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ЕЖЕМЕСЯЧНЫЙ НАУЧНЫЙ ЖУРНАЛ

Медицинские новости Грузии
საქართველოს სამედიცინო სიახლენი

GEORGIAN MEDICAL NEWS
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GMN: Georgian Medical News is peer-reviewed, published monthly journal committed to promoting the science and art of medicine and the betterment of public health, published by the GMN Editorial Board since 1994. GMN carries original scientific articles on medicine, biology and pharmacy, which are of experimental, theoretical and practical character; publishes original research, reviews, commentaries, editorials, essays, medical news, and correspondence in English and Russian.
GMN is indexed in MEDLINE, SCOPUS, PubMed and VINITI Russian Academy of Sciences. The full text content is available through EBSCO databases.

GMN: Медицинские новости Грузии - ежемесячный рецензируемый научный журнал, издаётся Редакционной коллегией с 1994 года на русском и английском языках в целях поддержки медицинской науки и улучшения здравоохранения. В журнале публикуются оригинальные научные статьи в области медицины, биологии и фармации, статьи обзорного характера, научные сообщения, новости медицины и здравоохранения. Журнал индексируется в MEDLINE, отражён в базе данных SCOPUS, PubMed и ВИНИТИ РАН. Полнотекстовые статьи журнала доступны через БД EBSCO.

GMN: Georgian Medical News – საქართველოს სამედიცინო სიახლენი – არის ყოველთვიური სამეცნიერო სამედიცინო რეცენზირებადი ჟურნალი, გამოიცემა 1994 წლიდან, წარმოადგენს სარედაქციო კოლეგიისა და აშშ-ის მეცნიერების, განათლების, ინდუსტრიის, ხელოვნებისა და ბუნებისმეტყველების საერთაშორისო აკადემიის ერთობლივ გამოცემას. GMN-ში რუსულ და ინგლისურ ენებზე ქვეყნდება ექსპერიმენტული, თეორიული და პრაქტიკული ხასიათის ორიგინალური სამეცნიერო სტატიები მედიცინის, ბიოლოგიისა და ფარმაციის სფეროში, მიმოხილვითი ხასიათის სტატიები.
ჟურნალი ინდექსირებულია MEDLINE-ის საერთაშორისო სისტემაში, ასახულია SCOPUS-ის, PubMed-ის და ВИНИТИ РАН-ის მონაცემთა ბაზებში. სტატიების სრული ტექსტი ხელმისაწვდომია EBSCO-ს მონაცემთა ბაზებიდან.

WEBSITE
www.geomednews.com

К СВЕДЕНИЮ АВТОРОВ!

При направлении статьи в редакцию необходимо соблюдать следующие правила:

1. Статья должна быть представлена в двух экземплярах, на русском или английском языках, напечатанная через **полтора интервала на одной стороне стандартного листа с шириной левого поля в три сантиметра**. Используемый компьютерный шрифт для текста на русском и английском языках - **Times New Roman** (**Кириллица**), для текста на грузинском языке следует использовать **AcadNusx.** Размер шрифта - **12**. К рукописи, напечатанной на компьютере, должен быть приложен CD со статьей.

2. Размер статьи должен быть не менее десяти и не более двадцати страниц машинописи, включая указатель литературы и резюме на английском, русском и грузинском языках.

3. В статье должны быть освещены актуальность данного материала, методы и результаты исследования и их обсуждение.

При представлении в печать научных экспериментальных работ авторы должны указывать вид и количество экспериментальных животных, применявшиеся методы обезболивания и усыпления (в ходе острых опытов).

4. К статье должны быть приложены краткое (на полстраницы) резюме на английском, русском и грузинском языках (включающее следующие разделы: цель исследования, материал и методы, результаты и заключение) и список ключевых слов (key words).

5. Таблицы необходимо представлять в печатной форме. Фотокопии не принимаются. **Все цифровые, итоговые и процентные данные в таблицах должны соответствовать таковым в тексте статьи**. Таблицы и графики должны быть озаглавлены.

6. Фотографии должны быть контрастными, фотокопии с рентгенограмм - в позитивном изображении. Рисунки, чертежи и диаграммы следует озаглавить, пронумеровать и вставить в соответствующее место текста **в tiff формате**.

В подписях к микрофотографиям следует указывать степень увеличения через окуляр или объектив и метод окраски или импрегнации срезов.

7. Фамилии отечественных авторов приводятся в оригинальной транскрипции.

8. При оформлении и направлении статей в журнал МНГ просим авторов соблюдать правила, изложенные в «Единых требованиях к рукописям, представляемым в биомедицинские журналы», принятых Международным комитетом редакторов медицинских журналов - http://www.spinesurgery.ru/files/publish.pdf и http://www.nlm.nih.gov/bsd/uniform_requirements.html
В конце каждой оригинальной статьи приводится библиографический список. В список литературы включаются все материалы, на которые имеются ссылки в тексте. Список составляется в алфавитном порядке и нумеруется. Литературный источник приводится на языке оригинала. В списке литературы сначала приводятся работы, написанные знаками грузинского алфавита, затем кириллицей и латиницей. Ссылки на цитируемые работы в тексте статьи даются в квадратных скобках в виде номера, соответствующего номеру данной работы в списке литературы. Большинство цитированных источников должны быть за последние 5-7 лет.

9. Для получения права на публикацию статья должна иметь от руководителя работы или учреждения визу и сопроводительное отношение, написанные или напечатанные на бланке и заверенные подписью и печатью.

10. В конце статьи должны быть подписи всех авторов, полностью приведены их фамилии, имена и отчества, указаны служебный и домашний номера телефонов и адреса или иные координаты. Количество авторов (соавторов) не должно превышать пяти человек.

11. Редакция оставляет за собой право сокращать и исправлять статьи. Корректура авторам не высылается, вся работа и сверка проводится по авторскому оригиналу.

12. Недопустимо направление в редакцию работ, представленных к печати в иных издательствах или опубликованных в других изданиях.

При нарушении указанных правил статьи не рассматриваются.

REQUIREMENTS

Please note, materials submitted to the Editorial Office Staff are supposed to meet the following requirements:

1. Articles must be provided with a double copy, in English or Russian languages and typed or compu-ter-printed on a single side of standard typing paper, with the left margin of **3** centimeters width, and **1.5** spacing between the lines, typeface - **Times New Roman** (**Cyrillic**), print size - **12** (referring to Georgian and Russian materials). With computer-printed texts please enclose a CD carrying the same file titled with Latin symbols.

2. Size of the article, including index and resume in English, Russian and Georgian languages must be at least 10 pages and not exceed the limit of 20 pages of typed or computer-printed text.

3. Submitted material must include a coverage of a topical subject, research methods, results, and review.

Authors of the scientific-research works must indicate the number of experimental biological species drawn in, list the employed methods of anesthetization and soporific means used during acute tests.

4. Articles must have a short (half page) abstract in English, Russian and Georgian (including the following sections: aim of study, material and methods, results and conclusions) and a list of key words.

5. Tables must be presented in an original typed or computer-printed form, instead of a photocopied version. **Numbers, totals, percentile data on the tables must coincide with those in the texts of the articles.** Tables and graphs must be headed.

6. Photographs are required to be contrasted and must be submitted with doubles. Please number each photograph with a pencil on its back, indicate author's name, title of the article (short version), and mark out its top and bottom parts. Drawings must be accurate, drafts and diagrams drawn in Indian ink (or black ink). Photocopies of the X-ray photographs must be presented in a positive image in **tiff format**.

Accurately numbered subtitles for each illustration must be listed on a separate sheet of paper. In the subtitles for the microphotographs please indicate the ocular and objective lens magnification power, method of coloring or impregnation of the microscopic sections (preparations).

7. Please indicate last names, first and middle initials of the native authors, present names and initials of the foreign authors in the transcription of the original language, enclose in parenthesis corresponding number under which the author is listed in the reference materials.

8. Please follow guidance offered to authors by The International Committee of Medical Journal Editors guidance in its Uniform Requirements for Manuscripts Submitted to Biomedical Journals publication available online at: http://www.nlm.nih.gov/bsd/uniform_requirements.html
http://www.icmje.org/urm_full.pdf
In GMN style for each work cited in the text, a bibliographic reference is given, and this is located at the end of the article under the title "References". All references cited in the text must be listed. The list of references should be arranged alphabetically and then numbered. References are numbered in the text [numbers in square brackets] and in the reference list and numbers are repeated throughout the text as needed. The bibliographic description is given in the language of publication (citations in Georgian script are followed by Cyrillic and Latin).

9. To obtain the rights of publication articles must be accompanied by a visa from the project instructor or the establishment, where the work has been performed, and a reference letter, both written or typed on a special signed form, certified by a stamp or a seal.

10. Articles must be signed by all of the authors at the end, and they must be provided with a list of full names, office and home phone numbers and addresses or other non-office locations where the authors could be reached. The number of the authors (co-authors) must not exceed the limit of 5 people.

11. Editorial Staff reserves the rights to cut down in size and correct the articles. Proof-sheets are not sent out to the authors. The entire editorial and collation work is performed according to the author's original text.

12. Sending in the works that have already been assigned to the press by other Editorial Staffs or have been printed by other publishers is not permissible.

Articles that Fail to Meet the Aforementioned Requirements are not Assigned to be Reviewed.

ავტორთა საყურადღებოდ!

რედაქციაში სტატიის წარმოდგენისას საჭიროა დავიცვათ შემდეგი წესები:

1. სტატია უნდა წარმოადგინოთ 2 ცალად, რუსულ ან ინგლისურ ენებზე,დაბეჭდილი სტანდარტული ფურცლის 1 გვერდზე, 3 სმ სიგანის მარცხენა ველისა და სტრიქონებს შორის 1,5 ინტერვალის დაცვით. გამოყენებული კომპიუტერული შრიფტი რუსულ და ინგლისურენოვან ტექსტებში - **Times New Roman (Кириллица)**, ხოლო ქართულენოვან ტექსტში საჭიროა გამოვიყენოთ **AcadNusx.** შრიფტის ზომა – 12. სტატიას თან უნდა ახლდეს CD სტატიით.

2. სტატიის მოცულობა არ უნდა შეადგენდეს 10 გვერდზე ნაკლებს და 20 გვერდზე მეტს ლიტერატურის სიის და რეზიუმეების (ინგლისურ, რუსულ და ქართულ ენებზე) ჩათვლით.

3. სტატიაში საჭიროა გაშუქდეს: საკითხის აქტუალობა; კვლევის მიზანი; საკვლევი მასალა და გამოყენებული მეთოდები; მიღებული შედეგები და მათი განსჯა. ექსპერიმენტული ხასიათის სტატიების წარმოდგენისას ავტორებმა უნდა მიუთითონ საექსპერიმენტო ცხოველების სახეობა და რაოდენობა; გაუტკივარებისა და დაძინების მეთოდები (მწვავე ცდების პირობებში).

4. სტატიას თან უნდა ახლდეს რეზიუმე ინგლისურ, რუსულ და ქართულ ენებზე არანაკლებ ნახევარი გვერდის მოცულობისა (სათაურის, ავტორების, დაწესებულების მითითებით და უნდა შეიცავდეს შემდეგ განყოფილებებს: მიზანი, მასალა და მეთოდები, შედეგები და დასკვნები; ტექსტუალური ნაწილი არ უნდა იყოს 15 სტრიქონზე ნაკლები) და საკვანძო სიტყვების ჩამონათვალი (key words).

5. ცხრილები საჭიროა წარმოადგინოთ ნაბეჭდი სახით. ყველა ციფრული, შემაჯამებელი და პროცენტული მონაცემები უნდა შეესაბამებოდეს ტექსტში მოყვანილს.

6. ფოტოსურათები უნდა იყოს კონტრასტული; სურათები, ნახაზები, დიაგრამები - დასათაურებული, დანომრილი და სათანადო ადგილას ჩასმული. რენტგენოგრამების ფოტოასლები წარმოადგინეთ პოზიტიური გამოსახულებით **tiff** ფორმატში. მიკროფოტოსურათების წარწერებში საჭიროა მიუთითოთ ოკულარის ან ობიექტივის საშუალებით გადიდების ხარისხი, ანათალების შეღებვის ან იმპრეგნაციის მეთოდი და აღნიშნოთ სურათის ზედა და ქვედა ნაწილები.

7. სამამულო ავტორების გვარები სტატიაში აღინიშნება ინიციალების თანდართვით, უცხოურისა – უცხოური ტრანსკრიპციით.

8. სტატიას თან უნდა ახლდეს ავტორის მიერ გამოყენებული სამამულო და უცხოური შრომების ბიბლიოგრაფიული სია (ბოლო 5-8 წლის სიღრმით). ანბანური წყობით წარმოდგენილ ბიბლიოგრაფიულ სიაში მიუთითეთ ჯერ სამამულო, შემდეგ უცხოელი ავტორები (გვარი, ინიციალები, სტატიის სათაური, ჟურნალის დასახელება, გამოცემის ადგილი, წელი, ჟურნალის №, პირველი და ბოლო გვერდები). მონოგრაფიის შემთხვევაში მიუთითეთ გამოცემის წელი, ადგილი და გვერდების საერთო რაოდენობა. ტექსტში კვადრატულ ფჩხილებში უნდა მიუთითოთ ავტორის შესაბამისი N ლიტერატურის სიის მიხედვით. მიზანშეწონილია, რომ ციტირებული წყაროების უმეტესი ნაწილი იყოს 5-6 წლის სიღრმის.

9. სტატიას თან უნდა ახლდეს: ა) დაწესებულების ან სამეცნიერო ხელმძღვანელის წარდგინება, დამოწმებული ხელმოწერითა და ბეჭდით; ბ) დარგის სპეციალისტის დამოწმებული რეცენზია, რომელშიც მითითებული იქნება საკითხის აქტუალობა, მასალის საკმაობა, მეთოდის სანდოობა, შედეგების სამეცნიერო-პრაქტიკული მნიშვნელობა.

10. სტატიის ბოლოს საჭიროა ყველა ავტორის ხელმოწერა, რომელთა რაოდენობა არ უნდა აღემატებოდეს 5-ს.

11. რედაქცია იტოვებს უფლებას შეასწოროს სტატია. ტექსტზე მუშაობა და შეჯერება ხდება საავტორო ორიგინალის მიხედვით.

12. დაუშვებელია რედაქციაში ისეთი სტატიის წარდგენა, რომელიც დასაბეჭდად წარდგენილი იყო სხვა რედაქციაში ან გამოქვეყნებული იყო სხვა გამოცემებში.

აღნიშნული წესების დარღვევის შემთხვევაში სტატიები არ განიხილება.

Содержание:

HARDNESS AND ELASTIC MODULUS ASSESSMENT FOR TWO ALIGNER MATERIALS BEFORE AND AFTER THERMOCYCLING: A COMPARATIVE STUDY

Ezzuldin Yaseen Aljumaily*, Ali R. Al-Khatib.

Department of Paedodontic, Orthodontic, and Preventive Dentistry, College of Dentistry, University of Mosul, Mosul, Iraq.

Abstract.

Background: Orthodontic clear aligners as an alternative to traditional braces have become increasingly ubiquitous in the last few years. Therefore, understanding the properties of the aligner materials can help to produce more accurate results of the treatment and provide more data for orthodontists who are currently using or intend to use this technology. This study aimed to investigate the effect of thermocycling on some mechanical properties (Hardness and Elastic Modulus) of two thermoplastic products used in the fabrication of orthodontic aligners. **Materials and methods:** Two thermoplastic products of Duran® 0.75 mm and Erkodur® 1 mm were used in this study. A specially prepared disk fabricated from risen material with dimensions of (15mm) in diameter and (6mm) in thickness which was fabricated with a 3D printer was used for hardness assessment. Twenty sheets were thermoformed over the round disk for each product. Whereas, for elastic modulus, a Dog bone specimen with dimensions 8 mm in width and 150 mm in length was made from resin by using a 3D printer. The shore D hardness test was used to measure the hardness of the two products before and after thermocycling. For elastic modulus, thermoplastic sheets that were less than 1mm in thickness were measured according to the ASTMD 882-02 and those with 1mm were measured according to the ASTMD 638-02a. The elastic modulus was measured using a tensile test by a universal testing machine before and after thermocycling. **Results:** Erkodur model® was higher than Duran® in the hardness test before and after thermocycling. But, Erkodur model® showed significant, however, Duran® showed no significant change in hardness before and after thermocycling. The elastic modulus test for the two materials showed a significant difference between Duran® and Erkodur® models. The elastic modulus of Duran® was higher than Erkodur® before and after thermocycling. **Conclusions:** The hardness of the Erkodur® product was higher than that of Duran®, whereas the elastic modulus of the Duran® product was higher than Erkodur® before and after thermocycling. On the other hand, thermocycling reduces the hardness of the Erkodur® product more than that of Duran® and did not affect the elastic modulus of each product.

Key words. Mechanical properties, aligner materials, thermocycling.

Introduction.

Dental smiles and the appearance of teeth become a fundamental part of social life. For that reason, the number of patients seeking attractive orthodontic treatment has increased. To meet this need, the manufacturers started decreasing the configuration of metal brackets and introducing tooth-coloured ceramic brackets in addition to invisible or lingual brackets [1]. Hence, the esthetic orthodontic appliances have encountered a profound and quick advancing upset. A clear aligner is one of the most fascinating appliances to the patient as it is almost invisible and removable. Therefore, it will make less harm to the teeth whether via caries, calculus, or white spots that typically go with the fixed orthodontic treatment [2]. Orthodontic force quality created by orthodontic aligners relies primarily upon the hardness and flexible modulus of thermoplastic materials, the measure of activation, material thickness, and the fabricating interaction of the actual material [3].

Hardness is a mechanical property that indicates the ability of a material surface to withstand local deformation, and it is measured by applying a certain load for a specific time using a micro-hardness tester [4]. Based on previous investigations, the hardness of polymeric material is sensitive to residual monomer content material similar to material thickness [5]. Hence, the thickness of polymeric substances performs a position in pressure delivery, and the amount of deflection can affect structural characteristics and may additionally produce force delivery changes [6]. Hardness cannot be defined specifically as it is affected by multiple factors such as proportional limit, strength, ductility, etc. However, the measurement of the resistance to indentation is taken as an indicator of hardness measurement [7]. Measuring the hardness is important as it provides information that is significant together with the structural, quality control, and failure analysis in determining the capabilities of the material being used. Measuring the hardness is useful in predicting the number of forces applied by the aligners as they are greatly correlated [8].

The elastic modulus is the maximum critical characteristic of the thermoplastic material. The elastic modulus is an indicator of material stiffness. The stiffness of the thermoplastic material is responsible for aligner retention and forces [9]. Therefore, a better elastic modulus will result in greater tooth movement and enhance the retention of the aligner which will increase the difficulty of wearing and removal of the appliance by the patient. In contrast, low elastic modulus material will make easier placement and removal of the appliance, but with not enough force to produce the desired tooth movement [9].

Thermocycling has been extensively employed in dental research as it encourages material ageing in a laboratory setting by immersing objects repeatedly in distilled water at various temperatures [10]. When exposed to heat, humidity, constant forces, and saliva in the oral environment, resin polymers are not inert and are susceptible to change [11]. Therefore, it seems to sense that any weakening of aligner materials, whether after the manufacturing process [12] or after exposure to the oral environment [13], would limit their effectiveness, which would lead to less predictable tooth movements [14].

Experts ought to get the limits and abilities of the different types of aligners while choosing cases to treat them [15]. Nevertheless, understanding the properties of the aligner materials and plans can assist with delivering more precise aftereffects of the aligners and give more information to an orthodontist who is at present utilizing or planning to utilize this innovation [2]. According to the best knowledge of the researcher, limited information is available regarding the effects of thermocycling on hardness, and elastic modulus properties of two important products used in orthodontic aligner fabrication which are Erkodur® and Duran® products. Thus, this study aimed to assess and compare the effects of thermocycling on the hardness and elastic modulus of two different thermoplastic products used in the fabrication of orthodontic aligners. The study hypothesized that there is a significant difference in hardness, and elastic modulus between the two products used in the fabrication of orthodontic aligners before and after thermocycling.

Materials and methods.

The necessary ethical clearance was obtained from the College of Dentistry, University of Mosul which approved the study's protocol (UoM.Dent/H.DM.47/22).

Study sample: A total of 40 specimens were prepared from 2 types of hard thermoplastic material [Duran® form SCHEU-DENTAL GmbH\ Germany (0.75 mm), and Erkodur® from Erkodent Erich Kopp GmbH\ Germany (1 mm)]. They were divided into 2 major groups with 10 specimens before thermocycling and another 10 after thermocycling for each type respectively. AutoCAD (Autodesk company, USA) was used to obtain the appropriate dimensions for each model and export the STL file to a 3D printer (sprintRay pro95, USA) to print the model by using hard printing resin (photec, Zhejiang-China). For hardness testing, a round disk of resin material with a dimension of (15mm) in diameter and (6mm) in thickness was fabricated (figure 1). Whereas, for elastic modulus assessment, rectangular specimens (dog bone shape) were made with dimensions 8 mm in width and 150 mm in length. Each sample for each product was thermoformed over the model by using a thermoplastic vacuum device (MINISTAR S® SCHEU-DENTAL, Germany). After thermoforming procedures, the thermocycling process was conducted, and 200 cycles were chosen to cover the 2 weeks to maximize the simulation with oral conditions. Before thermocycling, each sample was immersed in 37°C distilled water for 24 h, and then, thermal cycles that included 5°C for the 20s, and 55°C for the 20s, with a transfer time of 12s were exerted in distilled water via a thermocycling machine was conducted.

Figure 1. Hardness testing model (0.05).

Hardness test: Shore D hardness test was used to measure the hardness of two products of hard thermoplastic materials (ISO7619-1:2010). According to the American Society for Testing Materials (ASTM D 2240-05), the minimum thickness allowed for a test specimen was 6 mm and in order to reach the required thickness, each material was thermoformed over a round disk of resin material with a diameter of 15mm [7,10,16] as follows:

1. Duran® samples: 20 sheets thermoformed (10 sheets before thermocycling and 10 sheets after thermocycling),
2. Erkodur-al® samples: 20 sheets thermoformed (10 sheets before thermocycling 10 sheets after thermocycling).

The process involved applying pressure to the material with an indenter on a flat surface and then recording the results after 15 seconds (ASTM D 2240-05). Ten samples of each of the two materials were examined. The flexible indentation depth of the spring-loaded indenter used in the Shore hardness apparatus (HT- 5610 D), which measures hardness on a scale from 0 to 100, is a measure of the material's Shore hardness. A reading of 0 Shore describes the maximum possible indentation of the rod into the specimen, and 100 Shore indicates almost no indentation at all or a very high resistance to indentation. Using a needle with a 30°-point angle and a 0.8mm diameter tip, Shore D is indicated for measurements on hard elastomer (figure 2). The process involved applying pressure to the material with an indenter on a flat surface and then recording the results after 15 seconds (ASTM D 2240-05). This procedure was conducted for each sample before and after thermocycling.

Elastic modulus test: The tensile test was used to determine the elastic modulus of thermoplastic materials. The American Society for Testing Materials (ASTM) states that thermoplastic sheets with a thickness of less than 4 mm should be measured in accordance with ASTM D 638-02a. Moulds for the tensile test specimens were created from rectangular resin specimens that were 150 mm in length and 8 mm in width (Figure 3A). According to the manufacturer's instructions, these thermoplastic sheets were thermoformed over the resin models, and after that, the samples were cut with scissors from the model.

A universal testing machine was used at a rate of 50mm/minute, and with an initial grasp separation of 100mm, (Figure 3B). Ten samples were taken from each product, and each sample was stretched along its axis until it raptured. Both before and after thermocycling, this operation was carried out. The statistical analyses included descriptive statistics and two means comparisons with a significant level ($p > 0.05$).

Results.

The means and standard deviation (SD) of the hardness tests of samples from the two study groups are listed in table 1. The highest mean value regarding hardness is 75.91 (5.69±) in Erkodur® groups before thermocycling, whereas the lowest mean value is 65.16 (6.77±) in Duran® groups after thermocycling. The means and standard deviation (SD) of the elastic modulus tests of samples from two study groups was listed in table 1. The highest mean value regarding E modulus is 2096.33(207.27±) in Duran® groups before thermocycling, whereas the lowest mean

Figure 2. *Hardness measurement by using shore D hardness (Shore D hardness tester \ India MART-INDIA 2022).*

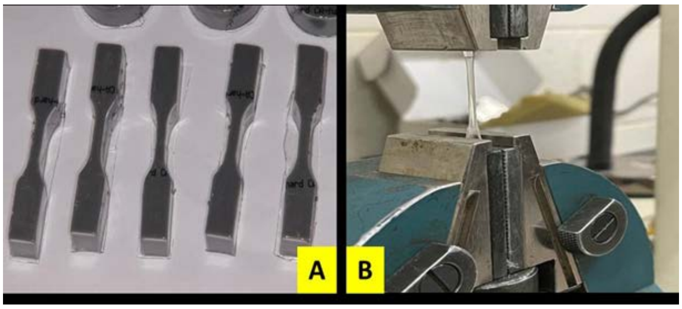

Figure 3. *Prepared mode (A) Elastic modulus model (B) Elastic modulus measurement.*

Table 1. *Descriptive statistics of the hardness and elastic modulus tests of different aligners.*

Variable	Mean	SD	Maximum	Minimum
Hardness for Duran® before thermocycling	65.48	±5.82	74.00	56.30
Hardness for Duran® after thermocycling	65.16	±6.77	76.20	55.60
Hardness for Erkodur® before thermocycling	75.91	±5.69	89.20	70.00
Hardness for Erkodur® after theromcycling	71.15	±2.69	77.00	68.20
The elastic modulus for Duran® before thermocycling	2096.33	±207.27	1815.00	2502.00
The elastic modulus for Duran® after theromcycling	1961.85	±54.27	1886.50	2073.00
The elastic modulus for Erkodur® before thermocycling	1388.09	±82.04	1202.20	1480.00
The elastic modulus for Erkodur® after theromcycling	1238.52	±230.92	861.40	1437.00

Table 2. *Comparison of Hardness before thermocycling and after thermocycling of two study groups.*

	t value	p value	Mean difference
Duran® group	0.114	0.911	0.32
Erkodur® group	2.388	0.033*	4.75
Significant at p<0.05* Measurements are in Newton.			

Table 3. *Comparisons of the hardness test between Duran® versus Erkodur®.*

	t- value	p-value	Mean difference
Before theromcycling	4.047	0.001*	10.42
After thermocycling	2.599	0.003*	5.99
*Significant at p<0.05			

Table 4. *Comparison of elastic modulus in Duran® groups before and after thermocycling.*

	t- value	*p*-value	Mean difference
Duran® groups	1.985	0.063	134.47
Erkodent® groups	1.930	0.070	149.57
*Significant at p<0.05 Measurements are in: MPa			

Table 5. *Comparison of elastic modulus between Duran® versus Erkodur® groups before and after thermocycling.*

	t- value	*p*-value	Mean difference
Before theromcycling	10.047	0.001*	708.24
After thermocycling	9.643	0.001*	723.33
*Significant at p<0.05 Measurements are in MPa			

value is 1238.52 (230.92±) in Erkodur® after thermocycling.

Comparison of Hardness before thermocycling and after thermocycling of two study groups was shown in table 2. No significant difference in hardness before and after thermocycling in the Duran® groups. Also, there was a significant difference in Erkodur® groups before and after thermocycling.

Comparison of hardness between Duran® versus Erkodur® groups before and after thermocycling were shown in table 3. There is a statistically significant difference between the two groups before thermocycling, also there was a statistically significant difference between the two groups after thermocycling (Duran® versus Erkodur®).

Comparison of Elastic modulus before thermocycling and after thermocycling of two study groups was shown in table 4. No significant difference in Elastic modulus in Duran® groups before and after thermocycling, also No significant difference in Elastic modulus in Erkodur® groups before and after thermocycling. The comparison between Duran® and Erkodur® groups regarding elastic modulus was conducted before and after thermocycling was shown in table 5. There is a statistically significant difference between them.

Discussion.

To produce accurate and predictable tooth movement, practitioners should know the limitations of aligner materials such as a change in hardness and modulus of elasticity. Research on the aligner materials' properties will provide the necessary information that can address problems and limitations that accompanied the aligner orthodontic treatment. For this reason, the current research tried to assess and compare the mechanical properties of aligner materials from two different products to find the suitable properties for the best aligner action.

Kohda et al. [17], indicated that there is a strong relationship between the hardness of different aligners and the amount of applied force by them. Thus, changes in hardness can correctly indicate changes in applied force and consequently the effectiveness of aligner therapy. Regarding our work and in contrast to Erkodur®, no significant difference in hardness value was recorded before and after thermocycling in Duran® groups. This is in agreement with Al Noor & Al-Joubori [7], however, the previously mentioned study used 1mm Duran® sheet in hardness test without thermocycling procedures. The expected effect of thermocycling is that it could make a change in the crystalline structure of the Erkodur® sheet. Iijima et al. [18], claimed that the hardness of aligners, such as Duran®, does not change significantly after 500 thermal cycles. Since every aligner is frequently used for about 2 weeks, the researchers in the current work exerted 200 thermal cycles, and similar to the mentioned study, it did not lead to changes in the hardness of Duran®.

It is important to mention that, Schuster et al. [11], showed an increase in the hardness of Duran® aligners after 14 days of intraoral ageing, however, they used a product of Duran® with 1 mm in thickness which has one layer of hard polyethylenterephthalat- glycol copolyester (PETG) but we used the new three-layer film generation of Duran® sheet that consists of 0.25 of copolyester (hard), followed by 0.25 of thermoplastic elastomer (soft) then, 0.25 of copolyester (hard). Another study by Bradley et al. [11] showed a decrease in the hardness of Invisalign® after use by patients for 44±15 days. However, it is difficult to compare the results as the previously mentioned were in-vitro studies.

The result of our study showed that the hardness was higher in Erkodur® than Duran® before thermocycling, also there was a significant difference between Duran® and Erkodur® after thermocycling (decrease in hardness of Erkodur). The previously mentioned events are in agreement with Nguyena [19], who mentions that Duran® has higher mechanical and thermal properties than Erkodur®. However, they used PRT-G 0.75 mm of Clear.

Aligner® (Scheu-Dental), ACE and A+ (Dentsply), and Invisalign® (Align Technology) in hardness comparison under the effect of stimulated intra- oral conditions. The results are difficult to compare with the available studies due to the difference in methodological aspects. However, it is worth mentioning that disagreement is recorded with Dalaie et al. [14], who indicated that the hardness of Duran® (1mm), and Erkodur® (0.8mm) did not differ significantly after thermoforming and ageing. Also, our findings are consistent with Al-Noor [7] who found that the hardness of three aligner types (Leone® 0.8mm, Duran® 1mm and Clear aligner® 0.5mm) had no significant differences in hardness comparison. Moreover, our results disagree with Alhendi et al. [6], who exposed different aligner sheets (Eon®, Clarity®, SureSmile®, Invisalign®) into artificial saliva for 2 weeks in 37c and found no significant differences among the systems in regard to hardness.

In the present study, the elastic modulus of Duran® and Erkodur® groups changed after thermocycling with a significant decrease in Erkodur® groups. This is in agreement with Ihssen et al. [20], yet Ihssen used 0.5mm thickness of Duran® and assessed the effect of immersion in distal water for 41h and 40 minutes, thermocycling with 1000 thermal cycles. However, they observed a significant decrease in elastic modulus after immersion and thermocycling. This can be explained by the Duran® group was minimal affect by thermocycling could be due to the number of cycles not being enough to make a change in the properties.

An agreement with our results could be recorded with Ryu et al. [12], who observed attenuation of the elastic modulus of Invisalign® after thermoforming. However, a direct comparison cannot be conducted due to methodological variations. Also, in agreement with Ryokawa et al. [21], who used 1mm of Duran® and observed no change in the elastic modulus of Duran® after thermoforming and after immersion in 37°C distilled water. Moreover, our results are in agreement with Tamburino et al. [22], who showed an increase in elastic modulus of the aligner materials of Duran® and Zendura® while Biolon® material decreased after thermoforming.

The current study disagrees with Hallmann and Gerngro [23] who found that elastic modulus and mechanical properties of Duran® 1mm were decreased after oral use. Moreover, in the present study, the elastic modulus of the Duran® group was higher than Erkodur® before and after thermocycling. This is in disagreement with Hallmann and Gerngro [23] who used a 1 mm sheet of Duran® after being stimulated of intra- oral conditions.

A study by Dalaie et al. [14] compared Duran® 1mm and Erkodent® 0.8 mm and observed in both materials that elastic modulus significantly decreased after both thermoforming and thermocycling. This difference in elastic modules could be explained by the properties of Duran® which may be higher than Erkodur® which showed a loss of thermo mechanical properties after thermocycling. This analysis showed that elastic modulus decreases significantly by increasing temperature and the intensity of this decrement is greater at higher temperatures, which emphasizes diminished mechanical properties at higher temperatures [22], with decreased for different properties with the gradual temperature variation [5,14,18].

The result of the current research could be explained by the difference in thickness between 0.75mm of Duran® and 1mm of Erkodur® or may be that the Duran® group showed minimal effect by hardness due to the compositions of material layers (three layers A: copolyesterhard, B: thermoplastic elastomer soft, C: copolyesterhard). Another explanation that is materials such as Hardcast® (polypropylene) crystalline or semi-crystalline plastic) are significantly decreased in mechanical properties after 2,500 thermal cycles. On the other hand, Duran® showed stable mechanical properties [18]. PETG should only be affected by temperature-induced crystallization to a very small extent, i.e., it is less likely to undergo annealing Nonetheless, it is likely that during immersion and thermocycling annealing takes place [24].

Aligner materials are resin polymers that change in a hot environment [25]. PET-G is classified to be amorphous or crystalline, the mechanical properties vary rapidly with temperature application over time. Change in the mechanical properties differs between amorphous and crystalline plastic as crystalline remains intact after thermoforming [26]. In addition, the polymer material may have molecular orientation depending on the processing method and conditioning used[26]. Thus, the hardness may change with the transformation of the amorphous into crystalline. Changes in the crystalline and amorphous structures or the release of plasticizers (plasticizer is a substance that is added to a material to make it softer and more flexible, to increase its plasticity, to decrease its viscosity, and/or to decrease friction during its handling in manufacture [27] probably are linked to changing in the hardness after exerting thermal cycling [14,28].

The elastic modulus is directly proportional to the force of the thermoplastic materials and inversely proportional to their thickness. Thus, the Elastic modulus was higher for thinner materials and lower for thicker materials [12]. If the thermoplastic materials were subjected to a temperature higher than the glass transition temperature, they can easily deform and decrease in thickness. Moreover, they change from the amorphous to the crystalline form with an increase in temperature, with the crystalline phase affecting the mechanical properties [28].

The limitation of this study is that intraoral ageing was only simulated by thermal cycling and fatigue that may be caused by occlusal force loading in addition to the other effects such as drink consumption or oral hygiene effects of the oral environment cannot be assessed.

Conclusion.

The hardness of the Erkodur® product was higher than that of Duran® before and after thermocycling which reduced the hardness of the Erkodur® product more than that of Duran®. The elastic modulus of the Duran® product was higher than Erkodur® before and after thermocycling that did not affect the elastic modulus of the two products.

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