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Веће научних области медицинских наука, на XIII седници одржаној дана 22. маја 2012. године, донело је

ОДЛУКУ

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Кандидат

Дејан Ђаласан

Предложени назив теме: "Утицај хируршке технике уградње микро и макродизајна имплантата на њихову стабилност у бочном сегменту горње вилице".

Одобрени назив теме: "Утицај хируршке технике уградње и микро и макро дизајна имплантата на њихову стабилност у бочном сегменту горње вилице".

ПРЕДСЕДНИК ВЕЋА

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Доставити:

- Факултету
- секретару Већа
- архиви Универзитета

БЕОГРАДСКИ УНИВЕРЗИТЕТ
СТОМАТОЛОШКИ ФАКУЛТЕТ
СЕКРЕТАРИЈАТ

ПРИМЉЕНО 24-05-2012

Орг. јед.	Број	Прилог	Предност
03	645/2		

NASTAVNO - NAUČNOM VEĆU STOMATOLOŠKOG FAKULTETA U BEOGRADU

Odlukom Nastavno-naučnog veća Stomatološkog fakulteta u Beogradu, donetom na četvrtoj redovnoj sednici u školskoj 2013/14. godini, održanoj 26.06.2014 godine, imenovani smo u komisiju za ocenu i odbranu završene doktorske disertacije dr Dejana Čalasan s naslovom »**UTICAJ HIRURŠKE TEHNIKE UGRADNJE I MIKRO I MAKRO DIZAJNA IMPLANTATA NA NJHOVU STABILNOST U BOČNOM SEGMENTU GORNJE VILICE**«.

Na osnovu pregleda priloženog materijala, komisija podnosi Nastavno-naučnom veću sledeći

I Z V E Š T A J

Dr Dejan Čalasan rođen je u Foči, 29. 03. 1975 godine. Osnovnu i srednju školu je završio u Foči. Diplomirao je školske 2000/01. godine na Stomatološkom Fakultetu u Beogradu sa prosečnom ocenom 9,21. Nakon pripravničkog staža obavljenog na klinikama Stomatološkog fakulteta u Beogradu, položila je stručni ispit 2002. godine.

Prvu godinu magistarskih studija iz naučne oblasti Oralna hirurgija na Stomatološkom fakultetu Univerziteta u Beogradu upisao je školske 2001/2002. godine. Položio je sve ispite predviđene planom i programom i odbranio magistarsku tezu sept. 2007. pod nazivom » **RADIOLOŠKA PROCENA GUSTINE KOSTI NAKON UGRADNJE ENDOOSEALNIH IMPLANTATA** «. Specijalistički ispit iz Oralne hirurgije položio je 2005. Godine sa **ODLIČNOM** ocenom. Zaposlen je na klinici za Oralnu hirurgiju stomatološkog fakulteta u Beogradu od 2002. godine kao asistent za naučne oblasti Oralna hirurgija, Oralna implantologija i Stomatološka anesteziologija.

Mr sci. Dejan Čalasan je, do sada, saopštio 13 radova na skupovima u zemlji i 6 radova na skupovima u inostranstvu, a objavio je 2 rada u inostranom stručnom časopisu koji je citiran u *Current Contents*. U ovom periodu, održao je i 2 predavanja po pozivu i bio mentor tri studentska rada.

Nastavno-naučno veće Stomatološkog fakulteta, Univerziteta u Beogradu je na petoj redovnoj sednici u školskoj 2013/2014. godini, održanoj 23.09.2014. godine usvojilo pozitivan izveštaj stručne komisije za ocenu predloga teme i imenovalo prof. dr Aleksu Markovića za mentora za izradu ove doktorske disertacije.

Doktorska disertacija Mr sci. dr Dejana Čalasan je napisana na 162 strane, raspoređene u 9 poglavlja: Kratak sadržaj, Uvod, Naučna osnova problema, Ciljevi istraživanja, Materijal i metod, Rezultati, Diskusija, Zaključci, Spisak literature. Dokumentovana je sa 58 fotografija, 7 slika, 42 tabele i 13 grafikona.

U **Uvodu** kandidat ukazuje na problematiku ugradnje implantata u bočnom segmentu gornje vilice s obzirom da u toj regiji preovladava kost male gustine, odnosno tip 3 i 4 (Q3 i Q4 po klasifikaciji Lekholma i Zarba). Takođe navodi da ugradnja implantata u kost male gustine predstavlja veliku problematiku za uspeh implantacijskog postupka, navodeći da je upravo loš kvalitet i nedovoljni kvantitet koštanog tkiva u pojedinim regijama osnovni krivac za gubitak implantata.

Kost male gustine predstavlja mehanički insuficijentnu sredinu koja neobezbeđuje dobru potporu implantatu posle ugradnje, omogućavajući mu mikropokrete u samom ležistu što rezultira fibroznom imkapsulacijom i odsustvom oseointegracije kao bitnog faktora za uspeh u implantatnoj terapiji.

Literaturni podaci su pokazali da je gustina kosti u regiji implantacije značajan prediktor uspeha implantatne terapije. Kost male gustine često prvenstveno neobezbeđuje dovoljnu primarnu stabilnost implantata te zahteva različite proceduralne postupke kako bi se rešio problem primarne,

a samim tim i sekundarne stabilnosti u kosti male gustine. Tu navodi mogućnost modifikacija hiruške tehnike ugradnje kojima se odstupa od standardnog hirurškog protokola i primenu implantata razlicitog dizajna. Od modifikovanih hirurških tehnika opisanih u literaturi najčešće su :tehnika lateralne kondenzacije kosti, ugradnja implantata šireg dijametra, angulacija i ugradnja implantata u kortikalni deo alveolarnog grebena, ugradnja implantata sa vratom iznad alveolarnog grebena, preparacija ležišta implantata manjim borerom, ugradnja implantata bez ureznice. Različite vrste implantata imaju i razlicit mikro i makro dizajn koji utiču na primarnu stabilnost i mogućnost implantata da izdrži opterećenje za vreme i posle procesa oseointegracije. Pod makrodizajnom se podrazumeva oblik implantata i dizajn navoja dok mikrodizajn se odnosi na materijal od koga su napravljeni implantati, morfologiju površine i oblaganje površine implantata različitim slojevima. Takodje makrodizajn implantata opisuje debljinu , dužinu implantata, zatim dubinu, širinu i gustinu navoja te ugao i oblik navoja. Posebno se ističe razlika izmedju samourezujućih i neurezujućih navoja , pri čemu je samourezujući navoj na implantatu definisan usecima u apikalnoj trećini koji omogućavaju ugradnju implantata u kost bez ureznice, angažujući istovremeno i opiljke kosti nastale prilikom uvrtnja a samim tim i veću kontaktnu površinu kost-implantat. Iz ovih razloga se samourezujući implantati preporučuju za ugradnju u kost male gustine kako bi se povećala stabilnost implantata nakon njihove ugradnje i poboljšao uspeh implantacije.

Mikrodizajn imlantata diktira vrstu i čistoću titanijuma neophodnu za izradu implantata koja se kreće na skali od 1-4, kao i površinsku hrapavost implantata deleći je na makro , mikro i nano hrapavost. U savremenoj imlantologiji implantatna površina je u zavisnosti od vrednosti (**Sa**) podeljena na : glatku(**Sa**< 0.5 μm), minimalno hrapavu (**Sa**= 0.5 – 1.0 μm), umereno hrapavu (**Sa** = 1.0 – 2.0 μm) i hrapavu(**Sa** > 2 μm) površinu pri čemu **Sa** predstavlja visinu šiljka i udubljenja na površini implantata. Takođe se u literaturi navodi da postoji više od 50 različitih parametara koji utiču na hrapavost površine ali se još ne zna u potpunosti njihov uticaj i značaj. Glavna klinička indikacija za korišćenje implantata hrapave površine je loš kvalitet ili smanjen obim kosti u koji se ugrađuje implantat. U ovakvim nepovoljnim kliničkim uslovima rani i jak kontakt kost-implant bi mogao biti koristan za omogućavanje većeg i bržeg opterećenja. U novije vreme razvijene su razne metode da bi se stvorila hrapava površina i poboljšala oseointegracija titanijumskih dentalnih implantata. Ove metode podrazumevaju: plazmiranje titanijumom, bombardovanje česticama keramike, nagrizanje kiselinom i anodizaciju.

U poglavlju **Naučna osnova problema** kandidat iznosi literaturne podatke o problematici ugradnje implantata u bočnom segmentu gornje vilice kao i čestim neuspesima implantacije uzrokovane smanjenim kvalitetom i kvantiteom koštanog tkiva u ovoj regiji. Budući da je u ovoj regiji zastupljena trabekularna kost ili kost male gustine i da je otežano postizanje primarne stabilnosti pri ugradnji implantata u takvu kost, u literaturi nalazimo podatke o primeni različitih modifikovanih tehnika koje su korištene u cilju postizanja bolje stabilnosti pri ugradnji implantata kao i uspeha implantacije . Jedna od njih je i tehnika lateralne kondenzacije koštanog tkiva prilikom preparacije implantatnog ležišta čime se u najvećoj meri čuva postojeći volumen kosti i minimalizuje hirurški protokol bušenja kosti. Sabijanjem kostanih gređica i povećava se gustina koštanog tkiva na mestu ugradnje implantata, pa se samim tim ova tehnika preporučuje u kosti lošeg kvaliteta . Takodje, u literaturi se mogu naći i podaci o uticaju različitog oblika i dizajna navoja implantata (makrodizajn), te njegove hrapavosti (mikrodizajna) na uspeh implantata u kosti male gustine. Primenom samourezujućih implantati u kosti male gustine povećavaju se njihova primarna stabilnost i pravilnije raspoređuje okluzalno opterećenje na okolnu kost sto doprinosi većem uspehu implantacije.

Uzimajući u obzir činjenicu da danas još uvek ne postoji jedinstven stav po pitanju prednosti i nedostataka primene različitih tehnika ugradnje dentalnih implantata u bočnim segmentima gornje vilice, kandidat navodi da je **radna hipoteza** ovog istraživanja bila da se povoljna primarna stabilnost implantata u kosti male gustine može postići primenom tehnike lateralne kondenzacije i ugradnjom implantata sa samourezujućim navojima.

U poglavlju **Ciljevi istraživanja** kandidat jasno navodi ciljeve istraživanja:

1. Ispitati vrednosti primarne i sekundarne stabilnosti implanatata sa neurezujućim navojima ugrađenih nakon preparacije ležište metodom lateralne kondenzacije kosti u kost male gustine.
2. Ispitati vrednosti primarne i sekundarne stabilnosti implanatata sa neurezujućim navojima ugrađenih nakon preparacije ležište standardnom tehnikom u kost male gustine
3. Ispitati vrednosti primarne i sekundarne stabilnosti implanatata sa samourezujućim navojima ugrađenih nakon preparacije ležište metodom lateralne kondenzacije kosti u kost male gustine
4. Ispitati vrednosti primarne i sekundarne stabilnosti implanatata sa samourezujućim navojima ugrađenih nakon preparacije ležište standardnom tehnikom u kost male gustine.
5. Uporediti dobijene vrednosti implantne stabilnosti između implantata sa samourezujućim i neurezujućim navojima ugrađenih nakon preparacije ležišta metodom lateralne kondenzacije i standardnom tehnikom u kost male gustine
6. Ispitati vrednosti primarne i sekundarne stabilnosti implantata hidrofobne površine ugrađenih u kost male gustine
7. Ispitati vrednosti primarne i sekundarne stabilnosti implantata hidrofilne površine ugrađenih u kost male gustine
8. Uporediti dobijene vrednosti implantne stabilnosti između implantata sa hidrofobnom i implantata sa hidrofilnom površinom ugrađenih u kost male gustine

U poglavlju **Materijal i metod** kandidat navodi sve segmente studijskog dizajna i opisuje metode koje su korišćene u eksperimentalnom i kliničkom istraživanju.

Kao analog humane vilične kosti kvaliteta Q3 i Q4 po klasifikaciji Lekholma i Zarba, u eksperimentalnoj studiji korišćena su svinjska rebra uniforme debljine koritkalog sloja od 2 mm pribavljena od već zaklanih životinja muškog pola, 6 meseci starih i 120 kg teških.

Tokom izvođenja eksperimenta uzorak je fiksiran donjom polovinom i potopljen u termostatom kontrolisano vodeno kupatilo na temperaturi $37 \pm 1^\circ\text{C}$. Gornja plovina uzorka je bila na sobnoj temperaturi (26°C).

Prema hirurškoj tehnici za preparaciju ležišta implantata i makro dizajnu implantata, uzorci kosti su metodom slučajnog izbora bili podeljeni u 4 grupe:

Prvu grupu činili su uzorci kosti u koju su nakon preparacije ležišta standardnom tehnikom, ugrađeni neurezujući implantati (Standard, Institut Straumann AG[®], Valdenburg, Švajcarska) dijametra 4,1mm i dužine 10mm pri torqu 35 N/cm.

Drugu grupu činili su uzorci kosti u koju su, nakon preparacije ležišta metodom lateralne kondenzacije kosti ugrađeni neurezujući implantati (Standard, Institut Straumann AG[®], Valdenburg, Švajcarska) dijametra 4,1mm i dužine 10mm pri torqu 35 N/cm.

Treću grupu činili su uzorci kosti u koju su nakon preparacije ležišta standardnom tehnikom, ugrađeni samourezujući implantati (BlueSky, Bredent GmbH&Co. Kg, Senden, Nemačka) dijametra 4,0mm i dužine 10mm pri torqu 35 N/cm.

Četvrtugrupu činili su uzorci kosti u koju su nakon preparacije ležišta metodom lateralne kondenzacije kosti, ugrađeni samourezujući implantati (BlueSky, Bredent GmbH&Co. Kg, Senden, Nemačka) dijametra 4,0mm i dužine 10mm pri torqu 35 N/cm.

U prvoj i trećoj grupi, ležište je preparisano standardnom hirurškom tehnikom uz upotrebu kolenjaka sa fizioidispenzerom (W&H, Burmoos, Austrija). Za implantatna ležišta iz prve grupe upotrebljavana je serija borera rastućeg dijametra: okrugli borer Ø1.4 mm i Ø2.3 mm, pilot boreri Ø2.2 mm i Ø2.8 mm i spiralni borer Ø3.5 mm (Institut Straumann AG[®], Valdenburg, Švajcarska) pri brzini od 500-600 obrtaja po minutu radi simulacije kliničkih uslova, dok je u trećoj grupi korišćena serija borera rastućeg dijametra do finalnog dijametra od 3,5mm (Bredent GmbH& Co.KG. Senden, Nemačka). Hlađenje je učinjeno fiziološkim rastvorom pri protoku od 50 ml/min. Nivo vode u vodenom kupatilu je održavan konstantnim aspiracijom fiziološkog rastvora u blizini mesta preparacije.

Uticaj hirurške tehnike kao i mikro i makro dizajna implantata na njihovu stabilnost u bočnom segmentu gornje vilice ispitivan je i u randomizovanoj kontrolisanoj kliničkoj studiji u kojoj je učestvovalo 46 pacijenata oba pola (26 ženskog i 20 muškog), prosečne starosti 39,3 godina dobrog opšteg zdravstvenog stanja sa krezubošću u premolarnoj i/ili molarnoj regiji gornje vilice, visinom rezidualnog alveolarnog grebena gornje vilice ≥ 10 mm i širinom ≥ 6 mm kod kojih je prisutna kost gustine Q4 ili Q3 prema klasifikaciji Lekholma i Zarba. Istraživanje je odobreno od strane Etičkog komiteta Stomatološkog fakulteta u Beogradu (br 36/20). Nakon pribavljanja informisanog pristanaka o učešću u studiji, kod pacijenata je ugrađeno ukupno 144 implantata u premolarno-molarnu regiju gornje vilice koji su bili podeljeni u sledeće grupe metodom slučajnog izbora :

Ia i Ib grupa: Ugradnja neurezujućih implantata (4,1x10 mm Standard, Institut Straumann AG[®], Valdenburg, Švajcarska) u ležišta preparirana tehnikom lateralne kondenzacije (**Ia**) i u ležišta preparirana standardnom hirurškom tehnikom (**Ib**).

IIa i IIb grupa: Ugradnja samourezujućih implantata (4,0x10mm BlueSky, Bredent GmbH&Co. Kg, Senden, Nemačka) u ležišta preparirana tehnikom lateralne kondenzacije (**IIa**) i u ležišta preparirana standardnom hirurškom tehnikom (**IIb**).

IIIa i IIIb grupa: Ugradnja implantata hidrofилne površine (4,1x10mm Bone Level SLActive, Institut Straumann AG[®], Valdenburg, Švajcarska) (**IIIa**) i implantata hidrofobne površine (4,1x10mm Standard SLA, Institut Straumann AG[®], Valdenburg, Švajcarska) (**IIIb**) u ležišta preparirana standardnom hirurškom tehnikom.

Merenje stabilnosti implantata vršeno je analizom rezonantne frekvencije (RFA) i to neposredno nakon ugradnje implantata kao i svake nedelje u periodu od 6 nedelja. Analiza rezonantne frekvencije vršena je aparatom marke Osstell[®] (Integration Diagnostics AB, Sävedalen, Švedska). Korišćeni su komercijalni transduktori prema tipu implantata: SmartPeg br. 4 za Standard implantat (Institut Straumann AG[®], Valdenburg, Švajcarska); SmartPeg br. 49 za BlueSky implantat (Bredent GmbH&Co. Kg, Senden, Nemačka) i SmartPeg br. 54 za Bone Level implantat (Institut Straumann AG[®], Valdenburg, Švajcarska). Transduktor je bio aktiviran magnetnim impulsom iz sonde aparata sa rastojanja 2-3 mm.

Podaci iz eksperimentalne i kliničke studije su statistički analizirani pomocu sledećih programa: Microsoft[®] Excel 2007-za formiranje baze podataka i tabele, Microsoft[®] Word 2007 - za tekstualnu obradu, SPSS ver. 17, Čikago, SAD - za statističku analizu podataka.

U studiji su praćena dva ishoda: stabilnost implantata izražena u ISQ i promena stabilnosti implantata u datoj nedelji posmatranja u odnosu na primarnu stabilnost (Δ ISQ). Dobijeni podaci statistički su analizirani sledećim parametrima: Aritmetička sredina, Medijana, Standardna devijacija, Minimum, Maksimum, 95% Interval poverenja

Značajnost razlike u promeni implantatne stabilnosti tokom 6 nedelja praćenja, unutar grupa, analizirana je najpre Fridmanovim testom, a potom po potrebi i Viloksonovim testom. Za procenu značajnosti razlike navedenih parametara između grupa primenjivan je najpre Kraskal-Volisov test, a potom po potrebi i Man-Vitnjev test.

Poglavlje **Rezultati** istraživanja se sastoji iz dve celina od kojih se prva odnosi na eksperimentalno a druga na kliničko istraživanje. Rezultati su prikazani pomoću tabela i grafikona na kojima su date vrednosti statističkih testova.

U eksperimentalnoj studiji najveću primarnu stabilnost ostvarili su samourezujuć

implantati ugrađeni tehnikom lateralne kondenzacije, a najmanju neurezujući implantati ugrađeni standardnom tehnikom

U klinickoj studiji samourezujući implantati ugrađeni u ležišta preparirana tehnikom lateralne kondenzacije ostvarili su najveću stabilnost tokom celokupnog perioda praćenja od 6 nedelja. Primarna i sekundarna stabilnost u 1. nedelji implantata ugrađenih u ležišta preparirana tehnikom lateralne kondenzacije, nije se statistički značajno razlikovala u odnosu na makrodizajn implantata. Od druge do šeste nedelje praćenja, samourezujući implantati ugrađeni u ležišta preparirana tehnikom lateralne kondenzacije ostvarili su statistički značajno veću stabilnost u poređenju sa neurezujućim implantatima nakon primene iste hirurške tehnike. Implantati ugrađeni nakon primene tehnike lateralne kondenzacije, ostvarili su statistički značajno veću stabilnost tokom celokupnog perioda praćenja u poređenju sa implantatima ugrađivanim standardnom hirurškom tehnikom bez obzira na makro dizajn implantata. Kada je primenjivana standardna hirurška tehnika, samourezujući implantati ostvarili su statistički značajno veću primarnu stabilnost kao i sekundarnu stabilnost tokom celokupnog perioda praćenja od 6 nedelja u poređenju sa neurezujućim implantatima.

Implantati hidrofilne SLActive površine ostvarili su statistički značajno veću primarnu stabilnost kao i sekundarnu stabilnost u poređenju sa implantatima hidrofobne SLA površine tokom celokupnog perioda praćenja. U grupi implantata hidrofilne površine, uočen je kontinuirani porast ISQ vrednosti tokom celokupnog perioda praćenja od 6 nedelja. Implantati hidrofobne površine ostvarili su kontinuirani pad ISQ vrednosti od 1. do 3. nedelje, sa najnižom prosečnom ISQ vrednosti u trećoj nedelji, nakon čega je od 4. nedelje nastupio kontinuirani porast ISQ vrednosti sa najvećom prosečnom vrednosti u šestoj nedelji.

Kandidat u **Diskusiji** tumači dobijene rezultate i poredi ih sa nalazima drugih, relevantnih studija. Takođe, navodi ograničenja studije-rezultati se odnose na kost male gustine kod koje je indikovana primena tehnike lateralne kondenzacije u odnosu na standardnu tehniku kao i upotreba samourezujućih implantata u odnosu na neurezujuće. U diskusiji se tumače i dobijeni rezultati različitog uticaja hidrofilne i hidrofobne površine implantata na kost male gustine i poredi sa nalazima drugih autora..

U **Zaključcima** istraživanja predstavljene su različite vrednosti stabilnosti implantata nakon njihove ugradnje u kosti male gustine. Statistički značajno veće vrednosti primarne i sekundarne stabilnosti implantata dobijene su kod implantata sa samourezujućim navojima i hidrofilnom površinom koji su ugrađeni primenom tehnike lateralne kondenzacije, u odnosu na implantate sa neurezujućim navojima i hidrofobnom površinom koji su ugrađeni standardnom hirurškom tehnikom. Zaključci su jasno formulisani i upućuju na mogućnosti postizanja što bolje implantatne stabilnosti u koštanom tkivu male gustine pri izvođenju hirurških implantoloških procedura kao i postizanja što boljeg uspeha implantacije.

Poglavlje **Literatura** sadrži 162 bibliografske jedinice iz domaće i strane relevantne literature.

Nakon uvida u dostavljeni tekst, komisija je jednoglasno ocenila da doktorska disertacija Mr sci. Dejan Čalasan pod nazivom „**UTICAJ HIRURŠKE TEHNIKE I MIKRO I MAKRO DIZAJNA IMPLANTATA NA NJHOVU STABILNOST U BOČNOM SEGMENTU GORNJE VILICE**” predstavlja samostalno, dobro dokumentovano istraživanje. Različiti uticaj hirurške tehnike, makro i mikro dizajna na stabilnost implantata u kosti male gustine je bio opisan u literaturi sa njihovim pojedinačnim uticajem, međutim skup ovih svih faktora na stabilnost implantata u kosti lošeg kvaliteta nije bio dovoljno obrađen u literaturi, pa ova doktorska disertacija ostvaruje značajan doprinos postojećim saznanjima o stabilnosti implantat u kosti male gustine u sklopu hirurških implantoloških procedura. Doktorska disertacija ispunjava sve kriterijume propisane Zakonom o Univerzitetu i statutima Univerziteta i Stomatološkog fakulteta u Beogradu.

Na osnovu iznetog predlažemo Nastavno-naučnom veću Stomatološkog fakulteta da prihvati izveštaj i oceni kao podobnu za javnu odbranu doktorsku disertaciju dr Dejana Čalasana pod nazivom „ **UTICAJ HIRURŠKE TEHNIKE I MIKRO I MAKRO DIZAJNA IMPLANTATA NA NJIHOVU STABILNOST U BOČNOM SEGMENTU GORNJE VILICE**”.

U Beogradu, 23.09.2014.

Prof. dr Snježana Čolić
Stomatološki fakultet, Univerzitet u Beogradu

Prof. dr Ljiljana Stojčev-Stajčić
Stomatološki fakultet, Univerzitet u Beogradu

Prof. dr Siniša Mirković
Medicinski fakultet, Univerzitet u Novom Sadu

Na osnovu člana 49. Statuta Stomatološkog fakulteta Univerziteta u Beogradu, Nastavno naučno veće Stomatološkog fakulteta, na VI redovnoj sednici u školskoj 2013/14. godini, održanoj 23.09.2014. godine, donelo je sledeću

O D L U K U

Usvaja se pozitivan izveštaj Komisije za ocenu završene doktorske disertacije **dr Dejana Čalasana**, pod nazivom „UTICAJ HIRURŠKE TEHNIKE UGRADNJE I MIKRO I MAKRO DIZAJNA IMPLANTATA NA NJIHOVU STABILNOST U BOČNOM SEGMENTU GORNJE VILICE“.

Imenovani/a će javno braniti doktorsku disertaciju, ukoliko dobije pozitivno mišljenje Veća naučnih oblasti medicinskih nauka Univerziteta u Beogradu, pred komisijom u sastavu:

1. prof. dr Snježana Čolić
2. prof. dr Ljiljana Stojčev Stajčić
3. prof. dr Siniša Mirković, Medicinski fakultet u Novom Sadu.

O b r a z l o ž e n j e

Veće naučnih oblasti medicinskih nauka, na sednici od 22.05.2012. godine, dalo je saglasnost na predlog teme doktorske disertacije dr Dejana Čalasana, pod nazivom „UTICAJ HIRURŠKE TEHNIKE UGRADNJE I MIKRO I MAKRO DIZAJNA IMPLANTATA NA NJIHOVU STABILNOST U BOČNOM SEGMENTU GORNJE VILICE“.

Imenovani/a je u časopisu „Oral Surgery, Oral Medicine, Oral Pathology, Oral Radiology, and Endodontology“, objavio/la rad pod nazivom: „Implant stability in posterior maxilla: bone-condensing versus bone-drilling: a clinical study“ (2011.) i u časopisu „Clinical Implant Dentistry and Related Research“, objavio/la rad pod nazivom: „Evaluation of Primary Stability of Self-Tapping and Non-Self-Tapping Dental Implants. A 12-Week Clinical Study“ (2011).

Imajući u vidu napred navedeno, Nastavno naučno veće Stomatološkog fakulteta Univerziteta u Beogradu, rešilo je kao u dispozitivu.

Odluku dostaviti: Imenovanom/oj, Univerzitetu u Beogradu, Odseku za nastavu, Veću, Komisiji (3) i Pisarnici.

Referent kadrovskog odseka
Violeta Rastović

Dekan
Stomatološkog fakulteta

Prof. dr Miroslav Vukadinović

Evaluation of Primary Stability of Self-Tapping and Non-Self-Tapping Dental Implants. A 12-Week Clinical Study

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ABSTRACT

Purpose: The aim of this study was to investigate the relationship between surgical techniques and implant macro-design (self-tapping/non-self-tapping) for the optimization of implant stability in the low-density bone present in the posterior maxilla using resonance frequency analysis (RFA).

Materials and Methods: A total of 102 implants were studied. Fifty-six self-tapping BlueSkyBredent® (Bredent GmbH&Co.Kg®, Senden, Germany) and 56 non-self-tapping Standard Plus Straumann® (Institut Straumann AG®, Waldenburg, Switzerland) were placed in the posterior segment of the maxilla. Implants of both types were placed in sites prepared with either lateral bone-condensing or with bone-drilling techniques. Implant stability measurements were performed using RFA immediately after implant placement and weekly during a 12-week follow-up period.

Results: Both types of implants placed after bone condensing achieved significantly higher stability immediately after surgery, as well as during the entire 12-week observation period compared with those placed following bone drilling. After bone condensation, there were no significant differences in primary stability or in implant stability after the first week between both implant types. From 2 to 12 postoperative weeks, significantly higher stability was shown by self-tapping implants. After bone drilling, self-tapping implants achieved significantly higher stability than non-self-tapping implants during the entire follow-up period.

Conclusions: The outcomes of the present study indicate that bone drilling is not an effective technique for improving implant stability and, following this technique, the use of self-tapping implants is highly recommended. Implant stability optimization in the soft bone can be achieved by lateral bone-condensing technique, regardless of implant macro-design.

KEY WORDS: dental implants, implant stability, resonance frequency analysis, surgical technique

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INTRODUCTION

The use of endosseous dental implants to restore missing teeth is an alternative treatment method that is becoming increasingly widespread.^{1,2} It is a well-known fact that primary stability has an essential role and is a prerequisite for successful osseointegration. In this way, insufficient primary implant stability resulting from a poor quality bone has been cited as the greatest potential risk factor for implant loss.^{3,4} The highest rate of implant failure is reported in the posterior maxilla, which contains a thin cortex and poor medulla strength with low trabecular density (classified as bone type IV).⁵ In oversized implant sites, lower bone-to-implant contact and lower primary implant stability, followed by delayed osseointegration have been documented. These are

considered to be a serious risk especially in challenging regions such as the posterior maxilla.⁶ In order to enhance primary stability it is preferable to choose a tapered implant, which creates lateral bone compression at the moment of implant insertion.⁷ After using the pilot drill, the bone layer adjacent to the implant site is progressively compacted with a series of bone condensers of increasing diameter, which results in better bone-to-implant contact and denser bone.

In addition to the quality and quantity of the bone and the surgical technique employed, the macro- or micro-design of the implant also has a significant influence on primary stability.⁸ Self-tapping implants have been available since 1983 and have mainly been used in regions with soft bone quality such as the maxilla. These are usually designed to avoid the use of tapping procedures for implant site preparation, which are replaced by the action of cutting edges incorporated into the lower, apical portion of the implant.⁹ This design reduces the need for a tapping procedure during placement surgery, and can improve both primary stability and implant survival rate.¹⁰

Resonance frequency analysis (RFA) is a recent, noninvasive, reliable, easily predictable, and objective method for quantifying primary and secondary implant stability.^{1,11} The implant-bone interface is measured as a reaction to oscillations exerted onto the implant/bone contact (resonance frequency), providing a unit of measurement known as implant stability quotient (ISQ).¹²

Data published in the literature suggest that bone condensation, together with the use of self-tapping implants, increases the stability of implants placed in soft bone, but their mutual interrelation remains unknown.^{1,13}

The aim of this study was to investigate the relationship between surgical techniques and implant macro-design for the optimization of implant stability in the low-density bone present in the posterior maxilla.

MATERIALS AND METHODS

Patients

This study was conducted in accordance with the Helsinki Declaration of 1975 and was approved by the Ethics Committee at the Faculty of Stomatology, University of Belgrade (Serbia) (No. 36/20). A total of 53 patients (25 women and 28 men), with an average age of 43.9 years, were included in the study, which was

carried out between January 2009 and October 2010 at the Clinic of Oral Surgery, Faculty of Stomatology, University of Belgrade (Serbia). Inclusion criteria were as follows: good general health (no subject was known to suffer from any allergies or metabolic bone diseases), nonsmokers, bilateral lack of one or more teeth in the premolar and/or molar region of the upper jaw, subantral bone height of >12 mm, width of the residual alveolar crest >6.2 mm, and bone density of D3 or D4 as classified by Lekholm and Zarb. Patients were given a detailed explanation of the forthcoming surgery, alternative treatments and possible complications, and all subjects signed an informed consent form. Patients were divided into study groups by simple randomization (using Random allocation software[®] version 1.0 developed by M. Saghaei Isfahan, Iran). Four study groups were formed according to the surgical technique to be used for implant site preparation and implant macro-design. In group I, bone condensation technique was used for implant site preparation and self-tapping implants were inserted, while in group II, non-self-tapping implants were placed following condensation technique. Patients in group III received self-tapping implants after bone drilling and in group IV, bone drilling was performed and non-self-tapping implants were placed.

Implants

A total of 102 implants were studied, 51 self-tapping BlueSky 4 × 10 mm (Bredent GmbH&Co.Kg[®], Senden, Germany), and 51 non-self-tapping Standard Plus 4.1 × 10 mm (Institut Straumann AG[®], Waldenburg, Switzerland), and placed in the posterior segment of the maxilla (Figures 1 and 2).

Surgical Procedures

Preoperative implant planning was carried out using Galileo's cone beam computed tomography imaging (Sirona[®], Bensheim, Germany), investigating subantral height and residual alveolar crest width as well as jawbone density (Figure 3). Bone density was later confirmed intraoperatively during implant site preparation by pilot drill. Before surgery, the mouth was rinsed with 0.12% chlorhexidine gluconate solution (Hibideks[®] DAP, Galenika, Belgrade, Serbia) for 1 minute and anti-edema therapy was administered: Dexamethasone ampoule 0008 intramuscularly (Dexason[®] Galenika,

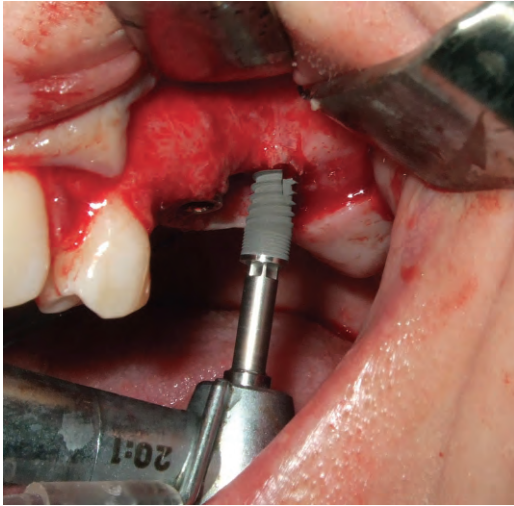


Figure 1 Self-tapping implant placement. Passage of the tapping portion of the implant through the bone and remaining part through the tapped canal.

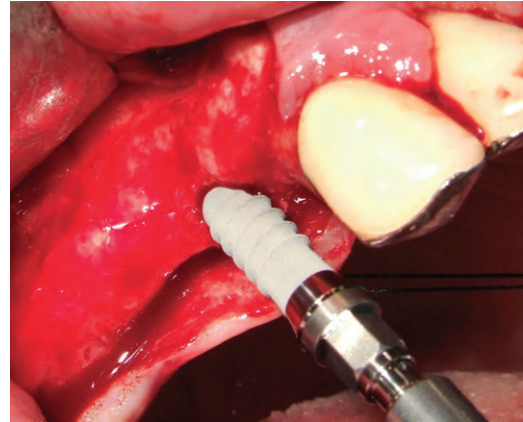


Figure 2 Non-self-tapping implant placement. Implant placement without pretapping with insertion torque of 35 Ncm.

Belgrade, Serbia) and antibiotic prophylaxis: amoxicillin 1.5 g/day or clindamycin 1.8 g/day divided into three doses that continued for 3 days postoperatively.

After administration of a local anesthesia solution (Ultracain D-S Forte®, Aventis, Frankfurt/Main, Germany), a midcrestal incision with two vertical releas-

ing incisions was made, and full-thickness buccal and palatal mucoperiosteal flaps were reflected. In groups I and II, bone-condensing technique was performed by pilot drill and then bone condensers of increasing diameter were applied (Osteotome Kit®, Straumann, Switzerland). Condensers of each successive diameter were left in place for 1 minute to allow gradual trabeculae compression (Figure 4). Implant site preparation in groups III and IV was performed using the bone-drilling

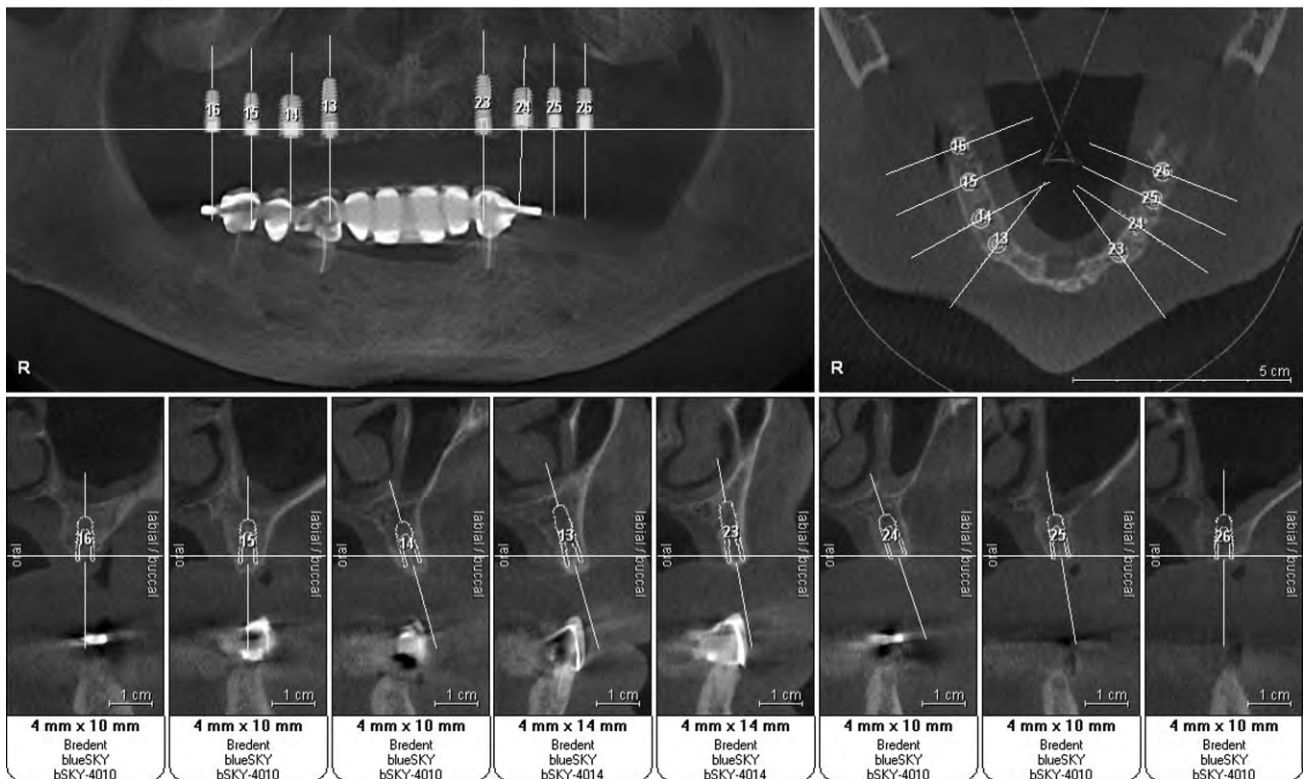


Figure 3 Preoperative implant planning. Assessment of jawbone density and optimal implant position using computed tomography imaging.

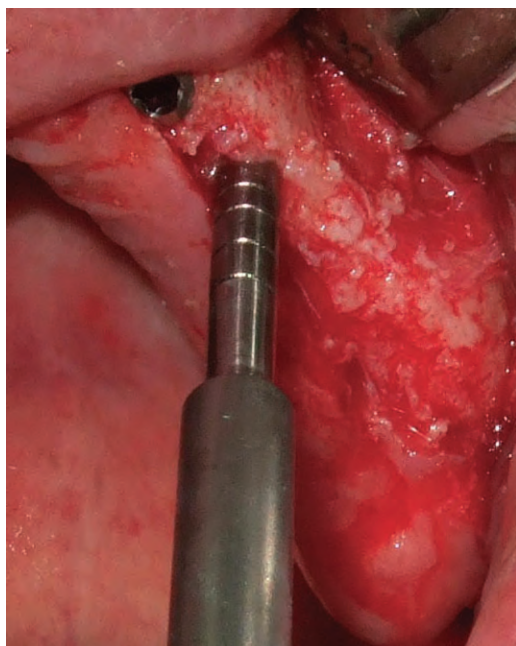


Figure 4 Implant site preparation. Bone condenser is lightly hammered to the appropriate depth with surgical mallet.

technique. Implant sites were gradually enlarged with pilot and spiral drills, using intermittent motions without additional pressure and a drill speed of 400–600 rpm, under copious irrigation by saline solution (Figure 5). After completing implant site preparation, all implants were placed without pretapping, and applied an insertion torque of 35 Ncm. The study involved a one-stage surgical protocol. Primary wound closure was achieved with single sutures that were removed after 7

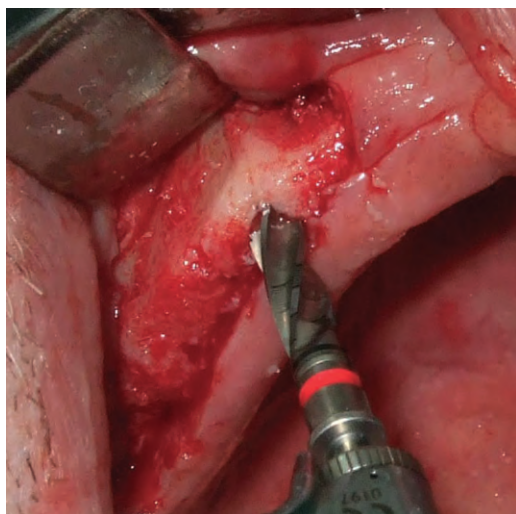


Figure 5 Implant site preparation. Drill progresses through the bony canal with intermittent motions under copious irrigation.

days. After 12 weeks, radiological control images were taken and fixed restorations were placed. Following this point in time, further RFA measurements were no longer a possibility.

Resonance Frequency Measurements

Implant stability measurements were taken using RFA with an Osstell Mentor® device (OsstellIntegration Diagnostics, Savadale, Sweden) and adequate transducers type 49 and type 4 for BlueSky and Standard Plus implants, respectively. RFA is described in the literature as a method for evaluating implant stability during the critical early healing period.¹⁴ All measurements were performed by the same surgeon, who was unaware of the composition of the study groups, and were taken immediately after implant placement and then weekly during the 12-week follow-up period. ISQ values range between 1 and 100; the higher the ISQ, the more stable the dental implant. An ISQ value of 47 was set as a threshold for excluding implants with lower ISQ values from further weekly analysis because of their questionable stability; these implants were covered and a two-stage protocol was planned in order to ensure their standstill condition.¹⁵ Measurements were taken as follows: the transducer was screwed to the inserted implant and stimulated magnetically by a buccolingually oriented probe. Each measurement was repeated until the same value was recorded twice, which was accepted as the authentic value.

Statistical Analysis

Descriptive statistics were calculated with measures of central tendency (mean and median), measure of dispersion (standard deviation), and 95% confidence interval. Data from 96 implants were analyzed using SPSS 17.0 software (SPSS Inc., Chicago, IL, USA), applying the Mann–Whitney *U* test or the Wilcoxon test according to the nature of the data. The significance level was established at $p < 0.05$.

RESULTS

From a total of 102 implants studied, six implants were excluded due to their low primary stability (ISQ 42–46): two from group II and four from group IV, and so data from a total of 96 implants were analyzed. ISQ values for all four study groups and other descriptive statistics are shown in Tables 1–4.

TABLE 1 Implant Stability Quotient (ISQ) in Human Posterior Maxilla: Influence of Implant Macro-Design in Relation with Bone Condensing

Evaluation Time	Implant Stability					95% CI
	Mean	Median	SD	Min	Max	
Primary stability	74.34	74.00	4.09	62	80	72.71–75.76
First week	73.13	74.00	3.80	62	79	71.71–74.55
Second week	71.33	71.00	3.78	59	79	69.92–72.75
Fourth week	68.77	68.00	3.94	55	77	67.29–70.24
Sixth week	69.97	70.00	3.35	59	77	68.72–71.22
Eighth week	71.93	71.00	2.71	64	78	69.85–72.03
10th week	72.67	72.00	2.66	65	79	70.61–72.72
12th week	73.54	72.00	2.58	66	79	70.76–73.12

Values expressed in ISQ.
CI = confidence interval.

Group I

In the first study group, a significant decrease in implant stability compared with primary stability was observed during the first week, and this trend continued up to the fourth week (Wilcoxon test, $p < 0.05$). From the sixth week ISQ values increased until the 12th week but they were still significantly lower than primary stability (Wilcoxon test, $p < 0.05$).

Group II

Data from the second study group indicated significantly lower ISQ values measured between the first and the twelfth postoperative weeks than ISQ values immediately after surgery (Wilcoxon test, $p < 0.05$). At 12

weeks, there were only a few cases for which ISQ values were higher than primary ISQ.

Group III

Analysis of ISQ values during follow-up in the third group showed significantly lower implant stability in the first 4 weeks compared with primary stability (Wilcoxon test, $p < 0.05$). ISQ from the sixth week on was significantly higher than primary stability (Wilcoxon test, $p < 0.05$).

Group IV

ISQ values measured from the first to the fourth postoperative weeks were significantly lower than primary stability (Wilcoxon test, $p < 0.05$). Values in the fourth

TABLE 2 Implant Stability in Posterior Maxilla: Bone Condensing and Non-Self-Tapping Implant Insertion

Evaluation Time	Implant Stability					95% CI
	Mean	Median	SD	Min	Max	
Primary stability	74.03	74.00	3.53	69	81	72.72–75.35
First week	72.70	73.00	3.20	68	79	71.51–73.89
Second week	69.70	69.00	2.20	67	76	68.88–70.52
Fourth week	68.37	68.00	1.65	66	73	67.75–68.98
Sixth week	70.33	70.00	1.21	69	74	69.88–70.79
Eighth week	70.85	70.00	1.19	69	75	69.82–70.12
10th week	71.40	71.00	1.12	70	76	70.13–70.96
12th week	71.88	72.00	1.10	70	77	70.84–70.95

Values expressed in ISQ.
CI = confidence interval.

TABLE 3 Implant Stability in Posterior Maxilla: Bone Drilling and Self-Tapping Implant Insertion

Evaluation Time	Mean	Implant Stability			Max	95% CI
		Median	SD	Min		
Primary stability	65.10	64.50	3.03	62	75	63.97–66.23
First week	64.27	63.00	3.53	61	78	62.95–65.59
Second week	63.43	63.00	3.43	60	77	62.15–64.71
Fourth week	63.27	62.00	3.47	59	75	61.97–64.56
Sixth week	66.60	66.00	2.19	64	75	65.78–67.42
Eighth week	67.21	66.00	2.07	63	75	65.92–67.59
10th week	67.98	67.00	1.93	64	75	66.27–67.62
12th week	68.20	67.00	1.81	64	74	66.40–67.70

Values expressed in ISQ.
CI = confidence interval.

postoperative week showed no significant difference from primary ISQ (Wilcoxon test, $p > 0.05$), while values measured from the sixth to twelfth weeks were significantly higher than primary stability (Wilcoxon test, $p < 0.05$). At the end of the follow-up period, all implants in this group showed significantly greater stability in relation to primary stability (Wilcoxon test, $p < 0.05$).

In all study groups, there was a decrease in implant stability from the first to fourth follow-up week, and minimum values were recorded in the fourth week. From the sixth week, the stability of implants was seen to increase steadily up to the 12th week (Tables 1–4).

Between-Group Comparison

The highest ISQ values were measured in group I, followed by group II with the second highest values, then

group III, and lastly group IV, showing the lowest values (Tables 1–4).

Data analysis for groups I and II showed that, following bone condensation, there were no significant differences between their respective primary stability (Mann–Whitney U test $p > 0.05$) or stability after the first week (Mann–Whitney U test $p > 0.05$) when self-tapping and non-self-tapping implants were compared. However, comparing ISQ values for the two implant macro-designs following bone condensation between the second and twelfth postoperative weeks, significantly higher stability was achieved by self-tapping implants (Mann–Whitney U test $p < 0.05$), except in the sixth week (Mann–Whitney U test $p > 0.05$).

Self-tapping implants placed after bone drilling achieved significantly higher stability than

TABLE 4 Implant Stability in Posterior Maxilla: Bone Drilling and Non-Self-Tapping Implant Insertion

Evaluation Time	Mean	Implant Stability			Max	95% CI
		Median	SD	Min		
Primary stability	61.20	61.00	1.63	58	64	60.59–61.81
First week	59.10	59.00	1.40	56	63	58.58–59.62
Second week	58.50	58.50	1.41	56	62	57.97–59.03
Fourth week	60.77	61.00	0.90	59	63	60.43–61.10
Sixth week	65.23	65.00	0.43	65	66	65.07–65.39
Eighth week	66.03	65.00	0.40	66	67	65.83–66.12
10th week	66.80	66.00	0.37	67	68	66.24–66.56
12th week	67.10	67.00	0.32	68	69	66.81–67.02

Values expressed in ISQ.
CI = confidence interval.

non-self-tapping during the entire follow-up period (Mann–Whitney U test $p < 0.05$). Implants with either macro-designs, placed after bone condensing, achieved significantly higher stability immediately after surgery, as well as during the entire 12-week observation period compared with implants placed following bone drilling (Mann–Whitney U test $p < 0.05$).

DISCUSSION

Endosseous dental implants offer a successful treatment option for the replacement of missing teeth. Primary implant stability is the main factor influencing the long-term success of endosseous implants and this depends on the implant's surface geometry, the surgical technique employed, and local bone quantity and quality.^{11,16}

Primary implant stability is difficult to achieve in the posterior maxilla. In the present study, six implants failed to achieve sufficient stability for one-stage surgery protocol. Most implants were placed in the jaws of postmenopausal women, and this outcome could be related to the reduced bone density that occurs as women age resulting from decreasing levels of estrogens.¹⁷ Indeed, one patient whose implants were excluded from the study, was later found to be suffering from osteoporosis. As the quantity and quality of bone are preset factors, this study aimed to determine links between surgical techniques and implant macro-design in order to subsequently improve implant stability in low-density bone.

Many methods have been used to measure stability and to detect possible implant stability problems. Various techniques, such as insertion and removal torque assessment, attempt to determine the conditions of the implant-bone interface. However, such methods can only be used during or after implant placement; they cannot be used for long-term assessment. RFA was chosen because it is a noninvasive, clinically suitable technique that can be used repeatedly for quantitative evaluation of implant stability in both intraoperative and postoperative situations, and the ISQ values obtained can be compared independently of the implant system used.¹² Although RFA has numerous advantages, many studies have indicated that it is incapable of providing sensitive responses to surrounding bone quality and that the sensitivity of this technique may be related to the performance of the RFA equipment used.^{18,19}

One of the more interesting results of this study is that, compared with bone-drilling technique, bone-condensing technique significantly increased primary

implant stability in low-density bone regardless of the macro-design of the implant used. This increased stability could be due to changes in the micromorphology of peri-implant trabecular bone caused by apico-lateral condensation. Several experimental studies using radiographic densitometry have found significant increases in trabecular thickness and reduction of its separation, as well as significant histomorphometric increases in bone-to-implant contact following bone condensation.^{20,21} Akca and colleagues have found that local bone micromorphology is the prevailing factor in the correct choice of implant design for achieving initial intraosseous implant stability.²² After implant site preparation by lateral condensing technique, peri-implant bone with density type IV can be transformed into the type III. Rabel and colleagues have noted that the use of self-tapping implants significantly increases primary stability in the soft bone, while in dense bone implant, macro-design is insignificant.²³ It is possible that condensation technique provides such good compression of trabecular bone that the further compression provided by self-tapping implants can have no further effect on implant stability.

However, after the bone-drilling technique, self-tapping implants did achieve significantly higher primary stability compared with non-self-tapping implants. This could be explained by the intimate bone-to-implant contact resulting from the compressive threads and the minute lateral displacement exerted on bone tissue during implant insertion, whereby loose bone trabeculae are pushed closer together. Thus, "local" bone contained in the pitch regions (between two adjacent implant threads) becomes denser. By improving the characteristics of the local bone in these regions – the bone responsible for primary stability – the implant receives firmer support. The result is increased primary stability.

Toyoshima and colleagues evaluated the stability of implants with two macro-designs placed in porcine iliac cancellous bone after drilling. Their study found significantly higher stability for self-tapping implants compared with non-self-tapping implants.²⁴

The present study found significant decreases in implant stability in all study groups during the first weeks of the 12-week follow-up period. This corresponds to the transition from primary mechanical stability provided by the old bone to biologic stability provided by the newly formed bone. During this period,

osteoclasts remove the existing bone, and the amounts of new bone formation are still insufficient to provide secondary stability. In this way, after the fourth postoperative week, a tendency toward increased stability would be expected in all study groups as a result of new woven and lamellar bone formation.²⁵

Assessing the ISQ values obtained in this study during early osseointegration, we observed a significant increase in the stability of self-tapping implants, regardless of which surgical technique had been used for site preparation. With self-tapping implants, bone healing secondary to excessive compressive forces exerted may be impaired due to microdamage of trabeculae followed by osteocyte apoptosis and osteoclast activation. But in our study, from the second postoperative week, the largest increase in stability was observed in the group of self-tapping implants placed after bone condensing. This finding suggests that the total compression, as a result of both lateral bone condensation technique and self-tapping implants, was within the physiological range and as such may have stimulated bone healing probably by activating the trauma-dependent repair mechanism known as “regional acceleratory phenomenon.” Therefore, a higher bone-to-implant contact ratio achieved in this way might explain our results.²⁶

One possible limitation of this study derives from variations in the implant neck features between the two implant systems used. The self-tapping implants used in this study had a fluted neck while the non-self-tapping implants had a smooth neck section. One might expect that the fluted neck would reduce initial stability due to the lack of threads engaging with whatever cortical bone is located at the crest of the alveolar ridge. However, according to our results, self-tapping implants achieved greater stability compared with non-self-tapping implants with both surgical techniques in spite of their fluted neck. This might be explained by the extremely thin layer of cortical bone present in the posterior maxilla, which does not provide sufficient support.²⁷

At planned implant sites, surgical technique and implant design should be chosen according to the characteristics of local bone. In low-density bone, such as the bone found in the posterior maxilla, a significant increase in implant stability can be achieved by lateral bone condensation technique regardless of the macro-design of the implant to be placed. However, when bone-drilling technique is used in this region, the use

self-tapping implants is to be recommended because this macro-design significantly increases implant stability.

CONCLUSION

Data from the current study suggested that bone drilling is not so powerful in improving implant stability, and after this technique, the use of self-tapping implants is highly recommended. Implant stability optimization in soft bone can be achieved by lateral bone-condensing technique, regardless of implant macro-design. The differences in the primary stabilities can be explained by variations in implant geometry, especially the presence of a self-tapping implant.

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Oral Surgery, Oral Medicine, Oral Pathology, Oral Radiology, and Endodontology

ORAL AND MAXILLOFACIAL SURGERY

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Implant stability in posterior maxilla: bone-condensing versus bone-drilling: a clinical study

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Objective. The aim of this clinical trial was to compare primary and secondary stability of implants placed by bone condensing versus the standard drilling technique in the posterior edentulous maxilla.

Study design. Forty-eight SLA Straumann implants 4.1 × 10 mm (Institut Straumann AG, Waldenburg, Switzerland) were placed into edentulous maxillary posterior region in the same positions bilaterally, using the bone condensation technique for one and the standard technique for the other side. Implant stability measurements were performed immediately after implant placement, as well as every week for the next 6 weeks by use of resonance frequency analysis (RFA). Data were analyzed using Mann-Whitney *U* and Wilcoxon tests.

Results. After bone condensing, significantly higher implant stability was recorded immediately after surgery as well as during the whole observation period of 6 weeks compared with bone-drilling technique (Mann-Whitney *U* test, *P* = .000).

Conclusions. The bone-condensing technique can be recommended as an alternate surgical approach for implant site preparation in reduced bone density to achieve greater implant stability in the posterior maxilla. (*Oral Surg Oral Med Oral Pathol Oral Radiol Endod* 2011;112:557-563)

Primary stability is one of the fundamental criteria for obtaining osseointegration. It depends on the implant design, surgical technique, bone density, and on the microscopic and macroscopic morphology of the implant used.¹

In dense bone, high primary stability is easily obtained, thus providing contact osteogenesis. In low-density bone, it is often difficult to obtain satisfactory primary stability. The lack of initial stability can result

in distant osteogenesis, a longer healing period, and a lower success rate.²

More or less dense trabecular bone surrounded by a thin layer of cortical bone is often present in posterior maxilla (class III and IV, Lekholm and Zarb).³ In this biologically challenged region for implant placement, it is often difficult to achieve good primary stability. It could be achieved by the undersized preparation technique, wider implant diameter, placement of conical implants or by condensing of the implant site.²

The bone-condensing technique was introduced to increase primary stability of dental implants in the posterior maxilla. This implant site preparation technique involves the use of implant-shaped instruments (bone condensers) by which the bone is compressed apically and laterally rather than removed. Bone condensing preserves as large a volume of existing maxillary bone as possible and increases its density so as to optimize the primary stability of implants in low-density bone.⁴

Compared with native trabecular bone, in compressed trabecular bone grafts, the increased amount of

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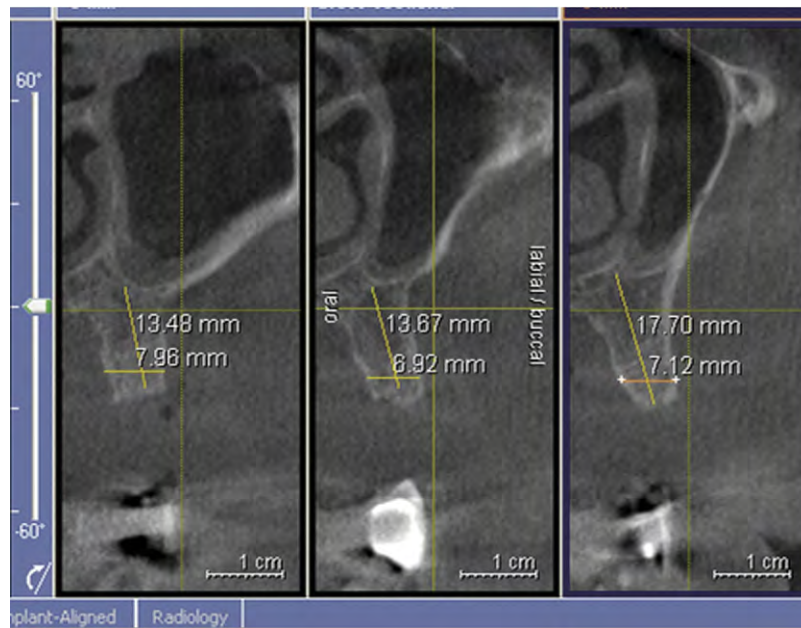


Fig. 1. Preoperative implant planning. Assessment of available jaw bone volume and density by using Galileos cone beam CT imaging.

new bone is formed and it is proportional to the degree of compression.⁵ This bone has enhanced density.⁶

Animal studies showed that the bone-condensing technique would improve primary stability of implants and compared with standard drilling, accelerate bone healing.⁷ Condensation significantly increases bone density in apical peri-implant area in relation to standard surgical technique.⁸

In contrast, Buchter et al.^{9,10} published that after bone condensing, microfractures in peri-implant bone have led to delayed bone recovery, impaired bone-to-implant contact and decreased implant stability. Also, longitudinal cracks and gap formation at the collar bone region, resulting in higher failure rates in cases of condensation techniques, have been reported.¹¹

As expected on the basis of theoretical considerations, the bone-condensing technique increased the success rate of implant therapy in the posterior maxillary region.¹² It can be assumed that one of the causes of improved success rate is greater implant stability in such prepared implant sites. There are no data to support clinical evidence of the dynamics in implant stability for those placed in condensed bone. The aim of this clinical trial was to compare primary and secondary stability of implants placed by condensing versus the standard drilling technique in the posterior edentulous maxilla.

MATERIAL AND METHODS

Forty-eight sand-blasted, large grit, acid-etched (SLA) Straumann implants (Institut Straumann AG,

Waldenburg, Switzerland) with the length of 10 mm and a diameter of 4.1 mm, were placed into edentulous maxillary posterior region of 8 nonsmoking and generally healthy patients (5 men and 3 women) between January and December 2009 at the Clinic of Oral Surgery, Faculty of Stomatology, University of Belgrade. Patient ages ranged from 20 to 65 years (mean 47.6 years). Inclusion criteria for implantation were (1) bilateral subantral bone height 12 mm, (2) 6.2 mm or more bone width, and (3) jaw bone density D3 or D4 according to Lekholm and Zarb classification. Bone density assessment and implant planning were performed using Galileos cone beam CT Imaging (Sirona, Bensheim, Germany) (Fig. 1). Bone density was then once again tactile reaffirmed, during the preparation of pilot osteotomy.

The study was approved by the Ethics Committee at the Faculty of Stomatology, University of Belgrade (Number 36/20).

Patient history data, necessary for surgical procedure, were collected through a questionnaire, completed by patients themselves. The whole procedure was explained in detail to each patient and all surgeries were performed after patient written consent.

All surgeries were performed under local anesthesia (Ultracaine D-S Forte, Aventis, Frankfurt/Main, Germany). Antibiotic prophylaxis was applied in all cases with amoxicillin (1.5 g) or clindamycin (1.8 g) daily, divided in 3 doses, administered for 3 days.

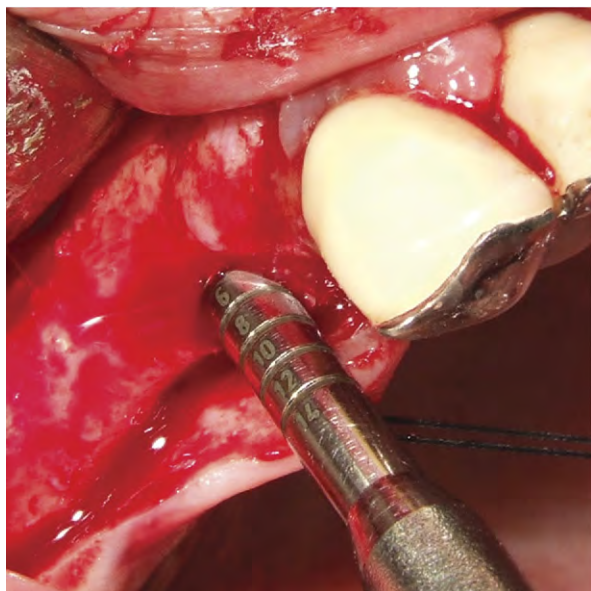


Fig. 2. Implant site preparation. Bone condenser is lightly hammered to the appropriate depth with a surgical mallet.

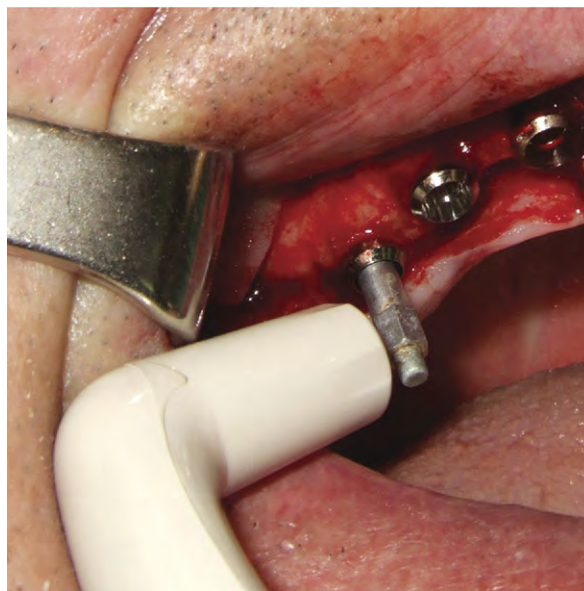


Fig. 3. Primary implant stability measurement by using RFA. The transducer is attached to the inserted implant and stimulated magnetically by the probe.

To provide uniform conditions in both study groups, implant placements were made in the same positions bilaterally, using the bone condensation technique for one side and the standard technique for the other side of the maxilla. Jaw side for the bone condensation or standard technique was randomly selected.

A midcrestal incision with 2 vertical releasing incisions was made bilaterally. Full-thickness buccal and palatal mucoperiosteal flaps were reflected, exposing the alveolar ridge at the sites of implant placement.

Implant sites, at the “bone-condensation” side, were prepared by pilot drill, followed by condensers of increasing diameter (Osteotome Kit, Straumann) (Fig. 2). Each condenser remained at the implant site for 1 minute before the next diameter was used. Finally, implants were inserted with the same insertion torque, 35 N/cm, also without pretapping.

At the “standard technique” side, the implant sites were gradually enlarged to 3.5 mm in diameter, with pilot and spiral drills, according to the standard protocol of the manufacturer (Straumann GmbH, Waldenburg, Switzerland). Implants were placed using insertion torque of 35 N/cm, without pretapping.

After the implantation, at both sides, primary wound closure was achieved with single sutures.

Implant stability measurements were performed immediately after implant placement, as well as every week for next 6 weeks¹³ by use of resonance frequency analysis (RFA). The analysis of RFA was made using an Osstell Mentor apparatus (Osstell,

Integration Diagnostics, Savadale, Sweden) with a commercially available transducer (type 4) adapted to Straumann implants. The transducer was maintained perpendicular to the implant and was hand-screwed into the implant body as recommended by the manufacturer (Fig. 3). Measurements were shown in ISQ (implant stability quotient) units, on the scale from 1 to 100 (100 as maximum implant stability). Each measurement was repeated, until the same value was recorded twice, which was accepted as the authentic value. All implant stability evaluations were done by 1 researcher who was blinded to the technique used to prepare the implant sites so as to achieve objective measurement.

Control digital panoramic radiographs were made immediately after the implant insertion, as well as after 6 weeks. Data were analyzed in SPSS ver. 17 software (SPSS, Inc, Chicago, IL). Descriptive statistics were performed with measures of central tendency (mean and median), measure of dispersion (standard deviation), and 95% confidence interval. For statistical analysis of data, the following tests and methods were used depending on the nature of the data: Mann-Whitney *U* test and Wilcoxon test. The significance level was .05.

RESULTS

Clinical observation

At first, 10 patients fulfilled the criteria for inclusion in the study; however, in the bone-condensing study group



Fig. 4. Control orthopantomogram image 1 year after early implant loading. Implants placed after bone condensing on the right and after bone drilling on the left side of the maxilla. Signs of unimpeded healing are observed. Implant in the region of 23 is excluded from the study because it did not meet the inclusion criteria.

the buccal lamella of the jaw was fractured during the implant site preparation in 1 patient. In the bone-drilling study group, the primary stability of implants in 1 patient was 42 ISQ. In both of these patients, implants were covered and 2-stage protocol was planned and patients were excluded from the study. Therefore, the study was conducted on 8 patients, ie, 48 implants. In all enrolled patients, the postoperative course was uneventful with minimal discomfort. Complications were not seen; implants from both study groups, bone-condensing as well as the standard technique, were clinically stable during the period of observation. Final prosthetic rehabilitation was performed for all implants 6 weeks after surgery when they were all eligible for early loading ISQ of greater than or equal to 65 (Fig. 4).

Within-group results

The recorded ISQ values and accompanying descriptive statistics for both study groups are presented in Table I.

Primary stability recorded after bone condensing was 74.03 ± 3.53 ISQ. In this study group, significantly smaller ISQ values were measured between the first and the sixth postoperative week than the values immediately after surgery (Wilcoxon test; $P = .000$). In the sixth week, the ISQ values observed for implants placed after bone condensing were higher than those for primary stability only in some cases.

In the control group (drilling), primary stability was 61.20 ± 1.63 ISQ. ISQ values measured from the first to third postoperative week in this group were significantly smaller than for the primary stability (Wilcoxon test, $P = .000$). ISQ values in the fourth postoperative week in the control group were not significantly different from the primary stability values (Wilcoxon test; $P = .230$), whereas values measured in the fifth and sixth weeks were

significantly higher than the primary stability (Wilcoxon test; $P = .000$). At the end of the analyzed period, all implants in this control group had a significantly greater stability in relation to their primary stability. However, this stability was still considerably less than those achieved in the bone-condensing group.

Between-group results

Implants placed after bone condensing had been performed achieved significantly higher stability immediately after surgery as well as during the whole observation period of 6 weeks compared with those placed following the conventional implant site preparation (Mann Whitney U test, $P = .000$; Table II).

From the first week postoperatively, there was a decline in stability of implants from both groups and the lowest ISQ values were observed in the third week: 66.70 ± 1.64 for bone condensing and 57.10 ± 1.45 for bone drilling. Implant stability started to increase in the fourth week postoperatively for both surgery techniques and it was continued until the sixth week (Fig. 5).

DISCUSSION

Excessive implant motion (between 50 and 150 μm) or poor implant stability results in tensile and shear motions, stimulating a fibrous membrane formation around the implant and causing displacement at the bone-implant interface, thus inhibiting osseointegration and leading to aseptic loosening and failure of the implant.¹⁴ Primary stability provides mechanical rest of implants after their insertion in the bone recipient site and thus creates the conditions for an undisturbed osseointegration. The bone condensation technique is recommended for increasing the stability of an implant placed in low-density bone, but its use is still controversial.

We noticed a significantly higher primary stability in the group where the bone condensation technique was performed compared with the standard technique. The result could be explained by changes in peri-implant trabecular bone micromorphology after its apicolateral condensation. Fanuscu et al.¹⁵ noted that lateral bone condensation significantly increased trabecular thickness and reduced its separation. Also, they found significant increase in relative bone volume in a 1-mm circular vicinity of implants placed after bone condensation. Implant stability quotient values in their study on cadavers were higher for implants placed with the bone condensing than those for the standard technique, but were not statistically significant. This discrepancy with our results could be caused by the difference in the density of bone present in the maxilla “in vivo” and in the iliac crest from fresh cadavers that are used as an experimental model in their study.

Table I. Implant stability in human posterior maxilla: descriptive statistics

<i>Parameter</i>							
<i>Evaluation time</i>	<i>Technique</i>	<i>Mean</i>	<i>Median</i>	<i>SD</i>	<i>Minimum</i>	<i>Maximum</i>	<i>95% confidence interval</i>
Primary stability	Condensing	74.03	74	3.53	69	81	72.72-75.35
	Drilling	61.20	61	1.63	58	64	60.59-61.81
1st week	Condensing	72.70	73	3.20	68	79	71.51-73.89
	Drilling	59.10	59	1.40	56	64	58.58-59.62
2nd week	Condensing	69.70	69	2.20	67	76	68.88-70.52
	Drilling	58.50	58.5	1.41	56	62	57.97-59.03
3rd week	Condensing	66.70	66	1.64	65	72	66.09-67.31
	Drilling	57.10	57	1.45	54	61	56.56-57.64
4th week	Condensing	68.37	68	1.65	66	73	67.75-68.98
	Drilling	60.77	61	0.90	59	63	60.43-61.10
5th week	Condensing	68.83	69	1.32	67	73	68.34-69.32
	Drilling	63.43	63	0.86	62	65	63.11-63.75
6th week	Condensing	70.33	70	1.21	69	74	69.88-70.79
	Drilling	65.23	65	0.43	65	66	65.07-65.39

Values expressed as implant stability quotient (ISQ).

Table II. Differences in the implant stability according to the surgical technique

<i>Evaluation time</i>	<i>Implant stability</i>		<i>P value*</i>
	<i>Bone condensing</i>	<i>Bone drilling</i>	
Primary stability	74.03 ± 3.53	61.20 ± 1.63	.000
1st week	72.70 ± 3.20	59.10 ± 1.40	.000
2nd week	69.70 ± 2.20	58.50 ± 1.41	.000
3rd week	66.70 ± 1.64	57.10 ± 1.45	.000
4th week	68.37 ± 1.65	60.77 ± .90	.000
5th week	68.83 ± 1.32	63.43 ± .86	.000
6th week	70.33 ± 1.21	65.23 ± .43	.000

Values are given in implant stability quotient (ISQ), expressed as mean ± standard deviation of the mean;

*Mann-Whitney *U* test; all values are statistically significant.

Significantly higher primary stability after condensation, we have found, could be the result of an improved peri-implant bone density and increased bone-to-implant contact. The supporting results were published by Proff et al.¹⁶ in the cadaveric study. In spongy bone, following bone condensing, a significant histomorphometric increase of bone-to-implant contact supported by radiographic densitometry was found. That resulted in slight, yet not significant increase of primary stability after bone condensing (67.00 ± 3.32 ISQ) compared with the conventional technique (65.60 ± 3.29 ISQ). Within the compact area, the condensing technique has not achieved such a benefit.

Strietzel et al.¹⁷ highlighted the advantage of using the condensing technique in types 3 and 4 bone, as well as possible deleterious effect on osseointegration when it was performed in dense bone. Implant sites where the preparation cannot be achieved by force of less than 20 MPa are not suitable for condensation, because the

stronger force damages osteocytes and bone microfractures appear that reduce mechanical competence of bone and stability of the implant.^{18,19} In clinical conditions, during bone condensing, defined force cannot be used and preoperative bone density assessment is important to achieve success outcome.

In accordance with our results, Kim et al.²⁰ confirmed that the trabecular compaction technique should be an effective surgical technique to increase primary stability in soft bone regions. In their animal study, after placing an implant in the femur of dogs, the groups with trabecular compaction technique showed higher ISQ values than groups with the conventional drilling. Also Choi et al.²¹ observed higher primary stability for implants placed in the maxilla of fresh-frozen cadavers after bone condensing compared with conventional drilling. In contrast, Buchter et al.¹⁰ concluded that following bone condensing for implant placement, decreased implant stability was achieved because of microfractures in peri-implant bone. On the other hand, Stavropoulos et al.²² noted that minor cracks in the coronal portion of the alveolar ridge observed after condensation in the dog mandible have not prevented good primary stability of implants. Total separation of bone fragments was not detected.

Over time, the primary mechanical stability of the implant is transformed into a secondary biological stability, which reflects regeneration and remodeling in bone-implant interface.²³ Results of this clinical trial presented significantly higher mean stability levels for implant sites prepared by bone condensing compared with bone drilling at all time points during the observation period of 6 weeks. This result could be a consequence of different bone regeneration patterns present after the use of 2 surgical techniques. Unlike the

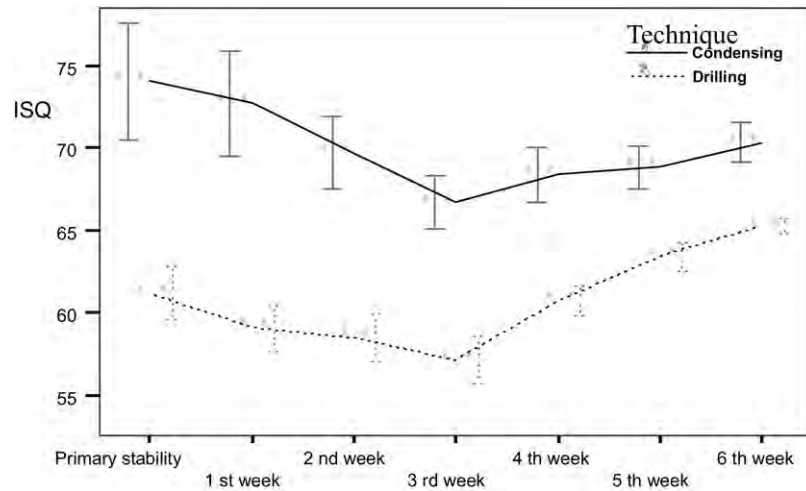


Fig. 5. Implant stability changes during healing period.

usual process of bone regeneration in the control group, the trauma-dependent repair mechanism known as “regional acceleratory phenomena” is expected after bone condensing. Mechanical stimuli could accelerate the formation of trabecular bone.²⁴ The local bone remodeling can be intensified up to 50 times.²⁵ In the animal study, local trauma caused by the osteotome technique has led to improved bone-to-implant contact ratio, over time.⁸ It is also found that comparing bone drilling and condensing, the latter generated significantly smaller amounts of heat, which potentially creates improved conditions for osseointegration.²⁶ Previously, enhanced osseointegration of dental implants in trabecular bone following bone condensing compared with standard technique was reported.⁸

The results of this clinical study indicate a significant decrease in implant stability in the third week in both study groups. This decline is in agreement with previous findings and could be explained by necrotic bone remodeling, which means the activity of osteoclasts that decrease the initial mechanical stability of the implant when the formation of new bone has not yet occurred to the level required to maintain implant stability. Indeed, in the second week, Berlundh et al.²⁷⁻²⁹ noticed ongoing bone remodeling in pitch regions of the implant, responsible for primary mechanical stability in their dog animal model. With respect to the interspecies differences in healing time, this phenomenon corresponds to the third week of healing in humans.

The interesting finding of our study is that even in the critical third week, regardless of the present fractured bone trabeculae noted in previous histologic studies, the stability of the implant after the condensation had not dropped below 60 to 65 ISQ as a suggested value for the

immediate loading of implants.^{8,30} In the control study group, significantly lower ISQ values were measured. One could speculate that the increase in implant stability after bone condensation creates the conditions for its earlier loading. This suggests the need to revise the existing loading protocols in low-density bone dealing with bone condensation technique. Successful outcome of immediate loading of implants placed following the condensing technique was published in a few clinical reports.^{13,31}

In the present study, implant stability started to increase from the fourth week as the result of woven combined with lamellar bone formation and in the sixth week implants from both groups obtained ISQ values suggested for the early loading protocol.²⁸ However, significantly higher ISQ values were recorded for bone-condensing compared with standard technique.

The variety of data present in the literature on the impact of bone condensing on the implant stability could be derived from differences in density and healing time between the different experimental animal models, as well as between animal models and maxillary bone. The applied biomechanical test could also have an impact. Resonance frequency analysis was used to evaluate the implant stability in this study. In the literature, it is proposed as the most acceptable clinical method for determination the primary and secondary implant stability as well as a valuable indicator for implant success and early failure.^{32,33}

In conclusion, the bone-condensing technique can be recommended as an alternate surgical approach for implant site preparation in reduced density bone so as to achieve greater implant stability. According to the results of this study, implants inserted in the bone after bone condensing had been performed met the criteria for im-

mediate loading as opposed to those placed after the standard technique, which fulfilled this requirement later in the healing period. More years of observation are needed to prove that the increased stability of dental implants provided by bone condensing will be preserved.

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Fakultet STOMATOLOŠKI

UNIVERZITET U BEOGRADU

Stručno veće za medicinske nauke

Broj zahteva _____

(naziv stručnog veća kome se zahtev upućuje, shodno
čl.6 Statuta Univerziteta u Beogradu i čl. 7. st.1
ovog pravilnika)

_____.god.

(Datum)

ZAHTEV

za davanje saglasnosti na izveštaj o urađenoj doktorskoj disertaciji

Molimo da, shodno članu 68. st.3. Zakona o univerzitetu ("Službeni glasnik RS" br. 20/98), date saglasnost na

izveštaj o urađenoj doktorskoj disertaciji kandidata

ĆALASAN ILIJA DEJAN

(ime, ime jednog od roditelja i prezime)

KANDIDAT ĆALASAN ILIJA DEJAN

(ime, ime jednog od roditelja i prezime)

prijavilo je doktorsku disertaciju pod nazivom

„UTICAJ HIRURŠKE TEHNIKE UGRADNJE I MIKRO I MAKRO DIZAJNA IMPLANTATA NA NJIHOVU STABILNOST GORNJE VILICE“

Univerzitet je dana 22.05.2012. svojim aktom pod br. 06-18704/14-12 dao saglasnost na predlog teme

doktorske disertacije koja je glasila

„„UTICAJ HIRURŠKE TEHNIKE UGRADNJE I MIKRO I MAKRO DIZAJNA IMPLANTATA NA NJIHOVU STABILNOST GORNJE VILICE“

Komisija za ocenu i odbranu doktorske disertacije kandidata

ĆALASAN ILIJA DEJAN

(ime, ime jednog od roditelja i prezime)

obrazovana je na sednici održanoj 23.09.2014 odlukom fakulteta pod br. 3/86

u sastavu:

ime i prezime člana komisije:	zvanje:	naučna oblast:
<u>SNJEŽANA ČOLIĆ</u>	<u>PROFESOR</u>	<u>KLINIČKE STOM. NAUKE</u>
<u>LJILJANA STOJČEV STAJČIĆ</u>	<u>PROFESOR</u>	<u>KLINIČKE STOM. NAUKE</u>
<u>SINIŠA MIRKOVIĆ</u>	<u>PROFESOR</u>	<u>KLINIČKE STOM. NAUKE</u>

Nastavno-naučno veće fakulteta prihvatilo je izveštaj Komisije za ocenu i odbranu doktorske

disertacije na sednici održanoj dana 26.06.2014.

DEKAN FAKULTETA

Prof. dr Miroslav Vukadinović

- Prilog:**
1. Izveštaj komisije sa predlogom
 2. Akt Nastavno-naučnog veća fakulteta o usvajanju izveštaja
 3. Primedbe date u toku stavljanja izveštaja na uvid javnosti, ukoliko je takvih primedbi bilo.