

Retrospective Cohort Study of the Clinical Performance of 1-Stage Dental Implants

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Purpose: To evaluate long-term clinical performance of 1-stage dental implant prostheses at a single clinic, emphasizing clinical and demographic characteristics that affect implant survival. **Materials and Methods:** Dental records of all 308 patients (674 implants) treated with 1-stage implants at Mayo Clinic from October 1993 through May 2000 were reviewed from implant placement to last visit. Exposure and outcome variables affecting performance were collected separately to control bias in the data collection process. Additional confounding factors (age and sex) were adjusted with the stratified Cox proportional hazards model. Implant survival was determined by means of a Kaplan-Meier survival estimate. The log-rank test was used to determine the role of clinical and demographic variables in implant survival. The relative risk associated with the possible effect of clinical and demographic variables on implant survival was estimated with the Cox proportional hazards model. **Results:** The implant survival rate ($n = 654$ implants) was 97% (mean \pm SD follow-up, 21.0 ± 18.8 months; range, 1 to 78 months). Performance bias was limited because nearly all patients were treated by 1 prosthodontist. Two implants failed after loading (6 and 9 months). The incidence of complications was less than 4%. Among the implant failures, use of heterogeneous bone graft was associated with 4.8 times more failures than was use of autogenous bone graft ($P = .04$). After augmentation, delaying implant placement for 5 to 6 months resulted in 8.6 times more failures than the rate after earlier placement ($P < .001$). **Discussion:** Retrospective review of the clinical performance of a 1-stage dental implant system yielded a 97% survival rate, with no failures noted after 13 months. Prosthetic complications were low, especially for fixed implant prostheses. **Conclusion:** Clinical performance of 1-stage dental implant prostheses between 1993 and 2000 demonstrated a high level of predictability. (INT J ORAL MAXILLOFAC IMPLANTS 2003;18:399–405)

Key words: dental implants, endosseous dental implantation, implant-supported prosthesis, retrospective studies, survival analysis

Reports of implant survival and prosthetic function have been described by clinicians worldwide after 2-stage procedures in edentulous and partially edentulous patients.^{1–9} Conversely, 1-stage

implant systems do not have as long a history of clinical follow-up, and the literature does not describe application by as many clinicians and patients.^{10–13} Nonetheless, the reported implant survival and prosthetic function for 1-stage systems generally equal those of 2-stage systems.

Long-term follow-up helps delineate time-dependent outcomes, both adverse and favorable.¹⁴ This point has been argued as important for rough-surface implants.¹⁵ The favorable outcomes reported for machined-surface implants may not be observed for otherwise similar but rough-surface devices. Such a concern for documentation of long-term survival is warranted, given reports of progressive bone loss associated with a particular rough-surface system.¹⁶ Although the differences in outcomes between 1- and 2-stage procedures are considerable, long-term performance differences may be attributable to factors other than surgical staging.

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Table 1 Patient Characteristics

Characteristic	No. of patients	No. of implants placed (failed)
Sex		
Male	139	314 (12)
Female	169	360 (8)
Age (y)		
< 30	54	99 (2)
30–39	50	99 (4)
40–49	62	118 (4)
50–59	49	112 (3)
60–69	48	140 (6)
70–79	34	79 (1)
≥ 80	11	27 (0)

This report describes clinical use of a 1-stage implant system between 1993 and 2000 at Mayo Clinic, Rochester, Minnesota. This retrospective cohort study reports on implants used in an outpatient medical group practice setting where care was provided largely by a single prosthodontist and surgical team (oral and maxillofacial surgeons or periodontists). This team approach to implant care used no strict inclusion or exclusion criteria for patient selection; thus, this is an effectiveness study. This study was initiated by a prosthodontist to enhance understanding of the clinical performance of the 1-stage implant system for the purposes of future informed consent and treatment planning. The purpose of this study was to measure the survival characteristics of the implants and prostheses.

MATERIALS AND METHODS

A retrospective cohort study was conducted comprising 674 single-stage dental implants (Straumann, Waldenburg, Switzerland) placed in 308 patients between October 1993 and May 2000. In accordance with a protocol approved by the Mayo Foundation Institutional Review Board, records were reviewed from the time of implant placement until the last known follow-up visit. Exposure and outcome variables affecting performance were collected separately to control bias. Records were rechecked for missing data to achieve less than 10% missing data for each variable and ensure the least effect on the estimates.¹⁷ The exposure variables of interest were age,

Table 2 Implant Characteristics

Characteristic	No. of patients	No. of implants placed (failed)
Type*		
4.1 mm [†]	189	419 (10)
Angled hollow cylindrical	59	129 (4)
Narrow neck [†]	28	64 (2)
4.8 mm [†]	21	44 (4)
Wide neck [†]	6	13 (0)
Length (mm) [‡]		
< 10	27	60 (0)
10	48	106 (5)
12	120	263 (9)
14	111	239 (6)
Location		
Mandibular posterior	124	273 (3)
Mandibular anterior	50	109 (3)
Maxillary posterior	64	141 (7)
Maxillary anterior	70	151 (7)

*Five unspecified (0.7%).

[†]Solid-body, screw-shaped implants.

[‡]Six unspecified (0.8%).

sex, need for augmentation, implant location, implant type and geometry, abutment type, prosthesis type, and condition of the opposing arch. The outcome variables were implant failure and prosthesis complications, including screw loosening or fracture, cement failure, prosthesis material fracture, and overdenture attachment problems.

Data analysis included a Kaplan-Meier estimate of implant survival, Cox proportional hazards model to estimate the influence (expressed as relative risk) of the exposure variables on implant survival, and stratified Cox proportional hazards model to adjust for confounding attributable to age and sex. The analysis was conducted with use of the SAS System 8e and JMP 4.04 (SAS Institute, Cary, NC).

RESULTS

The majority of the patients were women ($n = 169$; 55%), and they received the majority of implants ($n = 360$; 53%). The patients ranged in age from 15 to 95 years, with 154 patients (50%) between 38 and 56 years old (Table 1).

The most commonly used implant was the 4.1-mm solid-body screw-shaped implant, followed by the angled hollow cylindrical implant, the narrow-neck screw-shaped implant, and the solid 4.8-mm and wide-neck screw-shaped implants¹⁸ (Table 2). The implant length ranged from 8 to 14 mm. The implant location, by decreasing order of frequency, was mandibular posterior, maxillary anterior, maxillary posterior, and mandibular anterior (Table 2).

Table 3 Augmentation Characteristics

Characteristic	No. of patients	No. of implants placed (failed)
Augmentation*		
Yes	82	175 (12)
No	231	491 (8)
Type of graft†		
Onlay	67	148 (10)
Sinus inlay	15	21 (2)
Source of graft†		
Autogenous	71	153 (10)
Other	5	16 (2)

*Eight unspecified (1.1%).

†Six unspecified (0.8%).

Table 4 Prosthesis Characteristics

Characteristic	No. of implants (%)
Abutment*	
Octabutment	426 (67.7)
Solid-body abutments	
4-mm	69 (11.0)
5.5-mm	38 (6.0)
7-mm	9 (1.4)
Ball	88 (13.9)
Prosthesis type†	
Crown	345 (54.2)
Fixed partial denture	160 (25.2)
Overdenture	90 (13.5)
Hybrid	45 (7.1)
Opposing occlusion‡	
None	10 (1)
Natural	341 (6)
Porcelain	55 (0)
Gold	52 (0)
Implant	42 (0)
Mixed	50 (0)
Complete denture	94 (1)

*Forty-four unspecified (6.5%).

†Ten unspecified (1.5%).

‡Eleven unspecified (1.6%). Numbers represent no. of implants placed (failed).

Ridge augmentation was required in 175 implant sites, and the majority used bone from an autogenous source placed as onlay grafts (Table 3).

The octabutment was used most frequently, followed by solid-body and ball-attachment abutments^{19,20} (Table 4). The most frequent prosthesis was the single crown, followed by the fixed partial denture, overdenture, and full-arch fixed “hybrid” prosthesis (Table 4).

The Kaplan-Meier estimate of survival revealed 97% implant survival (Fig 1) (mean \pm SD follow-up, 21.0 \pm 18.8 months; range, 1 to 78 months). Among the 20 implant failures, only 2 occurred after prosthetic connection, and 75% occurred within 6 months of placement. No failures occurred after 13 months in this study (Fig 2). Table 5 shows the number of implants at risk during each year of the study, and Fig 2 illustrates the survival curve impact of the failures within the first 13 months. Also, no failures were observed among the 60 implants placed that were less than 10 mm long (Table 2).

After adjustment for age and sex, an estimate of the influence of the exposure variables on implant survival demonstrated that sex, age, implant length, abutment type, or prosthesis type did not contribute significantly to implant failure (all $P > .05$). With only 2 implant failures after prosthesis placement, no association between abutment or prosthesis type and implant failure was observed.

Although some failure associations were demonstrated, such associations do not suggest causation,²¹ but are observations of relative risks for implant failure in the patient sample reviewed. Analysis of the influence of opposing occlusion was limited by insufficient data from the failure subgroup. The existing data from 9 of the 20 failures suggest no negative effects of opposing occlusion and a protective influence for 2 groups: those with natural teeth and those with a complete denture. Although implant survival was high for all locations, no difference in survival occurred between the maxillary posterior and mandibular anterior groups, and mandibular posterior implants were 79% less likely to fail than maxillary anterior implants ($P = .03$). The 4.8-mm-diameter implants were 3.4 times more likely to fail than the 4.1-mm-diameter implants ($P = .04$). Implants placed into augmented sites were 5 times more likely to fail than implants placed into bone that did not require augmentation ($P < .001$). Sinus inlay augmentation was 6.7 times more likely to be associated with implant failure than onlay grafting ($P = .03$), and a heterogeneous source was 4.8 times more likely than an autogenous source to be associated with implant failure ($P = .04$). When augmentation was performed, implants placed 149 to 186 days after augmentation were 9.7 times more likely to fail than were implants placed simultaneously with the graft ($P < .001$).

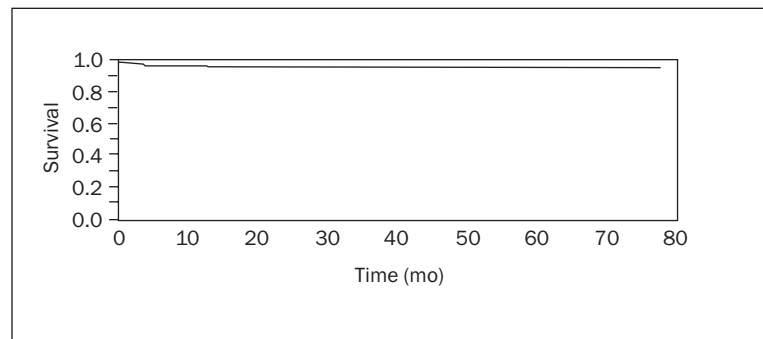


Fig 1 Cumulative 78-month survival curve.

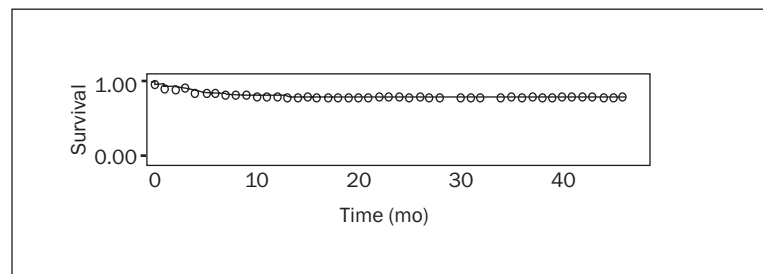


Fig 2 Short-term survival plot showing the implant failures before 13 months and a flat survival curve after 13 months.

Table 5 Implants at Risk by Year

Year	Implant total	Failed (no. and %)
1	267	19 (7.1)
2	212	1 (0.5)
3	58	0 (0)
4	52	0 (0)
5	56	0 (0)
6	10	0 (0)
7	19	0 (0)

Mechanical complications related to screw function and prosthetic durability were rare.²² Only 3 implants experienced abutment screw loosening (0.5%), and no abutment screw fractures occurred. Among the abutments allowing screw-retained prostheses, 15 prosthetic screws loosened (3.6%) and 4 fractured (0.9%). The mean duration until these complications were observed was 1.8 and 3 years for abutment and prosthetic screw loosening, respectively (both with approximately 1.5-year SDs), and 2 years for prosthetic screw fracture (with 16-day SD). No prosthesis fractures or cement failures were recorded.

Overdenture complications were related to the durability of the mechanical attachment mechanism. This varies among patients because of functional force and prosthesis movement differences, which can change significantly over time. Replacement of an overdenture matrix, spring component, or both was the most frequent complication in this group, accounting for 11 events in 9 patients (2.9% of the total population). The mean time to replacement for these patients was 2.7 years (Table 6).

DISCUSSION

A 78-month retrospective cohort study was conducted of patients treated with a 1-stage dental implant system at Mayo Clinic. Clinical outcomes related to implant and prosthesis survival were equal to or better than those with similar implant systems.

To determine the performance of an implant system in use during the previous 78 months, a retrospective review of the records of care was required. As a clinical trial design, retrospective evaluations are limited in the quality of data they can provide.²³ Unless the desired clinical data have been recorded

consistently and completely, findings are limited because of incomplete data collection and analysis. Typically, the results of such underrepresented analyses suggest a more positive performance than more complete data collection provides.²¹ In this study, the desire was to determine outcomes for all completed prosthodontic treatments that used a specific implant system. Mayo Clinic patient records include outcome data, and all patients who received implants were followed up routinely. Few practitioners in the surrounding communities provide implant care; thus, it is unlikely that patients with complications were not documented through a patient visit. This belief is supported by the fact that all patients presented for a 1-, 6-, or 12-month follow-up evaluation after prosthesis placement. The completeness and quality of the data were not concerns. Moreover, the data extraction process was repeated to minimize the number of incomplete entries (“unspecified” in footnotes to Tables 2 to 4; 6.5% in one group, but < 1.0% on average in other groups). Exposure and outcome data were collected separately to control bias.²⁴ This type of outcome analysis can be accomplished in any practice setting that has similar controls of data completeness and consistency. The observed outcomes specific to clinicians and patient groups allow comparison with reports of similar patient management decisions from other institutions.

A survival analysis enhances understanding of cumulative implant survival and the time course of implant failure. The survival rate of 97% at 78 months is strong evidence of clinical effectiveness. The fact that only 2 failures occurred after fabrication of prostheses is equally important to the patient and clinician. The consequences of implant failure are different before and after loading. For this series of patients, the minimal number of failures and minimal impact when failure occurred, because of its timing, are favorable clinical practice characteristics. The time to retreatment¹⁴ is an

Table 6 Prosthetic Complications

Prosthesis type	Complication*	
	Screw loosening	Screw fracture
Abutment	3 (647 ± 559)	0
Prosthesis	15 (1,109 ± 537)	4 (737 ± 16)
Cement failure	0	N/A
Porcelain fracture	1 (1,105)	N/A
Overdenture [†]		
Matrix replaced	2 (336)	N/A
Broken retention clip	2 (751)	N/A
Overdenture spring replaced	11 (972 ± 642)	N/A

*Values are no. of complications (no. of days to complication, mean ± SD).

[†]Eleven events in 9 patients (2.9%).

Table 7 Clinical Studies

Study	Duration of study (y)	No. of implants	No. of patients	Prosthesis type	Implant survival (%)	Implant success (%)	Other information
Buser et al ²⁵ 1990	1	100	70	FPD	—	98	HC, HS
Buser et al ²⁶ 1991	3	54	38	FPD	—	96.2	HC, HS
Astrand et al ²⁷ 1996	2	216	46	OD, Fx-hybrid	96	—	—
Buser et al ¹⁰ 1997	8	2,359	1,003	393 removable, 758 fixed	96.7	93.3	Mn better survival
Behneke et al ²⁸ 1997	3	320	109	9% CR; 75% OD; 16% FPD	98.1	—	Solid-screw implants
ten Bruggenkate et al ¹¹ 1998	6	253	126	—	—	97.3	All 6-mm implants
Mericske-Stern et al ²⁹ 2001	10	14,475	670	—	96.2	91.4	Subset of Noack et al ⁸
Astrand et al ³⁰ 2000	1	167	28	Mx-fixed	92.8	—	—
Brocard et al ¹² 2000	7	1,022	440	—	95.4 (5 y) 92.2 (7 y)	—	Elderly, edentulous-related failure
Hellem et al ³¹ 2001	9	109	72	—	99.1 (5 y)	—	Octabutments
Parein et al ³² 1997	5	N/A	46	Mn-OD; Fx-hybrid	95.7	—	HS
Moberg et al ³³ 2001	3	106	20	Fx-hybrid	96.8	—	100% stability
Mericske-Stern et al ¹³ 2001	11–19	132	71	—	91.4 (10 y); 84.6 (14 y)	—	HS

CR = crown; Fx = fixed; HC = hollow cylinder; HS = hollow screw; Mn = mandibular; Mx = maxillary; OD = overdenture. Dashes indicate data that were not reported.

important consideration when evaluating or comparing the effect of implant system use in a clinical practice and becomes more important for long-term comparison of systems with similar short-term clinical performance results.

Another related issue affecting time to retreatment involves performance of prostheses. The comparative durability of prostheses for various applications affects the overall treatment burden relative to maintenance. The low rate of mechanical complications and implant loss for this 1-stage implant system is a powerful combination of factors to manage tooth loss. The major prosthetic complication that was seen involved the overdenture prosthesis. Because of the prosthetic design, which combines tissue support and implant retention, such maintenance requirements associated with overdenture attachments are expected. In general, the mechanical strength of attachment components becomes an issue if changes in prosthesis design or support favor load to the components as opposed to the tissue. While categorized as a prosthetic complication, loss of attachment strength should be considered as part of the maintenance of such prostheses, and attachment selection should fit the time restraints of recall appointments to plan intervention.

Clinical documentation of this specific 1-stage system can be found in reports describing from 1 to 19 years of follow-up (Table 7). Of these, 6 reports provide results from 5 years or longer,^{10-12,29,31,32} and 2 reports provide data for various implants and prostheses.^{10,12} One report in particular¹² provides data from 10 private practice settings in which no strict inclusion or exclusion criteria were used. As in this report, such a setting can provide important, rigorous information regarding implant survival in an array of patients, and clinical conditions and patient needs drive decision-making instead of narrow indications established to favor efficacy or success. These types of effectiveness studies complement stricter criteria-driven studies; concern would be warranted if outcomes between them were different. Implant survival estimates in this report are comparable to those in the 2 long-term reports mentioned. As previously reported, the survival rate was better for the solid-screw implants; however, the results did not show a jaw difference in survival. These 78-month results also suggest clinical performance in this practice setting equal to the reported clinical performance of a standard 2-stage implant system used at Mayo Clinic for the past 18 years.^{3,7,25}

SUMMARY AND CONCLUSIONS

This study was initiated to document the clinical performance of a 1-stage dental implant system for informed consent and clinical decision-making purposes. The purpose of this study was to measure the survival characteristics of the implants and prostheses. The survival rate was 97%, and the incidence of prosthetic complications was low (< 4%). Implant failures occurred early—all within 13 months of placement, with only 2 implants failing after prosthetic loading. This clinical performance, coupled with the low incidence of prosthetic complications to date, suggests a favorable clinical outcome for the follow-up period. Longer follow-up is required to establish that short-term survival and prosthetic durability are maintained.

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