

Article

An Evaluation of the Influence of Natural Clay and Natural Clay/TiO₂ Nanocomposites on the Color Stability of Heat-Polymerized Maxillofacial Silicone After Disinfection

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Abstract

This study aimed to investigate the effect of time and different disinfecting agents on nanocomposite filler composed of natural clay nanoparticles (modified and non-modified) added to maxillofacial silicone elastomers and readymade pigment additives. A total of 360 disk-shaped samples were divided into nine pigment-based groups, each with four subgroups ($n = 10$) exposed to different disinfectants: distilled water, 1% sodium hypochlorite (NaOCl), 2% chlorhexidine (CHX), and effervescent tablets. Color changes (ΔE) were measured before and after disinfection using a colorimeter. The ΔE values were assessed against perceptibility ($\Delta E = 1.1$) and acceptability ($\Delta E = 3$) thresholds. Nanoclay additives were also characterized using FTIR, XRD and EDX. Statistical analysis, including ANOVA and post hoc HSD tests, revealed that while all samples exhibited some color change, most remained below the acceptability threshold. Colorless silicone showed minimal, non-significant change according to perceptibility threshold ($\Delta E = 1.1$). Blue pigments displayed significant change only with effervescent tablets. Red and mixed pigments showed perceptible changes with NaOCl, CHX, and effervescent tablets. However, nanoclay-containing specimens showed no significant perceptible alterations. Overall, despite minor perceptible changes in some pigments, all disinfecting agents tested resulted in color differences below the acceptability threshold, indicating their safe use for disinfecting maxillofacial silicone materials without compromising esthetics. Nevertheless, nanoclays are more reliable agents for the pigmentation of maxillofacial silicone as they show non-significant chromatic alteration.

Keywords: natural clay; color stability; nanocomposite; maxillofacial silicone; disinfection



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1. Introduction

Facial defects resulting from trauma, congenital conditions, cancer, or resection surgeries require repair for both esthetic and functional purposes. Maxillofacial prostheses are used to replace missing facial parts caused by deformities [1,2]. Despite advances in plastic surgery for deformity reconstruction, conditions with surgical contraindications and extensive defects continue to require the use of maxillofacial prostheses [3–5].

Silicones, although introduced in 1946, were first used by Barnhart in 1960 for creating extra-oral prostheses [6]. Silicone elastomers are the material of choice for constructing such prostheses due to their realistic appearance and ease of fabrication, and have surpassed conventional acrylic resins as the preferred material. They possess a range of desirable properties, including elasticity, heat resistance, and chemical stability [7–9].

The primary challenge in the construction of an optimal facial prosthesis lies in maintaining its appearance over time, as changes in color or physical properties can lead to degradation. Due to color degradation, the typical lifespan of facial prostheses is only 1–1.5 years [10]. Maxillofacial silicone can become contaminated with body fluids such as blood, sweat, and lacrimal secretions, as well as external pollutants [3]. In recent years, several studies have examined the color stability of pigmented and non-pigmented maxillofacial silicone elastomers. These evaluations involved the incorporation of inorganic opacifiers or organic ultraviolet light absorbers, followed by exposure to artificial aging conditions, environmental factors, and disinfectants [11–15].

Disinfection methods for maxillofacial prostheses include mechanical disinfection, such as manual rubbing or brushing. However, it is not recommended, as repeated brushing can roughen the surface of the material [16,17]. On the other hand, chemical disinfectants may alter the properties of silicones used in the fabrication of maxillofacial prostheses. Therefore, such changes must be evaluated during the prosthesis manufacturing process. Overall, disinfection approaches should be gentle on human tissues while maintaining the properties of silicone [18,19].

Silicone elastomers can be strengthened by improving their mechanical properties, resulting in longer-lasting maxillofacial prostheses [20]. The mechanical and physical properties of such facial prosthetic materials have been substantially enhanced. However, color instability frequently limits the service life of facial prostheses and causes esthetic issues for patients. The color change inherent in maxillofacial silicone elastomers becomes noticeable 6–12 months after fabrication, so identifying the factors that accelerate their degradation can assist clinicians in extending their lives [21].

The ideal maxillofacial materials should possess optical and mechanical properties similar to those of the original human tissue being replaced. Additionally, these materials must retain their properties throughout their usage [22].

The optical properties of maxillofacial silicone, influenced by the type and concentration of fillers, additives, and pigments used, play a crucial role in determining the required physical and mechanical properties of silicone prostheses. Therefore, the composition of these prostheses must be customized to meet the requirements for a durable and flexible material that fulfills clinical demand [23]. In previous studies, the application of various pigments did not have any significant protective effect on maxillofacial silicone in terms of color degradation over time. This observation was particularly evident when red coloring agents were employed as opposed to white coloring agents [24].

In light of these limitations, there is growing interest in alternative pigmenting or reinforcing agents that improve color stability while preserving the physicochemical properties of silicone elastomers. Natural clays (NCs) are a promising option due to their stability, compatibility with the silicone matrix, and protective effects against environmental and chemical degradation, however, their native properties often require modification for advanced applications. Acid and alkaline activation are used to increase porosity, surface reactivity, and interfacial compatibility with polymer matrices. Additionally, TiO₂ pillaring expands interlayer spacing and enhances structural stability and functional performance. The main goal of these modifications is to produce multifunctional clay-based nanofillers with improved dispersion and performance in polymer nanocomposites [25–27]. For example, the practice of using clay as a hair cleanser has been prevalent in certain regions

since ancient times [28]. Clays are hydrous aluminosilicates, typically found as the colloid fraction of soils, sediments, rocks, and water. They can be made up of a combination of fine-grained clay minerals and clay-sized crystals of other minerals, such as quartz, carbonate, and metal oxides [29,30]. Clays have a significant impact on the environment because they can act as natural scavengers of pollutants via ion exchange, adsorption, or a combination of the two [31].

Color instability and material degradation remain major clinical limitations of maxillofacial silicone prostheses, particularly after repeated disinfection procedures necessary for hygiene maintenance. Conventional pigments and additives undergo photochemical and chemical degradation, leading to progressive discoloration and reduced service life. To overcome this limitation, the present study explores, for the first time, the incorporation of natural clay and TiO₂-modified natural clay nanocomposites as eco-friendly additives to improve the color stability of maxillofacial silicone following simulated long-term disinfection.

This study aimed to investigate the effect of various disinfectants on nanocomposites composed of NC nanoparticles used as pigments in maxillofacial silicone elastomers. The null hypothesis was that there is no difference between maxillofacial silicone samples colored with pigment and NC after disinfection with various agents.

2. Materials and Methods

2.1. Materials

The following materials were obtained from their respective manufacturers: parts A and B of M511 HTV maxillofacial silicone elastomer (Technovent Co., Ltd., Bridgend, UK), dry pigment (brilliant red, blue, and yellow; Technovent Co., Ltd., Bridgend, UK), hydrochloric acid (HCl, 32%, 10 M, Merck KGaA, Darmstadt, Germany), titanium (IV) butoxide (Ti (OCH₂CH₂CH₂CH₃)₄, 97%, Mw = 340.32 g mol^{−1} Merck KGaA, Darmstadt, Germany), nitric acid (HNO₃, 60%, Mw = 63.01 g mol^{−1}, Merck KGaA, Darmstadt, Germany), and Natural clay (NC) from Darbandikhan located in Sulaimani City-Kurdistan region of Iraq was collected.

2.2. Clay Preparation

For the NC fractionation, the clay was first separated by suspending it in water. Then, the suspension was left undisturbed for 24 h, during which time the heavy fraction was allowed to settle, and the light fractions were separated. The clay floating in the suspension comprised the light fraction of the mixture. The suspension acquired from the light fraction was left to stand again until a precipitate formed. Then, the suspension was carefully removed, and the obtained precipitate was dried.

2.3. Clay Activation

The NC powder was first sieved with a 200 mesh, diluted with 2 M HCl at a ratio of 2:10 *w/v* at 70 °C, and stirred at 300 rpm for 3 h. Furthermore, the remaining solid was separated via centrifugation for 10 min at 5000 rpm and rinsed five times with distilled water to remove the residual acid on the sample surface and obtain a neutral pH. Then, the sample was dried overnight at 100 °C and sieved. Calcination was then performed at 500 °C for 2 h to eliminate the Cl[−] bond in the clay, resulting in the formation of nano-sized acidic clay (AC). In the same way, base-activated clay (BC) using sodium was prepared by mixing 2 M sodium hydroxide (NaOH) with NC at a ratio of 2:10 *w/v*.

2.4. Pillarization Agent Preparation

A pillarization solution was produced by combining 15 mL of titanium (IV) butoxide ($\text{Ti}(\text{OCH}_2\text{CH}_2\text{CH}_2\text{CH}_3)_4$, 97%, $M_w = 340.32 \text{ g mol}^{-1}$, Merck) with 18 mL of absolute ethanol (99.8%, $M_w = 46.07 \text{ g mol}^{-1}$, Merck KGaA, Darmstadt, Germany) and stirring at room temperature for 20 min until a clear solution was obtained. This solution was added drop-by-drop to 37.5 mL of 1 M HNO_3 nitric acid (60%, $M_w = 63.01 \text{ g mol}^{-1}$) while stirring vigorously for 1.5 h. The pH of the resulting solution was adjusted to 1.5–2.0 with 98% NaOH ($M_w = 40 \text{ g mol}^{-1}$) and vigorous stirring for 30 min.

2.5. Clay Pillarization

Three grams of activated clay was added gradually to the Ti pillaring solution while stirring with a magnetic stirrer at 30°C for 18 h until a homogeneous suspension was obtained. After that, the sample was left to age for 24 h at room temperature. The resulting product was separated, rinsed multiple times with distilled water until the pH was neutral, and then dried overnight at 70°C . The dried solid was then calcinated at 500°C for 2 h to obtain TiO_2 -pillared clay (TiC). Figure 1 provides a schematic flowchart outlining the sequential stages involved in the preparation, activation, and pillarization of natural clay.

2.6. Characterization Methods

The prepared samples were structurally characterized via X-ray powder diffractometry (XRD) using monochromatized $\text{Cu-K}\alpha$ radiation (X'Pert Pro, Malvern Panalytical, Almelo, The Netherlands). XRD patterns were obtained within a 2θ scanning angle range of 5° to 80° at a rate of 0.026° per second. A Fourier transform infrared (FTIR) spectrometer (IRAffinity-1, Shimadzu, Kyoto, Japan) was used to record FTIR spectra using the KBr pellet method. The FTIR spectra of the samples were acquired in a wavenumber range of $400\text{--}4000 \text{ cm}^{-1}$. The chemical composition was analyzed using energy-dispersive X-rayspectroscopy (EDX) with a Bruker Quantax 200 (Bruker, Billerica, MA, USA) during scanning electron microscopy (SEM).

2.7. Experimental Design and Sample Preparation

A total of 360 disk-shaped specimens (2 mm thick, 20 mm diameter) [32,33] were prepared and evenly divided into four main groups according to the disinfection protocol ($n = 90$ per group): distilled water [DW], 1% sodium hypochlorite [NaOCl], 2% chlorhexidine [CHX], and effervescent tablets [Eff.]. Each disinfection group (90 specimens) was subsequently subdivided into nine experimental subgroups ($n = 10$ per subgroup) based on the type of pigmentation or clay incorporated into the silicone material as shown in Figure 2. Control specimens were fabricated without any pigments or nanoclays. The study groups were prepared by adding different pigments (brilliant red, blue, yellow, and a mixture of these) and clays (NC, AC, BC, and TiC).

In accordance with the manufacturer's guidelines, the M511 maxillofacial silicone elastomer supplied as a base (Part A) and a catalyst (Part B) was mixed at a weight ratio of 10:1. The combined amount of pigment and nanoclay corresponded to 0.2% of the total silicone weight [33–36]. Silicone components A and B were initially measured using a digital electronic analytical balance (Nimbus[®] Analytical, Adam Equipment Inc., Oxford, CT, USA). Subsequently, Parts A and B were mixed according to the manufacturer's instructions in a vacuum mixer (AX-2000C, Aixin Medical Equipment Co., Ltd., Tianjin, China) for 5 min at a rotational speed of 360 rpm under a vacuum of 0.09 MPa to produce the M511 silicone control group without pigments or nanoclays. Specimens containing pigments and nanoclays were prepared by first weighing the pigment or nanoclay, incorporating it into Part A of the M511 silicone, and mixing for 10 min under vacuum; however, a vacuum

was not applied during the initial 2 min of mixing to prevent aspiration of the additives. The mixing bowl was then allowed to cool to room temperature to compensate for heat generated by rotation, which could reduce the working time of the material. Part B was subsequently added to the mixture, followed by an additional 5 min of mixing under vacuum [37]. The resulting mixture was transferred into molds using a metal spatula and placed in a vacuum chamber for 2 min to eliminate air bubbles formed during mold loading. The molds were then placed in a pressure pot (Pentola a pressione typodont, Leone S.p.A., Sesto Fiorentino, Firenze, Italy) at 0.2 MPa for 2 min to smooth the surface of the material and disrupt superficial air bubbles. The mold was then closed and subjected to a hydraulic press at 0.03 MPa for 5 min. Finally, the molds were sealed and secured with G-clamps, and polymerization was carried out for 1 h in a hot-air oven (Mettmert, Mettmert GmbH+Co., KG, Schwabach, Germany).

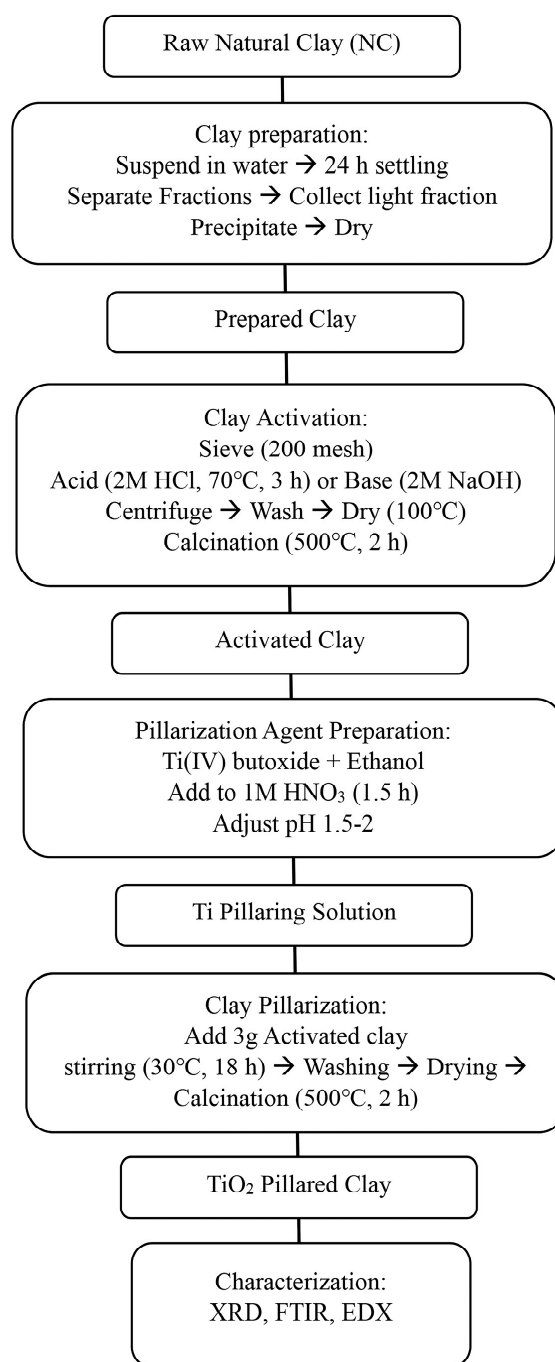


Figure 1. Schematic flowchart of the preparation, activation, and pillarization of natural clay.

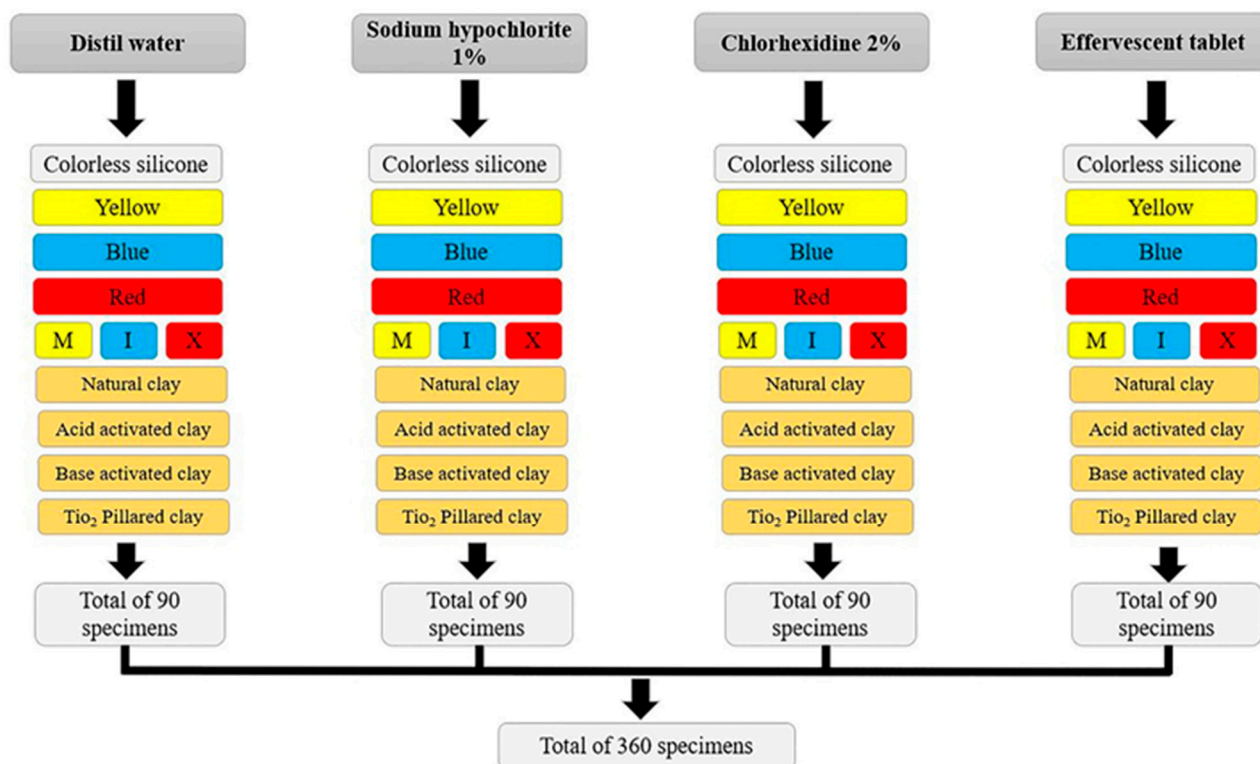


Figure 2. Flowchart of specimen preparation and distribution.

Following demolding, the specimens were rinsed with water, washed using a liquid detergent, and dried with absorbent tissue paper. Excess material was removed using scissors, and specimens with visible defects were excluded prior to testing. All samples were stored in a black container to prevent unintended color alteration. Color evaluation was conducted using a digital colorimeter (WR10QC colorimeter, FRU, Shenzhen, China). Measurements obtained prior to each disinfection cycle were designated as baseline controls. The specimens were subjected to disinfection for a total duration of 30 h. Upon completion of the disinfection process, the samples were again washed with water and liquid soap, dried with tissue paper, and remeasured. Color data were recorded using the CIELab color space, which represents color using lightness (L), red–green (a), and yellow–blue (b) coordinates. The L, a, and b parameters were recorded for each specimen at baseline and after 30 h of disinfection. Color variation (ΔE^*) was subsequently calculated from the mean changes in ΔL , Δa , and Δb using the following equation [38]:

$$\Delta E^* = \left[(\Delta L)^2 + (\Delta a)^2 + (\Delta b)^2 \right]^{1/2} \quad (1)$$

2.8. Disinfection Procedures

Four different disinfecting procedures were selected for sample disinfection (Table 1). DW was used as a control solution; CHX was obtained from Aqua Medikal, İstanbul, Türkiye; NaOCl solution (1%) was prepared by diluting 100 mL of 5.2% NaOCl (from TehnoDent Co., Ltd., Severnyi, Belograd, Russia) in 520 mL of DW; and the effervescent solution was prepared by dissolving two effervescent denture cleansing tablets (Reckitt Benckiser Healthcare Ltd., Kingston Upon Hull, UK) in 500 mL of DW at room temperature. The samples were immersed in each solution for 30 h, and the examined period simulated approximately 1 year, because 30 h represents 360 days of service for a 5-min daily treatment [38–40].

Table 1. The actual and simulated time distribution for the disinfection procedure of maxillofacial silicone.

Disinfection Procedures	Procedure Duration	Simulated Years of Service
Distilled water	30 h	1 year
Sodium hypochlorite solution (1%) (TechnoDent Co., Ltd., Severnyi, Belograd, Russia)	30 h	1 year
Chlorhexidine (2%) (Aqua Medikal, Istanbul, Türkiye)	30 h	1 year
Effervescent tablet (Reckitt Benckiser Healthcare Ltd., Kingston Upon Hull, UK)	30 h	1 year

3. Results

The XRD analysis was performed on samples of NC activated with an acidic solution (AC), base-activated clay using sodium (BC), and Ti-pillared clay (TiC) to investigate alterations in structural properties caused by the addition of titanium pillars into the interlayer space, as depicted in Figure 3. The XRD pattern of natural clay, given in Figure 3a, indicates that the clay is composed of montmorillonite (International Conference on the Diffraction Structure of Crystals, according to Inorganic Crystal Structure Database (ICSD) 51636) with peaks at 2θ angles of 6.35° and 19.86° ; kaolinite (ICSD 84263) with a peak at a 2θ angle of 12.55° ; albite (ICSD 68913) with peaks at 2θ angles of 22.08° and 29.55° ; quartz (ICSD 89278) with peaks at 2θ angles of 26.58° , 39.56° , 50.26° , and 60.03° ; and orthoclase (ICSD 81137) with peaks at 2θ angles of 23.72° , 25.19° , 36.13° , 36.7° , 43.20° , 45.90° , 47.60° , and 48.6° [41,42]. Some differences in peak intensities were observed between samples that received different pre-treatments. The results in Figure 3b,c show that the clay is highly heterogeneous, so pre-treatments with sodium and an acidic solution are mandatory to reduce the content of non-clay minerals that negatively interfere with the clay properties [43,44]. As seen in Figure 3d, kaolinite, with a peak at a 2θ angle of 12.55° , disappeared due to cation exchange in the interlayers of nanoclay as a result of titanium nanoparticle surface loading. Upon the formation of TiO_2 on the clay surface, the peak corresponding to 26.6° in nanoclay shifted to 26.7° . This could be due to the formation of rutile TiO_2 . The other main diffraction peaks of TiO_2 appeared at 29.9° , 36.6° , and 50.2° , assigned to the (110), (044), and (200) planes, respectively [45]. The average crystallite size on the samples was calculated by using the Scherrer equation, as seen in Equation (2). For natural clay, the resulting calculated crystal size was 45.69 nm. After acid activation, the calculated size increased to 52.32 nm, indicating a partial structural rearrangement and possible crystal growth. For sodium-exchanged clay, the crystallite size measured was 50.85 nm, and for Ti-pillared clay, it was measured to be 49.89 nm. This suggests that the addition of titanium altered the size of the crystalline domains.

$$D = \frac{k \lambda}{\beta \cos \theta} \quad (2)$$

FTIR spectroscopy is used to analyze both organic and inorganic samples. The samples are exposed to infrared radiation, causing the frequency of the radiation to match the natural frequency of the bond. This increases the amplitude of the vibration, allowing the infrared to be seen [46]. The FTIR spectra ($400\text{--}4000\text{ cm}^{-1}$) of NC, AC, BC, and TiC are shown in Figure 4. The FTIR spectra of NC from Figure 4a present strong bands at 3431 cm^{-1} and 1434 cm^{-1} , which are related to the stretching mode of the OH group and the bending mode of molecular water, respectively. The absorption of these bonds decreased, which indicates that surface hydroxyl groups enable condensation under different pre-treatments, as shown in Figure 4b,c. Increased peaks in the spectral region, as well as in the free OH area, and reduced noise indicate a cleaner and more non-interfering structure. This

indicates that the activation process can significantly reduce impurities in the clay. The activation process removed impurities from the structure lattice; hence, the clay became more physically active [47]. With activation, the cations on the clay interlayer could be replaced by H^+ , as H^+ is a small cation that generally replaces larger cations such as Ti^{+4} during the clay pillarization process [48]. The broad band over the range of $400\text{--}554\text{ cm}^{-1}$, related to the bending and stretching modes of $Ti\text{--}O\text{--}Ti$ and characteristic of well-ordered titanium oxide, is shown in Figure 4d [45,49].

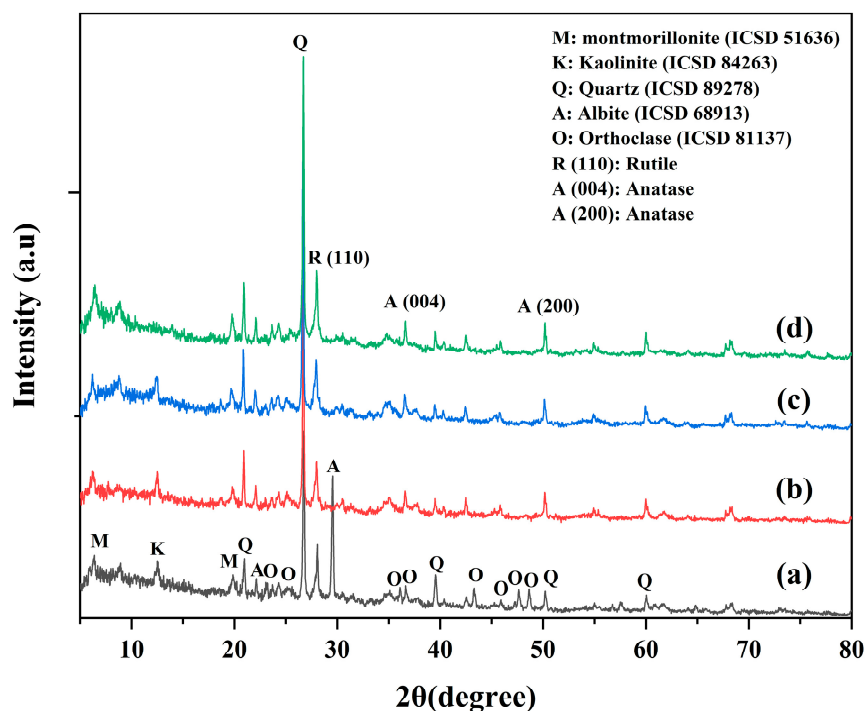


Figure 3. X-ray diffraction (XRD) patterns of nanocomposite samples: (a) NC matrix, (b) nanocomposite with TiO_2 nanoparticles, (c) nanocomposite with increased TiO_2 dispersion, and (d) nanocomposite with the highest TiO_2 content.

The chemical compositions of the samples (NC, AC, BC and TiC) are presented in Table 2. Energy-dispersive X-ray spectroscopy (EDX) serves as a technique for chemical microanalysis, employed alongside scanning electron microscopy (SEM) to ascertain the elemental makeup of the materials. Figure 5 displays the EDX spectra for all samples, confirming the presence of elements such as silicon (Si), aluminum (Al), Potassium (K), Magnesium (Mg), Iron (Fe), and oxygen (O) in the clay, and titanium (Ti) doped variants. The EDX results verified the inclusion of dopants (Ti), and a comparison between the elemental compositions of undoped and doped clay evaluated the effectiveness of the doping process.

Table 2. The chemical compositions of samples (NC, AC, BC and TiC).

	SiO ₂	TiO ₂	Al ₂ O ₃	Fe ₂ O ₃	MnO	MgO	CaO	Na ₂ O	K ₂ O	P ₂ O ₅	(SO ₃)	LOI	Sum
NC	45.4	0.8	12.5	6.2	0.1	4.3	11.96	1.5	1.9	0.1	0.04	14.9	99.64
AC	57.4	0.9	15.6	7.5	0.1	5.0	1.3	1.9	2.4	0.1	<0.01	7.5	99.70
BC	57.5	0.8	16.8	6.3	0.1	6.1	0.8	1.6	2.1	0.1	<0.01	7.6	99.80
TiC	58.4	1.3	16.0	7.6	0.1	4.2	0.7	1.7	2.3	0.1	<0.01	7.1	99.50

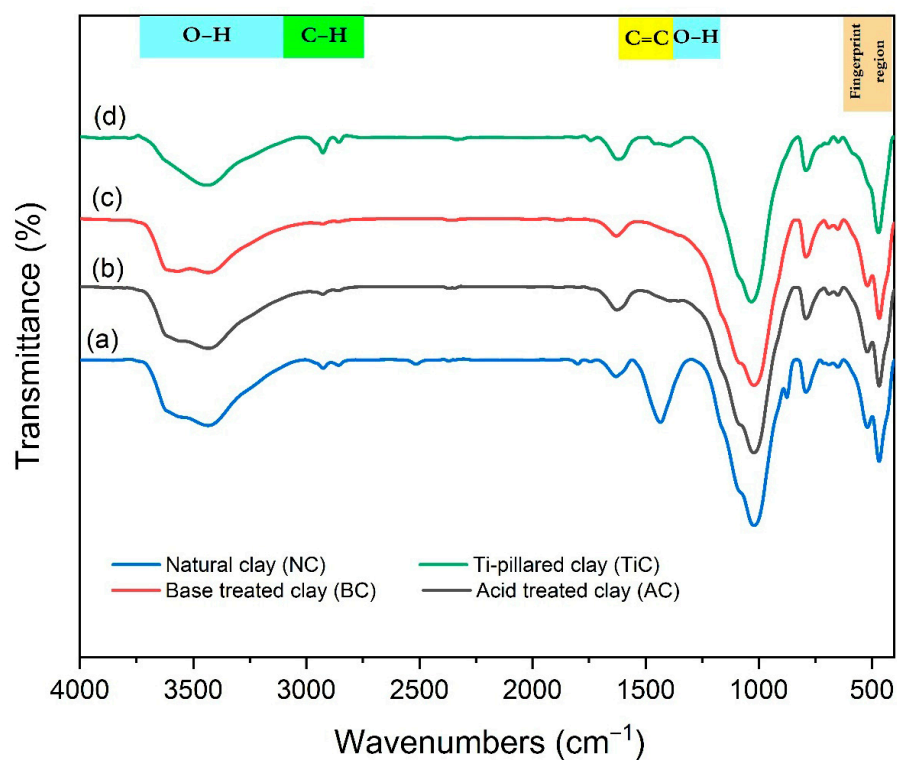


Figure 4. FTIR spectra of clay-based nanocomposites: (a) NC, (b), (BC), (c) AC, and (d) TiC.

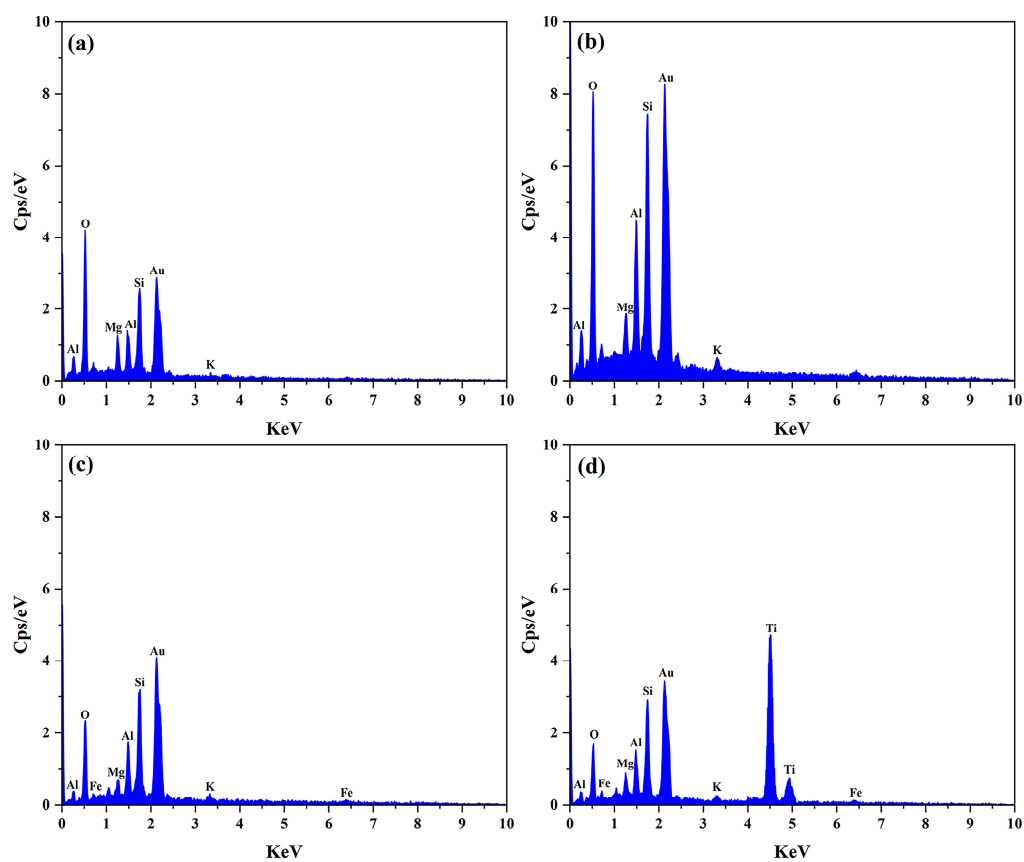


Figure 5. EDX elemental analysis of: (a) NC, (b) AC, (c) BC, and (d) TiC.

Descriptive data, including the means, standard deviations, minimum, and maximum of ΔE^* based on Tukey's HSD, from the pigmented and non-pigmented maxillofacial

silicone specimens subjected to different disinfecting solutions are presented in Table 3. Statistically significant alterations in specimens with different coloring agents ($p < 0.05$) were based on the perceived and acceptable values.

Table 3. Descriptive analysis of pigmented and non-pigmented maxillofacial silicone specimens subjected to different disinfecting solutions in comparison with perceived and acceptable values.

Additive Agent Type	Disinfecting Solution	Mean ΔE	Std	Minimum	Maximum	p -Value *	
						Perceived	Acceptable
Non-pigmented silicone	DW	1.3203	0.6553	0.5201	2.5218	0.967443	0.0001
	1% NaOCl	1.0518	0.5674	0.4786	2.2653	1.0000	0.0001
	2% CHX	1.4274	0.8090	0.4836	2.7505	0.9280	0.0001
	Eff.	0.8515	0.4386	0.2569	1.5265	0.9995	0.0001
Blue pigment	Distilled water	1.1738	0.4629	0.4589	1.7788	0.9999	0.0001
	1% NaOCl	1.4500	0.3518	0.9247	1.9343	0.6358	0.0001
	2% CHX	1.1310	0.5624	0.5842	2.2118	1.0000	0.0001
	Eff.	2.6497	1.5822	0.6863	4.7389	0.0003	0.9907
Yellow pigment	DW	0.7291	0.4200	0.3234	1.5084	0.5228	0.0001
	1% NaOCl	0.8808	0.2724	0.5229	1.3898	0.9726	0.0001
	2% CHX	0.7604	0.4078	0.1712	1.3874	0.9100	0.0001
	Eff.	0.9283	0.2652	0.5000	1.2704	0.9999	0.0001
Red pigment	DW	1.5569	0.6298	0.5831	2.8559	0.2204	0.0001
	1% NaOCl	2.3260	0.5685	1.5391	3.2466	0.0001	0.0080
	2% CHX	2.4742	0.9241	1.5351	4.5471	0.0012	0.4080
	Eff.	2.4350	1.1361	0.1625	4.3719	0.0032	0.7992
Mixed pigment	DW	1.4181	0.2043	1.1484	1.9125	0.7339	0.0001
	1% NaOCl	2.3087	0.2810	2.0411	2.9469	0.0001	0.0057
	2% CHX	2.1822	0.2249	1.8809	2.5707	0.0002	0.0170
	Eff.	2.2185	0.1426	1.8823	2.4075	0.0217	0.4140
Natural clay additive	DW	0.7777	0.1926	0.5332	1.0304	0.7180	0.0001
	1% NaOCl	1.0207	0.4544	0.3986	1.7667	0.9999	0.0001
	2% CHX	1.0464	0.3852	0.4702	1.7125	1.0000	0.0001
	Eff.	0.8759	0.4387	0.2015	1.3763	0.9998	0.0001
Acid-activated clay additive	DW	0.6159	0.2552	0.2131	1.1123	0.1555	0.0001
	1% NaOCl	0.9474	0.3501	0.1913	1.5535	0.9984	0.0001
	2% CHX	0.8575	0.2410	0.3082	1.1295	0.9911	0.0001
	Eff.	0.8848	0.4127	0.3910	1.6589	0.9999	0.0001
Sodium-activated clay additive	DW	0.8885	0.4148	0.2452	1.7584	0.9755	0.0001
	1% NaOCl	1.1480	0.4829	0.7029	2.0905	1.0000	0.0001
	2% CHX	1.3499	0.5979	0.6360	2.4377	0.9889	0.0001
	Eff.	1.9157	1.0065	0.7080	3.8094	0.2933	0.0390
TiO ₂ clay additive	DW	0.5982	0.2361	0.2909	0.9683	0.1220	0.0001
	1% NaOCl	0.9794	0.3892	0.4826	1.5567	0.9998	0.0001
	2% CHX	1.0858	0.3734	0.5526	1.7993	1.0000	0.0001
	Eff.	0.9671	0.4524	0.2809	1.6167	0.9999	0.0001

* p -value compared to the perceived and acceptable ΔE values after the disinfection process.

Table 4 shows the inferential statistics findings (ANOVA test) for alterations in color (ΔE^*). After being treated with different disinfectants, all examined specimens from the non-pigmented, pigmented, and clay-pigmented groups exhibited a chromatic alteration ($\Delta E^* > 0$). The ΔE^* values for the red and mixed pigment groups exhibited statistical

significance, except with distilled water treatment. However, these values did not deviate significantly from the acceptable values upon treatment with CHX and eff.

Table 4. ANOVA test results for color changes (ΔE^*) after immersion in different disinfecting solutions.

		SS	DF	MS	F	<i>p</i> -Value
Immersion in distilled water	Between groups	46.405349	10	4.640535	32.13373	0.000 *
	within groups	14.296907	99	0.144413		
	Total	60.702255	109			
Immersed in 1% NaOCL	Between groups	52.6908	10	5.2691	35.0888	0.000 *
	within groups	14.8662	99	0.1502		
	Total	67.557	109			
Immersion in CHX	Between groups	53.249031	10	5.325	21.30558	0.000 *
	within groups	24.743072	99	0.2499		
	Total	77.992103	109			
Immersion in eff.	Between groups	69.7116	10	6.9712	13.5522	0.000 *
	within groups	50.9251	99	0.5144		
	Total	120.6367	109			

* *p*-value showed highly significance difference.

Table 5 delineates the findings of the ANOVA analysis concerning variations in color (ΔE^*) attributed to immersion in each disinfecting solution used in the current study. The application of any disinfecting solution did not yield statistically significant results in the colorless, yellow, red, NC, or AC groups. Nevertheless, disinfecting maxillofacial silicone samples containing the blue pigment with eff. resulted in a significantly higher ΔE value ($p < 0.05$). On the other hand, when DW was used as a disinfectant, it produced the lowest ΔE value for the specimens with mixed pigments, which was statistically significantly different from the results obtained with other solution types. Furthermore, the BC and TiO₂ specimens demonstrated statistically significantly elevated ΔE values when immersed in the eff. and CHX solutions, respectively.

Table 5. ANOVA analysis and post hoc test results showing the effect of different solutions on pigmented and non-pigmented groups.

Additive Agent Type	SS	DF	MS	F	<i>p</i> -Value	DW vs. Group	NaOCL vs. Groups	CHX vs. Groups	Eff. Vs. Groups
Non-pigment silicone	2.0404	3	0.6801	1.7022	0.1839	NS			
	14.384	36	0.3996						
	16.4247	39							
Blue pigment	15.2591	3	5.0864	6.4431	0.0013	0.8982 vs. NaOCL	0.8982 vs. DW	0.9995 vs. DW	0.0037 vs. DW
	28.4195	36	0.7894			0.9995 vs. CHX	0.8526 vs. CHX	0.8526 vs. NaOCL	0.0230 vs. NaOCL
	43.6786	39				0.0037 vs. eff.	0.0230 vs. eff.	0.0027 vs. eff.	0.0027 vs. CHX
Yellow pigment	0.2715	3	0.0905	0.743	0.5335	NS			
	4.3849	36	0.1218						
	4.6564	39							
Red pigment	5.5983	3	1.8661	2.6057	0.0667	NS			
	25.7812	36	0.7161						
	31.3795	39							
Mixed pigment	4.9867	3	1.6622	31.8555	0.000 *	0.000 * vs. NaOCL	0.000 * vs. DW	0.000 * vs. DW	0.000 * vs. DW
	1.8785	36	0.0522			0.000 * vs. CHX	0.6070 vs. CHX	0.6070 vs. NaOCL	0.8136 vs. NaOCL
	6.8651	39				0.000 * vs. eff.	0.8136 vs. eff.	0.9843 vs. eff.	0.9843 vs. eff.
Natural clay Additive	0.479	3	0.1597	1.0929	0.3646	NS			
	5.2592	36	0.1461						
	5.7382	39							
Acid-activated clay additive	0.6336	3	0.2112	2.009441	0.13	NS			
	3.7839	36	0.1051						
	4.4175	39							

Table 5. Cont.

Additive Agent Type	SS	DF	MS	F	p-Value	DW vs. Group	NaOCL vs. Groups	CHX vs. Groups	Eff. Vs. Groups
Sodium-activated clay additive	5.7138	3	1.9046	4.2902	0.011	0.8198 vs. NaOCL	0.8198 vs. DW	0.4202 vs. DW	0.0076 vs. DW
	15.9822	36	0.4439			0.4202 vs. CHX	0.9049 vs. CHX	0.9049 vs. NaOCL	0.0651 vs. NaOCL
	21.696	39				0.0076 vs. eff.	0.0651 vs. eff.	0.2465 vs. eff.	0.2465 vs. eff.
TiO ₂ clay additive	1.3614	3	0.4538	3.2923	0.0314	0.1180 vs. NaOCL	0.1180 vs. DW	0.0281 vs. DW	0.1368 vs. DW
	4.9621	36	0.1378			0.0281 vs. CHX	0.9181 vs. CHX	0.9181 vs. NaOCL	0.9999 vs. NaOCL
	6.3235	39				0.1368 vs. eff.	0.9999 vs. eff.	0.8905 vs. eff.	0.8905 vs. eff.

* p-value showed highly significance difference.

4. Discussion

The stated null hypothesis was rejected because all disinfection procedures induced chromatic alterations in the tested maxillofacial silicone elastomers. These results demonstrate that disinfection affects color stability, regardless of material composition, and may compromise the long-term esthetic durability of maxillofacial prostheses.

Color change is one of the most important parameters when evaluating the performance of a facial prosthesis from a patient's perspective. One of the common problems associated with its use is the discoloration of silicone. Several environmental factors, such as solar radiation, humidity, temperature, and airborne pollutants, as well as routine cleaning, can induce color alterations in maxillofacial silicone prostheses [50,51].

Here, specimens treated with DW in all groups showed chromatic alteration. This is because even without disinfection facial silicone undergoes a color change independent of the pigment type and the pigmentation technique used, since the material itself undergoes aging, with consequent changes in its physical and chemical properties. This may be due to continuous polymerization; the low-level but continuous release of sub-products during the polymerization of silicones causes not only dimensional alterations in the silicone (shrinkage) but also alterations in its chromatic pattern. This result is in agreement with previous studies [39,52,53].

The ΔE values gradually increased over 30 h of disinfection; this may be due to the continuous release of byproducts during silicone polymerization, leading to dimensional alterations in the silicone (shrinkage) as well as alteration in the chromatic pattern [39]. The silicone specimens colored with natural nanoclays generally showed lower chromatic alteration compared to those colored with pigments; this may be related to the particle sizes of the pigments and natural nanoclays, with the latter having smaller particle sizes. Silicone presents a low level of cohesive energy, resulting in weak molecular interactions. Therefore, small particles aggregate with the silicone, while larger particles are easily separated [54,55].

The specimens disinfected with the effervescent tablet presented high ΔE values. Alkaline peroxides, such as effervescent tablet, are commercial products widely used for complete denture hygiene. These products provide oxygen release to enable the removal of fragments and staining [56]. Although oxygen-based commercial cleaning eliminates slight staining, it also whitens the prostheses, as confirmed by other studies [39]. The colorless group did not present significant whitening with the effervescent tablet. This result is associated with the composition of colorless silicone, which is clear [18]. The use of an alkaline peroxide effervescent tablet to clean facial prostheses should be avoided because this substance can promote color alterations by removing pigments from the superficial layer of the silicone through the oxygen release mechanism [39,57].

The results of the present study showed that colorless silicone specimens exhibited color alteration ($\Delta E > 0$) after simulated chemical disinfection. Colorless silicone underwent changes when exposed to different substances commonly used for cleaning prostheses; these results are in accordance with other studies [34,58,59].

The groups disinfected with CHX did not exhibit the greatest color change; however, after 30 h of disinfection with CHX, all groups showed chromatic alteration, and most were above the perceptible threshold because this compound can cause dental staining and color alteration [60,61]. Ariani et al. proved the efficacy of 0.2% chlorhexidine gluconate against microorganisms in biofilms present on silicone facial prostheses [62]. The 2% CHX solution is biocompatible, and immersion disinfection is considered the most favorable technique for treating facial silicone prostheses [57]. The results of this study agreed with some previous studies [33,53]. However, they contrasted with the observations of Goiato et al. and Chotprasert et al., who found CHX to produce the greatest color alterations [34,63]. These inconsistencies in color changes among studies may have been due to differences in specimen preparation, methodology, exposure conditions, the active ingredients present in the disinfectant, and study duration.

Hypochlorite has known disinfectant activity, which is the ability to eliminate bacteria; however, it also has bleaching activity, causing discoloration due to the reaction of chlorine with calcium hydroxide [64]. A weak NaOCl solution can be used to disinfect prostheses made of silicone [38,65]. In the present study, 1% NaOCl was associated with the greatest color change, regardless of the pigment and nanoclay added. Therefore, it appears that NaOCl acts as a fading agent during the disinfection process. This result agrees with the work of Eleni et al. (2013) and Cabral et al. (2018) [38,52]. Thus, disinfection with NaOCl solution is not recommended.

The greatest color change was observed in specimens containing red pigment and cleaned with NaOCl. This result contrasts with the work of Cevik and Yildirim-Bicer (2017) [66], which showed that after disinfection, red pigment showed the least chromatic alteration. However, our study is in agreement with their findings that NaOCl caused the greatest color change.

Chemical prosthesis cleansing agents vary in their mode of action, and their main constituents can be classified as hypochlorites, peroxides, neutral peroxides, enzymes, acids, and disinfectants [67]. However, depending on their composition, these cleansing agents can have deleterious effects on resilient relining materials, causing damage to the material's physical properties, such as an increase in absorption and solubility [68]. As such, the choice of a chemical agent for prosthesis cleansing should be based not only on its antimicrobial properties but also on its compatibility in order to preserve the physical properties of the material surface as much as possible [69].

This study has several limitations that may affect its findings. First, it only tested one type of maxillofacial silicone with four disinfectants, which may not be representative of the variety of silicones and disinfection methods used in practice. The 30-hour immersion simulating 1 year of use might not accurately reflect real-world conditions, which involve additional factors such as temperature and pollutants. This study focused solely on color changes (ΔE), neglecting mechanical properties such as tensile strength, which are important for prosthesis durability. Additionally, this study did not account for long-term aging effects or evaluate other pigments and additives, leaving gaps in the understanding of broader impacts on color stability and prosthesis durability.

5. Conclusions

This study highlights the need to enhance the properties of maxillofacial silicone elastomers using natural clay nanoparticles to improve durability and esthetic lifespan while resolving color degradation complications. This study shows that while CHX and NaOCl can effectively disinfect maxillofacial silicone prostheses, they also cause apparent alterations in color, especially with prolonged exposure. As a result, cleaning agents must be carefully selected to preserve the aesthetic properties of the prosthetic material. Natural

nanoclays are highly reliable for pigmenting maxillofacial silicone, as they exhibit the least color change after various disinfection procedures.

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Abbreviations

The following abbreviations are used in this manuscript:

NaOCl	Sodium hypochlorite
CHX	Chlorhexidine
HTV	Heat-Temperature-Vulcanized
ΔE	Color Difference (Delta E*)
XRD	X-Ray Diffraction
FTIR	Fourier Transform Infrared Spectroscopy
SPSS	Statistical Package for the Social Sciences

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