Non-interventional Results Summary

Study Number: 213380
Title: A Post-hoc Pooled Analysis of GSK CH Clinical Data Investigating the Efficacy of Denture Adhesive creams containing PMV/MA &CMC on Denture Retention and Bite Force
Sponsor: GSK Sponsored
Study Center: NA
Actual First Subject First Visit: 17-Dec-2020
Actual Last Subject Last Visit: 19-May-2021
Product / Medicine: 30 percent (%) Poly (Methylvinylether/Maleic Acid) Sodium- Calcium Mixed Partial Salt + 24% Sodium Carboxymethylcellulose
Rationale: The aim of this pooled analysis study was to aggregate individual participant level data from GlaxoSmithKline Consumer Health (GSK CH) Bite force (BF) studies on denture adhesive creams containing 30% Poly methyl vinyl /maleic anhydride (PMV/MA) & 24% carboxymethylcellulose (CMC) to assess efficacy overall and within sub-groups.
Phase: N/A
Study Period: 17-Dec-2020 to 19-May-2021
Study Design: This was the pooled analysis of individual participant level data from selected GSK CH BF studies with consistent subject eligibility characteristics (completely edentulous maxillary arch, well-made complete denture, qualifying maxillary BF less than or equal to [≤]9 pounds [lbs]) and BF data available. All studies were single-center, examiner-blind, randomized. 7 studies were crossover, 1 study was monadic and 1 study was parallel design.
Actual Enrolment: 322
Study Population: The participant populations included male and non-pregnant, non-lactating female at least 18 years of age, in good general and mental health, with completely edentulous maxillary arch and using a well-made, moderately well-fitting dentures. The study criteria for inclusion in the pooled analysis included: 1. Clinical studies conducted by GSK CH with: • Access to study protocols and study reports • Access to individual information sources/study data. 2. Study design and subject inclusion criteria in agreement with pre-defined study selection criteria • Subject eligibility based on study inclusion criteria: a. Completely edentulous maxillary arch b. Well-made complete dentures according to the design and construction criteria used in GSK CH studies (GSKCH Clinical Study Report L3510566 2008) c. Qualifying maxillary incisal BF readings (without adhesive) less than or equal to 9 pounds (lbs) at the screening and subsequent pre-treatment baseline bites. • Raw BF data available.
Study Investigators/Centers: NA
Data Source: Nine GSK CH study reports - L3510566, RH02446, RH02443, 206233, 207545, 203114, RH02035, RH01686, PCLBF2009-09
Indication(s): Denture Retention
Study Exposures, Outcomes:

Primary Outcome:

1. Area-Over-Baseline (AOB) Over 12 hours

Secondary Outcome:

1. AOB up to 0.5, 1, 3, 6 and 9 hours
2. Raw Mean BF Measurement Between Adhesive and No Adhesive at 0.5, 1, 3, 6, 9 and 12 hours
3. Within-Treatment Change from Baseline in Raw BF Measurement up to 0.5, 1, 3, 6, 9 and 12 hours

Data Analysis Methods: Efficacy data for each study was pooled and analyzed together. Analyses focused on the 12-hour assessment, the longest time point in these studies and considered a scientifically valid endpoint for potential efficacy. The pooled analyses of efficacy data were performed on all subjects in the intent-to-treat (ITT). For all statistical analyses, the assumption of normality and homogeneity of variance in the Analysis of Covariance (ANCOVA) model were investigated.

Limitations: N/A

Study Results:

Number of Participants:	**Overall**
Randomised, N	322
Completed, n (%)	311 (96.6)
Did not complete study, n (%)	11 (3.4)
Did not meet study criteria, n (%)	3 (0.9)
Adverse Events, n (%)	2 (0.6)
Lost to follow-up, n (%)	1 (0.3)
Protocol violation, n (%)	3 (0.9)
Other, n (%)	2 (0.6)
Demographics/Baseline Characteristics	**Overall**
Total N	322
Age in Years, Mean (SD)	68.7 (9.55)
Gender, n (%)	
Male	127 (39.4)
Female	195 (60.6)
Race, n (%)	
African American/African Heritage	125 (38.8)
American Indian or Alaskan Native	2 (0.6)
White - White/Caucasian/European Heritage	194 (60.2)
Multiple	1 (0.3)

Primary Outcome Results:

Outcome Measure 1: Area-Over-Baseline (AOB) Over 12 hours (AOB0-12)

	Test Adhesive (n=223)	**No Adhesive (n=200)**
Mean (SE)	5.1120 (0.29168)	2.5668 (0.30843)
Statistical Analysis: Comparison of Test Adhesive with No Adhesive		
Adjusted Mean Difference (SE)	2.5452 (0.42997)	
95% Confidence Interval	(1.7000, 3.3904)	

p-value	<0.0001	
Secondary Outcome Results:		
Outcome Measure 2: AOB up to 0.5, 1, 3, 6 and 9 hours		
	Test Adhesive	**No Adhesive**
AOB (0-0.5)	n=224	n=202
Mean (SD)	2.0907 (0.14815)	1.1388 (0.15621)
Statistical Analysis: Comparison of Test Adhesive with No Adhesive		
Adjusted Mean Difference (SE)	0.9518 (0.21806)	
95% Confidence Interval	(0.5232, 1.3805)	
p-value	<0.0001	
AOB (0-1)	n=224	n=202
Mean (SD)	3.3654 (0.21601)	1.7545 (0.22777)
Statistical Analysis: Comparison of Test Adhesive with No Adhesive		
Adjusted Mean Difference (SE)	1.6108 (0.31794)	
95% Confidence Interval	(0.9858, 2.2358)	
p-value	<0.0001	
AOB (0-3)	n=224	n=201
Mean (SD)	4.6732 (0.26816)	2.3203 (0.28348)
Statistical Analysis: Comparison of Test Adhesive with No Adhesive		
Adjusted Mean Difference (SE)	2.3529 (0.39521)	
95% Confidence Interval	(1.5760, 3.1298)	
p-value	<0.0001	
AOB (0-6)	n=224	n=200
Mean (SD)	5.0919 (0.28572)	2.4964 (0.30282)
Statistical Analysis: Comparison of Test Adhesive with No Adhesive		
Adjusted Mean Difference (SE)	2.5955 (0.42165)	
95% Confidence Interval	(1.7667, 3.4244)	
p-value	<0.0001	
AOB (0-9)	n=223	n=200
Mean (SD)	5.1862 (0.29161)	2.5652 (0.30836)
Statistical Analysis: Comparison of Test Adhesive with No Adhesive		
Adjusted Mean Difference (SE)	2.6210 (0.42987)	
95% Confidence Interval	(1.7760, 3.4660)	
p-value	<0.0001	
Outcome Measure 3: Raw Mean BF Measurement at 0.5, 1, 3, 6, 9 and 12 hours		
0.5 hour	n=224	n=202
Mean (SE)	6.7806 (0.29629)	4.8769 (0.31243)
Statistical Analysis: Comparison of Test Adhesive with No Adhesive		
Adjusted Mean Difference (SE)	1.9037 (0.43612)	

95% Confidence Interval	(1.0464, 2.7610)	
p-value	<0.0001	
1 hour	n=260	n=239
Mean (SE)	7.6981 (0.30641)	5.0622 (0.32310)
Statistical Analysis: Comparison of Test Adhesive with No Adhesive		
Adjusted Mean Difference (SE)	2.6359 (0.45101)	
95% Confidence Interval	(1.7494, 3.5225)	
p-value	<0.0001	
3 hours	n=224	n=201
Mean (SE)	8.1588 (0.32872)	5.3311 (0.34745)
Statistical Analysis: Comparison of Test Adhesive with No Adhesive		
Adjusted Mean Difference (SE)	2.8277 (0.48443)	
95% Confidence Interval	(1.8755, 3.7800)	
p-value	<.0001	
6 hours	n=224	n=200
Mean (SE)	8.0266 (0.86459)	5.1513 (0.87398)
Statistical Analysis: Comparison of Test Adhesive with No Adhesive		
Adjusted Mean Difference (SE)	2.8753 (0.49575)	
95% Confidence Interval	(1.9007, 3.8498)	
p-value	<.0001	
9 hours	n=223	n=200
Mean (SE)	7.7831 (0.33408)	5.3949 (0.35314)
Statistical Analysis: Comparison of Test Adhesive with No Adhesive		
Adjusted Mean Difference (SE)	2.3882 (0.49238)	
95% Confidence Interval	(1.4203, 3.3561)	
p-value	<.0001	
12 hours	n=223	n=200
Mean (SE)	7.1889 (0.32236)	4.9416 (0.34076)
Statistical Analysis: Comparison of Test Adhesive with No Adhesive		
Adjusted Mean Difference (SE)	2.2472 (0.47512)	
95% Confidence Interval	(1.3133, 3.1812)	
p-value	<.0001	
Outcome Measure 4: Within-Treatment Change from Baseline in Raw BF Measurement up to 0.5, 1, 3, 6, 9 and 12 hours		
0.5 hour	n=224	n=202
Mean (SE)	4.1813 (0.29629)	2.2776 (0.31243)
1 hour	n=224	n=202
Mean (SE)	5.0988 (0.30641)	2.4629 (0.32310)
3 hours	n=224	n=201

Mean (SE)	5.5567 (0.32872)	2.7290 (0.34745)
6 hours	n=224	n=200
Mean (SE)	5.4268 (0.86459)	2.5516 (0.87398)
9 hours	n=223	n=200
Mean (SE)	5.1816 (0.33408)	2.7934 (0.35314)
12 hours	n=223	n=200
Mean (SE)	4.5873 (0.32236)	2.3401 (0.34076)

Safety Results:

Given the focus on efficacy, pooled data from the Safety Population were not analysed; information on adverse event/safety profile of study treatments can be obtained from the individual study reports.

Conclusion:

The primary objective and pre-defined success criterion (a difference of >2 lbs between adhesive and no adhesive groups in AOB0-12) of this pooled analysis were met. Statistically significant greater incisal BF was demonstrated with the use of a 30% PMV/MA & 24% CMC denture adhesive cream compared to no adhesive ($p<0.0001$). Use of denture adhesive significantly increased incisal BF compared to no adhesive at every time point measured (0.5–12 hours, $p<0.0001$). Maxillary dentures treated with a 30% PMV/MA & 24% CMC adhesive cream achieved maximum hold at 3 hours; 88% of maximum denture hold was maintained 12 hours after adhesive application. Furthermore, statistically significant differences were observed in changes from baseline in both groups ($p<0.0001$) at all time points, except for 6 hours. Overall, this pooled analysis of data from 9 studies comparing use of denture adhesive creams containing 30% PMV/MA & 24% CMC against no adhesive favoured the use of denture adhesives.