Archives of Dental and Medical Sciences
e-ISSN: 3122-721X
Year 2026; Issue 2



ADMS
ARCHIVES OF DENTAL & MEDICAL SCIENCES

Journal homepage-
adms.manipal.edu.my

# Comparison of two different impression materials for fabrication of complete dentures – a randomized control trial

**Silpa Madhuri Chikkala[1*], Anoop Mayya[1], Sameer Kumar Vandrangi[1], Siti Nuradawiyah binti Md Suhaili[1], Noor Sharefah Ameera binti Syed Nazir[1], Hanis Zulaikha binti Zulkefli[1], Gowri a/p Supramaniam[1]**

*[1] Faculty of Dentistry, Manipal University College Malaysia.*
*[1*]Faculty of Dentistry, Manipal University College Malaysia, Jalan Batu Hampar, Bukit Baru, Melaka -75150, Malaysia, Phone numbers: +60 11-2306 9354, e-mail address: silpa.chikkala@manipal.edu.my*

Article information
DOI: 10.71354/7st5fg57
Received 29 September 2025; Accepted 08 December 2025

## Abstract

Introduction: Zinc Oxide Eugenol (ZOE) and silicone are among the most widely used materials, each offering distinct advantages and limitations. ZOE. The objectives of the present study were to compare the effectiveness of ZOE and silicone impression materials in complete denture fabrication with respect to denture retention, stability, support, post-insertion sore spots, and oral health-related quality of life. Methodology: A randomized controlled trial was conducted among 20 completely edentulous patients (ACP Class I and II). Participants were randomly assigned to ZOE or silicone groups (n=10 each). Outcomes were assessed after two weeks using a 5-point Likert scale, clinical evaluation of sore spots, and OHIP-EDENT questionnaire. Data were analyzed using Mann–Whitney U and Fisher's exact tests ($p < 0.05$). Results: No significant differences were found between the groups in retention, stability, support, sore spots, or OHRQoL ($p > 0.05$). Conclusion: ZOE and silicone impression materials demonstrated comparable clinical performance and patient satisfaction in complete denture fabrication.

***Keywords***: *Impression materials, edentulous, retention, stability, support, sore spot, oral health related quality of life*

## Introduction

In the evolving field of prosthodontics, the careful selection of impression materials is a critical factor in determining denture quality, particularly for edentulous patients who often prefer non-surgical approaches. Among the available options, Zinc Oxide Eugenol (ZOE) and silicone are widely used, each offering distinct properties that significantly influence various aspects of the denture fabrication process[2].

ZOE, valued for its excellent flow characteristics, plays a crucial role in accurately capturing fine anatomical details. Its inherent rigidity after setting ensures stability of the impression and preservation of recorded structures. However, its limitations become evident in terms of retention, especially in areas with complex anatomy or

undercuts[1-3]. This presents a challenge in cases where optimal retention is essential for treatment success.

In contrast, silicone materials, renowned for their elasticity, provide a clear advantage in retention, particularly when managing difficult anatomical configurations. Their flexibility allows better adaptation to surface irregularities in the oral cavity, making them suitable for diverse patient anatomies [4-5]. Nonetheless, variations in setting times among different silicone formulations require careful selection according to clinical needs.

As the pursuit of higher denture quality continues, clinicians increasingly rely on evidence-based comparisons to clarify the advantages of one material over another[2,3]. The comparative evaluation of ZOE and silicone presented here seeks to highlight their differences, supporting informed clinical decisions aimed at improving standards in denture prosthodontics. Ultimately, the interplay of patient-specific factors, anatomical challenges, and material properties underscores the dynamic nature of prosthodontics and the ongoing need for research and refinement to achieve excellence in dental care.

Hence, in this study we will be assessing the stability and support of complete dentures fabricated between Zinc Oxide Eugenol and silicone impression material among edentulous patients attending using 5-point Likert scales, post insertion sore spots in the impression surface between Zinc Oxide Eugenol and silicone impression material and oral health related quality of life between Zinc Oxide Eugenol and silicone impression material among edentulous patients using OHIP-EDENT [6-11].

## Methodology

The trial proposal was approved by the institutional research committee. A randomized controlled trial was conducted among edentulous patients attending institutional clinic. The primary objective was to compare two impression materials, zinc oxide eugenol (ZOE) and silicone, used in the fabrication of complete dentures.

Eligible participants included completely edentulous patients classified as ACP Class I or II, who were available for follow-up and had provided written informed consent. Exclusion criteria included: (1) allergy to ZOE or silicone, (2) severe xerostomia, and (3) ACP Class III or IV. A total of 20 participants were recruited consecutively and randomly assigned (1:1 ratio) into ZOE or silicone groups using simple randomization generated via random.org.

### Blinding

Outcome assessors and supervising faculty remained blinded to the impression material used. Operators and investigators were not blinded due to the nature of the intervention.

### Interventions

For both groups, preliminary impressions were made with alginate in stock metal trays. Custom trays were fabricated with auto-polymerizing resin. Border molding was performed with greenstick compound. In the ZOE group, the final impression was made using zinc oxide eugenol paste with a wax spacer. In the silicone group, the final impression was made using light-body silicone with a full wax spacer. All subsequent steps of denture fabrication (jaw relation, try-in, processing, finishing, and delivery) were standardized across both groups [12,13].

### Trial procedure

Each participant received one set of dentures fabricated from their allocated impression material. Dentures were worn for a trial period of two weeks before evaluation.

*Outcome measures*

Primary outcome: Patient-reported perception of denture retention, stability, and support, measured on a 5-point Likert scale.

Secondary outcomes: Incidence of post-insertion sore spots (assessed clinically as present = 1, absent = 0), OHRQoL measured using the OHIP-EDENT questionnaire and patient-reported preferences regarding comfort and satisfaction with the dentures.

**Statistical analysis**

Data was analyzed using Epi Info software. The Mann–Whitney U test was applied for ordinal data (Likert scale and OHIP-EDENT scores), while Fisher's exact test was used for categorical data (sore spots). Statistical significance was set at $p < 0.05$.

## Results

A total of 20 participants agreed to participate in the study and all of them were recruited from April 2023 to November 2023; follow-up finished January 2024. All samples were evaluated based on the three main objectives in the study and those evaluations described in the table.

Table 1 provides an overview regarding the sociodemographic profile of patients that participated in this research. It comprises of 4 variables which include age of patient, their gender, race as well as the ACP classification.

The survey data in terms of retention, stability and support of denture was presented in Table 2. We investigated two dependent variables: the material composition comprising zinc oxide eugenol and silicone impressions. At the post treatment assessment, in terms of ACP class I, patients expressed high satisfaction levels with both materials, as evidenced by Likert scores of

4 and 5, respectively, as assessed by the evaluator. Regarding ACP class II, our findings indicate that the dentures exhibit commendable retention, stability, and support. Consequently, no significant differences were observed in retention (ZOE; p=0.6501, silicone; p=0.7290), stability (ZOE; p=0.3092, silicone; p=0.9049), or support (ZOE; p= 1.0000, silicone; p=0.5023) ratings between the dentures fabricated from both materials.

All samples underwent comprehensive evaluation across two parameters, the details of which are provided in Table 3. Regarding post-insertion sore spots, our analysis demonstrates compelling evidence that most denture wearers did not manifest any sore spots following a two-week wearing period, regardless of the material used. Table 3 shows that with ZOE impressions, 80% of patients in ACP Class I did not have post-insertion sore spots, and 60% in ACP Class II were also sore spot-free. However, 20% of patients in ACP Class I and 40% in ACP Class II did experience sore spots with ZOE impressions. Interestingly, silicone impressions had the same percentage of absence of sore spots for both ACP Class I and II as ZOE impressions [p=1.0000], which was unexpected.

Table 4 shows the comparison between median (Q1, Q3) distribution of OHIP-EDENT-N scores for zinc oxide eugenol impressions and silicone impressions. There were 7 domains that were assessed in the OHIP-EDENT score including functional limitation, physical pain, psychological discomfort, physical disability, psychological disability, social disability, and handicap. After wearing the dentures for the 2-week periods, it was found that there was no association between oral health related quality of life and the two impression materials ($p > 0.05$).

**Table 1. Socio Demographic profile of patient (n=20)**

| Variables | ZOE | Silicone | P- value |
|---|---|---|---|
| | Frequency (%) | Frequency (%) | |
| **Age** | | | |
| <60 | 0 | 2 (20.0) | 0.5435 |
| 60-70 | 6 (60.0) | 1 (10.0) | |
| >70 | 4 (40.0) | 7 (70.0) | |
| Mean (SD) | 67.6 (6.92) | 69.5(7.37) | |
| **Gender** | | | |
| Male | 5 (50.0) | 7 (70.0) | 0.3736 |
| Female | 5 (50.0) | 3 (30.0) | |
| **Race** | | | |
| Malay | 0 | 2 (20.0) | |
| Chinese | 10 (100.0) | 7 (70.0) | 0.0679 |
| Indian | 0 | 1 (10.0) | |
| **ACP classification** | | | |
| Class I | 5 (50.0) | 5 (50.0) | 1.0000 |
| Class II | 5 (50.0) | 5 (50.0) | |

**Table 2. Differences in comfort, stability, and support of dentures by Likert scores**

| Outcome variables | ZOE Median (IQR) | Silicone Median (IQR) | P- value |
|---|---|---|---|
| **ACP Class 1** | | | |
| Retention | 5 (4, 5) | 4 (4, 5) | **0.650** |
| Stability | 5 (4, 5) | 4 (4, 4) | **0.309** |
| Support | 4 (4, 4) | 5 (3, 5) | **0.999** |
| **ACP Class 2** | | | |
| Retention | 4 (4, 5) | 4 (4, 5) | **0.729** |
| Stability | 3 (3, 5) | 4 (4, 5) | **0.905** |
| Support | 4 (4, 4) | 4 (3, 4) | **0.502** |

*Mann–Whitney U test. P < 0.05 is significant*

**Table 3. Post insertion sore spots in patient's oral cavity**

| Outcome variables | ZOE Frequency (%) | Silicone Frequency (%) | P- value |
|---|---|---|---|
| **ACP Class 1** | | | |
| Absent | 4 (80.0) | 4 (80.0) | **0.999** |
| Present | 1 (20.0) | 1 (20.0) | **0.999** |
| **ACP Class 2** | | | |
| Absent | 3 (60.0) | 3 (60.0) | **0.999** |
| Present | 2 (40.0) | 2 (40.0) | **0.999** |

*Fisher's exact test. P < 0.05 is significant*

**Table 4. Oral health related quality of life**

| Outcome variables | Zoe Median (IQR) | Silicone Median (IQR) | P- value |
|---|---|---|---|
| **ACP Class 1** | | | |
| Functional limitation | 1 (1, 3) | 3 (2, 3) | 0.501 |
| Physical pain | 3 (3, 3) | 1 (1, 4) | 0.588 |
| Psychological discomfort | 1 (0, 2) | 0 (0, 2) | 0.729 |
| Physical disability | 1 (1, 2) | 0 (0, 1) | 0.381 |
| Psychological disability | 1 (1, 2) | 1 (0, 2) | 0.502 |
| Social disability | 3 (3, 3) | 3 (3, 3) | 0.317 |
| Handicap | 2 (1, 2) | 2 (1, 2) | 0.513 |
| **ACP Class 2** | | | |
| Functional limitation | 3 (2, 3) | 2 (1, 2) | 0.217 |
| Physical pain | 1 (1, 4) | 4 (1, 4) | 0.811 |
| Psychological discomfort | 0 (0, 2) | 2 (0, 2) | 0.512 |
| Physical disability | 0 (0, 1) | 2 (0, 2) | 0.381 |
| Psychological disability | 1 (0, 2) | 2 (0, 2) | 0.635 |
| Social disability | 3 (3, 3) | 3 (3, 3) | 0.317 |
| Handicap | 2 (1, 2) | 2 (1, 2) | 0.513 |

*Mann–Whitney U test. $P < 0.05$ is significant*

## Discussion

The results showed that there were no significant differences in retention, stability, and support between the groups. This indicated that the retention of dentures made from both zinc oxide eugenol and silicone impression materials demonstrated comparable and satisfactory levels of retention. In addition, patients with alveolar ridges containing undercuts were not included as part of the criteria, which may have influenced the outcomes, as the impact of these undercuts on denture retention was not eliminated. According to a previous study, the retention of complete dentures produced using zinc oxide eugenol was reported to be superior compared to other final impression materials [12,13]. Patients selected were free from systemic diseases in that study, as such conditions could affect denture retention. Conditions such as Parkinson's disease, dyskinesia, and abnormalities in the temporomandibular joint may lead to prosthetic failure due to reduced neuromuscular control; however, these factors were not excluded in our study. In contrast, another study reported no significant differences in retention and stability associated with the final impression procedure, which aligns with our findings.

The other objective of our study was to assess patients for the presence of sore spots within denture-covered areas, specifically comparing the effects of two impression materials [14,15]. After comprehensive data analysis, our findings indicated no statistically significant differences between the two materials in relation to the incidence of sore spots. In essence, our study suggests that there was no notable disparity in the manifestation of sore spots when comparing the two groups. This contrasts with earlier findings where pressure-indicating materials were used to detect defects on denture fitting surfaces [16]. In the present study, however, assessors evaluated the presence of red and inflamed areas as indicators of sore spots. Furthermore, our observations agree with another clinical study that similarly reported no significant differences between zinc oxide eugenol and light-body silicone. Collectively, these findings contribute to the growing body of evidence regarding impression material performance in complete denture fabrication.

In our study analysis of patients seeking complete denture fabrication further revealed no notable associations between oral health-related quality of life and the type of impression material

used after two weeks of denture wear. The OHIP-EDENT scores demonstrated no significant differences in oral health-related quality of life between dentures fabricated with silicone or zinc oxide eugenol ($p > 0.05$). The OHIP-EDENT questionnaire evaluates seven domains, including functional limitation, physical pain, psychological discomfort, physical impairment, psychological disability, social disability, and handicap [16]. A previous study evaluating the impact of conventional rehabilitation on oral health-related quality of life among edentulous patients reported positive improvements across most domains, except for physical pain and social disability, which were slightly negative likely attributed to the adaptation period associated with new dentures [17]. In contrast, our study showed no significant differences across all domains. Differences in patient characteristics, evaluation timings, and sampling may account for these variations. The nuanced nature of these findings highlights the importance of understanding contextual factors influencing post-treatment experiences and supports the need for individualized patient care. In this study, after two weeks of denture wear, no correlation was found between oral health-related quality of life and the two impression materials.

Even though this study provides meaningful insights, it is important to acknowledge its limitations. Our sample size included only 10 participants per group, which may have limited the accuracy of the findings. Furthermore, the inclusion criteria focused solely on completely edentulous patients requiring both upper and lower complete dentures. Evaluation of retention, stability, support, sore spots, and oral health-related quality of life was conducted after only two weeks of denture wear. However, this timeframe may not be sufficient to capture full patient adaptation, potentially influencing the results. Recognizing these constraints is essential for addressing these limitations in future studies.

In contrast, silicone materials, renowned for their elasticity, provide a clear advantage in retention, particularly when managing difficult anatomical configurations.

Systemic conditions were not used as exclusion criteria, although they may influence neuromuscular control, salivary flow, and patient adaptation to dentures. This may have introduced variability in outcomes such as retention, stability, and sore spot incidence. The inclusion of patients with mild or undiagnosed neuromuscular conditions (e.g., early Parkinson's disease, TMJ dysfunction, dyskinesia) may have affected denture performance independently of the impression material used. Failing to stratify or control for systemic health variables may have contributed to the absence of statistically significant differences between the groups, potentially masking subtle effects of the impression materials. Future studies should consider screening for systemic diseases, severity grading, or subgroup analysis to better isolate the true impact of impression materials on denture outcomes.

## Conclusion

Following a two-week period of denture wear, patients exhibited an absence of sore spots within their oral mucosa. Furthermore, an improvement in the oral health-related quality of life was reported by patients who received dentures constructed from either material. These findings underscore the comparable efficacy and patient satisfaction associated with dentures fashioned from silicone and zinc oxide eugenol impressions, thereby highlighting the potential for both materials to contribute positively to oral health outcomes and overall quality of life

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