



ORIGINAL RESEARCH PAPER

Dental Science

EFFECT OF DISINFECTION ON THE PHYSICAL PROPERTIES OF MAXILLOFACIAL SILICONE MATERIAL : A SYSTEMATIC REVIEW

KEY WORDS:

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ABSTRACT

Purpose – Prosthetic results are largely dominated by physical and mechanical properties of materials used. This systematic review aims to identify and interpret results of studies that evaluated effect of disinfection on physical properties of maxillofacial silicone elastomers. **Method** – Search for all articles regarding the topic, written in English language only, before December 2021 was carried out using electronic search in PubMed, Google Scholar and Scopus. Also a manual search in all major Prosthodontic, Research and Biomaterial journals was carried out. **Results** – After initial search, screening and final selection, 28 studies were selected for review based on inclusion-exclusion criteria. Among the studies selected only 1 study was published before year 2000 describing the influence of disinfectant on physical properties of maxillofacial silicone elastomer. Though 27 studies have been published in the period between 2008 to 2021, depicting the change of trend in research in maxillofacial prosthodontics. **Conclusion**- Disinfection influence various physical properties of maxillofacial silicone elastomer. Currently no ideal silicone material is available for prosthetic rehabilitation. So there is a need for more search and research to develop a successful maxillofacial silicone elastomer. Also the literature describing selection of disinfectant and protocol for disinfection of silicone is highly variable. Hence the standardization organisations or scientific community must design a standard protocol for disinfection procedure to improve longevity of silicone prosthesis and health of surrounding natural tissues.

INTRODUCTION

Maxillofacial defects can be congenital or caused by cancer, trauma, or tumor surgery. These defects create functional, aesthetic and psychological lacunae in individual's personal and professional life [1]. Rehabilitation of defects can be done surgically or by using prosthesis. Success of maxillofacial prostheses depends mainly on the physical and mechanical properties of the material used.

An ideal maxillofacial prosthetic material should have optimum physical and mechanical properties [2]. Various materials like ivory, rock, metals and quartz have been found among the ruins of Egyptian, Chinese, Aztec, and even ancient Syrian civilizations [3].

Silicones were introduced in 1946 but were used, for the first time by Barnhart in 1960 for extra oral prosthesis [4]. Silicone is a combination of organic and inorganic compounds and chemically they are termed as polydimethyl siloxane.

Silicone became popular over other materials as they have a range of good physical properties, low degree of toxicity, easier to manipulate, chemical inertness, high degree of thermal and oxidative stability. Further they can be stained intrinsically or extrinsically to give them more lifelike natural appearance [5,6].

Though silicone elastomers are the most commonly used material for rehabilitation but they present multiple limitations. Most common problems observed are related to tear strength, color stability, color matching, tensile strength, surface roughness and ability to safely disinfect the material.

Numerous studies have evaluated physical properties and also evaluated influence of various interventions on these physical properties. This systematic review aims to interpret the results of studies that evaluated the effect of disinfection on the physical properties of maxillofacial silicone elastomers.

METHOD

Selection

The PICO method used in this study was:
 Population – Silicone elastomers for maxillofacial rehabilitation.
 Intervention – Effect of disinfection procedure.
 Comparison – the physical properties of material evaluated before disinfection.
 Outcome – Interpretation of changes in the physical properties after disinfection.
 PICO question – Does disinfection procedure of maxillofacial silicone elastomer cause any changes in physical properties?

Data sources

An electronic search was carried out in PubMed, Google scholar and Scopus for peer reviewed scientific studies regarding the effect of disinfectant on the physical properties of maxillofacial silicone. MeSH (Medical Subject Headings) terms used for search were “maxillofacial silicone” or “disinfection”, “silicone elastomer” or “disinfection” and “physical properties” or “disinfection”.

The search included only English language articles published in peer reviewed journals. Also a manual search in all major prosthodontic, biomaterial and research journals was carried out. The studies were identified based on the inclusion and exclusion criteria described in Table 1.

Selection of studies

Selection of studies for systematic review is summarised in Figure 1. Initially independent search for studies was carried out by two authors and were reviewed for removal of duplicate studies or studies not fulfilling the inclusion, exclusion criteria.

After initial screening the data was assessed by an independent investigator specialized in the field. Any disagreement among the authors was resolved by Cohen Kappa analysis. So, after complete analysis 28 studies were selected based on the PICO question and according to inclusion-exclusion criteria.

Data analysis

Data were obtained from all included studies and tabulated into following subheadings as Year, Study, Silicone material investigated, Disinfection protocol, Physical property evaluated and observations. The complete data is summarised in Table 2.

RESULTS

After electronic and manual research it was observed that most of the studies published from year 1965 to 2000 were based on preliminary evaluation of physical properties of maxillofacial silicone. Studies relating to any intervention by disinfectant were bleak in that time period.

In this review only one study by Haug SP et al has been include before year 2000. However with progression of time scenario has changed. From 2009 onwards a large number of studies have been published describing the influence of disinfectant on physical properties.

In this review 10 studies were published in the period from 2000 to 2010. Also with introduction of new materials recent publications (2010-2021) have shown a comparative evaluation of influence of different disinfectants on physical properties of maxillofacial silicone elastomer. In this review 17 studies have been include published in time period 2010 to 2021.

The number of research studies published evaluating the physical properties and studies showing the influence of disinfectant on the physical properties of maxillofacial silicone elastomer is summarised in Figure 2.

The maxillofacial silicone elastomeric material evaluated in the study is summarised in figure 3. A high variability is observed in published studies regarding the selection of disinfectant and also the disinfection protocol used (Figure 4).

DISCUSSION

An ideal maxillofacial prosthetic material should have optimum physical and mechanical properties and should maintain these properties during their service lifetime of the prosthesis. Materials commonly used these days for fabrication of facial prostheses are acrylic resins, acrylic copolymers, vinyl polymers, polyurethane elastomers and silicone elastomers [31].

Silicone became popular over other materials as they have a range of good physical properties, low degree of toxicity, easier to manipulate, chemical inertness, high degree of thermal and oxidative stability. Further they can be stained intrinsically or extrinsically to give them more lifelike natural appearance. Silicones have range of properties from rigid plastics through elastomers to fluids. They exhibit good physical properties over a range of temperature. Silicon can be cured at room temperature or heat.

Silicone facial prostheses can be retained using a variety of tools of which adhesives (skin glue) and dental implants are currently the most common ones.

Maintaining hygiene of the prosthesis is important for the health of the soft tissue underneath the prosthesis and for preserving the prosthesis itself in a good condition.

Cleansing a facial prosthesis (with or without glue) or the skin (with or without an implant suprastructure) can be a difficult task, especially for patients with limited manual dexterity or visual problems, which is common in elderly who present the largest group amongst the facial prostheses wearers.

The routine method used currently to prevent biofilm formation on silicone facial prostheses is to instruct patients to

clean their prostheses meticulously. Silicone materials are more difficult to clean than resins as these materials are permeable so are more susceptible to microbial colonization [32]. Neutral soap, gentle brushing using a soft nylon bristles A variety of cleansing agents like CHX and isopropyl alcohol have been recommended.[33,34]

I Tear Strength

Hattamleh et al [14]and Madiha Fouad et al [20] claimed reduction in tear strength values after disinfection. A significant reduction in the values of tear strength was observed after disinfection.

This reduction could be attributed to the propagation of cross-linking that occurs as the material is exposed to moisture. Immersion in disinfecting solutions accelerates the polymerization of silicone [14]. Although tear strength increase upon cross-linking, it is also reduced with too high level of cross-linking due to the formation of obstacles that prevent the molecules from sliding past each other, resulting in inelastic brittle material that ruptures at lower deformation.[20]

II Tensile Strength

Eleni PN et al[17] decribed alteration of tensile properties, reported significant reduction in tensile strength with different disinfection procedures. Hatmleh et al[14] reported that changes of elatomers after disinfection with antimicrobial cleansing solution probably caused by decomposition of cleansing solution into carbon monoxide, carbon dioxide and sulphur dioxide which could alter tensile properties.

III Surface Roughness

Goaito et al[8], Mohd Moudaffer[20], Babu AS et al [24] published slight decrease in surface roughness post disinfection. The partial decrease in the surface roughness might be due to continuous polymerization which promotes further arrangement and supplement of polymer chain leading to fine, smooth silicone surface with the time [8].

It can also be explained that the test specimens when immersed in disinfectant continuously, there might be some adsorption of disinfecting agent to the surface of polymer causing swelling of surface [25].

Iv Hardness

An increase in hardness of maxillofacial silicone elastomer have been observed in studies by Haug SP et al[7], Goiato et al [8], Guiotti AM[9], Eleni PN et al[18], Fouad M, Moudhaffer M[20], Babu AS, Manju V, Gopal VK,[24] Cevik P, Bicer AZ[26]. Goiato et al[8] have described increase in hardness due to continuous polymerization process[8] and increase in cross linking of polymeric chains. Guiotti AM et al[9] have described increase in hardness attributable to evaporation of volatile by products

V Color Stability

Hatamleh MM, Watts DC[11], Haddad MF et al[13] Eleni PN et al[18] Fouad M, Moudhaffer M[20] Guiotto et al[21] Babu AS, Manju V, Gopal VK[24] Mehta S, Nadeeshwar DB[23] Chamaria A, Aras MA, Chitre V, Rajagopal P[29] reported color instability of maxillofacial silicone elastomers following disinfection. Haddad MF et al[13] in their study described greatest color change when disinfected with neutral soap.

The disinfection is done through digital friction which can remove nanoparticles(pigments) on the superficial layer of material. Hatamleh et al[11] in their study reported that chemical disinfectant can interact with silicone, break chain bonds and decompose the elastomer, thus adversely affecting color stability. Pesqueria et al[15] explained that sodium perborate based disinfectant (fittydent denture cleansing tablet) mainly acts by liberation of oxygen. They

remove all stains, also causing whitening of prosthesis so causes significant color change. Babu AS et al[24] explained significant color change is because of the continuous release of subproducts during continuous polymerization of silicones

Limitations of This Review

The limitation of the systematic review was that none of RCTs were available while addressing the present focused question, the overall conclusion is based on the data available, all the studies varied in the silicone elastomers being investigated, the standards followed in fabricating test specimens, the investigational testing protocols, the disinfectant material used and also the disinfection protocol applied. In addition, only studies published in English were reviewed in the study.

CONCLUSION

This systematic review suggests that multiple studies on the influence of disinfectant on the physical properties of maxillofacial silicone elastomer have been published in the past. But till date none of the available maxillofacial elastomer evaluated was resistant to changes in physical properties caused by disinfection procedure.

So there is a need to develop an "ideal" maxillofacial silicone elastomer. Also a high variability has been observed in the selection of disinfectant and also in the disinfection procedure followed. So for longevity of prosthesis and for good health of underlying tissues a standard disinfection protocol is necessary. hence it is necessary for the scientific community to reach to a consensus and together improve quality of life of patients using maxillofacial prosthesis.

Table 1: Criteria for inclusion and exclusion of studies

| Inclusion criteria | Exclusion criteria |
|---|--|
| Studies published in English language till December 2021. | Publications in language other than English. |
| Only original studies | Review articles |
| Maxillofacial silicone elastomer, modified silicone elastomer (filled/reinforced) | Maxillofacial resin material. |
| Influence of disinfection on Physical properties (tear strength, tensile strength, hardness, dimensional stability, color stability, percentage elongation) evaluation. | Natural aging, outdoor aging and weathering. |
| Artificial aging using disinfectants | |

Figures

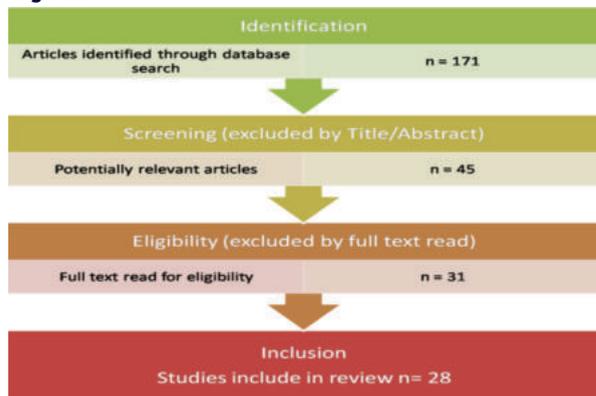


Fig1: Article selection preferred reporting items for systematic review based on inclusion and exclusion criteria

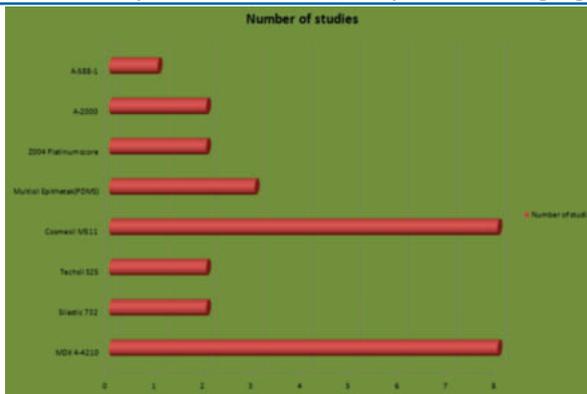


Fig 2 : Type of Maxillofacial silicone evaluated in various studies

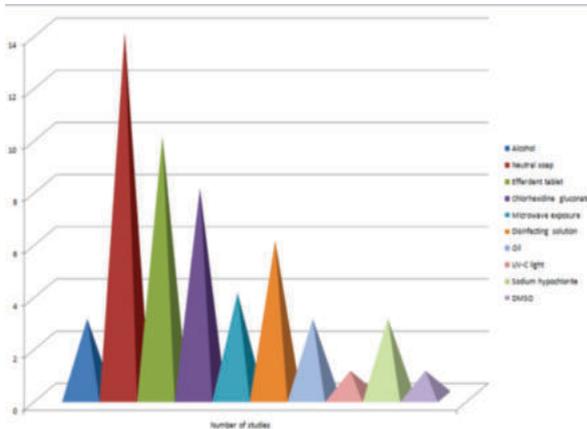


Fig 3 : Type of Disinfectant used in various studies

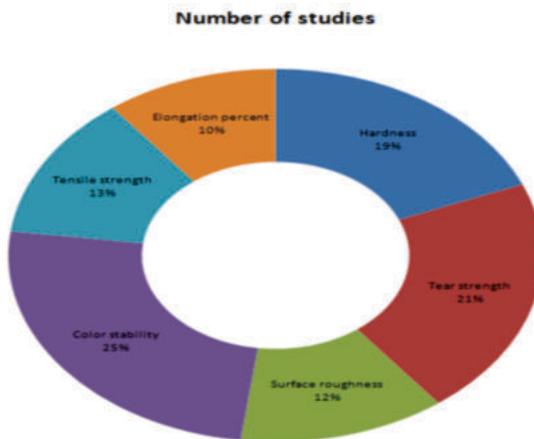


Fig 4 : Physical property of Maxillofacial silicone evaluated in various studies

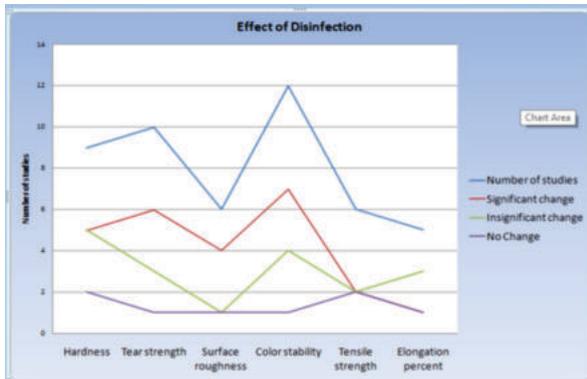


Fig 5 : Effect of Disinfection on various physical properties

Table 2: Critical evaluation of selected studies

| Year | Study | Silicone material investigated | Disinfection protocol | Physical property evaluated | Observation |
|------|--|---|--|---|--|
| 1992 | Haug SP Adres CJ, Munoz CA, Okamura M [7] | A-2186 | 1-Propanol | Tear strength, Tensile strength, hardness | a. Decrease in Tensile strength and tear strength b. Increase in hardness |
| 2009 | Goiato et al [8] | MDX 4-4210 Silastic 732 | a. Neutral pH soap – daily for 60 days b. Efferdent tablets – three times a week for 60 days | Hardness and surface roughness | a. Increase in hardness b. Slight decrease in surface roughness |
| 2010 | Guiotti AM, Goiato MC, Santos DM [9] | MDX 4- 4210 | 4% Chlorhexidine Gluconate, which was sprayed for 1 minute – daily for 1 year | Shore A hardness | Increase in hardness |
| 2010 | Goiato MC et al [10] | MDX 4- 4210 | Neutral soap, Efferdent tablet, 4% Chlorhexidine – 3 times a week for 60 days | Dimensional stability | Significant dimensional changes |
| 2010 | Hatamleh MM, Watts DC [11] | Techsil S25 | Immersion in silicone cleansing solution for 30 hours | Color stability | Significant color change |
| 2010 | Goiato MC et al [12] | MDX 4-4210 | Neutral soap, Efferdent tablet, 4% Chlorhexidine – 3 times a week for 60 days | Hardness | Increase in hardness |
| 2011 | Haddad MF et al [13] | MDX 4-4210 | Neutral soap, Efferdent tablet, 4% Chlorhexidine – 3 times a week for 60 days | Color stability | No significant change |
| 2011 | Hatamleh MM, Polyzois GL, Silikas N, Watts DC [14] | Techsil S25 | Immersion in silicone cleansing solution for 30 hours | Tensile strength, Tear strength, Hardness | Significant decrease |
| 2012 | Pesqueria AA et al [15] | MDX 4-4210 | Neutral soap, Efferdent tablet | Dimensional stability, Detail reproduction | a. Significantly affected dimensional stability b. No change in detail reproduction |
| 2013 | Dharrab AA, Tayel SB, Abodaya MH [16] | Cosmesil M 511 | Immersion in acidic, alkaline and sebum solution for 6 months | Color stability, surface roughness | Insignificant changes |
| 2013 | Eleni PN et al [17] | Multisil epithetak (PDMS), Chlorinated polyethylene (CPE) | a. Microwave exposure – daily for 3 minutes b. Sodium Hypochlorite solution (1% w/w) - Immersion for 30h c. Neutal soap- Immersion for 30h d. Disinfecting solution (Daro B – 200-09) - Immersion for 30h | Tensile strength, Microindentation properties | Significant change (Greatest with microwave exposure and least with disinfecting solution) |
| 2013 | Eleni PN et al [18] | Multisil epithetak (PDMS), Chlorinated polyethylene (CPE) | a. Microwave exposure – daily for 3 minutes b. Sodium Hypochlorite solution (1% w/w) - Immersion for 30h c. Neutal soap- Immersion for 30h d. Disinfecting solution (Daro B – 200-09) - Immersion for 30h | Hardness, Color stability | Significant changes a. For PDMS – microwave exposure caused minimal change. b. For CPE – Sodium hypochlorite caused minimal change) c. PDMS material more color stable than CPE |
| 2014 | Eleni PN, Krokida M, Polyzois G, Gettleman L [19] | Multisil epithetak (PDMS), Chlorinated polyethylene (CPE) | a. Microwave exposure – daily for 3 minutes b. Sodium Hypochlorite solution (1% w/w) - Immersion for 30h c. Neutal soap- Immersion for 30h d. Disinfecting solution (Daro B – 200-09) - Immersion for 30h | Dynamic mechanical thermal changes | Significant reduction in mechanical properties |
| 2016 | Fouad M, Moudhaffer M [20] | Cosmesil M511 | a. Microwave exposure – 3 minutes b. Neutral soap – 75 minutes c. 4% Chlorhexidine gluconate – 10 minutes (All Exposure for 3 times a week for 60 days.) | Tear strength, Surface hardness, Surface roughness, Color stability | a. Significant decrease in tear strength b. Significant increase in surface hardness c. Significant reduction in surface roughness d. Color instability |

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|------|---|--|---|---|--|
| 2016 | Guiotto et al [21] | MDX4-4210 | a. Neutral soap – immersion for 30 seconds b. 4% Hydrastis Canadensis - immersion for 10 minutes c. Cymbopogon nardus extract - immersion for 10 minutes | Shore A hardness, Color stability | a. Decrease in hardness b. Color instability |
| 2017 | Nagane P [22] | M511 Technovent, A2186 FactorII | a. Fittydent tablet (Sodium perborate monohydrate) b. Neutral soap (Immersion for 30 minutes, three times a week for 60 days) | Hardness, Surface roughness | No significant change |
| 2017 | Mehta S, Nadeeshwar DB [23] | M511 maxillofacial silicone, Z004 Platinum Silicone rubber | Fittydent denture cleansing tablets – immersion for 30h | Color stability | Significant change |
| 2018 | Babu AS, Manju V, Gopal VK [24] | A-2186, Cosmesil M511 | a. Fittydent tablet (Sodium perborate – immersion for 3 minutes monohydrate) b. 4% Chlorhexidine – immersion for 10 minutes c. Neutral soap – rubbed for 30 seconds (Disinfection for three times a week for 60 days) | Color stability, Hardness, Surface roughness | a. Significant change in color b. Significant increase in hardness c. Significant decrease in surface roughness (Minimal changes observed with 4% Chlorhexidine) |
| 2018 | Tetteh S, Bibb RJ, Martin SJ [25] | M511 Platinum silicone | a. Tea tree oil b. Manuka oil (Immersion for 30 hours) | Hardness, Elongation at break, tensile strength, tear strength | a. Significant change in hardness and elongation at break b. No change in tensile and tear strength |
| 2018 | Cevik P, Bicer AZ [26] | A-2000 | a. Neutral soap b. Effervescent tablets c. 0.2% Chlorhexidine d. 4% Chlorhexidine e. 1% Sodium hypochlorite | Hardness, Color evaluation | a. Increase in hardness b. Color instability (0.2% Chlorhexidine – most suitable disinfectant) |
| 2018 | Devi KM, Narayana RD, Nayar S [27] | Cosmesil M511 | a. Neutral soap – immersion for 30h b. Clinsodent effervescent denture cleansing tablet – immersion for 30h | Color stability | Significant color change |
| 2019 | Miranda NB et al [28] | MDX4-4210 MED-4014 | a. 11% Propolis extract aqueous solution in alcohol b. 2% Chlorhexidine (Disinfection for three times a week for 60 days) | Optical parameters, Hardness | a. Significant increase in opacity b. Insignificant increase in hardness |
| 2019 | Chamaria A, Aras MA, Chitre V, Rajagopal P [29] | A-2000 | a. 2% Chlorhexidine b. Antibacterial soap | Color stability | a. 2% Chlorhexidine – clinically acceptable color change b. Antibacterial soap – not advisable as a disinfectant |
| 2019 | Al-Jumaili QB, Salim SA [30] | M511, Technovent | a. 3% sodium hypochlorite b. 2% Thymol | Shore A hardness, Color stability | Insignificant change |
| 2020 | Faiza Mohammed Hussain Abdul-Ameer[31] | a. Heat temperature vulcanizing (HTV) Cosmesil M511 silicone b. Room temperature vulcanizing (RTV) VST50F | a. alcoholic extract of <i>Salvadora persica</i> b. 2% chlorhexidine digluconate | Tear strength and Hardness | Significant decrease |
| 2021 | Nayera S. Radey, Ahmed M. Al Shimy, Dawlat M. Ahmed[32] | MED-4210 | Antimicrobial silicone-cleaning solution(B-200–12, Daro Inc., Lakeside, AZ) | Tensile strength, percentage elongation, tear strength and shore A hardness | Significant change |

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|------|---|---------------------------------------|--|-----------------|----------------------|
| 2021 | Aya Mohamed Fawzy, Nada Sherin El Khourazaty[33] | Multisil-Epithetik, bredent GmbH | Neutral soap | Color stability | Insignificant change |
| 2021 | Gabriela Malateaux, Rodrigo Salazar-Gamarra, Jefferson de Souza Silva, Vanessa Gallego Arias Pecorari, Ivana Barbosa Suffredini, Luciano Lauria Dib[34] | medical silicone (A-588-1; Factor II) | a. distilled water b. 0.12% chlorhexidine c. UV-C LED light d. dimethyl sulfoxide [DMSO]. | Color stability | Insignificant change |

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