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Research / Araştırma Makalesi

In Vivo Evaluation Of Two Different Protocols For The Fabrication Of Implant-Supported Overdenture Prostheses

İmplant Destekli Overdenture Protezlerin Üretimi İçin İki Farklı Protokolün İn Vivo Değerlendirilmesi

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ABSTRACT

Background: This study focuses on the balanced distribution of relative masticatory pressure in two implant-supported overdenture rehabilitations and evaluates the effectiveness of the treatment protocol in achieving this. This study aims to compare, via a digital occlusal analyzer, the clinical effectiveness of the modified traditional protocol followed in two implant-supported mandibular overdenture rehabilitation with the traditional protocol.

Methods: A total of 20 patients were included in the study and with the help of envelope drawing were randomly allocated into two groups: Group I (control/traditional protocol), Group II (test/modified traditional protocol). The distribution of the relative masticatory pressure, the change in masticatory pressure (Δp values) [including presence or absence of premature contacts and balanced/unbalanced pressure distribution] and treatment process management parameters were recorded utilizing OccluSence® for each patient, predelivery and at delivery. Data was statistically evaluated with t tests and chi-square tests, and significance level was set to $\alpha = 0.05$.

Results: No significant differences existed in masticatory pressure distribution and premature contacts between groups predelivery and at delivery. Predelivery, the test group showed significantly more balanced pressure than control's ($p<0.005$); however, this difference disappeared at delivery ($p>0.370$). In the management of the treatment process, the test group exhibited a statistically significant difference than control's group. ($p<0.000$).

Conclusions: This study has demonstrated that the protocol is effective for achieving balanced distribution of masticatory pressure in two-implant-supported overdentures. However, the findings require validation through larger-scale studies.

Keywords: Complete denture, Mandibular implant-supported overdenture, Occlusal equilibration, Axiographic record, Removable overdenture.

ÖZ

Arka plan: Bu çalışma, iki implant destekli overdenture protez rehabilitasyonlarında göreceli çiğneme basıncının dengeli dağılımına odaklanmakta ve bu amaca ulaşmada tedavi protokolünün etkinliğini değerlendirmektedir. Bu çalışma, dijital oklüzal analiz cihazı aracılığıyla, iki implant destekli alt çene overdenture protez rehabilitasyonunda uygulanan modifiye geleneksel protokolün klinik etkinliğini geleneksel protokolle karşılaştırmayı amaçlamaktadır.

Yöntemler: Çalışmaya toplam 20 hasta dahil edilmiş ve zarf çekme yöntemiyle rastgele iki gruba ayrılmıştır: Grup I (kontrol/geleneksel protokol), Grup II (test/modifiye geleneksel protokol). Her hasta için, teslim öncesinde ve teslim anında, göreceli çiğneme basıncının dağılımı, çiğneme basıncındaki değişim (Δp değerleri) [erken temasların varlığı veya yokluğu ve dengeli/dengesiz basınç dağılımı dahil] ve tedavi süreci yönetim parametreleri Occlusence® kullanılarak kaydedilmiştir. Veriler t testleri ve ki-kare testleri ile istatistiksel olarak değerlendirilmiş ve anlamlılık düzeyi $\alpha = 0{,}05$ olarak belirlenmiştir.

Sonuçlar: Teslim öncesinde ve teslim anında gruplar arasında çiğneme basıncı dağılımı ve erken temaslarda anlamlı bir fark bulunmamıştır. Teslim öncesinde, test grubu kontrol grubuna göre anlamlı derecede daha dengeli bir basınç göstermiştir ($p<0.005$); ancak bu fark teslim sırasında ortadan kalkmıştır ($p>0.370$). Tedavi sürecinin yönetiminde, test grubu kontrol grubuna göre istatistiksel olarak anlamlı bir fark göstermiştir ($p<0.000$).

Sonuç: Bu çalışma, protokolün iki implant destekli overdenture protezler'de çiğneme basıncının dengeli dağılımını sağlamada etkili olduğunu göstermiştir. Bununla birlikte, bulguların daha büyük ölçekli çalışmalarla doğrulanması gerekmektedir.

Anahtar Kelimeler: Tam protez, Alt çene implant destekli overdenture protez, Oklüzal dengeleme, Aksiyografik kayıt, Hareketli overdenture protez.

Introduction

Although developing technologies in prosthodontics offer new treatment alternatives for complete edentulism, conventional complete dentures continue to be a viable treatment option.[1] The two main disadvantages of complete dentures, namely retention and stability, cause these patients to face difficulties with chewing and speaking in their daily lives.[2] These difficulties are more pronounced, particularly in mandibular complete dentures. Prosthodontics offers new alternatives to complete dentures for the treatment of complete edentulism. These are: implant-supported fixed dentures and implant-retained dentures.[3,4]

Although implant-supported fixed restorations are the primary choice in daily clinical practice[5,6], implant-supported overdentures can be a better option as they are less invasive and more economical in cases with anatomical limitations or when systemic health is not suitable.[7,8] Although the implant-supported overdenture is recommended as a standard treatment option[9,10], particularly for the edentulous mandible, it is more expensive and time-consuming compared to complete denture therapy.[11] Furthermore, they have disadvantages such as loss of retention and stability caused by the bending, wear, detachment, or fracture of retentive components, and the corrosion of these components.[12] Although these require short- and long-term maintenance needs[13], the improvement in quality of life through enhanced chewing capacity provides patient satisfaction.[14] However, conventional mandibular overdentures are now considered time-consuming and expensive due to the prevalence of digital workflows.[15]

Failures can occur in implant-supported overdentures. To minimize and prevent the occurrence of implant and prosthesis complications, a number of factors must be taken into account.[16] Failures are often caused by complications originating from the attachment systems. Although there is no consensus regarding attachment systems, it has been reported that the Locator attachment system may experience fewer failures.[17]

As with all prosthetic treatments, the long-term success of implant-supported overdentures largely depends on correct occlusion. Although whether the overdenture framework is manufactured by conventional methods or by CAD/CAM milling is a factor that can directly affect the achievement of occlusal balance, conclusive data supporting this relationship remain insufficient.[18]

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In removable complete dentures and implant-supported overdentures, achieving occlusal balance is the primary objective for clinicians. The established occlusal balance plays a role in preventing alveolar bone resorption, thereby supporting the long-term stability of the prostheses.[19] Technology offers a digital solution to this challenge. A digital occlusal analyzer allows clinicians to make computer-guided adjustments for occlusal force. This assists the clinician in making measurable improvements to achieving balanced prosthesis occlusion.[20]

This allows clinicians to evaluate the distribution of occlusal forces and make the necessary adjustments to achieve a balanced force distribution. With this digital technology, it can be determined whether the force is distributed equally, with 50% on the right side and 50% on the left side. The achieved balance enhances the adaptation of the prosthesis to the tissue, and this ensures a more balanced transmission of occlusal forces during chewing.[21]

Studies indicate that excessive occlusal loading is the primary factor that may lead to bone loss and subsequent implant failure, though this can be biomechanically controlled.[22,23] On the other hand, in edentulous patients, alveolar bone loss cannot be stopped; however, resorption can be reduced by using implant-supported overdentures instead of conventional complete dentures for rehabilitation.[24] Furthermore, the functionally balanced performance of dentures can positively influence biomechanical outcomes.[25]

Studies examining various prosthetic configurations, including complete dentures and implant-supported dentures, have been evaluated in the light of systematic reviews and meta-analyses. These evaluations have determined that there are significant differences in the effects of the said prosthetic treatments on the surrounding tissues and emphasize the need for a more holistic perspective in assessing these treatment options.[26]

However, more clinical data are needed to determine the effectiveness of current protocols in achieving balanced occlusal load distribution in two-implant supported overdenture rehabilitation.

This study aims to compare, via a digital occlusal analyzer, the clinical effectiveness of the modified traditional protocol followed in two implant-supported mandibular overdenture rehabilitation with the traditional protocol. The null hypothesis of the study is that there will be no difference in the clinical effectiveness of the rehabilitations between the protocols followed.

This study aims to compare, via a digital occlusal analyzer, the clinical effectiveness of the modified traditional protocol followed in two implant-supported mandibular overdenture rehabilitation with the traditional protocol. The null hypothesis of the study is that there will be no difference in the clinical effectiveness of the rehabilitations between the protocols followed.

Materials and Methods

The materials and equipment that were used in the study are summarized in **Table 1**.

Table 1. Materials/Equipment

Materials/equipment	Name	Manufacturer
Impression material (alginate hydrocolloid)	Hydrogum 5	Zhermack S.p.A/Via Bovazecchino, 100 45021 Badia Polesine Rovigo, Italy
Impression material (condensation silicone)	Zetaplus	Zhermack, Badia Polesine Italy
Impression material (condensation silicone)	Zetalabor	Zhermack, Badia Polesine Italy
Impression material (condensation silicone)	Durosil L	President Dental GmbH, Kesselbodenstraße 5, 85391, Allershausen, Germany
Rigid impression material (green sticks/cones impression compound)	Impression compound	Kerr, Markova 238, Czech Republic
Rigid impression material (pink sticks/cones impression compound)	ISO functional	GC, Tokyo, Japan
Impression compound application device	WoxonDMCG Hummer	Gwangju Metropolitan City, South Korea
Rigid impression material (zinc oxide-eugenol)	Cavex outline,	Haarlem, Holland
Acrylic denture teeth	Denture Pe	United Group Dental, Ankara, Turkey
Electric wax knife	IQ WAXER NT light	YETI Dentalprodukte GmbH, Industriestraße 3 78234 Engen, Germany
Dental wax	Cavex set up wax	Cavex Haarlem, Holland
Dental wax	Aesthetic denture wax (hard)	Candulor AG, Glattpark, Switzerland
PMMA, acrylic (chemical-cured)	Integra (self-cured acrylic)	United Group Dental, Ankara, Turkey
PMMA, acrylic (heat-cured)	Integra (heat-cured acrylic)	United Group Dental, Ankara, Turkey
Electronic recorder system	ARCUSdigma II	KaVoDentalGmbH, Biberach, Germany
Facebow	ARCUSevo	KaVoDentalGmbH, Biberach, Germany
Articulator	PROTARevo Digma	KaVoDentalGmbH, Biberach, Germany
Electric silicone wax gun	Bosch PKP 18-E	Robert Bosch GmbH 70839 Gerlingen-Schillerhöhe, Germany
Computerized occlusal analysis system	OccluSense®	Dr. Jean Bausch GmbH & Co. KG, Cologne, Germany
Articulating material	Red, blue and green articulation silk	Dr. Jean Bausch GmbH&Co.KG, D-50769 Cologne, Germany

Study design

When the study was designed, no similar design was found in the literature. However, for calculating the sample size, the in vivo study by Van Brakel R et al. on 20 edentulous patients undergoing two implant-supported overdenture rehabilitation was taken into account.[27] The study was designed as a prospective (forward-looking), human-participant, within-subject left-right comparative design. A total of 20 edentulous patients (10 males and 10 females) requiring maxillary complete dentures and mandibular overdenture treatment, with completed surgical phases, were included in the study. Of these, it was found that the implant surgeries of 17 patients had been completed within the last 3 months, while the implant surgeries of the remaining 3 patients had been performed 3 years ago. The patients were allocated into groups using the closed-envelope method (n=10) and divided into two groups: Group I (control / traditional protocol), Group II (test / modified traditional protocol). Patients who met the following criteria were included in the study: successful osseointegration of the implants, systemic health, smoking no more than 10 cigarettes per day, presence of two mandibular implants in the interforaminal region, absence of pathologies contraindicating prosthetic treatment, and similar treatment needs. Patients with any muscular disorders, history of bruxism, impaired neuromuscular control, or temporomandibular joint disorders were excluded from the study.

Assessment of occlusal equilibration

Occlusal equilibrations were estimated by OccluSense®. The OccluSense® sensor is a 60μm thin color coated foil with a printed circuit containing 1018 pressure sensitive pixels which are able to capture 256 levels of pressure. The height of the columns visualizes the relative masticatory pressure between all contact points of the full arch (**Fig. 1**). The colors show the change in masticatory pressure of the occlusal contact points in relation to each other and thus visualize the nature of each contact point (**Fig. 2**). The system maps all contact points and pressure distribution across the entire dental arch, with each quadrant visualized in a single graphic. For each patient, the appropriate sensor was selected, attached to the OccluSence® handpiece and positioned intraorally parallel to the occlusal plane, and the patient was asked to bite down for 4 seconds to collect the data. The obtained data is sent wirelessly to İPad-App. The data were obtained during intercuspal position (ICP) / maximum intercuspidation (MIP) and collected at two different time points: predelivery (during the try-in appointment) and at delivery (at the delivery of the prostheses). The clinical effectiveness of the protocols was evaluated based on the distribution of the relative masticatory pressure, the change in masticatory pressure (Δp values) [including presence or absence of premature contacts and balanced/unbalanced pressure distribution] and the management of the treatment process. The obtained data were tabulated and statistically analysed for each group.

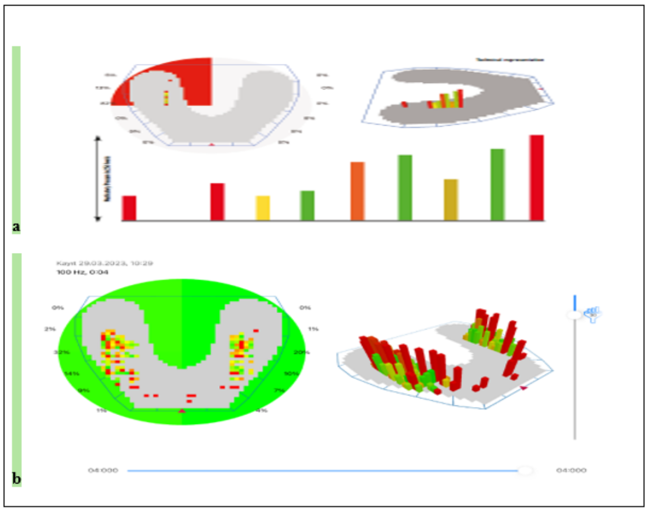

Figure 1. Graphic presentation of the relative masticatory pressure

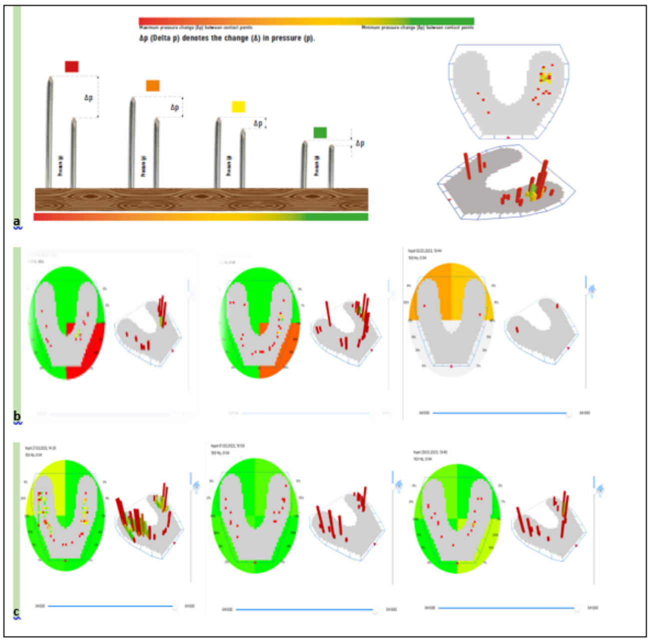

Figure 2. Graphic presentation of the change in masticatory pressure: (**a**) pressure variation (Δp) (**b**) premature contacts and unbalanced pressure distribution (**c**) balanced pressure distribution

Clinical procedures/removable prosthesis construction

Group I (control group / traditional protocol)

In Group I the traditional complete denture manufacturing steps were as follows. The workflow of the group I is summarize **Fig. 3**. Preliminary impressions were conducted with alginate and a study model (gypsum) was obtained. Custom trays were produced from PMMA (chemical cure acrylic) on the study models. To ensure hermetic closure, green sticks were placed on the tray border by using an impression compound application device, and final impressions were performed with ZnOE impression material. The master casts were prepared; after being blocked, sharp undercut areas with additional baseplate wax (denture wax) record bases were produced from PMMA (chemical cure acrylic). Wax rims were prepared on the record bases. A fox ruler was used to control the inclination of the upper wax rim. After the clinical vertical dimension of the occlusion was determined, the preliminary centric relation was recorded. The upper and lower jaw master casts were transferred from this record to the articulator, which could only elicit an opening and closing movement without any adjustment. tooth alignments were completed under the guidance of the inclination of the wax rims. The correct centric relation (CR) and vertical dimension of occlusion (VDO) were confirmed in the try-in appointment. First measurements (predelivery) were performed with OccluSence®. After the wax-up was completed, the prostheses were fabricated with PMMA (heat-cured acrylic) packing. After the prostheses were completed, the clinical setting was established. During the clinical adaptation process, the selective grinding (elimination of occlusal errors) procedure step was performed while the prostheses were located in the patient's mouth. After the clinical setting step was completed, the retained elements (ball abutment and attachment housing) were connected to the mandibular overdenture prothesis with PMMA (chemical cure acrylic). Afterwards, the second set of measurements (at delivery) with OccluSence® was performed, and the prostheses were delivered.

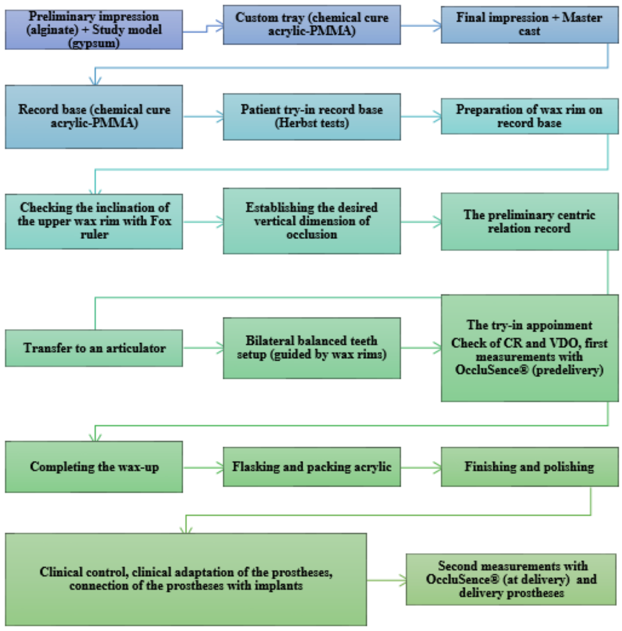

Figure 3. Group I workflow diagram

Group II (test group / modified traditional protocol)

In Group II, the modified traditional protocol was followed. The utilized protocol is summarized in **Fig. 4**.

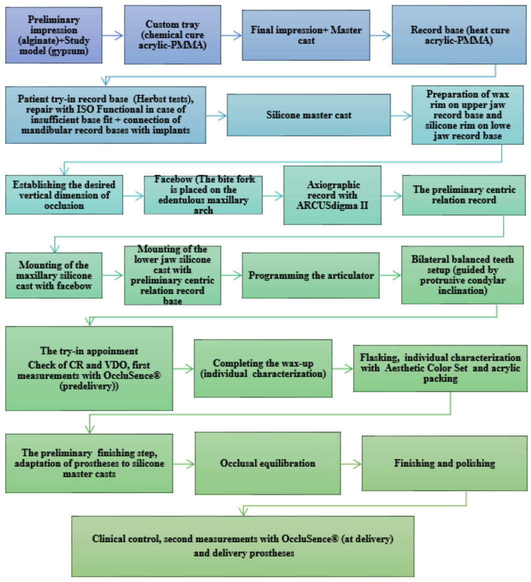

Figure 4. Group II workflow diagram

As was performed in group II, preliminary impressions were performed with alginate, and a study model (gypsum) was obtained. Custom trays were produced from PMMA (chemical cure acrylic) on the study models. To ensure hermetic closure, green sticks were placed on the tray border by using an impression compound application device, and final impressions were performed with ZnOE impression material. Record bases (chemically cured acrylic-PMMA) were not prepared on the master casts.

Figure 5. (a) Wax modelling on the master cast, original base made of PMMA (heat-cured acrylic), connection of the mandibular record base with implant-retentive elements before measurements; **(b)** preparation of the master silicone cast, wax rim on the maxillary record base and silicone rim on the mandibular record base, removal of the nose support, loosening of the fixing nut of the facebow and removal of the head and ear supports, mounting of the maxillary silicone master cast on the articulator; **(c)** image of the completed transfer on the articulator and notation of individual dynamic parameters, completion of the wax-up, when considering keratinized and nonkeratinized mucosa, selective grinding (eliminating occlusal errors) on the articulator

The master casts were covered with additional baseplate wax (denture wax), and record bases were fabricated with PMMA (heat-cured acrylic) packing (**Fig 5a**). After the record bases were finished, their fits were clinically verified. Possible base and tissue compatibility defects due to acrylic polymerization were detected at this stage and repaired with ISO Functional (pink sticks/cones impression compound) additions. After the repair of the record bases, the laboratory putty was pressed into the alveolar surface of the record base, and paper clips were used to retain the plaster that reinforces this half of the mould (which represented the preparation of the silicone master casts) (**Fig 5b**). After the silicone master casts were prepared, ISO Functional (pink sticks/cones impression compound) additions were removed from the repaired areas, and PMMA (chemical cure acrylic) was added to these areas, after which the repairs were made. The sections of the mandibular record base corresponding to the positions of the implants were drilled to produce openings (**Fig 5a**).

The necessary areas of the mandibular record base were corrected so that the border lengths of the record bases did not extend to the nonkeratinized mucosa. In addition, the undercuts (or sharp bony prominence structures on the buccal alveolar contour) were evaluated, and the relevant areas of the record base were corrected as necessary, thus preventing interference with the prosthesis entryway. After these two important control procedures were conducted, the retained elements (ball abutment and attachment housing) were connected to the mandibular record bases with PMMA (chemical cure acrylic) (**Fig 5a**). Although wax rims were prepared on the upper jaw record bases, silicone rims were prepared on the lower jaw record bases (**Fig 5b**). The silicone rims were glued onto the record bases by using fast adhesive. After the vertical dimension of the occlusion was determined, the measurement procedures for obtaining individual condylar guidance parameters with ARCUSdigma II were initiated. First, the ARCUSevo facebow was applied over the edentulous upper jaw. Care was taken not to change the position of the upper arch on the skull base while the bite fork and calotte (with the fork attaching to the facebow via a locking device) were separated from the facebow. The patient was registered to the device, and the measurement process was initiated in the direction of the selected axis (an arbitrary axis). During the measurement process, the necessary steps were followed in accordance with the available software in the device. The paraocclusal attachment portion of the ARCUSdigma II system was fixed to the silicone rims on the lower record base through the bucco-vestibular sulcus with silicone. In this step of the process, care was taken to ensure that the applied silicone did not possess any protrusions that could interfere with mandibular movements. The upper arch of the system containing 8 signal receivers was adapted to its location on the ARCUSevo facebow. After the lower arc (transmitter) containing 4 signal transmitters of the system (which can be fixed with a magnet) was applied on the mandibular part adapted to the lower silicone rims, the necessary data were obtained from the patients without guidance. After the individual condylar guidance data were obtained, the measurement process was terminated by determining the preliminary centric relation record. The bite fork and calotte were reattached to the facebow. Additionally, the ear and glabellar supports were removed, and the facebow was adapted to the PROTARevo Digma, which is the fully adjustable articulator of the system (**Fig 5b**). First, the upper jaw silicone master casts were mounted to the articulator. The lower jaw silicone master casts were subsequently mounted via preliminary maxillomandibular relation records. The articulator was programmed with the data determined for each case, and the data were noted on the casts (**Fig 5c**). Tooth alignments were completed (**Fig 5c**). First measurements (predelivery) were performed with OccluSence®. After the wax-up was completed, the prostheses were fabricated with PMMA (heat-cured acrylic) packing. After the preliminary finishing of the prostheses, they were adapted to the functional silicone master casts on the articulator, and occlusal equilibrations were performed on the programmed articulator with personal data (Fig **5c**). The clinical fit of the prostheses was verified. The second set of measurements (at delivery) was performed utilizing OccluSence® at delivery, and the prostheses were delivered. **Fig. 6** shows a case example.

Figure 6. Case example; finished prostheses, individually characterized by the wax-up, try-in appointment, and conditions of old prostheses, with an oriented lower occlusion plane in different inclinations

In the study, the dependent variables were: the distribution of relative masticatory pressure, the change in masticatory pressure (Δp values) [including the presence or absence of premature contacts and balanced/unbalanced pressure distribution], and the management of the treatment process. The independent variable was the protocol type. In the study, the independent variables were evaluated by analyzing the data associated with the dependent variables.

Statistical evaluation

The study results were evaluated with the IBM SPSS Statistics 25 (SPSS Inc., Chicago, IL, USA) package. The means and standard deviations were used as descriptive statistical methods in the evaluation of the data. The Kolmogorov-Smirnov test was used to determine that the data were normally distributed. A t test was used to test the differences between the variables, and a chi-square test was used to assess the relationships between the categorical variables. The findings were evaluated at the 95% confidence interval and 5% significance level.

Results

In total, 20 patients were enrolled in the study (10 males and 10 females). Their mean age at intervention was 62,7± 11.68 years, ranging from 45 to 82 years. Each patient received maxillary complete denture and two implant-supported mandibular prostheses, keeping the patient as a statistical unit. As planned in the study, the prostheses for all patients were successfully completed. No patients withdrew from or were excluded from the study. Thus, the initial sample size remained unchanged, and the study was completed with the control group (n=10) and the test group (n=10). While prosthetic rehabilitations in the control group were completed using conventional methods, those in the test group were completed with the modified conventional method. According to the protocols followed, the distribution of 100% relative masticatory pressure for each participant (predelivery [during the try-in appointment] and at delivery [at the delivery of the prostheses]) are summarized separately for the right and left sides in **Table 2**.

Predelivery and at delivery, there were no significant difference in the distribution of the relative masticatory pressure. [predelivery right side; control— 41.50 ± 27.59 and test— 51.10 ± 18.26 (p=0.370), left side; control— 58.50 ± 27.59 and test— 48.90 ± 18.26 (p=0.370), at delivery right side; control— 43.30 ± 34.94 and test— 48.70 ± 15.85 (p=0.576), left side; control— 56.70 ± 30.94 and test— 51.30 ± 15.85 (p=0.629)]. The distribution in the test group was more balanced compared to the control group, but the differences was not statistically significant (p > 0.05).

When examining the changes in masticatory pressure (Δp values) predelivery, pemature contacts were detected in 2 cases (right side) in the test group and 6 cases (2 right side, 4 left side) in the control group. Premature contacts were less frequent in the test group compared to the control group. However, this difference was not statistically significant (right side: p = 0.712; left side: p = 0.054). In the test group, balanced Δp values were detected in 8 cases and unbalanced Δp values in 2 cases, whereas in the control group, balanced Δp values were observed in 1 case and unbalanced Δp values in 9 cases. When these values were compared, the difference between them was statistically significant (p <0.005). (**Table 3**)

At delivery, when examining the changes in masticatory pressure (Δp values), premature contacts were detected in 4 cases in the test group (1 on the right side, 3 on the left side) and 6 cases in the control group (2 on the right side, 4 on the left side). Premature contacts were less frequent in the test group compared to the control group. However, this difference was not statistically significant (right side: p = 1.000; left side: p = 1.000). In the test group, balanced Δp values were detected in 6 cases and unbalanced Δp values in 4 cases, whereas in the control group, balanced Δp values were observed in 3 case and unbalanced Δp values in 7 cases. However, this difference was not statistically significant (p = 0.370). (**Table 3**)

The analysis of the treatment process management showed a statistically significant difference in the test group compared to the control group (p <0.005). (**Table 4**)

Table 2. The effect of the protocols that were followed in both groups on the distribution of relative masticatory pressure

		Control group										Test group										Control group	Test group	Difference between groups
		Patients																				M (SD)	M (SD)	p
	Side	1	2	3	4	5	6	7	8	9	10	1	2	3	4	5	6	7	8	9	10			
Predelivery	Right	80	41	7	31	41	7	84	26	30	68	39	72	46	54	50	20	50	88	46	46	41.50 (27.59)	51.10 (18.26)	0.370
	Left	20	59	93	69	59	93	16	74	70	32	61	28	54	46	50	80	50	12	54	54	58.50 (27.59)	48.90 (18.26)	0.370
At delivery	Right	40	0	23	71	39	23	100	31	25	81	17	66	74	40	43	50	39	46	56	56	43.30 (34.94)	48.70 (15.85)	0.576
	Left	60	100	77	29	61	77	0	69	75	19	83	34	26	60	57	50	61	54	44	44	56.70 30.94	51.30 (15.85)	0.629

Notes: statistical analysis of the distribution of relative masticatory pressure among groups.
The distribution of 100% relative masticatory pressure for the right and left sides separately
*t test, M: mean, SD: standard deviation, *Significant difference as p < 0.05*

Table 3. The effect of the protocols that were followed in both groups on the change in masticatory pressure (Δp values)

			Control group																				Difference between groups
		Side	Patients																				p
			1	2	3	4	5	6	7	8	9	10	1	2	3	4	5	6	7	8	9	10	
Predelivery	PC	Right	+	-	-	-	-	-	+	-	-	-	-	+	-	-	-	-	-	+	-	-	0.712
		Left	-	-	+	-	-	+	-	+	+	-	-	-	-	-	-	-	-	-	-	-	0.054
	B / UB		UB	B	UB	UB	UB	UB	UB	UB	UB	UB	B	UB	B	B	B	B	UB	B	B	B	**0.005***
At delivery	PC	Right	-	-	-	-	-	-	+	-	-	+	-	+	-	-	-	-	-	-	-	-	1000
		Left	-	+	-	-	+	-	-	+	+	-	+	-	-	+	-	-	+	-	-	-	1000
	B / UB		UB	UB	B	B	UB	B	UB	UB	UB	UB	UB	UB	B	UB	B	B	UB	B	B	B	0.370

Notes: statistical analysis of the change in masticatory pressure (Δp values) [including presence or absence of premature contacts and balanced/unbalanced pressure distribution] among groups.
*PC: premature contact, B / UB: balanced / unbalanced, statistically significant differences presented in bold, Chi-square test, *Significant difference as p < 0.05*

Table 4. The effect of the protocols that were followed in both groups on the treatment process management

		Control group										Test group										Differnce between groups
		Patients																				p
		1	2	3	4	5	6	7	8	9	10	1	2	3	4	5	6	7	8	9	10	
Predelivery	Balanced		x									x		x	x	x	x	x		x	x	**0,000***
	Unbalanced	x		x	x	x	x	x	x	x	x		x						x			
At delivery	Balanced			x	x		x							x		x	x		x	x	x	
	Unbalanced	x	x			x		x	x	x	x	x	x		x			x				

*Notes: statistical analysis of the treatment process management among groups. The distribution of relative masticatory pressure (Table 1) and the change in masticatory pressure (Δp values) (Table 2) were evaluated together among the groups. Statistically significant differences presented in bold, Chi-square test, *Significant difference as p< 0.05*

Discussion

This is the first study known to the authors that compared the clinical effectiveness of the treatment protocol in two implant-supported mandibular overdenture rehabilitations using a digital occlusal analyzer. The results of this trial showed that the modified traditional treatment protocol in two implant-supported mandibular overdenture rehabilitations demonstrated better outcomes compared to the traditional treatment protocol, including more balanced relative masticatory pressure distribution values, fewer premature contacts, less variation in masticatory pressure values between occlusal contact points and more effective management of the treatment process. Based on these findings, the null hypothesis is rejected. It can be suggested that clinicians could consider modifying treatment protocols in two implant-supported overdenture rehabilitations based on the specific requirements of the case.

Currently, rehabilitations performed with traditional complete dentures continue to constitute a significant portion of prosthetic treatment in the management of completely edentulous patients. In prosthetic dentistry, complete dentures—long regarded as the primary treatment option for edentulism—are associated with two major complications: lack of retention and instability, which are reported as the primary causes of patient dissatisfaction and anxiety.[28]

Implant-supported mandibular overdentures, introduced in prosthodontics in the mid-1980s, are offered as an alternative to convantional complete dentures, particularly for patients who are not considering fixed implant-supported treatment. The 2002 McGill Consensus Statement recommended this treatment option as a first-choice therapy for patients, and it was later endorsed by the 2009 York Consensus Statement.[9,10]

Bilateral balanced occlusion is recommended for implant overdentures, especially if there is a complete denture located in the opposite arch, due to the fact that it provides equal load distribution between the implants and mucosa and stability during function.[29,25] The balanced distribution of centric and eccentric occlusal forces on the supporting tissues positively impacts the stability of prostheses, which is one of the critical factors influencing the patient's comfort while using the prostheses.[30-32] The achievement of occlusal balance implies the presence of simultaneous occlusal contacts, which is also the key factor for optimal muscle activity.[33]

As in all prosthetic rehabilitations, complete denture or implant-supported overdenture rehabilitations aim to achieve an equal distribution of 100% masticatory force for the right and left sides. When evaluating the distribution values of relative masticatory pressure—the primary outcome variable of the study—in accordance with the followed protocols, it was observed that the test group exhibited a more balanced distribution compared to the control group. Additionally, analysis of the standard deviation values revealed that the test group showed significantly less variability between predelivery and at delivery values than the control group.

In clinical practice, occlusal contacts have most commonly been detected using articulation paper or foil.[34] While these diagnostic methods can accurately determine the precise location of occlusal contacts, they cannot reliably measure their force.[35] Although qualitative methods are effective for determining the location of occlusal contact points, quantitative methods additionally provide information on the sequence of contact formation and pressure intensities.[36,37] Digital occlusal analyzers have been developed to detect occlusal contacts and also measure the relative intensity of forces at each occlusal position.[31]

Digital occlusal analyzers, such as the more affordably produced and marketed OccluSens®[38], provide clinicians with valuable data on the balance of occlusal forces, including right-left side balance relative to the midsagittal plane, and their relative intensity. Furthermore, this device possesses a built-in articulation paper for marking occlusal contacts on the teeth[39]. However, studies on the use of the device are insufficient[37], and research on its reliability is lacking.[39]

During mastication, the presence of premature contacts and cuspal interferences cannot be diagnosed easily because it may be refkexly avoided. This may lead to severe occlusal disharmonies resulting in impaired masticatory function. [40-43] In the study, fewer premature contacts were detected in the test group compared to the control group, both predelivery and at delivery. Additionally, when the exchange values between the occlusal contact points were taken into account, the test group exhibited a more balanced change compared to the control group.

The obtained data suggest that using more retentive bases for determining/recording maxillo-mandibular relationships in removable prosthodontics may be beneficial. Loss of base stability can compromise the accuracy of the data acquired. The fact that the values obtained in the test group are statistically significant compared to the control group in the predelivery balanced/unbalanced analysis supports that the rules being more retentive during the data recording phase contribute positively from a clinical perspective.

In three cases within the test group, new retentive components could not be procured for the patients due to financial constraints. As a result, in these three patients, the connection between the retained elements (ball abutment and attachment housing) and record bases could not be established prior to data recording, as per the protocol followed in the other seven cases in the group. Instead, the existing retentive components within the old prostheses were removed before the delivery of the new prostheses and reused for attaching the new prostheses. In these cases, the values analyzed prior to delivery were balanced; however, the measurements taken during the delivery of the prostheses were found to have changed negatively. This situation suggests that in two implant-supported mandibular overdenture cases, the distribution of chewing pressure may change after connecting the prostheses to the retentive components (ball abutment and attachment housing)

In the test group, heat-cured acrylic bases were fabricated for both the maxilla and mandible, as per the protocol. In the literature, the fabrication of heat-cured acrylic bases is referred to as the ‘’double-processing technique’’.[44] However, this approach requires curing the base in a flask twice. Although it is thought that this might negatively affect the dimensional stability of the acrylic material, recent literature reports that dimensional changes due to polymerization shrinkage of the acrylic are more significant during the first flask curing stage, while changes after the second flask curing are minimal.[45]

Conventional complete denture and implant-supported overdenture fabrication techniques require a series of clinical and laboratory procedural steps. This process leads to a number of problems, primarily originating from the PMMA (heat-cured acrylic) material, which have clinical implications. To improve the quality of PMMA material and eliminate all the problems arising during the production process, new materials along with computer-aided technology offer potential solutions.[46] Although a recent study [47] reported that bases produced with CAD-CAM technology demonstrated more successful results, there are also studies that have found 3D printed bases to be successful.[48,49] In fact, some of these studies have reported better results in terms of force distribution. The data obtained with the protocol followed in the test group indicate that similar results can be achieved both in the production of the bases and in terms of force distribution. However, it requires a series of procedural steps that must be meticulously followed. Furthermore, this study suggests that in implant-supported overdenture prostheses, the fit of the base may be compromised when the prostheses or bases are connected to the implant attachment components, and this could adversely affect force distribution.

The temporomandibular joint (TMJ) is the core structure housing the dynamic components of the stomatognathic system. In our study, which aimed to acquire these elements—also referred to as individual condylar guidance parameters— the ARCUSdigma II jaw motion tracking system was utilized. Mandibular movement recording is independent of dentition[50], and these technologies enable three-dimensional (3D) and real-time dynamic analysis (4D).[51] Studies conducted with these non-invasive technologies support the systems' specificity, sensitivity, and reliability.[52-54] However, the accuracy of digital recordings may be directly related to the type of digital device and the recording technique.[55,56]

No protocol has been defined in the literature for obtaining individual condylar guidance parameters from completely edentulous patients. When using the ARCUSdigma II system, the para-occlusal device must remain stable during measurements, as the lower arch (transmitter) carrying ultrasonic signal transmitters with magnets is attached to it. Due to its weight, this setup may cause tilting effects on the lower base plate during recording. In the test group, following the protocol, connecting the bases to implant-retained components after their verification enabled the acquisition of these data. Obtaining TMJ-related parameters allowed for a more comprehensive evaluation—from the design to the production of personalized occlusion/articulation.

Although the ability to reproduce jaw movement by re-simulating it with individual guidance parameters obtained from articulator systems is considered one of the good solutions, the high cost of the systems and the fact that they require different usage procedures limit their clinical usability.[57]

In both groups, the targeted treatment process involved the absence of premature contacts predelivery, as well as relative masticatory pressure values exhibiting minimal variation between occlusal contact points. This resulted in an equal distribution of masticatory pressure values across the right and left sides, a balance that was successfully maintained during delivery. Within this context, the analysis of treatment process management revealed a statistically significant difference in the test group compared to the control group.

At present, due to the developments in Computer-Aided Design - Computer-Aided Manufacturing (CAD-CAM) technology, production techniques for complete prostheses are improving on a daily basis. Therefore, the number of clinic appointments is reduced, and the production processes of prostheses are possible with less human interventions. The literature has reported positive results with respect to the usability/clinical performance of prostheses when simplified complete denture fabrication techniques are compared with conventional prosthesis fabrication steps.[58-60]

The protocol followed in the test group, when considering current complete denture production techniques, was observed to have disadvantages such as requiring additional equipment and involving distinct clinical and laboratory procedural steps. However, it offered advantages such as enabling the correction of potential discrepancies in the fabricated denture bases caused by polymerization shrinkage prior to prosthesis delivery, adjusting the marginal lengths, eliminating areas that might obstruct the insertion path of the denture base, and ensuring the elimination of occlusal errors on the articulator after the finishing processes of the prostheses.

In the test group, the axiography protocol was followed using facebow transfer and an adjustable articulator for jaw movement simulation.[53] However, there is no consensus on which reference plane or facebow method[61−63] is the most accurate.[64] Furthermore, there is a lack of evidence that the use of a facebow in complete dentures improves clinical performance; simpler approaches may yield similar results.[65] In clinical practice, the choice of protocol is determined by the targeted level of accuracy, the patient's individual needs, and the clinician's occlusal philosophy.[64]

Conclusion

Within the limitations of the current study, it can be concluded that the modified traditional protocol applied predelivery and at delivery demonstrated better results compared to the conventional protocol in terms of the distribution of relative masticatory pressure, presence of premature contacts, pressure variation between occlusal contact points (balanced / unbalanced), and treatment management values.

Değerlendirme / Peer-Review

İki Dış Hakem / Çift Taraflı Körleme

Etik Beyan / Ethical statement

It is declared that during the preparation process of this study, scientific and ethical principles were followed and all the studies benefited are stated in the bibliography.

Bu çalışmanın hazırlanma sürecinde bilimsel ve etik ilkelere uyulduğu ve yararlanılan tüm çalışmaların kaynakçada belirtildiği beyan olunur.

Benzerlik Taraması / Similarity scan

Yapıldı – ithenticate

Etik Bildirim / Ethical statement

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Çıkar Çatışması / Conflict of interest

Çıkar çatışması beyan edilmemiştir.

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Veri Analizi | Data Analysis: TT (%80), İY (%20)
Makalenin Yazımı | Writing up: TT (%90), İY (%10)
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