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EFFECT OF COMMERCIAL MOUTHWASH CONTAINING SODIUM FLUORIDE AND SODIUM MONOFLUOROPHOSPHATE ON THE SURFACE ROUGHNESS OF ORTHODONTIC NICKEL-TITANIUM ARCHWIRES: IN VITRO-INFORMED CONSIDERATIONS

Ahmed Ali Alawi Qaraah*
0009-0002-1067-5792
Cebu Doctors' University
Mandaue City, Cebu, Philippines

*Corresponding Author: Ahmedqaraah@gmail.com

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Abstract

Background. Nickel–Titanium (NiTi) orthodontic archwires are widely used because of their superelasticity, shape memory, and ability to deliver light continuous forces. Their surface integrity may be altered by chemical exposure in the oral environment. Fluoride-containing mouthwashes are commonly used for caries prevention, but commercial formulations contain multiple ingredients and their effects on orthodontic materials may vary with formulation and exposure conditions.

Methods. This in vitro quantitative experimental study evaluated a commercial Fluocaril mouthwash containing sodium fluoride (NaF) and sodium monofluorophosphate (MFP) on the surface roughness of NiTi orthodontic archwires. Forty-four 0.017 × 0.025-inch NiTi specimens were randomly allocated to a mouthwash group ($n = 22$) or artificial-saliva control group ($n = 22$). Specimens were exposed for 21 days. The intervention group received 1 minute 30 seconds of undiluted mouthwash daily, followed by distilled-water rinsing and storage in fresh artificial saliva; control specimens remained in artificial saliva. Surface roughness (Ra) was measured by Atomic Force Microscopy (AFM). Group differences were analyzed using Welch's independent-samples t-test at $\alpha = 0.05$.

Results. Mean surface roughness was higher in the commercial-mouthwash group (22.76 ± 1.37 nm) than in the artificial-saliva group (11.52 ± 0.74 nm). The between-group difference was statistically significant, $t(32.303) = 33.828$, $p < .001$, with a mean difference of 11.24 nm and Cohen's $d = 10.20$.

Conclusion. Under the conditions of this in vitro study, the tested commercial mouthwash formulation was associated with a substantial increase in NiTi surface roughness compared with artificial saliva. Because the study did not isolate NaF, MFP, pH, or other formulation ingredients, the observed change cannot be attributed to fluoride alone and should not be interpreted as evidence of a clinical effect on friction, treatment duration, or wire failure. Further studies should compare individual and combined fluoride formulations, measure pH and other chemical characteristics, and evaluate corrosion, friction, ion release, and mechanical properties.

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Keywords. *Atomic Force Microscopy; commercial mouthwash; nickel–titanium archwires; orthodontics; sodium fluoride; sodium monofluorophosphate; surface roughness.*

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Research Highlights

What is the current knowledge?

- NiTi orthodontic archwires are widely used because of their superelasticity, shape memory, and favorable force-delivery characteristics.
- Fluoride-containing environments have been reported to affect the protective oxide layer and surface characteristics of NiTi alloys, but the magnitude of the effect depends on chemical formulation and exposure conditions.
- Surface roughness is a measurable material characteristic that can be relevant to corrosion and friction; however, friction and clinical treatment efficiency were not measured in the present study.
- NaF and MFP differ in fluoride-release behavior, while commercial mouthwashes may contain additional ingredients that can also interact with orthodontic materials.
- Fluoride toothpaste was not evaluated in this study; toothpaste concentration, formulation, and contact conditions differ from those of mouthwash and should not be assumed to have the same effect.

What is new in this study?

- Evaluated a commercially available mouthwash formulation containing both NaF and MFP as a whole rather than attempting to attribute the observed effect to either fluoride salt separately.
- Used AFM to quantify nanoscale surface roughness after a standardized 21-day intermittent-exposure protocol in which intervention specimens were returned to artificial saliva between daily mouthwash exposures.
- Demonstrated a statistically significant difference in NiTi surface roughness between the commercial-mouthwash and artificial-saliva groups.
- Identified formulation-related factors—including fluoride concentration, pH, and non-fluoride ingredients—as important variables for future mechanistic studies rather than assuming that fluoride alone caused the observed change.
- Provides provisional, research-informed considerations for orthodontic product selection while emphasizing that the findings are in vitro and do not establish clinical effects on friction, treatment duration, or mechanical failure.

INTRODUCTION

Nickel–Titanium (NiTi) orthodontic archwires are among the most widely used materials in contemporary orthodontic treatment because of their superelasticity, shape memory, biocompatibility, and ability to deliver relatively light continuous forces. These characteristics are particularly useful during alignment and leveling. However, the surface integrity of NiTi can be influenced by the oral environment, including fluctuations in temperature and pH, salivary electrolytes, mechanical stress, and exposure to oral hygiene products (Uysal et al., 2022; Brantley, 2020; Al-Horini et al., 2022).

Maintaining oral hygiene is especially important during fixed orthodontic treatment because brackets and archwires create plaque-retentive areas and increase the risk of enamel demineralization and gingival inflammation (Almutairi et al., 2023). Fluoride mouthwashes are used as adjuncts for caries prevention. The tested Fluocaril Bi-Fluoré 25 mg mouthwash was labeled as containing a total fluoride concentration of 250 ppm, supplied as 200 ppm sodium fluoride (NaF) and 50 ppm sodium monofluorophosphate (MFP). The product label also lists non-fluoride ingredients including surfactants, solvents/humectants, preservatives, flavoring agents, zinc sulfate, and other formulation components. Therefore, when a commercial mouthwash is studied, its observed effect should be interpreted as the effect of the formulation as a whole rather than automatically attributed to fluoride alone. Fluoride toothpaste is a separate exposure: Fluocaril Bi-Fluoré 250 mg toothpaste contains a substantially higher total fluoride concentration (2,500 ppm) and has different use and contact conditions; it was not evaluated in the present study.

Surface roughness is an important measurable characteristic of orthodontic archwires because chemical or mechanical alteration of the surface can be associated with corrosion behavior, frictional resistance, and bacterial adhesion (Rokaya et al., 2018; Mohan & Jain, 2022; Farrag et al., 2024). Previous studies have reported surface deterioration of orthodontic wires following exposure to fluoride-containing agents, but the magnitude and direction of changes vary with fluoride concentration, pH, exposure duration, alloy, and analytical method (Chitra et al., 2020; Ehrami et al., 2022; Condò et al., 2022; Khan et al., 2022). Importantly, the present study did not measure friction, treatment duration, corrosion rate, ion release, or mechanical properties; therefore, these outcomes cannot be inferred directly from the measured Ra values.

The principal knowledge gap addressed by this study is not whether NaF or MFP individually can affect orthodontic materials, but whether a real-world commercial formulation containing both compounds is associated with measurable nanoscale surface alteration under repeated exposure. The study therefore evaluates the commercial product as a complete formulation. This distinction is important because the product's pH and non-fluoride ingredients may contribute to its interaction with NiTi surfaces. The pH of the tested mouthwash was not measured in the present experiment, and the product information reviewed did not provide a pH value; consequently, acidity is considered a potential explanatory factor but cannot be quantified or assigned a causal role in the observed findings.

Hence, this study aimed to evaluate the effect of a commercial mouthwash containing sodium fluoride and sodium monofluorophosphate on the surface roughness of NiTi orthodontic archwires compared with artificial saliva. The resulting in vitro-informed considerations are framed as provisional, research-informed hypotheses and baseline parameters for material-selection research, preliminary in vitro risk assessment, and future clinical investigation; they are not clinical prescribing rules or established orthodontic standards.

LITERATURE REVIEW

Theoretical Foundations of Orthodontic Nickel–Titanium Archwire Behavior

NiTi archwires derive their clinical behavior from reversible austenitic–martensitic phase transformations that support shape memory and superelasticity (Brantley, 2020; Al-Horini et al., 2022; Maroof et al., 2022). Contemporary NiTi products differ in alloy composition, thermal treatment, manufacturing, and surface modification, all of which can affect force delivery, surface morphology, and corrosion behavior (Amaya et al., 2020; González et al., 2023; Sanders et al., 2022; Stoyanova-Ivanova et al., 2024).

A naturally formed titanium-oxide passive layer contributes substantially to the corrosion resistance of NiTi. Its stability, however, depends on the surrounding chemical environment. Fluoride ions, acidity, chloride-containing electrolytes, temperature, and exposure time can influence passive-layer stability and electrochemical behavior (Khan et al., 2022; Uysal et al., 2022; Fróis et al., 2023). The resulting surface changes may be detected as changes in nanoscale roughness, even when the alloy retains its gross structural form.

Surface roughness is therefore useful as a material-level outcome, but it should not be equated automatically with a measured clinical consequence. Prior orthodontic research links roughness with frictional resistance and surface degradation, yet the magnitude of any clinical effect depends on bracket material, ligation, archwire alloy, surface geometry, and loading conditions (Krishnan & Kumar, 2004; Rokaya et al., 2018; Farrag et al., 2024). In the present study, Ra is interpreted strictly as the measured surface characteristic.

Fluoride-Containing Mouthwashes and Their Interaction with Orthodontic Materials

Fluoride-containing mouthwashes are commonly used as adjuncts to oral-hygiene measures in orthodontic patients because fixed appliances increase plaque retention and the risk of white spot lesions. NaF provides readily available fluoride ions, whereas MFP is a fluoride-phosphate compound with different fluoride-release kinetics (Satou et al., 2022, 2023). Commercial products may combine these compounds with surfactants, humectants, preservatives, flavoring agents, antimicrobial components, and pH-modifying ingredients; these constituents can influence the chemical environment experienced by an archwire.

Fluoride–NiTi interactions have been investigated through surface microscopy, friction testing, corrosion measurements, and ion-release studies. Fluoride exposure can destabilize the passive oxide layer under some conditions, particularly when combined with an acidic environment, thereby promoting localized surface alteration (Chitra et al., 2020; Condò et al., 2022; Ehrami et al., 2022; Pastor et al., 2022). However, the presence of fluoride in a formulation does not prove that fluoride alone is responsible for an observed change in a commercial product.

NaF and MFP should not be treated as interchangeable exposures. NaF releases free fluoride more readily, whereas MFP has different release kinetics and has been reported to interact less aggressively with orthodontic materials in some experimental comparisons (Geramy et al., 2017; Satou et al., 2022). Because the present study did not include separate NaF-only and MFP-only groups, it cannot determine the individual or synergistic contribution of either salt. It evaluates the tested commercial formulation containing both compounds.

Surface Roughness, Corrosion, and Atomic Force Microscopy Evaluation

Surface roughness can be quantified using parameters such as Ra and RMS. Increased roughness may be associated with corrosion and frictional resistance, but these relationships are context dependent and require direct measurement when clinical or mechanical conclusions are intended (Mohan & Jain, 2022; Farrag et al., 2024; Makrygiannakis et al., 2025).

Common analytical methods include scanning electron microscopy, profilometry, and AFM. AFM provides three-dimensional topographical information at the nanoscale and can quantify Ra without conductive coating or destructive sectioning. Its ability to evaluate small, localized regions makes it suitable for detecting subtle surface alterations in orthodontic wires (Mohan & Jain, 2022; Mei & Guan, 2023; Müller-Renno & Ziegler, 2024).

AFM measurements are influenced by scan area, tip condition, operating mode, sample preparation, and analysis settings. Standardized tapping-mode scanning, multiple measurement areas, consistent settings, and blinded evaluation can improve comparability across specimens. These methodological considerations support the use of AFM in the present study while also emphasizing that Ra represents a surface-topography outcome rather than a direct measure of corrosion rate or clinical performance.

Research Gap and Rationale for the Current Study

The literature collectively shows that NiTi surface behavior is affected by alloy characteristics, fluoride exposure, pH, exposure time, and the broader chemical environment. Evidence from studies of wire roughness and surface morphology (Abdulhameed et al., 2024; Mohan & Jain, 2022; Chitra et al., 2020), fluoride mouthwashes (Ehrami et al., 2022; Makrygiannakis et al., 2025), corrosion mechanisms (Khan et al., 2022; Fróis et al., 2023; Patajinadachote et al., 2018), ion release (Pastor et al., 2022; Mikulewicz et al., 2024), mechanical behavior (Pratap et al., 2021; Amaya et al., 2020), and surface-modification approaches (Bącela et al., 2020; Witkowska et al., 2025) supports the need to distinguish material-level observations from clinical outcomes.

Despite this body of work, relatively little evidence directly addresses a commercially available mouthwash containing both NaF and MFP using AFM-based nanoscale roughness assessment. Existing studies also differ in fluoride concentration, product formulation, exposure schedule, wire type, and analytical method. These differences make direct comparison difficult and support evaluation of the complete commercial formulation under a clearly defined exposure protocol.

Conceptual framework. The independent exposure condition was the immersion environment: artificial saliva or a commercial mouthwash formulation containing NaF and MFP. The exposure process included daily intermittent mouthwash contact, distilled-water rinsing, and storage in artificial saliva at 37°C. The primary dependent variable was AFM-derived Ra in nanometers. The proposed clinical considerations are an output of the observed difference in Ra, interpreted together with the literature and the study's limitations. This framework deliberately avoids assuming that fluoride concentration, pH, or any single ingredient caused the outcome because those variables were not separately manipulated.

Artificial saliva was used as the control medium because it provides an electrolyte-containing aqueous environment against which the additional daily exposure to the commercial mouthwash could be compared. It does not reproduce the full biological complexity of natural saliva, including proteins, enzymes, cells, and dynamic flow. Thus, the control represents a standardized laboratory comparator rather than a complete simulation of the oral cavity.

METHODOLOGY

Design

This study employed a quantitative experimental in vitro design with random allocation of specimens to an intervention group and a control group. The term "randomized controlled trial" was not used because the study involved no human participants. The independent variable was the exposure condition (commercial mouthwash versus artificial saliva), and the dependent variable was AFM-measured surface roughness (Ra). Random allocation was used to reduce allocation bias among the 44 laboratory specimens.

Environment

The experimental procedures were conducted at the Institute of Chemistry Research Building, National Science Complex, University of the Philippines, Diliman, Quezon City, Philippines. The laboratory procedures were performed during the experimental period following institutional laboratory safety protocols. The facility provided appropriate equipment for chemical preparation, controlled incubation, and nanoscale surface evaluation. Samples were incubated at 37°C to simulate intraoral temperature conditions during the 21-day experimental period.

Data Sources

The study utilized 44 NiTi orthodontic archwire specimens (0.017 × 0.025 inch). Sample size was determined in R using a two-sample *t*-test calculation with an anticipated standardized effect size of 0.867, 80% power, and $\alpha = 0.05$, yielding 22 specimens per group. This value corresponds to an anticipated Cohen's *d* of approximately 0.87 rather than "86.7%." The specimens were obtained from an authorized supplier to maintain product consistency.

The specimens were randomly allocated into two groups:

- Control group *(n* = 22): NiTi archwire segments maintained in artificial saliva throughout the 21-day period.
- Intervention group (*n* = 22): NiTi archwire segments receiving daily exposure to the commercial Fluocaril mouthwash and then maintained in artificial saliva between exposures.

Each archwire was sectioned into standardized 5-mm segments before immersion to minimize variation in exposed surface area. The commercial mouthwash was used undiluted. The tested Fluocaril Bi-Fluoré 25 mg formulation was labeled as containing 250 ppm total fluoride (200 ppm NaF and 50 ppm MFP). The product label also lists multiple non-fluoride ingredients; therefore, the intervention was treated analytically as a complete commercial formulation rather than as a fluoride-only solution. The pH of the mouthwash was not measured in this experiment, and no pH value was identified on the product label; it was therefore not used as an explanatory variable.

Instruments

Surface evaluation was performed using Atomic Force Microscopy (AFM), which provides three-dimensional nanoscale characterization of surface topography. AFM was selected because it permits quantitative roughness assessment without destructive sectioning or conductive coating. The primary outcome reported in this article was average surface roughness (Ra), expressed in nanometers.

The AFM was operated in tapping mode with a silicon cantilever to minimize lateral contact and potential surface damage. Multiple scan areas were evaluated for each specimen using consistent settings, and the technician performing the scans was blinded to group allocation. Ra was calculated from the AFM topographical data. RMS and maximum height were available as surface descriptors but were not used as primary outcomes in the statistical comparison.

Data Collection Procedure

Before the experiment, specimens were cleaned, standardized, randomly allocated, and placed individually in sealed polypropylene containers. Both groups were maintained at 37°C. The artificial-saliva condition served as the laboratory control because it provides a standardized electrolyte-containing aqueous environment for comparison with the added daily mouthwash exposure.

Control specimens remained completely immersed in artificial saliva at 37°C for 21 days, with daily replacement of the artificial saliva. This provided a stable comparator over the experimental period and controlled for the effects of storage in an aqueous electrolyte medium.

Intervention specimens remained in artificial saliva between exposures. Once daily, each specimen was removed and immersed in undiluted commercial mouthwash for 1 minute 30 seconds, corresponding to three 30-second rinsing periods combined into a standardized daily exposure. The specimen was then rinsed with distilled water, dried under standardized conditions, and returned to fresh artificial saliva at 37°C. This intermittent protocol was intended to model repeated clinical contact more realistically than continuous immersion in mouthwash. The 21-day duration was selected as a standardized three-week repeated-exposure period that allows cumulative surface changes to be assessed while avoiding continuous mouthwash immersion.

At the end of the 21-day period, all specimens were rinsed with distilled water, dried, mounted for AFM analysis, and scanned by a blinded technician. The mean Ra value for each specimen was used as the experimental unit for statistical analysis.

Data Analysis

Data were analyzed using IBM SPSS Statistics version 23. Means and standard deviations summarized Ra values. Normality was assessed using the Kolmogorov–Smirnov test. Equality of variances was assessed using Levene's test. The Kolmogorov–Smirnov results indicated no evidence against normality for either group: commercial mouthwash, $D = 0.101$, $p = .200$; artificial saliva, $D = 0.145$, $p = .200$. Levene's test indicated unequal variances, $F = 5.323$, $p = .026$.

Because the variance assumption was violated, the Welch version of the independent-samples *t*-test was used to compare the two groups. Statistical significance was set at $\alpha = .05$. The mean difference and Cohen's *d* were reported as measures of magnitude. The very large observed standardized difference was interpreted as a property of this laboratory dataset and not as a clinical effect size.

Ethical Considerations

Ethical approval was obtained from the Cebu Doctors' University Institutional Biosafety Committee before the experimental procedures. Because the study involved only in vitro orthodontic materials and commercial chemical solutions and did not involve human or animal participants, informed consent was not applicable.

Laboratory procedures followed institutional biosafety and chemical-safety protocols. Personal protective equipment was used during sample preparation and chemical handling, and fluoride-containing solutions and chemical waste were handled and disposed of according to institutional Environmental Health and Safety procedures.

RESULTS

Average Surface Roughness

After 21 days, AFM-measured Ra was compared between the commercial-mouthwash and artificial-saliva groups. The commercial-mouthwash group showed approximately twice the mean surface roughness of the control group (22.76 vs. 11.52 nm), as summarized in Table 1.

Table 1.

Average Surface Roughness (Ra) of NiTi Orthodontic Archwires After 21 Days in Commercial Mouthwash or Artificial Saliva

Group	*n*	Mean Ra ± SD (nm)
Commercial Mouthwash	22	22.76 ± 1.37
Artificial Saliva (Control)	22	11.52 ± 0.74

Note. Ra = average surface roughness.

Between-Group Difference in Surface Roughness

The mean Ra was 22.76 ± 1.37 nm for specimens exposed to the commercial mouthwash and 11.52 ± 0.74 nm for specimens maintained in artificial saliva. Thus, the observed mean difference was 11.24 nm, with higher values in the intervention group.

Table 2.

Welch Independent-Samples t-Test Comparing Ra Between Commercial Mouthwash and Artificial Saliva

Cohen's d	Mean difference (nm)	t	df	*p*-value	Decision
10.20	11.24	33.828	32.303	< .001	Reject the Ho

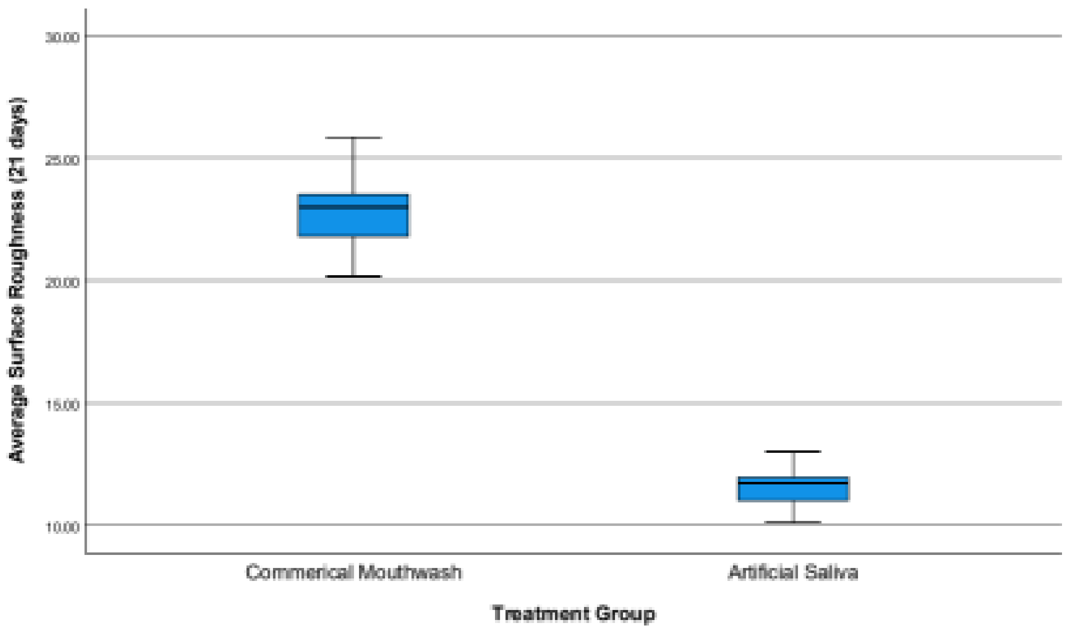
Note. α = .05; p values reported as two-sided. Because Levene's test indicated unequal variances, the Welch t-test was used.

The Welch independent-samples *t*-test showed a statistically significant difference in Ra between the commercial-mouthwash and artificial-saliva groups, $t(32.303) = 33.828$, $p < .001$. The mean difference was 11.24 nm. Cohen's *d* was 10.20, indicating a very large standardized difference in this dataset. The large magnitude should be interpreted cautiously because effect-size magnitude in an in vitro surface-roughness experiment does not establish a corresponding clinical effect.

Figure 1 provides a visual comparison of the distributions of Ra values in the two groups. The commercial-mouthwash values are centered substantially higher than the artificial-saliva values, consistent with the statistically significant between-group difference reported in Table 2.

Figure 1.

Visual Comparison of the Distributions of Ra Values in the Two Groups



DISCUSSION

The present study demonstrated that NiTi archwire specimens exposed to the tested commercial mouthwash formulation had significantly greater Ra than specimens maintained in artificial saliva for 21 days. The result establishes a clear association between exposure to the complete commercial formulation and increased nanoscale surface roughness under the experimental conditions. It does not, by itself, establish that fluoride was the sole cause, because the mouthwash contained other ingredients and the pH was not measured.

The finding is consistent with previous studies showing that fluoride-containing agents can alter orthodontic wire surfaces. Ehrami et al. (2022) reported increased surface roughness after exposure to sodium fluoride mouthwashes, while Condò et al. (2022) described surface pitting and alteration of the passive oxide layer after fluoride exposure. Pastor et al. (2022) reported increased nickel and titanium ion release after exposure to fluoride-containing mouthwashes. These studies support a plausible chemical mechanism involving alteration of the passive surface layer, but they do not establish that the same mechanism, to the same extent, occurred in the present commercial formulation.

The present study should also be distinguished from studies that directly measured friction. Makrygiannakis et al. (2025) and Farrag et al. (2024) summarized evidence linking surface alteration with frictional resistance, but friction was not measured in the present experiment. Therefore, the current data support a statement about increased surface roughness only. Any implication for sliding mechanics, treatment duration, or force delivery should be framed as a possible clinical implication requiring direct mechanical or clinical testing.

A plausible explanation for the observed roughness increase is chemical alteration of the NiTi passive oxide layer. Fluoride availability and acidic conditions can influence the stability of this layer, while the overall effect of a commercial product may also depend on its other ingredients and exposure schedule (Khan et al., 2022; Patajinadachote et al., 2018; Fróis et al., 2023). Because pH was not measured in the present study and no single-ingredient comparator was included, the mechanism should be regarded as plausible rather than demonstrated.

The main contribution of this study is therefore the evaluation of a real commercial formulation containing both NaF and MFP using AFM under an intermittent, saliva-based 21-day protocol. The study does not demonstrate a synergistic or additive effect of NaF plus MFP because there were no NaF-only or MFP-only groups. Its novelty lies in evaluating the complete combined formulation as encountered in practice and documenting the associated nanoscale surface response.

Taken together, these findings add to the literature by showing that a commercially formulated NaF–MFP mouthwash can be associated with a substantial increase in NiTi surface roughness under a defined intermittent, saliva-based exposure protocol. The direction of the finding is compatible with Ehrami et al. (2022), who reported increased surface roughness after fluoride mouthwash exposure, and with Condò et al. (2022), who described surface alterations after exposure to fluorinated agents. Pastor et al. (2022) further reported fluoride-related changes in metal-ion release, supporting the broader interpretation that fluoride-containing environments can influence orthodontic alloys. However, the present study extends rather than reproduces these findings because it evaluated a complete commercial formulation containing both NaF and MFP and quantified nanoscale roughness by AFM. The contribution is therefore formulation-specific and material-level, not evidence that all fluoride products behave similarly or that NaF and MFP act synergistically.

The interpretation is also consistent with the scoping evidence summarized by Makrygiannakis et al. (2025), which indicates that fluoride mouthwashes may affect corrosion and mechanical characteristics of orthodontic appliances but also emphasizes heterogeneity among products and experimental protocols. Farrag et al. (2024) demonstrated that chemical exposure can alter corrosion behavior and surface topography of nitinol archwires, reinforcing the importance of distinguishing a surface descriptor such as Ra from direct mechanical outcomes. In the present experiment, the approximately 11.24-nm higher mean Ra should therefore be interpreted as evidence of material-surface alteration under the tested conditions, while any inference about frictional resistance remains mechanistic and hypothesis-generating.

From a mechanistic perspective, the result may reflect changes in the titanium-oxide passive layer promoted by the combined chemical environment of the commercial product. Fluoride availability, acidity, ionic composition, and exposure duration can interact with passive-film stability, but the present design did not manipulate these variables independently. The finding that the intervention specimens returned to artificial saliva between daily exposures is relevant because it distinguishes the present protocol from continuous immersion studies and more closely represents repeated contact. Nevertheless, artificial saliva remains a simplified electrolyte model and cannot reproduce salivary flow, proteins, pellicle formation, oral clearance, microbial biofilm, mastication, or temperature and pH fluctuations. Thus, the present results provide a controlled material-level signal that warrants further testing rather than a complete representation of intraoral behavior.

The study also has implications for how orthodontic biomaterial evidence should be translated into practice. A statistically significant increase in Ra is relevant to material characterization, but clinical decisions require evidence across several linked outcomes, including corrosion kinetics, ion release, bracket–archwire friction, force delivery, fatigue, and biological tolerance. The absence of these measurements is not a minor technical limitation; it defines the boundary of what the current experiment can legitimately conclude. Accordingly, the practical value of the study is best viewed as identifying a formulation-specific surface response that can be used to formulate testable hypotheses for subsequent mechanical and clinical studies.

Strengths of the study include random allocation of specimens, standardized wire dimensions, controlled incubation at 37°C, intermittent rather than continuous mouthwash exposure, storage of intervention specimens in artificial saliva between exposures, blinded AFM assessment, and explicit testing of normality and variance assumptions. AFM also provided quantitative nanoscale topography, allowing the surface response to be expressed in nanometers.

Several limitations should be considered. First, the study was in vitro and could not reproduce salivary proteins, biofilm, mastication, dynamic temperature changes, or fluctuating oral pH. Second, only one commercial formulation and one NiTi wire type were tested. Third, the pH of the mouthwash was not measured, and therefore its contribution cannot be quantified. Fourth, the commercial formulation contained non-fluoride ingredients that were not isolated experimentally. Finally, the study measured only Ra; frictional resistance, corrosion rate, metal-ion release, fatigue, and mechanical properties were not directly assessed.

Scope and Limitations

The recommendations that follow are strictly limited to material-selection research and preliminary in vitro risk assessment. They should not be interpreted as clinical prescribing rules, treatment protocols, or definitive safety standards. Mechanical friction, bracket–archwire interactions, corrosion kinetics, ion release, and mechanical failure were not evaluated in this study. Likewise, biologic variables including in vivo salivary flow, pellicle formation, oral clearance, biofilm, mastication, and fluctuating oral conditions were not reproduced. Consequently, the present surface-roughness findings cannot predict actual clinical performance, rate of tooth movement, treatment duration, or risk of wire failure.

The in vitro-informed considerations are therefore structured as future hypotheses and baseline parameters to guide pH-controlled laboratory experiments, multi-arm formulation comparisons, multi-center mechanical testing, and appropriately designed in vivo clinical trials.

CONCLUSION

The tested commercial mouthwash formulation containing sodium fluoride and sodium monofluorophosphate produced significantly higher NiTi surface roughness than artificial saliva after the 21-day experimental protocol. The study therefore answers its primary objective by demonstrating a significant between-group difference in Ra. Because only a complete commercial formulation was compared with artificial saliva, the study cannot determine whether NaF, MFP, pH, or other ingredients were individually responsible for the observed change, nor can it establish clinical effects on friction or treatment duration. These findings support only in vitro-informed considerations for material-selection research and preliminary risk assessment; they do not constitute clinical guidelines.

RECOMMENDATIONS

The following in vitro-informed considerations are presented as provisional, research-based hypotheses rather than established clinical standards.

1. Practice considerations. Orthodontists may consider the complete formulation of a mouthwash—including fluoride concentration, pH when available, and other active or inactive ingredients—when selecting adjunctive oral-hygiene products for patients with NiTi archwires. However, the present in vitro finding should not be used to routinely avoid fluoride mouthwashes when fluoride is indicated for caries prevention. Patient counseling should emphasize appropriate use according to product instructions and individualized professional assessment, while avoiding unnecessary or prolonged exposure of orthodontic materials. Any decision to modify a preventive regimen should balance caries-prevention needs with the available evidence on material compatibility.
2. Policy and material-management considerations. Manufacturers and professional organizations should encourage transparent reporting of fluoride concentration, formulation components, and pH when available, together with standardized compatibility testing against common orthodontic alloys. Policy or institutional guidance should not classify all fluoride-containing products as incompatible with NiTi on the basis of the present study. Instead, material-selection policies should prioritize product-specific evidence, standardized laboratory testing, and subsequent clinical validation.
3. Education and training considerations. Postgraduate orthodontic and dental training programs may use this study as an example of how biomaterial evidence should be interpreted cautiously. Trainees should be taught to distinguish surface roughness measurements from corrosion rate, friction, ion release, and clinical outcomes, and to recognize the importance of formulation-specific evidence when counseling patients about oral-hygiene adjuncts.
4. Theoretical and research-framework considerations. The findings support a formulation-specific biomaterials framework in which exposure chemistry, passive-layer stability, surface roughness, and downstream mechanical behavior are treated as related but distinct levels of evidence. Future conceptual models should test these links experimentally rather than assume

that an increase in Ra necessarily produces a clinically meaningful increase in friction or treatment duration.

5. Future research directions. Future studies should compare NaF-only, MFP-only, combined NaF–MFP, and non-fluoride formulations; measure pH and other relevant chemical properties; evaluate multiple NiTi alloys and manufacturers; and use standardized intermittent exposure protocols. Direct measurement of corrosion kinetics, nickel/titanium ion release, bracket–archwire friction, mechanical properties, fatigue, and surface chemistry should be included. Multi-center mechanical testing and appropriately designed in vivo clinical trials are needed before any definitive clinical guidance can be considered.

List of Abbreviations

AFM – Atomic Force Microscopy
BSL-2 – Biosafety Level 2
EHS – Environmental Health and Safety
IBM SPSS – International Business Machines Statistical Package for the Social Sciences
MFP – Sodium Monofluorophosphate
NaF – Sodium Fluoride
NiTi – Nickel–Titanium
PPE – Personal Protective Equipment
Ra – Average Surface Roughness
Rms – Root Mean Square Roughness
SEM – Scanning Electron Microscopy
TiO_2 – Titanium Dioxide

Declarations

Ethical approval and consent to participate
This study was granted ethics approval/exemption by the Cebu Doctors' University Institutional Biosafety Committee (IBC) prior to the commencement of the study. As this investigation was an in vitro laboratory study involving Nickel–Titanium orthodontic archwires and commercially available chemical solutions, no human participants or identifiable personal data were involved. Consequently, informed consent was not required. All laboratory procedures were conducted in accordance with institutional biosafety and laboratory safety guidelines, and no personal information was collected or processed during the study.

Consent for publication
Not applicable. No individual participant data are reported.

Availability of data and materials
The datasets generated and analyzed during the current study are available from the corresponding author upon reasonable request.

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Declaration of Generative AI and AI-assisted Technologies
The authors used ChatGPT (OpenAI) and Grammarly AI solely for language editing and readability enhancement. All scientific content, analyses, interpretations, and conclusions were developed, reviewed, and approved by the authors, who take full responsibility for the content of this manuscript.

Competing Interests
The authors declare no competing interests.

Author's Contributions
A.A.Q. conceived and designed the study, developed the research methodology, conducted the experimental procedures, performed the formal statistical analysis, interpreted the data, prepared the original manuscript draft, developed the tables and figures, and managed the overall execution and administration of the project. The author read and approved the final manuscript.

Contributor Roles (CRediT):
* Conceptualization: **A.A.Q.**
* Methodology: **A.A.Q.**
* Formal Analysis: **A.A.Q.**
* Writing – Original Draft: **A.A.Q.**
* Visualization: **A.A.Q.**
*Project Administration: **A.A.Q.**

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