

A Comparison of Three Different Attachment Systems for Mandibular Two-Implant Overdentures: One-Year Report

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ABSTRACT

Background: There is a lack of clinical studies on the self-aligning attachment system (Locator®; Zest Anchors, Inc. homepage, Escondido, CA, USA) for two-implant-retained overdentures in the edentulous mandible. Therefore, a comparison of the Locator with two traditional designs (a rotational gold matrix and a rubber O-ring type) in clinical 1-year use was conducted.

Materials and Methods: From 2003 to 2007, 60 patients received two Osseotite® TG Standard implants (BIOMET 3i Implant Innovations, Palm Beach Gardens, FL, USA) in the intraforaminal area of the edentulous mandible. The implants were left unloaded for 3.5 months, randomized to three different attachment systems, and loaded through a mandibular overdenture. Twenty-three patients received a self-aligning attachment system (Locator) and 33 patients a ball attachment (Dal-Ro® [BIOMET 3i Implant Innovations] $n = 25$; TG-O-Ring® [Cendres & Metaux SA, Biel-Bienne, Switzerland] $n = 8$). After 12 months of delivery of the overdentures, the oral situation was evaluated: prosthodontic maintenance and biologic complications, subjective patients' experience, and oral health-related life quality (Oral Health Impact Profile [OHIP-G 49]).

Results: After 1-year of clinical service, 8 of 120 implants were lost (9.6%). The Locator system brought up 34 prosthetic complications, especially the need for change of the male parts or activation because of loss of retention. The TG-O-Ring patients showed 14 complications, most of them the change of the O-Rings. The patients with the Dal-Ro abutment had seven minor complications in 12 months of clinical use. Biologic complications and patients' oral health-related life quality showed no significant difference among the three experimental groups.

Conclusions: Prosthodontic maintenance was restricted to loss of retention for all systems. Within the observation period of this study, the self-aligning attachment system showed a higher rate of maintenance than the ball attachments. The patients' oral health-related life qualities as well as the biologic parameters do not differ when using the three abutment systems.

KEY WORDS: abutment, attachment system, dental implant, edentulous mandible, locator, prospective, randomized, self-aligning attachment system, traditional ball attachment

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INTRODUCTION

In the rehabilitation of the edentulous mandible, implant-retained overdentures represent a viable and cost-effective treatment.¹ A stabilization by implants can increase the satisfaction of the patients² and can help to sustain the bone.^{3,4} Various randomized clinical studies have been carried out to evaluate the patients' life quality comparing normal (ND) and two-implant-borne dentures.^{5–11} In all studies, the implant-borne

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dentures were able to convince the patients compared with NDs. According to the McGill consensus statement on overdentures, a two-implant overdenture should become the standard of care of the edentulous mandible, although there is evidence that the implant overdenture is superior only in those situations with less than adequate mandibular ridge height.^{4,12} To connect implants with overdentures, self-aligning attachment systems (for example, the Locator®; Zest Anchors homepage, Escondido, CA, USA) and traditional ball attachments (eg, Dal-Ro® [BIOMET 3i Implant Innovations, Palm Beach Gardens, FL, USA] and TG-O-Ring® [Cendres & Metaux SA, Biel-Bienne, Switzerland]) are available. The need of prosthodontic maintenance varies from system to system. Accordingly, several studies have been conducted to evaluate this effort. For example, ball attachments in several studies have shown to have less^{13–16} repair frequencies than bar-clip attachments. Whereas one group described a higher repair frequency.² Further on, ball attachments have shown to need a significantly higher level of maintenance on isolated crowns than attachments with resilient telescopic crowns.¹⁷ No comparison concerning prosthodontic maintenance between traditional ball attachments and the self-aligning attachment system has been conducted yet. Therefore, the focus of this study is specifically on the Locator attachment system on a comparative basis to the Dal-Ro and the TG-O-Ring attachment systems.

The Locator – the self-aligning implant attachment system in the center of this study – has been on the market since 2000. Because of the unique design of the Locator, the patrix (male) is the replaceable nylon insert on the undersurface of the overdenture. The matrix (female) is by virtue, again of its unique design, the overdenture abutment on the implant. This is quite different to the Dal-Ro and TG-O-Ring, which have traditional ball abutments as the patrices (males) (Figure 1). Dal-Ro is the version that has superseded the original Dalbo® attachment system. The TG-O-Ring has distinct similarities with the original SteriOSS O-ring attachment system (white rubber ring), which is no longer marketed. The Locator system has become widely applied, and it is sold by several implant companies. Though, there are only a few studies concerning this system. Schneider and Kurtzman^{18,19} publicized an introduction of the system. Chung and colleagues²⁰ and Ochiai and colleagues²¹ conducted an in vitro study each to measure

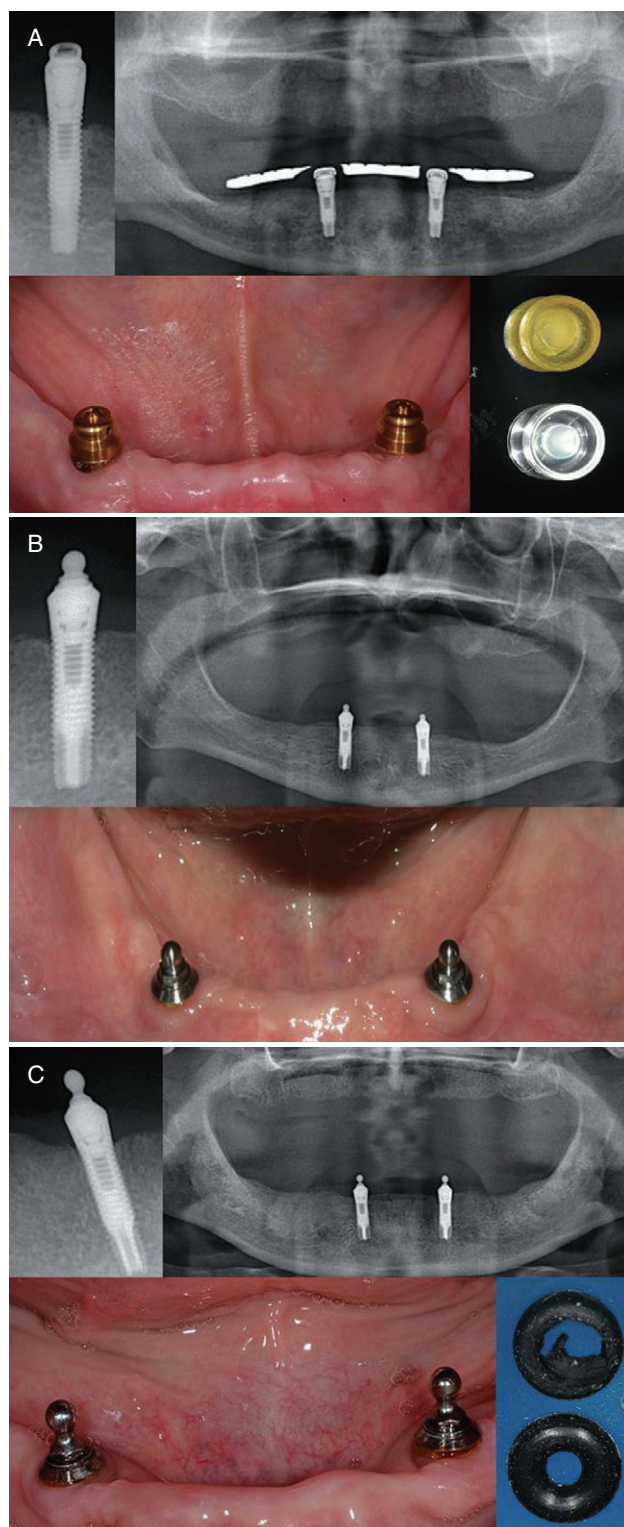


Figure 1 Radiologic and clinical views on the different abutment systems: (A) Locator (panoramic X-ray with prosthesis) with attachment matrices (below: new; above: after clinical use), (B) Dal-Ro, and (C) TG-O-Ring with attachment matrices (below: new; above: after clinical use).

retention and affecting forces. Celik and Uludag²² compared in vitro the photoelastic stress at a model of the mandible comparing the Locator with other systems. Until now, there is no in vivo study of the self-aligning attachment system available.

The aim of this randomized, clinical prospective study was a comparison of the provision of the Locator abutment system with the Dal-Ro and the TG-O-Ring for two-implant overdentures of the edentulous mandible. The primary aim was to compare the prosthodontic maintenance of the three systems. Furthermore, the clinical stability of the prosthesis, as well as the soft tissue situation and the patients' appraisal, was defined.

MATERIALS AND METHODS

Design of the Study

This is a prospective, randomized clinical study.²³ The primary outcome criterion was the prosthodontic maintenance of the self-aligning attachment system in comparison with the two traditional ball attachment systems as the control group. Secondary outcome criteria were the retention of the prosthesis, the measurement of the biologic, peri-implant parameters, and the patients' oral health-related life quality. The study was carried out in the Department of Oral and Maxillofacial Surgery, Johannes Gutenberg-University, Mainz, Germany, and was approved by the local ethical committee.

Test Group

The Locator implant attachment system is a self-aligning double-retention cylinder with retention surfaces on the inner and outer areas. Incorporated in the basis of the denture is a metal body. In this body, nylon elements in the negative form of the abutment, the male parts, can be engaged to connect the prosthesis with the implant. In doing so, the male parts stay flexible and allow a resilient connection between abutment and overdenture with a limit of 1.2 mm in vertical direction and 8° in all directions. The nylon male parts exist in different color-coded designs with different retention forces. It can compensate a total variance of two intraforaminal implants up to 40°.¹⁸

The manufacturer stated that because of the self-positioning design, abrasion, just as the damaging of the attachment, can be largely avoided. So, the attachment system is supposed to satisfactorily maintain retention for up to 56,000 cycles.

Control Group

Both control anchoring systems are traditional ball attachments to connect the implants with the underpart of the overdenture. In the Dal-Ro system, the matrix, which is situated in the cover prosthesis, consists of a metal body and an inner element with four circular arranged and resilient metal lamellae. These permit the engagement of the spherical head into the metal body. The retention force is variable because of the rotation of the lamellae in the metal body. The TG-O-Ring also consists of a matrix, though it has a circular cavity in medium height, which is used to position and to fix the replaceable and elastic O-Ring, which engages the abutment in the matrix. The O-Rings exist in one form only; the retention force is not variable.

Patients

A total of 60 patients, 15 males and 45 females, with an average age of 64 years (46–95 years; Figure 2), were included in this study, and implants were placed between March 2003 and October 2006. Fifty-five patients were edentulous in the mandible. In five patients, the left teeth were extracted prior to implantation. Two and a half months after the extraction of the teeth and healed extraction alveoli, the dental implantation took place. The healing period was planned to be 3 months, but some patients insisted to receive the implants earlier or later. Criteria for inclusion were an edentulous mandible and a sufficient bone level for implantation. The patients were excluded from the study if (1) the treatment could affect the patients' health condition because of the occurrence of systemic diseases (only American Society of Anaesthesiologists Patient Status classification [ASA-PS] I and II were included), active infections, radiation in the patients history, smoking habits, or neoplastic lesions in the area of concern and (2) patient cooperation appeared questionable. The patients agreed with a written informed consent.

Oral Health-Related Life Quality

In the context of the preplanning of the operation, the patients received the Oral Health Impact Profile (OHIP-G 49) questionnaire. This is an instrument to measure the oral health-related life quality of adult patients. In regard to its significance, this questionnaire

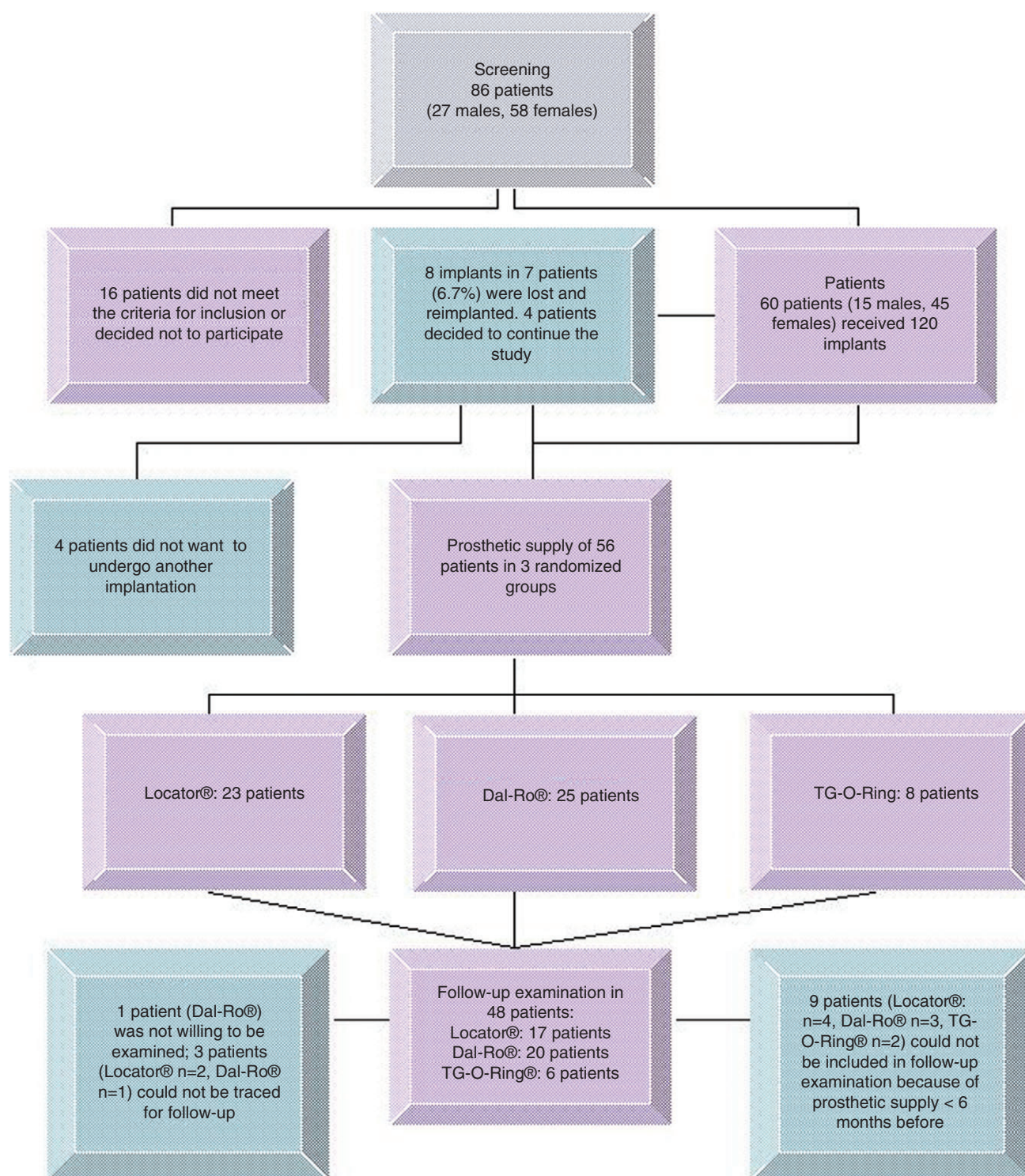


Figure 2 Flowchart of the patients.

has been examined in several national and international studies.^{24–26}

The oral health-related life quality describes the subjective experience of one's oral health. It is delivering complementary information concerning clinical

indications of oral diseases. Essential parts are functional restrictions of the masticatory system, orofacial pain, dentofacial aesthetics, and the psychosocial influence of the oral health. This instrument makes it possible to gain a fast overall view to judge the

psychosocial affections on oral health. The 49 questions can be added up with the information of their frequency (0 = never, 1 = barely, 2 = now and then, 3 = often, 4 = very often).

Operation

The insertion of the implants as well as the follow-up examinations was done in the Department of Oral and Maxillofacial Surgery as described by the manufacturer. Two Osseotite® TG Standard implants (diameter 4.0 mm; length 10, 11.5, or 13 mm) with a mucosal passage of 2.8 mm (BIOMET 3i Implant Innovations) were inserted in the intraforaminal mandible of the canine area.

After implantation, a medicamentous therapy with antibiotics, analgetics, and chlorhexidine mouthrinse was conducted. The patients were allowed to wear dentures only for aesthetic reasons until prosthetic loading.

Prosthetic Supply

After an average time of 3.5 months after implantation, the prosthetic supraconstruction was integrated in the Department of Prosthodontics. Originally, it was planned to wait for exactly 3 months for prosthetic supply, but because of the patients' compliance, a longer average period of time was needed. The prostheses of the mandible were newly made in 36 patients because of the age of the former provision. In 10 patients, the existent denture was used, and in 2 patients, loco regional bedding plastics of the mandible were carried out. The prosthesis was positioned in bilateral balanced occlusion.

The patients were randomized for the different abutment systems. Each patient's name was substituted for a number. The numbers were chosen out of a list at random by the investigator at the time of prosthetic supply. No further blinding was done. Twenty-three patients were provided with a Locator, 25 received a Dal-Ro, and 8 patients got a TG-O-Ring attachment. The unequal patient groups are because of patient dropouts (see Figure 2) and a randomized list with uneven groups. The incorporation of the female parts was effected in direct procedure in all cases.

No data regarding the advantages or disadvantages of the comparison of the different systems were available at this time. Nondisclosure was guaranteed until allocation. After prosthetic supply, the patients were informed about the obtained system.

Follow-Up

The recall was carried out with a mean of 12 months after prosthetic supply. The overdenture was removed, and the basis of the prosthesis was examined. The bodies of the attachments were examined visually for signs of wear, fissures, break lines, or loss. In the next step, the abutment was surveyed for stability, coating, and signs of wear as well.

The overdenture was inserted and removed by the investigator to appraise the retention force of the attachment and describe it on a subjective scale from 1 to 5 (1 = very high; 2 = high; 3 = average; 4 = weak; 5 = very weak). If the value was 4 or 5, the Locator male part or the O-Ring was changed, or the Dal-Ro cartridge was adjusted. If a loosening occurred to happen on one side, the parts were changed/adjusted on both sides to obtain a consistent retention. To gain comparable results, this step of the examination was carried out always by the same examiner. Though, the subjective nature of this examination has to be considered.

In the next step, the peri-implant situation was examined. The gingiva was surveyed for pathologic processes. In the mesial and distal of the implants, the probing depth was measured with a dental probe.

Subsequently, the patients' satisfaction was measured again by using the questionnaire OHIP-G 49.

RESULTS

Sixty patients were provided with the different anchoring methods for overdentures. Eight of 120 implants in seven patients (90.4%) were lost. In those cases, another implantation was done. In 48 patients, the follow-up examination could be conducted. At the time of the examination, eight patients could not be included because the prosthetic supply had been made in less than 6 months before. One patient was not willing to come to the hospital, and three patients could not be traced.

In 43 cases, both of the questionnaires (preoperative and at least 6 months after prosthetic supply) could be attended (see Figure 2).

Prosthodontic Maintenance

In 24 of 48 patients (50%), a significant loss of retention was detectable. Relating to the different attachment groups, 12 of 17 patients of the Locator, 7 of 25 of the Dal-Ro, and 5 of 6 of the TG-O-Ring groups needed a correction of the retention.

TABLE 1 Prosthetic Complications in Locator, Dal-Ro, and TG-O-Ring Attachments

	Locator (n = 25)	Dal-Ro (n = 23)	TG-O-Ring (n = 8)
Primarily too high retentions	4	0	0
Change of male parts of activation because of loss of retention after 12 months	24	4	10
Preterm loss of retentions	4	0	3
Loss of male parts or Dal-Ro fracture	2	1	1
Fracture of the prosthesis	1	1	0
Total	35	6	14

In 1 year of clinical use, a total of 56 prosthetic complications appeared. The Locator exhibited four primarily too high retentions (Dal-Ro = 0; TG-O-Ring = 0); 24 times of change of male parts or activation because of loss of retention after 12 months were necessary (Dal-Ro = 4; TG-O-Ring = 10). A preterm loss of retentions occurred in the Locator four times (Dal-Ro = 1; TG-O-Ring = 3); a loss of male parts was seen in four cases (Dal-Ro = 1 fracture; TG-O-Ring = 1). The prosthesis broke one time (Dal-Ro = 1; TG-O-Ring = 0; Table 1).

In the Locator group, 17 patients could be controlled for retention, which was three times assessed as “very weak” and once as “very high.” In the Dal-Ro group, the weakest retention was counted once; the highest retention was nine times. Under the six patients with a TG-O-Ring, the retention of the prosthesis was described once as “very weak.” The highest retention could not be evaluated within this attachment system.

Biologic Parameter

In seven cases, a recession of the soft tissue was seen (Locator = 1; Dal-Ro = 4; TG-O-Ring = 2). In two implants of the Dal-Ro group, hyperplastic changes of the soft tissue were seen. In one case, the peri-implant soft tissue was inflamed.

The measurements with the dental probe revealed that all values were 1 to 5 mm. Eighty-seven were found below 4 mm.

Oral Health-Related Life Quality

The OHIP analysis that was conducted on 43 patients showed a significant advancement comparing the pre-operative status and the status 1 year after prosthetic

loading (mean total score 91 vs 68 points; Figure 3). In a comparison between the total scores of all three experimental groups, no significant difference in the patients’ oral health-related life quality could be found (Figure 4).

DISCUSSION

The study compared a self-aligning attachment system with two traditional ball abutments for two-implant-retained overdentures in the edentulous mandible in 1 year of clinical use. The primary outcome criterion was the prosthodontic maintenance in the clinical use of the different systems.

The Locator group showed 75.5% losses of retentions because of the wear of the male parts, which made a change of these parts necessary. In all cases, both of the male parts were affected. Most patients did not realize the slow loss of retention of the Locator, which can be seen by the examiner. This leads to the conclusion that the supply with the Locator system demands an annual follow-up. The same conclusion was seen with the TG-O-Ring system. The wear of the O-Ring was the most frequent complication as well. The least effort in regard to repair and renovation was found in the Dal-Ro system with a rate of 24%.

To sum these findings up, a noticeable higher level of maintenance could be found when using the Locator system. As the change of the male parts is cost and time effective, the additional work and expenses are minimal.

Secondary outcome criteria were the retention of the prosthesis, the measurement of peri-implant parameters, and the patients’ satisfaction.

The comparison of the retention of the overdentures points at a tendency to higher values in the Dal-Ro group (mean = 1.85) opposite to the Locator

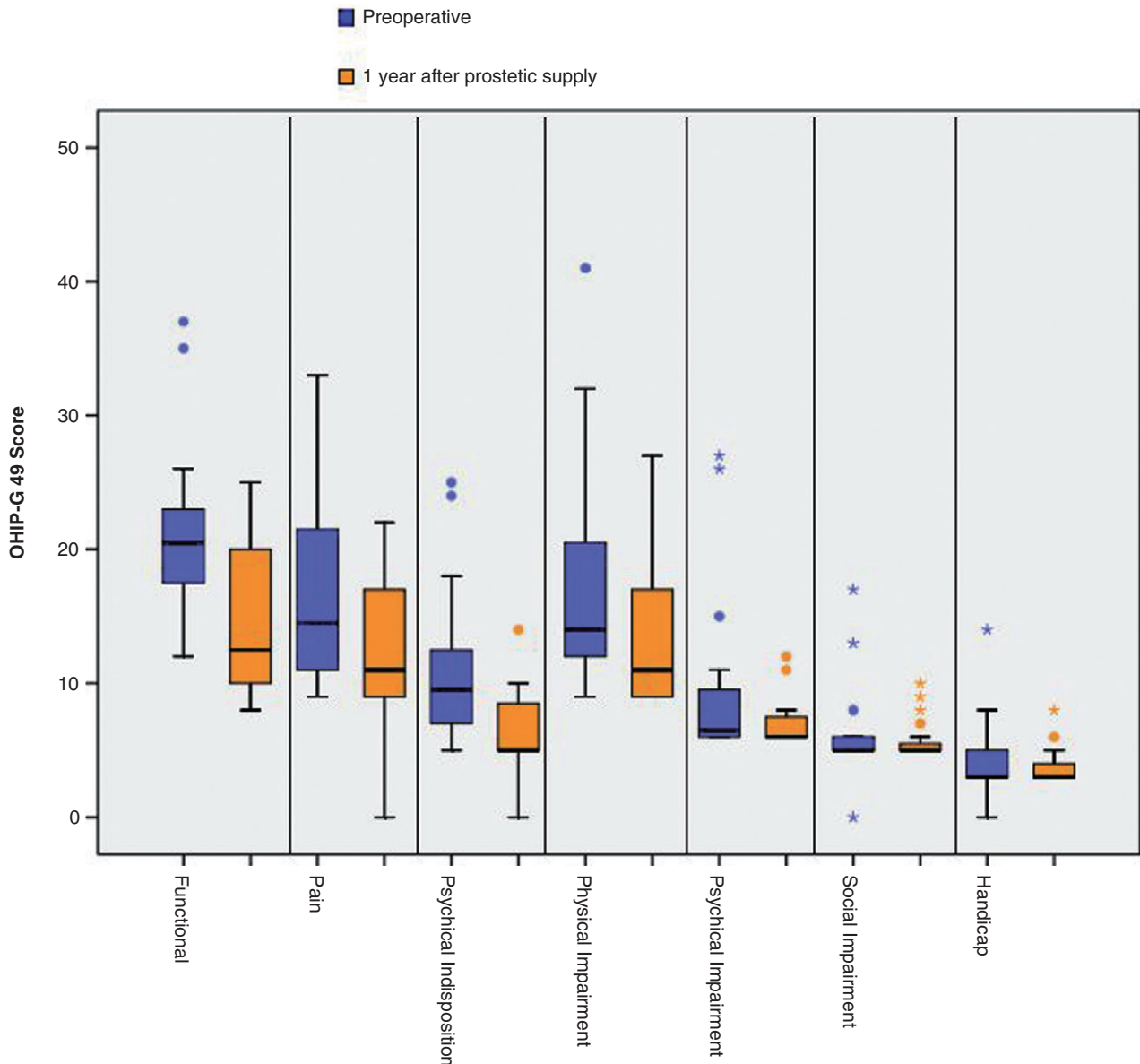


Figure 3 Cumulative Oral Health Impact Profile (OHIP-G 49) analysis preoperative and 1 year after prosthetic supply.

(mean = 3.6) and the TG-O-Ring groups (mean = 3.3). No in vivo studies relating the difference of these three attachment systems could be found.

While using the different attachments, distinctive features in regard to the handling attracted the attention of the examiner. The Dal-Ro and TG-O-Ring attachments impart to the patient and examiner a feel- and hearable snap-in, which is missing while using the Locator attachment. Therefore, the patients, when using the Locator, have to be instructed to that effect. In comparison to Dal-Ro and TG-O-Ring, the Locator needs a noticeable higher effort to position. Very often, a bite is not sufficient, and a bimanual press on is necessary. For this reason, higher forces to draw off are needed.

The findings concerning the peri-implant complications indicate that the supply of two-implant-borne overdentures does not cause problems concerning the soft tissue.

Furthermore, this study could confirm that, regarding the OHIP-G 49 questionnaire, the patients' oral health-related life quality after dental implantation and prosthetic supply improves in all fields that were examined. These findings are conforming to a comparable study of Awad and colleagues²⁷ with a similar group of patients. The mean difference was an ascent of 33.1 points per question. The highest success (difference pre- and postoperative of a total of 298 points) of the subjective evaluation refers to an advancement

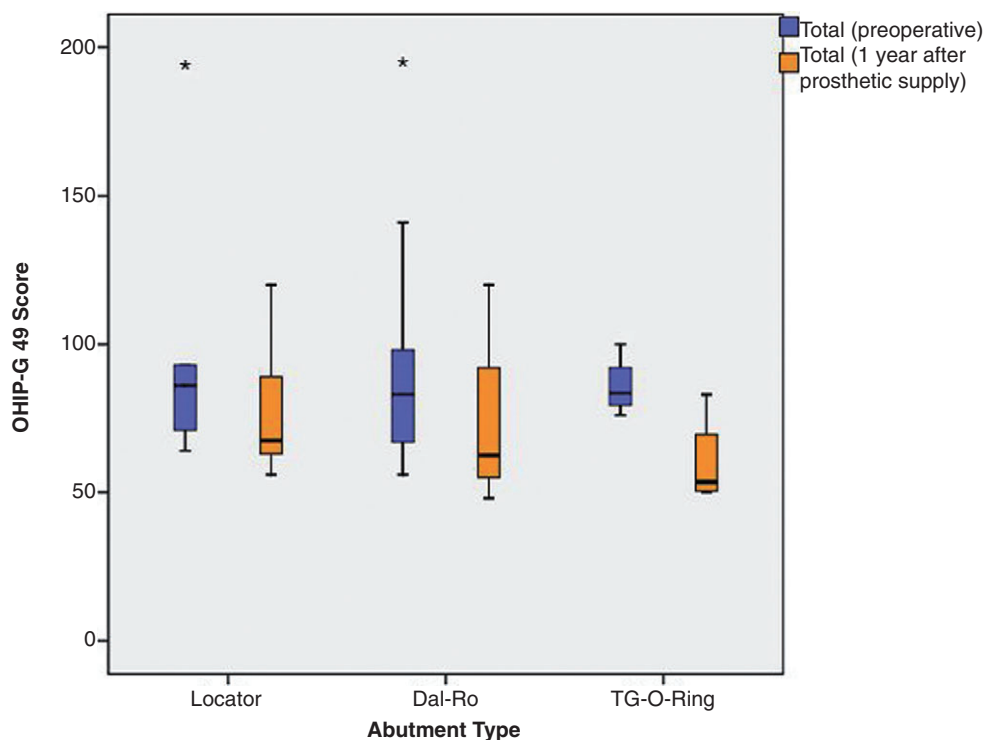


Figure 4 Oral Health Impact Profile (OHIP-G 49) analyses preoperative and 1 year after prosthetic supply in comparison of the different abutment systems.

regarding functional restrictions (ability to chew, to speak, impairment in regard to digestion, appearance, sense of taste, and fitting of the prosthesis).

The comparison between the different abutment systems examined did not show any significant difference. This result is not concordant to similar studies concerning participant satisfaction, although in the study at hand, less patients have been surveyed, and none of the following studies carried out an evaluation of the Locator system. Cune and colleagues²⁸ determined the patients' satisfaction with implant-supported mandibular overdentures using magnet, bar-clip, and ball-socket attachments, which resulted in a strong patients' preference of bar-clip and ball-socket attachments over magnet attachments. In an 8-year follow-up study, Timmerman and colleagues²⁹ found a higher patient satisfaction for bar systems in comparison with ball attachments. Though, the main point of interest in this study was on retention and stability of the mandibular overdenture. In a 10-year randomized study, Naert and colleagues³⁰ could show the best results concerning patient satisfaction for ball attachments followed by the bar system and, lastly, magnets.

The research parameter of the secondary hypothesis is related only on peri-implant parameters and OHIP

score. The research value of the probing is limited and has been questioned.³¹ Therefore, the conclusion has to be confirmed in further studies with an additional parameter.

CONCLUSIONS

The different attachments, together with two-implant-retained mandibular overdentures, represent a predictable and successful option to treat edentulous patient concerning the restoration of patients' oral functions.

The retention elements do not affect the patients' satisfaction, but they lead to different rates of complications and different needs for prosthetic after treatment. According to the results, the use of the self-aligning attachment system accounts for more prosthodontic maintenance than the use of the traditional ball abutments.

There is no evidence for one outstanding attachment system. The choice of systems should be orientated on the individual clinical situation and the individual needs of the patients.

The results of this study have to be evaluated carefully because of the small number of patients examined, the unequal group size – especially the small number of participants in the TG-O-Ring group – and the short

observation period (1 year) at hand. Therefore, they should be considered preliminary.

Because of its reduced size, the double-retention cylinder system broadens the spectrum of alternative patients' provision with two-implant-borne dental overdentures.

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