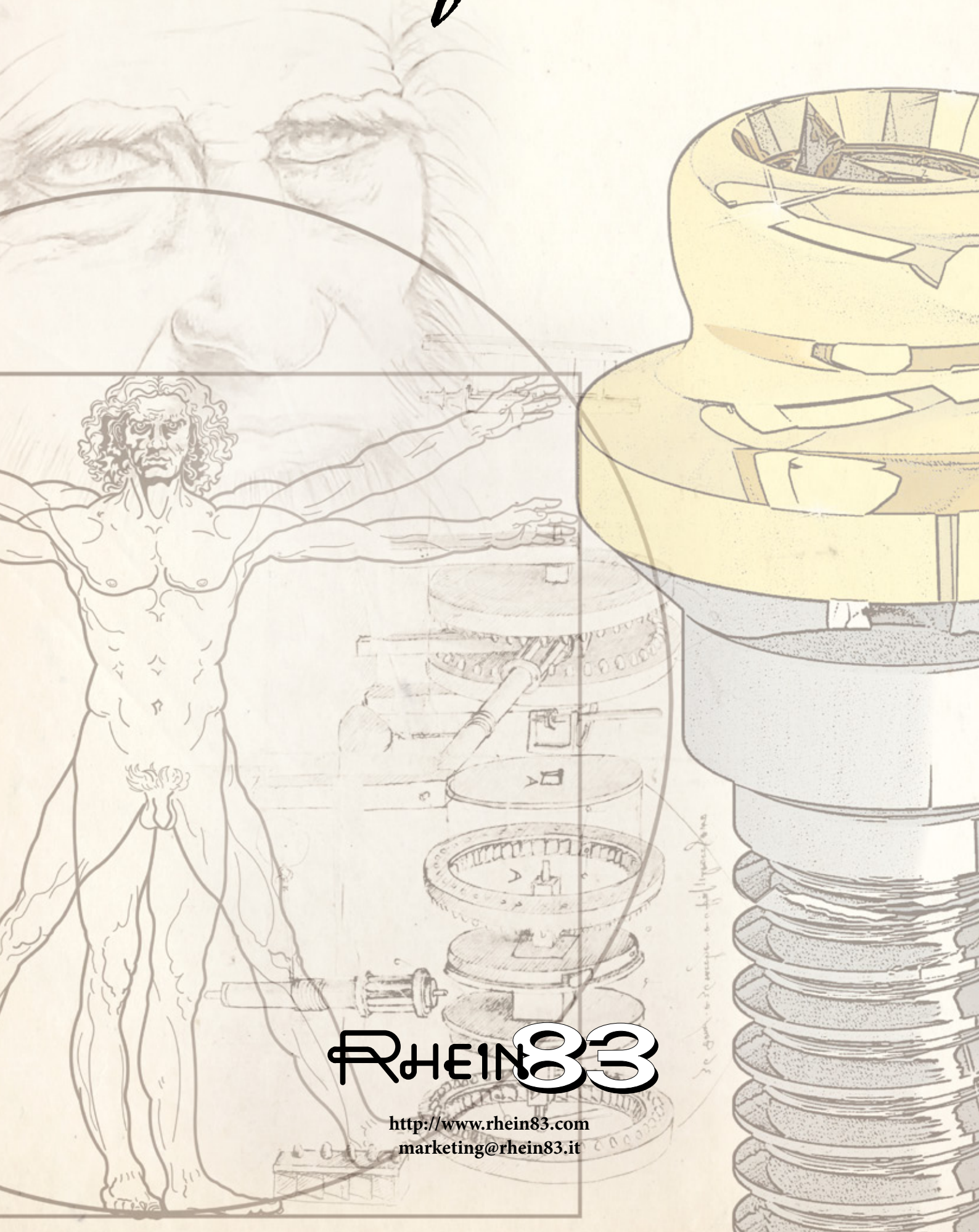


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***“Those who fall in love with the practice without science are like the helmsman who enters a ship without a rudder or compass, who never has certainty where he goes. Practice must always be built upon good theory.***

***Leonardo Da Vinci***

***“But first I will gain experience before I go any further, because it is my intention to carry on the experience first and then, with reason, demonstrate why that experience is forced to operate in this way”***

***Leonardo Da Vinci***

***“The great goal of science is to cover the greatest number of empirical facts with logical deductions drawn from the least number of hypotheses or axioms”***

***Albert Einstein***

Evidence based-dentistry is the discipline that correlates the clinical decisions taken during the practice with the scientific evidence in literature. Nowadays, it is essential to be able to provide patients with treatments conducted according to the logic of evidence based-dentistry, both in terms of the repeatability of the approach and the predictability of the results. As far as the management and regulation of the doctor-patient relationship is concerned, these aspects have acquired an important significance from a medical-legal point of view.

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***Comparison of Two Low-Profile  
Prosthetic Retention  
System Interfaces: Preliminary  
Data of an In Vitro Study***

Gabriele Cervino, Marco Montanari, Dario Santonocito, Fabiana Nicita, Riccardo Baldari,  
Claudio De Angelis, Gianni Storni and Luca Fiorillo

Published: 27 November 2019  
Prosthesis



# Comparison of Two Low-Profile Prosthetic Retention System Interfaces: Preliminary Data of an In Vitro Study

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Received: 27 October 2019; Accepted: 21 November 2019; Published: 27 November 2019

**Abstract:** In recent years, a major research goal of companies has been to create mechanical components suitable for rehabilitation that are safer and more reliable. Evaluating their biomechanical features could be a way to improve them. The purpose of this study was to evaluate the different biomechanical features of low-profile retentive systems (Rhein®). Two different attachment systems were tested: OT Equator® Smart Box and Locator® R-TX. Once a machine was created for the simulation of the connection and disconnection of the attacks in a combined manner, it was possible to evaluate these parameters over time. Attachments were mounted in two different configurations of the divergence angle: 10° and 50°. The drop retention force proved to be stable over time. The Locator® R-TX attachment experienced a more rapid decrement of the retention force than the OT Equator® Smart Box. Both tested systems experienced a high drop in retention; this drop tended to stabilize after 1.5 years of use, and it was correlated with the divergence angle. The OT Equator® Smart Box system underwent this loss of retention more gradually than the Locator® R-TX. This study demonstrates preliminary results from a bioengineering and biomechanical point of view, providing useful information for the continuous improvement of these devices and, therefore, for the quality of patients' oral health.

**Keywords:** dentistry; oral rehabilitation; dental implant; bioengineering; biomechanical

## 1. Introduction

### 1.1. Background

Implant-supported mandibular overdentures retained by two implants are a cost-effective treatment option for edentulous patients [1,2]. This treatment improves the stability and retention of the mandibular complete denture and patients' masticatory function compared with conventional removable dentures [2–4].

Retention of a removable denture is an important property that allows the forces of dislodgement to be resisted in a direction opposite to its path of placement [5,6]. Several attachment systems have been developed to improve the retention characteristics and stability of implant-

supported overdentures, such as splinted (bar attachment) or unsplinted systems (o-ring/ball/spherical types, magnets, telescopic crowns, or stud attachments) [7].

The performance of implant-supported overdentures depends on the retentive capacity of the attachment system employed, providing forces that are strong enough to prevent overdenture displacement [8,9]. Biomechanical knowledge of different attachment systems could help clinicians to select the proper attachment for each case [10–12].

Among the attachment systems, stud attachments are widely accepted for their lower technique sensitivity, better affordability, easier repairability, and their ability to be successfully positioned on resorbed edentulous ridges [10,13]. Attachment system selection depends on a variety of factors that should be identified early in the treatment sequence, such as the alignments of the implants, the retention value needed, the available vertical and horizontal prosthetic space, and the jaw morphology [14,15]. Ultimately, the decision is usually based on the clinician's experience and preference [10,11].

Several stud attachment systems have been developed over the years, including OT Equator® (Rhein83, Bologna, Italy) and Locator® R-TX (Zest Anchors Inc, Escondido, CA, USA). The OT Equator® attachment consists of a titanium male abutment with a hard coating of titanium nitride and a semispherical shape reminiscent of ball attachments that supports a stainless-steel retentive cap housing nylon retentive inserts available with four levels of retention encoded with a color. The OT Equator® Smart Box is a container of caps with an innovative design which, thanks to a tilting mechanism with a rotation fulcrum, allows for the passive insertion of the attachment even in conditions of divergence up to 50°. Four types of retention caps are available: extra-soft, soft, standard, and hard.

A next-generation Locator® R-TX attachment system was recently introduced to improve the limitations associated with conventional Locator attachments. The new features include an aesthetic, harder, and more wear-resistant titanium carbon nitride coating, dual-retentive features on the external surface of the abutment, and a reduction in the coronal abutment dimension. The denture attachment housings are designed to permit a 50% increase in pivoting capability and up to a 30° correction per implant as opposed to a maximum of 20° correction per implant with a conventional locator. Moreover, Locator® R-TX offers one set of inserts (gray = zero retention, blue = low retention, pink = medium retention, white = high retention) with improved design to resist edge deformation.

## 1.2. Aim

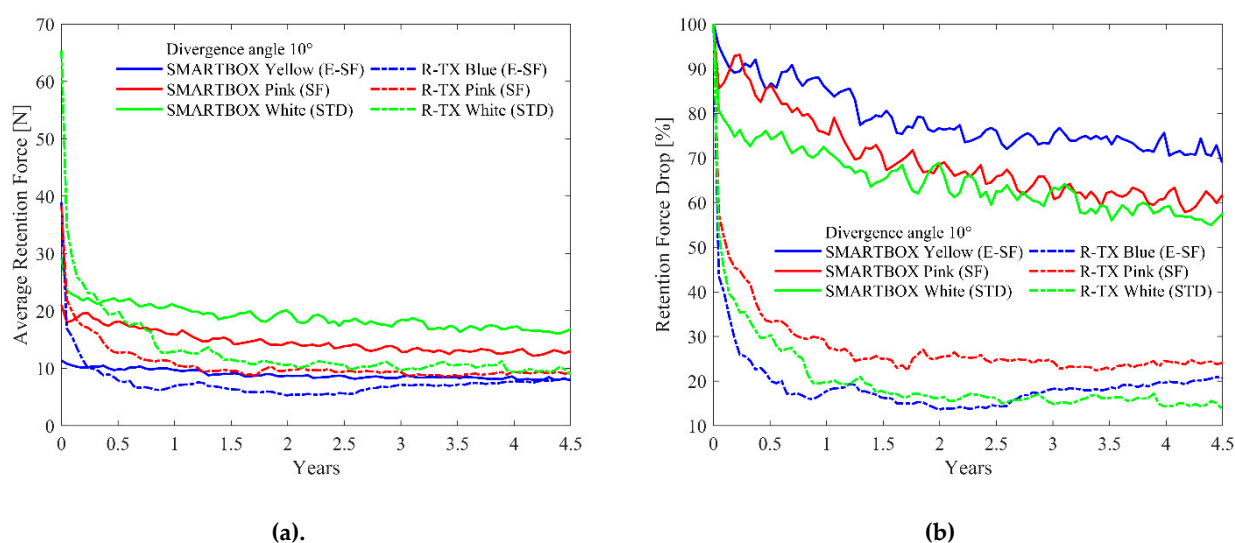
This study aimed to evaluate the retention force of these two attachment systems for overdenture. In particular, the study sought to evaluate the maximum force required to remove the overdenture while comparing three types of retentive caps for each attachment system over time.

## 2. Results

During each cycle, the maximum force of the removal phase was registered, and the average value with standard deviation was estimated for the three tests. The average retention force vs. time, in years, was plotted for each of the two different classes of attachment systems.

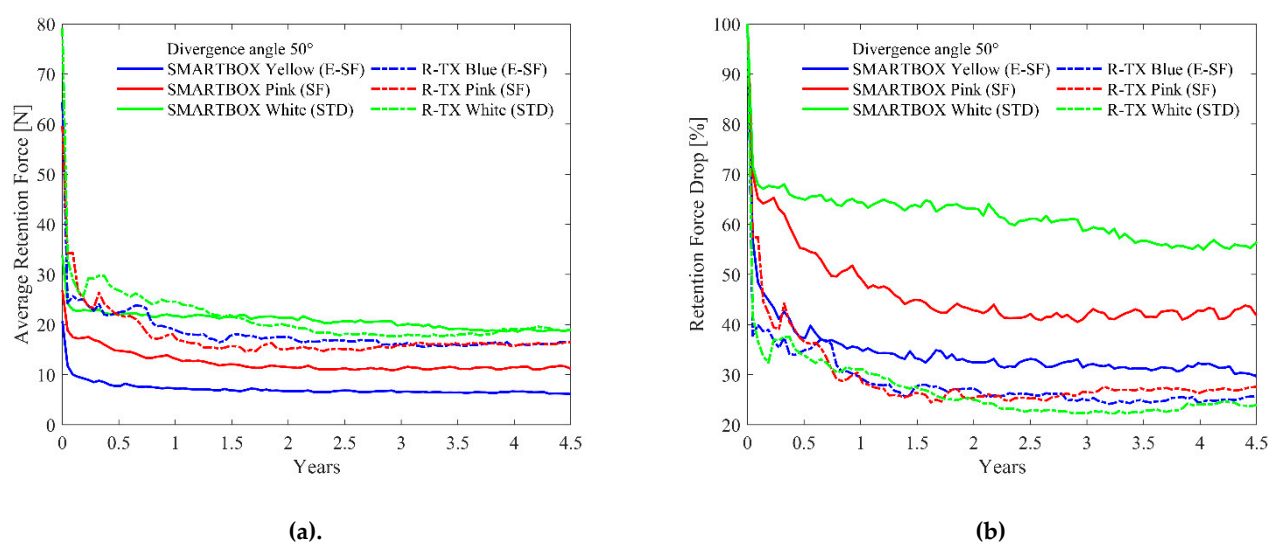
For a divergence angle of 10° (Figure 1a), the Locator® R-TX attachment experienced a rapid decrement of the retention force in the first half year. The value tended to stabilize after 2 years, converging, independently of the cap retention class, to a force value of  $9.0 \pm 0.7$  N (extra-soft:  $8.2 \pm 3.8$  N; soft:  $9.4 \pm 1.0$  N; standard:  $9.4 \pm 1.7$  N). The OT Equator® Smart Box attachment system experienced a more gradual change in the retention force, which tended to stabilize after 2.5 years, maintaining a different retention force for the three different cap classes (extra-soft:  $7.9 \pm 1.1$  N; soft:  $12.6 \pm 1.4$  N; standard:  $16.8 \pm 2.5$  N). As reported in Figure 1b, after 1 year the Locator® R-TX system presented a dramatic drop in the retention force (extra-soft: 16.43%; soft: 24.96%; standard: 17.85%), while the OT Equator® Smart Box presented a gradual slope change in the force drop, with a final drop after 4.56 years of 62.42% (extra-soft: 69.73%; soft: 59.97%; standard: 57.56%) vs. 20.17% for the Locator® R-TX attachment (extra-soft: 21.20%; soft: 24.80%; standard: 14.52%).





**Figure 1.** (a) Average retention force for a divergence angle of 10°; (b) Average retention force for a divergence angle of 50° (1096.49 cycles for the year).

For a divergence angle configuration of 50°, both the attachment systems experience a force retention change during the first half year (Figure 2a,b). In particular, the Locator® R-TX attachment showed an abrupt change with a final average value of the retention force after 4.56 years of  $17.5 \pm 1.6$  N with a small difference between cap retention classes (Extra-Soft:  $16.5 \pm 5.0$  N; Soft:  $16.6 \pm 8.5$  N; Standard:  $19.4 \pm 3.04$  N), but maintaining a higher retention force compared to the Smart Box system. On the other hand, the Smart Box attachment tended to stabilize to a different value of the retention force. It maintained the resistance class during the time (Extra-Soft:  $6.2 \pm 0.1$  N; Soft:  $11.2 \pm 0.5$  N; Standard:  $19.3 \pm 0.5$  N).



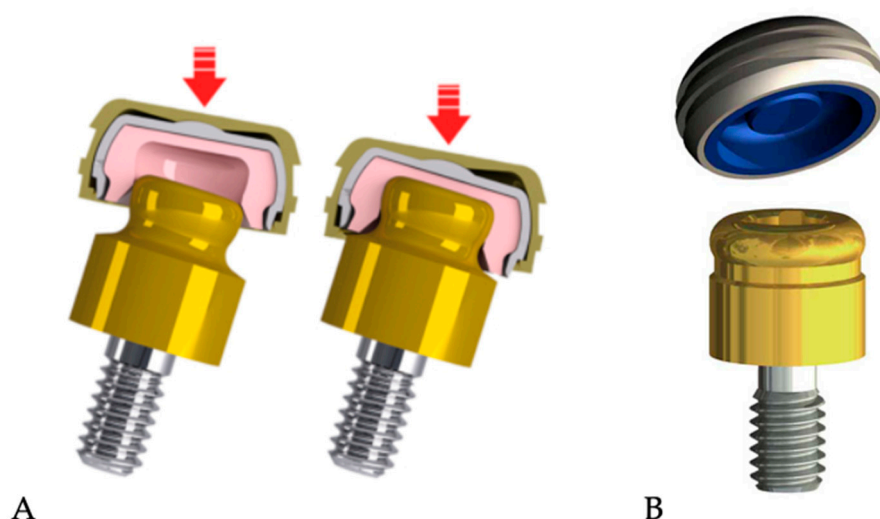
**Figure 2.** (a) Retention drop force for a divergence angle of 10°; (b) Retention drop force for a divergence angle of 50° (1096.49 cycles for the year).

Both the attachments experience a high drop in the retention force, which tended to stabilize after about 1.5 years (Figure 2b). All of the Locator® group reached up to 26.04% drop in the retention force after 4.56 years (Extra-Soft: 25.71%; Soft: 27.88%; Standard: 24.54%), while the Smart Box group

revealed a higher retention force drop with respect to the 10° divergence angle configuration, but smaller compared to the Locator® attachment (Extra-Soft: 30.25%; Soft: 41.94%; Standard: 57.11%).

### 3. Discussion

Smart Box® is an abutment container that, thanks to a tilting mechanism with a rotation fulcrum, allows passive insertion even in extreme divergences up to 50°. This feature allows forces passivation and, therefore, better predictability characteristics of our rehabilitation [16–18]. It does improve the quality of life of our patients, avoiding complex and invasive surgery, in many cases necessary to perform a fixed implant-prosthetic rehabilitation. This is one of the advantages of this systematic. As shown from Figure 3 in detail, the insertion of the Smartbox® also occurs with divergent angles. Other retentive systems, such as the Locator®, do not allow divergence angles up to 50°, and it is, therefore, possible that residual forces are created in our prosthesis, or in the structure, or on dental implants' position. Residual forces could damage mechanical components or cause biological damages [18,19]. The Overdenture is a mobile prosthesis, on dental implants, stable and comfortable; the upper one may not have a palate plate. Many patients have difficulty keeping their removable prosthesis stable, particularly that of the jaw, or they have difficulty bearing the palate in the case of the upper arch. The dentures are removable (detachable), so they could be cleaned easily (they allow hygienic maneuvers on implants), an advantage for elderly patients with reduced mobility and with lost dexterity. At the same time, these prostheses are perfectly stable during chewing and talking. It is the simplest type of implant-prosthetic rehabilitation in which two or four dental implants are positioned in the anterior area of the jaw or the maxilla. A functional set-up is thus obtained in which the prosthesis is anchored to the implants anteriorly and rests on the mucosa [19,20]. From the obtained results in this simulation, the retention force is greater over time using the OTEquator® rather than the other systematics, especially in the case where there is disparallelism between dental implants. The drop of retention force is higher on the Locator®, and this gives a lower guarantee of duration over time and the worst predictability of oral rehabilitation. Certainly, it should be considered that this is a simulation, and the insertion and disconnection cycles have been tested in a short period that could somehow alter both the internal nylon inserts and the metal boxes themselves.



**Figure 3.** (A) Smart Box® and Equator® detail scheme; (B) Locator® R-TX.

### 4. Materials and Methods

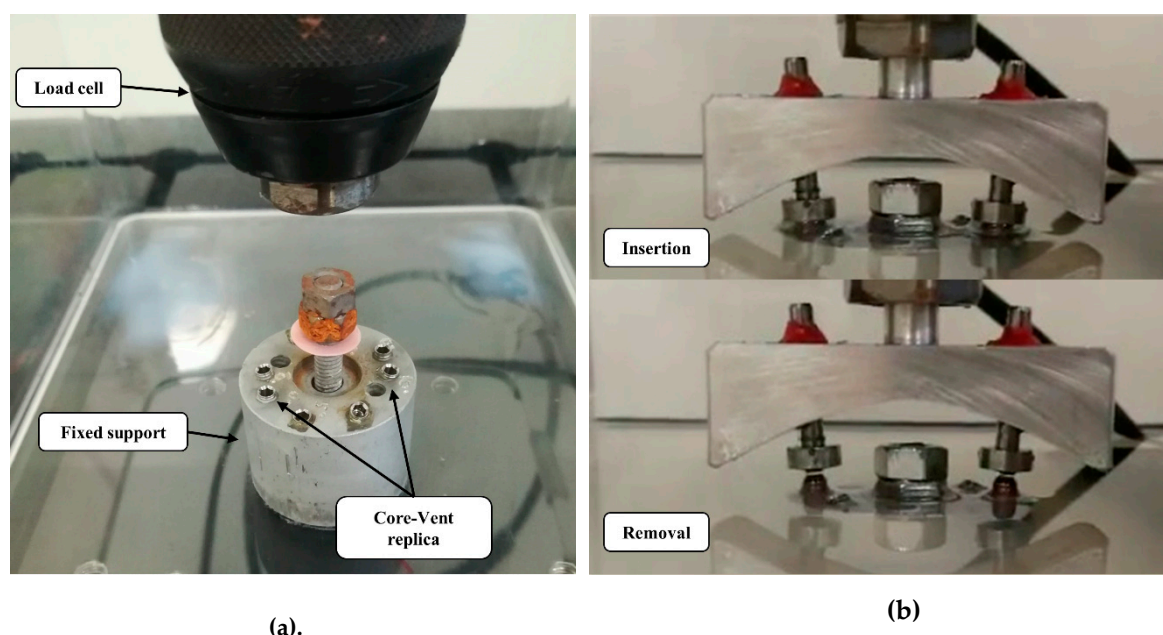
Two different attachment systems with three different classes of retentive caps were tested: OT Equator® Smart Box and Locator® R-TX. In Table 1 the three cap classes from the manufacturer adopted for each of the two attachment systems with the respective nominal retention force are reported [21,22].



**Table 1.** Cap classes for the attachment systems.

Cap Class	OT EQUATOR® SMART BOX	LOCATOR® R-TX
Extra-Soft (E-SF)	Yellow (0.60 kg)	Blue (0.68 Kg)
Soft (SF)	Pink (1.20 kg)	Pink (1.36 kg)
Standard (STD)	White (1.80 kg)	White (2.27 kg)

The tests simulate the insertion-removal cycle of the overdenture from the attachment system evaluating the maximum force needed to detach the implant overdenture from the attachment system. Two implant replicas Core-Vent, diameter 3 mm with internal hexagon, were fixed into a dedicated specimen with auto polymerizing PMMA resin (DuraLay, GC Pattern Resin) to simulate the elastic mobility behavior of the osteointegrated implant (Figure 4a).

**Figure 4.** (a) Testing setup; (b) Insertion and removal phase during one test cycle.

The tested attachment systems (patrix) were screwed onto the implant replicas according to the instructions of the manufacturers. The OT Equator® and the Locator® R-TX were screwed with a torque in the range of 22 to 25 Ncm, adopting, respectively, the OT Equator® screwdriver (Rhein83) and the Locator® screwdriver (Zest). Afterward, the female components were incorporated into the notched surface of the matrix mounting, with the two components already connected, adopting a direct pick-up technique. Finally, the matrix mounting was connected to the load cell of an electrodynamic tensile testing machine MTS Acumen 807.001 (MTS headquarters, Eden Prairie, MN, USA) with a load cell of 1.5 kN (Figure 4b). The testing machine was adopted to induce a vertical uniaxial dislodging force to the attachment system, simulating actual clinical situations. Each retentive cap was subjected to 5000 insertion–separation cycles, assuming 4.56 years of removing and inserting the overdenture three times a day [21,22], this means that there are 1096.49 insertion cycles for a year. The cycle routine consists of 2.5 mm upwards in 2.5 seconds, 0.1 seconds of stop, and 2.5 mm downwards in 2.5 seconds with 1.5 seconds of connection on the attachment to allow the elastic recovery of the attachment components [23]. During the test, artificial saliva, Sinopia, was used as a lubricant at a constant temperature of 37 °C, simulating potential normal conditions of the oral cavity.

A couple of attachments for each of the two adopted systems were mounted in two different configurations of divergence angle: the former with an angle of 10° (−5° /+ 5° from the main axis), the latter with an angle of 50° (−25° /+ 25° from the main axis). For each cap, three tests were performed, for a total number of twelve tests per divergence angle configuration.

## 5. Conclusion

The obtained results from this in vitro study could provide useful information for the performance improvement of retentive systems. Already the discrepancy of results in favor of the Equator system is a good starting point to understand what is the ideal morphology for a retentive system with higher retention force over time.

**Author Contributions:** Conceptualization, M.M., R.B., C.D.A., and G.S.; methodology, D.S., R.B., C.D.A., and G.S.; software, D.S., R.B., C.D.A., and G.S.; validation, D.S., R.B., C.D.A., and G.S.; data curation, D.S., R.B., C.D.A., and G.S.; writing—original draft preparation, D.S. and L.F.; writing—review and editing, L.F. and F.N.; supervision, G.C. and L.F.; project administration, G.C.

**Funding:** This research received no external funding.

**Conflicts of Interest:** The authors declare no conflict of interest.

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***Effectiveness of Ball Attachment Systems  
in Implant Retained  
and Supported-Overdentures:  
A Three to Five Year Retrospective  
Examination***

Luca Ortensi, Matteo Martinolli, Carlo Borromeo, Francesco Mattia Ceruso,  
Marco Gargari, Erta Xhanari, and Marco Tallarico

Published: 1 September 2019  
Dentistry journal



## Article

# Effectiveness of Ball Attachment Systems in Implant Retained- and Supported-Overdentures: A Three- to Five-Year Retrospective Examination

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Received: 19 June 2019; Accepted: 14 August 2019; Published: 1 September 2019



**Abstract:** Purpose: To evaluate implant and prosthetic survival rates, complications, patient satisfaction, and biological outcomes of patients rehabilitated with a ball attachment system for implant retained- and supported-overdentures (IOV), which was in function for 3 to 5 years. Methods: This retrospective study evaluated data collected from patients treated between April 2001 and May 2018 with IOV on splinted and non-splinted implants and a ball attachment system. Patients were followed for 36 to 206 months (mean follow-up was  $128.1 \pm 51.9$  months). Data were collected at the 3- and 5-year follow-up examination. Outcome measures were implant and prosthetic survival rates, technical complications, marginal bone loss (MBL), oral health impact profile (OHIP), and periodontal parameters (bleeding on probing and plaque index). Results: A total of 46 patients (16 males and 30 females) with 124 implants were included in this study. Twenty-five implant-retained overdentures were delivered on 53 unsplinted implants, while the other 21 patients received an implant-supported overdentures and the implants were splinted. At the five-year follow-up examination, one implant and one prosthesis failed in the unsplinted group, resulting in a cumulative survival rate of 97.8% at the patient level. Two minor technical complications were experienced. Conclusions: Implant overdenture retained or supported by ball attachment systems showed high implant and prosthetic survival and success rates. A low number of complications, high patient satisfaction, and successful biological parameters were experienced in the mid-term follow-up. Data need to be confirmed by further randomized trials.

**Keywords:** implant overdenture; metal bar; ball attachments; dental implants

## 1. Introduction

Edentulism is defined as “the state of being without any natural permanent teeth. It is an irreversible condition that is evident in age groups of 65 years and older, and was previously considered part of the normal aging process” [1]. To make matters worse, edentulousness is often associated by lower quality of life due to negatively affecting general as well as oral health [2]. Elderly patients could be forced to modify their dietary habits in favor of less fibrous foods, due to an important

reduction in masticatory function. Because of this behavior the risk of cardiovascular diseases and gastrointestinal disorders may increase [2]. Phonetic and speech functions are also affected particularly after the loss of anterior teeth, making edentulous patients less confident and limited to interacting with other people [3,4]. Trying to solve these problems, in these cases, dental implants can be invaluable. To overcome the above problems implant-retained and -supported overdentures have been proposed during last decades for restoring completely edentulous patients, as an alternative and more effective treatment modality to the conventional complete removable denture. High long-term success rates and improved patients' quality of life were reported for implant-retained and -supported overdentures [5–7]. Implant-supported overdenture (I-SO) takes the bite force through the implants and into the jawbone, providing the most natural and effective bite for patients. However, treatment is usually more expensive since a greater number of implants are required. With implant retained overdenture (I-RO), the gingiva and the underlining bone absorb the bite force. Fewer dental implants are required, so treatment is more cost-effective and often it may be possible to use mini dental implants.

Various attachment systems have been used for years as retentive elements for root overdentures and are now being used almost exclusively to stabilize an overdenture to the installed as implants, including, but not limiting to, balls, magnets, bars, and telescopic attachments [1]. According to a recent Cochrane Systematic Review, there is no sufficient evidence to determine the true effectiveness of different attachment systems for mandibular overdentures, on patient's needs and satisfaction, prosthodontic success, maintenance, and costs [8]. Among these, ball attachments are the more simple, commonly used and well-proven attachment systems used for anchorage on both splinted and non-splinted implants [9,10], offering high retentive ability, reduced loading forces along the implants, and aid in correcting disparallelism between the implants. However, their clinical application requires more vertical and buccolingual spaces, potentially encroaching on the tongue space, particularly in tapered arches. In addition, gingival hyperplasia around the attachment system may complicate the plaque control and the hygiene maintenance.

This retrospective study primarily sought to examine the effectiveness of ball attachment systems for implant overdentures in daily practice. Then, if there are some differences when implants were splinted. The study was written according to the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) guidelines.

## 2. Materials and Methods

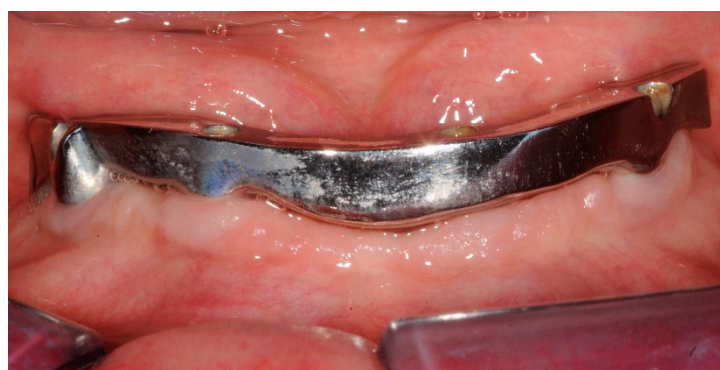
This study was designed as an open cohort, retrospective, comparative case series study conducted according to the Declaration of Helsinki of 1975, as revised in 2013. A retrospective chart review of existing data, documents, radiographs, and digital files was performed at one center in Italy to evaluate data collected from fully edentulous patients treated between April 2001 and May 2018. Data analysis was designed to preserve the anonymity of the patients. After considering the study design and protocol, the ethical committee of the University of Aldent declared no objection to this research. Any edentulous patients in at least one arch, aged 18 years or older, that required an implant-based restoration were considered eligible for this study. Completely edentulous patients were considered but only one arch was included in the study. Additional inclusion criteria were a Cawood and Howell class II to VI [11], refusing guided bone reconstruction, and the need of lip support. Exclusion criteria were general contraindications to oral surgery, heavy smoking ( $\geq 10$  cigarettes/day), immediate post-extractive implants, untreated periodontitis (full-mouth bleeding on probing (BoP), a full-mouth plaque index (PI) of  $\leq 25\%$ ), allergy or adverse reactions to the restorative materials, and lack of written informed consent.

One to five submerged implants were placed using a conventional free-hand approach, according to the manufacturer's guidelines. All the implants were placed in the interforaminal or in the pre-maxillary region. An expert surgeon performed all the surgical and prosthetic procedures. Three types of implants were used during the study period.

Three to five months after implant placement, definitive impressions were taken and the models were mounted in a dental articulator in centric relation, using a facial bow, at the established occlusal vertical dimension. Esthetics and function were evaluated and approved by both the patient and the clinician at the try-in appointments. Afterward implant overdentures were delivered. Patients with unsplinted implants received an implant-retained overdenture. A newly developed completely removable denture was delivered on 1 to 5 implants according to a previously published protocol [12]. After delivery of the final prosthesis, all the attachment systems (Ball attachments, OT Cap, Rhein'83, Bologna, Italy) were incorporated chairside into the fitting surface of the overdenture, directly chairside. Patients with splinted implants received an implant-supported overdenture, delivered on 3 to 4 implants. Either the conventional melting technique or newly developed CAD/CAM technologies were used to fabricate the implant-bar and the metal counterpart according to a previously published protocol [13] (Figures 1–3). Factors that had influenced the choice between splinted and unsplinted implants were patients' needs and requests, and the clinician's recommendation that included health, lifestyle, diet choices, and cost. All the laboratory procedures were accomplished by an expert dental technician (CB). Follow-up visits were scheduled at 1 and 6 months after delivery of the implant overdenture, and then annually. At each follow-up examination, occlusal adjustment was performed if needed. Periapical radiographs were made annually, with a film holder (Rinn XCP, Dentsply, Elgin, IL, USA). The patients were strongly instructed on the daily maintenance hygienic procedures and underwent a professional cleaning by a dental hygienist every 6 months.



**Figure 1.** Melted implant-bar, occlusal view at three years follow up.



**Figure 2.** Front view at three years follow up. Good hygiene maintenance and no inflammation of the keratinized mucosa.





**Figure 3.** CAD/CAM implant-bar and the metal counterpart, front view at three years follow up.

### 3. Outcome Measures

**Implants and prosthesis failures:** An implant was considered a failure if it presented with any mobility, progressive marginal bone loss (annual bone loss of  $>0.2$  mm after the physiological bone remodeling), and suppuration, or any mechanical complications rendering the implant unusable (i.e., implant fracture). A prosthesis was considered a failure if it needed to be replaced with another prosthesis for any reason.

**Complications:** Any biological (pain, swelling, suppuration, etc.) and/or technical (screw loosening, fracture of the framework and/or the veneering material, etc.) complications were considered. Implants and prosthesis failures and complications were assessed and treated by the treating clinicians at each center.

**Marginal bone loss (MBL):** Digital periapical radiographs were made with the paralleling technique using commercially available film holders. Mesial and distal bone level changes were measured as the distance from the implant shoulder and the most coronal bone to implant contact, and then averaged. Radiographs were taken at the definitive prosthesis delivery (implant loading) and then yearly. The difference between each follow-up and the baseline was taken as the marginal bone loss. An independent outcome assessor measured all the radiographs using calibrated software (DFW2.8 for Windows, Soredex, Tuusula, Finland).

**The Oral Health Impact Profile (OHIP-21)** A questionnaire, with 21 questions divided into seven subscales (functional limitations, physical pain, psychological discomfort, physical disability, psychological disability, social disability, and handicap), with two to four questions each, was completed by patients. Patients were instructed to choose from five possible responses ranging from 1 (never) to 5 (very often). The questionnaire was administered by an independent dentist before treatment and yearly after definitive prosthesis delivery.

The bleeding index and plaque index were evaluated yearly around each implant-abutment interface using a periodontal probe (PCPUNC156, Hu-Friedy, Milan, Italy) by an independent blinded dental hygienist. Four sites were evaluated (yes = 1/no = 0) at each implant-abutment complex, and averaged between them.

### 4. Statistical Analysis

All data analysis was carried out according to a pre-established analysis plan using SPSS Statistics for Macintosh (Version 22.0, IBM, Armonk, NY, USA). Descriptive analysis was performed using means, standard deviations, and a 95% confidence interval, as well as median and interquartile ranges (IQR: First quartile; median; third quartile). Fisher's exact test for count data was used to evaluate statistically significant differences between centers for implant and prosthetic failures and

complications. Comparison of the means for OHIP scores between the baseline and the follow-ups was performed by paired tests. Patients were grouped based on their facial type assessment (brachycephalic, dolichocephalic, and mesocephalic) and treated arch (mandible and maxilla). The mean differences in MBL and OHIP between different subgroups were compared using a mixed-model repeated-measures analysis of variance (ANOVA). Fisher's exact test for count data was used to evaluate statistically significant differences between centers for implant and prosthetic failures and complications.

## 5. Results

A total of 46 patients (16 males and 30 females) with 124 implants were included in this study. Of these, 27 patients were treated in the mandible and 19 in the maxilla. Twenty-five implant-retained overdentures were delivered on 53 unsplinted implants (18 in the mandible and 7 in the maxilla), while the other 21 patients (9 in the mandible and 12 in the maxilla) received an implant-supported overdenture and the implants were splinted. Patients were followed for 36 to 206 months (mean follow-up was  $128.1 \pm 51.9$  months). Data were collected at 3- and 5-year follow-up examinations. Patients' characteristics were reported in Table 1.

**Table 1.** Patients' characteristics.

	Total (n = 46)	Unsplinted (n = 25)	Splinted (n = 21)	p-Value
Age	$69.2 \pm 8.1$	$72.8 \pm 7.4$	$64.8 \pm 7.6$	0.0008 *
Male	16 (34.8%)	8 (32.0%)	8 (38.1%)	0.7604
Mandible	27 (58.7%)	18 (72.0%)	9 (42.9%)	0.0716
Smokers	7 (15.2%)	3 (12.0%)	4 (19.0%)	0.6857
Mean follow-up (range) in months	$128.1 \pm 51.9$ (36 to 206)	$129.2 \pm 57.4$ (36 to 194)	$126.7 \pm 45.7$ (36 to 206)	0.8689
Mean number of implants	2.7 (1 to 5)	2.1 (1 to 5)	3.4 (2 to 4)	0.0000 *
Failed implants	1	1	0	1.0
Failed prosthesis	1	1	0	1.0
Complications	4	1	3	0.3180

\* Statistically significant.

At the three-year follow-up examination, one implant and one prosthesis failed in the unsplinted group, resulting in a cumulative survival rate of 97.8% at the patient level. Two minor technical complications were experienced. The first complication was the detachment of one steel housing in the unsplinted group, and the second was the need to rebase a buccal flange of an implant-supported overdenture, due to food entrapment. Both complications were resolved chairside within 15 to 20 min. At the five-year follow-up examination, no other implants or prostheses failed. Two minor complications were experienced, both in the splinted group. The first complication was the detachment of one steel housing, then the second was the detachment of an upper central incisor. The first complication was resolved chairside in 15 min, while the second was resolved chairside in 60 min.

All the data from 46 patients were analyzed at the 1- and 3-year visit levels, while data from 37 patients were analyzed after 5 years of function (unsplinted, n = 19, and splinted, n = 18). Overall outcome measurements are reported in Table 2.

**Table 2.** Overall outcome measurements during follow-up.

	Before *	1 Year *	3 Years *	5 Years §
HOIP	$74.04 \pm 11.65$	$32.26 \pm 9.21$	$32.81 \pm 7.34$	$33.0 \pm 7.36$
Marginal bone loss		$0.22 \pm 0.30$	$0.38 \pm 0.40$	$0.46 \pm 0.40$
Bleeding on probing		$0.05 \pm 0.10$	$0.07 \pm 0.16$	$0.09 \pm 0.18$
Plaque index		$0.09 \pm 0.15$	$0.06 \pm 0.12$	$0.07 \pm 0.14$

\* Unsplinted n = 25; splinted n = 21. § Unsplinted n = 19, splinted n = 18.

When comparing data between splinted and unsplinted group, there was no statistically significant difference in all the outcomes measured, including the Oral Health Impact Profile (Table 3), marginal bone loss (Table 4), bleeding on probing (Table 5), and the plaque index (Table 6).

**Table 3.** Oral Health Impact Profile.

Group	Before *	1 Year *	3 Years *	5 Years §
Unsplinted	75.0 ± 12.8	32.2 ± 8.6	31.6 ± 6.6	31.4 ± 5.9
Splinted	72.9 ± 10.3	34.5 ± 10.0	34.4 ± 8.1	34.7 ± 8.5
<i>p</i> -Value	0.5419	0.4069	0.2467	0.1892

\* Unsplinted n = 25; splinted n = 21. § Unsplinted n = 19, splinted n = 18.

**Table 4.** Marginal bone loss.

Group	1 Year *	3 Years *	5 Years §
Unsplinted	0.20 ± 0.24	0.35 ± 0.37	0.41 ± 0.32
Splinted	0.24 ± 0.36	0.41 ± 0.45	0.51 ± 0.48
<i>p</i> -Value	0.6468	0.9931	0.4729

\* Unsplinted n = 25; splinted n = 21. § Unsplinted n = 19, splinted n = 18.

**Table 5.** Bleeding on probing.

Group	1 Year *	3 Years *	5 Years §
Unsplinted	0.04 ± 0.11	0.07 ± 0.13	0.05 ± 0.13
Splinted	0.06 ± 0.09	0.08 ± 0.19	0.08 ± 0.14
<i>p</i> -Value	0.5115	0.7286	0.4162

\* Unsplinted n = 25; splinted n = 21. § Unsplinted n = 19, splinted n = 18.

**Table 6.** Plaque index.

Group	1 Year *	3 Years *	5 Years §
Unsplinted	0.09 ± 0.15	0.07 ± 0.17	0.06 ± 0.16
Splinted	0.10 ± 0.06	0.10 ± 0.16	0.11 ± 0.19
<i>p</i> -Value	0.7923	0.8350	0.4492

\* Unsplinted n = 25; splinted n = 21. § Unsplinted n = 19, splinted n = 18.

When comparing the number of failed implants, prostheses, and complications between patients with different restorative statuses of the opposing arch, there was no statistically significant difference in all the outcomes measured (*p*-value from 0.6139 to 1.000).

## 6. Discussion

This study aimed to evaluate implant and prosthetic survival rates, any complications, patient satisfaction, and biological outcomes of patients treated with implant overdentures (IOV) and a ball attachment system, on splinted and non-splinted implants, in function for 3 to 5 years. The main limitation of the present study is its retrospective nature, which means there are potentially several biases. Then, because this research was designed as a retrospective cohort study, the clinician should interpret with caution the data that emerged in this paper.

Nowadays, implant-retained or -supported overdentures (IOD) can be considered a viable treatment option increasing masticatory function and improving satisfaction by making up for insufficient retention and stability of a conventional denture [14]. Retention force as well as prosthetic



complications of ball and bar attachment systems were evaluated by several studies. Sadowsky [15], in a review of the literature, reported that a single ball attachment allows for less technique sensitive and lower costs compared to other attachment systems. However, ball attachments seem to be less retentive than the bar designed retention. Accordingly, Naert and co-workers [16] showed that a single attachment allow for lower retention compared to a metal bar.

In the present study at the three-year follow-up examination, one implant and one prosthesis failed in the unsplinted group, resulting in a cumulative survival rate of 97.8% at patient level. No statistically significant differences were found between splinted and unsplinted IOV. Recent literature reported successful long-term implant and prosthetic outcomes of patients rehabilitated with an implant-supported overdenture [17–19]. The cumulative implant success rate was more than 96% after 15 years of function [17]. Failed implants were commonly experienced in the maxilla, as observed in the present retrospective analysis.

In this retrospective study authors found only two minor technical complications. The first complication was the detachment of one steel housing in the unsplinted group, then the second was the need to rebase a buccal flange of an implant-supported overdenture, due to food entrapment. Both complications were resolved chairside within 15 to 20 min. At the five-year follow-up examination, no other implants or prostheses failed. Two minor complications were experienced, both in the splinted group. The first complication was the detachment of one steel housing, then the second was the detachment of an upper central incisor. The first complication was resolved chairside in 15 min, while the second was resolved chairside in 60 min.

Five years after loading, the mean marginal bone loss observed in the present research was  $0.46 \pm 0.40$  mm, with a minimum of 0.12 mm and a maximum of 2.13 mm. It might be noticed that these results may be in line or even better of the mean marginal bone loss reported by Meijer et al. [20]. The authors report a mean marginal bone loss of 1.0 and 1.1 mm with implant-retained overdenture in function for 5 and 10 years, respectively. According to the results of a systematic review of Cehreli et al. [21], there was no statistically significant difference between splinted or unsplinted implants as well as between different types of attachment systems.

Plaque scores decreased slightly during the follow-up, independently by the number of the implants and the type of attachment systems used. On the other hand, Elsyad et al. [22] reported an increased plaque scores in similar treatments. The authors stated that the reasons could be the resiliency of the attachments, which allows denture movements and accumulation of plaque under the denture. Moreover, age-related problems such as a decreased awareness could affect oral hygiene practice of the patients [23].

It is widely accepted that conventional completely removable dentures have less satisfaction results in patient's lives compared to IODs [24–29]. In the present study, high patient satisfaction was reported, with no statistically significant differences for different IODs design or attachment systems. On the other hand, Tallarico et al., in a long-lasting retrospective study, reported that splinting the implants may reduce the number of mechanical complications. In the same study, Locator attachments showed a higher number of complications compared with other attachment systems [29].

When comparing data between splinted and unsplinted groups, this retrospective study failed to find any statistically significant difference in all the outcomes measured.

## 7. Conclusions

Implant overdenture retained or supported by ball attachment systems showed high implant and prosthetic success rates, a low number of mechanical and biological complications, high patient satisfaction, and good biological parameters, in both the short and mid-term follow-up evaluation. Data need to be confirmed by further randomized trials.

**Author Contributions:** L.O. performed all the surgical and prosthetic treatments (acquisition of the data) and final approval of the version to be published. M.M. had substantial contributions to the conception of the work; the analysis, and interpretation of the data; drafting the work and final approval of the version to be published. C.B. is the dental technician who performed all the rehabilitations and final approval of the version to be published. F.M.C. and M.G. performed a critical revisions for important intellectual content, and final approval of the version to be published. E.X. took contact with the editorial board and final approval of the version to be published. M.T. had substantial contributions to the conception and design of the work and interpretation of the data; drafting the work and final approval of the version to be published.

**Funding:** This research received no external funding.

**Conflicts of Interest:** The authors did not receive any materials/products or financial support for this investigation.

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***Feasibility of Low Profile Attachments  
to Improve Quality of Life on Patients  
with Implant-Retained Mandibular Overdenture:  
1-Year Preliminary Results of a Multicenter  
Prospective Case Series Study***

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Published: 5 October 2018  
OHDM Vol. 17

# Feasibility of Low Profile Attachments to Improve Quality of Life on Patients with Implant-Retained Mandibular Overdenture: 1-Year Preliminary Results of a Multicenter Prospective Case Series Study

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## Abstract

**Aim:** The purpose of this multicenter prospective case series study evaluated peri-implant marginal bone loss, complications, oral health impact profile, and soft tissue parameters in patients with mandible implant overdenture retained on two low profile attachments. **Methods:** This study was designed as a multicenter prospective case series study conducted according to the Declaration of Helsinki of 1975, as revised in 2008. Patients that required an implant-retained overdenture to rehabilitate a complete edentulous mandible were considered eligible for this research. Patients were consecutively enrolled and treated in seven centers in Italy between February 2012 and March 2017. The last follow-up was in May 2018. **Results:** A total of 40 mandibular implant-retained overdentures were delivered on 40 participants (26 females and 14 males) with a mean age of 67.5 years. All the participants were followed for at least one year (mean 21.3 months, range 12 to 60) after implant loading. At the one-year follow-up examination, no implants and no prostheses failed. Three mechanical complications were experienced at two different centers. One fully acrylic implant-retained overdenture fractured 8 months after its delivery in a patient with brachycephalic facial type. **Conclusions:** It may be concluded that implant overdenture showed high implant and prosthetic survival rates, low complications, high patient satisfaction, and good biological parameters after one year of follow-up.

*Key Words: Overdenture, Prosthesis, Low-profile attachments, Implant*

## Introduction

With the increase of an elderly population, there is a growing number of edentulous. Edentulism can lead to significant functional impairment, and unfavorable esthetic and psychological changes in patients [1]. Restrictions in diet, speech impairment, loss of soft-tissue support directly or indirectly contribute to the global burden of disease.

The conventional method for treating edentulism is to provide complete dentures. However, progressive loss of alveolar bone may contribute to loss of retention and stability, and hence masticatory function, patient discomfort and pain [2]. To overcome these problems, when a fixed implant-supported prosthesis is not indicated (e.g. excessive inter-arch discrepancy, financial problems, etc.) the use of Implant-Retained Overdentures (IOD) were shown to be successful in rehabilitating the edentulous patients, with a high implant success rate [3-8].

The attachment systems for dental implant overdentures can be classified into the self-standing type and bar-type. Self-standing type attachments, such as ball attachment, magnet attachment, and Locator, have advantages such as easiness in oral hygiene maintenance and the possibility of using in a narrow inter-arch space. On the other hand, limits could be found in parallel implant placement requirement, and stability of the implant overdentures lesser to that of bar-type [9,10].

Implant-retained overdentures have become a well establish option for the prosthetic treatment of the complete edentulous mandible, both with immediate and the delayed loading protocols. Nevertheless, the inter-arch space required for an

implant-retained overdenture, measured from the implant platform to the incisal edge is approximately 12-14 mm.

Inadequate inter-arch space may improve the risk of mechanical complications. Several attachment systems have been introduced to retain an implant overdenture. Among these, low profile attachment system may be a better choice to safe inter-arch space and also to potentially reduce number of complications.

The aim of this multicenters prospective case series study was to evaluate peri-implant marginal bone loss, complications, oral health impact profile, and soft tissue parameters in patients with mandible implant overdenture retained on two low profile attachments. The study was written according to the STROBE guidelines [11].

## Materials and Methods

This study was designed as a multicenter prospective case series study conducted according to the Declaration of Helsinki of 1975, as revised in 2008. Patients that required an implant-retained overdenture to rehabilitate a complete edentulous mandible were considered eligible for this research. Patients were consecutive enrolled and treated in seven centers in Italy between February 2012 and March 2017. The last follow-up was in May 2018. The eligibility criteria were reported in (Table 1). Study protocol was designed to collect data up to the five years after implant loading. This manuscript presents the preliminary data at one-year after loading examination.

**Table 1.** Eligibility criteria adopted for this study.

Inclusion and exclusion criteria	
Complete edentulous mandible	General contraindications to oral surgery
ASA I and II	Pregnancy or nursing
Aged 18 years or older	Intravenous bisphosphonate therapy
Provided written consent to this research	Alcohol or drug abuse
	Heavy smoking ( $\geq 20$ cigarettes/day)
	Radiation therapy to the head or neck region within the last five years
	Parafunctional activity
	Untreated periodontitis
	Allergy or adverse reactions to the restorative materials
	Absence of teeth/denture in the opposite jaw

### Surgical Protocol

A single dose of an antibiotic (2 g of amoxicillin or 600 mg of clindamycin if allergic to penicillin) was administered one hour before implant placement.



**Figure 1.** Post-op x-ray with two implant.



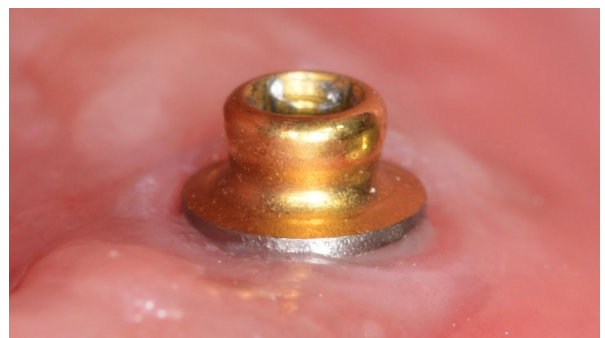
**Figure 2.** Soft tissue healing.

Local anesthesia was administered and a mucoperiosteal flaps elevated. Non submerged implants were placed, as parallel as possible, in the interforaminal region maintaining an inter-implant distance ranging between 15 mm and 25 mm (Figures 1 and 2).

After surgery, patients received medication and oral hygiene instructions. A cold and soft diet was recommended for ten days. Smokers were encouraged to stop smoking for three days postoperatively. Patients were divided into three groups based on their facial type assessment: brachycephalic, dolichocephalic and mesocephalic. Cephalic index was used to assess the facial type measuring the ratio of the maximum head breadth to the maximum head length [12].

### Prosthetic Protocol

Two months after implant placement, low-profile attachments (OT Equator, Rhein83, Bologna, Italy) were screwed onto the implants, with a torque of 22-25 Ncm (Figures 3 and 4). The cuff heights of the low-profile attachments ranged from 0.5 mm to 7.0 mm, based on the height of the peri-implant soft tissue, measured with the color-coded millimeter Cuff Height Measurer Gauge (Rhein 83), immediately after healing abutment removal.



**Figure 3.** Clinical intraoral image of two mandibular low profile attachments.

All the patients received a new complete removable denture. Nevertheless, the operators were free to deliver the complete removable denture in the way they considered most appropriate. The research protocol did not affect individual operator preference regarding how to deliver the implant-

retained overdenture. However, variabilities between operators were collected and analyzed (Table 2).



**Figure 4.** Magnification of the Equator (Rhein83) low profile attachment after 1 year of function.

**Table 2.** Variability's between operators

Variability's between operators	
Metal-reinforced overdenture	Yes or No
Restorative material (teeth portion)	Composite, resin or ceramic
Occlusion	Anterior guidance, group function, bilateral balanced
Steel housing fixing	Dental laboratory or patient's mouth

After delivery of the implant-retained overdenture, the occlusion was adjusted and clinical pictures and standardized periapical radiographs of the implants were made. Patients were recalled for maintenance every 6 months for the entire study period. Operators could decide to recall patients more frequently (every 3 to 4 months) if necessary.

Patients were divided into three groups based on their facial type assessment: brachycephalic, dolichocephalic and mesocephalic.

### Outcome Measures

- Implants and prosthesis failures: an implant was considered a failure if it was presented with any mobility, progressive marginal bone loss and suppuration or any mechanical complications rendering the implant unusable (i.e. implant fracture). A prosthesis was considered a failure if it needed to be replaced with another prosthesis for any reason.
- Complications: any biological (pain, swelling, suppuration, etc.) and/or mechanical (screw loosening, fracture of the framework and/or the veneering material, etc.) complications were considered. Implants and prosthesis failures and complications were assessed and treated by the treating clinicians in each center.
- Marginal bone loss: digital periapical radiographs were made with the paralleling technique using commercially available film holders. Mesial and distal bone level changes were measured as the distance from the implant

shoulder and the most coronal bone to implant contact, and then averaged. Radiographs were taken at the definitive prosthesis delivery (implant loading) and then yearly. Difference between each follow-up and baseline were taken as marginal bone loss. An independent outcome assessor measured all the radiographs using calibrated software (DFW2.8 for Windows, Soredex, Tuusula, Finland).

- Oral Health Impact Profile (OHIP-21) A questionnaire with 21 questions, divided in seven subscales (functional limitations, physical pain, psychological discomfort, physical disability, psychological disability, social disability, and handicap), with two to four questions each, was completed by patients. Patients were instructed to choose from five possible responses ranging from 1 (never) to 5 (very often). The questionnaire was administered by an independent dentist before treatment and yearly after definitive prosthesis delivery.
- Bleeding index and plaque index were evaluated yearly around each implant-abutment interface using a periodontal probe (PCPUNC156, Hu-Friedly, Milan, Italy) by an independent blinded dental hygienist. Four sites were evaluated (yes=1 / no=0) at each implant-abutment complex, and averaged between them.

All data analysis was carried out according to a pre-established analysis plan using SPSS Statistics for Macintosh (Version 22.0, IBM, Armonk, N.Y., U.S.). Descriptive analysis was performed using means, standard deviations and a 95% confidence interval, as well as median and interquartile ranges (IQR: first quartile; median; third quartile). Fisher exact test four count data was used to evaluate statistically significant differences between centers for implant and prosthetic failures and complications. Comparison of the means for OHIP scores between the baseline and the follow-ups was performed by paired tests. The mean differences in MBL and OHIP between different facial type assessments were compared using a mixed-model repeated-measures analysis of variance (ANOVA). Fisher exact test four count data was used to evaluate statistically significant differences between centers for implant and prosthetic failures and complications.

### Results

Initially, 49 patients were selected, but only 40 were included in this single cohort prospective study. Six patients were excluded because of the presence of hopeless teeth that needed to be extracted at the same time as implant placement. Two patients were heavy smokers and one patient presented parafunctional habits. Finally, a total of 40 mandibular implant-retained overdentures were delivered on 40 participants (26 females and 14 males) with a mean age of 67.5 years. All patients presented natural teeth, fixed or removable prosthesis in the opposite arch, with stable occlusion. Participants were followed for at least one year (mean 21.3 months, range 12 to 60) after implant loading. At the one-year follow-up examination, no implants and no prostheses failed. Three mechanical complications were experienced at two different centers. One fully acrylic implant-retained overdenture fractured 8 months after its delivery in a patient with brachycephalic facial type. The



prosthesis was repaired chairside and a metal-reinforcement was applied. In two different patients of the same centre, early replacement of the retentive caps was needed. Extra-soft (yellow, 600 g) retentive caps were replaced chairside with stronger retentive caps, both in patients with mesocephalic facial type. There was no statistically significant differences between centers ( $P=0.2530$ ), as well as, between different facial type ( $P=0.3978$ )

One year after implant loading, mean marginal bone loss of  $0.29 \pm 0.51$  mm (95% CI 0.00 to 0.35). OHIP score at baseline was  $76.9 \pm 6.3$  (95% CI from 76.0 to 78.0). One year after delivery of the implant-retained overdenture, OHIP was  $22.5 \pm 4.5$  (95% CI from 20.6 to 23.4). The difference was statistically significant ( $54.4 \pm 6.7$ ; 95% CI from 53.9 to 58.1;  $P=0.0000$ ) with better value at the one-year follow-up examination.

At the one-year follow-up session, bleeding index was  $0.08 \pm 0.07$  (0.00; 0.08; 0.13); while the plaque index was  $0.13 \pm 0.14$  (0.00; 0.10; 0.20).

Among 44 patients, 5 were with brachycephalic facial type, 9 with dolichocephalic facial type, and the others 30 with mesocephalic facial type.

At the one-year follow-up examination, the differences in MBL and OHIP between different facial type assessments were not statistically significant. The mean MBL was  $0.21 \pm 0.17$  mm (brachycephalic);  $0.6$  mm- $1.1$  mm (dolichocephalic); and  $0.2$ - $0.14$  mm (mesocephalic). The  $P$  value was 0.1922. The mean OHIP difference between baseline and one year follow-up examination was  $51 \pm 3.2$  (brachycephalic);  $56.9$ - $5.5$  (dolichocephalic); and  $54.2$ - $7.4$  (mesocephalic). The  $P$  value was 0.2887.

## Discussion

This multicenter prospective case series study evaluated peri-implant marginal bone loss, complications, oral health impact profile, and soft tissue parameters in patients with mandible implant overdenture retained on two low profile attachments. In the present study, high implant cumulative survival rate was found after one year of loading. In fact, no implant failure occurred during the first year of function. This data is in agreement with implant survival rates of locator-retained overdentures, experienced by Elsyad et al. (96.9% after one year) [13].

In the present study, only three mechanical complications were experienced at two different centers using low profile attachments. All of these patients were easily treated with short chairside procedures. One fully acrylic implant-retained overdenture fractured eight months after its delivery in a brachycephalic patient. The prosthesis was repaired chairside and a metal-reinforcement was applied. In two different patients of the same centre, early replacement of the retentive caps was needed. In accordance with the international literature, the few studies that mentioned aspects of prosthetic aftercare provided to implant-retained overdentures reported similar or higher complications with other attachment components [14-16]. Among these, fractures of the acrylic resin or teeth [17,18], and overdenture adjustments [15,16] were the most frequent.

In the present study, one year after delivery of the implant-retained overdenture, all patients were highly satisfied. Considering OHIP score, the difference found during this prospective study was statistically significant with better value at the one-year follow-up examination. Implant attachments could positively contribute to the retention of the mandibular dentures and consequently led to higher rates of patient satisfaction. Furthermore, statistically significant improvement in all the OHIP categories was reported in all of the patients, after one-year of function; according to Awad et al. [19], high patient satisfaction was reported during the follow-up, mainly due to improved denture stability and masticatory function.

Nowadays, implant-retained overdentures can be considered a viable treatment option when bone volume is reduced. The IODs increase the masticatory function and improve satisfaction by making up for insufficient retention and stability of a conventional denture.

In the present study, one year after implant loading, a mean marginal bone loss of  $0.29 \pm 0.51$  mm occurred (95% CI 0.00 to 0.35). This result is in line with recent literature data [20]. This phenomenon of up to one mm bone loss has been described previously and is related to maturation of bone after implant placement and adaptation of bone to withstand functional forces [21].

At the one-year follow-up session, bleeding index was  $0.08 \pm 0.07$  (0.00; 0.08; 0.13); while the plaque index was  $0.13 \pm 0.14$  (0.00; 0.10; 0.20). A plaque scores was reported in other studies for locator attachments [22,23]. This may be due to the resiliency of both attachments, which allow for denture movements, accumulation of food particles and plaque under the denture [23].

Although there were no statistical differences between facial types, the limited amount of patients as well as the short follow-up could have hidden some differences. For this reason, RCT studies conducted specifically in these patients or a longer follow-up will help to evaluate if there is any correlation.

## Conclusions

Within the limitations of this study, it may be concluded that implant overdenture showed high implant and prosthetic survival rates, low complications, high patient satisfaction, and good biological parameters after a one year follow-up. Additional prospective clinical studies with larger samples and RCT will be needed to better understand these preliminary results.

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***FEM Analysis of Dental Implant-Abutment Interface  
Overdenture Components and Parametric Evaluation  
of Equator<sup>®</sup> and Locator<sup>®</sup> Prosthodontics Attachments***

Marco Cicciù, Gabriele Cervino, Dario Milone and Giacomo Risitano

Published: 16 February 2019  
Materials

## Article

# FEM Analysis of Dental Implant-Abutment Interface Overdenture Components and Parametric Evaluation of Equator<sup>®</sup> and Locator<sup>®</sup> Prosthodontics Attachments

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Received: 13 January 2019; Accepted: 13 February 2019; Published: 16 February 2019



**Abstract:** The objective of this investigation was to analyze the mechanical features of two different prosthetic retention devices. By applying engineering tools like the finite element method (FEM) and Von Mises analyses, we investigated how dental implant devices hold out against masticatory strength during chewing cycles. Two common dental implant overdenture retention systems were analyzed and then compared with a universal—common dental abutment. The Equator<sup>®</sup> attachment system and the Locator<sup>®</sup> arrangement were processed using the FEM Ansys<sup>®</sup> Workbench. The elastic features of the materials used in the study were taken from recent literature. Results revealed different responses for both the devices, and both systems guaranteed a perfect fit over the axial load. However, the different design and shape involves the customized use of each device for a typical clinical condition of applying overdenture systems over dental implants. The data from this virtual model showed different features and mechanical behaviors of the overdenture prosthodontics attachments. A three-dimensional system involved the fixture, abutment, and passant screws of three different dental implants that were created and analyzed. Clinicians should find the best prosthetic balance to better distribute the stress over the component, and to guarantee the patients clinical long-term results.

**Keywords:** overdenture attachments; implant abutment connections; stress distribution; FEM

## 1. Introduction

The management of the atrophic mandible using dental implants is a common technique. The lower jaw is a complex anatomical district and the presence of the tongue reduces the contact surface of the removable prosthesis [1,2]. Recently, the possibility of positioning two or more dental implants in the anterior mandible gives clinicians the opportunity to increase the removable prosthesis retention or to fix partial or complete lower dentures [1–5]. Quality assurance of health care delivery has emphasized the importance of the patient's perceptions of medical therapies since the early seventies. The patient's desires, both before and after a medical therapy, are fundamental to the final satisfaction with the treatment outcomes [6–9]. This is even more critical today, as the current practice of evidence based medicine requires that patients be actively engaged in the decision making process with regards to their treatment. Moreover, evaluating the expectations of patients before the treatment starts appears to be an essential prerequisite to achieve successful patient reports on long-term clinical outcomes [10,11]. Though removable prosthesis can offer high aesthetics, the main limit of such dental rehabilitation is related to their retention. Dental implants and related prosthodontics treatment

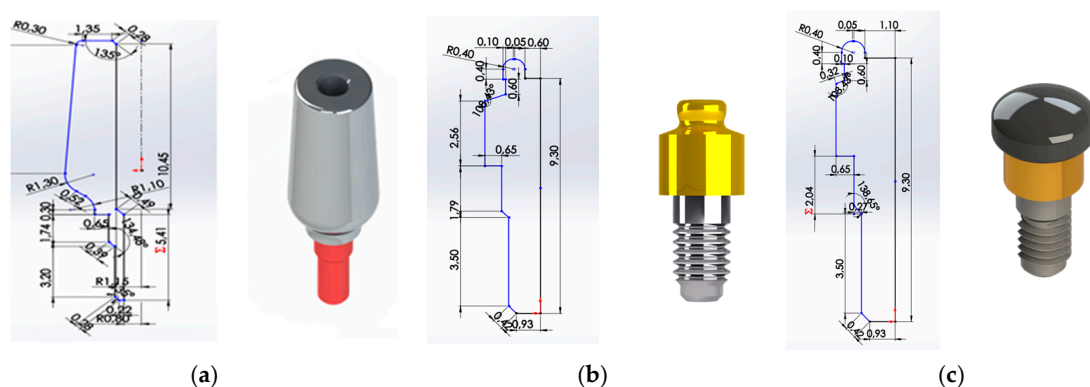


offer high levels of oral health linked to the quality of life, and are particularly important in times of population aging as the edentulousness percentage continues to be relevantly high [12–15]. The best attachment system choice is also related to the duration and possibility of the dental implant survival from a healthy distribution of the tension during the masticatory cycle. Numerous papers have recently recreated the masticatory system by engineering tools for simulating the long term stress over the dental, bone of the jaws, and prosthodontics components. FEM is a computer method for stress analysis. The effect of loading strengths over the dental implant elements and peri-implant bone can be recorded by applying the equivalent Von Mises stress, expressed in MPa. The difference in tension distribution is usually presented by different colors, where red is the maximum stress [2,4,7,16–21]. The present study was aimed at evaluating three different attachment systems for dental implants overdentures, to propose a better prosthodontics solution related to edentulous mandibular ridge restoration.

The homogeneous distribution of tensional forces developed on dental devices during the masticatory cycles is influenced not only by the number and the position of the dental implants, but by the structural material, the shape, and the diameter of the singular component(s)' geometry [1,2]. The present investigation was performed on different prosthetic elements of retention to point out possible failures related to any fracture of the structural components or any overload on the bone tissue. FEM was used to better evaluate the mechanical features of each implant-prosthetic component. The Ansys® program was used to conduct the analysis, using three different implant systems:

- (1) UNIVERSAL ABUTMENT,
- (2) LOCATOR<sup>®</sup> ABUTMENT,
- (3) EQUATOR<sup>®</sup> ABUTMENT.

A comparative analysis was performed to complete the systems, using a type of implant and various “pillars” and “abutments” connected by metric threading (Figure 1). The dimensions of the system components were not provided; therefore, it was necessary to go through a “reverse engineering” process. It was necessary to refer to prosthesis catalogues to acquire the initial measures. Furthermore, due to the lack of many measures, photos were used to derive them. The reverse engineering operation inevitably introduced approximations. Moreover, we used the obtained dimensions to create the geometry of the three-dimensional models in the SolidWork® program. High importance was given to the materials (titanium alloy and bone) and to the parameters of the simulations, such as the definition of the contact surfaces, the mesh, and the loading conditions and the constraints. The results of the tests were available in the form of graphic simulations and data, which were compared to understand the optimal configuration between the systems analyzed. Finally, the Von Mises stress solutions were used and applied to the data.



**Figure 1.** 2D Sketch and rendering, (a) universal abutment, (b) locator abutment, (c) equator abutment, measured in mm.

## 2. Materials and Methods

Key parameters, which influence the accuracy of the results of the FEM system, were underlined. Among these, we considered, the detailed geometry of the system and the surrounding bone to be modeled, the boundary conditions and constraints, the material properties, the load conditions—repeated based on times related to the masticatory cycle, the bone—implant interface, the test of convergence, and the validation of the model.

Solid models of jaw arches, dental implants, and prosthetic overdenture elements were recreated from Roster images, which were processed using a 3D CAD “version 2014” in FEM. The analysis process was then divided into the following two phases as done in the pre-processing: the finite element model construction phase, and the post-processing: processing and representation of solutions [3,4].

### 2.1. Reverse Engineering

The model dimensions were realized from the implant-prosthetic components and the images were made real using the small details of their physical-chemical characteristics, provided by the scientific literature and from the brand catalogues (Figure 2). The missing measurements were acquired using an electronic microscope, where the characteristics are reported in Table 1.

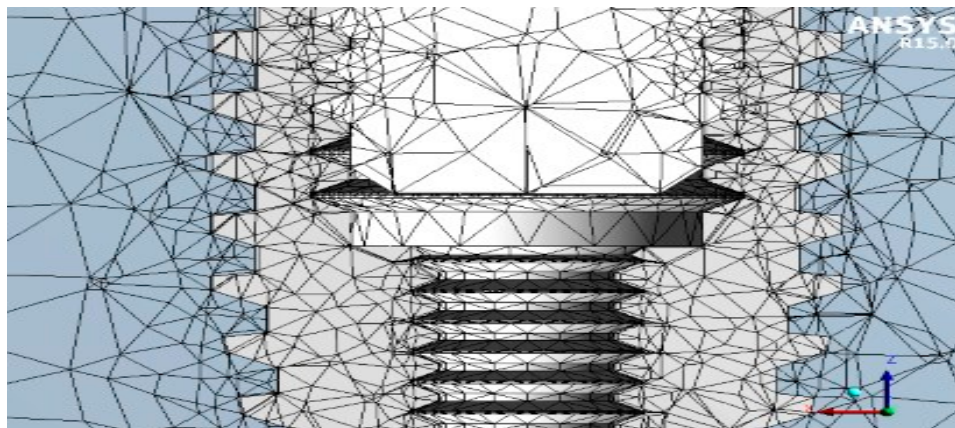


Figure 2. Reverse engineering.

Table 1. Electronic microscope properties.

<b>Resolution</b>	640 × 480 pixel
<b>Zoom</b>	5×
<b>Color</b>	Black
<b>Software</b>	Windows 2000/2003/XP/Vista/Linux/10
<b>Dsp</b>	24 bit
<b>Software bit</b>	Usb 2.0–Usb 1.1
<b>Model</b>	Usb

The modeling phase was performed using SolidWork<sup>®</sup>, where the information was passed from the physical system to a mathematical model, extrapolated from the same number of variables and “filtering out” the remaining ones. Figure 3 shows an example of the reverse engineering process.



Figure 3. 3D modelling.

## 2.2. Finite Element Analysis

Consequently, after obtaining these three-dimensional CAD models, the FEA jaw-implant-prosthesis was performed using the Ansys® Workbench (Figure 4). A 3D linear static structural simulation was performed showing the relation (stress and strain) between the bone and the implant prosthodontics elements: fixture, Universal abutment, Equator®, and Locator® systems.

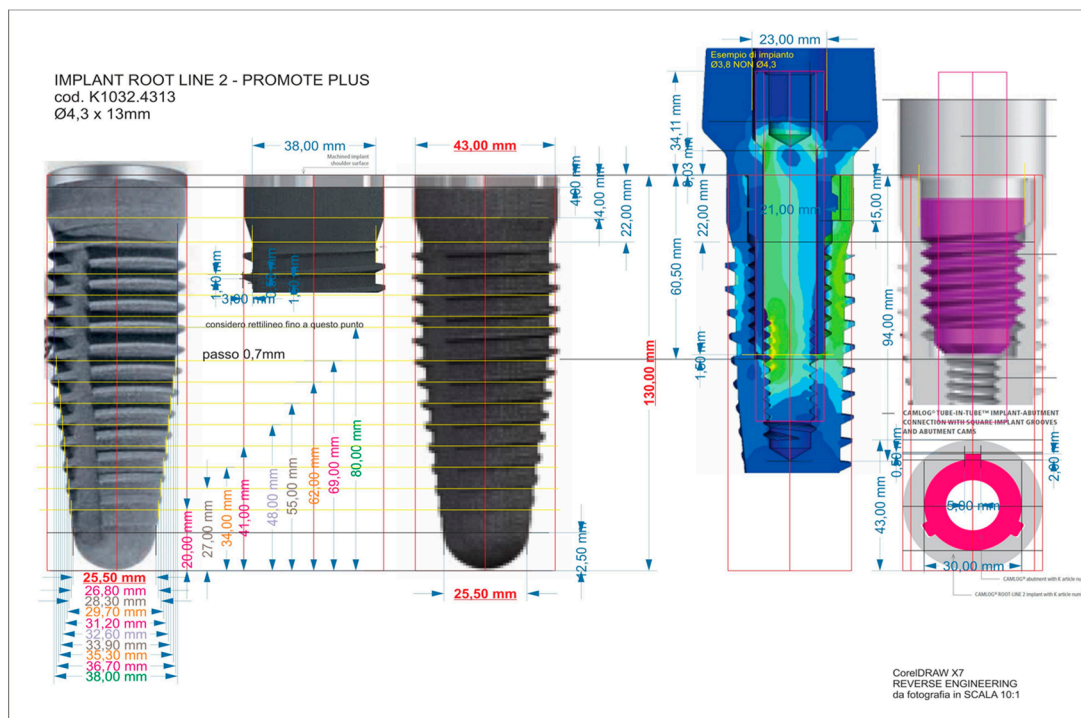


Figure 4. Reverse engineering of the dental implant used as anchorage.

### 2.2.1. Mechanical Characteristic of the Materials

The same stress was applied to the different implants and the consequent strength distribution was evaluated. The properties of the materials were specified in terms of Young's modulus, Poisson's ratio, and density. The different physical behavior of the materials was considered, with respect to the occlusal loading and the lateral forces. The titanium alloy (Ti6Al4V) under examination could be considered homogeneous, linear, and isotropic, whilst the bone tissues (cortical and cancellous) that should be anisotropic were considered as orthotropic (Table 2). Therefore, different deformation features along the three main space directions in response to stress were noticed [1,3–5,8,21–24].

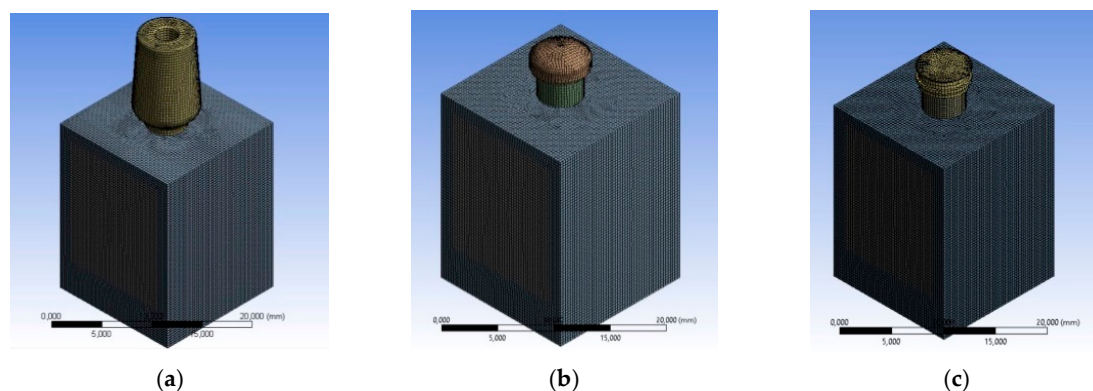
**Table 2.** Properties of the materials.

Material C	Cortical Bone	Cancellous Bone	Ti6Al4V
Density	1.8 g/cm <sup>3</sup>	1.2 g/cm <sup>3</sup>	4.510 g/cm <sup>3</sup>
E <sub>xx</sub>	9.60 GPa	0.144 GPa	105 GPa
E <sub>yy</sub>	9.60 GPa	0.099 GPa	105 GPa
E <sub>zz</sub>	17.8 GPa	0.344 GPa	105 GPa
$\nu_{xy}$	0.55	0.23	0.37
$\nu_{yz}$	0.30	0.11	0.37
$\nu_{xz}$	0.30	0.13	0.37
G <sub>xy</sub>	3.10 GPa	0.053 GPa	38.32 GPa
G <sub>yz</sub>	3.51 GPa	0.063 GPa	38.32 GPa
G <sub>xz</sub>	3.51 GPa	0.045 GPa	38.32 GPa

### 2.2.2. Mesh

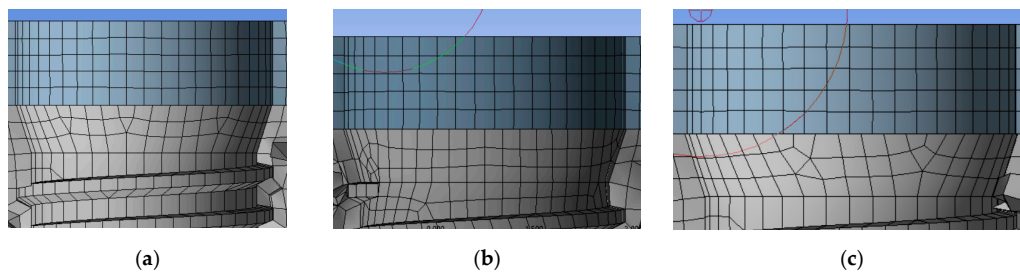
A method of discretization that foresees the use of a tetrahedral element with an independent algorithm and a lower limit of 0.2 mm in size was assigned to the whole elements of geometry. The 3D Hexa mesh was composed of many elements of second order SOLID186 (3D elements with 6 faces, 20 nodes, where each node had 3 degrees of freedom Dx, Dy, Dz).

Figure 5 shows the mesh of the three different implants and Figure 6 shows node and element numbers for each implant. The number of tetrahedral elements was close to 230,000; while ensuring the lightness of the simulation, the number of elements testified to the accuracy of the model.



**Figure 5.** Meshing process, (a) mesh of the universal prosthesis, (b) mesh of the locator prosthesis, (c) mesh of the equator prosthesis.





**Figure 6.** Meshing process, (a) mesh of the universal prosthesis, (b) mesh of the locator prosthesis, (c) mesh of the equator prosthesis.

In a detailed analysis, it was noted that the mesh of the cortical bone was of a blue color, while the cancellous bone was gray in color (Table 3).

**Table 3.** Number of elements and nodes, respectively, of the three analyzes.

	UNIVERSAL	LOCATOR	EQUATOR
Nodes	902,969	878,286	899,799
Elements	234,022	230,457	236,527

### 2.2.3. Boundary Conditions

The components of the dental implants were tested using a compression load of 800 N [4–8]. All the loads were distributed on the prosthodontics components surface in contact (screwed) with the dental implant. The bone-implant and the bone—bone contact conditions established in this FEM analysis are reported in Table 4 as follows:

**Table 4.** Frictional value considered for each analyzed system. The processing considered K as a global coefficient applied to the thread of the dental implant's supported surface.

Equator Abutment			
Target Bodies	Contact Bodies	BONDED	FRECTIONAL
external retention matrix	inner sheath	//	
inner sheath	abutment	//	
implant	abutment		0.3 K
implant	cortical bone		0.2 K
cortical bone	cancellous bone	//	
implant	cancellous bone		0.2 K
Locator Abutment			
Target Bodies	Contact Bodies	BONDED	FRECTIONAL
retention insert	abutment	//	
implant	abutment		0.3 K
implant	cortical bone		0.2 K
cortical bone	cancellous bone	//	
implant	cancellous bone		0.2 K
Universal Abutment			
Target Bodies	Contact Bodies	BONDED	FRECTIONAL
abutment	screw		0.3 K
implant	screw		0.3 K
implant	abutment		0.3 K
implant	cortical bone		0.2 K
cortical bone	cancellous bone	//	
implant	cancellous bone		0.2 K

For all the threaded connections, a bolt pretension in accordance with the installation requirements was considered.

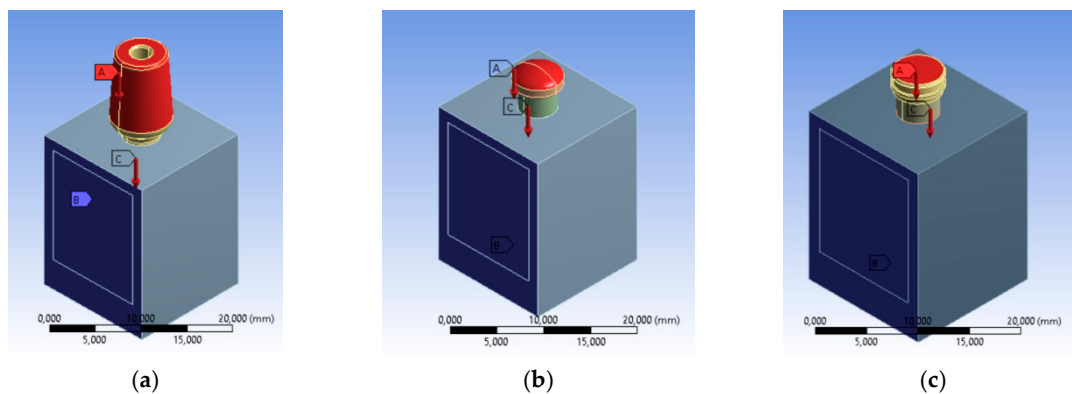
$$M \text{ [N cm]} = K D P$$

K is a global coefficient that takes into account the friction coefficients on the thread and on the support surfaces, the screw coefficients: diameter/pitch ratio (and thus screw angle) in our case was worth 0.2.; D is the nominal thread diameter in mm; P is the preload or axial pre-tensioning of Newton that we intended to dare to the screw.

Specifically:

1. implant/bone;  $P \text{ [N]} = M / (0.2 D) = 40 \text{ N}$ ;
2. lacator abutment;  $P \text{ [N]} = M / (0.2 D) = 50 \text{ N}$ ;
3. equator abutment;  $P \text{ [N]} = M / (0.2 D) = 50 \text{ N}$ ;

With regards to the constraints, the lateral sides of the bone and the lower face were bound (Figure 7).



**Figure 7.** Loading conditions, constraint conditions and contacts, (a) universal prosthesis, (b) locator prosthesis, (c) equator prosthesis.

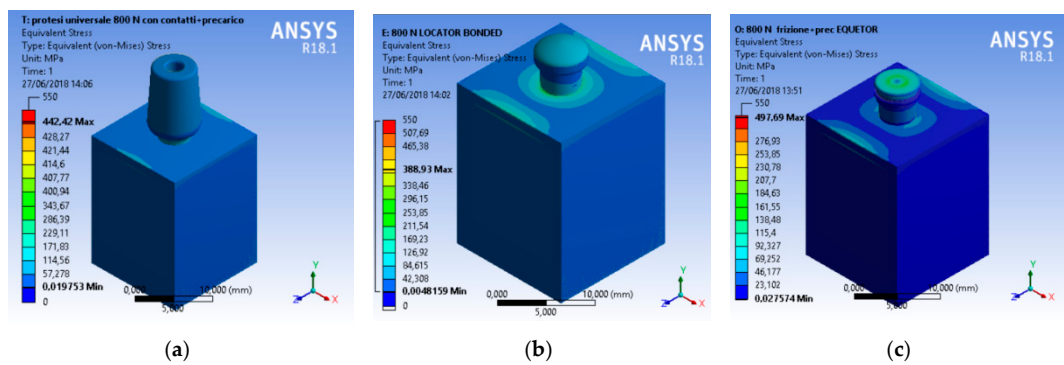
### 3. Results and Discussion

Compared to all the papers currently available in the scientific literature, this paper was the only study presenting a simulation that was as complete as possible, that is, contact between the surfaces of non-penetration with the friction and preloading of the connecting screw. In the past, to achieve a simpler and faster simulation, it was preferable to use a “joint” connection between the parties and not to take preload into account. Nevertheless, this was to the detriment of the truthfulness of the results. Instead, the authors found a good compromise to achieve results that were as close to reality as possible [3–9,24].

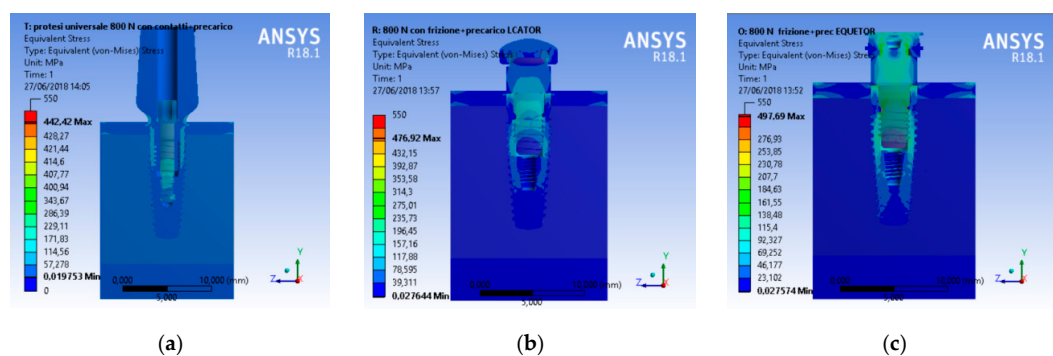
A CAD model of each component was recreated and then united in a single model with a relative constrain. At the same time, the aim of the research was to analyze the total stress on the three different geometries. A compression vertical load of 800 N was applied to the model. The Von Mises analysis was applied to the study to record the weak points of the system and around the bone tissue by color (red and yellow represented high stress).

A scale of values from 0 to 550 MPa was created to evaluate the stress in order to standardize the scale of values for all the simulations.

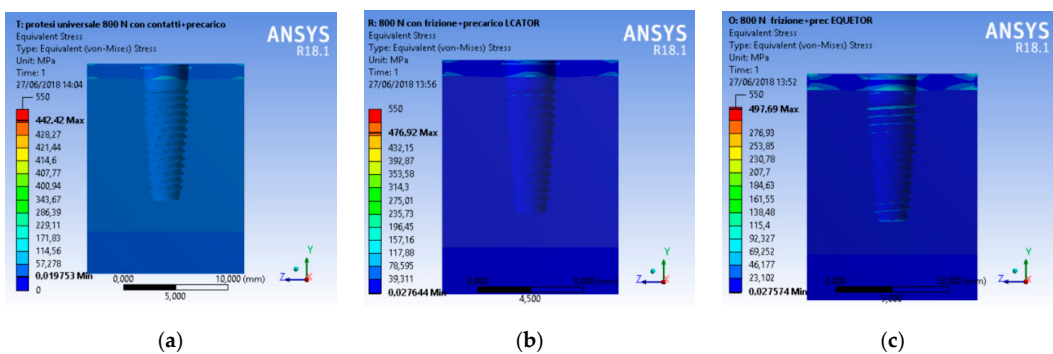
From an initial analysis, it was deduced that the whole system was not prejudiced (Figure 8). As observed, no system reached failure due to static rupture. In general, from the extension of the stressed areas, the following results were registered, that is, the system that stressed the bone less was the universal prosthesis, the system that most stressed the bone was the locator prosthesis, and the system that had the highest peak stress value was the equator prosthesis.



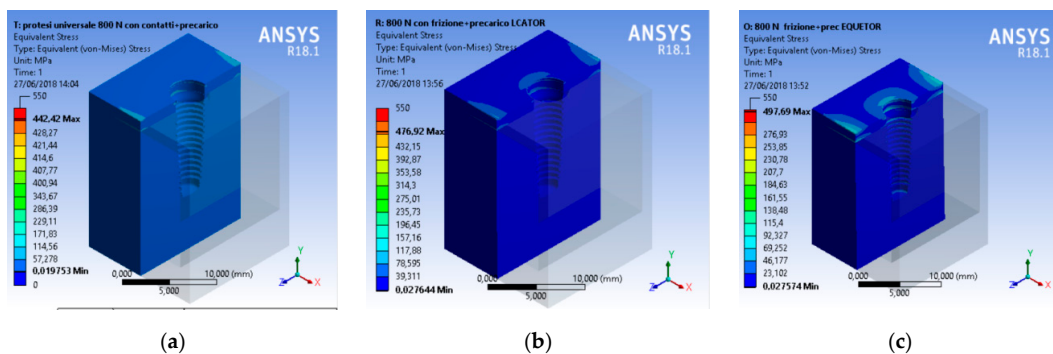
**Figure 8.** Von Mises results of the complex bone fixture and prosthodontics attachments. Three-dimensional view of the stress distribution, (a) universal prosthesis abutment, (b) locator prosthesis abutment, (c) equator prosthesis abutment (Figures 9–11).



**Figure 9.** Von Mises results of the complex bone fixture and prosthodontics attachments, (a) universal prosthesis, (b) locator prosthesis, (c) equator prosthesis.



**Figure 10.** Von Mises results referred to the bone at the maximum stress, (a) universal prosthesis, (b) locator prosthesis, (c) equator prosthesis.



**Figure 11.** Von Mises results, (a) universal prosthesis, (b) locator prosthesis, (c) equator prosthesis.

In detail, in the thread area, the stresses reached were:

From the point of view of the dental fixture, it could be observed that:

Even though all the recreated prosthodontics components represented a unique system involved in the masticatory cycle, the most stressed element of the fixture remained the connecting screw (Figures 12–14).

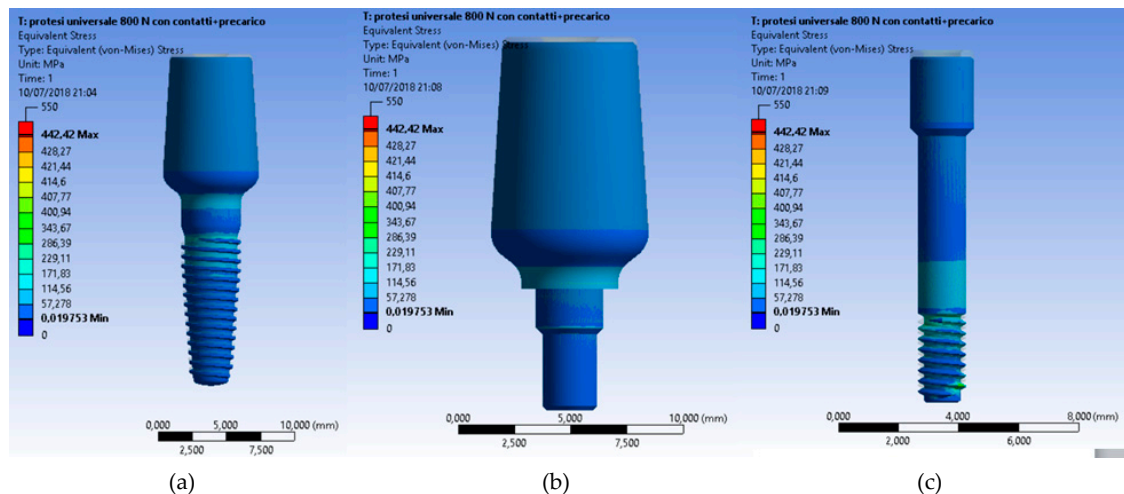


Figure 12. Von Mises results at (a) the universal abutment system prosthesis, (b) a particular of the abutment, (c) and the stress of the connection screw.

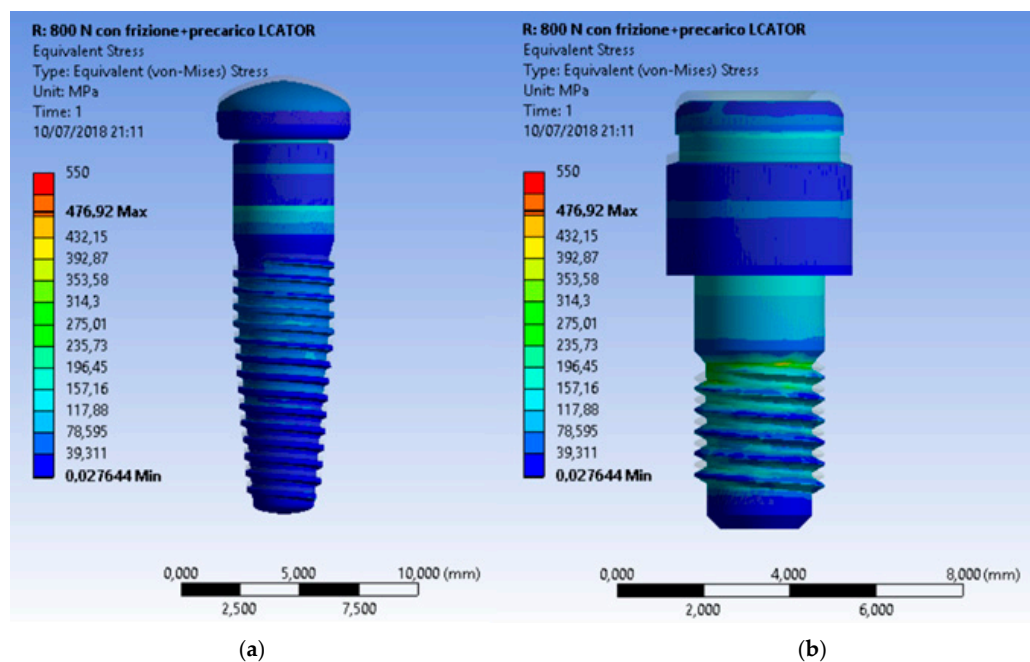
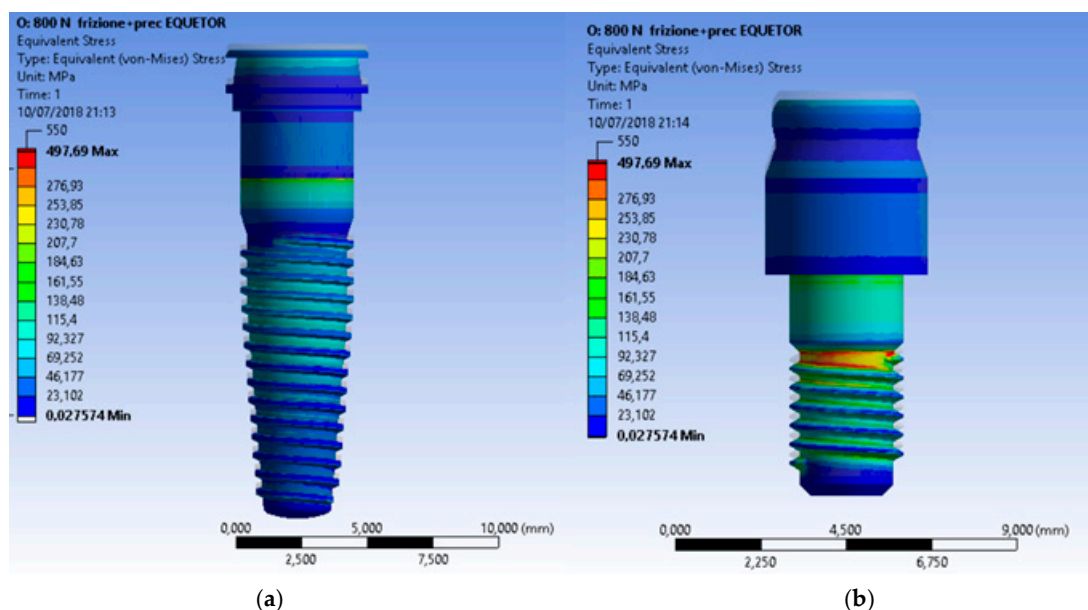


Figure 13. Von Mises results of the Locator<sup>®</sup> system and a particular of the locator with no fixture.





**Figure 14.** Von Mises results of the Equator<sup>®</sup> system and a particular of the locator with no fixture.

In the second sample, the dental implant and abutment were investigated. The universal abutment had the most stress compared to the other cases. There was also an increase in the stress on the system compared to the previous case.

Finally, the last test showed how the most stressed system was the universal abutment. Therefore, the most recommended element is the geometry and shape of the universal abutment. However, there was less stress on the implant compared to the previous case.

For mandibular implant-based overdentures, different retention systems have been developed to fix the prosthesis over the dental implants. International literature agrees with regards to the minimum number of two dental implants located in the inter-foramina area [16–19]. However, regarding the retention systems, the topic remains quite debated [1,5,9,19]. The retention and stability characteristics were mainly provided by implants through attachments. Therefore, different attachment systems were created for connecting implant-retained mandibular overdentures to the underlying implants. Independent connections to each implant abutment with O-rings or splinting of implants with bar/clip attachments are the most common approaches that have been used. The bar overdenture is a popular choice because of its load sharing, but its cost is high and patients sometimes prefer to have higher stability with a lower cost [20–23].

Recently, several published papers underlined how in the field of implant dentistry, the knowledge of key parameters related to the bone implant integration phenomena still remained of significance for clinical long-term success. A deep investigation of the biomechanics of the oral cavity anatomy and physiology mechanism resulted in fundamental knowledge of the bone mechanical properties, as well as an accurate definition of the jawbone geometry [24–32].

Over the last 20 years, biomaterial shape and design have widely benefited from the integration of finite element analyses in the product development process. This system of analysis adopts an approach of computing reactions over a discrete number of points across the domain of interest. For medical device shape, this typically translates into verifying device performance in a virtual domain that is representative of its planned real-life application [24–28].

The advantages of FEM in the biomedical field are numerous. The most impressive advantage is related to the possibility that FEM can enable early device performance testing prior to costly prototyping and bench testing. Correspondingly, integration of the FEM process into medical device realization can decrease costs over the product development cycle. Such savings come to fruition by way of tentatively speeding up the process and reducing bench-testing iterations.

From the other side, the disadvantages of FEM for medical device design reside mainly within the high expertise required to properly navigate the computational platform while avoiding making costly mistakes from ambitious misinterpretations [18,30–32].

Therefore, even though the method was able to create all the micromechanical characteristics of the medical device, it still remains hard to reproduce all the body clinical features placed into a dynamic contest. The data of the presented investigation offered a challenge compared to the recent literature. The presence of a K coefficient for avoiding a boundary system could be classified as a new step method for considering the integration between a static medical device and a dynamic human body wears.

Specifically, in the field of dentistry, the geometry of several prosthetic devices for retained overdenture structure is widely treated in recent literature for evaluating the integration and the wear related to the masticatory cycles. The Locator<sup>®</sup> system (Zest Anchor, Escondido, CA, USA) has been widely investigated, with several published documents using in vitro and clinical study. Its mechanical features are related to its small shape size, its retention capacity over a long time, and its wide tolerance to being used with high angulation dental implants. The Equator<sup>®</sup> system (Rhein 83, Bologna, Italy) has been recently studied because it was commercially launched in 2007. This attachment can be used for both the overdenture with direct connection and for the overdenture to connect a secondary structure. As in the present investigation, the OT Equator showed similar retention capacity to the Locator system [31–38].

A review and meta-analysis on dental implant overdenture attachments and their influence on peri-implant bone loss performed by Keshk et al. and published in 2017, revealed how there are no statistically significant differences between the type of overdenture attachment analyzed with regard to marginal bone loss, bleeding index, gingival index, and plaque index. In conclusion, no significant differences in prosthodontics maintenance and peri-implant conditions could be related to a different overdenture retained attachment system. This result was also highlighted in the present study; however, the shape of the two systems were characterized by different geometry, and thus, could be reflected through different but not significant strength distributions during the masticatory cycle [39].

#### 4. Conclusions

The data from the present investigation clearly underlined how the locator and equator system offered better stress distribution compared to the traditional universal abutment.

Moreover, within the limitation of the present “in vitro” study, the Von Mises analysis underlined how both prosthodontics overdenture retainer systems tolerated well the masticatory stress, though the Equator<sup>®</sup> system involve less of the bone peri-implant tissues. Specifically, the results could be interpreted as follows:

The Equator<sup>®</sup> and Locator<sup>®</sup> retention systems offered adequate retention systems and overdenture prosthesis support. The universal abutment supported low stress up until about 442 MPa. Therefore, this in vitro study underlined how the shape of the Locator<sup>®</sup> distributes the stress over the dental implant and that the gum retainer could be supported for a long time as compared to the other systems. The limit of the components fracture occurred at 476.92 MPa. Moreover, the shape of the Equator<sup>®</sup> retained system seems to collect the strength over the head of the retainer. These conditions favored the higher stress on the retainer gum. The advantage was related to the minor stress located around the peri-implant bone tissue and fixture. Moreover, the Locator System can overload and support stress until 497.69 MPa.

**Author Contributions:** M.C. was the author responsible for writing the paper, corresponding author G.C. was the chief reviewer for collecting the data, and was responsible for the language proofing and revision; D.M. was responsible for the funding acquisition data; G.R. Supervision, review collection.

**Funding:** This research received no external funding.

**Acknowledgments:** Authors want to thank Prof. Alan Scott Herford (Loma Linda University) for checking the English style and grammar of the whole paper.

**Conflicts of Interest:** The authors declare no conflict of interest.

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***Multicenter Retrospective Analysis of Implant  
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Published: 11 December 2018  
Dentistry journal



Article

# Multicenter Retrospective Analysis of Implant Overdentures Delivered with Different Design and Attachment Systems: Results Between One and 17 Years of Follow-Up

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Received: 20 September 2018; Accepted: 19 November 2018; Published: 11 December 2018



**Abstract:** Purpose: To analyze implant and prosthetic survival rates, complications, patient satisfaction, and biological parameters of patients rehabilitated with implant overdentures (IOV) on splinted and nonsplinted implants and different attachment systems, in function for one to 17 years. Methods: This retrospective study evaluated data collected from patients rehabilitated with implant overdentures between January 2001 and December 2016 in nine different centers. Outcome measures were implant and prosthetic success rates, mechanical complications, marginal bone loss (MBL), oral health impact profile (OHIP), bleeding on probing, and plaque index. Results: A total of 581 implants were installed in 194 patients. Patients were followed for a mean period of 60.6 months (range 6–206). Eighty-nine patients received 296 low profile attachment (OT Equator), 62 patients received 124 ball attachments, and 43 patients received 107 Locator attachments. In eighty-three patients the implants were splinted with computer aided design/computer aided manufacturing (CAD/CAM) or casted bar. At the last follow-up, 10 implants failed in eight patients. Statistical significance was found for failed prostheses ( $P = 0.0723$ ) and complications ( $P = 0.0165$ ), with better values for splinted implants. No statistically significant differences were found in proportion of implant and prosthetic failure ( $P > 0.05$ ). At a five-year follow-up, proportion of complications ( $P = 0.0289$ ) and failed prostheses ( $P = 0.0069$ ) were statistically higher for IOV on Locator attachments. No difference was founded in MBL at one- and two-year follow-up between different attachment systems ( $P > 0.05$ ). Statistically significant improvement in all the OHIP categories was reported in all the patients, after one year of function. Conclusions: Implant overdenture showed high implant and prosthetic survival rates, low complications, high patient satisfaction, and good biological parameters in the long-term follow-up. Splinting the implants may reduce number of mechanical complications. Locator attachments showed higher number of complications. Further studies are needed to confirm these preliminary results.

**Keywords:** Implant; overdenture; prosthesis

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## 1. Introduction

Edentulism can be associated to significant functional impairment as well as unfavorable aesthetic and psychological changes in patients. Problems related to edentulism incorporate limitations in diet and reduced ability to eat certain foods [1–3], speech impairment, loss of support for facial musculature, and decreased vertical dimension [4]. Furthermore, edentulism has been defined from The World Health Organization as a physical handicap [5].

For decades, complete removable denture was the conventional solution for treating edentulism. However, conventional complete denture (CCD) can restore chewing function only partially [6]. Furthermore, complete edentulism has an inevitable progressive and irreversible process of basal bone loss [7,8]; leading to augmented difficulties for the denture patient, especially in relation to the mandible [9]. Problems related to increasing basal bone loss include less retention and stability, augmented hyperplasia and ulceration of the underlying mucosa, increased loss of function due to soreness and pain, impaired psychosocial functioning [10] and an augmented risk of choking [11]. To overcome these problems, when a fixed implant-supported prosthesis is not indicated (e.g., excessive inter-arch discrepancy, financial problems, etc.) the use of implant overdentures (IOD) were shown to be successful in rehabilitating the edentulous patients [12–14], with high implant success rate [15]. Furthermore, denture stability, masticatory function and patient satisfaction significantly increased when compared with CCDs [16–19]. According to the glossary of prosthodontic terms, an overdenture is any removable dental prosthesis that covers and rests on one or more remaining natural teeth, the roots of natural teeth, and/or dental implants. Implant overdenture can be implant-retained or implant-supported.

The implant-retained overdenture transfers masticatory forces to the dental implants and to the underlying bone (and the alveolar mucosa). The purpose of the dental implants is to avoid the lateral and vertical dislodgment of the complete denture. An implant-supported overdenture transfers all of the masticatory forces to the dental implants, and as a consequence, to the alveolar and basal bone, such as a fixed solution. This type of prosthesis offers the advantages of being completely supported by implants for increased comfort, but is removed by the patient to maintain proper oral hygiene. Ideally, an implant-supported prosthesis, transferring more load to the implants, requires an increased number of dental implants for its successful outcome compared to an implant-retained prosthesis. However, biomechanics is not the only criterion in the treatment planning of the edentulous patient. Other factors, such as esthetics, speech, cost, ease of maintenance, and patient expectations, play a major role in treatment planning.

Over the years, implant-retained overdentures have been increasingly accepted as an alternative to conventional dentures for oral rehabilitation of edentulous patients; consequently, the type of implant attachment and application methods were diversely developed. The attachment systems for dental implant overdentures can be classified into the self-standing type and bar-type [15]. Self-standing type attachments, such as ball attachment, magnet attachment, and the Locator, have advantages such as easiness in oral hygiene maintenance and possibility of using in a narrow inter-arch space. On the other hand, limits could be found in parallel implant placement requirement, and stability of the implant overdentures lesser to that of bar-type [20–22].

Despite several advantages of implant overdenture, biological (e.g., nonosseointegration, mucositis with or without inflammatory hyperplasia, peri-implantitis) and biomechanical complications (e.g., bar fracture, fracture or detachment of the clip anchorage, fracture of the prosthesis or parts of it) can occur during function. Scientific evidence from literature review shows higher frequency of prosthetic complications, particularly for maxillary implant-retained or implant-supported overdentures [20]. On the other hands, short term independent follow-up studies

showed lower level of complications with both implant-retained and supported-overdentures [20–25]. Furthermore, in most of these study, the reported complications were minor technical issues, resolved chairside. While, the overall incidence of biological complications, such as, peri-implantitis, remain lower due to high level of hygiene maintenance with removable denture compared with fixed solutions. These data are encouraging comparing to biological and technical complications reported with fixed solutions [26].

Recently, computer aided design/computer aided manufacturing (CAD/CAM) titanium bar were developed to fully stabilize an implant-overdenture (“over-implant”) for both mandible and maxilla, showing high oral health-related quality of life and low incidence of complications [23,24].

The aim of this retrospective study is to report implant and prosthesis survival rates, mechanical complications, patient satisfaction, and biological parameters of patients rehabilitated with an implant-retained or -supported overdentures (IODs) on nonsplinted or splinted implants and different attachment systems, in function for a mean period of five years (1 to 17 years).

## 2. Materials and Methods

A retrospective chart review of existing data, documents, radiographs, and digital files was performed by at each center to evaluate data collected from fully or partially edentulous patients, aged 18 years or older, rehabilitated with an IOD on 1 to 6 implants between January 2001 and December 2016. Data analysis was designed to preserve the anonymity of the patients. Nine expert clinicians performed all surgical and prosthetic procedures in nine private practice centers in Italy. Restorations were delivered by a variety of dental technician in Italy. This study was conducted according to the principles embodied in the Helsinki Declaration of 1975 for biomedical research involving human subjects, as revised in 2000. Patients gave their written informed consent for all the surgical and prosthetic treatments.

Any potential implant locations were considered eligible in this study. Inclusion criteria were: any completely or partially edentulous patients who received an IOD retained or supported by one to six implants with at least 6 months after loading follow-up. Exclusion criteria were: general medical contraindication to oral surgery (American Society of Anesthesiologists, ASA, class III or higher), irradiation in the head and neck area less than one year before implant installation, psychiatric problems, alcohol or drug abuse.

All patients received preoperative photographs, either periapical radiographs or panoramic x-rays, and model casts for initial screening and evaluation. Before implant placement, all of the patients received a single dose of an antibiotic (2 g of amoxicillin or 600 mg of clindamycin or 500 mg azitromycin if allergic to penicillin). Patients received 1 to 6 implants placed according to the drilling protocol recommended by the manufacturer. A flapless approach was planned in the case of post-extractive implants or in a healed site, depending on the width of the available keratinized mucosa. In cases of bone regeneration, implants were placed six to nine months later. In the case of immediate post-extractive implants, residual teeth were extracted as atraumatically as possible. Implant insertion was then planned along the lingual socket wall, about 1.5 mm below the buccal alveolar crest. The residual socket was grafted with particulated heterologous bone. Loading protocols varied based on implant stability. Nonsubmerged protocol or immediate loading (within 48 h of implant placement) was performed in the case of an implant torque insertion of at least 35 Ncm. After implant placement, all of the patients received oral and written recommendations on medication, oral hygiene maintenance and diet. Postoperative antibiotic therapy (1 g of amoxicillin or 300 mg of clindamycin or 500 mg azitromycin) was 6 and 18 hours after the intervention. Analgesics (500 mg of paracetamol plus 30 mg of codeine, or 600 mg of ibuprofen or 100 mg of nimesulide) were administered as needed. Final restorations were delivered between two to seven months after implant placement.

Patients were rehabilitated with both implant-retained or -supported overdentures. In case of implant-retained overdentures, pre-existing or a new developed complete removable dentures were used followed standardized techniques [25]. Implant-retained overdentures were delivered on 1 to 5



unsplinted implants. The following attachment systems were used: Equator attachments (OT Equator, Rhein83, Bologna, Italy), ball attachments (OT Cap, Rhein83), or Locator attachments (Zest Dental Solutions, Carlsbad, CA, USA) (Figures 1–4). The Rhein83 OT Equator is a low profile castable and direct implant overdenture attachments with a low vertical profile of 2.1 mm and diameter of 4.4 mm. This system offers multiple solutions for overdenture treatment planning when vertical space limitations are a consideration.



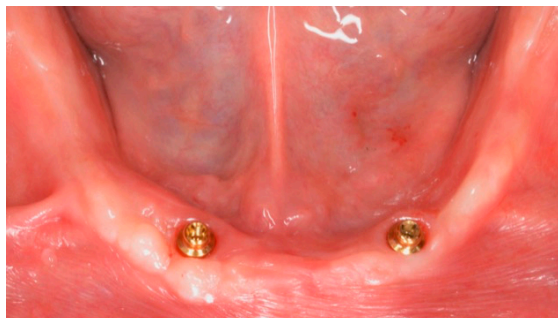
**Figure 1.** Mandibular overdenture bar with balls attachments.



**Figure 2.** Ten-year follow-up of maxillary overdenture with castable attachments.



**Figure 3.** Five-year follow-up of CAD/CAM mandibular overdenture with Locator attachments. Worn attachments in the retentive area, signs of wear due to the rigidity of the attack that makes it work are in the area of maximum circumference.



**Figure 4.** Two-year follow-up of mandibular overdenture with low profile attachments (OT Equator).

All the attachment systems were incorporated chairside into the fitting surface of the overdenture. All dentures were designed or rebased (if the pre-existing dentures were used) to obtain an optimal mucosa support. Most of dentures were reinforced with a cast cobalt-chromium framework. Denture teeth were set with the lingualized occlusion.

In case of implant-supported overdentures, three to six implants were used. Either conventional melting technique or newly developed CAD/CAM technologies were used to fabricate the implant-bar and the metal counterpart according to a previously published protocol [23,24]. Standardized laboratory procedures were accomplished by various dental technicians, according to a previously published protocol [23,24]. The occlusion was developed to deliver a mutually protected articulation and adjusted to avoid any premature contacts. Follow-up visits were scheduled at one and six months after prostheses delivery and then annually. At every follow-up visit, occlusal adjustment was performed if needed, and periapical radiographs with a film holder (Rinn XCP, Dentsply Intl) were made annually. The participants were instructed on daily maintenance hygienic procedures and underwent a professional cleaning by a dental hygienist every four to six months.

### 3. Outcome Measures

An implant was classified as successful when the following criteria were fulfilled: it did not cause pain or suppuration, did not show any mobility, did not show any signs of RX radiolucency, did not show peri-implant bone loss  $>1.5$  mm (first year) and then  $>0.2$  mm (yearly). An implant was classified as surviving when the implant remained in the jaw and was stable after the prosthesis was removed.

A complete implant-retained or supported Fixed Dental Prosthesis (FDP) was defined as successful when the dental prosthesis remained in function and the esthetic evaluation was satisfactory.

Biologic (pain, swelling, or suppuration) and/ or technical complications (fracture of the framework and/or the veneering material, screw loosening, or screw and/or implant fracture) were recorded.

Marginal bone loss (MBL) was evaluated yearly on intraoral digital radiographs made with the paralleling technique using a film holder (Rinn XCP, Dentsply Intl). All readable radiographs were displayed in an image analysis program (DFW2.8 for Windows; Soredex) that was calibrated for every image using the known pitch of two consecutive implant threads. The radiographs were accepted or rejected for evaluation based on the clarity of the implant threads. Mesial and distal bone level changes were calculated to the nearest 0.01 mm. The patient was used as the statistical unit of the analysis.

The quality of life was assessed by the Oral Health Impact Profile (OHIP-21) questionnaire, which was completed by the participants. The questionnaire consists of seven subscales (functional limitations, physical pain, psychological discomfort, physical disability, psychological disability, social disability, and handicap), with two to four questions each. Participants chose among five possible responses for each question as follows: never, hardly ever, occasionally, fairly often, and very often. Items were scored on a five-point, ordinal-type scale ranging from 1 (never) to 5

(very often). Lower OHIP total scores are suggestive of improvement in oral health-related quality of life (OHRQoL). The questionnaire was administered before treatment and then yearly.

Soft tissue parameters around the implant/abutment interfaces were assessed yearly with a plastic periodontal probe (Plast-o-Probe; Dentsply Maillefer). The bleeding index (BI) was evaluated at 4 sites around each implant according to the Mombelli index, and the plaque index (PI) was evaluated for each implant according to the same author.

Patient data were collected in a spreadsheet (Numbers Version 3.6.1 for Mac OS X 10.11.4). A biostatistician with expertise in dentistry analyzed the data using SPSS software for Mac OS X (version 22.0; SPSS Inc., Chicago, IL, USA) for statistical analysis. Descriptive analysis was performed for numeric parameters using mean  $\pm$  standard deviation with confidence interval (95% CI). Median and interquartile (IRQ) values were also calculated for bleeding on probing and plaque index in order to give a better description of our data set. Analysis of the ten-year cumulative implant survival rate (CSR) was performed at patient level, according to the life table method and illustrated with Kaplan–Meier survival curves. Differences in the proportion of patients with implant failures, prosthesis failures and complications (dichotomous outcomes) were compared between using the Fisher’s exact probability test and the Risk Ratio (.95 Confidence Interval). Differences of means at patient level for continuous outcomes (OHIP, marginal bone loss, BoP and PI) were compared by independent sample *t* tests. All statistical comparisons were conducted at a 0.05 level of significance.

#### 4. Results

Nine centers reported data from 581 implants, installed in 194 patients (120 females and 74 males; mean age 68.6 years, range 39–90) that received one to six implants. Five patients received only one implant; 92 patients received two implants each; 15 patients received three implants each; seven patients received four implants each; five patients received five implants each; and seven patients received six implants each (Table 1).

**Table 1.** Implant distribution.

Number of Implants	1 Implant	2 Implants	3 Implants	4 Implants	5 Implants	6 Implants
Number of patients	5	92	15	70	5	7

Thirty-three patients used to smoke more than 10 cigarettes per day (17.0%). Patients were followed for a mean period of 60.6 months (range 6–206). Sixty-nine patients (35.6%) with 249 implants (42.9%) were rehabilitated in the maxilla; while, 125 patients (64.4%) with 332 implants (57.1%) were rehabilitated in the mandible. Eight-nine patients received 296 OT Equator attachments (Rhein83), 62 patients received 124 ball attachments, and 43 patients received 107 Locator attachments (Zest). In 83 patients the implants were splinted (29 CAD/CAM titanium bar and 54 Croma Cobaltium bar made with conventional lost wax technique), while, in 111 patients the implants were unsplinted (Table 2). Of these, 72 implant-retained overdentures were metal-reinforced. Most of the splinted implant-supported overdentures was designed with only one bar (one-piece, *n* = 79) while four metal bars were two-piece. The counterpart was made with conventional lost wax casting technique in 62 patients, while, in 21 patients the counterpart was made using laser melting technique. In 60 patients, the veneering material was composite, in 130 was resin, and in four patients was ceramic. Most of the patients (*n* = 116) were mesocephalic, while 42 were brachycephalic, and 23 dolichocephalic. In 13 patients data on facial type was not available. Patients and implants characteristics were reported in Tables 3–6.

**Table 2.** Attachment distribution.

Attachment	OT Equator	Ball Attachments	Locator
Number of patients	89 (296)	62 (124)	43 (107)

**Table 3.** Patients and implants characteristics according to the different centers.

Centre	Patients (Implants)	Mean Follow-Up	Maxilla	Splinted	Unsplinted	Failed Implants Last FU	Failed Prosthesis Last FU	Complications Last FU
MT	19 (62)	22 (12–48)	6	10	9	0	0	2
AC	14 (30)	17.1 (12–24)	0	0	14	1	0	4
MM	19 (70)	28 (8–44)	13	14	5	4	0	1
RS	28 (72)	30.4 (12–74)	7	4	24	0	3	2
PV	8 (20)	19.5 (12–36)	1	2	6	0	0	1
EF	9 (34)	31.1 (12–54)	6	7	2	1	0	2
LO	66 (176)	104 (6–206)	26	26	40	1	2	7
GM	18 (76)	49 (12–88)	7	18	0	0	0	0
GV	13 (41)	79.5 (13–150)	3	2	11	3	0	6
Total	194 (581)	60.6 (6–206)	69	83	111	10	5	25

**Table 4.** Implants outcomes according to the different location (maxilla or mandible).

Location	Patients (Implants)	Implant	Splinted	Unsplinted	Failed Implants Last FU	Failed Prosthesis Last FU	Complications Last FU
Maxilla	69	249	47	22	7	2	11
Mandible	125	332	36	89	3	3	14
Total	194	581	83	111	10	5	25
P Value					0.0360	1.000	0.3752

**Table 5.** Patients distribution according to the Cawood and Howell classification.

Cawood & Howell Classes	%	Number of Patients
C&H II	16.6	30
C&H III	35.3	64
C&H IV	33.7	61
C&H V	6.1	11
C&H VI	8.1	15

**Table 6.** Patients distribution according to the occlusal scheme.

Occlusal scheme	%	Number of Patients
Anterior	5.7	11
Group function	39.2	76
Bilateral	55.1	107

Two biological complications were experienced in one smoking patient, resulting in 3 mm of bone loss at the one year of follow-up examination. The patient was enrolled in a strictly hygiene maintenance program with visit every four months, and no further pathological bone loss was experienced. No major biological complications were experienced, such as implant suppuration or mobility.

At the one-year follow-up examination (194 patients with 581 implants), seven implants (1.2%) in five patients (2.6%) failed. All the implants failed in the maxilla in class VI of Cawood and Howell patients ( $P = 0.0002$ ). Only one prosthesis failed (0.5%). Fourteen complications were experienced in 13 patients (6.7%). At the two-year follow-up examination (126 patients with 385 implants), one implant (0.3%) in one patient (0.8%) failed. One prosthesis failed (0.8%). Four complications were experienced in 4 patients (3.2%). At the three-year follow-up examination (103 patients with 218 implants), one implant (0.5%) in one patient (1.0%) failed. Two prostheses failed (1.9%). Two complications were experienced in two patients (1.9%). At the five-year follow-up examination (61 patients with 181 implants), one implant failed (0.6%) in one patient (1.6%). One prosthesis failed (1.6%). Five complications were experienced in five patients (8.2%).



Overall, 10 implants (1.7%) failed in eight patients (4.1%). No statistically significant differences were found between failure in the maxilla and mandible (7/242 versus 3/329;  $P = 0.1079$ ). Of these, 70% of the implant failures were experienced before loading. A total of five prosthesis failed scoring a cumulative survival rate of 97.4%. A total of 25 complications were experienced in 24 patients resulting in a cumulative implant success rate of 87.6%. Most of the complications were experienced in the unsplinted group. There was a statistically significant difference when comparing the overall number of complications and the number of the placed implants to retain an implant overdenture, with higher value when four implants were used ( $P = 0.000465$ ).

At the five-year follow-up examination, no statistically significant difference was found for failed implants between splinted and unsplinted designs (4/79 versus 4/107;  $P = 0.7261$ ;  $RR = 0.9874$ ;  $0.9296$ – $1.0488$ ). Statistically significant difference was found for failed prostheses (0/83 versus 5/106;  $P = 0.0723$ ;  $RR = 1.0472$ ;  $1.005$ – $1.09037$ ) and complications (5/78 versus 20/91;  $P = 0.0165$ ;  $RR = 1.1463$ ;  $1.0343$ – $1.2704$ ), with better values for splinted implants. No statistically significant differences were found between overdentures delivered on splinted and unsplinted implants for OHIP, MBL, BoP, PI at each time points, up to five years on function ( $P \geq 0.05$ ).

Within the unsplinted group, at the five-year follow-up examination, no statistically significant difference was found for failed implants (1/71 versus 0/39;  $P = 1.0$ ;  $RR = 0.9861$ ;  $0.9594$ – $1.0135$ ); failed prostheses (5/67 versus 0/39;  $P = 0.1597$ ;  $RR = 0.9306$ ;  $0.8737$ – $0.9912$ ) and complications (9/63 versus 5/34;  $P = 1.0$ ;  $RR = 1.0037$ ;  $0.865$ – $1.1646$ ), between metal-reinforced or not reinforced IODs.

At the last follow-up examination, no statistically significant difference was found for failed implants between different attachment systems (OT Equator, Rhein83; OT Cap, Rhein83; and Locator, Zest Dental Solutions) with respectively 5/84; 2/60; and 3/40 ( $P = 0.6487$ ). On the contrary, statistically significant difference was found for failed prostheses (0/89; 1/61; and 4/39;  $P = 0.0069$ ) and complications (6/83; 8/54; and 10/33;  $P = 0.0289$ ), with better values for OT Equators (Rhein83) attachment systems.

Data from MBL between different attachment systems were available at the one- and two-year follow-up examination. No statistically significant differences were found between groups. At the one-year follow-up examination, the mean MBL was 0.32 mm; 0.24 mm; and 0.29 mm for OT Equator ( $n = 60$ , Rhein83), OT Cap ( $n = 56$ , Rhein83) and Locator, ( $n = 26$ , Zest Dental Solutions), respectively ( $P = 0.4640$ ). At two-year follow-up examination, the mean MBL was 0.36 mm; 0.34 mm; and 0.36 mm for OT Equator ( $n = 36$ , Rhein83), OT Cap ( $n = 50$ , Rhein83) and Locator, ( $n = 19$ , Zest Dental Solutions), respectively ( $P = 0.062$ ).

One-year after loading ( $n = 142$ ), the mean marginal bone loss was  $0.28 \pm 0.43$  mm ( $0.11$ – $0.26$ ). Two years after loading ( $n = 105$ ), the mean marginal bone loss was  $0.35 \pm 0.54$  mm ( $0.07$ – $0.27$ ). The difference from the previous follow-up was not statistically significant ( $P = 0.2602$ ). Three years after loading ( $n = 67$ ), the mean marginal bone loss was  $0.38 \pm 0.45$  mm ( $0.09$ – $0.31$ ). The difference from the previous follow-up was not statistically significant ( $P = 0.7386$ ). Five years after loading ( $n = 46$ ), the mean marginal bone loss was  $0.46 \pm 0.41$  mm ( $0.16$ – $0.39$ ). The difference from the previous follow-up was not statistically significant ( $P = 0.3535$ ). No differences were found in MBL between different facial types at each follow-up (Table 7).

**Table 7.** MBL (mm) between different facial types.

Facial Type	1 Year	2 Years	3 Years	5 Years
Brachyfacial	$0.33 \pm 0.45$ ( $n = 38$ )	$0.43 \pm 0.54$ ( $n = 34$ )	$0.5 \pm 0.56$ ( $n = 24$ )	$0.45 \pm 0.26$ ( $n = 13$ )
Dolico-facial	$0.17 \pm 0.1$ ( $n = 19$ )	$0.17 \pm 0.13$ ( $n = 12$ )	$0.23 \pm 0.26$ ( $n = 8$ )	$0.37 \pm 0.34$ ( $n = 5$ )
Mesofacial	$0.23 \pm 0.23$ ( $n = 84$ )	$0.25 \pm 0.29$ ( $n = 59$ )	$0.33 \pm 0.40$ ( $n = 35$ )	$0.47 \pm 0.47$ ( $n = 28$ )
	$P = 0.1063$	$0.0534$	$P = 0.2368$	$P = 0.8821$

The OHIP questionnaire were delivered in 162 patients. Before treatment (baseline), mean OHIP was  $73.1 \pm 9.4$  ( $71.1$ – $74.0$ ). One year after loading, 153 patients answered to the questionnaire. The mean

OHIP was  $26.8 \pm 9.1$  (22.6–25.5). The difference was statistically significant ( $P = 0.0000$ ). Two years after loading OHIP values were available from 109 patients. The mean value was  $28.1 \pm 8.7$  (23.9–27.1). The difference from baseline was statistically significant ( $P = 0.0000$ ). Three years after loading OHIP values were available from 71 patients. The mean value was  $31.1 \pm 7.9$  (27.1–30.8). The difference from baseline was statistically significant ( $P = 0.0000$ ). At the 5-year follow-up examination, 55 patients answered the questionnaire. The mean OHIP was  $32.4 \pm 7.2$  (28.6–32.4). The difference from baseline was statistically significant ( $P = 0.0000$ ).

One-year after loading ( $n = 153$ ), the mean bleeding on probing was  $0.07 \pm 0.10$  mm (0.00; 0.02; 0.13). Two years after loading ( $n = 106$ ), the mean bleeding on probing was  $0.11 \pm 0.17$  mm (0.00; 0.06; 0.13). The difference from the previous follow-up was statistically significant ( $P = 0.0460$ ). Three years after loading ( $n = 70$ ), the mean bleeding on probing was  $0.09 \pm 0.18$  mm (0.00; 0.00; 0.13). The difference from the previous follow-up was not statistically significant ( $P = 0.5639$ ). Five years after loading ( $n = 45$ ), the mean bleeding on probing was  $0.10 \pm 0.17$  mm (0.00; 0.00; 0.13). The difference from the previous follow-up was not statistically significant ( $P = 0.9361$ ).

One-year after loading ( $n = 151$ ), the mean plaque index was  $0.12 \pm 0.15$  mm (0.00; 0.05; 0.25). Two years after loading ( $n = 106$ ), the mean plaque index was  $0.12 \pm 0.17$  mm (0.00; 0.00; 0.20). The difference from the previous follow-up was not statistically significant ( $P = 0.9957$ ). Three years after loading ( $n = 70$ ), the mean plaque index was  $0.12 \pm 0.17$  mm (0.00; 0.00; 0.22). The difference from the previous follow-up was not statistically significant ( $P = 0.9986$ ). Five years after loading ( $n = 45$ ), the mean marginal bone loss was  $0.09 \pm 0.16$  mm (0.00; 0.00; 0.13). The difference from the previous follow-up was not statistically significant ( $P = 0.3378$ ).

## 5. Discussion

This retrospective study evaluated long-term implant and prosthetic success rates, mechanical complications, oral health impact profile, marginal bone loss, bleeding on probing and plaque index of 581 implants placed on 194 patients to deliver implant-retained or -supported overdentures and followed for up to 17 years in function.

The main limitation of this study is its retrospective nature. As such, only a few cases (29.4%) were within the five to 17 years cohort, the clinician should interpret with caution data emerged in this paper. Moreover, thickness of the mucosa was not evaluated in this research. However, the relatively high overall number of implants and patients, as well as the relatively long period of follow-up may provide important insight helpful in a daily practice.

According literature data [15], in the present study, the implant cumulative survival rate was 95.9% at patient level, after 17 years of loading, with an average follow up of five years. Furthermore, according to Awad et al. 2000 [27], high patient satisfaction where reported during the follow-up, mainly due to improved denture stability and masticatory function.

Although well-established results are reported in the international literature, there are no specific guidelines or consensus regarding the number of implants needed to deliver an implant-retained or -supported overdenture. In clinical practice, four endosseous implants are considered the minimum number needed for maxillary overdenture treatment, while only two for the mandibular overdenture, as determined based on survival rate studies [28–32]. In the present study, although no statistically significant difference was reached, implants placed in the maxilla fail three times more than implants installed in the mandible, particularly in Cawood and Howell class VI patients. Accordingly, most of the overdenture in the mandible were delivered on two implants (86.4%) while in the maxilla, 59.1% of the prosthesis were delivered on four implants. Nevertheless, even in Cawood and Howell class VI patients, an implant-supported overdenture on four implants seem to be the gold standard to reduce implant failure.

In the present study, 111 patients received an implant retained-overdenture delivered on unsplinted implants, while in 83 patients the implants were splinted by means of 29 CAD/CAM titanium bar and 54 Cr-Cb bar made with conventional melting technique. Even if a splinted design

has been considered a more reliable option [33–35], authors found no statistical differences between overdenture on splinted and not splinted implants for implant failure, OHIP, MBL, BoP, PI at each point in time, up to five years on function ( $P \geq 0.05$ ). Nevertheless, prosthetic failure and complications were statistically lower in the splinted group. Conversely, Slot et al. [34] in a systematic review of maxillary overdentures, found a survival rate of 98.2% in case of six implants and a bar anchor-age, a survival rate of 96.3% in case of four implants and a bar anchorage, and a survival rate of 95.2% in case of four unsplinted implants with ball attachment system, after one year of treatment.

Nowadays, implant-retained or -supported overdentures can be considered a viable treatment option when bone volume is reduced. The IODs increase the masticatory function and improve satisfaction by making up for insufficient retention and stability of a conventional denture [28].

In the present study, when splinted implants were used to support a maxillary or mandibular implant overdenture, less complications were experienced compared to conventional implant-retained overdenture on unsplinted implants, independently by the presence of a metal reinforcement. A probable motivation should be that the occlusal forces were distributed onto the connected implants and the metallic bar, also requiring an increased number of implants for its successful outcomes [36–38]. Also in a five-year prospective study of Krennmair et al. less prosthodontic maintenance, i.e., for clip activation/fracture, was referred when four interforaminal splinted implants were used to support a mandibular overdenture [38].

The present study failed to found statistically significant differences related to different facial type, in any of the investigated outcomes ( $P > 0.05$ ). In a study of Ahmad et al. [39] the gonial angle was found to be significantly correlated with residual ridge resorption associated with implant-retained overdentures. Although in the present study no differences were found, a trend of higher marginal bone loss was found in brachyfacial individuals. In these patients, an implant-supported overdenture could be a valid treatment option to prevent biological complication associated with higher marginal bone loss.

In the present study, Locator attachments showed higher number of complications and prosthetic failure. These results are in agreement with the research of Krennmair et al. that reported more post insertion aftercare (activation of retention) for Locator attachment compared to the ball anchors [37,38]. A possible explanation for this results could be that the shape of the OT Equator retained system seems to collect minor stress around the periimplant bone tissue and the fixture itself [40]. Nevertheless, confounding factors, such as the number of implants could influenced the results. In fact, when standard commercial attachments are used dangerous occlusal forces can be partially distributed on mucosa only under denture retained on one or two implants, and the axial mobility cannot help in increase of use of mucosal supporting, reducing implant loading [41,42]. In the present study, statistically significant differences in complications were found when four implants are used to retain an implant overdenture.

Overall, in the present study, five prostheses have to be remade, while 25 complications were experienced in 24 patients. Most of them were tooth or matrix detachment resolved, chairside in less than 60 minutes. According to the international literature, the few studies that mentioned aspects of prosthetic aftercare provided to implant-retained maxillary overdentures reported complications with the attachment components [43], fractures of the acrylic resin or teeth [44,45], or overdenture adjustments [43].

Five years after loading the mean marginal bone loss was  $0.46 \pm 0.41$  mm, with a minimum of 0.12 mm and a maximum of 2.13 mm. It might be noticed that these results may be in line or even better of the mean marginal bone loss reported by Meijer et al. 2014 [46]. The authors report a mean MBL of 1.0 and 1.1 mm with implant-retained overdenture in function for 5 and 10 years respectively. According to the results of a systematic review of Cehreli et al., in the present study there was no statistically significant difference between splinted or unsplinted implants as well as between different type of attachment systems [47].

It is widely accepted that conventional complete removable denture has less satisfaction results in patients life compared to IODs [12,18,19,48,49]. In the present study, statistically significant improvement in all the OHIP categories was reported in all the patients, after one year of function. No differences were found for different IODs design or attachment systems.

Plaque scores increased slightly during function independently by the number of the implants and the type of anchorage. Elsyad MA et al. reported that this increase in plaque scores could be associated to the resiliency of both attachments, which allow denture movements and accumulation of plaque under the denture [50]. Also age related problems as decreased awareness could affect oral hygiene practice of the patients [49].

The elastic material of the retentive matrix of OT Equator may allow to distribute on a larger surface the retentive capacity, resulting in a longer lasting retention due to the wear reduction at the circumference.

The rigid attachments such as the Locators only work on the circumference and have very thin rigid material matrices.

It should be noticed that the retentive force of the Locator and OT Equator attachments is obtained through mechanical interlocking and frictional contact between the male and female. An ideal attachment system should provide a high and stable retentive force with a low lateral force to the implant, not only in the parallel placement of the implant, but also in the implant inclination during recurrent dislodging [51]. The retention feature of the Locator and OT Equator attachments is a frictional contact, which derives from a dimensional misfit between the slightly oversized male and the smaller diameter of the female abutment.

Both attachments investigated in this paper had the same clinical advantages, nevertheless, a less number of complications and prosthetic failure can be expected using OT Equator. A possible explanation could be that the retentive caps of the OT equator are made of elastic material while Locator uses rigid material. Elastic material seems to work better than rigid. Furthermore, the smaller size of the OT Equator may allow for an improved design of the overdenture leaving more space for the veneering materials. Furthermore, by exploiting the low profile of the OT Equator the clinician can better manage the prosthetic spaces according to a better aesthetic result.

## 6. Conclusions

Implant overdenture showed high implant and prosthetic survival rates, low complications, high patient satisfaction, and good biological parameters in the long-term follow-up. Splinting the implants may reduce number of complications. Locator attachments showed higher number of complications. Further studies are needed to confirm these preliminary results.

**Author Contributions:** M.T. had substantial contributions to the conception and design of the work; the acquisition (is one of the involved centers), analysis, and interpretation of the data; drafting the work and final approval of the version to be published. L.O., A.C., E.F., G.M., M.M., R.S., G.V. and P.V. had substantial contributions to the acquisition of the data (all are involved centers due to the multicenters nature of the study) and final approval of the version to be published. M.M. had substantial contributions to the conception of the work; the analysis, and interpretation of the data; drafting the work and final approval of the version to be published. R.R. had substantial contributions to the conception and design of the work; interpretation of the data; critical revisions for important intellectual content, and final approval of the version to be published.

**Funding:** This research received no external funding.

**Conflicts of Interest:** The authors did not receive any materials/products or financial support for this investigation.

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***Long-term survival analysis of standard-length and short implants with multifunctional abutments***

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Published: 2019  
Journal oral rehabilitation

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Article type : Original Article

**Long-term survival analysis of standard-length and short implants with multifunctional abutments**

*Short title:* Survival of multifunctional abutments

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This article has been accepted for publication and undergone full peer review but has not been through the copyediting, typesetting, pagination and proofreading process, which may lead to differences between this version and the Version of Record. Please cite this article as doi: 10.1111/joor.12791

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## **Long-term survival analysis of standard-length and short implant with multifunctional abutments**

### **Abstract**

**Background:** Spherical shape and connecting bypass screw of the OT Equator abutment (Rhein, Italy) provides several retentive possibilities, even in non-parallel implants.

**Objective:** This study assessed the long-term survival of standard-length and short implants receiving this multifunctional abutment.

**Methods:** Partially edentulous patients (44 males and 64 females) (mean age  $58.2 \pm 10.5$  years), rehabilitated with a fixed implant-supported prosthesis where the OT Equator abutments (Rhein) were applied. Follow-up evaluations were performed up to 5 years following prosthesis delivery. Kaplan–Meier survival analysis and Cox regression analysis were used to determine whether the distribution of time to failure differed based on implant characteristics (length and region), adjusting for sex ( $\alpha = 0.05$ ).

**Results:** In total, 216 implants ( $5 \times 8$  mm,  $n = 126$ ;  $5 \times 6$  mm,  $n = 90$ ) (Betwice, Mech & Human, Italy) were installed. The average follow-up period was 25.3 months ( $\pm 19.3$  months). Eight failures occurred, with most observed before loading ( $n = 6$ ). Cumulative survival rates (CSR) at implant and abutment levels were 94.3% and 97.1%, respectively. Regarding implant length, CSRs were 97.8% and 90.6% for short and standard-length implants, respectively, with no difference between

subgroups (Log rank:  $\chi^2 = 1.34$ , df = 1, P = 0.25). No significant difference was also found between implants of maxilla (CSR = 92.2%) and mandible (CSR = 95.5%; Log rank:  $\chi^2 = 0.08$ , df = 1, P = 0.78).

**Conclusion:** The OT Equator abutment (Rhein) showed a stable clinical performance, with continuous and predictable survival.

**Key-words:** dental abutment, clinical trial, dental implants, Kaplan Meier analysis, survival analysis.

## BACKGROUND

The clinical use of dental implants has spread worldwide due to high predictability and good long-term clinical performance, with minimal marginal bone resorption and low complication rates in completely and partially edentulous patients.<sup>1</sup> However, evidence suggests that prosthetic complications are common, especially when implants are in function.<sup>1,2</sup> Therefore, several factors should be addressed to establish trustworthy evidence for implant-based prosthesis survival.

Preferably, dental implants should be installed parallel to each other and to the adjacent teeth, and consequently aligned to axial forces.<sup>3</sup> However, surgical difficulties, such as the inadequacy of alveolar bone and restriction of mouth opening, might lead to orientation failures and poor implant positioning.<sup>1,2</sup> In this sense, improper angulation of implants is among the most difficult problems to overcome in the planning and execution of treatment with implant-supported prostheses.

Previously reported treatment modalities for malpositioned dental implants involve the use of hybrid prostheses, customized and angled abutments, and milled or cast metal bars for totally edentulous rehabilitation.<sup>4-7</sup> The use of angled abutments may increase the stress transferred to supporting implants and adjacent bone, with direct effects on the prosthesis.<sup>8</sup> In addition, only moderate malpositioning can be treated using these alternatives, and few reports, most of which are case reports and case series, have described the performance of such angled components.<sup>4-7,9</sup>

The use of a special abutment with non-parallel implants to obtain a favorable path of insertion and removal may be promising.<sup>9</sup> However, spherical components available on the market are designed usually for overdentures and does not allow for prosthesis fixation with screws. To overcome this limitation, a new OT Equator abutment (Rhein, Bologna, Italy) was developed.<sup>10</sup> This component is based on a customized spherical abutment, without the head and neck of the sphere, but maintaining the equatorial part (Figure 1).<sup>10</sup> In addition, at the center of the sphere, additional threads were added to house a connection screw.<sup>10</sup> An undercut polytetrafluoroethylene Seeger ring is also part of the system. It is installed in the abutment interior to protect against unscrewing of the prosthesis while avoiding apical movement of the connective junction to the abutment level (Figure 1).<sup>10</sup> The unique abutment design allows a multi-functional use of the component. Basically, this abutment may be used as two distinct forms, in a fixed-partial prosthesis, with a connecting bypass screw, or as a standard overdenture component.<sup>10</sup>

It also provides a wide range of retentive possibilities, even for non-parallel implants.<sup>10,11</sup> With a low vertical profile of 2.1 mm and diameter of 4.4 mm, the OT Equator abutment (Rhein) fits into patients mouths with vertical space limitations; it

can also be placed over standard-length ( $\geq 8$  mm) and short ( $< 8$  mm) implants.<sup>10,12</sup> In addition, this component can be applied to temporary and definitive prostheses, by using the same anchoring system. Despite the advantages, this new abutment system is not indicated for single crowns since it does not present anti rotational components.

Considering the increasing lifespans of patients, the achievement of long-term clinical support for every treatment protocol is imperative.<sup>13</sup> Survival data for this component from a large population, using it under clinical routine remains scarce. Thus, the aim of this clinical trial was to examine the long-term survival of dental implants where these OT Equator abutment (Rhein) were applied, considering implant length, region (maxilla or mandible), and, in cases of failure, the time until implant loss.

## **MATERIALS AND METHODS**

### **Study design and sample selection**

The eligible population for this longitudinal study, comprised only partially edentulous patients, who sought treatment with fixed implant-supported dental prostheses at the University of Modena and Reggio Emilia and the University of Ferrara, Italy. All patients were treated consecutively and prostheses were placed over at least two implants (length  $\leq 8$  mm), splinted in the same screw-retained prosthetic structure, using the OT Equator abutment (Rhein).

Participants with active periodontal infection; poor oral hygiene (full-mouth plaque and bleeding scores  $> 20\%$ ); immunosuppressive disorders; severe blood, renal, and/or liver disease; history of radiotherapy in the head and neck region; known or suspected current malignant disease; history of anti-tumor chemo-therapy

within the previous 12 months; uncontrolled diabetes (glycosylated hemoglobin level > 7 mg/%); pregnancy or lactation; alcohol or drug abuse; smoking > 5 cigarettes/day; psychiatric problems or unrealistic expectations; previous treatment with intravenous aminobisphosphonates; inflammatory or autoimmune diseases of the oral cavity; and previous augmentation procedures in the study area were excluded. In case of surgical problems, that result in mal positioned implants; those implants were excluded, since it might configure a confounding factor to the survival analysis.

The Ethics Committee of the University of Ferrara approved this study (number 71/2013). All participants provided written informed consent. Panoramic radiography and computed tomography (CT) were performed to assess bone quality and quantity, including measurement of the height and width of the supporting bony ridge. Detailed case studies and treatment plans were made for all patients based on images, articulated cast models, and diagnostic wax-ups. Data were gathered on patient age, sex, smoking habit, medical history (diabetes, heart disease, osteoporosis), parafunction (self-reported bruxism), implant length and region (maxilla/mandible), installation level (above, in, below the alveolar crest), implant prosthesis material (metal-ceramic, zirconia, acrylic resin), type of antagonist (natural tooth, metal-ceramic crown, acrylic resin prosthesis), loading protocol (immediate, conventional), implant features, and study withdrawal.<sup>14</sup>

### **Implant placement and prosthetic rehabilitation**

In all patients, the same surgical protocol and treatment plan were followed based on each patient needs. Based on diagnostic wax-ups, a multifunctional (tomographic and surgical) guide was produced and used during CT examination. Panoramic and CT images were evaluated carefully, and surgical planning was



carried out. In the day before the intervention, all patients received prophylaxis and oral hygiene instructions. An antibiotic (1 g amoxicillin) and an anti-inflammatory drug (1 g acetaminophen) were administered prophylactically 1 h before the intervention. Antibiotic administration continued for 5 days after surgery. Patients used 0.12% chlorhexidine mouthwash for 1 min immediately before the intervention and thereafter twice daily for 7 days. Local anesthesia was induced by infiltration with 4% articaine chlorhydrate containing 1:100,000 adrenaline. A midcrestal incision was made and a full-thickness flap was elevated to expose the alveolar bone. At least two standard-length (8 mm length) or short (6 mm length) implants were placed in each patient. All implants were cylindrical, with an internal connection, and presented a double acid-etching surface (Betwice, Mech & Human, Italy).

The same operator, with experience in treatment employing short implants, placed all implants following the manufacturer's recommendations. A manual torque device was used to evaluate insertion torque.

The OT Equator abutment (Rhein) was screwed to each implant with 35 Ncm torque, and the flaps were closed using mono-nylon sutures. When primary implant stability ( $\geq 40$  Ncm torque) was not achieved, prosthetic loading was postponed for at least 3 months. In such cases, a protective cap was installed over the component and the old removable denture was adapted and relined for use during the healing period.

Two prosthodontics experts performed all clinical prosthetic procedures. Based on the diagnostic wax-up, a provisional acrylic prosthesis was fabricated in each case and screwed to the OT Equator abutment (Rhein) to promote progressive implant loading. In cases of immediate loading, this provisional prosthesis was

adapted directly and relined intraorally over the abutment. After finishing and polishing, the provisional prosthesis was screwed to the abutment with 20 Ncm torque.

For each definitive prosthesis, open tray impressions were taken and the OT Equator abutment (Rhein) position was transferred to a stone cast. The castable connectors of the abutment system were adapted into the abutment replicas and a wax-up of the structure was made, with splinting of all implants. After the completion of casting, the Seeger ring was compressed and inserted into the cylinder using a proper tool from the system. Try-in of the titanium structure was performed. The metal structure was recovered with metal-ceramic, zirconia, or acrylic resin, according to the individual requirements of the clinical situation. All prostheses were screwed onto OT Equator abutments (Rhein) (at 20 Ncm torque), and the screw access holes were protected with composite resin. The occlusal contacts were carefully checked and adjusted.

### **Follow-up evaluation**

Follow-up evaluations were performed 6 months after prosthesis delivery and annually thereafter for up to 5 years. At each follow-up visit, clinical parameters were assessed and standardized intra-oral radiographs were obtained. Implant failure was defined as the implant removal for any reason. The date of implant removal or the last scheduled follow-up visit at which implants were in function was recorded. The time (in months) between implant placement and the last visit was defined as the implant survival period.

## **Statistical analysis**

Descriptive statistics consisted of means and standard deviations, medians and interquartile ranges and percentages. Kaplan–Meier survival analysis was used to determine whether the distribution of time to failure differed based on implant characteristics (length and position). Censoring was considered when no failure occurred or the patient dropped out of the study. Previously, the pattern of censoring for implant length and region were analyzed using scatterplots as an assumption of the test, to test if they were fairly equally spread over time. Further, a Log rank test was conducted to determine whether the survival distribution differed according to each of these characteristics.

Finally, Cox regression models were used to examine the possible interaction of “sex” on survival time, considering implant length and region as independent variables. All analyses were performed using SPSS 24.0 software (IBM, Armonk, NY, USA) by one of the authors (PMC, Applied Statistics Specialist), considering a 5% significance level.

## **RESULTS**

### **Characteristics of the implant and patient cohort**

The sample involved 108 patients (44 male and 64 female) with a mean age of 58.2 years ( $\pm$  10.5 years - ranging from 34 – 85 years). Characteristics of the volunteers and implant features are summarized in Table 1.

A total of 216 implants were placed, 126 of them were standard-length (5 × 8 mm), whereas 90 of the implants were short (5 × 6 mm). Most implants were placed in the mandible (69%), below the crestal bone level (60.2%), and using the

conventional two-step loading protocol (61.6%; Table 1). Metal-ceramic with titanium framework was the most frequently used material for the implant-supported fixed prostheses (68.5%), followed by acrylic resin (29.2%). High frequencies of metal-ceramic prostheses (40.7%) and natural teeth (31.5%) were observed in the antagonist arches (Table 1).

The average follow-up period was 25.3 months ( $\pm$  19.3 months). More specifically, 71 implants were monitored for at least 6 months, 29 for 1 year, 53 for 2 years, 14 for 3 years, 20 for 4 years, and 29 for 5 years. Four patients were lost to follow up due to death ( $n$  = 3) and removal of two implants at the patient's will ( $n$  = 1).

### **Survival analysis**

Eight implant losses occurred during the study period. Six (66.7%) failures occurred before loading and the other two (33.3%) occurred after loading. Failure percentage was higher for standard-length implants (5 x 8 mm;  $n=6$ ), for those placed in the mandible ( $n=6$ ) and for those where the conventional two-step loading protocol was applied ( $n=5$ ).

At the end of the 5-year study period, overall cumulative survival rates (CSRs) were 94.3% at the implant level and 97.1% at the abutment level, with 209 implants remaining in function (Figures 2 and 3). Regarding implant length, censored cases were distributed fairly evenly over time, with no dissimilarity between subgroups (standard-length/short); the CSRs found were 97.8% and 90.6% for 5 x 6-mm and 5 x 8-mm implants, respectively (Figure 4), with no significant difference between them (Log rank:  $X^2 = 1.34$ ,  $df = 1$ ,  $P = 0.247$ ). Cox regression analysis showed no significant interaction of sex ( $P = 0.972$ ).

Considering the region, the CSRs found were 92.2% and 95.5% for the maxilla and mandible, respectively (Figure 5), with no significant difference between subgroups (Log rank:  $X^2 = 0.08$ ,  $df = 1$ ,  $P = 0.777$ ). Again, Cox regression analysis showed no significant interaction of sex ( $P = 0.938$ ).

Table 2 summarizes the mean survival time according to implant length and region.

## DISCUSSION

Long-term survival data are required to better assess the safety and predictability of a certain treatment.<sup>2,13,15,16</sup> Usually, the CSR is estimated only at implant level; however, the focus of the present study was on the performance of the novel abutment. Therefore, two analyses of CSR were performed; the first was at the implant level (day of the implant install until the last follow up observation) and the second was at the abutment (just after definitive prosthesis placement until the last follow up observation), resulting in an overall CSR of 94.3% and 97.1%, respectively. Although, in most of previous studies, the survival rate was not considered at the abutment level, similar CSR values, at implant level, were found, varying from 94.5%<sup>17</sup> to 95.6%,<sup>18</sup> even after 5 year of fixed partial implant prostheses in function.<sup>17,18</sup> It might indicates that the use of this novel abutment do not interfere with the long-term performance of the prosthesis.

In general, eight of the 216 implants failed, and no patient have lost more than one implant. Moreover, no prosthetic complications requiring prosthesis or abutment replacement were observed and most failures (75%) occurred before final prosthetic loading. In contrast, a recent literature review<sup>2</sup> reported that approximately 70% of implant losses occur after prosthetic loading. However, several other studies<sup>13,15,19,20</sup> have shown higher rates of earlier failure, in agreement with our finding. According to



Jemt,<sup>13</sup> early failure, especially in short implants, seems to be related more to healing problems during osseointegration than to maintenance or overloading issues. Therefore, the focus should be more to avoid bone overheating and reduced blood supply.<sup>13</sup> It also is important to emphasize that the sample of the present study was very homogeneous since only the OT Equator abutment (Rhein) was used and all prostheses were performed in a similar way (screw retained implant-supported prostheses). In this sense, the loss of only two implants at post-loading situation reinforced that the major problem seems to be related more to the osseointegration than to overloading or prosthetic complications from the abutment itself.

Low failure rates, as shown in the present study, hinder deep analysis, such as the estimation of hazard ratios. However, the present sample allowed the analysis considering two subgroups (implant length and maxillary arch). The first analysis yielded CSRs of 97.8% and 90.6% for short and standard-length implants, respectively, with no significant difference. Short implants were commonly associated with lower survival rates, especially because of reduced bone-to-implant contact.<sup>21,22</sup> However, the recent literature demonstrates no difference in the CSR of short and standard-length implants, probably due to advances in surface treatment and more careful treatment planning.<sup>23,24</sup> The placement of more standard-length implants (n=126) than short (n=90) implants in this study may also contributed to the increased number of failures in the former group (6/8 failures).

Regarding the maxillary arch subgroup analysis, CSRs were 95.5% and 92.2% for the mandible and maxilla, respectively. Although the majority (6/8) of implant failures occurred in the mandible, the difference in CSR was not significant, which is also showed in previous studies.<sup>13,25</sup> Although some authors have suggested that the poor quality of maxillary bone increases implant loss,<sup>26,27</sup> the high

density of mandibular bone could also contribute to reduce of the blood supply, jeopardizing osseointegration. This possibility is based on the theory that early failure is closely related to the healing process, and probably explains the higher rate of implant loss in the mandible.<sup>8</sup> In addition, mandibular implants are usually placed at more demanding sites with greater masticatory loading, which also contributes to explain this pattern of loss.<sup>13</sup>

Clinical trials including many patients and involving long-term follow up have many methodological challenges and problems. Thus, to better control data, with a low risk of misinterpretation, only implant failure and follow-up time were considered in determining CSRs and constructing life tables. Moreover, no control group was considered in the present study, which could represent a limitation. Nevertheless, future studies comparing the OT Equator abutment (Rhein) with conventional abutments are encouraged to increase the predictability of such treatment, especially for fixed implant-based prostheses.

## **CONCLUSION**

High CSR at implant (94.3%) and abutment (97.1%) levels were observed without major prosthetic complications, suggesting a continuous, stable, and predictable survival of the OT Equator abutment component.

## **CONFLICT OF INTEREST**

Authors declare no conflict of interest and emphasize that this clinical trial was not funded by any company or source of founding.

## DISCLOSURE, ACKNOWLEDGEMENT AND FUNDING

Authors acknowledge the Rhein Company (Bologna, Italy) for the support with the OT Equator abutment and declare that no funding was used during the study development.

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**Table 1** Summary of sample and implant characteristics.

			Number (Percentage)
<b>Sample characteristics</b>	Sex	Male	44 (40.7%)
		Female	64 (59.3%)
	Medical history	Healthy	91 (84.3%)
		Controlled type 2 diabetes	3 (2.8%)
		Controlled hypertension	5 (4.6%)
		Controlled osteoporosis	9 (8.3%)
	Self-reported bruxism	No	84 (77.8%)
		Yes	24 (22.2%)
	Smoking habit	None	87 (80.6%)
		Light	21 (19.4%)
<b>Implants characteristics</b>	Implant length	8 mm	126 (58.4%)
		6 mm	90 (41.6%)
	Implant position	Maxilla	67 (31%)
		Mandible	149 (69%)
	Implant placement relative to crestal bone level	Above	8 (3.7%)
		At	78 (36.1%)
		Below	130 (60.2%)
	Loading protocol	Immediate	83 (38.4%)
		Conventional	133 (61.6%)
	Fixed Prosthesis material	Metal-ceramic (titanium framework)	148 (68.5%)
		Acrylic resin (CoCr reinforcement)	63 (29.2%)
		Not reported	5 (2.3%)
	Type of antagonist tooth	Natural tooth	68 (31.5%)
		Metal-ceramic	88 (40.7%)
		Acrylic resin	41 (19%)
		Not reported	19 (8.8%)

**Table 2** Mean survival time (months) according to implant characteristics.

		Survival time		
		Mean	SE	Confidence interval (95%)
Implant length	6 mm	58.7	0.89	56.9 to 60.5
	8 mm	56.9	1.23	54.5 to 59.3
Position	Mandible	57.6	0.96	55.7 to 59.5
	Maxilla	58.4	1.12	56.2 to 60.6

## FIGURES LEGENDS

**Fig 1** Components and internal mechanism of the OT Equator abutment (Rhein).

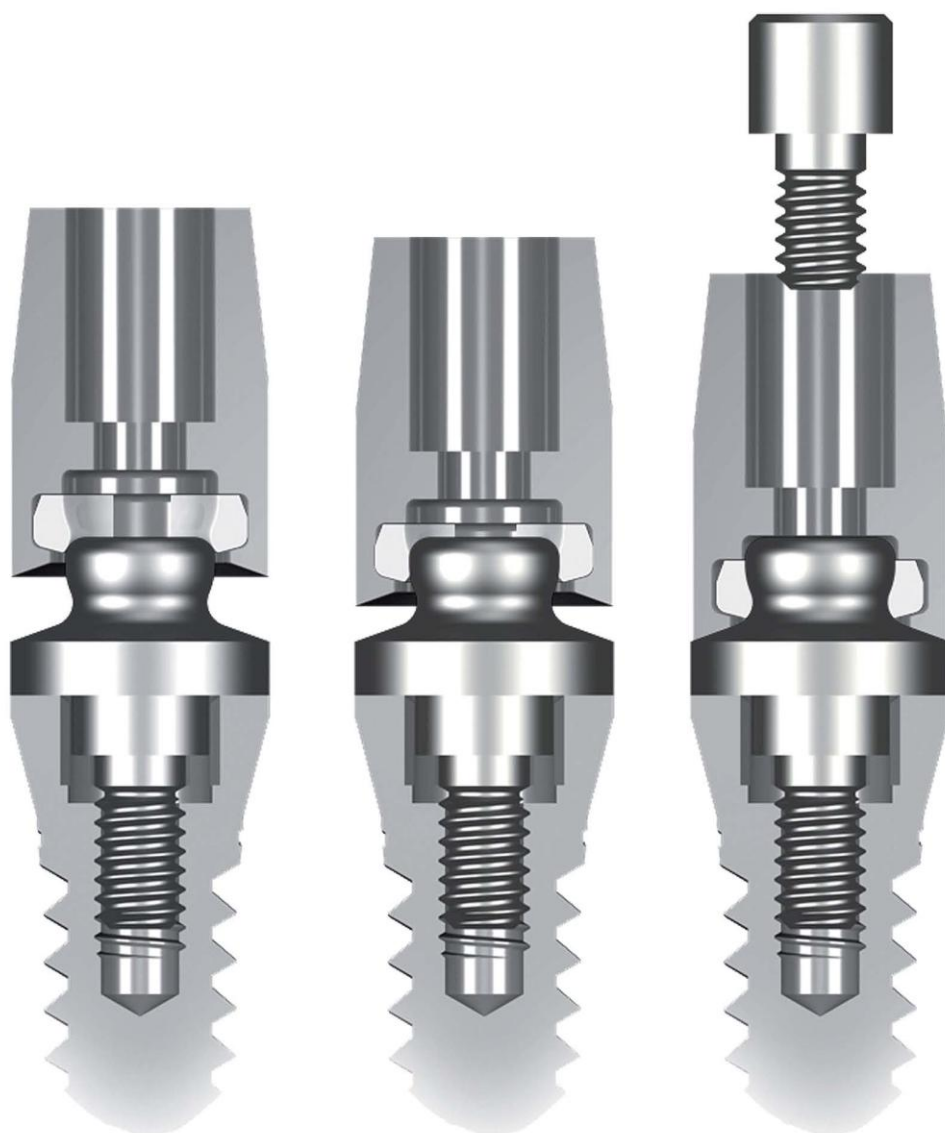
**Fig 2** Overall survival analysis at the implant level (108 patients, 216 implants).

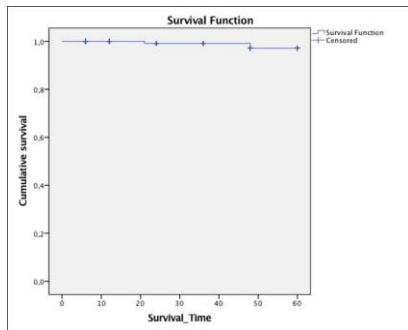
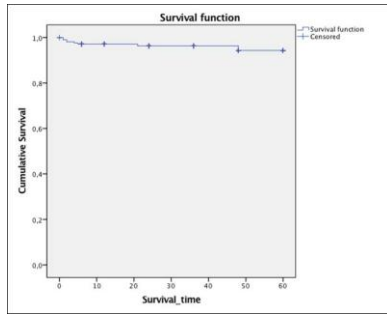
Cumulative survival rate was 94.3%.

**Fig 3** Overall survival analysis and distribution function at the abutment level (104 patients, 208 abutments). Cumulative survival rate was 97.1%.

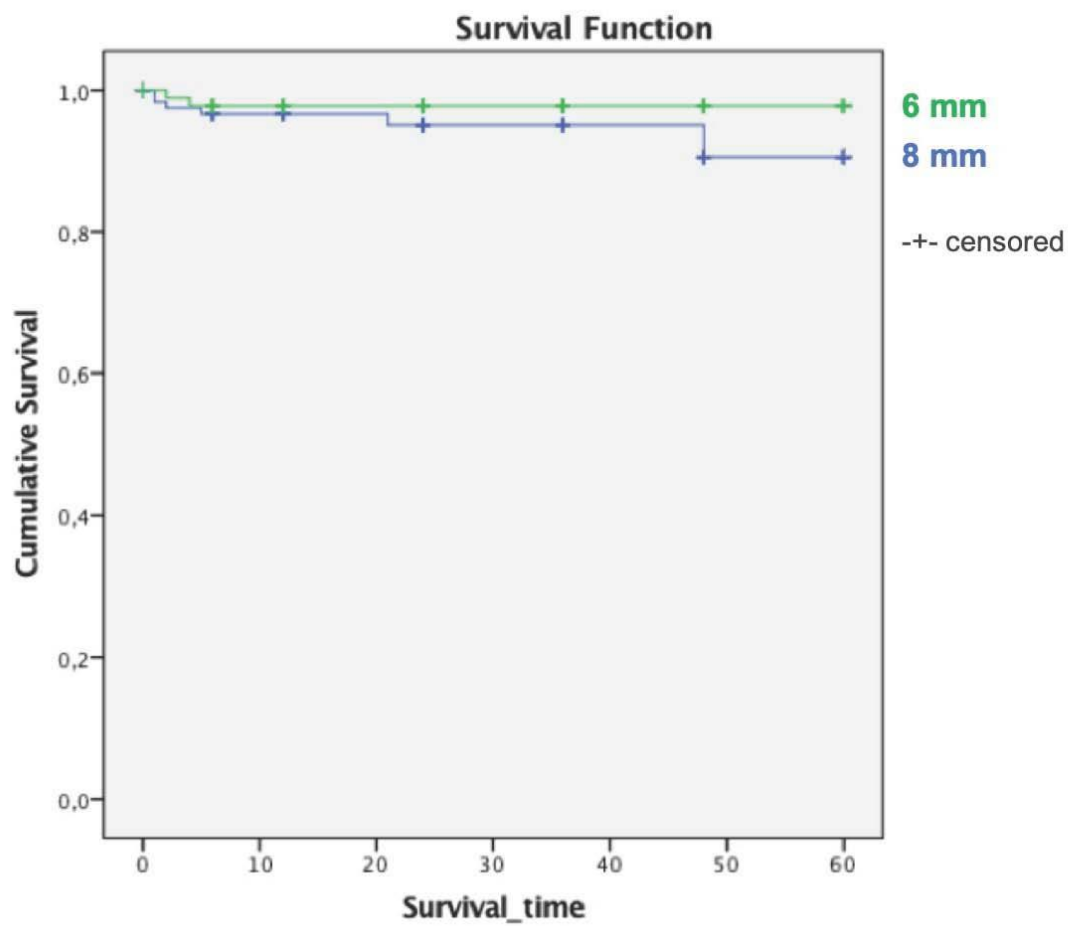
**Fig 4** Survival analysis according to implant length (Log Rank;  $X^2 = 1.341$ ;  $df = 1$ ;  $P = 0.247$ ).

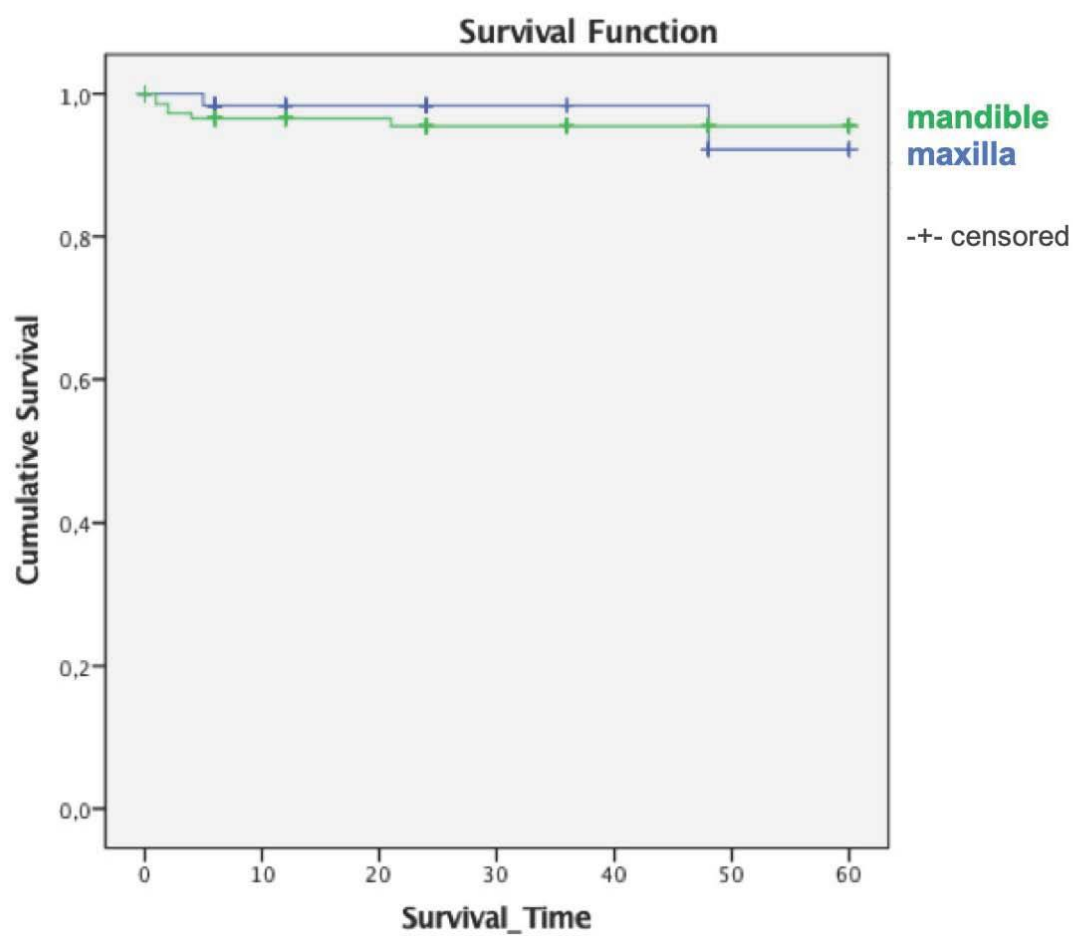
**Fig 5** Survival analysis according to implant region (Log Rank;  $X^2 = 0.08$ ;  $df = 1$ ;  $P = 0.777$ ).











***Virtual implant planning in the  
edentulous maxilla: criteria for  
decision making of prosthesis design***

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Published: 2012  
Clinical oral implant research

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# Virtual implant planning in the edentulous maxilla: criteria for decision making of prosthesis design

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**Key words:** computer-assisted implantology, decision making, edentulous maxilla, three-dimensional, virtual implant planning

## Abstract

**Objectives:** To evaluate prosthetic parameters in the edentulous anterior maxilla for decision making between fixed and removable implant prosthesis using virtual planning software.

**Material and methods:** CT- or DVT-scans of 43 patients (mean age  $62 \pm 8$  years) with an edentulous maxilla were analyzed with the NobelGuide™ software. Implants ( $\geq 3.5$  mm diameter,  $\geq 10$  mm length) were virtually placed in the optimal three-dimensional prosthetic position of all maxillary front teeth. Anatomical and prosthetic landmarks, including the cervical crown point (C-Point), the acrylic flange border (F-Point), and the implant-platform buccal-end (I-Point) were defined in each middle section to determine four measuring parameters: (1) acrylic flange height (FLHeight), (2) mucosal coverage (MucCov), (3) crown-Implant distance (CID) and (4) buccal prosthesis profile (ProsthProfile). Based on these parameters, all patients were assigned to one of three classes: (A)  $\text{MucCov} \leq 0$  mm and  $\text{ProsthProfile} \geq 45^\circ$  allowing for fixed prosthesis, (B)  $\text{MucCov} = 0\text{--}5$  mm and/or  $\text{ProsthProfile} = 30^\circ\text{--}45^\circ$  probably allowing for fixed prosthesis, and (C)  $\text{MucCov} \geq 5$  mm and/or  $\text{ProsthProfile} \leq 30^\circ$  where removable prosthesis is favorable. Statistical analyses included descriptive methods and non-parametric tests.

**Results:** Mean values were for FLHeight 10.0 mm, MucCov 5.6 mm, CID 7.4 mm, and ProsthProfile  $39.1^\circ$ . Seventy percent of patients fulfilled class C criteria (removable), 21% class B (probably fixed), and 2% class A (fixed), while in 7% (three patients) bone volume was insufficient for implant planning.

**Conclusions:** The proposed classification and virtual planning procedure simplify the decision-making process regarding type of prosthesis and increase predictability of esthetic treatment outcomes. It was demonstrated that in the majority of cases, the space between the prosthetic crown and implant platform had to be filled with prosthetic materials.

Atrophy of the maxillary jawbone as a result of complete tooth loss has a significant impact on treatment planning and implant prosthetics. According to Sadowsky (2007) an implant-supported fixed prosthesis can achieve optimal esthetics, phonetics, and hygiene access for patients with a minimally resorbed residual ridge. Therapy is significantly more complex in situations of moderate and especially advanced loss of soft and hard tissues (Henry 2002). Apart from tooth length, axis, color, and gingival exposure, oro-facial esthetics comprises also physiognomic aspects (Sutton et al. 2004). Facial support and natural lip mobility are crucial outcome parameters and important aspects that influence the decision between fixed and removable implant prostheses (Mericske-Stern et al. 2000; Neves et al. 2004). There are therefore two important parameters to

consider: the emergence profile of the artificial tooth and the volume of hard and soft tissue that needs replacement.

The change in philosophy from "bone-driven" to "restoration-driven" implant dentistry was established with regard to the prosthetic reconstruction. The concept of virtual planning aims to optimize function and esthetics prior to implant placement (Garber 1995).

In this context, computer-assisted implant-planning software have significantly improved and provide clinicians excellent tools for pre-operative implant planning (Katsoulis et al. 2009). Careful and detailed treatment planning is enhanced (Ganz 2005).

Various systems for computer-guided template-based implant treatment are available on the market while high accuracy can only be achieved with well-fitting guides during

**Date:**  
Accepted 25 November 2011

**To cite this article:**  
Avrampou M, Mericske-Stern R, Blatz MB, Katsoulis J, Virtual implant planning in the edentulous maxilla: criteria for decision-making of prosthesis design. *Clin. Oral Impl. Res.* 24 (Suppl. A100), 2013, 152–159  
doi: 10.1111/j.1600-0501.2011.02407.x

CT scan and surgery (Schneider et al. 2009; Vasak et al. 2011). The goal is to ensure highly predictable and precise transfer of the planned three-dimensional (3D) implant position and angulation to the clinical procedures and implant placement. This is of particular importance in situations with only limited amounts of bone or critical proximity to limiting anatomical structures (Jung et al. 2009). In selected cases, a flapless procedure that is sometimes combined with an immediate implant-loading protocol has been suggested (van Steenberghe et al. 2005; Rubio Serrano et al. 2008). The jaw bone is often thin and atrophic in the anterior maxilla, which significantly affects the esthetic results of implant prostheses due to insufficient lip support (Flanagan 2005). Undesirable complications related to morphological and technical aspects may arise during the prosthetic phase or after delivery of the prosthesis (Salama et al. 2009). Variances in crown-to-implant positions relative to the required lip support create different scenarios for implant-supported full-arch prostheses.

In a recent Consensus report on biomechanics and risk management, it was concluded that further research on guided surgical protocols and critical evaluation in regards to esthetic outcomes and prosthetically related complications is needed (Sanz & Naert 2009). However, prosthetic parameters that may be evaluated virtually with an implant-planning software are not sufficiently examined and explored in their broad variety of applications. Even though computed technology facilitates precision of surgical steps, the selection of the appropriate treatment plan is complex and the predictability of the esthetic outcome is sometimes questionable (Calvani et al. 2007).

Therefore, this study determined anatomical and prosthetic landmarks on patient's CT or DVT and analyzed prosthetic parameters in the anterior region of the completely edentulous maxilla by means of computer-guided virtual implant planning.

The aim of this study was to identify and define anatomical and prosthetic criteria for prosthetically driven implant planning and for the decision-making process on the most appropriate prosthesis design in the anterior edentulous maxilla.

## Material and methods

### Patient data

Data of computed tomography or digital volume tomograms (CT or DVT) from 43

patients (24 female and 19 male) with edentulous maxillae were evaluated in this study. The mean patient age was 62 years (between 48 and 81 years). All of them were patients of record in the Department of Prosthodontics (School of Dental Medicine, University of Bern) and were examined during the period between January 2006 and December 2009 for implant-supported prostheses. This survey was part of a quality-control assessment during the dental examination and was approved by the institutional ethical review board. All patients had given written informed consent for their participation in the study. Exclusion criteria were patients with a history of palate or tuberosity surgery, presence of any stomatological disease that could affect soft and hard tissues, and patients taking medications (cyclosporin A, calcium channel blockers, phenytoin) that have an influence on soft-tissue quality (growth and hyperplasia). Smoking was not an excluding factor (11 patients were smokers). A panoramic radiograph was available for all patients before the treatment-planning phase.

### Computer-assisted implant planning

Computer-assisted planning was applied (NobelGuide™ software, Nobel Biocare, Gothenburg, Sweden) for detailed pre-surgical analysis and 3D virtual implant placement in relation to the prospective crown position. A well-fitting, functional, and pleasing denture or a prosthetic set-up that was optimized in respect to esthetic and functional parameters (Waliszewski 2005; Kamashita et al. 2006) were used as radiographic templates (Table 1). During the clinical try-in of the tooth set-up functional and esthetic aspects were evaluated with particular attention to the vertical dimension of occlusion, the facial support and the lip position (Figs 1 and 2). CT or DVT were obtained from all patients with the radiographic templates *in situ* (Loubele et al. 2006; Eggers et al. 2009). The templates were properly positioned during the radiographic procedure without any space between the radiographic template and the palatal mucosa. With the corresponding



Fig. 1. Extra-oral lateral view of a patient with an edentulous maxilla showing a wide naso-labial angle and insufficient lip-support.



Fig. 2. Same patient with a set-up *in situ* replacing the lost hard and soft tissues of the atrophic maxilla and thus supporting the upper lip.

**Table 1.** Guidelines and checklist for a denture or set-up to be used in virtual implant planning

Denture guidelines and checklist
Denture satisfying the demands of support, stability and retention
Control of inter-jaw relation: space for prosthesis
Correct vertical dimension
Correct position of teeth (parallel to horizontal plane, correct inclination, form and size, vertical dental midline coincident with the facial midline)
Esthetically pleasant denture (lip and facial support, front teeth exposition, alignment, smile line, lip-line, gummy-smile)
Acceptable phonetics



software, both hard and soft tissues were visualized in high-quality images.

Implants were virtually planned in the position of all front teeth to obtain measurements between the anticipated implant position and the prosthesis design in the anterior region, based on the following planning guidelines.

1. The implant had a minimum of 3.5 mm, preferably  $\geq 4$  mm diameter and a minimum of 10 mm intra-osseous length.
2. The virtual 3D implant position was determined in the most accurate location in reference to the tooth position in the radiographic template or denture.
3. The planned implant position and axis had to allow for palatal screw access and direct screw retention. Such an implant position allows for a prosthetic reconstruction that does not require either angled abutments or correction of inclination.
4. The bucco-palatal inclination of the implant axis was designed with respect to the residual alveolar bone and tooth position. With regard to point 2, the prosthetic determinant had a priority. While this may cause a more vertical implant angulation in relation to the buccally oriented jawbone, it prevents the implant shoulder being placed too far buccally, with a negative impact on esthetics. Otherwise, an implant position that does not respect the jawbone anatomy in all aspects may require additional surgical interventions. Minor local bone grafting (guided bone regeneration, GBR) was considered acceptable.

#### Prosthetic and anatomical landmarks

Cross sections of the CT scans in the middle of the maxillary incisors and canines as represented by the radiographic template were used to determine anatomic and prosthetic landmarks (Fig. 3). The occlusal plane was defined as parallel to the horizontal plane on the computer screen and served as a reference for the measurements. The following landmarks were determined as the reference points for the measurements in the middle of each anterior tooth (Fig. 4).

1. Central cervical point (C-Point).
2. Acrylic flange border (F-Point).
3. Implant platform buccal end (I-Point).

The following measurements were carried out, and reproducibility of the digitizing process was confirmed by means of double determination of all measurements by one

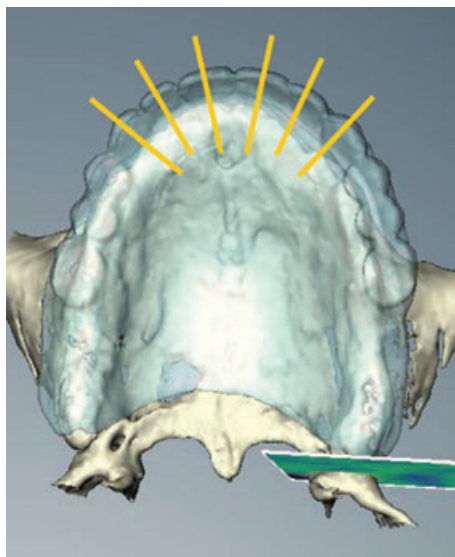


Fig. 3. Based on the set-up in the 3D reconstruction of the CT/DVT scan six cross sections were positioned in the middle of each anterior tooth.

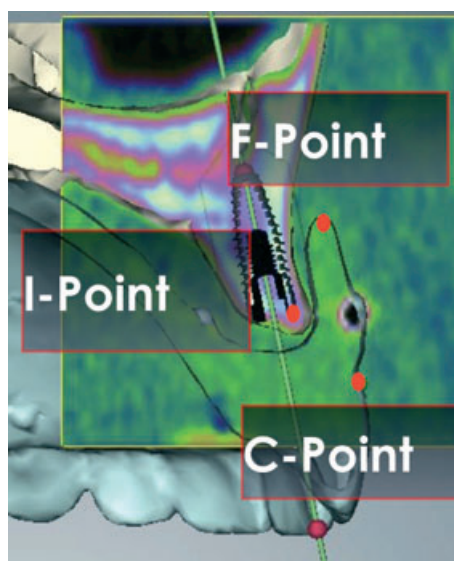


Fig. 4. Determination of the prosthetic and anatomical landmarks (reference points) in the cross sections. I-Point: The buccal end of the implant platform, F-Point: The end of the buccal acrylic flange, and C-Point: The central cervical point on each anterior tooth.

and the same examiner (intra-examiner reproducibility revealed excellent IICs = 0.85–0.96):

1. FLHeight: vertical distance from C-Point to F-Point, which is representative of the flange height (Fig. 5).
2. MucCov: vertical distance from I-Point to F-Point, representing the coverage of the mucosa from the acrylic flange above implant neck (Fig. 6).
3. CID: distance from C-Point to I-Point (Fig. 7). This measure is important for

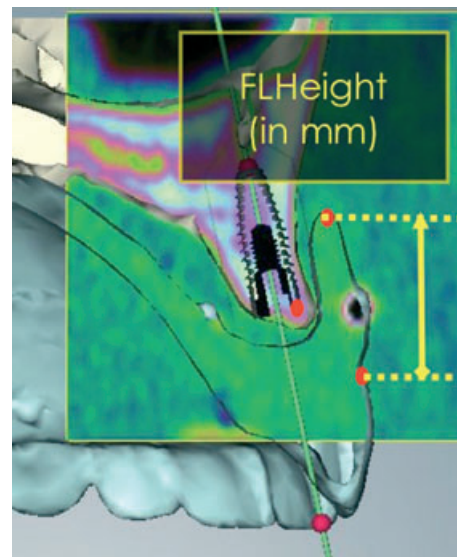


Fig. 5. Measured parameters in the cross sections: Total flange height.

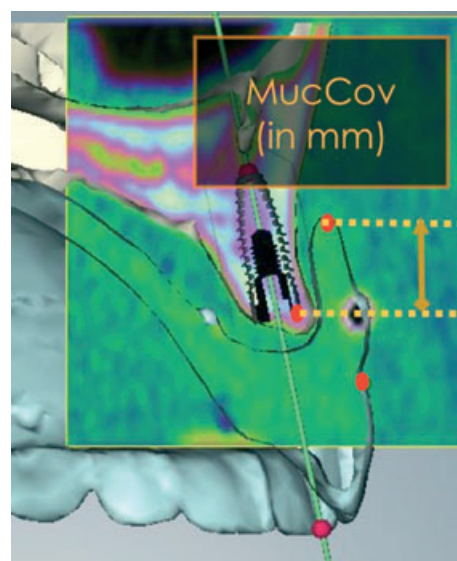


Fig. 6. Measured parameters in the cross sections: Acrylic flange covering buccal mucosa above the implant platform.

the emergence profile of prosthetic reconstructions and need for artificial soft tissue replacement.

4. ProsthProfile: buccal profile of the prosthesis as determined by the angle between the tangential line connecting C-Point, I-Point, and the horizontal plane (Fig. 8).

These measurements are representative for the parameters: emergence profile and tissue volume.

#### Classification for decision making

Based on the three landmarks (C-Point, F-Point, and I-Point), the following criteria for

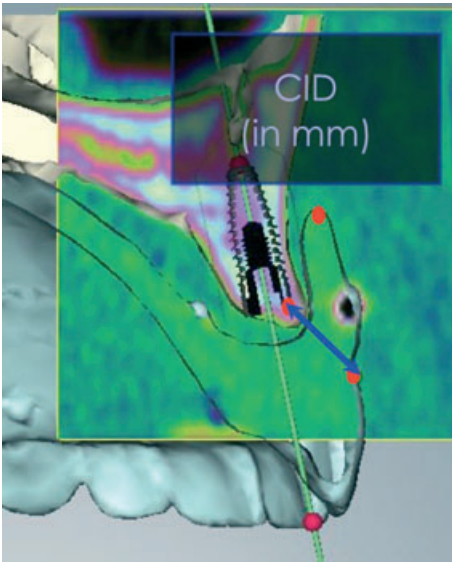


Fig. 7. Measured parameters in the cross sections: Space between prosthetic crown and implant platform.

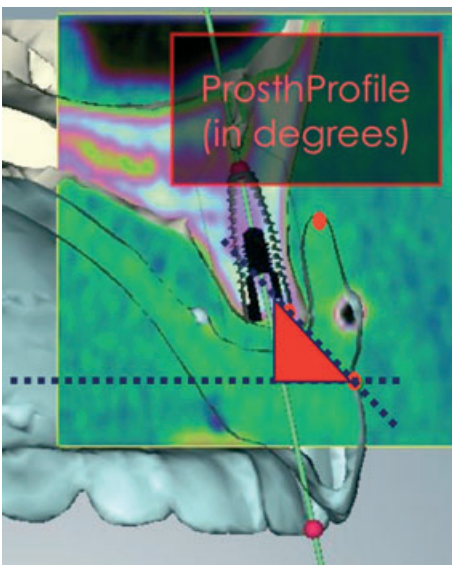


Fig. 8. Measured parameters in the cross sections: Angular aspect of buccal profile.

prosthetic decision making were established for MucCov and ProsthProfile.

1. A) MucCov  $\leq 0$  mm, B) MucCov 0–5 mm, and C) MucCov  $\geq 5$  mm
2. A) ProsthProfile  $\geq 45$  degrees, B) ProsthProfile 30–45 degrees, and B) ProsthProfile  $\leq 30$  degrees.

While MucCov was considered to provide information about esthetic needs, ProsthProfile was associated with hygiene, lip function, phonetics, cantilevers, and resulting biomechanics.

More specifically, MucCov A and B indicated situations where no (negative values) or moderate (0–5 mm) need for lip support was

required. When the mucosal coverage exceeded 5 mm, lip support was strongly needed. ProsthProfile A and B were indicative for normal ( $\geq 45$  degrees) or slightly altered (30–45 degrees) profile of the restoration enabling normal function.

ProsthProfile C less than 30 degrees was representative for a very steep transition from the crown to the implant that may cause functional problems (Jemt 1991; Schnitman 1999; Coachman et al. 2010).

The following classification for decision making was proposed (Table 2).

Class A: MucCov  $\leq 0$  mm and ProsthProfile  $\geq 45$  present a favorable situation for a fixed prosthesis with a crown design (Fig. 9).

Class B: MucCov 0–5 mm and/or ProsthProfile 30–45 degrees, sites may allow for a fixed prosthesis with hybrid design (Fig. 10).

Class C: MucCov  $\geq 5$  mm and/or ProsthProfile  $\leq 30$  degrees, a removable prosthesis with a buccal flange is advised (Fig. 11).

#### Statistical analysis

Statistical analyses were carried out with the SPSS software (SPSS 17.0, SPSS, Chicago, IL, USA). Descriptive statistics consisted of mean value, standard deviation, minimum, and maximum for all variables. Mann–Whitney *U*-test was used for the comparison between left and right side measurements and the comparison between genders. Chi-squared test was used for comparison of group proportion.

## Results

#### Measurements for prosthetic and anatomical landmarks

There was no statistical difference between the left and right sides and therefore data were

**Table 2. Classification for decision making based on the proposed criteria**

		Mucosal Coverage (MucCov)		
		0mm	0-5mm	5mm
Prosthesis Profile (ProsthProfile)	≥45 degrees	A Fixed prosthesis Crown design	B Probably fixed prosthesis Hybrid design	C Removable overdenture or total prosthesis
	30-45 degrees			
	≤30 degrees			



Fig. 9. Fixed implant-supported prosthesis with no need for pink material in the cervical region (crown design).



Fig. 10. Fixed implant-supported prosthesis with artificial gingiva (hybrid design).



Fig. 11. Removable implant-supported prosthesis with extended labial flange (Removable OD).

matched. Mean values were for FLHeight 10.0 mm, MucCov 5.6mm, CID 7.4 mm, and ProsthProfile 39.1 degrees. Table 3 presents values for FLHeight, MucCov, CID, and ProsthProfile in the positions of the central and lateral incisors as well as the canines.

A wide range of acrylic flange height was observed (3.5–17 mm). Measurements of ProsthProfile varied substantially between 0 and 89.7 degrees, particularly in lateral incisor and canine areas. Zero degrees were measured in sites where the cervical point of crown was positioned in the same horizontal plane and just in front of the implant platform, while maximum values around 90 degrees were associated with sites where the cervical part was positioned at a distance underneath the implant platform.



### Classification for decision making

According to the proposed classification, 70% of the patients fulfilled class C criteria (removable OD), 21% class B (probably fixed prosthesis – hybrid design) and 2% class A criteria (fixed prosthesis – crown design). For three patients, implant planning could not be performed due to advanced horizontal and vertical atrophy of the ridge (Table 4).

### Discussion

A primary aim of the present study was to define criteria for the analysis of the edentulous anterior maxilla and the relative position of the artificial teeth. These criteria are primarily related to the emergence profile of prosthetic crowns and the volume of hard and soft tissue to be replaced in the atrophic maxilla.

During the last years, systematical analyses were proposed to help the decision making for the treatment of the edentulous maxilla. Bedrossian et al. presented three factors (presence or absence of a composite defect, visibility or lack of the residual risk during clinical evaluation and quantity of available bone through radiographic evalua-

tion) as the major guidelines for the type of maxillary implant-supported reconstruction (Bedrossian et al. 2008). Bidra and Agar presented a 3D analysis based on various esthetic concepts for implant planning in the edentulous maxilla (Bidra & Agar 2010; Bidra 2011). A classification of patients was proposed into four categories to help choose the appropriate design of a fixed prosthesis. In this classification, the prosthetic space decreases and complexity increases from Class I to Class IV requiring design changes of the prosthesis or surgical procedures to allow an esthetic fixed implant-supported prosthesis. Malo et al. in a pilot study presented a planning protocol for the rehabilitation of the edentulous maxilla. They remarked a limit of 45 degrees between implants and prosthesis for normal lip function. Authors focused that an increased angulation may compromise lip movement when smiling and may provide food entrapment in transition zone (Malo et al. 2008).

The same considerations for an appropriate design of artificial gingiva emergence profile was extensively analyzed in a recent three-part article (Coachman et al. 2009, 2010; Salama et al. 2009). A software that allowed for

3D simulation reported data on soft and hard tissue reconstruction in fixed partial prostheses for replacement of front teeth. The authors emphasized the role of virtual planning for a correct esthetic, hygienic, and functional result in the anterior maxilla.

In the present study, a similar philosophy of virtual analysis was applied to focus on prosthetic parameters that directly influence the decision-making process of a specific design in the cervico-apical area of a fixed or a removable reconstruction. While many patients request a fixed implant-supported restoration with a crown design, there may be a need for facial support with an acrylic flange even if implants can be placed in a proper position.

Definitely the desire of the patient is of major importance and should always be considered in combination with a detailed diagnostic examination. The prosthesis design in the edentulous maxilla should not be selected randomly or just on the basis of the patient's or the operator's preference. Zitzmann and Marinello proposed a treatment concept that enables the practitioner to choose the appropriate type of restoration in consultation with the patient before the surgical procedure has been initiated (Zitzmann & Marinello 2000a,b,c). The presented systematical analysis and the followed classification gives dentists the possibility to evaluate in detail the relationship of anatomical structures, implant position and teeth position and to explain specific aspects with the patient. Thus misunderstanding, possible difficulties, esthetic expectations, and need for surgical procedures can be evaluated during the initial diagnostic phase.

In the edentulous maxilla, the anterior zone is most demanding from an esthetic, functional, physiognomic, and phonetic point of view. To overcome these complex requirements during oral rehabilitation, various prosthetic reconstructions are proposed for the treatment of the edentulous maxilla (Mericske-Stern et al. 2000; Zitzmann & Marinello 2000a,b,c; Sadowsky 2007; Chronopoulos et al. 2008). In one study, 36% of patients presented bone deficiencies that hindered prosthetically ideal placement of implants (Andersson et al. 1995).

In the present study, it was demonstrated that in the majority of cases, the space between the prosthetic crown and implant platform had to be filled with prosthetic materials. Furthermore, a buccal flange is needed to provide lip and facial support as indicated by measurements such as CID (range between 3.5 and 13.1 mm), MucCov

**Table 3.** Medians, mean values, standard deviation (SD), and range of the parameters measured for the six maxillary front teeth

	Tooth position					
	13	12	11	21	22	23
FLHeight (in mm)						
Median	10.0	10.8	9.6	9.4	10.9	10.1
Mean	10.1	10.7	9.3	9.0	10.8	10.2
SD	2.2	2.2	2.1	2.1	2.2	2.0
Range	4.0–16.0	4.6–17.0	4.6–15.3	3.5–15.8	5.3–17.0	6.2–14.7
MucCov (in mm)						
Median	5.9	6.2	5.7	5.5	5.9	5.0
Mean	5.5	6.1	5.3	5.3	5.7	5.4
SD	2.6	2.9	2.6	2.9	3.4	2.6
Range	–2.7–9.6	–1.9–11.4	–1.8–8.7	–2.2–10.8	–2.8–11.6	–0.2–11.4
CID (in mm)						
Median	7.5	7.6	7.4	6.9	8.2	7.6
Mean	7.2	7.6	7.2	7.0	7.9	7.5
SD	1.6	1.4	2.0	1.4	1.7	1.7
Range	3.7–10.3	3.8–10.7	3.9–12.4	3.9–10.9	4.9–13.1	3.5–12.1
ProsthProfile (in degrees)						
Median	42.6	42.8	36.8	34.3	40.3	42.1
Mean	40.5	41.2	36.0	35.0	40.2	41.4
SD	17.8	21.5	19.8	18.2	15.8	14.6
Range	0.0–80.8	0.0–90	0.0–67.0	0.0–67.1	6.2–67.5	0.0–82.1

**Table 4.** Allocation of patients and sites according to the proposed classification

Classification	Patients N (%)	Sites N (%)
A – Fixed PD (crown design)	1/43 (2.3%)	3.9
B – Probably fixed PD (hybrid design)	9/43 (20.9%)	32.4
C – Removable (OD with labial flange)	30/43 (69.8%)	63.8
No implant planning possible	3/43 (7.0%)	–
Total	43 (100%)	100

(range between  $-2.8$  and  $11.6$  mm) and FLHeight (range between  $3.5$  and  $17$  mm). The broad ranges of all measurements indicated a high individual variability. From a prosthodontic point of view, the restoration of lost tissue can be achieved with either fixed or removable prostheses. Gingival prostheses take several form and various authors have described their uses and methods of construction. Acrylic materials, composites, and pink porcelain are described in the literature for the replacement of lost soft and hard tissues (Tallents 1983; Blair et al. 1996; Botha & Gluckman 1999; Barzilay & Irene 2003). Selection and extent of artificial tissues are related to facial support, emergence profile of the artificial tooth, and the tooth angulation. The use of a full flange extension is mentioned for esthetic advantages (Fortin et al. 2002). However, the application of gingival prostheses may be limited to certain clinical situations where oral hygiene is manageable, function proper and esthetics acceptable. With a removable design, a larger volume of tissue can be replaced and a proper cleaning is still feasible (Barzilay & Irene 2003).

Linear measurements, however, are not sufficient in the decision-making process and measurements of angles (ProsthProfile) are important. We considered mucosal coverage (MucCov) and prosthesis buccal profile (ProsthProfile) the most important factors for appropriate treatment planning. In the present study, planning included implants of a minimum  $10$  mm length. Nevertheless, the comparable survival rates of short rough surfaced implants with standard implants, a tendency of higher failure rates in the maxilla and the lack of randomized clinical trials for fixed implant-supported restorations in the upper jaw, restricted the use of shorter in the analysis (Pommer et al. 2011; Sun et al. 2011; Telleman et al. 2011).

The mean mucosal coverage was about  $5.5$  mm and only few patients showed negative values, meaning that acrylic flanges extended under or closely beneath the implant platform with no or only minimal need for lip support. A  $5$  mm extension over the platform was used as the limit for distinction between moderate and advanced cases. The limits for mucosal coverage were put regarding hygienic principles. The design of a normal implant-supported bridge dictates no extension of the materials over the ridge edge. Nevertheless, alternative designs were proposed in the literature providing patients with fixed prosthesis but with flange extensions. These gingival prostheses are predisposing to plaque accumulation

more easily and necessitate high ability of dental hygiene. In this study, the limit of  $0$  mm was the favorable one for correct oral hygiene. A limit value of  $5$  mm was used for the cases where a fixed prosthesis could be realized under esthetic compromises or in cases where a minimum overlapping of the ridge with artificial gingiva could be designed but with very demanding oral hygiene.

The mean buccal prosthesis profile (ProsthProfile) was around  $39 \pm 18$  degrees with a wide range of values between a minimum of  $0$  and a maximum of  $89.7$  degrees. The higher the value, the more perpendicular the position of the crown in relation to the implant platform was. In contrast, lower values represented a crown that was positioned closer to the vertical place. It was proposed that the buccal edge of prosthetic gingiva should not be beyond  $45$  degrees in relation to the occlusal plane. Its end should also not extend beyond the natural gingival buccal edge when observed laterally (Coachman et al. 2010). In another study, it was proposed that angulation between implants and prosthesis should not exceed  $45$  degrees. Increased angulation may compromise lip movement when smiling and provide food trap in transition zone (Malo et al. 2008). In these previous publications, the limit of  $45$  degrees was related to implant angulation and ridge shape. In our study, the same limit was used but in relation to horizontal plane for a fixed implant-supported prosthesis. A lower limit of  $30$  degrees was proposed to include the cases where a steeper profile could be allowed with some compromises.

In the present study, the buccal profile mean values were found to be mostly lower than the limit of  $45$  degrees.

We found that only  $4\%$  fulfilled the criteria to qualify them for a fixed prosthesis (MucCov  $\leq 0$  mm and ProsthProfile  $\geq 45$  degrees). The position of the crown allowed a physiological transition from implant to the prosthesis (crown) and provided a physiological emergence profile and support. Sixty-four percent of sites were assigned to the group that would benefit from a buccal flange. The remaining  $32\%$  included sites with characteristics between a fixed and removable prosthetic solution.

A secondary aim of the study was the allocation of the examined patients.

According to the literature, a minimum number of six implants for a fixed implant-supported reconstruction and four implants for a removable overdenture are needed in the upper jaw providing high survival rates of

implants and prosthesis (Lambert et al. 2009; Sagat et al. 2010). In this article, analysis was carried out with the regard of the front region. The analysis consisted two parts. First of all an analysis per site was performed classifying the possible implant's site to one of the groups. This allowed characterization of each site for the possibility of implant insertion and the relationship with the clinical crown position. By accepting the cut-off values, descriptive statistics gave an idea of the tooth loss results. Subsequently, a second analysis was completed giving directions per patient. An even distribution of six implants in the anterior and the posterior region of the maxilla is the most accepted in the literature. For our study, a minimum of two sites in the front area allowing for implant insertion within the limits of each group, was used for the classification per patient. The results showed that only one patient ( $2.3\%$ ) fulfilled the criteria for a fixed design while  $9$  ( $21\%$ ) could receive a fixed prosthesis with a hybrid design.

Such criteria and measurements may also be helpful when major grafting procedures must be planned in the atrophic maxilla. Bone grafting dimension and quantity could be determined according to these criteria with the help of adequate implant-planning software.

While the presented criteria are helpful for treatment-planning considerations, clinical aspects of individual physiognomy are also important. A low lip line (no gingiva exposed) is advantageous for fixed prostheses with regard to esthetic demands for the upper jaw (Mericske-Stern et al. 2000) as some compromises regarding the emergence profile and teeth lengths may be acceptable. Phonetic problems have been reported more often with fixed prostheses than with overdentures (Jemt 1991; Lundqvist et al. 1992). Impaired phonetics appears to depend also on the palatal design of the prosthesis, which was not considered in the present study.

Technical complications are also described to be associated with compromised implant planning and reconstruction type (Aglietta et al. 2009; Zurdo et al. 2009). It is suggested that favorable 3D implant position and proper choice of the prosthetic design limit the technical complexity of the prosthesis and subsequently reduce technical complications. It was demonstrated that full-arch reconstructions that were planned using implant planning software and CAD/CAM procedures, showed less prosthetic complications than conventionally planned and produced ones (Katsoulis et al. 2011).

Although measurements for the four points FLHeight, MucCov, CID, and ProsthProfile were carried out by one and the same examiner and reproducibility of the digitizing process was confirmed by means of double determination of all measurements, this may be considered as a weak point in the study design. However, the results for the classification for the population investigated showed a clear tendency. Furthermore, the type and quality of the criteria for decision making were defined before the measurements were performed.

It should be noted that defined decision-making criteria do not replace critical assessment of a set-up under clinical conditions. Implant-planning softwares alone are not able

to sufficiently evaluate facial support, lip position and its relationship to the maxillary teeth without a set-up that is tried in and clinically evaluated. However, it is advantageous that clinical observations before implant placement are visualized and verified virtually in combination with simulated optimum 3D implant position. Through this step, treatment outcomes and the choice of prosthetic design become more predictable in the anterior zone of the edentulous maxilla.

## Conclusions

The proposed classification and virtual planning procedure simplify the decision-making

process regarding type of prosthesis and increase predictability of esthetic and functional treatment outcomes. An idealized prosthetic set-up is an essential tool for the clinical assessment of a patient with an edentulous maxilla and is a requirement for proper computer-based virtual implant planning. It was demonstrated that in the majority of cases, the space between the prosthetic crown and implant platform had to be filled with prosthetic materials. Only few patients were found suitable for fixed implant-supported prostheses with crown design due to moderate or advanced maxillary atrophy.

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Published: 01 September 2013  
Annals of Oral & Maxillofacial Surgery



Montanari M, Battelli F, Callea M, Corinaldesi G, Sapigni L, Marchetti C, Tadini G, Mancini EG, Grecchi F, Clarich G, Salinas CF, Fedele G, Piana G. Oral rehabilitation with implant-supported overdenture in a child with hypohidrotic ectodermal dysplasia. *Annals of Oral & Maxillofacial Surgery* 2013 Sep 01;1(3):26.

This is a provisional PDF file.

# **Oral rehabilitation with implant-supported overdenture in a child with hypohidrotic ectodermal dysplasia**

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## **Abstract**

Ectodermal Dysplasia syndromes (EDs) are a heterogeneous group of inherited diseases characterized by abnormal development of tissues of ectodermal origin. The most common form of EDs is X-linked Hypohidrotic Ectodermal Dysplasia (XL-HED) characterized by abnormalities of the skin, teeth, hair and sweat glands. The intraoral abnormalities include hypodontia, malformed teeth (conically shaped) and reduced alveolar ridge height. It causes severe impairment of chewing, swallowing, speech, esthetics and affects social relation. Early dental treatment at 2-3 years is essential to improve oral function and reduce the social impairment. This may include resin bonded restorations to conventional prosthetic treatment. In some cases suffering from severe hypodontia, however, conventional prostheses are inadequate due to lack of retention and instability. The replacement of teeth by implants is usually restricted to patients with completed cranio-facial growth; however implants can be used as abutments for overdentures. The present study reports a 9-year follow up case in a child affected with XL-HED accompanied by anodontia. At 2 yrs of age, conventional upper and lower removable prostheses were fabricated. Subsequently, at age 11 years and 11 months; the patient was treated with a lower implant supported overdenture placed on two tapered implants (3.8 x 10 mm) in the anterior mandible. CBCT (Cone Beam Computer Tomography) of the mandible was done and dicom data used to obtain a rapid stereolithographic model.



## Introduction

Ectodermal Dysplasias are a heterogeneous group of inherited disorders characterized by dysplasia of tissues of ectodermal origin (hair, nails, teeth, skins and glands).<sup>1</sup> Clinically, it may be divided into two broad categories: the X-linked hypohidrotic form and the hidrotic form. Hypohidrotic Ectodermal Dysplasia (HED) is characterized by the triad oligo/anodontia, hypotricosis, hypo/anhydrosis (Christ-Siemens-Tourane syndrome). The incidence of HED is about 1/100,000. Mutation in the ectodysplasin-A (EDA) and ectodysplasin-A receptor (EDAR) genes are responsible for X-linked and autosomal HED.<sup>2</sup> More rare occurs a mutation in EDARADD, and recently WNT10A has been reported to be causative of HED.<sup>3</sup> The clinical features include sparse, fine hair, missing or conical teeth, decreased sweat and mucous glands, hypoplastic skin, and heat intolerance with exercise or increased ambient temperature.<sup>4</sup> Complete or partial anodontia and malformation of teeth are the most frequent dental findings. Incisors and canines are often conical in shape, while primarily second molars, if present, are mostly affected by taurodontism.<sup>5</sup> The diagnosis of HED in the neonatal and early infancy period may be difficult since sparse hair and absent teeth are a normal finding at this age.<sup>6</sup> During childhood the diagnosis is more easily made on the basis of history and clinical examination. Dental abnormalities are the most common complaint. Treatment is supportive and includes protection from heat exposure, skin, hair ear, nose and nail care, genetic counseling for family planning and early oral prosthetic rehabilitation. A dental multidisciplinary team that includes a pediatric dentist, an orthodontist, a prosthodontist and an oral and maxillofacial surgeon is necessary for a successful outcome. Prosthetic rehabilitation has been recommended as an essential part in HED management due to functional, esthetic, and psychological indications.<sup>7</sup> Conventional prosthodontic rehabilitation in young patient is challenging because of the anatomical abnormalities of existing teeth and alveolar ridges.<sup>8</sup> The

conically shaped teeth and “knife-edge” alveolar ridges result in poor retention and instability of dentures. Moreover, dentures must permit a correct pattern of growth in addition to jaw expansion.<sup>9</sup>

## **CASE REPORT**

A 2-year-old patient affected with Ectodermal Dysplasia and anodontia was rehabilitated with removable upper and lower prostheses. The prosthetic rehabilitation was provided to allow a correct masticatory function and normal physiological development. A monthly follow up of the patient was performed and, with time, conventional prostheses showed reduced retention especially in the mandibular jaw; therefore a different prosthetic treatment approach was necessary. At the age of 11 years and 11 months, the fabrication of an upper conventional and a lower implant-supported overdenture was indicated. The implants were two endosseus implants (position #33 and #43) in the anterior aspect of the mandibular jaw. The pre-prosthetic diagnostic steps included obtaining an Orthopantomogram (OPT) and CBCT (MyRay®, Cefla, Italy) 3D-images of the patient. Row DICOM data were elaborated using a 3D imaging software (OsiriX®, Pixmeo, Switzerland). The radiographic images showed a remarkable multi-dimensional atrophy of the mandibular alveolar process (Fig. 1), therefore two tapered implants measuring (3.8 x 10 mm) was the option of choice. A Virtual model of mandibular bone was used to obtain a resin model of the mandibular jaw of the patient (Fig. 2). The surgical procedure of implant placement was simulated in the resin model of the mandible and a surgical template was fabricated to guide implant placement on the anterior aspect of the mandible. The insertion of two tapered screw implants under local anesthesia with a novel biomimetic calcium-phosphate enriched titanium treatment (Anodic Spark Deposition, BioSpark) was possible and resulted in safe primary stabil-

ity (Fig. 3). A Cephalometric radiograph was taken after implant placement to evaluate correct implant positioning. After a submerged healing period of two months, the implants were exposed and two ball-attachments (Rhein 83, Bologna, Italy) were connected to the implants in order to increase lower prosthesis retention. In order to fabricate custom impression trays, initial maxillary and mandibular impressions were obtained using stock trays with an irreversible hydrocolloid material. Final impressions were made with light-body polysulfide rubber base impression material. On the final casts, a base of auto polymerizing resin was constructed and a wax rim was added to the base. Preliminary occlusal relations were recorded and the patient's vertical dimension of occlusion was established by assessing phonetic and esthetic criteria. The mandibular cast was mounted on the articulator. Acrylic resin teeth specific for children dentures were selected and mounted. Denture try-in was performed and, after adjustments, were inserted on ball-attachment. The patient was monitored clinically every month for the following three years.

## **DISCUSSION**

Early oral rehabilitation improves oral function, phonetics and esthetics, reducing social impairment. Mandibular growth in a sagittal and transverse direction showed no adverse effects on implant position. The fixtures advanced with the mandible, maintaining their original relationship with the bone. After three years of follow-up, the mandibular implant-supported overdenture was well accepted from the patient who reported excellent masticatory and esthetic improvements (Tab. I).

Implants can be successfully placed, restored and loaded in growing patients with Ectodermal Dysplasia. Several Authors in the literature reported good results with implant-supported overdentures in patients with Ectodermal Dysplasia.<sup>10</sup> Others reported a great number of implant failure in these patients<sup>11</sup> that can be due to the rigid connection of implants and the large diameter

of implants compared with the width of bone crest. The majority of authors placed implants after 13 yrs to avoid displacement of implants or exposition of implants because of craniofacial growth.<sup>12</sup> On the other hand, Gukes et al placed implants in 3-year-old patient.<sup>13</sup>

In the present study case report implants were placed when he was 7 years old because the most important center of growth had already performed its function and after this age the growth occurred where the prosthesis could not interfere.<sup>14, 15</sup> The prosthesis was connected with implants using two ball-attachments in order to avoid a rigid connection to allow mandibular growth and to reduce interference with the patient's growth. Factors such as good stability and retention of the implants-supported overdenture, reduction of micro-movement typical of conventional prostheses, excellent esthetics and substantial masticatory improvement maintained the patient's acceptance of the prosthesis.<sup>16</sup>

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### **Figure legends**

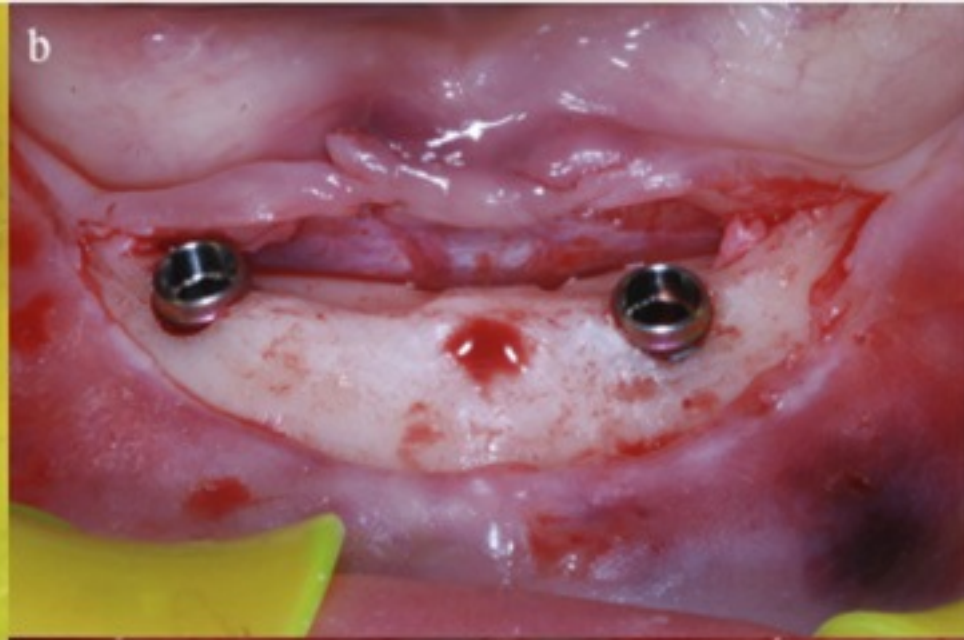
**Fig. 1:** Radiographic images of the mandibular alveolar process

**Fig. 2:** Virtual model of mandibular bone used to obtain a resin model of the mandibular jaw of the patient

**Fig. 3:** Patient after the treatment

**Table I:** Evaluation of prosthesis acceptance, masticatory improvement, esthetic improvement and phonetic improvement. + fairly good, ++ good, +++ very good

Patient	Number of mandibular teeth	Prosthetic acceptance	Masticatory improvement	Esthetic improvement	Phonetic improvement
K.I.	0	+++	+++	+++	+++











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