

# Maxillary 3-implant removable prostheses without palatal coverage on Locator abutments – a case series

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**Running title:**

3-implant maxillary removable prosthesis

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## Abstract

**Objectives:** To present the clinical outcomes of patients with an edentulous maxilla treated with a removable prosthesis without palatal coverage retained by Locator abutments on three titanium implants. **Material and Methods:** All the patients in a private dental clinic consecutively treated up to six years earlier were invited for a follow-up examination (n=23). Two implants were placed bilaterally and one implant anteriorly in a tripod pattern. All patients underwent a clinical and radiological examination and completed questionnaires related to their experiences and satisfaction with the reconstructions. The prosthesis and implants were examined for adverse biological or technical aspects. Patient satisfaction and quality of life outcomes were collected using a self-reported Denture Satisfaction Scale and OHIP-20. Statistical analyses were limited to descriptive statistics. **Results:** Twenty-one of 23 invited participants consented to participate. We report in this paper the outcomes of the study participants who had received their implants more than 2 years ago (n=12). None of their 36 implants gave any indications of mobility or tenderness upon percussion. Suppuration was observed on one implant. Probing around the implants caused no (53%) or minor bleeding (47%). The incidence of adverse biological and technical events was near non-existent. The rates of replacement of male attachments varied, as did any changes of male attachment retention force. All participants described the task of insertion and removal of the prosthesis as unproblematic. The marginal bone loss ranged between 0 and 5.3 mm. The OHIP-20 and the Denture Satisfaction Questionnaire scores were high. **Conclusions:** The results in this clinical study are positive and promising. Admittedly, the study design is purely retrospective and observational with a small participant cohort, so the technical solution of placing three implants in the edentulous maxilla to retain a removable prosthesis should be appraised further in more controlled studies.

Keywords: Dentures; Follow-Up Studies; Edentulous; Patient Satisfaction; Quality of Life; Retrospective Studies; Self Report; Titanium

## Introduction

Patients with a fully edentulous maxilla who desire an implant-retained prosthesis may receive different treatments, depending on general and local conditions (Zarb et al. 2013). The literature abounds with descriptions of technical solutions, ranging from a fixed solution retained by 4 axial or tilted implants and upwards (Heydecke et al. 2012) or a removable solution supported by 2 up to 10 splinted or free-standing implants (Roccuzzo et al. 2012). Initiatives to define the standard of care for the fully edentulous maxilla by critically appraising and comparing the cost-effectiveness of different prosthodontic solutions have not yet reached consensus (Schley et al. 2011).

Patients restored with a maxillary removable prosthesis appear to require more maintenance visits when the prosthesis is retained by two splinted or free-standing implants in comparison to four implants that have been splinted with a cast or milled bar (Slot et al. 2010, Raghoobar et al. 2014). Whether the costs associated with the additional maintenance needs in the end outweighs the added costs of two additional implants and bars is still uncertain (Stoumpis & Kohal 2011, Bassi et al. 2013, Dudley 2013). Moreover, current reviews on this topic refer to data from primary studies where the non-splinted implants were fitted mostly with ball attachment systems of various designs, which likely have introduced confounding by virtue of variations in resistance against wear and degradation in the oral environment (Alsabeeha et al. 2009).

In late 2007, two patients were referred to a private specialist clinic practice in Norway where the three first authors of this paper are affiliated (A.M., C.H. & H.O-B.). The two patients wished to restore a fully edentulous maxilla with a prosthesis supported by implants. Both patients expressed a desire for a fixed solution. However, it became clear during the clinical examinations that only a few intraoral positions were suitable for a surgical placement of a dental implant without prior surgical site enhancement. Both patients were reluctant to endure augmentation surgery to enable the placement of several implants to retain a complete fixed dental prosthesis. At the time, one systematic review had concluded that the evidence foundation for choosing the optimal design for a maxillary removable prosthesis was limited only to ball- and bar-solutions, as well as weak and rather contradictory (Sadowsky 2007). However, another

contemporaneous paper describing results of a small case series alleged that stud-type attachments on four or six unsplinted implants could successfully retain a maxillary removable prosthesis without a palatal coverage (Cavallaro & Tarnow 2007). The concept of a palate-free prosthesis appealed to both patients.

From a clinical perspective, the prevailing consensus on standard of care at the time was that the implants had to be minimum 10 mm long, and placed surgically with a best possible relative parallelism and perpendicularly to the axial load vector. A second element was to achieve a maximal anterior-posterior spread of the implants intraorally. For the two patients, however, combining these requirements with the anatomical constraints in the edentulous maxilla allowed only space for the placement of three implants. After weighing up the positive aspects versus risks of possible adverse outcomes, both patients agreed with the surgeon-prosthodontist team to plan for a removable prosthesis without a palatal coverage retained by three free-standing implants fitted with Locator abutments (Zest Anchors, LLC, Escondido, CA, USA) (Figure 1).

At the first recall examination after the completion of the treatment, both patients reported remarkably high satisfaction with their new prosthesis. The positive outcomes prompted therefore the clinicians to provide the same solution for a third and fourth patient with limited bone and unwilling to undergo bone augmentation surgery. Although anecdotal, the clinicians perceived the treatment approach as beneficial, while the incidence of patient-reported problems seemed minor. The technical solution was therefore subsequently offered to other patients who for different reasons decided not to proceed with site augmentation to enable placement of multiple implants in the maxilla.

The objective of this report is to present the clinical outcomes of the first 21 consecutive patients with an edentulous maxilla treated with a removable prosthesis without palatal coverage retained by Locator abutments on three implants, one placed in the central incisor region and the two other in a more or less equilateral distance from the central implant.

## Materials and Methods

The Norwegian regional research ethics board approved the research protocol prior to commencing the study (ref. 2013/1446/REK Nord). All the patients in a private dental clinic consecutively treated with a maxillary removable prosthesis without palatal coverage supported by three dental implants were invited to participate in a follow-up examination (n=23). The patients received a free implant hygiene session and prosthesis cleaning, but no fiduciary compensation. Additional information required from the participants in this clinical study beyond routine care was a request to submit two treatment satisfaction questionnaires. The questionnaire response data were managed according to directives established by the Norwegian patient privacy ombudsperson.

The current study cohort consists of all consecutive patients with an edentate maxilla, alternatively with terminal maxillary teeth, restored with a removable prosthesis without palatal coverage retained by Locator abutments on three implants. The patients with terminal teeth received in all cases an interim immediate prosthesis while the jaw healed for 3 to 5 months prior to implant surgery. None of the patients received any form of site augmentation or extraction socket grafting.

The patients received commercially available implants made from titanium with a microrough surface surgically placed according to the manufacturer's instructions.

During 2007 to 2010, implant systems from 3 different manufacturers were used, i.e., Osseospeed (Astra Tech, Mølndal, Sweden), Osstem (Osstem, Seoul, Korea) and Straumann SLA tissue level and bone level implants (Straumann, Waldenburg, Switzerland).

In brief, the surgical procedures included antibiotics use at the discretion of the oral surgeon, local anesthetics, full flap incisions, placement of two implants bilaterally and one implant anteriorly with relative parallelism in sites considered radiographically to have the best bone. Hence, the implants were placed in the 15-13, 12-22 and 23-25 regions. At the onset around 2007, emphasis was made to place the implants with the best possible relative parallelism perpendicularly to the axial loading, but this constraint became less rigid few years later. All implants were located submerged under the

mucosa during the healing period, while the existing removable prosthesis was relieved and lined with a soft silicone-based reline material (GC Reline Soft, GC Corp., Leuven, Belgium). After approximately 3-4 months of healing, Locator abutments (ZEST Anchors, Escondido, CA, USA) were fitted to the implants, and new prostheses were made from heat-cured poly-methyl-methacrylate. All prostheses were reinforced with a metal alloy framework made from cobalt-chromium. All prostheses were constructed with prefabricated acrylic teeth (Premium and Mondial PALA Teeth, Heraeus Kulzer GmbH, Hanau, Germany) designed with a bilateral balanced occlusion, which were in a few situations lingualized due to the dentition of the mandible, and without anterior contacts in habitual occlusion.

All prostheses incorporated three Locator male attachments with active retention, i.e., 680 (blue), 1361 (pink) or 2268 (clear) grams of retentive force. The choice of the male attachment retentive force was based principally on the patient-reported ease of placing and loosening their prosthesis.

All patients were taught how to practice optimal home oral care, explained the need to seek regular maintenance care and requirement to uphold good oral hygiene. All patients were invited to return to the specialist clinic practice for follow-up dental care, or to continue to receive dental care from their regular dentist.

### Base-line recording

Before the commencement of treatments, all patients had self-reported general health conditions that could entail risk of adverse outcomes. Recordings were made of general and local factors that could affect the prognosis of the implants and prosthesis, including the occurrence of systemic disease, regular medication use and smoking status. Pre-surgery and post-operative panoramic radiographs taken at the day of implant surgery, complemented with radiographs taken at the second-stage surgery upon the connection of abutments.

### Follow-up examinations

All patients underwent a clinical and radiological examination and completed questionnaires related to changes in general health aspects, as well as their

experiences and satisfaction with the reconstructions and eventual need for repair sessions during the last year.

### **Intra-oral status**

The radiographic examination comprised an orthopantomogram. The clinical examination included a basic periodontal examination with the use of an UNC-15 (University of North Carolina) manual periodontal probe. Outcomes measured were the presence or absence of peri-implant suppuration or fistula, the modified plaque and sulcus bleeding indices (Mombelli et al. 1987) and the probing depth (Buser et al. 1990).

### **Examination of prosthesis and implants**

The removable prosthesis was carefully examined for any technical flaws. Adverse technical events included loss of retention, or fracture and/or chipping of the removable prosthesis. Adverse mechanical events included loosening of the male attachment or fracture of an implant. The stability of all implants was assessed, and any sign of mobility along with pain and discomfort was interpreted as a definitive sign of implant failure.

The male attachment were replaced with new attachments of the same or more retentive force if the patient reported problems with placing and loosening their prosthesis, or complaints of dislodgment during function. The patients were also advised to replace the attachments in case of noticeable wear facets or ledges on the central pillar of the nylon attachment. The detached male attachments rings were not subjected to further detailed examinations

### **Patient satisfaction and quality of life outcomes**

Patient-based outcomes were collected using a self-reported Denture Satisfaction Scale (Allen et al. 2001) and the short form version of the Oral Health Impact Profile questionnaire (OHIP-20) (Allen & Locker, 2002). The scores from the Denture Satisfaction Scale were analyzed globally and related to functional status. The OHIP scores was also analyzed globally and next divided into function-related questions as well as questions related to psychosocial issues. Sub-scale scores were created by summing the responses to the respective questions.

## Radiographic analyses

All radiographs were analyzed by using public domain software (ImageJ, U.S. National Institute of Health, USA) by an independent examiner. Reference bone levels on the mesial and distal sides were determined by measuring the distance between the implant platform and the most apical point of the alveolar crestal bone surrounding the implant. The loss in crestal bone height in relation to the implant shoulder over the observation period was calculated relative to the bone level measured on the radiographs made at the time of implant placement, alternatively at the time of abutment placement.

## Statistical analyses of clinical and radiographic parameters

Statistical analyses were limited to descriptive statistics applied on the clinical and radiographic data, and questionnaire outcomes. Statistical analysis was performed using SPSS software version 22 (SPSS Inc., Chicago, IL, USA).

## Results

Twenty-three consecutive patients with an edentulous maxilla have been provided with a removable prosthesis without palatal coverage retained by Locator abutments on three implants. All received invitation to partake in this clinical study. Twenty-one consented, while one patient has passed away and another declined because of a stroke. Of the consenting participants, 12 have received their implants more than 2 years ago, and the data from this cohort of study participants is described in detail below.

The average age of the six male and six female participants was 69 years (SD = 9), with a period of edentate maxilla ranging between 3 months and 10 years (average 3 years). Seven of the 12 participants conveyed that the primary reason for electing the removable option on three implants was caused by lack of enough bone for more implants, while the remaining five stated that financial considerations influenced their decision to proceed with a removable solution.

Each study participant had received three implants of either Astra Tech, (n=7) or Straumann SLA (n=5), between 2 to 6 years earlier (Table 1). The majority of the



implants had been placed in the maxilla characterized according to the Lekholm and Zarb jaw grading system as shape “C”, with the bone qualities “3” (n=21) or “2” (n=6) or “4” (n=3). Six implants had been placed in a maxilla characterized as shape “D” and having the bone qualities “3” (n=3) or “2” (n=3).

Ten of the 12 study participants attended their regular dentists for regular dental care, while two continued the maintenance care at the specialist clinic practice.

At the time of clinical examination, 10 of the 12 study participants reported that they did not remove their prosthesis during the nighttime, and seven of these showed clinical signs of denture stomatitis. None of the 36 implants showed any indications of mobility or tenderness upon percussion. Suppuration was observed on one implant. On the individual implant level, the plaque levels was generally good with no (61%) or minor (25%) plaque levels. Probing around the implants did not cause bleeding (53%), or elicited only minor bleeding (47%).

There was no relationship between the performance of the removable prosthesis and three implants in the maxilla, nor patient satisfaction as a function of the state of the dentition in the mandible, i.e., natural teeth (n=3), partial edentate without (n=3) and with (n=1) removable prosthesis, natural teeth combined with fixed prosthesis (n=2), removable complete prosthesis (n=1), or removable tooth-retained complete prosthesis (n=2).

The incidence of adverse biological and technical events was near non-existent as reported by the study participants and recorded in the patient charts. No implants were lost. None of the Locator abutments showed any clinically relevant wear. The rates of replacements of male attachments varied, as did any changes of male attachment retention force (Table 2). While 3 participants had not replaced any male attachments, the remaining participants replaced their male attachments between 2 to 59 months after prosthesis delivery (average 25 months). At this point two participants received male attachments with more retention than inserted originally. Five participants undertook a second replacement between 16 to 46 months after prosthesis delivery (average 31 months). Two participants had replaced their male attachments

respectively three and five times over the follow-up time period. All participants described the task of insertion and removal of the prosthesis as unproblematic.

The marginal bone loss around the supporting implants measured on the radiographs ranged between 0 and 5.3 mm, with a mean of 0.4 mm (SD 0.7) (Table 3). In one situation a mid-placed implant where suppuration and approximately 5 mm marginal bone loss was observed after approximately 2 years. Further bone loss was avoided after an open flap surgery with implant surface debridement and decontamination procedures, and the bone level has remained stable since the surgery. The bone loss appeared to be similar for the anterior middle implants (Mean 0.4 mm, (SD 0.8)) versus the posteriorly placed implants (Mean 0.4mm (SD 0.6)).

The patient satisfaction scores, as judged by the OHIP-20 scores were good in general, with relatively minor variation amongst the study participants (Table 4). The satisfaction scores described according to the denture satisfaction questionnaire appeared to be good, as the respondents were totally (n=5) or very (n=6) or reasonably satisfied (n=1) with their denture (Table 5). Moreover, the participants described the surgery as totally (n=6) or very (n=6) satisfactory. As to a question of whether they would redo the surgery again if needs arose, six responded with a yes, without any hesitation, two stated yes, very probably, and four answered with a yes, probably.

## Discussion

The results in this clinical study are positive and promising, but admittedly, the current study cohort is too small to recommend authoritatively that the described technical solution should be adopted. However, a case can be made that the solution makes sense from a theoretical biomechanical perspective. The center of the accumulated load in the maxilla upon maximal occlusion is located some distance posteriorly to the palatal incisal papilla and this area has, albeit in another context, been referred to as “the center of force” (Olivieri et al. 1998), alternatively “the occlusal load center” (Shinogaya et al. 2001, 2002). Conceptually, a removable prosthesis should ably resist displacement caused by vertical and lateral forces if it is supported by a three-legged frame projecting equidistantly from this “center” and with reasonably equilateral

distances between the three implant positions. The idea of tripodizing implants in this manner to support a removable maxillary prosthesis seems not to have received much attention in the basic sciences literature (Brunski 2014). Clinically, the notion has been appraised in two separate patient cohorts by a research group in New Zealand, with relative positive outcomes in the first cohort after 1 year (Payne et al. 2004), 2 years (Al-Zubeibi et al. 2011) and 10 years (Ma et al. 2015), as well as in the smaller second cohort after 1 year (Osman et al. 2013).

The Locator system include a male attachment that is made from nylon with varying retention force against the abutment. They are intended to be replaced due to a gradual loss of retentive force caused by their wear against the abutment upon prosthesis dislodgment. The study participants in the current cohort experienced different incidences of replacements, which corroborates observations made in other clinical studies (Vere et al. 2012, Cordaro et al. 2013, Ma et al. 2015). Likely, the extent of wear of attachment systems is multifactorial (Alsabeeha et al. 2009), in line with other tribological phenomena intraorally. The wear of the attachment is primarily localized on the central pillar and is circumferential unless there is a relative angulation, which induce more localized wear facets or ledges relative to the implant angulation (Rabbani et al. 2015).

A weakness of the current study is that no measurements were made of the patient-reported OHIP and denture satisfaction scores before commencing the prosthetic treatment, so there are no comparisons between before and after treatment. Moreover, OHIP likely changes over time, which was not addressed in the current follow-up study. Nevertheless, the study participants reported good OHIP (table 4) and satisfaction (table 5) scores, judged in comparison with analogous studies of maxillary removable prostheses without palatal coverage and retained by stud-type attachments on e.g., 2 (Zembic et al. 2013, Zembic & Wismeijer 2014), 3 (Al-Zubeidi et al. 2011) or 4 (Troeltzsch et al. 2013, Wang et al. 2015) free-standing implants. The study participants commented particularly the value of avoiding a palatal coverage, which allowed them to feel the food texture, temperature and to some extent taste. Interestingly, this patient feedback diverge somewhat from conclusions based on experimental cross-over studies over several months stating that patients have only minor or no opinions about

preference for palatal coverage (de Albuquerque Jr et al. 2000, Zembic & Wismeijer 2014). In contrast, on balance, it has been theorized that palatal coverage inhibits bolus formation during mastication, which is required for comfortable swallowing. The wearers therefore increase the number of mastication strokes until the swallowing threshold to compensate for the lowered masticatory performance (Sato et al. 2013). Moreover, palatal coverage affects the oral perception adversely, possibly because of a reduction of the intraoral stereognostic abilities (Kumamoto et al. 2010). Some individuals may adapt and others may maladapt to these circumstances. The observation that patients report effortless insertion and removal of the prosthesis corroborates earlier findings (Vere et al. 2012).

From an economic perspective, the described technical solution appear to be more affordable than a bar-retained or a fixed solution. Estimates of the relative costs of the actual supraconstruction, as based on prices obtained from a commercial dental laboratory in Norway, is 1:1.8 and 1:2.9 versus a bar-retained prosthesis on 4 implants and a fixed solution on 6 implants respectively (raw numbers: NOK14373 vs NOK 25483 vs NOK 41853). Obviously, the costs over time depend on accrued maintenance time and need to replace worn components. In the past, investigators have raised concern that patients with an implant-supported prosthesis without a palatal coverage may experience more mechanical and technical adverse outcomes compared to those without (Palmqvist et al. 1994, Widbom et al. 2004, Sadowsky 2007, Slot et al. 2010, Raghoobar et al. 2014). In the current study, however, the incidence of repairs so far has been very low, consistent with studies on removable palatal-free maxillary prostheses retained by Locator abutments (Cordaro et al. 2013, Wang et al. 2015)

A factor to consider with regard to a possible failure of an implant is that a remake of the removable prosthesis on a tripod solution is not necessarily required. The small vertical space required by a Locator attachment system facilitates the retrofitting into the existing prosthesis, as compared to the vertical space required to accommodate the retentive elements of a ball or bar-solution into the prosthesis. The replacement implant may positioned in the same osteotomy site, or in an alternative position. Moreover, there is no longer a great emphasis on placing multiple implants in a relative parallel vertical alignment since several clinical studies show minor effects of non-axial loading

of implants in the maxilla (Malo et al. 2005, Testori et al. 2008, Tealdo et al. 2008). Nevertheless, the inter-abutment divergence should not exceed 20 degrees according to the manufacturer of the Locator attachment system.

A criticism of the current data is that the follow-up time of these first twelve consecutive patients vary from two to 6 years, and that the study design is purely retrospective and observational. A second patient cohort is currently under recruitment for a prospective study, with an aspiration that the future clinical observation will corroborate these first promising findings.

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Table 1. Lengths and diameters (mm) of implants (n=12 patients x 3 implants)

$\emptyset$	L	8 or 9	10	11	12 or 13	Total
3,3	-	-	7	-	2	9
3,5	1	-	-	5	6	12
4,0 / 4.1	2	-	4	2	-	8
4,5	-	-	-	4	3	7
Total:	3	-	11	11	11	36

Table 2. The frequency of replacements of Locator male attachments indicated by months since delivery of prosthesis and attachment retention force represented by color codes. (B)lue: 680 Grams, (P)ink: 1361 Grams, (C)lear: 2268 Grams. (n=12 study participants)

Base-line	Replace #1 (mths)	Color	Replace #2 (mths)	Color	Replace #3 (mths)	Color	Replace #4 (mths)	Color	Replace #5 (mths)	Color	Follow-up (mths)
PCP	22	Blue	41	Blue	54	Pink	58	Pink	74	Clear	74
PPP	8	Pink	34	Pink	43	Pink					33
P-C	26	Pink	46	Clear							50
PPP	15	Pink	17	#2Pink 1Clear							41
CPP	2	Pink	16	Pink							28
BBB	59	Pink									66
PPP	41	Pink									72
BBB	33	Blue									46
BBB	19	Pink									26
BBB	-										36
BBB	-										47
PPP	-										28
Average:	25		31		49						

Table 3. Peri-implant bone loss of the study participants (n=12 patients, each with 3 implants) recorded radiographically at their last clinical examination (2,3,4 or 6 years).

	2 yrs		3 yrs		4 yrs		6 yrs	
	N=2 patients, 6 implants		N=5 patients, 15 implants		N=3 patients, 9 implants		N=2 patients, 6 implants	
mm	mes	dis	mes	dis	mes	dis	mes	dis
0-0,9	6	6	15	12	7	7	3	1
1-1,9				2	1	1	2	5
2-2,9				1			1	
3-3,9								
4-4,9								
5+					1*	1*		

\* Suppuration and rapid bone destruction observed after approximately 2 years around the anterior implant. Process ceased following open flap surgery, implant surface debridement and decontamination procedures. Bone level remaining stable since the surgery.

Table 4. OHIP-20 total and subscale scores for study participants treated with a removable prosthesis with partial palatal coverage retained by three free-standing implants fitted with Locator abutments (n=12).

	Mean	SD	Median	min	max
Total	<b>29,4</b>	6.6	26	21	43
Functional Limitation	<b>7.7</b>	1.8	8	5	11
Physical Pain	<b>6.1</b>	1.9	6	4	9
Psychological Discomfort	<b>3.1</b>	1.1	3	2	5
Physical Disability	<b>3.9</b>	0.9	4	3	5
Psychological Disability	<b>2.7</b>	1.2	2	2	5
Social Disability	<b>3.6</b>	1.4	3	2	7
Handicap	<b>2.4</b>	0.7	2	2	4
Functional	<b>17.7</b>	3.4	17	12	22
Psychosocial	<b>11,8</b>	3.9	10	8	21

Table 5. Satisfaction scores with the surgical aspect and the maxillary prosthesis reported by the study participants treated with a removable prosthesis with partial palatal coverage retained by three free-standing implants fitted with Locator abutments (n=12 patients)

	Totally satisfied	Very satisfied	Reasonably satisfied
1. How satisfied are you with your denture?	5	6	1
2. How satisfied are you with the retention of your denture?	6	5	1
3. How satisfied are you with the stability of your denture?	3	6	3
4. How satisfied are you with the comfort of your denture?	4	7	1
5. How satisfied are you with the occlusion of your denture?	4	6	2
6. How satisfied are you with the appearance/ aesthetics of your denture?	7	4	1
7. How satisfied are you with the ability to speak with your dentures?	6	5	1

Figure 1. The first patient in the current study cohort that received a removable prosthesis with partial palatal coverage retained by three free-standing implants fitted with Locator abutments. At the time, the implants were placed with best possible relative parallelism perpendicularly to the axial loading and a maximum antero-posterior spread of the implants. Post-implant surgery radiograph (top) from fall 2007, other figures from fall 2013.

