

Title

Implant-Supported Immediately Loaded Complete Arch Rehabilitations with a Mean Follow-up of 10 Years: A Prospective Clinical Study

Running Title

Long term follow-up of failures and complication

Authors (First [Given name] Middle Last [Family name])

Gianluca Martino Tartaglia^{1,2} DDS, PhD, Marco Farronato¹ DDS, MS, Chiarella Sforza³ MD, MS, Avinash S. Bidra⁴ BDS, MS, FACP

Institutions

1. Department of Medicine, Surgery and Dentistry, Fondazione IRCCS Ca' Granda, Ospedale Maggiore Policlinico, University of Milan, Milano, Italy; SST Dental Clinic, Segrate, Italy
2. Private Practice, SST Dental Clinic, Segrate, Italy
3. Department of Biomedical Sciences for Health, Functional Anatomy Research Center (FARC) Università degli Studi di Milano, Milano, Italy.
4. Department of Reconstructive Sciences, University of Connecticut Health Center, Farmington, CT, USA

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Correspondence: Dr. Gianluca Martino Tartaglia, Università degli Studi di Milano – Department of Medicine, Surgery and Dentistry, Fondazione IRCCS Ca' Granda, Ospedale Maggiore Policlinico, Milano, Lombardia, Italy; Private Practice, SST Dental Clinic, Segrate, Italy E-mail: gmtartaglia@gmail.com

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ABSTRACT

Purpose: To evaluate the complication-free and failure-free survival rates of porcelain fused to zirconia (PFZ) and all-resin complete arch fixed implant-supported prostheses over a mean follow-up of 10-years.

Material and methods: Subjects with either all-resin or PFZ complete arch fixed implant-supported prostheses on 4 or 6 implants were followed prospectively for 10 years. Cumulative survival rates of prostheses without any catastrophic mechanical complications (resolved without replacing the prosthesis) and free of prosthesis failure (requiring the replacement or removal of the prosthesis) were calculated using life table analysis for up to 10 year period. Additional descriptive variables for various prosthesis events were recorded, such as sex, smoking and drinking status of subjects.

Results: A total of 36 subjects with a total of 68 prostheses (53 all-resin and 15 PFZ) were available for evaluation with a mean follow-up of 10-years (SD 1.47; range: 8-13 years). The study registered an overall 90% prostheses survival rate - 78% for males and 94% for females; 91% for PFZ and 87% for all-resin; and a 31% complication-free prosthesis survival rate - 13% for males and 38% for females; 29% for PFZ and 31% for all-resin at 10 years.

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A slight decrease in survival rate was identified in the first 3 years since the initial treatment (from 100% to 93%). The number of complications increased with time, especially after the 6th year after the initial treatment.

Conclusion: Despite the number of reparable mechanical complications, the results confirmed the long-lasting features of both PFZ and all-resin complete arch fixed implant-supported prostheses over a 10-year period. There was however an increased number of mechanical complications after 6 years which may entail additional treatment cost for patients.

KEYWORDS: prosthesis; zirconia; resin; complications; failure; survival rate; implant

Complete arch fixed implant-supported prostheses (CAFIP) offer an excellent solution for rehabilitation of patients with terminal dentition or completely edentulous patients.¹⁻³ Initially, a 3 to 6 month unloaded healing period was usually recommended for osseointegration before prosthesis loading. However, implant placement with immediate occlusal loading with provisional complete arch prostheses has also proven to be a successful clinical option.¹⁻³ The immediate implant-supported prosthesis placed at the day of surgery provided the cross-arch stabilization needed for osseointegration.⁴⁻⁶ Similarly, the use of fewer implants and distally tilted implants revolutionized the use of implant-supported immediately prostheses even in patients.⁹ This modality of treatment of edentulous patients is not without possible surgical, technical, and mechanical complications. The first risks for complications were identified in the late 1990s as implant component fractures, screw loosening and prosthesis fracture.^{9,14}

Despite today's technological improvements, the complications described 3 decades ago still persist. The long-term implant and prosthetic successes are determined by the careful performance of the treatment itself as well as by the patients' compliance with instructions, such as specific dietary suggestions, hygiene, and recall appointments.¹⁵ The success and survival rates of implant-supported prostheses are reported and well known in short-term follow-ups. A number of 1 year, 5 year and few 10-years follow-up studies evaluating the reconstruction using all-resin or porcelain fused to zirconia (PFZ) exist, assessing both survival rates and complication of implants and prostheses.¹⁶⁻¹⁸ The prosthesis framework fracture, chipping of veneered porcelain, denture teeth debonding/delamination, crown fracture, abutment, and prosthetic screw loosening or implant failure are among the most frequent complications related to the CAFIP.¹⁵ Similarly, bone resorption, accumulation of plaque, bleeding on probing, increased periodontal probing depth are common long-term complications associated with the treatment.¹⁹

In short term to medium term follow-ups (up to 5 years), the cumulative survival rate of implants varies among studies from 87.89% to 100%.^{18, 20, 21, 22} The survival rate of implants supporting metal ceramic and all ceramic prostheses are within the same range.¹⁶ The cumulative survival rates of prostheses themselves vary from 93.3% to 100%, with the most common complication being chipping and fracture or loosening of abutments or prosthesis screws.^{16, 18} In a long-term follow up (10 years), the cumulative survival rates of implants vary among the studies from 78.3% to 98.9%.²³⁻²⁵ and the cumulative acrylic prosthetic survival rates range from 82 to 100%, with the most common complications being the same as in case of short- to mid-range follow-ups.^{5, 26-29}

In a previous study, a group of subjects who had received CAFIP made of all-resin or PFZ were followed for 5 years.³⁰ The CAFIPs supported by 4 or 6 implants of both maxilla and mandible had annual complication and failure rates of 6.6% and 4.6%, respectively; and the overall complication free survival rates (prostheses without occurrence of any reparable mechanical complications) were

75.5% and 85.5% (at 60 months). Prosthetic material did not influence complication and failure risks and all-resin and PFZ prostheses were both deemed clinically successful.³⁰

The purpose of this study was to evaluate the long-term survival and complication-free survival rates in a mean follow-up of 10.01 years (SD 1.47, min 8 years, maximum 13 years) of this CAFIP performed in a private practice setting with both all-resin and PFZ materials. The implant survival rate, prostheses failure-free survival rate and prostheses complication-free survival rate are described.

Materials and methods

In 2012, 113 patients (53 men and 60 women, mean age 65 years, age range 42-90 years) were selected from a private practice from dental hygiene clinical recall appointments. Patients previously received a 4- to 6- implant-supported full arch rehabilitations from May 2005 to December 2012 in one or both jaws (Milde Implants; Titanmed, Bergamo, Italy). Two different materials of prostheses were used: polymethyl methacrylate (Apex Dental, Milano, Italy) veneered with acrylic resin (Lucitone, Dentsply, Charlotte, USA) and resin teeth (Ivoclar, Naturno, Italy). The second material was zirconia (Zirite, Keramo, Tavernerio, Como, Italy) veneered with ceramic (CZR Noritake Kizai Co. Ltd, Nagoya, Japan); the results of the short-term (5 years) follow-up of their treatments had been published previously, as well as inclusion criteria.³⁰ In brief, criteria were as follows: age over 18 years, completely edentulous maxilla or mandible or presence of teeth with short-term survival prognosis, adequate bone height for placement of at least 10-mm long and 4-mm wide implants, and the refusal of any kind of bone augmentation procedures. Information about tobacco and alcohol use was collected; all patients who declared to be habitual tobacco users were categorized as “smokers”, while “drinkers” were subjects that continuously consumed more than half a liter of alcoholic beverages daily for at least 1 year.³⁰

In December 2018, subjects suitable for long-term follow-up (with minimum of 8 years after the initial treatment) were selected out of the original 113 subjects included in the previous 5-year study. Only patients still attending their recall visits at the clinic were included. The comparison of the current sample to the sample studied in the previously published 5-year follow-up is presented in Table 1. All clinical evaluations were performed by an independent clinician who had not been involved in the original surgical and prosthetic procedures. Details about the clinical procedures can be found in the previous publication.³⁰

The study was conducted in accordance with the principles of Helsinki Declaration. The Institutional Review Board approved the study. Subjects were informed about the objectives of this study and their consent was obtained to be a part of this investigation. All subjects signed a new informed consent form.

The criteria for success and complications of treatment were defined in accordance with literature^{31,32} and as in the 5-year follow-up study.³⁰ In summary, implant was considered successful if no pain, suppuration, swelling, mobility, discomfort, ongoing pathological processes, signs of peri-implantitis, neuropathies, or persistent paresthesia was observed during recall appointments.^{30,31} The successful outcomes of prostheses were defined as prostheses in function, without discomfort or pain, and with absence of report of dissatisfaction by subjects. Complications were classified as reparable problems such as reparable fracture, restoration or retightening of abutment-prosthesis screws, loosening of access holes, and all grades of porcelain chipping of zirconia.³² Failures were classified as problems requiring replacement such as non-reparable fractures (zirconia) and implant failure.³⁰

Chi-square test was used to compare the selected sample to the previously published 5-year follow-up and to assess intra-sample differences between males and females. In survival analysis, prostheses were censored if they had not experienced the end-point of interest at the end of the follow-up. The statistical analysis was based on the life table analysis technique.³⁵ Cumulative survival

rates for complication-free prostheses (survival of prosthesis without occurrence of any reparable complication) and failures-free prostheses (survival rate of prosthesis without failure) were calculated for every year in 10 year follow-up. Cumulative rates were calculated for all subjects together, and for males and females separately. Survival curves were compared by logrank test to assess the significance of observed differences between males and females, smokers and non-smokers, drinkers and non-drinkers and prosthetic and occluding teeth materials. A p-value 0.05 was considered statistically significant.

Results

Descriptive characteristics of the sample are presented in Tables 1 and 2. Number of implants, sex distribution, number of patients with both maxillary and mandibular prostheses, and number of all-resin prostheses in the sample identified for this follow-up did not significantly differ from the 5-year follow-up sample (Chi-square test, Table 1). A total of 50 subjects were eligible for this study. Fourteen subjects were lost due to death, lack of communication or change of dental clinic. Therefore, the analysis was performed on a sample of 36 subject (26 (72%) females and 10 (28%) males) with a mean follow-up of 10.01 years (SD 1.47, minimum 8 years, maximum 13 years), and with a mean age of 64.5 years (SD 9.66, range 42 – 80 years), treated with 68 complete arch prostheses (34 maxillary and 34 mandibular) on 4 or 6 implants (total of 359 implants). Out of these, 53 were all-resin prostheses and 15 were PFZ prostheses. However, not all subjects were followed-up for 10 years and additional drop-outs occurred. If subject couldn't be followed at corresponding year, prostheses were classified as drop-outs in the life table. No differences between males and females in number of smokers/drinkers, maxillary/mandibular arches, prosthetic and occluding teeth material and number of implants and implant failures were observed (Chi-square test, Table 2).

Twenty-eight subjects presented with at least one complication during the follow-up.

Considering all arches, complications were observed in 44 of them. Table 3 presents cumulative rate of complication-free survival time for every year of follow-up. Overall, a cumulative complication-free survival rate of 31% at 10 years was observed, and cumulative complication-free survival rate of 13% and 38% were observed for males and females respectively.

Men had a higher risk of mechanical complications over the follow-up period compared to women.

Maxillary arches had a lower complication-free survival rates than mandibular ones at 10 years (24% and 38% respectively) but results are not statistically significant (p -value >0.05); and alcohol consumers and smokers had lower complication-free survival rates than non-alcohol consumers and non-smokers at 10 year follow-up (25% and 32% vs 13% and 34%). While results are not significant in case of alcohol consumers, the differences in complication-free survival rates of smokers are significant (p -value = 0.006). Figure 1 shows cumulative complication free survival rates for 15 PFZ and 53 all- resin prostheses, with PFZ exhibiting more complications and lower complication-free survival rates (29% vs 31%) but observed differences are not statistically significant (p -value >0.05).

Six subjects had a framework failure of at least 1 prosthesis during the follow up period.

Considering all prostheses, 7 failures were found and overall cumulative survival rate was 90% at 10 years; 78% for males and 94% for females. Table 4 presents cumulative survival rates of failure-free prosthesis for every year of 10 year follow-up. Interestingly, none of the smokers presented with a prosthetic failure while failure occurred in non-smoking group of subjects (cumulative survival rate 88% at 10 years). Alcohol consumers had higher chance of failure, with cumulative survival rate of 88% in comparison to non-alcohol consumers (90%) but observed differences were not statistically significant (p -value >0.05). Cumulative survival rates for two different materials remained high at 10 years – 91% for all-resin and 87% for PFZ with no statistical differences (p -value >0.05) (Fig 1).

DISCUSSION

The All-on-4 and All-on-6 treatment concepts addressed previous problems related to the treatment of edentulous jaws.¹² Three different factors should be taken into consideration when assessing the success of full arch implant supported rehabilitation, namely (1) survival rate of implants; (2) complications related to prosthesis; and (3) survival rate of the prosthesis framework itself.

Nevertheless, a number of publications focus only on implant survival rates (or implants survival rates together with prosthesis survival rates) and are omitting complications and complication free survival rates of prostheses. Complications, even if not directly causing the failure of the CAFIP, are an important factor in a full arch rehabilitation causing patients to return to the clinic and increase the total cost of the treatment. The present study describes follow-up of 36 subjects (68 full arch prostheses) up to 10 years assessing all three mentioned factors, presenting implant and prosthetic survival rates, and additional complication-free survival rates. The number of subjects considered in this follow-up is lower compared to the previously published 10-years follow-ups: 127 prostheses by Wittneberg et al.,²⁵ 1072 subjects by Malo et al ,²⁷ 245 subjects by Malo et al.²⁹

Our study showed that 11% of all implants were lost over time (representing 89% implant success rate). The finding is lower than some of previous 10-year follow-up success rates (93%²³, 95.5%²⁵ or 93-96.9%²⁷⁻²⁹), which needs future investigation. However, the observed implant success rate falls between rates observed in other previous studies.^{12,24} Around 35% of prostheses remained completely complication free during the follow-up. As in the case of failures, no significant differences between CAFIPs made from all-resin versus PFZ were detected. The sex had an influence on the complication rates - men exhibited significantly higher risk of complications likely due to anatomical differences in maxilla and mandible and higher occlusal and shear forces compared to women.^{26,33} This finding is in accordance with the 5-year follow-up results.³⁰

Biological and technical complications of implant-supported prostheses are relatively frequent, the most common being chipping or fracture of the veneering material, occlusal screw loosening or loss of retention.^{25,26,34} The same complications were observed in the present follow-up study, resulting in a 68% complication-free survival rate in the first 6 years after the initial treatment, decreasing rapidly to 31% at 10 years. In a single subject, the number of complications gradually increased with time -14 complications occurred from the 6th to the 10th year after treatment, which may be also caused by bruxism or other parafunctional habits. Our short term findings are in accordance with previously published data, however, in the long-term follow-up, the results differ and the complication rates remain relatively constant.^{25,27} The use of newer materials such as monolithic or predominantly monolithic zirconia may offer promising alternative solutions to the most common complication, related to chipping and fracture of veneering material.^{36,37}

The results of the current investigation showed relatively stable failure-free survival rates. A decrease in failure-free survival rate was identified in the first 3 years after the initial treatment (from 100% to 93%). No significant differences were observed between failure-free survival rates of all-resin and PFZ prostheses. The recent literature shows two different trends in long-term survival rates of acrylic prostheses –high prostheses survival rates in 10- to 18- years follow-up study (99.6%)²⁷, 94.8% at 10 years,²⁹ 99.2 % at 13 years.²⁸ On the other hand are studies reporting lower survival rates, such as (82%).²⁶ Our results confirm that the survival rate of prostheses in a long-term follow-up remains high despite the number of observed reparable mechanical complications and implant failures; both PFZ and all-resin seem to satisfactory fulfill the long-term durability requirements for successful treatment. It is imperative that clinicians emphasize the importance of lifelong need for routine professional maintenance for patients with these prostheses.³⁸

CONCLUSIONS

Within the limitations of this prospective study on 36 patients with a mean follow-up period of 10 years, the following conclusions were drawn. Overall implant survival rate 89% was observed. There was a 90% prostheses survival rate and a 31% complication-free prosthesis survival with men having more complications than women. There were also an increased number of mechanical complications after 6 years. Complete arch fixed implant-supported prostheses made of all-resin and porcelain fused to zirconia materials had similar survival of the prostheses itself, but require regular lifelong professional maintenance to address mechanical complications.

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TABLES

Table 1. Comparison between the study sample from the 5-year follow-up study²⁷ and the present 10-year follow-up study

	5-year follow-up ²⁷	10-year follow-up	p-value*
Number of subjects	113	36	
Number of implants (n. per person)	1058 (9.32)	359 (9.97)	0.749
Males n. (%)	53 (46%)	10 (28%)	0.182
Both maxillary and mandibular prostheses n. subjects (%)	101 (89%)	32 (89%)	0.98
Prosthesis material resin n. (%)	166 (78%)	53 (78%)	0.949

*p-value from Chi-squared test

Table 2. Sample characteristics of study participants at the 10-year follow-up period

	Males (n = 10)	Females (n = 26)	p-value*
Number of smokers (%)	2 (15%)	2 (8%)	0.361
Number of drinkers (%)	2 (15%)	2 (8%)	0.362
Number of maxillary arches	9	25	0.901
Number of mandibular arches	9	25	
Material of prosthesis			
<i>Porcelain fused to zirconia prostheses</i>	3 (17%)	12 (24%)	0.520
<i>All-resin</i>	15 (83%)	38 (76%)	
Material of prosthetic teeth			
<i>Zirconia</i>	2 (11%)	14 (28%)	0.287
<i>Resin</i>	15 (83%)	35 (70%)	
<i>Combination of resin and zirconia</i>	1(6%)	1 (2%)	
Number of implants	96	263	0.891
Number of implant failures	13	28	0.713

*p-value from Chi-squared test

Table 3. Life table survival analysis of complication-free prostheses at the 10 year follow-up period

Time since procedure (years)	Prostheses at start of interval	Drop-outs during interval	Prostheses at risk	Complications during interval	qt	pt	Pt
1	68	0	68	4	0.06	0.94	0.94
M	18	0	18	1	0.06	0.94	0.94
F	50	0	50	3	0.06	0.94	0.94
2	64	0	64	4	0.06	0.94	0.88
M	17	0	17	4	0.24	0.76	0.72
F	47	0	47	0	0.00	1.00	0.94
3	60	0	60	2	0.03	0.97	0.85
M	13	0	13	1	0.08	0.92	0.67
F	47	0	47	1	0.02	0.98	0.92
4	58	0	58	2	0.03	0.97	0.82
M	12	0	12	1	0.08	0.92	0.61
F	46	0	46	1	0.02	0.98	0.90
5	56	0	56	2	0.04	0.96	0.79
M	11	0	11	1	0.09	0.91	0.56
F	45	0	45	1	0.02	0.98	0.88
6	54	0	54	8	0.15	0.85	0.68
M	10	0	10	4	0.40	0.60	0.33
F	44	0	44	4	0.09	0.91	0.80
7	46	0	46	10	0.22	0.78	0.53
M	6	0	6	1	0.17	0.83	0.28
F	40	0	40	9	0.23	0.78	0.62

8		36	2	35	5	0.14	0.86	0.45
	M	5	1	5	1	0.22	0.78	0.22
	F	31	1	31	4	0.13	0.87	0.54
9		29	6	26	3	0.12	0.88	0.40
	M	3	1	3	1	0.40	0.60	0.13
	F	26	5	24	2	0.09	0.91	0.49
10		20	4	18	4	0.22	0.78	0.31
	M	1	0	1	0	0.00	1.00	0.13
	F	19	4	17	4	0.24	0.76	0.38

q^t - probability of complication during the time interval

p^t - probability of complication free prosthesis in the time interval

P^t - cumulative probability of complication free prosthesis at the beginning of the time interval

Table 4. Life table survival analysis of all failure-free prosthesis at the 10 year follow-up period

Time since procedure (years)	Prostheses at start of interval	Drop-outs during interval	Prostheses at risk	Failures during interval	qt	pt	Pt
1	68	0	68	2	0.03	0.97	0.97
M	18	0	18	1	0.06	0.94	0.94
F	50	0	50	1	0.02	0.98	0.98
2	66	0	66	2	0.03	0.97	0.94
M	17	0	17	2	0.12	0.88	0.83
F	49	0	49	0	0.00	1.00	0.98
3	64	0	64	1	0.02	0.98	0.93
M	15	0	15	0	0.00	1.00	0.83
F	49	0	49	1	0.02	0.98	0.96
4	63	0	63	0	0.00	1.00	0.93
M	15	0	15	0	0.00	1.00	0.83
F	48	0	48	0	0.00	1.00	0.96
5	63	0	63	0	0.00	1.00	0.93
M	15	0	15	0	0.00	1.00	0.83
F	48	0	48	0	0.00	1.00	0.96
6	63	0	63	1	0.02	0.98	0.91
M	15	0	15	1	0.07	0.93	0.78
F	48	0	48	0	0.00	1.00	0.96
7	62	0	62	1	0.02	0.98	0.90
M	14	0	14	0	0.00	1.00	0.78
F	48	0	48	1	0.02	0.98	0.94

8		61	8	57	0	0.00	1.00	0.90
	M	14	4	12	0	0.00	1.00	0.78
	F	47	4	45	0	0.00	1.00	0.94
9		53	12	47	0	0.00	1.00	0.90
	M	10	2	9	0	0.00	1.00	0.78
	F	43	10	38	0	0.00	1.00	0.94
10		41	15	34	0	0.00	1.00	0.90
	M	8	4	6	0	0.00	1.00	0.78
	F	33	11	28	0	0.00	1.00	0.94

q^t - probability of failure during the time interval

p^t - probability of failure free prosthesis in the time interval

P^t - cumulative probability of failure free prosthesis at the beginning of the time interval

FIGURE LEGENDS

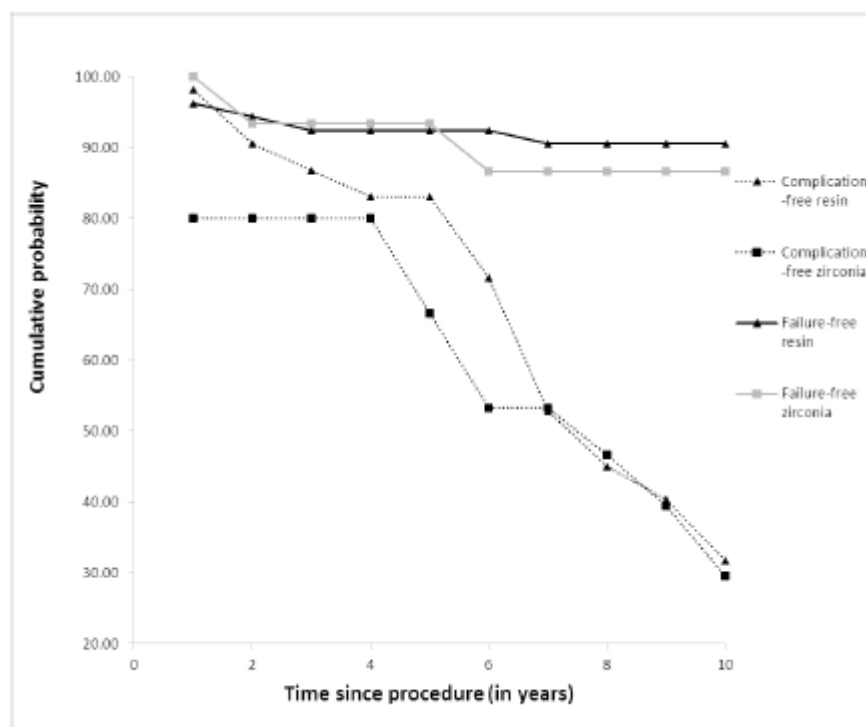


Figure 1 Cumulative probability of failure-free and complication-free all-resin and PFZ prostheses in follow-up.