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Minimally invasive approaches for implant-supported overdentures in the atrophied mandible

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Objectives: The study compares three minimally invasive approaches for the retention of implant supported mandibular complete dentures, particularly focusing on patient satisfaction.

Background: The McGill Consensus Statement recommends restoration of the edentulous mandible with an overdenture retained on two implants. Alternatively, less invasive treatment concepts with shorter treatment times have been developed for critical cases.

Material and Methods: Thirty-nine patients (with a total of 78 implants) with advanced mandibular bone atrophy were randomly assigned to three groups: "single standard implant-retained overdentures" (SSO) and "mini-implant-retained overdentures" (MO), which was further subdivided into "two mini-implant-retained overdentures" (TMO) and "four mini-implant-retained overdentures" (FMO). The technical and biological parameters and oral health-related quality of life were evaluated over a 10-year period. Data were analysed for group comparisons and longitudinal trend analysis.

Results: Sixteen patients (42%) dropped out during the study period. At the time of follow-up, 98.4% of the implants were in situ. The first need for technical intervention occurred after 3.8 ± 1.1, 4.2 ± 0.9, and 4.6 ± 1.3 years in the TMO, SSO, and FMO groups, respectively. Attachment exchange (39%) was the most frequently performed intervention in all groups. Healthy peri-implant and mucosal conditions were observed in 74% and 40% of patients after 1 and 10 years, respectively. The OHIP-G14 score was 22.6 before implantation, 7.6 at 1 year (effect size [ES]: 1.1), and 5.4 at 10 years (ES: 2.3).

Conclusion: Irrespective of the minimal concept selected, complete mandibular dentures retained on implants improved the subjective perception of the quality of life. Application of these alternative minimal concepts may be practical in clinical practice.

KEYWORDS
ball attachment, implant-retained overdenture, locator attachment, mini-implants, older adults, quality of life

1 | INTRODUCTION

Prosthetic treatment of edentulous patients remains a relevant issue in clinical practice. Conventional complete dentures are usually the first therapeutic intervention. Some patients with complete dentures are not satisfied due to anatomical conditions or difficulty in adaptation. The majority of complaints result from inadequate retention of the mandibular dentures.

According to the McGill Consensus Statement, the use of an overdenture retained on two implants is the treatment of choice if adequate retention of the mandibular denture cannot be achieved through conventional methods.[1] This can lead to improved comfort and chewing performance, resulting in increased acceptance of prostheses, satisfaction, and quality of life.[2]

The number of patients who have to undergo a high number of operations before implantation owing to a severely atrophied jawbone and those with a high risk of complications owing to general diseases increases with age. These older adults who could benefit considerably from improved retention of the mandibular prostheses tend to be reluctant about implant placement.[3,4]

Accordingly, alternative treatment strategies have been developed to reduce the surgical risk and the number and duration of treatment sessions. One such approach is the reduction of the number of abutments to one standard-sized implant in the symphyseal region.[5] These single standard implant-retained overdentures (SSO) show long-term stability if adequate planning and follow-up care are provided.[6] Chairside incorporation of attachments into existing dentures can be performed without significant effort. However, supporting the prosthesis with a single implant can have disadvantages, such as an increased risk of fracture in the attachment region or adverse static conditions due to more degrees of freedom.

Another approach is to use mini-implant-retained overdentures (MO). The insertion of two or four reduced-diameter implants (mini-implants) in the canine or premolar region is suitable for patients with a limited amount of bone.[7,8] They are usually offered by the manufacturer as one-piece implants comprising a ball-head abutment integrated into the implant with corresponding prefabricated matrices. Clinically, multiple one-piece implants may lack the ability to compensate for axial deviations.[8] Similarly, activation of worn attachment elements can be difficult with one-piece implants.

Both strategies have been clinically investigated and are valid treatment options. The primary objective is to enhance patients' quality of life. Thus, it is necessary to evaluate whether the effort required for surgical interventions justifies the improvement of oral health-related quality of life (OHRQoL) for alternative treatment strategies in the short term. Several studies have investigated this,[9–11] and long-term studies have been conducted on individual approaches with promising results.[6,12] It is important to compare these different approaches to implant-supported prostheses further to determine how they affect the quality of life in the long term, particularly in terms of wear and the associated aftercare requirements. This study compares the different approaches and their impact on the quality of life over time.

We postulated that OHRQoL would improve with clinical significance after implant retention of the mandibular overdentures, regardless of the approach used. Furthermore, we expected that OHRQoL would remain at this level throughout the observation period.

2 | MATERIALS AND METHODS

This study was conducted at the University Clinic for Prosthodontics of the Martin Luther University Halle-Wittenberg, between 2011 to 2022. It was performed in accordance with the tenets of the Declaration of Helsinki and approved by the Ethics Committee of the Martin Luther University Halle-Wittenberg (approval date: May 27, 2011).

2.1 | Patient selection

Patients with advanced mandibular bone atrophy who were dissatisfied with their existing mandibular complete denture were enrolled. The participants were legally competent patients with previous mandibular tooth extraction performed at least 3 months prior, sufficient bone volume in the interforaminal space to place implants without augmentation, and an edentulous maxilla or a maximum of three residual teeth in the maxilla. Patients with untreated severe systemic diseases, such as diabetes or osteoporosis, uncontrolled caries or periodontal disease in the maxilla, or allergies to the materials used were excluded. In addition, patients who had developed conditions after undergoing radio- or bisphosphonate therapy, those who required augmentation in the planned implant area, pregnant women, or those who were incapable of complying with instructions were excluded. All patients provided written informed consent for participation in the study.

2.2 | Material and interventions

The existing complete dentures were assessed for sufficiency before the start of the study. If necessary, the existing complete dentures were modified, or complete dentures were newly fabricated. Mandibular complete dentures found to be sufficient were duplicated in resin (3D-resin, Bredent, Senden, Germany). Possible implant positions were milled on the duplicate prosthesis, and one or more radio-opaque measuring balls (5 mm) were applied. The residual bone height was measured using an orthopantomogram with the duplicate prosthesis in place. The duplicate prosthesis was subsequently converted into a surgical guide.

The patients were randomly allocated to two groups: SSO and MO. The MO group was further subdivided into two mini-implant retained overdentures (TMO) and four mini-implant retained overdentures (FMO). Uninvolved third parties carried out the randomisation by drawing lots.

2.3 | Insertion of the single standard implants

Antibiotic prophylaxis (amoxicillin 2000 mg or clindamycin 600 mg) was performed 1 h before the start of the operation. The implants (blueSKY; length 8, 10, or 12 mm; Ø 3.5 or 4.0 mm; Bredent Medical; Senden, Germany) were placed according to the manufacturer's surgical protocol. The surgical site was visualised under local anaesthesia. Crestal drilling, pilot drilling, and implant placement were performed in the symphyseal region using a surgical guide. A saliva-proof suture closure was applied, and a final radiograph was taken immediately after insertion. The patients were abstained from prostheses for 1 week. The complete mandibular denture was adjusted 1 week postoperatively and provisionally relined with ViscoGel (Dentsply Sirona; Bensheim, Germany) if necessary. The implant was uncovered under local anaesthesia after a healing phase of at least 3 months. Osseointegration was clinically tested and the denture base was readjusted after insertion of the gingiva former. After 2 weeks, a locator abutment (SKY Locator; Bredent Medical), adjusted to the required height of 2.4–6 mm, was inserted. The matrix (Zest Anchors; Carlsbad, USA) was integrated into the denture base using Qu-Resin (Bredent Medical).

Patients in this group who reported poor retention of the mandibular prosthesis during follow-up examinations were provided with the opportunity to undergo re-implantation in the canine region.

2.4 | Insertion of reduced-diameter implants

Antibiotic prophylaxis (amoxicillin 2000 mg or clindamycin 600 mg) was performed 1 h before the start of the operation. The reduced-diameter implants (miniblueSKY, Ø 2.8 mm; Bredent Medical) were placed according to the manufacturer's surgical protocol. The surgical site was visualised under local anaesthesia. Crestal drilling, pilot drilling, and implant placement in the symphyseal region were performed using a surgical guide. A saliva-proof suture closure was applied, and the implants healed transmucosally. A final radiograph was taken immediately after insertion. The patients were abstained from prostheses for 1 week. The mandibular complete denture was adjusted 1 week postoperatively. The denture was provisionally relined with ViscoGel if necessary. After a healing period of 3 months, the implant was loaded by incorporating the matrices (Sky-O-Ring, Bredent Medical) into the denture base chairside with Qu-Resin.

Patients in the TMO group who reported poor retention of the mandibular prosthesis during follow-up examinations were provided with the opportunity to undergo re-implantation in the second premolar region, if possible.

2.5 | Follow-up examinations and test parameters

The patients were followed up quarterly at the Department of Prosthodontics of Martin Luther University during the first year after implant loading. In addition to regular dental follow-ups, probing depths (PD; 4-point measurement with periodontometer UNC15, Hu Friedy, Chicago, USA), approximal plaque index (API), and sulcus bleeding index (SBI) were examined. A radiographic examination was performed if peri-implant tissue changes were suspected.

TABLE 1 Classification of the condition of the peri-implant tissues according to the study by Schwarz et al.[12]

Classification	SBI[a]	PD[b] [mm]	Radiographic bone loss [mm]
Healthy peri-implant tissues	<1	<3	None
Peri-implant mucositis	>1	<3	None
Peri-implantitis	0–5	>3	
Mild peri-implantitis			<0.5
Moderate peri-implantitis			0.5–2
Severe peri-implantitis			2–5

Abbreviations: PD, probing depth; SBI, sulcus bleeding index.
[a]Sulcus bleeding index.
[b]Probing depth [mm].

Biological parameters were classified into four groups according to Schwarz et al.[13] (Table 1).

Technical complications, including wear of primary or secondary attachment parts, fractures of the denture base, implant fracture, or loosening of screw-retained attachments, were documented. Furthermore, the denture base's fit was checked using FitChecker (GC Germany GmbH, Bad Homburg, Germany), and relining performed if necessary.

Additionally, patients were asked to evaluate OHRQoL using the Oral Health Impact Profile (OHIP)-G14 questionnaire.[14] The summated scale was calculated based on the responses to 14 validated items. Each response was scored from 0 to 4 points. A higher OHIP score indicated a lower OHRQoL at the time of the survey and the preceding 3-month interval. The OHIP-G14 score prior to implantation was recorded as the baseline score.

The final examination was conducted after 10 years. In the meantime, due to their radius of residence and limited mobility, some patients returned to their family dentists. They were asked to carry out extensive and precise diagnostics, especially with regard to technical and biological interventions. No study protocol was recorded during this period. The transfer of the patient history was requested in writing before the last final examination. The final examination was scheduled after 10 years.

2.6 | Statistical analysis

Statistical analyses were performed using IBM SPSS Statistics 28 (IBM Corporation, Armonk, New York, USA) and MS Excel (Redmond, Washington, USA).

The primary endpoint of this study was the mean change in the OHIP-G14 score within and between the different groups. Previous studies investigated the minimum important difference (MID) between the sum scores of longitudinally completed OHIP-G14

questionnaires and identified a MID value of 2 as relevant.[15] Another approach to determine the extent of change is the calculation of effect sizes. They were calculated by dividing the mean of change scores (baseline vs. follow-up sum score) by the standard deviation of the baseline scores. Effect size statistics of less than 0.2 indicated a small clinically meaningful magnitude of change, 0.2–0.7 a moderate change, and >0.7 a large change.

The sample size was calculated based on the previously published study by John et al.[16] considering mean OHIP-G14 scores of 25 for edentulous patients and 17 for patients with removable partial dentures (SD = 9) as reference values. With a power of 0.80 and type-1 error of 0.05, the sample size was calculated as 20 per group using the formula for two independent sample studies.

The normal distribution of the collected data was determined using Kolmogorov–Smirnov and Shapiro–Wilk tests. The measured data of the two groups were compared using the log-rank test, two-factor analysis of variance, and the chi-square test. The level of statistical significance was set at $\alpha = 0.05$.

3 | RESULTS

3.1 | Descriptive statistics

From the 48 patients originally included in the study, a total of 39 patients were finally treated with 78 implants (Figure 1, Table 2). At the 1-year follow-up examination, one study participant in the SSO group had died, and one implant from one patient in the SSO group and one implant from one patient in the MO group had been removed due to the lack of osseointegration. At the final follow-up examination, 98.4% of the inserted implants of the recalled group were in situ. One patient from the SSO group and one patient from the TMO group chose the option of additional implants.

Twenty-three patients were re-examined after 10 years. Ten patients died between the 1-year follow-up and the final follow-up examination, three patients had relocated, and three could not participate in the final examination for personal reasons (Figure 1). The dropout rate was the highest in the MO group, with the TMO subgroup showing the proportionally highest dropout.

3.2 | Examination of the prostheses

The mean duration until the first intervention due to technical complications was 3.8 ± 1.1 (TMO), 4.2 ± 0.9, and 4.6 ± 1.3 years in the TMO, SSO, and FMO groups, respectively. Most technical interventions included the replacement of worn attachment parts (Figure 2).

3.3 | Examination of implants

The mean API of the follow-up differed from that of the initial study group. The API was 13 ± 26% at 1 year and 36 ± 40 at 10 years. Similarly, the PBI was 8 ± 20% in the initial study group and 23 ± 31% at 1 year to 28 ± 42% at 10 years. The highest measured PD was 2.8 ± 0.5 mm (2–4 mm) after 1 year and 3.9 ± 1.7 mm (2–8 mm) after 10 years. The average bone loss after 1 year was 1.6 ± 2.1 mm (0–2 mm) and 0.6 ± 0.3 mm (0–6 mm) after 10 years. The patients were divided into four groups based on the measured values (Table 3).

One year after implant placement, 74% of patients had healthy peri-implant and mucosal conditions. Mucositis was observed in 20% of patients. Mild periimplantitis was observed in one patient (2.6%). At the final follow-up examination, 40% of patients had healthy periodontal tissues, whereas 17% of patients had mucositis. Varying degrees of peri-implantitis were observed in 23% of patients (Table 3). There were no differences in peri-implant tissue condition between the groups ($P = .43$).

3.4 | Oral Health Impact Profile

The OHIP score reported by the study participants was used as an indicator of changes in the OHRQoL during the follow-up period. Before implantation, the average OHIP score was 22.6, which decreased to 7.6 in the first year (large effect size, see Table 4). At the final follow-up examination, the OHIP score was further reduced to 5.4 (Figure 3). Figure 4 presents the distribution of the OHIP sum values of the three groups in percentiles.

4 | DISCUSSION

The study results demonstrated a clinically significant improvement in the OHRQoL of edentulous patients following retention of a mandibular total denture on either a standard implant or a set of mini-implants. As QoL was also at a consistently high level at the final follow-up, the null hypothesis was accepted.

Prosthetic restoration has a major influence on the change of the OHIP-G14 sum score, an indicator of OHRQoL.[14,17,18] The advantage of implant-retained mandibular complete dentures over conventional mucosa-retained complete dentures in terms of support, masticatory efficiency, and quality of life has already been demonstrated in previous studies.[19–24] In our study, both the placement of complete dentures on single implants and mini-implants were found to have a positive effect on the OHRQoL of the study participants.

Since patients with ill-fitting mandibular complete dentures participated in the present study, the mean OHIP score of the study cohort at baseline was significantly higher than the average score of patients wearing a complete denture.[16] This aspect might be explained by the fact that only patients characterised by an atrophic mandible were included in this study. This prerequisite may have led to a generally worse fit of the conventional complete dentures than that in the normal population and may have resulted in a high OHIP-G14 sum score. A difference of 15 points on average was observed in the subsequent follow-up examinations. The significant

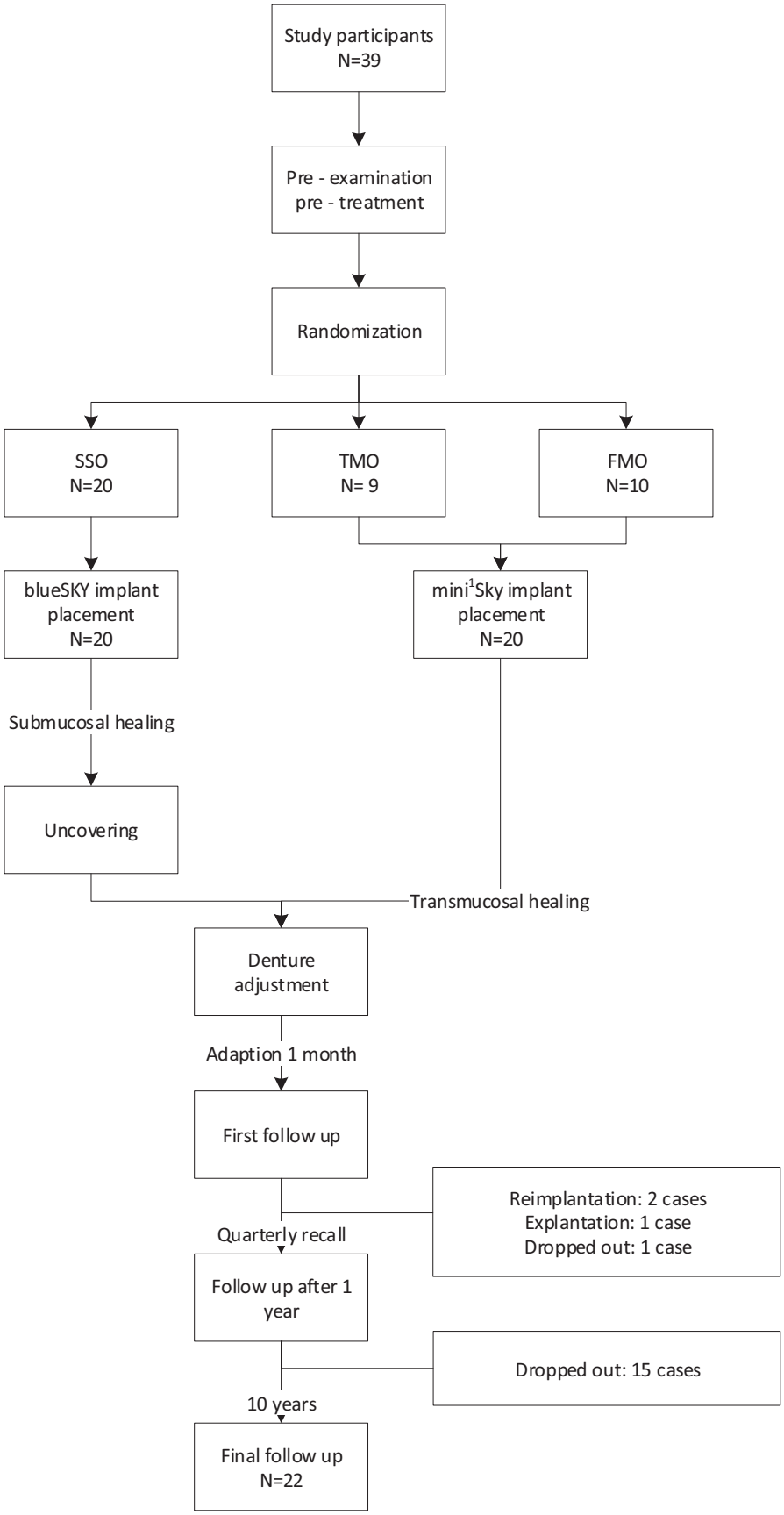

FIGURE 1 Flowchart of the study course.

difference in OHRQoL was due to the high level of dissatisfaction at the beginning of the study. Other studies that evaluated overdentures on two standard-sized implants after 1 year demonstrated comparable results in OHIP-G14, despite the patients not

being dissatisfied initially.[25,26] The average OHIP score at the 1-year follow-up examination corresponded to the normal values of patients with removable dentures attached to the remaining teeth.[16]

Moreover, in accordance with the results already described in the literature, the number of implants was of secondary importance in the present study.[27] At the time of the final examination, the OHRQoL of the MO group was comparable with the results available after 1 year. An average difference of 6 points from the 1-year follow-up examination was observed in the SSO group. This trend was also observed in other study designs.[16] This observation might be justified by the fact that for many of those affected, other factors related to increasing age may be present, which has a greater influence on general life satisfaction than does oral health.

TABLE 2 Study cohort and its distribution among the study groups.

	Baseline		1-y follow-up	Final examination
	n (♀:♂[%])	Mean age [y]	n (♀:♂[%])	n (♀:♂[%])
SSO[a]	**20 (85:15)**	**68**	**19 (89:11)**	**13 (92:8)**
MO[b]	**19 (47:53)**	**65**	**19 (47:53)**	**10 (80:20)**
TMO[c]	9 (55:45)	66	9 (55:45)	4 (100:0)
FMO[d]	10 (40:60)	67	10 (40:60)	6 (67:33)
Total	**39 (67:33)**	**66**	**38 (68:32)**	**23 (87:13)**

Abbreviations: FMO, four mini-implant-retained overdentures; SSO, single standard implant-retained overdentures; TMO, two mini-implant-retained overdentures.

[a]Single standard implant-retained overdentures.

[b]Mini-implant-retained overdentures.

[c]Two mini-implant-retained overdentures.

[d]Four mini-implant-retained overdentures.

Thus, as the OHIP-G14 sum scores at the 1-year follow-up examination did not show any significant differences between the groups, all treatment concepts were considered to have a comparable impact on the quality of life.

Additionally, implant survival rate as well as biological and technical complications did not differ between the groups during the observation period. The overall implant survival rate for all implants investigated after 10 years was 98.4% in this study. Previous studies found comparable values of 93.3% in implant survival when complete dentures were retained on two standard-sized implants, which is considered the gold standard.[28] The survival rate of single implants retaining a mandibular complete denture was also comparable with that of two implants in other studies,[5] whereas the survival rate of mini-implants was comparable with that of standard-sized implants.[29] The change in the peri-implant soft tissue conditions around the implants was comparable with the results of previous studies, irrespective of the group to which the implants belonged.[14,30]

Additionally, no significant differences were observed between the groups concerning the frequency and time of the occurrence of the first technical complication, which mainly involved the replacement of worn components. The observed time period of approximately 4 years until the frequent occurrence of technical complications related to ball or locator abutments was also consistent with that reported in other studies.[31]

However, efforts to restore prosthesis retention varied within the groups. Locator exchange was only possible in the SSO group in the cases of wear. As one-piece mini-implants were inserted in the MO group, these required an increased follow-up effort when wear of the non-replaceable primary parts occurred. In these cases, retention improvement was achieved by adjusting the retention strength of the fabricated secondary parts using alternative materials, such as attachment silicone (retention.sil,

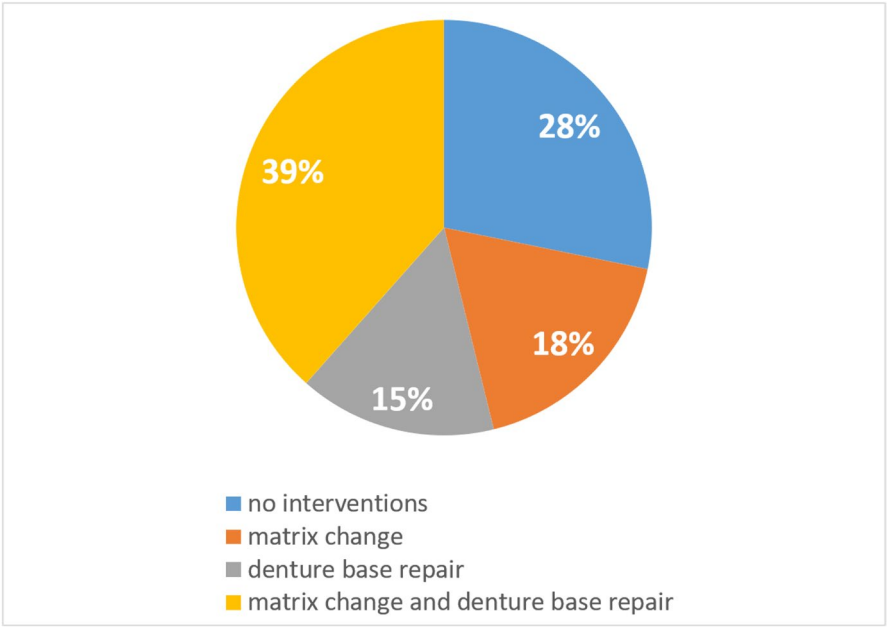

FIGURE 2 Repairs over the 10-year period. [Colour figure can be viewed at wileyonlinelibrary.com]

TABLE 3 Classification of the study group according to Schwarz et al[13] (Table 1).

	1-year follow-up			10-year follow-up		
Classification	n	Percentage [%]	Valid percentage [%]	n	Percentage [%]	Valid percentage [%]
Healthy peri-implant tissues	26	66.7	74.3	8	20.5	40
Peri-implant mucositis	8	20.5	22.9	3	7.7	15
Peri-implantitis						
Mild periimplantitis	1	2.6	2.9	4	10.3	20
Moderate periimplantitis	0	0	0	1	2.6	5
Severe periimplantitis	0	0	0	4	10.3	20
Total	35	89.7	100	20	51.3	100
Missing values	4	10.3		19	48.7	
Total	39	100		39	100	

TABLE 4 Changes in mean OHIP scores over time by group, with effect sizes.

	Baseline	1 year			10 years		
Group	OHIP G14 sum score (SD)	OHIP G14 sum score (SD)	Effect size (ES)	Effect size description	OHIP G14 sum score (SD)	Effect size (ES)	Effect size description
SSO	23.6 (13.8)	8.1 (10.8)	1.1	Large	4.9 (10.5)	1.4	Large
MO	21.6 (14.4)	7.11(11.8)	1.0	Large	6.1(6.6)	1.1	Large
TMO	12.6 (12.7)	4.3 (4.1)	0.7	Moderate	6.0 (7)	0.5	Moderate
FMO	29.7 (11.0)	9.9 (16.3)	1.8	Large	6.2 (6.1)	2.2	Large
Total	22.6 (14.0)	7.6 (11.2)	1.1	Large	5.4 (8.5)	2.3	Large

Abbreviations: ES, effect size; FMO, four mini-implant-retained overdentures; MO, mini-implant-retained overdentures; OHIP, oral health impact profile; SD, standard deviation; SSO, single standard implant-retained overdentures; TMO, two mini-implant-retained overdentures.

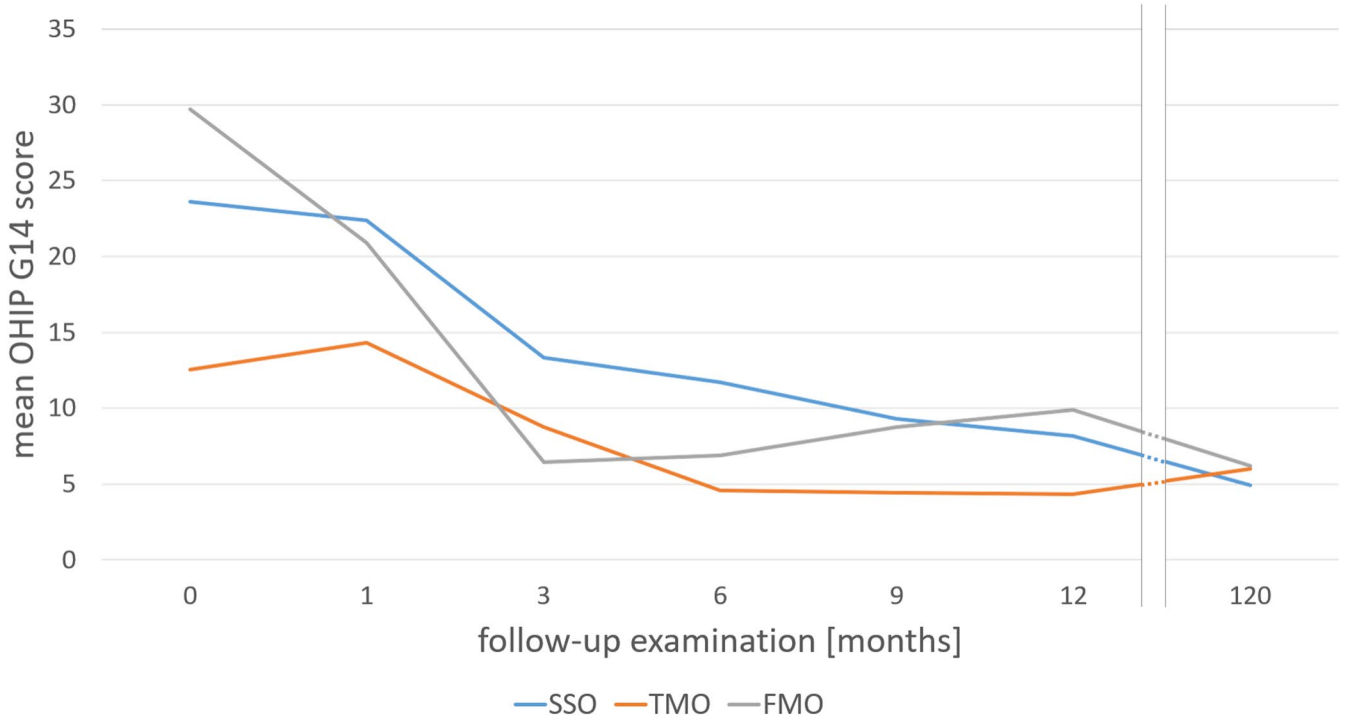

FIGURE 3 Progression of the OHIP mean value. OHIP, Oral Health Impact Profile. [Colour figure can be viewed at wileyonlinelibrary.com]

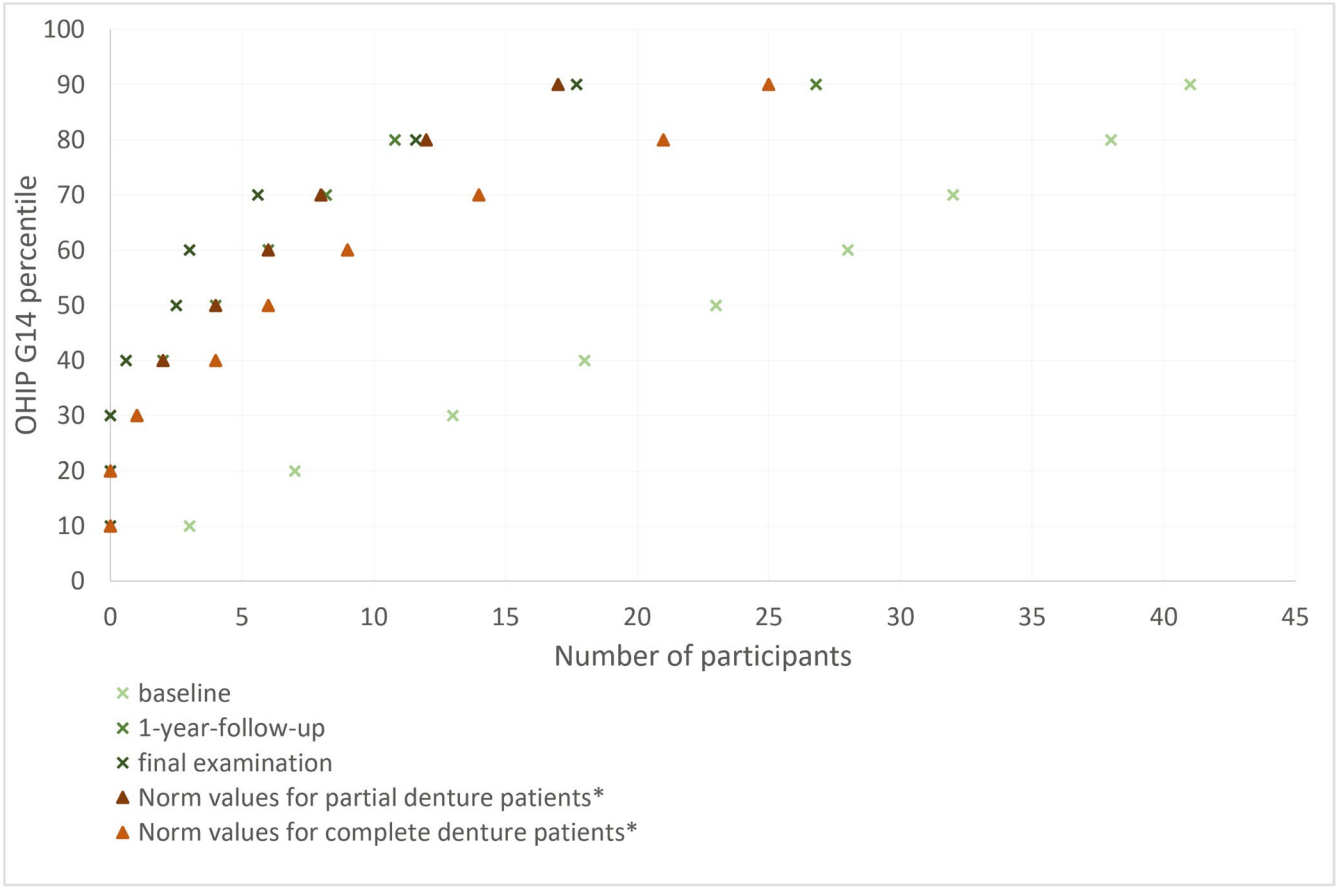

FIGURE 4 Progression of the OHIP percentile. OHIP, Oral Health Impact Profile; *, John et al[16]. [Colour figure can be viewed at wileyonlinelibrary.com]

Bredent; Senden, Germany), or by soldering metal substances. As the patients mostly were of advanced age and with limited mobility, the aim was to minimise the follow-up effort and adjust the restoration as quickly as possible chairside. From this point of view, multipiece implant systems with the possibility to change abutments in case of wear were easier to handle during the whole observation period.

4.1 | Limitations of the study

The study analysed the values recorded for survival, the need for technical interventions, and the condition of surrounding tissue to classify clinical success. Therefore, further research may be necessary to draw more definitive conclusions. It is important to note that while these values may show tendencies, the small number of subjects examined in the final follow-up precludes significant statistical analysis.

The study was designed as a pilot study. The size of the final study group was considerably lower than the sample size required to calculate statistical significance. Thus, although the dropout rate in this group of patients with a relatively high average age was comparable with that of other studies,[32,33] the long-term results can only represent an approximate clinical estimate and should be verified via follow-up studies with larger numbers of participants.

Another aspect that has to be critically discussed is the long-term absence of many patients after the first year of follow-up. The residence of the participants was distributed within a radius of 70 km from the investigation centre. After the first year of follow-up, many patients continued to be treated by their general dentists in the absence of complaints owing to the large distance from their place of residence. Thus, no midterm findings could be collected in some cases. However, as this study focused on clinical success in older adults and the satisfaction of the study participants, the results might still be regarded as clinically relevant. Nevertheless, conclusions regarding implant survival, technical complications, and peri-implant tissue changes must be evaluated critically.

Additionally, the OHIP-G14 score reflects the subjective perception of the respondents. Various individual factors influenced these responses. For example, the OHIP-G14 questionnaire was administered by members of a team of clinicians. This creates the risk that study participants will give socially desirable answers that may differ from their actual perception.[34] Ideally, a non-involved individual should administer the OHIP questionnaires. Lastly, clinical examiners diverged over the 10-year period, possibly influencing the clinical assessment of the patients' intraoral development.

5 | CONCLUSION

Clinically significant improvement in the oral quality of life of edentulous patients following retention of a mandibular total denture on either a standard implant or a set of mini-implants were observed. The significant and sustained improvement in the quality of life (combined with lower surgical effort) may outweigh the aftercare and surgical risk in older adults with an atrophic edentulous mandible. Thus, these concepts should be considered in daily clinical practice.

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CONFLICT OF INTEREST STATEMENT

The authors declare no conflict of interest.

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