# A Short-Term Clinical Trial on Selected Outcomes for Immediately Loaded Implant-Supported Mandibular Overdentures

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***Purpose:*** This clinical trial aimed to evaluate the outcomes of implant-supported mandibular overdentures (ISMOs) using 2 different loading protocols. ***Materials and Methods:*** Two groups of 10 edentulous patients each were selected for the study. Each patient received 2 implants placed in the mandibular canine sites. After 1 week, ISMOs were delivered to the 10 patients in the test group, while conventional mandibular dentures were delivered to the 10 patients in the control group. The conventional prostheses were converted to ISMOs after 3 months. Treatment outcomes for the ISMOs were evaluated 1 year after implant surgery. ***Results:*** The number of appointments and time needed for fabrication of ISMOs revealed statistically significant differences between the patient groups. The requirements for prosthodontic maintenance of ISMOs in the test group were higher than those in the control group; however, these differences were not statistically significant. The mean marginal bone resorption for each group was 0.3 mm after 1 year. ***Conclusion:*** The results of this clinical trial suggest that early loading of a specific length of implants used to support mandibular overdentures does not jeopardize treatment outcomes during the first year of service. *Int J Prosthodont 2006;19:515–519.*

There is clinical evidence that 2 dental implants can successfully retain a mandibular overdenture. Such prostheses require a minimal surgical intervention,[1] are substantially less expensive to fabricate,[2,3] are easier to clean,[4,5] readily accommodate esthetic and phonetic variables,[3] provide better support for facial muscles,[6] and offer higher patient satisfaction levels.[3,7,8]

A common method for retaining implant-supported mandibular overdentures (ISMOs) is a combination of adjustable metal clips attached to a bar connecting 2 or more implants.[9–11] Alternatively, individual ball abutments can be used with unsplinted implants.[12,13] Studies comparing splinted and unsplinted implants suggest that there are no differences in implant or prosthesis clinical performance.[14,15] Short-term clinical studies have also shown that early loading protocols for 2 unsplinted implants supporting mandibular overdentures appear to be successful.[16,17]

The number of adjustments and repairs required to maintain ISMOs have been shown to be substantial[18,19] and are usually required within the first year of service.[10,15,20,21] The prosthodontic problems encountered have been related to the materials used and considered technical in nature,[10] and reported difficulties include fracture of the retentive gold caps, acrylic resin, and denture teeth, as well as the need for frequent reactivation of the retentive elements.[22,23]

This study used individual ball abutments and an early loading approach in the evaluation of selected prosthodontic outcomes regarding adjustments and repairs of ISMOs 1 year after surgery.

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## Materials and Methods

Twenty edentulous patients (8 men, 12 women, mean age 62 years) were selected and examined clinically and radiographically by an oral surgeon and a prosthodontist, according to pre-established inclusion and exclusion criteria. Selected patients had to be edentulous with at least 1 year of maladaptive experience wearing conventional complete dentures, medically and psychologically suited for implant surgery, able to complete study forms, and available for the duration of the study. Patients were excluded if they had insufficient bone height for at least 2 15-mm dental implants, systemic or neurologic diseases, a history of head and neck radiation, or a need for additional preprosthetic surgery. Ethical approval was obtained from the Hacettepe University Ethics Committee, Ankara, Turkey.

### *Surgical Procedures*

The 20 selected patients provided informed consent. Following antimicrobial prophylaxis (2-g amoxicillin ), each patient received 2 15-mm implants (Brånemark, TiUnite RP MKIII, Nobel Biocare) placed bilaterally in the canine region of the mandible under local anesthesia (Ultracaine D-S, Hoechst Marion Roussel). An experienced oral surgeon placed all implants according to a strict surgical protocol for Brånemark System implants (Nobel Biocare). The patients were randomly assigned to 2 groups: a test group (group T), in which ball attachments (3 mm, 29020, Nobel Biocare) were screwed into the fixtures immediately after implant placement; and a control group (group C), in which healing abutments (5 mm, Nobel Biocare) were attached to the implants.

### *Prosthodontic Procedures*

**Test group (group T).** The fabrication of new complete maxillary dentures and ISMOs followed standardized techniques.[17,18] Five days after surgery, the sutures were removed and preliminary impressions were taken with a stock tray using alginate (Cavex, CA37). Secondary impressions were taken with a custom-made tray using Coltex Medium impression material (Coltex Medium, Coltene/Whaledent). The ball abutment replicas were placed into the impression material after the impression was removed from the mouth. Wax occlusal rims were created after the master models (Moldano type III, Bayer) were obtained 5 days after surgery. Teeth try-in (Major Dent), corrections, and fabrication of acrylic resin dentures (Meliodent, Heraeus Kulzer) were performed 6 days after surgery. The maxillary complete denture and ISMOs with respective gold caps (29025, Nobel Biocare) were delivered to the patients 1 week after surgery. All prostheses were made by the same dental technician.

**Control group (group C).** ISMOs were fabricated using the same procedures as for group T, and conventional dentures were delivered to patients 1 week after implant surgery. However, care was taken to ensure that the conventional mandibular denture did not contact the implants. Three months after surgery, the healing abutments were replaced with ball attachments (3 mm, Nobel Biocare) screwed to implants. A reline impression procedure (Coltex Medium, Coltene/Whaledent) was performed and the ISMOs were delivered the next day.

### *Statistical Analysis*

SPSS 11.0 software for Windows (SPSS) was used for all statistical analysis. A 2-tailed *t* test was used for comparison of treatment groups with respect to age, while a 2-sided chi-square test was used for comparison of the distribution of gender between the 2 groups. The Mann-Whitney *U* test was used for comparison of the prosthetic outcomes between the 2 groups, since the data did not meet the criteria of normality in distribution of variance. In all statistical tests, a significance level of .05 was chosen.

## Results

The number of apointments and amount of time regarding the fabrication, maintentance, adjustment, and repair of the ISMOs for each group were recorded. All patients were recalled 1, 3, 6, 9, and 12 months after implant surgery.

The mean ages of the patients in groups T and C were $62.4 \pm 8.6$ and $62.3 \pm 7.1$, respectively, and the difference between the 2 groups was not statistically significant ($P > .05$, 2-tailed *t* test). Comparison of treatment groups with respect to gender showed no significant difference (2-sided chi-square test, $P > .05$). The female patients ($n = 12$) outnumbered male patients ($n = 8$) by a ratio of 1.5 to 1. All implants in both groups were considered successful at the end of the 1-year follow-up period.

### *Appointments and Fabrication Time*

Regarding both the number of appointments and the amount of time required to fabricate and maintain the prostheses, comparisons were made based on whether the retaining implants of ISMO were early or conventionally loaded.

The average number of treatment appointments for diagnosis, implant surgery, and prosthesis fabrication for both groups are shown in Fig 1. The differences be-

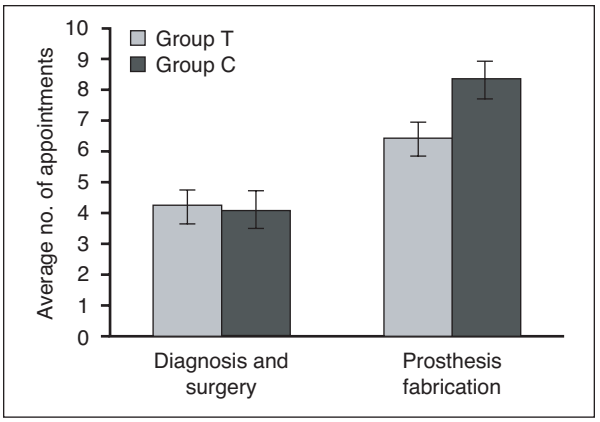


**Fig 1** Average number of appointments for diagnosis and implant surgery and for prosthesis fabrication. The difference between the groups was not statistically significant for diagnosis and implant surgery ($P > .05$); however, the difference was statistically significant regarding prosthesis fabrication ($P < .001$).

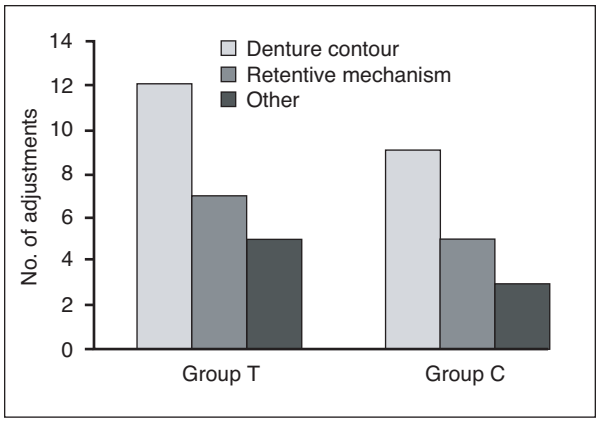


**Fig 2** Number and type of adjustments made to the ISMOs for each group.

tween the 2 groups regarding diagnosis and implant surgery were not statistically significant (Mann-Whitney *U* test, $P > .05$), whereas the time for fabrication of both the ISMOs and opposing maxillary complete dentures was statistically significant between the groups (Mann-Whitney *U* test, $P < .001$).

Regarding the overall amount of time, rather than the number of appointments, to fabricate the prostheses for groups T and C, the difference was statistically significant (Mann-Whitney *U* test, $P < .001$). Groups T and C needed an average of $5.3 \pm 0.5$ and $6.8 \pm 0.2$ hours, respectively. The chair time was measured in 15-minute increments, starting when the patient was seated and ending when the patient was dismissed.

### *Overdenture Adjustments*

An adjustment was defined as any treatment to the denture that did not involve the addition of new material or the replacement of broken or missing components or material. If such additions or replacements were required, they were defined as a repair.

Regarding the overall number of appointments needed for adjustments of ISMOs, 24 (12 = denture contour, 7 = retentive mechanism, 5 = other) and 17 (9 = denture contour, 5 = retentive mechanism, 3 = other) appointments were needed for groups T and C, respectively (Fig 2). The retentive mechanism adjustments included activation of the gold cap. Other types of postinsertion adjustments included occlusal adjustment and ball abutment tightening. Each patient required at least 1 adjustment. None of the causes for adjustment showed statistically significant difference between the 2 groups ($P > .05$, Mann-Whitney *U* test) (Fig 3).

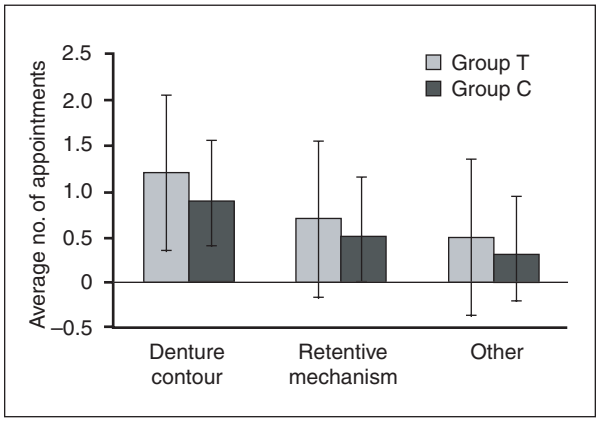


**Fig 3** Average number of appointments needed for ISMO contour, retentive mechanism, and other. None of these causes for adjustment showed statistically significant difference between the 2 groups ($P > .05$).

### *Overdenture Repairs*

The ISMOs of all patients required a limited number of repairs compared to the number of adjustments. Five patients in group T and 6 patients in group C did not need any ISMO repairs. However, the number of overall repairs performed to ISMOs of the patients was 6 in group T and 4 in group C. The patients of groups T and C required an average of 0.4 and 0.2 appointments for relining, respectively, and this was not statistically significant (Mann-Whitney *U* test, $P > .05$). Both groups required an average of 0.2 appointments for other repairs. Repairs classified as "other" included cracked or fractured dentures and loose or lost denture teeth.

## Discussion

More appointments and time were needed for fabrication of the ISMOs in group C. This is because the mandibular complete dentures in group C were relined and converted to ISMOs after 3 months of healing time, and thus 2 more appointments were needed than for patients in group T. The values regarding fabrication time and number of appointments for ISMOs were in agreement with previous studies.[15,23]

All patients were recalled 1, 3, 6, 9, and 12 months after implant surgery. The overall number of preestablished appointments for the entire patient population was 100. In total, 41 appointments (24 for group T; 17 for group C) were needed for all patients. All adjustments were performed easily in the chair.

The most common adjustment for all patients was denture contouring (n = 21) (Fig 3).[21,24] The number of appointments for denture contouring was higher for patients of group T. This may be explained by the early loading protocol used for this group, since gingival and bone healing after implant surgery may result in morphologic changes of both soft and bone tissue, thus altering the support of the denture.

The need for activation of gold caps was limited in this study, which is different from other studies.[15,20] The other studies in the literature have used plastic O-rings or titanium caps, which are different from the gold caps used in the present study.[25–27] The results of this study suggest that gold caps worked properly in 1-year of service.

Five patients in group T and 4 patients in group C needed repair of their ISMOs. The frequency of relining the ISMOs was lower than reported elsewhere.[15,28–30] Four patients, 2 for each group, required replacement of fractured or lost denture teeth.

The mean numbers of appointments and repairs needed for ISMOs in group T were slightly higher than those of group C, but the difference was not statistically significant. Further, only 1 patient in group T had problems with her ISMO (3 = denture contour, 2 = retentive mechanism, 2 = other), and thus her maintenance values increased the overall and average values of group T.

The standardized intraoral radiographs of the coronal parts of the implants were obtained using an impression coping attached to a plastic film holder at implant placement and 12 months postsurgery. The average marginal bone resorption for groups T and C were 0.3 ± 0.2 mm and 0.3 ± 0.1 mm, respectively. All implants were considered successful because they showed less than 1 mm of marginal bone resorption after 1 year.[31] The mean marginal bone resorption was slightly higher than the data from another study.[13] This difference might have resulted from the different type and length of implants used, as well as from different chewing forces.

The early and delayed loading protocols were applied with a specific 15-mm implant, which is traditionally employed for submerged healing. Nonetheless, taking into account the short observation period and small sample size, a 100% implant success rate with both early and delayed loading protocols using ball abutments was noted, and these results are in agreement with previously published work including a larger patient group and longer duration.[17]

## Conclusions

The 1-year results in this clinical trial indicate that early loading of mandibular overdentures retained by 2 unsplinted 15-mm implants does not appear to jeopardize short-term prosthodontic and radiographic outcomes.

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*Literature Abstract*

**The color of human gingiva and mucosa: Visual measurement and description of distribution**

The purpose of this clinical observational study was to assess the color of human, attached, papillary gingiva and oral mucosa in Caucasians by visual color matching using the Munsell color system. The study also attempted to describe factors that influence soft tissue color. A convenient sample of 150 subjects (48% males, 52% females) participated in this study. All color evaluations took place in a windowless and air-conditioned room that was illuminated by 2 daylight neon lights with a color temperature of 6,500, a color-rendering index of 97, and brightness values ranging from 1,000 to 1,600 lx. One examiner (screened negative for color blindness) performed all evaluations. A self-administered questionnaire was also used to collect information on age, gender, grades of skin color, fluoride intake, oral hygiene habits, presence and type of prosthetic restoration, and eating habits. Statistical evaluation was performed by using frequency tables and multiple regression. The maxillary attached gingiva lay between Munsell colors 7/6 2.5R and 8/4 10R. The maxillary interincisal papilla fell between 7/6 2.5R and 7/4 5R. The 5 most frequent Munsell colors for mucosa of the maxillary region were 6/6 2.5R, 7/6 2.5R, 6/8 5R, 5/8 7.5RP, and 5/6 10RP. The color patterns in the mandible were similar to those of the maxilla. The observed color trends appeared to be independent of one another. Few of the hypothesized confounding variables were significant in the regression models for the color of oral tissues of the maxilla. Unfortunately, the variances explained by these models were very small, with $R^2$ values no higher than 0.25.

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