CONFIDENTIAL

STATISTICAL ANALYSIS PLAN FOR PROTOCOL 207545

A Bite Force Study Assessing Two Currently Marketed Denture Adhesive Products Compared to No-Adhesive Control

BIOSTATISTICS DEPARTMENT
GLAXOSMITHKLINE CONSUMER HEALTHCARE

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The purpose of this Statistical Analysis Plan is to describe the planned analyses and output to be included in the Clinical Study Report for Protocol 207545. This Statistical Analysis Plan (SAP) will be approved before the study is unblinded and database frozen.

1 Study details

The objective of this 3-treatment, 3-period, randomized, crossover, bite force (BF) study is to compare BF measurements over a 12 hour period of a currently marketed denture adhesive cream (Protefix) based on carbomer technology, with a currently marketed denture adhesive cream (Super Poligrip Free, positive control), and a negative/no treatment control. A short questionnaire regarding the flavor and texture characteristics of each denture adhesive after a single use will also be used to generate data for these attributes. Also questionnaire regarding the product ooze, denture removal and site staff questionnaire will be used to generate data.

In this study, a bite force transducer system will be used to measure incisal BF until dislodgement of maxillary complete denture. Subjects in this study will have dentures judged to be clinically acceptable and moderately well-fitting using the Kapur (Olshan modification) criteria. Dentures will also be judged to be well made using the design and construction criteria. BF measurements will be taken over a 12-hour time period to compare strength of the test adhesive over time against the positive and negative (no adhesive) controls.

1.1 Study design

This single centre, randomized, crossover study will be a randomized three-treatment, three-period, examiner blind [to the examiner performing the BF examination] design in subjects with well-made and moderately well-fitting maxillary complete dentures. Written informed consent will be obtained from participants before the implementation of any study procedure.

At the Screening Visit (Visit 1), subjects will be screened for eligibility and ability to perform the BF manoeuvres according to stated inclusion/exclusion criteria. Dentures will be removed from the subject's mouth and cleaned. An oral soft tissue (OST) examination will be performed before the lower denture (if applicable) is secured using Super Poligrip Free denture adhesive. The examiner will record triplicate bite force measurements without denture adhesive. These will be referred to as "training bites" as the subject becomes accustomed to the bite-force equipment and procedure. Four (4) further BF measurements will be made; 2 of these 4 'qualifying' bites must be reproducible (±2lb) for a subject to be eligible for the study and all 4 of the "qualifying" bites must be less than or equal to 9 pounds. Subjects meeting all of the inclusion criteria with no exclusions will return for Visit 2.

On each test day (Visits 2-4), subjects will report to the study site without denture adhesive placed in their dentures, and will undergo an OST examination and have their dentures cleaned. As described for the screening visit, the lower denture will be stabilized as needed and three "practice bites" performed before a 4th (baseline bite) is performed with no adhesive used on

the maxillary denture. The baseline bite and one of the practice bites must be within 2lbs of each other and the Baseline bite must be <=9lbs. Denture adhesive treatment (or no treatment as per the randomization schedule) will then be applied by a member of study staff (ideally the same member of staff throughout the study) as per the application instructions, and the dentures will be worn by the subject. Incisal BF measurements will be made at 0.5, 1, 3, 6, 9 and 12 hours after the dentures are placed in the mouth. After 0.5 hours assessment the subjects will be asked to answer a short questionnaire about product ooze (Appendix II). The questions will be completed by the subjects themselves and these responses will then be given to study site staff to transcribe to the electronic Case Report Form (eCRF). At the one hour time point, subjects will complete another short questionnaire relating to the aftertaste and texture of the assigned denture adhesive (Appendix III). This will be completed by the subject in a quiet environment without external influence. Again, study staff will transcribe subject responses to the eCRF.

Immediately following the last (12 hour) incisal BF measurement, subjects will remove their upper dentures by themselves and will remove excess adhesive from the mouth, facilitated by and removal confirmed by site study staff prior to the final OST exam. Subjects will be asked to answer another short questionnaire pertaining to ease of removal of the denture from the mouth as well as preferences concerning denture fit and comfort, likes and dislikes over the 12 hour period (Appendix IV, Questions 1-4) and ease of extrusion of the adhesive from the tube (Appendix IV, Question 5). No questionnaire will be administered for the negative/no treatment control arm. All subject responses will be transcribed by site staff to the eCRF. Following denture removal, and completion of the associated questionnaire, site staff will clean the denture before returning to the subject at the end of the treatment phase. Site staff will also be asked to evaluate the ease of cleaning the denture adhesive from the denture (Appendix V).

These assessments will be followed by the final post-treatment OST examination. The final OST exam will be conducted only after study staffs have confirmed that excess adhesive is removed from the subject's mouth.

These procedures will be repeated in a crossover manner. There will be at least 24 hours (up to 14 days) between treatment visits to allow recovery from the BF procedures.

1.2 Study objectives

Objectives	Endpoints
Validation:	
To compare incisal BF for Super Poligrip Free denture adhesive versus no adhesive over 12 hours	Area over Baseline (AOB) up to 12 hours.
Primary Objective	**Primary Endpoint**
To compare incisal BF for Protefix denture adhesive versus no adhesive over 12 hours	AOB up to 12 hours.

Objectives	Endpoints
Exploratory Objectives	**Exploratory Endpoints**
To compare incisal BF for Protefix denture adhesive versus Super Poligrip Free denture adhesive over 12 hours.	AOB up to 12 hours.
To compare incisal BF for Super Poligrip Free denture adhesive versus no adhesive over 9 hours	AOB up to 0.5, 1, 3, 6 and 9 hours
To compare incisal BF for Protefix denture adhesive versus no adhesive over 9 hours	AOB up to 0.5, 1, 3, 6 and 9 hours
To assess subjects' preference with regards to denture adhesive ooze	Scores from subject-completed questionnaire on product ooze, at 0.5 hours use
To assess subject's preference with flavour/after-taste and texture, denture comfort and adaptation	Scores from subject-completed questionnaire on flavour/after-taste and texture, denture comfort and adaptation after 1 hour
To assess subjects' preference with ease of denture removal, denture comfort and adaptation and ease of extrusion of the adhesive from the tube	Scores from subject-completed questionnaires on ease of denture removal, denture comfort and adaptation and ease of extrusion of the adhesive from the tube at 12 hours
To assess clinical staff's preference for ease of denture adhesive removal and cleaning	Scores from clinical staff-completed questionnaire on ease of denture adhesive removal after 12 hours

1.3 Treatments

The following study products will be used in this study:

Test Product: Protefix Denture Adhesive, Crème Mint (Germany marketplace)
Reference Product: Super Poligrip Free Adhesive Cream (USA marketplace)
Negative Control: No adhesive

1.4 Timepoints and visit windows

Time windows for the test day visits and bite force assessments will be reviewed during the blinded data review. According to the protocol there will be at least 24 hours (up to 14 days) between treatment visits to allow recovery from the bite force procedures. Also according to the protocol no post adhesive application bite force measurements will be made earlier than the specified time and not later than 5 minutes after the specified time.

2 Data analysis

Data analysis will be performed by inVentiv Health Clinical. Prior to database closure a Blind Data Review Meeting (BDRM) will be conducted in which various aspects of the trial will be discussed and agreed. The statistical analysis software used will be SAS version 9.4.

2.1 Populations for analysis

Tables described in this section will be produced for all randomized subjects, with the exception of subject disposition which is based on all screened patients.

2.1.1 Subject disposition

All subjects who sign the informed consent form will be accounted for in this study. Screen failures will be defined as subjects who do not meet all the Inclusion criteria and/or meet at least on Exclusion criteria. A summary will be provided of the number of subjects screened and the number of screen failures (including reason not randomized).

The number and percent of subjects who received study treatment will be provided, and who did/did not complete the study (including reason for withdrawal). The table will also summarize the number and percent of subjects assigned to each analysis populations (safety, intent to treat (ITT), and per protocol (PP) (if needed)). This will be done by treatment group and for all groups combined (Overall). Percentages will be based on the number of randomized subjects.

A similar table will also summarize the disposition (number and percent who did/did not complete the treatment (including reason for withdrawal)) of randomized subjects by randomized treatment sequence and period.

2.1.2 Protocol violations

Subject protocol violations will be categorized and summarized by treatment group. This will include the number and percent of ITT subjects excluded from the PP population by violations category and the number and percentages of subjects with data excluded from the Per Protocol analysis by violation category. This will be done by treatment group and for all groups combined (Overall).

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

Major violations of the protocol procedures identified as liable to influence the efficacy outcome are as follows:

- Violation of inclusion or exclusion criteria at screening that may affect efficacy
- Violation of pre-treatment baseline bite force continuance criteria

- Treatment administration errors

- Use of prohibited treatment or medication before or during the study which may affect the assessment of efficacy.

The following will be included in the review of protocol violations but will be evaluated on a case-by-case basis to determine whether the data should be excluded from a PP analysis:

- Test day visits separated by less than 24 hours or greater than 14 days will be reviewed on a case-by case basis prior to database lock to determine if any time points for any of the subjects will be excluded.

- Bite force measurements outside the time window of ±5 min. for the 0.5, 1, 3, 6, 9, and 12-hour assessments, will be reviewed on a case-by-case basis prior to database freeze to determine if any time points for any of the data will be excluded. (Note: For the ITT analysis, assessments will be assigned to the nominal visit, irrespective of whether the assessment took place within the time window)

Protocol violations which warrant exclusion of data from the efficacy analysis will be identified by clinical research director (or designee) and the study statistician with decisions documented and approved prior to the un-blinding of the study.

2.1.3 Analysis populations

Definition analysis populations are defined.

Population	Definition / Criteria	Analyses Evaluated
Safety	• All subjects who are randomized and received treatment at least once during the study. • This population will be based on the treatment the subject actually received.	• Safety
Intent-To-Treat (Treated or Exposed)	• Comprise of all randomized subjects with at least one post baseline assessment of efficacy. • This population will be based on the treatment to which the subject was randomized. • Any subject who receives a treatment randomization number will be considered to have been randomized.	• Efficacy

Population	Definition / Criteria	Analyses Evaluated
	• All randomized subjects with at least one post baseline assessment of efficacy.	
Per-Protocol (Treated or Exposed)	• The Per Protocol (PP) population will be a subset of the ITT population • Subjects with a protocol violation that is deemed to affect efficacy assessments in all study periods will be excluded from the PP population. • Subjects with a protocol violation that is deemed to affect efficacy assessments in some (but not all) study periods will be part of the PP population, but their data will be excluded from the period(s) affected by the protocol violation for a PP analysis. • An analysis on the PP population will be performed for the primary efficacy variable if there is more than 10% difference in the number of subjects evaluable in any of the treatment groups for the ITT and PP populations. A decision on whether a PP analysis will be performed will be made prior to study unblinding. • Protocol deviations that would exclude subjects from the PP population are defined in Section 2.1.2 (Protocol Deviations).	• Per Protocol (PP) population

The numbers of subjects included in each of the analysis populations will be presented (Table 14.1.1).

2.1.4 Subgroups/Stratifications

There are no planned subgroup analyses or stratification in this study.

2.2 Patient demographics/other baseline characteristics

Demographic and baseline characteristics summaries will be produced for the Safety, ITT and PP (if needed) populations.

2.2.1 Demographic characteristics

Categorical demographic variables include sex, race and ethnicity. These variables will be summarized by the number and percentage of subjects with each relevant characteristic in each

treatment group and for all group combined (Overall) (Table 14.1.3). Age will be summarized by the mean, standard deviation, median, minimum and maximum values in each treatment group and for all group combined (Overall).

The summary of baseline bite force data will be summarized by treatment group as part of the efficacy presentations using descriptive statistics

2.2.2 General medical history

Medical history data will not be presented in the study report. A data listing will be produced for evaluation of protocol violations only at the blinded data review stage.

2.3 Treatments (study drug, rescue medication, other concomitant therapies, compliance)

2.3.1 Study Product/drug Compliance and Exposure

All information collected related to subject denture application/exposure (including any deviations) will be available in the subject listings. The adhesive will be applied to dentures by one member of the study staff therefore excellent compliance is anticipated. Compliance will not be summarized.

A listing of treatment compliance will be produced for the evaluation of protocol violations.

2.3.1 Concomitant medication

All information collected related to subject previous and concomitant medication will be available in the subject listings. Medications will be coded according to the GSKDrug Dictionary.

Concomitant medication/non-drug treatments data will not be presented in the study report. A data listing will be produced for evaluation of protocol violations only at the blinded data review stage.

2.4 Analysis of efficacy

Study Validity
The primary objective is to compare incisal bite force of the test adhesive versus no adhesive over 12 hours, $AOB_{0\text{-}12}$. The study validity will first be evaluated by comparing Super Poligrip Free vs no adhesive for $AOB_{0\text{-}12}$. Demonstrating study validity ($p<0.05$ for Super Poligrip Free vs no adhesive) is a prerequisite to performing all other treatment comparisons. No further significance testing will be performed if the initial validation step is not achieved.

The study validity will be analyzed using an analysis of covariance (ANCOVA) model with $AOB_{0\text{-}12}$ values as the response, treatment group and period as fixed effects; subject-level baseline bite force value, and [period level baseline minus subject-level baseline] as covariates.

Subject will be included as a random effect. From this model, treatment difference between groups (Super Poligrip Free vs. no adhesive (negative control)) will be tested.

2.4.1 Primary efficacy endpoint

2.4.1.1 Primary efficacy endpoint definition

The AOB over 12 hours for the incisal BF (lbs) (denoted by $AOB_{0\text{-}12}$) is the primary efficacy variable.

To calculate this variable first the AUC is calculated from 0 to 12 hours using the trapezoid method; we denote this by $AUC_{0\text{-}12}$. The area under curve (AUC) (the bite force time) will be calculated using the trapezoidal method and using nominal time points from 0, 0.5, 1, 3, 6, 9 and 12 hours respectively.

$$\text{AUC} = \frac{1}{2}\sum_{i=0}^{n}(t_{i+1} - t_i)(y_{i+1} + y_i)$$

$AOB_{0\text{-}12}$ is defined as $(AUC_{0\text{-}12})/12$ minus baseline BF (lbs). This transformation will return the measurement to the same scale as the original observations whilst also looking at the average amount of improved force over time by subtracting the baseline value (AOB). Higher values of AOB demonstrate a stronger BF over time than lower values.
$AUC_{0\text{-}12}$ will be calculated for the interval starting at the time (t0) of the baseline reading (y0) and ending at the time (t12) of the last valid reading (y12).

$AOB_{0\text{-}12}$ is equivalent to the area under the curve ($AUC_{0\text{-}12}$) above the pre-treatment baseline value, and adjusts for any differences in pretreatment baseline bite force.

$$\text{AOB} = \frac{1}{2}\sum_{i=0}^{n}(t_{i+1} - t_i)(y_{i+1} + y_i) \text{ - } (y_0 \text{ x } 12)$$

Missing readings will be ignored and interpolation will be made between pre and post the missing values, if necessary. In the case of more than one missing value or if the 12 hour value or the baseline value is missing, the AOB will be set to missing.

2.4.1.2 Statistical hypothesis, model, and method of analysis

The primary objective is to compare incisal bite force of Protefix denture adhesive (test adhesive) versus no adhesive (negative control) over 12 hours, AOB (0-12).

The null hypothesis will be stated as follows:

$H_0 := \mu_{\text{negative control}} = \mu_{\text{test adhesive}}$

There is no difference in the mean bite force AOB at 12 hours between the test adhesive vs. no adhesive (negative control).

The alternative hypothesis will be:

$H_1 := \mu_{\text{negative control}} \neq \mu_{\text{test adhesive}}$

There is difference in the mean bite force AOB at 12 hours between the test adhesive vs. no adhesive (negative control).

An analysis of covariance (ANCOVA) model will be used with $AOB_{0\text{-}12}$ values as the response, with treatment group and period as fixed effects; subject-level baseline bite force value, and [period level baseline minus subject-level baseline] as covariates. Subject will be included as a random effect. From this model, treatment differences between groups (the test adhesive vs. no adhesive (negative control) will be tested.

Subject level baseline values will be calculated as the mean of the subject's pre-treatment baseline values across periods within a subject and period level baseline is the baseline value for each period.

All statistical tests will be 2-sided with a significance level of 0.05.

Statistical and/or graphical procedures will be used to assess the assumptions underlying any statistical testing (e.g., heterogeneity of slopes for the covariance model, normality, homogeneity of variance, etc.). When the assumptions of the planned testing method do not hold, transformations, alternative analysis models/methods, or non-parametric tests (e.g., the Wilcoxon Sign Rank test) may be considered.

From the above ANCOVA model, treatment differences between groups (Test adhesive versus no adhesive), 95% confidence intervals and p-values, will be provided. In addition, adjusted mean, SEs, 95% CIs and corresponding p-values will be provided for each treatment group.

2.4.1.3 Supportive analyses

Not Applicable.

2.4.2 Secondary efficacy variables

There are no secondary efficacy variables.

2.4.3 Exploratory efficacy variables

The two exploratory objectives related to bite force are mentioned below;

- To compare the incisal bite force over a 12 hour (AOB up to 12 hours) for Protefix denture adhesive versus Super Poligrip Free denture adhesive

- To compare incisal bite force for each of the test adhesives (Super Poligrip Free denture adhesive and Protefix denture adhesive) versus no adhesive over 9 hours (AOB at 0.5, 1, 3, 6, and 9 hours).

These two exploratory endpoints will be analyzed and summarized using the same model and methods described for the primary efficacy endpoint.

The exploratory objectives related to questionnaires are mentioned below;

- To assess subject's preference with regards to denture adhesive ooze
- To assess subject's preference with flavour/after-taste and texture, denture comfort and adaptation
- To assess subject's preference with ease of denture removal, denture comfort and adaptation and ease of extrusion of the adhesive from the tube
- To assess clinical staff's preference for ease of denture adhesive removal and cleaning

The results from the questionnaire(s) will be summarized using descriptive statistics (number and percent) by treatment group.

Denture Adhesive Weight;

Denture adhesive weight data (difference between denture weight before and after adhesive application) will be summarized using summary statistics by treatment group.

2.4.4 Handling of missing values/censoring/discontinuations

For calculation of $AOB_{0\text{-}12}$, linear interpolation will be used in the case of missing values. If more than one of the assessments during the 12 hour period is missing or if the 12 hour or the baseline value is missing, the $AOB_{0\text{-}12}$ will be set to missing. The same missing data handling rule will be applied to the calculation of AOB over 0.5, 1, 3, 6 and 9 hours.

2.4.5 Safety

2.4.5.1 Adverse events and Serious Adverse Events

All summaries of safety will be performed using the safety population and will be analyzed based on treatment actually received. No formal statistical testing will be performed on summary comparisons related to safety related measurements.

All AEs will be coded using medical dictionary for regulatory activities (MedDRA). Adverse events will be classified by system organ class (SOC) and by preferred term (PT). In addition, prior to database lock all AEs are reviewed by the Clinical Research Director (or designee) and categorized as either oral or non-oral. Safety will be assessed based on any oral Adverse Events (this includes those that are identified as treatment emergent oral soft tissue (OST) abnormalities and spontaneously reported oral AEs). Any new or worsening OST condition that occurs after the OST examinations at Screening is recorded as an AE.

Adverse events will be summarized using descriptive statistics (frequency tables) by treatment group. Summary tables will indicate both the number of events and the number (percent) of subjects involved. Summaries of AEs will include only treatment emergent adverse events (TEAEs) unless otherwise noted. Treatment emergent events are defined as new adverse events that occur on or after the date/time of the first supervised use of the randomized treatment (or events aggravated in severity following treatment). Events with an onset date/time prior to first use of a treatment will be considered as non-treatment emergent. Listing of AEs (including non-treatment emergent from All Subjects) will be provided.

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 and worsens, the AE will be considered emergent in both the period in which it started and also the period in which it worsened.
The following summary tables and listings will be presented by treatment group.

- Table of treatment emergent AEs by Oral/Non-Oral and Preferred Term
- Table of treatment emergent AEs by SOC and Preferred Term
- Table of Treatment emergent treatment related AEs by Oral/Non-Oral and Preferred Term
- Listing of all AEs (including Non-treatment emergent from All Subjects).
- Listing of serious AEs. (if there are none a null listing will be produced, if there are >5 treatment emergent SAEs a table will be produced by SOC and PT)
- Table of Non Serious treatment emergent AEs by SOC and Preferred Term. (only produced if there are > 5 SAEs)
- Listing of incidents (if there are none a null listing will be produced)

No inferential analyses will be performed to compare treatments with respect to safety.

2.5 Analysis of other variables

Not applicable.

2.6 Interim analysis

There is no interim analysis planned in this study.

2.7 Sample size calculation

Up to 75 subjects will be screened to randomize approximately 45 subjects to ensure that 42 evaluable subjects complete the study.

A sample size of 42 subjects completing all treatment periods will provide 90% power to demonstrate study success. Study success is defined as achieving both (a) study validity (Super Poligrip Free superior to no adhesive) and (b) superiority of the Protefix product compared to no adhesive (primary objective). The clinically relevant difference detectable is 2.30 lbs for $AOB_{0\text{-}12}$, using two-sided t-tests with a 5% significance level, assuming a residual standard deviation (square root of within mean square error) of 2.83 lbs. The estimate of residual standard deviation was obtained as the higher of the observed variability from two previous bite force studies conducted at Oral Health Research Institute (OHRI) (GSK studies CCI and CCI).

3 Changes to the Protocol Defined Statistical Analysis Plan

There were no changes or deviations to the originally planned statistical analysis specified in the protocol amendment 4 [(Dated: 17/MAR/2017)].

4 Top-line Summary

The following outputs will be produced for the top-line report.

Table/Listing/Figure No.	**Title**
Table 14.1.1	Subject Disposition by Treatment Group across Study Treatment Periods - All Screened Subjects
Table 14.1.6	Protocol Violations Leading to Exclusion from Per Protocol Analysis by Treatment Group– Intent To Treat Population
Table 14.2.1	Summary of Bite Force (lbs.) Over Time by Treatment Group – Intent To Treat Population
Table 14.2.2.1	Summary of Bite Force AOB by Time and Treatment Group – Intent To Treat Population
Table 14.2.2.2 (If needed)	Summary of Bite Force for AOB (0-12 hours) by Treatment Group – Per Protocol Population
Table 14.2.3.1	Statistical Analysis of Bite Force AOB by Time and Treatment group – Intent To Treat Population
Table 14.2.3.2 (If needed)	Statistical Analysis of Bite Force for AOB (0-12 hours) by Treatment Group– Per Protocol Population
Table 14.3.1	Treatment Emergent Adverse Events by Oral/Non-Oral and Preferred Term – Safety Population
Listing 16.2.1	Listing of All Adverse Events – All Screened Subjects
Listing 16.2.7*	Listing of Incident – Safety Population
Figure 14.2.1	Mean Incisal Bite Force (lbs) Over Time by Treatment group - Intent-to-Treat Population

Figure 14.2.2 (If needed)	Mean Incisal Bite Force (lbs) Over Time by Treatment group - Per Protocol Population

* If there are none a null listing will be produced.

5 List of Tables, Figures and Listings

All tables, figures and listings include the following footnotes:
Test Adhesive: Protefix Denture Adhesive, Crème Mint (Germany marketplace)
Reference Adhesive: Super Poligrip® Free Adhesive Cream (USA marketplace)
No Adhesive

For the list of tables and figures below, PP population tables and figures will only be produced if there is more than a 10% difference between the ITT and PP populations in any of the treatment groups.

Table No.	**Table Title (including population)**	**Template**
Table 14.1.1	Subject Disposition by Treatment Group across Study Treatment Periods - All Screened Subjects	Section 6
Table 14.1.2	Subject Disposition by Sequence Group and Period – All Screened Subjects	Section 6
Table 14.1.3	Demographic Characteristics – Safety Population	Section 6
Table 14.1.4	Demographic Characteristics – Intent To Treat Population	Table 14.1.3
Table 14.1.5 (If needed)	Demographic Characteristics – Per Protocol Population	Table 14.1.3
Table 14.1.6	Protocol Violations Leading to Exclusion from Per Protocol Analysis by Treatment Group– Intent To Treat Population	Section 6
Table 14.2.1	Summary of Bite Force (lbs.) Over Time by Treatment Group – Intent To Treat Population	Section 6
Table 14.2.2.1	Summary of Bite Force AOB by Time and Treatment Group – Intent To Treat Population	Table 14.2.1
Table 14.2.2.2 (If needed)	Summary of Bite Force for AOB (0-12 hours) by Treatment Group – Per Protocol Population	Table 14.2.1
Table 14.2.3.1	Statistical Analysis of Bite Force AOB by Time and Treatment group – Intent To Treat Population	Section 6
Table 14.2.3.2 (If needed)	Statistical Analysis of Bite Force for AOB (0-12 hours) by Treatment Group– Per Protocol Population	Table 14.2.3.1

Table 14.2.4.1	Summary of Sensory Questionnaire by Treatment Group– Intent To Treat Population	Section 6
Table 14.2.4.2	Summary of Product ooze Questionnaire by Treatment Group– Intent To Treat Population	Table 14.2.4.1
Table 14.2.4.3	Summary of Denture Removal Questionnaire and Questionnaire for Site Staff Cleaning the Denture by Treatment Group– Intent To Treat Population	Table 14.2.4.1
Table 14.2.5	Summary of Denture Adhesive Weights (grams) – Intent To Treat Population	Section 6
Table 14.3.1	Treatment Emergent Adverse Events by Oral/Non-Oral and Preferred Term – Safety Population	Section 6
Table 14.3.2	Treatment Emergent Adverse Events by System Organ Class (SOC) and Preferred Term – Safety Population	Table 14.3.1
Table 14.3.3	Treatment Related Treatment Emergent Adverse Events by Oral/Non-Oral and Preferred Term – Safety Population	Table 14.3.1
Table 14.3.4[#]	Non-Serious Treatment Emergent Adverse Events by System Organ Class (SOC) and Preferred Term – Safety Population	Table 14.3.1

. # only produced if there are >5 SAEs.

Figure No.	**Figure Title (including population)**	**Template**
Figure 14.1.1	Subject Profiles of Bite Force (lbs) Over Time by Treatment Group- Intent-to-Treat Population	Section 6
Figure 14.2.1	Mean Incisal Bite Force (lbs) Over Time by Treatment group - Intent-to-Treat Population	Section 6
Figure 14.2.2 (If needed)	Mean Incisal Bite Force (lbs) Over Time by Treatment group - Per Protocol Population	Figure 14.2.1
Figure 14.3.1	Bar Plot of the Responses for Sensory Questionnaire by Treatment Group - Intent-to-Treat Population	Section 6

Listing No.	**Listing Title (including population)**	**Template**
Listing 16.2.1	Listing of All Adverse Events – All Screened Subjects	Section 6
Listing 16.2.2*	Listing of Serious Adverse Events – All Screened Subjects	Listing 16.2.1

Listing 16.2.3	Protocol Violations Leading to Exclusion from Per Protocol Analysis – Intent To Treat Population	Section 6
Listing 16.2.4	Listing of Randomization Information– Randomized Subjects	Section 6
Listing 16.2.5	Denture Removal Questionnaire, Question 3 (Please DESCRIBE below what you liked or dislike about the denture adhesive)- Intent To Treat Population	Section 6
Listing 16.2.7*	Listing of Incident – Safety Population	Section 6

* If there are none a null listing will be produced

6 Template for Tables, Figures and Listings

PROTOCOL: 207545 PROGRAM RUN DATE: DDMMMYYYY

TABLE 14.1.1
SUBJECT DISPOSITION BY TREATMENT GROUP ACROSS STUDY TREATMENT PERIODS

STUDY POPULATION: ALL SCREENED SUBJECTS (N=XX)

	TEST ADHESIVE N (%)	REFERENCE ADHESIVE N (%)	NO ADHESIVE N (%)	OVERALL N (%)
TOTAL SUBJECTS SCREENED				XX
SUBJECTS NOT RANDOMISED:				XX
DID NOT MEET STUDY CRITERIA				XX
ADVERSE EVENT				XX
ETC	..	..	..	..
STARTED TREATMENT*	XX	XX	XX	XX
COMPLETED	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
DID NOT COMPLETE:	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
DID NOT MEET STUDY CRITERIA	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
ADVERSE EVENT	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
ETC	..	..	..	..
SUBJECTS RANDOMISED				XX
SAFETY POPULATION	XX	XX	XX	XX (XX.X)
ITT POPULATION	XX	XX	XX	XX (XX.X)
PP POPULATION	XX	XX	XX	XX (XX.X)

* This is a Cross-over Study. Subjects are included in a given column/treatment group if they started that study period. Percentages are based on this number.

Note: Completed/Not Completed status and the number of subjects in each study Population is treatment period-specific therefore, for any given row of this table, the sum of treatment column entries will be greater than or equal to the Overall column entry.

Data Source: filename.xpt

Programming note: All percentages are to be computed using number of subjects randomized as the denominator.

PROTOCOL: 207545 PROGRAM RUN DATE: DDMMMYYYY

TABLE 14.1.2
SUBJECT DISPOSITION BY SEQUENCE GROUP AND PERIOD

STUDY POPULATION: ALL SCREENED SUBJECTS (N=XX)

	SEQ 1 N (%)	SEQ 2 N (%)	SEQ 3 N (%)	SEQ 4 N (%)	SEQ 5 N (%)	SEQ 6 N (%)	OVERALL N (%)
TOTAL SUBJECTS SCREENED							XX
SUBJECTS NOT RANDOMISED:							XX
DID NOT MEET STUDY CRITERIA							XX
ADVERSE EVENT							XX
ETC	..	..	..	..	..	..	..
SUBJECTS RANDOMISED	XX	XX	XX	XX	XX	XX	XX
PERIOD 1:							
STARTED PERIOD:	XX	XX	XX	XX	XX	XX	XX
COMPLETED	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
DID NOT COMPLETE:	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
DID NOT MEET STUDY CRITERIA	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
ADVERSE EVENT	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
ETC	..	..	..	..	..	..	..
WASHOUT PERIOD 1:							
STARTED PERIOD:	XX	XX	XX	XX	XX	XX	XX
COMPLETED	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
DID NOT COMPLETE:	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
DID NOT MEET STUDY CRITERIA	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
ADVERSE EVENT	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
PERIOD 2:							
STARTED PERIOD:	XX	XX	XX	XX	XX	XX	XX
COMPLETED	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
DID NOT COMPLETE:	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
DID NOT MEET STUDY CRITERIA	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
ADVERSE EVENT	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
ETC	..	..	..	..	..	..	..
PERIOD 3:							
STARTED PERIOD:	XX	XX	XX	XX	XX	XX	XX
COMPLETED	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)

DID NOT COMPLETE:	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
DID NOT MEET STUDY CRITERIA	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
ADVERSE EVENT	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
ETC	..	..	..	..	..	..	..
SAFETY POPULATION	XX	XX	XX	XX	XX	XX	XX
ITT POPULATION	XX	XX	XX	XX	XX	XX	XX
PP POPULATION	XX	XX	XX	XX	XX	XX	XX

Seq1=A/B/C; Seq2=A/C/B; Seq3=B/A/C; Seq4=B/C/A; Seq5=C/A/B; Seq6=C/B/A
Where, A= Protefix Denture Adhesive; B= No Adhesive; C= Super Poligrip Free Denture Adhesive

Data Source: filename.xpt

Programming note: Percentages to be computed using number of subjects starting each period as the denominator.
Washout period is defined per subject as the interval starting the date after the last dose of each treatment through the day before the date of the first dose of the next treatment in the sequence.

PROTOCOL: 207545 PROGRAM RUN DATE: DDMMMYYYY

TABLE 14.1.3
DEMOGRAPHIC CHARACTERISTICS

STUDY POPULATION: SAFETY (N=XXX)

	TEST ADHESIVE (N=xx)	REFERENCE ADHESIVE (N=xx)	NO ADHESIVE (N=xx)	OVERALL (N=xx)
SEX N (%)				
MALE	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
FEMALE	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
RACE N (%)				
AFRICAN AMERICAN/AFRICAN HERITAGE	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
AMERICAN INDIAN OR ALASKAN NATIVE	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
ASIAN - CENTRAL/SOUTH ASIAN HERITAGE	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
ASIAN - EAST ASIAN HERITAGE	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
ASIAN - SOUTH EAST ASIAN HERITAGE	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
WHITE - ARABIC/NORTH AFRICAN HERITAGE	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
ETHNICITY N (%)				
HISPANIC OR LATINO	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
NOT HISPANIC OR LATINO	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
AGE (YEARS)				
N	XX	XX	XX	XX
MEAN	XX.X	XX.X	XX.X	XX.X
SD	XX.XX	XX.XX	XX.XX	XX.XX
MEDIAN	XX.X	XX.X	XX.X	XX.X
MINIMUM	XX	XX	XX	XX
MAXIMUM	XX	XX	XX	XX

Data Source: filename.xpt

PROTOCOL: 207545 PROGRAM RUN DATE: DDMMMYYYY

TABLE 14.1.6

PROTOCOL VIOLATIONS LEADING TO EXCLUSION FROM PER PROTOCOL ANALYSIS BY TREATMENT GROUP

STUDY POPULATION: INTENT TO TREATMENT (N=XXX)

	TEST ADHESIVE (N=xx)	REFERENCE ADHESIVE (N=xx)	NO ADHESIVE (N=xx)	OVERALL (N=xx)
NUMBER OF SUBJECTS WITH AT LEAST ONE MAJOR PROTOCOL VIOLATION				XX (XX.X)
NUMBER OF SUBJECTS EXCLUDED FROM THE PER PROTOCOL POPULATION				XX (XX.X)
MAJOR PROTOCOL VIOLATIONS FOR SUBJECTS EXCLUDED FROM THE PER PROTOCOL POPULATION:				
VIOLATION 1				XX (XX.X)
VIOLATION 2				XX (XX.X)
MAJOR PROTOCOL VIOLATIONS LEADING TO DATA EXCLUSION ONLY:				
VIOLATION 1	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
VIOLATION 2	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)

Data Source: filename.xpt

PROTOCOL: 207545 PROGRAM RUN DATE: DDMMMYYYY

TABLE 14.2.1

SUMMARY OF BITE FORCE (LBS.) OVER TIME BY TREATMENT GROUP

STUDY POPULATION: INTENT TO TREATMENT (N=XXX)

	TEST ADHESIVE (N=xx)	REFERENCE ADHESIVE (N=xx)	NO ADHESIVE (N=xx)
BASELINE			
N	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
0.5 HOUR			
N	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

Data Source: filename.xpt

Programming note: Repeat for 1, 3, 6, 9 and 12 HOURS.

This is the same shell for Table 14.2.2.1. In that table first summaries AOB (0-12 Hours) followed by AOB (0-0.5 Hour), AOB (0-1 Hour), AOB (0-3 Hours), AOB (0-6 Hours) and AOB (0-9 Hours).

PROTOCOL: 207545 PROGRAM RUN DATE: DDMMMYYYY

TABLE 14.2.3.1
STATISTICAL ANALYSIS OF BITE FORCE AOB BY TIME

STUDY POPULATION: INTENT TO TREATMENT (N=XXX)

	TEST ADHESIVE (N=xx)	REFERENCE ADHESIVE (N=xx)	NO ADHESIVE (N=xx)
AOB 12 HOURS			
ADJUSTED MEAN(SE)[1]	X.XX (X.XXX)	X.XX (X.XXX)	X.XX (X.XXX)
95% CI[1]	(X.XX,X.XX)	(X.XX,X.XX)	(X.XX,X.XX)
P-VALUE[1]	0.XXXX	0.XXXX	0.XXXX
TREATMENT COMPARISONS FOR VALIDATION OF THE STUDY	DIFFERENCE [1,2]	95% CI [1]	P-VALUE[1]
REFERENCE ADHESIVE VS NO ADHESIVE	X.XX	(X.XX, X.XX)	0.XXXX
TREATMENT COMPARISONS	DIFFERENCE [1,2]	95% CI [1]	P-VALUE[1]
TEST ADHESIVE VS NO ADHESIVE	X.XX	(X.XX, X.XX)	0.XXXX
TEST ADHESIVE VS REFERENCE ADHESIVE	X.XX	(X.XX, X.XX)	0.XXXX
AOB 0.5 HOUR			
ADJUSTED MEAN(SE)[1]	X.XX (X.XXX)	X.XX (X.XXX)	X.XX (X.XXX)
95% CI[1]	(X.XX,X.XX)	(X.XX,X.XX)	(X.XX,X.XX)
P-VALUE[1]	0.XXXX	0.XXXX	0.XXXX
TREATMENT COMPARISONS	DIFFERENCE [1,2]	95% CI [1]	P-VALUE[1]
REFERENCE ADHESIVE VS NO ADHESIVE	X.XX	(X.XX, X.XX)	0.XXXX
TEST ADHESIVE VS NO ADHESIVE	X.XX	(X.XX, X.XX)	0.XXXX
TEST ADHESIVE VS REFERENCE ADHESIVE	X.XX	(X.XX, X.XX)	0.XXXX

[1] From ANCOVA with factors for subject (random effect), period and treatment, and subject-level and period-level pre-treatment baseline bite force (parameterized as period-level minus subject-level) as covariates.

[2] Difference is first-named treatment minus second-named treatment such that a positive difference favors the first named treatment.

Data Source: filename.xpt

Programming note: Repeat for 1, 3, 6, 9 and 12 HOURS.

PROTOCOL: 207545 PROGRAM RUN DATE: DDMMMYYYY

TABLE 14.2.4.1

SUMMARY OF SENSORY QUESTIONNAIRE BY TREATMENT GROUP

STUDY POPULATION: INTENT TO TREATMENT (N=XXX)

SENSORY QUESTIONNAIRE	TEST ADHESIVE (N=xx) N (%)	REFERENCE ADHESIVE (N=xx) N (%)
1. HOW WOULD YOU RATE YOUR OVERALL OPINION OF THE DENTURE ADHESIVE?		
1 - DISLIKE EXTREMELY	xx (xx.x)	xx (xx.x)
2 – DISLIKE MODERATELY	xx (xx.x)	xx (xx.x)
3 – DISLIKE SLIGHTLY	xx (xx.x)	xx (xx.x)
4 - NEITHER LIKE NOR DISLIKE	xx (xx.x)	xx (xx.x)
5 – LIKE SLIGHTLY	xx (xx.x)	xx (xx.x)
6 – LIKE MODERATELY	xx (xx.x)	xx (xx.x)
7 – LIKE EXTREMELY	xx (xx.x)	xx (xx.x)
2. HOW MUCH DID YOU LIKE/ DISLIKE THE TASTE OF THE DENTURE ADHESIVE?		
1 - DISLIKE EXTREMELY	xx (xx.x)	xx (xx.x)
2 – DISLIKE MODERATELY	xx (xx.x)	xx (xx.x)
3 – DISLIKE SLIGHTLY	xx (xx.x)	xx (xx.x)
4 - NEITHER LIKE NOR DISLIKE	xx (xx.x)	xx (xx.x)
5 – LIKE SLIGHTLY	xx (xx.x)	xx (xx.x)
6 – LIKE MODERATELY	xx (xx.x)	xx (xx.x)
7 – LIKE EXTREMELY	xx (xx.x)	xx (xx.x)

Data Source: filename.xpt

Programming note: Please display similar summary for the remaining questions (Questions 3,4,5,6 and 7).

PROTOCOL: 207545 PROGRAM RUN DATE: DDMMMYYYY

TABLE 14.2.5

SUMMARY OF DENTURE ADHESIVE WEIGHTS (GRAMS)

STUDY POPULATION: INTENT TO TREATMENT (N=XXX)

	TEST ADHESIVE (N=xx)			REFERENCE ADHESIVE (N=xx)		
	WEIGHT OF DENTURES BEFORE ADHESIVE APPLICATION	WEIGHT OF DENTURES AFTER ADHESIVE APPLICATION	DIFFERENCE (BEFORE – AFTER) ADHESIVE APPLICATION	WEIGHT OF DENTURES BEFORE ADHESIVE APPLICATION	WEIGHT OF DENTURES AFTER ADHESIVE APPLICATION	DIFFERENCE (BEFORE – AFTER) ADHESIVE APPLICATION
N	XX	XX	XX	XX	XX	XX
MEAN	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX
SD	XX.XXX	XX.XXX	XX.XXX	XX.XXX	XX.XXX	XX.XXX
SD	XX.XXX	XX.XXX	XX.XXX	XX.XXX	XX.XXX	XX.XXX
MEDIAN	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX
MINIMUM	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
MAXIMUM	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X

Data Source: filename.xpt

PROTOCOL: 207545 PROGRAM RUN DATE: DDMMMYYYY

TABLE 14.3.1

TREATMENT EMERGENT ADVERSE EVENTS BY ORAL/NON-ORAL AND PREFERRED TERM

STUDY POPULATION: SAFETY (N=XXX)

	TEST ADHESIVE (N=xx)			REFERENCE ADHESIVE (N=xx)			NO ADHESIVE (N=xx)			OVERALL (N=XX)		
	n	(%)	nAE	n	(%)	nAE	n	(%)	nAE	n	(%)	nAE
NUMBER OF SUBJECTS WITH NO AE	XX	(XX.X)	XX	XX	(XX.X)	XX	XX	(XX.X)	XX	XX	(XX.X)	XX
NUMBER OF SUBJECTS WITH AT LEAST ONE AE	XX	(XX.X)	XX	XX	(XX.X)	XX	XX	(XX.X)	XX	XX	(XX.X)	XX
ORAL	XX	(XX.X)	XX	XX	(XX.X)	XX	XX	(XX.X)	XX	XX	(XX.X)	XX
SENSITIVITY OF TEETH	XX	(XX.X)	XX	XX	(XX.X)	XX	XX	(XX.X)	XX	XX	(XX.X)	XX
ORAL MUCOSAL EXOLIATION	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
BRONCHITIS	XX	(XX.X)	XX	XX	(XX.X)	XX	XX	(XX.X)	XX	XX	(XX.X)	XX
COUGH	XX	(XX.X)	XX	XX	(XX.X)	XX	XX	(XX.X)	XX	XX	(XX.X)	XX

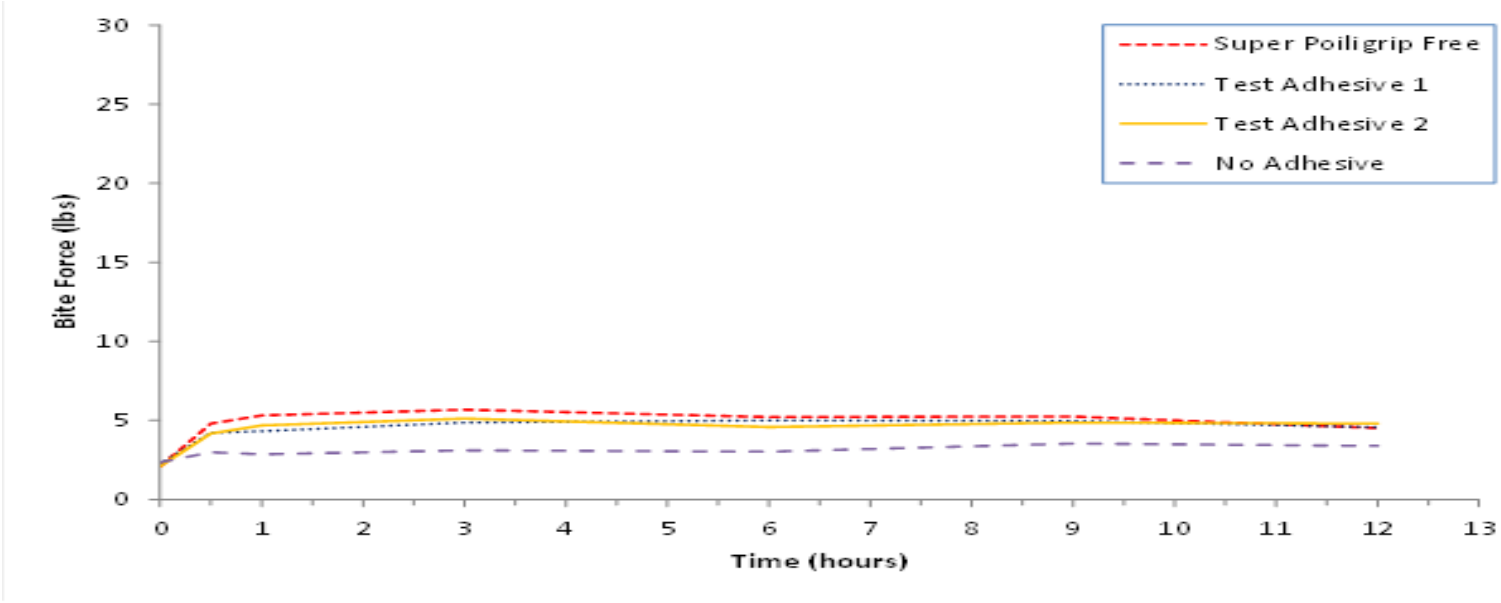
n (%) = Number (percent) of subjects nAE = Number of adverse events.

Data Source: filename.xpt

PROTOCOL: 207545 PROGRAM RUN DATE: DDMMMYYYY

FIGURE 14.1.1
SUBJECT PROFILES OF BITE FORCE (LBS) OVER TIME BY TREATMENT GROUP
STUDY POPULATION: INTENT TO TREAT (N=XXX)

Subject = 01S000x



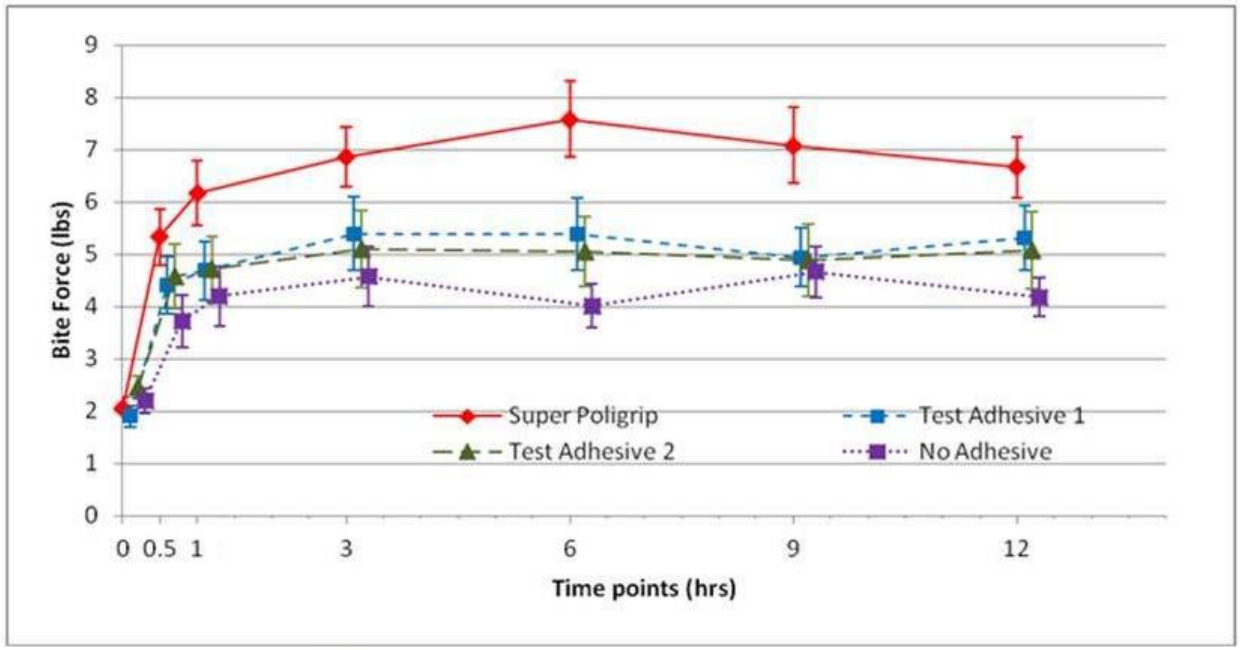
Data Source: filename.xpt

Programming Note: This is mock figure, please use the below treatment label ‘TEST ADHESIVE’, ‘REFERENCE ADHESIVE’ AND ‘NO ADHESIVE’. Please keep axes consistent with Figure 14.2.1.

PROTOCOL: 207545 PROGRAM RUN DATE: DDMMMYYYY

FIGURE 14.2.1
MEAN INCISAL BITE FORCE (LBS) OVER TIME BY TREATMENT GROUP

STUDY POPULATION: INTENT TO TREAT (N=XXX)



Values are raw means and standard errors

Data Source: filename.xpt

Programming Note: This is mock figure, please use the below treatment label as ‘TEST ADHESIVE’, ‘REFERENCE ADHESIVE’ AND ‘NO ADHESIVE’.

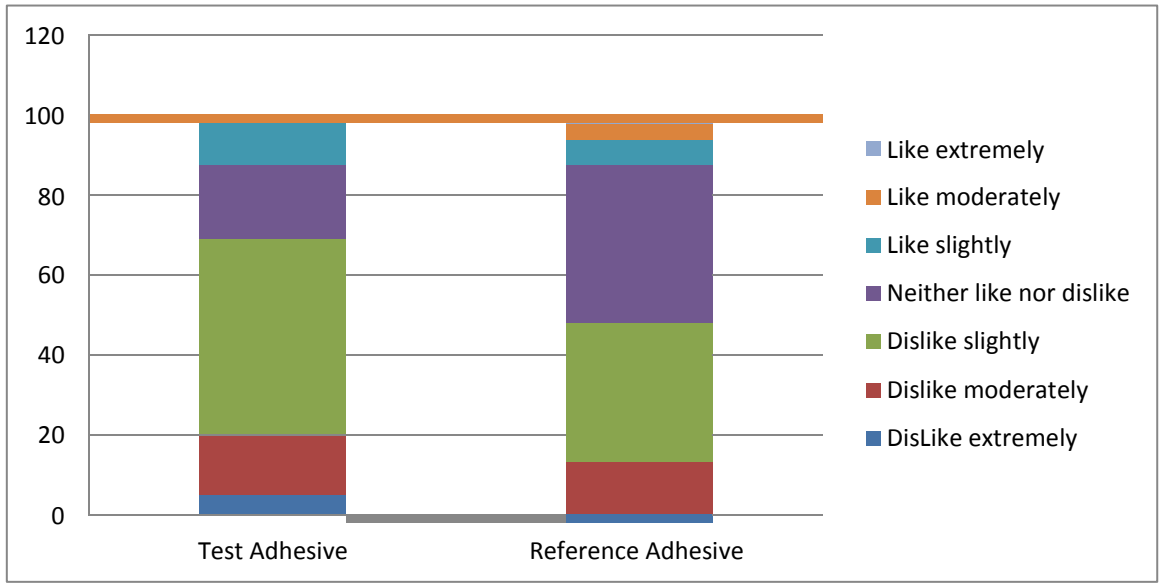
PROTOCOL: 207545 PROGRAM RUN DATE: DDMMMYYYY

FIGURE 14.3.1

BAR PLOT OF THE RESPONSES FOR SENSORY QUESTIONNAIRE BY TREATMENT GROUP

STUDY POPULATION: INTENT TO TREAT (N=XXX)

QUESTION 1. HOW WOULD YOU RATE YOUR OVERALL OPINION OF THE DENTURE ADHESIVE?



Data Source: filename.xpt

Programming Note: Please repeat figure for remaining sensory questions.

PROTOCOL: 207545 PROGRAM RUN DATE: DDMMMYYYY

DATA LISTING 16.2.1
LISTING OF ALL ADVERSE EVENTS

STUDY POPULATION: ALL SCREENED (N=XXX)
TREATMENT GROUP: TEST ADHESIVE

SUBJECT NUMBER	SEX/AGE / RACE [1]	ADVERSE EVENT (PREFERRED TERM) [SYSTEM ORGAN CLASS]	START DATE (STUDY DAY) [2]	START TIME	END DATE	END TIME	FREQUENCY/ INTENSITY [3]	RELATED TO STUDY PRODUCT	ACTION TAKEN RE STUDY PRODUCT	OUTCOME	SERIOUS?	WITHDREW?[4]
PPD												

[1] Age in years; Sex: F = Female, M = Male; Race: A = Asian, B = Black or African American, I = American Indian or Alaska Native, H = Native Hawaiian or Other Pacific Islander, W = White, M = Multiple.
[2] Study day is the day relative to start of treatment, Day 1 being the day of first treatment. Period day is the day relative to the start of treatment being received in that period, day being the day of treatment in that period. If no value is displayed this relates to an AE for a non-randomised subjects.
[3] INT = Intermittent and SGLE = Single.
[4] Did subject withdraw from study as a result of this adverse event?

Data Source: filename.xpt

PROTOCOL: 207545 PROGRAM RUN DATE: DDMMMYYYY

DATA LISTING 16.2.3

PROTOCOL VIOLATIONS LEADING TO EXCLUSION FROM PER PROTOCOL ANALYSIS

STUDY POPULATION: INTENT TO TREAT (N=XXX)

SUBJECT NUMBER	TREATNMENT SEQUENCE [1]	PROTOCOL VIOLATION	PERIOD AFFECTED BY VIOLATION
PPD		XXXXX XXXXX	PPD

[1] A= Protefix Denture Adhesive; B= No Adhesive; C= Super Poligrip Free Denture Adhesive

Data Source: filename.xpt

PROTOCOL: 207545 PROGRAM RUN DATE: DDMMMYYYY

DATA LISTING 16.2.4

LISTING OF RANDOMIZATION INFORMATION– RANDOMIZED SUBJECTS

STUDY POPULATION: RANDOMIZED SUBJECTS (N=XXX)

SUBJECT NUMBER	TREATNMENT SEQUENCE [1]	RANDOMIZATION NUMBER	RANDOMIZATION DATE
PPD			DDMMYYYY
			DDMMYYYY

[1] A= Protefix Denture Adhesive; B= No Adhesive; C= Super Poligrip Free Denture Adhesive

Data Source: filename.xpt

PROTOCOL: 207545 PROGRAM RUN DATE: DDMMMYYYY

DATA LISTING 16.2.5

DENTURE REMOVAL QUESTIONNAIRE, QUESTION 3 (PLEASE DESCRIBES BELOW WHAT YOU LIKED OR DISLIKE ABOUT THE DENTURE ADHESIVE)

STUDY POPULATION: INTENT TO TREAT (N=XXX)

SUBJECT NUMBER	VISIT NUMBER	TREATMENT	LIKED/DISLIKED	RESPONSES
PPD				

Data Source: filename.xpt

PROTOCOL: 207545 PROGRAM RUN DATE: DDMMMYYYY

DATA LISTING 16.2.7
LISTING OF INCIDENT

STUDY POPULATION: SAFETY (N=XXX)
TREATMENT GROUP: TEST ADHESIVE

SUBJECT NUMBER	VISIT NUMBER	SEQUENCE NUMBER	INCIDENT
PPD			XXXXXX
			XXXXXX
			XXXXXX

Data Source: filename.xpt