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Patient satisfaction with mini-implant stabilised full dentures. A 1-year prospective study

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SUMMARY **The purpose of this study was to evaluate patient-centred outcomes with regard to function and comfort after placement of mini-implants for stabilisation of complete dentures. The trial was designed as a prospective cohort of 12-months duration and involved 21 subjects in the age of 50–90 years having a full denture in the maxilla or the mandible with poor stability during function. Flapless installation of 2–4 narrow-body Dentatus Atlas® implants was performed and retention for the existing denture was obtained by the use of a silicone-based soft lining material (Tuf-Link®). Patients' judgement of perceived satisfaction with function and comfort of the dentures was recorded at baseline, 1- and 12-months post-treatment using 10-centimetre visual analogue scales (VAS) and a questionnaire. Clinical examination of the conditions of the peri-implant soft tissues was performed at 12 months. Nineteen of the 21 patients were available for the 12-month follow-up examination. The two drop-out subjects lost all implants within 1 month and rejected retreatment. Further six subjects lost 1–2 implants, but were sucessfully retreated by insertion of new implants. Overall satisfaction, chewing and speaking comfort were all markedly improved from pre-treatment median VAS scores of around 4–5 to median scores of 9·0–10 (10 = optimal) at the final examination. The prevalence of positive answers to questions regarding stability/function of the denture increased significantly to almost 100% for all questions. Treatment involving maxillary dentures and the use of short implants (7–10 mm) was associated with an increased risk of implant failure. The results indicate that placement of mini-implants as retentive elements for full dentures with poor functional stability has a marked positive impact on the patients' perception of oral function and comfort as well as security in social life.**

KEYWORDS: **case series, dental implants, dentures, mini-implants, prospective**

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Introduction

Although most subjects wearing a complete denture may be fairly satisfied with function and aesthetic of their prosthesis, a significant percentage of subjects complains about poor speaking and chewing comfort due to poor stability of their denture (1). In case of pronounced alveolar ridge resorption, relining or redoing, the denture may not be sufficient to satisfy the patient's demands (2, 3).

The placement of implants to support the full denture (overdenture treatment) can be an effective approach to improve elderly patients' chewing ability (4, 5), speaking comfort and overall satisfaction with the denture (6, 7). In a recent report from a consensus meeting (8), the implant-supported overdenture was considered to be the preferred treatment option for rehabilitating patients with edentulous mandibles. Furthermore, a recent meta-analysis (9) concluded that, compared with removable full dentures, an implant-retained overdenture is more satisfying for the patient, but its impact on the quality of life needs to be evaluated. However, the cost of this type of treatment solution is often an obstacle

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for the patient (10). Furthermore, in patients with a markedly resorbed alveolar process, bone augmentation surgical procedures may be required for implant placement, with the consequence of an increase in costs and total treatment time. Moreover, edentulous elderly patients often present with compromised medical conditions that may preclude more advanced surgical interventions. In fact, a main reason for declining implant treatment, even when offered for free, is fear of pain and complications (11, 12).

In case of a markedly resorbed bone crest, the use of narrow-body implants may offer an alternative to bone augmentation procedures (13–22). A recent literature review (23) reported no significant difference in failure and complication rates between narrow-body implants and standard-diameter implants.

Narrow-body implants/mini-implants (<3·0 mm in diameter), initially used to support temporary reconstructions (24, 25) and for orthodontic anchorage (26), have the advantage to be easily installed with a flapless surgery (27), thereby reducing surgical time and post-operative discomfort (28). Mini-implants have also been used to support overdentures (5, 27, 29–32). Potential advantages of this treatment alternative for the edentulous patient were suggested to be a reduction in treatment time, surgical discomfort and costs (33, 34). However, limited information is available in the literature with regard to patient-centred outcomes of the treatment.

The aim of this study was to evaluate whether the placement of mini-implants (diameter 1·8–2·4 mm) for stabilisation of full dentures may improve patient-centred outcomes with respect to satisfaction with function and comfort of the full denture.

Material and methods

Study design

The trial was designed as a prospective cohort of 12-months duration and conducted at two centres. The Committee on investigations involving human subjects at the University of Gothenburg approved the study protocol (Dnr 191-09). All patients were given oral and written information in lay terms describing the purpose and design of the study and a signed consent was obtained before patients were entered into the study. The study was carried out in accord with the recommendations of the Helsinki declaration.

Study sample

A power calculation revealed that a sample of 20 subjects would give a power of 80% of detecting as significant ($P < 0{\cdot}05$) a difference in terms of discomfort of 30% between two interview occasions.

The target population was subjects in the age of 50–90 years having a complete denture in the maxilla and/or the mandible with poor stability during function.

Subjects were entered into the trial based upon the following criteria:

1 Dissatisfied with the function of the denture due to poor stability in function.
2 Available for scheduled appointments.

Subjects who had been subjected to radiation therapy to head or neck were excluded from participation, but no other medical conditions (i.e. cardiovascular disease, rheumatoid arthritis, diabetes, osteoporosis), medications or smoking were considered as reasons for excluding the patient unless there were contraindications for the use of local anaesthetics.

Treatments procedure

Before the start of study, the operator at each participating centre attended a training session on the treatment and examination procedures to be used.

After a screening examination including a panoramic or a 3-dimensional radiographic examination to evaluate the dimensions of the jaw, the fitting of the removable full denture was evaluated. If considered poor, an impression was taken to reline the denture at a dental laboratory. Re-evaluation was performed after 1 month to collect baseline data and confirm the need and willingness to have implant treatment performed.

Following local subperiosteal anaesthesia, four narrow-body implants (Dentatus Atlas®*) were placed in the anterior segment of the jaw according to the manual of the manufacturer (Fig. 1). Because of anatomical limitations, one patient received only

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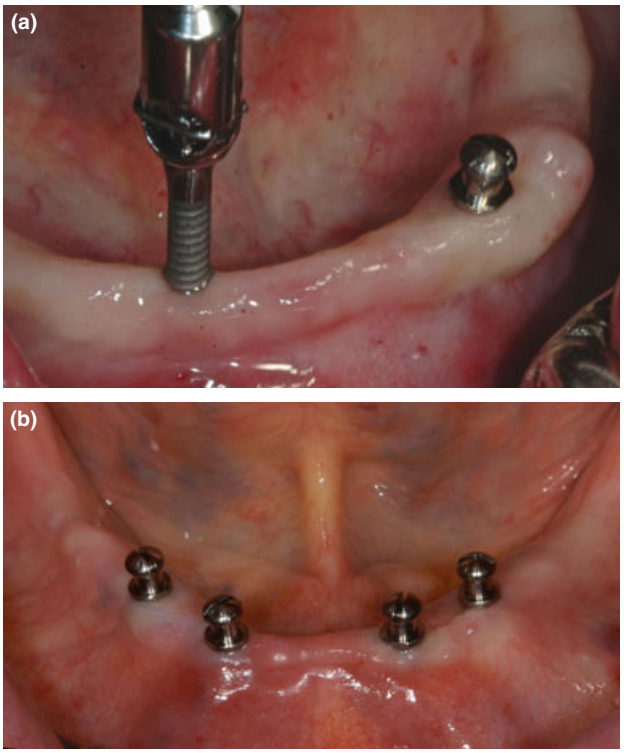

Fig 1. (a) Photos illustrating the flapless implant placement and (b) the appearance immediately following the completion of the treatment.

three implants and one patient two implants. No flap was elevated; however, in some cases, a small crest incision was performed to access the bone crest. Following placement, the implant with its coronal ball design as a retentive element for the denture extended about 3 mm above the level of the mucosa. Appropriate space was prepared in the denture with a specifically designed bur (Fig. 2) to allow for immediate replacement of the denture without direct contact with the resin base. The prepared concavities in the denture were filled with a 2-component soft reliner (Fig. 3) (Tuf-Link®*), and the denture was replaced on the implants. After polymerisation, any excess of reliner was removed. The time required for completion of the treatment was recorded.

The patients were instructed not to remove the denture for 3 days. Careful instructions regarding subsequent daily cleaning of the denture and the implants were given. After one week, the patients were recalled for control of the stability of the denture and oral hygiene reinstructions if indicated.

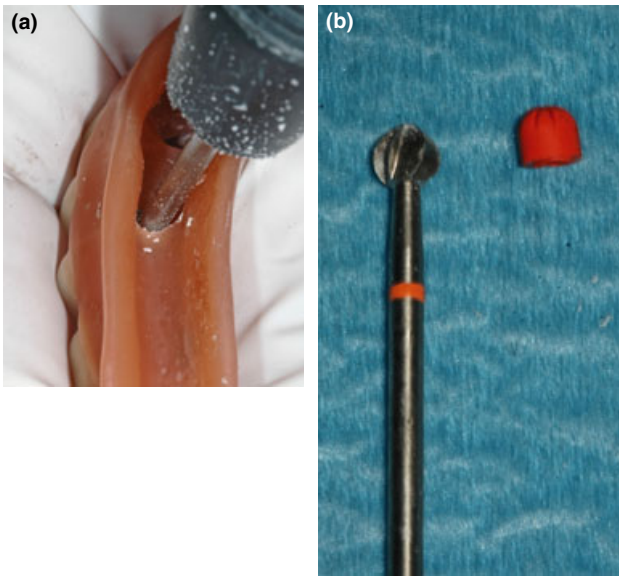

Fig. 2. Preparation of retentive space for the resilient silicone. On the right, one of the specifically designed burs for space making.

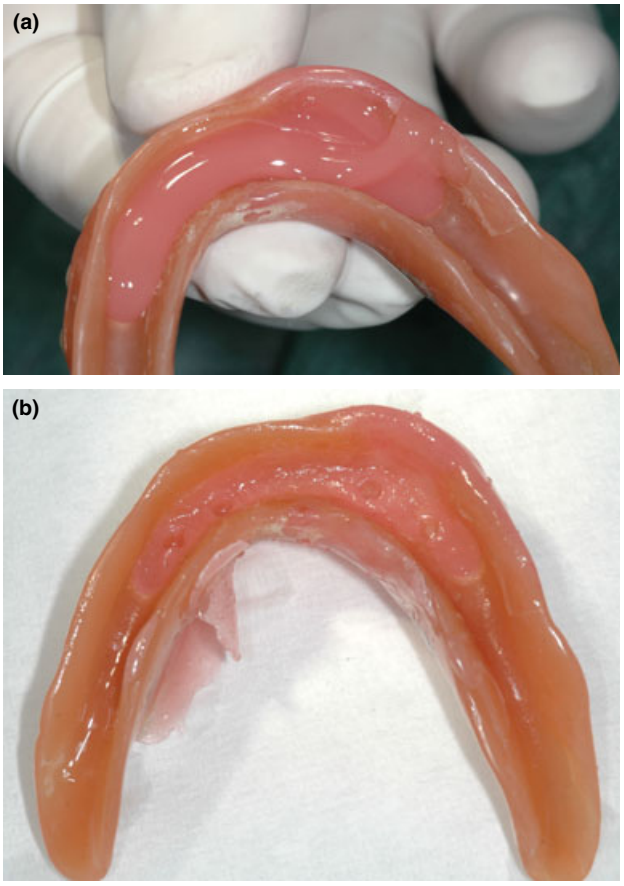

Fig. 3. The silicon inserted before placing the denture in the mouth and after polymerisation before removing the excess.

Examinations and assessments

Patient-centred outcomes. Degree of perceived satisfaction with the full denture was judged by the patient using 10-centimetre visual analogue scales (VAS) and yes/no questions and recorded at baseline, 1- and 12-months post-treatment. A dental assistant distributed the questionnaire.

VAS scorings:

1 How would you rate your overall satisfaction with the function of your denture?
2 How would you rate your chewing ability with your denture?
3 How would you rate your ability to speak with your denture?
4 How would you rate your overall discomfort with your denture?

Questions with yes/no answers:

1 Are you satisfied with your denture?
2 Can you chew properly any food?
3 Does the denture move during chewing?
4 Do you get food particles under the denture during chewing?
5 Do you have problems in pronouncing certain words?
6 Does the denture move while you are speaking?
7 Do you feel comfortable with your denture in social life?
8 Have you experienced pain from the mucosa under the denture?

In addition, any adverse events (pain, swelling) and use of drugs for post-treatment pain control were recorded at the 1-month re-examination.

Clinical assessments. At 12-month post-treatment, the following variables were assessed at four aspects around each implant and the highest score/value was recorded:

1 *Plaque score:* absence/presence of plaque at the tissue margin (35).
2 *Bleeding on probing (BoP):* absence/presence of bleeding following superficial probing.
3 *Probing depth:* the distance between the soft tissue margin and bottom of the probeable pocket measured with a mm-graded Hu-Friedy PCP15 periodontal probe.

In addition, *implant stability was judged by percussion.*

Data analysis

The data were collected in an Excel sheet and analysed using SPSS statistical software (20.0†). Descriptive data analyses included mean value and standard deviation for continuous variables, median and interquartile (IQ) range for nonparametric variables, and frequency distribution for dichotomous variables. Difference between the baseline and the 1- and 12-month examinations was tested with the nonparametric Friedman test for multiple-related group comparison and *post hoc* comparison with Mann–Whitney *U*-test with Bonferroni correction, while McNemar test for related samples was used to test the distribution of dichotomous variables. A correlation analysis was run to test potential relationships between implant failure and jaw of treatment and implant length. A P-value $< 0{\cdot}05$ was considered as statistically significant.

Results

Twenty-three subjects complaining about poor stability and discomfort of the denture were after the screening examination recruited for the study. After having received detailed information about design and content of the study, two subjects decided not to participate. Thus, 21 patients were treated and included in the analysis.

The demographic characteristics and anamnestic information of the patient sample are given in Table 1. The mean age was 71 years and 57% were women. Thirteen of the 21 patients (61%) presented with compromised health conditions and considered themselves not in a condition to receive conventional

Table 1. The subject sample-demographic and anamnestic data at baseline

Age, mean (range)	71 (54–85)
Females/Males	12/9
Smokers	3
Medical conditions	
Taking medication	13
Cardiovascular disease	6
Rheumatic problems	5
Diabetes	1
Dry mouth	4

†IBM Svenska AB, Stockholm, Sweden.

implant surgical treatment. For the other patients, economic restrictions (29%) and fear of surgical treatment (10%) were reasons to accept involvement in the study. The average treatment time was 45 min (SD 18·5) for the implant placement and 30 min (SD 11·9) for the relining of the denture.

Table 2 reports all complications recorded during the study interval. Eight patients experienced loss of implants (primarily during the first 3 months). Six of these patients were successfully retreated by placement of new implants. Two patients who lost all their implants (one maxillary and one mandibular case, each with four implants) refused retreatment and were dismissed from further follow-up.

At baseline (pre-treatment), the median value for the patient-rated chewing ability with their dentures was 4·5 (IQ range 1·8–4·9) on the 10-cm VAS scale (Table 3). Ninety-one percentage of the subjects experienced that the denture was moving during chewing and 86% that food particles often were trapped under denture. Forty-three percentage of the patients felt uncomfortable in social life due to poor stability of the denture. The median VAS score with regard to the ability to speak with the denture in place was 5·8 (IQ range 1·7–7·7), and the degree of overall satisfaction with the denture was 3·3 (IQ range 1·8–5·8) on the 10-cm VAS scale.

The placement of mini-implants to support the full denture resulted in a marked improvement of the patients' perception of function and comfort (Table 3). All patients (the two cases with loss of all implants excluded) reported an improved chewing and speaking comfort at the 1-month follow-up examination; increase in median VAS score from 4·5 to 9·3 (IQ

Table 2. Description of treatment and complications for each patient.

Pat #	Jaw	No. of implants placed	Lost implants	Other complications	Comments
1	Mand	4	1 after 1 month	–	Lost implant replaced and maintained at 12 months
2	Mand	4	0	–	–
3	Mand	4	0	–	–
4	Max	4	1 after 3 weeks 3 after 1 month	Patient had pain but no swelling	Patient refused retreatment
5	Max	4	0	–	–
6	Max	4	1 after 1 month 1 after 5 months	–	Lost implant replaced and maintained at 12 months The second lost implant not replaced because the patient was satisfied with the stability of the denture
7	Mand	4	0	–	–
8	Mand	4	1 after 2 months	–	Lost implant replaced and maintained at 12 months
9	Mand	4	0	–	Mandible extremely atrophic
10	Mand	4	1 after 1 week	Swelling during healing	Lost implant replaced but lost after 3 months Severely compromised general health status
11	Mand	4	0	–	–
12	Mand	4	1 after 2 weeks 1 after 2 months 2 after 4 months	Considerable pain for 2–3 weeks after implant placement	Patient refused retreatment
13	Mand	4	0	–	–
14	Mand	4	0	–	–
15	Mand	4	1 after 1 week	–	Implant was placed close to an extraction socket. Lost implant replaced and in function at 12 months
16	Mand	4	0	–	–
17	Mand	4	0	–	–
18	Mand	3	2 after 2 weeks	Lateral perforation of the bone during implant placement	Very narrow ridge. Lost implants replaced and maintained at 12 months
19	Mand	4	0	–	–
20	Mand	3	0	–	–
21	Max	2	0	–	–

Table 3. Results with regard to the patients' judgement of satisfaction with the denture

Questions	Pre-treatment (n = 21)	1 month (n = 19)	12 months (n = 19)
Can you chew properly any food? (% with 'yes' answer)	33%	100%	100%
Does the denture move during chewing? (% with 'yes' answer)	91%	0%	0%
Do you get food under the denture during chewing? (% with 'yes' answer)	86%	21%	21%
How would you rate your chewing ability with your denture?* (median and IQ range)	4·5 (1·8–4·9)	9·3 (9·0–10)	9·0 (8·9–10)
Do you have problems in pronouncing some words? (% with 'yes' answer)	52%	0%	0%
Does the denture move while you are speaking? (% with 'yes' answer)	57%	0%	0%
Do you feel comfortable with your denture in social life? (% with 'yes' answer)	57%	100%	100%
How would you rate your ability to speak with your denture?* (median and IQ range)	5·8 (1·7–7·7)	10·0 (9·0–10)	9·3 (8·9–10)
Have you experienced pain from the mucosa under the denture? (% with 'yes' answer)	29%	5%	5%
How would you rate your overall discomfort with your denture?† (median and IQ range)	5·4 (2·2–7·7)	10 (9·1–10)	10 (8·9–10)
Are you satisfied with your denture? (% with 'yes' answer)	52%	100%	100%
How would you rate your overall satisfaction with the function of your denture?‡ (median and IQ range)	3·3 (1·8–5·8)	9·8 (8·9–10)	9·0 (9·0–10)

*10-cm VAS scale: 0 = Very poor, 10 = Without problem.
†10-cm VAS scale: 0 = Terrible, 10 = None at all.
‡10-cm VAS scale: 0 = Very dissatisfied, 10 = Fully satisfied.

range 9·0–10) and from 5·8 to 10 (IQ range 9·0–10), respectively (10 = optimal). The rating of the overall satisfaction increased to 9·8 (IQ range 8·9–10). The improvement between baseline and 1 month was statistically significant for all dichotomised questions (McNemar test) as well as for the VAS scale evaluations (paired t-test with Bonferroni compensation for multiple testing). Between the 1-month and 12-month follow-up examinations, no statistically significant changes were observed. At the final examination, the ratings of overall satisfaction, chewing and speaking comfort showed median scores of 9·0–10 on the 10-cm VAS scale and all yes/no questions revealed marked positive patient-centred outcomes of the treatment.

The clinical conditions of the implants at the 12-month examination revealed a subject mean plaque score of 20%, a mean bleeding on probing score of 30% and a mean pocket probing depth of 2·3 mm (range 1–6 mm). All implants were judged by clinical evaluation to be stable.

Of the total of 16 implants that were lost (20% of initially placed implants), 11 implants (69%) were lost within the first month after placement. The implant failure rate was significantly higher in the maxilla than in the mandible (43% versus 15%, Spearman correlation analysis P = 0·009; Table 4). Furthermore, the analysis revealed a significant negative correlation between the length of the implant and failure rate (P = 0·013; Table 5).

Discussion

The present study was designed as a prospective cohort with the focus on patient-reported outcome measures of the treatment with mini-implants as retentive elements for dentures with poor functional stability in edentulous patients. The results demon-

Table 4. Cross tabulation of failed implants versus jaw

	Failed implants		
	No	Yes	Total
Jaw			
Maxilla	8	6	14
Mandible	56	10	66
Total	64	16	80

Significant correlation between jaw and failure ratio (Spearman) P = 0·023.

Table 5. Cross tabulation of failed implants versus implant length (Long = 14 mm, Medium = 10 mm, Short = 7 mm)

	Failed implants		
	No	Yes	Total
Implant length			
Long	29	1	30
Medium	26	13	39
Short	9	2	11
Total	64	16	80

Significant correlation between implant length and failure ratio (Spearman) $P = 0{\cdot}009$.

strated a marked improvement in chewing and speaking comfort and a high degree of appreciation of the perceived overall improvement following treatment.

Implant-supported overdenture treatment in general is reported to have great acceptance by the patients (7, 9). In the present study, however, the denture was not attached to the mini-implants and hence not giving any occlusal support, but the soft silicone adaptation of the existing denture to the implants prevented the displacement during function. All patients referred to feel safer with regard to the risk of dislodgment of the denture when speaking and eating, evaluating it as a great improvement in comfort in comparison with their experience of years with an unstable denture. In this respect, our observations support a previous report by Griffitts *et al.* (30). showing markedly improved comfort, retention, chewing and speaking ability following placement of mini-implants as an adjunct for retention of dentures in edentulous patients. Furthermore, recent studies by Elsyad and co-workers showed that the use of a resilient soft reliner improved patient comfort and reduced soft tissue complication compared with the use of clip attachment over bars (36, 37). Taken into consideration the positive patient-centred outcomes, and the reduction in treatment time with this treatment approach compared with standard implant-supported overdenture therapy, the use of mini-implants and a resilient soft reliner as alternative means for retension/stabilisation of a full denture is promising. Elderly patients often are anxious for perceived risks with surgical intervention and for this reason reject a conventional implant-supported overdenture treatment (11). In our study, one session of a mean treatment time of 1·5 h was sufficient to provide stability to the patient's existing denture, and for none of the cases, the total treatment time exceeded 2 h. In addition, as calculated in the publication by Griffitts *et al.* (30), the cost estimation for treatment with mini-implants is significantly lower than for standard implants with attachment retentions.

Although the results of our and other studies point to the usefulness of this treatment approach for improved retention and stabilisation of the dentures in edentulous patients with markedly reduced dimensions of the alveolar process, further studies including larger cohorts and longer follow-up periods are indicated to assess the long-term prognosis of the treatment. More difficult would be to design a randomised controlled trial, as this category of elderly patients often is anxious for perceived risks with an invasive surgical procedure, or consider their general health conditions as too compromised, and therefore reject a conventional implant-supported overdenture treatment (11).

In comparison with previous studies on the use of narrow-body implants or mini-implants as an adjunct for retention of full dentures (29, 30, 33, 38), a comparatively higher rate of implant failures was observed in the current study, and for two of 21 patients treated (10%), the treatment was a failure with loss of all inserted implants. The difference in reported implant failure rate may partly be related to the selection of patient samples and jaws treated. Analysis of the implant failure rates for maxillary and mandibulary jaws revealed a significant difference in the current study; 43% in the maxilla compared with 15% in the mandible. In the edentulous maxilla, the cortical walls are usually thinner than in the mandible, which might result in inferior primary stability of the implants. In fact, a majority of the implant failures occurred during the early phase of follow-up.

Furthermore, as the clinicians who performed the treatment had no or only limited previous experience with the treatment method, some of the early implant failures may have been related to inadequately prepared spacing for the implants in the denture, resulting in excessive load to the implants during the healing phase. It should also be recognised that most of patients presented with poor self-retention of the denture due to severe resorption of the alveolar bone ridge.

A recent study in which six mini-implants were installed to stabilise full maxillary dentures with or without palatal coverage also reported high implant

failure rates; 21·6% and 46·2%, respectively (39). The authors attributed the high failure rate to facial angulations of maxillary implants, a thick masticatory mucosa that necessitated longer implant abutments, and disparallelism of the unsplinted implants that may have produced micromovements in conjunction with multiple insertions and removals of the prosthesis.

The short- and medium length mini-implants (7–10 mm) presented a higher failure rate than the long mini-implants (14 mm), 38% versus 3%. The fact that the use of the long implants in the replacement of the lost implants resulted in maintenance of the implants in proper function throughout the observation period further indicates that long implants should be selected for the best prognosis of the treatment.

In conclusion, the placement of mini-implants as retentive elements for full dentures with poor functional stability had a marked positive effect on the patients' perception of oral function and comfort as well as security in social life. However, the treatment approach may be less predictable in the maxilla and with the use of short implants (7–10 mm).

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