

Clinical Trial Evaluating Relative Effectiveness of Two Commercial Denture Adhesives

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ABSTRACT

Objective: This randomized, cross-over, blinded clinical trial evaluated relative performance of two commercial denture adhesive creams using gnathodynamometry as a method of denture hold assessment.

Methods: A total of 23 healthy adult volunteers with complete maxillary dentures were randomly assigned to a treatment sequence consisting of the following two treatments used three times each: (1) Fixodent® Control (FC) denture adhesive cream and (2) Super Poligrip® Original (SPGO) denture adhesive cream. Both denture adhesives were used according to the manufacturer's recommendations, one product per day for 9 hours. Bite force measurements were taken daily using gnathodynamometry at Baseline (before the adhesive application) and at 1, 3, 5, 7, and 9 hours following the adhesive application. Oral soft tissue examination was performed daily at Baseline and after the 9-hour measurement. Efficacy was assessed by computing daily area under the bite force by time curves (AUC) and comparing mean bite force values at individual time points.

Results: Subjects presented with the mean (SD) age of 73.2 (8.9) years, and the mean Baseline bite force (SE) of 0.8 (0.07) lb. Use of both products resulted in significant increase in bite force relative to baseline at each individual time point. Relative to each other, the use of FC resulted in significantly ($p < 0.001$) greater bite force values relative to SPGO at each time point and in significantly ($p < 0.001$) greater total AUC from 1-9 h. Both products were well-tolerated.

Conclusion: Use of FC denture adhesive cream provides greater improvement in denture hold relative to SPGO over a 9-hour period as measured by gnathodynamometry.

PURPOSE

The objective of this randomized, blinded, cross-over clinical trial was to evaluate the relative performance of two commercial denture adhesive creams using gnathodynamometry as a method of denture hold assessment.

MATERIALS AND METHODS

- 23 healthy adult volunteers with complete maxillary dentures were randomly assigned to a treatment sequence consisting of the following two treatments used QD three times each (for a total of 6 days): (1) Fixodent® Control (FC) denture adhesive cream and (2) Super Poligrip® Original (SPGO) denture adhesive cream.
- Both denture adhesives were used according to the manufacturer's recommendations, one product per day for 9 hours.

FC Application Pattern



SPGO Application Pattern



- Bite force measurements were taken daily using gnathodynamometry at Baseline and at 1, 3, 5, 7, and 9 hours following the adhesive application.
- Oral soft tissue exams performed at Baseline and after the 9-hour measurement.
- Efficacy was assessed by computing daily area under the bite force by time curves (AUC) and comparing mean bite force values at individual time points.

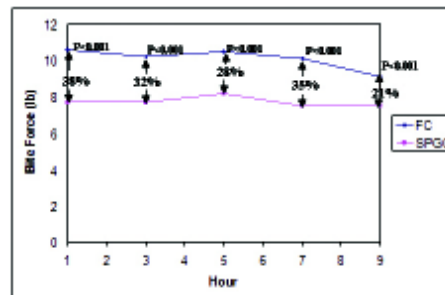
RESULTS

Efficacy: Subjects presented with the mean (SD) age of 73.2 (8.9) years, and the mean Baseline bite force (SE) of 0.8 (0.07) lb. Use of both products resulted in significant increase in bite force relative to baseline at each individual time point. Relative to each other, the use of FC resulted in statistically significantly ($p < 0.001$) greater bite force values relative to SPGO at each time point and in statistically significantly ($p < 0.001$) greater total AUC from 1-9 h (Figure 1, Table 1). The difference between products exceeded 20% for all individual time points and was 32% for AUC. Both products were well-tolerated.

Table 1: Mean (SE) Bite Force Improvement Over Time and AUC

Hour	Fixodent Control Mean (SE)	Super Poligrip® Original Mean (SE)	p-value
Baseline	0.8 (0.07)	0.8 (0.07)	0.56
1	10.6 (1.1)	7.7 (1.1)	< 0.001
3	10.2 (1.0)	7.7 (1.0)	< 0.001
5	10.5 (0.9)	8.2 (0.9)	< 0.001
7	10.1 (0.9)	7.5 (0.9)	< 0.001
9	9.1 (0.9)	7.5 (0.9)	< 0.001
AUC (1-9)	81.3 (7.2)	61.4 (7.2)	< 0.001

Figure 1: Mean Bite Force Improvement Over Time



CONCLUSION

Use of Fixodent Control denture adhesive cream provides greater improvement in denture hold relative to Super Poligrip® Original over a 9-hour period as measured by gnathodynamometry.