BASIC SCIENCE RESEARCH

Thermoforming Process for Fabricating Oral Appliances: Influence of Heating and Pressure Application Timing on Formability

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Objectives: This study was designed to examine the influence of heating and pressure application timing for thermoplastic soft materials on formability during the thermoforming process.

Methods: Ethylene vinyl acetate (EVA) and a high shock-absorbing material (Hybrar) were used. Five specimens (20 × 10 × 4 mm) were heated to temperatures of 60, 80, 100, 120, 140, 160, 180, and 200°C and then placed under a 4 N static weight with an indentation tip. The forming capability index (FI) was evaluated by rating the shape, size, and surface texture changes of the indentation tip reproduction in specimens using specially developed scales. The suitable temperature range for forming (STF) was determined by FI. Heat-holding capability of the two materials was also evaluated by the temperature changes in the cooling process using a digital thermometer. Timing of air pressure application was examined with the time-dependent change in negative pressure among three types of forming machines.

Results: STF of the EVA (80–120°C) was lower than that for Hybrar (140–160°C). The time required to reach the lower limit of the STF was statistically different between the two materials (EVA: 41 seconds, Hybrar: 13 seconds) ($p < 0.05$). The maximum negative pressure (MNP) of the three forming machines ranged from −12 to –60 cmHg and time to reach the temperature, 5–60 seconds.

Conclusions: The results suggest that heating conditions for each type of sheet material should be predetermined by the STF. Forming process should be performed with the high MNP before reaching the lower limit of the STF.

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INDEX WORDS: thermoforming, soft oral appliance, temperature, plasticity, formability

ALTHOUGH soft removable appliances, such as athletic mouth guards,[1,2] soft occlusal splints,[3-5] bleaching[6-8] or drug delivery trays, and splints used to treat sleep apnea, have been widely used clinically, the impact of their accuracy of fit has not been well recognized or studied. Soft materials are often selected due to a simple fabricating procedure using their thermoplasticity. Precise fit of soft oral appliances is critical to gaining patients' compliance; however, little is known about factors influencing the thermoplasticity of soft materials in relation to the formability and accuracy of fit.

The fabrication procedure of soft oral appliances[8-13] using sheet-type materials like ethylene vinyl acetate (EVA) consists of several stages: the preparation of a working cast, the softening of the sheet material using heat, and the forming process using either positive or negative pressure. During each stage, several factors may influence the final accuracy of fit. Regarding the stage for the working cast preparation, Yonehata et al[14] reported that the residual moisture of the working cast is one of the most critical factors for accuracy, especially when a vacuum-forming machine is used. The types of surface lubricating media for the working cast also influence the accuracy of fit because some surface lubricating media decrease the air permeability of the working casts.[15]

This study was designed to examine the influence of heat and pressure application time for thermoplastic soft materials on formability during the pressure-forming fabrication process.

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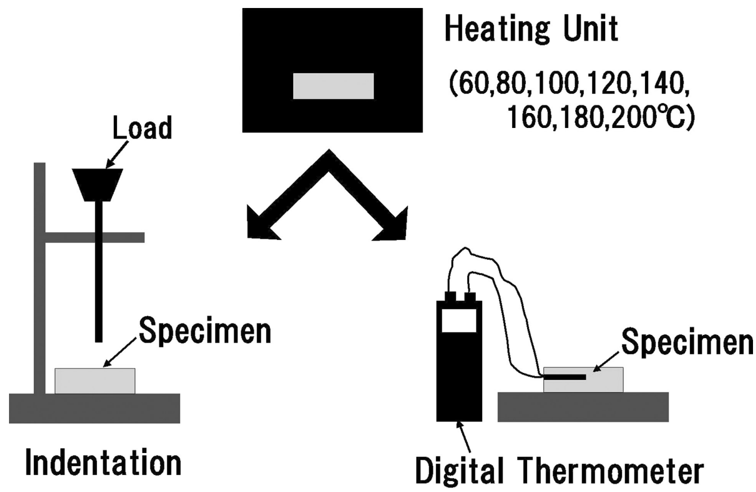

Figure 1. Loading test machine with the round cross-section indentation tip with 4 N of weight.

We attempted to determine the following clinical variables:

(1) The most suitable temperature range for the forming process, (2) the working time duration for the forming process, and (3) the optimum timing of the application of the vacuum for forming.

Materials and Methods

The specimens (20 × 10 × 4 mm) were made from sheet-type EVA material (Erkoflex Lot.581140, Erkodent, Pfalzgrafenweiler, Germany) and a newly developed high shock-absorbing material (Hybrar EC5-3-C, Lot040103, Kuraray, Tokyo, Japan). Hybrar was originally developed for industrial applications and subsequently proved to be safe for use in the food industry, according to the safety standards of the Japanese Ministry of Health and Labor.[16]

Five specimens of each material were heated to temperatures of 60, 80, 100, 120, 140, 160, 180, and 200°C in an electric furnace and then placed under the static loading test machine with a round cross-section (3.0 mm in diameter) indentation tip with 4 N of weight for 5 minutes (Fig 1). This 4 N of weight was used to simulate 0.2 bar of air pressure, because usually approximately 2 N of pressure per square cm of pressure is applied to the sheet as in the case of the vacuum-forming machine.

Table 1. Criteria for the Forming Capability Index (FI)

Item	*Standard*	*Point*
Shape	Line angle of the tip is all clear	1
	Part of the line angle tip is not clear	0
Thickness	Thickness at the tip is 1–3 mm	1
	Thickness at the tip is <1, >3 mm	0
Surface texture	Without discoloration	0
	With discoloration	−1

The suitable temperature range for forming capability (STF) was evaluated with the rating scale (formability index: FI) in Table 1. The FI was defined by rating the extent to which the shape, thickness, and changes in surface texture of the indentation head reproduced in each specimen. A single operator performed the rating procedure for each category according to the definition modified from previously reported rating systems[17] as shown in Table 1. A preliminary rating test was conducted by rating five specimens at three times to validate the consistency of the rating procedure.

Time-dependent changes in temperature of the two materials during the cooling processes were measured with a digital thermometer placed inside specimens to analyze the heat-holding capability and working time of the material. Five specimens of each material were heated to the median temperature of the STF for measuring the cooling process. The working time for the forming process was determined by the time required to reach the lowest temperature from the median temperature of the STF.

To examine the optimum timing for applying negative pressure or vacuum for the forming process, time-dependent changes in the negative forming pressures of the three forming machines (Vacuum Adaptor I, T&S, Travelers Rest, SC; Vacfomat, Dreve, Una, Germany; Erkoform, Erkodent) were measured with a digital pressure meter. Measurements were repeated five times for each machine. Statistical analysis with t tests ($p < 0.05$) were performed for FI rating, STF, and the time required to reach the lower limit of the STF using Stat view (SAS Institute, Cary, NC).

Results

Figure 2 shows the results of the FI rating and STF. With the FI, the STF were determined to range

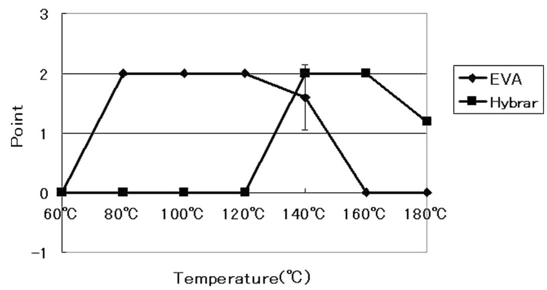

Figure 2. Forming capability (STF) over a range of temperatures. STF point 3 indicates the best in the rank.

from 80–120°C for EVA and from 140–160°C for Hybrar, where statistically higher rates were obtained ($p < 0.01$). When the sheet temperature fell below the lower limit of the STF, the reproduction of the indentation head became shallow and unclear. When the temperature was raised to higher than the upper limit of the STF, the decrease in the sheet thickness at the indentation head became larger with discoloration of the material.

Figure 3 shows the time required to reach the lower limit of the STF for each material. There was a statistically significant difference between times required to reach the lower limit of the STF between two materials (EVA: 41 seconds, Hybrar: 13 seconds) ($p < 0.05$), which indicates Hybrar has a shorter working time than EVA.

Figure 4 shows time-dependent changes in the negative pressures of three types of forming machines. The maximum negative pressure (MNP) of the three types of vacuum-forming machines was −12 cmHg for the Vacuum adaptor, −53 cmHg for Vacfomat, and −60 cmHg for Erkoform. The times required to reach the MNP were 5 seconds for the vacuum adaptor, 10 seconds for Vacfomat, and 60 seconds for Erkoform.

Discussion

Although the size and shape of specimens used in this study were different from those of actual soft oral appliances, it is still possible to speculate on the general behavior of materials with the obtained results.

The most suitable temperatures for the forming process derived from our results using FI were in the range of 80–120°C for EVA and from 140–160°C for Hybrar (Fig 2). From our results and manufacturers' specifications, over these ranges, EVA (<180°C) and Hybrar (<200°C) are not suitable for the forming process, because the oxidization process starts over 200°C and decomposition starts over 250°C in these materials.[18] These results indicate that sheet material should neither be overheated nor underheated. Although material heated over the suitable temperature range is still usable, discoloration or a change in surface texture could occur, as observed in this study. Underheating is also not recommended, since the detail of the working cast would not be reproduced.

The time required to reach the lower limit of the temperature range was 40 seconds for EVA and 15 seconds for Hybrar (Fig 3); in other words, EVA has a relatively larger heat-holding capability and longer working time. The time required to reach the MNP with three types of vacuum-forming machines ranged from 5–60 seconds. Since the working time of the sheet material is

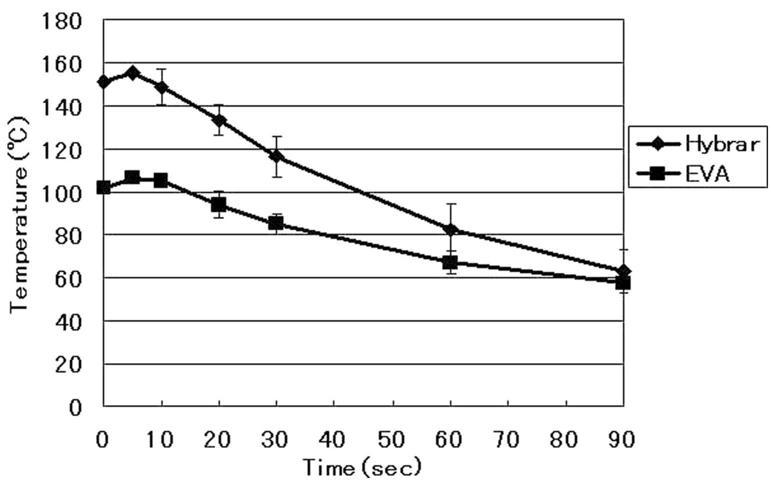

Figure 3. Working times for thermoforming as measured by the time to reach the lower STF limit. Brackets in the figure indicate one standard deviation of 10 time measurements.

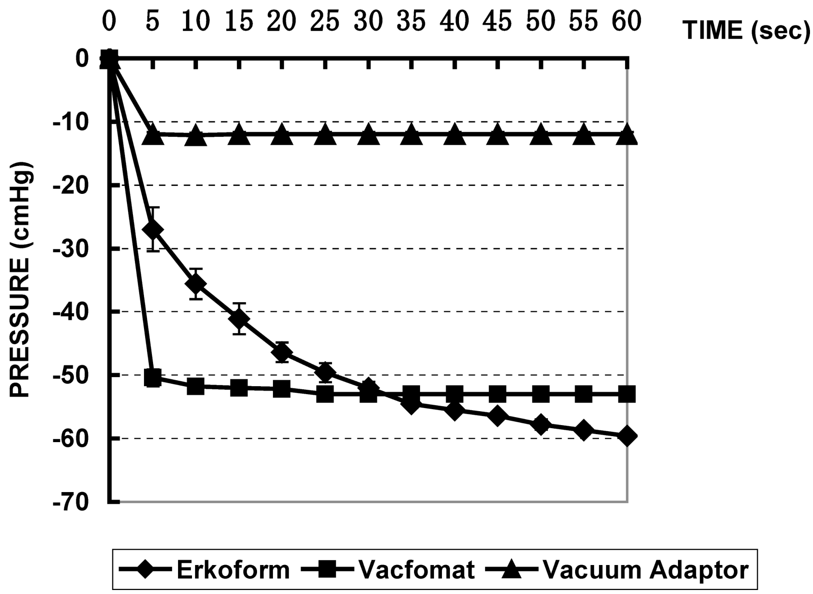

Figure 4. Time for forming machine to reach maximum negative pressure (MNP). Brackets in the figure indicate one standard deviation of 10 time measurements.

limited, due to the heat-holding capability of each material, it is desirable to use a forming machine that reaches maximum positive or negative pressure in as short a time as possible. For EVA, any of three types of machine can be used, although it is necessary to choose the type of forming machine that can reach maximum negative or positive pressure within a short working time.

Conclusions

Within the limitations of our study, we may draw the following conclusions:

1. The most suitable temperature range for the forming process was determined to be 80–120°C for EVA and 140–160°C for Hybrar, based on the evaluation of Formability Index ($p < 0.01$).
2. The working time for the vacuum forming process of EVA was longer (40 seconds) than Hybrar's (15 seconds) ($p < 0.05$).
3. It is important to choose the type of forming machine that can reach maximum negative or positive pressure according to the material working time.

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