

1 **Stabilizing mandibular complete dentures by a single midline**  
2 **implant - influence on quality of life:2-year results from a**  
3 **randomized clinical trial comparing different loading protocols**  
4

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38 **Original article**

39 **Stabilizing mandibular complete dentures by a single midline**  
40 **implant - influence on quality of life: 2-year results from a**  
41 **randomized clinical trial comparing different loading protocols**  
42

43 **Abstract**

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

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

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

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

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

63

## 64 **1. Introduction**

65

66 The demographic change is accompanied by an increase in elderly persons in dental routine  
67 business. In 2014, 32.8% of the German population between 75 and 100 years was completely  
68 edentulous [1]. In the US, the prevalence of edentulism in the same age group was 24.1% in  
69 2012, which means that about one-quarter of the people older than 75 years were edentulous  
70 [2]. Loss of teeth leading to edentulism can result in negative consequences like changes in  
71 bone quantity and denture stability, reduction of chewing efficiency and, subsequently an  
72 increased risk of malnutrition [3,4]. Both, loss of teeth and edentulism can be associated with a  
73 reduced oral-health-related quality of life (OHRQoL), which is one part of quality of life  
74 (HRQoL), that is influenced by oral health aspects [5,6]

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

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

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

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

101

## 102 **2. Material and Methods**

### 103 *2.1 Study design and setting*

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

### 111 *2.2 .Eligibility criteria*

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

#### 114 *2.2.1 Inclusion criteria:*

115 - Edentulous males and females between the ages of 60 and 89.

116 - No contraindication for implant placement

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

126 *2.2.2 Exclusion criteria:*

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

133

134 *2.3 Description of study sample*

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

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

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

157

#### 158 *2.4 Clinical procedures*

159 The participants received a single midline implant in the mandible (Camlog ScrewLine;  
160 Promote Plus, Camlog Biotechnologies, Basel, Switzerland, lengths 11mm, diameter 3.8mm).  
161 The existing denture bases were reconstructed with corresponding matrices (Dalbo-Plus  
162 Elliptic, Cendres+Métaux, Biel, Switzerland) to the ball anchors, which were placed on the  
163 implant as one part of the suprastructure. Implants in Group A were immediately loaded after  
164 placement. Participants in Group B underwent a second stage surgery after a healing period of  
165 3 months. A more detailed description of the clinical procedures is provided in another  
166 publication of the same group [28].

167

#### 168 *2.5 HRQoL assessment*

169 The German version of the SF-36, which was executed self-administered by all participants was  
170 applied to assess HRQoL [29,30]. This questionnaire is comprised of 36 questions, which can  
171 be summarized into eight domains. These eight domains are defined as followed: physical  
172 functioning (PF), bodily pain (BP), general health perceptions (GH), physical role functioning  
173 (RP), emotional role functioning (RE), social role functioning (SF), vitality (VT) and mental  
174 health (MH). The domains can be combined into a physical (PCS) and a mental (MCS)  
175 component summary. The scores of each domain were converted linearly to a scale, ranging  
176 from 0 (worst HRQoL) to 100 (best HRQoL). For the calculation of the component summaries  
177 the SF-36 scales were Z-transformed, and subsequently multiplied by respective coefficients  
178 for MCS and PCS, based on data of the American normative sample from 1998 [31]. The  
179 resulting average value of the American sample is 50 with a standard deviation of 10.  
180 HRQoL was assessed on three occasions: at baseline before implant placement, and at follow-  
181 up at 4 respectively 24 months after loading.

182

### 183 *2.6 Statistical analyses*

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

193

## 194 **3 Results**

195 *3.1 Overall treatment effect on HRQoL*

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

204

205 *3.2 Influence of the loading protocol on HRQoL*

206 Over the whole study period, PCS and MCS scores decreased, independent of the loading  
207 protocol (Table 2). In Group A, the median PCS score showed a statistically non-significant ( $p$   
208  $= 0.554$ ) relative increase of 0.02 from baseline to 4 months. From baseline to 24 months, there  
209 was a decrease of 0.05, which was also not statistically significant ( $p = 0.170$ ). In Group B,  
210 there was a statistically non-significant ( $p = 0.554$ ) relative decrease of the median PCS-score  
211 of 0.02 from baseline to 4 months, whereas the decrease of 0.04 from baseline to 24 months  
212 was statistically significant ( $p = 0.020$ ). Comparing the relative median changes between the  
213 two groups, the differences were neither significant at the 4-month follow-up ( $p = 0.218$ ) nor at  
214 the 24-month follow-up ( $p = 0.584$ )

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

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

225

226

## 227 **4 Discussion**

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

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

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

246           There are several studies analyzing the impact of implant therapy on OHRQoL [35,36],  
247 but only a few studies focus on the impact of implant therapy on HRQoL. One study comparing  
248 HRQoL, measured by the SF-36 questionnaire, as well as OHRQoL of subjects, who received  
249 a two implant-retained mandibular denture, or otherwise a conventional mandibular full  
250 denture, showed significantly higher OHRQoL scores in subjects who received an implant-  
251 retained overdenture. For HRQoL, a statistically significant increase was only found in the  
252 subgroup social role function[6]. Results of other studies are similarly showing, that there were  
253 no significant changes in HRQoL, but significant improvements in OHRQoL measurements in  
254 participants, who received dental implants to retain overdentures. These improvements were  
255 not found in participants receiving new or relined conventional full dentures [37,38]. According  
256 to literature, changes of oral health status must be fundamental to have an influence on HRQoL  
257 [39].

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

266           The normative MCS score in the German population aged 60-69 years was 50.2, and for the  
267 age group 70-79 years it was 50.1. The overall MCS score of the study participants was 56.3 at  
268 baseline and 55.5 at the 24-month follow-up. The normative PCS score in the German  
269 population aged 60-69 years was 46.2, and for the age group 70-79 years it was 44.1. The overall  
270 MCS score of the study participants was 48.6 at baseline and 46.6 at the 24-month follow-up  
271 [31]. Comparing the SF-36 scores of the study sample to the normative age-dependent data of

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

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

284 The statistically significant changes in the PCS values after 24 months of all  
285 participants' ratings and in Group B seemed to be a statistical phenomenon with no clinical  
286 relevance. The relative median PCS score change was 0.5 in the whole study sample, 0.5 in  
287 Group A and 0.4 in Group B. This indicates that the relative median change was the higher in  
288 Group A compared to Group B, without reaching statistical significance. Nevertheless, there  
289 was a statistically significant worsening of the physical component of HRQoL. Generally, it is  
290 always advisable to question, if a statistically significant finding is also clinically meaningful  
291 [40]. Answering this questions according to SF-36 scores is hardly possible as the knowledge  
292 on HRQoL is still limited, especially in dental medicine [12]. Besides those statistical analyses,  
293 another way to quantify PROs is by using the concept of the minimal clinically important  
294 difference (MCID). The MCID was originally defined as the smallest difference in score in the  
295 domain of interest which patients perceive as beneficial [41]. The concept was developed to  
296 overcome the difficulties in the interpretation of PROs, purely based on statistical findings. In

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

301

## 302 **5. Conclusion**

303  
304 Within the limitations of the present study it can be concluded that:

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

311

## 312 **6. Compliance with Ethical Standards:**

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

314

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316 Foundation, KE 477/8-1).

317

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

322

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

325

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443 **7. Figures**

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446

447 **Fig. 1:** Study flowchart (CONSORT flowchart)

448

449

450

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

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

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

- 458 • Bone augmentation required (n=6)
- 459 • Local anesthesia ineffectual (n=1)
- 460 • Insufficient primary stability (n=3)
- 461 • Randomization error (n=1)

462 c: Lost during follow-up (n=1)

463 d: Implant failure (n =5)

464 e: Implant failure (n=1)

465 f: Implant failure (n=4)

466 g: Lost during follow-up (n=1)

467 h: Lost during follow-up (n=3)

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

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

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

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

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

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

479

480

481 **Fig. 2:** Changes of PCS and MCS scores

482

483 Median-, minimum-, and maximum, as well as 25<sup>th</sup> percentiles and 75<sup>th</sup> percentiles of PCS (physical component  
484 summary) and MCS (mental component summary) scores, of Group A and Group B at baseline, 4 months- and  
485 24 months after loading.