip Application; C = No Adhesive.
Admin.: Administration.

Protocol 208397 Program Run Date: DDMMYYYY

Listing 16.2.5.3
Concomitant Medications and Significant Non-Drug Therapies Taken During Treatment
All Randomized Subjects

Treatment Sequence: A-B-C

Subject Number	Age/Sex/Race[1]	Drug Name [GSK Drug Synonym]	Medication Assigned Period	Reason for Medication	Route of Admin.	Dose per Admin. (Unit)	Frequency	Start Date (Study Day[2])	End Date/ Ongoing
XXXXXX	XX/M/A6	XXXXXX [XXXXXX]	1	XXXXXX	XXXXXX	XXXXXX (xx)	XXXXXX	DDMMMYYYY (XX)	Ongoing
XXXXXX	XX/M/A6	XXXXXX [XXXXXX]	2	XXXXXX	XXXXXX	XXXXXX (xx)	XXXXXX	DDMMMYYYY (XX)	DDMMMYYYY

[1] Age in years; Sex: F = Female, M = Male; Race: A1 = African American/African Heritage, A2 = American Indian Or Alaskan Native,A3 = Asian-Central/South Asian Heritage, A4 = Asian-East Asian Heritage, A5 = Asian-Japanese Heritage, A6 = Asian-South East Asian Heritage, N = Native Hawaiian Or Other Pacific Islander, W1 = White-Arabic/North African Heritage, W2 = White - White/Caucasian/European Heritage, MT = Multiple Races.
[2] Study day is relative to the date of dose of treatment.
A = Conventional Application; B = Continuous Strip Application; C = No Adhesive.
Admin.: Administration.

Protocol 208397 Program Run Date: DDMMYYYY

Listing 16.2.6.1
Food Occlusion Test
All Randomized Subjects

Treatment Sequence: A-B-C

Subject Number	Age/Sex/Race[1]	Period	Was the Food Occlusion Test Performed?	Date/Time of the Test	Weight of Peanuts (grams)		
					Upper Denture	Lower Denture	Combined Dentures
XXXXXX	XX/M/A6	1	Yes	DDMMMYYYY:HH:MM:SS	X.XXXXX	X.XXXXX	XX.XXXXX
		2	Yes	DDMMMYYYY:HH:MM:SS	X.XXXXX	X.XXXXX	XX.XXXXX
		3	Yes	DDMMMYYYY:HH:MM:SS	X.XXXXX	X.XXXXX	XX.XXXXX
XXXXXX	XX/M/A6		No				
---							

[1] Age in years; Sex: F = Female, M = Male; Race: A1 = African American/African Heritage, A2 = American Indian Or Alaskan Native,A3 = Asian-Central/South Asian Heritage, A4 = Asian-East Asian Heritage, A5 = Asian-Japanese Heritage, A6 = Asian-South East Asian Heritage, N = Native Hawaiian Or Other Pacific Islander, W1 = White-Arabic/North African Heritage, W2 = White - White/Caucasian/European Heritage, MT = Multiple Races.
A = Conventional Application; B = Continuous Strip Application; C = No Adhesive.

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Listing 16.2.6.2
Subject's Questionnaire Response
All Randomized Subjects

Treatment Sequence: A-B-C

Subject Number	Age/Sex/Race[1]	Period	Date/Time Subject Completed Questionnaire	Aware of Peanuts Under Your Denture?	How Would you Rate the Amount of Peanut Particles[2]	How Would you Rate the Irritation of Peanuts[3]	How Bothered Were you by the Peanuts[4]
XXXXXX	XX/M/A6	1	DDMMMYYYY:HH:MM:SS	Yes	1	2	10
		2	DDMMMYYYY:HH:MM:SS	Yes	2	2	10
		3	DDMMMYYYY:HH:MM:SS	Yes	1	3	2
XXXXXX	XX/F/W2	2	DDMMMYYYY:HH:MM:SS	No			

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[1] Age in years; Sex: F = Female, M = Male; Race: A1 = African American/African Heritage, A2 = American Indian Or Alaskan Native,A3 = Asian-Central/South Asian Heritage, A4 = Asian-East Asian Heritage, A5 = Asian-Japanese Heritage, A6 = Asian-South East Asian Heritage, N = Native Hawaiian Or Other Pacific Islander, W1 = White-Arabic/North African Heritage, W2 = White - White/Caucasian/European Heritage, MT = Multiple Races.
[2] 1 = None; 10 = Numerous.
[3] 1 = Not at all Irritating; 10 = Extremely Irritating.
[4] 1 = Not at all Bothered; 10 = Extremely Bothered.
A = Conventional Application; B = Continuous Strip Application; C = No Adhesive.

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Listing 16.2.6.3
Denture Dislodgement Assessment
All Randomized Subjects

Treatment Sequence: A-B-C

Subject Number	Age/Sex/Race[1]	Period	Date/Time of Visit	Number of Denture Dislodgements
XXXXXX	XX/M/A6	1	DDMMMYYYY:HH:MM:SS	XXX
		2	DDMMMYYYY:HH:MM:SS	XXX
		3	DDMMMYYYY:HH:MM:SS	XXX
XXXXXX	XX/F/W2	1	DDMMMYYYY:HH:MM:SS	XXX

---				

[1] Age in years; Sex: F = Female, M = Male; Race: A1 = African American/African Heritage, A2 = American Indian Or Alaskan Native,A3 = Asian-Central/South Asian Heritage, A4 = Asian-East Asian Heritage, A5 = Asian-Japanese Heritage, A6 = Asian-South East Asian Heritage, N = Native Hawaiian Or Other Pacific Islander, W1 = White-Arabic/North African Heritage, W2 = White - White/Caucasian/European Heritage, MT = Multiple Races.
A = Conventional Application; B = Continuous Strip Application; C = No Adhesive.

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Listing 16.2.7.1.1
All Adverse Events
All Randomized Subjects

Treatment Sequence: A-B-C

Subject Number	Age/ Sex/ Race[1]	Period	Adverse Event (Preferred Term) [System Organ Class]	Start Date/ Time/Study Day[2]	End Date/ Time	Frequency/ Intensity	Related to Study Product?	Action Taken with Study Product	Outcome	Serious ?	Subject Withdrawn
XXXXXX	XX/F/N	x	HEADACHE (NERVOUS SYSTEM DISORDER) [xxxxxxx]	31MAR2017/ HH:MM:SS/ 3	DDMMMYYYY/ HH:MM:SS	SINGLE EPISODE/ MILD	No	NOT APPLICABLE	RECOVERED/ RESOLVED	NO	NO

@@ Adverse events with verbatim text ending in this are classified as Oral AEs.
[1] Age in years; Sex: F = Female, M = Male; Race: A1 = African American/African Heritage, A2 = American Indian Or Alaskan Native,A3 = Asian-Central/South Asian Heritage, A4 = Asian-East Asian Heritage, A5 = Asian-Japanese Heritage, A6 = Asian-South East Asian Heritage, N = Native Hawaiian Or Other Pacific Islander, W1 = White-Arabic/North African Heritage, W2 = White - White/Caucasian/European Heritage, MT = Multiple Races.
[2] Study day is the day relative to start of treatment..
A = Conventional Application; B = Continuous Strip Application; C = No Adhesive.

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Programming Note for Listing 16.2.7.1.2:

- *Repeat the same layout for listing 16.2.7.1.2*
- *Population should be used 'Non randomized Subjects'*
- *The fifth column should be only 'Start Date'*
- *Column of period will not be displayed.*

- *Add footnote 'Only SAEs are collected for non -randomized subjects'*
- *Delete the footnote related to study day and adjust the numbers accordingly.*

Protocol 208397 Program Run Date: DDMMYYYY

Listing 16.2.7.2
Incidents
All Randomized Subjects

Treatment Sequence: A-B-C

Subject Number	Age/Sex/Race[1]	Period	Date/Time of Visit	Any Incidents	Incident
XXXXXX	XX/M/A6	1	DDMMMYYYY/HH:MM:SS	Yes	XXXXXX
		2	DDMMMYYYY/HH:MM:SS	Yes	XXXXXX
		3	DDMMMYYYY/HH:MM:SS	Yes	XXXXXX
		3	DDMMMYYYY/HH:MM:SS	Yes	XXXXXX
XXXXXX	XX/F/W2	2	DDMMMYYYY/HH:MM:SS	Yes	XXXXXX

---					

[1] Age in years; Sex: F = Female, M = Male; Race: A1 = African American/African Heritage, A2 = American Indian Or Alaskan Native,A3 = Asian-Central/South Asian Heritage, A4 = Asian-East Asian Heritage, A5 = Asian-Japanese Heritage, A6 = Asian-South East Asian Heritage, N = Native Hawaiian Or Other Pacific Islander, W1 = White-Arabic/North African Heritage, W2 = White - White/Caucasian/European Heritage, MT = Multiple Races.
A = Conventional Application; B = Continuous Strip Application; C = No Adhesive.

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Listing 16.2.7.3
Oral Soft Tissue Examination
All Randomized Subjects

Treatment Sequence: A-B-C

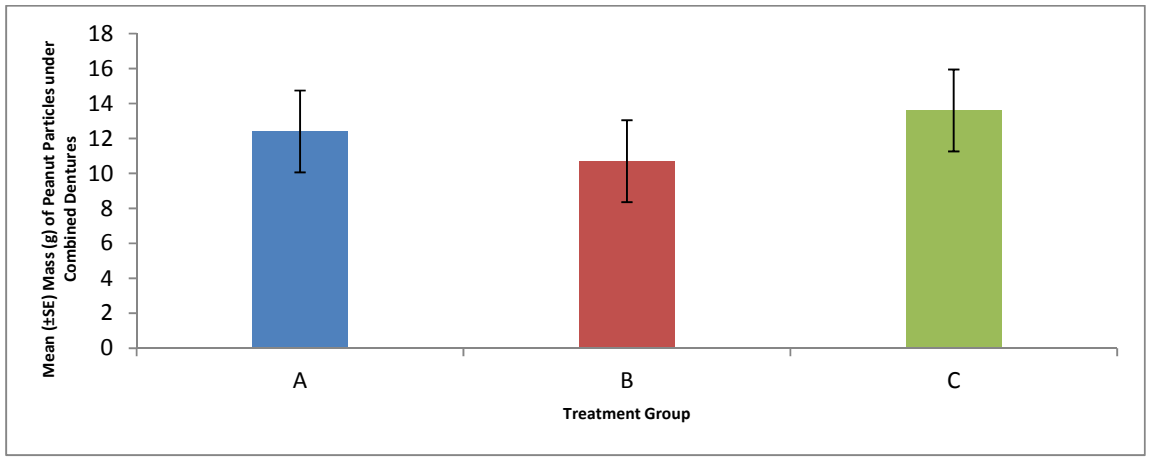
Subject Number	Age/Sex/ Race [1]	Visit	Date/Time of Visit	Time point	Maxillary Mucogingival Fold	Maxillary Edentulous Gingival Mucosa	Maxillary Hard Palate	Maxillary Soft Palate	Mandibular Edentulous Gingival Mucosa	Gingival Mucosa	Labial Mucosa	---
XXXXXX	XX/M/A6	1	DDMMMYYYY/ HH:MM:SS		Normal	Abnormal/ Location: XXXXXX/ XXXXXX	Not Examined/ XXXXXX	---	---	---	---	---
		2	DDMMMYYYY/ HH:MM:SS	Pre	Normal	Abnormal/ Location: XXXXXX/ XXXXXX	Not Examined/ XXXXXX	---	---	---	---	---
				Post	Normal	Abnormal/ Location: XXXXXX/ XXXXXX	Not Examined/ XXXXXX	---	---	---	---	---
		3	DDMMMYYYY/ HH:MM:SS	Pre	Normal	Abnormal/ Location: XXXXXX/ XXXXXX	Not Examined/ XXXXXX	---	---	---	---	---
		---										
---												

[1] Age in years; Sex: F = Female, M = Male; Race: A1 = African American/African Heritage, A2 = American Indian Or Alaskan Native,A3 = Asian-Central/South Asian Heritage, A4 = Asian-East Asian Heritage, A5 = Asian-Japanese Heritage, A6 = Asian-South East Asian Heritage, N = Native Hawaiian Or Other Pacific Islander, W1 = White-Arabic/North African Heritage, W2 = White - White/Caucasian/European Heritage, MT = Multiple Races.
A = Conventional Application; B = Continuous Strip Application; C = No Adhesive.

Protocol 208397 Program Run Date: DDMMYYYY

Figure 14.2.1
Bar Chart of Mean (±SE) for Mass (g) of Peanut Particles under Combined Dentures by Treatment Group
Intent-to-Treat Population

Study Population: Intent-to-Treat Population (N=XXX)



A = Conventional Application; B = Continuous Strip Application; C = No Adhesive.

Program: xxxxxx.sas Source: Filename

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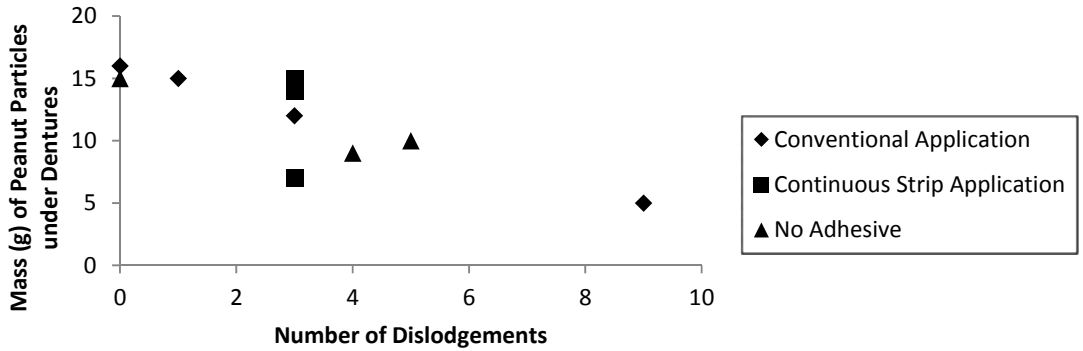
Figure 14.2.4.1
Scatter Plot of Mass (g) of Peanuts against Number of Denture Dislodgements by Treatment Group
Intent-to-Treat Population

Study Population: Intent-to-Treat Population (N=XXX)



Program: xxxxxx.sas Page x of y
Source: Filename

Programming Note: The max value on the x-axis will be dependent on the max number of dislodgements, therefore may be > 10. Same is applicable for y-axis. Please also offset the starting point of 0 on the axis, so we don't have lots of data points on the actual y-axis scale.