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

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 3rd, 8th, 15th, 30th day, and at the 1-, 3- and 5-year follow-up examinations. Statistical analysis comprised descriptive methods, X² 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 3rd and 8th 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
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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, consequent 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) oppositively.

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prirodni zubi gube kasnije u životu, ali postotak starije populacije jednako 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 dužijeg 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 financijskih ograničenja, općih zdravstvenih problema ili neadekvatnoga volumena kosti, što se često događa kod nositelja mobilih 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 prouzročenim 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 suprotom od kazaljke na satu (6 – 8, 10 –13). Resorpcija rezidualnoga alveolarnoga grebena mandibule gotovo je četiri puta izražena u odnosu prema maksilu (6 – 8). Zato je skupina stručnjaka predložila da minimum terapije za bezube pacijente bude pokrovnog proteza retinirana na dvama implantatima u donjoj čeljusti i potpuna u gornjoj čeljusti (McGill konsensus iz 2002. godine) (14). McGill konsensus 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 retiniranjem na četirima miniimplantatima preporučuje se kao alternativa totalnoj pokrovnog protezi retiniranoj na dvama implantatima (14,16 – 19).

Ishodi terapije iz perspektive pacijentana, tj. kako oni sami procjenjuju učink terapije (dPROM) u vezi s kvalitetom života ovisno o oralnome zdravlju (OHRQoL), estetikom ili inačicama odnosno slično (17, 20, 25, 27). Zato je skupina stručnjaka predložila da minimum terapije za bezube pacijente bude pokrovnog proteza retinirana na dvama implantatima u donjoj čeljusti i potpuna u gornjoj čeljusti (McGill konsensus iz 2002. godine) (14). McGill konsensus 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 retiniranjem na četirima miniimplantatima preporučuje se kao alternativa totalnoj pokrovnog protezi retiniranoj na dvama implantatima (14,16 – 19).

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

Cilj ovog istraživanja bio je procijeniti s pomoću ishodišta da terapije iz perspektive pacijentana (procjena kvalitete života ovisne o oralnome zdravlju: OHRQoL i orofacijalna estetika) koliko je vremena potrebno za prilagodba na konvencionalne potpune proteze (skupina CD), a koliko za prilagodba 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 successfull. 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 miniimplantatima u donjoj čeljusti te na potpunu protezu u gornjoj čeljusti (skupina MIDI-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 makski i novom pokrovnom protezom retiniranom miniimplantatima (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 rasporedi 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 svi četiri miniimplantata koji su bila ugrađena na početku istraživanja i koji su bili kategorizirani kao uspješni. U statističku analizu uvršteni su samo nijovii podatci. 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 proteze platio je Hrvatski zavod za zdravstveno osiguranje.

**Kirurški postupak ugradnje miniimplantata**

Svim sudionicima raspođenima u skupinu MDI-OD ugrađena su četiri miniimplantata s kuglastom glavom i to na mjestima prijašnjih drugih sjekutiča (32, 42) i prvih pretkrunjaka (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 pomičnim grebenom (engl. flabby ridge) i debljim sluznicom 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 specialistom stomatološke protekte. Duljina i širina miniimplantata određene su na temelju raspoloživogoluma kosti izmjerenog na preoperativnom CBCT-u i ortopantomogramskim snimkama. Primijenjena je tehnika bez odzidanja mukoperistalnoga režnja ili tehnika uz odzidanje mukoperistalnoga režnja, ovisno o morfologiji raspoložive kosti. Tehnika uz odzidanje mukoperistalnoga režnja koristena je kada je bilo potrebno izrazititi tanak i šiljast alveolarni greben ili kada je bilo potrebno ukloniti pomično tkivo sluznice. Za ugradnju MIDI-ja korišteni su fiziodispenser (W&H Implantmed, GmbH, Austrija) i fizijološka otopina za vanjsko hlađenje svrđala. Mjesta za ugradnju implantata pre-
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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 administered 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 antisepctic 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.

Prothodontic 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 housings 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 uvijek 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 prepriječnje određena je ovisno o kvaliteti kosti procijenjenoj na CBCT-u (Hounsfieldove jedinice). Preparacije su radene jedan, dva ili tri mm kraće od dužine samoga implantata (duža prepriječnja radila se u gušćoj kosti), osim kada je implantat trebao za-vršiti u gustome mandibularnome kotuku (gustoča D1). U tom slučaju preparirana je cijela dužina implantata. Za tehni-ku bez odzivanja mukoperiostalnoga režnja izmjena je širina nepomične alveolarnje mukoze te je uzeta u obzir pri planira-nju dužine implantata. Antibiotici su korišteni iz profilaktič-nih razloga (2 g amoksicilina ili 600 mg klindamicina jedan sat prije kirurškoga zahvata). Ugradnja MDI-ja obavljena je uvijek u lokalnoj anesteziji (Ubistesine forte 4% ili Mepiba-stesin 3%, 3M). Svaki MDI inseriran je u prepariranje ležište i rotiran u smjeru kazaljke na satu, čineći pritisak prema dolje (tehnika samorezujućeg uvijanja). Miniimplantati su postav-ljeni u preparirano ležište s pomoću nosača (plastični nosač za prere iz originalnog pakiranja), zatim su lepirti-ključem rotirani prema dolje i na kraju s pomoću moment-ključa. Miniimplantati su uvijani u preparirano ležište sve dok cijela hrapanja površina s navojem nije bila u kosti. Transmukozni dio glatke površine izdazio je iz pričvršćene mukoze u usnu šupljinu s ku-glom prema jugu. Pacijenti su poslije kirurškoga zahvata dobili standardne upute – bez toplih napitaka, alkohola i pušenja dva dana, stavljanje lenjenih obloga za hlađenje te prema po-trebi analgetici (nesteroidni protuupalni lijekovi). Propisan im je i antiseptik za ispiranje usta (klorhksidin-glukonat 0,12 %) u trajanju od pet dana te su im dane detaljne utrede o održava-nju oralne higijene. Raspon momenta sile na ključu pri ugrad-jnji 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 funkcijski otisci. Zatim je registrirana vertikalna dimenzija zagriz na centričnoj relaciji s pomoću zagriznih šabloni te se pretrese u poluprilagodljivi artikulator. Pri postavljanju zuba korišteni su poluanatomski umjetni zubi i shema lingualizirane 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 prilagodena, 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 po-moću samostrovdjavnjajućeg akrilata i uz korištenje gumenih prstenova za blokiranje podminiranih područja i periimplan-tatne 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 (the worst score, 5= the best score). Higher scores represented better esthetics. All patients also filled in the same questionnaires on the 3rd, 8th, 15th, and 30th 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 3rd, 8th, and 15th 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±6.2 years) than in the CD group (68.9±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 5th year, while three MDI-OD patients were not available at least at the one of the recall examinations. All of them were excluded.

D two iskusna specijalista stomatološke protetike, koji nisu bili uključeni u izradu proteza, procjenjivali su kvalitetu reten cije i stabilnosti te estetiku i okluziju novih proteza. Mo giće ocjene bile su sljedeće: nekvalitetne proteze, prosječ no kvalitetne ili visokokvalitetne proteze. U istraživanje su uključeni samo pacijenti s visokokvalitetnim novim proteza ma. 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 prirodni zub (FPD), djelomična proteza (RPD)]. Također su morali ispuniti validirane upitnike, odnosno upitnik OHIP-EDENT koji se sastoja od 19 pitanja (28) i orofacialnu estetsku lje stvicu (OES) od osam pitanja (29). Upitnik OHIP-EDENT sastoja 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 sastoja 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 jed nake upitnike 3., 8., 15. i 30. dan poslije predaje proteza. Iste procjene ponavljane su poslije 12 mjeseci nošenja proteza, te poslije 3 i 5 godina. Kontrole su obavljene u stomatološkoj ordinaciji dan poslije predaje proteze 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 podaci 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 naša mladi (65,1±6,2 godine) nego oni u skupini CD (68,9±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 sukcesivnom 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.

| OHIP19 EDENT | OES |
|--------------|-----|
| Mann-Whitney U | 285.00 |
| Wilcoxon W | 750.00 |
| Z | -3.30 |
| P (2-tailed • dvosmjerni) | <0.001** |

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.

Orofacial esthetics (OES) • Orofacijalna estetska ljestvica (OES)

Table 1. Značajnost razlika, procijenjena Mann-Whitneyjevim U testom, između nositelja potpunih proteza (CD) i nositelja donje pokrovne proteze na miniimplantatima i gornje potpune proteze (MDI – OD) u kvaliteti života ovisno o oralnome zdravlju (OHRQoL) i u orofacijalnoj estetskoj ljestvici (OES) na svim kontrolnim pregledima

ORAL HEALTH-RELATED QUALITY OF LIFE (OHRQoL) • KVALITETA ŽIVOTA OVISNA O ORALNOME ZDRAVLJU (OHRQoL)

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 miniimplantatima i gornje potpune proteze (MDI-OD) zajedno sa standardnim devijacijama

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

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

Table 1

| OHIP19 EDENT | OES |
|--------------|-----|
| Mann-Whitney U | 285.00 |
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Oral Health-Related Quality of Life (OHRQoL) • Kvaliteta života ovisna o oralnome zdravlju (OHRQoL)
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<.01), except on the 3rd and the 8th day, when there was no significant difference between the groups. On the 15th 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 1st year of denture wearing (Fig. 1, Table 2), but almost two times more in the CD wearers. 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.

| Table 2 | Significance of the differences between the periods of observation for the CD and the MDI-OD groups assessed by the Friedman test |
|---------|-------------------------------------------------------------------------------------------------------------------|
| OES     | CD wearers                                                                                                         | MDI-ODs                                                                 |
|         | Mean Rank • Srednji rang                                                                                         | Mean Rank • Srednji rang                                                                                   |
| OES - 1 day • 1 dan                             | 5.19                                                              | N=36                                                                                                      | 5.13                                                                 |
| OES - 3 days • 3 dana                           | 5.39                                                              | N=36                                                                                                      | 5.42                                                                 |
| OES . 8 days • 8 dana                           | 5.53                                                              | N=36                                                                                                      | 5.55                                                                 |
| OES - 15 days • 15 dana                         | 5.65                                                              | N=36                                                                                                      | 5.73                                                                 |
| OES - 30 days • 30 dana                         | 5.72                                                              | N=36                                                                                                      | 5.82                                                                 |
| OES - 1 year • 1 godina                         | 4.93                                                              | N=36                                                                                                      | 5.02                                                                 |
| OES - 3 years • 3 godina                        | 2.33                                                              | N=36                                                                                                      | p<0.001**                                                           |
| OES - 5 years • 5 godina                        | 1.25                                                              | N=36                                                                                                      | 2.18                                                                 |
|                      |                                                                   |                                                                  | p<0.001**                                                           |

| OHRQoL | CD wearers                                                                                                         | MDI-ODs                                                                 |
|---------|-------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------|
|         | Mean Rank • Srednji rang                                                                                         | Mean Rank • Srednji rang                                                                                   |
| OHIP19 - 1 day                                | 3.67                                                              | N=36                                                                                                      | 2.72                                                                 |
| OHIP19 - 3 days                               | 5.99                                                              | N=36                                                                                                      | 6.55                                                                 |
| OHIP19 - 8 days                               | 6.42                                                              | N=36                                                                                                      | 6.87                                                                 |
| OHIP19 - 15 days                              | 3.68                                                              | N=36                                                                                                      | 3.90                                                                 |
| OHIP19 - 30 days                              | 1.90                                                              | N=36                                                                                                      | 1.95                                                                 |
| OHIP19 - 1 year                               | 1.93                                                              | N=36                                                                                                      | 2.07                                                                 |
| OHIP19 - 3 years                              | 5.31                                                              | N=36                                                                                                      | 5.08                                                                 |
| OHIP19 - 5 years                              | 7.11                                                              | N=36                                                                                                      | 6.87                                                                 |

Značajnost 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 promotranja, posebno za skupinu CD i posebno za skupinu MDI-OD, procijenjena je Friedmanovim testom za zavisne uzorke i prikazana u tablici 2.
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 3rd and the 8th day and then gradually decreased (the 15th 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 3rd day and 8th 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 mu cosa, 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 3rd and 8th 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 30th 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 languag-

Rasprava

Nije razjašnjeno koliko dugo se pacijenti prilagodjuju na nove konvencionalne potpune proteze u objema čeljustima (CD) ili na gornju potpunu protezu nasuprot donje pokrovne potpune proteze koja se retinira na ćetiri miniimplantata (MDI – OD). Zato smo osmisili kliničko prospektivno istraživanje na temelju ishoda prema procjenama samih pacijenata, tj. pacijenti su procjenjivali kvalitetu života ovisno 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 nizke vrijednosti nakon 30 dana. Rezultati su ostali nepromijenjeni tijekom prve godine nošenja proteze. Obrazac rezultata OHIP EDENT-a bio je sličan u objema skupina. 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 proizlaze bol i nelagodnost na ležištu, bol i nelagodnost poslije slabije žvačne sposobnosti (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 kao i kod klasičnog izbora za procjenu retenciju 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 usklađivanja okluzije te zacijeljivanja bolnih mjesta, 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 skupina, ali uz znatno bolju kvalitetu života ovisno o oralnome zdravlju (OHRQoL) u skupini MDI-OD (slika 1.). Prilagodba na nove proteze u objema skupinama traje do mjeseč 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 proteze, 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 3rd year and even more at the 5th 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 tooth 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.
Kvaliteta života pacijenata s miniimplantatima ili konvencionalnim protezama Topić i sur.

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 acquisition, 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.C. – 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.

Sukob interesa
Svi autorji izjavljajo da nisu bili v sukobu interesa.

Sazetak
Cilj rada: Autori ovog istraživanja procjenjuju prilagodbu na proteze i njihov potegodišnju kliničku upotrebu uspoređujući pacijente s obje potpune proteze (CD) i one s mandibularnom pokrovnom protezom na miniimplantatima nasuprot maksilarnoj 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 potegodišnju studiju, a 30 ispitanika (20 žena) u skupini MDI-OD. Svi su dobili nove CD-e, ali u skupini MDI-OD četiri miniimplantata ugrađena su interforaminalno u mandibulu prije izrade proteze. Sudionici su ispunjavali sljedeće upitnike: OHIP-EDENT i OES prvi dan poslije predaje proteze, zatim 3., 8., 15., 30. dan, te na kontrolnim pregledima poslije 1., 3 i 5 godina. Statistička analiza uključila je deskriptivne metode, t-test, t-test za nezavisne uzorke te Friedmanov i Mann-Whitneyev test. Rezultati i zaključak: Prilagodba na nove proteze bila je u objema skupina završena u roku od mjesec dana. Skupina MDI-OD imala je znatno bolju kvalitetu života (OHIP-EDENT) od skupine CD na svim kontrolama, osim 3. i 8. dana, vjerojatno zbog žulanja i boli, zbog čega je skupina MDI-OD također imala ograničenje pri funkciji u prvim dana poslije predaje novih proteza. Poslije treće i pete godine OHIP-EDENT se pogoršao (p < 0,01) u objema skupina. No pogoršanje je bilo znatno kraćje kod nositelja konvencionalnih proteza (p < 0,01) u odnosu prema skupini MDI-OD. Orofacijalna estetika dobila je visoke ocjene u objema skupina. Ocjene za estetiku počele su se smanjivati tek poslije treće godine i to podjednako u i u jednoj i u drugoj skupini.

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