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# Adaptation to New Dentures and 5 Years of Clinical Use: A Comparison between Complete Denture and Mini-implant Mandibular Overdenture Patients based on Oral Health-Related Quality of Life (OHRQoL) and Orofacial Esthetics

## *Prilagodba na nove proteze i pet godina kliničke uporabe: praćenje kvalitete života ovisne o oralnome zdravlju i orofacialne estetike kod pacijenata s potpunim ili pokrovnim protezama na miniimplantatima*

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### Abstract

**Objective of work:** It is unclear how long patients need to adapt to new dentures. This study assessed adaptation and five years of clinical use, comparing complete denture wearers (CDs) and mini-implant mandibular overdenture wearers opposing a maxillary CD (MDI-OD), based on oral health reported quality of life (OHRQoL) and orofacial esthetics (OES). **Material and Methods:** A total of 36 subjects in the CD group (25 females) and 30 subjects in the MDI group (20 females) completed the 5-year study. All patients received new CDs, but in the MDI-OD group, four mini-implants were inserted interforaminally in the mandible before denture manufacture. Participants filled in the OHIP-EDENT and OES questionnaires one day after dentures' delivery, on the 3<sup>rd</sup>, 8<sup>th</sup>, 15<sup>th</sup>, 30<sup>th</sup> day, and at the 1-, 3- and 5-year follow-up examinations. Statistical analysis comprised descriptive methods,  $\chi^2$  test, independent t-test, Friedman, and Mann-Whitney test. **Results and Conclusions:** Both groups' adaptation to new dentures was completed within a month. The MDI-OD group had significantly better OHRQoL in all follow-ups except for the 3<sup>rd</sup> and 8<sup>th</sup> day, probably due to soreness and pain, the reason why the MDI-OD group had limitation in functioning in the first days after new dentures' delivery. Already after the third year and at the fifth year, OHRQoL worsened ( $p<0.01$ ) in both groups. However it was significantly more pronounced in the conventional CD wearers ( $p<0.01$ ) than in the MDI-OD group. Orofacial esthetics was highly scored in both groups. The scores dropped down only after three years, equally in both groups.

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### Introduction

Despite numerous advances in dental medicine, inventions of new dental materials, and new technologies, tooth loss remains a reality, especially in an aged population (1). Recent trends in dental medicine indicate that natural teeth

### Uvod

Unatoč napretku dentalne medicine i pojavi mnogobrojnih novih dentalnih materijala i novih tehnologija, gubitak zuba i dalje je stvarnost, osobito u starijoj populaciji (1). Posljednji trendovi u dentalnoj medicini upućuju na to da se

are lost later in life, but a percentage of the aged population is also growing fast due to improvements in general medicine, better health care, and other facilities. Today people can expect to live into their sixties and beyond (2, 3). Therefore, although a trend of a decline of complete edentulism is present in high-income countries, edentulous patients will still be growing due to the increase of life expectancy (4,5). For a long time, complete dentures (CD) have been the only treatment option for edentulous subjects (5). Nowadays, therapeutic possibilities have improved by introducing dental implants, however only to those who can access such treatment. Many subjects cannot afford implant treatment either due to economic problems, general health issues, or inadequate bone volume, usually present in removable denture wearers (5-8). Therefore, CDs will continue to be the only option for most edentulous subjects (9). Subjects who have been wearing removable dentures for a certain period are faced with problems elicited by continuous residual ridge resorption and bone atrophy, mucosal inflammation and injuries, development of a flabby ridge, consequential loss of denture stability, and reduction of a vertical dimension of occlusion with a contra-clockwise rotation of the mandible (6-8, 10-13). The mandible's residual alveolar ridge atrophy is almost four times more pronounced (6-8). Therefore a panel of experts proposed that the minimum treatment for completely edentulous subjects is a two-implant retained overdenture (OD) in the mandible and a CD in the maxilla (McGill consensus) (14). The McGill consensus is based on the evidence that dental implants significantly reduce a rate of residual ridge atrophy, not only at the implant site but also in distant areas (11,15). In subjects with narrow alveolar ridges, rehabilitation with mandibular overdenture (OD) retained on four mini-implants has been recommended as the alternative to two-implant OD (14, 16-19).

The outcomes from a patients' perspective, i.e., dental patient-reported outcome measures (dPROM) related to their oral health-related quality of life (OHRQoL), esthetics, or other self-perceived measures, are becoming the most important factors in evidence-based dentistry (20-24). Sometimes the therapist's and the patient's opinions of the effectiveness of a therapy can be different, and patients may be unsatisfied (20,25, 26).

The duration of adaptation to conventional CDs or implant-overdentures (IOD) can vary depending on many factors, such as previous removable denture experience, expectations, psycho-social and cultural factors, quality of a denture bearing area (attached mucosa and the alveolar bone), quality of new dentures, etc. (17,20,25,27). Therefore, it is not completely clarified how long a patient needs to adapt to new dentures and are there any differences in adaptation between conventional CD wearers and those with mandibular mini-implant ODs.

This study aimed to assess how long it needs for a patient, based on the self-reported outcome measures: oral health reported quality of life (OHRQoL) and orofacial esthetics (OES), to adapt to complete CDs and how long it needs to adapt to mini-implant mandibular ODs (MDI-OD) oppos-

prirodni zubi gube kasnije u životu, ali postotak starije populacije jednak je tako brzo raste zbog napretka opće medicine i bolje zdravstvene skrbi. Danas ljudi mogu očekivati da će doživjeti šezdesete godine i da će biti stariji (2, 3). Zato će, iako je u zemljama s visokim dohotkom zabilježen pad potpune bezubosti, broj bezubih pacijenata i dalje rasti zbog sve duljega životnoga vijeka (4, 5). Dugo su potpune proteze (CD) bile jedina terapijska mogućnost kad je riječ o bezubim pacijentima (5). Danas su one poboljšane ugradnjom dentalnih implantata, ali samo za one koji su u mogućnosti dobiti (ili platiti) takvu vrstu terapije.

Mnogi pacijenti ne mogu si priuštiti terapiju implantatima zbog finansijskih ograničenja, općih zdravstvenih problema ili neadekvatnoga volumena kosti, što se često događa kod nositelja mobilnih proteza (5 – 8). Stoga će potpune proteze i dalje biti jedina opcija za većinu bezubih osoba (9). Pacijenti koji su se određeno vrijeme služili potpunim protezama susreću se s problemima prouzročenima kontinuiranom resorpcijom rezidualnoga grebena i atrofijom kosti, upalama i ozljedama oralne sluznice, razvojem pomičnoga grebena, posljedičnim gubitkom stabilnosti proteze i smanjenjem vertikalne dimenzije okluzije s rotacijom mandibule u smjeru suprotnom od kazaljke na satu (6 – 8, 10 – 13). Resorpcija rezidualnoga alveolarnoga grebena mandibule gotovo je četiri puta izraženija u odnosu prema maksili (6 – 8). Zato je skupina stručnjaka predložila da minimum terapije za bezube pacijente bude pokrovna proteza retinirana na dvama implantatima u donjoj čeljusti i potpuna u gornjoj čeljusti (McGillov konsenzus iz 2002. godine) (14). McGillov konsenzus utemeljen je na dokazima da zubni implantati značajno smanjuju resorpciju rezidualnoga alveolarnoga grebena, ne samo na mjestu ugradnje implantata nego i na udaljenim područjima (11, 15). Kod pacijenata s uskim alveolarnim grebenima, rehabilitacija donjom pokrovnom protezom retiniranom na četirima miniimplantima preporučuje se kao alternativa totalnoj pokrovnoj protezi retiniranoj na dvama implantatima (14,16 – 19)

Ishodi terapije iz perspektive pacijenata, tj. kako oni sami procjenjuju učinak terapije (dPROM) u vezi s kvalitetom života ovisnom o oralnome zdravlju (OHRQoL), estetikom ili nekom drugom mjerom, postaju najvažniji čimbenici u stomatologiji temeljnoj na dokazima (20 – 24). Kadak se mišljenja terapeuta i pacijenata o učinkovitosti terapije mogu razlikovati, pa pacijenti nisu zadovoljni terapijom (20, 25, 26).

Prilagodba na konvencionalne potpune proteze ili pokrovne proteze na implantatima može varirati ovisno o mnogim čimbenicima, kao što su iskustvo u vezi s mobilnim protezama, očekivanja, psihosocijalni i kulturološki čimbenici, kvaliteta ležista proteze (pričvršćna sluznica i alveolarna kost), kvaliteta novih proteza i slično (17, 20, 25, 27). Zato nije u cijelosti razjašnjeno koliko dugo treba pacijentu da se priladi na novu protezu i postoje li razlike u prilagodbi između nositelja konvencionalnih potpunih proteza i onih s donjim pokrovnim protezama na miniimplantima.

Cilj ovog istraživanja bio je procijeniti s pomoću ishoda terapije iz perspektive pacijenata (procjena kvalitete života ovisne o oralnome zdravlju: OHRQoL i orofacialna estetika) koliko je vremena potrebno za prilagodbu na konvencionalne potpune proteze (skupina CD), a koliko za prilagodbu na

ing a maxillary CD. The aim was also to compare the groups over the five years in function.

## Material and methods

### Sample

This study included completely edentulous subjects who were rehabilitated either with new conventional complete dentures (CDs) or with one new conventional CD in the maxilla and one new mini-implant retained OD in the mandible. Forty-four subjects were included at the baseline in the CD group and 36 in the MDI-OD group. It was planned to assign patients randomly into the CD or the MDI-OD group (odd or even numbers), but some participants did not want to be rehabilitated with implants due to fear or general health problems; therefore, they were assigned to the CD group. Subjects with wide residual ridges who could receive two standard-sized implants and an OD were also excluded. After five years of follow-up, only 36 subjects in the CD group were available and 30 subjects in the MDI group who had all four mini-implants which were inserted at baseline and which were successful. Only their self-reported data were included in the statistical analysis. After insertion of four mini-implants, new dentures were made: at the Department of Removable Prosthodontics, School of Dental Medicine, Zagreb, Croatia; and at the Dental Private Office, Makarska. All mini-implants were inserted, and all dentures were made following the same criteria in a period from September 2015 to December 2016. The Ethics Committee of the School of Dental Medicine in Zagreb (No. 05-PA-26-6/2015) approved the study. The costs of the MDIs were covered by the research grant No. 1218/2014 (Croatian Science Foundation) and the cost of dentures by the Social Insurance.

### Surgical procedures for mini-implant insertion

All participants assigned into the MDI-OD group received four ball-type MDIs in sites of their previous second incisors (32, 42) and first premolars (34, 44). The Dentium, South Korea mini-implants were 2.0-2.5 mm wide and 10-14 mm long. Participants with a flabby ridge and mucosal thickness higher than 4 mm were excluded, and also patients who could receive standard-sized implants. Two experienced surgeons performed all surgical procedures after consulting a specialist in Prosthodontics. The MDIs' length and width were determined based on the available bone volume measured on pre-operative CBCTs and panoramic radiographs. The surgical procedures were made either by a flapless or an open-flap technique, depending on the morphology of available bone. The open-flap technique was applied when a pointed slim alveolar ridge was leveled or when movable mucosal tissue needed to be de-attached. A physio-dispenser (W&H Implantmed, GmbH, Austria) and a saline solution for external drill cooling were used for the MDI insertion. The implant sites were prepared using pilot and final drills. The final drill diameter was always smaller than the MDI diameter (1.3-1.5 mm wide drills for 2.0 mm wide MDIs;

pokrovne proteze retinirane na miniimplatima u donjoj čeljusti te na potpunu protezu u gornjoj čeljusti (skupina MDI-OD). Cilj je također bio uspoređivati te dvije skupine tijekom pet godina u funkciji.

## Materijal i metode

### Uzorak

U ovo istraživanje bili su uključeni potpuno bezubi rehabilitirani pacijenti ili oni s novim konvencionalnim potpunim protezama (CD) u objema čeljustima ili s novim konvencionalnim CD-om u maksili i novom pokrovnom protezom retiniranom miniimplatima (MDI – CD) u mandibuli. Na početku su u skupini CD bila 44 ispitanika, a u skupini MDI-OD 36. Planirano je da se pacijenti nasumično rasporede u skupinu CD ili MDI-OD (neparni ili parni brojevi), ali neki sudionici zbog straha ili općih zdravstvenih problema nisu željeli rehabilitaciju implantatima pa su raspoređeni u skupinu CD. Ispitanici sa širokim rezidualnim grebenima u koje je bilo moguće ugraditi dva implantata standardne veličine kao potporu pokrovnoj protezi, također su bili isključeni. Nakon pet godina praćenja, samo je 36 ispitanika u skupini CD bilo dostupno, kao i 30 u skupini MDI-OD, a koji su imali sva četiri miniimplantata koja su bila ugrađena na početku istraživanja i koji su bili kategorizirani kao uspješni. U statističku analizu uvršteni su samo njihovi podaci. Nakon ugradnje četiriju miniimplantata izrađene su nove proteze u Zavodu za mobilnu protetiku Stomatološkog fakulteta u Zagrebu i u privatnoj Ordinaciji dentalne medicine u Makarskoj. Svi su miniimplantati ugrađeni i sve nove proteze izrađene prema istim kriterijima od rujna 2015. do prosinca 2016. Ovo istraživanje odobrilo je Etičko povjerenstvo Stomatološkog fakulteta u Zagrebu (br. 05-PA-26-6/2015). Troškovi miniimplantata bili su pokriveni projektom Hrvatske zaklade za znanost (HRZZ br. 1218/2014), a troškove izrade proteza platio je Hrvatski zavod za zdravstveno osiguranje.

### Kirurški postupak ugradnje miniimplantata

Svim sudionicima raspoređenima u skupinu MDI-OD ugrađena su četiri miniimplantata s kuglastom glavom i to na mjestima prijašnjih drugih sjekutića (32, 42) i prvih pretkutnjaka (34, 44). Ugrađeni miniimplantati (Dentium, Južna Koreja) bili su široki od 2,0 do 2,5 mm i dugi od 10 do 14 mm. Iz istraživanja su bili isključeni sudionici s pomicnim grebenom (engl. *flabby ridge*) i debljinom sluznice većom od 4 mm, te pacijenti kojima su se mogli ugraditi implantati standardne veličine. Dva iskusna kirurga obavila su sve kirurške zahvate nakon konzultacija sa specijalistom stomatološke protetike. Duljina i širina miniimplantata određene su na temelju raspoloživoga volumena kosti izmjereno na preoperativnom CBCT-u i ortopantomogramskim snimkama. Primjenjena je tehnika bez odizanja mukoperiostalnoga režnja ili tehnika uz odizanje mukoperiostalnoga režnja, ovisno o morfologiji raspoložive kosti. Tehnika uz odizanje mukoperiostalnoga režnja korištena je kada je bilo potrebno izravnati tanak i šljast alveolarni greben ili kada je bilo potrebno ukloniti pomicno tkivo sluznice. Za ugradnju MDI-ja korišteni su fizioredispenser (W&H Implantmed, GmbH, Austrija) i fiziološka otopina za vanjsko hlađenje svrdala. Mjesta za ugradnju implantata pre-

1.8–2.3 mm wide drills for 2.5 mm wide MDIs). The depth preparation was determined dependent on the bone quality assessed on the CBCTs (Hounsfield units). The preparations were made one, two, or three mm less than the implant length (longer preparation was performed in denser bone), except when the implant had to end in the dense lower mandibular cortex (D1 density). In that case, the whole implant length was drilled. For the flapless technique, the width of alveolar mucosa was measured and accounted. Antibiotics were administrated for prophylactic reasons (2 g amoxicillin or 600 mg Clindamycin one hour before the surgical procedure). All preparations and MDI insertions were made under local anesthesia (Ubistesine forte 4% or Mepivastesin 3%, 3M). Each MDI was inserted into the prepared hole and rotated clockwise, exerting a downward pressure (self-tapping insertion technique). The mini-implants were placed into the preparation hole by a carrier (plastic finger driver from the original package), then were rotated downwards by a thumb wrench, and finally, the torque wrench. The whole roughened threaded MDI surface was inserted into the bone. The transmucosal part of the smooth surface emerged from the attached mucosa into the oral cavity with the ball-type head. The patients were given the standard post-surgical instructions: no hot beverages, alcohol, or smoking for two days, ice-packs for cooling, and analgesics (non-steroid anti-inflammatory drugs) if necessary. An antiseptic mouth rinse (chlorhexidine gluconate 0.12%) was also prescribed for five days, and detailed instructions for oral hygiene maintenance were given. A range of final insertion torque values varied between 30 and 55 Ncm. New dentures were delivered and loaded 7–10 days after mini-implant insertion in the respective group.

#### Prosthodontic protocol (Complete denture or mini-implant overdenture manufacture)

All CDs and mandibular MDI-ODs were fabricated following the same procedures. After the alginate impressions, custom trays were made, and custom (individual) impressions were obtained for each patient. Then a vertical jaw relation in a centric position was registered by occlusal rims and transferred into a semi-adjustable articulator. Next, the semi-anatomical artificial teeth and a lingualized occlusion scheme with no occlusal balance were applied. After artificial teeth set-up in a trial denture and verification of satisfactory esthetics and antagonistic contacts in centric relation, the new CDs were processed. After new dentures delivery and mounting of metal-housings with O-rings in the MDI-OD group, the occlusion was checked and adjusted if necessary, oral mucosa was inspected for soreness, and the denture was trimmed off when necessary during adaptation. All mandibular overdentures were strengthened with a CoCr metal framework not to fracture. At the MDI-OD deliveries, four metal housing with O-rings (matrices) were mounted directly in the patient's mouth using a self-curing acrylic resin and block-out spacers (block-out shims).

parirana su s pomoću pilot-svrdala i završnih svrdala. Konačni promjer svrdla uviјek je bio manji od promjera MDI-ja (1,3 – 1,5 mm široko svrdlo za MDI širine 2,0 mm; svrdlo širine 1,8 – 2,3 mm za MDI širine 2,5 mm). Dubina preparacije određena je ovisno o kvaliteti kosti procijenjenoj na CBCT-u (Hounsfieldove jedinice). Preparacije su rađene jedan, dva ili tri mm kraće od dužine samoga implantata (duža preparacija radila se u gušćoj kosti), osim kada je implantat trebao završiti u gustome mandibularnome korteksu (gustoća D1). U tom slučaju preparirana je cijela dužina implantata. Za tehniku bez odizanja mukoperiostalnoga režnja izmjerena je širina nepomične alveolarne mukoze te je uzeta u obzir pri planiranju dužine implantata. Antibiotici su korišteni iz profilaktičnih razloga (2 g amoksicilina ili 600 mg klindamicina jedan sat prije kirurškoga zahvata). Ugradnja MDI-ja obavljena je uviјek u lokalnoj anesteziji (Ubistesine forte 4 % ili Mepivastesin 3 %, 3M). Svaki MDI inseriran je u preparirano ležište i rotiran u smjeru kazaljke na satu, čineći pritisak prema dolje (tehnika samorezujućeg uvijanja). Miniimplantati su postavljeni u preparirano ležište s pomoću nosača (plastični nosač za prste iz originalnog pakiranja), zatim su leptir-ključem rotirani prema dolje i na kraju s pomoću moment-ključa. Miniimplantati su uviјani u preparirano ležište sve dok cijela hrapava površina s navojem nije bila u kosti. Transmukozni dio glatke površine izlazio je iz pričvrstne mukoze u usnu šupljinu s kuglastom glavom. Pacijenti su poslije kirurškoga zahvata dobili standardne upute – bez toplih napitaka, alkohola i pušenja dva dana, stavljanje ledenih obloga za hlađenje te prema potrebi analgetici (nesteroидni protuupalni lijekovi). Propisan im je i antiseptik za ispiranje usta (klorheksidin-glukonat 0,12 %) u trajanju od pet dana te su im dane detaljne upute o održavanju oralne higijene. Raspon momenta sile na ključu pri ugradnji implantata varirao je između 30 i 55 Ncm. Nove proteze isporučene su i opterećene od 7 do 10 dana nakon ugradnje miniimplantata u skupini MDI-OD.

#### Protetički protokol (potpune proteze i pokrovne proteze retinirane miniimplantatima)

Sve potpune i pokrovne proteze u mandibuli napravljene su jednakim postupcima. Nakon alginatnih otisaka izrađene su individualne žlice te su svakom pacijentu uzeti funkcionalni otisci. Zatim je registrirana vertikalna dimenzija zagriza u centričnoj relaciji s pomoću zagriznih šablonu te prenesena u poluprilagodljivi artikulator. Pri postavljanju zuba korišteni su poluanatomski umjetni zubi i shema lingvalizirane okluzije. Nakon ugradnje umjetnih zuba u šablonu i provjere zadovoljava li estetika te antagonističkih kontakata u centričnoj relaciji, slijedila je polimerizacija i obrada proteza. Nakon predaje novih proteza i ugradnje metalnih kućišta s O-prstenovima u skupini MDI-OD, provjerena je okluzija te je prema potrebi prilagođena, a rubovi proteze adaptirani su pri predaji. Sve pokrovne proteze u mandibuli bile su ojačane metalnim skeletom (CoCr) kako bi se prevenirale frakture. Pri predaji MDI-OD-a, četiri metalna kućišta s O-prstenovima (matrice) ugrađena su direktno u pacijentova usta s pomoću samostvrdnjavajućeg akrilata i uz korištenje gumenih prstenova za blokiranje podminiranih područja i periimplantne mukoze.

Two experienced specialists in Prosthodontics who were not involved in the CD or OD manufacture assessed the quality of new dentures for retention, stability, esthetics, and occlusion. The possible assessments were: low-quality, average quality, or high-quality dentures. Only patients with high-quality new dentures were recruited in the study. The weighted kappa statistics showed satisfactory agreement between the observers ( $\kappa = 0.808$ ).

#### Questionnaires: d-PROMS

One day after the new CD or MDI-OD delivery, the patients had to fill in data about gender, age, and their previous dental status [fixed partial denture or natural teeth (FPD); removable partial denture (RPD)]. They also had to fill in the validated questionnaires, i.e., the OHIP-EDENT questionnaire consisting of 19 questions (28) and the orofacial esthetic scale (OES), consisting of eight questions (29). The OHIP-EDENT comprised 19 questions with answers from 0 (without problems) to 4 (maximum problems). Lower scores represent better OHRQoL. The OES comprised eight questions with answers from 1 to 5 (1-the worst score, 5= the best score). Higher scores represented better esthetics. All patients also filled in the same questionnaires on the 3<sup>rd</sup>, 8<sup>th</sup>, 15<sup>th</sup>, and 30<sup>th</sup> days. The same assessments were repeated after 12 months, after 3 years, and after 5 years of wearing a denture. The checks were made in a dental office one day after delivery, the 3<sup>rd</sup>, 8<sup>th</sup>, and 15<sup>th</sup> day. If patients needed any more denture adjustments, they came to a dental office, but if not, they were assessed by telephone. The summary score of each of the two questionnaires was divided by the number of questions. Then, the data were entered for statistical analysis.

#### Statistical analysis

The IBM-SPSS Statistics for Windows (Version 20.0.; IBM Corp) was used. Descriptive statistics (mean values and standard deviations) were calculated.  $X^2$  test and independent t-test were also used. Changes over time were analyzed by Friedman's non-parametric test for related samples in each group, while the significance of the differences between the CD and the MDI-OD group was assessed with the non-parametric Mann-Whitney U test.

#### Results

A total of 36 participants in the CD group completed the five-year study: 25 were females and 11 males. In the MDI-OD group, from a total of 30 participants who completed the study, 20 were females, and 10 were males. No gender difference was observed between the groups ( $X^2=0.058$ ;  $df=1$ ;  $P=.809$ ). The participants in the MDI-OD group were a bit younger ( $65.1 \pm 6.2$  years) than in the CD group ( $68.9 \pm 8.2$  years) ( $t=2.08$ ,  $df=64$ ;  $P=.04$ ). From the baseline of 36 patients in the MDI-OD group, one patient lost two MDIs in the first year, one patient lost one MDI after two years, and one patient lost all four mini-implants in the 5<sup>th</sup> year, while three MDI-OD patients were not available at least at the one of the recall examinations. All of them were exclud-

Dva iskusna specijalista stomatološke protetike, koji nisu bili uključeni u izradu proteza, procjenjivali su kvalitetu retencije i stabilnosti te estetiku i okluziju novih proteza. Moguće ocjene bile su sljedeće: nekvalitetne proteze, prosječno kvalitetne ili visokokvalitetne proteze. U istraživanje su uključeni samo pacijenti s visokokvalitetnim novim protezama. Statistička analiza pokazala je zadovoljavajuće slaganje između promatrača (*weighted kappa*,  $\kappa = 0.808$ ).

#### Upitnici: procjena terapije iz perspektive stomatološkog pacijenta (d-PROMS)

Jedan dan poslije predaje novih proteza (CD ili MDI-OD) pacijenti su morali ispuniti podatke o spolu, dobi i prethodnom stomatološkom statusu [most ili prirodnii zubi (FPD), djelomična proteza (RPD)]. Također su morali ispuniti validirane upitnike, odnosno upitnik OHIP-EDENT koji se sastojao od 19 pitanja (28) i orofacijalnu estetsku ljestvicu (OES) od osam pitanja (29). Upitnik OHIP-EDENT sastojao se od 19 pitanja s odgovorima od 0 (bez problema) do 4 (maksimalni problemi). Manji zbroj bodova pokazuje bolju kvalitetu života ovisnu o oralnome zdravlju (OHRQoL). Upitnik OES sastojao se od osam pitanja s odgovorima od 1 do 5 (1 – najlošija ocjena, 5 – najbolja ocjena). Veći zbroj bodova značio je bolju estetiku. Svi pacijenti ispunjavali su jednake upitnike 3., 8., 15. i 30. dan poslije predaje proteza. Iste procjene ponavljane su poslije 12 mjeseci nošenja proteze, te poslije 3 i 5 godina. Kontrole su obavljene u stomatološkoj ordinaciji dan poslije predaje proteza te zatim 3., 8. i 15. dan. Ako su pacijenti trebali neku prilagodbu proteze, došli bi u ordinaciju, no ako nisu, na pitanja iz upitnika odgovarali su telefonski. Zbroj bodova iz svakoga od dvaju upitnika podijeljen je s brojem pitanja. Zatim su ti podatci uneseni za statističku analizu.

#### Statistička analiza

Korišten je IBM-SPSS statistički program za Windows (verzija 20.0.; IBM Corp). Izračunata je deskriptivna statistika (srednje vrijednosti i standardne devijacije). Također su korišteni  $X^2$  test i t-test za nezavisne uzorke. Promjene tijekom vremena analizirane su Friedmanovim neparametrijskim testom za zavisne uzorke u svakoj skupini, a značajnost razlika između skupina CD i MDI-OD procijenjena je neparametrijskim Mann-Whitneyjevim U testom.

#### Rezultati

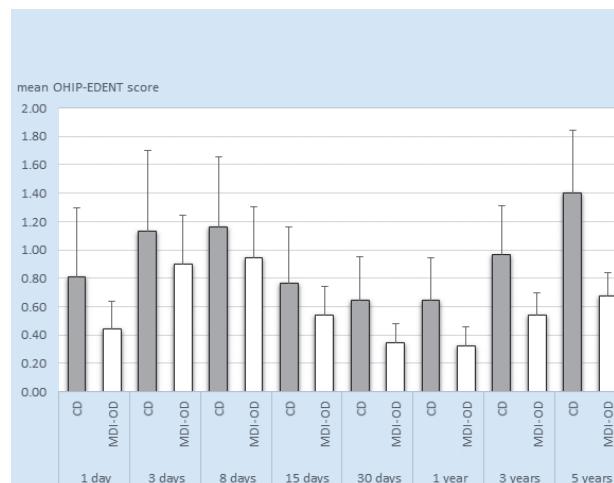
Od 36 pacijenata u skupini CD 25 su bile žene, a 11 muškarci. U skupini MDI-OD, od ukupno 30 pacijenata, 20 su bile žene, a 10 muškarci. Nije pronađena značajna razlika između skupina prema spolu ( $X^2=0.058$ ;  $df = 1$ ;  $P = 0.809$ ). Ispitanici u skupini MDI-OD bili su nešto mlađi ( $65.1 \pm 6.2$  godine) nego oni u skupini CD ( $68.9 \pm 8.2$  godine) ( $t = 2.08$ ,  $df = 64$ ;  $P = 0.04$ ). Od početnoga broja (36 pacijenata) u skupini MDI-OD, jedan pacijent izgubio je dva mini-implantata u prvoj godini, jedan je izgubio jedan MDI nakon dvije godine, a jedan pacijent izgubio je sva četiri mini implantata u petoj godini. Tri pacijenta u skupini MDI-OD nisu bila ni na jednom uskcesivnom pregledu. Oni su isključeni iz istraživanja o OHRQoL-u i OES-u. Poslije 5 godina

ed from the OHRQoL and OES research. A total of 95,14% mini-implants remained successful after five years. A total of 90,09% of patients had successful all four mini-implants after 5 years. Of the 44 patients in the CD group, eight did not respond to at least one of the recall examinations and were excluded. Only those patients who responded to all recalls were statistically analyzed.

Mean OHIP-EDENT scores in the CD and the MDI-OD groups and standard deviations are presented in Figure 1.

Mean OES scores in the CD and the MDI-OD group and standard deviations are presented in Figure 2.

The significance of the differences between the CD and the MDI-OD group for the OHRQoL and OES at each of the recall examinations is presented in Table 1.



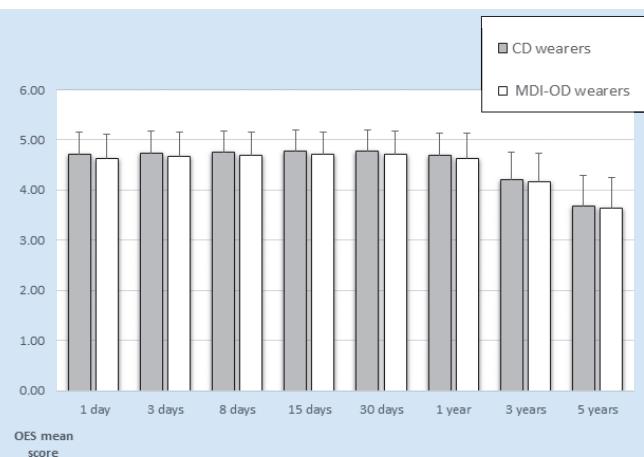
**Figure 1** Mean OHIP-EDENT scores in the CD group and the MDI-OD group together with standard deviations

**Slika 1.** Srednje vrijednosti bodova OHIP-EDENT u skupini nositelja totalnih (potpunih) proteza (CD) i u skupini nositelja donje pokrovne proteze na miniimplantima i gornje potpune proteze (MDI-OD) zajedno sa standardnim devijacijama

od ukupnoga broja ugrađenih miniimplantata ostalo je 95,14% uspješnih, a 90,09 % pacijenata imalo je sva četiri uspješna miniimplantata nakon 5 godina. Od 44 pacijenta u skupini s konvencionalnim protezama (CD), osam nije došlo ni na jedan kontrolni pregled i zato su bili isključeni iz daljnog istraživanja. Statistički su analizirani samo oni pacijenti koji su došli na sve kontrolne preglede tijekom petogodišnjega kliničkoga praćenja.

Srednje vrijednosti bodova upitnika OHIP-EDENT u skupinama CD i MDI-OD zajedno sa standardnim devijacijama nalaze se na slici 1.

Srednje vrijednosti bodova upitnika OES u skupinama CD i MDI-OD zajedno sa standardnim devijacijama nalaze se na slici 2.



**Figure 2** Mean OES scores in the CD group and the MDI-OD group together with standard deviations

**Slika 2.** Srednje vrijednosti OES bodova u skupini nositelja totalnih (potpunih) proteza (CD) i u skupini nositelja donje pokrovne proteze na miniimplantima i gornje potpune proteze (MDI-OD) zajedno sa standardnim devijacijama

**Table 1** Significance of the differences between the CD and the MDI-OD groups for the OHRQoL and OES at the recall examinations assessed by the Mann-Whitney U test.

**Tablica 1.** Značajnost razlika, procijenjena Mann-Whitneyevim U testom, između nositelja potpunih proteza (CD) i nositelja donje pokrovne proteze na miniimplantima i gornje potpune proteze (MDI-OD) u kvaliteti života ovisnoj o oralnome zdravlju (OHRQoL) i u orofacialnoj estetskoj ljestvici (OES) na svim kontrolnim pregledima

#### Oral Health-Related Quality of Life (OHRQoL) • Kvaliteta života ovisna o oralnome zdravlju (OHRQoL)

OHIP19 EDENT	OHIP19 1 day • 1. dan	OHIP19 3 days • 3. dan	OHIP19 8 days • 8. dan	OHIP19 15 days • 15. dan	OHIP19 30 days • 30. dan	OHIP19 1 year • 1 godina	OHIP19 3 years • 3 godine	OHIP 19 5 years • 5 godina
Mann-Whitney U	285.00	431.00	403.50	355.00	292.50	298.50	197.00	188.50
Wilcoxon W	750.00	896.00	868.50	820.00	757.50	763.50	662.00	653.50
Z	-3.30	-1.41	-1.76	-2.39	-3.21	-3.14	-4.44	-4.55
P (2-tailed • dvosmjeri)	<0.001**	<b>0.160 NS</b>	<b>0.080 NS</b>	0.020*	<0.001**	<0.001**	<0.001**	<0.001**

#### Orofacial esthetics (OES) • Orofacialna estetska ljestvica (OES)

OES	OES 1 day • 1. dan	OES 3 days • 3. dan	OES 8 days • 8. dan	OES 15 days • 15. dan	OES 30 days • 30. dan	OES 1 year • 1 godina	OES 3 years • 3 godina	OES 5 years • 5 godina
Mann-Whitney U	494.00	504.00	503.50	494.50	497.00	509.00	527.50	529.50
Wilcoxon W	959.00	969.00	968.50	959.50	962.00	974.00	992.50	994.50
Z	-0.66	-0.55	-0.56	-0.71	-0.69	-0.45	-0.16	-0.14
P	0.51 NS	0.58 NS	0.58 NS	0.48 NS	0.49 NS	0.65 NS	0.87NS	0.89 NS

**Table 2** Significance of the differences between the periods of observation for the CD and the MDI-OD groups assessed by the Friedman test  
**Tablica 2.** Značajnost razlika tijekom vremena, u skupini nositelja potpunih proteza (CD) i u skupini nositelja donje pokrovne proteze na miniimplantatima i gornje potpune proteze (MDI-OD) s pomoću Friedmanova testa

OES	CD wearers			MDI-ODs		
	Mean Rank • Srednji rang			Mean Rank • Srednji rang		
OES - 1 day • 1 dan	5.19	$X^2=197.387$ $df = 7$ $p<0.001^{**}$	N=36	5.13	$X^2=170.032$ $df = 7$ $p<0.001^{**}$	N=30
OES - 3 days • 3 dana	5.39			5.42		
OES . 8 days • 8 dana	5.53			5.55		
OES - 15 days • 15 dana	5.65			5.73		
OES - 30 days • 30 dana	5.72			5.82		
OES - 1 year • 1 godina	4.93			5.02		
OES - 3 years • 3 godina	2.33			2.18		
OES - 5 years • 5 godina	1.25			1.15		
OHRQoL	CD wearers			MDI-ODs		
	Mean Rank • Srednji rang			Mean Rank • Srednji rang		
OHIP19 - 1 day	3.67	$X^2=171.32$ $df = 7$ $p<0.001^{**}$	N=36	2.72	$X^2=162.610$ $df = 7$ $p<0.001^{**}$	N=30
OHIP19 - 3 days	5.99			6.55		
OHIP19 - 8 days	6.42			6.87		
OHIP19 - 15 days	3.68			3.90		
OHIP19 - 30 days	1.90			1.95		
OHIP19 - 1 year	1.93			2.07		
OHIP19 - 3 years	5.31			5.08		
OHIP 19 - 5 years	7.11			6.87		

The significance of the differences between each period of observation for the CD group and the MDI-OD group was assessed by the Friedman test for related samples and shown in Table 2.

Results showed that after one day of denture wearing, the CD group had significantly worse OHRQoL (higher OHIP-EDENT scores) than the MDI-OD wearers. At all clinical examinations, OHRQoL was significantly better in the MDI-OD group than in the CD group ( $p<0.01$ ), except on the 3<sup>rd</sup> and the 8<sup>th</sup> day, when there was no significant difference between the groups. On the 15<sup>th</sup> day, the difference was significant at  $p<.05$ . After 30 days, the scores were the lowest in both groups (Fig. 1, Table 2), but were significantly higher in the CD wearers (Fig. 1, Table 1). The scores remained unchanged during the 1<sup>st</sup> year of denture wearing (Fig. 1, Table 1, Table 2). However, after three years of denture wearing, the scores significantly rose in both groups (Fig. 1, Table 1, Table 2), but almost two times more in the CD wearers. After five years, the scores again increased significantly and were significantly higher in the CD wearers than in the MDI-OD wearers.

Orofacial esthetics was highly scored in both groups from the baseline throughout the first year of follow-up ( $p>0.05$ ), and then the scores reduced at the 3-year and 5-year follow-up ( $p<0.05$ ). There was no significant difference in OES mean scores between the groups for any observed periods.

Značajnosti razlika između skupine CD i MDI-OD za OHRQoL i OES na svakome od kontrolnih pregleda prikazani su u tablici 1.

Značajnost razlika između svakoga razdoblja promatrana, posebno za skupinu CD i posebno za skupinu MDI-OD, procijenjena je Friedmanovim testom za zavisne uzorke i prikazana u tablici 2.

Rezultati su pokazali da je već prvi dan nošenja novih proteza, skupina CD imala znatno lošiju kvalitetu života ovisnu o oralnome zdravlju (OHRQoL; veće vrijednosti bodova OHIP-EDENT-a) od skupine MDI-OD. Nadalje, i na svim kliničkim pregledima OHRQoL je bio znatno bolji u skupini MDI-OD u usporedbi sa skupinom CD ( $p < 0,01$ ), osim trećega i osmoga dana kada između njih nije bilo značajne razlike. Već 15. dan razlika je bila ponovo značajna  $p < 0,05$  (bolja kvaliteta života u skupini MDI-OD). Poslije 30 dana bodovi su bili najniži u objema skupinama (slika 1., tablica 2.), ali bili su znatno viši (lošija kvaliteta života) kod onih koji su imali konvencionalne totalne proteze (slika 1., tablica 1.). Bodovi iz upitnika OHIP-EDENT ostali su nepromijenjeni tijekom prve godine nošenja proteze (slika 1., tablice 1 i 2.). Međutim, nakon tri godine znatno su porasli u objema skupinama (slika 1., tablice 1. i 2.), ali gotovo dvostruko više kod pacijenata koji su nosili CD. Nakon pet godina bodovi su se ponovno znatno povećali u obje skupine (< OHRQoL), ali su bili znatno viši (manja kvaliteta života) kod ispitanika s CD-om nego kod onih s MDI-OD-om.

Orofacijalna estetika bila je vrlo visoko ocijenjena u objema skupinama od početka istraživanja (predaja proteza) i tijekom prve godine ( $p > 0,05$ ), a zatim su se bodovi pogoršali u trećoj i petoj godini ( $p < 0,05$ ). Nije bilo značajne razlike u ocjenama za OES između navedenih skupina u bilo kojem promatranom razdoblju.

## Discussion

It has not been clarified how long a patient needs to adapt to new CDs or to a maxillary CD opposing four mini-implant OD in the mandible (MDI-OD). Therefore, we designed a clinical prospective cross-over study based on dental patient self-reported measures, i.e., OHRQoL and OES. The OHIP-EDENT questionnaire has already been psychometrically validated in many countries and languages and was a logical choice for assessing OHRQoL for edentulous patients (28,30-33). After the first day of new denture wearing, the OHIP EDENT scores gradually increased through the 3<sup>rd</sup> and the 8<sup>th</sup> day and then gradually decreased (the 15<sup>th</sup> day) and reached the lowest values after 30 days in both groups. The scores remained unchanged throughout the first year of denture wearing. The pattern of OHIP EDENT scores was similar in both groups. However, significantly lower values (better OHRQoL) were recorded in the MDI-OD group after one day, 15 days, 30 days, 1, 3, and 5 years of denture wearing. The difference between the groups was not significant only on the 3<sup>rd</sup> day and 8<sup>th</sup> day, although MDI-OD group still had better OHRQoL. It has already been reported that in the first days of new denture wearing, dentures usually cause inflammation of underlying mucosa, soreness, pain and discomfort, and consequently low masticatory performance (34,35). Although mini-implants offer better retention and stability to mandibular overdenture than residual alveolar ridge to conventional mandibular CDs, when soreness and pain are present, patients cannot chew properly even if retention and stability of their dentures offer such possibility. That was probably why no statistically significant difference was found between the groups on the 3<sup>rd</sup> and 8<sup>th</sup> days. After denture and occlusal adjustments and healing of sore spots, the OHIP EDENT scores dropped on the 15th day in both groups, and the MDI-OD group again revealed significantly better OHRQoL. The lowest scores recorded on the 30<sup>th</sup> day remained unchanged over the first year of new denture wearing in both groups, with significantly better OHRQoL in the MDI-OD group (Figure 1). The adaptation to new dentures lasts up to one month in both groups. Better OHRQoL recorded in the MDI-OD group than in the conventional CD wearers is in line with many other reports on implant overdenture patients (17, 27, 36-38). IODs are associated with significantly better patient quality of life and masticatory performance. After 3 and 5 years of denture wearing, scores significantly rose in both groups (worse OHRQoL), but almost two times higher in the CD group (worse OHRQoL) than in the MDI-OD group. Although mini-implants offer better retention and stability to the mandibular denture and allow better masticatory function, we must keep in mind that those patients still have CDs in the maxilla, which may lose retention over time. The matrices' O-rings in the MDI-OD group also lose retention over time and must be changed.

As another d-PROM, the OES questionnaire has been used in our study. The OES is the one-dimensional questionnaire developed to assess orofacial esthetics and has been psychometrically adopted in many countries and languages.

## Rasprava

Nije razjašnjeno koliko dugo se pacijenti prilagođuju na nove konvencionalne potpune proteze u objema čeljustima (CD) ili na gornju potpunu protezu nasuprot donje pokrovne potpune proteze koja se retinira na četiri miniimplantata (MDI – OD). Zato smo osmisili kliničko prospективno istraživanje na temelju ishoda prema procjenama samih pacijenata, tj. pacijenti su procjenjivali kvalitetu života ovisnu o oralnome zdravlju (OHRQoL) i orofacialnu estetiku (OES). OHIP-EDENT je psihometrijski upitnik već validiran u mnogim zemljama i na mnogim jezicima te je bio logičan izbor za procjenu OHRQoL-a kod bezubih pacijenata (28, 30 – 33). Poslije prvoga dana nošenja nove proteze bodovi OHIP EDENT-a postupno su se povećavali 3. i 8. dan, a zatim su se smanjivali (15. dan) te u objema skupinama dosegli najniže vrijednosti nakon 30 dana. Rezultati su ostali nepromijenjeni tijekom prve godine nošenja proteze. Obrazac rezultata OHIP EDENT-a bio je sličan u objema skupinama. Međutim, statistički su značajno niže vrijednosti (bolja kvaliteta života ovisna o oralnome zdravlju: OHRQoL) zabilježene u skupini MDI-OD poslije jednoga dana, 15 dana, 30 dana, te 1, 3 i 5 godina nošenja proteze. Razlika između skupina nije bila značajna samo 3. i 8. dan, iako je skupina MDI-OD ipak i tada imala bolji OHRQoL. Već se zna da u prvim danima nošenja proteze, ako su nove, obično prouzroče upalnu promjenu sluznice na ležištu, bol i nelagodu te posljedično slabiju žvačnu sposobnost (34, 35). Iako miniimplantati omogućuju bolju retenciju i stabilnost donjoj protezi nego samo rezidualni alveolarni grebeni kod konvencionalnih potpunih proteza, ako su prisutni bol i upala, pacijenti ne mogu pravilno žvakati čak ako im to omogućuju retencija i stabilnost njihovih proteza. Vjerojatno zbog toga nije pronađena statistički značajna razlika između skupina tijekom trećega i osmoga dana. Nakon prilagodbe proteza i brušenja rubova i uskladivanja okluzije te zacjeljivanja bolnih mesta, bodovi iz upitnika OHIP EDENT smanjili su se 15. dan u objema skupinama, ali je skupina MDI-OD ponovno imala znatno bolju kvalitetu života: OHRQoL. Najniži bodovi, zabilježeni 30. dan, ostali su nepromijenjeni tijekom prve godine nošenja novih proteza u objema skupinama, ali uz znatno bolju kvalitetu života ovisnu o oralnome zdravlju (OHRQoL) u skupini MDI-OD (slika 1.). Prilagodba na nove proteze u objema skupinama traje do mjesec dana. Bolji OHRQoL zabilježen u skupini MDI-OD nego kod nositelja konvencionalnih CD-a i u skladu je s mnogim drugim istraživanjima o pacijentima s pokrovnim protezama na implantatima (IOD) (17, 27, 36 – 38). IOD-i su povezani sa znatno boljom kvalitetom života i boljim žvačnim učinkom. Poslije 3 i 5 godina nošenja proteza, bodovi su značajno porasli u objema skupinama (pogoršanje OHRQoL-a), ali gotovo dva puta više u skupini s konvencionalnim potpunim protezama nego u skupini MDI-OD. Iako miniimplantati omogućuju bolju retenciju i stabilnost donje proteze te bolju žvačnu funkciju, moramo imati na umu da ti pacijenti još uvijek imaju potpunu protezu u maksili koja s vremenom može imati slabiju retenciju. Retenciju s vremenom također gube „O“ gumeni prstenovi u matricama kojima se

es worldwide (29, 39-43). It was developed because OHIP questionnaires lack questions related to orofacial esthetics.

The summary scores of 8 OES questions were divided by the number of questions to obtain mean scores. Both, the CD and the MDI-OD group gave high scores to esthetics and their esthetic appearance of the lower third of the face (Fig. 1). The scores remained unchanged over the one year, but afterward, the scores dropped down at the 3<sup>rd</sup> year and even more at the 5<sup>th</sup> year recall examination (Fig 1, Table 2). The pattern was same in both groups, and there was no significant difference between the groups ( $p>0.05$ , Table 1). The artificial teeth and denture materials absorb colors from food and drinks and stain over time (44-47). Calculus can also be present on dentures. Artificial teeth wear and show cracks or fractures. All mentioned facts were the probable reasons for lower scoring of orofacial esthetics after 3 and 5 years. Loss of vertical dimension of occlusion due to residual ridge atrophy can also be present, more pronounced in the CD group, as described in dental literature (6-9). However, the CD group did not give worse scores to orofacial esthetics than the MDI-OD group at the three and 5-year examinations. The influence of jaw bone atrophy on the aesthetic rehabilitation of edentulous patients has not been studied extensively. One study found out that increased volume of lips and cheeks after rehabilitation was important in improving facial aesthetics and patients with non-atrophic ridges were more satisfied than patients with extensive residual ridge atrophy (48). However, follow-up over a longer period was not performed in that study. Our patients already had a status of atrophied residual alveolar bone at the study's baseline, as patients who could receive wider implants (more bone) were excluded. It is well known that bone resorption is more pronounced in the early stages after teeth extraction, while the rate reduces over time. The majority of our patients had already atrophied bone. Therefore, a small rate of bone loss was possible over an observation period of 5 years and did not influence the OES outcomes.

Based on the obtained data, our prospective clinical cross-over study confirmed that the process of adaptation to both, new CDs or to new mini-implant overdentures opposing maxillary CDs is completed within a month. However, the MDI-OD group presented significantly better OHRQoL (lower OHIP-EDENT scores) than the CD group all the time, except on the third and the eighth day after dentures' delivery. After three years of denture wearing, OHRQoL worsened significantly in both groups, but two times more pronounced in the conventional CD wearers. In addition, the OES scores also worsened after three years of denture wearing equally in both groups.

retiniraju potpune pokrovne proteze na miniimplantatima pa se moraju zamijeniti.

Kao još jedan ishod iz perspektive pacijenta (d-PROM), u našem istraživanju korišten je upitnik OES. To je jednodimenzijski upitnik za procjenu orofacialne estetike i psihometrijski je prihvaćen u mnogim zemljama i na jezicima diljem svijeta (29, 39 – 43). Razvijen je zato što u upitnicima OHIP-a, kojima se procjenjuje kvaliteta života ovisna o oralnom zdravlju, nedostaju pitanja vezana za orofacialnu estetiku.

Zbroj bodova 8 OES pitanja dijeli se s brojem pitanja da bi se doble srednje vrijednosti. I skupina CD i skupina MDI-OD odlično su ocijenile estetiku proteza i estetski izgled donje trećine lica (slika 2.). Bodovi su ostali nepromjenjeni tijekom prve godine, ali su se poslije u trećoj godini smanjili, a još više na petogodišnjem kontrolnom pregledu (slika 2., tablica 2.). Obrazac je bio isti u objema skupinama, a nije bilo značajne razlike između skupina na bilo kojemu kontrolnome pregledu ( $p > 0,05$ , tablica 1.). Umjetni zubi i materijali za proteze upijaju boju iz jela i pića te se ona s vremenom promjeni (44 – 47). Kamenac se također može pojaviti na protezama. Umjetni se zubi troše te dobivaju pukotine ili se dijelovi odlome. Sve navedene činjenice vjerojatno su bile razlog za nižu ocjenu orofacialne estetike poslije 3 i 5 godina. Gubitak vertikalne dimenzije okluzije, zbog atrofije rezidualnih grebena, također se može pojaviti, a to je, prema stomatološkoj literaturi, izraženije u skupini CD (6 – 9). No CD skupina ipak nije lošije ocijenila orofacialnu estetiku od skupine MDI-OD na trogodišnjim i petogodišnjim pregledima. Utjecaj atrofije čeljustne kosti na estetsku rehabilitaciju bezubih pacijenata nije detaljno proučavan. Jedna studija pokazala je da je povećani volumen usana i obraza poslije rehabilitacije važan za poboljšanje estetike lica, a pacijenti s neatrofičnim čeljustima bili su zadovoljniji od pacijenata s opsežnom rezidualnom atrofijom grebena (48). No u toj studiji nije provedeno dugotrajnije praćenje. Naši pacijenti već su na početku studije imali atrofirani rezidualni alveolarni greben, jer su oni koji su mogli dobiti šire implantate standardnih dimenzija (veći volumen kosti) bili isključeni iz istraživanja. Također se zna da je resorpcija kosti izraženija u ranim fazama nakon vađenja zuba te se stopa resorpcije s vremenom smanjuje. Većina naših pacijenata već je imala atrofiranu kost. Zato je, pretpostavlja se, bio moguć samo mali gubitak kosti tijekom petogodišnjega razdoblja istraživanja i vjerojatno nije utjecao na ishode orofacialne estetike.

Na temelju dobivenih podataka, naša prospективna klinička presječna studija potvrdila je da se proces prilagodbe na nove potpune proteze, ili na novu donju pokrovnu protezu na miniimplantatima nasuprot kojoj je konvencionalna potpuna proteza, završava u roku od mjesec dana. Međutim, skupina MDI-OD imala je znatno bolju kvalitetu života ovisnu o oralnome zdravlju (OHRQoL: manji bodovi OHIP-EDENT) od skupine CD u svim promatranim razdobljima, osim trećega i osmoga dana poslije predaje novih proteza. Poslije tri godine nošenja proteza, OHRQoL se značajno pogoršao u objema skupinama, ali dva puta više u skupini CD (nositelji konvencionalnih potpunih proteza). Osim toga, rezultati OES-a također su se pogorsali poslije tri godine i to podjednako u objema skupinama.

## Conflict of interest

All authors of the manuscript declare no conflict of Interest

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**Author's contribution:** J.T. – collected majority of data in the group MDI-ODs, entered data into the database, collected literature, interpreted data, drafted the manuscript; R. P-G. – collected majority of data in the group conventional CDs, entered data into the database, collected literature, drafted the manuscript, participated in the research design; S.P-K. – contributed to data aquisition, literature reading, critical manuscript reading, participated in research design, mentor ; I.K. – collected data and literature, drafted manuscript, interpreted data ; N.P. – collected data, drafted manuscript, participated in research design and data interpretation; A.P. - interpretation of results, drafting the manuscript; A.Č. – research design and concept, statistical analysis, data interpretation, critically revised and approved the manuscript. All authors gave the final approval and agree to be accountable for integrity and accuracy of the study.

### Sažetak

**Cilj rada:** Autori ovog istraživanja procjenjuju prilagodbu na proteze i njihovu petogodišnju kliničku upotrebu uspoređujući pacijente s obje potpune proteze (CD) i one s mandibularnom pokrovnom protezom na miniimplantatima nasuprot maksilarnej potpunoj protezi (MDI-OD) na temelju kvalitete života ovisne o oralnome zdravlju (OHRQoL) i orofacialne estetike (OES). **Materijal i metode:** U CD skupini ukupno je 36 ispitanika (25 žena) završilo petogodišnju studiju, a 30 ispitanika (20 žena) u skupini MDI-OD. Svi su dobili nove CD-e, ali u skupini MDI-OD četiri miniimplantata ugradena su interforaminalno u mandibulu prije izrade proteze. Sudionici su ispunjavali sljedeće upitnike: OHIP-EDENT i OES prvi dan poslije predaje proteza, zatim 3., 8., 15., 30. dan, te na kontrolnim pregledima poslije 1, 3 i 5 godina nošenja. Statistička analiza uključila je deskriptivne metode,  $\chi^2$  test, t-test za nezavisne uzorke te Friedmanov i Mann-Whitneyev test. **Rezultati i zaključak:** Prilagodba na nove proteze bila je u objema skupinama završena u roku od mjesec dana. Skupina MDI-OD imala je znatno bolju kvalitetu života (OHRQoL) od skupine CD na svim kontrolama, osim 3. i 8. dana, vjerojatno zbog žuljanja i boli, zbog čega je skupina MDI-OD također imala ograničenje pri funkciji u prvim daniма poslije predaje novih proteza. Poslije treće i pete godine OHRQoL se pogoršao ( $p < 0,01$ ) u objema skupinama. No pogoršanje je bilo znatno izraženije kod nositelja konvencionalnih proteza ( $p < 0,01$ ) u odnosu prema skupini MDI-OD. Orofacijalna estetika dobila je visoke ocjene u objema skupinama. Ocjene za estetiku počele su se smanjivati tek poslije tri godine i to podjednako u i u jednoj i u drugoj skupini.

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## Sukob interesa

Svi autori izjavljuju da nisu bili u sukobu interesa.

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**Doprinos autora:** J.T. – prikupila većinu podataka u skupini MDI-ODs i unijela ih u bazu podataka, prikupila literaturu, interpretirala podatke, pisala nacrt teksta; R. P. G. – prikupila većinu podataka u skupini konvencionalnih CD-a i unijela ih u bazu podataka, prikupila literaturu, izradila nacrt teksta, sudjelovala u osmišljavanju istraživanja; S. P. K. – sudjelovala u prikupljanju podataka, čitanju literature, kritičkom čitanju teksta, sudjelovala u oblikovanju istraživanja, mentorica; I. K. – prikupljala podatke u objemu skupinama, proučavala recentnu literaturu, pisala nacrt teksta, interpretirala podatke i dala ideje za raspravu; N. P. – prikupljao podatke, pisao nacrt teksta, sudjelovao u osmišljavanju istraživanja i interpretaciji podataka; A. P. – interpretacija rezultata, pisanje teksta; A. Č. – dizajn i koncept istraživanja, statistička analiza, interpretacija podataka, kritički revidirala, korigirala i odobrila tekst. Svi autori dali su konačno odobrenje i suglasni su da snose odgovornost za integritet i točnost istraživanja.

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