



Ružica Bandić^{1*}, Katarina Vodanović^{1*}, Ivna Vuković Kekez¹, Ivana Medvedec Mikić^{2,3}, Ivan Galic^{3,4}, Danijela Kalibović Govorko^{1,4}

Thickness Variations of Thermoformed and 3D-Printed Clear Aligners

Varijacije u debljini termoformiranih i 3D-printanih prozirnih ortodontskih udlaga

- ¹ Department of Orthodontics, University of Split School of Medicine
Katedra za ortodonciju Medicinskog fakulteta Sveučilišta u Splitu
 - ² Department of Endodontics and Restorative Dental Medicine, University of Split School of Medicine
Katedra za endodonciju i restaurativnu dentalnu medicinu Medicinskog fakulteta Sveučilišta u Splitu
 - ³ Department of Oral Surgery, University of Split School of Medicine
Katedra za oralnu kirurgiju Medicinskog fakulteta Sveučilišta u Splitu
 - ⁴ Department of Maxillofacial Surgery, University Hospital of Split
Zavod za maksilofacialnu kirurgiju KBC-a Split
- * Authors contributed equally to this work • Autori su jednako pridonijeli ovom radu

Abstract

Objective: To assess thickness variations of thermoformed and 3D-printed clear aligners. **Materials and Methods:** Six different thermoplastic materials with different initial thicknesses were used for aligner thermoforming using Biostar® device (Biostar®, SCHEU-DENTAL GmbH, Iserlohn, Germany). Also, two different dental resins were used to create the printed aligners in three digitally designed thicknesses using IZZI Direct printer (3Dtech, Zagreb, Croatia). The aligners were measured using an electronic micrometer (ELECTRONIC UNIVERSAL MICROMETER, Schut Geometrical Metrology, Groningen, The Netherlands, accuracy: 0.001 mm) on a total of 20 points per aligner. Statistical analysis was performed using the JASP program (JASP, University of Amsterdam, Amsterdam, The Netherlands). **Results:** The difference between the thermoformed and printed groups was statistically significant. Significant differences between different thermoformed materials and between 3D-printed materials were found. The thickness of thermoformed aligners deviated more in the upper jaw, whereas the thickness of printed aligners deviated more in the lower jaw. Both differences were statistically significant. The greatest average deviation from the initial thickness was found in Duran 0.75; Erkodur 0.6; Erkocol-Pro 1.0; IZZI 0.5; NextDent 0.6 and NextDent A 0.6. NextDent group had the lowest deviations for all teeth of both jaws, except for upper and lower first molar where NextDent A group was more accurate. **Conclusions:** Thermoformed aligners showed decreased values, while printed ones showed mostly increased values compared to the original material thickness. The highest mean deviation belonged to IZZI group, and the NextDent group had the lowest mean deviation. The thickness of both aligners was lower at the edges compared to the thickness at cusps and fissures.

Ružica Bandić: ORCID 0000-0003-0811-6983;
Katarina Vodanović: ORCID 0000-0001-6985-584
Ivana Vuković Kekez: ORCID 0000-0001-9616-420X

Ivana Medvedec Mikić, ORCID 0000-0003-0202-3399
Ivan Galic: ORCID 0000-0003-0387-9535
Danijela Kalibović Govorko: ORCID 0000-0002-2598-9009

Received: January 5, 2024

Accepted: April 30, 2024

Address for correspondence

Danijela Kalibović Govorko
University of Split School of Medicine
Department of Orthodontics
danijela.kalibovic.govorko@mefst.hr

MeSH Terms: Orthodontic Appliances
Removable; Three-Dimensional
Printing; Synthetic Resins

Author Keywords: Orthodontics;
Printing; Three-dimensional;
Orthodontic Appliances; Removable

Introduction

Clear aligners are transparent, removable orthodontic appliances that represent an alternative to conventional orthodontic treatment (1). Their advantages over fixed orthodontic appliances are as follows: improved aesthetics and comfort, reduced in-chair time and emergency visits, less pain and better quality of life for the patients (2-5). However, clear aligners still have several limitations, such as the inability to treat certain types of malocclusions, dependence on the patient's motivation and production costs (3, 4).

The standard clear aligners fabrication workflow includes digital image acquisition via intraoral scanning, virtual treat-

Uvod

Ortodotske udlage su prozirni, mobilni ortodontski aparati i alternativa su konvencionalnom ortodontskom liječenju (1). Njihove prednosti u odnosu na fiksne ortodontske naprave jesu poboljšana estetika i udobnost, manje vremena provedenog na kontrolama i u hitnim posjetima, manje bolesti i bolja kvaliteta života pacijenata (2 – 5). No te naprave još uvejk imaju nekoliko ograničenja, kao što su nemogućnost liječenja određenih vrsta malokluzija, ovisnost o motivaciji pacijenta i troškovi proizvodnje (3, 4).

Standardni postupak izrade prozirnih ortodontskih udlaga uključuje intraoralno skeniranje zubnih lukova, virtu-

ment planning and 3D-printing of a series of orthodontic models. Subsequently, thin thermoplastic sheets are heated and pressed over physical models. Finally, after the thermoforming process, aligners are trimmed and polished and are ready for clinical use (6).

Apart from being time-consuming, thermoforming can affect the material properties and subsequently clinical performance of the appliance. Significant changes in flexural and elastic modulus, hardness, Young's modulus, and transparency of clear aligners after thermoforming were observed (7-10).

The development of digital technologies and 3D printing offers new possibilities such as 3D printing of clear aligners directly from a digital file, thus eliminating the cumulative errors that can occur during thermoplastic fabrication (11). 3D printing generates significantly less waste than the conventional thermoforming method, thus increasing efficiency and reducing the adverse impact on the environment (1, 12, 13). Other benefits are good accuracy and fit, load- and deformation resistance and shorter production time (1, 12). In comparison with thermoformed aligners, 3D printed aligners have superior mechanical and geometrical properties and are more suitable for intraoral use due to their resistance to mastication and biting forces (11, 14). They can also deliver optimal forces for orthodontic tooth movement (15).

The influence of changes in aligner thickness on the forces required for tooth movement needs to be considered when planning orthodontic treatment with clear aligners (2, 16, 17). According to the study by Gao et al., aligners with higher thicknesses and gingival edge exerted higher forces than thinner ones without an edge (18). Mechanical properties of clear aligners depend on material type, thickness, and amount of activation. Appliances fabricated from thinner thermoplastic materials and those with greater amount of activation deliver lower orthodontic forces (19). Elkholy et al. recommended a novel sequence in clear aligner treatment with new thinner aligners for significant amount of force reduction. This approach may reduce the risk of root resorption by tooth overloading (20, 21). However, another study reported sufficient tooth movement and similar effect on the principal stresses in periodontal ligament using clear aligners with different thicknesses, with thicker aligner exerted only slightly higher load on the tooth compared to thinner one (22).

Mantovani et al. analyzed the thickness of thermoformed aligners and their research showed that it was not homogenous, especially in the molar regions. Consistent aligner thickness is clinically important; otherwise some orthodontic tooth movements can be reduced (23). Although thermoforming is a reproducible process, thickness of thermoformed clear aligners is decreased compared with the original thickness of the thermoplastic sheet (24, 25). Regarding differences across the arch, thickness and gap width of thermoformed aligners are smaller at anterior teeth and gingival regions than that at posterior teeth and occlusal surfaces (26). On the other hand, the results of a previous study have revealed that 3D printed clear aligners have higher thickness compared to digital designed dimensions (27). Post-printing

also planiranje liječenja i 3D printanje niza ortodontskih modela. Tankе termoplastične folije zatim se zagrijavaju i prešaju preko fizičkih modela. Na kraju, poslije procesa termoformiranja, ortodontske udlage se obrezuju i poliraju te su spremni za kliničku uporabu (6).

Uz to što oduzima mnogo vremena, termoformiranje može utjecati na svojstva materijala i posljedično na klinička svojstva aparata. Nakon toga postupka uočene su značajne promjene u modulu elastičnosti, tvrdoći, Youngovu modulu i prozirnosti ortodontskih udlaga (7 – 10).

Razvoj digitalnih tehnologija i trodimenzionalnog ispis-a nudi nove mogućnosti kao što je 3D printanje ortodontskih udlaga izravno iz digitalne datoteke čime se eliminiraju kumulativne pogreške koje se mogu pojaviti tijekom termoformiranja (11). 3D printanje generira znatno manje otpada od konvencionalne metode termoformiranja, čime se povećava učinkovitost i smanjuje negativni utjecaj na okoliš (1, 12, 13). Ostale su prednosti dobra točnost i prilagodba, otpornost na opterećenje i deformaciju te kraće vrijeme proizvodnje (1, 12). U usporedbi s termoformiranim ortodontskim udlagama, 3D printane ortodontske udlage imaju superiorna mehanička i geometrijska svojstva te su prikladnije za intraoralnu upotrebu zbog otpornosti na žvačne sile (11, 14). Također otpuštaju optimalne sile za ortodontski pomak zuba (15).

Pri planiranju ortodontskog liječenja ortodontskim udlagama potrebno je uzeti u obzir utjecaj promjene debljine ortodontskih udlaga na sile potrebne za pomak zuba (2, 16, 17). Prema istraživanju Gaoa i suradnika, ortodontske udlage s većom debljinom i gingivnim rubom producirale su veće sile od onih tanjih bez ruba (18). Mehanička svojstva ortodontskih udlaga ovise o vrsti materijala, debljinu i iznosu aktivacije. Aparati izrađeni od tanjih termoplastičnih materijala i oni s većim iznosom aktivacije, daju manje ortodontske sile (19). Elkholy i suradnici preporučili su novi slijed u terapiji ortodontskim udlagama, s novim tanjim ortodontskim udlagama za značajno smanjenje sile. Takav pristup može smanjiti rizik od resorpцијe korijena zbog preopterećenja zuba (20, 21).

Međutim, autori jedne druge studije izvijestili su o dovolnjem pomicanju zuba i sličnom učinku na parodontni ligament u korištenju ortodontskih udlaga različitih debljina, pri čemu je deblja ortodontska udlaga samo malo više opterećivala zub od tanje (22).

Mantovani i suradnici analizirali su debljinu termoformirane ortodontske udlage i njihovo je istraživanje pokazalo da ona nije homogena, osobito u području molara. Konzistentna debljina ortodontske udlage klinički je važna jer se inače neki ortodontski pomaci zuba mogu smanjiti (23). Iako je termoformiranje ponovljiv proces, debljina termoformiranih ortodontskih udlaga smanjena je u usporedbi s izvornom debljinom termoplastične folije (24, 25). Kad je riječ o razlici duž zubnoga luka, debljina i širina razmaka između zuba i aparata termoformiranih ortodontskih udlaga manja je na prednjim Zubima i gingivnim dijelovima nego na stražnjim Zubima i okluzalnim površinama (26). S druge strane, u jednoj studiji autori ističu da su 3D printane ortodontske udlage deblje u usporedbi s digitalno dizajniranim dimenzi-jama (27). Uvjeti nakon printanja također su vrlo važni pri

conditions are also very important when printing clear aligners. Different temperatures and curing time durations may influence possible clinical efficiency of appliances (28).

Material and methods

In this study the thickness of thermoformed and 3D printed clear aligners was examined. Intraoral scan of a eugnathic patient was taken with Trios scanner (3Shape, Copenhagen, Denmark) and STL file was created using Maestro 3D Ortho Studio, version 5 (AGE Solutions®, Pontedera, Italy). 3D models of patient's dentition were printed from STL file using IZZI Ortho printer (3Dtech, Zagreb, Croatia). Thermoplastic sheets were thermoformed on printed models using Biostar® device (Biostar®, SCHEU-DENTAL GmbH, Iserlohn, Germany). Three samples of six different materials with different initial thickness were used: Duran+ (0.5 mm, 0.625 mm, 0.75 mm; Duran+, SCHEU-DENTAL GmbH); Erkodur (0.5 mm, 0.6 mm, 0.8 mm; Erkodur, Erkodent Erich Kopp GmbH, Pfalzgrafenweiler, Germany); Zendura A (0.76 mm; Zendura A, Bay Materials LLC, Fremont, California, USA), Erkoloc-Pro (1.0 mm, 1.3 mm; Erkoloc-Pro, Erkodent Erich Kopp GmbH); Zendura FLX (0.76 mm; Zendura FLX, Bay Materials LLC); CA PRO+ (0.75 mm; CA PRO+, SCHEU-DENTAL GmbH).

Printed aligners were printed directly from the patient's STL file using two different dental resins. IZZI standard (3DTech, Zagreb, Croatia) is an opaque resin that is normally used to produce dental models via 3D printing (group IZZI). NextDent Ortho Flex resin (NextDent B.V., Soesterberg, the Netherlands) is used for 3D printing of dental splints and retainers. We used NextDent resin to produce two groups of aligners: one group was produced according to the manufacturer's instructions (group NextDent) and another, with modified post-printing protocol, without draining of the residual resin (group NextDent A). All 3D printed aligners were produced using IZZI Direct printer (3Dtech, Zagreb, Croatia) in three digitally designed thicknesses (0.5 mm, 0.6 mm i 0.7 mm). Two samples of each material were printed. The study's sample size was computed using the resource equation method (29).

Left sides of the upper and lower aligners were used for the analysis. All samples were measured by three measurers using electronic micrometer (ELECTRONIC UNIVERSAL MICROMETER, Schut Geometrical Metrology, Groningen, the Netherlands, accuracy: 0.001 mm) on a total of 20 points per aligner. The thickness of aligner on central incisor was measured at: vestibular edge, incisal edge, cingulum and palatal/lingual edge; on canine at: vestibular edge, cusp tip, cingulum and palatal/lingual edge; on first premolar at: vestibular edge, buccal cusp tip, central fissure, palatal/lingual cusp tip and palatal/lingual cusp tip; on first molar at: vestibular edge, mesiobuccal cusp tip, distobuccal cusp tip, central fissure, mesiopalatal/mesiolingual cusp tip, distopalatal/distolingual cusp tip and palatal/lingual edge.

The data were checked for normality by using the Kolmogorov-Smirnov test, and they showed non-parametric distribution. Basic statistical parameters were calculated for

ispisu prozirnih ortodontskih udlaga. Različite temperature i trajanje polimerizacije mogu utjecati na kliničku učinkovitost aparata (28).

Materijal i metode

U ovoj studiji ispitivana je debljina termoformiranih i 3D printanih ortodontskih udlaga. Intraoralni sken eugnath pacijenta snimljen je skenerom Trios (3Shape, Copenhagen, Danska), a STL datoteka napravljena je u programu Maestro 3D Ortho Studio, verzija 5 (AGE Solutions®, Pontedera, Italija). 3D modeli pacijentove denticije isprintani su iz STL datoteke korištenjem printerja IZZI Ortho (3Dtech, Zagreb, Hrvatska). Termoplastične ploče termoformirane su na printanim modelima s pomoću uređaja Biostar® (Biostar®, SCHEU-DENTAL GmbH, Iserlohn, Njemačka). Upotrijebljena su po tri uzorka svakoga od šest različitih materijala drukčije početne debljine: Duran+ (0,5 mm, 0,625 mm, 0,75 mm; Duran+, SCHEU-DENTAL GmbH); Erkodur (0,5 mm, 0,6 mm, 0,8 mm; Erkodur, Erkodent Erich Kopp GmbH, Pfalzgrafenweiler, Njemačka); Zendura A (0,76 mm; Zendura A, Bay Materials LLC, Fremont, Kalifornija, SAD), Erkoloc-Pro (1,0 mm, 1,3 mm; Erkoloc-Pro, Erkodent Erich Kopp GmbH); Zendura FLX (0,76 mm; Zendura FLX, Bay Materials LLC); CA PRO+ (0,75 mm; CA PRO+, SCHEU-DENTAL GmbH).

Printane ortodontske udlage rađene su izravno iz pacijentove STL datoteke od dviju različitih dentalnih smola. IZZI standard (3DTech, Zagreb, Hrvatska) opakna je smola koja se inače koristi za izradu dentalnih modela 3D printanjem (grupa IZZI). NextDent Ortho Flex smola (NextDent B.V., Soesterberg, Nizozemska) upotrebljava se za 3D printanje zubnih udlaga i retencijskih naprava. Od NextDent smole proizveli smo dvije skupine ortodontskih udlaga: jednu prema uputama proizvođača (skupina NextDent) i drugu, s modificiranim protokolom nakon printanja, bez cijedenja zaostale smole (skupina NextDent A). Svi 3D printane ortodontske udlage proizvedene su s pomoću printerja IZZI Direct (3Dtech, Zagreb, Hrvatska) u trima digitalno dizajniranim debljinama (0,5 mm, 0,6 mm i 0,7 mm). Printana su po dva uzorka svakog materijala. Veličina uzorka studije izračunata je metodom jednadžbe resursa (29).

Za analizu je korištena lijeva strana svake gornje i donje ortodontske udlage. Tri mjeritelja mjerila su sve uzorke elektroničkim mikrometrom (ELECTRONIC UNIVERSAL MICROMETER, Schut Geometrical Metrology, Groningen, Nizozemska, točnost: 0,001 mm) na ukupno 20 točaka po ortodontskoj udlazi. Debljina ortodontske udlage na središnjem sjekutiku mjerena je na vestibularnom rubu, incizalnom rubu, cingulumu i palatinalnom/lingvalnom rubu; na očnjaku na vestibularnom rubu, vrhu krvžice, cingulumu i palatinalnom/lingvalnom rubu; na prvom pretkutnjaku na vestibularnom rubu, vrhu bukalne krvžice, središnjoj fisuri, vrhu palatinalne/lingvalne krvžice; na prvom kutnjaku na vestibularnom rubu, vrhu meziobukalne krvžice, vrhu distobukalne krvžice, središnjoj fisuri, vrhu meziopalatalinalne/meziolingvalne krvžice, vrhu distopalatalinalne/distolingvalne krvžice i palatinalnom/lingvalnom rubu.

each variable. The Kruskal-Wallis non-parametric test and Dunn Post-hoc test with Bonferroni correction were used to determine statistically significant differences between samples. The significance level was set at $p<0.05$. Statistical analysis was performed in JASP program (JASP, University of Amsterdam, Amsterdam, the Netherlands).

Results

Different measurers

The mean value of the measured deviation percentage from the declared thickness for three measurers was: measurer 1 (-22,115%), measurer 2 (-21,675%) and measurer 3 (-21,731%) but those differences between measurers weren't statistically significant (Kruskal-Wallis test, $p=0,878$).

Thermoformed vs. 3D printed aligners

Descriptive statistics of the deviation percentage from the declared thickness for samples produced by conventional thermoforming method and samples produced by 3D printing is presented in Table 1. The difference between the thermoformed and printed groups was statistically significant (Kruskal-Wallis test, $p<0.001$).

Table 1 Percentages of deviations from declared thickness for different manufacturing process
Tablica 1. Postotak odstupanja od deklarirane debljine za različite procese proizvodnje

Manufacturing process • Proizvodni proces	N	Mean	SD	SE	Coefficient of variation • Koeficijent varijacije
Thermoforming	3960	-39.764	14.096	0.224	-0.354
3D printing	2160	11.020	21.434	0.461	1.945

Thermoformed materials

The mean values of thickness deviation percentage of different thermoformed aligners, from lowest to highest were: Zendura A (-32,408%), Zendura FLX (-35,455%), Duran (-35,993%), Erkodur (-37,446%), CA PRO+ (-42,604%) and Erkoloc-Pro (-53,31%). Significant differences between different thermoformed materials were found (Kruskal-Wallis test, $p<0.001$). Dunn's Post Hoc Comparisons with Bonferroni correction for thermoformed materials are presented in Table 2.

3D printed materials

The mean thickness deviation percentages of printed aligners from lowest to highest were: NextDent (+4,04%), NextDent A (+5,883%) and IZZI (+23,137%). According to the Kruskal-Wallis test, the difference between printed materials was found (Kruskal-Wallis test, $p<0.001$) and Dunn's post-hoc analysis with Bonferroni correction showed significant difference between IZZI group and both NextDent groups, while between NextDent and NextDent A no statistically significant difference was found (Table 3).

Normalnost podataka provjerena je Kolmogorov-Smirnovljevim testom i pokazali su neparametrijsku distribuciju. Za svaku varijablu izračunati su osnovni statistički parametri. Za utvrđivanje statistički značajnih razlika između uzoraka korišteni su Kruskal-Wallisov neparametrijski test i Dunnov post-hoc test s Bonferronijevom korekcijom. Razina značajnosti postavljena je na $p < 0,05$. Statistička analiza obavljena je u programu JASP (JASP, Sveučilište u Amsterdamu, Nizozemska).

Rezultati

Različiti mjeritelji

Srednja vrijednost izmjerenog postotka odstupanja od deklarirane debljine za tri mjeritelja bila je: mjeritelj 1 (-22,115 %), mjeritelj 2 (-21,675 %) i mjeritelj 3 (-21,731 %), ali te razlike među mjeriteljima nisu bile statistički značajne (Kruskal-Wallisov test, $p = 0,878$).

Termoformirane vs. 3D printane ortodontske udlage

Deskriptivna statistika postotka odstupanja od deklarirane debljine za uzorce proizvedene konvencionalnom metodom termoformiranja i uzorce proizvedene 3D printanjem nalazi se u tablici 1. Razlike između termoformiranih i printanih skupina bila je statistički značajna (Kruskal-Wallisov test, $p < 0,001$).

Termoformirani materijali

Srednje vrijednosti postotka odstupanja u debljini različitih termoformiranih ortodontskih udlaga, od najmanje do najveće, bile su: Zendura A (-32,408 %), Zendura FLX (-35,455 %), Duran (-35,993 %), Erkodur (-37,446 %), CA PRO+ (-42,604 %) i Erkoloc-Pro (-53,31 %). Utvrđene su značajne razlike između različitih termoformiranih materijala (Kruskal-Wallisov test, $p < 0,001$). Dunnova post-hoc usporedba s Bonferronijevom korekcijom za termoformirane materijale prikazana je u tablici 2.

3D printani materijali

Prosječni postotak odstupanja u debljini printanih ortodontskih udlaga od najmanjega do najvećega bio je: NextDent (+4,04 %), NextDent A (+5,883 %) i IZZI (+23,137 %). Prema Kruskal-Wallisovu testu utvrđena je razlika između printanih materijala (Kruskal-Wallisov test, $p < 0,001$), a Dunnova post-hoc analiza s Bonferronijevom korekcijom pokazala je značajnu razliku između IZZI skupine i obje NextDent skupine, a između NextDenta i NextDenta A nije ustanovljena statistički značajna razlika (tablica 3.).

Upper vs. lower jaw

The difference between thickness deviations in upper and lower jaw, for both thermoformed and printed aligners was analyzed. The thickness of thermoformed aligners deviated more in the upper jaw and the difference was statistically significant (Kruskal-Wallis test, $p < 0.001$) (Supplement Table 1). The difference between the upper and lower jaw for printed aligners was also significant with more thickness deviations in the lower jaw (Kruskal-Wallis test, $p < 0.001$) (Supplement Table 2).

Table 2 Dunn's Post Hoc Comparisons with Bonferroni correction for thermoformed materials

Tablica 2. Dunnova post-hoc usporedba s Bonferronijevom korekcijom za termoformirane materijale

Comparison	z	W _i	W _j	p	p _{bonf}
CA PRO + - Duran	-7.309	1.773.688	2.282.246	< .001***	< .001***
CA PRO + - Erkodur	-5.413	1.773.688	2.150.341	< .001***	< .001***
CA PRO + - Erkoloc-Pro	11.738	1.773.688	907.401	< .001***	< .001***
CA PRO + - Zendura A	-9.330	1.773.688	2.568.778	< .001***	< .001***
CA PRO + - Zendura FLX	-6.534	1.773.688	2.330.469	< .001***	< .001***
Duran – Erkodur	2.681	2.282.246	2.150.341	0.007**	0.110
Duran – Erkoloc-Pro	24.994	2.282.246	907.401	< .001***	< .001***
Duran – Zendura A	-4.118	2.282.246	2.568.778	< .001***	< .001***
Duran – Zendura FLX	-0.693	2.282.246	2.330.469	0.488	1.000
Erkodur – Erkoloc-Pro	22.596	2.150.341	907.401	< .001***	< .001***
Erkodur – Zendura A	-6.014	2.150.341	2.568.778	< .001***	< .001***
Erkodur – Zendura FLX	-2.589	2.150.341	2.330.469	0.010**	0.144
Erkoloc-Pro – Zendura A	-22.512	907.401	2.568.778	< .001***	< .001***
Erkoloc-Pro – Zendura FLX	-19.283	907.401	2.330.469	< .001***	< .001***
Zendura A – Zendura FLX	2.797	2.568.778	2.330.469	0.005**	0.077

* p <05, ** p <01, *** p <001

Same material with different initial thicknesses

Deviations from initial thicknesses of aligners produced from the same material but with several different initial thicknesses (Duran 0.5 mm, 0.625 mm and 0.75mm; Erkodur 0.5 mm, 0.6 mm and 0.8 mm; Erkoloc-Pro 1.0 mm and 1.3 mm; IZZI 0.5 mm, 0.6 mm, 0.7 mm; NextDent 0.5 mm, 0.6 mm and 0.7 mm; NextDent A 0.5, 0.6 and 0.7 mm) were compared. The greatest average deviation from the initial thickness was found in Duran 0.75 (-37.149%); Erkodur 0.6 (-37.897%); Erkoloc-Pro 1.0 (-58.331%); IZZI 0.5 (+27.997%); NextDent 0.6 (+5.954%) and NextDent A 0.6 (+10.337%) (Table 4).

The analysis of thickness deviations from three different initial thicknesses of Duran material showed a significant difference between Duran 0.625 mm and Duran 0.75 mm (Kruskal-Wallis test, $p=0.007$; Dunn's Post Hoc, $p=0.008$,) (Supplement Table 3). Erkodur material showed no signifi-

Gornja čeljust vs. donja čeljust

Analizirana je razlika između odstupanja debljine u gornjoj i donjoj čeljusti za termoformirane i za printane ortodontske udlage. Debljina termoformiranih ortodontskih udlaga više je odstupala u gornjoj čeljusti i razlika je bila statistički značajna (Kruskal-Wallisov test, $p < 0.001$) (dopunska tablica 1.). Razlika između gornje i donje čeljusti za printane ortodontske udlage također je bila značajna s većim odstupanjima u debljini u donjoj čeljusti (Kruskal-Wallisov test, $p < 0.001$) (dopunska tablica 2.).

Table 3 Dunn's Post Hoc Comparisons with Bonferroni correction for printed materials.

Tablica 3. Dunnova post-hoc usporedba s Bonferronijevom korekcijom za printane materijale

Comparison	z	W _i	W _j	p	p _{bonf}
IZZI – NextDent	17.288	1.445.626	877.349	< .001***	< .001***
IZZI – NextDent A	16.035	1.445.626	918.525	< .001***	< .001***
NextDent – NextDent A	-1.253	877.349	918.525	0.210	0.631

* p <05, ** p <01, *** p <001

Table 4 Percentages of deviations from the declared thickness for materials with several different initial thicknesses – descriptive statistics
Tablica 4. Postotak odstupanja od deklarirane debljine za materijale s više različitih početnih debljina – deskriptivna statistika

	Initial thickness • Početna debljina	N	Mean	SD	SE	Coefficient of variation • Koeficijent varijacije
Duran	0.5	360	-36.584	12.928	0.681	-0.353
	0.625	360	-34.246	13.022	0.686	-0.380
	0.75	360	-37.149	13.168	0.694	-0.354
Erkodur	0.5	360	-37.297	11.807	0.622	-0.317
	0.6	360	-37.897	11.859	0.625	-0.313
	0.8	360	-37.145	12.353	0.651	-0.333
Ercoloc-Pro	1	360	-58.331	7.459	0.393	-0.128
	1.3	360	-48.289	9.414	0.496	-0.195
IZZI	0.5	240	27.997	18.413	1.189	0.658
	0.6	240	25.427	15.235	0.983	0.599
	0.7	240	15.988	13.237	0.854	0.828
Nextdent	0.5	240	0.354	19.077	1.231	53.865
	0.6	240	5.954	22.906	1.479	3.847
	0.7	240	5.813	20.962	1.353	3.606
Nextdent A	0.5	240	8.532	24.823	1.602	2.910
	0.6	240	10.337	18.461	1.192	1.786
	0.7	240	-1.220	16.483	1.064	-13.511

cant difference in thickness changes between different initial thicknesses (Kruskal-Wallis test, $p=0.565$), while the difference in thickness deviations between two initial thicknesses of Ercoloc-Pro material was statistically significant (Kruskal-Wallis test, $p<0.001$). Thickness deviations of IZZI material with 0.7 mm initial thickness were significantly different from thickness deviations of both IZZI 0.5 mm and IZZI 0.6 mm (Kruskal-Wallis test, $p<0.001$; Dunn's Post Hoc, $p<0.001$) (Supplement Table 4). The analysis of thickness deviations from three different initial thicknesses of NextDent material showed that NextDent 0.5 mm was significantly different from NextDent 0.6 mm and NextDent 0.7 mm (Kruskal-Wallis test, $p=0.003$; Dunn's Post Hoc, $p=0.011$, $p=0.006$) (Supplement Table 5). In the case of NextDent material with a modified post-printing protocol (NextDent A group), significant differences in thickness deviations between NextDent A 0.7 mm and both other groups NextDent A 0.5 mm and NextDent A 0.6 mm were found (Kruskal-Wallis test, $p<0.001$; Dunn's Post Hoc, $p<0.001$) (Supplement Table 6).

Variations due to tooth type

The percentage of thickness changes for each tooth of the upper and lower jaw was analyzed. If the results of both thermoformed and printed aligners in the upper and lower jaw are considered together, the Ercoloc-Pro material had the highest number of deviations (Supplement Tables 7 and 8). On each tooth, the Ercoloc-Pro was thinned by more than 50% after the thermoforming process and the greatest thinning was found at the upper first molar (-58.146%). NextDent group had the lowest deviations for all teeth of both jaws, except for the upper and lower first molar where NextDent A group was more accurate. Significant differences between different materials for teeth in both the upper and lower jaw were found (Kruskal-Wallis test, $p<0.001$) (Supplement Tables 9-16).

ku u promjenama debljine između različitih početnih debljina (Kruskal-Wallisov test, $p = 0,565$), a razlika u odstupanju u debljini između dviju početnih debljina materijala Ercoloc-Pro bila je statistički značajna (Kruskal-Wallisov test, $p < 0,001$). Odstupanja u debljini materijala IZZI s početnom debljinom od 0,7 mm, značajno su se razlikovala od odstupanja u debljini i IZZI 0,5 mm i IZZI 0,6 mm (Kruskal-Wallisov test, $p < 0,001$; Dunnov post-hoc test, $p < 0,001$) (dopunska tablica 4.). Analiza odstupanja u debljini od triju različitih početnih debljina materijala NextDent pokazala je da se NextDent 0,5 mm značajno razlikuje od NextDenta 0,6 mm i NextDenta 0,7 mm (Kruskal-Wallisov test, $p = 0,003$; Dunnov post. hoc test, $p = 0,011$, $p = 0,006$) (dopunska tablica 5.). U slučaju materijala NextDent s modificiranim posljeprintanim protokolom (skupina NextDent A) utvrđene su značajne razlike u odstupanjima u debljini između NextDenta A 0,7 mm i obje druge skupine NextDenta A 0,5 mm i NextDenta A 0,6 mm (Kruskal-Wallisov test, $p < 0,001$; Dunnov post-hoc test, $p < 0,001$) (dopunska tablica 6.).

Varijacije ovisno o vrsti zuba

Analiziran je postotak promjene u debljini za svaki zub gornje i donje čeljusti. Ako se rezultati termoformiranih i printanih ortodontskih udlaga u gornjoj i donjoj čeljusti promatraju zajedno, materijal Ercoloc-Pro imao je najveći broj odstupanja (dopunske tablice 7. i 8.). Na svakom zubu Ercoloc-Pro je stanjen za više od 50 % poslije procesa termoformiranja, a najveće stanjenje zabilježeno je na prvoj gornjem molaru (-58,146 %). Skupina NextDent imala je najmanju odstupanja za sve zube obiju čeljusti, osim za gornji i donji prvi molar gdje je skupina NextDent A bila preciznija. Utvrđene su značajne razlike za vrstu zuba između različitih materijala u gornjoj i donjoj čeljusti (Kruskal-Wallisov test, $p < 0,001$) (dopunske tablice 9. – 16.).

Table 5 Percentage of deviation from declared thickness for different measuring points on the tooth for thermoformed aligners – descriptive statistics

Tablica 5. Postotak odstupanja od deklarirane debljine za različite mjerne točke na zubu za termoformirane alignere – deskriptivna statistika

Measuring points • Mjerna mjesta	N	Mean	SD	SE	Coefficient of variation • Koeficijent varijacije
1	1998	-39.649	13.511	0.302	-0.341
2	1566	-42.147	14.407	0.364	-0.342
3	396	-30.922	12.055	0.606	-0.390

Table 6 Percentage of deviation from declared thickness for different measuring points on the tooth for printed aligners – descriptive statistics

Tablica 6. Postotak odstupanja od deklarirane debljine za različite mjerne točke na zubu za printane alignere – deskriptivna statistika

Measuring points • Mjerna mjesta	N	Mean	SD	SE	Coefficient of variation • Koeficijent varijacije
1	1080	11.002	21.394	0.651	1.944
2	864	6.906	19.285	0.656	2.793
3	216	27.567	21.917	1.491	0.795

Variations due to the position of measuring points

To determine changes in thickness according to tooth morphology, measured points were grouped in three groups: 1-protrusive forms (cusps, incisal edge and cingulum), 2-all aligner edges (vestibular, palatal, lingual), and finally 3-all fissures on first premolars and first molars.

The percentage of deviation for thermoformed aligners was the highest on the edges (Table 5). The differences between the three morphological groups for thermoformed aligners were significant (Kruskal-Wallis test, $p < 0.001$; Dunn's Post Hoc, $p < 0.001$) (Supplement Table 17).

In the printed aligner group, the highest deviation from the declared thickness was found at fissures (+28.567%), and the lowest at the edges (+6.906%) (Table 6). Although all deviations were positive, the printed aligner group also followed the trend of thinner edges and thicker fissures. The difference between different measuring points of the teeth for printed aligners was statistically significant (Kruskal-Wallis test, $p < 0.001$; Dunn's Post Hoc, $p < 0.001$) (Supplement Table 18).

Discussion

Light continuous forces are required to achieve ideal orthodontic tooth movement. Otherwise, the rate of the tooth movement will be slower or root resorption may occur (30). Aligner thickness is one of the factors that can affect the biomechanical characteristics of aligners and must be considered when planning orthodontic treatment (2, 16, 17). From the previous studies, it is known that appliance thickness has an impact on forces and moments during treatment with aligners (18, 31-33).

Clear aligners for clinical use are produced by the thermoforming process; however, the development of 3D printing makes it possible to print aligners directly from a digital file (1, 34).

In this study, the variations of aligner thickness after thermoforming and 3D printing were analyzed and compared. Measurements were made with a digital micrometer with the accuracy of 0.001 mm. All samples were measured

Odstupanja zbog položaja mjernih točaka

Kako bi se odredile promjene u debljini prema morfološkom zuba, izmjerene točke grupirane su u tri skupine: 1. izbočeni dijelovi (kvrižice, incizalni rub i cingulum), 2. svi rubovi ortodontske udlage (vestibularni, palatinalni, lingvalni) i 3. sve fisure na prvim pretkutnjacima i prvim kutnjacima.

Postotak odstupanja za termoformirane ortodontske udlage bio je najveći na rubovima (tablica 5.). Razlike između triju morfoloških skupina za termoformirane ortodontske udlage bile su značajne (Kruskal-Wallisov test, $p < 0.001$; Dunnov post-hoc test, $p < 0.001$) (dopunska tablica 17.).

U skupini printanih ortodontskih udlaga najveće odstupanje od deklarirane debljine utvrđeno je u fisurama (+28,567 %), a najmanje na rubovima (+6,906 %) (tablica 6.). Iako su sva odstupanja bila pozitivna, skupina printanih ortodontskih udlaga također je pratila trend tanjih rubova i debljih fisura. Razlika između različitih mjernih točaka zuba za printane ortodontske udlage bila je statistički značajna (Kruskal-Wallisov test, $p < 0,001$; Dunnov post-hoc test, $p < 0,001$) (dopunska tablica 18.).

Rasprrava

Za postizanje idealnoga ortodontskog pomaka zuba potrebne su lagane kontinuirane sile. U suprotnom bit će sporija brzina pomicanja zuba ili se može dogoditi resorpcija korijena (30). Debljina ortodontske udlage jedan je od čimbenika koji može utjecati na njezine biomehaničke karakteristike i mora se uzeti u obzir pri planiranju ortodontske terapije (2, 16, 17). Iz dosadašnjih istraživanja poznato je da debljina aparata utječe na sile i momente tijekom terapije ortodontskim udlagama (18, 31 – 33).

Prozirne ortodontske udlage za kliničku upotrebu prizvode se postupkom termoformiranja, no razvoj 3D printanja omogućio je njihovu izradu izravno iz digitalne datoteke (1, 34).

U ovom istraživanju analizirane su i uspoređene varijacije u debljini ortodontskih udlaga poslije termoformiranja i 3D printanja. Mjerenja su obavljena digitalnim mikrometrom točnosti 0,001 mm. Sve su uzorke tri puta mjerila tri neovisna

three times by three independent measurers. According to statistical analysis, there was no significant difference between the measurers (Kruskal-Wallis test, $p=0.878$), which means that the measurement method is repeatable.

The results of this study showed that the printed aligners had significantly lower deviations from the planned thickness than thermoformed ones (Kruskal-Wallis test, $p<0.001$) and potentially more predictive treatment outcomes. Thermoformed aligners were thinner than the original thermoplastic foil in all measured samples, while thickness of printed aligners tended to increase in comparison to the thickness of digital files.

Our results were in concordance with the study of Park et al. whose results also showed differences between thermoformed and 3D-printed groups. Thermoformed aligners had reduced thickness in comparison to the original foil and 3D-printed aligners were thicker than digitally designed files (35). Another study also examined thickness changes after thermoforming and 3D printing of clear aligners (36). A digital calliper was used for measuring the thickness in the middle and at both ends of rectangular specimens. The results showed that the average thickness of PET-G (Polyethylene terephthalate glycol) specimens was only 54,7% of the initial thickness, while the one of 3D printed specimens was 12% higher than the thickness designed in the digital file (36).

From the previous research, it is known that thermoforming is a reproducible process but can reduce aligner thickness (25). The study by Palone et al. showed that both gap width and aligner thickness after thermoforming are different across the arch and between aligner manufacturers (26). In another study, the thickness of four types of aligners was analyzed before and after thermoforming, and the latter was reduced by 0.017-0.022 (37). Ryokawa et al. reported that thermoformed material thicknesses ranged from 74,9 to 92,6% of the nominal sheet thicknesses (38).

The heating of thermoplastic foil and the use of pressure during the thermoforming process as well as material composition can affect both, the mechanical and physical properties of aligners (10, 24). Different thermoplastic polymers are used for clear aligner production via thermoforming. The most commonly used polymers are PET-G and TPU (Thermoplastic polyurethane) (6). They are transparent and have good mechanical properties (39, 40). To achieve better properties, polymer blends have also been developed (6).

Our analysis of the thermoformed aligners showed negative thickness deviations at all measuring points. Similar to other studies that found differences in biomechanical properties between single- and multi-layered thermoplastic materials (41, 43), the results of our study showed that Ercoloc-Pro, multi-layered material had the highest mean thickness deviation (-53,31%), while single-layered Zendura A had the lowest (-32,408%). When several thicknesses of the same thermoformed material were compared, significant differences were observed between Duran 0,625 and Duran 0,75 (Kruskal-Wallis test, $p=0,007$; Dunn's Post Hoc, $p=0,008$), as well as between Ercoloc-Pro 1,0 and Ercoloc-Pro 1,3 (Kruskal-Wallis test, $p<0,001$).

In the group of 3D-printed aligners, the greatest mean deviation from digitally designed thickness was found in

mjeritelja. Prema statističkoj analizi nije bilo značajne razlike između mjeritelja (Kruskal-Wallisov test, $p = 0,878$), što znači da je metoda mjerjenja ponovljiva.

Rezultati ove studije pokazali su da printane ortodontske udlage znatno manje odstupaju od planirane debljine nego termoformirani (Kruskal-Wallisov test, $p < 0,001$) i imaju potencijalno predvidljivije ishode liječenja. Termoformirane ortodontske udlage bile su tanje od originalne termoplastične folije u svim mjerjenim uzorcima, a debljina printanih ortodontskih udlaga imala je tendenciju povećanja u usporedbi s planiranim debljinom iz digitalnih datoteka.

Naši rezultati bili su u skladu sa studijom Parka i suradnika čiji su rezultati također pokazali razlike između termoformiranih i 3D printanih skupina. Termoformirane ortodontske udlage imale su smanjenu debljinu u usporedbi s izvornom folijom, a 3D printane ortodontske udlage bile su deblje od digitalno dizajniranih datoteka (35). U drugom istraživanju autori su također ispitivali promjene u debljini poslije termoformiranja i 3D printanja prozirnih ortodontskih udlaga (36). Za mjerjenje debljine u sredini pravokutnih uzoraka i na oba kraja korišten je digitalni kaliper. Rezultati su pokazali da je prosječna debljina PET-G (polietilen tereftalat glikola) uzorka bila samo 54,7 % početne debljine, a kod 3D printanih uzoraka bila je 12 % veća od debljine planirane u digitalnoj datoteci (36).

Iz dosadašnjih istraživanja poznato je da je termoformiranje ponovljiv proces, ali može smanjiti debljinu ortodontske udlage (25). Studija Palonea i suradnika pokazala je da se širina razmaka i debljina ortodontske udlage poslije termoformiranja razlikuju s obzirom na promatrani dio zubnoga luka i između proizvođača ortodontskih udlaga (26). U drugoj studiji analizirana je debljina četiriju vrsta ortodontskih udlaga prije termoformiranja i poslije toga postupka, a potonja je smanjena za 0,017 do 0,022 (37). Ryokawa i suradnici izvjestili su da se debljina termoformiranog materijala kreće od 74,9 do 92,6 % nominalne debljine folije (38).

Zagrijavanje termoplastične folije i korištenje pritska tijekom procesa termoformiranja, kao i sastav materijala, mogu utjecati na mehanička i fizikalna svojstva ortodontskih udlaga (10, 24). Različiti termoplastični polimeri koriste se za proizvodnju prozirnih ortodontskih udlaga termoformiranjem. Najčešće korišteni su PET-G i TPU (termoplastični poliuretan) (6). Prozirni su i imaju dobra mehanička svojstva (39, 40). Za postizanje boljih svojstava proizvode se i mješavine polimera (6).

Naša analiza termoformiranih ortodontskih udlaga pokazala je negativna odstupanja u debljini na svim mjernim točkama. Slično rezultatima drugih istraživanja, prema kojima postoje razlike u biomehaničkim svojstvima između jednoslojnih i višeslojnih termoplastičnih materijala (41, 43), rezultati našeg istraživanja pokazali su da Ercoloc-Pro, višeslojni materijal, ima najveće (-53,31 %), a jednoslojna Zendura A najmanje srednje odstupanje debljine (-32,408 %). Usporedbom nekoliko debljina istoga termoformiranoga materijala uočene su značajne razlike između Durana 0,625 i Durana 0,75 (Kruskal-Wallisov test, $p = 0,007$; Dunnov post-hoc test, $p = 0,008$) i između Ercoloc-Proa 1,0 i Ercoloc-Proa 1,3 (Kruskal-Wallisov test, $p < 0,001$).

U skupini 3D printanih ortodontskih udlaga najveće srednje odstupanje od digitalno planirane debljine utvrđeno

IZZI group (+23.137%). The mean deviation value for NextDent group was only +4.04% and it was closest to the initial thickness. IZZI group was significantly different from both NextDent groups (Kruskal-Wallis test, $p < 0.001$; Dunn's Post Hoc, $p < 0.001$). When several thicknesses of the same printed material were compared, IZZI 0.7 was significantly different from both IZZI 0.5 and 0.6 (Kruskal-Wallis test, $p < 0.001$; Dunn's Post Hoc, $p < 0.001$), NextDent 0.5 from both NextDent 0.6 and 0.7 (Kruskal-Wallis test, $p = 0.003$; Dunn's Post Hoc, $p = 0.011$, $p = 0.006$) and NextDent A 0.7 from both NextDent A 0.5 and 0.6 (Kruskal-Wallis test, $p < 0.001$; Dunn's Post Hoc, $p < 0.001$).

Since IZZI resin was originally used for model rather than aligner printing, its subpar performance was somewhat expected. The results of our study are in accordance with another study investigating the effect of digitally designed thickness on 3D-printed clear aligners, in which Edelmann et al. reported that 3D-printing could increase aligner thickness by more than 0.2 mm (27). Lee et al. have explained that a possible reason for aligner thickness increase after 3D printing could be the usage of high definition projector as a light source in DLP printers (36). Other possible causes of aligner overbuilding are over-penetration of light in transparent materials during 3D printing, print orientation, as well as polymerization of residual resin during the post-curing process (27, 36, 44).

When comparing thickness deviations between the upper and lower jaw, significant differences were found in both groups (Kruskal-Wallis tests, $p < 0.001$). The thickness of thermoformed aligners deviated more in the upper jaw, while in the case of printed aligners it deviated more in the lower jaw. If the thickness on each tooth was analyzed separately, aligners produced from Erkocol-Pro material were thinned by more than 50% on all teeth of the upper and lower jaw, whereas both NextDent groups had the lowest deviations.

For both, the thickness of thermoformed and printed aligners was significantly lower at edges than at cusps and fissures ($p < 0.001$). It is important to note that in the case of printed aligners, thickness deviations of all three groups (edges, cusps and fissures) were positive and that the thickness of edges was closest to digitally designed (+6.906%). These results are in line with the results from other studies (23, 24, 26, 35). Mantovani et al. reported that Invisalign thickness was not consistent across the arch, but a significant difference was found only between gingivolingual and occlusal sites in the molar region (23). Another research reported that aligner thickness was generally smaller at anterior teeth and gingival sites, unlike the thickness at the posterior teeth and occlusal surfaces, and only one of the six tested commercial materials had homogeneous thickness across the arch (26). Similar results were obtained in another study where thermoplastic materials, both single- and multi-layered, had reduced thickness at buccal and buccogingival areas (35). This can be due to different tooth anatomy and less stretching of thermoplastic foil in the occlusal and posterior regions during the thermoforming process (24). As for printed aligners, Park et al. reported that they also were thicker at incisal and occlusal areas. This can happen due to errors in layering during 3D printing of complex tooth morphology (35).

je u skupini IZZI (+23,137 %). Srednja vrijednost odstupanja za grupu NextDent bila je samo +4,04 % i bila je najbliža početnoj debljini. Skupina IZZI značajno se razlikovala od obiju skupina NextDenta (Kruskal-Wallisov test, $p < 0,001$; Dunnov post-hoc test, $p < 0,001$). Kada se uspoređuje nekoliko debljina istoga printanog materijala, IZZI 0,7 značajno se razlikuje od IZZI-ja 0,5 i 0,6 (Kruskal-Wallisov test, $p < 0,001$; Dunnov post-hoc test $p < 0,001$), NextDent 0,5 od NextDenta 0,6 i 0,7 (Kruskal-Wallisov test, $p = 0,003$; Dunnov post-hoc test, $p = 0,011$, $p = 0,006$) i NextDent A 0,7 od NextDenta A 0,5 i 0,6 (Kruskal-Wallisov test, $p < 0,001$; Dunnov post-hoc test, $p < 0,001$).

Budući da je smola IZZI izvorno korištena za ispis modela, a ne ortodontske udlage, njezina je loša izvedba donekle bila očekivana. Rezultati naše studije u skladu su sa studijom koja je istraživala utjecaj digitalno dizajnirane debljine na 3D printane ortodontske udlage, u kojoj su Edelmann i suradnici izvijestili da 3D printanje može povećati debljinu ortodontske udlage za više od 0,2 mm (27). Lee i suradnici objasnili su da bi mogući razlog za povećanje debljine ortodontske udlage nakon 3D printanja mogao biti korištenje projektora visoke razlučivosti kao izvora svjetla u DLP printerima (36). Drugi mogući uzroci za povećano zadebljavanje ortodontske udlage jesu prekomjerno prodiranje svjetla u prozirne materijale tijekom 3D printanja, orientacija printa i polimerizacija zaostale smole tijekom procesa naknadnog stvrnjavanja (27, 36, 44).

Usporedbom odstupanja u debljini između gornje i donje čeljusti utvrđene su značajne razlike u objema skupinama (Kruskal-Wallisov test, $p < 0,001$). Debljina termoformiranih ortodontskih udlaga više je odstupala u gornjoj čeljusti, a kod printanih ortodontskih udlaga više je odstupala u donjoj čeljusti. Ako se posebno analizira debljina na svakome zubu, ortodontske udlage proizvedene od materijala Erkocol-Pro istanjile su se za više od 50 % na svim Zubima gornje i donje čeljusti, a za obje skupine NextDenta zabilježena su najmanja odstupanja.

I za termoformirane i za printane ortodontske udlage debljina je bila značajno manja na rubovima nego na krvžicama i fisurama ($p < 0,001$). Važno je napomenuti da su kod printanih ortodontskih udlaga odstupanja od debljine u svim trima skupinama (rubovi, krvžice i fisure) bila pozitivna te da je debljina rubova bila najbliža digitalno dizajniranoj (+6,906 %). Ti su rezultati u skladu s rezultatima u drugim studijama (23, 24, 26, 35). Mantovani i suradnici izvijestili su da debljina ortodontske udlage Invisalign nije bila konzistetna u cijelome zubnom luku, ali je značajna razlika pronađena samo između gingivolingvalnih i okluzalnih mjeseta u molarnoj regiji (23). I u dugom istraživanju istaknuto je da je debljina ortodontskih udlaga općenito manja na prednjim Zubima i mjestima uz gingivu, za razliku od debljine na stražnjim Zubima i okluzalnim površinama, a samo je jedan od šest testiranih komercijalnih materijala imao homogenu debljinu duž cijelog luka (26). Slični rezultati dobiveni su u studiji u kojoj su termoplastični materijali, jednoslojni i višeslojni, imali smanjenu debljinu na bukalnom i bukogingivnom području (35). To može biti posljedica drukčije anatomije zuba i manjeg istezanja termoplastične folije na okluzalnim i posteriornim regijama u procesu termoformiranja (24). Kad je riječ o printanim ortodontskim udlagama, Park i suradnici izvijestili su da su i oni deblji u incizalnim i okluzal-

The success of orthodontic treatment depends, among other things, on the quality of the appliances that are being used. The quality of the appliance is reflected in the ability of appliance to move the tooth to the planned position in the planned time without causing any damage. Material manufacturers often fail to mention the potential problems that end users may encounter. Therefore, an independent research like ours is very important, especially when new things are introduced such as the current transition from thermoforming to 3D printing. Direct 3D printing of orthodontic aligners brings numerous advantages compared to previous production technology; it saves time, and human resources, reduces waste, and it is clear that this is the future of orthodontic aligner production. However, as our research has shown, despite great progress, it is still necessary to work on the development of materials and technology that will justify the abandonment of thermoforming, which, despite its many shortcomings, still works quite well in everyday practice.

This research was co-financed by the European Union from the European Regional Development Fund under the Operational Program Competitiveness and Cohesion 2014–2020

Conclusions

Thermoformed aligners had significantly more thickness deviations than printed ones. All thickness deviations of thermoformed aligners were negative. Erkocol-Pro (PET-G/TPU) differed the most and Zendura A (TPU) the least from the initial thickness of the thermoplastic sheet; Thickness deviations of printed aligners were mostly positive. The highest mean deviation had IZZI group, while NextDent group had the lowest one. For both, the final thickness of thermoformed and direct-printed aligners was significantly smaller at edges than at cusps and fissures.

Conflict of interest: None declared

Author's contribution: R. B., K. V., I. V. K. - data collection, analysis and interpretation of results, original draft preparation; I. M. M., I. G. - reviewing and editing; D. K. G. - study conception and design, analysis and interpretation of results, reviewing and editing

Sažetak

Cilj: Procijeniti varijacije debljine termoformiranih i 3D printanih prozirnih ortodontskih udlaga. **Materijali i metode:** Šest različitih termoplastičnih materijala s različitim početnim debljinama korišteno je za termoformiranje ortodontskih udlaga pomoću Biostar® uređaja (Biostar®, SCHEU-DENTAL GmbH, Iserlohn, Njemačka). Također, dvije različite dentalne smole korištene su za izradu 3D-printanih ortodontskih udlaga u tri digitalno dizajnirane debljine pomoću IZZI Direct pisača (3Dtech, Zagreb, Hrvatska). Ortodontske udlage su izmjerene elektroničkim mikrometrom (ELECTRONIC UNIVERSAL MICROMETER, Schut Geometrical Metrology, Groningen, Nizozemska, točnost: 0,001 mm) na ukupno 20 točaka po ortodontskoj udlazi. Statistička analiza provedena je s pomoću programa JASP (JASP, Sveučilište u Amsterdamu, Amsterdam, Nizozemska). **Rezultati:** Razlika između termoformiranih i printanih skupina bila je statistički značajna. Pronađene su značajne razlike između različitih termoformiranih materijala i između 3D printanih materijala. Debljina termoformiranih ortodontskih udlaga više je odstupala u gornjoj čeljusti, dok je debljina printanih ortodontskih udlaga više odstupala u donjoj čeljusti. Obje su razlike bile statistički značajne. Najveće prosječno odstupanje od početne debljine utvrđeno je kod Durana 0,75; Erkodur 0,6; Erkocol-Pro 1,0; IZZI 0,5; NextDent 0,6 i NextDent A 0,6. NextDent skupina imala je najmanja odstupanja za sve zube obiju čeljusti, osim za gornji i donji prvi kutnjak gdje je NextDent A skupina bila preciznija. **Zaključci:** Termoformirane ortodontske udlage pokazale su smanjene vrijednosti, dok su printane pokazale uglavnom povećane vrijednosti u usporedbi s izvornom debljinom materijala. Najveću srednju devijaciju imala je skupina IZZI, a najmanju srednju devijaciju skupina NextDent. Debljina obje ortodontske udlage bila je manja na rubovima u usporedbi s debljinom na krvžicama u fisurama.

nim područjima. To se može dogoditi zbog pogrešaka u slojevanju tijekom 3D printanja složene morfologije zuba (35).

Uspjeh ortodontskog liječenja ovisi, između ostalog, i o kvaliteti aparata koji se koriste. Kakvoća se ogleda u njihovoj mogućnosti da pomaknu Zub u planirani položaj u planiranom vremenu bez ikakva oštećenja. Proizvođači materijala često propuštaju spomenuti potencijalne probleme s kojima se krajnji korisnici mogu susresti, a ovakva neovisna istraživanja vrlo su važna, posebno kada se uvode nove stvari, kao što je trenutačni prijelaz s termoformiranja na 3D printanje. Izravni 3D ispis ortodontskih ortodontskih udlaga ima brojne prednosti u usporedbi s dosadašnjom proizvodnom tehnologijom – štedi vrijeme i ljudske resurse, smanjuje otpad i jasno je da je to budućnost u proizvodnji ortodontskih udlaga. No, kako je naše istraživanje pokazalo, unatoč velikom napretku, potrebno je još raditi na razvoju materijala i tehnologije koji će opravdati odustajanje od termoformiranja koje, unatoč mnogobrojnim nedostatcima, još uvjek dosta dobro funkcioniра u svakodnevnoj praksi.

Ovo istraživanje sufinancirala je Europska unija iz svojega Fonda za regionalni razvoj u sklopu operativnog programa Konkurentnost i kohezija 2014. – 2020.

Zaključci

Termoformirane ortodontske udlage znatno su više odstupale u debljini od printanih. Sva odstupanja u debljini termoformiranih ortodontskih udlaga bila su negativna. Erkocol-Pro (PET-G/TPU) razlikovala se najviše, a Zendura A (TPU) najmanje od početne debljine termoplastične folije. Odstupanja u debljini printanih ortodontskih udlaga bila su uglavnom pozitivna. Najveću srednju devijaciju imala je skupina IZZI, a najmanju skupina NextDent. I kod termoformiranih i printanih ortodontskih udlaga debljina je bila znaczajno manja na rubovima nego na krvžicama i fisurama.

Sukob interesa: Autori nisu bili u sukobu interesa.

Doprinos autora: R. B., K. V., I. V. K. – prikupljanje podataka, analiza i interpretacija rezultata, priprema izvornog nacrta, I. M. M., I. G. – recenziranje i priređivanje; D. K. G. – konceptacija studije i dizajn, analiza i interpretacija rezultata, recenziranje i uredovanje

Zaprimljen: 5. siječnja 2024.

Prihvaćen: 30. travnja 2024.

Adresa za dopisivanje

Danijela Kalibović Govorko
Medičinski fakultet Sveučilišta u Splitu
Katedra za ortodonciju
danijela.kalibovic.govorko@mefst.hr

MeSH pojmovi: mobilne ortodontske naprave; trodimenzionalni otisak

Autorske ključne riječi: Ortodoncija; 3D-printanje; Ortodontski aparati; Mobilni

References

- Tartaglia GM, Mapelli A, Maspero C, Santaniello T, Serafin M, Farronato M, et al. Direct 3D Printing of Clear Orthodontic Aligners: Current State and Future Possibilities. *Materials (Basel)*. 2021 Apr;5(14):1799.
- Weir T. Clear aligners in orthodontic treatment. *Aust Dent J*. 2017 Mar;62 Suppl 1:58-62.
- Zheng M, Liu R, Ni Z, Yu Z. Efficiency, effectiveness and treatment stability of clear aligners: A systematic review and meta-analysis. *Orthod Craniofac Res*. 2017 Aug;20(3):127-133.
- Tamer I, Oztas E, Marsan G. Orthodontic Treatment with Clear Aligners and The Scientific Reality Behind Their Marketing: A Literature Review. *Turk J Orthod*. 2019 Dec;1;32(4):241-246.
- Miller KB, McGorray SP, Womack R, Quintero JC, Perelmuter M, Gibson J, et al. A comparison of treatment impacts between Invisalign aligner and fixed appliance therapy during the first week of treatment. *American journal of orthodontics and dentofacial orthopedics: official publication of the Am J Orthod Dentofacial Orthop*. 2007 Mar;131(3):302.e1-9.
- Bichu YM, Alwafi A, Liu X, Andrews J, Ludwig B, Bichu AY, et al. Advances in orthodontic clear aligner materials. *Bioact Mater*. 2022 Oct 20;22:384-403.
- Dalaie K, Fatemi SM, Ghaffari S. Dynamic mechanical and thermal properties of clear aligners after thermoforming and aging. *Progress in orthodontics*. 2021;22(1):15. Epub 2021/06/29.
- Ryu JH, Kwon JS, Jiang HB, Cha JY, Kim KM. Effects of thermoforming on the physical and mechanical properties of thermoplastic materials for transparent orthodontic aligners. *Korean J Orthod*. 2018 Sep;48(5):316-325.
- Golkhani B, Weber A, Keilig L, Reimann S, Bourauel C. Variation of the modulus of elasticity of aligner foil sheet materials due to thermoforming.. *J Orofac Orthop*. 2022 Jul;83(4):233-243.
- Tamburrino F, D'Anto V, Bucci R, Alessandri-Bonetti G, Barone S, Razionale AV. Mechanical Properties of Thermoplastic Polymers for Aligner Manufacturing: In Vitro Study. *Dentistry journal*. 2020;8(2).
- Jindal P, Juneja M, Siena FL, Bajaj D, Breedon P. Mechanical and geometric properties of thermoformed and 3D printed clear dental aligners. *Am J Orthod Dentofacial Orthop*. 2019 Nov;156(5):694-701.
- Peeters B, Kiratli N, Semeijn J. A barrier analysis for distributed recycling of 3D printing waste: Taking the maker movement perspective. *J Clean Prod*. 2019;241:118313.
- Bayirli B, Kim-Berman H, Puntillo A, editors. *Embracing Novel Technologies in Dentistry and Orthodontics*. 2020.
- Jindal P, Worcester F, Siena FL, Forbes C, Juneja M, Breedon P. Mechanical behaviour of 3D printed vs thermoformed clear dental aligner materials under non-linear compressive loading using FEM. *J Mech Behav Biomed Mater*. 2020 Dec;112:104045.
- Hertan E, McCray J, Bankhead B, Kim KB. Force profile assessment of direct-printed aligners versus thermoformed aligners and the effects of non-engaged surface patterns. *Prog Orthod*. 2022 Nov 29;23(1):49.
- Wheeler TT. Orthodontic clear aligner treatment. *Seminars in Orthodontics*. 2017;23:83-9.
- Phan X, Ling PH. Clinical limitations of Invisalign. *J Can Dent Assoc*. 2007;73(3):263-6.
- Gao L, Michelhaus A. Forces and moments delivered by the PET-G aligner to a maxillary central incisor for palatal tipping and intrusion. *The Angle orthodontist*. 2017;87(4):534-41.
- Kohda N, Iijima M, Muguruma T, Brantley WA, Ahluwalia KS, Mizoguchi I. Effects of mechanical properties of thermoplastic materials on the initial force of thermoplastic appliances. *Angle Orthod*. 2013 May;83(3):476-83.
- Elkholy F, Schmidt F, Jager R, Lapatki BG. Forces and moments delivered by novel, thinner PET-G aligners during labiopalatal bodily movement of a maxillary central incisor: An in vitro study. *The Angle orthodontist*. 2016;86(6):883-90.
- Elkholy F, Schmidt F, Jager R, Lapatki BG. Forces and moments applied during derotation of a maxillary central incisor with thinner aligners: An in-vitro study. *Am J Orthod Dentofacial Orthop*. 2017 Feb;151(2):407-415.
- Seo JH, Eghan-Acquah E, Kim MS, Lee JH, Jeong YH, Jung TG, et al. Comparative Analysis of Stress in the Periodontal Ligament and Center of Rotation in the Tooth after Orthodontic Treatment Depending on Clear Aligner Thickness-Finite Element Analysis Study. *Materials (Basel)*. 2021;14(2).
- Mantovani E, Parrini S, Coda E, Cugliari G, Scotti N, Pasqualini D, et al. Micro computed tomography evaluation of Invisalign aligner thickness homogeneity. *Angle Orthod*. 2021 May 1;91(3):343-348.
- Lombardo L, Palone M, Longo M, Arveda N, Nacucchi M, De Pasqualis F, et al. MicroCT X-ray comparison of aligner gap and thickness of six brands of aligners: an in-vitro study. *Progress in orthodontics*. 2020;21(1):12.
- Bucci R, Rongo R, Levate C, Michelotti A, Barone S, Razionale AV, et al. Thickness of orthodontic clear aligners after thermoforming and after 10 days of intraoral exposure: a prospective clinical study. *Progress in orthodontics*. 2019;20(1):36.
- Palone M, Longo M, Arveda N, Nacucchi M, Pascalis F, Spedicato GA, et al. Micro-computed tomography evaluation of general trends in aligner thickness and gap width after thermoforming procedures involving six commercial clear aligners: An in vitro study. *Korean J Orthod*. 2021 Mar 25;51(2):135-141.
- Edelmann A, English JD, Chen SJ, Kasper FK. Analysis of the thickness of 3-dimensional-printed orthodontic aligners. *Am J Orthod Dentofacial Orthop*. 2020 Nov;158(5):e91-e98.
- Jindal P, Juneja M, Bajaj D, Siena F, Breedon P. Effects of post-curing conditions on mechanical properties of 3D printed clear dental aligners. *Rapid Prototyping Journal*. 2020;ahead-of-print.
- Mead R. *The Design of Experiments*. New York. Cambridge University Press; 1988: 634. p.
- Proffit WR. *Contemporary orthodontics*. William R. Proffit, editor. 5th ed. ed. St. Louis, Mo: Elsevier/Mosby; 2013.
- Hahn W, Dathe H, Fialka-Fricke J, Fricke-Zech S, Zapf A, Kubein-Meesenburg D, et al. Influence of thermoplastic appliance thickness on the magnitude of force delivered to a maxillary central incisor during tipping. *Am J Orthod Dentofacial Orthop*. 2009 Jul;136(1):12.e1-7; discussion 12-3.
- Alhasyimi AA, Ayub A, Farmasyanti CA. Effectiveness of the Attachment Design and Thickness of Clear Aligners during Orthodontic Anterior Retraction: Finite Element Analysis. *European journal of dentistry*. 2023.
- Grant J, Foley P, Bankhead B, Miranda G, Adel SM, Kim KB. Forces and moments generated by 3D direct printed clear aligners of varying labial and lingual thicknesses during lingual movement of maxillary central incisor: an in vitro study. *Prog Orthod*. 2023 Jul 10;24(1):23.
- Maspero C, Tartaglia GM. 3D Printing of Clear Orthodontic Aligners: Where We Are and Where We Are Going. *Materials (Basel)*. 2020;13(22).
- Park SY, Choi SH, Yu HS, Kim SJ, Kim H, Kim KB, et al. Comparison of translucency, thickness, and gap width of thermoformed and 3D-printed clear aligners using micro-CT and spectrophotometer. *Sci Rep*. 2023 Jul 5;13(1):10921.
- Lee SY, Kim H, Kim HJ, Chung CJ, Choi YJ, Kim SJ, et al. Thermo-mechanical properties of 3D printed photocurable shape memory resin for clear aligners. *Sci Rep*. 2022 Apr 15;12(1):6246.
- Dasy H DA, Asatrian G, Rózsa N, Lee HF, Kwak JH, . Effects of variable attachment shapes and aligner material on aligner retention. *Angle Orthod*. 2015 Nov;85(6):934-40.
- Ryokawa H MY, Fujishima A, Miyazaki T, Maki K. The mechanical properties of dental thermoplastic materials in a simulated intra-oral environment. *Orthodontic Waves*. 2006(65(2)):64-72.
- Dupaix RB BM. Finite strain behavior of poly(ethylene terephthalate) (PET) and poly(ethylene terephthalate)-glycol (PETG). *Polymer*. 2005;46(13):4827-38.
- Frick RA. Characterization of TPU-elastomers by thermal analysis (DSC). *Polymer Testing*. 2004(23(4)):413-7.
- Jia L, Wang C, Wang C, Song J, Fan Y. Efficacy of various multi-layers of orthodontic clear aligners: a simulated study. *Comput Methods Biomed Engin*. 2022 Nov;25(15):1710-1721.
- Lombardo L, Martines E, Mazzanti V, Arreghini A, Mollica F, Siciliani G. Stress relaxation properties of four orthodontic aligner materials: A 24-hour in vitro study. *Angle Orthod*. 2017 Jan;87(1):11-18.
- Simunovic L, Jurela A, Sudarevic K, Bacic I, Mestrovic S. Differential Stability of One-layer and Three-layer Orthodontic Aligner Blends under Thermocycling: Implications for Clinical Durability. *Acta Stomatol Croat*. 2023 Dec;57(4):286-299.
- McCarty MC, Chen SJ, English JD, Kasper F. Effect of print orientation and duration of ultraviolet curing on the dimensional accuracy of a 3-dimensionally printed orthodontic clear aligner design. *Am J Orthod Dentofacial Orthop*. 2020 Dec;158(6):889-897.