

Influence of expiration date on the dimensional accuracy of elastomers
Influência da data de validade na estabilidade dimensional dos elastômeros
Influencia de la fecha de caducidad en la estabilidad dimensional de los elastómeros

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Abstract

Impression materials are used to make models in different dentistry fields, with emphasis on oral rehabilitation with fixed and removable prostheses or dentures. The aim was to compare the dimensional accuracy of impressions based on polyvinylsiloxane (Express) and polyether (Impregum Soft) elastomers performed 2 years after their expiration date to impressions that did not exceed this period. Impressions were performed over matrix with metal tray; they were removed after polymerization and divided into 4 groups (n=5). Dimensional accuracy was evaluated through optical microscopy on the 20- μ m line at 25-mm length (ISO 4823 standard). Dimensional accuracy values (%) were subjected to two-way ANOVA (material \times expiration date) and Tukey's test ($\alpha=0.05$). Based on the analysis of expiration date as independent factor ($p=0.017$), mean dimensional accuracy values recorded for elastomer impression 2 years after expiration date (99.89%) were statistically lower than values recorded for the non-expired one (99.92%). Changes resulting from the use of elastomers 2 years after their expiration date do not affect the dimensional accuracy of prostheses deriving from these impressions.

Keywords: Dental impression materials; Elastomers; Date of validity of products.

Resumo

Os materiais de impressão são utilizados na confecção de modelos em diferentes áreas da odontologia, com ênfase na reabilitação oral com próteses fixas e removíveis ou dentaduras. O objetivo foi comparar a estabilidade dimensional de impressões baseadas em elastômeros de polivinilsiloxano (Express) e poliéter (Impregum Soft) realizadas 2 anos após sua data de validade com impressões que não ultrapassaram esse período. As impressões foram realizadas sobre matriz com moldeira metálica; eles foram removidos após a polimerização e divididos em 4 grupos (n = 5). A estabilidade dimensional foi avaliada por microscopia óptica na linha de 20 μ m com comprimento de 25 mm (padrão ISO 4823). Os valores de estabilidade dimensional (%) foram submetidos a ANOVA two-way (material x data de validade) e teste de Tukey ($\alpha = 0,05$). Com base na análise da data de validade como fator independente ($p =$

0,017), os valores médios de estabilidade dimensional registrados para a impressão de elastômero 2 anos após a data de expiração (99,89%) foram estatisticamente inferiores aos valores registrados para o não expirado (99,92%). As alterações decorrentes do uso dos elastômeros 2 anos após o seu vencimento não afetam a estabilidade dimensional das próteses decorrentes dessas impressões.

Palavras-chave: Materiais para moldagem odontológica; Elastômeros; Prazo de validade de produtos.

Resumen

Los materiales de impresión son utilizados para la confección de modelos en las diferentes áreas de la odontología, con énfasis en la rehabilitación oral con prótesis fijas, removibles o prótesis totales. El objetivo fue comparar la estabilidad dimensional de las impresiones utilizando elastómeros de polivinilxilosano (Express) y poliéter (Impregum Soft) realizadas 2 años después de su fecha de caducidad con impresiones que no excedan este tiempo. Las impresiones fueron realizadas sobre una matriz con cubeta metálica; fueron removidos luego de la polimerización y divididos en 4 grupos ($n = 5$). La estabilidad dimensional fue evaluada por microscopía óptica en la línea de $20 \mu\text{m}$ con longitud de 25 nm (norma ISO 4823). Los valores de la estabilidad dimensional (%) fueron sometidos a ANOVA two-way (material x fecha de caducidad) y prueba de Tukey ($\alpha = 0,05$). Con base en el análisis de fecha de caducidad como factor independiente ($p = 0,017$), los valores promedio de la estabilidad dimensional registrados para la impresión con elastómeros 2 años luego de la caducidad (99,89%) fueron estadísticamente inferiores a los valores registrados para los no caducados (99,92%). Las alteraciones resultantes del uso de elastómeros 2 años luego de su caducidad no afectan la estabilidad dimensional de las prótesis utilizadas con estas impresiones.

Palabras clave: Materiales de impresión dental; Elastómeros; Fecha de caducidad de productos.

1. Introduction

Impression materials are used to make models in different dentistry fields, with emphasis on oral rehabilitation with fixed and removable prostheses or dentures (Kim et al., 2001; Carlo et al., 2010); these materials must be capable of copying dental morphology and soft tissues in order to make satisfactory prostheses (Perakis, Belser & Magne, 2004). The first high-accuracy impression materials were used in the 1950s; they comprised elastomeric

printing materials consisting of rubber materials that, besides not requiring the use of special equipment, enabled easy handling and demanded lesser working hours (Guiraldo et al., 2018). Nowadays, elastomeric molding materials such as polysulfide, polydimethylsiloxane, polyvinylsiloxane and polyether, which have different chemical reactions and specific setting features, are available in the market (Vitti, Correr-Sobrinho & Sinhoreti, 2011).

Polyether has good tear resistance and enables excellent reproduction of details (Donovan & Chee, 2017). Polyether is composed of low molecular weight polyether, silica (filler) and plasticizer (Anusavice, 2003). During manipulation, 1,2-epoxy-ethane and tetrahydrofuran copolymer react to α , β -unsaturated acids, such as crotonic acid, in order to produce the final polymer and aromatic sulfonate through cationic polymerization (Guler et al., 2013). Polyvinylsiloxane results from the polymerization reaction of vinyl terminals of divinylpolysiloxanes using polymethylhydroxysiloxane as cross reaction agent in the presence of platinum catalyst (Islamova et al., 2016). It presents high elasticity, dimensional stability, lesser contraction, accurate and detailed reproduction; besides, it is non-toxic and non-irritating (Gonçalves et al., 2011). In addition to copying the intended anatomical region, these materials must be capable of remaining dimensionally stable (Guiraldo et al., 2012). Thus, the aim of the current study was to compare the dimensional accuracy of impressions based on polyvinylsiloxane and polyether elastomers performed 2 years after their expiration date to that of impressions based on materials that did not exceed this period.

2. Materials and Methods

Materials

Elastomeric dental materials used in the current study comprised polyvinylsiloxane (Express; 3M Deutschland GmbH, Seefeld, Germany) and polyether (Impregum Soft; 3M Deutschland GmbH) within the expiration date or 2 years after it.

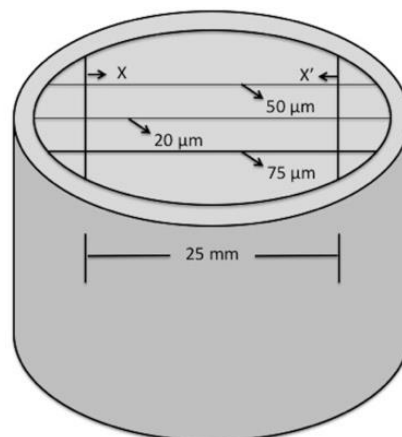
Methods

Elastomers were handled in compliance with all manufacturer's instructions (environment with controlled temperature – $23^{\circ}\text{C} \pm 2^{\circ}\text{C}$ and relative humidity – $50\% \pm 10\%$); impressions were prepared over matrix comprising 20-, 50-, and 75- μm lines, and performed under pressure with perforated metal tray - in compliance with ISO 4823 (ISO 4823, 2000) -

using polyvinylsiloxane and polyether expired for 2 years or within the expiration date. After elastomer polymerization, impressions were removed from the metal matrix and divided into four groups (n = 5) based on different elastomers and on expiration date (group polyvinylsiloxane within the expiration date, group polyvinylsiloxane expired for 2 years, group polyether within the expiration date, group polyether expired for 2 years).

Dimensional accuracy (DA) of impressions was analyzed in optical microscope (Scanning Tunneling Microscope, Olympus Optical Co Ltd, Japan), at 0.5 μm accuracy. It was calculated by subtracting the distance between lines X and X' over the 20- μm line on the matrix (DM), from the distance between lines, on the impression material (DI), which was divided by DM and multiplied by 100, as shown in the following equation: $DA = [(DI - DM)/DM] \times 100$, which is in compliance with ISO 4823 (ISO 4823, 2000), as shown in Figure 1. Then, 100% was added to equation results (Guiraldo et al., 2015).

Figure 1: Schematic representation of matrix in accordance with ISO 4823.



Source: Authors.

Statistical analysis

Quantitative statistical analysis was performed in the Minitab 16 software (Minitab, State College, PA, USA). Dimensional accuracy values (%) were subjected to Kolmogorov-Smirnov test, which was followed by two-way ANOVA (material \times expiration date) and Tukey's test ($\alpha=0.05$).

3. Resultados

Mean dimensional accuracy (%) values recorded for different groups are shown in Table 1. There was not statistically significant difference in mean dimensional accuracy values between material and expiration-date combinations ($p=0.555$). The mean dimensional accuracy values were: 99.91% to group polyvinylsiloxane within the expiration date, 99.88% to group polyvinylsiloxane expired for 2 years, 99.92% to group polyether within the expiration date and 99.90% to group polyether expired for 2 years.

Table 1. Dimensional accuracy measured according to ISO 4823 in material and expiration-date combinations.

Elastomer	Dimensional Accuracy (%)	
	Within expiration date	2 years after expiration
Polyvinylsiloxane	99.91 (0.02)	99.88 (0.01)
Polyether	99.92 (0.03)	99.90 (0.01)

There was not statistically significant difference in mean dimensional accuracy values between material and expiration-date combinations, based on the Tukey test, at 5% significance level. SDs are shown between parentheses. SDs: Standard deviations. Source: Authors.

Table 2 shows dimensional accuracy (%) results recorded for independent factor ‘material’. There was not statistically significant difference in mean dimensional accuracy values recorded for independent factor ‘material’ ($p=0.280$).

Table 2. Dimensional accuracy measured according to ISO 4823 for independent factor ‘material’.

Elastomer	Dimensional Accuracy (%)
Polyvinylsiloxane	99.90 (0.01)
Polyether	99.91 (0.01)

There was not statistically significant difference between mean values, based on Tukey’s test, at 5% significance level. SDs are shown between parentheses. SDs: Standard deviations. Source: Authors.

Table 3 shows dimensional accuracy (%) results recorded for independent factor 'expiration date'. Dimensional stability values were statistically lower in models generated from elastomers expired after 2 years (99.89%; $p=0.017$) than elastomers within expiration date (99.92%).

Table 3. Dimensional accuracy measured according to ISO 4823 for independent factor 'expiration date'.

Expiration Date	Dimensional Accuracy (%)
Within expiration date	99.92 (0.03) A
2 years after expiration date	99.89 (0.01) B

Mean values followed by different uppercase letters in columns statistically differed from each other in Tukey's test, at 5% significance level. SDs are shown between parentheses. SDs: Standard deviations. Sources: Authors.

4. Discussion

Dental surgeons can find dental elements presenting great loss of dental tissue during their professional practice. Thus, these professionals can recommend direct or indirect restorations based on the level of these losses (Pereira et al., 2010). One of the most important steps in indirect metallic, or non-metallic, restorations lies on producing accurate impression of the tooth to be restored, and of its adjacent tissues, in order to reproduce the correct association among all oral cavity structures (Pereira et al., 2010). In addition, other treatments, such as removable prostheses or dentures, also require reproducing oral cavity structures. Thus, the success of some dental treatment types depends on the accuracy of models generated from impressions (German, Carrick & McCabe, 2008). Different types of impression materials are available today and newer materials are also being introduced on a regular basis with the advancement of knowledge. Polyvinylsiloxane and polyether are the materials presenting the longest dimensional accuracy times after polymerization reaction; however, the literature lacks studies conducted with products used after their expiration date. Thus, the current study has evaluated the post-polymerization dimensional accuracy of polyvinylsiloxane (Express) and polyether (Impregum Soft) used 2 years after their expiration date.

Elastomers are formed by polymer molecules that get together due to cross-links

during the setting reaction and form a three-dimensional network through polymerization process. Unlike rigid molding materials, these materials present elastic behavior after the polymerization reaction. Elastomers are a viscous liquid before polymerization; however, they are featured as viscoelastic solid material after polymerization (Anusavice, 2003). The setting reaction (polymerization) could be affected by the elastomers' expiration date. However, the current study did not find significant difference in dimensional accuracy of elastomers based on analyses applied to material and expiration-date combinations (Table 1) and to independent factor 'material' (Table 2). Clearly, dimensional accuracy is a prerequisite for success¹⁵. The present study has only found statistically significant difference in the analysis applied to independent factor 'expiration date' (Table 3). However, the difference in dimensional accuracy between elastomers within the expiration date (99.92%) and the ones expired after 2 years (99.89%) do not clinically affect the final result of prostheses deriving from these impressions.

According to SESA Resolution n. 496/2005, which regulates the technical standard that establishes conditions for the installation and operation of dental care establishments and provides related measures in Brazil (Chapter XV), dental surgeons are responsible for controlling the expiration date and compliance of dental materials used in procedures carried out by them in order to avoid infractions that result in fines. However, the aim of the present study was not to validate expired products. In addition, the reason for not using expired products goes beyond the fines. Manufacturers carry out tests to assess products' effectiveness and chemical behavior over time in order to determine their shelf life. Then, expired product using may not get to the expected result or harm prostheses made with them. In addition, the present study has only evaluated one property of these materials; thus, it is necessary conducting future studies evaluating other properties before suggesting that manufacturers should extend their products' shelf life.

4. Conclusion

Based on results in the current study, it was possible concluding that changes resulting from the use of elastomers 2 years after their expiration date do not affect the dimensional accuracy of prostheses deriving from these impressions.

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