Complications of Dental Implants: Identification, Frequency, and Associated Risk Factors

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Purpose: *This study sought to identify the types, frequencies, and risk factors associated with complications following placement of dental implants. It was hypothesized that one or more factors could be identified that are associated with an increased risk for complications and may be modified by the clinician to enhance outcome.* ***Materials and Methods:*** *A retrospective cohort study design was used that included patients who received Bicon implants (Bicon, Boston, MA) between 1992 and 2000. Predictor variables were grouped into demographic, medical history, implant-specific, anatomic, prosthetic, and reconstructive categories. Complications were grouped into inflammatory, prosthetic, operative, and major or minor categories. Cox proportional hazards regression models were developed to identify risk factors for complications.* ***Results:*** *The sample was composed of 677 patients. The overall frequency of implant complications was 13.9% (10.2% inflammatory, 2.7% prosthetic, 1.0% operative), of which 53% were minor. The multivariate Cox model revealed that smoking, use of 1-stage implants, and reconstructive procedures were statistically associated with an increased risk for overall complications ($P \leq .05$). The median duration of follow-up was 13.1 months (range 0 to 85.6 months).* ***Discussion:*** *A lower frequency of complications was found compared to mean frequencies calculated from past reports. Investigations examining the influence of smoking and reconstructive procedures on implant complications are recommended.* ***Conclusion:*** *Of the 3 factors associated with an increased risk for complications, tobacco use and implant staging may be modified by the clinician to enhance outcome.* INT J ORAL MAXILLOFAC IMPLANTS 2003;18:848–855

Key words: *complications, dental implants, proportional hazards models, retrospective cohort study, risk factors*

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This material was presented at the General Session of the International Association for Dental Research, San Diego, CA, March 7, 2002.

Over the last 25 years, dental implants have evolved into a predictable technology for replacing teeth. Despite the widespread implementation and acceptance of this treatment modality, there is a paucity of available scientific data identifying types and frequency of complications, as well as risk factors associated with implant complications. This was succinctly stated by Avivi-Arber and Zarb, who concluded that "... extensive long-term implant studies are needed to determine which specific criteria comprise optimal functional and esthetic results with minimum risk of morbidity."[1]

Given this relative dearth of information in the literature regarding complications associated with implant treatment, the first specific aim of this project was to identify the types and frequencies of complications associated with implants. The second specific aim was to identify risk factors associated with implant complications. It was hypothesized that there exists a set of one or more risk factors associ-

ated with implant complications that may be modified by the clinician to enhance patient outcome.

MATERIALS AND METHODS

Study Design and Sample

To address the specific aims, a retrospective cohort study design was used that included a study sample derived from a population of patients who received Bicon implants (Bicon, Boston, MA) at the Implant Dentistry Centre, Faulkner Hospital, Boston, Massachusetts. All implants were placed between May 1992 and July 2000. Patients whose charts were available for review were included in the study. The clinical experience of the practitioners placing the implants ranged from zero to many years.

Study Variables

Predictor Variables. The predictor variables, ie, exposures or risk factors for complications, are outlined below.

1. *Demographic Variables.* These variables included gender and age at the time of implant placement.
2. *Health Status Variables.* Patient health status was defined according to the American Society of Anesthesiology (ASA) system from level I to level V.[2] ASA I is defined as a normal healthy patient, while ASA V is defined as a moribund patient. Also noted was the presence of a condition, specifically diabetes, liver disease, or immunosuppression, associated with poor wound healing. Tobacco use at the time of implant placement was also recorded.
3. *Anatomic Variables.* These variables included *(1)* implant location, whether maxilla or mandible, anterior or posterior; *(2)* bone quality (types 1 to 4); and *(3)* proximity of the implant to natural dentition or other implants. Bone quality was determined at the time of implant surgery upon examination of the contents of the flutes of a 3.5-mm reamer extracted from the osteotomy. Type 1 bone was defined as compact, nearly bloodless bone that completely filled the flutes of the reamer. Bone quality was categorized as type 4 when little or no bone filled the reamer flutes. Type 2 and type 3 bone were intermediate grades. The relationship of the implant to other dentoalveolar structures was identified with the following categories: no teeth (edentulous), 1 natural tooth, 2 natural teeth, 1 implant, 2 implants, or 1 natural tooth and 1 implant.
4. *Implant Variables.* These variables included implant diameter (3 to 5 mm); implant length (6 to 13 mm); well size (2 or 3 mm); coating (uncoated, titanium plasma-sprayed [TPS], or hydroxyapatite [HA]); and staging (1- or 2-stage placement). Abutment diameter and angulation (0, 15, or 25 degrees) were also recorded.
5. *Prosthetic Variables.* Prosthetic variables were grouped into 2 categories: removable (overdenture) or fixed (crown or fixed partial prosthesis).
6. *Reconstructive Variables.* The use of a reconstructive procedure was documented in the patient chart if the recipient site was enhanced with at least one of the following procedures: barrier membrane, internal sinus lift, lateral sinus lift, ridge splitting procedure, onlay graft, inlay graft, or bone grafting (autologous or synthetic). The timing of the reconstructive procedure was recorded and classified in relation to the timing of implant placement. Specifically noted was whether the reconstructive procedures and implant surgeries were carried out simultaneously or separately.
7. *Other Variables.* Perioperative antibiotic use, the identity of the oral surgeon (2 clinicians) who placed the implants, and the identity of the clinician who restored the implant(s) were documented.
8. *Survival Analysis.* The following information was recorded: dates of implant, abutment, and restoration placement; and date of the first complication (when applicable).

Outcome Variables. The primary outcome variable was the presence or absence of a complication following implant placement. The date of the first implant complication was documented and then the complication was categorized into 1 of 3 groups: inflammatory, operative, or prosthetic. Inflammatory complications included the following conditions:

1. Implant mobility, as evidenced by documentation in the chart
2. Pain, defined as the patient's complaint of pain at least 7 days after implant surgery requiring dispensation of additional pain medication or additional follow-up appointments
3. Infection, defined as the presence of purulent exudate, fistula(e), cellulitis, sinusitis, or written diagnosis of infection requiring antibiotic treatment or other therapeutic agent (ie, chlorhexidine gluconate)
4. Peri-implantitis, defined as the radiographic evidence of progressive peri-implant bone loss or radiolucency associated with the implant
5. Impaired wound healing, as evidenced by soft tissue breakdown occurring 21 days or more after implant surgery, exposing bone, graft material, or the implant
6. Gingival recession requiring free gingival graft procedure

Inflammatory complications were further categorized as major or minor. A major complication was defined as a complication that occurred more than 2 times or resulted in implant failure. A minor complication was defined as a complication occurring only 1 or 2 times and not associated with implant loss.

Prosthetic complications included:

1. Abutment fracture or loosening
2. Need for O-ring replacement less than 12 months after placement of the prosthesis
3. Need for occlusal or prosthetic adjustment more than 2 weeks after definitive restoration
4. Need for recementation of loose fixed prosthesis within 2 weeks of delivery

Operative complications included:

1. Inadvertent placement of an implant into the sinus or the submandibular space
2. Paresthesia, defined as the patient's subjective complaint of numbness/tingling lasting at least 7 days after implant surgery

While many of the complications under consideration may be considered clinically minor and easily managed, one of the guidelines used in developing the list of complications was whether the complication resulted in an unscheduled visit for evaluation and treatment. Unscheduled visits are at minimum straightforward and are related to treatable problems, but they represent inconveniences to both the patient and the clinician. Some of the complications identified are not unique to implant dentistry and also occur in conventional restorative dentistry and dentoalveolar surgical procedures. The aforementioned list of complications was developed to reflect the global scope of minor and major challenges when implants are used to replace missing teeth.

Data Analysis

Complication frequencies and descriptive statistics were computed with SAS statistical software (Version 8.0; SAS Institute, Cary, NC). Descriptive statistics were computed for all study variables.

Cox proportional hazards regression was employed to identify risk factors related to implant complications. Potential risk factors for complications were identified using the bivariate Cox proportional hazards regression model and were considered candidate variables if $P \leq .15$. Variables meeting this criterion were included in the multivariate Cox proportional hazards model to identify variables statistically associated ($P \leq .05$) with complications.

RESULTS

Between 1992 and 2000, 702 patients received implants at the Implant Dentistry Centre. Records were unavailable for 25 patients as a result of chart misplacement, patient relocation, or death. The final sample was composed of 677 patients who received 2,349 implants. The median duration of follow-up was 13.1 months (range, 0 to 85.6 months). Because patients commonly had more than 1 implant placed, the issue of correlated observations arises.[3] To produce statistically valid inferences for clinical interpretation, 1 randomly selected implant per patient was chosen for analysis. The results that follow are based on 677 patients and 677 implants.

Descriptive statistics of the sample are summarized in Table 1. Of note, 50.1% of the subjects were women. The average age was 53.5 ± 13.9 years. The vast majority of patients were healthy (99.1% were classified ASA I or II). Tobacco use at the time of implant placement was reported by 10.3% of patients. The majority of implants were placed in type 4 bone (51.1%). Less than 20% of the implants were placed using a 1-stage procedure. Approximately one-third of the implant sites were associated with reconstructive procedures.

Overall Complications

The overall frequency of implant complications with associated unscheduled office visits was 13.9% (94/677) (Fig 1). Fewer than half of these, 46.8% (44/94), were major complications. Based on the bivariate analysis, tobacco use ($P = .01$), staging ($P = .003$), prosthesis type ($P = .03$), and the use of reconstructive procedures ($P = .024$) were associated with an increased risk for complications (Table 2). The multivariate model was constructed using these candidate variables as well as age and gender (Table 3). For current tobacco use, the adjusted hazard ratio was 2.31 ($P = .0051$; 95% confidence interval [CI], 1.29 to 4.16) suggesting that smokers are 2.31 times more likely to have implant complications than nonsmokers. The adjusted hazard ratio for implant staging was 2.56 ($P = .0013$; 95% CI, 1.45 to 4.55), with 1-stage implants having an increased risk for complications. The use of reconstructive procedures was also associated with an increased risk for complications (adjusted hazard ratio 1.18; $P = .017$; 95% CI, 1.03 to 1.34).

Inflammatory Complications

The overall frequency of inflammatory complications was 10.2% (69/677) (Fig 2). Slightly over half of these complications, 52.2% (36/69), were major (ie, the implant experienced more than 2

Table 1 Descriptive Statistics of Patient Sample (n = 677)

Variable	
Demographic	
Mean age (y)*	53.5 ± 13.9 (range 16.9–92.5)
Male/female	338/339 (49.9%/50.1%)
Health status	
ASA status (n = 673)†	
ASA status I	329 (48.9%)
ASA status II	338 (50.2%)
ASA status III	6 (0.9%)
Medically compromised (n = 671)	57 (8.5%)
Tobacco users (n = 553)	57 (10.3%)
Anatomic	
Maxilla/mandible	425/252 (62.8%/37.2%)
Anterior/posterior	206/471 (30.4%/69.6%)
Proximity to local anatomic structures (n = 670)	
No teeth	39 (5.8%)
1 adjacent tooth	50 (7.5%)
2 natural teeth	259 (38.7%)
1 adjacent implant	85 (12.7%)
2 adjacent implants	55 (8.2%)
1 tooth + 1 implant	182 (27.1%)
Bone quality (n = 546)	
Type 1	4 (0.7%)
Type 2	126 (23.1%)
Type 3	137 (25.1%)
Type 4	279 (51.1%)
Implant-related	
Implant diameter (n = 641)	
3 to 3.5 mm	195 (30.4%)
4 to 4.5 mm	260 (40.6%)
5 mm	168 (26.2%)
6 mm	18 (2.8%)
Implant length (n = 641)	
4 to 6 mm	10 (1.6%)
8 mm	156 (24.3%)
11 mm	433 (67.5%)
14 mm	42 (6.6%)
Coating (n = 593)	
Uncoated	115 (19.4%)
Titanium plasma-sprayed	187 (31.5%)
Hydroxyapatite	291 (49.1%)
Well size (n = 675)	
2 mm	599 (88.7%)
3 mm	76 (11.3%)
Staging (n = 676)	
One stage	108 (16.0%)
Two stages	568 (84.0%)
Immediate placement	78 (11.5%)
Abutment-related	
Diameter (n = 467)	
3 to 4 mm	118 (25.3%)
5 to 5.5 mm	258 (55.2%)
6 to 6.5 mm	91 (19.5%)
Angle (n = 589)	
0 degrees	435 (73.9%)
15 degrees	138 (23.4%)
25 degrees	16 (2.7%)
Prosthesis type	
Crown and fixed	632 (93.4%)
Removable	45 (6.6%)
Perioperative	
Antibiotic used?	574 (84.8%)
Reconstructive procedure performed	242 (35.8%)

*Mean ± standard deviation.
†Data are missing for some variables. When the data are missing, the number in parentheses represents the sample size of the available data.

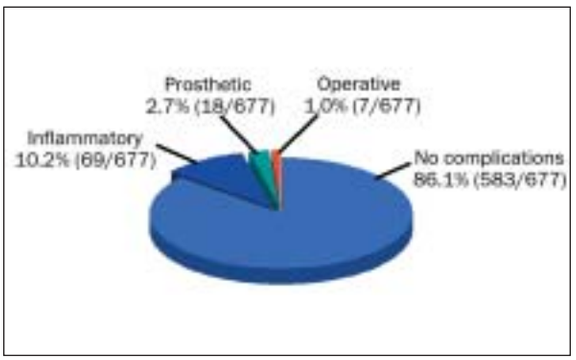

Fig 1 Implant complications: Identification and enumeration (n = 677 implants and 677 patients). The overall complication rate was 13.9% (94/677).

Table 2 Bivariate Analyses of Potential Factors Associated with Implant Complications: Overall Implant Complications (n = 94)

Variable	Hazard ratio	95% CI	*P* value
Mean age (y)	1.01	0.99–1.02	.55
Gender	0.3	0.62–1.40	.74
Tobacco use	2.14	1.20–3.82	.01*
Staging (1 vs 2)	0.43	0.25–0.75	.003*
Prosthesis type (removable vs fixed)	1.27	1.02–1.57	.03*
Reconstructive procedure performed (yes vs no)	1.15	1.02–1.29	.024*

Cox proportional hazards regression model was used; *statistically significant.

Table 3 Multivariate Cox Model (Adjusted): Analysis of Potential Factors Associated with Implant Complications

Exposure	Hazard ratio	95% CI	*P* value
Tobacco use* (smoker vs nonsmoker)	2.31	1.29–4.16	.0051§
Reconstructive procedure† (yes vs no)	1.18	1.03–1.34	.017§
Implant staging‡ (1- vs 2-stage)	2.56	1.45–4.55	.0013§
Age (older vs younger)	1.0041	0.98–1.01	.89
Gender (female vs male)	0.92	0.58–1.44	.72
Prosthetic type (removable vs fixed)	1.97	0.92–4.21	.083

*In comparison to nonsmokers, smokers have 2.31 times increased risk for implant complications.
†In comparison to nonreconstructed implant sites, sites associated with reconstructive procedures have a 1.18 times increased risk for implant complications.
‡In comparison to 2-stage procedures, 1-stage procedures have 2.56 times increased risk for implant complications.
§Statistically significant.

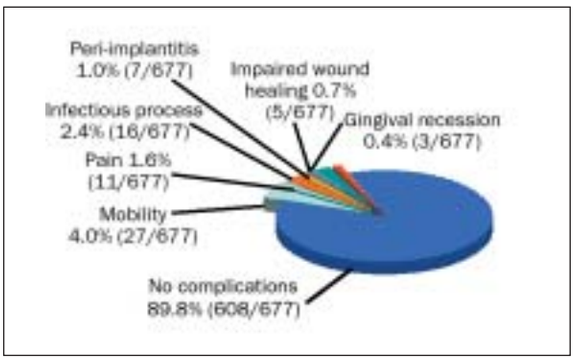

Fig 2 Breakdown of inflammatory complications (overall frequency was 10.2%, or 69/677).

Table 4 Bivariate Analyses of Potential Factors Associated with Implant Complications: Inflammatory Complications (n = 69)

Variable	Hazard ratio	95% CI	*P* value
Mean age (y)	1.00	0.98–1.02	.88
Gender	0.98	0.61–1.57	.92
Tobacco use	2.62	1.41–4.84	.002*
Jaw (maxilla vs mandible)	0.65	0.38–1.09	.10*
Staging (1 vs 2)	2.80	1.57–5.00	.0005*
Reconstructive procedure performed (yes vs no)	1.13	0.98–1.30	.11*

Cox proportional hazards regression model was used; *statistically significant.

inflammatory complications or failure). Most inflammatory complications were attributed to implant mobility (4.0%, 27/677), infection (2.4%, 16/677), and pain (1.6%, 11/677). Bivariate analysis revealed that current tobacco use (P = .002), implant location (maxilla versus mandible, P = .10), staging (P = .0005), and use of reconstructive procedures (P = .11) were potential risk factors for inflammatory complications (Table 4). The multivariate model included the variables previously listed, as well as age and gender. For current tobacco use, the adjusted hazard ratio was 3.26 (P = .0002; 95% CI, 1.74 to 6.10). The adjusted hazard ratio for implant staging was 3.03 (P = .0004; 95% CI, 1.64 to 5.56), with single-stage implant placement associated with an increased risk for inflammatory complications. The use of reconstructive procedures also increased the likelihood of inflammatory complications (adjusted hazard ratio 1.17; P = .049; 95% CI, 1.001 to 1.36).

Prosthetic Complications

The overall frequency of prosthetic complications was 2.7% (18/677) (Fig 1). The bivariate Cox model indicated that implant location (anterior versus posterior, P = .0004); type of prosthesis (removable versus fixed, P = .0001); implant proximity (P = .0009); bone quality (P = .044); and abutment angulation (P = .043) were statistically associated with prosthetic complications at $P \leq .15$ (Table 5). A multivariate model was not constructed because of the small number of prosthetic complications.

Operative Complications

The overall frequency of operative complications was 1.0% (7/677) (Fig 1). Bivariate Cox proportional hazards regression showed that age (P = .10); jaw (maxilla versus mandible, P = .089); use of reconstructive procedures (P = .072); and restorative dentist (P = .099) were associated with operative complications at $P \leq .15$ (Table 6). As with prosthetic complications, the paucity of sample size precluded multivariate analysis.

DISCUSSION

To date, most clinical implant research has focused on descriptions and factors associated with implant success. Systematic reports of complications and associated risk factors are limited. The authors sought to address this deficiency in the literature by implementing a study with 2 specific aims: *(1)* to identify the types and frequencies of complications associated with placement of Bicon implants, and *(2)* to identify risk factors associated with implant complications. It was hypothesized that risk factors associated with implant complications could be identified that might be modified by the clinician to enhance patient outcome and reduce the frequency of unscheduled visits to manage the complications.

The Bicon implant system was chosen for investigation for 2 reasons. First, the clinicians at the Implant Dentistry Centre-Faulkner Hospital permitted the authors free and unfettered access to a large patient sample. Second, few clinical studies have addressed the Bicon implant system. A prospective 4-year study of 168 patients who received 432 Bicon implants to replace posterior dentition reported a 0.74% frequency of abutment loosening, a 0.5% frequency of abutment fracture, and a 3.71% frequency of crown replacement necessitated by cement failure or porcelain fracture.[4]

Based on the present results, the overall frequency of implant complications occurring after placement of Bicon dental implants was 13.9%. At first glance,

Table 5 Bivariate Analyses of Potential Factors Associated with Implant Complications: Prosthetic Complications (n = 18)

Variable	Hazard ratio	95% CI	*P* value
Mean age (y)	1.002	0.97–1.04	.92
Gender	1.14	0.45–2.89	.78
A/P location	0.13	0.043–0.40	.0004*
Proximity of implant	0.53	0.36–0.77	.0009*
Bone quality	0.48	0.24–0.98	.044*
Abutment angulation	1.02	1.02–3.83	.043*
Prosthesis type (removable vs fixed)	7.81	2.76–22.12	.0001*

Cox proportional hazards regression model was used; A/P = anterior/posterior; *statistically significant.

Table 6 Bivariate Analyses of Potential Factors Associated with Implant Complications: Operative Complications (n = 7)

Variable	Hazard ratio	95% CI	*P* value
Mean age (y)	1.05	0.99–1.11	.10*
Gender	0.38	0.08–2.04	.27
Jaw (maxilla vs mandible)	4.14	0.80–21.36	.089*
Reconstructive procedure performed (yes vs no)	4.51	0.88–23.26	.072*
Operator-dependent (restorative dentist)	0.42	0.15–1.18	.099*

Cox proportional hazards regression model was used; *statistically significant.

13.9% may appear to be a high complication rate. One purpose of this study was to capture or describe the global morbidity of managing implant patients. As such, the majority (53.2%) of the complications included would be considered by many clinicians to be trivial or nuisance complications, but they are significant in that minor complications result in unscheduled patient visits. Unscheduled patient visits are an inconvenience for both the patient and clinician. Additionally, many of the complications included, especially the prosthetic complications, are not unique to restorative implant dentistry, eg, repeated occlusal adjustments or recementation of loose prostheses. A recent study reported the amount of maintenance required to provide acceptable implant-retained mandibular overdentures. In a sample of 58 patients, a total of 327 return visits were made for adjustments, of which 59% were unscheduled.[5] Many patients also underwent some form of grafting to enhance the recipient site, and the addition of more procedures contributes to an increased likelihood of complications. Finally, since the Implant Dentistry Centre is both a patient care and teaching setting, many of the procedures were performed by clinicians inexperienced with implants under the supervision of experienced clinicians.

In terms of overall complications, the multivariate Cox proportional hazards regression model indicated that smoking at the time of implant placement, use of reconstructive procedures, and 1-stage implants were statistically associated with an increased risk for overall implant complications. Inflammatory complications composed 10.2% of the complications, followed by prosthetic and operative complications, at 2.7% and 1.0%, respectively. The specific types and frequency of inflammatory complications included mobility (4.0%), infection (2.4%), pain (1.6%), peri-implantitis (1.0%), delayed wound healing (0.73%), and gingival recession (0.44%). Slightly over half (52.1%) of the inflammatory complications were major. The multivariate model identified the same variables—smoking at the time of implant placement (P = .0002, hazard ratio 3.26), use of reconstructive procedures (P = .049, hazard ratio 1.17), and 1-stage implants (P = .0004, hazard ratio 3.03)—as risk factors for inflammatory complications. Prior reports have associated smoking, poor oral hygiene, surgical inexperience, lack of attached mucosa, and loose abutment screws with inflammatory complications.[1,6–19]

Analyses of prosthetic and operative complications were limited because of the small number of patients who experienced these complications. Regardless, the multivariate Cox model showed that no variables were statistically associated with prosthetic complications. Past reports have attributed prosthetic complications to excessive loading, location (anterior versus posterior), an insufficient number of implants supporting a prosthesis, abutment screw material, and implant diameter less than 3.5 mm.[1,7,14,16,20–29] In retrospect, it might have been wise to have included oral habit history (eg, bruxism), as well as the number of implants supporting a prosthesis, as predictor variables in this study.

The multivariate Cox regression model indicated that the placement of implants in the maxilla (P = .048, hazard ratio 5.22) and the use of reconstructive procedures (P = .002, hazard ratio 1.84) were statistically associated with an increased risk of operative complications. Earlier studies have attributed operative complications to surgical experience, severe mandibular or maxillary bone loss, pressure on the nerve secondary to postsurgical edema, elevated temperatures secondary to conduction through the implant, and scar formation.[1,20,30–34]

When appropriate, a distinction between major and minor complications was made, since it was believed to be important to differentiate between outcomes that could be considered "minor inconveniences" and those for which the outcome had more ominous implications. Unfortunately, it was not possible to categorize operative and prosthetic complications because of the nature of the definitions and small number of outcomes. As a result of this broad definition of complications, it was often not possible to compare the incidence of complications observed in this study to other studies. When a comparison was possible, we found a lower frequency of complications in the present study compared to mean frequencies calculated from past reports.[1,6–8,20–22,30–46] In general, discrepancies between the present findings and other studies may be attributed to differences in patient population sizes, the use of multivariate analysis, non-inclusion of certain predictor variables in this model, selection bias, differences in the definitions of certain complications, differences in the duration of the follow-up period, inaccurate patient recall, and loss of patients to follow-up.

Two risk factors identified in this study, smoking and 1-stage implants, can be modified to some extent by the clinician. It is believed this knowledge will allow the clinician to decrease complication rates, eg, by offering 2-stage implants or encouraging cessation of smoking prior to implant placement, and to engage the patient in a more informed discussion of treatment options.

CONCLUSION

The present report demonstrated that complications associated with Bicon dental implants occurred with a 13.9% frequency in this study population. The most commonly observed complications were inflammatory (10.2%), followed by prosthetic (2.7%) and operative (1.0%). Most of the implants (62%) associated with complications did not fail.

Multivariate Cox proportional hazards regression identified smoking, 1-stage implants, use of reconstructive procedures, and placement of implants in the maxilla as risk factors for implant complications. Two of these 4 risk factors, smoking and 1-stage implants, can be modified by the clinician. It is suggested that subsequent studies attempt to identify additional modifiable risk factors to minimize morbidity and enhance patient outcome. Investigations examining the influence of smoking and reconstructive procedures on implant complications are recommended. The findings of the current study may be used to decrease the incidence of implant-associated complications and to better assist the patient in selecting the most appropriate treatment option.

ACKNOWLEDGMENTS

We would like to acknowledge the clinicians and support staff of the Implant Dentistry Centre, Faulkner Hospital, Boston, Massachusetts, for their cooperation in this study and unrestricted access to patient records. The authors would also like to recognize Drs Shadi Daher and Ali Muftu for their role in clinical data collection.

This project received funding from the following sources: Department of Oral and Maxillofacial Surgery Research Fund (NEM), Oral and Maxillofacial Surgery Foundation Student Training Award (VVW), NIH/NIDCR Dentist Scientist Award K16 DE000275 (SKC), and NIH/NIDCR Mid-career Investigators Award K24 DE000448 (TBD).

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