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Comparative Evaluation of Effectiveness of Addition of Antifungal Agents on Physical and Mechanical Properties of Maxillofacial Silicone - A Systematic Review and Meta-Analysis

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Abstract

Replacement for the congenital defect is the major upliftment for the patient in terms of ones well being physically and socially. Maintenance of the prosthesis is other major factor to prevent fungal growth. Therefore, addition of the antifungal agent is of utmost importance to silicon prosthesis and to study the physical and mechanical effect of these antifungal agents on silicon prosthesis is a key.

A systematic review and metanalysis was carried out following the PRISMA guideline on various electronic databases, following which the articles that met the inclusion and exclusion criteria were sorted and a data analysis was done. Results were tabulated and with the available data the study concluded that addition of antifungal agent on maxillofacial silicon had statistically significant influence on physical and mechanical properties.

INTRODUCTION

Congenital defects are the most common cause of maxillofacial anomalies. Apart from this surgical trauma, external resection or combination of both can result in facial defects. These defects affect the ones well-being either physically, mentally, psychosocially. Autoplastic reconstruction is one of its kind where there are favourable conditions present.

Maxillofacial prosthesis is always a functional and aesthetic alternative when surgical repair alone cannot be fulfilled. Silicon elastomers are the current, hence widely used material in the field of maxillofacial prosthodontics. Silicon materials were introduced in the year of 1960. Silicon is widely acceptable material because of its physical, mechanical, biocompatible properties. Texture of this material is quite similar to human skin.

One of the most common drawbacks of these material is that it enhances the growth of several fungi. Yeast infections are of great concern as they are the most prevalent in oral cavity as well as skin. The colonization of these fungi over maxillofacial silicon elastomer is of clinical concern. Hence, several antifungal agents have been incorporated into the silicon elastomer. Antifungal agents per say have been classified as synthetic and natural. Synthetic antifungal agents like nystatin, ketoconazole, clotrimazole have proven to

be great antifungal agent by inhibiting the cell wall permeability of the fungi but at the same time have several disadvantages, that is the rise in systemic complication as well as emergence of resistance. Therefore, the rise in natural herbal antifungal agents have substituted the synthetic ones because of their lesser adverse effect. Herbal antifungal agent is one of its kind of natural, plant-based alternative to the synthetic ones. Both of these agents have been used tremendously in their own ways.

However, there are various deteriorating factors that affect the micro polymeric structure as well as macrodefects of silicon elastomer in terms of their physical and mechanical properties like tear strength, surface roughness, colour stability, shore hardness after addition of the herbal antifungal agents.

This comparative analysis will provide useful understandings of material science breakthroughs, allowing dental surgeon and researchers to make more educated decisions when selecting or creating antifungal-modified silicone elastomers for maxillofacial prosthetic applications. The study of this subject is critical for improving patient care, maintaining the longevity and usefulness of maxillofacial prosthesis, and resolving the ongoing issues provided by fungal infections in the field of facial rehabilitation.

Therefore, this systematic review aims to study the effect of incorporation of antifungal agent on the physical and mechanical properties of maxillofacial silicon elastomer.

Methods

A systematic review of literature and meta-analysis was performed. This study followed the (PRISMA 2020) Preferred Reporting Items for Systematic Review 2020[1], the Cochrane Handbook for systematic reviews of interventions, version 5.1.0. and 4th Edition of the JBI Reviewer's Manual and was registered at PROSPERO under registration code CRD42024505176.

Eligibility criteria:

[A] Inclusion criteria:

a. **Population:** Studies involving maxillofacial silicone specimens included irrespective of the brand of the material used.
b. **Intervention:** Studies including exposure of maxillofacial silicone to antifungal agents such as chitosan, nanoparticles such as silver (Ag), Titanium (Ti), Zinc oxide (ZnO), etc irrespective of the concentration of the agent involved.
c. **Comparison:** Studies including maxillofacial silicone specimens without addition of antifungal agents will be used as comparison or control group.
d. **Outcome:** Studies giving information about physical and mechanical properties such as hardness, tear strength, tensile strength, color stability, percent elongation in both the groups.
e. **Study design**

1. Studies published in any language where English translation is possible.
2. Studies published till 31-01-2024
3. Invitro studies were included
4. Studies with full-text articles were included.

[B] Exclusion criteria:

1. Studies not fully available in the database.
2. Single group studies without the control group were excluded
3. Review reports, case series and animal studies were excluded.
4. Studies providing only abstract and not full text.

5. Studies not mentioning required outcomes were excluded

Search strategy

Studies were selected based on the PICOS inclusion criteria in the review protocol. Two reviewers assessed titles and abstracts to identify potentially eligible studies. Any queries were discussed with a third reviewer.

- The preferred reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) for conducting a meta-analysis were followed.
- The electronic data resources consulted for elaborate search were Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE, CINAHL, EMBASE, PsycINFO, Scopus, ERIC, ScienceDirect with controlled vocabulary and free text terms. (Table 1)
- Articles published until 31/01/2024 were searched, without any restriction concerning the publication's language.

Focused review question:

Is there any difference in the physical and mechanical properties of maxillofacial silicone on addition of antifungal agents?

Search Strategy according to PICOS:

Population	(maxillofacial[All Fields] AND ("silicones"[MeSH Terms] OR "silicones"[All Fields] OR "silicone"[All Fields])) OR (maxillofacial[All Fields] AND ("elastomers"[MeSH Terms] OR "elastomers"[All Fields] OR "elastomer"[All Fields]))
Intervention	((((("antifungal agents"[All Fields] OR "antifungal agents"[MeSH Terms] OR ("antifungal"[All Fields] AND "agents"[All Fields]) OR "antifungal agents"[All Fields] OR ("antifungal"[All Fields] AND "agent"[All Fields]) OR "antifungal agent"[All Fields]) AND ("chitosan"[MeSH Terms] OR "chitosan"[All Fields])) OR (("silver"[MeSH Terms] OR "silver"[All Fields]) AND ("nanoparticles"[MeSH Terms] OR "nanoparticles"[All Fields]))) OR (("titanium"[MeSH Terms] OR "titanium"[All Fields]) AND ("nanoparticles"[MeSH Terms] OR "nanoparticles"[All Fields]))) OR (("zinc oxide"[MeSH Terms] OR ("zinc"[All Fields] AND "oxide"[All Fields]) OR "zinc oxide"[All Fields]) AND ("nanoparticles"[MeSH Terms] OR "nanoparticles"[All Fields]))
Comparison	("control"[All Fields] AND "groups"[All Fields]) OR "control groups"[All Fields]) AND comparison[All Fields]
Outcome	(((((("tensile strength"[MeSH Terms] OR ("tensile"[All Fields] AND "strength"[All Fields]) OR "tensile strength"[All Fields]) OR ("hardness"[MeSH Terms] OR "hardness"[All Fields])) OR (percent[All Fields] AND elongation[All Fields])) OR ("physical phenomena"[MeSH Terms] OR ("physical"[All Fields] AND "phenomena"[All Fields]) OR "physical phenomena"[All Fields] OR ("physical"[All

	Fields] AND "properties"[All Fields]) OR "physical properties"[All Fields])) OR (mechanical[All Fields] AND properties[All Fields])

Overall Search strategy in PubMed

	Number of items obtained
(((maxillofacial[All Fields] AND ("silicones"[MeSH Terms] OR "silicones"[All Fields] OR "silicone"[All Fields])) OR (maxillofacial[All Fields] AND ("elastomers"[MeSH Terms] OR "elastomers"[All Fields] OR "elastomer"[All Fields]))) AND (((((("antifungal agents"[All Fields] OR "antifungal agents"[MeSH Terms] OR ("antifungal"[All Fields] AND "agents"[All Fields]) OR "antifungal agents"[All Fields] OR ("antifungal"[All Fields] AND "agent"[All Fields]) OR "antifungal agent"[All Fields]) AND ("chitosan"[MeSH Terms] OR "chitosan"[All Fields])) OR (("silver"[MeSH Terms] OR "silver"[All Fields]) AND ("nanoparticles"[MeSH Terms] OR "nanoparticles"[All Fields]))) OR (("titanium"[MeSH Terms] OR "titanium"[All Fields]) AND ("nanoparticles"[MeSH Terms] OR "nanoparticles"[All Fields]))) OR (("zinc oxide"[MeSH Terms] OR ("zinc"[All Fields] AND "oxide"[All Fields]) OR "zinc oxide"[All Fields]) AND ("nanoparticles"[MeSH Terms] OR "nanoparticles"[All Fields])))) AND ((((("tensile strength"[MeSH Terms] OR ("tensile"[All Fields] AND "strength"[All Fields]) OR "tensile strength"[All Fields]) OR ("hardness"[MeSH Terms] OR "hardness"[All Fields])) OR (percent[All Fields] AND elongation[All Fields])) OR ("physical phenomena"[MeSH Terms] OR ("physical"[All Fields] AND "phenomena"[All Fields]) OR "physical phenomena"[All Fields] OR ("physical"[All Fields] AND "properties"[All Fields]) OR "physical properties"[All Fields])) OR (mechanical[All Fields] AND properties[All Fields]))	389

The above mentioned was the final search history for the databases accessed till the month of January 2024.

Selection of studies

The title and the abstract of each study were reviewed and critically assessed by two independent reviewers. The methods used to apply the selection criteria were the following:

1. integration of the searched outcomes to delete duplicate entries
2. examination of titles and abstracts to delete clearly irrelevant articles
3. recovery of the full text of potentially relevant articles
4. binding and gathering of multiple articles of the very same study
5. examination of the articles' full text to verify the degree of compliance that the studies had with the eligibility criteria
6. establishing connection with researchers, if necessary, to clarify the study's eligibility
7. deciding about the study's inclusion and proceeding with data gathering.

Data extraction

Two reviewers independently extracted data from the included studies. Disagreements were again resolved through discussion. Data gathered was carried out using a verification list of items that were considered for data extraction. The main items of this list were as follows:

1. Authors, Year and Title of study
2. Country
3. Study design
4. Sample size
5. Intervention
6. Comparison
7. Outcomes
8. Methods of outcome assessment
9. Conclusion and other items

Details regarding the publication and the study, the participants, settings, the interventions, the comparators, the outcome measures, study design, statistical analysis and results, and all other relevant data (funding; conflict of interest etc.) were carefully and accurately extracted from all included studies. Data extraction was done and accurately recorded in the excel sheets for all the primary outcomes separately.

Critical appraisal of retrieved studies (Risk of bias assessment)

The risk of bias assessment used the QUIN tool (risk-of-bias tool for assessing in vitro studies conducted in dentistry). The study's quality assessment was conducted according to a fixed set of domains of bias (Clearly stated aims/objectives; Detailed explanation of sample size calculation; Detailed explanation of sampling technique; Details of comparison group; Detailed explanation of methodology; Operator details; Randomization; Method of measurement of outcome; Outcome assessor details; Blinding Statistical analysis; Presentation of results). QUIN final assessment was performed by categorizing each of the study features at 'low', 'medium', or 'high' risk of bias. Scores for studies are awarded according to the following. Adequately specified = 2; inadequately specified = 1; not specified = 0; not applicable indicates that this category would not be counted.[2]

Meta-analysis

Meta-analysis was conducted on the studies that provided information on similar outcomes.

Assessment of Heterogeneity:

Clinical heterogeneity refers to differences between studies with regards the participants, interventions, comparators, settings, and outcomes. Methodological heterogeneity refers to the study design and the methodological quality of the studies (risk of bias).

The I square statistic (I^2) represents the percentage of the variability in effect estimates that is due to heterogeneity. I^2 is the proportion of observed dispersion of results from different studies included in a meta-analysis that is real, rather than spurious.

Heterogeneity was considered statistically significant if $P < 0.05$. A rough guide to the interpretation of I^2 given in the Cochrane handbook is as follows:

a. from 0 to 30%, the heterogeneity might not be important;
b. from 30% to 60%, it may represent moderate heterogeneity;

c. from 50% to 90%, it may represent substantial heterogeneity;
d. from 75% to 100%, there is considerable heterogeneity.

History

Download history Clear history

Search	Add to builder	Query	Items found	Time
#6	Add	Search ((((maxillofacial silicone) OR maxillofacial elastomer)) AND ((((antifungal agent) AND chitosan) OR silver nanoparticles) OR titanium nanoparticles) OR zinc oxide nanoparticles)) AND ((((((tensile strength) OR hardness) OR tear strength) OR percent elongation) OR physical properties) OR mechanical properties)	370	11:52:30
#5	Add	Search ((((((tensile strength) OR hardness) OR tear strength) OR percent elongation) OR physical properties) OR mechanical properties	1943349	11:52:22
#4	Add	Search control	5929944	11:50:58
#3	Add	Search (control) AND comparison	3523689	11:50:44
#2	Add	Search ((((antifungal agent) AND chitosan) OR silver nanoparticles) OR titanium nanoparticles) OR zinc oxide nanoparticles	134995	11:50:24
#1	Add	Search (maxillofacial silicone) OR maxillofacial elastomer	2768	11:49:29

Results

Study selection

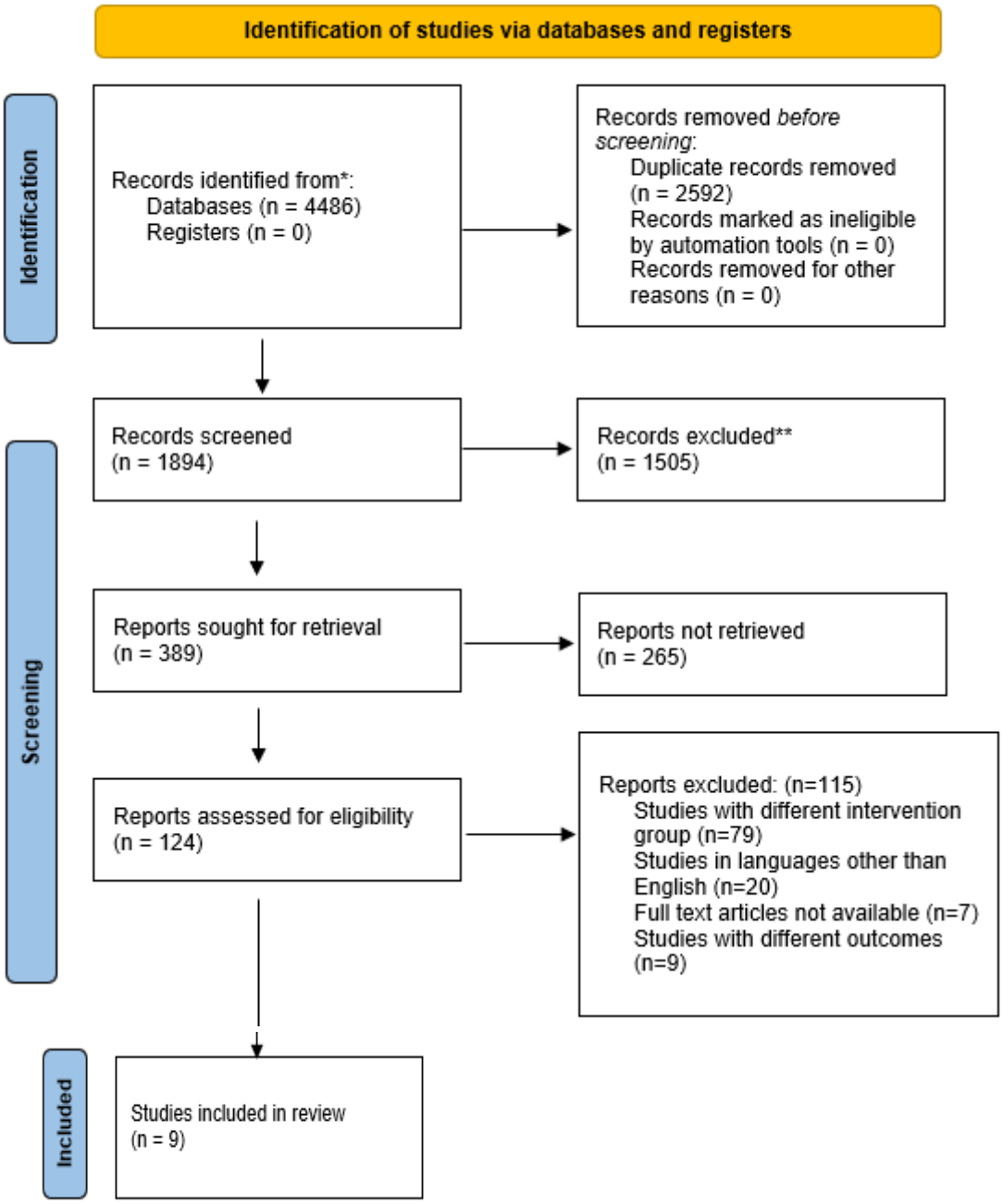
The initial electronic database search on PubMed/MEDLINE, Cochrane library and DOAJ resulted in 4486 titles. 2592 articles were cited as duplicates. After screening the abstracts, 389 relevant titles were selected by two independent reviewers were sought for retrieval and 265 were excluded for not being related to the topic. Following examination and discussion by the reviewers, 124 articles were selected for full-text assessment. By manual evaluation of reference lists of the selected studies did not deliver additional papers. After pre-screening, application of the inclusion and exclusion criteria and handling of the PICO questions, 9 studies remained. Nine studies were included in the qualitative synthesis which were subjected for data extraction and statistical analysis. (Figure 1)

Study characteristics

Nine studies were included in this systematic review (Table 1). All the studies showed invitro study design. These studies were conducted in different parts of world – Iraq[3,4,6], UK[5], Saudi Arabia[8,10], Turkey[9], India[7,11]. Only one study (Karaman 2022) mentioned details regarding ethical approval for conducting the research. Silver nano-particles were included in four[3,7,8,11] studies, one study used different concentrations of chitosan[4], one study[5] used tea tree oil and Manuka oil as antifungal agent. In study by Jaffer 2019[6], authors used different concentrations of siwak extract. Titanium dioxide nanoparticles were used in three studies[9-11].

The conclusions of studies indicated that addition of antifungal agents did not produce any significant difference in the physical and mechanical properties of maxillofacial silicones. Some studies found a reduction in hardness of the silicone, however tear strength and tensile strength were not affected.

Figure 1: PRISMA 2020 flow diagram



Risk of bias assessment

Quality assessment of invitro studies (Table 2)

For assessment of risk of bias according to QUIN tool, the percentage value is calculated based on total score. If the study has score >70%, risk of bias is low, for 50-70% risk of bias is moderate. For studies <50% score, risk of bias is high.

Among the included studies, one study[11] showed low risk of bias while remaining showed medium risk. None of the included studies mentioned details regarding sample size calculation, sampling technique and randomization.

Meta-analysis

Data synthesis was carried out using a descriptive synthesis, with an overview of the characteristics of each included study. For quantitative synthesis, a summary of the combined estimate related to the intervention effect was calculated as a mean of the differences of the effects of post-intervention in individual studies.

Effect measures

The standardized mean difference is used as a summary statistic in meta-analysis when all studies assess the same outcome but measure it in a variety of ways. In this circumstance it is necessary to standardize the results of the studies to a uniform scale before they can be combined. Hence for quantitative assessment in this study, standardized mean difference (SMD) was use as effect measure.

Quantitative assessment was conducted on hardness, tensile strength, tear strength and percent elongation parameters using two different interventions – silver nanoparticles, titanium nanoparticles irrespective of the concentration of the particles used in different individual studies.

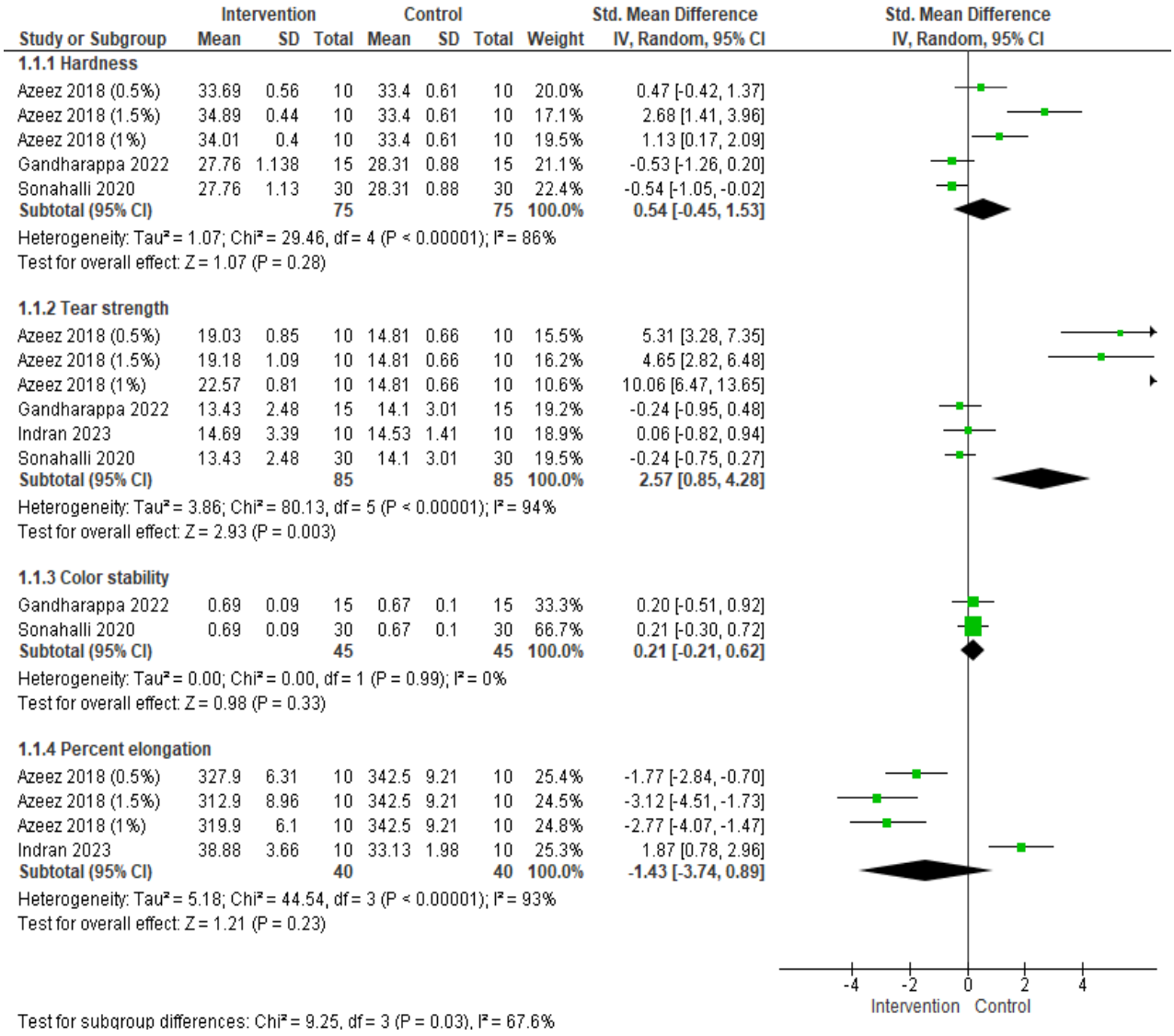
1. Silver nano-particles

For evaluation of hardness with and without silver nanoparticles, three studies[3,7,8] were included. A total of 75 specimens were evaluated in intervention and control groups. The pooled value obtained was 0.54[-0.45, 1.53] indicating that the hardness was greater with incorporation of silver nanoparticles as compared to without their use. Overall, the results were not statistically significant ($p>0.05$). random effects model was used for assessment because of high heterogeneity ($I^2=86\%$).

For evaluation of Tear strength with and without silver nanoparticles, four studies[3,7,8,11] were included. A total of 85 specimens were evaluated in intervention and control groups. The pooled value obtained was 2.57[0.85, 4.28] indicating that the tear strength was greater with incorporation of silver nanoparticles as compared to without their use. Overall, the results were statistically significant ($p<0.05$). random effects model was used for assessment because of high heterogeneity ($I^2=94\%$).

For evaluation of color stability with and without silver nanoparticles, two studies[7,8] were included. A total of 45 specimens were evaluated in intervention and control groups. The pooled value obtained was 0.21[-0.21, 0.62] indicating that the color stability was greater with incorporation of silver nanoparticles as compared to without their use. Overall, the results were not statistically significant ($p>0.05$).

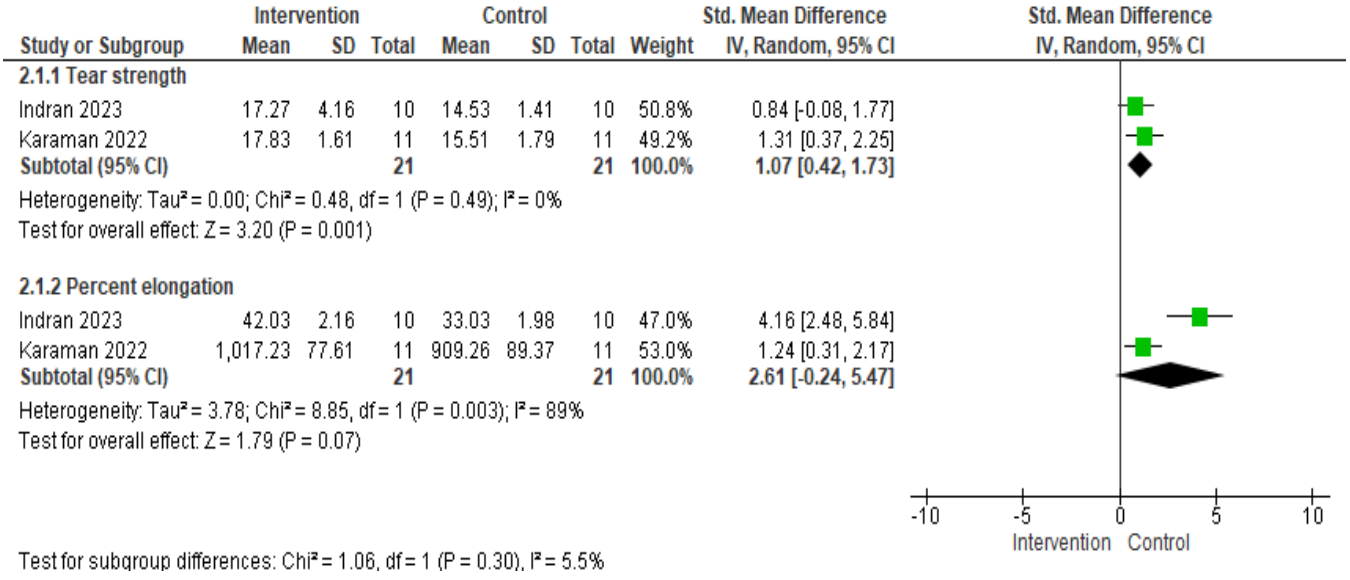
For evaluation of percent elongation with and without silver nanoparticles, two studies[3,11] were included. A total of 40 specimens were evaluated in intervention and control groups. The pooled value obtained was -1.43[-3.74, 0.89] indicating that the percent elongation was reduced with incorporation of silver nanoparticles as compared to without their use. Overall, the results were not statistically significant ($p>0.05$). random effects model was used for assessment because of high heterogeneity ($I^2=93\%$).



2. Titanium nano-particles

For evaluation of Tear strength with and without titanium nanoparticles, two studies[9,11] were included. A total of 21 specimens were evaluated in intervention and control groups. The pooled value obtained was 1.07[0.42, 1.73] indicating that the tear strength was greater with incorporation of titanium nanoparticles as compared to without their use. Overall, the results were statistically significant ($p<0.05$).

For evaluation of percent elongation with and without titanium nanoparticles, two studies[9,11] were included. A total of 21 specimens were evaluated in intervention and control groups. The pooled value obtained was 2.61[-0.24, 5.47] indicating that the percent elongation was greater with incorporation of titanium nanoparticles as compared to without their use. Overall, the results were not statistically significant ($p>0.05$). random effects model was used for assessment because of high heterogeneity (I^2=89%).



Discussion

Candidiasis is a menacing infection in most of the immunocompromised individual, geriatric ones as well as patient under several medications. Rise in these infections have affected the systemic as well as oral health of the patients.

Silicon elastomer material is an increasing substitute for the reconstruction of lost functional body parts[12]. Maintenance of these materials are of particular importance to patients. Improper handling and poor sustenance can prevail fungi like infections.[13] To prevent such infections several antifungal agents are available in market and thus there increasing trend has benefited the patients from fungal infections. The effect of such antifungal substitute on their physical and mechanical properties are drastic.[7] Therefore, this systematic review was undertaken to compare and evaluate the incorporation of antifungal agent on the physical and mechanical property of maxillofacial silicon elastomer.

The meta-analysis demonstrated that the addition of antifungal agents had a statistically significant influence on the physical and mechanical properties of maxillofacial silicone. While some studies revealed increases in tensile strength, tear resistance, and hardness, others found potential limitations in these qualities. The selection of antifungal agents, concentration, and technique of incorporation were found as key factors impacting results.

Furthermore, antifungal agents effects on the color stability, flexibility, and biocompatibility of maxillofacial silicone were investigated. The review emphasized the importance of standardized testing methodologies and long-term investigations to determine the clinical relevance of these findings.

Colour stability:

Silicon prosthesis often gets dull because of its lack of colour stability. The addition of these nanoparticles improves the colour stability. Therefore, in our study the results suggested that there was an increase in the colour stability after addition of nanoparticles but there was no statistically significant difference. Similar results were obtained in one of the studies done by Praveen et al on-silver nanoparticles which was used as antifungal agent at a particular concentration and its effect on mechanical properties were studied.[8]

Tear strength

Our results concluded that with the incorporation of silver nanoparticles seemed to have a statistically significant difference in the tear strength after incorporation of these agents. Yet another study done by Al-Hakam et al, used chitosan as an antifungal agent and concluded that effect of this agent on tear strength seems to be increased because of the residual monomer that get trapped within the silicon elastomer which acted as an impurity.[4]

Hardness:

The texture of the silicon should be compatible to the skin which is indirectly related to the hardness. A study done by Nadia et al also concluded the similar results when compared to our study that addition of siwak agent on maxillofacial silicon resulted in increased hardness as the concentration of the agent as well as time of immersion was increased. But the results were not statistically significant.[6]

As noted from our systematic review that the addition of SiO_2, ZnO, TiO_2, had a variational effect on mechanical properties like hardness and tensile strength but the results were not statistically significant similar results were also noted by Gamze et al in his study.[9]

Strength

1. The systematic review and meta-analysis approaches provide a full investigation of the current literature, resulting in a comprehensive understanding of antifungal agents' effects on the physical and mechanical properties of maxillofacial silicone.
2. The research uses a comparative evaluation to objectively compare various antifungal agents, providing significant insights into their relative effectiveness. This can assist clinicians and researchers in determining the best agents for improving silicone characteristics.
3. There is few or no quantitative assessment conducted on hardness, tensile strength, tear strength and percent elongation parameters using two different interventions – silver nanoparticles and titanium nanoparticles attempted earlier. Our meta-analysis improves the statistical power and reliability of the conclusions.

Limitation

1. Only articles that were in English language were included
2. Only in vitro studies were included in the study, clinical on human trials might have different results when investigated
3. The study of this invitro cannot be generalised for human trials, more relevant studies can be done to assess these physical properties in human.

Future scope

Further studies can also be carried out to assess the effect of various antimicrobial and antiviral agents on physical properties. The effect of various other nanoparticles can be assessed on the biophysical properties. To generalise the results and to have an impact on clinical decisions and outcome, in-vivo studies with Randomised controlled trial designs should be conducted. This systematic review and meta-analysis open a new vista of translational research

Conclusion:

Within the limitation of the systematic review and meta-analysis our study concluded that significant difference in the tear strength is observed on incorporation of antifungal agent silver nanoparticles or Titanium nano-particle as compared to without their use.

The antifungal agent and concentration should be carefully chosen to strike a balance between antifungal activity and material integrity. Future research should focus on creating optimal formulations that give efficient antifungal protection while maintaining the key features of maxillofacial silicone for better patient outcomes.

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