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## Posterior single implants immediately loaded using one abutment at one time and temporary abutment in the posterior mandible without bone augmentation: a report on six-month outcomes data obtained from a prospective randomized controlled split-mouth clinical trial

Neposredno opterećenje posteriornih implantata u mandibuli primenom definitivnog i privremenog nosača: šestomesečni rezultati prospektivnog randomizovanog kontrolisanog *split-mouth* kliničkog istraživanja

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## Abstract

Background/Aim. Given that frequent manipulation of the abutment during immediate loading can have a negative impact on the surrounding peri-implant hard and soft tissues, the concept "one abutment at one time" (OAO) has been introduced and documented in daily clinical practice. The aim of the study was to evaluate changes in periimplant bone levels, clinical and radiographic parameters, and patient perspectives during the six-month follow-up period. Methods. The study was designed as a randomized controlled clinical trial. Patients with bilaterally healed sites in the posterior mandible received implants with a diameter of no less than 3.5 mm and a length of at least 8 mm. Based on randomization, patients were divided into a test group and a control group. Patients who were in the test group received implants that were immediately loaded with definitive abutments. In contrast, patients in the control group received implants where healing abutments were placed, followed by temporary abutments. Implants were immediately loaded with provisional restorations within the first seven

## Apstrakt

**Uvod/Cilj**. S obzirom na to da česta manipulacija nosačem (*abutment*-om) tokom neposrednog opterećenja može imati negativan uticaj na okolna tvrda i meka tkiva oko implantata, u svakodnevnu kliničku praksu uveden je i dokumentovan koncept "jedan po jedan nosač" (*one abutment at one time* – OAO). Cilj rada bio je da se tokom perioda praćenja od šest

days. They were delivered over the test group's definitive abutment and the control group's temporary abutment. Probing depth, bleeding on probing, clinical attachment level, plaque index, and keratinized tissue width were measured. Patient-Reported Outcome Measures and the Oral Health Impact Profile - 19 (OHIP-19) questionnaires were noted. Results. Out of 24 included patients, 22 completed the six-month follow-up. Peri-implant bone loss between study groups was comparable (mesial: t = -0.798, df = 21, p = 0.434; distal: t = 1.688, df = 21, p = 0.106), without statistical inter-group significance. OHIP-19 total scores significantly decreased after three months and remained similar six months after the implant placement in both groups without statistically relevant clinical inter-group changes. Conclusion. The OAO approach and provisional abutments showed comparable effectiveness regarding the immediate loading of posterior single implants.

## Key words:

## dental abutments; dental implants; mandible; methods; surveys and questionnaires.

meseci procene promene u nivou periimplantne marginalne kosti, kliničkim i radiografskim parametrima i perspektivi pacijenata. **Metode**. Studija je osmišljena kao randomizovano kontrolisano kliničko ispitivanje. Pacijenti sa bilateralno zalečenim mestima u posteriornoj mandibuli dobili su implantate prečnika ne manjeg od 3,5 mm i dužine od najmanje 8 mm. Na osnovu randomizacije, pacijenti su podeljeni u testiranu grupu i kontrolnu grupu. Pacijenti u

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testiranoj grupi dobili su implantate neposredno opterećene odgovarajućim definitivnim nosačom, dok su pacijenti u kontrolnoj grupi dobili implantate na koje su postavljene kapice za zarastanje, a zatim privremeni nosači. Implantati su u prvih sedam dana neposredno opterećeni privremenim zubnim nadoknadama koje su postavljene preko definitivnih nosača u testiranoj grupi i preko privremenih nosača u kontrolnoj grupi. Praćeni klinički parametri bili su dubina sondiranja, krvarenje na provokaciju, nivo pripojnog epitela, plak indeks i širina keratinizovanog tkiva. Zabeleženi su rezultati upitnika mere ishoda i percepcije od strane pacijenata i upitnika o zadovoljstvu i uticaju na oralno zdravlje (*Oral Health Impact Profile 19 –* OHIP-19). **Rezultati**. Od ukupno 24 uključena pacijenta, 22 su završila šestomesečno praćenje.

Gubitak kosti oko implantata između ispitivanih grupa bio je uporediv (mezijalno: t = -0,798, df = 21, p = 0,434; distalno: t = 1,688, df = 21, p = 0,106), bez statističke međugrupne značajnosti. Ukupni rezultati OHIP-19 upitnika značajno su se smanjili posle tri meseca i ostali slični šest meseci nakon ugradnje implantata u obe grupe, bez statistički značajne kliničke promene među grupama. **Zaključak**. Pimena OAO koncepta opterećenja privremenim nosačom pokazala je uporedivu efikasnost u pogledu neposrednog opterećenja posteriornih pojedinačnih implantata.

## Ključne reči:

zub, nosač proteze; zubi, implantati; mandibula; metode; ankete i upitnici.

## Introduction

Over the past decade, implant dentistry has undergone a patient-centric transformation with the development of advanced techniques in implant placement and loading. The demand to accelerate the course of the treatment, in accordance with biological principles and patient's expectations and comfort, leads to the shift towards immediacy in implant dentistry. Evaluating outcomes in oral implantology by combining the placement and loading protocols is crucial. The literature data have shown that the combination of immediate loading of implants placed in healed posterior sites is associated with high survival and success rates <sup>1</sup>.

Another important factor is the fact that the stability of both hard and soft tissues around the implant determines the lasting success of implant procedures. The integrity of the peri-implant supracrestal attachment depends on the good condition of the sulcular epithelium, the impermeability of the junctional epithelium, and the elasticity of the connective tissue<sup>2</sup>. The arrangement of peri-implant connective tissue fibers is parallel even without direct attachment to the implant/abutment and thus represents a vulnerable and weak point<sup>3</sup>. The repeated disruption of this implant-mucosal barrier due to repeated healing abutment/impression, copings/other prosthetic components manipulation, definitive abutment detachment, and reattachment could potentially lead to downward migration of the supracrestal attachment, thereby exacerbating marginal bone loss (BL) – MBL<sup>4</sup>. Furthermore, patients dislike frequent soft tissue manipulation due to the associated discomfort and prolonged chair time.

To reduce the oscillation of post-implantation changes, the existing literature presents several strategies aimed at consolidating peri-implant hard and soft tissues. There are various recommendations related to the characteristics of the abutment <sup>5</sup>, morphology <sup>6</sup>, and composition <sup>7, 8</sup>, as well as measures to prevent microgap and micromovement <sup>9, 10</sup>, refine implant-abutment platforms <sup>11</sup> and connections <sup>12</sup>, and optimize the timing of definitive abutment activation <sup>13, 14</sup>.

The one abutment at one time (OAO) approach, assisted by the implementation of the digital workflow, opposing conventional analog procedures, has exhibited comparable clinical outcomes in terms of MBL and soft tissue alterations <sup>15</sup>. Nevertheless, a scarcity of randomized, split-mouth clinical studies evaluating both clinical and radiological consequences, along with patient perspectives, interferes with a comprehensive assessment of these two methodologies within immediate loading protocols (ILPs).

Therefore, the aim of this study was to assess changes in peri-implant bone levels during the six-month follow-up period using the OAO concept, compared to provisional abutments of single immediately loaded posterior implant crowns, as well as to evaluate clinical parameters and changes in patient perspectives.

## Methods

#### Study design

The study was designed as a split-mouth, doubleblinded, randomized, patient-oriented, controlled clinical trial. All subjects were recruited at the Implant Center, Faculty of Dental Medicine, University of Belgrade, Serbia, from September 2021 to March 2022. The study was approved by the institutional Ethics Committee of the Faculty of Dental Medicine prior to study commencement (No. 36/16, from June 7, 2021), and each participant signed an informed consent. This research was conducted in full accordance with the Helsinki Declaration of 1975 and subsequent amendments. It was registered in ClinicalTrials.gov (NCT05668494) and carried out in accordance with the CONSORT statement.

#### **Participants**

From a pool of 38 adult patients evaluated for potential participation, 24 individuals met the inclusion criteria, which were as follows: patients showcasing bilaterally healed sites with at least one adjacent tooth, specifically in the posterior mandible premolar or molar region. Adequate restorative space was characterized by an interocclusal plane distance surpassing 20 mm in conjunction with a keratinized tissue band spanning a minimum of 2 mm (from crest to mucogingival junction). The osseous architecture was conducive to accommodating an implant with a diameter of no less than 3.5 mm and a length of at least 8 mm. Adult patients aged 20

and above, in sound physical and mental health conditions (classified as ASA I) were included. Patients were committed to adhering to the study protocol, as demonstrated by signing an informed consent.

Exclusion criteria involved patients with a history of head and neck radiotherapy or bisphosphonate medication, along with those presenting acute periodontitis, caries, or periapical radiolucency in the vicinity of adjacent teeth. Patients who had previous bone augmentation in the region of the posterior mandible were excluded from the study. Individuals with suboptimal oral hygiene, physical limitations impeding regular oral care, pregnant or breastfeeding females, smokers, and substance abusers were also excluded from the study.

#### Preoperative parameters

At the inclusion phase, a single calibrated examiner recorded clinical parameters, which were registered and stored in specially designed case record forms. Clinical periodontal parameters such as probing depth (PD), bleeding on probing (BOP), clinical attachment level (CAL), and plaque index (PI) were recorded for each patient around every tooth, and keratinized tissue width (KTW) was measured at the future implant site, as well as at sites mesially and distally to the planned implant position. Furthermore, Patient-Reported Outcome Measures (PROMs) and the Oral Health Impact Profile (OHIP-19) questionnaires were noted.

#### Prosthetic procedure

On the same day, a digital (3Shape, Trios system, Gerabutment-level impression  $(GM^{TM})$ many) Abutment Scanbody) was performed on the test group of implants; implant-level digital impression on the control group was also obtained (GM<sup>™</sup> Universal Abutment Scanbody). Provisional restorations were made of polymethyl methacrylate (PMMA) (Telio® CAD, Ivoclar Vivadent, Schaan, Lichtenstein), following digital protocol. Within the first seven postoperative days, they were delivered over the definitive abutment for the test group and over the temporary abutment (GM<sup>™</sup> temporary abutment) for the control group. The virtual design of provisionals was made in 3D design software (Exocad-Matera 2.3, Exocad, Darmstadt, Germany), and the milling of PMMA blocks was performed in a 5-axis milling machine (Zenotec Select, Wieland, Pforzheim, Germany). At the end of the twelve-week period, provisional restorations were removed. The control group received the selected GM<sup>™</sup> abutment instead of the temporary abutment. Digital scanning was repeated in the same manner, using the abutment-level scanbodies, and the definitive restorations were delivered to the patients. Monolithic zirconia screw-retained single crowns (IPS emax ZirCad Prime Esthetic, Ivoclar, Liechtenstein) were placed over the GM<sup>™</sup> abutments with an occlusal screw torque of 10 N-cm. The monolithic zirconia screwretained restorations were fabricated following digital protocol.

#### Outcomes

The primary outcome variable was MBL changes, while the secondary outcome variables were clinical parameter changes, PROMs, and OHIP-19.

MBL was assessed as the difference between the marginal bone height and the implant shoulder. Intraoral radiographs using a customized radiographic holder and intraoral scans (3Shape, Trios system, Germany) were captured before the implant placement (T0), after temporary (T1) and definitive restoration delivery (T2), and on six-month follow-ups (T3). The mesial and distal vertical lines representing the distance between the marginal bone and implant shoulder were digitally measured and recalculated according to the radiographic distortion. Clinical parameters were assessed on T1 to T3.

OHIP-19 questionnaire was filled by the patients at T0 to T3. It consisted of 19 questions divided into seven domains: functional limitation, physical disability, physical pain, psychological disability, psychological discomfort, social disability, and handicap. Responses were delivered on a 5-point Likert-type scale ranging from 0 - "never" to 4 - "constantly". The score for each domain was calculated, and the sum of the seven domain scores represented the total OHIP-19 score. Additionally, PROMs were assessed using a questionnaire comprising five items: comfort, appearance, masticatory function, taste, and overall satisfaction. Patients were asked to answer these parameters by picking up one of the following answers: very unsatisfied, unsatisfied, fair, satisfied, and very satisfied <sup>16</sup>.

#### Sample size

To detect an annual reduction of MBL, which is in accordance with the study of Canullo et al. <sup>13</sup>, with a two-tailed 5% significance level and a power of 80%, a sample size of 24 patients was necessary, given an anticipated dropout rate of 10%.

Randomization was carried out using sealed envelopes with side allocation instructions, so both the surgeon and the patient were blinded for the group side during the implant placement. After implant placement, randomization envelope was opened, showing which side of the patient's mouth would be the test group and which the control group.

#### Statistical analysis

Descriptive statistics were calculated for patients' baseline and implant site characteristics, clinical parameters, patients' PROM levels of satisfaction, and OHIP-19 total scores. For the non-normality of the distribution of continuous variables, the Shapiro-Wilk normality test was used. The median of KTW at mesial and distal tooth, insertion torque, implant stability quotient (ISQ), clinical parameters [KTW, probing pocket depth (PPD), CAL, BOP, and PI] around the implant and for all teeth, BL and OHIP-19 total scores, together with 95% confidence interval (CI) for the median was calculated, based on exact Wilcoxon

sign rank test or sign test. Group differences were analyzed with the Wilcoxon signed rank test or Munzel-Brunner rank (MBR) test <sup>17</sup> for paired samples of numerical variables. An appropriate test was used after checking the symmetry of the distribution (for a single variable in CI of the procedure or the paired differences in the analysis of the group effect) with histogram and Miao-Gel-Gastwirth symmetry test <sup>18</sup>. Paired samples of ordinal variables (bone quality, PROMs domains' level of satisfaction) were compared with the MBR test.

Brunner-Langer repeated measures nonparametric analysis of variance (ANOVA) was used for testing the effects of group, time, and their interaction on KTW around the implant, on PROMs domains' level of satisfaction, and on OHIP for Edentulous Patients (OHIP-EDENT) total score. In the case of the significant effect, paired values were compared with the MBR test. Specifically, it examined the possibilities of improvement of PROMs domain level of satisfaction and decrease of OHIP-EDENT total scores during the time were tested for the control and test groups. In the case of the significant time effect on PROMs domains' level of satisfaction, without a significant effect of interaction, an increase in the level of satisfaction during time was further analyzed separately for the control group and the test group due to the ordinal nature of the satisfaction scale. In *post hoc* multiple comparisons, the false discovery rate was controlled using Benjamini-Hochberg's method <sup>19</sup>.

The level of significance was set at 0.05. Statistical analysis was performed in statistical software R, version 4.3.0 (using R packages stats, lawstat <sup>20</sup>, exactRankTests <sup>21</sup>, DescTools <sup>22</sup>, nparcomp <sup>23</sup>, nparLD <sup>24</sup>).

## Results

A total of 22 patients out of 24 included patients completed the six-month follow-up. Descriptive statistics of patients' characteristics are presented in Table 1.

#### Table 1

Descriptive statistics of patients' characteristics		
Variable	Value	
Patients age	$40.45 \pm 10.58$	
female	14 (63.6)	
male	8 (36.4)	
Smoker		
no	16 (72.7)	
yes (light)	6 (27.3)	
Systematic disease		
no	18 (81.8)	
yes	4 (18.2)*	
Disease		
no	17 (77.3)	
yes, completed treatment	2 (9.1)	
yes, ongoing treatment	3 (13.6)	
Medication allergy		
no	19 (86.4)	
yes	3 (13.6)	
Parafunctional bruxism		
no	21 (95.5)	
yes	1 (4.5)	
Periodontal disease		
no	16 (72.7)	
yes	6 (27.3)	
Adjacent right mesial tooth		
natural dentition	20 (90.9)	
crown or bridge	2 (9.1)	
edentulous	0 (0)	
Adjacent right distal tooth		
natural dentition	15 (68.2)	
crown or bridge	2 (9.1)	
edentulous	5 (22.7)	
Adjacent left mesial tooth		
natural dentition	19 (86.4)	
crown or bridge	3 (13.6)	
edentulous	0 (0)	
Adjacent left distal tooth	× /	
natural dentition	12 (54.5)	
crown or bridge	2 (9.1)	
edentulous	8 (36.4)	

## Table 1 (continued)

Table 1 (continueu)	
Variable	Value
Right antagonist tooth	
natural dentition	12 (54.5)
crown or bridge	4 (18.2)
edentulous	6 (27.3)
Left antagonist tooth	
natural dentition	12 (54.5)
crown or bridge	2 (9.1)
edentulous	8 (36.4)
Time from right tooth extraction in years	$13.77 \pm 9.60$
Time from left tooth extraction in years	$12.91 \pm 10.16$
Reason for right tooth extraction	
endo complication	11 (50)
fracture	4 (18.2)
caries	3 (13.6)
anodontia	2 (9.1)
periodontitis	2 (9.1)
Reason for left tooth extraction	
endo complication	11 (50)
fracture	3 (13.6)
caries	4 (18.2)
anodontia	2 (9.1)
periodontitis	2 (9.1)
Data are described as numbers (percen	tages) for categorical

Data are described as numbers (percentages) for categorical variables and as mean  $\pm$  standard deviation for continuous variables.

\* 3 patients with hypertension

Table 2

Insertion torque (Ncm), implant stability quotient for implants in control temporary abutment and test (definitive) abutment groups

			-	-
Variable	Mean $\pm$ SD	Median	Min–Max	95% CI for median
Insertion torque				
control group	$45.23 \pm 5.66$	45	40-60	[42.5, 47.5]
test group	$43.86 \pm \ 2.64$	45	40-50	[42.5, 45.0]
Mean ISQ *				
control group	$78.52 \pm 4.18$	78.55	70–86	[76.5, 80.5]
test group	$79.36 \pm 5.42$	80.65	61–86	[77.9, 81.8]

Ncm – Newton centimetre; SD – standard deviation; CI – confidence interval; \*Mean of mesial, distal, vestibular, and oral implant stability quotient (ISQ).

The mean time elapsed from tooth extraction was 13.77  $\pm$  9.60 months and 12.91  $\pm$  10.16 months for the right and left jaw sides, respectively. In 50% of the cases, endodontic complication was the main reason for tooth loss. Descriptive statistics of insertion torque, mean ISQ, and 95% CI for median are presented in Table 2. There were no significant differences between the control and test groups concerning insertion torque values (V = 25.5, *p* = 0.344) and mean ISQ (V = 90, *p* = 0.589).

# Changes in key clinical parameters in the control and test groups over time

Descriptive statistics of KTW, measured at mesial and distal tooth to the edentulous site at the beginning of the study, at future implant site, and at three months in control and test group, mean PPD, CAL, BOP, and PI, measured for all teeth at the beginning of the study and after six months, as well as mean PPD, CAL, BOP, and PI, measured at the implant site at six months in control and test group, together with 95% CI for median are presented in Table 3. In terms of the overall changes of clinical parameters over time (for all teeth), there were significant changes in values of PPD (V = 136.5, p = 0.002), CAL (V = 177.5, p = 0.005), and PI (V = 38, p = 0.005), but no significant changes of values of BOP (t = -0.340, df = 21, p = 0.737). Values of PPD and CAL were significantly lower at six months, while values of PI were slightly higher.

In terms of inter-group comparisons at six months, there were no significant differences in values of PPD (V = 129.5, p = 0.369), CAL (V = 138.5, p = 0.436), BOP (V = 50, p = 0.773), nor PI (V = 60.5, p = 0.635). Effect of time on KTW at implant site was statistically significant (F = 13.965, df<sub>1</sub> = 1, df<sub>2</sub> =  $\infty$ , p < 0.001), with no significant effect of group (F = 0,177, df<sub>1</sub> = 1, df<sub>2</sub> =  $\infty$ , p < 0.674), nor significant effect of interaction of time and group (F = 2.030, df<sub>1</sub> = 1, df<sub>2</sub> =  $\infty$ , p < 0.154). Values of KTW at the implant site, measured at three months, were significantly lower for both groups than values of KTW measured at the future implant site.

Table 3

Variable	Group	Mean $\pm$ SD	Median	Min–Max	95% CI for median
KTW	_				
at mesial tooth					
beginning	control	$3.82 \pm 1.14$	4	2-6	[3.0, 4.5]
	test	$3.82 \pm 1.10$	3.5	2-6	[2.5, 4.5]
at distal tooth					
beginning	control	$3.68 \pm 1.43$	3.5	1–7	[2.5, 4.5]
0 0	test	$3.64 \pm 1.29$	4	1–6	[2.5, 4.5]
at implant site	4 1	$2.77 \pm 1.41$	4	1 7	[2045]
beginning 3 months	control	$3.77 \pm 1.41$ $3 \pm 0.93$	4	1-7	[3.0, 4.5]
5 months beginning	control	$3 \pm 0.93$ 3.68 ± 1.43	3 4	2–5 1–6	[2, 4]
3 months	test	$3.08 \pm 1.43$ $3.18 \pm 1.01$	4	1-6	[2.5, 4.5]
Mean PPD	test	$5.16 \pm 1.01$	5	1-5	[2.5, 4]
all teeth					
beginning	both	$2.49 \pm 0.35$	2.55	1.7-3.0	[2.35, 2.65]
6 months	both	$2.35 \pm 0.29$	2.40	1.6–2.9	[2.35, 2.05]
around implant	bour	$2.55 \pm 0.27$	2.40	1.0-2.9	[2.2, 2.3]
	control	$2.56 \pm 0.46$	2.70	1.5-3.3	[2.3, 2.8]
6 months	test	$2.50 \pm 0.40$ $2.50 \pm 0.27$	2.50	2.0-3.2	[2.35, 2.65]
Mean CAL		2100 2 0127	2100	210 012	[2100, 2100]
all teeth					
beginning	both	$2.59 \pm 0.54$	2.65	1.0-3.5	[2.40, 2.85]
6 months	both	$2.45 \pm 0.44$	2.50	1.1-3.2	[2.35, 2.60]
around implant					
-	control	$2.45 \pm 0.77$	2.50	0.8-3.8	[2.15, 2.80]
6 months	test	$2.41\pm0.51$	2.30	1.3-3.5	[2.25, 2.65]
BOP					
all teeth					
beginning	both	$5.18 \pm 3.91$	4.0	2-18	[3, 5]
6 months	both	$7.23 \pm 9.70$	3.5	1–45	[2,7]
around implant					
6 months	control	$12\pm18.48$	1.0	0-71	[0, 16]
	test	$11.36 \pm 17.31$	0	0–50	[0, 17]
PI					
all teeth					
beginning	both	$7.95 \pm 9.61$	4	2-37	[3, 7]
6 months	both	$17.77 \pm 13.86$	14	3–59	[7, 25]
around implant					
6 months	control	$14.55 \pm 21.01$	8.5	0-83	[0, 18]
0 111011110	test	$14.45 \pm 22.06$	0	0–67	[0, 17]

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KTW - keratinized tissue width; PPD - periodontal probing depth (in mm); CAL - clinical attachment level (in mm); BOP – bleeding on probing (in %); PI – plaque index (in %). For other abbreviations, see Table 2.

## Table 4

## Bone loss (BL) after six months of implant placement for control and test group

Crown/Side		$\Delta F$	3L	
Group/Side -	Mean $\pm$ SD	Median	Min–Max	95% CI for median
Control				
mesial	$0.08\pm0.15$	0	0-0.57	[0, 0.10]
distal	$0.10\pm0.27$	0	0-1.21	0
Test				
mesial	$0.07 \pm 0.14$	0	0-0.48	[0, 0.10]
distal	$0.12\pm0.19$	0	0-0.59	[0, 0.21]

 $\Delta$ BL= BL at six months – BL at baseline. For other abbreviations, see Table 2.

## Bone loss after six months

Descriptive statistics of BL six months after implant placement for the control and test group are presented in Table 4. BL was similar between the groups (mesial: t = -0.798, df = 21, *p* = 0.434; distal: *t* = 1.688, df = 21, *p* = 0.106).

## Patients' self-reported measures (OHIP-19 and PROMs)

At the beginning of the study, patients of both groups were mostly very unsatisfied or unsatisfied concerning all of the PROMs domains, while they were mostly satisfied or

very satisfied at three months after the procedure and similarly at six months. These observations of the improvement in the level of satisfaction were confirmed with formal statistical testing (e.g., Brunner Munzel repeated measures ANOVA). Analyzing the comfort, there were significant effects of time (F = 123.813,  $df_1 = 1,67$ ,  $df_2 = \infty$ , p < 0.001) and their interaction (F = 6.628, df<sub>1</sub> = 1,67,  $df_2 = \infty$ , p < 0.003). In multiple comparisons, there were significant improvements in PROMs comfort scores during the given time in the control group [before implantation  $(t_0)$ vs. three months after implantation  $(t_{3m})$ : t = 11, df = 21, p < 0.001,  $t_0$  vs. six months after implantation ( $t_{6m}$ ): t = 77.121, df = 21, p < 0.001 and also in the test group ( $t_0$ vs.  $t_{3m}$ : t = 11, df = 21, p < 0.001,  $t_0$  vs.  $t_{6m}$ : t = 11, df = 21, p < 0.001). In terms of the appearance of PROMs, there is a significant effect of time (F = 107.396, df<sub>1</sub> = 1,47, df<sub>2</sub> =  $\infty$ , p < 0.001). In multiple comparisons, there were significant improvements in PROMs appearance level of satisfaction during the given time in the control group ( $t_0$  vs.  $t_{3m}$ : t = 9.562, df = 21, p < 0.001,  $t_0$  vs.  $t_{6m}$ : t = 10.334, df = 21, p < 0.001) and also in the test group ( $t_0$  vs.  $t_{3m}$ : t = 9.602, df = 21, p < 0.001,  $t_0$  vs.  $t_{6m}$ : t = 9.949, df = 21, p < 0.001). Concerning the PROMs masticating function, there is a significant effect of time (F = 65.931, df<sub>1</sub> = 1,82, df<sub>2</sub> =  $\infty$ , p < 0.001). In multiple comparisons, there were significant improvements in PROMs masticating function level of satisfaction during the time in the control group ( $t_0$  vs.  $t_{3m}$ : t = 11.599, df = 21, p < 0.001,  $t_0$  vs.  $t_{6m}$ : t = 14.501, df = 21, p < 0.001) and also in the test group ( $t_0$  vs.  $t_{3m}$ : t = 16.962, df = 21, p < 0.001,  $t_0$  vs.  $t_{6m}$ : t = 18.110, df = 21, p < 0.001). In terms of PROMs taste, there is a significant effect of time (F = 65.909, df<sub>1</sub> = 1,71, df<sub>2</sub> =  $\infty$ , p < 0.001). In multiple comparisons, there were significant improvements in PROMs taste level of satisfaction during the given time in the control group ( $t_0$  vs.  $t_{3m}$ : t = 20.029, df = 21, p < 0.001,  $t_0$ vs.  $t_{6m}$ : t = 24.674, df = 21, p < 0.001) and also in the test group ( $t_0$  vs.  $t_{3m}$ : t = 20.029, df = 21, p < 0.001,  $t_0$  vs.  $t_{6m}$ : t = 35.611, df = 21, p < 0.001). Regarding the overall satisfaction of PROMs, there was a significant effect of time (F = 139.827, df<sub>1</sub> = 1,52, df<sub>2</sub> =  $\infty$ , p < 0.001). In multiple comparisons, there were significant improvements in PROMs overall satisfaction during the given time in the control group ( $t_0$  vs.  $t_{3m}$ : t = 11, df = 21, p < 0.001,  $t_0$  vs.  $t_{6m}$ : t = 11, df = 21, p < 0.001) and also in the test group ( $t_0$  vs.

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 $t_{3m}$ : t = 11, df = 21, p < 0.001,  $t_0$  vs.  $t_{6m}$ : t = 11, df = 21, p < 0.001). There was a significant improvement in the level of satisfaction after three months of the procedure in both groups, which was maintained after six months. Groups did not differ significantly in their level of satisfaction.

Descriptive statistics of the OHIP-EDENT total scores gathered at the beginning of the study, after three months, and after six months from the implant placement in each of the groups are presented in Table 5. At the beginning of the study, patients of both groups had much higher OHIP-EDENT total scores compared to three months after the implant placement and similarly at six months. These observations of a big decrease in OHIP-EDENT total scores are confirmed by formal statistical testing (e.g., Brunner Munzel repeated measures ANOVA). There is a significant effect of time (F = 179.050,  $df_1 = 1,80$ ,  $df_2 = \infty$ , p < 0.001). In multiple comparisons, the time effect was further analyzed for both groups as a whole (taking the mean value of scores for each patient). There were significant decreases in OHIP-EDENT total scores after three months ( $t_0$  vs.  $t_{3m}$ : t = -145.978, df = 21, p < 0.001) and after six months ( $t_0$  vs.  $t_{6m}$ : t = -349.967, df = 21, p < 0.001), in comparison to the OHIP-19 total scores at the beginning of the study. OHIP-19 total scores significantly decreased after three months and remained similar six months after the implant placement in both groups.

## Discussion

Implant dentistry has undergone a paradigm shift over the past decade, with a heightened focus on patient-centered care and innovative techniques for implant placement and loading. The demand for expedited treatment timelines that align with patient expectations and comfort has led to a reevaluation of adequate case selection in ensuring successful outcomes of an ILP. The present study tried to analyze the effects of the definitive abutment (OAO concept) within the ILPs of single posterior mandibular implants restored digitally, clinically, radiographically, and through patientrelated outcomes. The results of this study revealed several key insights. The analysis of clinical parameters, such as KTW, PPD, CAL, BOP, and PI, indicated that both the control and the test group experienced significant changes over six months.

OHIP-EDENT	Mean $\pm$ SD	Median	Min–Max	95% CI for median
Beginning				
control group	$6.32\pm5.37$	4	2-26	[4, 8]
test group	$5.77 \pm 5.55$	4	0–28	[4, 6]
3 months				
control group	$0.18\pm0.50$	0	0–2	0
test group	$0.18\pm0.39$	0	0-1	0
6 months				
control group	$0.09\pm0.29$	0	0-1	0
test group	$0.05\pm0.21$	0	0-1	0

**OHIP-EDENT** – Oral Health Impact Profile for Edentulous Patients; For other abbreviations, see Table 2.

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Repetitive reconnection of the abutment in the postimplant placement period affects peri-implant soft and hard tissues <sup>13, 25, 26, 27</sup>. The OAO concept was introduced by Canullo et al. 13 to avoid and reduce aesthetical complications as a result of tissue changes. Numerous studies have demonstrated the applicability of this concept in clinical situations 13, 25, 26, 27, although strict patient selection seemed mandatory. The overall conclusion is that this concept is clinically relevant, with statistically slightly better results in terms of marginal bone levels, but without clinical relevance when compared to standardized prosthetic protocols <sup>28</sup>. The results of the present study are in line with the published data, emphasizing the fact that the application of one abutment onetime protocol can be introduced into daily clinical practice since it is very user-friendly equally from the patient's and clinician's point of view and is associated with the results comparable to conventional prosthetic procedures.

One of the primary outcome measures of the present study, MBL, was carefully evaluated in both groups. The analysis demonstrated no significant differences in BL between the control group (provisional abutments) and the test group (OAO approach) after six months. This suggests that both strategies can effectively manage bone stability in the short term. The results of this research are in line with the published data <sup>28</sup>, with the additional comparative analysis of both ILPs within the same patient (split-mouth design). Moreover, careful case selection, adherence to proper surgical placement of implants, the use of Aqua<sup>®</sup> surface implants, and rigorous postoperative care protocols may contribute to the overall success of both approaches.

PROMs, as assessed through the OHIP-19, as well as the shortened version of the index for partially edentulous patients <sup>16</sup>, revealed significant improvements in patients' levels of satisfaction, comfort, and overall well-being throughout the study. This suggests that not only do both implant strategies contribute to clinical success, but they also positively influence patients' quality of life and oral healthrelated quality of life. Slightly better indices have favored using a definitive abutment since this procedure is more comfortable for the patient.

The success rates of single monolithic zirconia screwretained restorations achieved in this study are still the subject of the literature debate in terms of material selection and long-term follow-up but with promising results <sup>29</sup>. This study has verified that the implementation of digital prosthetic workflow and selection of ILP is a predictable, precise, effective, and dependable process <sup>30</sup>. Another study has demonstrated that patients reported greater satisfaction in terms of comfort when utilizing the intraoral scanner compared to the conventional polyether impression method <sup>15</sup>.

It is important to acknowledge the limitations of this study. The six-month follow-up period offers insights into short-term outcomes, but a longer observation period is essential to ascertain the sustainability of these results over time. Additionally, the study focused on posterior single implants, and the applicability of these findings to different implant scenarios warrants further investigation.

### Conclusion

The results of this study shed light on the comparable effectiveness of the OAO approach and provisional abutments in the context of immediate loading of posterior single implants. This study contributes to the existing body of knowledge in implant dentistry by offering insights into periimplant tissue stability, patient satisfaction, and clinical outcomes within immediate loading protocols. Further research encompassing longer follow-up periods and diverse implant scenarios is necessary for further understanding of these implant strategies and their implications for long-term success.

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#### REFERENCES

- Gallucci GO, Hamilton A, Zhou W, Buser D, Chen S. Implant placement and loading protocols in partially edentulous patients: A systematic review. Clin Oral Implants Res 2018; 29 Suppl 16: 106–34.
- Zheng Z, Ao X, Xie P, Jiang F, Chen W. The biological width around implant. J Prosthodont Res 2021; 65(1): 11–8.
- 3. *Lindhe J, Berglundh T.* The interface between the mucosa and the implant. Periodontol 2000 1998; 17(1): 47–54.
- Guo T, Gulati K, Arora H, Han P, Fournier B, Ivanovski S. Race to invade: Understanding soft tissue integration at the transmucosal region of titanium dental implants. Dent Mater 2021; 37(5): 816–31.
- Mangano C, Mangano FG, Shibli JA, Roth LA, d'Addazio GD, Piattelli A, et al. Immunohistochemical Evaluation of Peri-Implant Soft Tissues around Machined and Direct Metal Laser Sintered (DMLS) Healing Abutments in Humans. Int J Environ Res Public Health 2018; 15(8): 1611.
- Soliman G, Guazzato M, Klineberg I, Chang MC, Ellakwa A. Influence of Platform Switching, Abutment Design and Connection Protocols on the Stability of Peri-Implant Tissues. A Sys-

tematic Review. Eur J Prosthodont Restor Dent 2021; 29(4): 194–207.

- Canullo L, Annunziata M, Pesce P, Tommasato G, Nastri L, Guida L. Influence of abutment material and modifications on periimplant soft-tissue attachment: A systematic review and metaanalysis of histological animal studies. J Prosthet Dent 2021; 125(3): 426–36.
- Kim JJ, Lee JH, Kim JC, Lee JB, Yeo IL. Biological Responses to the Transitional Area of Dental Implants: Material- and Structure-Dependent Responses of Peri-Implant Tissue to Abutments. Materials (Basel) 2019; 13(1): 72.
- Li Z, Gao S, Chen H, Ma R, Wu T, Yu H. Micromotion of implant-abutment interfaces (IAI) after loading: correlation of finite element analysis with in vitro performances. Med Biol Eng Comput 2019; 57(5): 1133–44.
- Block MS. Evidence-Based Criteria for an Ideal Abutment Implant Connection-A Narrative Review. J Oral Maxillofac Surg 2022; 80(10): 1670–5.
- 11. Amid R, Ardakani MRT, Tohidi R, Kadkhodazadeh M. Bacterial Microleakage at the Implant-Healing Abutment Interface in

Two Different Implant Designs: Platform Switching versus Platform Matching. J Long Term Eff Med Implants 2021; 31(1): 33–42.

- Kraus RD, Espuelas C, Hämmerle CHF, Jung RE, Sailer I, Thoma DS. Five-year randomized controlled clinical study comparing cemented and screw-retained zirconia-based implantsupported single crowns. Clin Oral Implants Res 2022; 33(5): 537–47.
- Canullo L, Bignozzi I, Cocchetto R, Cristalli MP, Iannello G. Immediate positioning of a definitive abutment versus repeated abutment replacements in postextractive implants: 3-year follow-up of a randomised multicentre clinical trial. Eur J Oral Implantol 2010; 3(4): 285–96.
- 14. Hamudi N, Barnea E, Weinberg E, Laviv A, Mijiritsky E, Matalon S, et al. The Association of the One-Abutment at One-Time Concept with Marginal Bone Loss around the SLA and Platform Switch and Conical Abutment Implants. J Clin Med 2021; 11(1): 74.
- Hanozin B, Li Manni L, Lecloux G, Bacevic M, Lambert F. Digital vs. conventional workflow for one-abutment one-time immediate restoration in the esthetic zone: a randomized controlled trial. Int J Implant Dent 2022; 8(1): 7.
- Molina A, Sanz-Sánchez I, Martín C, Blanco J, Sanz M. The effect of one-time abutment placement on interproximal bone levels and peri-implant soft tissues: a prospective randomized clinical trial. Clin Oral Implants Res 2017; 28(4): 443–52.
- 17. Munzel U, Brunner E. An Exact Paired Rank test. Biometrical Journal 2002; 44(5): 584–93.
- Miao W, Gel YR, Gastwirth JL. A new test of symmetry about an unknown median. In: Hsiung AC, Ying Z, Zhang CH, editors. Random Walk, Sequential Analysis and Related Topics. Singapore: WSPC; 2006. pp. 199–214.
- 19. *Wilcox* RR. Introduction to robust estimation and hypothesis testing. 3rd ed. Boston: Academic Press; 2012. p. 608.
- Gastwirth JL, Gel YR, Hui WLW, Lyubchich V, Miao W, Noguchi K. Tools for Biostatistics, Public Policy, and Law. R package version 3.6; 2023. Available from: https://CRAN.Rproject.org/package=lawstat
- Hothorn T, Hornik K. exactRankTests: Exact Distributions for Rank and Permutation Tests. R package version 0.8-35; 2022. Available from: https://CRAN.R-project.org/package=exact RankTests

- 22. Signorell A. DescTools: Tools for Descriptive Statistics. R package version 0.99.54; 2023. Available from: https://CRAN.R-project.org/package=DescTools
- 23. Konietschke F, Placzek M, Schaarschmidt F, Hothorn LA. nparcomp: An R Software Package for Nonparametric Multiple Comparisons and Simultaneous Confidence Intervals. J Stat Softw 2015; 64(9): 1–17.
- Noguchi K, Gel YR, Brunner E, Konietschke F. nparLD: An R Software Package for the Nonparametric Analysis of Longitudinal Data in Factorial Experiments. J Stat Softw 2012; 50(12): 1–23.
- 25. Degidi M, Nardi, D, Piattelli A. 2011. One abutment at one time: non-removal of an immediate abutment and its effect on bone healing around subcrestal tapered implants. Clin Oral Implants Res 2011; 22(11): 1303–7.
- 26. Grandi T, Guazzi P, Samarani R, Garuti G. Immediate positioning of definitive abutments versus repeated abutment replacements in immediately loaded implants: effects on bone healing at the 1-year follow-up of a multicentre randomised controlled trial. Eur J Oral Implantol 2012; 5(1): 9–16.
- 27. *Degidi M, Nardi D, Daprile G, Piattelli A*. Nonremoval of immediate abutments in cases involving subcrestally placed postextractive tapered single implants: a randomized controlled clinical study. Clin Implant Dent Relat Res 2014; 16(6): 1–12.
- Atieh MA, Tawse-Smith A, Alsabeeha NHM, Ma S, Duncan WJ. The One Abutment-One Time Protocol: A Systematic Review and Meta-Analysis. J Periodontol 2017; 88(11): 1173–85.
- Donker VJJ, Raghoebar GM, Jensen-Louwerse C, Vissink A, Meijer HJA. Monolithic zirconia single tooth implant-supported restorations with CAD/CAM titanium abutments in the posterior region: A 1-year prospective case series study. Clin Implant Dent Relat Res 2022; 24(1): 125–32.
- Marković A, Mišić T, Janjić B, Šćepanović M, Trifković B, Ilić B, et al. Immediate Vs Early Loading of Bone Level Tapered Dental Implants With Hydrophilic Surface in Rehabilitation of Fully Edentulous Maxilla: Clinical and Patient Centered Outcomes. J Oral Implantol 2022; 48(5): 358–69.

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