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Mandibular two-implant overdentures with CAD-CAM milled bars with distal extensions or retentive anchors: a randomized controlled trial.

Abstract (word: 250/250)

Objective: This randomized controlled trial (RCT) aimed to demonstrate the noninferiority of mandibular 2-implant overdentures (IODs) on a CAD-CAM milled bar with long distal extensions (MBDE) against IODs on retentive anchors (RA).

Methods: Forty edentulous participants rehabilitated with a maxillary conventional denture and a mandibular 2-IOD participated in this trial. They were randomized into two groups [Control group (CG): RA + gold matrices; Experimental group (EG): MBDE + gold clip]. The outcomes included implant survival rate (ISR), chewing efficiency [quantitative (VoH) and subjective (SA) assessments], peri-implant marginal bone-levels (PI-MBL), maximum bite-force (MBF), and patient-reported outcomes [oral health impact profile (OHIP-EDENT) and denture satisfaction index (DSI)]. Outcomes were recorded at baseline (BL), two weeks (T_0), 6-months (T_1) and at 1-year (T_2) after the intervention. Intra- and inter-group analyses were performed using regression models with α=0.05.

Results: 38 participants completed the T_2 visit (CG: n=19, age=74.7±7.8y; EG: n=19, age=70.3±10.7y). At T_2, there was no implant loss in either of the groups (ISR=100%). There were no significant differences between the groups for the PI-MBL changes (p=0.754).

Improvements occurred faster in the EG than in the CG, but over the observation time, there were no differences between the trial groups for VoH, MBF, OHIP-EDENT, and the DSI, except for SA being significantly better in the EG group (p=0.022).

Conclusions: The results of this RCT confirm that mandibular 2-IODs with a CAD-CAM milled bar with long distal extensions are not an inferior treatment to the conventional IODs on retentive anchors in the short term (1-year).

Key Words: Randomized controlled trials [MeSH topic]; Dental implants; Denture; Dental Prosthesis, Implant-supported; Prosthodontics; Humans

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1 | Introduction

The orofacial system is compromised because of tooth loss, which could be the result of a multitude of factors including biologic or iatrogenic factors as well as trauma (Felton, 2009). Edentulous individuals suffer from problems related to eating, speech, esthetics as well as with social interaction (Fiske, Davis, Frances, & Gelbier, 1998). Even though the rehabilitation of the edentulous jaws with complete dentures may help restore the lost tissues, esthetics and phonetics; oral function and patient satisfaction still remain slightly compromised (Carlsson, 2006). In particular, the chewing efficiency and the bite force of these individuals remain substantially impaired when compared to dentate or partially dentate individuals (Krall, Hayes, & Garcia, 1998). However, the advent of implant overdenture (IOD) therapy has demonstrated an improvement in the chewing efficiency (F. M. van Kampen, van der Bilt, Cune, Fontijn-Tekamp, & Bosman, 2004), the Oral Health Related Quality of Life (OHRQoL) (Emami, Heydecke, Rompre, de Grandmont, & Feine, 2009), the maximum bite-force (MBF), the masseter muscle thickness (Müller, et al., 2012; Müller, et al., 2013; Schimmel, et al., 2010; Schimmel, et al., 2011), and patient satisfaction (Visser, Raghoebar, Meijer, Batenburg, & Vissink, 2005; Awad, Lund, Dufresne, & Feine, 2003; Awad, et al., 2003). In addition to those functional and psycho-social improvements, IODs are assumed to provide structural benefits such as a deceleration of bone loss in the peri-implant area (Behneke, Behneke, d'Hoedt, & Wagner, 1997; Jemt, et al., 1996; Naert, Gizani, Vuylsteke, & van Steenberghe, 1998).

Mandibular IODs with two inter-foraminal implants are often considered as the recommended standard of care for edentulous patients (Feine, et al., 2002; Thomason, et al., 2009; Thomason, Kelly, Bendkowski, & Ellis, 2012). However, such anterior implant support implies sinking of the posterior part of the denture when occlusal load is applied during mastication. This may lead to an increased posterior bone resorption when implants support only the anterior zone of the IOD (Jacobs, Schotte, van Steenberghe, Quirynen, & Naert, 1992; Elsyad & Shoukouki, 2010; Mosnegutu, Wismeijer & Gerarts, 2015). Achieving posterior support for a mandibular IOD usually requires the placement of additional implants in the premolar or molar area. This implies a more invasive surgery with added risks, with an increased treatment and healing time along with higher treatment costs and eventually increasing the morbidity of the patient (Schimmel, Müller,

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Suter, & Buser, 2017). Splinting large sections of the mandible might also interfere with mandibular flexure and lead to implant loss (Miyamoto, et al., 2003). Moreover, distal implants are more difficult to clean for elderly patients with reduced vision and manual dexterity and/or their caretakers. To avoid the aforementioned risks, whilst keeping the functional advantages of a posterior support, bars on two implants with long distal extensions seem to be an attractive alternative. It has been reported that the posterior denture support significantly reduced the horizontal bone loss under mandibular IODs (Behneke, 1996). However, the conventional soldered extensions fractured regularly due to their incapacity to withstand the functional occlusal load (Waddell, Payne, & Swain, 2006). Recent developments in computer aided designing and computer aided manufacturing (CAD-CAM) techniques allow the manufacturing of milled bars from a single block of metal, avoiding the need for soldering and other fusion processes, yet very little evidence is available on the maintenance needs of such superstructures (Katsoulis, Brunner, & Mericske-Stern, 2011; Ueda, Kremer, Katsoulis, & Mericske-Stern, 2011). However, for mandibular IODs insufficient evidence exists to make a clear recommendation for a specific attachment type based on its effectiveness (Payne, et al., 2018). A recent Cochrane review on IODs concluded that a need for trials evaluating different types of attachments for IODs but using the same number of implant and the same implant system was necessary; the review further concluded that research on bar attachments manufactured by CAD-CAM was necessary (Payne, et al., 2018).

Hence this trial was undertaken to conduct a non-inferiority trial to test whether a new experimental treatment concept (CAD-CAM milled bar with long distal extensions) is not unacceptably less efficacious than a standard control protocol (retentive anchors) in use (Hahn, 2012; Oczkowski, 2014). Therefore, the null hypothesis for this RCT (non-inferiority trial) was that mandibular 2-implant overdentures with CAD-CAM milled titanium bar attachments with long distal extensions are not inferior to those with retentive anchors in terms of peri-implant marginal bone changes (PI-MBL), chewing efficiency, OHRQOL and patient satisfaction.

2 | Methods

This randomized controlled trial (RCT) is reported with adherence to the Consolidated

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Statement of Reporting Trials (CONSORT) statement (Schulz, Altman, Moher, & Group, 2010). This trial was conducted in compliance with the developed protocol, the current version of the Declaration of Helsinki, the ICH-GCP or ISO EN 14155 (as far as applicable) as well as all national and local legally applicable requirements. The trial was approved from the ethical committee for research on humans at the University Hospitals of Geneva (CEREH No.11-173/Psy 11-020). The first patient was recruited on the 15 March 2013, the last on the 4 October 2017.

2.1 | Trial design

This parallel, single-center, intention-to-treat RCT was designed with an allocation ratio of 1:1.

2.2 | Participants

Edentulous participants with maxillary complete dentures and mandibular IODs were recruited from the patient pool at the Division of Gerodontology and Removable Prosthodontics in the University Clinics of Dental Medicine at the University of Geneva in Switzerland. Participants were recruited if they fulfilled the predetermined inclusion and exclusion criteria as listed in Table 1.

2.2.1 | Participant groups

Participants were randomized into a control group (CG, n=20) and an experimental group (EG, n=20). All participants had a maxillary complete denture and a mandibular 2-IOD. All the implants in the trial participants were standard tissue-level-regular-neck implants (Institut Straumann AG, Basel, Switzerland) placed in the interforaminal region of the mandible. The implant surfaces were either with an SLA® or SLActive® surface (Institut Straumann AG, Basel, Switzerland). The implant lengths ranged between 6-12 mm with implant diameters of either 3.3 or 4.1 mm. The mean functional period of the implants *in situ* in the trial participants was 8.2±4.7 years (range: 1– 22 years).

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2.2.2 | Sample size

Sample size calculation could not be performed for this trial because of a lack of reference data. Therefore, the sample size was based on previously published studies of similar nature where sufficient statistical power was achieved with 18 participants (van der Bilt, van Kampen, & Cune, 2006; F. van Kampen, Cune, van der Bilt, & Bosman, 2003). Hence, 20 participants for each group was fixed in this trail and was deemed sufficient for recruitment in order to achieve sufficient power and also account for possible drop-outs over time (typical dropout percentage of 10%).

2.2.3 | Randomization

2.2.3.1 | Sequence generation

The randomization sequence was generated using an online sequence generator (https://www.randomizer.org/). A block randomization was implemented and four blocks of 10 non-unique numbers per set were generated.

2.2.3.2 | Allocation concealment

The generated numbers were in sequentially numbered opaque envelopes which were sealed. The envelopes were stored under lock and key with the principal investigator (FM) and were only opened after the participant signed the consent form and consented to participate.

2.2.3.3 | Implementation

The randomization sequence was generated by a co-investigator (MS_2). Enrollment of the participants was done by two investigators (MS_1 & SM) and the assignment of the participants to the trial groups was done by the principal investigator (FM). All interventions were carried out by a single specialist prosthodontist (MS_1).

2.2.3.4 | Blinding

Blinding was not possible in this trial.

2.3 | Recruitment and treatment protocol

Participants were contacted by a letter, followed by a telephone call or contacted during

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their routine control/maintenance visits. Cognitive impairment and depression were ruled out by means of a Mini Mental State Examination (MMSE) (Folstein, Folstein, & McHugh, 1975) and Hospital Anxiety & Depression Scale (HADS) (Zigmond, & Snaith, 1983) tests, during the screening visits. Co-morbidities and the current medication were evaluated by the patient medical records or by history taking and when necessary, by confirmation from the treating physician. Xerostomia was excluded by collecting whole saliva after chewing a wax-specimen for 5 minutes (Dormenval, Budtz-Jorgensen, Mojon, Bruyere, & Rapin, 1998). Maximum bite force (MBF) was recorded by means of a digital force gauge (Imada digital force gauge, Imada Co., Ltd, 99 Jinnoshiden-cho aza Kanowari Toyohashi, Japan). A short clinical examination assessed the clinical situation of the implants using the Buser implant success criteria (Buser, Weber, & Lang, 1990) and Mombelli index (Mombelli, van Oosten, Schurch, & Lang, 1987). A written and informed consent completed the screening visit. Further exclusion was based on the post-hoc exclusion criteria as stated in Table 1.

2.4 | Interventions

2.4.1 | Control group (CG)

The control group (Figure 1 & 2) participants received a reline, or a replacement denture where the old denture did not fulfill the Marxkors quality criteria (Marxkors, 1988). The Marxkors criteria assesses the quality of complete dentures and classifies it into four categories (Marxkors, 1988):

1- perfect, no deviation from ideal
2- slight deviation from ideal, acceptable without modifications
3- needs modification, not acceptable without adjustments
4- not acceptable, needs to be replaced

The majority of participants had existing retentive anchors which could be used as patrices. Where necessary, existing other stud-type attachments were changed to retentive anchors. If existing retentive anchors were worn or considered not acceptable, they were also replaced with new retentive anchors on the commencement of RCT. The existing matrices were removed from the dentures and space was verified using a silicone material (Fit Checker, GC Europe N.V., Leuven, Belgium). After border molding

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with low-fusing compound (Impression Compound, Kerr Dental, Bioggio, Switzerland) a wash impression was performed with a polyether impression material (Impregum™, 3M Oral Care, St. Paul, MN, USA). This was then sent to the dental laboratory where a master dental technician processed the overdenture along with the incorporation of the new matrices (Dalbo® PLUS, Cendres + Métaux SA, Biel Switzerland), before the IOD was inserted the same day. Recall and maintenance visits were performed as stipulated by the trial protocol, additional adjustments and repairs took place as requested by the patient.

2.4.2 | Experimental group (EG)

For the participants of the EG, existing attachments were removed by means of a torque control ratchet with forces inferior to 35 Ncm, otherwise the post-hoc exclusion criteria applied (Table 1). Replacement dentures were manufactured for the mandibular jaws. The tooth set up in wax and the master mandibular models were scanned using a laboratory scanner (Straumann® Cares® scanner, Institut Straumann AG, Basel, Switzerland). The scan data was imported into a software (Cares®, Institut Straumann AG, Basel, Switzerland) to design the CAD-CAM milled bars (REF: 010.1091). The bars were designed using the configuration of Dolder® Bar U-shape (standard) as provided by the Cares® software. The design of the bar was carried out, respecting the space requirements for both cleanability and the denture. The mean inter-implant distances calculated was 25.3 mm. Long distal extensions (15 mm) were added and their design approved by the investigators (MS_1 & FM) before being sent to the Cares® milling center for fabrication. Although the recommended length for cantilever bars is between 5 mm and 7 mm and should not extend 15 mm (Meriscke-Stern, 1996; Meriscke-Stern, 2000; Elsyad, Al-Mahdy, Salloum, & Elsaih, 2013). However, this length was chosen as an experimental length to verify that a reconstruction with this length did not produce any detrimental effects to the implants, while accomplishing the intended posterior support. Upon receiving the fabricated bars, they were first verified for passive fit on the model and then clinically tried-in on the patient (Figure 3 & 4) using the Sheffield test (one screw test). The tooth set up in wax and the bar were then sent to a master dental technician for finalizing the denture without a metal infrastructure. The placement of the bar-clips (Elitor®, Cendres + Métaux SA, Biel, Switzerland) was performed according to standard

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procedures in a dental laboratory. At the insertion visit, the bars were first tightened on the implants at 35 Ncm according to the manufacturer's instructions. The IOD was then delivered. Recall and maintenance visits were performed similar to the CG.

2.5 | Outcome measures

The outcome measures were recorded at the following timepoints: at baseline (BL) before intervention and at T_0, T_1, and T_2.

2.5.1 | Implant survival and peri-implant conditions

At each recall visit, the implants were clinically examined and inspected using success criteria published by Buser, et al. (Buser, et al.1990). The peri-implant conditions and signs of inflammation were classified using the Mombelli's indices (mPI and mBI) (Mombelli, et al.1987).

2.5.2 | Chewing efficiency (CE)

CE was evaluated with a two-color mixing ability test using a commercially available validated chewing gum (Vivident Xylit Fruitswing Karpuz/Asai Üzümü, Perfetti van Melle, Turkey) adhering to the previously validated and published procedure (Schimmel, et al., 2015). Each participant was given the test chewing gum and requested to chew for 20 cycles. The chewed gum was collected in a transparent cellophane pouch without saliva contamination. A visual subjective assessment (SA) with five graded categories ranging from SA1 (insufficient chewing) to SA5 (perfect chewing) was first done by a single investigator (MS_1) as described by Schimmel and coworkers (Schimmel, Christou, Herrmann, & Müller, 2007). The chewing gum was subsequently flattened to a wafer of uniform thickness of 1 mm. Both sides of this wafer were scanned with a conventional flatbed scanner (Epson Perfection V800 Photo Scanner, Epson America, CA, USA) with a resolution of 500 dots per inch (dpi). These images were then analysed for the variance of hue (VoH) using a purpose-built freeware (ViewGum software, dHAL Software, Kifissia, Greece). VoH is a measure for color mixture of the specimens; the better the color blending, the higher is the chewing efficiency and vice versa (Halazonetis, Schimmel, Antonarakis, & Christou, 2013). The evaluation of VoH may be described with

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a log10 association on the base of chewing cycles and is able to discriminate between various degrees of oral impairment (Buser, et al., 2018; Elsig, et al., 2015; Müller, et al., 2012)

2.5.3 | Maximum voluntary bite force (MBF)

MBF was assessed between the maxillary and mandibular first molar for both sides. The participant was requested and encouraged to bite down as hard as possible on the force gauge until it leveled to a beep (Occlusal Force-Meter GM 10®, Nagano Keiki Co., Ltd.; 1-30-4 Higashimagome, Ohta-ku, Tokyo, Japan) (Nakatsuka, Usui, Masuda, Rugh, & Kurihara, 2006). The mean of six recordings (3 x right, 3 x left) was used for analysis.

2.5.4 | Peri-Implant Marginal Bone Level (PI-MBL) changes

The standardized panoramic radiographs (OPTs) were digitized and 4 parallel lines were drawn corresponding to the shoulder and the apical end of the implant on Adobe Photoshop Elements 2.0 (Adobe Systems Inc., San Jose, CA, USA). One line each was placed at the shoulder and apical end of the implant and the other two at the defined bone level on the mesial and distal aspect of the implant. Knowing the implant length and using the implant-shoulder as a reference point, bone levels were calculated through a simple rule of three with an image processing and analysis freeware (ImageJ, V1.44, https://imagej.nih.gov) (Bragger, 1998; Bragger, et al., 2004). A single investigator (RB) performed the PI-MBL measurements. PI-MBL were measured at BL and T_2 time points.

2.5.5 | Occlusal contacts (OCs)

Adjustments and repairs were provided during the observation period, according to the trial protocol, and as requested by the patient. The OCs were marked with an occlusal indicator foil (Hanel 12µm, Coltène/Whaledent, Langenau, Germany). The occlusal views of all dentures were photographed and the number of contact points counted for the molar-, the premolar-canine and the incisor areas. Comparisons were performed between T_0 and T_2 time points.

2.5.6 | Denture satisfaction index (DSI)

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The DSI was evaluated by means of a visual analogue scale (VAS) based questionnaire (Allison, Locker, Jokovic, & Slade, 1999), which was administered after training each participant in using this form of scale. Nine different items were covered in this questionnaire that included ease of cleaning, general satisfaction, speech, comfort, aesthetics, stability, chewing ability, function and the general oral condition. Some items had sub-items resulting in a total of 23 items to mark. In this trial the DSI questionnaire (Rashid, et al., 2011) administered was in the validated French version.

2.5.7 | Oral Health Related Quality of Life (OHRQoL)

The oral health impact profile (OHIP-EDENT) questionnaire was developed and validated to assess the impact of oral disorders on OHRQoL in edentulous participants rehabilitated with complete dentures (Allen & McMillan, 2002; Awad, Al-Shamrany, Locker, Allen, & Feine, 2008; Slade & Spencer, 1994). It contains 20 questions in seven domains and is proven to be sensitive to changes in prosthetic treatment and oral health (Allen & Locker, 2002; Awad, et al., 2003; Heydecke, Locker, Awad, Lund, & Feine, 2003). For each of the questions, participants are asked how frequently they have experienced the event during the last four weeks. Responses are given on a five-point scale ranging from 0 (never) to 5 (always). It is important to bear in mind that a low score corresponds to a good OHRQoL. In the present trial the validated French version of the OHIP-EDENT was utilized (Allison, Locker, Jokovic, & Slade 1999). This instrument has been successfully used in previous studies (Schimmel, et al., 2011).

2.6 | Statistical methods

Data was checked for normal distribution using Shapiro-Francia, tests. In the case of a non-Gaussian distribution, data was converted using the usual transforms. The square root transformation normalized successfully VoH and OHIP-EDENT, whereas mean bite force was normalized with a natural log transform. Variables were tested with one-way ANOVA. Post-hoc tests comprised Bonferroni correction for repeated comparisons. Linear mixed regression models were used to determine the effects of group and time on the different outcomes. The models were run without and with interactions between the group and the various timepoints using the interaction terms “Gp#TP” as well as adjusting

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for various factors such as sex, age and occlusal contacts along with the following interaction terms “Gp#TP#sex”, “Gp#TP#Age” and “Gp#TP#OC”, respectively. Mixed models take into account the repeated measures design. The statistical unit was the participant for all outcome parameters except for implant survival where the implant was considered as the unit. All statistics were performed with the STATA statistical software, version 16.1 (StataCorp, College Station, Texas, 2019).

3. | Results

Forty participants were recruited in this trial. Two participants, one from each trial arm, dropped out, one for health reasons (CG) and one immediately after being informed on the randomized treatment allocation (EG). Finally, 38 participants (CG: n=19, mean age: 74.7±7.8 years; EG: n=19, mean age: 70.3±10.7 years) were analyzed for the outcome measures in this trial; their baseline demographics and the clinical characteristics are listed in Table 2. The entire enrollment and allocation process for each trial group, with details on the numbers of participants, who were randomly assigned, received interventions, and analyzed for the outcome measures, are detailed in the flow diagram (Figure 5).

3.1 | Implant survival and peri-implant conditions

At the T_2 recall visit, no implant was lost. At BL, there were no differences between the two trial groups for the implant plaque (PI) and bleeding (BI) indices (Table 2). At the T_2 recall period, there was an increase in the PI (p=0.027) and the BI (p=0.019) within the EG but not in the CG; however, there was no statistically significant difference between the groups (Table 3).

3.2 | Chewing efficiency

In both groups, there was a tendency for improvement in the VoH at T_2 but this was not statistically significant (Table 4). The VoH comparisons of within group improvements between the groups with interactions of timepoint revealed no differences (Table 5). Post hoc power analysis (mean VoH at T_2, t-tests, effect size=0.0385, α err prob=0.05)

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revealed a power of 1-β err prob= 0.212 for the current trial. To achieve a power of 90%, a sample size of 143 participants must be included in each group (total n=286).

In the SA, there was improvement with the CG only at T_2 recall when compared with baseline (p=0.021, Table 4); while, within the EG the SA showed an improvement at T_0, T_1 and T_2 (p<0.001, Table 4) when compared to baseline. This improvement in EG was significant when compared within the groups with interactions (p=0.022, Table 5). When analyzing the effect of various factors such as sex, age and occlusal contacts on the improvement of VoH, only age showed an influence (p=0.018, Table 6), with older participants chewing less efficiently. None of the above-mentioned factors showed any influence on the SA.

3.3 | Maximum bite force (MBF)

The MBF significantly improved from baseline in both CG and EG at T_1 and T_2 (Table 4). The improvement tended to be higher in the EG, but inter-group comparisons did not reveal a significance (Table 5). The MBF was neither affected by age, sex nor occlusal contacts (Table 6). Post hoc power analysis (mean MBF at T_2, t-tests, effect size=0.7253, α err prob=0.05) revealed a power of 1-β err prob= 0.9916 for the current trial.

3.4 | Peri-implant marginal bone level (PI-MBL) changes

The mean PI-MBL changes calculated at T_2 for the CG and the EG were -0.21±0.640 mm and -0.14±0.671 mm, respectively. There was no significant difference between the two trial groups in terms of PI-MBL changes until the T_2 recall (Table 7). Post hoc power analysis (mean PI-MBL at T_2, t-tests, effect size=0.0392, α err prob=0.05) revealed a power of 1-β err prob= 0.218 for the current trial. To achieve a power of 90%, a sample size of 138 participants must be included in each group (total n=276).

3.5 | Occlusal Contacts

The number of anterior incisal contact points increased over time within the control group (p=0.019, Table 8); whereas it was stable within the experimental group (p=0.174, Table 8). Between the groups at the end of T_2, the number of anterior incisal contact points was

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higher in the CG (p=0.026, Table 8); whereas the number of molar contact points was higher in the EG (p=0.044, Table 8).

3.6 | OHRQoL (OHIP-EDENT)

The overall OHRQoL in the CG showed significant improvement at T_2 (p=0.003, Table 4). In the EG, it showed a significant improvement already after 2-weeks (p=0.002) which leveled with little variation of the median until T_2 (p<0.001, Table 4). There were no differences between the groups in terms of the interaction with timepoints (Table 5), but OHRQoL seems to be affected by age, in that elder participants show improved OHRQoL (p=0.003, Table 6).

3.7 | Patient's denture satisfaction (DSI)

There was a steady increase in the DSI in CG only at T_2 (p=0.046, Table 4, Figure 8). While the EG participants showed an increase in the DSI already at 2-weeks (p<0.001), at 6-months (p<0.001) and at T_2 (p<0.001) with little variation of the median (Table 4). There were no significant differences between the groups with relation at any given timepoint (Table 5). Occlusal contacts seem to influence the DSI, with more occlusal contacts being associated with a higher denture satisfaction (p=0.021, Table 6).

4. | Discussion

The findings of this RCT demonstrate that mandibular 2-IODs on a CAD-CAM milled bar with long distal extensions are not inferior to 2-IODs on conventional retentive anchors. Therefore, the null hypothesis cannot be not rejected.

However, these results have to be interpreted in view of the inherent shortcomings of any clinical trial. The matching of EG and CG was very close, but there were significant differences for DSI and OHRQoL. Furthermore, all of the EG mandibular dentures were replaced for technical reasons, whereas only some insufficient mandibular IODs were replaced in the CG. This implies that all of the EG dentures presented new occlusal

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surfaces, whereas those of the CG fulfilled the Marxkors quality criteria (Marxkors, 1988), but were not necessarily like brand-new denture teeth. Another shortcoming of the trial design was that a poor implant axis was not considered an exclusion criterion. Although during the T_2 follow up no implant was lost, the occlusal load distribution and/or the marginal bone level changes might have been affected by axe divergences' or implant inclinations. Inherent shortcomings also relate to the large variation since implant placement, as participants were recruited from the patient pool of the university clinic with already existing functional implants. It must be borne in mind that the follow-up period reported here is short (1-year) and the sample size is small. However, studies with similar samples sizes have been published in the past that have demonstrated differences between the trial groups. Therefore, the sample size in the current trial can be considered as acceptable (Ma, Tawse-Smith, De Silva, Atieh, Alsabeeha & Payne, 2016; Payne, Tawse-Smith, Wismeijer, De Silva, & Ma, 2017). Owing to the short follow-up period (1-year), the results of this trial may be considered as preliminary results, nevertheless meaningful.

The chewing efficiency improved significantly in both groups as with other studies of similar nature (Boven, Raghoebar, Vissink, & Meijer, 2015; Elsyad & Khairallah, 2017; Khalid, et al., 2020), when evaluated according to the Subjective Assessment (SA) of the degree for color mixture by the investigator. However, the onset of the improvement was faster in the EG (T_0) than in the CG (T_2) and the overall effect was more evident in the EG than in the CG. This functional advantage did not reflect when analyzing objectively the VoH of the chewed specimen, but this is most likely due to the difference in statistical testing, as SA is a categorical variable and VoH a continuous one. To detect improvement in CE after implant placement, VoH needs a minimum of 1-year to show significant improvement. Perhaps the small sample size may have played a role in not eliciting the differences, and as stated earlier the post hoc tests revealed a required sample size of 143 participants in each group to achieve a power of 90%. Masking could have eliminated investigator bias in the subjective assessment of the chewing gums. Since the SA was judged by a single operator (MS_1), who was extremely experienced in reading the color mixture of the specimen, it can be assumed that the readings were consistent (Enkling, et al., 2019).

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It seems intuitive, that adding posterior support to the 2-implant overdenture would increase the MBF and chewing efficiency, as the denture saddles are no longer supported by the mucosa, but by the rigid extension of the implant bar (Oh, Saglik, & Bak, 2020). In a complete denture, the highest chewing forces are measured in the center of mastication, located at the lowest point of the ridge, parallel maxillary and mandibular ridges, and ideally an inter-crestal angle of 90°. In most complete denture cases, this is located between the second premolar and the first molar. With 15 mm extensions, the superstructures used in the EG of this trial reached almost to this point, thus providing a sound support during mastication (Katsoulis, Walchli, Kobel, Gholami, & Mericske-Stern, 2015; Quirynen, Quirynen, & Duyck, 2015; Semper, Heberer, & Nelson, 2010). Since all the EG dentures were equipped with brand-new occlusal surfaces, it might have supported the faster improvement of the subjective chewing ability. However, significant improvements were also observed in the CG. With the simple replacement of the housings for the retentive anchors and/or existing stud-attachments, a certain improvement in denture retention might already have been achieved. However, the long time required before any statistical significance may indicate that the reline of the denture base might be the cause of the improved subjective chewing ability. A more intimate contact to the denture-bearing tissue and new functional border molding might have limited the food being trapped under the denture base. With time, the new denture intaglio surface settles into the denture-bearing tissues, which in turn, become less sensitive and can accept more load without painful protest. The 1-year delay before the CG participants demonstrated significant improvement of their subjective chewing ability corresponds to the observations on denture adaptation in complete denture wearers. The maximum MBF improved significantly in both groups after 6 months, and continued to be higher than at baseline until the T_2 observation. Since the EG were provided with implant support close to the center of mastication, we would have expected a higher MBF from the beginning, since pain from the mucosa would not limit the exerted force (Muller, Heath, & Ott, 2001). However, despite encouragement during the testing, participants might not have volunteered to exert the full force on their mandibular denture, as it was a requirement of the ethics committee that they would be informed on the experimental nature of their superstructure. Hence, they might have just been careful in order to avoid

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damage to their long-extension bars. Moreover, it has been demonstrated that even after receiving implant rehabilitation and the MBF being increased, participants may still refrain from using the maximal potential (Maniewicz, et al., 2019). A similar effect was observed in a study on maximum bite force in edentulous participants with fixed implant reconstructions. Those who had experienced chipping before the testing of the maximum bite force provided significantly mandibular forces than those who did not (Luraschi, et al., 2012). Furthermore, whether the small sample size could have influenced the indifference between the groups was ruled out with post hoc tests as the post hoc power analysis (mean MBF at T_2, t-tests, effect size=0.7253, α err prob=0.05) revealed a power of 1-β err prob= 0.9916 for the current trial which could be considered sufficient.

Both OHRQoL and DSI improved significantly in both groups, as observed in studies with similar outcomes (Abdou, Elgamal, Mohammed Askar, & Youssef Al-Tonbary, 2019; Yunus, et al., 2016), but the onset of improvement in our trial was earlier in the EG (T_0) than in the CG (T_2). Over the observation period, no difference was observed between EG and CG, although the level of significance was higher in the EG (CG $p<0.046$, versus EG $p<0.0001$). As discussed earlier, the speed of improvement might be related to the amount of adaptation required. The more stable and retentive the denture, the mandibular the need for the central nervous system to alter habitual movement pattern to function with the denture (Müller, Link, Fuhr, & Utz, 1995). Whereas studies report that the 2-implant IOD on ball attachment presents a rotational axis and consequently do not prevent the posterior denture saddles from sinking in (Emami, et al., 2019; Emami, de Souza, Bernier, Rompre, & Feine, 2015; Kimoto, et al., 2011). This may not be the case for the distal-extension bar overdentures (Tang, Lund, Tache, Clokie, & Feine, 1999). Hence the larger support area might have influenced positively the subjective denture satisfaction (DSI) and the OHRQoL of the participants. When interpreting these findings, it also has to be born in mind, that at baseline, CG participants were significantly more satisfied with their dentures, and they presented a significantly better OHRQoL. This initial difference might have masked the intervention effect on these outcome parameters. Likewise, OHRQoL proved to be influenced by age, and the average age of the CG was 4.4 years higher than in the EG. It is a well-established paradox in gerodontology, that with age, the OHRQoL becomes better and the subjective treatment demand for a given

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pathology or functional impairment declines (Steele, et al., 2004; Wickop, Wöstmann, Ferger, & Kolb, 1998). Although the age difference between the groups was not significant, the given difference might also have contributed to masking the treatment effect on OHRQoL and DSI.

The present RCT confirms the non-inferiority of the 2-implant long bar IOD over the 2-IOD with retentive anchors over a 1-year period of time. The clinical outcome parameters do not seem to be different, some of them even better or faster appearing. The patient reported outcome measures (PROMs) confirm that there is no difference between the groups (Khalid, Yunus, Ibrahim, Elkezza, & Masood, 2017), but the baseline characteristics of the PROMs might have masked a potential superiority of the novel overdenture design as seen in other studies comparing overdentures with different attachments. Given the proof of non-inferiority, potential benefits and shortcomings of this novel treatment concepts should be investigated over a longer period of time. The length of the extension with 15 mm is beyond the recommendations of the manufacturer. Although the bar is milled out of one piece of metal, it may still fatigue over time and fracture. The maintenance need and long-term cost-effectiveness between the two denture designs has to be evaluated. There are sporadic reports of fractures of narrow diameter implants (3.3mm) when being restored with extension bars in a 2-implant configuration. However, these reports are rare, but might pose a risk for long-term technical failures in the EG.

An important advantage of the long extension bar is the protection of the posterior alveolar ridge from occlusal pressure (Elsyad, Alameldeen, & Elsaih, 2019; Elsyad, Alokda, Gebreel, Hammouda, & Habib, 2017), along with enhanced retention and stability which can contribute to improved chewing efficiency as well as enhanced patient satisfaction. Careful analysis of the OPTs over time might evince if the bone resorption under the extensions, or even beyond, is slowed down, or bone apposition takes place under the extension, as observed in previous studies with cantilever bars (Elsyad, et al. 2017). If this assumption is confirmed, the question arises whether a mandibular bone resorption goes along with an anteriorization of the occlusal contacts in the same jaw, which was demonstrated in 2-implant overdentures with a rotational axis. To avoid the

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development of a combination syndrome (Kelly, 1972), a close monitoring of the distribution of the occlusal contacts and frequent relines are recommended when a rotational axis is present. Cost and treatment time for remounting and relining to correct this anteriorization of the occlusal contacts might be lowered, and the risk of developing a combination syndrome moderated. The results also indicated, that the number of posterior contacts is positively influencing denture satisfaction. Hence a stable occlusion over time might be a desirable advantage of the novel bar-design. Despite these potential advantages over time, associated risks have to be assessed. The 1-year survival of the superstructure and the related treatment modality is not sufficient to recommend it as a definite clinical protocol. Hence the patient cohort of this RCT will be further followed.

With age, the ability to manage a denture diminishes, along with reduced vision, smell, tactile sensitivity and dexterity. Several studies confirmed that bars are more difficult to clean than retentive anchors, especially on the lingual aspect (Assad, Abd El-Dayem, & Badawy, 2004; Park, Shin, & Lee, 2019). This can be confirmed by the findings of the present RCT. Plaque accumulation on the implants does not only favor the development of a peri-implantitis, but may also present a risk for aspiration pneumonia in patients with swallowing disorders and poor immune defense. Management of an implant overdenture on a bar may become difficult when the patient becomes fragile and dependent on care. Last but not least, the long extensions may present a source of injury of the antagonistic tissues when the denture is not worn during the night. In view of these potential risks, the described novel treatment modality might be more adequate for independently-living and “fit” edentulous elders.

The possibility to provide implant overdentures on bars with just 2 implants instead of the traditional 4 implants opens this treatment concept to a larger group of patients and indications. Cost and surgical morbidity are inherently reduced. Implant support can even be provided where the available bone, the general health of the patient or finances preclude placing 4 implants. This might be particularly the case for oncology patients with bony defects following surgery, or multi-morbid patients who would benefit from an extended implant support when poly-pharmacy has rendered their mucosa dry and sensitive. However, as in all implant-overdenture treatment concepts, denture

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management has to be closely monitored as the patient ages and the reconstruction has to be simplified along with the functional decline of the patient (Müller, & Schimmel, 2016). Placing implants is a life-long commitment for the patient and the dentist (Müller, & Barter, 2016).

5. | Conclusions

The results of this RCT confirm that mandibular 2-IODs with a CAD-CAM milled bar with long distal extensions are not an inferior treatment to the conventional IODs on retentive anchors in the short term (1-year).

Conflicts of interests

The authors declare that they have no conflicts of interest in relation to this trial.

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Figure Legends

Figure 1. One of the participants in the control group with two retentive anchors as patrices.

Figure 2. Overdenture in the control group showing Dalbo® PLUS matrices on the intaglio surface of the retentive anchor overdenture.

Figure 3. One of the participants in the experimental group with a CAD-CAM milled titanium bar with long distal extensions.

Figure 4. Overdenture in the experimental group showing gold clips on the intaglio surface of bar attachment overdenture.

Figure 5. Flow diagram showing the enrollment, with number of participants randomized, allocated to each trial group, dropouts along with reasons for dropouts and number analyzed for outcome measures.

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Table 1. Inclusion and exclusion criteria for the recruitment of trial participants

Inclusion criteria
• Completely edentulous participants who live independently and are not dependent for care
• Willing to participate and sign an informed consent
• Participants must be rehabilitated with a maxillary conventional complete denture and with a mandibular implant overdenture on 2 implants
• The implants must have been loaded for a minimum period of 1 year
• Implants must be Regular Neck Straumann tissue level implants
• Participants must present with a unilateral maximum bite force of more than 30 N on each side
• The prostheses must be or can be rendered functionally satisfying
• Implants must be clinically successful and osseointegrated according to the Buser criteria
Exclusion criteria
• History of repeated unjustifiably missed appointments
• Severe dissatisfaction with existing denture without corresponding clinical findings
• Xerostomia with a Stimulated Salivary Flow Rates (SSFR) of less than 0.7 ml / min
• Multiple co-morbidities (more than 3 chronic diseases which require treatment)
• History of IV-bisphosphonate therapy
• Peri-implantitis with a BOP>2
• Implants placed mesial of the canine position
• Severe dementia or depression
Post hoc-exclusion criteria
• Peri-implant bone loss of more than ¼ of the implant length (OPT)
• Attachments not removable with torque forces inferior to 35 Ncm

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Table 2. Baseline demographics of the trial participants

	Control	Experimental	Total	P-value
Participants	N=19	N=19	N=38	
Men	9	9	18	1.000
Women	10	10	20	1.000
Age	74.7 ± 7.8	70.3 ± 10.7	72.5 ± 9.5	0.155
Plaque index	1.2 ± 1.0	1.5 ± 1.6	1.3 ±1.3	0.488
Bleeding index	0.5 ± 0.5	0.4 ± 0.5	0.5 ± 0.5	0.416
Peri-implant marginal bone level	2.7 ± 0.9	2.4 ± 0.6	2.6 ± 0.7	0.337
Anterior occlusal contacts	5.6 ± 0.8	5.5 ± 1.8	5.6 ± 1.4	0.910
Posterior occlusal contacts	14.0 ± 2.8	13.8 ± 2.4	13.9 ± 2.6	0.804
CE-Variance of hue	0.4 ± 0.2	0.3 ± 0.1	0.3 ± 0.2	0.146
CE-Subjective assessment	2.5 ± 0.7	2.7 ± 0.6	2.6 ± 0.6	0.454
Maximum bite force	160.7 ± 87.5	212.7 ± 121.5	186.7 ± 107.7	0.065
Overall OHIP 20	14.2 ± 15.6	23.8 ± 21.3	19.0 ± 19.1	0.046
Overall DSI	90.4 ± 9.8	80.3 ± 18.2	85.4 ± 15.3	0.041

Abbreviations: N, number; CE, Chewing efficiency; OHIP, Oral health impact profile; DSI, Denture satisfaction index; p-value, Bonferroni correction threshold for significance (P<0.002)

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Table 3. Implant survival and peri-implant conditions observed in the trial groups

Implant Survival						
Timepoint	Implants present		Implants failed (dropout)		Total (ISR%)	
	CG	EG	CG	EG		
Baseline	40	40	0 (0)	0 (0)	40/40 (100%)	40/40 (100%)
1-year	38	38	0 (2)	0 (2)	*38/38 (100%)	*38/38 (100%)
Peri-implant condition in the two trial groups						
Timepoints / Parameter	Control group (mean±SD)		Experimental group (mean±SD)			[a]P-value
Baseline						
Plaque Index	1.16 ± 0.95		1.46 ± 1.58			0.488
Bleeding Index	0.53 ± 0.47		0.41 ± 0.46			0.416
2-weeks						
Plaque Index	0.91 ± 0.76		0.37 ± 0.68			**0.026**
Bleeding Index	0.39 ± 0.46		0.05 ± 0.16			**0.005**
6-months						
Plaque Index	1.09 ± 0.70		1.46 ± 1.27			0.266
Bleeding Index	0.51 ± 0.58		0.38 ± 0.45			0.440
1-year						
Plaque Index	0.96 ± 0.98		1.61 ± 1.78			0.175
Bleeding Index	0.42 ± 0.48		0.41 ± 0.46			0.936
[b]P-value						

Abbreviations: ISR%, Implant survival rate %; CG, control group; EG, experimental group; * Dropout implants were not considered as failures as they were still in situ and in function at the regular recall visits;
SD, standard deviation; [a]P, inter-group comparison; [b]P-intra-group comparison; significance, P<0.05 (ANOVA)

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Table 4. Within subject analysis of the two trial groups

		Control				Experimental			
Parameter	Timepoint	Coefficient	95%CI	P-value	R-square	Coefficient	95%CI	P-value	R-square
CE-Variance of hue	Baseline	0.000	--	--		0.000	--	--	
	2-weeks	0.002	-0.062, 0.065	0.956	0.009	0.012	-0.048, 0.072	0.696	0.013
	6-months	-0.031	-0.094, 0.033	0.346		-0.027	-0.088, 0.032	0.374	
	1-year	-0.009	-0.073, 0.054	0.776		-0.007	-0.067, 0.053	0.820	
CE-Subjective assessment	Baseline	0.000	--	--		0.000	--	--	
	2-weeks	0.105	-0.208, 0.419	0.511	0.038	0.579	0.253, 0.905	**<0.001**	0.238
	6-months	0.158	-0.156, 0.471	0.324		0.789	0.464, 1.115	**<0.001**	
	1-year	0.368	0.055, 0.682	**0.021**		0.895	0.569, 1.220	**<0.001**	
Maximum bite force	Baseline	0.000	--	--		0.000	--	--	
	2-weeks	-0.027	-0.187, 0.133	0.744	0.032	0.042	-0.101, 0.186	0.563	0.056
	6-months	0.171	0.011, 0.332	**0.036**		0.184	0.040, 0.327	**0.012**	
	1-year	0.167	0.007, 0.327	**0.041**		0.265	0.121, 0.408	**<0.001**	
OHIP-20	Baseline	0.000	--	--		0.000	--	--	
	2-weeks	-0.016	-0.733, 0.702	0.966	0.036	-1.632	-2.678, -0.584	**0.002**	0.085
	6-months	-0.509	-1.227, 0.208	0.164		-1.519	-2.566, -0.472	**0.004**	
	1-year	-1.093	-1.812, 0.376	**0.003**		-1.711	-2.758, -0.664	**<0.001**	
Overall DSI	Baseline	0.000	--	--		0.000	--	--	
	2-weeks	-0.329	-4.451, 3.792	0.876	0.030	11.710	5.969, 17.450	**<0.001**	0.123
	6-months	0.574	-3.547, 4.695	0.785		14.363	8.622, 20.103	**<0.001**	
	1-year	4.203	0.082, 8.324	**0.046**		10.198	4.457, 15.939	**<0.001**	

Abbreviations: CE, Chewing efficiency; OHIP, Oral health impact profile; DSI, Denture satisfaction index; CI, confidence interval; significance, P<0.05

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Table 5. Linear mixed regression models showing the improvement in the two groups with interactions between groups against timepoints (Gp#TP) with confidence intervals set at 95% (95%CI) and significance at P<0.05. When the interaction term is significant it means that the evolution of the parameter values over time is not parallel for the two groups.

Parameter	Interaction	Coefficient	95%CI	P-value	R-squared
CE-Variance of hue	Gp#TP	0.002	-0.085, 0.090	0.960	0.055
CE- Subjective assessment	Gp#TP	0.526	0.074, 0.978	**0.022**	0.261
Maximum bite force	Gp#TP	0.097	-0.118, 0.312	0.375	0.157
OHIP-20	Gp#TP	-0.618	-1.887, 0.651	0.340	0.077
Overall DSI	Gp#TP	5.995	-1.072, 13.062	0.096	0.101

Abbreviations: CE, Chewing efficiency; OHIP, Oral health impact profile; DSI, Denture satisfaction index; CI, confidence interval

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Table 6. Linear mixed regression models showing the influence of age, sex and occlusal contacts on the improvement in the two groups with interactions between group, timepoint and sex/age/occlusal contacts (Gp#TP#Sex; Gp#TP#Age; Gp#TP#OC) with confidence intervals set at 95% (95%CI) and significance at P<0.05. When the interaction term is significant it means that the evolution of the parameter values over time is not parallel for the two groups and conditions.

Parameter	Interaction	Coefficient	95%CI	P-value
CE-Variance of hue	Gp#TP#sex	0.023	-0.400, 0.088	0.461
	Gp#TP#Age	0.004	0.001, 0.008	**0.018**
	Gp#TP#OC	-0.002	-0.011, 0.006	0.569
CE-Subjective assessment	Gp#TP#sex	-0.302	-0.360, 0.300	0.858
	Gp#TP#Age	-0.012	-0.030, 0.006	0.201
	Gp#TP#OC	0.011	-0.032, 0.053	0.622
Maximum bite force	Gp#TP#sex	-0.198	-0.472, 0.077	0.158
	Gp#TP#Age	0.000	-0.015, 0.015	0.964
	Gp#TP#OC	-0.001	-0.024, 0.023	0.949
OHIP-20	Gp#TP#sex	0.593	-0.611, 1.800	0.335
	Gp#TP#Age	-0.098	-0.016, -0.032	**0.003**
	Gp#TP#OC	0.078	-0.051, 0.206	0.236
Overall DSI	Gp#TP#sex	-1.300	-8.386, 5.786	0.719
	Gp#TP#Age	0.297	-0.091, 0.684	0.134
	Gp#TP#OC	-0.821	-1.519, -0.124	**0.021**

Abbreviations: CE, Chewing efficiency; OHIP, Oral health impact profile; DSI, Denture satisfaction index; CI, confidence interval; OC, occlusal contacts

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Table 7. Peri-implant marginal bone level changes at 1-year in the two trial groups

Group	Mean±SD	95%CI
Control	-0.205±0.640	-0.515, 0.105
Experimental	-0.137±0.671	-0.471, 0.197
P-value	0.754	

Abbreviations: SD, standard deviation; p-value, Student's t-test; significance, P<0.05

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Table 8. Differences in the occlusal contacts within and between the groups over the recall period.

Contact /Timepoint	Control group (mean±SD)	Experimental group (mean±SD)	[a]P-value
Incisor			
2–weeks	0.84±1.34	0.11±0.32	
1-year	2.00±1.56	0.32±0.58	
Total	1.42±1.55	0.21±0.47	**<0.001**
[b]P-value	**0.019**	0.174	
C-PM			
2–weeks	13.53±3.34	12.84±2.95	
1-year	14.42±3.34	13.95±3.05	
Total	13.97±3.33	13.39±3.01	0.429
P-value	0.414	0.263	
Molar			
2–weeks	11.68±4.79	14.68±4.03	
1-year	10.42±2.99	14.84±3.98	
Total	11.05±3.99	14.76±3.95	**<0.001**
[b]P-value	0.953	0.904	

Abbreviations: SD, standard deviation; [a]P, inter-group comparison; [b]P-intra-group comparison; significance, P<0.05 (ANOVA); C-PM, Canine-premolar

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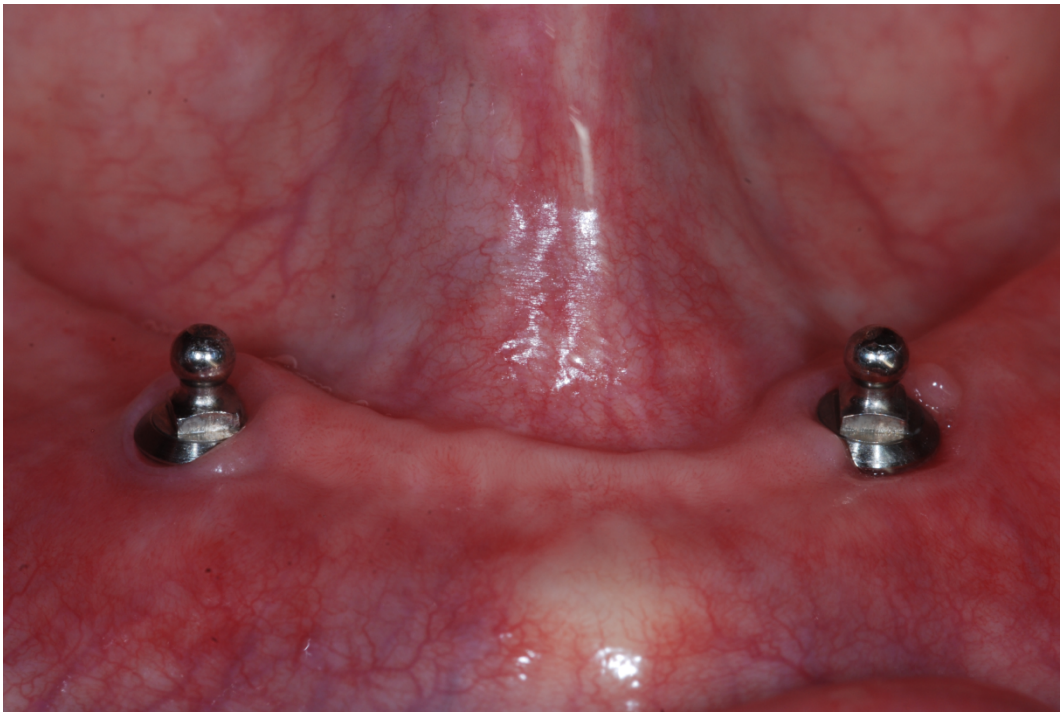

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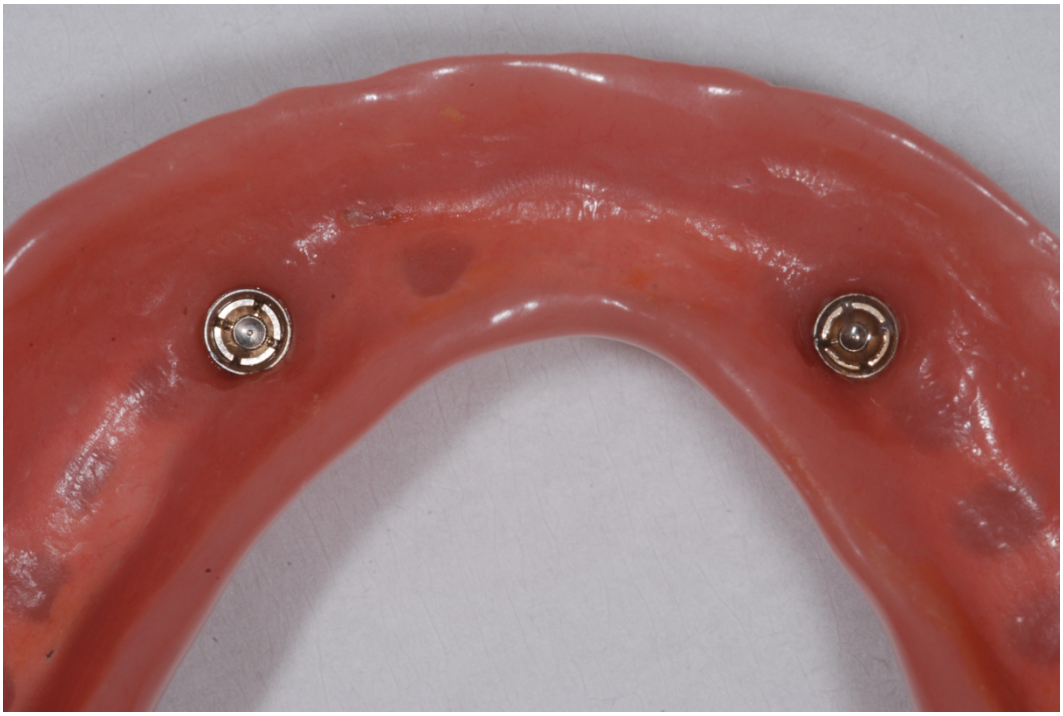

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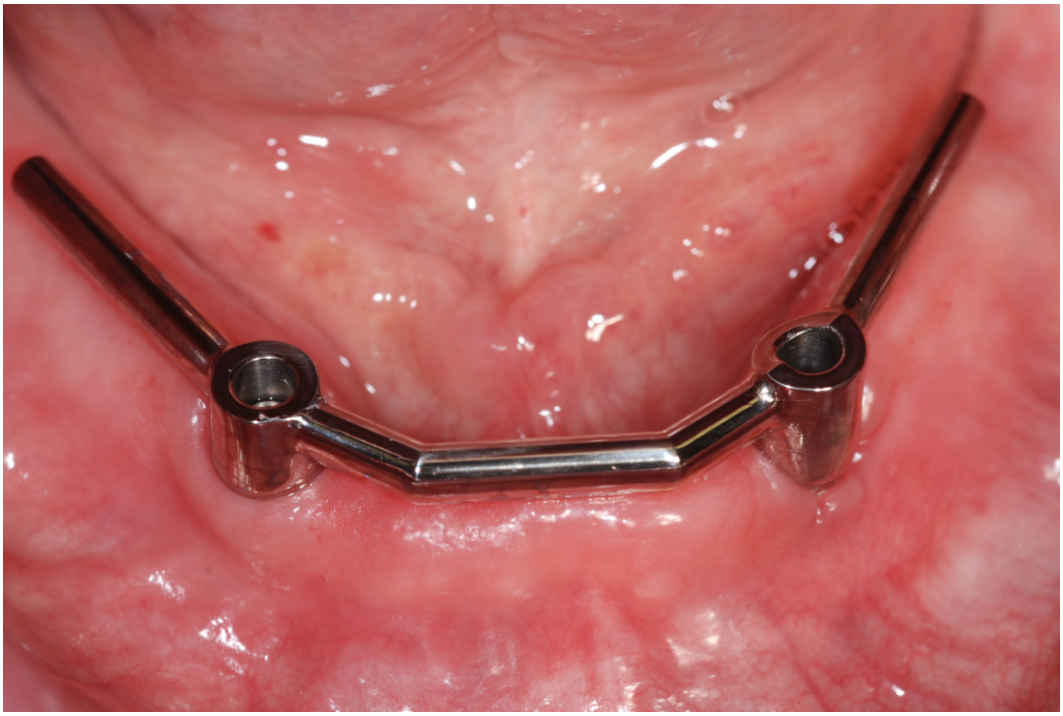

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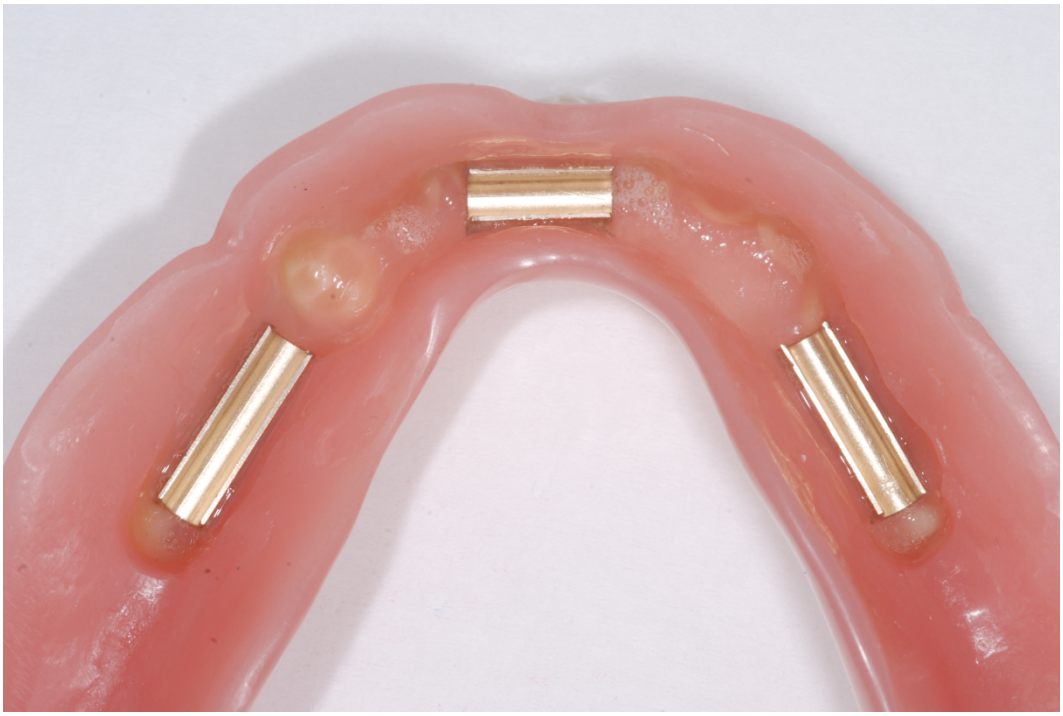

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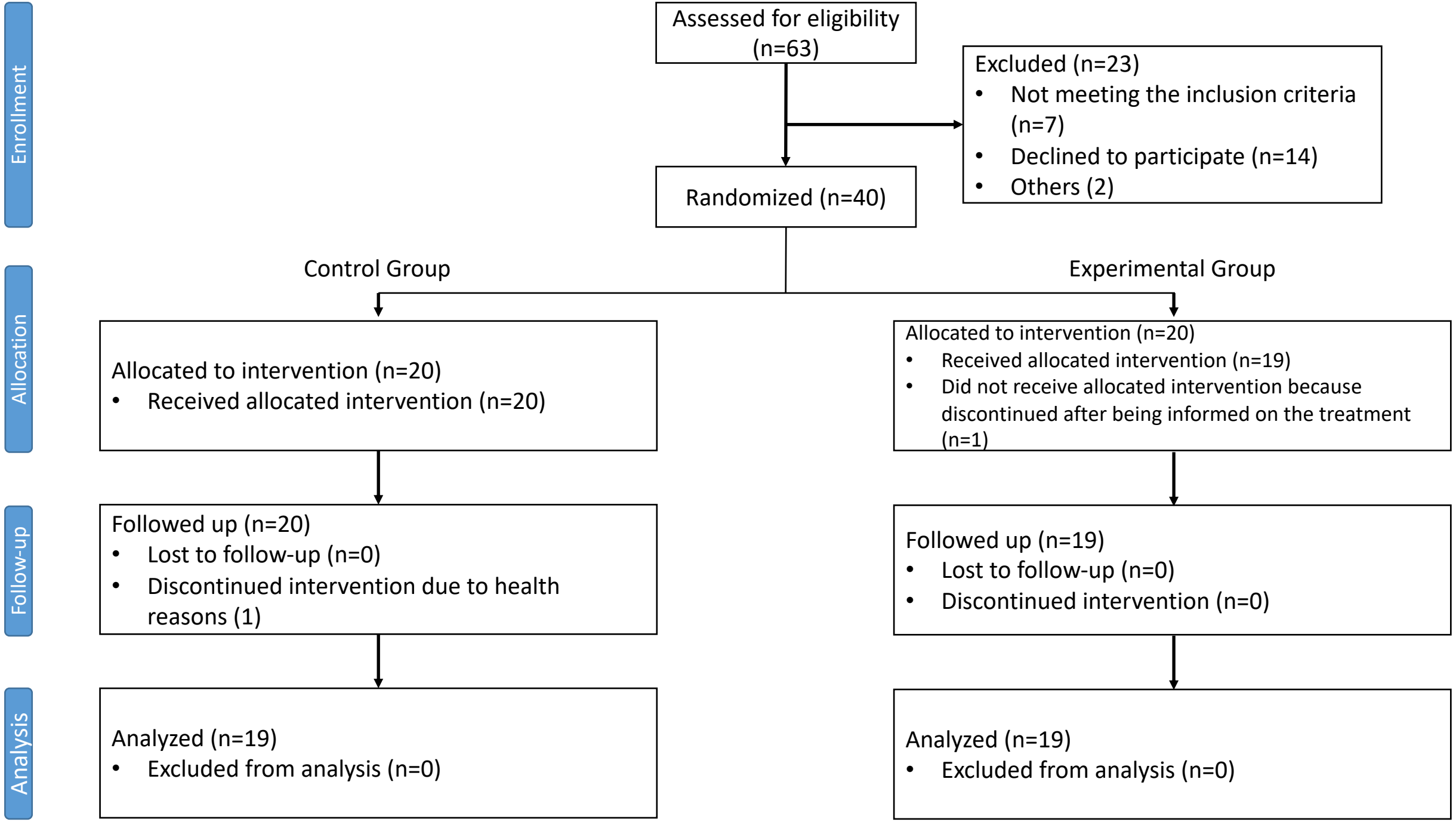
Enrollment
Allocation
Follow-up
Analysis
Assessed for eligibility (n=63)
Excluded (n=23)
• Not meeting the inclusion criteria (n=7)
• Declined to participate (n=14)
• Others (2)
Randomized (n=40)
Control Group
Experimental Group
Allocated to intervention (n=20)
• Received allocated intervention (n=20)
Allocated to intervention (n=20)
• Received allocated intervention (n=19)
• Did not receive allocated intervention because discontinued after being informed on the treatment (n=1)
Followed up (n=20)
• Lost to follow-up (n=0)
• Discontinued intervention due to health reasons (1)
Followed up (n=19)
• Lost to follow-up (n=0)
• Discontinued intervention (n=0)
Analyzed (n=19)
• Excluded from analysis (n=0)
Analyzed (n=19)
• Excluded from analysis (n=0)