Impact of New Complete Dentures on Oral Health–Related Quality of Life: A 12-Month Follow-up

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Purpose: To assess oral health–related quality of life (OHRQoL) in edentulous subjects before and after 3, 6, 9, and 12 months of oral rehabilitation with conventional complete dentures (CDs) and to compare their OHRQoL to dentate subjects. Materials and Methods: A total of 148 subjects were selected and divided into three groups: G1 = edentulous in maxillary arch (n = 68, mean age = 61.37 ± 8.91 years); G2 = completely edentulous (n = 50, mean age = 65.14 ± 8.91 years); and G3 = control group (dentate, n = 30, mean age = 60.03 ± 6.88 years). OHRQoL was assessed using the Brazilian version of the Oral Health Impact Profile-Edentulous (OHIP-EDENT) questionnaire at four different times: baseline (pretreatment) and 3, 6, 9, and 12 months after oral rehabilitation with a new CD. The data showed nonparametric distribution and were submitted to Kruskal-Wallis test (α = .05). Results: The impact of OHRQoL was higher for the edentulous groups compared to the control group at baseline (P < .05). Treatment significantly improved OHRQoL after 3 months of prosthesis use, and this effect was maintained during all 12 months of evaluation (P > .05). Conclusion: Oral rehabilitation with conventional CDs in one or both arches improved OHRQoL in edentulous patients after 3 months of prosthesis use, and its effect was maintained for up to 12 months. Int J Prosthodont 2022;35:287–293. doi: 10.11607/ijp.7645

Tooth loss impacts oral health–related quality of life (OHRQoL) in individuals due to its inevitable sequelae, impairment of esthetics, masticatory and nutritional deficiencies, and low self-esteem, which contribute to disability, impairment, and handicap. The most accessible treatment option for edentulous subjects is oral rehabilitation with conventional complete dentures (CDs). However, wearing CDs can affect quality of life and patient satisfaction, since this type of prosthesis can present limitations related to esthetics, support, retention, and stability. OHRQoL has been used to measure the impact of the loss of natural teeth and of the available treatment options, and there are many instruments used to evaluate it. However, several studies have used the Oral Health Impact Profile-Edentulous...
(OHIP-EDENT) in CD wearers. This instrument is specific for edentulous patients and is an appropriate tool for measuring edentulism problems.⁷

Studies have reported a significant reduction in the levels of dysfunction, discomfort, and disability associated with edentulism after 1 month of CD treatment.⁸ However, a few studies have reported no improvement in OHRQoL prior to 6 weeks.⁹,¹⁰ This fact can be explained by the fact that a period of at least 3 months is required to achieve neuromuscular adaptation to a CD.¹¹

Of the seven articles selected in a systematic review¹² that aimed to evaluate whether treatment with new CDs improves quality of life, only one¹³ evaluated the impact of new CDs on OHRQoL over a period of 12 months of follow-up, but did not use the appropriate instrument for the edentulous patient, and none of the studies used dentate elderly patients as a control group. Replacing unsatisfactory CDs with new ones has the strong potential to contribute to OHRQoL. However, based on the heterogeneity, risk of bias, and low certainty of the evidence that some studies presented, well-designed studies are necessary due to the importance that CDs still present in contemporary dentistry.¹⁴

Therefore, doubts still remain over the benefit of replacing old CDs the patient has already adapted to with new prostheses and whether this would be immediately noticeable or whether a longer follow-up time would be required; moreover, if the impact on OHRQoL over time or in comparison to dentate patients would be significant even after adaptation to these new prostheses. Based on these considerations, this clinical research aimed to assess the OHRQoL of edentulous subjects using OHIP-EDENT before and after oral rehabilitation with conventional CDs with evaluations at 3, 6, 9, and 12 months after placement and to compare their OHRQoL to dentate subjects.

**MATERIALS AND METHODS**

**Ethical Approval, Type of Study, and Sampling**

This longitudinal controlled clinical trial study was approved by the local Ethics Committee in Research of Nova Friburgo Dental School, Fluminense Federal University, Brazil (process number 880.827) prior to the start of the study. Written informed consent was obtained from all included patients. This study was submitted to the Brazilian Registry of Clinical Trials (UTN Number: U1111-1211-5013). The findings of this study were reported in accordance with the CONSORT (Consolidated Standards of Reporting Trials) guidelines.¹⁵

The sample size of the experimental group was calculated based on mean difference and SD before and after treatment based on a pilot study conducted by this research group, adopting α = .05 and β = 0.8. In order to compensate for patient loss during the study, a total of 10% was added to the sample. Thus, the sample reached a minimum of 30 participants per group.

A consecutive sample was taken from patients who sought CD treatment attending a public dental clinic in a dental school in Brazil over the course of 1 year (2016–2017). Patients were invited to participate and divided into groups G1 (edentulous maxilla and complete or partially dentate mandible) and G2 (both arches edentulous). The control group (G3) was composed of a consecutive sample of dentate elderly individuals obtained from a public clinic in the same city. The inclusion of G3 was in order to have a parameter group, as it is not possible to measure the OHRQoL of patients in need of new dentures when they had their natural teeth, it was decided to select a group that would represent them at that moment, and care was taken when selecting the control group to match the participants by age, sex, ethnicity, socioeconomic status, and education level. The purpose of G3 was to obtain information on how OHRQoL would be impacted when the participants had teeth compared to when they lost their teeth (before treatment) and to compare how much this quality of life could be improved over time after rehabilitation.

To be included, subjects needed to address the following criteria: aged over 50 years, and adequate cognitive ability and understanding to be able to respond to the questionnaire. In addition, for inclusion in G1, subjects had to have presented with an edentulous maxilla for a minimum of 5 years, with the mandible fully dentate or partially dentate when wearing a removable partial denture. For G2, subjects had to be fully edentulous in both arches for a minimum of 5 years. Participants in both G1 and G2 had to present adequately healthy tissue to support removable prostheses. The control group (G3) included fully dentate subjects or subjects with only the molars missing. Patients were excluded if they presented severe periodontal disease or motor or cognitive impairments.

**Data Collection**

**Clinical data**

The rehabilitation of patients with conventional CDs was performed by undergraduate students (n = 5) with the same level of experience under supervision of a specialist in prosthodontics (A.M.C.M.). New dentures were fabricated according to the following clinical sequence: primary and secondary impressions; recording of the arch relationships; and trial insertion and fitting of the dentures. After denture insertion, post-denture insertion instructions were explained to the patients. After initial placement, the patients were reviewed, and adjustments of the CDs were made as needed.

**Nonclinical data**

Participants were asked about their sociodemographic characteristics, including their age, gender, ethnicity,
years of education, and socioeconomic data, determined by classification according to the Brazilian class system. The Brazilian class system is divided into five letters (A, B, C, D, and E) and sometimes divided further (ie, B1, B2, C1, and C2). The criteria for placing someone in a class involves a point system. Higher levels of education and higher salaries give more points, as well as having things like piped water and paved streets; generally, class A indicates upper class, class B indicates upper middle class, class C indicates middle class, and classes D and E indicate lower class. Care was taken to match these characteristics among groups.

The Brazilian version of the OHIP-EDENT questionnaire was used to assess OHRQoL. The questionnaire consists of 19 questions divided into 7 domains: functional limitation; psychologic disability; physical pain; psychologic discomfort; physical disability; social disability; and handicap. The questionnaire was applied by the same trained researcher in interview form (C.S.F.S.). Responses were made on a three-grade Likert-type scale where 0 = never; 1 = sometimes; 2 = almost always; and 3 = always. The higher the value obtained on the questionnaire, the higher the impact on OHRQoL. OHRQoL assessment was conducted before treatment (baseline) and at 3, 6, 9, and 12 months after treatment.

### Statistical Analysis

Shapiro-Wilk test revealed nonparametric distribution of data. Chi-square, Mann-Whitney U, and Kruskal-Wallis tests were performed for comparing groups according to sociodemographic data. Kruskal-Wallis test was performed for comparing groups and treatment throughout time. A significance level of 5% was adopted, and all analyses were performed on Statistical Analysis System (SAS) version 9.3 software.

### RESULTS

Participant enrollment is described in Fig 1. Table 1 shows demographic characteristics of the study sample, including gender, ethnicity, socioeconomic situation, age, education level, and time spent using removable prostheses. The frequency was similar among groups.

Results on OHIP-EDENT comparing groups and the different times of evaluation are presented in Table 2. The impact of OHRQoL was higher for the edentulous groups (G1 and G2) compared to the control group (G3) at baseline \((P < .05)\). The treatment significantly improved OHRQoL after 3 months of prosthesis use, and this effect was maintained during all 12 months of the evaluation \((P > .05)\). The treatment of the edentulous group (G2) compared to the control group (G3) presented a
Clinical Research

The International Journal of Prosthodontics

Enrollment

Longitudinal controlled clinical trial
(n = 152)

Edentulous patients
(n = 122)

Dentate patients
(n = 30)

Excluded (n = 4)
- Motor disabilities (n = 1)
- Cognitive impairment (n = 1)
- Low high ridge bone (n = 2)

Included patients
(n = 118)

G1: maxillary CD
(n = 68)

G2: full-mouth CD
(n = 50)

Dropouts (n = 28)
- Withdrawn (n = 14)
- Died (n = 2)
- Lost contact (n = 2)
- Discontinued intervention (n = 10)

Dropouts (n = 6)
- Withdrawn (n = 3)
- Died (n = 1)
- Lost contact (n = 2)

Dropouts (n = 6)
- Withdrawn = 3
- Lost contact = 3

Dropouts (n = 4)
- Withdrawn = 2
- Lost contact = 2

Dropouts (n = 12)
- Withdrawn = 6
- Discontinued intervention n = 6

Analyzed (n = 92)
- Motor disabilities (n = 1)
- Cognitive impairment (n = 1)
- Low high ridge bone (n = 2)

Fig 1 CONSORT flow diagram representing the study design.
and 3, 6, 9, and 12 months after treatment with new OHRQoL, and patient satisfaction before and after placement of the new prostheses, this impact was maintained for up to 12 months. The null hypothesis was also rejected considering the comparison to dentate subjects, as the impact on OHRQoL was higher when the patient needed a new prosthesis. However, after placement of the new prostheses, this impact was reduced, and the edentulous groups presented better averages than the dentate group. This indicates the important improvement of OHRQoL in these patients.

CD treatment for edentulous arches is still a reality for many patients and can affect quality of life. Although it presents limitations, this type of therapeutic option meets clinical expectations quite significantly when favorable conditions are present. It is not always possible to choose implant therapy, since general health conditions may contraindicate or contribute to treatment failure, and the higher cost may present as a limitation.

The impact of complete tooth loss and the available treatment options on OHRQoL can be evaluated with many instruments; however, the OHIP-EDENT is a specific instrument for edentulous patients and is an important tool that is able to measure different levels of health problems as well. Therefore, due to its specificity and good psychometric properties, this instrument was chosen to be used in this study as a way to obtain data for the evaluation of the impact of tooth loss and the use of proper CDs on OHRQoL.

The use of OHIP-EDENT for comparison before and after new CDs has been used in the literature. The option to evaluate the use of a new CD in the long term starting at 3 months was based on a previous study emphasizing that neuromuscular adaptation occurred after 3 months of use of a new CD; thus, early evaluation of the use of a new CD before 3 months may compromise the outcome. In a recent systematic review and meta-analysis, 3 months of evaluation was also used as a parameter.

The present study aimed to evaluate the OHRQoL of edentulous patients in one or both arches over time and to compare it to a control group. Attention was given to match the research volunteers by socioeconomic condition, as well as age and education level. These data from the sample are in agreement with other studies that evaluated OHRQoL as well, since variation in these conditions could interfere with the results of this instrument, creating a significant bias.

It is possible to notice that, at baseline, there was a significant difference between all groups, with a significant OHRQoL impairment in completely edentulous subjects (G2), followed by partially edentulous (G1) subjects, followed by a small effect in the control group (G3). However, after 3 months of wearing CDs, this difference decreased significantly and continued decreasing during the 12-month follow-up. A numerical analysis alone can infer that, over time, G1 and G2 presented better OHRQoL than controls. However, despite the statistically significant difference between G1, G2, and G3, all groups presented with a low impact on OHRQoL at the end of 12 months. This may be due to the fact that patients in G1 and G2 compared the treatment outcome to their initial situation, when there was great dissatisfaction with various conditions, such as masticatory inefficiency, poor esthetics, low self-esteem, and nutritional deficiencies, among others.

In order to obtain results closer to the real condition of these patients, it would have been necessary to compare them at three different times: when they still had their natural teeth, when they became users of a CD, and after the period of follow-up. In addition, the fact that they received treatment may also influence the responses of patients in G1 and G2, which gives greater weight to the results obtained.

### DISCUSSION

The null hypothesis was that there would be no difference between OHRQoL and patient satisfaction before and 3, 6, 9, and 12 months after treatment with new dentures or compared to dentate subjects. This hypothesis was rejected. Oral rehabilitation with conventional CDs improved the OHRQoL of edentulous patients in one or both arches after 3 months of prosthesis use, and its effect was maintained for up to 12 months. The null hypothesis was also rejected considering the comparison to dentate subjects, as the impact on OHRQoL was higher when the patient needed a new prosthesis. However, after placement of the new prostheses, this impact was reduced, and the edentulous groups presented better averages than the dentate group. This indicates the important improvement of OHRQoL in these patients.

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<table>
<thead>
<tr>
<th>Table 2 Mean ± SD OHIP-EDENT Scores for Each Group</th>
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<tbody>
<tr>
<td>Partially edentulous</td>
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<tr>
<td>Baseline 28.83 ± 19.49 A, b</td>
</tr>
<tr>
<td>3 mo 0.48 ± 1.85 A, b</td>
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<tr>
<td>6 mo 0.29 ± 1.57 A, b</td>
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<tr>
<td>9 mo 0.14 ± 14.02 A, b</td>
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<tr>
<td>12 mo 0.14 ± 0.64 A, b</td>
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Kruskal-Wallis test. Different uppercase superscript letters indicate a significant difference between groups, and lowercase superscript letters indicate significant differences between time periods within groups (P < .05).
G1 presented better OHRQoL results than G2. The patients presented more difficult adaptation to CDs in both arches than to one CD opposed to natural teeth; however, this difference decreased over the follow-up period as neuromuscular adaptation of the new prostheses occurred. It is also important to emphasize that the greater the number of teeth, the greater the impact on OHRQoL. The lack of all teeth contributes to disability, impairment, and handicap. Edentulous individuals frequently report more chewing difficulties than dentate individuals and therefore constitute the group most likely to change their diet. Therefore, fully edentulous patients present a lower quality of life when compared to partially edentulous patients.

The results obtained for the dentate group should also consider that the patients in this group may not have the same complaints as the edentulous patients, but also often do not present with an ideal oral condition. Esthetic dissatisfaction, presence of noncarious cervical lesions, unsatisfactory restorative treatments, and gingival inflammation due to the presence of biofilm, among other factors, may interfere negatively in OHRQoL. However, when compared to the edentulous ones, these complaints become clinically insignificant, since these conditions are less critical than edentulism.

The results obtained in this study are in accordance with some studies that also reported a decrease in the impact on OHRQoL in edentulous patients due to CD treatment using OHIP-EDENT, although the follow-up periods were different. Only a few studies used this specific instrument; however, none of them realized a follow-up of 12 months.

The lack of previous research with longer follow-up has been previously detected in the literature, which supports the importance of the present study. Therefore, it is reasonable to infer that the present results represent important data that should be discussed in future studies, since this property represents a tool of significant importance for validation of the results obtained in addition to making it possible to compare these data to studies that make scientific evidence more consistent and reliable.

Generalizing these results, this is the first study using an appropriate instrument to detect changes in OHRQoL over a period of 12 months of follow-up. These changes in OHRQoL were detected by the OHIP-EDENT instrument after 3 months of prosthetic use and showed that the effect of new CDs is maintained for up to 12 months. This finding could potentially help clinicians understand the magnitude of benefits associated with the treatment of edentulous arches with CDs. So, these results can be developed further to help evaluate other studies with a pre-post design analyzing the impact of CD treatment in other populations and to help support political actions and research in public health areas.

CONCLUSIONS
Oral rehabilitation with conventional CDs in one or both arches improves OHRQoL of edentulous patients after 3 months of prosthesis use, and this effect is maintained for up to 12 months.

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The author contributions were as follows:

REFERENCES
Management and Sequelae of Dental Implant Removal

Inappropriate and unnecessary implant therapy driven by an erroneous belief that dental implants provide enhanced function and esthetics over diseased or failing teeth has led to a growing burden of implant complications across the globe. Specifically, esthetic and biologic complications frequently lead to an unfavorable prognosis for dental implants. Often, these complications cannot be managed predictably to improve the condition or satisfy patient demands. In such circumstances, implant removal needs to be considered. Currently, minimally invasive methods based on reverse torque engineering are key to preserve peri-implant soft and hard tissues. Implant replacement is now feasible, as evidenced by the high survival rates of implants placed at previously failed sites. Notwithstanding these data, clinicians should still carefully consider the expendability of an implant and whether its replacement will satisfy the prosthetic, biomechanical, and esthetic demands of the patient. Where future implant placement is desired, protocols undertaken for soft/hard tissue grafting and implant placement should be based on defect morphology and soft and hard tissue characteristics. Currently, however, a lack of knowledge of the biologic events and dimensional changes that arise following implant removal renders decision-making complex and challenging, and recommendations remain largely based on empirical speculation. This article will review the indications for implant replacement for prosthetic, biomechanical, and esthetic complications alongside considerations in decision-making, planning, implementation, and outcomes of implant replacement.

Monje A, Nart J. Periodontol 2000 2022;88:182-200. References: 78. Reprints: Alberto Monje, amonjec@umich.edu — Steven Sadowsky, USA