

Practice-Based Evidence from 29-Year Outcome Analysis of Management of the Edentulous Jaw Using Osseointegrated Dental Implants

Matilda Dhima, DMD, MS,¹ Vladimira Paulusova, MD,² Christine Lohse, MS,³ Thomas J. Salinas, DDS,⁴ & Alan B. Carr, DMD, MS⁵

Keywords

Edentulous jaw; dental implants; outcome analysis; practice-based evidence; hybrid; implant-retained dental prosthesis; complications; follow-up; management.

Correspondence

Alan B. Carr, DMD, MS, Mayo Clinic 200 1st St. SW, Rochester, MN 55905. E-mail: carr.alan@mayo.edu

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Abstract

Purpose: The aim of this retrospective study was to summarize practice-based evidence associated with long-term outcomes (>20 years) in the management of edentulous patients. The patient population was managed with implant-supported prostheses, following the original osseointegration protocol, provided over the period from 1983 to 1991 in the group prosthodontics practice at the Mayo Clinic. The data are an example of practice quality assurance monitoring and are used to refine care delivery when needed and to provide information regarding expected outcomes in a shared decision-making interaction with prospective patients.

Materials and Methods: Two hundred and sixty four patients with at least one edentulous jaw were identified. Of these, 255 completed their care and follow-up at the Mayo Clinic (209 mandible only, 35 maxilla only, 11 mandible and maxilla). Prosthodontic outcomes categorized as anticipated or unanticipated prosthetic and biologic events and the respective interventions required for each were recorded to assess follow-up event dynamics for this care modality.

Results: The mean duration of follow-up for 190 of the 255 patients (65 died at a mean follow-up of 12.6 years) was 13.0 years (median 13.6; range 0.3 to 28). At least one prosthetic event was experienced by 148 patients (58%), and 81 (32%) experienced at least one biologic event. Overall, patients experienced 3.8 times more prosthetic events than biologic events. Twenty-four (9%) patients experienced 35 implant failures. Overall survival rates at 20 years were 86% for prostheses, 15% survived free of any event, and 92% experienced survival free of implant failure (95% confidence interval).

Conclusion: Anticipated and unanticipated prosthetic events occur throughout the life of the hybrid prosthesis. Prosthetic events significantly surpass (four times more) biologic events and occur significantly later in the follow-up. For this patient group, 8.6% (22/255) had implant-supported prostheses remade during follow-up in this patient population. These findings support the recommendation that prosthodontic care for missing teeth be thought of in a "chronic condition" context, recognizing that long-term outcome monitoring to provide realistic care expectations is important for demonstrating care value in oral health promotion.

¹Assistant Professor, Mayo Clinic College of Medicine and Chief Resident, Prosthodontics and Maxillofacial Prosthetics, Department of Dental Specialties, Division of Prosthetic and Esthetic Dentistry, Mayo Clinic, Rochester, MN

²Assistant Professor, Department of Dentistry, Faculty of Medicine and University Hospital in Hradec Králové, Charles University, Prague, Czech Republic

³Statistician, Department of Biostatistics, Mayo Clinic, Rochester, MN

⁴Professor, Mayo Clinic College of Medicine and Consultant, Department of Dental Specialties, Division of Prosthetic and Esthetic Dentistry, Mayo Clinic, Rochester, MN

⁵Professor, Mayo Clinic College of Medicine and Consultant, Chair, Department of Dental Specialties, Division of Prosthetic and Esthetic Dentistry, Mayo Clinic, Rochester, MN

Management of tooth loss over the past three decades has grown in scope due to the demonstrated predictability of dental implants. The original introduction of dental implants to North America demonstrated a predictable application for the edentulous jaw, and similar clinical application began across the United States and Canada as a result. Canada as a result. Canada as a proach in consultation (i.e., informing patients as to the difference between and results of options available to them), have provided edentulous patients evidence as to benefit and harm based on published reports that now reach three decades.

Meaningful decision making with patients seeking prosthodontic care involves sharing clinical outcome evidence that reflects the patient perspective of the care provided and is associated with a period of time that has significance relative to the care expectations of patients.⁶ For the permanent condition "tooth loss," the expectation of replacements providing adequate performance for an extended period of time is understandable. In this long-term health-care context, tooth loss is similar to other chronic conditions in medicine and requires long-term management⁷ of time-dependent events, which are often unique to the selected prosthetic management option.⁸ This perspective suggests that outcome measures discussed with patients should reflect meaning from a patient perspective over a period of time that captures time-dependent differences of value to shared decision-making needs.⁹

Much research has been reported from clinical trials related to implant outcomes. 10-12 The applicability of clinical trial-based evidence to practice has been the subject of many reports. 13,14 Expressed concerns over trials in general and those involving "procedural specialties" include issues of generalizability, the use of surrogate outcomes, and short-term outcome applicability or meaningfulness. 16 Evidence obtained from practice settings that provide care outcomes of importance to patients can add valuable insight to providers interested in monitoring quality and patients interested in hearing about care expectations. Care outcomes from practice, termed practice-based evidence (PBE¹⁶) is complementary to trial-based evidence (complementary in that trial evidence demonstrates which treatment is effective; practice evidence demonstrates what results are observed when an effective treatment is provided), as it addresses evidence needs when trials are not performed or when care outcomes are needed for long-term chronic conditions.

This report provides practice evidence for the management of edentulism using cantilevered fixed implant prostheses for patients presenting to the Mayo Clinic from 1983 to 1991. The report provides outcome data for prosthesis survival and biological and technical outcomes for original osseointegrated surgical and prosthetic protocols, and represents PBE over a period of care of up to 29 years.

Materials and methods

A retrospective cohort was identified of all patients receiving edentulous implant care from 1983 to 1991. Appropriate institutional review board approval was obtained. The cohort comprised 308 patients with at least one edentulous jaw receiving an implant-supported prosthesis following the original Brånemark protocol. ^{17,18} Complete records review (electronic

Table 1 Characteristics of data collected

Patient characteristics	Age
	Gender
	Geographical identity
	Living status
	Smoking history
	Medical comorbidities
Clinical characteristics	Implant dates by stage
	Prosthesis type
	Prosthesis placement date
	Opposing dentition
Event(s) characteristics	Event type/date
	Event interventions/number/date
	Visits to last appointment

and paper) resulted in 28 patients being excluded due to incomplete or missing documentation, and 15 patients excluded due to written patient requests on file for their records not to be used for research.

The remaining 265 patient records were reviewed, and data were sought from diagnostic, treatment, and follow-up phases. Data were abstracted by two clinicians familiar with the record environment and the data "exposures" sought. Initial abstraction efforts were formally reviewed by duplicating abstraction for 12 charts to assure completeness and accuracy. All data were collected on a secure Microsoft Excel 2010 file.

Data abstracted included both patient and clinical characteristics and event-related data (Table 1), following event reporting designations used in clinical-trial monitoring for human protection.¹⁹ Prosthetic and biological outcome events are categorized as anticipated (when prosthetically functional; biologically reversible) or unanticipated (when prosthetically harmful with continued function; biologically irreversible and requiring care) (Table 2).

Overall survival, survival free of event, and survival free of implant failure were estimated using the Kaplan-Meier method. Overall survival was designated by prosthesis presence in the mouth with or without anticipated events. Survival "free of event" was defined as prosthesis present and with no record of any event(s). The duration of follow-up for overall survival was calculated from the date of implant placement to the date of patient death or last check-up. The duration of survival free of event was calculated from the date of implant to the date of the first event or last check-up. The duration of survival free of implant failure was calculated from the date of implant to the date of first implant failure or last follow-up. All statistical analyses were performed using the SAS software package (SAS Institute, Cary, NC).

Results

The mean duration of follow-up for 190 of the 255 patients (65 died at a mean follow-up of 12.6 years) was 13.0 years (median 13.6; range 0.3 to 28). The majority of the 255 patients (97%) underwent surgery and prosthesis placement at Mayo Clinic, while 9 (3%) had their prosthesis fabricated elsewhere. Relative to age, gender, and arch restored, there were no differences

Table 2 Description of anticipated and unanticipated prosthetic and biologic events

Prosthetic events			
Anticipated Lip biting Change of opposing dentition Loose opposing denture Lost composite filling Difficulty cleaning under prosthesis Loose opposing overdenture Loose O rings Tooth broken opposing partial denture Lost gold matrix Prosthesis tooth fracture Prosthesis tooth wear	Unanticipated Fractured gold screw Loose abutment Fractured abutment screw Fractured multiple abutment screws Prosthesis fracture Broken opposing denture Fractured acrylic base Distorted implant platform Removal of failed implant		
Tooth broken on opposing denture Loose gold screw			

Biologic events			
Anticipated	Unanticipated		
Plaque/calculus	Periapical radiolucency		
Hyperplasia	Infection		
Tingling when flossing	Mobile implant		
Paresthesia	Benign/malignant process		

All events types were collected and categorized. Anticipated/unanticipated designations were chosen to assist clarification of recall dynamics. An event associated with continued functional performance and reversible return to biological health is considered as less disruptive to follow-up, which is anticipated. An event that leads to harm with function and is irreversible biologically would be more demanding at follow-up, both an unanticipated and undesirable outcome.

between patient groups. Regarding residence, 78% (7 of 9) of the patients restored elsewhere where National residents, compared to 44% National residents in the Mayo-treated cohort (Table 3). Single-arch prostheses were provided the majority of the time (209 mandibular, 35 maxillary), and 11 patients received both mandibular and maxillary prostheses. The 255 patients received 1325 implants, 1089 in the mandible and 236 in the maxilla.

The average age of cohort patients was 56.4 years [68 (27%) less than 50 years of age, 83 (33%) between 50 and 60 years of age, 104 (41%) over 60 years of age] at the time of implant placement. In this group of implant patients, these patients were largely existing denture wearers with a history of maladaptation to removable prostheses. Patients were followed an average of 11.8 years from the time of implant placement to last check-up [140 (53%) followed over 10 years, 96 (36%) followed over 15 years, and 58 (23%) followed over 20 years]. Patients returned for an average of five visits per year after prosthesis placement.

Overview of prosthesis survival

Overall prosthesis survival rates at 5, 10, 15, and 20 years following the date of implant reveal a 20-year survival rate of 86% (Fig 1). Survival free of prosthetic or biologic events for the same time intervals reveals 51% at 5 years and 11% at

Table 3 Summary of patient specific features

Feature (n = 255 completed rehabilitations)	Mean (range)		
Age at first implant in years Years from first implant to last check-up Overall number of visits Number of visits per year	56.4 (9–82) 11.8 (0.0–27.9) 23.8 (0–113) 4.3 (0–69)		
Sex Female Male	N (%) 190 (75) 65 (25)		
Residence National Local Regional International	111 (44) 84 (33) 53 (21) 7 (3)		
Arch restored Mandible Maxilla Both mandible and maxilla	209 (82) 35 (14) 11 (4)		
Prosthetic design Metal acrylic Spark erosion Bar with RPD Metal ceramic Bar milled/OD Metal acrylic—switch to spark erosion Metal acrylic—switch to bar with RPD Metal acrylic—switch to metal ceramic Smoker Cardiovascular disease Osteoporosis GERD Hypertension Hyperlipidemia Carcinoma Feature (n = 9 prostheses placed elsewhere) Age at first implant in years Years from first implant to last check-up Sex	229 (90) 8 (3) 7 (3) 3 (1) 1 (<1) 4 (2) 2 (1) 1 (<1) 82 (32) 136 (53) 59 (23) 28 (11) 185 (73) 164 (64) 34 (13) Mean (median; range) 60.6 (61; 43–81) 0.5 (0.5; 0.0–1.1) N (%)		
Female Male Residence National	6 (67) 3 (33) 7 (78)		
Regional Arch restored Mandible Maxilla Both mandible and maxilla	7 (78) 1 (11) 1 (11)		
Prosthetic design Metal acrylic Spark erosion Unknown	2 (22) 1 (11) 6 (67)		

Local: State of Minnesota.

Regional: North Dakota, South Dakota, Nebraska, Wisconsin, Iowa. National: United States of America excluding local and regional.

International: Outside the United States of America.

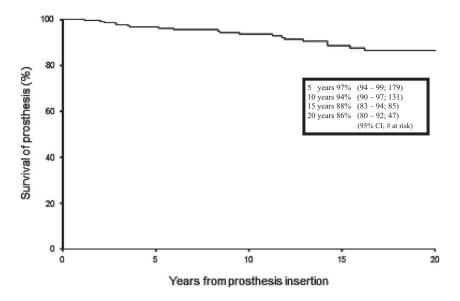


Figure 1 Overall prosthesis survival.

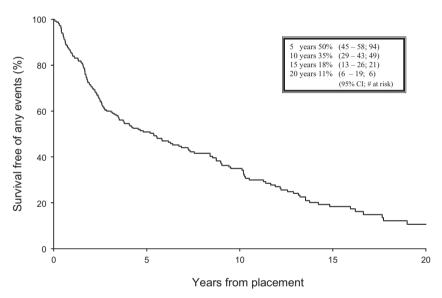


Figure 2 Prosthesis survival free of any events.

20 years (Fig 2). Prosthesis survival free of any prosthetic events is shown in Figure 3. Survival free of implant failure rates for the same time intervals reveals that at 20 years, 12% of the prostheses had experienced implant failure (Fig 4). Of the prostheses, 15% survived free of any event, and 92% experienced survival free of implant failure (95% confidence interval).

Twenty two of the cohort patients (8.6%) had a prosthesis remake. The timing of the remakes ranged from 1.2 to 25.6 years following the date of implant insertion (mean 9.6 years). The most common reason for a prosthesis remake was due to prosthetic events, and was often related to repeated events suggesting the need for improved prosthesis-implant fit.

Overview of events

A summary of prosthetic and biologic events, both those anticipated and unanticipated, is shown in Table 4. There were over three times as many prosthetic events as biologic events in this

patient group. Regarding the prosthetic events, unanticipated events occurred more commonly, they required fewer than two visits on average to resolve, and were seen from year 1 through year 26 of follow-up (mean 7.6 years from implant placement). Regarding biologic events, anticipated events occurred more than twice as frequently as unanticipated events, both types were resolved in two or fewer visits, and each type was seen sooner, on average, than prosthetic events.

The mean number of prosthetic events observed per patient was two times more than the mean number of biologic events observed per patient (4.3 and 2.1, respectively). The mean number of unanticipated prosthetic events observed per patient was 4, while the mean number of unanticipated biologic events observed per patient was 1.5.

On average, the first anticipated prosthetic events occurred 10.5 years after implant placement and significantly later than the first anticipated biologic event, which occurred 4.1 years after implant placement (Table 4). The mean number of visits

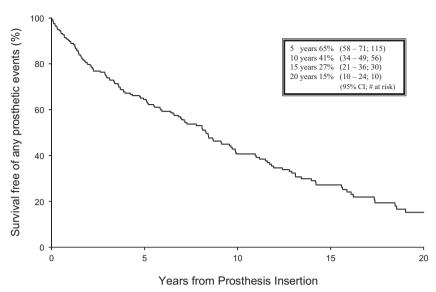


Figure 3 Prosthesis survival free of any prosthetic events.

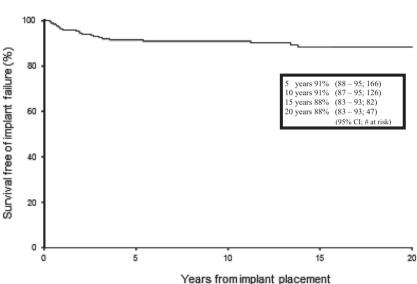


Figure 4 Prosthesis survival free of implant failure.

to address anticipated prosthetic events were 2.8 (range 1 to 8) with 43% of them addressed in one visit. The mean number of visits to address anticipated biologic events was 1.4 (range 1 to 9) with 72% of them addressed in one visit (Table 4).

Table 5 summarizes events at the patient level. Over one-third of the patients experienced no prosthetic or biologic events over the period of follow-up. Nearly one-fourth of the patients experienced both types of events, one-third experienced only prosthetic events, and less than one-tenth experienced only biologic events. Well over half (58%) experienced at least one prosthetic event, and for the patients with at least one event (i.e., at least one prosthetic or biologic event) the mean time to their first event was approximately 5 years.

Most common prosthetic and biologic events

Table 6 shows fractured screws and abutments were the top two prosthetic events observed; occurring at the 6- to 7-year mean time period and requiring a single visit to address more than 85% of the time. The third most common prosthetic event observed, wear, occurred at a much later mean time period (14 years) and, as would be expected, required more visits to address. The most frequent prosthetic event was fracture of a single gold screw, which on average occurred 7.4 years after prosthesis insertion. The most frequent biologic event was peri-implant soft tissue hyperplasia, which on average occurred 3.3 years after implant placement.

Implant failures

Fewer than 10% of the patients experienced 35 implant failures over the course of the observation period. Ten failures occurred less than 1 year after implant placement, with the remaining 25 implant failures occurring in patients a mean of 4.7 years (range 1 to 13.1) after implant placement. Nineteen of the implant failures occurred in the mandible and 16 in the maxilla.

Table 4 Summary of anticipated and unanticipated events and visits to address events

		Years from implant placement	Visits to resolve event	Visits to resolve event N (%)			
	N	Mean (Range)*	N	1	2	>2	
Prosthetic	643						
Anticipated	251	10.5 (0.4–25.3)	2.8 (1–8)	107 (43)	40 (16)	104 (41)	
Unanticipated	392	7.6 (0.3–26.0)	1.7 (1–12)	312 (80)	27 (7)	53 (14)	
Biologic	169						
Anticipated	117	4.1 (0.3–21.3)	1.4 (1-9)	85 (72)	27 (23)	5 (4)	
Unanticipated	52	5.0 (0.1–19.5)	2.1 (1–8)	18 (35)	23 (44)	11 (21)	

^{*}All values are listed for sample sizes ≤3.

Table 5 Summary of patient experiences with events

Event type	Patients N (%) N _{total} = 255	Years from implant placement to the first event Mean (range)
At least one prosthetic	148 (58)	4.9 (2.6; 17 days to 26.0 years)
At least one biologic	81 (32)	
Only prosthetic	86 (34)	
Only biologic	19 (7)	
Prosthetic and biologic	62 (24)	
None	88 (35)	

This failure cohort also experienced mostly unanticipated prosthetic events. Of particular note for this edentulous population is the finding that opposing dentition type did not have a statistically significant impact on implant failure or time of failure. For the group, 60% had an opposing complete denture, and 31% had natural opposing dentition.

Discussion

The evidence-based history in prosthodontics is longstanding. It began with a formal scholarly exposure to the principles involved at McMaster University in the early 1990s, followed by educational workshops targeting dissemination of these principles to residency directors and educators, and included publication of prosthodontic-specific evidence-based learning

and practice aids modeled after those originally published in medicine. 20

Since that time, progress has been made in the understanding of clinical evidence and its application to the clinical encounter of patient care. Yet clinical trial reports consistently fall short of providing outcomes that delineate long-term expectations that patients and providers use to understand complex care decisions in prosthodontics. This does not mean that evidence-based efforts are not worthwhile, but does suggest the need to consider defining best practice using evidence complimentary to trial-based evidence and doing so with careful understanding as to how much confidence we can infer from evidence sources to our unique situations. This article suggests that evidence from practice, systematically collected and studied by conscientious practitioners, should be considered.

Long-term practice outcome data

The data in this report represent outcomes from a time frame of care beginning 29 years ago; it serves as an example of a database maintenance report used as part of practice monitoring, and its specific use will be to (1) guide decisions regarding scheduling of maintenance visits, and (2) inform shared decision-making discussions with patients in a group prosthodontic practice. The practice scope requires database use to systematically monitor care quality, and for the chronic condition of missing teeth, doing so allows identification of time-dependent influences on the clinical course, categorized

Table 6 The three most common prosthetic and biologic events and how they were addressed

Event		N (%)	Years from implant placeme to the first event	visits to address N	Visits to address N (%)		
	Тор 3		Mean (range)		1 visit	2 visits	>2 visits
Prosthetic N = 643	Fractured screw	113 (18)	7.4 (0.6–25.5)	1.4 (1–9)	100 (89)	4 (4)	9 (8)
	Fractured abutment	73 (11)	6.4 (0.9–25.5)	1.3 (1–5)	64 (88)	3 (4)	6 (8)
	Wear	63 (8)	13.9 (2.3–23.2)	4.6 (1-8)	5 (8)	4 (6)	56 (86)
Biologic N = 169	Hyperplasia	97 (57)	3.3 (0.3–15.4)	1.4 (1-9)	68 (70)	25 (26)	4 (4)
-	Mobile implant	23 (14)	3.4 (0.1-13.4)	1.7 (1-4)	11 (48)	10 (43)	2 (9)
	Infection	15 (9)	6.3 (0.2–19.5)	2.2 (1–5)	3 (20)	8 (53)	4 (27)

Table 7 Summary of patient-centered questions for informed health care decisions as suggested by the Patient-Centered Outcomes Research Institute. Available online at http://www.pcori.org/research-we-support/pcor/.*

Patient centered questions to ask

- 1 "Given my personal characteristics, conditions and preferences, what should I expect will happen to me?"
- 2 "What are my options and what are the potential benefits and harms of those options?"
- 3 "What can I do to improve the outcomes that are most important to me?"
- 4 "How can clinicians and the care delivery systems they work in help me make the best decisions about my health and healthcare?"

as clinical outcomes. Such a systematic monitoring, analyzing, and responding to outcomes of care with a quality target in mind is a longstanding goal of outcomes research.²²

Outcomes research

Outcomes research has meant various things to different groups over the past few decades. Lee et al share a historical perspective of this confusing field and summarize current understanding of outcomes research as being concerned with improving clinical practice as applied to patients treated outside clinical trials.²³ Specific to the field of prosthodontics, outcomes are the consequences of management decisions for missing and defective teeth, made at the individual patient level, involving multiple factors of importance to the patient and, based on the clinical findings, the clinician. A fundamental principle involved in the patient-provider interaction is that the patient elects to pursue care for self-defined reasons.²⁴ Therefore, in shared decision-making discussions, all factors important to a management decision must have value to the individual electing the intervention. 9 Consequently, pertinent outcomes should be identified as consistent with patient expectations, helpful to providers in quality assurance (QA) monitoring relative to meeting treatment targets, and providing data for summary and sharing with patients considering care. When outcomes directly address common patient concerns regarding expectations, options, benefit and risk, and self-care they directly inform best practices (Table 7).

Outcome comparison

It is important to view the evidence in this report against previous reports. Favorable long-term outcomes have been shown for edentulous patients treated using a two-stage surgical protocol, machined titanium implants, and implant-supported cantilevered prostheses at the abutment level. 11,12,18 Several articles have also reported implant and prosthetic component performance events such as loose and fractured screws, prosthesis superstructure wear and fracture, alteration of opposing dentition, and even the need for prosthesis replacement. 18,25-28 Reports of prosthesis maintenance needs and the impact of implant failures on long-term care are important, yet when reports are limited in

patient sample size and length of follow-up, 12,18 and when concern exists as to how applicable the outcomes are to an individual practice, it is difficult to know with surety if practice change is required. This overall prosthesis survival of 86% at 20 years is similar to the lower limit of previous reports in the literature, which ranged from 84% to 34%¹² to 100%. ¹¹ Material fatigue of superstructure and first-generation implant components contributed to the events observed. Unlike other studies that showed minimal prosthetic events, 10,11 this study reveals significantly more prosthetic events than biologic events. Furthermore, prosthetic events occurred significantly later than biologic events. The anticipated prosthetic events occurred on average more than 10 years after initial treatment, while unanticipated prosthetic events occurred on average almost 8 years after initial treatment. As suggested in the literature, ^{10-12,17} time-dependent outcomes are critical to understand from a prosthetic maintenance perspective. The comparative difference between event types (four times more prosthetic events than biologic events) is not in agreement with previous reports, which described minimal screw fractures, screw loosening, wear, and loss of access fillings. Prosthesis tooth wear was the third most common event with 65 (10%) patients, consistent with previous literature¹² when differences in the size of the patient population were taken into account (308 patients in this study vs. 45 to 58 patients). An early study¹⁰ showed that, on average, a patient received 2.27 implant-retained prostheses (range 1 to 4), more than reported in this study.

Population characteristics

The population in this report represents approximately six times more patients than similar patient populations reviewed in the literature. Regarding the comparability of patients, the patients in this cohort included all patients from implant care inception through 1991. No selection bias is expected, and all data are part of the current clinical outcome database used prospectively. The inclusion of a large portion of patients who travel some distance for care (44% National patients) is unique, yet follow-up remains robust, as 140 (53%) patients have been followed for 10 years, 96 (36%) for more than 15 years, and 58 (23%) for more than 20 years.

Events

With 75% of this patient population still living after 30 years of initial treatment, the data reveal that time-dependent events become more frequent. Also, biologic events reflect a remarkable biological tolerance over time. Although the majority of the prosthetic events could be addressed in one or two visits, visits ranged from 1 to 9. This information is valuable for describing potential long-term care needs, and financial and maintenance expectations associated with such treatment. One in three patients experienced no events during follow-up; one of four experienced both a biological and prosthetic event; 58% had at least one prosthetic event.

Prosthetic events were felt to be related to cantilever constructions and are not unexpected, given previous reports. ^{30,31} Screw loosening related to the prosthetic screw is known to have a design safety feature of this original system, placing the most "at-risk" component in a retrievable location. The

^{*}Last accessed on February 9, 2013.

data support the finding that prosthetic events were managed in timely manner on average.

Biologic events can be characterized as low in severity, resolved in a timely manner, and when involving a failure of an implant, this did not always detract from prosthesis function. Regarding implant failure, approximately one out three (10/35) failed in the first year, and failure was not associated with opposing dentition type. This implant survival finding of 88% (83 to 93, 95% CI) at 20 years is consistent with other studies of a similar patient population. ¹⁰⁻¹²

Prosthesis-specific survival

The findings of this report suggest that patients considering similar care have a very good chance (86%) that at 20 years they will have a functioning prosthesis. When we found the need to remake a prosthesis, it occurred infrequently (22 of 255 patients) and at varying times after the original prosthesis (from 1.2 to 25.6 years). This outcome compares very favorably with conventional fixed prostheses, where one systematic review describes an 89% 10-year survival estimate.³²

Practice application

As this practice evolves, we are faced with considering what key findings from this time period can best inform current and future care. The patient population in this report is more homogenous than edentulous patients seen in the last 5 to 10 years. In 1983 when this treatment approach was implemented, presenting patients had been edentulous for several years and were considered for care based on presentation with significant residual alveolar ridge resorption and attendant maladaptation to conventional prostheses. This type of patient with such significant residual ridge resorption resulted in a significantly large restorative space to accommodate implant and prosthetic components for resin to metal prostheses. On the contrary, current populations being managed with implant-supported prostheses also include patients who received elective extractions, creating situations with potentially limited restorative space. This situation more often requires consideration of strategically prescribed terminal implants, which reduces or eliminates cantilever influences.

Conclusion

This report of practice-based outcome evidence from a 29-year follow-up period of implant prostheses provides long-term data useful for practice QA and shared decision-making patient discussions.

The clinical events associated with patient follow-up visits revealed the following:

- 1. Overall prosthesis survival at 20 years was 86%.
- Prosthetic events occur significantly later and more frequently than biologic events.
- The most common prosthetic event was fractured gold screws, and the most common biologic event was hyperplasia.

These findings support the suggestion that prosthodontic care for edentulism be managed within a "chronic condition" context

for a more realistic understanding of maintenance expectations for patients and providers.

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