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# Frequently used extraoral maxillofacial prosthetic materials and their longevity – A comprehensive review

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ABSTRACT

The longevity of an extraoral prosthesis depends on its physical and mechanical properties and user maintenance. Faced with multiple outcome measures, researchers find it difficult to determine the most appropriate extraoral prosthetic material. This comprehensive review evaluates the most used extraoral prosthesis materials and qualitatively assesses their longevity and function. The study aims to identify and interpret the results of current updates on the factors that affect longevity and functionality. This comprehensive review summarizes and evaluates differences in the properties of commonly used extraoral maxillofacial prosthetic materials. The review was planned to focus on all factors related to the longevity and function of the extraoral maxillofacial prosthetics. An electronic search covered English articles in PubMed, Scopus, Google Scholar, Web of Science, and grey literature. Manual searching was also performed. Six authors participated in the screening. Search engines extracted 1107 records, and 88 studies were included for qualitative and bias assessments. Silicones are the most frequently used extraoral maxillofacial prosthetic materials. Heat-cured silicones are more color-stable than those cured at room temperature. Additional ingredients and processing techniques affect prosthesis longevity.

## 1. Introduction

The surgical treatment of head and neck cancer often results in complex facial defects leading to various degrees of functional impairment and facial disfigurement [1]. Despite the surgical reconstruction of such defects, the esthetic results are sometimes disappointing, and multiple operations may be necessary [2]. Prosthetic reconstruction has proven an excellent alternative to such surgeries, especially after resection of the orbit, ear, or nose. It can promote well-being and provide a higher quality of life for these patients, especially those with resected orbit, ear, or nose [3]. Overall satisfaction with facial prostheses is high [4], but some limitations and challenges exist [5–8]. The mechanical and physical properties of the prosthetic material limit the success of prosthetic facial rehabilitation. The materials used in this area include facial silicones, acrylic resin copolymers, vinyl polymers, and polyurethane elastomers [9]. The longevity of prosthetic material is affected by environmental and weathering conditions [5,10], aging [11–13], chemical composition [14–16], disinfection method[17,18], processing technique [10], pigments [19] and others [20–23]. The literature reports problems related to the physical and mechanical properties of these materials, such as color stability, tear strength, hardness, marginal and surface integrity, solubility, water absorption, and bacterial adhesion [17,19,24–26]. Since all of these may impact longevity, there is no ideal extraoral prosthetic material at present, nor is there a consensus on the most serviceable material [26]. This comprehensive review aims to survey currently available facial prosthetic materials to identify the facial prosthesis material with the highest longevity and functionality. Most studies have been conducted on

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silicone elastomers and acrylic resins; therefore, the current research focuses mainly on these two groups of materials. The null hypothesis of this study is that all materials used to fabricate facial prostheses, whether acrylic or silicone-based, have similar longevity and functionality and need to be remade after 1.5 to 2 years due to color change and changes in properties.

A long-lived facial prosthesis material's ideal mechanical and physical properties include high tensile strength, abrasion resistance, tear strength, and edge strength. In addition, it should have low glass transition temperature, low surface tension, specific gravity, and low thermal conductivity. The ideal material should also be non-inflammable, nonabsorbent, odorless, and transparent, allowing the incorporation of cosmetic colorants. Other significant properties include color stability, dimensional stability, the ability to remain soft during use, tissue compatibility, non-allergenicity, and nontoxicity. It should also be inert to solvents and adhesives, permeable to moisture release from underlying tissues, and resistant to microbial growth. The longevity of such materials depends on their long-term color stability, tear strength resistance, and ability to be cleaned. They should resist microbial adhesion and possess ideal physical, mechanical, and biological properties for prolonged prosthesis function [28].

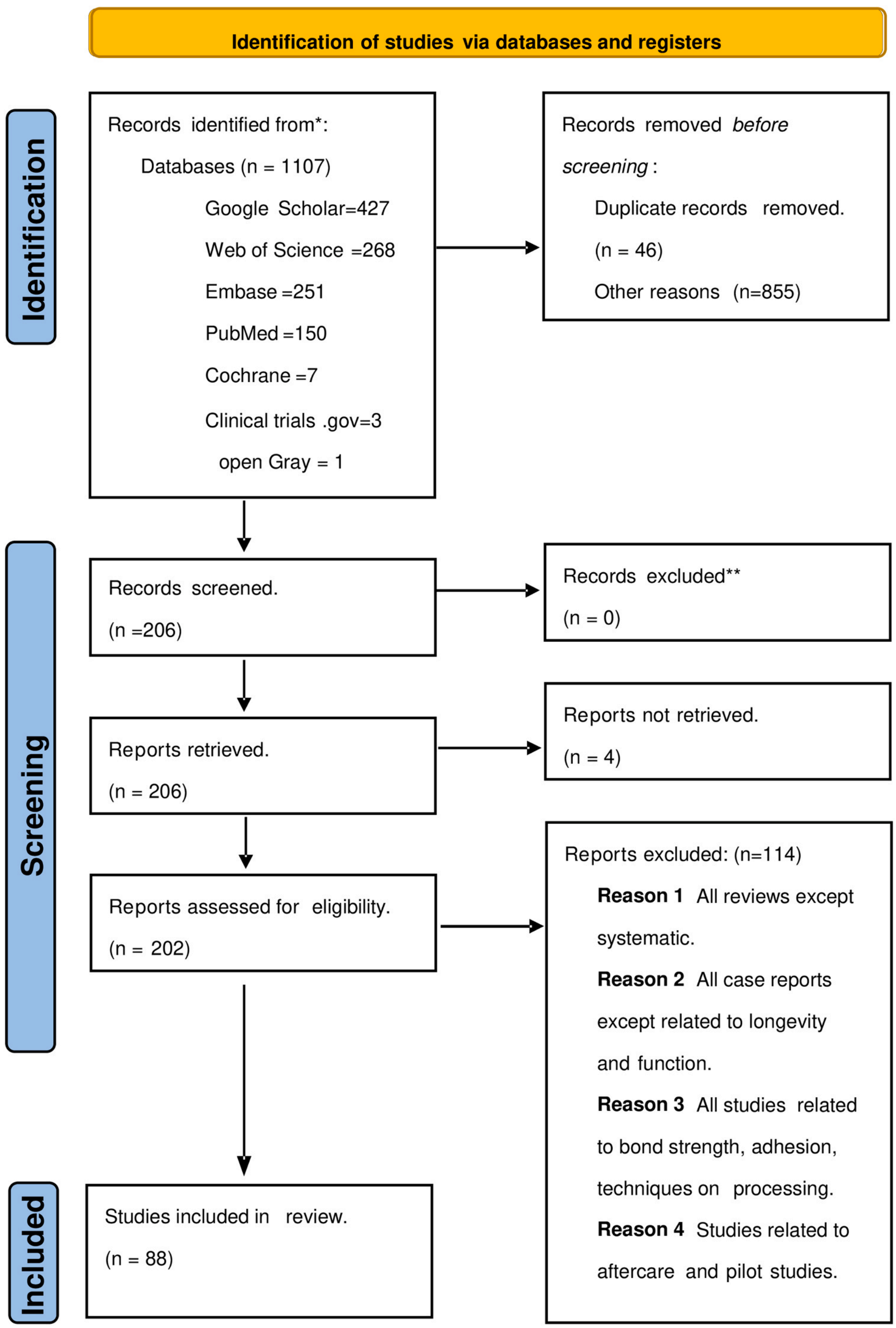


**Fig. 1.** PRISMA Flow Chart for the selection of articles for this study.

## 2. Materials and method

The methodology conforms to the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) checklist, and data were collected following the PRISMA flow chart (Fig. 1).[27] This review is a collaboration between Tokyo Medical and Dental University and the College of Dentistry, Ajman University. The College of Dentistry, Ajman University, approved the comprehensive review. The ethical committee approval number for the Study is RN: D-F-H-5-Dec.

The focus question for the study was to evaluate the most commonly available extraoral prosthesis materials and to qualitatively assess their longevity and function based on the literature review. The inclusion criteria for this study were articles evaluating extraoral prostheses materials, specifically the properties affecting their longevity and functionality. Eligibility criteria included studies that reported such materials' physical, mechanical, and biological properties and their dimensional, color, and processing stability. All reviews were excluded except systematic reviews. Other excluded articles were the studies on bond strength, silicone acrylic interface studies, and techniques not related to processing or color change, apart from one case study without follow-up. Adhesion and retention studies, aftercare studies, pilot studies, and articles written in languages other than English were also eliminated.

Further criteria were applied to identify only articles dealing with extraoral maxillofacial prosthesis materials and factors affecting their longevity (Fig. 1). A pilot study search was conducted online, covering databases between January 2010 and September 2022. An electronic search was performed for English articles in PubMed, Scopus, Google Scholar, Web of Science, Embase, Cochrane, Clinical trials, and grey literature. Manual searching was also conducted. The standard Mesh term applied by all reviewers were as follows. (Facial OR maxillofacial OR extraoral OR nasal, OR orbital, OR auricular OR face OR nose OR eye OR ear OR midface) AND (Prosthesis* OR defect*) AND (material*) AND (longevity OR shelf-life or half-life OR functionality OR weather* OR patient satisfaction OR durability OR serviceability OR color stability).

### 2.1. Review protocol

The relevance of the articles was verified by triple screening. The initial screening was done by article title, excluding duplicates. The second screening was based on the abstracts. The third screening involved the independent reading of the full text of all the remaining articles by four reviewers to verify that they met the inclusion criteria. This yielded 88 articles, which three reviewers rechecked, and data was extracted for qualitative synthesis.

A total of 1107 articles was initially identified from the databases, viz., Google Scholar (n = 427), Web of Science (n = 268), Embase (n = 251), PubMed (n = 150), Cochrane Reviews (n = 7), ClinicalTrials.gov (n = 3) and Open Grey (n = 1). After the initial screening, 855 articles that did not fit the inclusion criteria were excluded. In the second screening, 46 duplicates were removed.

In the third screening, a total of 206 articles were reviewed by four authors. Of the 206 articles, the full text could not be retrieved for four articles. (Fig. 1) Of the remaining 202 articles, 114 articles were further excluded. The final count was 88 articles, which were further reviewed for the material used, type of study, and outcome. (Table 1). All articles that were related to intraoral prostheses, pigmentation studies, psychological management, retention aids for maxillofacial prostheses, apps to match skin color, 3D printing, and all articles in other languages other than English were excluded. The selected articles were also evaluated for bias, and the results were reported (Table 2 and Table 3) based on a Modified CONSORT (Consolidated Standards of Reporting Trials) table [29].

### 2.2. Data collection

The data for the qualitative analysis was entered into an Excel sheet to list all 88 articles by author name, title, journal, date of publication, type of research design, abstract, the prosthetic material used, and their outcomes.

The included studies are listed in Table 1 with the relevant data. The review process based on Faggion CM was used to qualitatively evaluate the selected articles reporting in vitro studies. The final set of 88 articles is summarized in Table 1. However, only 85 articles are summarized in Table 2 for bias testing since systematic reviews and articles reporting clinical observations were removed from bias testing.

## 3. Results

This review included 88 articles, mostly in vitro laboratory studies. Among them, 78 articles were related to evaluating silicone extraoral prosthesis materials, and eight articles considered acrylic extraoral prosthetic material. A single case report assessed edge strength in a silicone prosthesis following tulle incorporation, and another evaluated the change in color of an extraoral implant retained prosthesis. From this analysis, it is evident that silicones are the most frequently used extraoral prosthetic materials. Their disadvantages include reduced longevity due to the inevitable degradation of their physical and mechanical properties over time. The literature review summarises the often-tested properties (Table 4).

### 3.1. Color stability

In a total of 41 articles assessed for the color change, the authors evaluated silicone materials including Silastic MDX 4–4210, Silastic 732 RTV, A-2000, M511 elastomer, heat-Lentaflex, self-cure Rapid flex, /type A Cosmesil M511 (CosM511), Cosmesil M522 (CosM522), Multisil-Epithetic (Mult-Epit), Z004 Platinum Silicone Rubber, A-120, Zetalabor silicone, Vipisil, Silasto 30 premium, Silasto 30 HTV, three different medical-grade polydimethylsiloxanes (PDMS), and an experimental chlorinated polyethylene (CPE). Other silicone materials included for testing were Silastic 382 medical grade elastomer, types of condensation, and addition silicone (Table 1).

Adding Titanium oxide nanocoating to A-2000 provided good color stability [30]. Another study with A-2000 reported similar results with adding white dry pigments but deteriorated in color with yellow pigment [31]. The addition of various nano-oxides to different silicones, such as M511 elastomer, has been reported by several authors. In a study using M511, intrinsic pigmentation was associated with the highest color stability, with no change in color observed following the use of the nano-ZnO [32].

Color stability varies with the choice of silicone and the mold used to make the silicone prosthesis. In one study where M511 was used with different colored stone molds, greater and lesser color deterioration was associated with green and blue dental stones vs reddish-brown dental stones, respectively [33]. Pigmented silicone specimens are more susceptible to color instability after weathering than non-pigmented, whether heat-cured or cured at room temperature. Non-pigmented heat-cured silicone specimens resisted color change [34].

Some researchers reported on the use of intrinsic pigmentations. With A-2186, two studies linked the use of yellow pigment and UV light exposure to color change, respectively. Two other studies demonstrated an association between titanium opacifiers with better color stability after artificial aging (Table 1). Table 1 compares the color changes in silicone and acrylic materials such as MDX4–4210, heat-Lentaflex to self-cure Rapidaflex and colorless Classico self-cure. The results demonstrated color instability with all pigmented specimens. Four different studies explored color stability with MDX4–4210. Two reported its color instability. The others show that adding ceramic pigment and an opacifier increased color stability in MDX4–4210.

**Table 1**
Studies included in this research.

| N | Authors | Material used | Study | Result |
|---|---|---|---|---|
| 1 | Gary, JJ; et al. Huget, EF; Powell, LD | A2186 | In vitro. | The color change was observed with three different pigments (30 specimens), with a significant change in Hansa's yellow pigment. |
| 2 | Paulini, MB; dos Santos, DM; Neto, CLDM; Et al. | MDX4-4210, A-120 | In vitro. | Physical properties and color (160 specimens) After NTP TT (nonthermal plasma treatment and accelerated aging), A-120 had consistent results in color |
| 3 | Goiato, MC; dos Santos, DM; Souza, JF; Moreno, A; Pesqueira, AA | N1 acrylic | In vitro. | Good post-aging color stability |
| 4 | Kiat-Amnuay, Sudarat; Mekayarajjananonth, Trakol; Powers, John M; Chambers, Mark S; Lemon, James C; | MDX4-4210 | In vitro. | Color stability with artificial aging.<br>Color stability is maximum with dry pigments and titanium white-added samples. |
| 5 | Goiato, MC; Pesqueira, AA; dos Santos, DM; Zavanelli, AC; Ribeiro, PD | MDX4-4210, 732 | In vitro. | Color stability of silicones affected by efferdent and neutral soap |
| 6 | Bishal, AK; Wee, AG; Barao, VAR; Yuan, JCC; Landers, R; Sukotjo, C; Takoudis, CG | A-2000 | In vitro. | The nano-oxide coating enhances color stability. |
| 7 | Farah, A; Sherriff, M; Coward, T | M511 | In vitro. | Color change with aging treatment was observed for both types of materials in three different environments. |
| 8 | Han, Y; Zhao, YM; Xie, C; Powers, JM; Kiat-Amnuay, S | A-2186 | In vitro. | The color change was observed with yellow silicone pigment with all three types of nano-oxide coating (TiO2/ ZnO/ CEo2). |
| 9 | dos Santos, DM; Goiato, MC; Sinhoreti, MAC; Fernandes, AUR; Ribeiro, PD; Dekon, SFD | MDX4-4210, Lentaflex, Rapidaflex, Classico | In vitro. | Color stability of 3 polymers 3 and 1 silicone (40 specimens)<br>All pigmented specimens had color instability in resin and silicone. |
| 10 | Kantola, R; Lassila, LVJ; Tolvanen, M; Valittu, PK | MDX4-4210 | In vitro. | The color stability of the thermochromic pigment was demonstrated to be poor as it is UV-sensitive. |
| 11 | Canadas, MDB; Garcia, LFR; Consani, S; Pires-de-Souza, FCP | Classico acrylic | In vitro. | Eye sclera resins with different polymerization, color stability, and surface properties was assessed.<br>Dry heat is associated with less surface porosity, but all methods produce the same color stability. |
| 12 | Guiotti, AM; Goiato, MC; dos Santos, DM; Vechiato, AJ; Cunha, BG; Paulini, MB; Moreno, A; de Almeida, MTG | MDX4-4210 | In vitro. | The color stability of two pigments and one dry opacifier was tested post-exposure to disinfection agents.<br>All three showed color instability. |
| 13 | dos Santos, DM; Goiato, MC; Moreno, A; Pesqueira, AA; Dekon, SFD; Guiotti, AM | MDX4-4210 | In vitro. | The addition of pigments and opacifiers influenced the physical properties of silicone (hardness, absorption, and solubility) after artificial aging. |
| 14 | Chamaria, A; Aras, MA; Chitre, V; Rajagopal, P | A-2000 | In vitro. | Pigmented and non-pigmented samples were exposed to different disinfectants.<br>Chlorhexidine 2% produced minimal color change. |
| 15 | Goiato, MC; Haddad, MF; Pesqueira, AA; Moreno, A; dos Santos, DM; Bannwart, LC | MDX4-4210 | In vitro. | Effervescent tablets and neutral soap were used on the silicone material to which opacifiers (Barium sulfate, titanium dioxide, and colorless) were added, to test color stability.<br>All samples showed color instability. |
| 16 | Moreno, A; Goiato, MC; dos Santos, DM; Haddad, MF; Pesqueira, AA; Bannwart, LC | N1 Resin, colourless resin | In vitro. | Chlorhexidine 4% produced the greatest color change. |
| 17 | Pesqueira, AA; Goiato, MC; dos Santos, DM; Haddad, MF; Ribeiro, PD; Sinhoreti, MAC; Sundefeld, MLMM | Facial silicone | In vitro. | Hypochlorite and CHX adversely impacted the change in microhardness and roughness. |
| 18 | Hatamleh, MM; Watts, DC | MDX4-4210 | In vitro. | Disinfection and aging on colorless and pigmented silicones<br>The ceramic pigment had greater color stability. |
| 19 | Hatamleh, MM; Polyzois, GL; Silikas, N; Watts, DC | TechSil S25 | In vitro. | Aging produced changes in the color stability of silicone, with the greatest alteration being with non-pigmented silicone. |
| 20 | Akash, RN; Guttal, SS | M511 | In vitro. | The impact of added nano-oxides on color stability in silicones showed intrinsic pigmentation and the addition of ZnO to produce the most stable color. |
| 21 | Han, Y; Kiat-amnuay, S; Powers, JM; Zhao, YM | A-2186 | In vitro. | Effect of nano oxide on silicone.<br>The incorporation of Ti, Zn, or Ce nano-oxides improved mechanical properties. |
| 22 | Han, Y; Powers, JM; Kiat-amnuay, S | MDX4-4210 | In vitro. | Different opacifier effects on color stability.<br>UV mineral-based light protectingagent groups caused the minimal color change |
| 23 | Nguyen, CT; Chambers, MS; Powers, JM; Kiat-amnuay, S | MDX4-4210 | In vitro. | Effect of opacifiers on mechanical properties<br>UV mineral-based light-protecting degraded mechanical properties. |
| 24 | Bibars, ARM; Al-Hourani, Z; Khader, Y; Waters, M | M511, Z004, A2000 | In vitro. | With and without thixotropic effect on mechanical properties.<br>Z004 silicone showedthe highest tensile and tear strength followed by A2000 and M511, regardless of the addition ofThixotropic agent. |
| 25 | Polyzois, GL; Eleni, PN; Krokida, MK | Silasto 30, Premium 2 | In vitro. | Shelf life and effect on properties.<br>The average time-to-replacement for a facial prosthesis is 6-18 months. |

(*continued on next page*)

**Table 1** (*continued*)

| N | Authors | Material used | Study | Result |
|---|---|---|---|---|
| 26 | Cifter, ED; Ozdemir-Karatas, M; Baca, E; Cinarli, A; Balik, A; Sancakli, E; Gokcen-Rohlig, B | M511 | In vitro. | Color stability was tested on silicone material with different dental stone processing techniques.<br>Green and blue dental stones cause less, and reddish-brown stones the most, color degradation in silicone elastomers. |
| 27 | Hu, XX; Pan, XL; Johnston, WM | PDMS, CPE | In vitro. | Intrinsic pigments affect the viscoelastic properties of the silicone material. |
| 28 | Goiato, MC; dos Santos, DM; Gennari, H; Zavanelli, AC; Dekon, SFD; Mancuso, DN | Classico | In vitro. | Chemical disinfection did not affect the microhardness of the acrylic material used for the ocular prosthesis. |
| 29 | dos Santos, DM; Goiato, MC; Moreno, A; Pesqueira, AA; Haddad, MF | MDX4–4210 | In vitro. | Aging on color stability of silicone.<br>The opacifier protects facial silicone against color instability. |
| 30 | Al-Harbi, FA; Ayad, NM; Saber, MA; ArRejaie, AS; Morgano, SM | A-2186, MED-4210 | In vitro. | Outdoor exposure and color change.<br>TechSil S25 retained physical properties and color best after outdoor weathering in a hot, humid climate. |
| 31 | Hatamleh, MM; Polyzois, GL; Nuseir, A; Hatamleh, K; Alnazzawi, A | 45 years since 1969 | Systematic review | None of the current materials show ideal longevity and function. |
| 32 | Polyzois, G; Lyons, K | Silasto 30, premium | In vitro. | Shelf life.<br>Silasto 30 HTV is shelf-stable during natural use. |
| 33 | Hatamleh, MM; Watts, DC | TechSil S25 | In vitro. | Color stability is affected by the mixing method and porosity. |
| 34 | Eleni, PN; Krokida, MK; Charitidis, CA; Koumoulos, EP; Tsikourkitoudi, VP; Ziomas, I; Polyzois, GL | Elastomer 42 | In vitro. | Lab aging hardens materials by photodegradation and hydrolysis. |
| 35 | Eleni, PN; Krokida, M; Polyzois, G; Gettleman, L; Bisharat, GI | TechSil 25, M511 | In vitro. | Aging produces hardening with most materials but softening with Cosmesil M511 and CPE. |
| 36 | Eleni, PN; Katsavou, I; Krokida, MK; Polyzois, GL; Gettleman, L | Elastomer 42, TechSil 25, M511, CPE | In vitro. | Lab-based aging and change in physical properties.<br>M511 and CPE are softer and more ductile after aging. |
| 37 | Miranda, NB; de Arruda, JAA; de Almeida, SBM; dos Santos, EG; Medeiros, IS; Moreno, A | Al-513 | In vitro. | Immersion in 11% alcoholic and glycolic green propolis extracts produced clinically unacceptable andperceptible changes. |
| 38 | Eleni, PN; Krokida, MK; Polyzois, GL; Gettleman, L | PDMS, CPE | In vitro. | Microwave exposure and hypochlorite solution affect CPEsignificantly. |
| 39 | Eleni, PN; Perivoliotis, D; Dragatogiannis, DA; Krokida, MK; Polyzois, GL; Charitidis, CA; Ziomas, I; Gettleman, L | PDMS, CPE | In vitro. | Tensile and micro indentation properties of PDMS and CPE were altered post-disinfection with fourdifferent disinfection procedures. |
| 40 | Eleni, Panagiota N.; Krokida, Magdalini K.; Polyzois, Gregory L.; Gettleman, Lawrence | PDMS, CPE | In vitro. | The best disinfecting agent for CPE is sodium hypochlorite solution, but microwave disinfection is for PDMS. |
| 41 | Polyzois, GL; Eleni, PN; Krokida, MK | Mollomed S20, S21, S24, S27EP-A, Episil | In vitro. | Mollomed samples showed visually unacceptable color changes in the outdoor aging process. |
| 42 | dos Santos DM, Goiato MC, Sinhoreti MA, Moreno A, Dekon SF, Haddad MF, Pesqueira AA. | MDX4-4210, Resins, Rapidaflex, Lentaflex | In vitro. | All samples showed color variation. |
| 43 | Mancuso DN, Goiato MC, Dekon SF, Gennari-Filho H. | 732, MDX 4-4210 | In vitro. | Silastic 732 RTV and Silastic MDX 4-4210 showed similar color changes post-aging. |
| 44 | Aziz T, Waters M, Jagger R. | Factor II, Cosmesil HC, Nusil, Cosmesil St, Prestige | In vitro. | Tear strength, tensile strength, percentage elongation, hardness, water absorption, and water contact angles were tested.<br>Factor II, Cosmesil HC, and Nusil had higher tear strength.<br>Nusil showed higher tensile and elongation strength.<br>Factor II had lower sorption.<br>Cosmesil St and Prestige were harder. |
| 45 | Fernandes, Aline Úrsula Rocha; Goiato, Marcelo Coelho; dos Santos, Daniela Micheline; | Acrylic resin | In vitro. | Effect of weathering on the opacity of acrylic resin on four types of acrylics.<br>Opacity increased with weathering time. |
| 46 | Goiato, Marcelo C; Haddad, Marcela F; Sinhoreti, Mário AC; dos Santos, Daniela M; Pesqueira, Aldiéris A; Moreno, Amália; | MDX 4-4210 | In vitro. | Opacifier content and disinfection on accelerated aging colour change<br>90 samples lab study<br>Opacifiers altered dimensional changes in silicone. |
| 47 | Goiato, Marcelo Coelho; Moreno, Amália; dos Santos, Daniela Micheline; de Carvalho Dekon, Stefan Fiuza; Pellizzer, Eduardo Piza; Pesqueira, Aldiéris Alves; | Acrylic resin Classico | In vitro. | Ocular prosthesis color stability on type of polymerization and aging 80 artificial iris 60 painted 20 printed.<br>Color stability was significantly greater with the painted iris than with the printed one. |
| 48 | Goiato, Marcelo Coelho; Pesqueira, Aldiéris Alves; Santos, Daniela Micheline dos; Dekon, Stefan Fiúza de Carvalho; | MDX 4-4210, 732 | In vitro. | Change in hardness after the use of the cleansing solution.<br>MDX 4-4210 showed increased hardening and roughening post-disinfection than Silastic 732. |
| 49 | Guiotti, Aimée Maria; Goiato, Marcelo Coelho; dos Santos, Daniela Micheline; | MDX4-4210 | In vitro. | Aging produced marginal deterioration of the silicone. |
| 50 | Guiotti, Aimée Maria; Goiato, Marcelo Coelho; dos Santos, Daniela Micheline; | MDX4-4210 | In vitro. | The hardness of silicone progressively increased following a stable period of 6-12 months. |
| 51 | Gunay, Yumushan; Kurtoglu, Cem; Atay, Arzu; Karayazgan, Banu; Gurbuz, Cihan Cem; | A-2186 | In vitro. | Incorporating nylon tulle into silicone improved the strength and tear resistance of the latter. |

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**Table 1** (*continued*)

| N | Authors | Material used | Study | Result |
|---|---|---|---|---|
| 52 | Kiat-amnuay, Sudarat; Beerbower, Meghan; Powers, John M; Paravina, Rade D; | A-2000 | In vitro. | Color stability and aging<br>Dry earth opacifiers Artskin white 10% and titanium white 15% prevented color instability of silicone over time. |
| 53 | Kiat amnuay, Sudarat; Johnston, Dennis A; Powers, John M; Jacob, Rhonda F; | A-2186 | In vitro. | Color stability with the titanium white dry earth opacifier showed better color stability after microwave exposure than specimens with the red pigment group. |
| 54 | Kiat Amnuay, Sudarat; Lemon, James C; Powers, John M; | A-2186 | In vitro. | Color stability artificial aging of four different opacifiers and 300 specimens<br>10% Artskin white followed by Ti white, 10% showed the best color stability compared to other pigments. Red pigment showed the least color stability. |
| 55 | Mancuso, Daniela Nardi; Goiato, Marcelo Coelho; Santos, Daniela Micheline dos; | 732, MDX4-4210 | In vitro. | Both silicones showed similar color stability without pigments.<br>Ceramic pigment powder produced the least color variation. |
| 56 | Polyzois, Gregory L; Tarantili, Petroula A; Frangou, Mary J; Andreopoulos, Andreas G; | Episil | In vitro. | Evaluation of physical prop (tensile strength and modulus, elongation, tear strength, hardness, weight, and color change) after storing in simulated skin secretions.<br>Minimal changes in physical properties were observed over six months. |
| 57 | Reis, Ricardo César dos; Carvalho, Jose Carlos Mesquita; | Acrylic resin | In vitro. | Iris color stability of acrylic resin ocular prosthesis paint.<br>Color stability was greatest with yellow and lowest with blue iris color. |
| 58 | Stathi, K; Tarantili, PA; Polyzois, G; | MDX4-4210 | In vitro. | Accelerated aging of silicones and change in properties.<br>UV radiation did not significantly affect the properties of silicone.<br>Silica nanofiller reinforced the silicone material but could not prevent color change. |
| 59 | Tran, Ngoc H; Scarbecz, Mark; Gary, John J; | A-2186 | In vitro. | Color change with UV light absorber (UVA) and hindered amine light stabilizer (HALS) improved color stability in a few samples. |
| 60 | Bankoglu, Merve; Oral, Ihsan; Gül, Esma Basak; Yilmaz, Handan; | M511, M522, Multisil-Epithetic | In vitro. | Colorants and spectrophotometers evaluated different pigmented specimens of various silicones for one year.<br>Color stability was greatest with Cosmesil M511 containing white pigment. |
| 61 | Charoenkijkajorn, Dittaya; Sanohkan, Sasiwimol; | MDX4-4210 | In vitro. | Incorporating 1.5% nano zinc oxide improved color stability after artificial aging. |
| 62 | Kheur, MG; Sethi, T; Coward, T; Jambhekar, SS; | M511<br>Z004 | In vitro. | Changes in hardness and weathering conditions.<br>Room temperature curing reduced the hardening of both materials with time.<br>. |
| 63 | M Shihab, Noor; M Abdul-Ameer, Faiza; | VST-50 | In vitro. | Pigmented and non-pigmented groups were assessed for hardness, tear strength, and surface roughness.<br>Intrinsic pigments improved while aging reduced material properties. |
| 64 | Mehta, Siddharth; Nandeeshwar, DB; | M511<br>Z004 | In vitro. | Color stability, disinfection, facial secretions spectrophotometer study.<br>The neutral soap solution did not significantly alter color, but other factors (sebum, outdoor weathering, and acidic perspiration) did. |
| 65 | Nimonkar, Sharayu V; Sathe, Seema; Belkhode, Vikram M; Pisulkar, Sweta; Godbole, Surekha; Nimonkar, Pranali V; | M511 | In vitro. | A mobile phone colorimeter application was used to check colour change.<br>Increasing the value of a colour by 2-3% using the mobile calorimetric app during material manipulation can result in an excellent esthetic outcome. |
| 66 | Radey, Nayera S; Al Shimy, Ahmed M; Ahmed, Dawlat M; | MDX4- 4210 | In vitro. | Nano-TiO2 in different concentrations was added, and their effect on mechanical properties after artificial aging was assessed.<br>2.5% nano-TiO2 reinforced the silicone material and demonstrated antiaging properties. |
| 67 | Rahman, Ahmed Mushfiqur; Jamayet, Nafij Bin; Nizami, Md Minhaz Ul Islam; Johari, Yanti; Husein, Adam; Alam, Mohammad Khursheed; | Maxillofacial silicone | Systematic review and meta-analysis. | Under different weathering conditions, no material showed ideal properties. |
| 68 | Abdullah H.A., Abdul-Ameer F.M. | VST-30 | In vitro. | Samples with a rayon flocking showed a highly significant decrease in hardness and a significant increase in tear strength, with non-significant differences in surface roughness, tensile strength, and elongation percentage. |
| 69 | Hulterstrom A.K., Berglund A., Ruyter I.E., | Maxillofacial silicone | In vitro. | Addition-type silicones showed no solubility and water sorption. |
| 70 | Shakir D.A., Abdul-Ameer F.M. | VST-50 F, M511 | In vitro.<br>Two types of maxillofacial elastomers where the nano-TiO2 powder was applied as a nanofiller | Two types of maxillofacial elastomers where the nano-TiO2 powder was applied as a nanofiller.<br>Adding 0.25% VST50F RTV and 0.2% for Cosmesil M511 HTV improved the elastomer's mechanical properties. |
| 71 | Goiato M.C., Pesqueira A.A., dos Santos D.M., Antenucci R.M., Ribeiro P.P. | MDX4-4210, 732 | In vitro.<br>Storage time | Storage time.<br>MDX 4-4210 silicone showed minimal dimensional |

(*continued on next page*)

**Table 1** (*continued*)

| N | Authors | Material used | Study | Result |
|---|---|---|---|---|
| | | | | changes.<br>Both materials showed no dimensional change after disinfection. |
| 72 | Karayazgan B., Gunay Y., Evlioglu G. | Maxillofacial silicone | Clinical report. | Increased edge strength and tear resistance. |
| 73 | Keyf F. | Maxillofacial silicone | Clinical report. | Auricular prosthesis showed dramatic color instability after one year. |
| 74 | Visser A., Raghoebar G.M., Van Oort R.P., Vissink A. | Different materials. | One-year follow-up of 95 patients with facial prosthesis. | Remaking of the prosthesis was necessary after 1.5 to 2 years because of:<br>1. Discoloration (31.2%)<br>2. Resin clip detachment from silicone (25.3%)<br>3. Silicone tear (13.3%)<br>4. Lack of proper adaptation (10.9%) |
| 75 | Spinelli G.M., Asher E. | Maxillofacial silicone | Clinical report. | Microbial growth occurs on silicone prosthesis if improperly maintained. |
| 76 | Farah Rashid, Aparna Barman, Taseef Hasan Farook, Nafij Bin Jamayet, Mohd Firdaus Bin Yhaya, and Mohammad Khursheed Alam | Maxillofacial silicone | Systematic review. | Color stability was affected most by nano-fillers and the type of color used in the mixing. Other factors included the experimental conditions, weathering, the color of investment plaster, and the method of color detection. |
| 77 | Ceyda Başak İnal, Merve Bankoğlu Güngör, Meral Bağkur, Seçil Karakoca Nemli | M511, Derma-sil 10, Derma-sil 30 | In vitro. | Red specimens showed significantly higher color instability in the M511 group, but orange-brown specimens in the Derma-sil 30 group. Aging significantly decreased the hardness values of M511 red and orange-brown groups among all groups. |
| 78 | Wen Xin Chong, Yee Xuan Lai, Minati Choudhury, and Fabian Davamani Amalraj | M511 | In vitro. | Silicone elastomers with sub-10-nm AgNPs displayed antimicrobial properties In vitro against S. aureus, C. Albicans, and mixed species. |
| 79 | Israa E Hussein | VST-50 F | In vitro. | Nano-ZrO2 improved the tear strength and tensile strength of VST-50 F RTV maxillofacial silicone but increased the hardness within the standard limit. |
| 80 | Natdhanai C, Binit S, and Kawin S | Maxillofacial silicones | In vitro. | Chlorhexidine solution and liquid soap resulted in the highest color change.<br>Pre-colored silicone showed higher color stability than its hand-colored counterpart. |
| 81 | Bilge Turhan Bal, Merve Bankoglu Güngör, Seçil Karakoca Nemli, Cemal Aydın and Yeliz Kas ķo Arıcı, | Maxillofacial silicone | In vitro. | Among the UV protective agents, Ethylhexyl salicylate improved color stability. |
| 82 | Ahmed Mushfiqur Rahman, Nafij Bin Jamayet, Minhaz Ul Islam Nizami, Yanti Johari, DClinDent, Adam Husein, DClinDent, and Mohammad Khursheed Alam | N-120, A-2000, A-2006, M-511, A-103 | In vitro. | The surface roughness tear strength (TS) and percentage elongation were affected by weathering for all materials.<br>A-2000 showed the least TS changes.<br>A-2006 demonstrated significant changes in percentage elongation.<br>M-511 exhibited the highest mean value for surface roughness.<br>A-103 SE showed statistically significant differences in both. |
| 83 | Ashika S. Mohan, Manju V, Anna Serene Babu, Krishnapriya | Maxillofacial silicone | In vitro. | All groups showed significant changes in the physical and mechanical properties post-aging.<br>The samples with nano-TiO2 of 40-nm particle size/2% concentration had the highest hardness.<br>Color stability and surface roughness were higher in samples with 1% and 2% nano-TiO2 of 20-nm particle size. |
| 84 | Aya Mohamed Fawzy and Nada Sherin El Khourazaty | Maxillofacial silicone | In vitro. | No significant change in color change with neutral soap (shampoo).<br>There was a significant increase in color change in the natural weathering group. The difference between the groups was at one and two months. |
| 85 | Abha. N and Sudeep. S | Maxillofacial silicone | In vitro. | Color instability of the pigmented specimens tested for High-Temperature Vulcanization—HTV & Room Temperature Vulcanization—RTV silicone elastomers above acceptable limits. |
| 86 | Mason T. Bates, Jacqueline K. Chow, John M. Powers, Sudarat Kiat-amnuay | A-2000, M511 | In vitro. | Significant differences in color measurements were found for all silicone groups after artificial aging. |
| 87 | Nebras F.A, Mohammed A.H.H & Saja A.M | VST-06 | In vitro.<br>Color changes after 46 h of artificial weathering. | Color changes after 46 h of artificial weathering.<br>Surface roughness decreased with aging. |
| 88 | Praveen G, Bhupendra S R, Ashfaq Y, Pratik A, Gaurav P, Krishna T, Sirisha K | Maxillofacial silicone | In vitro. | The addition of silver nanoparticles at 20 ppm concentration decreased the hardness of silicone elastomer without affecting tear strength and color stability. |

### 3.2. Physical and mechanical properties

Apart from color stability, factors such as surface roughness, degradation, decreased edge strength, sorption, and hardness affect the longevity of the extraoral maxillofacial prosthesis material (Table 1). The physical properties most frequently assessed in extraoral prosthetic materials include hardness, absorption, solubility, and surface degradation (Table 4), as they directly influence the long-term longevity of the

**Table 2**
Summary of the 85 articles (Exempted systematic reviews and case reports. Y-Yes, N-No, P partially mentioned.).

| Author names | Item 1 | Item 2a | Item 2b | Item 5 | Item 6 | Item 7 | Item 10 | Item 11 | Item 12 | Item 13 |
|---|---|---|---|---|---|---|---|---|---|---|
| Gary JJ; et al. 2001 | Y | Y | Y | Y | Y | N | Y | Y | Y | Y |
| Paulini, MB., et al. 2020 | Y | Y | Y | Y | Y | N | Y | Y | Y | Y |
| Goiato, MC; et al. 2010 | Y | Y | N | Y | Y | N | Y | Y | Y | Y |
| Kiat-Amnuay, et al. 2006 | Y | Y | N | Y | Y | N | Y | Y | Y | N |
| Goiato, MC; et al. 2009 | Y | Y | N | Y | Y | N | Y | Y | Y | Y |
| Bishal, AK; et al. 2019 | Y | Y | Y | Y | Y | N | Y | Y | Y | Y |
| Farah, A; et al. 2018 | Y | Y | Y | Y | Y | N | Y | Y | Y | N |
| Han et al. 2010 | Y | Y | Y | Y | Y | N | Y | Y | Y | N |
| Dos Santos et al. 2010 | Y | Y | N | Y | Y | N | Y | Y | Y | N |
| Kantola, R; et al. 2013 | Y | Y | Y | Y | Y | N | Y | Y | Y | N |
| Canadas, MDB., 2010 | Y | Y | N | Y | Y | N | Y | Y | Y | Y |
| Guiotti, AM. 2016 | Y | Y | Y | Y | Y | N | Y | Y | Y | Y |
| dos Santos, DM, 2012 | Y | Y | Y | Y | Y | N | Y | Y | Y | Y |
| Chamaria et al. 2019 | Y | Y | Y | Y | Y | N | Y | N | P | N |
| Goiato et al. 2011 | Y | Y | Y | Y | Y | N | Y | N | P | N |
| MoreN et al. 2013 | Y | Y | Y | Y | Y | N | Y | N | P | N |
| Pesqueira et al. 2011 | Y | Y | P | Y | Y | N | Y | N | P | Y |
| Hatamleh et al. 2010 | Y | Y | Y | Y | Y | N | Y | N | P | N |
| Hatamleh et al. 2011 | Y | Y | Y | Y | Y | N | Y | N | P | N |
| Akash et al. 2015 | Y | Y | P | Y | Y | N | Y | N | P | N |
| Han et al. 2008 | Y | Y | Y | Y | Y | N | Y | N | P | N |
| Han et al. 2013 | Y | Y | Y | Y | Y | N | Y | N | P | N |
| Nguyen et al. 2013 | Y | Y | Y | Y | Y | N | Y | N | P | N |
| Bibars et al. 2018 | Y | Y | Y | Y | Y | N | Y | Y | P | N |
| Polyzois et al. 2011 | Y | Y | Y | Y | Y | N | Y | N | P | N |
| Cifter et al. 2017 | Y | Y | Y | Y | Y | N | Y | N | P | N |
| Hu et al. 2014 | Y | Y | Y | Y | Y | N | Y | Y | Y | Y |
| Goiato et al., 2009 | Y | Y | Y | Y | Y | N | Y | Y | Y | Y |
| dos Santos, DM; et al. 2009 | Y | Y | Y | Y | Y | N | Y | Y | Y | N |
| Al-Harbi, FA; et al. 2015 | Y | Y | Y | Y | Y | N | Y | Y | Y | N |
| Hatamleh, MM; 2016 | Y | Y | Y | Y | Y | N | Y | Y | Y | Y |
| Polyzois, G; 2014 | Y | Y | Y | Y | Y | N | Y | Y | Y | N |
| Hatamleh, MM; 2010 | Y | Y | N | Y | Y | N | Y | Y | Y | N |
| P.N. Eleni et al. 2011 | Y | Y | Y | Y | Y | N | Y | Y | Y | N |
| Eleni, PN; Krokida, M; et al. 2011 | Y | Y | Y | Y | Y | N | Y | Y | Y | N |
| Eleni, PN; et al. 2009 | Y | Y | N | Y | Y | N | Y | Y | Y | N |
| Miranda, NB; et al. 2019 | Y | Y | Y | Y | Y | N | Y | Y | Y | N |
| Eleni, PN; Krokida, MK; et al. 2014 | Y | Y | Y | Y | Y | N | Y | Y | Y | N |
| Eleni, PN; Perivoliotis, D; et al. 2013 | Y | Y | Y | Y | Y | N | Y | Y | Y | Y |
| Eleni, PN; et al. 2014 | N | Y | Y | Y | Y | N | Y | Y | P | N |
| Eleni, PN; Perivoliotis, D; et al. 2013 | Y | Y | Y | Y | Y | N | Y | Y | P | Y |
| Eleni, Panagiota N; et al. 2013 | N | Y | Y | Y | Y | N | Y | Y | P | N |
| Polyzois, GL; et al. 2011 | Y | Y | Y | Y | Y | N | Y | Y | P | N |
| dos Santos DM; et al. 2012 | N | Y | P | Y | Y | N | Y | Y | Y | Y |
| Mancuso DN; et al. 2009 | Y | Y | P | Y | Y | N | N | N | P | N |
| Aziz T; et al. 2003 | Y | Y | P | Y | Y | N | Y | Y | P | N |
| Fernandes, Aline Úrsula Rocha; et al. 2010 | N | Y | P | Y | Y | N | Y | Y | P | N |
| Goiato, Marcelo C, et al. | Y | Y | P | Y | Y | N | Y | P | P | N |
| Goiato, Marcelo Coelho; et al. | Y | Y | P | Y | Y | N | Y | Y | P | Y |
| Goiato, Marcelo Coelho; et al. 2009 | N | Y | P | Y | Y | N | Y | Y | P | Y |
| Guiotti, Aimée Maria; et al. 2010 | N | Y | P | Y | Y | N | N | N | P | N |
| Guiotti, Aimée Maria; et al. 2010 | N | Y | P | Y | Y | N | Y | Y | P | N |
| Gunay, Yumushan; et al. 2008 | Y | Y | P | Y | Y | N | Y | Y | P | N |
| Kiat-amnuay, Sudarat; et al. 2009 | Y | Y | Y | Y | Y | N | Y | Y | P | N |
| Kiat-amnuay, Sudarat; et al. 2005 | Y | Y | P | Y | Y | N | Y | Y | P | N |
| Kiat-amnuay, Sudarat; et al. 2002 | Y | Y | P | Y | Y | N | Y | Y | P | N |
| Mancuso, Daniela Nardi; et al. 2009 | N | Y | P | Y | Y | N | Y | N | P | Y |
| Polyzois, Gregory L; et al. 2000 | Y | Y | P | Y | Y | N | Y | Y | P | N |
| Reis, Ricardo César dos; et al. 2008 | N | Y | P | Y | Y | N | Y | Y | P | N |
| Stathi, K; et al. 2010 | N | Y | Y | Y | Y | N | N | N | P | N |
| Tran, Ngoc H; et al. 2004 | Y | Y | P | Y | Y | Y | Y | Y | P | N |
| Bankoglu, Merve; et al. 2013 | Y | Y | P | Y | N | N | Y | N | P | N |
| Charoenkijkajorn, Dittaya; et al. 2020 | Y | Y | P | Y | Y | N | Y | Y | P | Y |
| Kheur, MG; et al. 2012 | N | Y | P | Y | Y | N | Y | N | P | N |
| M Shihab, Nor; et al. 2018 | N | Y | Y | Y | Y | N | Y | N | P | N |
| Mehta, Siddharth; et al. 2017 | Y | Y | P | Y | Y | N | Y | Y | P | N |
| Nimonkar, Sharayu V; et al. 2020 | Y | Y | P | Y | Y | N | Y | Y | P | N |
| Radey, Nayera S; et al. 2012 | Y | Y | Y | Y | Y | N | Y | Y | P | N |
| Abdullah H.A; et al. 2018 | Y | Y | P | Y | Y | N | Y | N | P | N |
| Hulterstrom A.K; et al. 2008 | N | Y | Y | Y | Y | N | Y | N | P | N |
| Shakir D.A; et al. 2018 | Y | Y | P | Y | Y | N | Y | N | P | N |
| Goiato M.C; et al. 2008 | N | Y | P | Y | Y | N | Y | P | P | N |
| Farah Rashid; et al. 2021 | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y |
| Ceyda B; et al. 2021 | N | Y | Y | Y | Y | N | Y | Y | P | N |

(*continued on next page*)

**Table 2** (*continued*)

| Author names | Item 1 | Item 2a | Item 2b | Item 5 | Item 6 | Item 7 | Item 10 | Item 11 | Item 12 | Item 13 |
|---|---|---|---|---|---|---|---|---|---|---|
| Wen X.C; et al. 2021 | Y | Y | Y | Y | Y | N | Y | Y | P | N |
| Israa E.H; et al. 2021 | Y | Y | Y | Y | Y | N | Y | Y | P | N |
| Natdhana; et al. 2022 | N | Y | P | Y | Y | Y | Y | Y | P | N |
| Bilge T.B; et al. 2021 | Y | Y | Y | Y | Y | N | Y | Y | P | N |
| Ahmed M R; et al. 2022 | Y | Y | Y | Y | Y | N | Y | Y | P | Y |
| Ashika S.M; et al. 2021 | Y | Y | P | Y | Y | N | Y | Y | P | N |
| Aya M F; et al. 2021 | Y | Y | N | Y | N | N | Y | Y | P | N |
| Abha N; et al. 2022 | N | Y | P | Y | Y | N | Y | Y | P | N |
| Mason T. B; 2021 | N | Y | Y | Y | N | N | Y | Y | P | N |
| Nebras F. A; 2022 | N | Y | N | Y | Y | N | Y | Y | P | N |
| Praveen G; 2022 | N | Y | P | Y | N | N | Y | Y | P | N |

**Table 3**
Assessment criteria as per Modified CONSORT [29].

| Assessment criteria | ITEM Number |
|---|---|
| Structured summary | Item 1 |
| Scientific background and rationale | Item 2 a |
| Specific Objectives/ Hypothesis | Item 2 b |
| Sample size determination | Item 5 |
| Sample preparation and analysis | Item 6 |
| Allocation concealment mech | Item 7 |
| Statistical methods | Item 10 |
| Estimated size of the effect and its precision (for example, 95% confidence interval | Item 11 |
| Discussion on trials, potential bias, and imprecision | Item 12 |
| Funding | Item 13 |

**Table 4**
Frequently evaluated properties.

| Properties evaluated | Number of articles |
|---|---|
| Color change/stability | 41 |
| Physical properties alone | 15 |
| Mechanical properties alone | 13 |
| Physical properties and color stability | 4 |
| Optical properties | 3 |
| Dimensional stability | 2 |
| Dynamic Mechanical Thermal properties | 2 |
| Mechanical/ physical properties and color stability | 1 |
| Tensile strength and micro indentation | 1 |
| Lifespan and aftercare of prosthesis | 1 |
| Microbial growth on the prosthesis | 2 |

material. They also affect longevity indirectly via their effect on prosthesis color. Table 1 summarizes 14 studies based on the physical properties of these materials (Table 4). Several authors explored the mechanical properties of these materials, such as tensile strength, micro-indentation, and dynamic mechanical and thermal analysis, in their evaluation of color and dimensional stability. Silicones showed increased roughness after either nonthermal plasma treatment (NTP TT) or accelerated aging. This indicates surface disintegration due to sorption and solubility over an extended period of use because of exposure to environmental influences, body fluids and secretions, and cleansing or disinfecting solutions, causing the material to harden and change color (Table 1)[35–39].

### 3.3. Analysis of qualitative bias for in-vitro studies

Most studies did not report the allocation concealment mechanism (Table 2). Many also failed to mention the techniques of blinding, sample size determination, and randomization. Funding sources are not mentioned in most studies.

Our analysis shows that the most tested and used material was MDX4–4210, followed by A-2186, M511 Maxillofacial Rubber, A-2000, Z004, Cosmesil, and Silastic 732 RTV silicon. The best evidence on MDX4–4210 suggests color instability relative to Silastic 732 RTV, but adding ceramic pigment and opacifiers can increase the color stability.

The following observations were made from our qualitative review. Both the acrylic-based and silicone-based extraoral maxillofacial prosthesis need replacement after 1.5 to 2 years. For both acrylic and silicone-based materials, the colour instability was the primary reason for requiring change. For silicone-based materials, apart from the color change, the physical and mechanical properties are altered by the constant use of weathering and cleansing materials. Many authors observed that adding white titanium and nano oxide pigments and not using yellow pigments could increase color stability. The fabrication technique using blue or green dental stone was favoured over the reddish-brown dental stone as it tended to cause color instability in silicone-based materials. Amongst the cleansing materials, chlorhex 2% and sodium hypochlorite showed better color stability. The tear strength increased using rayon flocking, and edge strength increased with tulle incorporation.

The limitation includes the fact that microbial growth is observed on surfaces of silicones. The reasons cited are sebum, outdoor weathering, acidic perspiration, and chemicals used to clean and disinfect silicones, which can cause hardening and increase surface roughness. Only a few articles have been published on the microbial growth of different extraoral silicone materials. Hence, future research is required to confirm how surface properties and microbial adhesions can be decreased, what material to use, and how the shelf life of extraoral prosthesis can be enhanced.

## 4. Discussion

The types of material used for extraoral prosthesis are evaluated by their processing properties and physical, mechanical, and biological properties [40,41]. This review focuses on the longevity of prostheses and, therefore, includes only studies related to the mechanical, physical, and biological properties of such materials. The survey indicates a strong preference for silicone products vulcanized at room temperature and intrinsically colored with dry pigments and artist's oils to fabricate extraoral prostheses [42].

Our review indicates that most studies use silicone as an extraoral prosthesis material, which agrees with earlier reports [43,44]. Among the silicone prosthesis materials covered by our review, MDX4–4210 was the most studied, followed by A-2186, M511 Maxillofacial Rubber, A-2000, Z004, Cosmesil, and Silastic 732 RTV silicon. Color stability, the key to the cosmetic aspect of extraoral prosthetic materials, was the most common area of interest. In the present review, 30 articles explored color changes in extraoral prosthetic material. According to the literature review by Rahman et al., many researchers have examined color changes in silicone without aging, after artificial aging, or after outdoor weathering [26]. Overall, silicone elastomers are affected by the environment and by constant use. It may be concluded that the ideal silicone material that can retain its color beyond two years is yet to be developed [45]. Al Dharrab et al. observed that storage conditions can affect silicone elastomers' physical and mechanical properties. Their report demonstrates the superior stability of M511 elastomers under varying storage conditions compared to the maxillofacial silicone system, HT platinum rubber, and medical grade Technovent [46]. Many authors recommended using tulle to increase silicone materials' edge strength [20,47].

Our review shows color stability to be the research focus of most studies, followed by the physical and mechanical properties of various silicone elastomers. There was a dearth of studies on aftercare effects and microbial growth on silicone elastomers. Only two studies reported these prostheses' mean life span and microbial growth incidence on the prostheses, respectively (Table 1). The literature indicates that the average lifespan of the prosthesis extends from a minimum of 6–12 months to a maximum of 24 months[25,11,48].

Color deterioration is observed to adversely affect the longevity of silicone prostheses, posing the most significant challenge in this field. Color changes mainly occur in three stages. The first point is the manipulation of the material, with color change depending on the type of pigments, technique of pigmentation, and the material used [49,50]. Secondly, the vulcanization procedures may alter the color, varying with the choice of mold and curing technique. Finally, the color may change during aftercare because of exposure to sweat, environmental conditions, and soap or other cleansing solutions [17,51].

The most excellent color stability and longevity were observed with intrinsic coloration using ceramic colorants [52]. Another study shows more significant discoloration with extrinsic compared to intrinsic pigmentation [53]. Some studies report titanium white pigment's beneficial effect on silicone's colour stability under UV exposure [54]. Among the various pigments, yellow silicone showed the greatest discoloration [55]. Studies simulating the color change in a lipid medium like sebum showed lipid absorption by the silicone prosthesis, with accelerated degradation and decreased longevity [11,56]. Hence, silicone prostheses have lower longevity in hot and humid climates [52]. Several studies also report color changes during the aftercare period following exposures to disinfecting solutions such as soap, peroxide, and chlorhexidine gluconate [57,58,5].

The present analysis indicates MDX4–4210 to be the most frequently used and studied material, followed by A-2186, M511 Maxillofacial Rubber, A-2000, Z004, Cosmesil, and Silastic 732 RTV silicon. Despite its high frequency of use, MDX4–4210 is less color-stable than Silastic 732 RTV and A-2000 (Table 1). This may be corrected by adding ceramic pigments and nano zinc oxides [59]. According to a survey by Markt et al., colour instability was the most common factor associated with reduced longevity [60]. Andres et al., in their survey report, indicated that MDX4–4210 is a material preferred and used by 41% of clinicians [61,62]. Dorsey et al. conducted a study on MDX4–4210, concluding that it had good tear resistance and was softer than Silastic 382, with no reaction by-products. It had adequate tear strength and edge strength without the need to add reinforcement materials. MDX4–4210 also possesses hardness similar to human skin and is amenable to a thin-edge design due to its tear resistance. The present review corroborates earlier reports on MDX4–4210, the most thoroughly studied material [63].

The following observations were made from our qualitative review. Both the acrylic-based and silicone-based extraoral maxillofacial prosthesis need replacement after 1.5 to 2 years. For both acrylic and silicone-based materials, the colour instability was the primary reason for requiring change. For silicone-based materials, apart from the color change, the physical and mechanical properties are altered by the constant use of weathering and cleansing materials. Many authors observed that white titanium and nano oxide pigments and not using yellow pigments could increase color stability. The fabrication technique using blue or green dental stone was favored over the reddish-brown dental stone as it tended to cause color instability in silicone-based materials. Amongst the cleansing materials, chlorhex 2% showed better color stability. The tear strength increased using rayon flocking, and edge strength increased with tulle incorporation.

The limitation includes that microbiological studies were few and need more research to identify if they affect skin contact in any way.

## 5. Conclusion

- ✓ Silicones are the most frequently used extraoral maxillofacial prosthetic materials compared to acrylic-based materials.
- ✓ Heat-cured silicones show superior color stability compared to those cured at room temperature.
- ✓ Intrinsic pigmentation, using molds of the correct color, and proper processing techniques promote the longevity of the prosthesis.
- ✓ White-coloured pigments and nano-oxides enhance color stability even after weathering without compromising the physical and mechanical properties.
- ✓ Tulle incorporation increased the edge strength of the silicone prosthesis.
- ✓ Proper maintenance can ensure increased shelf life by protecting the prosthesis from harsh environments and using mild disinfectants.

## Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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