Evaluation of Oral Health in Adult Smokers Who Switched from Cigarettes to Nicotine Pouches

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76th Tobacco Science Research Conference September 24-27, 2023, Norfolk, Virginia USA



— FAMILY OF COMPANIES ——







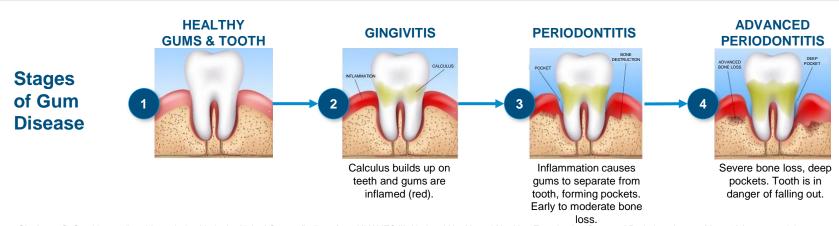
Background

Smoking is a major risk factor for periodontitis (NHANES IIIa)



Gingivitis is the early stage leading to periodontitis

Subgingival microflora of smokers with gingivitis is preceded by an **increase in abundance of periodontal-pathogens**



a Tomar SL, Asma S. Smoking-attributable periodontol. 2000 May;71(5):743-51. doi: 10.1902/jop.2000.71.5.743. PMID: 10872955.

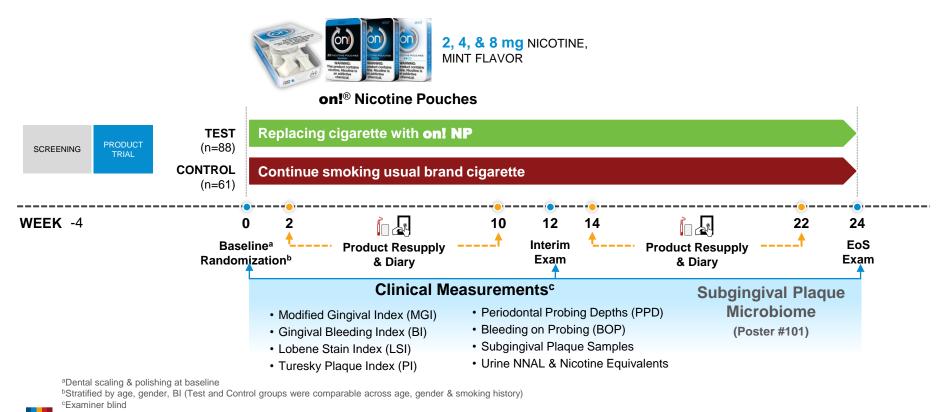


Objective

The objective of this study was to characterize the changes in gingival inflammation, dental plaque, and extrinsic dental stain of adult smokers who switched to on!® nicotine pouches (NP) compared to those who continued to smoke (CS) combustible cigarettes for 24 weeks.



Study Design



ltria | Altria Client Services | 76th Tobacco Science Research Conference | September 24-27, 2023 |

KEY Inclusion & Exclusion Criteria



- Between the ages of 23 and 65 years
- Generalized gingivitis (MGI ≥ 1.75 and BI ≥ 10 bleeding sites) at the Screening and Baseline visits
- Currently smoke at least 10 cigarettes per day



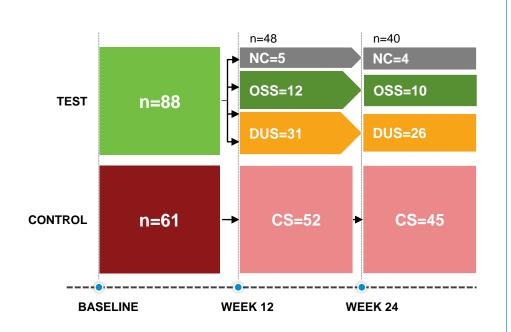
- Severe periodontitis
- Dental work affecting the measurements
- Dental conditions that require medical intervention

MGI = Modified Gingival Index; BI = Bleeding Index



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Results: Study Populations



Two subgroups in Test group were analyzed at Weeks 12 and 24



OSS

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on! Switcher Subgroup

Used at least one NP since the last visit and

Average cigarette per day (CPD) ≤ 10% of baseline level and

Total NNAL* (ng/g creatinine) ≤ 25% of baseline level



DUS

Dual Use Subgroup

Used at least one NP since the last visit and

Average cigarette per day (CPD) > 10% of baseline level and

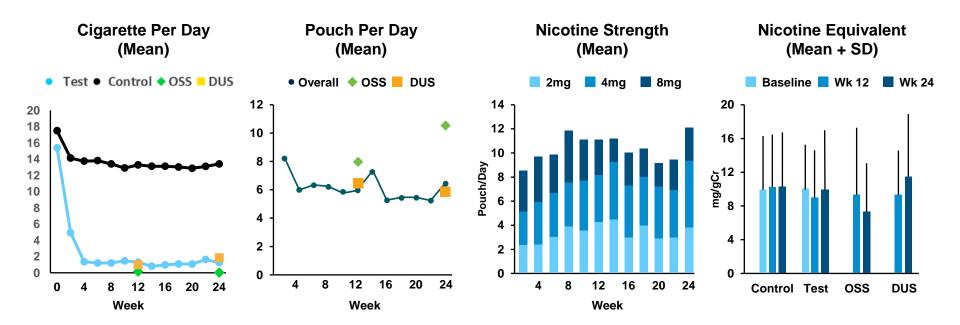
Total NNAL* (ng/g creatinine) > 25% of baseline level

Drop Out	Test	Control
Lost to follow-up	19	4
Schedule Conflict	10	2
AE: COVID19+	12	10
AE: Other	2	
Non-compliance	5	
Total	48	16

NC = Not Classified (not using on! pouches since last visit); OSS = on!® Switchers Subgroup; DUS = Dual Use Subgroup; CS = Cigarette Smoking AE = Adverse Events; CPD = Cigarette Per Day; NNAL = 4-[methylnitrosamino]-1-[3-pyridyl]-1-butanol



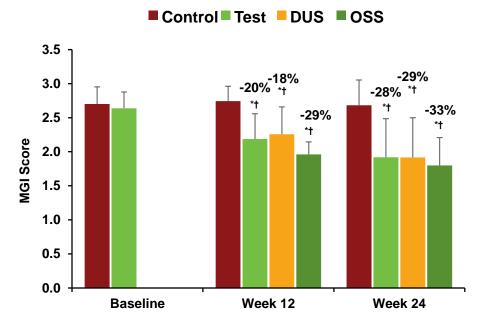
Results - Product Use





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Results - Modified Gingival Index



Score	Criteria	
0	Normal (absence of inflammation)	
1	Mild inflammation (slight change in color, little change in texture) of any portion of the entire gingival unit	
2	Mild inflammation of the entire gingival unit	
3	Moderate inflammation (moderate glazing redness edema, and/or hypertrophy) of the gingival unit	
4	Severe inflammation (marked redness and edema/hypertrophy, spontaneous bleeding or ulceration) of the gingival unit	

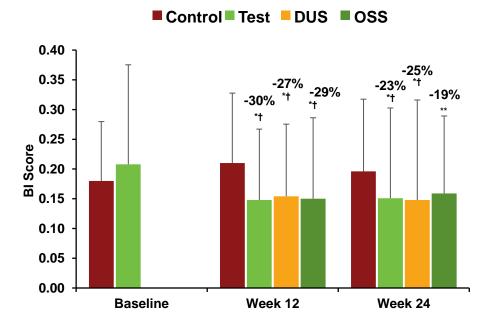
Data shown as Mean + SD

^{*} p < .0001 vs Baseline; † p < .0001 vs Control; % = % difference vs Control; DUS = Dual Use Subgroup; OSS = on!® Switchers Subgroup; MGI = Modified Gingival Index.



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Results – Bleeding Index



Score	Criteria	
0	Absence of bleeding after 30 seconds	
1	Bleeding observed after 30 seconds	
2	Immediate bleeding observed	

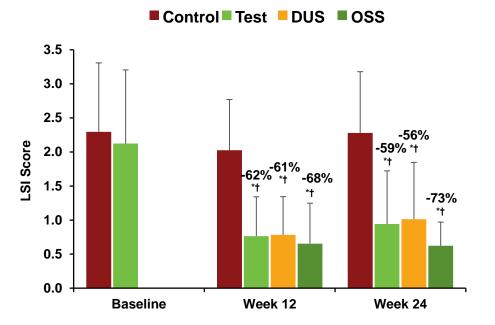
Data shown as Mean +SD

^{*} p < .05 vs Baseline; † p < .05 vs Control; ** p = .097 vs Baseline; % = % difference vs Control; DUS = Dual Use Subgroup; OSS = on!® Switchers Subgroup; GBI=Gingival Bleeding Index.



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Results – LSI Composite Scores



Score	Criteria (Stain Area)	Criteria (Stain Intensity)
0	No stain detected	No stain
1	Stain up to one-third of the region	Light stain – yellow/tan
2	Stain up to two-thirds of the region	Moderate stain – medium brown
3	Stain over more than two-thirds of the region	Heavy stain – dark brown/black

Data shown as Mean + SD

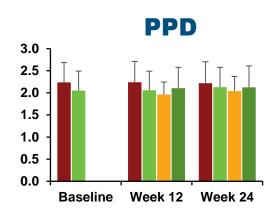
^{*} p < .0001 vs Baseline; † p < .0001 vs Control; % = % difference vs Control; DUS = Dual Use Subgroup; OSS = on!® Switchers Subgroup; LSI = Lobene Stain Index.

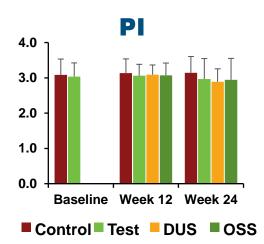


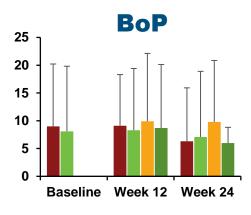
Other Indices

No differences were observed for the following indices

- Periodontal Pocket Depth (PPD)
- Plaque Index (PI)
- Bleeding on Probing (BoP)







Data shown as Mean +SD



Limitations

- The small sample size limits generalizability to the population.
- The 24-week duration of the study may limit the conclusions regarding the long-term oral health effects.
- The exclusion criteria, specifically moderate to severe periodontitis, may limit our ability to draw conclusions regarding the reversibility of the clinical outcomes among these individuals.



Conclusions

- Switching from smoking combustible cigarettes to on!® nicotine pouches significantly reduced levels of gingival inflammation (20+%) and extrinsic dental stain (~70%) relative to continue smoking cigarettes.
- Dual use of on!® nicotine pouches with cigarettes results in a substantial reduction in cigarette consumption (>50%) thus, correspondingly lowering gingival inflammation and dental stain.
- No measurable changes were observed for other clinical measures of oral health (PPD, PI, and BoP).
- Overall, completely switching from cigarettes to on!® nicotine pouches is unlikely to have negative oral health effects.



