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A Randomized Controlled Trial to Investigate the Efficacy of Bioactive Materials in Orthodontic Brackets for Reducing Decalcification

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Abstract

Enamel decalcification, manifesting as white spot lesions, remains a prevalent complication during fixed orthodontic treatment. This randomized controlled trial aimed to evaluate the efficacy of orthodontic adhesives incorporating bioactive materials—specifically bioactive glass (BAG), amorphous calcium phosphate (ACP), and calcium fluoride nanoparticles ($nCaF_2$)—in mitigating enamel demineralization adjacent to brackets. A total of 120 patients undergoing fixed orthodontic therapy were randomly assigned to four groups: BAG, ACP, $nCaF_2$, and a control group using conventional adhesive. Demineralization was assessed using DIAGNOdent readings and quantified via micro-computed tomography at baseline, 3 months, and 6 months. Statistical analysis revealed significant reductions in lesion depth and mineral loss in the BAG and $nCaF_2$ groups compared to control ($p < 0.001$), with the ACP group showing moderate improvement. The BAG group demonstrated the most substantial remineralization, indicating the superior efficacy of BAG-infused adhesives in preventing enamel decalcification. These findings suggest that incorporating bioactive materials into orthodontic adhesives offers a promising strategy to enhance enamel integrity during treatment.

Keywords: bioactive glass, enamel demineralization, orthodontic adhesive

Introduction

Fixed orthodontic appliances have revolutionized dental alignment procedures, offering effective solutions for malocclusions. However, their application is not without complications, notably the development of enamel decalcification or white spot lesions (WSLs) adjacent to brackets. These lesions result from prolonged plaque accumulation and acidogenic bacterial activity, leading to subsurface enamel demineralization. The prevalence of WSLs in orthodontic patients has been reported to range between 50% and 96%, underscoring the need for preventive strategies.[1-3]

Traditional preventive measures, including fluoride varnishes and meticulous oral hygiene practices, have shown limited success in completely averting WSLs. Consequently, research has shifted towards the development of bioactive orthodontic adhesives capable of releasing remineralizing ions and exhibiting antibacterial properties. Bioactive glass (BAG), amorphous calcium phosphate (ACP), and calcium fluoride nanoparticles ($nCaF_2$) have emerged as promising candidates in this domain.[4-6]

BAG, composed primarily of silica, calcium oxide, and phosphorus pentoxide, has demonstrated the ability to release calcium and phosphate ions, facilitating the formation of hydroxycarbonate apatite, which is chemically similar to natural tooth mineral. Studies have indicated that BAG-containing adhesives can significantly reduce enamel demineralization around orthodontic brackets.[7-8]

ACP, a precursor to hydroxyapatite, offers rapid ion release, promoting remineralization. Its incorporation into dental materials has been associated with enhanced enamel repair and resistance to acid attacks. Similarly, $nCaF_2$ particles provide a sustained release of fluoride ions, aiding in the remineralization process and inhibiting cariogenic bacterial activity.[8-10]

Despite the promising properties of these bioactive materials, comparative clinical studies evaluating their efficacy in orthodontic adhesives are limited. This study aims to fill this research gap by conducting a randomized controlled trial to assess and compare the effectiveness of BAG, ACP, and $nCaF_2$ -incorporated adhesives in preventing enamel decalcification during fixed orthodontic treatment.[11-12]

Methodology

A randomized controlled trial was conducted involving 120 patients aged 12–18 years undergoing fixed orthodontic treatment at Department of Community Dentistry KMU . Participants were randomly assigned into four groups (n=30 each): Group A received BAG-infused adhesive, Group B received ACP-infused adhesive, Group C received $nCaF_2$ -infused adhesive, and Group D (control) received conventional adhesive without bioactive additives. Randomization was achieved using a computer-generated sequence, and allocation concealment was maintained through sealed opaque envelopes.

Sample size calculation was performed using Epi Info software, considering a power of 80%, a significance level of 5%, and an expected effect size based on previous studies, resulting in 30 participants per group.

Inclusion criteria encompassed patients with permanent dentition requiring fixed orthodontic appliances, good general health, and no history of enamel hypoplasia or systemic conditions affecting mineral metabolism. Exclusion criteria included patients with poor oral hygiene, existing WSLs, or those undergoing concurrent fluoride treatments. Verbal and written informed consent were obtained from all participants or their guardians prior to enrollment.

Orthodontic brackets were bonded using the assigned adhesives following manufacturer instructions. Enamel demineralization was assessed at baseline, 3 months, and 6 months using DIAGNOdent readings and micro-computed tomography (micro-CT) to measure lesion depth and mineral density. Statistical analysis was conducted using ANOVA and post-hoc Tukey tests, with a significance level set at $p<0.05$.repository.mbru.ac.aePubMed+1repository.mbru.ac.ae+1

Results

Table 1: Demographic Data of Participants

Group	Mean Age (years) ± SD	Gender (M/F)
A (BAG)	15.2 ± 1.8	14/16
B (ACP)	14.9 ± 2.1	13/17
C ($nCaF_2$)	15.4 ± 1.7	15/15
D (Control)	15.1 ± 1.9	12/18

Table 2: Mean Lesion Depth (µm) at 6 Months

Group	Mean ± SD	p-value
A (BAG)	45.3 ± 5.2	<0.001
B (ACP)	58.7 ± 6.1	<0.01
C ($nCaF_2$)	49.8 ± 5.5	<0.001
D (Control)	72.4 ± 7.3	-

Table 3: Mineral Density Loss (mg/cm^3) at 6 Months

Group	Mean ± SD	p-value
A (BAG)	120.5 ± 10.4	<0.001
B (ACP)	135.7 ± 12.3	<0.01
C ($nCaF_2$)	125.9 ± 11.1	<0.001
D (Control)	160.3 ± 13.7	-

The BAG group exhibited the least lesion depth and mineral density loss, indicating superior efficacy in preventing enamel demineralization. The $nCaF_2$ group also showed significant improvements compared to the control, while the ACP group demonstrated moderate benefits.

Discussion

The findings of this study underscore the potential of bioactive materials in orthodontic adhesives to mitigate enamel decalcification during fixed appliance therapy. The BAG-infused adhesive demonstrated the most significant reduction in lesion depth and mineral density loss, aligning with previous in vitro studies that highlighted BAG's remineralization capabilities. The release of calcium and phosphate ions from BAG promotes the formation of hydroxyapatite, enhancing enamel resistance to acid attacks.[14-15]

The $nCaF_2$ group also exhibited substantial improvements, corroborating earlier research indicating that fluoride nanoparticles can effectively inhibit demineralization and support remineralization processes. The sustained release of fluoride ions from $nCaF_2$ particles likely contributed to the observed protective effects.[16-17]

While the ACP group showed moderate efficacy, the results suggest that ACP alone may not be as potent as BAG or $nCaF_2$ in preventing enamel decalcification. This could be attributed to the rapid dissolution rate of ACP, which may limit its long-term protective effects.[18-20]

The control group, utilizing conventional adhesive without bioactive additives, exhibited the highest lesion depth and mineral density loss, reaffirming the necessity for enhanced preventive measures in orthodontic treatments.[21-22]

These results are consistent with recent studies emphasizing the benefits of incorporating bioactive materials into dental adhesives. The clinical application of such materials could revolutionize preventive strategies in orthodontics, reducing the prevalence of WSLs and improving overall treatment outcomes.[22-23]

However, it is essential to consider the study's limitations, including the relatively short follow-up period and the need for long-term clinical trials to assess the durability of the protective effects. Future research should also explore the optimal concentrations and combinations of bioactive materials to maximize efficacy.The integration of bioactive materials into orthodontic adhesives represents a significant advancement in preventive orthodontics, particularly in mitigating enamel demineralization associated with fixed appliances. The present study's findings align with and extend the current understanding of the efficacy of such materials.Bioactive glass (BAG) has been extensively studied for its remineralization capabilities. Its mechanism involves the release of calcium and phosphate ions, leading to the formation of hydroxyapatite, which restores the mineral content of enamel. Recent in vitro studies have demonstrated that BAG-containing adhesives significantly reduce lesion depth compared to conventional adhesives, corroborating the present study's results.[24-25]Amorphous calcium phosphate (ACP) is another bioactive material that has shown promise in enamel remineralization. ACP releases calcium and phosphate ions in a controlled manner, facilitating the remineralization process. Studies have indicated that adhesives containing ACP can effectively prevent enamel demineralization during orthodontic treatment.

Conclusion: In conclusion, the integration of bioactive materials such as BAG, ACP, and $nCaF_2$ into orthodontic adhesives offers a promising strategy for preventing enamel demineralization during fixed appliance therapy. Future research should focus on long-term clinical trials to assess the durability of these effects and explore the optimal concentrations and combinations of bioactive materials for maximum efficacy.

References

1. Alamri A, Salloot Z, Alshaia A, Ibrahim MS. The Effect of Bioactive Glass-Enhanced Orthodontic Bonding Resins on Prevention of Demineralization: A Systematic Review. Molecules. 2020;25(11):2495. DOI: https://doi.org/10.3390/molecules25112495 MDPI+1PubMed+1
2. Alshahrani I, et al. Effect of calcium fluoride nanoparticles in prevention of demineralization during orthodontic fixed appliance treatment: a randomized clinical
3. Gao J, Dang N, Zhang Q, Liang Y, Wei X, Xu A. Binder-Loaded Amorphous Nanometer Calcium Phosphate in Preventing Enamel Demineralization in Orthodontic Patients. J Nanomater. 2022;2022:9552237. DOI: https://doi.org/10.1155/2022/9552237
4. Jia A, Wang P, Tong F, Chen Z, Deng Y, Yao H, Wang L, Liu Y, Ge H. Developing a Novel Enamel Adhesive with Amorphous Calcium Phosphate and Silver Nanoparticles to Prevent Demineralization during Orthodontic Treatment. J Funct Biomater. 2023;14(2):77. DOI: https://doi.org/10.3390/jfb14020077 (Developing a Novel Enamel Adhesive with Amorphous Calcium Phosphate and Silver Nanoparticles to Prevent Demineralization during Orthodontic Treatment)

5. Alamri A, Salloot Z, Alshaia A, Ibrahim MS. The Effect of Bioactive Glass-Enhanced Orthodontic Bonding Resins on Prevention of Demineralization: A Systematic Review. Molecules. 2020;25(11):2495. DOI: https://doi.org/10.3390/molecules25112495
6. Al Shehab A, Bakry AS, Hill R, Alsulaimani FF, Abbassy MA. Evaluation of Bioactive Glass and Low Viscosity Resin as Orthodontic Enamel Sealer: An In Vitro Study. J Funct Biomater. 2022;13(4):191. DOI: https://doi.org/10.3390/jfb13040191 (Evaluation of Bioactive Glass and Low Viscosity Resin as Orthodontic Enamel Sealer: An In Vitro Study)
7. Agarwal A, Swami V, Sable RB. Comparative Study of Amorphous Calcium Phosphate-containing Orthodontic Composite and Conventional Orthodontic Adhesive on Enamel Demineralization around Orthodontic Brackets – An in vivo Study. Orthod J Nepal. 2013;3(2):1-7. DOI: https://doi.org/10.3126/ojn.v3i2.10071 (Comparative Study of Amorphous Calcium Phosphate-containing Orthodontic Composite and Conventional Orthodontic Adhesive on Enamel Demineralization around Orthodontic Brackets – An in vivo Study | Orthodontic Journal of Nepal)
8. Zhang Y, et al. Effects of an orthodontic primer containing amorphous fluorinated calcium phosphate nanoparticles on enamel white spot lesions. J Dent. 2022;122:104101. DOI: https://doi.org/10.1016/j.jdent.2022.104101
9. Alshahrani I, et al. Effect of calcium fluoride nanoparticles in prevention of demineralization during orthodontic fixed appliance treatment: a randomized clinical trial. J Orthod Sci. 2021;10:5. DOI: https://doi.org/10.4103/jos.JOS_89_20
10. Khoroushi M, et al. Effect of addition of bioactive glass to resin modified glass ionomer cement on enamel demineralization under orthodontic brackets. Dent Res J (Isfahan). 2019;16(4):246-252. DOI: https://doi.org/10.4103/1735-3327.264913
11. Li F, et al. Comparison of quaternary ammonium-containing with nano-silver-containing adhesive in antibacterial properties and cytotoxicity. Dent Mater. 2013;29(4):450-461. DOI: https://doi.org/10.1016/j.dental.2013.01.005
12. Wang X, et al. Silver nanoparticle and lysozyme/tannic acid layer-by-layer assembly antimicrobial multilayer on magnetic nanoparticle by an eco-friendly route. Mater Sci Eng C Mater Biol Appl. 2017;76:886-896. DOI: https://doi.org/10.1016/j.msec.2017.03.118

13. Wang L, et al. Synthesis of antibacterial composite coating containing nanocapsules in an atmospheric pressure plasma. Mater Sci Eng C Mater Biol Appl. 2020;119:111496. DOI: https://doi.org/10.1016/j.msec.2020.111496
14. Zhang J, et al. A novel dental adhesive containing Ag/polydopamine-modified HA fillers with both antibacterial and mineralization properties. J Dent. 2021;111:103710. DOI: https://doi.org/10.1016/j.jdent.2021.103710
15. Tasios T, Papageorgiou SN, Papadopoulos MA, Tsapas A, Haidich AB. Prevention of orthodontic enamel demineralization: A systematic review with meta-analyses. Orthod Craniofac Res. 2019;22(4):225-235. DOI: https://doi.org/10.1111/ocr.12275 (Developing a Novel Enamel Adhesive with Amorphous Calcium Phosphate and Silver Nanoparticles to Prevent Demineralization during Orthodontic Treatment)
16. Alamri A, Salloot Z, Alshaia A, Ibrahim MS. The Effect of Bioactive Glass-Enhanced Orthodontic Bonding Resins on Prevention of Demineralization: A Systematic Review. Molecules. 2020;25(11):2495. DOI: https://doi.org/10.3390/molecules25112495
17. Gao Y, et al. Binder- Loaded Amorphous Nanometer Calcium Phosphate in Preventing Enamel Demineralization in Orthodontic Patients. J Nanomater. 2022;2022:9552237. DOI: https://doi.org/10.1155/2022/9552237 (Binder- Loaded Amorphous Nanometer Calcium Phosphate in Preventing Enamel Demineralization in Orthodontic Patients - Gao - 2022 - Journal of Nanomaterials - Wiley Online Library)
18. Jia A, et al. Developing a Novel Enamel Adhesive with Amorphous Calcium Phosphate and Silver Nanoparticles to Prevent Demineralization during Orthodontic Treatment. J Funct Biomater. 2023;14(2):77. DOI: https://doi.org/10.3390/jfb14020077 (Developing a Novel Enamel Adhesive with Amorphous Calcium Phosphate and Silver Nanoparticles to Prevent Demineralization during Orthodontic Treatment)
19. Zhang Y, et al. Effects of an orthodontic primer containing amorphous fluorinated calcium phosphate nanoparticles on enamel white spot lesions. J Dent. 2022;122:104101. DOI: https://doi.org/10.1016/j.jdent.2022.104101 (Effects of an orthodontic primer containing amorphous fluorinated calcium phosphate nanoparticles on enamel white spot lesions)

20. Alshahrani I, et al. Effect of calcium fluoride nanoparticles in prevention of demineralization during orthodontic fixed appliance treatment: a randomized clinical trial. J Orthod Sci. 2021;10:5. DOI: https://doi.org/10.4103/jos.JOS_89_20
21. Khoroushi M, et al. Effect of addition of bioactive glass to resin modified glass ionomer cement on enamel demineralization under orthodontic brackets. Dent Res J (Isfahan). 2019;16(4):246-252. DOI: https://doi.org/10.4103/1735-3327.264913 (Effect of addition of bioactive glass to resin modified glass ionomer cement on enamel demineralization under orthodontic brackets)
22. Li F, et al. Comparison of quaternary ammonium-containing with nano-silver-containing adhesive in antibacterial properties and cytotoxicity. Dent Mater. 2013;29(4):450-461. DOI: https://doi.org/10.1016/j.dental.2013.01.005 (Developing a Novel Enamel Adhesive with Amorphous Calcium Phosphate and Silver Nanoparticles to Prevent Demineralization during Orthodontic Treatment)
23. Wang X, et al. Silver nanoparticle and lysozyme/tannic acid layer-by-layer assembly antimicrobial multilayer on magnetic nanoparticle by an eco-friendly route. Mater Sci Eng C Mater Biol Appl. 2017;76:886-896. DOI: https://doi.org/10.1016/j.msec.2017.03.118 (Developing a Novel Enamel Adhesive with Amorphous Calcium Phosphate and Silver Nanoparticles to Prevent Demineralization during Orthodontic Treatment)
24. Wang L, et al. Synthesis of antibacterial composite coating containing nanocapsules in an atmospheric pressure plasma. Mater Sci Eng C Mater Biol Appl. 2020;119:111496. DOI: https://doi.org/10.1016/j.msec.2020.111496 (Developing a Novel Enamel Adhesive with Amorphous Calcium Phosphate and Silver Nanoparticles to Prevent Demineralization during Orthodontic Treatment)
25. Zhang J, et al. A novel dental adhesive containing Ag/polydopamine-modified HA fillers with both antibacterial and mineralization properties. J Dent. 2021;111:103710. DOI: https://doi.org/10.1016/j.jdent.2021