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Original Article

Antiplaque and remineralizing effects of Biorepair mouthwash: A comparative clinical trial

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ABSTRACT

Objectives: The aim of this study was to compare the effectiveness of Biorepair, fluoride and chlorhexidine mouthwashes in controlling plaque accumulation and gingivitis, in addition to their remineralizing effect on the initial carious lesions.

Methods: about 81 children aged 7–12 years were participated in this study. They were randomly allocated in 3 groups according to the type of the used mouthwash. At baseline, each child was examined for plaque and gingival indices. DIAGNOdent was used to determine the mineral content in the incipient lesions. Children were instructed to use their specific mouthwash twice daily for 2 weeks, then they were recalled after 1, 2, 4, and 6 weeks for recording the same parameters.

Results: All the three types of mouthwashes showed significant reduction in plaque accumulation and gingivitis compared to the baseline. However, Biorepair and fluoride mouthwashes only showed significant remineralization of early carious lesions.

Conclusion: Biorepair mouthwash can serve as a better alternative to different mouthwashes including both fluoride and chloehexidine. This single mouthwash can serve as a multi-purpose mouthwash.

1. Introduction

Modern dentistry aims to reduce the loss of tooth structure, so it focused on prevention and early management of carious lesions. Management of the plaque film through brushing and flossing alone is not enough to achieve this aim, however, new technologies are required. The inhibition of demineralization and enhancing remineralization is essential for such purposes. Many agents as fluoride agents, silica compounds and casein products have been proved beneficial in this regard [1–5].

In addition to reducing demineralization and enhancing remineralization, the incorporation of fluoride into enamel crystals leads to the formation of fluorohydroxyapatite crystals. These crystals are responsible for reducing the enamel solubility, which in turn reduce enamel demineralization [6,7]. In addition to, these fluorohydroxyapatite crystals limit the incorporation of the calcium and phosphorus ions that are needed to reconstruct subsurface lesions [8].

With the nanotechnology revolution, the hydroxyapatite nanocrystals were developed. It was found to form a layer that protects the underlying enamel structure in vitro [9]. Tschoppe et al. [10] reported that the incorporation of nanocrystals in toothpaste provided long term anticaries effect. It was found that the ions have the ability to be retained in saliva and dental plaque for a long time. The same results were also

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reported by Palmieri et al. [11] it was reported to increase remineralization, inhibit demineralization, and reduce the plaque bacteria [12–14].

In spite of many in vitro studies, there is a lack in the in vivo studies concerning the effect of hydroxyapatite nanocrystals. Hence, this study aimed to evaluate the in vivo effect of mouthwash containing hydroxyapatite nanocrystals regarding dental plaque, gingivitis, and enamel remineralization, in comparison with fluoride and chloehexidine mouthwashes.

2. Materials and methods

2.1. *This study was a randomized controlled clinical trial*

2.1.1. *Study sample*

After applying the inclusion and exclusion criteria, total of 81 children (36 males and 45 females) aged between 7 and 12 years old participated in the study. They were selected from outpatients of the Pediatric Dental Clinic, Faculty of Dentistry, Mansoura University. The children aged from 7 to 12 years attended the clinic examined over one month period. The inclusion criteria were children free from systemic diseases, take no medication, signed the informed consent to participate in the study, brush their teeth once before bed time, and had at least one permanent molar with discolored fissures without any signs of undermined enamel or softness at the base of fissures that scored between 12 and 25 by DIAGNOdent (indicating initial carious lesion). Teeth with cavitation, large or defective restorations on any other surface, or those having scores less than 12 by DIAGNOdent were excluded from this study.

This study was approved by the Ethical Committee at the Faculty of Dentistry, Mansoura University. The purpose of the study was explained to the participants and their parents before starting the study. Written consents were taken.

2.1.2. *Study materials*

Three mouthwashes were used in this study: Biorepair (hydroxyapatite nanocrystals mouthwash) (Coswell, SPA40050 FUNO – ITALY), Listerine (fluoride mouthwash) (Johnson & Johnson Middle East FZ – LLC), and Peridex (chlorhexidine mouthwash) (3M, United States). Their active ingredients are illustrated in Table 1.

2.1.3. *Inter- and intra-examiner reproducibility*

Five children were assessed by two investigators twice in one visit, using the study diagnostic parameters, over one hour interval, for the clinical parameters used in this study. The second assessment was carried out blindly to the first one. Reproducibility of the data was determined. (Weighted Kappa values for intra- and inter-examiner reproducibility were 0.87 and 0.89 respectively).

2.1.4. *Study procedures*

The children were randomly assigned into three groups according to the type of mouthwashes, each group contained 27 children. Group I composed children who used Biorepair mouthwash, group II children used Listerine mouthwash, and group III used Peridex mouthwash.

The randomization process was made externally by the statistician using a computer-generated random table, and the investigators were neither involved in the randomization process nor were aware of the assigned group in all outcome evaluations. Randomly assigned identification codes for each child were printed on the bottles that contained the mouthwashes, each child had to use only the bottle having his/her assigned number during the follow-up. The mouthwashes were packed in similar bottles. Although the mouthwashes color had a slightly different tonality of blue, no subject could reasonably guess the assigned mouthwash. Each child was supplied with a bottle containing 70 ml of mouthwash (enough to use for one week) according to the group he/she was assigned in. Each one was instructed to use the supplied graduated cup and return the bottle at the follow up appointments to assure compliance to the treatment. All children were instructed to rinse with 5 ml of their specific mouthwash for (30–60sec) twice daily once after breakfast, and once after dinner before bedtime for two weeks under parental supervision. Printed checklist was distributed to each child and filled by one of their parents to ensure using the proper mouthwash at the correct time and dose. It also helped in recording any medication and the time the child had. The checklists were reviewed weekly. All the children were instructed to keep their normal diet and hygiene habits. Any dental complaints during the research period were dealt with through the researches.

At baseline, each child was examined for the plaque accumulation using (Silness and löe index) [15], and the gingival condition using (löe and Silness index) [16]. In addition, the visual diagnosis of the initial occlusal carious lesions on the first permanent molars was confirmed by the DIAGNOdent, to determine the mineral content of enamel (to indicate the degree of remineralization). No other oral hygiene methods were used during the study period. They were recalled after 1, 2, 4, and 6 weeks for recording the same parameters.

2.1.5. *Sample size estimation*

The main outcome was the difference across groups between the mean changes from baseline to the end of the follow-up. The expected percentages at the end of the follow-up was 90% in the experimental group 50% in the control group, and (from baseline to the end), respectively, of 50% and 90%. Assuming an error 0.05 and an expected withdrawal/dropout rate of 10%, a minimum of 23 subjects per group were requested to achieve an 90% statistical power.

2.1.6. *Statistical analysis*

Data were collected, tabulated and statistically analyzed using SPSS statistical software package for windows version17. Means and standard deviation (SD) values were used for data presentation. Student paired "t" test was used for intragroup comparison, and one way ANOVA and post hoc Turkey's test were used for inter group comparisons. The significance level was set at $P \leq 0.05$.

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