Effect of Soft Lining Material Properties on Maximum Pressure Transmission and Shore a Hardness

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Abstract

This study aimed to evaluate the difference of maximum pressure transmission (MPT) beneath denture bases relined with different 4 soft lining materials (GC Soft-liner (GC), Visco-gel (VG), Sofreliner tough M (ST), and Ufi gel P (UP)), in 3 thicknesses (1, 2, and 3 mm) which stored for 1, 7, and 30 days. MPT of each group (n=10) was observed with pressure-sensitive sheets under impact drop test. Shore A hardness of each material (n=6) was evaluated. MPT and Shore A hardness were analyzed by three-way ANOVA and two-way repeated-measures ANOVA followed by Tukey test (α=.05).

The results showed that 1-mm thickness VG presented the highest MPT at all time points, while GC in each thickness presented the lowest MPT at day 1 and 7. The MPT at each thickness and Shore A hardness of ST and UP did not change among all time points ($P>.05$), but those of GC and VG showed significantly increase after 7-day immersion ($P<.05$).

In conclusion, relining denture with VG should be used in case which has at least 2-mm relining space available and limited to 7-day use. GC, ST, and UP in 1-to 3-mm thickness can dissipate pressure up to 30 days.

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Introduction

Soft lining materials are widely used to reline the tissue surface of removable dentures and have been a focus of research for many years. These materials provide a cushion effect[1,2] that prevents stress concentration from masticatory force. This could alleviate pain from denture soreness. Several studies found that the masticatory performance and satisfaction in denture wearers were improved when their dentures were relined with soft lining materials.[3-6] These materials are typically used in patients who present with traumatized oral mucosa, atrophic ridge, and bony undercut. They are also used in an immediate prosthesis or a removable denture to aid soft tissue healing after oral surgery.[2]

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Soft lining materials can be categorized into several types based on different criteria, such as chemical structure[7] and duration of use.[2,8,9] Based on chemical structure, soft lining materials can be divided into 2 groups: acrylic resin-based and silicone-based soft lining materials. The acrylic resin-based soft lining materials consist of 2 parts: powder and liquid. The powder part is commonly polyethyl methacrylate, while the liquid part depends on the intended use: long- and short- term use. The liquid part of acrylic-based soft lining materials for long-term use consists of methacrylate monomer, such as ethyl, n-butyl, or 2-ethoxyethyl methacrylate, and plasticizers. Long-term materials are available as heat polymerized or autopolymerized types. The liquid part of acrylic-based soft lining materials for short-term use consists of ethyl alcohol and plasticizers.[7] Some of short-term materials, so-called tissue conditioner, are free of monomer and no heat generation due to no polymerization process. The acrylic resin-based lining materials could provide good adhesion to the denture base due to their similarity in chemical structure.[10] However, the physical and mechanical properties of acrylic resin-based soft lining materials degrade over time because plasticizers and other soluble materials leach out into the water.[11] The silicone-based soft lining materials have a similar chemical composition to silicone impression materials, which is a crosslinking polymer between vinyl siloxane and hydride siloxane. These materials can provide adequate long-term elasticity without any plasticizers.[12,13]

The desired properties of soft lining materials are even pressure distribution and pressure transmission reduction.[11] Previous studies reported that an increase in thickness of soft lining materials led to the better stress distribution on the supporting structures.[14,15] Each soft lining material requires different sufficient thicknesses to effectively reduce the functional stress transmitted to the denture bearing area.[16,17] Several studies focused on measuring the pressure beneath the denture base with strain gauges[18], finite element analysis[19], pressure transducer[20,21], and pressure-sensitive sheets.[22,23] However, there is an insufficient information on which soft lining material could be used in cases of limited relining space. An observation from pressure-sensitive sheets can provide the pressure distribution patterns of different types, thicknesses, and storage times of soft lining materials beneath the denture base which have not been elucidated. Shore A hardness is another interesting property. It is a resistance of material against indenter. The greater rigidity of material resulted in the greater hardness value. Many factors are related to Shore A hardness such as viscoelastic, elastic modulus, and thickness of material. The Shore A hardness of the soft lining materials might also attribute to pressure distribution and transmission. Therefore, the Shore A hardness of these materials also needs to be investigated.

The purpose of the present study was to evaluate soft lining material efficiency in cases of limited relining space by comparing among 4 commercial soft lining materials in terms of the maximum pressure transmission (MPT) beneath denture bases under impact load at different storage times. The Shore A hardness of the different soft lining materials was also evaluated at different storage times. The null hypotheses were that 1) there would be no significant differences on MPT of different soft lining materials in different thicknesses at different storage times and 2) there would be no significant differences on the Shore A hardness of different soft lining materials at different storage times.

Materials and methods

Four soft lining materials, 2 tissue conditioners (GC Soft-liner (GC) (GC dental product Corporation, Tokyo, Japan), Visco-gel (VG) (Dentsply Caulk, Milford, USA)) and 2 silicone-based materials (Sofreliner tough M (ST) (Tokuyama Dental Corporation, Tokyo, Japan), Ufi gel P (UP) (Voco GmbH, Cuxhaven, Germany)), were examined in this study.

Impact drop test

Three hundred ninety baseplate wax specimens (15×15×3 mm^3) were fabricated. The 30-degree cusp angle of a mandibular first molar artificial acrylic tooth (FX posterior M36, Yamahachi Dental MFG., Co., Aichi, Japan) was placed in the center of each baseplate wax specimen with a dental surveyor (Ney Surveyor, Dentsply International, Inc., PA, USA). The occlusal surface of the artificial acrylic tooth was aligned parallel to the base of the wax. The wax specimens were invested in denture flasks, boiled out, replaced with denture base material (SR Triplex Hot, Ivoclar Vivadent, Schaan, Liechtenstein) at a powder/liquid ratio of 23.4 g/10 mL, and heat-polymerized following the recommendation of manufacturer. After heat polymerization, the base of the specimens was polished with copious water and silicon carbide paper, 600-grit, with a polishing machine (Nano 2000, Pace Technologies, Tucson, AZ, USA). After 24 h of storage in 37±1°C deionized water, the specimens were mounted into square holes (15×15 mm^2) of a customized metal mold by facing the denture tooth downward. Each soft lining material was prepared following the instructions of manufacturer, placed into the space to create a 1-, 2-, or 3-mm thickness of soft lining materials, and covered with a polyester film. A glass plate with a 2-kg-weight load was placed above the polyester film until the soft lining material set. The excess of the soft lining materials was trimmed. The specimens without soft lining material served as a control group. The specimens of each soft lining material at each thickness were divided into 3 groups (n=10) based on storage time and kept in 37±1°C deionized water for 1, 7, and 30 days before testing.

The impact drop test was modified from previous studies.[23,24] A round shaped metal indenter with a diameter of 5 mm was dropped directly on the artificial acrylic tooth at the central fossa. The mass and height of the round shaped metal indenter was adjusted to achieve a 50-N impact load that equals the average bite force of complete denture wearers.[25] Our pilot study determined that dropping a 1-kg-weight load attached with a round shaped metal indenter from a 4-mm height generated a 50-N impact load. The specimen was placed over the pressure-sensitive sheet on the flat metal base (Figure 1). The MPT was measured with super low pressure (LLW) sheets and low pressure (LW) sheets (Fuji Prescale Film, Fuji Photo Film Co., Ltd., Tokyo, Japan). The pressure-measuring range of the LLW sheet is between 0.5 to 2.5 MPa and that of the LW sheet is between 2.5 to 10.0 MPa. The LLW sheet was used first to measure the pressure transmission of each specimen. Each specimen was measured 3 times. The interval period between each measurement was 1 min. The pressure-sensitive sheets were scanned and interpreted with digital software (Fuji Film Pressure Distribution Mapping System FPD-8010E version 1.1) to obtain the MPT data. If the pressure transmission exceeded the maximum measuring ranges of the LLW sheets, the LW sheets were used. The waiting period between LLW sheets and LW sheets measurement was 3 min. The pressure distribution patterns of all experimental groups were also observed.

Shore A hardness test

A square shaped plastic plate with an internal round-shaped hole (6 mm in height and 35 mm in diameter) was placed on a flat glass plate. Each soft lining material mixture (n=6) was prepared following the instructions of manufacturer, placed into the hole of plastic plate, covered by a polyester film, and loaded with a 2-kg weight. The polyester film was removed after the material set. A specimen of each material is shown in Figure 2. The specimens were kept in 37±1°C deionized water for 24 h. The Shore A hardness of each specimen was evaluated at 5 different position following ISO specification 10139-2: 2016[9] with a Shore A durometer (GS-719G, Teclock Co, Ltd., Osaka, Japan) and immediately returned to the deionized water. The deionized water was changed every 7 days. The Shore A hardness test was repeatedly performed at day 7 and 30 at different evaluated positions.

Statistical analysis

The MPT and Shore A hardness data were analyzed for normal distribution with the Shapiro-Wilk test. The MPT were analyzed by three-way ANOVA with material, thickness, and storage time as main effects. Since the interaction among three main effects was indicated to be significant, two-way ANOVA was used to analyze two main effects between material and storage time followed by Post hoc Tukey test. The independent t test was used to analyze the MPT of all experimental groups compared with the control groups. The Shore A hardness data were analyzed by two-way repeated-measures ANOVA followed by Tukey test. Statistical software (SPSS v22, IBM Corp., Armonk, NY, USA) was used to analyze all data with significance level set at α=.05.

Results

Three-way ANOVA revealed that the MPT showed significant differences on three main factors (material, thickness, and storage time) and their interactions ($P<.001$). The results of two-way ANOVA at each thickness revealed that the MPT showed significant differences on two main factors (material and storage time) and its interaction ($P<.001$). The MPTs and pressure distribution patterns at each thickness of all experimental groups are demonstrated in Figure 3 and 4, respectively. The post-hoc test for comparing MPT between experimental groups at 1 mm-, 2 mm-, and 3 mm-thickness are demonstrated in Table 1-3, respectively. Comparing among materials in 1-mm thickness, the VG group demonstrated the highest MPT at all time points. When increasing thickness up to 2 mm, the MPT in VG group were comparable to the ST and UP groups at day 1 and 7. However, the 2- and 3-mm thickness VG groups demonstrated the highest MPT at day 30. The GC group in each thickness demonstrated the lowest MPT compared with the other materials at day 1 and 7. While the MPTs at day 30 in GC group were not significantly different from those in the ST and UP groups ($P>.05$). Comparing among storage times, the MPT of the GC and VG groups at each thickness between day 1 and 7 were not significantly different (P>.05), while those at day 30 were significantly increased compared with those at day 1 and 7 (P<.05). The MPTs of the ST and UP groups at each thickness were not significantly different among time points (P>.05). Independent t test results of the MPTs at each thickness of all soft lining materials at each time point demonstrated significantly lower than the control group (P<.001), except the 1-mm thickness VG group at day 30 showed no significant difference comparing the control group (P=.651).

Two-way repeated-measures ANOVA of the Shore A hardness demonstrated significant differences on two main factors (material and storage time) and their interaction (P<.001). The Shore A hardness of all groups are demonstrated in Figure 5. The Shore A hardness slightly increased with a longer storage time. The post-hoc test for comparing the Shore A hardness difference between groups are demonstrated in Table 4. The Shore A hardness of the GC and VG groups at day 30 were significantly higher than those at day 1 and 7 (P<.001). However, the Shore A hardness of the ST and UP groups at day 1, 7, and 30 were not significantly different (P>.05). The ST group demonstrated the highest hardness, while the GC group demonstrated the lowest hardness at all time points.

Discussion

The present study evaluated the effect of different materials and thicknesses of soft lining materials at different storage times on MPT. The Shore A hardness was also evaluated among different materials at different storage times. Statistical analysis denoted that both MPT and Shore A hardness were significantly different on the interactions. Thus, the null hypotheses were rejected.

Pressure-sensitive sheet was selected because it is affordable, simple, and suitable for static pressure measurement in wide pressure ranges. Pressure-sensitive sheet is a polyester film coated with a micro-encapsulated color-forming and a color-developing material. When the pressure applied, varying chroma of red patches on the pressure-sensitive sheets are developed and converted to the amount of pressure loading by software. The more intense of the developed color demonstrated the greater of the pressure. Moreover, this method also offers visualization of the pressure distribution pattern apart from MPT. This study is the first in illustrating the pressure transmission pattern under different soft lining materials at different thicknesses and storage times resulted from the impact force. The Shore A hardness were also investigated in the present study. A previous study found that Shore A hardness related to viscoelasticity of soft lining material.[26] The material containing suitable viscoelastic behavior and durability could replace a missing oral mucosa and provide a cushion effect to relive stress from occlusal loading.[27] Moreover, linear regression between Shore A hardness and Young's modulus of material was elucidated.[28] A previous study indicated a positive correlation between Young's modulus and surface hardness.[29] The material presenting high Young's modulus could directly distribute and transmit occlusal force to supporting tissue. Although ISO 10139-1: 2018 specification[8] recommended to measure the hardness of tissue conditioner using type AO durometer, the hardness of all tested materials was evaluated using type A durometer in order to compare the result from the same standard as also demonstrated in a previous study.[30]

Among 1-mm thickness soft lining materials, VG group showed the highest MPT at all time points. The MPT of the 1-mm thickness VG group showed approximately 40% reduction compared with that of control group at day 1 and 7. While there was no significant reduction in the MPT of 1-mm thickness VG group, less than 5% reduction, compared with that of control group at day 30 (P=.651). The pressure distribution of the 1-mm thickness VG group demonstrated high pressure transmission at the center of the specimen and became more intense over time as shown in Figure 4B. This finding supported that a 1-mm thickness VG was considered too rigid for denture relining based on a clinical observation.[17] Lack of cushion effect in soft lining materials could create high-concentrated pressure areas and attribute to denture soreness pain and alveolar bone resorption. When increasing VG thickness to 2 mm, the MPTs of VG group at day 1 and 7 were comparable to that of ST and UP groups (Figure 4B, 4C, and 4D). This advocates that VG is more effective in pressure dissipation when the material thickness is at least 2 mm as supported by a previous study.[17] The pressure transmission pattern in 3-mm thickness VG group demonstrated less high-pressure intensity with even pressure distribution than that of 2-mm thickness VG group (Figure 4B). Increasing the soft lining materials thickness reduces the stress to the underlying tissues.[14,15] However, the soft lining material thickness is limited by the vertical dimension and interocclusal rest space. To maintain the vertical dimension of occlusion, the tissue surface of the denture should be reduced to obtain sufficient space for the soft lining materials. This reduction could weaken the denture base strength. The denture base that was less than 1-mm thickness could be softened by the plasticizers of soft lining materials.[31] Moreover, relining with soft lining materials was not recommended in patients who had an interalveolar space less than 5 mm.[32]

The GC group presented the lowest of MPT at all thicknesses at day 1 and 7. Interestingly, at day 30, the MPT of the GC group was still comparable to those of the ST and UP groups at all thicknesses. The 1-, 2-, and 3-mm thickness GC groups could reduce the MPT more than 60%, 65%, and 70%, respectively, compared with control at day 1 and 7. This corresponded to the lowest hardness of GC group at all time points, followed by the UP, VG, and ST groups. The pressure distribution of the GC group at each thickness at day 1 and 7 showed the evenly distributed pressure. After 30-day water immersion, the pressure was less apparent in some areas (Figure 4A). This might attribute to the leaching out of the ethyl alcohol and plasticizers, resulting in large porosity in the texture of specimen.

Although GC and VG groups are categorized as the same material type due to their chemical composition, the MPT at each thickness and the Shore A hardness of the VG group were higher than the GC group at all time points. These findings might be explained by the viscosity of the liquid, the powder particle size and the differences in powder/liquid ratio between GC and VG resulted in different hardness values.[13] According to the manufacturer instructions, the mixture of the GC group at a powder/liquid ratio (2.2 g/1.8 g) contains more liquid proportion than that of the VG group (3 g/2 g). Moreover, the lower molecular weight of the plasticizer exhibits a higher leachability rate.[33] The lower molecular weight of dibutyl phthalate in the VG group (278.34 g/mol) might be related to the more material hardening over time when compared to the *butyl phthalyl butyl glycolate* in the GC group (*336.4 g/mol).*

At this juncture, GC would be a better choice for relining beneath the denture base especially in cases with limited relining space. Although GC group could provide the reduction of MPT up to 30 days, comparable to silicone-based lining material, this material should be clinically used with discretion in terms of duration of use. Moreover, the GC group demonstrated more porosities spreading within the specimen compared to the others (Figure 2). It should be taken into consideration that porosities within the materials might serve as a reservoir for microbial colonization.[34] This led to the inflammation and infection of oral tissue.

The MPT at all thicknesses and the Shore A hardness of silicone-based soft lining materials, the ST and UP groups, were not significantly different among time points (P>.05). These findings supported the previous studies that polyvinyl siloxane materials demonstrated a slight change in hardness values over time.[35] The constant elastic property of these materials is mainly from the crosslinking of polydimethyl siloxane.[12,26] The pressure distribution patterns of the ST and UP groups at each thickness were quite similar to each other at all time points (Figure 4C and 4D). Despite similar chemical composition, the ST group demonstrated a higher Shore A hardness compared with the UP group. A degree of the crosslinking of polydimethyl siloxane between ST and UP group might be different. Another reason of this result might attribute to the different mixing techniques. The specimen in the UP group, fabricated by hand-mixed technique, demonstrated higher porosity than ST group, fabricated by cartridge-mixed technique (Figure 2).

The results of the present study suggest that the selection of material type differs among clinical cases. Despite the same material type, each material has an individual characteristic and requires different thickness to evenly distribute the pressure transmitted to the supporting tissues. As the soft lining material thickness was increased, the MPT tended to decrease. However, the denture base strength and the other properties of each soft lining material type must be considered. The limitation of the present study is that the pressures beneath the impact drop test was in one direction. The *in vitro* environment did not fully reflect the clinical situation. The simulated masticatory loading might affect the results in the present study.

In conclusion, considering the pressure transmission and Shore A hardness of tested material, Visco-gel is recommended when relining space is available at least 2-mm and limited to 7-day use. GC Soft-liner, Sofreliner tough M, and Ufi gel P in 1-to 3-mm thickness can dissipate pressure up to 30 days.

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Declaration of Interest

The authors report no conflict of interest.

Groups	GC D1	GC D7	GC D30	VG D1	VG D7	VG D30	ST D1	ST D7	ST D30	UP D1	UP D7	UP D30
GC D1	-											
GC D7	1.00	-										
GC D30	.004*	.016*	-									
VG D1	.000*	.000*	.000*	-								
VG D7	.000*	.000*	.000*	.990	-							
VG D30	.000*	.000*	.000*	.000*	.000*	-						
ST D1	.000*	.000*	.104	.020*	.000*	.000*	-					
ST D7	.000*	.000*	.129	.015*	.000*	.000*	1.00	-				
ST D30	.000*	.000*	.104	.020*	.000*	.000*	1.00	1.00	-			
UP D1	.000*	.000*	.078	.029*	.000*	.000*	1.00	1.00	1.00	-		
UP D7	.000*	.000*	.168	.011*	.000*	.000*	1.00	1.00	1.00	1.00	-	
UP D30	.000*	.000*	.209	.008*	.000*	.000*	1.00	1.00	1.00	1.00	1.00	-

Table 1. Tukey Test of maximum pressure transmissions (MPa) in different 1-mm-thickness materials at different storage times. *: The mean difference is significant at the .05 level. D: Day.

Groups	GC D1	GC D7	GC D30	VG D1	VG D7	VG D30	ST D1	ST D7	ST D30	UP D1	UP D7	UP D30
GC D1	-											
GC D7	1.00	-										
GC D30	.004*	.001*	-									
VG D1	.000*	.000*	.422	-								
VG D7	.000*	.000*	.086	1.00	-							
VG D30	.000*	.000*	.000*	.000*	.000*	-						
ST D1	.000*	.000*	.793	1.00	.977	.000*	-					
ST D7	.000*	.000*	.667	1.00	.994	.000*	1.00	-				
ST D30	.000*	.000*	.624	1.00	.996	.000*	1.00	1.00	-			
UP D1	.000*	.000*	.918	1.00	.913	.000*	1.00	1.00	1.00	-		
UP D7	.000*	.000*	.538	1.00	.999	.000*	1.00	1.00	1.00	1.00	-	
UP D30	.000*	.000*	.635	1.00	.996	.000*	1.00	1.00	1.00	1.00	1.00	-

Table 2. Tukey Test of maximum pressure transmissions (MPa) in different 2-mm-thickness materials at different storage times. *: The mean difference is significant at the .05 level. D: Day.

Groups	GC D1	GC D7	GC D30	VG D1	VG D7	VG D30	ST D1	ST D7	ST D30	UP D1	UP D7	UP D30
GC D1	-											
GC D7	1.00	-										
GC D30	.015*	.001*	-									
VG D1	.000*	.000*	.001*	-								
VG D7	.000*	.000*	.000*	.944	-							
VG D30	.000*	.000*	.000*	.000*	.000*	-						
ST D1	.000*	.000*	.955	.087	.003*	.000*	-					
ST D7	.000*	.000*	.933	.109	.004*	.000*	1.00	-				
ST D30	.000*	.000*	.928	.114	.000*	.000*	1.00	1.00	-			
UP D1	.013*	.001*	1.00	.001*	.000*	.000*	.966	.948	.943	-		
UP D7	.014*	.001*	1.00	.001*	.000*	.000*	.963	.943	.938	1.00	-	
UP D30	.012*	.001*	1.00	.001*	.000*	.000*	.969	.952	.948	1.00	1.00	-

Table 3. Tukey Test of maximum pressure transmissions (MPa) in different 3-mm-thickness materials at different storage times. *: The mean difference is significant at the .05 level. D: Day.

Groups	GC D1	GC D7	GC D30	VG D1	VG D7	VG D30	ST D1	ST D7	ST D30	UP D1	UP D7	UP D30
GC D1	-											
GC D7	.991	-										
GC D30	.000*	.000*	-									
VG D1	.000*	.000*	.000*	-								
VG D7	.000*	.000*	.000*	1.00	-							
VG D30	.000*	.000*	.000*	.000*	.000*	-						
ST D1	.000*	.000*	.000*	.000*	.000*	1.00	-					
ST D7	.000*	.000*	.000*	.000*	.000*	.776	.724	-				
ST D30	.000*	.000*	.000*	.000*	.000*	.398	.346	1.00	-			
UP D1	.000*	.000*	.000*	.435	.417	.000*	.000*	.000*	.000*	-		
UP D7	.000*	.000*	.000*	.952	.945	.000*	.000*	.000*	.000*	.998	-	
UP D30	.000*	.000*	.000*	1.00	1.00	.000*	.000*	.000*	.000*	.570	.984	-

Table 4. Tukey Test of Shore A hardness in different materials at different storage times. *: The mean difference is significant at the .05 level. D: Day.

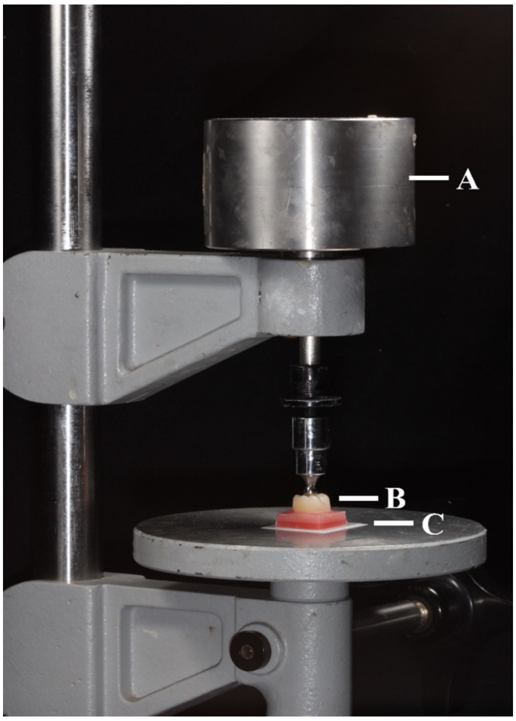

Figure 1. Impact load testing apparatus. A. 1-kg-weight load; B. Specimen; C. Pressure-sensitive sheet.

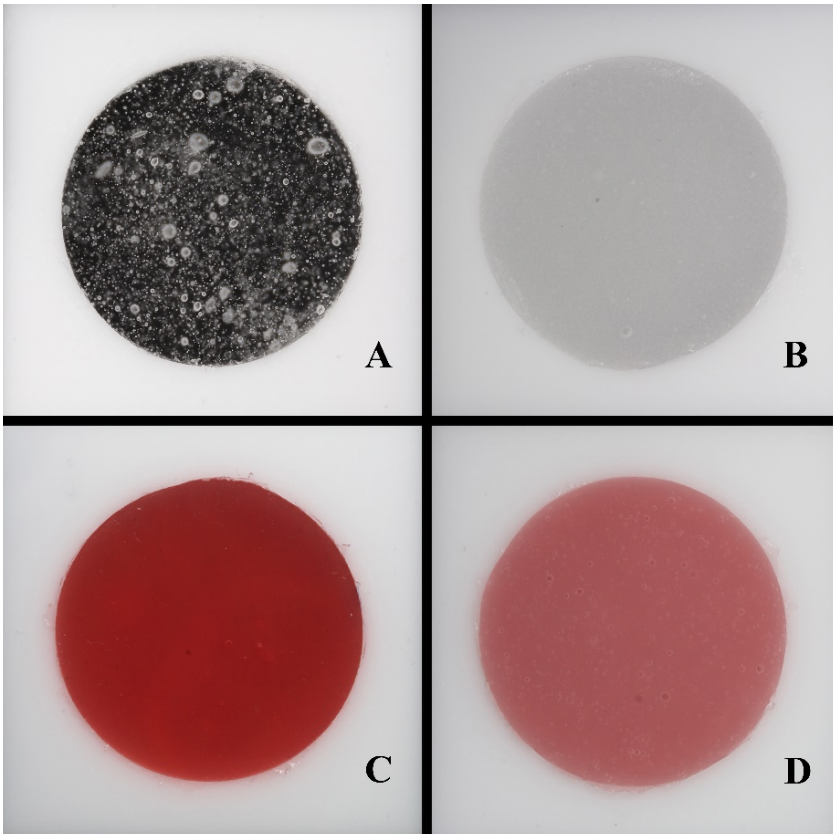

Figure 2. Specimen of each material in the Shore A hardness test. A. GC; B. VG; C. ST; D. UP.

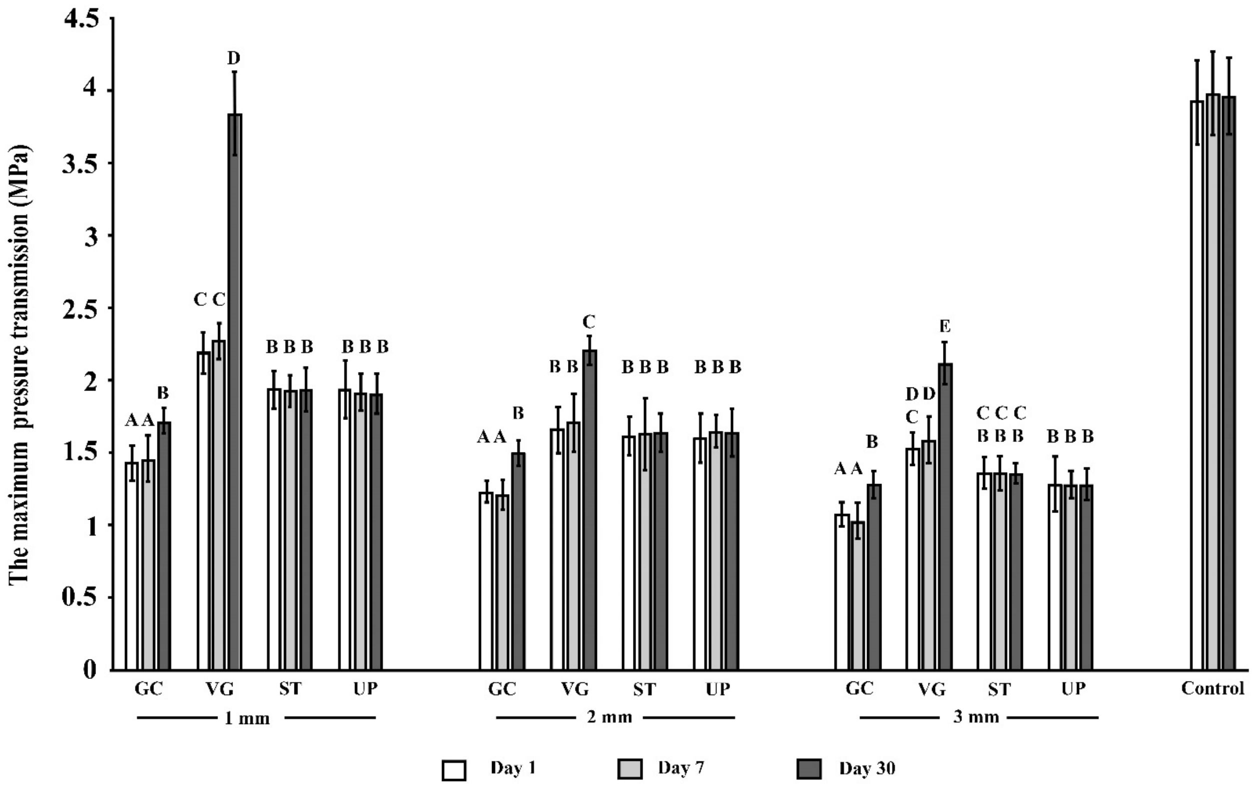

Figure 3. Mean and standard deviation of the maximum pressure transmissions (MPa) in different materials and thicknesses at different storage times. Within each thickness, bars with different letter were significantly different (P<.05).

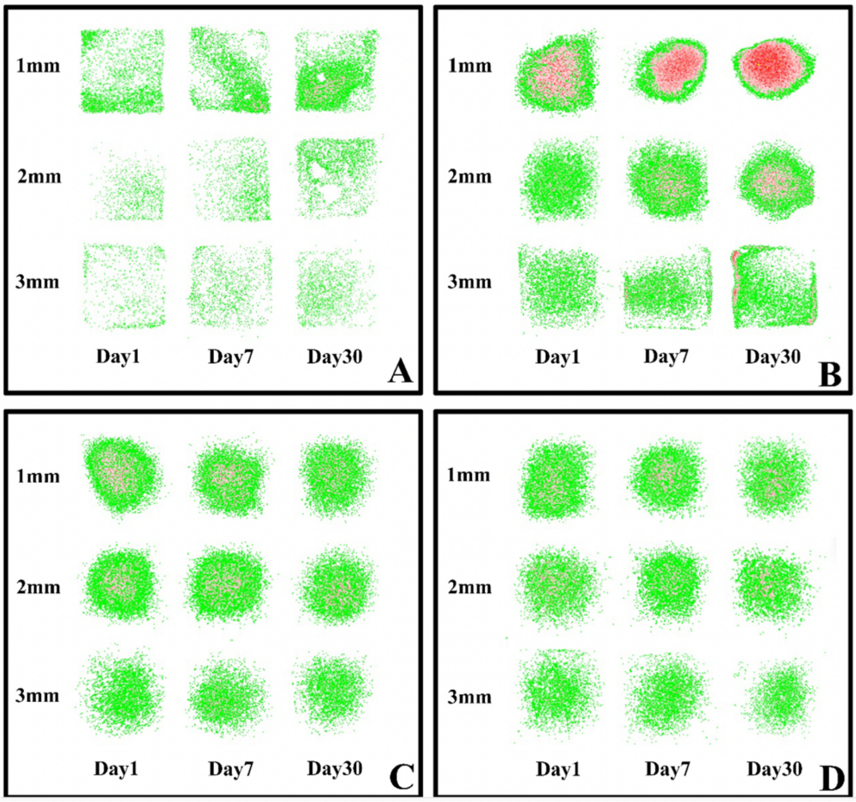

Figure 4. Representative pressure-sensitive sheets of the experimental groups. A. GC; B. VG; C. ST; D. UP.

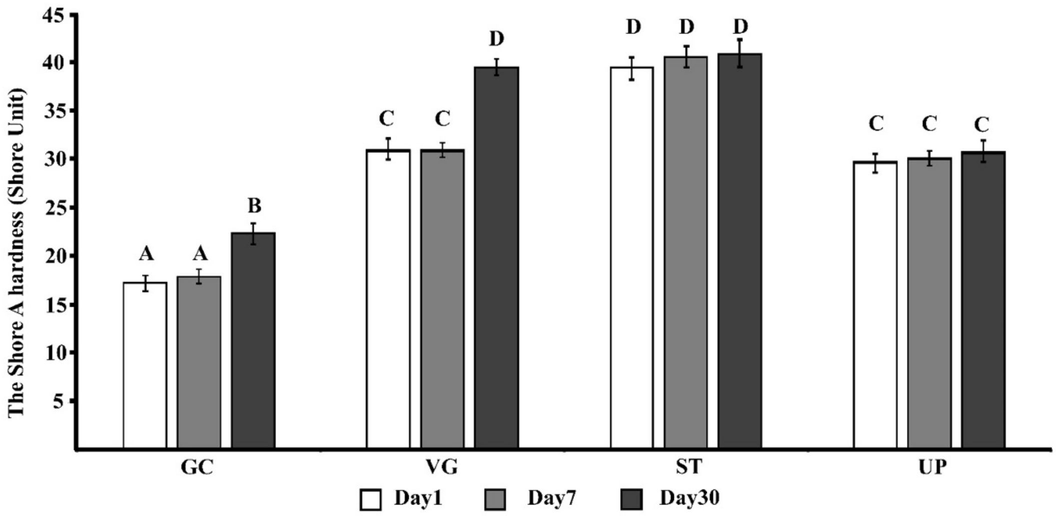

Figure 5. Mean and standard deviation of the Shore A hardness (Shore units) in different materials at different storage times. Bars with different letter were significantly different (P<.05).

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