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

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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 ± 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 (5×8 mm, $n = 126$; 5×6 mm, $n = 90$) (Betwice, Mech & Human, Italy) were installed. The average follow-up period was 25.3 months (± 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.¹ However, evidence suggests that prosthetic complications are common, especially when implants are in function.^{1,2} 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.³ However, surgical difficulties, such as the inadequacy of alveolar bone and restriction of mouth opening, might lead to orientation failures and poor implant positioning.^{1,2} 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.⁴⁻⁷ The use of angled abutments may increase the stress transferred to supporting implants and adjacent bone, with direct effects on the prosthesis.⁸ 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.^{4-7,9}

The use of a special abutment with non-parallel implants to obtain a favorable path of insertion and removal may be promising.⁹ 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.¹⁰ This component is based on a customized spherical abutment, without the head and neck of the sphere, but maintaining the equatorial part (Figure 1).¹⁰ In addition, at the center of the sphere, additional threads were added to house a connection screw.¹⁰ 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).¹⁰ 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.¹⁰

It also provides a wide range of retentive possibilities, even for non-parallel implants.^{10,11} 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 (≥ 8 mm) and short (< 8 mm) implants.^{10,12} 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.¹³ 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 ≤ 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.¹⁴

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 (≥ 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.^{2,13,15,16} 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%¹⁷ to 95.6%,¹⁸ even after 5 year of fixed partial implant prostheses in function.^{17,18} 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 review² reported that approximately 70% of implant losses occur after prosthetic loading. However, several other studies^{13,15,19,20} have shown higher rates of earlier failure, in agreement with our finding. According to

Jemt,¹³ 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.¹³ 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.^{21,22} 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.^{23,24} 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.^{13,25} Although some authors have suggested that the poor quality of maxillary bone increases implant loss,^{26,27} 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.⁸ In addition, mandibular implants are usually placed at more demanding sites with greater masticatory loading, which also contributes to explain this pattern of loss.¹³

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.

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Table 1 Summary of sample and implant characteristics.

			Number (Percentage)
Sample characteristics	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%)
Implants characteristics	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).







