

Influence of the number of implants in the edentulous mandible on chewing efficacy and oral health-related quality of life—A within-subject design study

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Abstract

Objectives: To investigate the chewing efficiency and oral health-related quality of life of edentulous patients wearing complete dentures, successively supported by one, two, and three implants in the mandible.

Methods: Thirteen (13) edentulous patients of at least 50 years of age received three implants in the mandible. After a conventional submerged healing period, the central implant was uncovered and connected to the denture base using a stud attachment. Two months later, chewing efficacy was evaluated, and the two lateral implants were uncovered and connected to the denture base. The central retention element was replaced by a short healing abutment with no connection to the denture base. Chewing efficiency was evaluated two months later. Afterward, the healing abutment of the central implant was replaced by a stud attachment and again connected to the denture base. Two months later, chewing efficacy was evaluated again. Oral health-related quality of life (OHRQoL) was measured at each recall visit using the summary score of the oral health impact profile. For statistical analysis of chewing efficacy, the changes from baseline (with no implants) to one, two, and three implants were used and tested by analysis of variance with repeated measurements.

Results: Chewing efficacy clearly increased after implant loading, with a significant increase when two implants were loaded ($p \leq .05$), compared to the chewing efficacy with no implants. OHRQoL also significantly improved after implant loading.

Conclusions: Within the limitations of the present clinical trial regarding the number of patients, chewing efficacy as well OHRQoL of edentulous patients improve after implant placement in the mandible, irrespective of the number of implants. The best chewing efficacy was achieved with two implants.

1 | INTRODUCTION

Edentulism is a chronic condition, which mostly affects the elderly. For decades, complete dentures were the only treatment option for

edentulous patients. Complete dentures are able to at least reduce the major functional problems associated with edentulism, but, although if they are technically well designed, patients are often very dissatisfied, especially with the retention of the mandibular complete

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denture (Müller et al., 1994; Pan et al., 2014). Dental implants are able to significantly improve satisfaction and quality of life of edentulous patients (Emami et al., 2009; Oh et al., 2016), and two international consensus conferences recommended two implants in the edentulous mandible as a minimal standard of care (Feine et al., 2002; Thomason et al., 2009). To further improve function, the use of three implants to stabilize a mandibular overdenture was proposed as early as the 1980s, which can be considered a compromise between the use of two and four implants in the edentulous mandible (Engquist et al., 1988). However, in the meantime, one single midline implant in the edentulous mandible has proven to be a valid alternative if more implants cannot be used (Kern & Passia, 2021; Nogueira et al., 2017, 2019).

To assess the function of complete dentures or implant overdentures, masticatory performance is a widely used instrument (Boven et al., 2015; Florencio Costa et al., 2020; Geertman et al., 1999; Ishikawa et al., 2007; Maniewicz et al., 2019). Different methods are well described in the literature. While some authors decided to use the swallowing threshold test (Prinz & Lucas, 1995), others measured the final particle size of natural food or test food after a certain number of chewing cycles (Miranda et al., 2019; Possebom et al., 2020), or the mixing ability of a two-colored chewing gum (Silva et al., 2018) or paraffin wax cubes (Khalid et al., 2020). Irrespective of the method used for evaluation, all authors agreed that masticatory performance increases tremendously with the insertion of dental implants (Boven et al., 2015). However, the literature provides different results regarding the influence of the number of implants on masticatory performance. One implant provides remarkable improvements compared to complete dentures with no implants (Amaral et al., 2019; Harder et al., 2011). When comparing one versus two implants, one investigation found a better masticatory performance for two implants (Paleari et al., 2018), while the other investigation could not confirm an inferior masticatory performance with one implant (de Resende et al., 2021). Authors from a systematic literature review concluded that implants placed in the edentulous mandible seem to improve masticatory function irrespective of the number of implants (Boven et al., 2015). Bhat et al. (2016) investigated the maximum bite force of ten edentulous patients who received three implants in the mandible, which were successively loaded with a follow-up interval of 1 month

each. They found a significant increase in the maximum bite force after loading of one implant compared to the baselined data with no implant. When two implants were loaded, bite force further increased with no statistical significance. Bite force further increased with three implants with no statistical significance compared to two implants but with a statistically significant increase compared to one implant.

To the best knowledge of the present authors, intraindividual chewing efficiency of edentulous patients with mandibular overdentures retained by either one, two, or three implants has never been investigated before. Therefore, it was the aim of the present clinical study to investigate the chewing efficacy of edentulous patients receiving three successively loaded dental implants in the mandible. The oral health-related quality of life was investigated as a secondary parameter, as well.

2 | MATERIALS AND METHODS

The Institutional Review Board of the Christian-Albrechts University at Kiel, Germany, approved the study design, and the trial was registered with the German Registry of Clinical Trials under DRKS ID: DRKS00011087. All study participants gave informed written consent before inclusion in the trial. The trial followed the CONSORT guidelines.

Between May 2016 and June 2020, patients were screened according to predefined inclusion and exclusion criteria (Table 1). The detailed reasons for exclusion of patients after screening are shown in Figure 1. After inclusion, baseline data regarding chewing efficacy an oral health-related quality of life (OHRQoL) were obtained. For evaluation of the chewing efficiency, patients chewed an artificial, standardized test food (Optocal) (Pocztaruk Rde et al., 2008) with 40 chewing cycles. The test food was collected in plastic cubes and disinfected with alcohol. After 24 h, it was sieved with a sieving apparatus (Retsch) with 5 sieves of different sizes (4 mm, 2 mm, 850 µm, 425 µm, 180 µm). The particles of the test food on each sieve were weighed using a laboratory scale (Analytic, Sartorius). The percentage of each of the 5 sieving capacities was calculated and was 100% for the total test food of each chewing sample. Additionally,

TABLE 1 In- and exclusion criteria

| Inclusion criteria | Exclusion criteria |
|--|--|
| Signed written informed consent to participate in the trial | Edentulous patients with contraindication for implant placement in the mandible caused by systematic diseases or local bone deficits |
| Edentulous male and female patients of at least 50 years of age | Patients satisfied with the retention of their mandibular denture or unsatisfied with the retention and/or stability of their denture in the maxilla |
| Existing complete dentures have been worn for at least 3 months | Remaining teeth or exciting implants in the maxilla or mandible |
| Despite technically acceptable complete dentures in both jaws, the patient is dissatisfied with the retention and/or stability of the mandibular denture | |
| Sufficient bone in the interforaminal area to place implants without bone augmentation | |
| No contraindication for implant placement | |

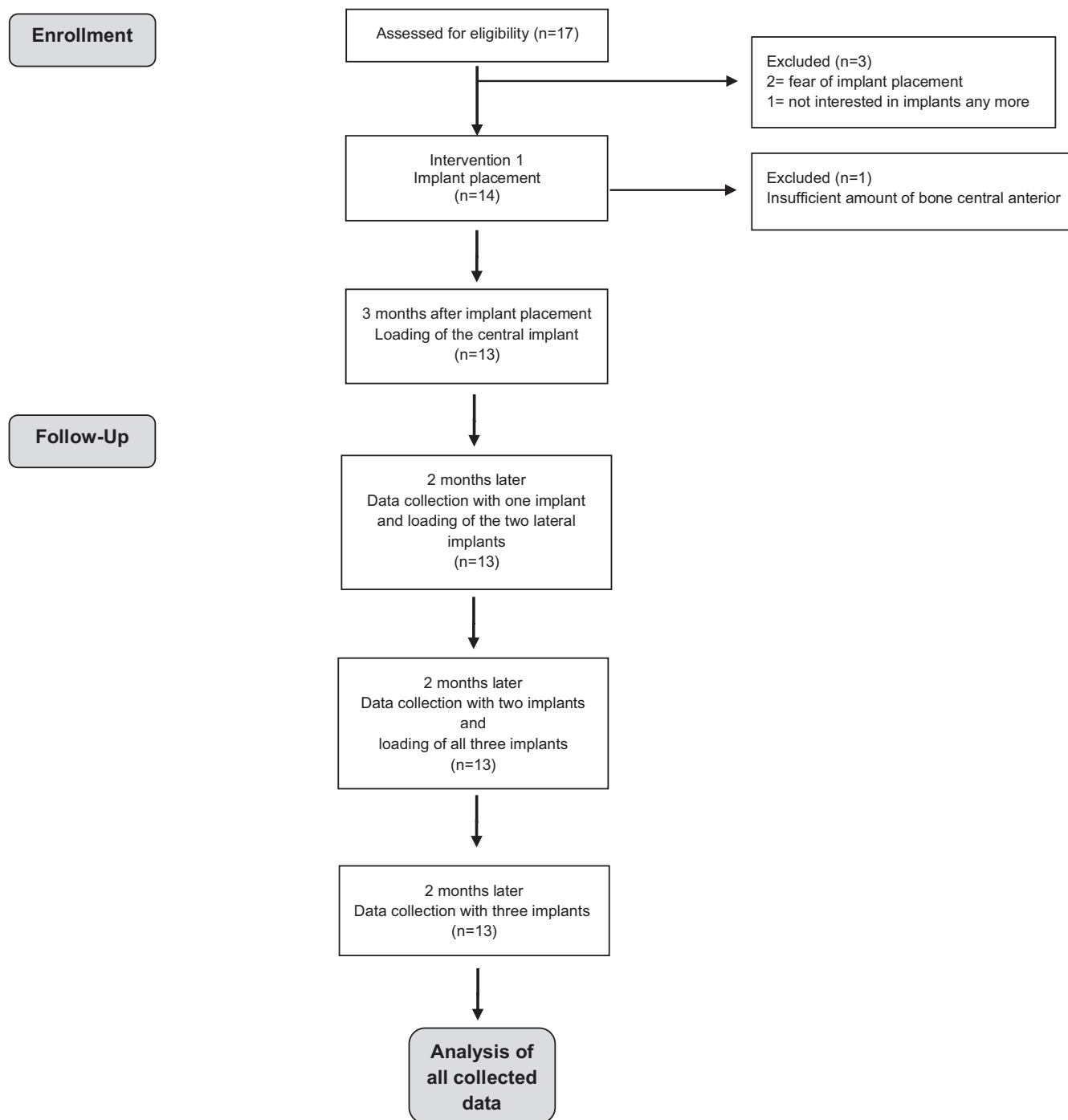


FIGURE 1 Study flowchart

a theoretical sieve, through which 50% of the chewed test food would pass, was calculated using the Rosin Rammler equation

$$Q_W(x) = 100 \left\{ 1 - \exp \left[- (x/x_{50})^h \ln 2 \right] \right\}$$

The summary score of the German 49-item Oral Health Impact Profile was used for evaluation of the OHRQoL.

Additionally, panoramic x-rays with radioopaque markers were taken to analyze the interforaminal amount of bone. Implants were placed under local anesthesia. A crestal incision between the two lower first premolars with little relieving cuts was chosen and after

elevating a full-thickness flap, implant site preparation was performed according to the manufacturer's instructions. In total, 39 implants (3.9 × 11.5 mm; V3, MIS Implants) were placed in the anterior mandible and in the area of the lower canines in 13 patients. As the study design excluded any bone augmentation procedures, the two implants in the canine region were placed with regard to the amount of bone without a predefined distance between the implants. A tripod support of the prostheses was ensured. A two-stage submerged healing protocol was chosen. During the healing period, all mandibular dentures were provided with a base-metal framework to

ensure fracture resistance. A reticulated design was chosen. Three months after implant placement, the central implant was uncovered and provided with an OT-Equator with a gingiva height of 3 mm (MIS Implants, Israel; Figure 2). The corresponding OT-Equator matrixe (MIS Implants, Israel; Figure 3) was integrated into the denture base intraorally using a self-curing bis-acrylate resin (LuxaPick-up, DMG). The incorporated framework was perforated in the area of the internal relief, if necessary. Two months later, chewing efficacy and OHRQoL were evaluated again. The two lateral implants were uncovered and connected to the denture base as earlier described with the same OT-Equator attachment (Figure 4). The two lateral implants were uncovered before loading and not together with uncovering the central implant to allow the soft tissue to adapt to the patrix of the retention element and not firstly to a short healing abutment. The central stud attachment was replaced by a short healing abutment on gingival level with no connection to the denture base to assure an overdenture retained by two implants. A vinyl polyether material (Fit-Checker advanced, GC Germany) was used to verify no contact between healing abutment and denture base. Another 2 months later, chewing efficacy and OHRQoL with two implants were evaluated and the central implant was again connected to the denture base (Figure 5a,b). Chewing efficacy and OHRQoL with three implants were evaluated after another 2 months.

Baseline data with no implants as well as data with one, two, and three implants were used for analysis.

2.1 | Sample size and statistical analysis

For chewing efficacy, a linear interpolation was used to identify a theoretical sieve through which 50% of the chewed test food would pass.

The primary endpoint is X_{50} . With an increasing number of implants, an increasing chewing efficacy can be assumed. With a sample size of 10, the one-sided paired t-test has a power of at least 80% to detect a difference of one standard deviation. At each time point,

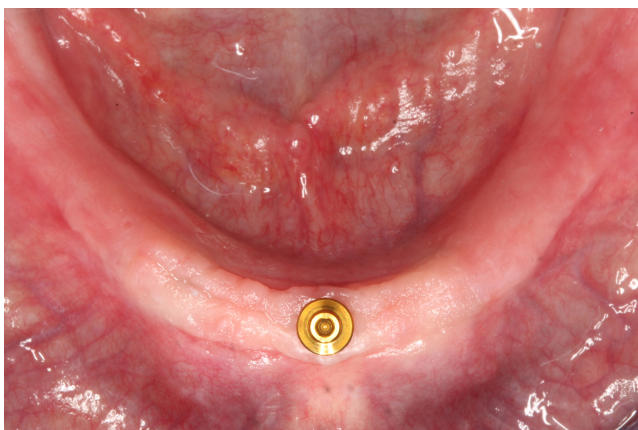


FIGURE 2 Intraoral view of OT-Equator matrixe on the midline implant



FIGURE 3 OT-Equator matrixe of the central implant integrated into the denture base



FIGURE 4 Intraoral view of the OT-Equator attachment on the two lateral implants, immediately after second-stage surgery, the midline implant is provided with a healing abutment

a loss to follow-up of no more than 10% is expected, so with an additional 3 subjects, the total sample size is 13.

Statistical analysis was performed using a linear model for repeated measurements with the relative changes of the individual chewing efficiency from baseline as the primary outcome. The normal distribution was assumed after one patient was identified as an outlier by the interquartile rule. The sphericity was tested (Mauchly) as well as the between-subject and the within-subject effects. The level of significance was 5% and multiple comparison of the within-subject contrast were adjusted by Bonferroni-Holm method. The Friedman test was used for analysis of the OHIP. Statistical analysis was carried out by SPSS (version 24).

3 | RESULTS

Thirteen patients, 7 males and 6 females, between 60 and 82 years of age received three implants and all of them attended each follow-up investigation. The implant survival rate was 100%. The most

frequent maintenance intervention was a relining of the maxillary complete denture, which had to be performed in 4 of the 13 cases. Chewing efficacy, represented by a theoretical sieve size, through which 50% of the chewed test food would pass, increased after implant placement ($p = .039$). Although the overall within-subject effects slightly missed the significance level ($p = .054$), the between-subject effect of the implants was large ($p = .001$) and already visible after loading of one implant ($p = .057$) and continued after loading the second implant ($p = .015$, Figure 6). Loading of the third implant did not clearly further improve chewing efficacy (Table 2). Chewing efficacy slightly decreased after loading the third implant in 7 patients, but continued to increase in 6 patients. Regarding OHRQoL, a statistically significant increase was observed after loading of the central implant ($p \leq .05$), compared to the baseline data. OHRQoL continued to increase with loading of two and three implants with no statistically significant difference compared to one implant ($p = .410$; Figure 7 and Table 3).

4 | DISCUSSION

The present clinical trial investigated the impact of the number of implants placed in the edentulous mandible on chewing efficacy. As a secondary parameter the OHRQoL was analyzed. To avoid any bias, chewing efficacy was chosen as the primary endpoint as this is considered an objective criterion for evaluation. Blinding was not possible because the patient knew the number of implants supporting the overdenture. That could lead to a psychologically guided better evaluation of the overdenture with an increasing number of implants.

The results clearly show that placing implants improved both parameters tremendously. Chewing efficacy clearly increased after loading one and two implants but a further increase in chewing efficacy was not clearly visible after loading the third implant. When interpreting the results, the relatively small number of patients together with a large scattering of the data at baseline and after loading of one implant has to be considered. The small number of

patients in this explorative clinical trial can be considered the weak part of the present investigation. With a greater number of patients, data with three implants might have lead to different results. The present findings are partly in line with those of Paleari et al., who investigated the masticatory performance of 21 edentulous patients, who were randomly assigned to receive either one or two implants in the mandible. After 3, 6 and 12 months, masticatory performance

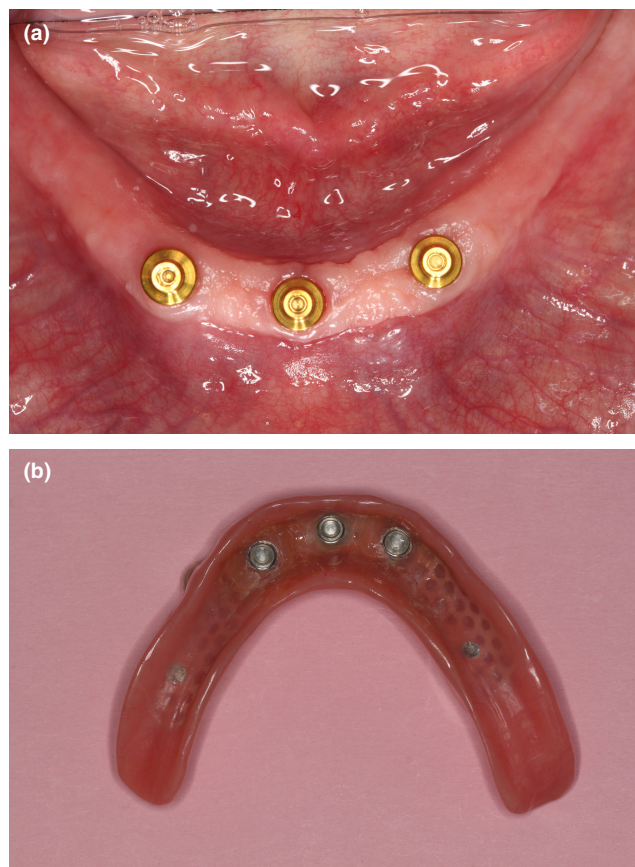


FIGURE 5 (a) Intraoral view of the OT-Equator patrices of all three implants. (b) OT-Equator matrices integrated into the denture base

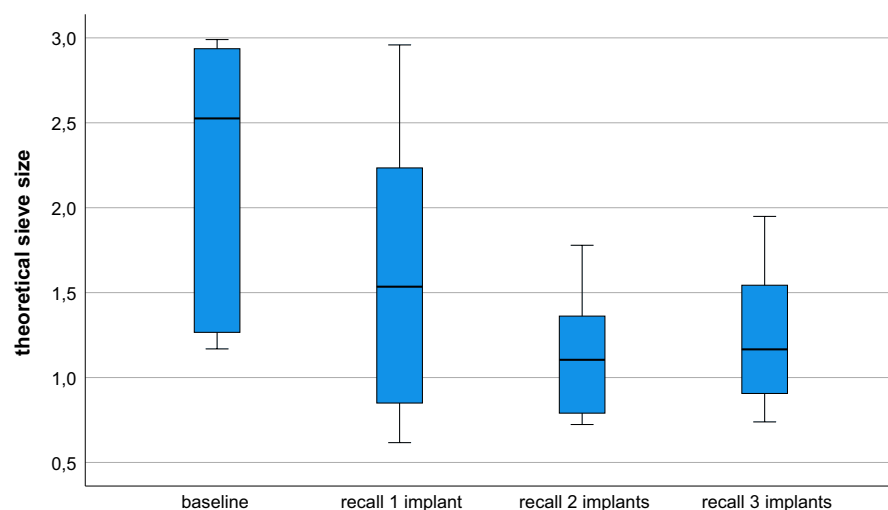


FIGURE 6 Box-plots showing a theoretical sieve size, through which 50% of the test food can pass

TABLE 2 Descriptive statistics of the relative differences in chewing efficacy between 1, 2 and 3 implants

| Relative differences | N | Minimum | Maximum | Mean | Standard deviation |
|----------------------|-------|---------|---------|-------|--------------------|
| 1 compared to 0 | 12.00 | -0.78 | 0.48 | -0.22 | 0.39 |
| 2 compared to 0 | 12.00 | -0.74 | -0.16 | -0.46 | 0.16 |
| 3 compared to 0 | 12.00 | -0.75 | 0.42 | -0.34 | 0.37 |

FIGURE 7 Box-plots showing the OHRQoL with one, two and three implants

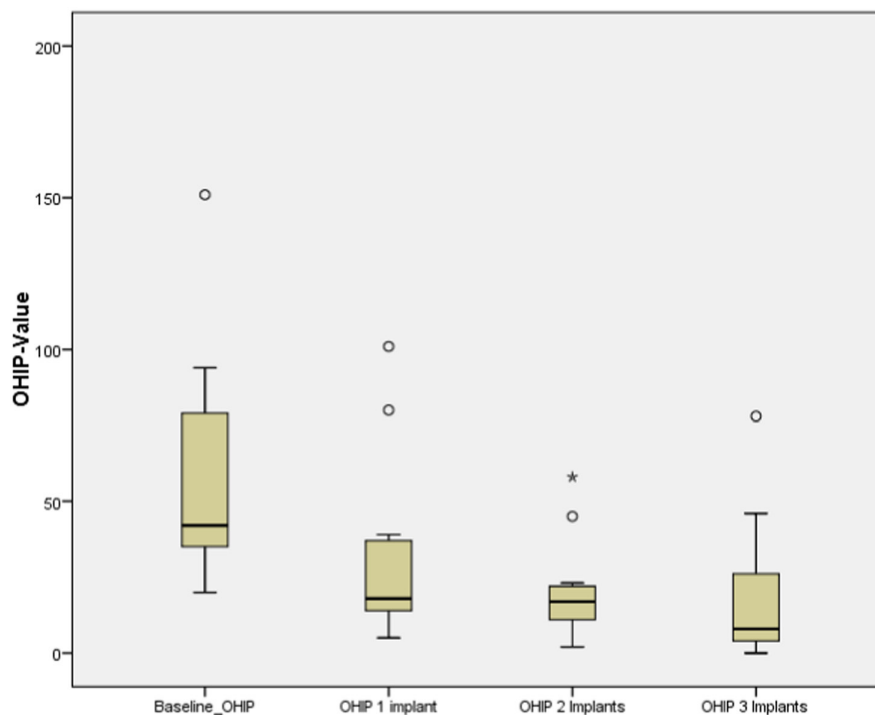


TABLE 3 Descriptive statistics of the OHIP-scores

| | N | Minimum | Maximum | Mean | Standard deviation |
|------------|-------|---------|---------|------|--------------------|
| Baseline | 20 | 5 | 151 | 59.3 | 36.6 |
| 1 implant | 12.00 | 5 | 101 | 31.1 | 28.4 |
| 2 implants | 12.00 | 2 | 58 | 19.8 | 15.6 |
| 3 implants | 12.00 | 0 | 78 | 19.9 | 22.8 |

of patients with two implants was significantly better than with no implants (Paleari et al., 2018). In this investigation, masticatory performance with one implant also significantly improved for all periods relative to baseline with no implants, and two implants performed significantly better than one implant.

In the present investigation, chewing efficacy slightly decreased after loading the third implant in 7 patients, but chewing efficacy continued to increase in 6 patients. A correlation between a decrease of chewing efficacy and a subjective loss of stability of the maxillary denture when loading the third implant can be assumed, as all four necessary relinings of the maxillary denture after loading the third implant were necessary for those patients, whose chewing efficacy decreased after loading the third implant. This might suggest that an increased number of implants in the edentulous mandible supporting removable dentures might destabilize the maxillary

complete denture, which is also observed for implant-retained fixed dental prostheses opposing maxillary complete dentures (Tsigarida & Chochlidakis, 2021). Again, the present findings should to be interpreted with extreme caution because the number of patients included in this exploratory study is rather low, which might be considered the weak part of the current study. To confirm these results, a clinical investigation with a greater number of patients would have to be performed.

Irrespective of the number of implants, chewing efficacy increased compared to the initial situation with no implants. This finding is in line with other investigations on chewing efficacy of complete denture wearers compared to overdenture wearers (Fueki et al., 2007; Possebon et al., 2020).

A cost-effectiveness analysis of implant overdentures, where the perceived chewing ability was used as the main parameter for

reflecting the patient's dental health state preference, revealed, that implant supported overdentures become more cost-effective over time compared to complete dentures (Zitzmann et al., 2006).

A review article on common methods for measuring the masticatory performance of edentulous patients wearing complete dentures or implant prostheses came to the conclusion, that the most valid outcomes for this type of assessment would be patient-based, i.e., questionnaires such as the oral health impact profile (OHIP). Those could be influenced by chewing or dietary assessments (Feine & Lund, 2006). However, another investigation found only a poor correlation between the masticatory performance and the patient perceived ability to chew (Slagter et al., 1992). In the present clinical trial, OHRQoL significantly improved after loading of one implant with a further but not significant increase after loading of two and three implants. This result is in line with another investigation on single implants to stabilize complete mandibular dentures (Schwindling et al., 2018). In this investigation, OHRQoL significantly improved after implant placement irrespective of the implant loading protocol. Other investigations clearly showed the positive impact of implants in the mandible on OHRQoL of older edentulous patients (Kutkut et al., 2018; Policastro et al., 2019).

In the present exploratory clinical trial, neither randomization nor counterbalancing of the order, in which the number of loaded implants were presented across the group of participants, was performed. This can be considered a weakness of the study, as time-related effects, carry-over effects, or learning effects over time cannot be completely excluded. However, as blinding was not possible in the present investigation, all participants knew the number of implants supporting their overdenture at every point in time. That would have also been the case, if randomization or counterbalancing had been performed.

5 | CONCLUSIONS

Masticatory performance as well OHRQoL of edentulous patients improves after implant placement in the mandible, irrespective of the number of implants. Masticatory performance improves with one implant and the best masticatory performance is achieved with two implants, which has to be considered with caution due to the limited number of patients in the current study.

AUTHOR CONTRIBUTIONS

Nicole Passia: Conceptualization (equal); formal analysis (equal); investigation (equal); project administration (equal); writing – original draft (equal); writing – review and editing (equal). **Mohamed Sad Chaar:** Data curation (equal); investigation (equal); writing – review and editing (equal). **Anna Krummel:** Data curation (equal); investigation (equal); writing – review and editing (equal). **Andreas Nagy:** Data curation (equal); investigation (equal); writing – review and editing (equal). **Sandra Freitag-Wolf:** statistical support (equal); writing – review and editing (equal). **Shurok Ali:** Data curation (equal); investigation (equal); writing – review and editing (equal). **Matthias**

Kern: Conceptualization (equal); data curation (equal); funding acquisition (equal); methodology (equal); writing – review and editing (equal).

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CONFLICT OF INTEREST

All authors declare that they have no conflict of interest.

DATA AVAILABILITY STATEMENT

Data available on request from the authors

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