Early Experience with Wide-Platform Mk II Implants. Part I: Implant Survival. Part II: Evaluation of Risk Factors Involving Implant Survival

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Part I of this study describes the survival of a wide-platform, wide-diameter implant (Wide-Platform Mk II). Beginning in January 1997, 85 Wide-Platform Mk II implants were placed in the jaws of 63 patients (35 males and 28 females). Male patients experienced 10 implant failures, and female patients lost 9 implants. The mean time of implant follow-up was 286 days (median, 280), with a maximum of 734 days and a minimum of 0 days. Implant loss was 19% in the mandible and 29% in the maxilla. Kaplan-Meier analysis showed a probability of implant failure after 1 year of 0.649 (confidence interval, 0.455 to 0.926) in the maxilla and of 0.751 (confidence interval, 0.616 to 0.915) in the mandible. No apparent relationship was noted between implant survival and implant length.

Part II of this study evaluated the association between the survival of a new implant design and a number of potential risk factors. A retrospective chart review was conducted for all patients who received Wide-Platform Mk II implants and who agreed to allow a medical records review for research purposes. Kaplan-Meier survival curves were used to assess the probability of implant survival relative to time. The relationships between implant survival and implant location, history of tobacco use, current tobacco use, sinus grafting, bruxism, and root canal therapy were assessed by Cox proportional hazards modeling. Although the hazard ratio showed an increased risk of implant failure with some factors, particularly a history of root canal therapy in the site of implant placement (hazard ratio 3.2, P = .10), none of the factors were statistically significant. The Wide-Platform Mk II implant used in this population group was associated with a high failure rate, but the failure rate was not related to any specific risk factors reviewed. (Int J Oral Maxillofac Implants 2001;16:208–216)

Key words: *dental implants, osseointegration, survival analysis, wide-platform dental implants*

The Mk II self-tapping implant (Nobel Biocare AB, Göteborg, Sweden) was introduced for pilot study in 1987. This implant was designed for universal applications, including use in low-density bone. Its use in multiple clinical applications, coupled with fewer surgical procedures, has made the design widely accepted. Results of the Mk II implants demonstrated cumulative success rates that were equal to or superior to those of standard Nobel Biocare implants.[1,2] Given this demonstration of efficacy, a wide-diameter, wide-platform Mk II implant was introduced to offer greater implant surface area for defined implant lengths. This implant was described as being particularly well suited for posterior areas. Although several studies have documented the success of standard-platform Mk II implants, there are no published reports on the Wide-Platform Mk II implant.

Implant performance has been suggested to be similar regardless of implant design. The dental implant literature reports a wide range of success criteria when implant performance is analyzed.[3] Success criteria may be as simple as having the implant "retained in the bone"[4] or may be as stringent as those described by Smith and Zarb.[5] Although unanimity regarding success is lacking, survival of implants is established by the presence or absence of implants in the oral cavity.

Studies that are initiated to evaluate the potential success of endosseous implant therapy have specific inclusion and exclusion criteria established for

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patient selection and for implant use.[6,7] However, after commercial distribution of the implants, clinical application is left to the discretion of independent dental practitioners. Theoretically, the dental practitioner bases the use of specific implants on the published evidence of previous success, individual clinical experience, and clinical judgment.

As the implant industry has developed, many new designs have been marketed without published reports of efficacy. The marketing of products without reliable clinical data seems to be related to a perception that the performance of clinical research may be too time-consuming and that the lost time will adversely affect patient care. When this assumption is made, the clinician is unaware of any specific considerations relative to bone quality, bone volume, medical considerations, patient habits, prosthetic materials, or any other factors that may affect the survival of the implant.

Part I of this article describes implant survival with a wide-platform, wide-diameter implant (Wide-Platform Mk II, Nobel Biocare) used in a clinical setting without specific inclusion and exclusion criteria. Part II evaluates specific factors affecting implant survival for the same group of patients.

MATERIALS AND METHODS

In Part I of this study, all patients who received endosseous Wide-Platform Mk II implants at the Mayo Clinic, Rochester, Minnesota, USA, were included for data analysis. Data on each patient were entered into a computer database at the time of implant placement. The location of each implant was recorded and categorized, ie, posterior mandible or posterior maxilla. The survival of each implant was documented by determining the presence or absence of implants; therefore, failure was defined as loss or removal of an implant. Factors such as bone loss, radiographic changes, mobility, or discomfort were not used as criteria for implant survival for the purpose of this article. The number of days in service was noted, as were the diameter and length of the implants placed in each arch.

Failure rates were estimated by Kaplan-Meier curves, and the significance of effects on failure rate was tested through Cox proportional hazard models. The possibility of dependence related to multiple implants in each patient was accounted for by using the robust standard error method of Wei and associates.[8]

For part II of this article, patient records, in which a written consent for participation in scientific research was included, were thoroughly reviewed. Notations were made of patient age, gender, oral habits, medical complications, tobacco use, medications used, and dental history at the site of implant placement. Radiographic findings and surgical data also were recorded.

Implant survival rates were calculated using Kaplan-Meier survival curves. Each implant was followed from the date of placement to either the date of failure or the date of last follow-up. Compiled data were analyzed to determine the relative risk of implant failure associated with each individual risk factor and with combined risk factors. Relationships between implant survival and implant location, history of tobacco use, current tobacco use, presence of an infected tooth at the implant site, sinus augmentation or lift, bruxism, and root canal therapy (with or without a retrograde amalgam) were assessed by the use of a marginal Cox proportional hazards model. The robust standard error method of Wei and associates[8] was used to determine the correlation within subjects with multiple implants.

RESULTS

Eighty-five Wide-Platform Mk II implants were placed; 35 implant-supported prostheses were placed in male patients and 28 were placed in female patients. Male patients experienced 10 implant failures, and females lost 9 implants. The mean time of implant follow-up was 286 days (median, 280), with a maximum of 734 days and a minimum of 0 days. These implants were placed in the posterior maxilla and posterior mandible only, because the limited width of the arches in the anterior regions prevented the placement of wide-diameter implants in this area. All implants were placed in partially edentulous arches. Natural teeth or fixed or removable partial dentures opposed all implant-supported restorations. Complete dentures opposed no restorations, nor were any of the restorations unopposed.

Fifty-seven implants were placed in the mandible, with 11 of those implants failing to osseointegrate or losing osseointegration (19% implant loss), whereas 8 of the 28 maxillary implants were lost, representing a maxillary failure rate of 29%. Kaplan-Meier survival estimates demonstrated a probability of 1-year implant survival of 0.751, with a 95% confidence interval (CI) of 0.616 to 0.915 for the mandible (Table 1). The same analysis in the maxilla showed a probability of survival of 0.649 (CI 0.455 to 0.926) (Table 2), while the combined data revealed a probability of survival of 0.713 (CI 0.596 to 0.853) (Fig 1). No statistically significant difference was found between implant survival for the

Table 1 Wide-Platform Implants Placed in Mandibular Arch

Days since placement	Years of service	Implants at risk	Failures in interval	Probability of implant survival	Confidence interval		Standard error
					Lower 95%	Upper 95%	
0	0.00	57	0	1.00	1.00	1.00	0.00
30	0.08	53	0	1.00	1.00	1.00	0.00
36	0.10	53	1	0.981	0.945	1.00	0.019
41	0.11	51	1	0.962	0.911	1.00	0.026
60	0.16	50	0	0.962	0.911	1.00	0.026
61	0.17	50	1	0.943	0.882	1.00	0.032
90	0.25	46	0	0.943	0.882	1.00	0.032
111	0.30	45	1	0.922	0.851	0.999	0.038
115	0.32	44	1	0.901	0.822	0.987	0.042
120	0.33	43	0	0.901	0.822	0.987	0.042
149	0.41	40	1	0.878	0.791	0.975	0.047
150	0.41	39	0	0.878	0.791	0.975	0.047
174	0.48	37	1	0.855	0.760	0.961	0.051
180	0.49	34	0	0.855	0.760	0.961	0.051
197	0.54	34	1	0.829	0.727	0.946	0.056
207	0.57	33	1	0.804	0.696	0.929	0.059
210	0.58	32	0	0.804	0.696	0.929	0.059
240	0.66	31	0	0.804	0.696	0.929	0.059
270	0.74	30	0	0.804	0.696	0.929	0.059
300	0.82	27	0	0.804	0.696	0.929	0.059
330	0.90	19	0	0.804	0.696	0.929	0.059
360	0.99	15	0	0.804	0.696	0.929	0.059
365	1.00	14	0	0.751	0.616	0.915	0.076
380	1.04	14	1	0.697	0.545	0.891	0.087

Probability of implant failure relative to time following surgical placement in mandibular arch. One additional implant failed to maintain osseointegration at 149 days following surgical placement but was not included in table since failure was observed following performance of statistical analysis.

Table 2 Wide-Platform Implants Placed in Maxillary Arch

Days since placement	Years of service	Implants at risk	Failures in interval	Probability of implant survival	Confidence interval		Standard error
					Lower 95%	Upper 95%	
0	0.0	28	0	1.00	1.00	1.00	0.000
30	0.1	25	0	1.00	1.00	1.00	0.000
60	0.2	25	0	1.00	1.00	1.00	0.000
90	0.3	25	0	1.00	1.00	1.00	0.000
120	0.3	23	0	1.00	1.00	1.00	0.000
150	0.4	23	0	1.00	1.00	1.00	0.000
167	0.5	23	1	0.957	0.877	1.00	0.043
180	0.5	22	0	0.957	0.877	1.00	0.043
210	0.6	21	0	0.957	0.877	1.00	0.043
240	0.7	17	0	0.957	0.877	1.00	0.043
261	0.7	17	2	0.844	0.695	1.00	0.084
270	0.7	14	0	0.844	0.695	1.00	0.084
300	0.8	14	0	0.844	0.695	1.00	0.084
327	0.9	13	1	0.779	0.607	1.00	0.099
330	0.9	12	2	0.649	0.455	0.926	0.118
360	1.0	9	0	0.649	0.455	0.926	0.118
365	1.0	9	0	0.649	0.455	0.926	0.118
402	1.1	9	1	0.577	0.378	0.882	0.125

Probability of implant failure relative to time following surgical placement in maxillary arch. One additional implant failed to maintain osseointegration at 624 days following surgical placement but was not included in table since failure was observed following performance of statistical analysis.

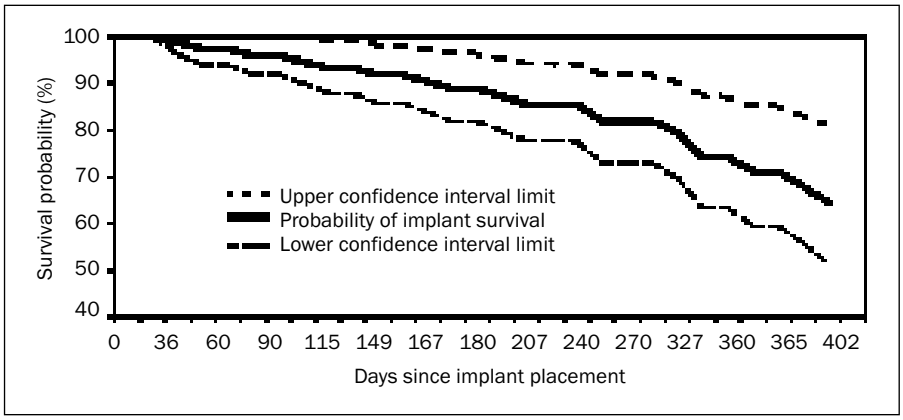

Fig 1 Probability of survival with Kaplan-Meier survival estimates. Combined maxillary and mandibular data are shown along upper and lower 95% confidence intervals.

maxilla and that for the mandible. The combined survival curves for the maxillary and mandibular implants are represented graphically in Fig 1.

Failures occurred with all implant lengths, and there was no relationship between shorter implants and higher failure rates for either maxillary or mandibular implants (Tables 3 and 4). The mean time until implant failure was 338 days in the maxilla (range, 167 to 624) and 167 days in the mandible (range, 36 to 380).

Part II of this study evaluated factors specific to the patients receiving implants. Seven patients (8 implants) were eliminated from the analysis because they declined to allow a medical record review for research purposes. A total of 55 patients (77 implants) remained for assessment of the features associated with implant survival.

Average patient age at implant placement was 52.2 years (SD 13.7; range, 19 to 81 years). Most (59.7%) implants were placed in male patients. The average time of follow-up was 297 days (SD 191; range, 0 to 734 days). During the course of the study, 16 implants failed, demonstrating a 1-year survival probability of 73.8% ($P = .05$). (Table 5).

More implants were located in the mandible (64.9%) than in the maxilla (35.1%) (Table 6). Although 33.3% of the implants were in patients with histories of tobacco use, only 9.3% were in patients who were current users of tobacco products. Thirty implants (39.0%) were placed in sites with histories of an infected tooth. For these 30 implants, the average time between infected tooth removal and implant placement was 4.2 years (SD 6.6; range, 70 days to 30 years). Two implants (2.6%) were placed in the maxilla of a patient who had a recent upper respiratory infection and a sinus augmentation. Seven implants (9.1%) were placed in patients with histories of bruxism. Ten implants (13.0%) were placed in patients with extracted teeth that had undergone root canal therapy. Four of these patients had retrograde amalgam restorations, and 6 were treated non-surgically. Three of the 4 implants with retrograde amalgams were in the same patient.

The associations between implant survival and recent upper respiratory infection and sinus grafts were not assessed because of the small number of implants with these features. In addition, the implant patients with root canal therapy and retrograde amalgam were combined with those without retrograde amalgam restorations. Some evidence existed that root canal therapy with or without retrograde amalgam was associated with an increased risk of implant failure (Table 7). A hazard ratio of 3.2 indicated that those implants with root canal therapy were more than 3 times more likely to experience implant failure than those without root canal therapy; however, this did not reach statistical significance ($P = .10$).

DISCUSSION

The success of implants in partially edentulous arches means that the use of implant-supported prostheses is predictable and long-lasting. Previous reports from the authors' institution on Brånemark System implants in the posterior maxilla and mandible demonstrated an absolute failure rate of less than 6%.[9] That report showed implant failures relative to time since surgical placement. Most failures occurred at phase 2 surgical uncovering or shortly thereafter. In that study, late failures were

Table 3 Failed Wide-Platform Implants

Site	Time before failure (days)	Time until restoration (days)	Time of prosthetic service (days)	Implant length (mm)	Implant diameter (mm)
Mandible					
L. second molar	61	Not restored	0	8.5	5.0
L. second molar	149	121	28	13.0	5.0
L. second molar	207	Not restored*	0	10.0	5.5
R. second premolar	115	Not restored*	0	13.0	5.0
R. first molar	36	Not restored*	0	13.0	5.0
R. first molar	41	Not restored*	0	13.0	5.5
R. first molar	174	150	24	13.0	5.0
R. first molar	197	162	35	11.5	5.0
R. first molar	362	208	154	13.0	5.0
R. first molar	380	125	255	13.0	5.0
R. second molar	111	Not restored*	0	10.0	5.5
Maxilla					
R. second molar	261	210	51	13.0	5.0
R. first molar	261	210	51	13.0	5.0
L. first premolar	327	Not restored†	0	11.5	5.0
L. first molar	167	Not restored†	0	13.0	5.0
L. first molar	330	195	193	11.5	5.0
L. first molar	402	277	125	8.5	5.0
L. first molar	624‡	214	410	11.5	5.0
L. second molar	330	195	135	10.0	5.5

*Implants that were lost at surgical uncovering or before placement of definitive restoration.
†Implants that were lost before surgical uncovering, at surgical uncovering, or before placement of definitive restoration.
‡One implant failed at day 624. Failure occurred after statistical analysis but before manuscript completion.

Table 4 Implant Distribution by Diameter, Length, and Outcome

Location	Diameter (mm)	Length (mm)	Implants placed	Implants removed	Percent failed
Maxilla	5.0	8.5	3	1	33
Maxilla	5.0	10.0	2	0	0
Maxilla	5.5	10.0	7	1	14
Maxilla	5.0	11.5	5	3	60
Maxilla	5.0	13.0	9	3	33
Maxilla	5.5	13.0	2	0	0
Mandible	5.0	8.5	6	1	17
Mandible	5.0	10.0	5	0	0
Mandible	5.5	10.0	4	2	50
Mandible	5.0	11.5	15	1	7
Mandible	5.0	13.0	22	6	27
Mandible	5.5	13.0	5	1	20

Table 5 Probability of Implant Survival at Different Time Intervals

Interval (days)	Probability of survival (%)*
30	100
60	98.6
90	97.2
180	89.3
365	73.8

*Kaplan-Meier survival curves ($P = .05$).

more often the result of implant fracture than loss of osseointegration.

The current report demonstrated a higher overall implant failure rate than that of the previous study.[9] Thus, a statistically significant decrease can be seen in implant survival with Wide-Platform Mk II implants in comparison with the implants used in the previous report. Because no statistically significant difference existed in survival between the maxillary and the mandibular implants at 1 year, the implant data were combined to predict implant survival at 1 year. These data demonstrated that the survival rate of Wide-Platform Mk II implants is predicted to be below the standards described by Albrektsson and coworkers (Fig 1).[10] Likewise, even when the upper 95% confidence limit is used, this implant would fail to achieve the standards set by the American Dental Association Certification program or those proposed by the Food and Drug Administration for a Class III medical device.[11] Even when the NIH/Harvard report from 1978 is used as the standard of acceptability,[12] survival of this implant continues to fall below the level of acceptance. Although the current article reports only preliminary data with a relatively small pool of patients, the use of statistical data analysis lends credibility to the observations. The failure to approach published standards should be of great concern.

Data on wide-diameter, standard-platform implants were included in the earlier report, showing clinical performance similar to that seen with the 3.75-mm and 4.0-mm-diameter implants.[9] Ivanoff and associates[13] have described a longer learning period with wide implants, as well as a tendency toward more bone loss, as compared to standard implants. That report, however, did not show failure rates as high as those seen in the present study. Likewise, Renouard and coworkers[14] described a survival rate for the wide-diameter, standard-platform implant of 91.8% after 1 year of loading. Although this rate is lower than some reports of standard implants, reaching statistical significance is unlikely.

Along with the low survival rate, the findings with Wide-Platform Mk II implants also demonstrated a difference in failure pattern. In the present report, 2 failed maxillary implants were never restored. One of these implants was removed at uncovering owing to mobility, and the other failed after a prolonged unloaded healing period of 327 days. In the mandible, 6 of the 11 failed implants were never restored. Three of these mandibular implants were lost prior to planned phase 2 surgery, 1 because of chronic discomfort and 2 because of spontaneous exfoliation. Of the remaining 3 nonrestored failed implants, 2 failed to achieve osseointegration after the normal healing time of 3 to 4 months, and the third failed to achieve osseointegration after a prolonged healing time of 207 days. The remaining 11 unsuccessful implants (5 in the mandible and 6 in the maxilla) failed to maintain osseointegration after placement of a restoration.

Table 6 Implant Factors Assessed

Factor	No. of implants	Percent of total
Location		
Maxilla	27	35.1
Mandible	50	64.9
History of tobacco use*		
No	50	66.7
Yes	25	33.3
Current tobacco use*		
No	68	90.7
Yes	7	9.3
Infected tooth at implant site		
No	47	61.0
Yes	30	39.0
Recent upper respiratory infection		
No	75	97.4
Yes	2	2.6
Sinus augmentation or graft		
No	75	97.4
Yes	2	2.6
Bruxism		
No	70	90.9
Yes	7	9.1
Root canal therapy		
No	71	92.2
Yes	6	7.8
Root canal therapy with retrograde amalgam		
No	67	94.8
Yes	4	5.2
Root canal therapy with or without retrograde amalgam		
No	67	87.0
Yes	10	13.0

*Assessed in only 75 implants, since 2 records were ambiguous regarding tobacco use.

Table 7 Implant Survival and Associated Factors

Factor	Hazard ratio*	*P* value
Implant in maxilla	1.5	0.44
History of tobacco use	0.8	0.75
Current tobacco use	2.4	0.16
Infected tooth at implant site	1.6	0.37
Bruxism	1.7	0.56
Root canal therapy with or without retrograde amalgam	3.2	0.10

*Cox proportional hazard modeling.

Previous experience with implant-supported restorations has demonstrated no tendency toward loss of integration once it has been established, nor has it demonstrated instances of spontaneous implant exfoliation.[9] The differing pattern of failure is a critical issue when patient satisfaction and cost of care are considered. An implant that has failed to achieve osseointegration at the surgical uncovering phase of treatment is easily removed and can soon be replaced. Healing time is lost, but most patients maintain an optimistic view of this complication. Failures at uncovering do not involve the additional time and expense of prosthetic reconstruction. In contrast, implants that fail to maintain osseointegration result in lost time and expense for both the patient and the restorative dentist.

Scientific implant studies require control of the factors to be evaluated. Prospective studies provide specific inclusion and exclusion criteria.[15–18] Thus, prospective clinical trials tend to demonstrate clinical performance for specific groups of patients that result in efficacy of treatment. This improved performance is in contrast to that seen in a clinical practice, in which inclusion and exclusion criteria are applied in a completely different way. Rather than excluding patients because of habits such as smoking[19,20] or medical conditions such as diabetes,[21] the clinician outside of the research setting may well provide the service, albeit after the provision of informed consent, with the understanding that this approach tests the effectiveness of that specific treatment in the individual patient in question.

When the clinician has the benefit of published material on new products, decisions can be based upon this information. If products reach the marketplace without published data having been supplied, the clinician must depend on clinical judgment and experience to provide effective treatment. Unfortunately, judgment and experience are gained from the use of different devices, that is, different implants. The judgment and experience may be valid as they relate to known commodities, but when the clinician is using a treatment for the first time and no frame of reference is available, unanticipated results may occur.

In Part II of this preliminary report, patient-specific information is provided in an effort to determine criteria that should be used in the decision to provide this service. As demonstrated in this report, a number of factors may be associated with the higher risk of failure, but none of these factors were statistically significant. The lack of statistical significance may be related to the few patients with risk factors in the study, or to a true lack of difference among the factors. Chance alone could have been responsible for the apparent associations, as observed in the hazard ratios. If that is true, the next implants placed into sites that had held a previously endodontically treated tooth may all succeed, transforming the apparent risk into a factor unworthy of consideration.

The present analysis makes the observed failure pattern for the Wide-Platform Mk II implant more perplexing than those seen for previous implants. The Wide-Platform Mk II implant reflected no change in thread configuration, material, or surface treatment from implants that were used before this time. The only changes in this implant from the previously used implants were in the diameter of the implant and the diameter of the restorative platform. This similarity in materials and design suggests that the survival rate of this implant should equal that of previous experience. This equality was not found, with the predicted survival being less than 65% at 402 days.

The cause of the late loss of implants in the present study group is unknown at this time. All failed implants were the result of a failure to achieve or maintain osseointegration. This lack of osseointegration is in contrast to previous reports, in which implant fracture was the most frequent cause of late failure. Surgical complications are most often implicated in early failure, either during or soon after the undisturbed healing period, while prosthetic factors are thought to be etiologic for failure following functional loading. This description of failure has not been observed in the authors' institution, where loss of osseointegration is seen as a rare occurrence.[9] Implant fracture is unlikely with wide-diameter implants because of the large volume of material used in the manufacture of these implants. This bulk of material provides a much higher resistance to the forces of mastication than does the standard-diameter implant. Other modes of late failure, such as peri-implantitis–induced bone loss, may be possible, but this was not observed in the current study.

Some explanations for the lower survival rate for the Wide-Platform Mk II implant may include inexperience with the implant that led to surgical complications, contamination of the implant that prevented normal integration, inadvertent transmucosal loading that interfered with the undisturbed healing period, increased diameter of the implant that encroached upon the critical volume of host bone to establish and maintain integration, and prosthetic factors that led to a failure to maintain osseointegration. Also, minor changes in configuration with this Mk II implant may have been responsible for the observed failure to achieve long-lasting osseointegration.

Review of the potential causes of complication found no clear sources. The makeup of the surgical team at the authors' institution has changed somewhat since the introduction of regular implant therapy in 1983, but all of the surgeons involved in the current study had previous experience with both standard-diameter and wide-diameter implants before they placed wide-diameter, wide-platform implants. Contamination of the implants from the manufacturer is unlikely, and contamination during surgical placement would not be specific to 1 individual implant. Transmucosal loading may be more likely to occur with the wider platform, but the restorative team seemed to be experienced enough in preventing such loading, as demonstrated in the previous study.[9] The restorative dentists routinely used techniques that have proven to be successful over many years, resulting in a very low rate of implant failure after prosthetic loading. Minor modifications to the Mk II implant probably would not result in such a drastic decrease in survival rate. The question of a critical bone volume surrounding the implant has been raised (personal communication, Dr Alan Carr, Ohio State University College of Dentistry, 1999), and critical bone volume may be important in implant survival. It is possible that the wider diameter of the Mk II Wide-Platform, Wide-Diameter implant may have encroached upon the volume of bone that is critical for implant survival. Such a situation may have occurred despite the experience of the surgical team. Unfortunately, no surgical data were available relative to bone volume in the peri-implant region.

The most likely explanation for the poor survival rate of this type of implant may be found in a combination of unfavorable events that culminated in the unexpected outcome. Without a known cause, it is difficult to find a solution. It is recognized that even minor changes in dimension, configuration, design, surgical protocol, or prosthetic approach may have profound clinical effects. The prudent clinician must be cautious when considering changes of any sort, because alteration of a successful treatment modality may result in less favorable outcomes. With the industrial propensity for rapid design changes that are often based upon intuition and a desire for innovation rather than clinical experimentation, the profession must recognize the potential for unfavorable results. Willingness to discard known results in favor of promised rewards must be tempered by the understanding that such action is not always predictable.

Multicenter data should be gathered relative to this specific type of implant to determine whether other centers are experiencing similar problems with implant integration. Clearly the statistical analysis of the preliminary data from this specific implant design demonstrates that it may be inferior to other implant designs. Although it is possible that this observation could be the result of chance, analysis of data shows that this is unlikely. Should this adverse result be found elsewhere, the indications, design, and handling of this specific implant should be reassessed.

CONCLUSIONS

Preliminary data with a new implant showed a decrease in short-term implant survival when compared with implant survival in long-term historical references from the same treatment institution. In Part I of the article, Kaplan-Meier analysis of the data predicted an implant survival rate that is lower than all currently acceptable standards. An unusual pattern of failure was observed, with most failed implants occurring after prosthesis fabrication. Part II revealed no specific patient-related factors, such as tobacco use, history of infection at the site of implant placement, or anatomic location of implants, to explain the unfavorable results. Data should be shared among other treatment institutions to determine whether the observed complications are limited to this treatment institution or whether they occur regularly with this implant.

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