ORIGINAL RESEARCH PAPER

Dental Science

"CLINICAL EVALUATION OF THE EFFECT OF A NOVEL LACTOFERRIN CONTAINING TOOTHPASTE AS AN ADJUNCT TO SCALING AND ROOT PLANING IN IMPROVING PLAQUE CONTROL AND GINGIVAL HEALTH- A RANDOMIZED CONTROLLED CLINICAL TRIAL".

KEY WORDS:

Dr. Maya Sanjiv Indurkar Professor & Head, Department of Periodontology, Government Dental College and Hospital, Aurangabad, Maharashtra, India

Dr. Swathy Krishna. J* Post-Graduate Student, Department of Periodontology, Government Dental College and Hospital, Aurangabad, Maharashtra, India *Corresponding Author

ABSTRACT

Aims and objectives: To evaluate the effect of a DENTE91® (novel lactoferrin based toothpaste) in comparison to Standard fluoride based toothpaste as an adjunct to scaling and root Planing in improving plaque control and gingival health. **Methodology:** This was an examiner-blinded, parallel group, randomized, controlled trial enrolled total 100 healthy subjects aged 18 to 35 years (both inclusive) who had dental biofilm induced gingivitis, with at least 20 natural teeth, who exhibited no evidence of clinical attachment loss and was ready to give written informed consent were enrolled. **Results:** Mean ± SD plaque Index score with Turesky–Gilmore–Glickman modification of Quingley Hein plaque index (S) was statistically significant within Test group (1.44 ± 0.40) and Control group (1.79 ± 0.36) as compared to baseline (2.48 ± 0.43 in Test group and 2.72 ± 0.33 in Control group). Mean % ± SD reduction in plaque index score at Week 4 was 42.04% ± 11.04% in Test group and 34.19% ± 14.21% in Control group as compared to baseline. Reduction in plaque index was comparable between Dente 91® (Test group) and Standard fluoride based toothpaste. Mean ± SD gingival Index score based on Loe and Silness, 1963 method was statistically significant at Week 4 (0.76 ± 0.38 in Test group and 1.34 ± 0.56 in Control group) when compared to baseline (22.70 ± 0.67 in Test group and 2.65 ± 0.52 in Control group). Mean % ± SD reduction in gingival Index score at Week 4 was 71.29% ± 12.96% in Test group and 48.54% ± 21.94% in Control group as compared to baseline. Reduction in Gingival Index score was statistical significant (p=0.001) in Dente 91® (Test group) compared to Standard fluoride based toothpaste (Control group). **Conclusion:** The main finding was that Test group who had used DENTE91® toothpaste containing lactoferrin had significantly better gingival health status than the Control group in terms of gingival inflammation and gingival bleeding. Significant reduction in plaque index score was comparable between Test group and Control group.

INTRODUCTION

Dental plaque is primary cause of gingival and periodontal diseases and it is also capable of reducing the pH at the surface of enamel to the levels that can cause dissolution of the hydroxyapatite crystals and initiates caries.[1]

Plaque-induced gingivitis is defined as an inflammatory response of the gingival tissues resulting from bacterial plaque accumulation located at and below the gingival margin.[2] Gingivitis is highly prevalent worldwide, with 46% of adults showing evidence of gingival bleeding and calculus (Community Periodontal Index score of 2), across all age categories.

Similarly, data from the WHO Global Oral Health Data Bank shows that 46% of 35–44-year-old have evidence of periodontitis[3]. One of the most significant risk factors for gingivitis is poor oral hygiene which in turn results in the accumulation of plaque.

Plaque control can be achieved mechanically or chemically. Mechanical plaque control includes patient orientation and implementation of meticulous oral hygiene techniques such as brushing teeth with antiplaque fluoride-containing toothpastes, use of toothbrushes (traditional or interdental), dental floss which are considered as a first conservative approach used to treat patients with such an inflammatory condition.[4]

The adjunctive use of an antibacterial agent for plaque control is also of benefit in those participants who are not able to effectively debride the oral surfaces of supragingival biofilms using mechanical procedures alone.

It is anticipated that a toothpaste formulation based on antibacterial components found naturally occurring in saliva can provide plaque control that is well tolerated by most patients. Use of therapeutic agents in toothpastes to produce an inhibitory action on plaque formation is now a well-established approach to improve gingival health[5].

Lactoferrin (LF) is a chelator of iron and a member of the transferrin family. It is a component of milk, saliva, tears, and secondary neutrophil granules[6]. LF exhibits antimicrobial activity and have been reported to inhibit the metabolism and growth of oral pathogens. The inhibitory effects of LF on biofilm formation by periodontopathic bacteria have also been reported[7]. Oral administration of LF also has been shown to reduce the number of periodontal pathogens in sub-gingival plaque. Therefore, combining LF as an anti-plaque agent in toothpaste is of interest in assessing clinical efficacy in oral hygiene. The aim of this randomized controlled, examiner-blind, clinical study was to assess the short-term effects of this composition containing LF as an adjunct to scaling and root planning in improving plaque control and gingival health in comparison to a commercially available toothpaste containing fluoride[8].

AIMS AND OBJECTIVES

To evaluate the effect of a DENTE91® (novel lactoferrin based toothpaste) in comparison to Standard fluoride based toothpaste as an adjunct to scaling and root Planing in improving plaque control and gingival health.

METHODOLOGY

This was an examiner-blinded, parallel group, randomized, controlled trial conducted in Department of Periodontology, Government Dental College and Hospital, Aurangabad. Total 116 systemically healthy subjects aged between 18 to 35 years (both inclusive) were screened.

Total 100 subjects who dental biofilm had induced gingivitis, with at least 20 natural teeth, who exhibited no evidence of clinical attachment loss and was ready to give written informed consent were enrolled. Subjects with known systemic disease, who were on anti-inflammatory, antibiotic

or antimicrobial therapy in the past 6 months, smokers and smokeless tobacco users, who had received periodontal treatment in the past 6 months, pregnant women and lactating mothers, allergic to any material used in study, and with acute necrotizing ulcerative gingivitis, acute herpetic gingivostomatitis, allergic gingivitis, gingivitis associated with skin diseases, gingivitis associated with endocrine-metabolic disturbances, gingivitis associated with hematologic-immunologic disturbances, gingival enlargement associated with medications, gingival tumors were excluded from the study.

At the start of the study, subjects underwent a systematic clinical examination. Baseline recordings (GI and PI scores) were made in order to assess the oral hygiene level of the subjects. All recordings were made by the same examiner. After disclosing plaque, baseline plaque scores were brought to zero by professional scaling, root planing and polishing with rubber cups and an abrasive paste. A simple random sampling was carried out using a lottery method. Subjects were randomized to either test (Group I - receiving Dente 91®) or control (Group II - receiving Standard fluoride based toothpaste) group in 1:1 ratio.

Of total 100 enrolled subjects, 51 subjects were randomized to Dente 91® group (toothpaste containing lactoferrin, nano-hydroxyapatite, xylitol, aqua, sorbitol, silica, glycerine, peg 8, sls, xanthan gum, fragrance, titanium dioxide, sodium saccharin, sodium benzoate). Remaining 49 subjects were randomized to Standard fluoride based toothpaste group (toothpaste containing triclosan, sodium fluoride, hydrated silica, glycerin, sorbitol, pvm/ma copolymer, sodium lauryl sulphate, flavour, cellulose gum, carrageenan, sodium hydroxide, sodium saccharin, water).

Subjects in both groups were advised to brush twice daily with prescribed toothpaste for 4 weeks. In addition, participants were asked to refrain from the use of dental products (other than those provided) during the study period and were also asked to abstain from any professional cleaning. Compliance with all study restrictions was checked at the beginning of each visit to the study site.

Of 51 subjects in Test group, 46 completed the regimen of 4 weeks of brushing teeth with Dente 91® toothpaste. Two subjects discontinued the intervention and 2 were lost to follow-up. Of 49 subjects in Control group, 46 completed the regimen of 4 weeks of brushing teeth with Standard fluoride based toothpaste toothpaste, 3 subjects were lost to follow-up.

Clinical measurements:

Diagnosis of dental biofilm induced gingivitis was performed by the clinical assessments which was based on plaque index (Turesky-Gilmore-Glickman modification of Quigley Hein Index, 1970) and gingival index (Loe and Silness, 1963) in 46 subjects in each group at baseline and were re-evaluated after 4 weeks by the same examiner.

OBSERVATION AND RESULTS:

The mean ± SD plaque Index score with Turesky– Gilmore–Glickman modification of Quingley Hein plaque index (S) for Test group at Week 4 was 1.44 ± 0.40 as compared to baseline score of 2.48 ± 0.43, plaque reduction score was statistically significant (p=0.001) at Week 4 when compared to baseline (Figure 1).

The mean ± SD plaque Index score with Turseky– Gilmore–Glickman modification of Quigley Hein plaque index (S) for Control group at Week 4 was 1.79 ± 0.36 as compared to baseline score of 2.72 ± 0.33, plaque reduction score was statistically significant (p=0.001) at Week 4 when compared to baseline (Figure 1). Mean % ± SD reduction in plaque index score at Week 4 was 42.04% ± 11.04% in Test group and 34.19 +-14.21% in Control group as compared to baseline. Reduction in plaque index was comparable between Dente 91® (Test group) and Standard fluoride based toothpaste (Control group) (Figure 2).

The mean ± SD gingival Index score based on Loe and Silness, 1963 method for Test group at Week 4 was 0.76 ± 0.38 as compared to baseline score of 2.70 ± 0.67, gingival Index score was statistically significant (p=0.001) at Week when compared to baseline (Figure 3).

The mean ± SD gingival Index score based on Loe and Silness, 1963 method for Control group at Week 4 was 1.34 ± 0.56 as compared to baseline score of 2.65 ± 0.52, gingival Index score was statistically significant (p=0.001) at Week when compared to baseline (Figure 3).

Mean % ± SD reduction in gingival Index score at Week 4 was 71.29% ± 12.96% in Test group and 48.54% ± 21.94% in Control group as compared to baseline. Reduction in Gingival Index score was statistical significant (p=0.001) in Dente 91® (Test group) compared to Standard fluoride based toothpaste (Control group) (Figure 4).

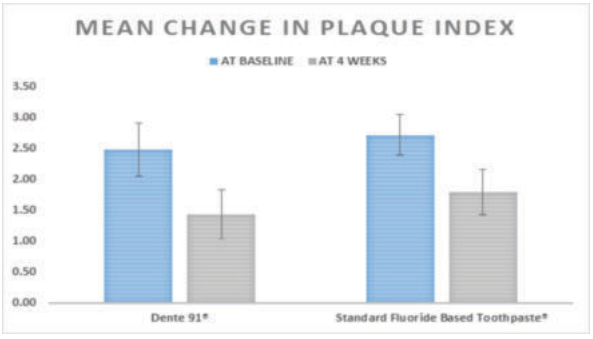

Figure 1: Mean Plaque Index score with Turesky–Gilmore–Glickman modification of Quigley Hein plaque index (S) for Test Group and Control Group at Baseline and Week 4

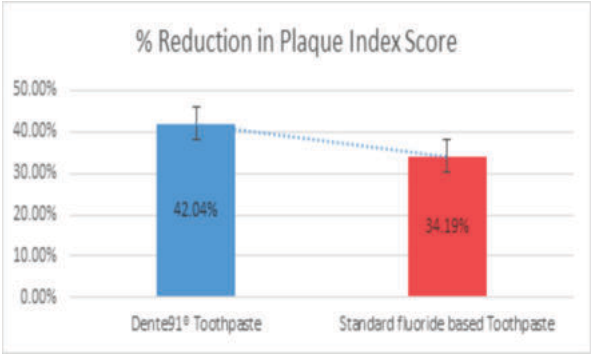

Figure 2: Mean % Plaque Index with Turesky– Gilmore–Glickman Modification of Quigley Hein plaque Index (S) for Test group and Control group at Baseline and Week 4

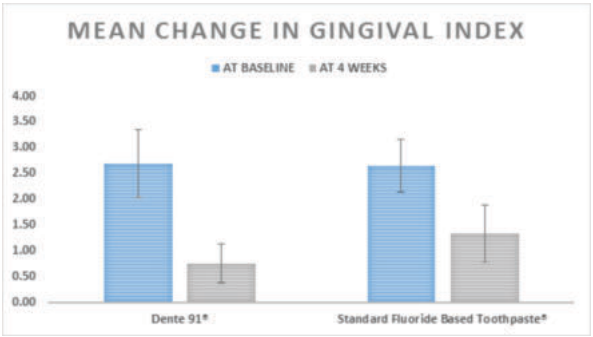

Figure 3: Mean Gingival Index Score Based on Loe and Silness 1963 Method for Test group and Control group at Baseline and Week 4

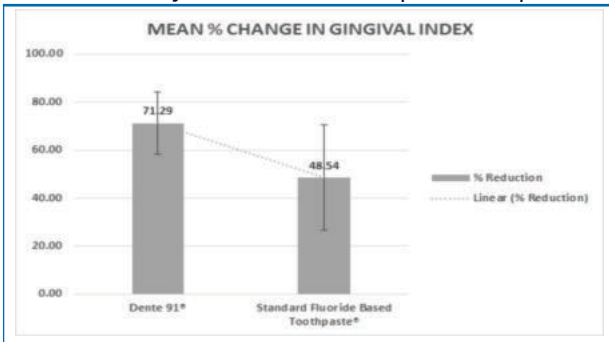

Figure 4: Mean % Gingival Index Score Based on Loe and Silness 1963 Method for Test group and Control group at Baseline and Week 4

DISCUSSION:

Mechanical plaque control play an essential role in prevention of gingivitis and periodontitis, however it is not adequately practiced by most individuals. Mechanical method for plaque control a regular basis is challenging, majority of population did not achieve the levels of plaque control needed to maintain gingival and periodontal health.[9]

Professional treatments is only available to minority of world's population[10], therefore an attempt to induce natural salivary antimicrobial defense mechanisms to improve plaque control and gingival health through novel lactoferrin containing toothpaste was planned in this study.

Hence, the aim of the present study was to compare the efficacy of novel lactoferrin containing toothpaste as an adjunct to scaling and root Planing in improving plaque control and gingival health with existing marketed product 'Standard fluoride based toothpaste'.

The efficacies of DENTE91® and Standard fluoride based toothpaste were compared using Plaque index (modification by Loe 1967), Turesky– Gilmore–Glickman modification of Quigley Hein index and on Loe and Silness, 1963 method.

Many studies reported reduced plaque index and gingival index in subjects using toothpaste containing the active ingredient of Standard fluoride based toothpaste, Triclosan co-polymer. This is a broad-spectrum antibacterial agent effective against both gram-positive and gram-negative bacteria.[11] Similar results were obtained for plaque index in Standard fluoride based toothpaste group in our study, however, mean % reduction in gingival Index score was statistically significant in DENTE91® group when compared to Standard fluoride based toothpaste group.

Both DENTE91® and Standard fluoride based toothpaste had significant reduction in plaque index score and gingival index score after 4 weeks of treatment when compared to baseline.

Considering totally different mechanisms of action of the 2 products tested in this study, further studies using robust and more sophisticated techniques to assess plaque and gingival index over longer evaluation periods is necessary to infer the efficacy results on larger population.

CONCLUSION:

The main finding was that Test group who had used DENTE91® toothpaste containing lactoferrin had significantly better gingival health status than the Control group in terms of gingival inflammation and gingival bleeding. Significant reduction in plaque index score was comparable between Test group and Control group.

One possible explanation, which requires further research, is that use of toothpaste, which contains enzymes and proteins that are naturally present in saliva, may augment salivary defense mechanisms in balancing the oral microbiota.

REFERENCES:

1. Kallar S, Pandit IK, Srivastava N, et al. Plaque removal efficacy of powered and manual toothbrushes under supervised and unsupervised conditions: A comparative clinical study. J Indian Soc Pedod Prev Dent. 2011;Issue, Vol29.
2. Murakami S, Mealey BL, Mariotti A, et al. Dental plaque–induced gingival conditions. J Clin Periodontol. 2018;45:S17-27.
3. World Health Organization, Periodontal Country Profiles: An Overview of CPITN Data in the WHO Global Oral Data Bank, (2017)
4. Cunha EJ, Auersvald CM, Deliberador TM, et al. Effects of active oxygen toothpaste in supragingival biofilm reduction: a randomized controlled clinical trial. Int J Dent. 2019.
5. (J. Serrano, M. Escribano, S. Roldán, C. Martín, D. Herrera, Efficacy of adjunctive anti-plaque chemical agents in managing gingivitis: a systematic review and meta-analysis, J. Clin. Periodontol. 42 (Suppl. 16) (2015) S106–S13)
6. B Lönnerdal, S Iyer. Lactoferrin: molecular structure and biological function, Annu Rev Nutr. 1995;15:93-110. doi: 10.1146/annurev.nu.15.070195.000521.
7. Wakabayashi H, Yamauchi K, Kobayashi T, Yaeshima T, Iwatsuki K, Yoshie H (2009) Inhibitory effects of lactoferrin on growth and biofilm formation of Porphyromonas gingivalis and Prevotella intermedia
8. Antimicrob Agents Chemother 53:3308–3316 16. Kondo I, Kobayashi T, Wakabayashi H, Yamauchi K, Iwatsuki K, Yoshie H (2008) Effects of oral administration of bovine lactoferrin on periodontitis patients. Jpn J Conserv Dent 51:281–291
9. Van der Weijden GA, Hioe KP. A Systematic Review of the Effectiveness of Self-performed Mechanical Plaque Removal in Adults with Gingivitis Using a Manual Toothbrush. J Clin Periodontol. 2005;32:6214–6228
10. Dadkhah M, Chung NE, Ajdaharian J, Wink C, Klokkevold P, Wilder-Smith P. Effects of a Novel Dental Gel on Plaque and Gingivitis: A Comparative Study. Dentistry (Sunnyvale). 2014;4(6):239. doi: 10.4172/2161-1122.1000239. PMID: 26052472; PMCID: PMC4454341.
11. Hioe KP, van der Weijden GA. The effectiveness of self-performed mechanical plaque control with triclosan containing dentifrices. Int J Dent Hyg. 2005;3:192–204.