

# The color stability of maxillofacial silicones: A systematic review and meta analysis

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## Abstract

**Aim:** This systematic review aims to identify and interpret results of studies that evaluated the changes in the color stability of maxillofacial prosthetic materials due to chemical instability of silicones and pigments and the effect of exposure to environmental conditions and aging factors on the same.

**Settings and Design:** This systematic review was conducted in accordance with the Preferred Reporting Items for Systematic reviews and Meta-Analyses guidelines (PRISMA).

**Materials and Methods:** Relevant articles written in English only, before November 15, 2019, were identified using an electronic search in the PubMed/Medline conducted to identify pertinent articles. The relevancy of the articles was verified by screening the title, abstract, and full text, if they met the inclusion criteria. A total of 42 articles satisfied the criteria, from which data were extracted for qualitative synthesis. This review protocol was registered in the International Prospective Register of Systematic Reviews (PROSPERO registration number CRD42019124562).

**Statistical Analysis Used:** Since considerable data heterogeneity was present in all studies except the ones on incorporation of TiO<sub>2</sub> for which meta-analysis using random effects model was performed.

**Results:** The database search resulted in 234 studies, of which 202 articles were excluded due to lack of relevance, duplication, and unavailability of data. The remaining 32 fulltext articles were assessed for eligibility, out of which 2 articles were excluded. Twelve articles were yielded by manual search. A total of 42 studies were included in the present systematic review. Due to heterogeneous data, meta-analysis could be only carried out with the effect of TiO<sub>2</sub> nano particle on color stability.

**Conclusions:** Although there has been extensive amount of research in this field, an ideal maxillofacial silicone exhibiting good color stability in various human and environmental aging conditions is yet to be identified. Human and environmental aging conditions have an adverse effect on the color stability and addition of TiO<sub>2</sub> nano particle seems to improve the same.

**Keywords:** Accelerated aging, aging, color stability, dust, maxillofacial silicones, nanoparticle, silicone elastomers, sweat, weathering

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## INTRODUCTION

Maxillofacial deformities can be congenital or caused by trauma or surgery. They cause enormous physical and psychological trauma to the patient. The defects result in disruption of the structural integrity of the maxillofacial region. Although advancements in plastic reconstruction have been proved helpful in the correction of such deformities, yet surgical contraindications and the extensive nature of the defects often demand the use of maxillofacial prostheses. The aim of such prosthesis is to restore form, function, and esthetics to improve the quality of life of the patient.<sup>[1]</sup>

Barnhart introduced elastomeric silicone for facial prosthesis in 1960.<sup>[2]</sup> Since then, silicone elastomers, chemically termed polydimethylsiloxane, have been the material of choice. These are of two types: room temperature-vulcanizing (RTV) silicone and heat temperature-vulcanizing silicone. Medical-grade silicone has been widely reported as better serviceable material for maxillofacial applications.<sup>[3]</sup>

Among the various contributing factors, properties of the maxillofacial prosthetic material play a crucial role in the final result of the prosthetic rehabilitation. The main challenge encountered in the performance of an ideal facial prosthesis is the degradation in appearance, either due to changes in color or deterioration of physical properties. The average service life of facial prosthesis is still only 1–1.5 years, mainly due to color degradation.<sup>[4]</sup>

This deterioration, according to Feldman, is due to various primary factors such as weathering including ultraviolet (UV) rays, temperature, moisture, and secondary factors such as deposition of microscopic residues in the porosities on the surface of the material and use of disinfecting agents.

Various additives such as colorants; pigments; opacifiers; UV absorbers – such as inorganic colorants (dry earth pigments); metal oxides; and organic colorants, which have double and triple bonds between carbon and hydrogen, are added in maxillofacial silicones to enhance their properties. Many authors in their reviews also describe the effect of pigments, UV light absorbers, and opacifiers on the color stability of maxillofacial materials.<sup>[5-9]</sup>

This systematic review aims to identify and interpret results of such studies that evaluated the changes in the color stability of maxillofacial prosthetic materials after additions of aforementioned materials as well as human secretions subjected to natural or artificial accelerated aging and outdoor weathering.

## MATERIALS AND METHODS

This systematic review was planned and conducted according to the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA Statement) checklist Recommendations<sup>[10]</sup> and was registered with PROSPERO (International Prospective Register of Systematic Reviews) (protocol number #CRD42019124562).

### Primary research question

How does addition of nanoparticle pigments, opacifiers, human, and environmental conditions affect the color stability of maxillofacial silicones?

### Eligibility criteria

The eligibility criteria were based on Population, Intervention, Comparators, and Outcomes. Further elaborated as follows: Population: all studies investigating color stability of maxillofacial silicones (*in vitro*). Intervention(s), exposure(s): maxillofacial silicon elastomers pigmented/modified with nanoparticles and exposed to environmental and human aging conditions; Comparator(s)/control: compare the color stability of unpigmented and unexposed (control); Outcome: changes observed in the color stability of maxillofacial silicones due to addition of nanoparticles, opacifiers, aging, weathering, and environmental conditions.

### Study design

All *in vitro* studies in which the color stability of maxillofacial silicones were mentioned.

### Inclusion

This systematic review included articles investigating the color stability of maxillofacial silicones *in vitro*. Color stability analysis of maxillofacial silicone elastomers against the effect of addition of nanoparticles and opacifiers and exposure such as aging factors (human body secretion i.e. sweat and sebum) and environmental factors like UV radiation, sunlight, dust, weathering. Only original research articles were included.

### Exclusion

Clinical case, case series, literature review, books, reports, letter to the editor, studies that could not collect the data, and publications in languages other than English were excluded from the review.

### Timing and effect measures

Color stability measured by either quantitative outcome (lab parameters) using reflectance spectrometer in terms of  $\Delta E$  were considered or qualitative outcome using visual method (subjective parameters), specifically measuring

the effect measures such as duration of stability and reduction in the grade of color change after addition of nanoparticles.

### Search strategy

An electronic search was conducted in MEDLINE-PubMed, Scopus, and Google Scholar to identify relevant articles published till November 15, 2019, with relevant articles written in English only. Controlled vocabulary (MeSH terms in PubMed) and free-text terms in the titles and/or abstracts were used to define the search strategy in all the databases. The search strategies were implemented with keywords based on each section of the PICO question, separated by the Boolean operator OR, and then all the sections were combined using the Boolean operator AND. Moreover, citations within references of articles from these journals were searched to identify more relevant studies.

The search strategy developed for Medline is summarized in Table 1.

### Screening and study selection

The initial literature search and screening were conducted by two independent reviewers (PG and SD). They assessed the potentially relevant publications, which were selected by title and abstract based on the above-mentioned inclusion criteria. Afterward, papers that fulfilled the inclusion criteria had their full texts reviewed in accordance with the exclusion criteria. The duplicates were removed manually. Any disagreement between the authors with the selection or rejection of studies was resolved carefully through discussion.

### Data extraction

Information of the included studies was collected by one of the reviewers (PG) and a second one (SD) cross-checked, independently, all the retrieved data. The following data

were systematically collected from each included study: publication details (authors, country, and year), sample characteristics (sample size), study methodology (material used, exposure time, and experimental condition), characteristics related to outcomes (relevant findings, visual or spectrometrical analysis), and outcome ( $\Delta E$  values) [Table 2].

### Assessment of risk of bias

Assessment of risk of bias was conducted through specific study design-related risk of bias assessment forms (Modified CONSORT Guidelines from the Guidelines for Reporting Preclinical *In vitro* Studies on Dental Materials by Clovis Mariano Faggino, from the *Journal of Evidence-Based Dental Practice*, 2012).<sup>[11]</sup> The criteria were divided into six main domains related to randomization, blinding, outcome data, and characteristics of the sample at baseline. The assessment of risk of bias was performed by rating each of the study criteria as “yes” (low risk of bias), “no” (high risk of bias), or “unclear” (not possible to find the information or uncertainty over the potential for bias). The risk-of-bias assessment was conducted by one of the reviewers and also cross-checked by the other [Table 3].

### Meta-analysis

Out of all the variables that were studied, studies on titanium dioxide nanoparticle showed homogenous data. Hence, meta-analysis was planned for five studies.<sup>[3,12-15]</sup> Out of five studies, one study did not mention the SD values, hence it was excluded.<sup>[14]</sup> Thus, this meta-analysis was performed on four studies which ranged between 2010 and 2018. In the rest of all the studies, considerable heterogeneity was present regarding the research design, methods used, outcome variables, and results and as a result, meta-analysis could not be carried out [Table 4].

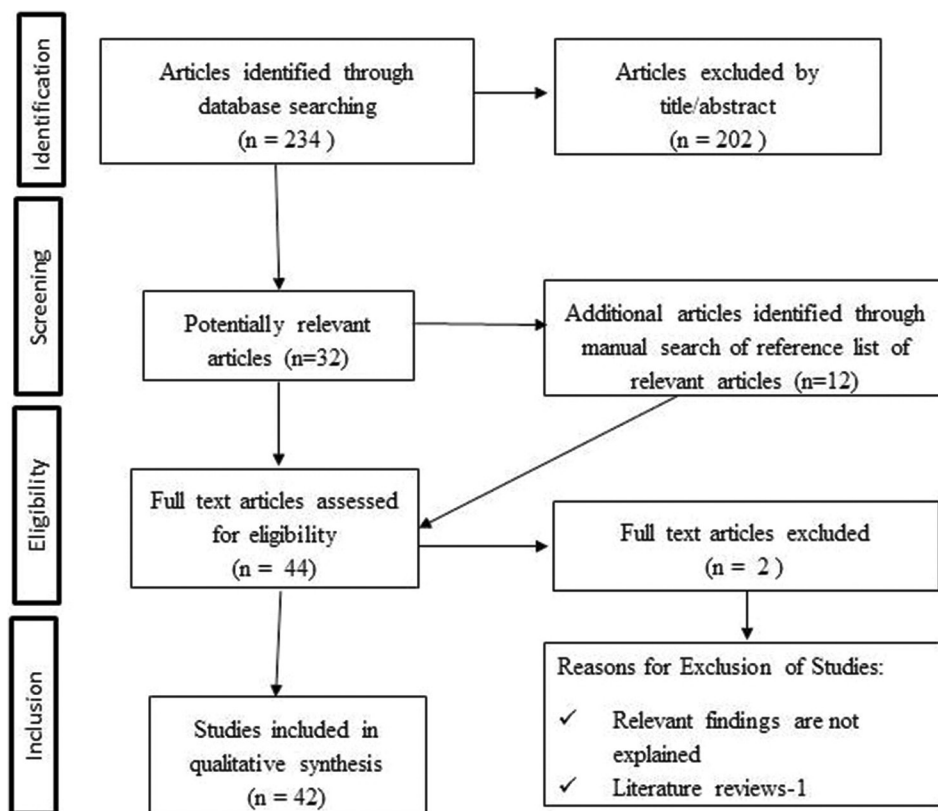
## RESULTS

The selection criteria were based on PRISMA statement flowchart [Figure 1]. The database search (P) resulted in 234 studies, of which 202 articles were excluded as they were irrelevant, duplicates, and unavailability of data. The remaining 32 fulltext articles were assessed for eligibility, out of which 2 articles were excluded. Twelve articles were yielded by manual search. A total of 42 studies were included in the present systematic review [Figure 1].

Among the 42 included articles, 3 were on incorporation of colorants, 24 were on incorporation of pigments, 8 were addition of opacifiers and 6 were addition of nanoparticles, 29 were exposure to artificial accelerated aging, 11 were exposed to natural weathering, and 7 studies were stored their samples in dark. Four studies showed the

**Table 1: Search strategy developed for MEDLINE**

Search strategy developed for MEDLINE
Silicone elastomers mp
Maxillofacial prostheses
Aging
Accelerated aging
Dust
Nanoparticles
Weather
Sweat
Color stability mp
1 or 2
3 or 4 or 5 or 6 or 7 or 8
10 and 11 and 12 and 9
Limit 12 to English
mp: Title, original title, abstract, name of substance word, subject heading, word



**Figure 1:** Article selection Preferred Reporting Items for Systematic Reviews and Meta-analyses flowchart based on inclusion and exclusion criteria

effect of human aging conditions such as sebum and acid perspiration.

The result for meta-analysis comparing the effect of incorporation of titanium dioxide on color stability of maxillofacial silicones is shown in Table 4. A fixed-effect model indicated a statistically significant ( $P < 0.001$ ) decline in the mean  $\Delta E$  (standardized mean difference [SMD] – 0.989) values in the study group as compared to that of the control group. However, a random-effects model indicated a statistically nonsignificant ( $P = 0.125$ ) decline in the mean  $\Delta E$  (SMD – 0.787) values in the study group as compared to that of the control group. Figure 2 shows the summary SMD from the fixed-effect model and random-effects model in the Forest plot, which presents contradictory results that might be attributed to heterogeneity or bias across the studies. Only one study reported the mean difference in opposite direction (increase in  $\Delta E$ ) as compared to that of other three studies. In such situation when research synthesis clearly indicated the presence of heterogeneity, inconsistency, and publication bias, results using random-effects model for meta-analysis are considered better than that of fixed-effect model. Although this meta-analysis could not provide clear evidence in favor of the study group which may be due to small sample size,

it undoubtedly provided a clue that the incorporation of titanium dioxide might be better than that of the control group if studies with large sample size with minimum publication bias are conducted in future [Figure 2].

### Study characteristics

The main characteristics of datasets from included studies are displayed in Table 2.

## DISCUSSION

The color stability of maxillofacial silicones has been reported to be affected by addition of pigments, opacifiers, nanoparticles, and various human and environmental factors, hence all these domains need to be studied. Extensive research done in the past failed to identify a single “ideal” maxillofacial prosthetic material that can withstand the impact of different human and environmental conditions on color changes and stability. Maxillofacial silicones currently used are known to last only for 6–24 months and may need replacement thereafter. Even in the retention period, their physical properties may change and result in color changes and stability. It has been hypothesized that addition of nanoparticles to maxillofacial silicones may prove beneficial for patients, but confirmatory evidence in humans is still lacking. Convincing evidence may be



**Table 2: Detailed chart related to studies included in the current systematic review**

Author, year and reference	Sample size	Silicones	Exposure	Colorants	Experimental conditions	Relevant findings
Craig <i>et al.</i> , 1978 <sup>[16]</sup>	n=5	Polyvinyl chloride, polyurethane, 3RTV and 1HTV	100, 300, 600, 900 h	Not mentioned	A	Polyurethane and silicone 44,210 showed no significant changes in luminous reflectance with aging. Largest change in luminous reflectance was seen for silicone 399
Koran <i>et al.</i> , 1979 <sup>[17]</sup>	n=3	RTV	900 h	Eleven dry mineral earth pigments	A	Three pigments (white, yellow and orange yellow) were less promising for clinical use
Takamata <i>et al.</i> , 1989 <sup>[18]</sup>	n=2	HTV, RTV	6 months	-	N, D	Aging rather than exposure to sunlight caused greater color change
Bryant <i>et al.</i> , 1994 <sup>[19]</sup>	n=9	RTV	300 h	Talc, nylon flock and photoprotective agents	A, D	Photoprotective agents showed no protection from discoloration of silicones by UV radiation
Lemon <i>et al.</i> , 1995 <sup>[20]</sup>	n=6	RTV	150, 450 kJ/m <sup>2</sup>	Pigments in oil base. UV light absorber	N, A	Artificial aging caused a greater change than outdoor aging. UV light absorber did not protect silicone from color changes
Beatty <i>et al.</i> , 1995 <sup>[5]</sup>	n=3	HTV	400, 600, and 1800 h	Dry earth pigments	A, D	Early color changes may result from degradation of UV light susceptible pigments, while long-term changes may occur due to changes within elastomer
Haug <i>et al.</i> , 1999-Part 3 <sup>[21]</sup>	n=5 (total-270)	1HTV, 2RTV	6 months	Dry earth pigments, rayon fibers, oil paints, liquid cosmetics	N, D	Changes in color, as a result of weathering, were noted in many of the colorant-elastomer combinations. Color change occurred not only to the colored, but also to uncolored materials over time without exposure to weathering. Colorants tended to protect the silicones from weathering
Polyzois 1999 <sup>[6]</sup>	n=10	3RTV	1 year	-	N	All silicone elastomers showed visually detectable color differences after outdoor exposure. Silskin 2000 showed highest color changes
Beatty <i>et al.</i> , 1999 <sup>[22]</sup>	n=5	HTV	400, 600 and 1800 h	Oil based pigments	A	Application of surface tints to a maxillofacial silicone prosthesis using an oil-pigmented adhesive was not likely to compromise the color stability of the prosthesis. Color stability may be improved if the pigment can be concentrated within the adhesive
Polyzois <i>et al.</i> , 2000 <sup>[23]</sup>	n=5	RTV	6 months	sebum and perspiration	A	Accelerated aging of silicone specimens in simulated perspiration and sebum, which corresponded with 11.5 years of clinical service, showed a visually perceptible effect on the color. Greater color changes by acidic perspiration than sebum solution
Gary <i>et al.</i> , 2001 <sup>[24]</sup>	n=10 (total-80)	HTV	80 days	One natural inorganic and 2 synthetic organic pigment	N	Outdoor weathering tests in which documented ASTM methods were used Mean color changes that occurred in Arizona (desert) were significantly larger than those in Florida
Kiat-Amnuay <i>et al.</i> , 2002 <sup>[25]</sup>	n=5 (total-300)	HTV	150, 300, 450 kJ/m <sup>2</sup>	Inorganic pigments and opacifiers	A	Mixing dry earth cosmetic pigments with opacifiers did not protect silicone A-2186 from color degradation over time, yellow ochre remained the most color stable over time
Tran <i>et al.</i> , 2004 <sup>[26]</sup>	n=10 (total 160)	HTV	3 months	3 pigments, UV light absorber and HALS	N	UVA and HALS had shown to effective in retarding the color change in certain circumstances
Kiat-Amnuay <i>et al.</i> , 2005 <sup>[27]</sup>	n=5 (total-25)	HTV	1.5 years	Opacifier - and dry earth pigment	A, ME	Lack of color stability of red dry earth pigmented A-2186 silicone maxillofacial elastomers was clinically significant after 12-month exposure to microwave energy as compared with yellow, burnt sienna, and opacified A-2186 dry earth pigments
Kiat-Amnuay <i>et al.</i> , 2006 <sup>[28]</sup>	n=5 (total-375)	2RTV	150, 300 and 450 kJ/m <sup>2</sup>	Oil pigments and dry earth opacifiers	A	Majority of color changes in all groups were nonperceptible. Oil pigments combined to opacifiers were seen to protect the silicones from color degradation

Contd...

Table 2: Contd...

Author, year and reference	Sample size	Silicones	Exposure	Colorants <sup>#</sup>	Experimental conditions	Relevant findings
Kiat-Amnuay <i>et al.</i> , 2009 <sup>[29]</sup>	n=5 (total-375)	RTV	450 kJ/m <sup>2</sup>	Silicone pigments, dry earth opacifiers	A	Both 10% and 15% Artskin white and titanium white opacifiers protected silicone from color changes. Calcined kaolin opacifier and yellow silicone pigment exhibited most pronounced color changes
Mancuso <i>et al.</i> , 2009 <sup>[30]</sup>	n=6 (total-48)	2RTV	163, 351, 692 and 1000 h	Pigments	A	No group had visually noticeable alterations in any of the accelerated aging time, independently of the addition or not of pigments
Goiato <i>et al.</i> , 2009 <sup>[31]</sup>	n=14 (total-28)	2RTV	immediately and 2 months	Efferdent and neutral soap	A	Storage time and disinfection statistically influenced color stability; disinfection acts as a bleaching agent in silicone materials
Han <i>et al.</i> , 2010 <sup>[12]</sup>	n=5 (total-230)	HTV	450 kJ/m <sup>2</sup>	Silicone pigments and nano oxides (CeO <sub>2</sub> and TiO <sub>2</sub> )	A	1% nano-CeO <sub>2</sub> and 2% and 2.5% nano-TiO <sub>2</sub> used as opacifiers for silicone A-2186 maxillofacial prostheses with mixed pigments exhibited the least color changes. Yellow silicone pigment mixed with all three nano-oxides significantly affected color stability of A-2186 silicone elastomer
Hatamleh and Watts 2010 <sup>[31]</sup>	n=8 (total-112)	HTV	Sebum solution, acidic perspiration for 6 months, 360 and 30 h	Intrinsic pigment, sebum solution and acidic perspiration	N, A, D, M	Mixed aging induced the greatest color changes. Pigments failed to protect silicones during outdoor weathering. Negligible color changes caused by cleaning solution
dos Santos <i>et al.</i> , 2011 <sup>[1]</sup>	n=10 (total-60)	RTV	252, 504, 1008 h	Two pigments (ceramic powder and oil paint) and one opacifier	A	Opacifier protected facial silicone against color degradation, and oil paint remained stable even without opacifier
Hatamleh and Watts 2011 <sup>[33]</sup>	n=8 (total-64)	HTV	Sebum 6 months and then expose for 6 and 360 h	Intrinsic pigment. manual versus mechanical mixing	A	Pores affected the color reproducibility as well as color stability, hence mechanical mixing under vacuum recommended
Goiato <i>et al.</i> , 2011 <sup>[34]</sup>	n=30 (total-90)	RTV	252, 504, 1008 h	Opacifier and disinfection using effervescent tablets, neutral soap and 4% chlorhexidine gluconate	A	Chlorhexidine promoted the greatest color alteration of the facial silicone compared to the other disinfectants. Accelerated aging affected the color stability of all groups. The barium sulfate opacifier was more stable in all periods
Pesqueira <i>et al.</i> , 2011 <sup>[35]</sup>	n=10 (total-60)	RTV	60 days-disinfection and 252, 504, and 1008 h	Pigments (makeup, ceramic powder), Efferdent and neutral soap	A	Ceramic pigment presented significantly greater color stability than makeup pigment. Neutral soap caused more discoloration than Efferdent in both pigment types
Filié Haddad <i>et al.</i> , 2011 <sup>[36]</sup>	n=30 (total-120)	RTV	60 days disinfection and 252, 504 and 1008 h	Pigments (makeup, ceramic powder) and opacifier (BaSO <sub>4</sub> )	A	Clinically acceptable color change occurred in all groups. The association between ceramic nanoparticles and BaSO <sub>4</sub> opacifier was the most stable condition in relation to color maintenance, without considering disinfection and the aging period
Polyzois <i>et al.</i> , 2011 <sup>[37]</sup>	n=10	HTV and RTV	1 year	None	D	Both material showed visually unacceptable color change
Kantola <i>et al.</i> , 2013 <sup>[8]</sup>	n=6	RTV	46 days	Thermochromic pigment	A	Thermochromic pigment is not suitable to be used in maxillofacial prosthesis
Bankoğlu <i>et al.</i> , 2013 <sup>[38]</sup>	n=5, (total-250)	2HTV and 1RTV	1 year	Silicone pigment and intrinsic and extrinsic coloration methods	D	Significant color changes were observed in both pigmented and unpigmented specimens, which were stored in dark environment and not exposed to sunlight
Han <i>et al.</i> , 2013 Part 1 <sup>[39]</sup>	n=225	RTV	450 kJ/m <sup>2</sup>	Opacifiers, oil pigment, intrinsic silicone pigment	A	All opacifiers and a UV mineral-based light-protecting agent improved the color stability of pigmented silicone MAD4-4210/ Type A after artificial aging

Contd...

**Table 2: Contd...**

Author, year and reference	Sample size	Silicones	Exposure	Colorants <sup>#</sup>	Experimental conditions	Relevant findings
Al-Dharrab <i>et al.</i> , 2013 <sup>[40]</sup>	n=15 (total-60)	HTV	6 months	Pigments in simulated acidic, alkaline and sebum solutions	A	There were no significant changes were observed in the color in control and testing storage medium
Al-Harbi <i>et al.</i> , 2015 <sup>[41]</sup>	n=6 (total-36)	1HTV and 2RTV	6 months	Pigments	N	Weathering caused unacceptable color change in all silicone elastomers. HTV showed better color stability than RTV
Akash and Guttal 2015 <sup>[13]</sup>	n=30 (total-90)	HTV	6 months	Intrinsic coloring agents and 2 nano-oxide ZnO, TiO <sub>2</sub>	N	Incorporation of nano-oxides improved the color stability of silicone elastomer and ZnO showed least color change and also acted as an opacifier
Bangera and Guttal 2014 <sup>[42]</sup>	n=10 (total-110)	HTV	6 months	Nano-oxides (Zn and Ti) at different concentration	A	Compared with Ti nano-oxides (2%2.5%), Zn nano-oxides in lesser concentrations provided more significant and consistent UV protection in elastomer
Griniari <i>et al.</i> , 2015 <sup>[43]</sup>	n=8 (total-96)	RTV	174 h	Pigments, immersion in disinfectants. (Soap solution, ethanol and distilled water)	A Photoaging	No structural changes of pigmented and unpigmented silicone elastomers were observed among all aging procedures. Recorded color changes for the materials tested were within the limits of clinical acceptability after all aging procedures Immersion in distilled water presented best color stability, whereas photoaging showed the poorest
Sethi <i>et al.</i> , 2015 <sup>[44]</sup>	n=10 (total-90)	RTV		2 dental stone and die stone coated with three different separating media	-	Among the investing materials studied, die stone showed the most color change. Among the separating media, die hardener showed the least color change
Shakir and Abdul-Ameer 2018 <sup>[14]</sup>	n=10 (total-60)	1RTV and 1HTV	24 h	TiO <sub>2</sub> nanofiller	A	Reinforcement of nano TiO <sub>2</sub> with specific concentrations for each maxillofacial silicone increase the service life of the prosthesis but not protect the silicone from color degradation
Eltayaar <i>et al.</i> , 2016 <sup>[15]</sup>	n=21 (total-127)	HTV	Sunlight 6 h, sweat 12 h, aging 10, 20, 30 days	TiO <sub>2</sub> , Al <sub>2</sub> O <sub>3</sub>	N, A	TiO <sub>2</sub> was more stable than Al <sub>2</sub> O <sub>3</sub> after 30 days regarding UV light. TiO <sub>2</sub> group showed more color alteration on exposure to sweat and sunlight
Mehta and Nandeeshwar 2017 <sup>[45]</sup>	n=8 (total-80)	2RTV	6 months	Simulated acidic perspiration, sebum, neutral soap and disinfectant	N	All specimen shows significant color change except immersion in neutral soap solution irrespective of the material used
Farah <i>et al.</i> , 2018 <sup>[46]</sup>	n=18	RTV	1500 h	Pigment pastes	N, A, D	The greatest color changes were observed for all specimens when exposed to accelerated aging. Nonpigmented and Indian yellow pigment demonstrated the highest color change. The organic pigment Logwood maroon demonstrated the best color stability
Bishal <i>et al.</i> , 2019 <sup>[3]</sup>	n=10 (total-20)	HTV	450 kJ/m2	Intrinsic pigments, nano-oxide coating	A	TiO <sub>2</sub> nanocoating was shown to be effective in reducing color degradation of the silicone elastomer exposed to artificial aging
Babu <i>et al.</i> , 2018 <sup>[47]</sup>	n=30 (total-60)	2HTV	Chemical disinfection-60 days, 1008 h (artificial aging)	Intrinsic pigment and three disinfectants	A	Accelerated aging and chemical disinfection caused a significant decrease in color stability

N: Natural, A: Accelerated aging, D: Dark, M: Mixed ageing in sebum and artificial day light exposure, ME: Microwave energy, RTV: Room temperature vulcanizing, HTV: Heat temperature vulcanizing, UV: Ultraviolet, HALS: Hindered amine light stabilizer, UVA: UV absorber

made available from prospective, randomized controlled trials (RCTs) only. However, it would not be ethical to expose patients to such interventions directly with *in vivo* studies. Retrospective evaluation with *in vitro* studies may be an appropriate and feasible option for testing the effects

of addition of nanoparticles to maxillofacial silicones as a basis for gathering further clinical evidence.

For the sake of clarity, discussion is divided in sections as follows:

**Table 3: Risk of bias assessment using modified CONSORT checklist**

Author, year and reference	Item 1	Item 2a	Item 2b	Item 3	Item 4	Item 5	Item 6	Item 7	Item 8	Item 9	Item 10	Item 11	Item 12	Item 13	Item 14	Risk of bias
Craig <i>et al.</i> , 1978 <sup>[16]</sup>	√	√	√	x	x	x	x	x	x	x	√	x	x	√	√	High
Koran <i>et al.</i> , 1979 <sup>[17]</sup>	√	√	√	x	x	x	x	x	x	x	√	x	x	√	√	High
Takamata <i>et al.</i> , 1989 <sup>[18]</sup>	√	√	√	x	x	x	x	x	x	x	√	x	x	√	√	High
Bryant <i>et al.</i> , 1994 <sup>[19]</sup>	√	√	√	x	x	x	x	x	x	x	√	x	x	√	√	High
Lemon <i>et al.</i> , 1995 <sup>[20]</sup>	√	√	√	x	x	x	x	x	x	x	√	x	x	√	√	High
Beatty <i>et al.</i> , 1995 <sup>[5]</sup>	√	√	√	x	x	x	x	x	x	x	√	x	x	√	√	High
Haug <i>et al.</i> , 1999 Part 3 <sup>[21]</sup>	√	√	√	x	x	x	x	x	x	x	√	x	x	√	√	High
Polyzois, 1999 <sup>[6]</sup>	√	√	√	x	x	x	x	x	x	x	√	x	x	√	√	High
Beatty <i>et al.</i> , 1999 <sup>[22]</sup>	√	√	√	x	x	x	x	x	x	x	√	x	x	√	√	High
Polyzois <i>et al.</i> , 2000 <sup>[23]</sup>	√	√	√	x	x	x	x	x	x	x	√	x	x	√	√	High
Gary <i>et al.</i> , 2001 <sup>[24]</sup>	√	√	√	x	x	x	x	x	x	x	√	x	x	√	√	High
Kiat-Amnuay <i>et al.</i> , 2002 <sup>[25]</sup>	√	√	√	x	x	x	x	x	x	x	√	x	x	√	√	High
Tran <i>et al.</i> , 2004 <sup>[26]</sup>	√	√	√	x	x	x	x	x	x	x	√	x	x	√	√	High
Kiat-Amnuay <i>et al.</i> , 2005 <sup>[27]</sup>	√	√	√	x	x	x	x	x	x	x	√	x	x	√	√	High
Kiat-Amnuay <i>et al.</i> , 2006 <sup>[28]</sup>	√	√	√	x	x	x	x	x	x	x	√	x	x	√	√	High
Kiat-amnuay <i>et al.</i> , 2009 <sup>[29]</sup>	√	√	√	x	x	x	x	x	x	x	√	x	x	√	√	High
Mancuso <i>et al.</i> , 2009 <sup>[30]</sup>	√	√	√	x	x	x	x	x	x	x	√	x	x	√	√	High
Goiato <i>et al.</i> , 2009 <sup>[31]</sup>	√	√	√	x	x	x	x	x	x	x	√	x	x	√	√	High
Han <i>et al.</i> , 2010 <sup>[12]</sup>	√	√	√	x	x	x	x	x	x	x	√	√	x	√	√	High
Hatamleh and Watts, 2010 <sup>[32]</sup>	√	√	√	x	x	x	x	x	x	x	√	x	x	√	√	High
dos Santos <i>et al.</i> , 2011 <sup>[11]</sup>	√	√	√	x	x	x	x	x	x	x	√	x	x	√	√	High
Hatamleh and Watts 2011 <sup>[33]</sup>	√	√	√	x	x	x	x	x	x	x	√	x	x	√	√	High
Goiato <i>et al.</i> , 2011 <sup>[34]</sup>	√	√	√	x	x	x	x	x	x	x	√	x	x	√	√	High
Pesqueira <i>et al.</i> , 2011 <sup>[35]</sup>	√	√	√	x	x	x	x	x	x	x	√	x	x	√	√	High
Filié Haddad <i>et al.</i> , 2011 <sup>[36]</sup>	√	√	√	x	x	x	x	x	x	x	√	x	xx	√	√	High
Polyzois <i>et al.</i> , 2011 <sup>[37]</sup>	√	√	√	x	x	x	x	x	x	x	√	x	x	√	√	High
Kantola <i>et al.</i> , 2013 <sup>[8]</sup>	√	√	√	x	x	x	x	x	x	x	√	x	x	√	√	High
Bankoğlu <i>et al.</i> , 2013 <sup>[38]</sup>	√	√	√	x	x	x	x	x	x	x	√	x	x	√	√	High
Han <i>et al.</i> , 2013 Part 1 <sup>[39]</sup>	√	√	√	x	x	x	x	x	x	x	√	x	x	√	√	High
Al-Dharrab <i>et al.</i> , 2013 <sup>[40]</sup>	√	√	√	x	x	x	x	x	x	x	√	x	x	√	√	High
Al-Harbi <i>et al.</i> , 2015 <sup>[41]</sup>	√	√	√	x	x	x	x	x	x	x	√	x	x	√	√	High
Akash and Guttal 2015 <sup>[13]</sup>	√	√	√	x	x	x	x	x	x	x	√	√	x	√	√	Low
Bangera and Guttal 2014 <sup>[42]</sup>	√	√	√	x	x	x	x	x	x	x	√	x	x	√	√	High
Griniari <i>et al.</i> , 2015 <sup>[43]</sup>	√	√	√	x	x	x	x	x	x	x	√	x	x	√	√	High
Sethi <i>et al.</i> , 2015 <sup>[44]</sup>	√	√	√	x	x	x	x	x	x	x	√	x	x	√	√	High
Shakir and Abdul-Ameer, 2018 <sup>[14]</sup>	√	√	√	x	x	x	x	x	x	x	√	√	x	√	√	Low
Eltayaar <i>et al.</i> , 2016 <sup>[15]</sup>	√	√	√	x	x	x	x	x	x	x	√	x	x	√	√	Unclear
Mehta and Nandeeshwar 2017 <sup>[45]</sup>	√	√	√	x	x	x	x	x	x	x	√	x	x	√	√	Unclear
Farah <i>et al.</i> , 2018 <sup>[46]</sup>	√	√	√	x	x	x	x	x	x	x	√	√	x	√	√	Unclear
Bishal <i>et al.</i> , 2019 <sup>[3]</sup>	√	√	√	x	x	x	x	x	x	x	√	√	x	√	√	Low
Babu <i>et al.</i> , 2019 <sup>[47]</sup>	√	√	√	x	x	x	x	x	x	x	√	x	x	√	√	High

**Table 4: The summary of findings of meta-analysis**

Study	N1	N2	Total	SMD	SE	95% CI	t	P	Weight (%)	
									Fixed	Random
Han <i>et al.</i> (2010)	5	5	10	1.296	0.64	-0.1802-0.772			10.11	21.26
Akash <i>et al.</i> (2014)	30	30	60	-1.088	0.274	-1.635-0.540			55.38	29.34
Shakir <i>et al.</i> (2016)	10	10	20	-1.394	0.482	-2.406-0.382			17.86	24.9
Bishal <i>et al.</i> (2018)	10	10	20	-1.616	0.499	-2.664-0.568			16.66	24.51
Total (fixed effects)	55	55	110	-0.989	0.204	-1.393-0.586	-4.861	<0.001	100	100
Total (random effects)	55	55	110	-0.787	0.509	-1.7950-0.222	-1.546	0.125	100	100

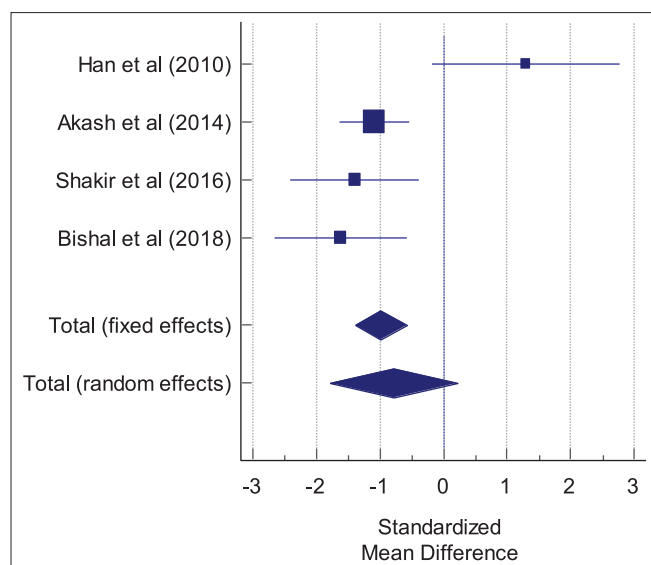
SMD: Standardized mean difference, CI: Confidence interval, SE: Standard error

### Effect of addition of various pigments and nano particles

Ceramic colorants have been proved to be most color stable than cosmetic colors as ceramic particles are smaller in size and they easily adhere to silicones and improve the color stability.<sup>[34]</sup> Out of various pigments investigated by researchers, yellow silicone pigment

was found to be less color stable than cosmetic yellow ochre, burnt sienna, and mars violet.<sup>[29]</sup> The inherent nature of silicones was said to be responsible for the color changes. However, in some studies, color changes were less in colored specimens and the authors concluded that colorants may have a protective effect on color stability of silicones.<sup>[21,41]</sup>





**Figure 2:** Forest plot showing summary of standardized mean difference from fixed effect model and Random effect model

Thermochromic pigment was tested by Kantola *et al.* who concluded that it is not suited to be used in maxillofacial prostheses.<sup>[8]</sup> Extrinsic coloration may reduce the incidence of discoloration in maxillofacial prosthesis.<sup>[38]</sup>

When exposed to UV light, the titanium white-pigmented sample remained color stable. UV-B exposure caused greater color change than UV-A exposure as a result of degradation of certain UV light-susceptible pigments, whereas long-term changes may reflect degradation of elastomer by UV light. The most pronounced color changes were observed with yellow silicone pigment in all nano-oxide combinations.<sup>[12]</sup> Titanium white opacifier was found to possess the most color stability because of its high intensity.<sup>[23]</sup> Yellow silicone pigment was found to markedly affect the color stability of all opacifiers, hence this pigment should be used cautiously.<sup>[29]</sup> Barium sulfate opacifier at 0.2% weight was found to protect silicone from color change after accelerated aging.<sup>[1]</sup> Chemical interaction between pigments and elastomer resulted in color changes, and the application of pigments into a surface was recommended.<sup>[22]</sup> The use of silicone elastomers containing certain inorganic or organic pigment mixed with the combination of an UV light absorber and a hindered amine light stabilizer may decrease the amount of color change in external prostheses.<sup>[26]</sup> Studies have shown that addition of nano-oxides at a concentration ranging from 1% to 3% to a silicone elastomer could improve its color stability. Nano-TiO<sub>2</sub>, ZnO, and CeO<sub>2</sub> are widely used as inorganic UV absorbers. UV absorbers do not migrate in a polymeric matrix, and their photo and thermal stability is not problematic even over decades.<sup>[48]</sup> Han *et al.*<sup>[12]</sup> conducted a study to assess the effect of different nano-oxide

concentrations of three compositions (Ti, Zn, and Ce) on the mechanical properties of a maxillofacial silicone elastomer and concluded that incorporation of Ti, Zn, or Ce nano-oxides at concentrations of 2.0% improved the overall mechanical properties of the silicone. When the concentrations of all three nano-oxides were 2%, the particle size in general, although irregular, seemed to be at the upper limit of the nano-scale classification of 0.100 μm; however, when the concentrations of nano-oxides were 3%, the SEM images showed that the nano-oxide particles had partly agglomerated. It was also concluded that the recommended concentration of nano-oxide should not exceed 2%–2.5%.<sup>[12]</sup> Akash and Guttal reported that addition of TiO<sub>2</sub> and ZnO (2% by weight) nanoparticles significantly improved the color stability of maxillofacial silicone.<sup>[13]</sup> TiO<sub>2</sub> nano-coating was shown to be effective in reducing color degradation of the silicone.<sup>[3]</sup>

In this systematic review, four studies on incorporation of titanium oxide were included for meta-analysis [Table 4]. The results indicate that incorporation of titanium oxide nanoparticles (2%–2.5%) improved the color stability of maxillofacial silicones.

#### Effect of human conditions/body secretions

The facial prostheses lie on the living human skin and sometimes mucosa it may absorb perspiration and sebum from sebaceous oil secretions and skin perspirations (i.e., acidic, alkaline). Such solutions have been ISO prepared 18 and used in conditioning silicone specimens to identify their effect on silicone prostheses color and properties. Greatest color changes occurred in simulated sebum solution under artificial daylight exposure, when different conditions were tested. Time was a significant variable affecting color stability under the above conditions.<sup>[32]</sup> Yanagisawa observed significant color change in two silicone elastomers which were immersed in a lipid medium for 24 h and irradiated with UV light for another 24 h. He attributed the cause of the color changes as the result of lipid absorption by the silicone and its oxidation resulting in degradation of the silicones.<sup>[49]</sup> Polyzois *et al.* evaluated<sup>[37]</sup> changes in Episil silicone elastomer after immersion in simulated sebum and acidic and alkaline perspirations for 6 months at 37°C and reported visually perceptible color changes after all 3 treatments, and color change in sebum was lesser than that in simulated perspirations. Hatamleh and Watts<sup>[32]</sup> evaluated color stability of TechSil S25 silicone under 7 conditions like artificial sebum, acidic perspiration, cleaning solution, outdoor weathering, dark storage, natural weathering, and for first time in simulated sebum under continuous artificial daylight exposure and found

that color changes in specimens occurred primarily due to inherent color instability of TechSil S25, because nonpigmented specimens stored in a sealed dark chamber showed significant color change. Another intrinsic factor responsible for chromatic alteration is continuing chemical polymerization of the silicone. Among the different test conditions used, the greatest color changes occurred in silicone samples stored in simulated sebum solution under artificial daylight exposure.

#### Effect of weathering and artificial aging conditions

The color stability has been investigated in majority of the studies under three conditions viz., darkness, artificial aging (thermocycling) and outdoor weathering. Only one study has investigated effect of mixed aging of sebum storage under accelerated daylight and found it to cause greatest color changes in pigmented specimens.<sup>[32]</sup> Out of these, darkness has caused the least effect on the color stability and this may be due to the inherent nature of the elastomer as factor of UV radiation doesn't come into play. Additional cross-linking caused by continued polymerization of the silicone or by side reactions among impurities present within the silicone also can contribute to this color change.<sup>[46]</sup> Platinum compounds which are used as catalysts in addition to polymerizing silicones are vulnerable to impurities causing color degradation. The reason for observed color changes can be either a chemical interaction or chemical incompatibility between pigments and elastomer, but this is yet to be confirmed by research. Inherent color instability of nonpigmented facial silicone elastomers primarily contributes to the color degradation of extraoral facial prostheses. As outdoor weathering more closely represents the natural environment, any changes in color observed after outdoor aging would therefore reflect the expected color changes of prosthesis in real life situations. The reason for color degradation due to UV light is accelerated crosslinking,<sup>[32]</sup> along with enhanced interaction of fatty acids with silicone leading to breakdown of the chain bonds. Also, air pollutants have been shown to affect silicone color. Studies show that the observed color changes are affected by the local weather conditions. It has been found that color changes after outdoor weathering performed in the hot and humid climate<sup>[41]</sup> were far more than British climate.<sup>[33]</sup> As the elastomer and colorant and methodology were similar in both investigations, it points out the fact that humidity and rainfall have a greater effect on colored elastomer than do heat and sun. However, to draw substantial conclusions, further investigations will be needed. In recent years, there has been a steady increase in the number of publications involving aging either artificial or outdoor as compared to no aging at all

reflecting the concern to improve the clinical shelf life in real life scenario.<sup>[50]</sup> There seems to be consensus on the fact that weathering or aging cause variable degrees of perceivable color changes in silicone prosthesis esthetics. However, direct comparisons between the studies to identify the most degrading factor(s) were not possible owing to nonuniformity in elastomers tested, pigments used, experimental protocols used, aging conditions, and testing methods.

#### Effect of disinfection

Goiato *et al.*<sup>[34]</sup> evaluated the effect of peroxide (Efferdent) disinfection on silicones (Silastic MDX 4-4210, and Silastic 732 RTV) and observed that Efferdent had a bleaching effect on silicones and caused color degradation. Pesqueira *et al.*<sup>[35]</sup> evaluated changes in MDX4-4210 silicone following two methods of disinfection, viz. Efferdent and neutral soap (Johnson and Johnson), and observed that neutral soap solution caused more color alteration than Efferdent, probably due to removal of surface pigments by the soap solution. Kiat-Amnuay *et al.*<sup>[29]</sup> assessed the effect of microwave energy exposure on color stability of silicone and reported a lack of color stability of red dry earth pigments ( $\Delta E > 1$ ) compared with the control (no pigment) group, and good stability of yellow ochre and burnt sienna ( $\Delta E < 0.35$ ). Babu *et al.* investigated color stability of two maxillofacial silicones, A2186 and Cosmesil M511 subjected to three disinfectants – Fittydent tablet, chlorhexidine gluconate 4%, and neutral soap and concluded that there was deterioration in color when subjected to chemical disinfection and accelerated aging.<sup>[46]</sup>

#### Effect of fabrication procedure

When compared the manual and mechanical mixing techniques on color stability of silicone, reduced number and percentage of pores were seen in comparison to manual mixing. Pores were seen to affect the resultant color of prosthesis. Hence, mechanical mixing under vacuum is recommended.<sup>[32]</sup> Among various investing material studied, die stone showed to affect the color stability the most. Among the separating media, die hardener showed the least color change. The best combination of an investing material and separating media as per this investigation is a dental stone (green) and alginate-based separating medium.<sup>[44]</sup>

#### Limitations of this review

The main limitation of the systematic review was that no RCTs were available addressing the present focused question, and that the overall conclusion is based on the pooled data as, all the studies varied in the silicone elastomers being investigated, the standards followed

in fabricating test specimens, the investigational testing protocols, and the specifications used in setting simulated aging conditionings (different artificial aging conditions) or outdoor weathering locations or no aging at all.

Finally, it may be questioned whether searching only one literature database, that is, Medline, involves a risk that important studies that fulfill the inclusion criteria of the present systematic review go un-noticed. In addition, only studies published in English were reviewed.

## CONCLUSIONS

This systematic review and meta-analysis indicate that many studies have been executed on color stability of maxillofacial prosthetic materials. Also, the variations in the studies are noted above. Despite the fact that there has been plenty of research over past few decades on this topic, it seems that the single “ideal” maxillofacial prosthetic material is yet to be identified. Moreover, maxillofacial prosthodontists worldwide still face problems with the serviceability and durability of facial prostheses.

Various studies have been done incorporating the nanoparticles, pigments and opacifiers in different conditions like disinfectants, sweat and sebum secretions. The aging, natural as well as artificial has been reported to affect the color stability adversely. The human conditions like sweat and sebum too are reported to contribute towards color degradation. However, these studies have high risk of bias due to lack of standardization, inadequate sample size, issues related to randomization process, blinding of the examiner, inferential statistics and estimated effect size. Very limited research exists on the suitability and durability of maxillofacial silicone elastomers in Asian countries, especially the ones with hot and humid environments.

The only variable that showed an indication of improved color stability using meta-analysis was incorporation of TiO<sub>2</sub>. For the rest of the variables in order to be able to draw a definitive conclusion randomized control trials with good research design are awaited. Therefore, it is imperative for the scientific community to continue the research on maxillofacial silicones and their necessary modifications to enhance the color stability and limit the clinical problems.

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There are no conflicts of interest.

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