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Success Rate of Two-Piece Zirconia Implants: A Retrospective Statistical Analysis

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Purpose: *About 10 years ago, one-piece zirconia implants were introduced to dentistry. The aim of the study was to evaluate the clinical success of two-piece zirconia implants regarding osseointegration using the manufacturers' warranty data.*

Materials and Methods: *Over a period of 4 years (2010–2014), the data of warranty replacements of 15,255 sold Zeramex implants were evaluated retrospectively and blinded.*

Results: *Three hundred fourty-seven (2.2%) nonosseointegrated implants were sent back. Zeramex T showed an average success rate of 96.7%, whereas Zeralock implants exhibited an average success rate of 98.5%. Furthermore, Zeramex Plus implants exhibit an average success rate of 99.4% within the investigated period. Assuming, that 2% of the failed implants were unreturned, the above-mentioned values show no changes. Assuming 5% (10%) of unreturned nonosseointegrated implants, the average success rate of Zeramex T decreases from 96.7% to 96.6% (96.4%) and of Zeralock from 98.5% to 98.4% (98.4%), respectively. The success rate of Zeramex Plus implants remains unchanged at 99.4%.*

Conclusion: *The results of this study imply that two-piece zirconia implants show competitive success rates, improved from >96.7% to >98.5% over three product generations. (Implant Dent 2016;25:1–6)*

Key Words: zirconia, dental implant, failure rate, two-piece implant, success rate

Titanium implants are used in dentistry since more than 40 years. In many published studies regarding complications, the success rate varies between 95% and 98%.[1,2] After osseointegration, periimplantitis is the most described risk, which is found in 10% of the implants after a 5- to 10-year period after placement of a titanium implant.[3] About ten years ago, zirconia implants were introduced to dentistry.[4] Especially, the use of roughened surfaces was described to improve osseointegration significantly.[5–13] In several animal studies, good osseointegration of zirconia implants could be demonstrated.[6,7,14] Furthermore, titanium intolerance was recently correlated in patients with implant failures.[15] In orthopedic surgery, zirconia is a well-known material for joint-replacements, but in dentistry, there were concerns regarding the materials properties for a long time. Therefore, the first dental zirconia implants were one-piece implants. From the surgical point of view as well from a prosthodontic perspective, one-piece implants have several disadvantages such as wound healing problems and undesirable loading during the healing period. To avoid such complications, an implant design comprising an implant body and a separate abutment should be the aim of dental zirconia implant systems as well. A review of the current literature shows that studies referring to clinical success are still limited,[8,9,12,16–20] because the number of investigated patients is low and/or only systemically healthy patients were included. Most of the clinical investigations only refer to one-piece zirconia implants.[10,11,21,22] Only three studies regarding two-piece implants could be identified.[22–24] Kohal et al[22] reported a prototype study in 2008, using not marketed implants, whereas Nevins et al[24] described 2011 a case report using two-piece implants. The first clinical study referring to two-piece implants was published in 2014[23] but still with the disadvantage of a relatively low number of patients and relatively strict inclusion criteria.

The aim of the study was to evaluate the clinical success of a two-piece zirconia implant (Zeramex implant system) regarding osseointegration using the manufacturers' statistical warranty data.

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MATERIALS AND METHODS

Over a period of 4 years (2010–2014), the statistical data of warranty replacements of 15,255 sold Zeramex implants (Dentalpoint AG, Zürich, Switzerland) were evaluated retrospectively and blinded. During this period, three different types of implants were distributed according to the level of development: Zeramex T, Zeramex T Zeralock (generally referred to as Zeralock), and Zeramex Plus. The implants are made of zirconium-dioxide (either ZrO2-**TZP**-HIP or ZrO2-**ATZ**-HIP). The different series of zirconia implants were produced from the following materials: Zeramex T: ZrO2-**TZP**-HIP; Zeralock: ZrO2-**ATZ**-HIP; and Zeramex Plus: ZrO2-**ATZ**-HIP. All implants undergo a surface treatment, that is grit blasting or acid etching (Fig. 1). Although all three systems undergo the same procedure generally, the acid etching was optimized from Zeramex T to Zeralock based on the results of Saulacic et al.[12] The surface modification procedure for Zeramex Plus remains unchanged compared with Zeralock. The company replaces nonosseointegrated implants as a warranty case, if the surgeon submits a detailed questionnaire regarding the case. The study was performed over all sold implants in the German speaking market (Germany, Austria, and Switzerland). All implants were included in the study (no exclusion criteria). The questionnaire contains the following parameters: age, sex, smoker, oral hygiene (good/poor), date of implantation, date of implant loss, bone quality (D1–D4), position of implant and prosthetic restoration (if applicable).

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The quality and the evaluation of the data were evaluated and certified by "QS Schaffhausen," according to the ISO 13485 standard. This is also ensured by the CE certification of the Zeramex implant system which is granted by an authorized third party (Notified Body). Implants were considered as failure, if an implant-loosening was observed during or after the healing period. Velytics Ltd., London, performed the statistical evaluation, which is an independent statistical company.

Nonosseointegrated implants were correlated with the number of implants sold in the same period (quarterly evaluation), and the percentage of the average success rate (average failure

Table 1. Gender and Smoker Status in Absolute Numbers and Percentage

Gender	No. Patients	Smoker	Nonsmoker	Not Specified
Male	142	22 (15%)	107 (75%)	13
Female	193	15 (8%)	163 (84%)	15
Not specified	12	0	1	11
Total	347	37	271	39

The not specified cases result from incorrectly filed warranty forms.

Table 2. Bone Classification From D1 to D3 in Absolute Numbers and Percentage

Gender	No. Patients	D1	D2	D3	D4	Not Specified
Male	142	10 (7%)	58 (41%)	53 (37%)	8 (6%)	13
Female	193	16 (8%)	78 (40%)	49 (25%)	5 (3%)	45
Not specified	12	0	0	2	0	10
Total	347	26 (7%)	136 (39%)	104 (30%)	13 (4%)	68

The not specified cases result from incorrectly filed warranty forms.

Table 3. Total Number of Implant Failures in the First, Second, and Third Year

Duration	Total No. Failures	Zeramex T	Zeralock	Zeramex Plus
First year	251	157	90	4
Second year	35	30	4	1
Third year	2	2	0	0
Total	288	185	94	5
Data not available	59			
Total	347			

In 59 cases, there were no correct data available because of incorrectly filed warranty forms.

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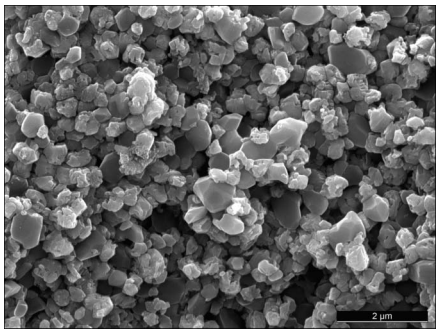

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Fig. 1. Zerafil implant surface. The image shows an REM image (×12,000 magnification).

Table 4. Total Number of Implant Failures in the First Year Related to the Time of Implant loss

Duration	Total No. Failures	Zeramex T	Zeralock	Zeramex Plus
Day 1	8	3	5	0
First month	32	23	9	0
Second month	39	17	21	1
Third month	18	12	6	0
First quarter total	97	55	41	1
Second quarter	87	57	29	1
Third quarter	46	30	14	2
Fourth quarter	21	15	6	0
First year total	251	157	90	4

The first 3 months are worked out separately, whereas the rest of the year is worked out quarterly.

Table 5. Reason of Implant Failure of the Zeramex System

Failure Reason	N (%)
Not osseointegrated: tissue healing	9 (4)
Not osseointegrated: acute infection	22 (10)
Not osseointegrated: not specified	198 (86)
Total	229

According to the questionnaire, the results are divided into acute infection, tissue healing, and not specified other reasons.

Table 6. Reason of Implant Failure of the Zeralock System

Failure Reason	N (%)
Not osseointegrated: tissue healing	4 (4)
Not osseointegrated: acute infection	16 (14)
Not osseointegrated: not specified	90 (82)
Total	110

According to the questionnaire, the results are divided into acute infection, tissue healing, and not specified other reasons.

rate) was calculated accordingly. From sale to implantation, a three-month delay time was assumed. To compensate for possibly unreturned nonosseointegrated implants, three calculations were made under the assumption that 2%, 5%, or 10% of the failed implants did not show up in the calculation. The calculation was summarized over the whole number of implants sold and was also divided into the different subgroups of: Zeramex T, Zeralock, and Zeramex Plus.

RESULTS

Over a period of 4 years, a total number of 15,255 implants were sold. 347 (2.2%) failed implants were sent back. 142 (41%) of the patients were men and 193 (56%) of the patients were women (3% not reported) (Table 1). The majority of the patients were nonsmokers (75% of men and 84% of women). The average age at the time of implant placement is 55 years across both male and female patients.

Regarding the bone classification (Table 2), the majority showed bone quality D2 and D3 (69%). D1 bone was reported in 7%, whereas D4 bone was found in 4% of the cases. Ignoring the data for which the bone classification is not specified, around 9% of the patients are classified as D1, 49% as D2, 37% as D3, and 5% as D4.

The majority of the nonosseointegrated implants were lost during the first year after placement (72%), whereas 10% of the implants were lost in the second year (Table 3). In the third year, the loss rate decreased nearly to 0 (0.6%). In 17% of the cases, the questionnaire was filled in inadequately. If the first year after implantation is viewed, the majority of the implants failed in the first and the second quarters (39%/35%). In the third and fourth quarters, the failure rate was approximately halved compared with the first two quarters (Table 4).

The reasons for implant failure (Tables 5 and 6) as stated by the users were tissue healing (4%) and acute infection (9% and 14%). In most of the cases, the users could not define any reason for the implant loss (86% and 82%).

Oral hygiene (Table 7) was reported being well in both female and male patients (83% and 84%).

Zeramex T presented an average success rate of 96.7% after >3 years,

Table 7. Oral Hygiene Over All Patients Loosing a Zirconium Implant Related to the Gender

Gender	No. of Patients	Poor Oral Hygiene	Good Oral Hygiene	Not Specified
Male	142	2	118 (83%)	22
Female	193	4	163 (84%)	26
Not specified	12	0	3	9
Total	347	6	284 (82%)	57

The oral hygiene is divided into good and poor. Not specified information due to incorrectly filed forms is stated separately.

Table 8. Implant Failure Rate From 2010 to 2014 Divided Into the 3 Different Implant Types Zeramex T, Zeramex Plus, and ZeralockTM

Implant Failure Rate by Series	2010		2011		2012		2013		2014		
Half Year	H1	H2	H1	H2	H1	H2	H1	H2	H1	H2	Average Failure Rate
Zeramex T		2.2%	3.1%	4.2%	2.4%	8.9%	6.4%	2.3%			2.2%
Teralock						1.9%	1.6%	1.3%	1.2%		1.5%
Zeramex Plus								0.6%	0.0%		0.6%

The failure rates are calculated for each half year (H1 and H2).

Table 9. Implant Failure Rate From 2010 to 2014 Divided Into the 3 Different Implant Types Zeramex T, Zeramex Plus, and Zeralock Assuming 2% of Those Not Reported

Implant Failure Rate by Series	2010		2011		2012		2013		2014		
Half Year	H1	H2	H1	H2	H1	H2	H1	H2	H1	H2	Average Failure Rate
Zeramex T		2.3%	3.1%	4.3%	2.5%	9.1%	6.5%	2.3%			3.3%
Teralock						1.9%	1.6%	1.4%	1.2%		1.5%
Zeramex Plus								0.6%	0.0%		0.6%

The failure rates are calculated for each half year (H1 and H2).

Table 10. Implant Failure Rate From 2010 to 2014 Divided Into the 3 Different Implant Types Zeramex T, Zeramex Plus, and Zeralock Assuming 5% of Those Not Reported

Implant Failure Rate by Series	2010		2011		2012		2013		2014		
Half Year	H1	H2	H1	H2	H1	H2	H1	H2	H1	H2	Average Failure Rate
Zeramex T		2.3%	3.2%	4.5%	2.6%	9.4%	6.7%	2.4%			3.5%
Teralock						2.0%	1.7%	1.4%	1.3%		1.6%
Zeramex Plus								0.6%	0.0%		0.6%

The failure rates are calculated for each half year (H1 and H2).

Table 11. Implant Failure Rate From 2010 to 2014 Divided Into the 3 Different Implant Types Zeramex T, Zeramex Plus, and Zeralock Assuming 10% of Those Not Reported

Implant Failure Rate by Series	2010		2011		2012		2013		2014		
Half Year	H1	H2	H1	H2	H1	H2	H1	H2	H1	H2	Average Failure Rate
Zeramex T		2.5%	3.4%	4.7%	2.7%	9.9%	7.1%	2.5%			3.6%
Teralock						2.1%	1.8%	1.5%	1.3%		1.6%
Zeramex Plus								0.6%	0.0%		0.6%

The failure rates are calculated for each half year (H1 and H2).

whereas Zeralock implants showed an average success rate of 98.5% after >2 years. Furthermore, Zeramex Plus implants exhibit an average success rate of 99.4% within the investigated period of >1 year (Table 8). Assuming that 2% (Table 9) of the failed implants were not sent back by the users, the above-mentioned values show no changes. Assuming that 5% (Table 10) and 10% (Table 11) of nonosseointegrated implants could not be incorporated in the statistical evaluation, the average success rate of Zeramex T decreases from 96.7% to 96.6% (96.4%) and of Zeralock from 98.5% to 98.4% (98.4%), respectively. The success rate of Zeramex Plus implants remains unchanged at 99.4%. Figure 2 shows the cumulated implant success rate of all types of sold Zeramex implants. The success rate follows the number of sold implant with a delay of approximately 4 to 6 months. F2

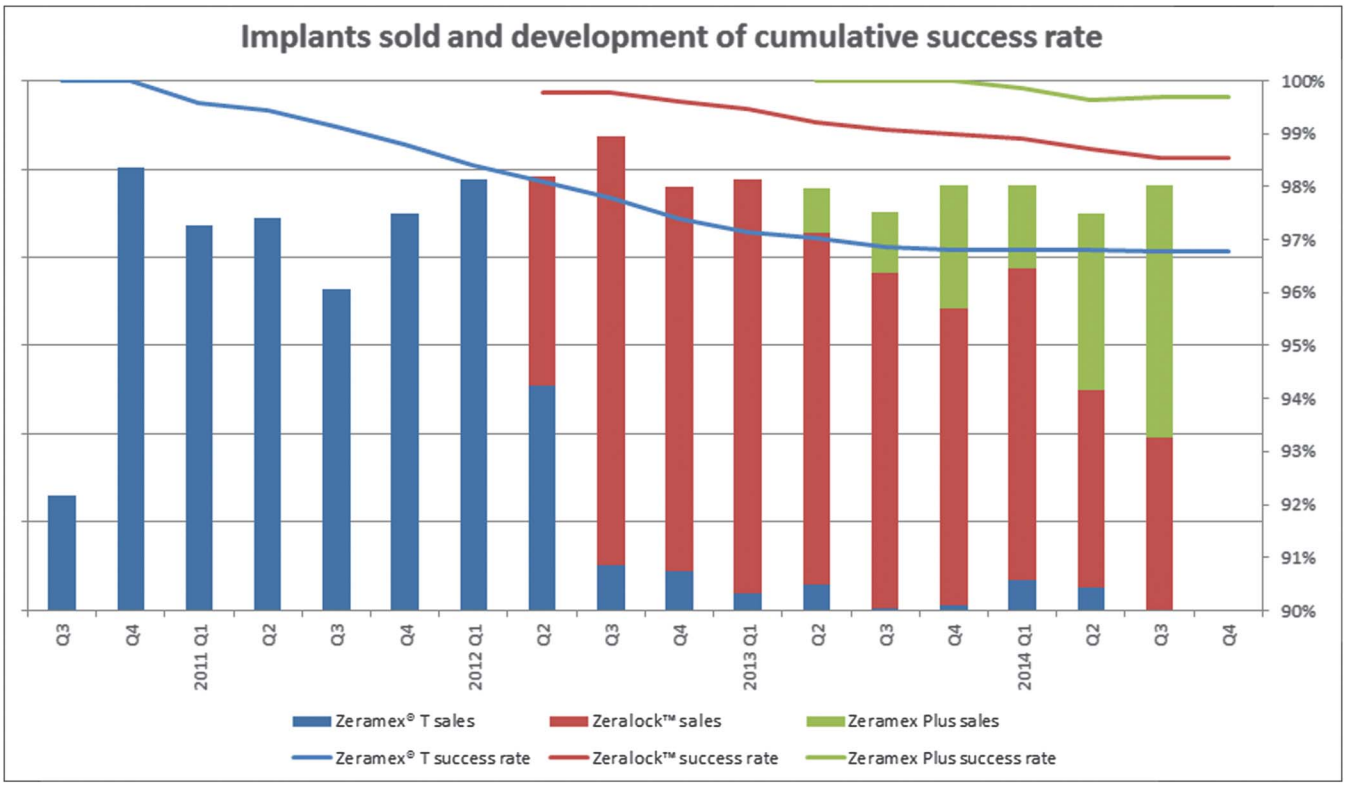

Fig. 2. Cumulated implant success rate of the 3 investigated implant surfaces Zeramex T, Zeramex Plus, and Zeralock. The bars show the number of sold implants, whereas the lines show the calculated success rate in percent.

DISCUSSION

The definition of implant success is not standardized; therefore, a comparison between different studies in the literature is difficult. The survival rate is easy to calculate because it refers to the percentage of survived implants at a defined point in time. The success rate is much more complicated, because several parameters have to be defined.[25] The statistical data in this study were limited because of the retrospective evaluation of the questionnaire, which had to be filed by the users for warranty replacement of lost implants. As the data contain exclusively failed (lost or loose) implants, only the survival rate could be calculated. Early implant loss is one of the problems in dental implantology[26]; therefore, many surgeons have concerns regarding this complication. As the observation period (sales period) started in 2010, a long-term observation was not possible at that point in time, and we focused on the short-term complications.

Regarding the current results, the comparison with the literature is very difficult, because no comparable study exists. Even regarding titanium implants, no manufacturer allowed to publish such data yet, because such data are regarded highly confidential. Regarding the current literature, a comparison with the development-accompanying study of Cionca et al[23] seems to be very promising, because it partially refers to the same implant system. Cionca et al[23] reported a 98% of cumulative survival rate in the period of placement to loading and 87% in the period from loading time up to 2 years. However, the comparison is difficult, because on the one hand, 32 patients is a relatively low number of cases, and on the other hand, the Cionca et al[23] used relatively strict inclusion criteria such as systemically healthy patients >20 years, single teeth treatment, and smoking less than 10 cigarettes a day. This study was performed over all ever-treated patients with no exclusion criteria. The current results refer to the complete range of patients and summarize all types of users from private practice to university hospitals, with no division into experienced users and/or beginners. Of course, some data are lacking because they are a retrospective analysis being dependent on the cooperation of practicing dentists with more or less interest in scientific research. In contrast to Cionca et al,[23] most implants (38%) were lost in the first quarter of a year. This means, that all of the implants were lost before loading, as the clinical protocol of Zeramex does not allow immediate loading. Within the investigated cohort of more than 15,000 placed implants, a relatively high average success rate of 96.7% for the Zeramex T implants and 98.5% for the Zeralock implants could be determined. Comparing Zeralock and Zeramex T, a significant decrease of failures can be shown between these two implant systems. The Zeramex Plus implants exhibit an average success rate of 99.4% after >1 year, but the investigated period may be considered too short to make a significant statement. Hence, these results could be interpreted as a additional increase of the success rate from Zeralock to Zeramex Plus in the first year. Additional studies have to be performed though to obtain more detailed data on Zeramex Plus.

Other studies regarding one-piece zirconia implants show survival rates from 74% to 98% depending on the period of investigation.[6–9] Kohal et al[22,27] calculated a survival rate of 95% in a prospective study. One of the biggest cohorts of patients was investigated by Oliva et al[28,29] in 2007 and 2010. Although the success rate was investigated, and not the survival rate, one-piece zirconia implants reached a value of 95%. Several studies exist regarding the success rate of zirconia implants.[10,11,21,22,27,30] A comparison with the current results is impossible, because in our cohort of patients, the investigation is starting with the loss of the implant. Clinical data such as bone loss, bleeding on probing, and chronic inflammation are limited as we could only evaluate the data of the returned warranty forms. One conclusion of this study may be the requirement to revise the warranty form. Much more data regarding patient details and clinical evaluation would be very helpful. In reality, this may result in a lower number of returned implants after failure, because especially users in private practice are not willing to spend more than 10 minutes on completing such warranty forms. The strength of this study is a cross-section over the reality in implantology without any restrictions and exclusion criteria. Therefore, users should not be stressed by complex and time consuming processes to get their failed implants replaced.

Regarding the question, how many of the lost implants were sent back by the users, we postulate, that we could include nearly all of them in our investigation. The price for an implant is more than $400; therefore, one should estimate that it is in every user interest to get it replaced for free. To calculate this error, we assumed that 2%, 5%, or 10% of the implants were not returned by the users, but the average success rate over all investigated implants only decreased from 96.7% to 96.4% under this worst-case estimation for. The reason for this moderate decrease is the high number of sold implants during the investigated period.

CONCLUSION

The results of this study imply that two-piece zirconia implants show highly competitive success rates, improved from 96.7% to 99.4% over three product generations. To compare the current results, other manufacturers are encouraged to publish comparable data of their systems as well.

DISCLOSURE

The authors claim to have no financial interest, either directly or indirectly, in the products or information listed in the article.

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