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Analyzing SHORE A hardness to assess the durability of soft denture lining materials

Analisando a dureza SHORE A para avaliar a durabilidade de materiais macios de revestimento de próteses

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ABSTRACT

Objective: Evaluate the "SHORE A" hardness in four denture soft lining materials at different time intervals. **Material and Methods:** Forty disc-shaped specimens, with dimensions of 15 mm × 3 mm, were distributed into four groups according to the materials: SC (Soft Confort); TS (Trusoft); UG (Ufi Gel P) and DS (Dentusoft) (n=10). The hardness measurements were performed using a portable digital hardness meter at 1 hour (h), 3 days (d), 7 d, 15 d, 30 and 60 d after preparation of specimens. The data were subjected to statistical analysis. **Results:** UG presented the highest hardness (39,09±2,27), followed by SC (34,36±8,52), DS (26,23±5,26) and finally TS (18,05±3,60), being that UG and TS had the smaller change in hardness between time intervals. The Repeated Measures ANOVA and Tukey's test showed that the variables (material and time) and their interaction had differences statistically significant (p≤0.05). **Conclusion:** The study reveals significant variations in hardness among different groups. The groups SC and DS experienced substantial changes in hardness from initial to final values, with the group SC exhibiting the most pronounced shift. These findings underscore the suitability of acrylic materials for temporary applications. On the other hand, the silicone material (UG) with the highest initial hardness, exhibited relatively minor changes in hardness, emphasizing their recommendation for long-lasting applications. Group TS, despite not being composed of silicone, also showed relatively minor changes in hardness, suggesting its potential suitability for specific applications where stability is desirable.

KEYWORDS

Denture liners; Dental prosthesis; Dental tissue conditioning; Hardness tests; Longevity.

RESUMO

Objetivo: avaliar a dureza "SHORE A" em quatro materiais de revestimento macio de próteses dentárias em diferentes intervalos de tempo. **Material e Métodos:** Quarenta corpos de prova em forma de disco, com dimensões de 15 mm × 3 mm, foram distribuídos em quatro grupos de acordo com os materiais: SC (Soft Confort); TS (Trusoft); UG (Ufi Gel P) e DS (Dentusoft) (n=10). As medições de dureza foram realizadas utilizando um durômetro digital portátil em 1 hora (h), 3 dias (d), 7 d, 15 d, 30 d e 60 d após a preparação das amostras. Os dados foram submetidos à análise estatística. **Resultados:** UG apresentou maior dureza (39,09±2,27), seguido por SC (34,36±8,52), DS (26,23±5,26) e TS (18,05±3,26), sendo que UG e TS tiveram a menor alteração na dureza entre os intervalos de tempo. A ANOVA de Medidas Repetidas e o teste de Tukey mostraram que as variáveis (material e tempo) e sua interação apresentaram diferenças estatisticamente significativas (p≤0,05). **Conclusão:** O estudo revela variações significativas na dureza entre os diferentes grupos. Os grupos SC e DS experimentaram mudanças substanciais na dureza dos valores iniciais para os finais, com o grupo SC exibindo a mudança mais pronunciada. Essas descobertas ressaltam a adequação dos materiais acrílicos para aplicações

temporárias. Por outro lado, o material de silicone (UG) com maior dureza inicial, apresentou alterações relativamente pequenas na dureza, enfatizando sua recomendação para aplicações de longa duração. O Grupo TS, apesar de não ser composto por silicone, também apresentou alterações relativamente pequenas na dureza, sugerindo sua potencial adequação para aplicações específicas onde a estabilidade é desejável.

PALAVRAS-CHAVE

Reembasadores de dentaduras; Prótese dentária; Condicionamento de tecido mole oral; Ensaios de dureza; Longevidade.

INTRODUCTION

Despite proper construction and fit, complete dentures made from rigid materials like polymethylmethacrylate (PMMA) can commonly cause discomfort and pain for patients while chewing and swallowing [1-3]. The loads received by the prosthesis, along with ridge resorption and fibromucosa height, affect support, retention, and stability of the prostheses, besides their mechanical performance [4]. This issue is particularly evident in the lower arch, making the prostheses adaptation more challenging than the maxillary one. Users of complete mandibular dentures often experience poor retention and stability [5]

To enhance the quality of life and offer functional and aesthetic advantages of complete dentures, lining materials are commonly used [6-8]. They can be categorized based on their chemical structures: hard liners, typically made of PMMA, and soft denture liners (SDL), which include plasticized acrylic resins, vinyl resins, rubber-based materials, and silicone rubbers. SDLs are further classified into permanent or temporary options, which encompass tissue conditioners, acrylic resin-based, and silicone-based materials (auto-polymerized and heat-polymerized) [9-11].

SDL have multiple advantages, including their versatility and ease of handling. They act as a cushion, absorbing and distributing functional stress, providing comfort for resorbed or sharp residual crests. Additionally, they protect healing sites, reduce edema, and control post-surgical bleeding, similar to a pressure bandage [2,11-13].

Despite the advantages of SDL, it has clinical limitations such as loss of softness over time due to the loss of soluble components [11]. This results in an increase in the material's hardness, along with water absorption, dimensional changes, and stresses on the liner-denture base interface, consequently reducing bond strength. This may cause debonding or microleakage between SDL and the prosthesis, leading to contamination by microorganisms [10,14]. Frequent replacement of the material is necessary to maintain its desired softness and functionality [13]. SDL also demands a smooth surface, which can be challenging for maintenance during clinical practice. Prolonged use leads to heightened difficulties in achieving satisfactory hygiene, as the material is prone to deterioration, resulting in increased roughness. Thereby a biofilm containing bacteria and yeasts accumulates on the surface, turning it into a reservoir for microorganisms, primarily *Candida albicans*, considered the main etiological factor of denture stomatitis. *C. albicans* can lead to a chronic inflammation and tissue irritation. Over time, this can contribute to bone resorption [12,15-19].

The inconsistent information regarding SDL properties, mostly the mechanical properties, challenges dental surgeons in determining the best applications for these materials. Consequently, determining the long-term mechanical performance of the SDL materials available on the market is clinically relevant [20]. The widely used "Shore A hardness" measurement characterizes polymers, elastomers, and rubbers by indicating their resistance to indentation (0 to 100 Shore units). A conical indenter is pressed against the material's surface, and the depth of the indentation is measured. The greater the material's resistance to penetration, the higher its Shore A hardness [1,21].

Hence, the objective of this study was to assess the Shore A hardness alterations of four short-term commonly used SDL, over specific time intervals through in vitro evaluations that simulate the duration of specific clinical scenarios. This approach potentially mimics the longevity of these materials while in use inside the oral cavity. The null hypothesis was that the material's hardness would not be affected by different time intervals.

MATERIALS AND METHODS

The present study used a detailed flowchart to guide the research, covering all stages of the experiment, represented in figure 1.

Specimen preparation

The materials used in this study are listed in Table I. A total of forty disc-shaped specimens were manufactured using a standardized aluminum mold, with dimensions of 15 mm diameter and 3 mm height. The specimens were distributed into four groups, each representing a distinct denture lining material: SC (Soft Confort), TS (Trusoft), UG (Ufi Gel P), and DS (Dentusoft).

Disc-shaped specimens were prepared according to the manufacturer's instructions. The material was poured into aluminum molds with a slight excess, and then the molds were finger pressed using a glass lid until close contact between them. After polymerization, the specimens were separated, coated with varnish following the manufacturer's recommendations, and subsequently conditioned in distilled water.

Hardness measure

Hardness measurements were conducted using a portable digital durometer, Novotest TS-C Shore A series 998-GS 709 (Novotest, Novomoskovsk, Ukraine), at specific time intervals (1 hour, 3 days, 7 days, 15 days, 30 days, and 60 days). Following the methodology outlined in the European Standard ISO 10139-1:2018 [22] the durometer was kept in a vertical position, applied the required force during the measurement process and stopped automatically when equilibrium between the indenter (the penetrating device) and the material's response was reached. Three measurements were taken from distinct, randomly chosen locations within each sample.

All samples were stored in distilled water at room temperature between measurements until the completion of the test, adhering to the standards set by the Deutsches Institut für Normung (DIN) 53505 and the American Society for Testing and Materials (ASTM) D2240/75.

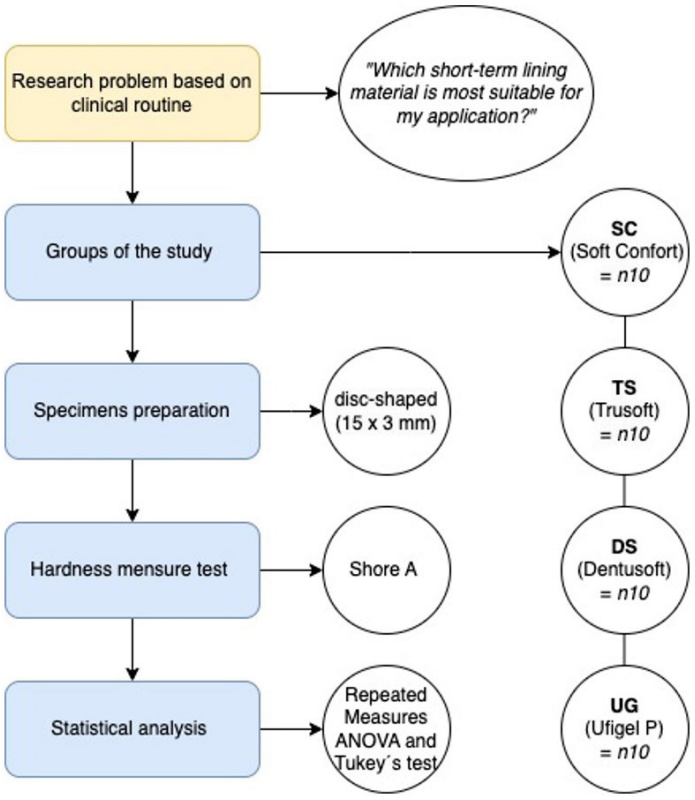

Figure 1 - Flow chart of the research's stages. The flowchart was designed to visualize and plan the sequence of activities conducted during the research. The initial yellow rectangle depicts the formulation of the research question. Subsequently, the four blue rectangles represent the stages of the materials and methods.

Table I - Materials used in this study

Material	Acronym	Type	Composition	Manufacturer	Batch number
Soft Confort	SC	Acrylic temporary soft liner - tissue conditioner	Powder: Polyethylmethacrylate (PEMA) Liquid: Phtalate ester (plasticizer) and Denatured alcohol	Dencril - VIPI Ltda, Pirassununga - SP, Brazil.	085563
Trusoft	TS	Acrylic temporary soft liner - autopolymeried acrylic resin	Powder: Pigmented Polyethylmethacrylate, cadmium pigments Liquid: Ethyl alcohol, Benzyl butyl phthalate, dibutyl phthalate	Bosworth Company, Skokie - IL, USA	JB9444
Dentusoft	DS	Acrylic temporary soft liner - tissue conditioner	Powder: Polyethylmethacrylate Liquid: Monomer N-Butyl Methacrylate Dibutyl Phthalate, and Denatured Alcohol	Densell, Buenos Aires - BUE, Argentina	PC0179
Ufi Gel P	UG	Tissue conditioner - autopolymeried silicone	base paste: Modified polydimethylsiloxanes Catalyst paste: platinum catalyst Adhesive: butanone and methacrylates	Voco GMBH, Cuxhaven - BS, Germany	1923716

Table II - Mean and SD of each material at each time

	1h	3d	7d	15d	30d	60d	Overall Mean
Trusoft	15.50 ± 3.56	16.05 ± 1.00	19.50 ± 1.08	18.70 ± 3.12	19.98 ± 4.44	18.56 ± 1.63	18.05 ± 3.60[a]
Dentusoft	15.26 ± 1.16	28.33 ± 1.58	28.01 ± 0.98	27.40 ± 0.81	28.40 ± 3.38	29.98 ± 0.63	26.23 ± 5.26[b]
Soft Confort	17.16 ± 1.31	31.95 ± 2.74	36.76 ± 2.31	40.46 ± 2.19	38.80 ± 1.16	41.05 ± 0.82	34.36 ± 8.52[c]
Ufi Gel P	37.50 ± 0.99	36.78 ± 1.00	37.63 ± 1.08	39.45 ± 0.81	41.63 ± 1.08	41.56 ± 1.27	39.09 ± 2.27[d]

Different superscript letters indicate the significant differences between groups (p≤0.05).

Statistical analysis

To conduct the statistical analysis, the mean and standard deviation (SD) of each soft denture liner material were calculated at each time point. The data were subjected to a Repeated Measures Analysis of Variance (Repeated Measures ANOVA), and multiple comparisons were performed using the Tukey's test, with a significance level of 5%. These analyses were performed using the software JAMOVI (version 2.3).

RESULTS

The mean and SD values of Shore A hardness (in Shore A unit) are present in Table II and Figure 2. Group UG showed the highest hardness among the materials tested at all times, except for 15 d, where SC showed the highest values between the groups (40.46±2.19). In the overall mean, group UG presented the highest hardness, followed by SC, DS and finally TS. In the chart, it is possible to observe that UG and TS had the smallest change in hardness between time intervals.

Tables III and IV show the within-subjects effect and between-subjects effects. It is possible to observe that both the variables and their interaction had differences statistically significant ($p \leq .001$) when the Repeated Measures ANOVA was applied to assess the influence of the independent variables (material and time).

In Table V, Tukey's test results show that some materials share similar hardness values at specific time points. For instance, groups DS and TS have similar hardness values after 1 h, while SC and UG share similarities at multiple time points (7 days, 30 days, and 60 days).

Table III - Within-Subjects effect

	SS	Degr.	MS	F	p
Time	3635	5	726.96	247.5	< .001
Time*Material	2332	15	155.46	52.9	<.001
Residual	529	180	2.94		

SS = sum of 3 squares; Degr. = degrees of freedom; MS = mean square; *p≤0.05

Table IV - Between-subjects effects

	SS	Degr.	MS	F	p
Material	15449	3	5149.7	374	<.001
Residual	496	36	13.8		

SS = sum of 3 squares; Degr. = degrees of freedom; MS = mean square; *p≤0.05

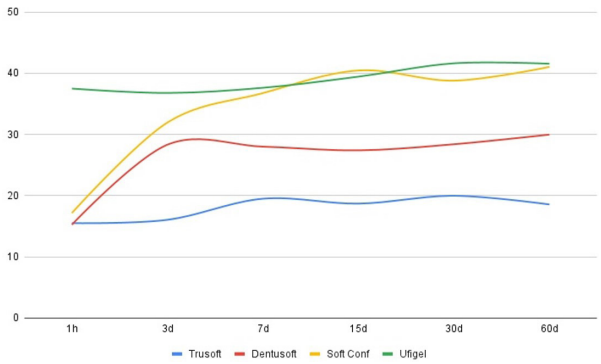

Figure 2 - Line chart showing the mean's hardness of each material over time. The graph visually presents the results from Table II. Trusoft (blue) exhibits the lowest hardness values throughout the entire measured time interval. Dentusoft (red) shows a significant increase from the initial time until the second measurement on day 3, after which it remains constant in second place. Soft Confort (yellow) nearly doubles its values on day 15 compared to the initial measurement, reaching the hardness values that Ufigel (green) already had since the initial measurement. Consequently, Ufigel exhibits the highest hardness values during the entire time interval and remains highly stable.

DISCUSSION

Based on the study results, the null hypothesis was rejected, as all tested groups exhibited a significant increase in hardness over time. Shore A hardness values averaged 18.05 (TS), 26.23 (DS), 34.36 (SC), and 39.09 (UG), with statistically significant differences (Table II). During the 1-hour period, no statistically significant differences in hardness were observed among groups DS, TS, and SC. Over time, acrylic-based materials undergo more significant hardness changes compared to silicone-based materials due to their viscoelastic behavior, resulting in higher degradation and damping loss [23-25]. The composition of acrylic-based materials, including polymers as PEMA and plasticizers such alcohol and dibutyl phthalate, affects material softness [11,26]. However, the hydrophilic nature of plasticizers may lead to leaching and deterioration as they can be replaced by water, liquid foods, saliva, and cleaning solutions [11,25,27-29].

Within the first 3 days, the DS group's hardness nearly doubled (from 15.26 to 28.33), and a similar trend was observed in the SC group (from 17.16 to 31.95) (Figure 2). This phenomenon can be attributed to the ongoing polymerization process of autopolymerized materials, which occurs at room temperature and continues over time, contributing to an increase in material hardness throughout its lifespan [30]. However, this increase is considered a disadvantage for a soft material, as higher hardness values correspond to a reduced ability to absorb the impact of mastication [31].

Surprisingly, between days 3 and 60, the DS group did not exhibit significant differences. In contrast, the SC group showed the highest degree of change between its initial and final values (from 17.16 to 41.05), supporting the findings of other authors [32,33] and suggesting that the SC formulation contains a higher amount of plasticizer and ethanol. This finding contrasts with the manufacturer's recommendations for a 3-month use.

Group TS, while statistically significant differences were observed, there were no significant changes in hardness, with values ranging from 15.50 to 19.98. Another study [34] examined the water absorption and solubility of DS and TS materials, indicating that the minimal changes observed in DS hardness between days 3 and 60 correlate with low solubility levels and

Table V - Comparison of means according to Tukey's test (5%)

Material	Time	Hardness	1	2	3	4	5	6	7	8	9
Dentusoft	1h	15.26	A								
Trusoft	1h	15.50	A								
Trusoft	3d	16.05	A	B							
Soft Conf	1h	17.16	A	B	C						
Trusoft	60d	18.56	A	B	C						
Trusoft	15d	18.70	A	B	C						
Trusoft	7d	19.50		B	C						
Trusoft	30d	19.98			C						
Dentusoft	15d	27.40				D					
Dentusoft	7d	28.01				D					
Dentusoft	3d	28.33				D					
Dentusoft	30d	28.40				D					
Dentusoft	60d	29.98				D	E				
Soft Conf	3d	31.95					E				
Soft Conf	7d	36.76						F			
Ufi Gel P	3d	36.78						F			
Ufi Gel P	1h	37.50						F	G		
Ufi Gel P	7d	37.63						F	G	H	
Soft Conf	30d	38.80						F	G	H	I
Ufi Gel P	15d	39.45						F	G	H	I
Soft Conf	15d	40.46							G	H	I
Soft Conf	60d	41.05								H	I
Ufi Gel P	60d	41.56									I
Ufi Gel P	30d	41.63									I

a diminished concentration of dibutyl phthalate and alcohol. As for TS, correlating with the molecular weight of its plasticizer. The elevated concentration of benzyl butyl phthalate, a plasticizer with a higher molecular weight, in the composition of TS may contribute to its low solubility [34,35].

These findings not only elucidate the performance characteristics of DS and TS but also offer insight into their suggested duration of use. The observed stability in the solubility and hardness throughout the evaluation period resonates with the manufacturer's recommendation for TS, endorsing its application for up to 12 months. In contrast, the DS manufacturer does not specify a recommended duration; rather, suggesting that reapplication can be considered in the event of discomfort.

Despite the manufacturers' recommended durations, previous studies have demonstrated that SDL are ideally suitable for short-term use, typically up to 14 days [10,36-38]. SDL excel in absorbing masticatory impacts, aiding in post-tooth extraction adjustments for immediate complete dentures, pre-prosthetic post-surgical cases, and preparing for permanent PMMA denture bases. In such cases, rapid adaptation may occur, leading to more frequent relining procedures [11,13,29]. Moreover, as the material's hardness increases, the surface becomes rough and irregular, heightening the risk of trauma [36].

The ISO 10139-1:2018 standard classifies SDLs into two categories: soft materials (type A) and extra soft materials (type B). According to the standard, for type A materials, the average hardness values after 2 hours of aging should range between 30 and 50, while for type B materials, they should be less than 30. After 7 days of aging, the Shore A hardness values for all materials must not exceed 60 [22]. In this study, the TS, DS, and UG groups were identified as type A materials, whereas the SC group was classified as type B. After 7 days, the hardness

values of all groups aligned with the standard's recommendations.

Group UG demonstrated high initial hardness values with minimal changes throughout the test. The substantial increase in hardness observed for DS and SC in comparison to UG indicates a significantly less stable hardness over time and corroborates with previous studies [1,9,25,30,39]. The hardness stability of silicones stems from their inherent elasticity, facilitated by the polydimethylsiloxane component, which achieves desired softness through cross-linking or filler addition. This eliminates the need for a plasticizer, resulting in low solubility [1,11,40]. Additionally, silicones exhibit hydrophobicity, low water absorption, and less sensitivity to temperature changes than acrylic materials, as emphasized in previous studies [26,41].

The Shore A hardness test results confirmed the superior performance of group UG, exhibiting the highest hardness values (17.16 to 41.05) and the most stable behavior over the 60-day period. It took 15 d to achieve a hardness close to 40, maintaining this level thereafter. Consequently, silicone materials are recommended for longer-term use [26], as suggested by the manufacturer for a medium-term usage ranging from 2 weeks to 2 years. In addition to their role in relining ill-fitted prostheses for enhanced comfort, these materials serve as effective cushioning agents, absorbing masticatory impact and providing support and stabilization for the prosthesis, aiding in adaptation to retentive areas [11].

Considering the limitations of this in vitro study, to obtain a more comprehensive understanding of SDLs' performance in real dental practice, future clinical and laboratory investigations must be conducted to simulate oral environment conditions, such as temperature changes, pH variations, fluid absorption, exposure to cleaning solutions, and colonization by microorganisms. Overall, this study contributes valuable insights into the hardness behavior of SDLs over time, assisting dental professionals in making informed decisions when selecting the appropriate material for specific clinical scenarios.

CONCLUSION

Based on the findings of this in vitro study, several key conclusions can be drawn:

- Trusoft consistently displayed the lowest hardness values throughout the test, showing only a minimal increase over time, with the highest hardness recorded at the 30-day mark;
- Dentusoft and Soft Confort exhibited a notable increase in hardness, primarily at the 3-day mark, followed by a more stable progression up to 60 days;
- Ufi Gel P, the only silicone-based material tested, maintained the highest hardness values throughout the test with a stable degree over time.

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Author's Contributions

NIG: Conceptualization, Methodology, Investigation, Formal Analysis, Data Curation, Writing - Original Draft Preparation, Writing - Review & Editing. FZP: Conceptualization, Methodology, Investigation, Formal Analysis, Data Curation, Writing - Original Draft Preparation, Writing - Review & Editing, Visualization. ALSB: Conceptualization, Methodology, Formal Analysis, Data Curation, Writing – Original Draft Preparation, Writing – Review & Editing, Visualization. JMFS: Conceptualization, Methodology, Investigation, Writing – Original Draft Preparation, Data Curation, Writing – Review & Editing. ESU: Conceptualization, Methodology, Investigation, Formal Analysis, Data Curation, Writing – Original Draft Preparation, Writing – Review & Editing, Visualization, Supervision, Project Administration.

Conflict of Interest

The authors have no proprietary, financial, or other personal interest of any nature or kind in any product, service, and/or company that is presented in this article.

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Regulatory Statement

Not applicable.

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