



# INFLUENCE OF THICKNESS INCREASE OF INTRAORAL AUTOPOLYMERIZING HARD DENTURE BASE LINERS ON THE TEMPERATURE RISE DURING THE POLYMERIZATION PROCESS

Anna Maria Dimiou, DDS,<sup>a</sup>

Konstantinos Michalakis, DDS, MSc, PhD,<sup>b</sup> and

Argirios Pissiotis, DDS, MS, PhD<sup>c</sup>

Aristotle University School of Dentistry, Thessaloniki, Greece;

Tufts University School of Dental Medicine, Boston, Mass

**Statement of problem.** Increasing the thickness of intraoral autopolymerizing hard denture base liners may result in a temperature rise and a burning sensation for patients.

**Purpose.** The purpose of the study was to determine whether increasing the thickness of hard autopolymerizing reline resin increases the temperature of the basal seat area of a denture during the polymerization process.

**Material and methods.** Four polyethyl methacrylate and 1 polymethyl methacrylate autopolymerizing reline resin products of 3 different thicknesses were tested. A cobalt-chromium edentulous maxillary cast was used to obtain 150 stone casts, 50 for each thickness of 1, 2, and 3 mm ( $n=10$ ). Polystyrene record bases were filled with the autopolymerizing reline resin mixture and placed on the cobalt-chromium cast, which was mounted on a reline index, to serve as denture substitutes. Two thermal probes were used to monitor the temperature rise, which was recorded at 30-second intervals until no further increase was noted. Collected data were subjected to a 2-way ANOVA and the Tukey honestly significant difference test ( $\alpha=.05$ ).

**Results.** The mean temperature increase for the chairside denture reline procedure ranged from 39.45°C for the 1-mm thickness to 46.10°C for the 3-mm thickness. The 2-way ANOVA found significant differences ( $P<.001$ ) among the different reline resin materials and thicknesses tested. All materials produced an exothermic chemical reaction. An increase in thickness was always accompanied by an increased temperature. The Tukey honestly significant difference test found that the highest temperature increase for all 3 thicknesses occurred in the polymethyl methacrylate resin.

**Conclusions.** The polymethyl methacrylate autopolymerizing hard denture base liner produced a significantly higher ( $P<.001$ ) exothermic reaction than the other materials included in this study. One of the polyethyl methacrylate resins presented a higher exothermic reaction than the polymethyl methacrylate product at a 3-mm thickness, but the difference was not statistically significant. The polymethyl methacrylate resin presented the highest mean time to reach the maximum temperature for all 3 thicknesses. (J Prosthet Dent 2014;111:512-520)

## CLINICAL IMPLICATIONS

In patients with extensive residual ridge resorption, a chairside hard reline should not be the first treatment option, owing to the discomfort that the elevated polymerization temperature may cause.

Tooth extraction results in the sequelae of continuous progressive bone resorption and bone remodeling of the edentulous jaws.<sup>1-3</sup> This procedure represents a chronic, physiologic,

and nonreversible process due to a combination of anatomic, metabolic, and functional factors.<sup>4-7</sup> However, the importance of each contributing factor has not yet been determined.

A possible therapeutic approach to the treatment of complete or partial edentulism includes the fabrication of a removable complete or partial dental prosthesis. These prostheses require a

<sup>a</sup>Resident, Division of Removable Prosthodontics, Department of Prosthodontics, Aristotle University School of Dentistry.

<sup>b</sup>Adjunct Associate Professor, Division of Graduate and Postgraduate Prosthodontics, Tufts University School of Dental Medicine; Assistant Professor, Division of Removable Prosthodontics, Department of Prosthodontics, Aristotle University School of Dentistry; Private practice, Thessaloniki, Greece.

<sup>c</sup>Professor and Head of Removable Prosthodontics, Aristotle University School of Dentistry.

thorough evaluation on a regular basis to determine whether they satisfy the biologic requirements, as well as the esthetic and functional needs of the patient.<sup>8</sup> The stability, support, and retention of the dentures should be carefully assessed, as ill-fitting dentures may contribute to compromised function and to mucosal trauma and lesions.<sup>8</sup> Furthermore, it has been postulated that denture base movement in any direction may cause tissue damage and contribute to a faster residual ridge reduction.<sup>9-12</sup> Therefore, if the stability, support, and retention of the denture is problematic, a relining or a rebasing procedure may be needed, depending on the extent of changes to the supporting tissues.<sup>13-15</sup>

Denture base relining involves the addition of a new base material on the intaglio surface of the denture to obtain a close adaptation with the denture foundation area.<sup>16,17</sup> Traditionally, this technique requires placement of an impression material or tissue conditioner on the intaglio side of the denture to capture the new form of the basal seat.<sup>8,18-21</sup> The completion of the procedure occurs in the laboratory with the use of a reline index.<sup>8</sup> This method is the one usually preferred by clinicians because of the good properties of the added material.<sup>22-29</sup> However, a major disadvantage of the indirect method is that it involves several laboratory stages that require the patient to be without the denture for a certain time. For that reason, several materials have been introduced to complete the reline procedure chairside, including a direct method, which is convenient, straightforward, and requires a short working time.<sup>30-32</sup> Furthermore, a previous *in vitro* study has found that the autopolymerizing direct chairside relining method results in smaller discrepancies at the posterior palatal seal area than indirect laboratory methods.<sup>33</sup> However, these materials have certain disadvantages, which include poor color stability, porosity, possible irritation to the oral soft tissues due to monomer excess, and heat generation, which may cause a thermal burn of the oral

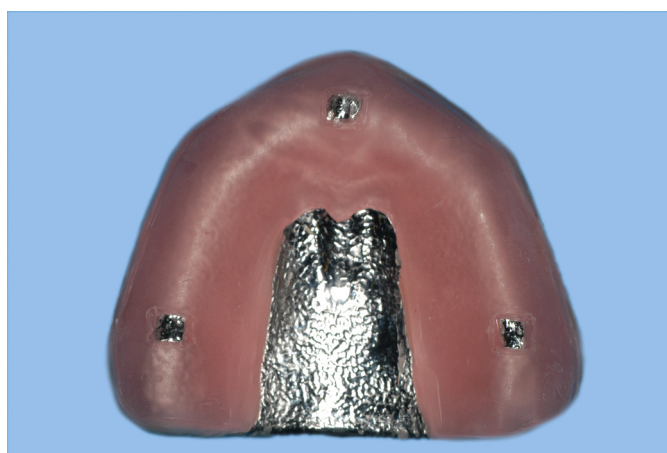
mucosa.<sup>34-39</sup> One *in vitro* study,<sup>31</sup> 2 studies performed both *in vitro* and *in vivo*,<sup>30,32</sup> and 1 *in vivo* study<sup>40</sup> have evaluated the temperature rise during the polymerization of materials used in the direct chairside technique. These studies concluded that the exothermic reaction of some of the materials produced mean temperatures close to normal body temperatures. Other materials presented temperatures even higher than those recommended by the American National Standards Institute/American Dental Association (ANSI/ADA) specification No. 17 for denture base provisional relining resin materials (75°C).<sup>41</sup> However, none of these studies considered the possible relationship between the quantity of bone loss (and therefore different thicknesses of the chairside reline material) and the temperature increase during the polymerization process.

The purpose of this study was to determine whether increasing the hard autopolymerizing reline resin thickness contributes to temperature increase at the basal seat area of the denture during the polymerization process. The null hypothesis was that the temperature rise during the polymerization is independent of the thickness of the hard autopolymerizing reline resin materials.

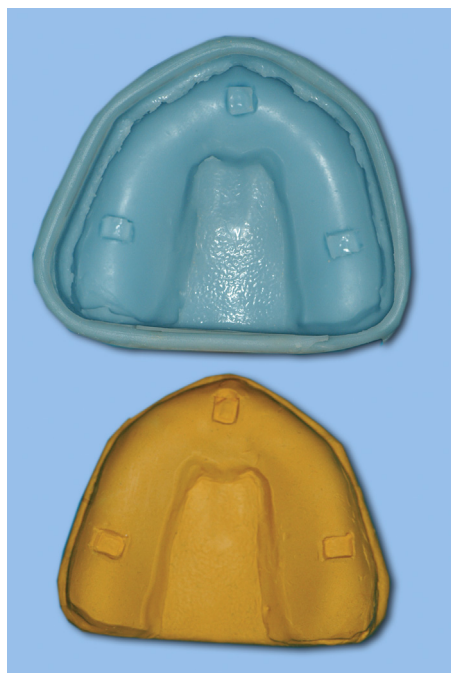
## MATERIAL AND METHODS

An edentulous maxillary cast without a base (thickness, 0.5 mm) was

fabricated in a cobalt-chromium (Co-Cr) metal alloy (Vitallium; Dentsply/Austenal). Record base wax (Tenatex Red; Kemdent) with a thickness of 1, 2, and 3 mm was applied to the cast along the alveolar ridge (Fig. 1). The palatal area remained uncovered to function as a definite stop and assist in the orientation and positioning of the specimens.<sup>42</sup> Then, wax strips (Utility Wax Strips; Coltène/Whaledent) and boxing wax (Boxing Wax; Coltène/Whaledent) were placed around the perimeter of the casts. A laboratory addition silicone (Degufom; DeguDent) material was mixed in a vacuum mixer (Twister Venturi; Renfert) and poured under vibration (Vibrator No. 200; Buffalo Dental Mfg Co) to fabricate 3 molds for each of the 3 thicknesses. Type III dental stone (Silky Rock; Whip Mix Corp) was mixed in a vacuum mixer (Twister Venturi; Renfert) and poured into the 3 molds. Therefore, 150 casts were obtained, 50 for each thickness (Fig. 2). A vacuum former machine (Tray-Vac; Buffalo Dental Mfg Co) was used to fabricate 0.80-mm-thick polystyrene record bases (Proform Record base Material; Keystone Industries) on the casts. Type V dental stone (Jade Stone; Whip Mix Corp) was used for the fabrication of 3 stone molds, 1 for each of the 3 record base thicknesses so they could be mounted on the upper side of the reline index (Fig. 3). The thermal probes of 2 calibrated digital precision thermometers (BAT 8; Bailey Instruments Inc) were soldered to



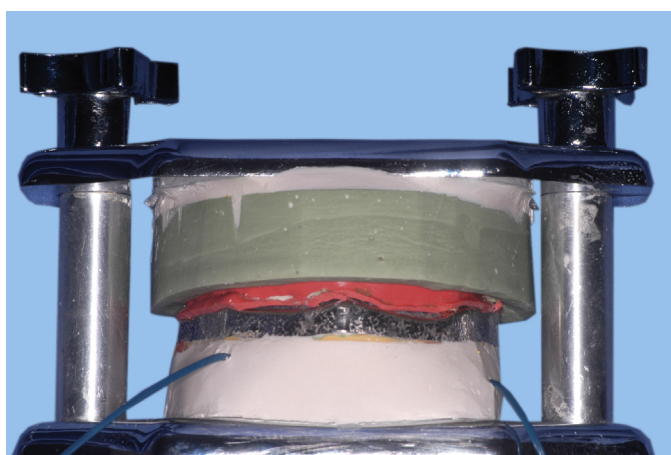
**1** Maxillary edentulous cobalt-chromium cast with 2-mm wax spacer.



**2** Polyvinyl siloxane mold and stone cast for polystyrene record base fabrication.



**3** Stone mold used for mounting of polystyrene record bases.



**4** Maxillary cobalt-chromium cast with polystyrene record base mounted on reline index.

the bottom surface of the cast, at the premolar regions on both sides of the arch. All thermal energy released from the exothermic reaction of the acrylic resin polymerization was transmitted from the Co-Cr alloy of the metal cast to the thermal probes.<sup>43,44</sup> The maxillary metal cast was mounted with Type III dental stone (Mounting Stone; Whip Mix Corp) on a reline index (Buffalo Dental Mfg Co) (Fig. 4). The metal cast/reline index/engaged thermal probes assembly was placed in a water bath (Digital Water Bath; Whip Mix Corp), containing distilled water at a temperature of 37°C. The assembly was then allowed to thermally equilibrate. The water bath was used to simulate intraoral conditions.

Five commonly used hard autopolymerizing reline resins were included in the study (Table I). For each of the reline materials, the monomer and polymer were measured and mixed according to the manufacturer's instructions. An electronic scale (Galaxy 110; Ohaus) with an accuracy of  $\pm 0.0001$  g was used to weigh the polymer of each resin material. A calibrated pipette (Biohit Proline; Biohit Oyj) was used to measure the monomer. The polystyrene record base was completely filled with the resin mixture and then positioned on the mounted maxillary cast, and the reline index was hand tightened. All excess resin material was removed from the margins of the metal cast. Immediately afterward, the metal cast/polystyrene record base/reline index/engaged thermal probes assembly was placed in a water bath. The temperature was recorded during polymerization at 30-second intervals until no further increase was noted. This procedure was repeated for all 10 specimens for each of the 3 thicknesses and the 5 resin materials tested, giving a total of 300 temperature rise recordings. The room temperature was a constant  $21 \pm 1^\circ\text{C}$ . Descriptive statistics, 2-way ANOVA ( $\alpha=.05$ ), and the Tukey honestly significant difference (HSD) ( $\alpha=.05$ ) tests were used to determine statistically significant differences in temperature rise for different

TABLE I. Reline resin materials tested

Brand	Manufacturer	Polymer	Monomer	Lot/Batch No.	Code
Tokuyama Rebase	Tokuyama Dental America Inc	PEMA	2-(Acetoacetoxy) ethyl methacrylate	098E61	TRB
Flexacryl Hard	Lang Dental Mfg	PEMA	<i>N</i> -Butyl methacrylate Dimethyl- <i>p</i> -toluidine	0923	FLX
GC Reline Hard	GC Corp	PEMA	Butoxyethyl methacrylate Benzyl methacrylate 1,6-HDDMA	1006292	HR
Rebaron	GC Corp	PMMA	Methyl methacrylate <i>N,N</i> -dimethyl- <i>p</i> -toluidine	1107042	RB
Ufi Gel Hard	Voco GmbH	PEMA	Bis-GMA UEDMA	1117276	UFH

PEMA, polyethyl methacrylate; PMMA, polymethyl methacrylate; 1,6-HDDMA, 1,6-hexanediol dimethacrylate; bis-GMA, bisphenol A-glycidyl methacrylate; UEDMA, urethane dimethacrylate.

reline resin materials and thicknesses. Statistical software (IBM SPSS v20.0; IBM Corp) was used for the analysis.

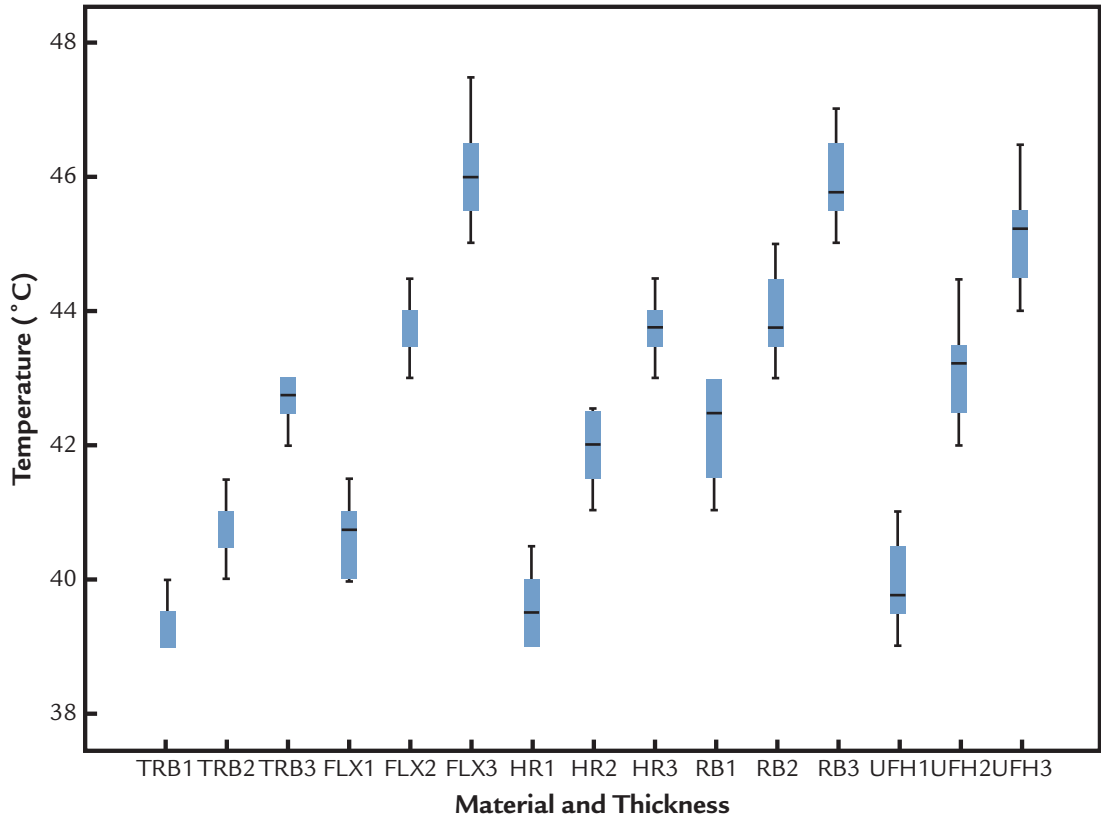
## RESULTS

The results of the descriptive statistics for mean temperature increase and standard deviation values of the reline resin materials at different thicknesses are summarized in Table II and Figure 5. The mean temperature increase for the chairside denture reline procedure ranged from 39.45°C for the 1-mm thickness TRB to 46.10°C for the 3-mm thickness FLX. The 2-way ANOVA found significant differences ( $P<.001$ ) between different reline resin materials and tested thicknesses (Table III). All materials produced an exothermic chemical reaction. For all tested materials, the increase of thickness was always accompanied by a significantly increased temperature value ( $P<.001$ ). The Tukey HSD test for the 1-mm thickness found that TRB, HR, and UFH did not present statistically significant differences ( $P=.574$ ) (Table IV). For the 2-mm thickness, UFH and FLX were not statistically different ( $P=.108$ ), and FLX was not different from RB ( $P=.995$ ) (see Table IV). Finally, the 3-mm thickness RB presented a smaller temperature increase, although not significantly

TABLE II. Descriptive statistics for temperature increase (°C) for each thickness (n=10)

Material	Thickness	Mean	SD
Tokuyama Rebase	1	39.45	0.50
	2	40.90	0.46
	3	42.65	0.41
	Total	41.00	1.40
Flexacryl Hard	1	40.70	0.59
	2	43.85	0.47
	3	46.10	0.77
	Total	43.55	2.33
GC Recline Hard	1	39.55	0.50
	2	41.90	0.51
	3	43.75	0.54
	Total	41.73	1.81
Rebaron	1	42.25	0.72
	2	43.95	0.64
	3	45.90	0.61
	Total	44.03	1.65
Ufi Gel Hard	1	39.85	0.67
	2	43.20	0.75
	3	45.20	0.75
	Total	42.75	2.35
Total	1	40.36	1.20
	2	42.76	1.31
	3	44.72	1.47
	Total	42.61	2.23

SD, standard deviation.



**5** Mean temperature increase and standard deviation values of reline resin materials at different thicknesses. TRB, Tokuyama Rebase; FLX, Flexacryl Hard; HR, GC Reline Hard; RB, Rebaron; UFH, Ufi Gel Hard. Number after code indicates thickness in millimeters.

**TABLE III.** Two-way ANOVA for basal seat temperature increase with different thicknesses and different reline resins

Source	Sum of Squares	df	Mean Square	F	P
Corrected model	689*	14	49	134	<.001
Intercept	272 385	1	272 384	744 370	<.001
Material	188	4	47.17	129	<.001
Thickness	477	2	238	652	<.001
Material × thickness	23	8	2.89	8	<.001
Error	49	135	.37		
Total	273 123	150			
Corrected total	738	149			

\*R<sup>2</sup>=.933 (adjusted R<sup>2</sup>=.926).

different ( $P=.954$ ) than FLX, and was in the same group with UFH ( $P=.115$ ) (see Table IV). The Tukey HSD test for all 3 thicknesses found that all resin reline materials were significantly different ( $P<.001$ ) from each other (see Table IV). TRB presented the lowest values, whereas RB presented the highest values of temperature rise. HR, UFH, and FLX presented intermediate values

with an ascending order. The Tukey HSD test for the material × thickness interaction found that RB with a thickness of 1 mm produced a statistically significantly higher exothermic reaction than TRB with a thickness of 2 mm. It was also found that 1-mm thickness RB was not statistically significantly different than the 3-mm thickness TRB ( $P=.275$ ) (Table V). With the exception

of TRB and HR, the rest of the tested materials with a thickness of 3 mm were not statistically significantly different ( $P=.072$ ) (see Table V). The mean time to reach the maximum temperature increased from the 1-mm to the 3-mm thickness. It ranged from 3.35 minutes for the 1-mm thickness relined with TRB to 6.81 minutes for the 3-mm thickness relined with RB (Table VI).

DISCUSSION

The present in vitro study investigated the effect of 3 different thicknesses of 5 commonly used intraoral hard reline denture autopolymerizing resin materials on temperature increase. The results of this study indicate that the temperature increase depends both on the thickness increase and the use of different resin reline materials. Therefore, the null hypothesis was rejected.

ANSI/ADA Specification No. 17 requires that the exothermal reaction of the denture base interim reline resin

**TABLE IV.** Tukey honestly significant difference test for basal seat temperature increase (°C) (n=10)

Material	1-mm Thickness			2-mm Thickness				3-mm Thickness				Overall				
	Subsets			Subsets				Subsets				Subsets				
	1	2	3	1	2	3	4	1	2	3	4	1	2	3	4	5
TRB	39.45			40.90				42.65				41.00				
HR	39.55				41.90				43.75				41.73			
UFH	39.85					43.20				45.20				42.75		
FLX		40.70				43.85	43.85			45.90	45.90				43.55	
RB			42.25				43.95				46.10					44.03
Significance	.574	1.000	1.000	1.000	1.000	.108	.995	1.000	1.000	.115	.954	1.000	1.000	1.000	1.000	1.000

TRB, Tokuyama Rebase; FLX, Flexacryl Hard; HR, GC Reline Hard; RB, Rebaron; UFH, Ufi Gel Hard.

**TABLE V.** Tukey honestly significant difference test for material × thickness interaction (°C) (n=10)

Material × Thickness	Subset						
	1	2	3	4	5	6	7
TRB1	39.45						
HR1	39.55						
UFH1	39.85	39.85					
FLX1		40.70	40.70				
TRB2			40.90				
HR2				41.90			
RB1				42.25			
TRB3				42.65	42.65		
UFH2					43.20	43.20	
HR3						43.75	
FLX2						43.85	
RB2						43.95	
UFH3							45.20
RB3							45.90
FLX3							46.10
Significance	.977	.118	1.000	.275	.775	.275	.072

TRB, Tokuyama Rebase; FLX, Flexacryl Hard; HR, GC Reline Hard; RB, Rebaron; UFH, Ufi Gel Hard.  
The number after the material code denotes the thickness in millimeters.

polymerization does not exceed 75°C. Furthermore, it is specified that the peak temperature shall occur between 6 and 15 minutes.<sup>41</sup> A study by Barclay et al<sup>39</sup> has found that the temperature that can be tolerated during hot beverage consumption varies between 46.8°C and 77.4°C among individuals. Given the fact that a hot beverage stays in the mouth for a few seconds, the 75°C and the 6- to 15-minute

peak temperature limit that ANSI/ADA Specification No. 17 requires is probably too high. The highest temperatures of the denture reline materials included in this study are well below the specification set by the ADA. The experimental setup of ANSI/ADA Specification No. 17 measures the temperature peak in specimens with an area of 39.3 cm<sup>2</sup> and a thickness of 2 mm.<sup>41</sup> The Co-Cr maxillary edentulous cast

used in the present study had a surface area of 42.9 cm<sup>2</sup>, and 3 different thicknesses were included to simulate clinical conditions with different degrees of resorption. The effect of thickness on temperature increase is statistically significant.

The results of the present study are in accordance with a previous in vivo study investigating the exothermic reaction produced by the same 5 materials.<sup>40</sup> In



**TABLE VI.** Minimum, maximum, and mean times to reach peak temperature

Material	Thickness	Mean	SD	Min	Max
Tokuyama Rebase	1	3.35	.54	2.30	4.00
	2	3.88	.42	3.30	4.30
	3	4.12	.16	4.00	4.30
	Total	3.78	.51	3.20	4.20
Flexacryl Hard	1	4.45	.67	3.30	5.30
	2	4.88	.42	4.30	5.30
	3	5.42	.42	5.00	6.00
	Total	4.92	.64	4.20	5.53
GC Reline Hard	1	3.62	.55	3.00	4.30
	2	4.15	.16	4.00	4.30
	3	4.48	.65	3.30	5.30
	Total	4.08	.60	3.43	4.63
Rebaron	1	5.18	.15	5.00	5.30
	2	6.15	.16	6.00	6.30
	3	6.81	.52	6.00	7.30
	Total	6.05	.75	5.67	6.30
Ufi Gel Hard	1	3.21	.14	3.00	3.30
	2	3.68	.55	3.00	4.30
	3	4.58	.51	4.00	4.30
	Total	3.82	.72	3.33	3.97
Total	1	3.96	.88	2.30	5.30
	2	4.55	.98	3.00	6.30
	3	5.08	1.08	3.30	7.30
	Total	4.53	1.08	2.87	6.30

SD, standard deviation; Min, minimum; Max, maximum.

that study, the authors tested only the materials with a thickness of 2 mm and found that TRB produced the least thermal increase, followed by HR and UFH, whereas RB and FLX produced the highest temperature scores. However, in the study of Yannikakis et al<sup>40</sup> the thermocouple measuring the peak temperatures was placed in the middle of the palatal area. In the present study 2 thermocouples were placed in the premolar regions of the residual ridge to collect data from more than 1 area and cross-check the recordings. The thermocouples were placed in the residual ridge and not in the palatal area, because the literature supports the notion that the hard palate resists resorption owing to the function of the levator and tensor veli palatini muscles,

which because of their tension counteract the pressure resorption usually seen under a denture base.<sup>42</sup> Therefore, the amount of autopolymerizing resin is usually less in the palatal area than in the residual ridge area.

When the resorbed residual ridge provides a space of 1 mm, the peak temperature produced by TRB, HR, and UFH was close to body temperature and as such would probably not annoy the patient. FLX and RB presented a slightly bigger temperature increase. At the 2-mm thickness, all materials produced mean peak temperatures above 40°C, whereas at the 3-mm thickness, the mean peak temperatures ranged between 42.65°C and 46.1°C. An interesting finding was that TRB with a thickness of 3 mm produced a slightly

greater temperature increase than RB with a thickness of 1 mm. RB was the only polymethyl methacrylate (PMMA) material; the rest were polyethyl methacrylates (PEMAs). Previous research on hard denture base liners has found that PMMA resins produce a stronger exothermic reaction than PEMA.<sup>40</sup> In vitro studies on autopolymerizing resins used for the direct fabrication of interim restorations have come to the same conclusion.<sup>44</sup> Recently manufacturers seem to have shifted from PMMA polymer composition to PEMA to reduce the peak temperatures produced by the hard denture base liners. One company even provides 2 materials in the dental market with different polymer and monomer compositions. The mean peak temperatures of these 2 materials differ significantly. The PEMA material (HR) presented the second lowest temperature increase, and the PMMA (RB) presented the highest peak temperatures for all thicknesses examined.

The highest mean temperature recorded by the materials included in the present study was close to 46°C, and the highest temperature reached by a specimen was 47.5°C. The maximum temperature that can be tolerated for extended periods without causing damage to the skin is 50.4°C.<sup>38</sup> However, the literature does not provide any specific information regarding the lowest temperature that may cause damage to the oral mucosa. The temperatures recorded in the present study would be unlikely to cause thermal injury to the mucosa. Nevertheless, the literature supports the notion that the maximum readily tolerated temperature for the mucosa is about 43°C.<sup>38</sup> Additionally, as already mentioned, an in vivo study has found that some people experienced discomfort when they consumed hot beverages at 46.8°C.<sup>39</sup> Therefore, the peak temperature produced by the 3-mm thickness of all products except TRB would probably cause some discomfort to a patient.

The time required to reach the peak temperature was above the time

registered by Yannikakis et al.<sup>40</sup> In the present study, the metal cast/polystyrene record base/reline index/engaged thermal probes assembly was placed in a water bath in an effort to simulate oral conditions. However, in vivo conditions cannot be reproduced exactly. In the past, the soft tissue adjacent to the acrylic resin that is polymerizing was thought capable of removing the heat faster by means of conduction and blood flow. This heat transfer depends on the heat source, the arterial temperature, the local tissue temperature, the thermal conductivity of the tissue, and the perfusion rate.<sup>43</sup>

Given that the peak temperatures recorded could cause discomfort to the patient, the products that presented faster polymerization may be considered as advantageous. Many manufacturers recommend the removal of the denture from the mouth during the polymerization process to eliminate the unpleasant burning sensation. However, warpage of the autopolymerizing acrylic resin may occur, and, as a result, the prosthesis will not fit the supporting tissues accurately.<sup>30</sup> Alternatively, spraying copious amounts of cold water on the border of the denture may help reduce the burning sensation.<sup>30</sup>

This study focused only on the influence of increasing the thickness of intraoral autopolymerizing hard denture base liners on the temperature rise during the polymerization process. Other parameters, including possible cytotoxicity, allergic reactions to monomer, and porosity of the polymerized liner were not considered but are equally important in choosing whether to use the direct or indirect method of reline.

## CONCLUSIONS

Within the limitations of this in vitro study, the following conclusions were drawn. The PMMA autopolymerizing hard denture base liner produced a significantly higher ( $P<.001$ ) exothermic reaction than the other materials included in this study. Flexacryl Hard, which is a PEMA resin, presented a

stronger exothermic reaction than the PMMA product at a 3-mm thickness, but the difference was not statistically significant. The PMMA resin presented the highest mean time to reach the maximum temperature for all 3 thicknesses.

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**Corresponding author:**  
Dr Konstantinos Michalakis  
3 Gregoriou Palama str  
Thessaloniki 54622  
GREECE  
E-mail: kmichalakis@hotmail.com

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## NOTEWORTHY ABSTRACTS OF THE CURRENT LITERATURE

### Treatment outcomes with removable partial dentures: a retrospective analysis

Rehmann P, Orbach K, Ferger P, Wöstmann B.  
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**Purpose.** This retrospective clinical study aimed to evaluate the long-term outcomes of clasp-retained, metal-framework removable partial dentures (RPDs) and their clasped teeth, the influencing factors on survival, and the type and number of repairs needed during the observation period.

**Materials And Methods.** The study is based on a convenience sample of 52 patients who received 65 RPDs with a total of 207 clasped teeth. The mean observation period was  $3.11 \pm 0.29$  years (maximum: 10 years). Patient gender, prosthesis location (maxilla/mandible), number and distribution (Kennedy class) of abutment teeth, and impact of a continuous follow-up program on a favorable outcome probability were analyzed. Statistical analysis was performed using the Kaplan-Meier method ( $P < .05$ ) in combination with Cox regression analysis.

**Results.** During the observation period, 9.2% of the RPDs ceased to function and 5.8% of the abutment teeth were extracted. Mean RPD survival time was  $8.07 \pm 0.66$  years, with a positive outcome probability of 90% after 5 years. Prosthesis location was the only parameter that significantly ( $P < .05$ ) impacted this probability.

**Conclusion.** Overall, the high survival probability and low extraction rate of the abutment teeth reported in this study indicate that RPDs designed according to hygienic principles are clinically successful.

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