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Long-term changes in oral health-related quality of life over a period of 5 years in patients treated with narrow diameter implants: A prospective clinical study

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ABSTRACT

Objectives: The aim of this study was to assess long-term changes in oral health-related quality of life (OHRQoL) over a period of 5 years in patients treated with narrow diameter implants (NDI) in the mandible for support of an overdenture.

Methods: In this prospective clinical study, a consecutive sample of 20 edentulous patients who had worn sufficient complete dentures for at least 12 weeks was provided with four immediately loaded one-piece titanium NDIs in the mandible. The German 49-item version of the Oral Health Impact Profile (OHIP) was applied to assess OHRQoL at baseline and all follow-ups (4 and 8 weeks, 3, 6, and 12 months, and 3 and 5 years after treatment was finished).

Results: Before treatment, OHRQoL was substantially impaired indicated by high OHIP summary score (39.9 points). Four weeks after treatment, a substantial treatment-induced drop of OHRQoL impairment was observed (21.8 OHIP points), and at all follow-ups, OHIP scores were lower than at baseline (15.9–26.5 OHIP points; ANOVA: $p < .001$). Based on mixed-effect linear regression analyses, the treatment-induced effect on OHRQoL improvement over the entire study period was statistically significant for the OHIP summary scores as well as for all four OHIP domains: Oral Function, Orofacial Pain, Orofacial Appearance, and Psychosocial Impact (all: $p < .001$).

Conclusions: This study suggests that four immediately loaded NDIs for the support of conventional complete dentures in edentulous patients with substantially impaired OHRQoL may lead to a long-lasting treatment-induced improvement in OHRQoL.

Clinical significance: The provision of four NDI in the edentulous mandible is a promising treatment option for patients with substantial OHRQoL impairment and a positive attitude towards implant treatment. Furthermore, patients can be informed that improvements in OHRQoL are expected to last for at least 5 years.

1. Introduction

The loss of own teeth is an event most people world-wide are confronted with during lifetime. Even though considerable success has been achieved with oral prevention strategies, caries and periodontitis are still highly prevalent and can finally lead to the loss of teeth [1]. However, during the last decades there was a shift in the incidence of tooth loss, *i.e.*, people keep their own teeth longer and tooth loss occurs later in life [2]. Accordingly, the prevalence of edentulism in specific age groups declined also in the past and is expected to decline further in the future. But at the same time, life expectancy has increased and will increase further. Therefore, it is not unexpected that, overall, the proportion of edentulous in persons aged 65 years or more is still high with values up to 78% [1]. Consequences of tooth loss and especially

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edentulism can be substantial for the individual. Chewing efficiency decreases and can lead to changes in diet, characterized by modified food choices and a shift to more unfavorable nutrition intake [3–5]. Furthermore, tooth loss has an impact on oral health-related quality of life (OHRQoL) with more teeth missing is related to higher OHRQoL impairment [6]. Generally speaking, lowest OHRQoL is observed in edentulous subjects [7]. Accordingly, edentulism is still a highly relevant entity and an important public-health problem.

Treatment options for edentulism usually involve conventional complete dentures (CD). And indeed, this option works very well for many patients in long-term improving their OHRQoL [8]. However, even after treatment with conventional CD, OHRQoL is still substantially lower than in patients with own teeth. This suggests that conventional CD might not completely solve the patients' problems but instead may also cause some additional discomfort and the sensation of a foreign body. Furthermore, conventional CD do not provide the tactile sensitivity of teeth and usually fail in sufficiently restoring a compromised chewing function [9,10]. This is especially true in patients with unfavourable conditions of soft and hard tissues such as increase atrophy of the alveolar bone [11], and in patients with higher needs with respect to denture stability. For these cases, implant support for the CD is a promising approach [12]. Options start with only one single implant in the mandibular midline to four or more implants. Considering the increasing age of patients being edentulous and requesting implant treatment for the support of CD, and comorbidities, medications, and age-related reduced general health status, these patients require interventions of low invasiveness and low burden. This substantially reduces the treatment options. A single dental implant in the mandibular midline seems to be the least burdensome treatment but has several disadvantages. One is the limited survival rate, another the high rate of aftercare needs [13]. That is, maintenance of the implant-supported CD will result in substantial burdens for the patients. Furthermore, long-term effects on patient-reported outcomes are missing [14–16]. Another promising approach is the use of narrow dental implants (NDIs) with diameters less than 3 mm. This approach allows placing implants in the alveolar bone in many cases with marked horizontal ridge atrophy without the need for augmentation procedures and without raising a flap. According to the recommendation of the ITI Consensus Statement [17], four of these one-piece implants should be placed in the interforaminal region.

The treatment with NDIs demonstrated not only satisfactory survival rates [18], but also substantial benefits for the patients in terms of improvements in their OHRQoL [19–21]. Two NDIs in the edentulous jaw were more effective in increasing OHRQoL when measured with the OHIP-EDENT [22], a 19-item short version of the Oral Health Impact Profile (OHIP) [23], than no implant support over a period of one year [19]. Improvement of OHRQoL when measured with the 49-version of the OHIP [23] has been shown one year after treatment [20], and two years after treatment when assessed with the Geriatric Oral Health Assessment Index (GOHAI) [21]. However, evidence of long-term effect of treatment with NDIs in edentulous patients on OHRQoL is still missing.

The aim of this study was to assess long-term changes in OHRQOL over a period of 5 years in patients treated with NDIs in the mandible for the support of an overdenture.

2. Methods

2.1. Subjects, study design and setting

In this prospective clinical study, a sample of 20 patients was consecutively recruited at the Department of Prosthodontics, School of Dentistry, University of Bern, Switzerland, between November 2010 and March 2012. For inclusion, patients had to be edentulous for at least 6 months and had worn sufficient complete dentures for at least 12 weeks, with both premolars and the first molar replaced and mounted according to the Gerber concept with a bilateral balanced lingualized occlusion. Furthermore, interforaminal bone was expected to have a minimum width of 4–5 mm and a minimum height of approximately 13 mm. Participants had to be living independently and to be in good general health (ASA classification grades 1 and 2) [24]. Potential participants were excluded in case of using bone altering medications, dental anxiety, or drug abuse. For more information see Enkling et al. [20].

This research was conducted in accordance with accepted ethical standards for research practice as described in the Declaration of Helsinki in its current version [25]. Study protocol underwent review and approval by the Institutional Review Board at University of Bern (Bern Cantonal Ethics Committee, CEC; No 26/10). Written informed consent was obtained from all participants prior to their enrolment.

2.2. Treatment characteristics

After crestal incision and preparation of a full-thickness flap, four one-piece titanium NDIs (diameter 1.8 mm, length 13 or 15 mm, MDI® system 3 M ESPE, distributed by condent gmbH, Hannover, Germany since 2016) were placed in the mandible (regions FDI 34, 32, 42, and 44) of each participant according to a standardized surgical protocol with an insertion torque ranging from 35 N cm to 45 N cm. The interface between rough implant surface and polished implant neck was placed epicrestally, and the interimplant distance was approximately 15 mm. The chirurgical part of the treatment was finished by suturing the flap. This was immediately followed by the prosthodontic part of the treatment with relieving the area of the implants in the preexisting prosthesis. The MH 2 matrices (3 M ESPE) were incorporated indirectly using a resin (PalaXpress Ultra, Heraeus-Kulzer, Hanau, Germany) after taking a reline impression with Impregum® (3M ESPE). Patients received the converted prostheses within 4 h.

Insertion torque of single implants was below 35 N cm in three patients. Implants in these patients were not loaded immediately but after 3 months of healing. The dentures were relined during healing time with a soft silicon (GC Reline™ soft, GC Corporation, Tokyo, Japan). All clinical procedures and examination were performed by a single operator (AvS). For more information on treatment characteristics see Enkling et al. [20].

2.3. Assessment of OHRQoL

The full-length Oral Health Impact Profile [23] with 49 items in its German version [26] (OHIP-G49) was applied to assess OHRQoL at baseline and all follow-ups (4 and 8 weeks, 3, 6, and 12 months, and 3 and 5 years after treatment was finished). For each OHIP-G49 item, participants were asked how frequently they had experienced the impact on their OHRQoL during the last month, with possible responses on a five-point ordinal rating scale (0—never, 1—hardly ever, 2—occasionally, 3— fairly often, and 4—very often). OHRQoL impairment was operationalized as the OHIP-G49 summary score – the simple sum of all 49 item frequencies, with potential summary scores ranging from 0 to 196 points. Higher scores indicate more problems, and hence lower OHRQoL. For the purpose of clarity, the OHIP-G49 summary score will simply be referred to as 'OHIP score'. Additionally, we computed summary scores for the four OHIP subscales named *Oral Function* (10 items), *Orofacial Pain* (7 items), *Orofacial Appearance* (6 items) and *Psychosocial Impact* (18 items) representing the four domains of OHRQoL that were recently determined and validated in a large international study [27–29].

Internal consistency as a measure of reliability was determined using Cronbach's alpha [30] and average inter-item correlation of all 49 items of the OHIP. According to commonly applied guidelines, the resulting alpha of 0.96 and the average inter-item correlation of 0.33 indicate satisfactory internal consistency and unidimensionality [31,32].

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