Stabilizing mandibular complete dentures by a single midline implant - influence on quality of life:2-year results from a randomized clinical trial comparing different loading protocols

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Original article

Stabilizing mandibular complete dentures by a single midline implant - influence on quality of life: 2-year results from a randomized clinical trial comparing different loading protocols

Abstract

Objectives: The knowledge about the influence of dental treatment on health-related quality of life (HRQoL) is still limited. The aim of this multicenter randomized controlled clinical trial was to assess the effect of stabilizing an existing complete denture, by means of a single mandibular implant, on HRQoL. Furthermore, the impact of the loading protocol, i.e. immediate or delayed loading, in edentulous patients was evaluated.

Methods: 158 participants aged 60 – 89 years, were randomly assigned to study Group A (immediate loading; n=81) and to Group B (delayed loading; n=78). All participants received a single midline implant in the mandible. The implants were either immediately loaded (Group A) or after a closed healing period of 3 months (Group B) by connecting the existing mandibular complete dentures to ball attachments. HRQoL was assessed with the Short Form-36 questionnaire of health (SF-36) at baseline, 4 months, and 24 months after implant loading.

Results: Improvement of HRQoL by means of a single-implant retained mandibular overdenture could not be demonstrated after 4 and 24 months of implant loading. Furthermore, the application of two different loading protocols did not influence HRQoL ratings of study participants.

Conclusion: The loading protocol is not a factor, influencing HRQoL in patients treated by a single midline implant in the edentulous mandible.

Clinical Relevance: A single midline implant in the edentulous mandible, stabilizing a mandibular complete denture cannot be recommended for improving HRQoL.

1. Introduction

The demographic change is accompanied by an increase in elderly persons in dental routine business. In 2014, 32.8% of the German population between 75 and 100 years was completely edentulous [1]. In the US, the prevalence of edentulism in the same age group was 24.1% in 2012, which means that about one-quarter of the people older than 75 years were edentulous [2]. Loss of teeth leading to edentulism can result in negative consequences like changes in bone quantity and denture stability, reduction of chewing efficiency and, subsequently an increased risk of malnutrition [3,4]. Both, loss of teeth and edentulism can be associated with a reduced oral-health-related quality of life (OHRQoL), which is one part of quality of life (HRQoL), that is influenced by oral health aspects [5,6]

Patient-reported outcomes (PROs) such as HRQoL or OHRQoL are among the most frequently used subjective assessments in clinical investigations. Patient-reported outcome measures (PROMs) are instruments, as for example questionnaires, to measure those PROs [7]. Generally, PROs can help to improve patient-clinician communication, clinical outcomes, and patient satisfaction [8]. Compared to earlier studies, the use of PROs in general medicine has emerged during the last decade, leading to a paradigm shift to “patient-centered care” [9]. This trend can also be observed in dental medicine [10,11]. Taking into account that besides improving patients health status, satisfying patients is one of the major goals in every medical discipline, this evolution seems logical [12]. At best, successful dental treatment does not only improve oral-, but also general health.

Oral rehabilitation of edentulous patients seems to be essential and shows a significant improvement in OHRQoL [13]. Especially the use of implant therapy shows better outcomes in OHRQoL[14–16]. Generally, two implant supported overdentures are recommended in the edentulous mandible, as achieving a sufficient retention with conventional full dentures is nearly impossible, especially when the mandible is severely resorbed [17,18]. Implant placement, and the use of implant-borne, respectively implant-retained dentures, results in an

increased stability and consequently in higher patient satisfaction [19]. This increased patient satisfaction is accompanied by an increased HRQoL [20,21]. Nevertheless, there are reasons, for example a severe bone resorption or financial limitations, which the application of the recommended two-implant protocol impossible. Two randomized clinical trials (RCTs) comparing overdentures, supported by one or two implants, showed no differences between those two concepts, regarding patient satisfaction [22,23].

The influence of the one-implant concept on HRQoL remains unclear. Therefore, the aim of the present study was to assess the effect of stabilizing an existing mandibular complete denture, by means of a single implant, on HRQoL and to determine the impact of the loading protocol, i.e. immediate or delayed loading.

2. Material and Methods

2.1 Study design and setting

This multi-center randomized controlled clinical trial (RCT) was conducted at nine prosthodontic departments of university-based dental clinics in Germany. It conforms to the CONSORT statement [24,25]. The study protocol was reviewed and approved by the Ethics Committee of the University Hospital Schleswig-Holstein (processing number: AZ 138/12) as well as the appropriate Ethics Committees of all other participating centers. All participants gave their informed written consent. The study was registered in the DRKS (German Clinical Trial Register; DRKS-ID: DRKS00003730).

2.2 .Eligibility criteria

Criteria for inclusion and exclusion, as given in a previous publication of the same group, were as follows [25]:

2.2.1 Inclusion criteria:

- Edentulous males and females between the ages of 60 and 89.
- No contraindication for implant placement

- Sufficient bone in the anterior mandible to allow successful implant placement without augmentation procedures
- A residual bone height of 11 to 20 mm at the least vertical height of the mandible (Class II and III) [26] and vertical bone height in the midline of the mandible of at least 13 mm
- Technically acceptable complete dentures in the mandible and the maxilla
- Dissatisfaction with the stability/retention of the existing mandibular complete denture, while the stability/retention of the existing maxillary denture was rated well by the participants
- Wearing of the existing dentures for at least 3 months
- A bilaterally balanced occlusal scheme

2.2.2 Exclusion criteria:

- Contraindication for implant placement in the mandible caused by systematic diseases or local bone deficits
- Denture height between base and denture tooth central anterior less than 6 mm
- Signs for depression according to Symptom Checklist-90 (SCL-90): T-scores of 70 or greater, or with two symptom scale scores of 70 or greater[27]
- Signs for incompliant subjects, who might not participate decent according to the test schedule

2.3 Description of study sample

Of the 224 initially screened subjects, 169 subjects were included in the study. Of those 169 participants, six were excluded prior to implant placement due to insufficient bone volume, four participants were excluded due to insufficient primary stability of the implants, and one participant was excluded during randomization, resulting in a final number of 158 subjects available for analyses. 81 participants (33 females; 48 males) were randomly assigned to Group A (immediate loading), and 77 participants (34 females; 43 males) were assigned to Group B (delayed loading). The mean age of participants in Group A was 70.4 years (range: 60–84) and in Group B 69.2 years (range: 60–86) (Table 1).

After 4 months of observation, SF-36 questionnaire data of 146 participants were obtained. Of those 146 participants, 74 belonged to Group A and 72 belonged to Group B. Twelve participants were lost during follow-up between baseline and the 4-month follow-up visit and were therefore excluded from further statistical analyses. Reasons for lost to follow-up are given in figure 1 (Fig. 1). During this time period, nine implants of Group A and one implant of Group B failed.

After 24 months of observation, the SF-36 questionnaire data of 131 participants were obtained. Of those 131 participants, 65 belonged to Group A and 66 belonged to Group B. 15 participants were lost during follow-up and were therefore excluded from further statistical analyses. Reasons for loss to follow-up of those participants are given in Fig.1, too. During this time period, no further implant failures, neither in the immediate loading nor in the conventional loading group, were recorded. For descriptive analyses, all available data were evaluated. For the calculation of relative changes, only data from participants who completed questionnaires at baseline and 4 months, respectively at baseline and 24 months, were statistically analyzed.

2.4 Clinical procedures

The participants received a single midline implant in the mandible (Camlog ScrewLine; Promote Plus, Camlog Biotechnologies, Basel, Switzerland, lengths 11mm, diameter 3.8mm). The existing denture bases were reconstructed with corresponding matrices (Dalbo-Plus Elliptic, Cendres+Métaux, Biel, Switzerland) to the ball anchors, which were placed on the implant as one part of the suprastructure. Implants in Group A were immediately loaded after placement. Participants in Group B underwent a second stage surgery after a healing period of 3 months. A more detailed description of the clinical procedures is provided in another publication of the same group [28].

2.5 HRQoL assessment

The German version of the SF-36, which was executed self-administered by all participants was applied to assess HRQoL [29,30]. This questionnaire is comprised of 36 questions, which can be summarized into eight domains. These eight domains are defined as followed: physical functioning (PF), bodily pain (BP), general health perceptions (GH), physical role functioning (RP), emotional role functioning (RE), social role functioning (SF), vitality (VT) and mental health (MH). The domains can be combined into a physical (PCS) and a mental (MCS) component summary. The scores of each domain were converted linearly to a scale, ranging from 0 (worst HRQoL) to 100 (best HRQoL). For the calculation of the component summaries the SF-36 scales were Z-transformed, and subsequently multiplied by respective coefficients for MCS and PCS, based on data of the American normative sample from 1998 [31]. The resulting average value of the American sample is 50 with a standard deviation of 10.

HRQoL was assessed on three occasions: at baseline before implant placement, and at follow-up at 4 respectively 24 months after loading.

2.6 Statistical analyses

The data tend to be skewed on the restricted interval [0,100] such that they did not follow a normal distribution, which was confirmed by the Shapiro-Wilk test. Therefore, the statistical analysis was done nonparametrically as follows: The Friedman test was used to assess the within patient's change over time (baseline to 4 months, and baseline to 24 months after implant loading), and the Wilcoxon rank sum test was used to assess the comparison of the two groups. For the latter test, the relative median change of baseline to 4- and 24-month data was calculated for each group individually and compared. The level of significance was set to $p \leq 0.05$ and was adjusted for multiple testing by the Bonferroni-Holm method. The resulting adjusted level of significance for the two component summaries (PCS and MCS) was $p \leq 0.025$.

3 Results

3.1 Overall treatment effect on HRQoL

Analyzing all participants' SF-36 questionnaires, it could be observed that PCS and MCS showed a decreasing tendency over time (Table 2). Regarding the relative median changes of all participants' PCS scores, there was a very small and not statistically significant (p = 0.706) relative median decrease of 0.01 from baseline to 4 months and a decrease of 0.05 from baseline to 24 months, which was statistically significant (p = 0.011). Participants' MCS scores were virtually identical for all assessments with almost negligible and statistically not significant differences between baseline and 4-month (-0.02; p = 0.164) and 24-month assessment (-0.01; p = 0.177; Table 3).

3.2 Influence of the loading protocol on HRQoL

Over the whole study period, PCS and MCS scores decreased, independent of the loading protocol (Table 2). In Group A, the median PCS score showed a statistically non-significant (p = 0.554) relative increase of 0.02 from baseline to 4 months. From baseline to 24 months, there was a decrease of 0.05, which was also not statistically significant (p = 0.170). In Group B, there was a statistically non-significant (p = 0.554) relative decrease of the median PCS-score of 0.02 from baseline to 4 months, whereas the decrease of 0.04 from baseline to 24 months was statistically significant (p = 0.020). Comparing the relative median changes between the two groups, the differences were neither significant at the 4-month follow-up (p = 0.218) nor at the 24-month follow-up (p = 0.584)

In Group A, the median MCS score showed a statistically non-significant (p = 0.580) relative decrease of 0.01 from baseline to 4 months. From baseline to 24 months, there was a decrease of 0.01 which was also not statistically significant (p = 0.221). In Group B, there was a statistically non-significant (p = 0.180) relative decrease of the median MCS-score of 0.03 from baseline to 4 months. The decrease of 0.001 from baseline to 24 months was also statistically non-significant (p = 0.498). Comparing the relative median changes between the

two groups, the differences were neither significant at the 4-month follow-up (p = 0.558) nor at the 24-month follow-up (p = 0.761). The relative median changes of PCS- and MCS-scores in Group A and Group B, the 95% Cis, as well as the according p-values are given in Table 3 and illustrated in figure 2 (Fig. 2)

4 Discussion

The stabilization of a mandibular complete denture by means of a single midline implant did not result in an improvement of participants' HRQoL. A decreasing tendency throughout the study period was found, independent of the applied loading protocol.

An effect size of 0.5 is regarded to show a clinically relevant difference between the treatment arms in an RCT [32]. Based on this assumption, the sample size for the primary outcome measure (implant survival) was calculated to be 74 in each treatment arm. Even though there was no sample size calculation for secondary outcomes in advance, there is for each domain of the SF-36 separately, a power of above 88% to detect differences of HRQoL, in the mean of the 0.5-fold standard deviation for normally distributed items. Hence, it is still possible that the study was underpowered in regard to the outcome measure HRQoL, but still, there was no effect size above 0.5. Furthermore, it can be assumed that the sample size was big enough to detect possible changes in this treatment concept on HRQoL, due to the sample size of comparable studies [33].

There are several instruments for measuring HRQoL (e.g. SF36, GHQ, Euro QoL) [34]. Because of that, a comparison of the existing results according to different questionnaires is almost impossible. The SF-36 questionnaire is one of the most commonly used generic instruments for measuring HRQoL. Therefore, this questionnaire was chosen for analyses in the present study.

There are several studies analyzing the impact of implant therapy on OHRQoL [35,36], but only a few studies focus on the impact of implant therapy on HRQoL. One study comparing HRQoL, measured by the SF-36 questionnaire, as well as OHRQoL of subjects, who received a two implant-retained mandibular denture, or otherwise a conventional mandibular full denture, showed significantly higher OHRQoL scores in subjects who received an implant-retained overdenture. For HRQoL, a statistically significant increase was only found in the subgroup social role function[6]. Results of other studies are similarly showing, that there were no significant changes in HRQoL, but significant improvements in OHRQoL measurements in participants, who received dental implants to retain overdentures. These improvements were not found in participants receiving new or relined conventional full dentures [37,38]. According to literature, changes of oral health status must be fundamental to have an influence on HRQoL [39].

At first the whole study sample was analyzed. This was done to show if there was an effect of the single midline implant treatment itself. Subsequently, the two study groups were analyzed separately, evaluating a potential influence of the loading protocol. There was a negligible deterioration in HRQoL during the observation period in both study groups, as well as in the whole sample. It would have been interesting if there had been a third study group, receiving only a relining of the existing conventional full denture, to compare the treatment effect on HRQoL. As the evaluation of the SF-36 questionnaire was a secondary outcome and because of financial reasons, a third study group was not included.

The normative MCS score in the German population aged 60-69 years was 50.2, and for the age group 70-79 years it was 50.1. The overall MCS score of the study participants was 56.3 at baseline and 55.5 at the 24-month follow-up. The normative PCS score in the German population aged 60-69 years was 46.2, and for the age group 70-79 years it was 44.1. The overall MCS score of the study participants was 48.6 at baseline and 46.6 at the 24-month follow-up [31]. Comparing the SF-36 scores of the study sample to the normative age-dependent data of

the German population, irrespective of general or oral health status shows, the scores of the study participants tend to be higher, even at baseline [31]. Those high ratings from the beginning, might be a reason why no significant improvements could be detected.

Values for HRQoL are similar for persons with a sufficient prosthetic oral rehabilitation and persons with a remaining natural dentition. In comparison to that, general health of people in need of prosthetic rehabilitation is significantly lower [37]. In the present study, existing mandibular complete dentures of participants who were not satisfied with the stability of the denture were stabilized by means of a single implant. This kind of treatment was not highly invasive, especially as no augmentation procedures had to be performed. It was assumed, that the stabilization could lead to an increased HRQoL, due to the low invasiveness, even though the changes were not fundamental. Nevertheless, an increase of HRQoL could not be detected, regardless of the applied loading protocol.

The statistically significant changes in the PCS values after 24 months of all participants' ratings and in Group B seemed to be a statistical phenomenon with no clinical relevance. The relative median PCS score change was 0.5 in the whole study sample, 0.5 in Group A and 0.4 in Group B. This indicates that the relative median change was the higher in Group A compared to Group B, without reaching statistical significance. Nevertheless, there was a statistically significant worsening of the physical component of HRQoL. Generally, it is always advisable to question, if a statistically significant finding is also clinically meaningful [40]. Answering this questions according to SF-36 scores is hardly possible as the knowledge on HRQoL is still limited, especially in dental medicine [12]. Besides those statistical analyses, another way to quantify PROs is by using the concept of the minimal clinically important difference (MCID). The MCID was originally defined as the smallest difference in score in the domain of interest which patients perceive as beneficial [41]. The concept was developed to overcome the difficulties in the interpretation of PROs, purely based on statistical findings. In

other study populations, the MCID was reported to be considerably higher for MCS and PCS values, than the changes that were found in the present study [42]. This supports the thesis that even the statistically significant decreases of the PCS scores in the present study do not represent a clinically meaningful change.

5. Conclusion

Within the limitations of the present study it can be concluded that:

- The provision of a single mandibular implant to stabilize a complete denture does not result in a meaningful change in HRQoL.
- The loading protocol (i.e. immediate vs. delayed loading) has no influence on HRQoL in single-implant retained overdentures.
- More research on HRQoL is mandatory, to understand what kind of dental treatment really has an impact on HRQoL

6. Compliance with Ethical Standards:

Conflict of interest: All authors declare that they have no conflict of interest.

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Ethical approval: All procedures performed in this study were conducted in accordance with the ethical standards of the Ethics Commission of the University Hospital Schleswig-Holstein, UKSH (AZ 138/12), with the Ethics Commissions of all other participating centers, and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed consent: Informed consent was obtained from all individual participants included in the study.

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7. Figures

Fig. 1: Study flowchart (CONSORT flowchart)

a: Excluded prior to intervention 1 (n=55)

- No match with eligibility criteria (n=37)
- Lost to follow-up (n=3)
- Noncompliance (n=5)
- Medical contraindication for implant placement (n=2)
- Withdrawal of consent (n=8)

b: Excluded during/after implant placement (n=11)

- Bone augmentation required (n=6)
- Local anesthesia ineffectual (n=1)
- Insufficient primary stability (n=3)
- Randomization error (n=1)

c: Lost during follow-up (n=1)
d: Implant failure (n =5)
e: Implant failure (n=1)
f: Implant failure (n=4)
g: Lost during follow-up (n=1)
h: Lost during follow-up (n=3)

- Death of participant (n=2)
- Lost during follow up (n=1)

i: Lost during follow-up (n=1)
j: Lost during follow-up (n=4)

- AE/SAE (n=1)
- Death of participant (n=2)
- Lost during follow up (n=1)

k: Lost during follow-up (n=7)

- AE/SAE (n=1)
- Death of participant (n=2)
- Lost during follow-up (n=4)

Fig. 2: Changes of PCS and MCS scores

Median-, minimum-, and maximum, as well as 25th percentiles and 75th percentiles of PCS (physical component summary) and MCS (mental component summary) scores, of Group A and Group B at baseline, 4 months- and 24 months after loading.