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SYSTEMATIC REVIEW

Evaluation of methodologies and additive efficacy on maxillofacial color longevity research: A systematic review and meta-analysis

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ABSTRACT

Statement of problem. The lifespan of maxillofacial silicone elastomer-based prostheses can be as short as 6 months, primarily because of sunlight-induced color degradation. Efforts to enhance color stability have led to incorporating additives that include nanoparticles, opacifiers, and ultraviolet (UV) blockers. However, variability in testing methods and the absence of standardized protocols have led to inconsistent findings, underscoring the need for uniform testing to evaluate the color stability of these materials effectively.

Purpose. The purpose of this systematic review and meta-analysis was to assess the methodologies used in maxillofacial color longevity research and to synthesize findings on the effectiveness of additives in enhancing the color stability of pigmented silicone formulations exposed to solar radiation.

Material and methods. This systematic review, adhering to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines, evaluated the impact of additives on color stability under solar radiation. Searches across PubMed, Web of Science, Embase, Scopus, and Cochrane databases (up to October 2024) followed the Population, Intervention, Comparator, Outcomes (PICO) criteria, limited to English-language studies. Articles were evaluated using a modified Consolidated Standards of Reporting Trials (CONSORT) guideline and quality-assessed with the Newcastle-Ottawa Scale, with high-quality studies (scoring 6 to 9) eligible for meta-analysis. A random-effects model in the RevMan Web tool was used, with heterogeneity assessed via the I^2 test and results presented in forest plots with 95% confidence intervals.

Results. A lack of standardized protocols persists in methodologies concerning specimen dimensions and pigmentation formulations, despite established weathering methods for both outdoor and artificial conditions. The meta-analysis demonstrated consistent improvements in color stability with additives under artificial weathering ($P<.001$), while no significant improvement was observed during a 3-month period of outdoor weathering ($P=.120$). High heterogeneity across studies was observed, largely associated with variability in silicone pigmentation formulations.

Conclusions. Additives including nanoparticles, opacifiers, and UV blockers enhance the color stability of maxillofacial prostheses; however, the inherent stability of pigments remains a critical factor. Future research should focus on developing standardized testing methods tailored to maxillofacial applications, ensuring representativeness for prostheses and accounting for silicone formulation parameters relative to UV penetration. (J Prosthet Dent xxxx;xxx:xxx-xxx)

The application of silicone elastomers in the field of maxillofacial prosthetics was first introduced in 1960 by Barnhart.[1] Since then, silicone has become the favored material for extraoral facial prostheses because of its ease of manipulation with pigments, mechanical properties, and biocompatibility.[2,3] Despite these advantages, a

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Clinical Implications

This review emphasized the necessity of standardized testing protocols to advance maxillofacial prosthesis research while identifying critical parameters influencing color stability. Clinicians should prioritize materials with demonstrated UV resistance to reduce discoloration and enhance prosthesis longevity. Advancements in material testing and formulation development are essential to improving patient outcomes and decreasing the frequency of prosthesis replacement.

major limitation of silicone-based prostheses is the lack of longevity associated with the degradation of colorants that are either embedded intrinsically or extrinsically applied over the base silicone material.[4–6] The lifetime of a prosthesis has been typically reported to be between 6 and 18 months, and discoloration is the primary reason for replacement.[7–9] Hence, it is crucial for maxillofacial prostheses to maintain color stability over extended periods not only for esthetic purposes and patient satisfaction but also to reduce the time and costs associated with prosthesis replacement.

Color degradation can be caused by factors that include exposure to cleaning agents, sunlight and climatic conditions, dust, smoking, human body secretions, and oils.[10–15] The most significant environmental factor has been reported to be solar radiation, particularly ultraviolet (UV) light within the 100- to 400-nm range, which induces photo-oxidative stress.[16,17] Polymer molecules and certain pigments are highly vulnerable to UV light, and the absorption of photons leads to the photodegradation and fragmentation of the molecule, causing a change in the molecule's shape that cannot be reversed.[18]

Demand for improved color stability has led researchers to incorporate additives including nanoparticles, opacifiers, and UV blockers into silicone formulations to enhance resistance against UV-induced discoloration.[19–40] Nanoparticles, smaller than the wavelengths of UV light, scatter and absorb UV radiation, forming a barrier that limits energy transfer to pigments and prevents bond cleavage and color loss.[24,41] Opacifiers such as titanium dioxide (TiO_2) and zinc oxide (ZnO) have been reported to increase opacity, restrict UV penetration, and confine photodegradation to surface layers, preserving deeper material integrity.[42] UV blockers operate via stabilization or absorption: hindered amine light stabilizers (HALSs) neutralize free radicals, while UV absorbers like benzophenones convert UV radiation into heat, mitigating photodegradation.[43]

The effects of additives on color stability have been evaluated through both in vitro artificial aging tests and outdoor exposure experiments designed to simulate a range of climatic conditions by varying temperature and humidity.[25,35,39,40,44] However, significant variability across maxillofacial silicones,[19,45] the polymerization process (room-temperature vulcanized (RTV) and high-temperature vulcanized silicones (HTV)),[20,21] pigment colors and sourcing,[39,44] specimen dimensions,[13,46] and weathering procedures[47–52] have been reported. This diversity, combined with the absence of unified testing protocols for assessing color stability and the lack of adherence to standards for both measurement and pigment selection,[53–55] has resulted in significant discrepancies in reported findings.

This systematic review and meta-analysis aimed to evaluate the methodologies used in maxillofacial color longevity research and to synthesize evidence by grouping studies with comparable experimental circumstances to assess the effectiveness of additives in enhancing the color stability of pigmented silicone formulations exposed to solar radiation. The research hypothesis was that sufficient statistical evidence would be found to determine whether incorporating these additives would improve resistance to solar radiation-induced color degradation.

MATERIAL AND METHODS

This systematic review was conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines.[56] The systematic search strategy is detailed in Table 1. Eligibility criteria were based on the Population, Intervention, Comparator, and Outcomes (PICO) framework. Searches were conducted across 5 databases: PubMed (All Fields), Web of Science Core Collection (Topic search), Embase Ovid (Multi-Field), Scopus (Title-Abs-Key), and Cochrane (Title-Abs-Key). No restrictions on publication date were applied, and studies published before November 2024 were considered eligible. Results from each database were imported into a software program (Endnote 20; Clarivate Analytics) where duplicates were removed both automatically and manually. Two independent reviewers (S.H.C., K.C.) screened titles and abstracts, retrieving full texts for potentially relevant studies. Full texts were then independently assessed by the same reviewers based on predefined inclusion and exclusion criteria, with excluded studies documented alongside reasons for exclusion. As tristimulus colorimeters have been reported to be unsuitable for high-accuracy absolute color measurements,[57] studies based on colorimeter measurements were excluded.

The search strategy included review papers, ensuring comprehensive coverage of the literature and minimizing the risk of duplication or the omission of relevant studies that could inform the current systematic review.

Table 1. Systematic search strategy used

Population (P)	All studies that examined the color stability of maxillofacial silicones under exposure to solar radiation, including both in vitro simulations and real-world outdoor conditions.
Intervention (I)	Testing groups with incorporation of various additives into maxillofacial silicone elastomers (i.e. nano- and micro-particles, sunscreens, UV stabilizers, absorbers, and opacifiers) to enhance color longevity.
Comparison (C)	Control groups examining formulation parameters, evaluated prior to aging through either in vitro artificial methods or natural weathering processes.
Outcomes (O)	Evaluation of methodologies employed in the included studies, with a focus on specimen details (dimensions and materials) and specified weathering conditions. Evaluation of formulation additives for their impact on color longevity.
Search terms	(((((silicone*) AND (colorant* OR pigment* OR dye*)) AND (weather* OR aging OR aged OR longevity OR color AND stability OR degradation)) AND (face OR facial OR maxillofacial OR prosthe* OR extraoral OR auricular OR ear OR nasal OR nose)) AND (nano* OR micro* OR particle* OR coat* OR sunscreen* OR block* OR protect* OR stabilizer* OR absor* OR opacifier*))
Databases accessed	PubMed, Web of Science Core Collection, Embase Ovid, Scopus and Cochrane
Inclusion criteria	Experimental studies and relevant review papers Color difference assessed using ΔE Specimens exposed to radiation including the UV spectrum
Exclusion criteria	Non-English language studies Inadequate information regarding weathering methodology Color measurement instruments other than spectrophotometers or spectroradiometers to ensure methodological consistency Unspecified model of color measurement instrument

Additionally, any study identified as relevant to the research question through the review papers but not retrieved in the initial database searches was added as an additional source using a reference mining approach.

Included articles were evaluated using a modified Consolidated Standards of Reporting Trials (CONSORT) guideline adapted for in vitro studies on dental materials.[58] As CONSORT was initially designed for randomized controlled trials (RCTs), certain criteria were inapplicable to these experimental studies, specifically items 6, 7, 8, 9, and 14. Items related to randomization, allocation concealment, personnel involvement, and blinding were excluded, as predefined groups and controlled conditions reduced the relevance of assessor bias. Screening parameters were categorized as either "yes" or "no" across 10 items, with 0 to 3 affirmative responses considered high risk of bias, those with 4 to 6 as unclear risk, and those with 7 to 10 as low risk.

Eligibility for inclusion in the meta-analysis was assessed by using the Newcastle-Ottawa Scale (NOS) for case-control studies.[59] The assessment checklist included predefined criteria for selection and exposure, while the comparability section required tailored scoring aligned with the study objectives. In this section, a score was awarded for part 1a only if the study included a testing group without the additive component, with other formulation aspects consistent with the additive-containing (intervention) groups. This additive-free group functioned as the control, enabling an analysis of the additive's impact on color stability as a secondary outcome measure. Studies scoring 0 to 2 were classified as poor quality, 3 to 5 as moderate, and 6 to 9 as high, with only high-quality studies eligible for meta-analysis. Both the modified CONSORT and NOS assessments were performed independently by a primary reviewer (S.H.C.) and verified by a secondary reviewer (K.C.), with interrater reliability evaluated via the Cohen kappa coefficient.

A meta-analysis was conducted using a random effects model in a software program (RevMan Web; The Cochrane Collaboration). Study groups were categorized based on the methodologies implemented. Heterogeneity among studies was assessed with the I^2 test, with values above 50% indicating considerable heterogeneity. Forest plots with 95% confidence intervals (Z test) were generated to display the meta-analysis results.

RESULTS

The literature selection process, detailed in a flow diagram (Fig. 1), identified 250 records, of which 52 were selected for full-text review. This process ultimately resulted in 28 studies being included in the qualitative synthesis. Table 2 outlines the experimental studies excluded after the full-text review,[60–76] along with the reasons for exclusion, while Table 3 provides a summary of the purpose and key findings of the determined review papers.[77–82] Full access to 1 review[83] was unavailable. A high level of agreement was observed between the 2 reviewers in their assessments (Cohen kappa=.947, $P<.001$).

The assessment using a modified CONSORT checklist showed that all met CONSORT items 1, 2a, 2b, 3, and 10. However, none fully addressed items 11 and 12 (Table 4). Item 11 was unmet because of the absence of effect size and confidence intervals, as outcomes were generally reported as mean ±standard deviation, which does not indicate study precision. None of the studies thoroughly examined potential sources of bias, and thus item 12, which addresses study limitations, was not fulfilled. Although none of the studies were rated as high risk of bias, most were classified as unclear, with 6 studies exhibiting low risk.

In accordance with the specimen details provided in the studies (Table 5), the most commonly used specimen

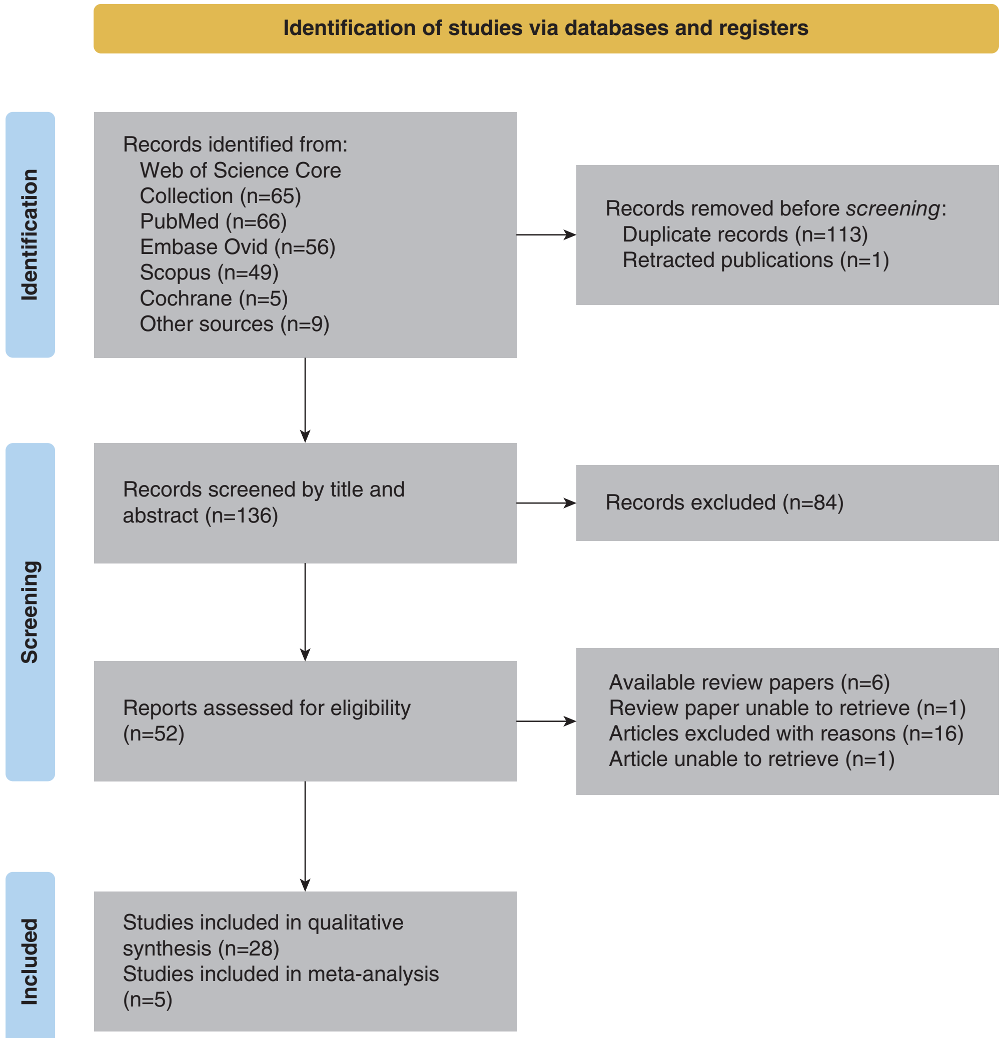


Figure 1. Preferred reporting items for systematic reviews and meta-analyses (PRISMA) flow diagram of the study selection process.

form was disk-shaped (86%), followed by sheet form (11%). The base area of the specimens ranged considerably, from as small as Ø5 mm for disk-shaped specimens to as large as 70×50 mm for sheet specimens.[30,45] The most common specimen thickness was 2 mm (61%), followed by 6 mm (18%). None of the studies referred to a suitable standardized method or provided justification for its representativeness in the context of maxillofacial prostheses. Only 1 study[13] referenced the International Organization for Standardization (ISO) 4823 standard,[46] for elastomeric impression materials that primarily addresses mechanical properties rather than color stability.

In terms of weathering methodologies, 6 studies used outdoor weathering tests and 24 used artificial weathering, with 2 studies[14,19] conducting both. The American Society for Testing and Materials (ASTM) G7 standard[51] was referenced by 3 studies,[19,21,38] 2 studies[19,38] also cited ASTM E782,[50] whilst the remaining 2 studies[29,39] did not follow a specific standard. Many studies referenced a standard method for artificial weathering (67%). Seven studies (29%)[6,19,20,22–24,28] used Society of Automotive Engineers (SAE) J1960[48] or cited the corresponding paper, 6 papers (25%)[13,26,27,30,33,34] used ASTM G53,[47] 2 studies[31,32] used ASTM G154[52] and 1 study[35] used ISO 4892–2.[49] Among the 8 studies that did not follow standard methods, 4 mentioned UV light without specifying the lamp type. Additionally, 79% of artificial weathering studies detailed thermal settings, such as black panel temperature or humidity.

Using the modified NOS scale, none of the studies were classified as low quality, with scores ranging from 4 to 8 (Table 4). A total of 13 studies were classified as high quality (score 6 to 9) and were eligible for inclusion in the meta-analysis. Among these, 5 studies tested groups with and without the examining additive and could be categorized based on methodological

Table 2. Articles excluded after full-text review with reasons

Author and Year	Title	Reason(s) for Exclusion
Verma et al 2003[60]	The color stability of maxillofacial elastomers in combination with UV inhibitors	Full text could not be obtained
Stathi et al 2010[61]	The effect of accelerated ageing on performance properties of addition type silicone biomaterials	Use of colorimeter for color measurement
Vasilakos and Tarantili 2010[62]	The effect of pigments on the stability of silicone/montmorillonite prosthetic nanocomposites	Use of colorimeter for color measurement
Hatamleh and Watts 2011[63]	Porosity and color of maxillofacial silicone elastomer	Use of colorimeter for color measurement
Kheur et al 2016[64]	Evaluation of the effect of ultraviolet stabilizers on the change in color of pigmented silicone elastomer: An in vitro study	Use of colorimeter for color measurement
Kheur et al 2017[65]	Effect of newly developed pigments and ultraviolet absorbers on the color change of pigmented silicone elastomer	Use of colorimeter for color measurement
Babu et al 2018[66]	Effect of chemical disinfectants and accelerated aging on maxillofacial silicone elastomers: An in vitro study	Appropriate color space not used
Bunyan and Abood 2019[67]	Color changes in dry pigmented tech-Sil25 maxillofacial elastomer after artificial weathering	Appropriate color space not used
Sonnahalli and Chowdhary 2020[68]	Effect of adding silver nanoparticle on physical and mechanical properties of maxillofacial silicone elastomer material-an in-vitro study	Inadequate detail regarding outdoor weathering method Model of spectrophotometer unspecified
Mohan et al 2021[69]	Effect of particle size of nano-oxides on color stability and mechanical properties of maxillofacial silicone elastomers: an in vitro study	Appropriate color space not used Model of spectrophotometer unspecified
Papachristou et al 2022[70]	Titanium dioxide/polysiloxane composites: preparation, characterization and study of their color stability using thermochromic pigments	Use of colorimeter for color measurement
Al-Kadi et al 2023[71]	Hybrid chitosan–TiO_2 nanocomposite impregnated in type A–2186 maxillofacial silicone subjected to different accelerated aging conditions: an evaluation of color stability	Use of colorimeter for color measurement
Abdalqadir et al 2023[72]	The impact of zirconium dioxide nanoparticles on the color stability of artificially aged heat-polymerized maxillofacial silicone elastomer	Use of colorimeter for color measurement
Mohammed et al 2023[73]	Influence of silver nanoparticles on color stability of room-temperature-vulcanizing maxillofacial silicone subjected to accelerated artificial aging	Use of colorimeter for color measurement
Abdalqadir and Azhdar 2023[74]	Zirconium dioxide nanoparticles effect on the color stability of maxillofacial silicone after outdoor weathering	Use of colorimeter for color measurement
Bugden 2023[75]	An investigation of the effects of topical sunscreen protection products under natural weather conditions on intrinsic color stability in maxillofacial silicones	Use of colorimeter for color measurement[a]
Gopika et al 2023[76]	Effect of titanium dioxide nanocoating on the color stability of room temperature vulcanizing maxillofacial silicone—an invitro study	Weathering method employed simulates only temperature and humidity aspects of environmental aging Model of spectrophotometer determined from image not text

TiO_2, titanium dioxide.

[a] Authors note that spectrophotometric data deemed unusable because of technical issues.

similarities. Studies that did not meet these criteria were excluded with reasons (Table 6).

The meta-analysis was conducted across 4 groups, each coded by weathering type (O for outdoor, A for artificial) and duration (months for outdoor, hours for artificial). The O3 group involved outdoor weathering for 3 months with specimens 2 to 2.4 mm thick and additive concentrations of 0.75% to 1% by weight.[21,39] The 3 artificial weathering groups used 2-mm thick specimens but varied in duration and additive concentrations: A300 (252 to 300 hours, 0.2% to 0.5%),[27,37] A600 (504 to 600 hours, 0.2% to 0.5%),[27,37] and A1000 (1000 to 1008 hours, 0.2% to 1%).[27,36] Forest plots were generated for all groups (Figs. 2–5). No statistical difference in color stability was observed with additives after 3 months of outdoor weathering (P=.120). In contrast, studies involving artificial weathering consistently demonstrated improved color longevity in pigmented silicone groups with additives (P<.001). Among the additives evaluated, ethylhexyl salicylate (UV-ES) at 0.5% by weight showed the most notable improvements in color longevity, as reflected by mean difference values,[37] but the degree of color stability enhancement was dependent on pigment color and sourcing. All groups exhibited high heterogeneity ($I^2 \geq 96\%$), reflecting significant variability in outcome measures.

DISCUSSION

The research hypothesis, that sufficient statistical evidence exists to demonstrate that incorporating these additives improves resistance to solar radiation-induced color degradation, was rejected based on outdoor weathering data over a 3-month period. However, the hypothesis was supported by all outcomes obtained from artificial weathering tests, which ranged from 252 to 1008 hours of aging, suggesting that both the type of aging with an adequate duration are critical factors for detecting statistically significant improvements.

Seven reviews on the color stability of maxillofacial silicones had been published prior to this review, though full

Table 3. Summary of existing review papers

Author and Year	Title of Review	Purpose and Key Findings
Kulkarni and Nagda 2014[77]	Color stability of maxillofacial silicone elastomers: A review of the literature	Laid foundation for series of reviews by summarizing existing literature on color stability of maxillofacial silicones, focusing on various weathering conditions, effect of disinfectants and body secretions, and additives that have been investigated. Provides broad overview, highlighting general trends in research and underscoring need for standardized testing protocols to facilitate more reliable comparisons between studies.
Sonnahalli and Chowdhary 2020[78]	Effect of nanoparticles on color stability and mechanical and biological properties of maxillofacial silicone elastomer: A systematic review	Evaluated effects of nanoparticles on mechanical, biological, and color stability properties of maxillofacial silicone elastomers. Key findings indicated that nanoparticles such as TiO_2, ZnO, and CeO_2 can significantly enhance color stability and mechanical properties (hardness and tensile strength) of maxillofacial silicone elastomers.
Gupta et al 2021[79]	The color stability of maxillofacial silicones: A systematic review and meta analysis	Summarized types of silicone used, categorizing them as either RTV or HTV, and cataloged exposure and experimental conditions across different studies. Additionally, investigated effects of incorporating nanoparticles like TiO_2 on color stability of maxillofacial silicones. Findings suggested that addition of TiO_2 enhanced color stability by mitigating environmental effects. Achieving ideal solution challenging because of variability in weathering durations and differing intervals of color measurements, which complicate direct comparisons between studies.
Rashid et al 2021[80]	Factors affecting color stability of maxillofacial prosthetic silicone elastomer: A systematic review and meta-analysis	Presented comprehensive review, summarizing various factors that contribute to color degradation of maxillofacial silicones. Review placed particular emphasis on studies that explored use of TiO_2 as strategy for improving color stability. Meta-analysis included in review concluded that incorporating TiO_2 at concentrations ranging from 5% to 15% by weight can significantly enhance color stability of maxillofacial silicones. Noted that optimal concentration of TiO_2 dependent on specific pigment color used, suggesting that tailored approach necessary to achieve best results for different silicone formulations.
Daivasigamani et al 2021[81]	Color stability of maxillofacial silicone materials after disinfection and aging procedures A systematic review	Presented focused examination of impact of various disinfectant solutions on color stability of maxillofacial silicones. Identified that common disinfectants could alter silicone properties, and nano-enhancements, such as TiO_2, contribute to improved durability, essential for maintaining esthetic quality of prostheses during routine hygiene care. Review noted that discoloration continues to limit clinical lifespan of prostheses to approximately 1 year.
Annamma et al 2024[82]	Frequently used extraoral maxillofacial prosthetic materials and their longevity – A comprehensive review	Evaluated durability and functionality of materials used in facial prosthetics, with focus on factors affecting longevity, including environmental conditions and processing techniques. Findings indicated that HTV silicone-based materials exhibit greater color stability, and that modifications using white pigments (primarily TiO_2) or nano-oxides can enhance material longevity.

CeO_2, cerium oxide; HTV, high-temperature vulcanized; RTV, room-temperature vulcanized; TiO_2, titanium dioxide; ZnO, zinc oxide.

Table 4. Characteristics of included studies with risk of bias evaluated using modified CONSORT and study quality measured using NOS criteria

Study	Modified CONSORT Guideline Items[a] and Overall Risk of Bias											NOS
Author and Year	1	2a	2b	3	4	5	10	11	12	13	Overall	Score
Lemon et al 1995[19]	Yes	Yes	Yes	Yes	No	No	Yes	No	No	Yes	Unclear	4
Beatty et al 1999[16]	Yes	Yes	Yes	Yes	No	No	Yes	No	No	Yes	Unclear	5
Kiat-amnuay et al 2002[20]	Yes	Yes	Yes	Yes	No	No	Yes	No	No	Yes	Unclear	6
Tran et al 2004[21]	Yes	Yes	Yes	Yes	No	No	Yes	No	No	Yes	Unclear	8
Kiat-amnuay et al 2006[22]	Yes	Yes	Yes	Yes	No	No	Yes	No	No	Yes	Unclear	5
Kiat-amnuay et al 2009[23]	Yes	Yes	Yes	Yes	No	No	Yes	No	No	Yes	Unclear	6
Mancuso et al 2009[45]	Yes	Yes	Yes	Yes	No	No	Yes	No	No	Yes	Unclear	5
Han et al 2010[24]	Yes	Yes	Yes	Yes	No	No	Yes	No	No	Yes	Unclear	5
Pesqueira et al 2011[13]	Yes	Yes	Yes	Yes	No	No	Yes	No	No	Yes	Unclear	5
Goiato et al 2011[25]	Yes	Yes	Yes	Yes	Yes	No	Yes	No	No	No	Unclear	5
Haddad et al 2011[26]	Yes	Yes	Yes	Yes	Yes	No	Yes	No	No	No	Unclear	6
dos Santos et al 2011[27]	Yes	Yes	Yes	Yes	No	No	Yes	No	No	Yes	Unclear	8
Han et al 2013[28]	Yes	Yes	Yes	Yes	No	No	Yes	No	No	Yes	Unclear	6
Pinheiro et al 2014[14]	Yes	Yes	Yes	Yes	Yes	No	Yes	No	No	Yes	Low	5
Akash and Guttal 2015[29]	Yes	Yes	Yes	Yes	No	No	Yes	No	No	Yes	Unclear	7
Guiotti et al 2016[30]	Yes	Yes	Yes	Yes	No	No	Yes	No	No	Yes	Unclear	5
Cevik and Yildirim-Bicer 2018[44]	Yes	Yes	Yes	Yes	Yes	No	Yes	No	No	Yes	Low	5
Bishal, Wee, Barao, et al 2019[31]	Yes	Yes	Yes	Yes	No	No	Yes	No	No	Yes	Unclear	6
Charoenkijkajorn and Sanohkan 2020[32]	Yes	Yes	Yes	Yes	No	No	Yes	No	No	Yes	Unclear	8
dos Santos et al 2020[33]	Yes	Yes	Yes	Yes	Yes	No	Yes	No	No	Yes	Low	6
Paulini et al 2020[34]	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No	Yes	Low	5
Bates et al 2021[35]	Yes	Yes	Yes	Yes	No	No	Yes	No	No	Yes	Unclear	5
Zarrati et al 2022[36]	Yes	Yes	Yes	Yes	No	Yes	Yes	No	No	Yes	Low	7
Turhan Bal et al 2023[37]	Yes	Yes	Yes	Yes	No	No	Yes	No	No	Yes	Unclear	8
Mahale et al 2023[38]	Yes	Yes	Yes	Yes	No	No	Yes	No	No	Yes	Unclear	5
Bankoğlu Güngör et al 2023[39]	Yes	Yes	Yes	Yes	No	No	Yes	No	No	Yes	Unclear	7
Kiat-amnuay et al 2023[6]	Yes	Yes	Yes	Yes	No	No	Yes	No	No	Yes	Unclear	5
Alkahtany et al 2023[40]	Yes	Yes	Yes	Yes	Yes	No	Yes	No	No	Yes	Low	6

CONSORT, Consolidated Standards of Reporting Trials; NOS, Newcastle-Ottawa Scale.

[a] Items considered: (1) Structured summary of trial design, methods, results and conclusions, (2a) scientific background and explanation of rationale, (2b) specific objectives and/or hypothesis, (3) the intervention of each group, including how and when it was administered, with sufficient detail to enable replication, (4) completely defined, prespecified primary and secondary measures of outcome, including how and when they were assessed, (5) how the sample size was determined, (10) statistical methods used to compare groups for primary and secondary outcomes, (11) for each primary and secondary outcome, results for each group, and the estimated size of the effect and its precision, (12) trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses, and (13) sources of funding and other support.

Table 5. Summary of specimen details and weathering methodologies from included studies

Study	Specimen		Weathering Methodology	
Author and Year	Form and Dimension[a]	Silicone (RTV or HTV)[b]	Setting and Interval	Standards and Conditions
	Sheet 60×45×2.4	MDX4–4210 (RTV)	Outdoor; 150, 300 and 450 kJ/m^2 Artificial; 150, 300 and 450 kJ/m^2	ASTM G7[51] and ASTM E782[50] Monthly average climate data not provided; however, noted that peak radiation levels in Florida during summer months can reach 1.0 W/m^2 at 340 nm. SAE J1960[48] Xenon arc (0.55 W/m^2 at 340 nm) Aging cycle consists of 40 min of light exposure only, 20 min of light exposure with front spray, 60 min of light exposure only, and 60 min of darkness with back spray. During light phases, black panel temperature maintained at 70 ±3 °C with relative humidity of 50 ±5%. In dark phases, temperature set to 38 ±3 °C with relative humidity of 95 ±5%.
Beatty et al 1999[16]	Disk Ø12.5×2	A–2186 (HTV)	Artificial; 400, 600 and 1800 h	Condition 1: Specimens exposed to UV-A radiation (320 to 400 nm) Condition 2: Specimens exposed to UV-B radiation (290 to 315 nm)
Kiat-amnuay et al 2002[20]	Disk Ø22×2	A–2000 (RTV)	Artificial	Details of weathering method not specified in text. Reference is made toLemon et al, 1995,[c,19] with authors affiliated with University of Texas Dental Branch at Houston.
Tran et al 2004[21]	Sheet 57×50×2.4	A–2186 (HTV)	Outdoor; 49.22 MJ/m^2 for Phoenix and 55.87 MJ/m^2 for Miami (295 to 385 nm)	ASTM G7[51] Average climate data and radiation during weathering period provided. Weathering locations cited include Phoenix, from November 2, 2001, to February 2, 2002, and Miami, from November 8, 2001, to February 5, 2002.
Kiat-amnuay et al 2006[22]	Disk Ø22×2	MDX4–4210 (RTV)	Artificial; 150, 300 and 450 kJ/m^2	SAE J1960[48] Xenon arc (0.55 W/m^2 at 340 nm) Aging cycle consists of 40 min of light exposure only, 20 min of light exposure with front spray, 60 min of light exposure only, and 60 min of darkness with back spray. During light phases, black panel temperature maintained at 70 ±3 °C with relative humidity of 50 ±5%. In dark phases, temperature set to 38 ±3 °C with relative humidity of 95 ±5%.
Kiat-amnuay et al 2009[23]	Disk Ø22×2	A–2000 (RTV)	Artificial; 150, 300 and 450 kJ/m^2	SAE J1960[48] Xenon arc (0.55 W/m^2 at 340 nm) Aging cycle consists of 40 min of light exposure only, 20 min of light exposure with front spray, 60 min of light exposure only, and 60 min of darkness with back spray. During light phases, black panel temperature maintained at 70 ±3 °C with relative humidity of 50 ±5%. In dark phases, temperature set to 38 ±3 °C with relative humidity of 95 ±5%.
Mancuso et al 2009[45]	Sheet 70×50×2	MDX4–4210 and Silastic 732 (RTV)	Artificial; 163, 351, 692 and 1000 h	Periods of alternating UV light and condensation of distilled water under heat and 100% humidity. Aging cycle includes 8 h of UV light to irradiate specimens at temperature of 60 ±3 °C, followed by 4 h of condensation without light at 45 ±3 °C.
Han et al 2010[24]	Disk Ø22×2	A–2186 (RTV)	Artificial; 150, 300 and 450 kJ/m^2	SAE J1960[48] Xenon arc (0.55 W/m^2 at 340 nm) Aging cycle consists of 40 min of light exposure only, 20 min of light exposure with front spray, 60 min of light exposure only, and 60 min of darkness with back spray. During light phases, black panel temperature maintained at 70 ±3 °C with relative humidity of 50 ±5%. In dark phases, temperature set to 38 ±3 °C with relative humidity of 95 ±5%.
Pesqueira et al 2011[13]	Disk Ø30×6[d]	MDX4–4210 (RTV)	Artificial; 252, 504, and 1008 h	ASTM G53–96[47] UV-B lamp Aging cycle included 8 h of UV light to irradiate the specimens at temperature of 60 ±3 °C, followed by 4 h of condensation without light at 45 ±3 °C.
Goiato et al 2011[25]	Disk Ø30×3	A–2000 (RTV)	Artificial; 252, 504, and 1008 h	Periods of alternating UV light and condensation of distilled water under heat and 100% humidity. Aging cycle includes 8 h of UV light to irradiate specimens at temperature of 60 ±3 °C, followed by 4 h of condensation without light at 45 ±3 °C.
Haddad et al 2011[26]	Disk Ø30×6	MDX4–4210 (RTV)	Artificial; 252, 504, and 1008 h	ASTM G53–96[47] UV-B exposure Aging cycle includes 8 h of UV light to irradiate specimens at temperature of 60 ±3 °C, followed by 4 h of condensation without light at 45 ±3 °C.
dos Santos et al 2011[27]	Disk Ø45×2	MDX4–4210 (RTV)	Artificial; 252, 504, and 1008 h	ASTM G53–96[47] UV-B lamp Aging cycle includes 8 h of UV light to irradiate specimens at temperature of 60 ±3 °C, followed by 4 h of condensation without light at 45 ±3 °C.

Table 5 (*Continued*)

Study	Specimen		Weathering Methodology	
Author and Year	Form and Dimension[a]	Silicone (RTV or HTV)[b]	Setting and Interval	Standards and Conditions
Han et al 2013[28]	Disk Ø22×2	MDX4–4210 (RTV)	Artificial; 150, 300 and 450 kJ/m^2	SAE J1960[48] Xenon arc (0.55 W/m^2 at 340 nm) Aging cycle consists of 40 min of light exposure only, 20 min of light exposure with front spray, 60 min of light exposure only, and 60 min of darkness with back spray. During light phases, black panel temperature maintained at 70 ±3 °C with relative humidity of 50 ±5%. In dark phases, temperature set to 38 ±3 °C with relative humidity of 95 ±5%.
Pinheiro et al 2014[e,14]	Disk Ø16×3	MDX4–4210 (HTV) and experimental silicone (RTV)	Artificial; 480 h	UV-B lamp Aging via 240 h of UV and 240 h of condensation at constant temperature of 50 °C.
Akash and Guttal 2015[29]	Disk Ø20×2	M511 (HTV)	Outdoor; 6 months	Roof of SDM College of Dental Sciences and Hospital, Dharwad, Karnataka, India from March 1, 2010 to August 31, 2010. Monthly average climate data and radiation during weathering period provided.
Guiotti et al 2016[30]	Disk Ø5×6	A–2000 (RTV)	Artificial; 1008 h	ASTM G53–96[47]
Cevik and Yildirim-Bicer 2018[44]	Disk Ø14×2	A–2000 (RTV)	Artificial; 1008 h	Periods of alternating UV light and condensation of distilled water under heat and 90% humidity. Aging cycle includes 8 h of UV light to irradiate specimens at temperature of 60 ±2 °C, followed by 4 h of condensation without light at 50 ±2 °C.
Bishal et al 2019[f,31]	Disk Ø5×2	A–2000 (HTV)	Artificial; 450 kJ/m^2	ASTM G154[52] UV-A lamp (1.55 W/m^2 at 340 nm) Aging via 10 cycles, each cycle includes 8 h of UV exposure at a black panel temperature of 70 ±3 °C, followed by 4 h of condensation at 50 ±3 °C.
Charoenkijkajorn and Sanohkan 2020[32]	Disk Ø20×3	MDX4–4210 (RTV)	Artificial; 12, 24, 48, and 72 h	ASTM G154[52] UV-A lamp (0.89 W/m^2 at 340 nm) Aging cycle includes 8 h of UV exposure at black panel temperature of 60 ±3 °C, followed by 4 h of condensation at 50 ±3 °C.
dos Santos et al 2020[33]	Disk Ø45×2	Silastic Q7–4735 (HTV)	Artificial; 1008 h	ASTM G53–96[47] Periods of alternating UV-B light and condensation of distilled water under heat and 100% humidity. Aging cycle includes 8 h of UV light to irradiate specimens at temperature of 60 ±3 °C, followed by 4 h of condensation without light at 45 ±3 °C.
Paulini et al 2020[34]	Disk Ø45×2	MDX4–4210 and A–102 (RTV)	Artificial; 1008 h	ASTM G53–96[47] Periods of alternating UV-B light and condensation of distilled water under heat and 100% humidity. Aging cycle includes 8 h of UV light to irradiate specimens at temperature of 60 ±3 °C, followed by 4 h of condensation without light at 45 ±3 °C.
Bates et al 2021[35]	Unspecified[g] t = 3	A–2000 and M511 (RTV)	Artificial; 450 kJ/m^2	ISO 4892–2[49] Variable temperatures, water spray, and different amounts of light.
Zarrati et al 2022[f,36]	Disk Ø15×2	Silbione (RTV)	Artificial; 1000 h	Aging cycle parameters set as follows: wavelength range of 300 to 400 nm, temperature at 60 °C, relative humidity at 65 ±5%, and energy intensity between 35 to 100 W/m^2. Water spray cycle consisted of 18 min on, followed by 102 min off.
Turhan Bal et al 2023[37]	Disk Ø15×2	M511 (HTV)	Artificial; 300 and 600 h	Fluorescent UV light exposure included both UV-A (340 nm) and UV-B (313 nm). Each aging cycle consisted of 8 h of UV exposure at 60 ±2 °C, followed by an 18-minute water spray and 4 h of condensation at 50 ±2 °C.
Mahale et al 2023[38]	Disk Ø30×6	A–2186 (RTV)	Outdoor; 6 months	ASTM G7[51] and ASTM E782[50] Roof of a dental institute affiliated with VSPM Dental College and Research Centre, located in Nagpur, India from February 2017 to August 2017 for 8 h daily (9:00 to 17:00). Monthly average climate data not provided, but maximum and minimum temperatures reported, with highest recorded temperature being 42.7 °C in April and May and lowest 29 °C in February 2022. Rainfall data also noted, with recorded total of 111 mm from June 1 to June 30, 2017, and average of 93.8 mm.
Bankoğlu Güngör et al 2023[39]	Disk Ø15×2	M511, TechSil S–25 and A–2000 (HTV)	Outdoor; 3 months and 1 year	Terrace in Ankara, Turkey, from June 2021 to June 2022, for 10 h daily (8:00 to 18:00). Monthly average climate data not provided but maximum and minimum temperatures reported, with highest recorded temperature being 40 °C in July 2021 and lowest −4 °C in January 2022.

Table 5 *(Continued)*

Study	Specimen		Weathering Methodology	
Author and Year	Form and Dimension[a]	Silicone (RTV or HTV)[b]	Setting and Interval	Standards and Conditions
Kiat-amnuay et al 2023[6]	Disk Ø22×2	A–2000, A–2006 and A–2186 (RTV with subsequent post-heat processing)	Artificial	Details of weathering method not specified in the text. Reference made to Lemon et al, 1995,[c,19] with authors affiliated with University of Texas Dental Branch at Houston.
Alkahtany et al 2023[40]	Disk Ø38×6	Vinyl-terminated polydimethylsiloxane; V-2K (HTV)	Artificial; 600, 1800, and 3000 h	UV-B broadband lamp (290 to 315 nm) at 0.2 mW/cm^2; 25 °C and 30% relative humidity

ASTM, American Society for Testing and Materials; HTV, high-temperature vulcanized; ISO, International Organization for Standardization; RTV, room-temperature vulcanized; SAE, Society of Automotive Engineers.

[a] For disk-shaped specimens, diameter (Ø) and thickness (t) are specified; for sheets, dimensions are provided as width×length×thickness.

[b] HTV silicone referred to materials prepared at 60 °C or higher, while those cured below this threshold were classified as RTV.

[c] Since the authors were affiliated with the same institution as the cited study, and used the same color measurement intervals, it was assumed they followed the same methodology.

[d] Author notes that a specimen thickness of 6 mm was used, following ISO specification 4823, which is designed to identify the properties of elastomeric impression materials.[46]

[e] Both outdoor and artificial aging were conducted; however, because of insufficient information on outdoor weathering conditions, the outcome measures from outdoor testing were excluded.

[f] Color measurements based on spectroradiometer.

[g] Author notes that both the color stability test and mechanical property assessment were conducted on the same specimens.

access to 1 paper[83] was unavailable. As shown in Table 3, TiO_2 frequently emerged as an effective additive for color stability, commonly used as an opacifier or nanoparticle. Calls for standardization in testing protocols were first made in 2014 and reiterated in 2021.[77,79] Notably, none of these reviews provided detailed descriptions of specimen dimensions or addressed methodological differences in evaluating the effectiveness of formulation additives, underscoring the need for the present review.

From the 28 full-text studies reviewed, the majority adhered to standardized weathering protocols for evaluating UV radiation effects. ASTM G7 was the most frequently used standard for outdoor testing, while SAE J1960, ASTM G154, ASTM G53 (replaced by ASTM G154 in 2000), and ISO 4892–2 were used for indoor testing. However, a significant gap was identified in standardized protocols for preparing silicone specimens in maxillofacial prosthesis research. Specimen dimensions varied, with 2-mm-thick disks most used; however, this thickness may not accurately represent typical maxillofacial prostheses, which are often thicker except at the edges and thinner for tissue blending. Thinner specimens may undergo accelerated color changes under UV exposure, allowing for shorter aging durations to assess intervention impact, yet this effect must be accounted for in the testing protocol to avoid skewed results.

Specimen opacity, which is influenced by factors such as thickness and pigment concentration, plays a critical role in color measurements by affecting how background colors impact perceived values. ASTM D2244–21,[55] which provides guidelines for calculating color tolerances, highlights the importance of using a consistent neutral background (black or white) suited to the material type, as background consistency is essential for reliable interstudy comparisons. Ideally, color measurements should be conducted against both black and white backgrounds to accurately assess opacity; at a minimum, the background color should be clearly reported to enhance reproducibility.[53]

Benchtop spectrophotometers generally include a designated background material, eliminating the need to specify background color. However, among studies using portable color measurement devices, only 3[29,37,40] reported the background color used. This lack of background specification underscores the need for stricter adherence to standardized background protocols in future research to improve consistency and reliability in color measurements.

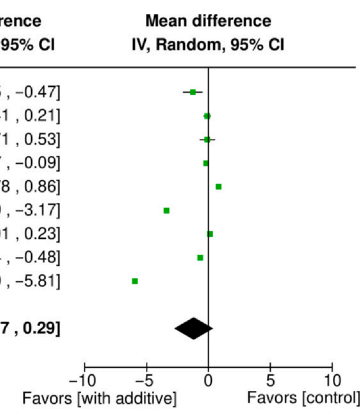
The categorization of studies eligible for meta-analysis required grouping based on parameters to ensure reliable comparisons across studies. Options considered included specimen thickness, weathering exposure or duration, additive concentration, and the formulation of pigmented silicones. However, the formulation of pigmented silicones could not be consistently accounted for because of the variability in pigment color, type,

Table 6. Articles excluded for meta-analysis with reasons

Author and Year	Title	Reason (s) for Exclusion
Kiat-amnuay et al 2002[20]	Effect of opacifiers on color stability of pigmented maxillofacial silicone A–2186 subjected to artificial aging	Lack of a pigmented control group without additive limits comparative analysis; control group was unpigmented but contained additive.
Kiat-amnuay et al 2009[23]	Influence of pigments and opacifiers on color stability of silicone maxillofacial elastomer	Lack of a pigmented control group without additive limits comparative analysis; control group was unpigmented but contained additive.
Haddad et al 2011[26]	Color stability of maxillofacial silicone with nanoparticle pigment and opacifier submitted to disinfection and artificial aging	All specimens underwent chemical disinfection for 60 days prior to weathering, introducing potential cumulative effects from both disinfection and UV exposure.
Han et al 2013[28]	Effect of opacifiers and UV absorbers on pigmented maxillofacial silicone elastomer, part 1: color stability after artificial aging	Lack of a pigmented control group without additive limits comparative analysis; control group was unpigmented but contained additive.
Akash and Guttal 2015[29]	Effect of incorporation of nano-oxides on color stability of maxillofacial silicone elastomer subjected to outdoor weathering	Absence of comparable studies with 6-month outdoor weathering duration limits the validity of direct comparisons across datasets. Specimen color changes were minimal, with mean ΔE values consistently below 1, indicating negligible perceptual differences.
Bishal et al 2019[31]	Color stability of maxillofacial prosthetic silicone functionalized with oxide nanocoating	Pigment concentration data were not disclosed, affecting reproducibility and comparison accuracy.
Charoenkijkajorn and Sanohkan 2020[32]	The effect of nano zinc oxide particles on color stability of MDX4–4210 silicone prostheses	The artificial aging period was limited to 72 h.
Alkahtany et al 2023[40]	Color stability, physical properties and antifungal effects of ZrO_2 additions to experimental maxillofacial silicones: comparisons with TiO_2	Isolating the effect of the additive was infeasible, as the control group included 13% silica, which was absent in the intervention groups, introducing a confounding variable.

TiO_2, titanium dioxide; ZnO, zinc oxide.

Study or Subgroup	Intervention Mean	Intervention SD	Intervention Total	Control Mean	Control SD	Control Total	Weight	Mean difference IV, Random, 95% CI
Bankoğlu Güngör et al; A-2000; UV-ES	5.66	0.8	10	6.92	1	10	10.8%	−1.26 [−2.05 , −0.47]
Bankoğlu Güngör et al; M511; UV-ES	5.93	0.3	10	6.03	0.4	10	11.1%	−0.10 [−0.41 , 0.21]
Bankoğlu Güngör et al; TechSil S-25; UV-ES	7.41	0.6	10	7.5	0.8	10	11.0%	−0.09 [−0.71 , 0.53]
Tran et al; Miami; A.red; Tinuvin 213+123	3.87	0.1	10	4.05	0.11	10	11.2%	−0.18 [−0.27 , −0.09]
Tran et al; Miami; B.sienna; Tinuvin 213+123	1.48	0.05	10	0.66	0.03	10	11.2%	0.82 [0.78 , 0.86]
Tran et al; Miami; H.yellow; Tinuvin 213+123	2.48	0.1	10	5.86	0.33	10	11.2%	−3.38 [−3.59 , −3.17]
Tran et al; Phoenix; A.red; Tinuvin 213+123	2.04	0.14	10	1.92	0.12	10	11.2%	0.12 [0.01 , 0.23]
Tran et al; Phoenix; B.sienna; Tinuvin 213+123	0.61	0.22	10	1.27	0.2	10	11.2%	−0.66 [−0.84 , −0.48]
Tran et al; Phoenix; H.yellow; Tinuvin 213+123	2.26	0.13	10	8.21	0.18	10	11.2%	−5.95 [−6.09 , −5.81]
Total			**90**			**90**	**100.0%**	**−1.19 [−2.67 , 0.29]**



Test for overall effect: Z=1.57 (*P*=.120)
Test for subgroup differences: Not applicable
Heterogeneity: Tau²=5.09; Chi²=10048.32, df=8 (*P*<.001); I²=100%

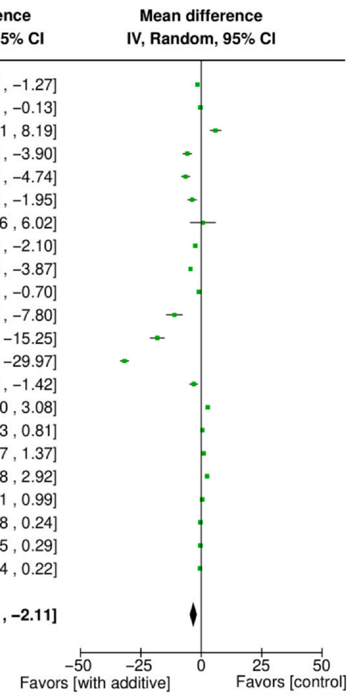
Figure 2. Forest plot of color stability enhancement via additive incorporation in pigmented silicone formulations for group O3. Data corresponds to 2- to 2.4-mm-thick specimens subjected to outdoor aging for 3 months with additive concentrations ranging from 0.75% to 1%.

manufacturer, preparation methods, and base silicone elastomer. Specimen thickness, weathering duration, and additive concentration were selected as primary grouping parameters, with the remaining heterogeneity largely attributed to differences in silicone formulation.

Extended UV exposure generally increased color change[37,39]; however, the meta-analysis of outdoor weathering data after 3 months (Figure 2) showed no significant additive effect on color stability, suggesting longer durations may be needed to evaluate intervention impacts. Artificial weathering tests consistently demonstrated that additives improved color longevity across all durations (Figures 3–5). However, certain pigments, such as specific shades of yellow, red, and blue, exhibited significant color changes under weathering conditions.[21,37] In contrast, white pigments demonstrated relatively greater stability.[37] The control formulations with less stable pigments showed substantial color changes, leading to disproportionately greater additive-driven improvements that may have skewed the overall data interpretation. Conversely, the more stable pigments exhibited minimal changes with additives, underscoring their inherent resistance to degradation and may only require additional stabilization for prolonged UV exposure.

Color stability was largely dependent on pigment color and sourcing, suggesting that a more accurate analysis of additive-induced improvements in color longevity could be achieved if pigments were classified based on their lightfastness. ASTM D4303[54] provides a relevant standard for this classification, categorizing colorants into ratings from I (excellent) to V (very poor). By selecting pigments with higher lightfastness ratings, researchers could minimize baseline variability and

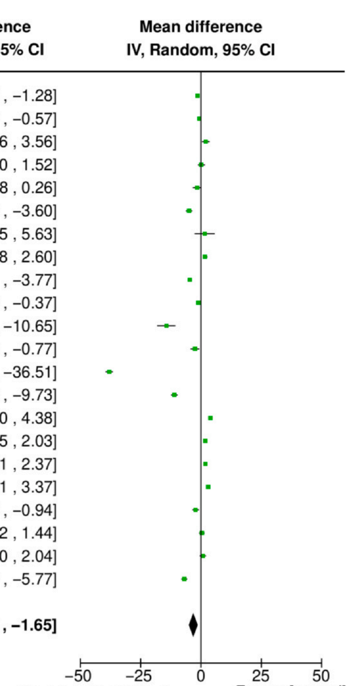
Study or Subgroup	Intervention Mean	Intervention SD	Intervention Total	Control Mean	Control SD	Control Total	Weight	Mean difference IV, Random, 95% CI
dos Santos et al; Ceramic powder; Barium sulfate	0.62	0.2	10	2.24	0.53	10	4.9%	−1.62 [−1.97 , −1.27]
dos Santos et al; Oil paint; Barium sulfate	0.66	0.17	10	1.03	0.34	10	4.9%	−0.37 [−0.61 , −0.13]
Turhan Bal et al; Blue; UV-BP	15.36	2.44	10	9.51	2.89	10	4.2%	5.85 [3.51 , 8.19]
Turhan Bal et al; Blue; UV-EM	3.69	1.11	10	9.51	2.89	10	4.4%	−5.82 [−7.74 , −3.90]
Turhan Bal et al; Blue; UV-ES	2.94	0.61	10	9.51	2.89	10	4.5%	−6.57 [−8.40 , −4.74]
Turhan Bal et al; Blue; UV-TD	5.66	1	10	9.51	2.89	10	4.4%	−3.85 [−5.75 , −1.95]
Turhan Bal et al; Mixed; UV-BP	14.01	8.69	10	13.38	0.49	10	2.6%	0.63 [−4.76 , 6.02]
Turhan Bal et al; Mixed; UV-EM	10.82	0.56	10	13.38	0.49	10	4.9%	−2.56 [−3.02 , −2.10]
Turhan Bal et al; Mixed; UV-ES	8.92	0.82	10	13.38	0.49	10	4.9%	−4.46 [−5.05 , −3.87]
Turhan Bal et al; Mixed; UV-TD	12.34	0.25	10	13.38	0.49	10	4.9%	−1.04 [−1.38 , −0.70]
Turhan Bal et al; Red; UV-BP	26.49	4.76	10	37.66	2.63	10	3.6%	−11.17 [−14.54 , −7.80]
Turhan Bal et al; Red; UV-EM	19.42	4.05	10	37.66	2.63	10	3.8%	−18.24 [−21.23 , −15.25]
Turhan Bal et al; Red; UV-ES	5.83	1.45	10	37.66	2.63	10	4.4%	−31.83 [−33.69 , −29.97]
Turhan Bal et al; Red; UV-TD	34.45	1.19	10	37.66	2.63	10	4.5%	−3.21 [−5.00 , −1.42]
Turhan Bal et al; White; UV-BP	4.36	0.5	10	1.72	0.51	10	4.9%	2.64 [2.20 , 3.08]
Turhan Bal et al; White; UV-EM	2.14	0.37	10	1.72	0.51	10	4.9%	0.42 [0.03 , 0.81]
Turhan Bal et al; White; UV-ES	2.69	0.39	10	1.72	0.51	10	4.9%	0.97 [0.57 , 1.37]
Turhan Bal et al; White; UV-TD	4.07	0.77	10	1.72	0.51	10	4.9%	2.35 [1.78 , 2.92]
Turhan Bal et al; Yellow; UV-BP	2.53	0.52	10	2.24	1.01	10	4.9%	0.29 [−0.41 , 0.99]
Turhan Bal et al; Yellow; UV-EM	1.77	0.53	10	2.24	1.01	10	4.9%	−0.47 [−1.18 , 0.24]
Turhan Bal et al; Yellow; UV-ES	1.76	0.72	10	2.24	1.01	10	4.8%	−0.48 [−1.25 , 0.29]
Turhan Bal et al; Yellow; UV-TD	1.68	0.76	10	2.24	1.01	10	4.8%	−0.56 [−1.34 , 0.22]
Total			220			220	100.0%	**−3.36 [−4.61 , −2.11]**



Test for overall effect: Z=5.27 (*P*<.001)
Test for subgroup differences: Not applicable
Heterogeneity: Tau^2=8.25; Chi^2=2045.91, df=21 (*P*<.001); I^2=99%

Figure 3. Forest plot of color stability enhancement via additive incorporation in pigmented silicone formulations for group A300. Data corresponds to 2-mm-thick specimens subjected to artificial aging (252 to 300 h) with additive concentrations ranging from 0.2% to 0.5%.

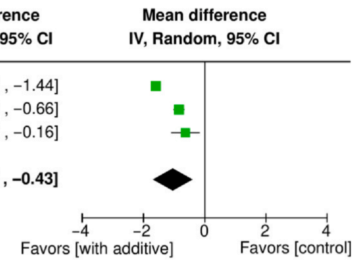
Study or Subgroup	Intervention Mean	Intervention SD	Intervention Total	Control Mean	Control SD	Control Total	Weight	Mean difference IV, Random, 95% CI
dos Santos et al; Ceramic powder; Barium sulfate	0.96	0.13	10	2.41	0.24	10	4.7%	−1.45 [−1.62 , −1.28]
dos Santos et al; Oil paint; Barium sulfate	0.71	0.28	10	1.48	0.17	10	4.7%	−0.77 [−0.97 , −0.57]
Turhan Bal et al; Blue; UV-BP	13.16	1.37	10	11.2	2.19	10	4.5%	1.96 [0.36 , 3.56]
Turhan Bal et al; Blue; UV-EM	11.26	0.88	10	11.2	2.19	10	4.6%	0.06 [−1.40 , 1.52]
Turhan Bal et al; Blue; UV-ES	9.59	2.07	10	11.2	2.19	10	4.5%	−1.61 [−3.48 , 0.26]
Turhan Bal et al; Blue; UV-TD	6.18	0.65	10	11.2	2.19	10	4.6%	−5.02 [−6.44 , −3.60]
Turhan Bal et al; Mixed; UV-BP	16.89	6.54	10	15.4	1.33	10	3.6%	1.49 [−2.65 , 5.63]
Turhan Bal et al; Mixed; UV-EM	16.99	0.95	10	15.4	1.33	10	4.7%	1.59 [0.58 , 2.60]
Turhan Bal et al; Mixed; UV-ES	10.71	0.65	10	15.4	1.33	10	4.7%	−4.69 [−5.61 , −3.77]
Turhan Bal et al; Mixed; UV-TD	14.2	0.2	10	15.4	1.33	10	4.7%	−1.20 [−2.03 , −0.37]
Turhan Bal et al; Red; UV-BP	36.33	5.7	10	50.74	2.1	10	3.8%	−14.41 [−18.17 , −10.65]
Turhan Bal et al; Red; UV-EM	48.19	1.97	10	50.74	2.1	10	4.5%	−2.55 [−4.33 , −0.77]
Turhan Bal et al; Red; UV-ES	12.68	1.37	10	50.74	2.1	10	4.5%	−38.06 [−39.61 , −36.51]
Turhan Bal et al; Red; UV-TD	39.65	0.65	10	50.74	2.1	10	4.6%	−11.09 [−12.45 , −9.73]
Turhan Bal et al; White; UV-BP	6.63	0.63	10	2.74	0.47	10	4.7%	3.89 [3.40 , 4.38]
Turhan Bal et al; White; UV-EM	4.43	0.29	10	2.74	0.47	10	4.7%	1.69 [1.35 , 2.03]
Turhan Bal et al; White; UV-ES	4.53	0.81	10	2.74	0.47	10	4.7%	1.79 [1.21 , 2.37]
Turhan Bal et al; White; UV-TD	5.68	0.5	10	2.74	0.47	10	4.7%	2.94 [2.51 , 3.37]
Turhan Bal et al; Yellow; UV-BP	13.53	1.3	10	15.84	1.78	10	4.6%	−2.31 [−3.68 , −0.94]
Turhan Bal et al; Yellow; UV-EM	16.15	0.43	10	15.84	1.78	10	4.6%	0.31 [−0.82 , 1.44]
Turhan Bal et al; Yellow; UV-ES	16.56	1.18	10	15.84	1.78	10	4.6%	0.72 [−0.60 , 2.04]
Turhan Bal et al; Yellow; UV-TD	8.87	0.76	10	15.84	1.78	10	4.6%	−6.97 [−8.17 , −5.77]
Total			220			220	100.0%	**−3.25 [−4.86 , −1.65]**



Test for overall effect: Z=3.97 (*P*<.001)
Test for subgroup differences: Not applicable
Heterogeneity: Tau^2=14.14; Chi^2=3712.24, df=21 (*P*<.001); I^2=99%

Figure 4. Forest plot of color stability enhancement via additive incorporation in pigmented silicone formulations for group A600. Data corresponds to 2-mm-thick specimens subjected to artificial aging (504 to 600 h) with additive concentrations ranging from 0.2% to 0.5%.

Study or Subgroup	Intervention Mean	Intervention SD	Intervention Total	Control Mean	Control SD	Control Total	Weight	Mean difference IV, Random, 95% CI
dos Santos et al; Ceramic powder; Barium sulfate	1.06	0.08	10	2.65	0.22	10	35.3%	−1.59 [−1.74 , −1.44]
dos Santos et al; Oil paint; Barium sulfate	0.8	0.21	10	1.64	0.21	10	34.9%	−0.84 [−1.02 , −0.66]
Zarrati et al; Nano-titanium dioxide	1.09	0.29	12	1.72	0.77	12	29.8%	−0.63 [−1.10 , −0.16]
Total			**32**			**32**	**100.0%**	**−1.04 [−1.65 , −0.43]**



Test for overall effect: Z=3.33 (P<.001)
Test for subgroup differences: Not applicable
Heterogeneity: Tau²=0.27; Chi²=46.90, df=2 (P<.001); I²=96%

Figure 5. Forest plot of color stability enhancement via additive incorporation in pigmented silicone formulations for group A1000. Data corresponds to 2-mm-thick specimens subjected to artificial aging (1000 to 1008 h) with additive concentrations ranging from 0.2% to 1%.

better isolate the effects of additives. This approach would not only help to maximize the longevity of maxillofacial prostheses by ensuring the use of more stable pigments but also improve the reliability of research outcomes.

Limitations of this systematic review included a shortage of experimental parameters available for meta-analysis grouping. While specimen thickness, aging type and duration, and additive concentration were considered, factors such as pigment color and sourcing contributed to heterogeneity. Future research should establish standardized specimen preparation protocols with detailed reporting of specimen thicknesses clinically representative of maxillofacial prostheses. Additionally, classifying pigments by established lightfastness ratings and documenting the background color and type used for color measurements would enable more accurate scaling of additive-induced improvements and provide a standardized framework for comparing results. Finally, future studies should examine factors affecting UV penetration in pigmented silicone, especially specimen thickness and opacity, to support the development of standardized testing methods for maxillofacial applications.

CONCLUSIONS

Based on the findings of this systematic review and meta-analysis, the following conclusions were drawn:

1. The lack of standardized methodologies, particularly regarding specimen dimensions and pigmented silicone formulations, contributed to significant variability in studies assessing color longevity for maxillofacial applications.
2. Adopting specimen dimensions that accurately represent maxillofacial prostheses would improve the reliability of outcome measures and enhance the consistency of research findings.
3. While additives such as opacifiers, nanoparticles, and UV blockers were found to improve color stability in pigmented silicone formulations, the inherent stability of the pigment itself plays a more decisive role, making the selection of color-stable pigments essential for long-term durability.

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