Madame Chair Salinas and Committee Members:

I would like to thank you for the opportunity to provide testimony on Tuesday, May 21st. As I heard the oppositions' arguments, it became clear that specialty recognition would be acceptable for the opposing Dentists, as long as they were included. Likewise, I was confused as to how Dr. Recker could argue that recognizing Dental Specialties as written in SB835 is unlawful and violates "commercial free speech," however by adding his clients to the list of Dental Specialists would then become acceptable and legal. Wouldn't that violate commercial free speech for another interest group or discipline of dentistry?

There were a few statements from the opposition suggesting I, as president of the Oregon Society of Oral & Maxillofacial Surgeons, provided false and misleading testimony that was, according to Dr. Steven Little, an "obvious misrepresentation of the truth." I would like to respond by communicating what I see as the truth regarding General Dentists providing more advanced treatments and procedures for the general public.

The Dental Implant Safety Workgroup was referenced multiple times. I have attached salient information as to what was communicated to the workgroup members in writing. There are a couple of pie charts that I have referenced in the past. However, as any scientist, researcher, or statistician can attest, data can be interpreted many ways. So rather than arguing about one's interpretation of the data verses another**, I think the big picture is that the Board of Dentistry identified a concern for public safety**. They analyzed their own data and used their best judgement to determine that General Dentists surgically placing implants deserved more attention. The Dental Implant Safety Workgroup **did not** spend time discussing a systemic problem from specialists needing to improve their surgical outcomes for the public. The workgroup spent many evenings discussing ways to guide General Dentists that have not received enough education and training so they may obtain more competencies with the hopes of reducing poor outcomes and subsequent complaints. I recall every member of the workgroup agreeing that additional training after dental school is necessary to become competent in placing implants. This workgroup consisted of General Dentists, Oral & Maxillofacial Surgeons, and Periodontists. The workgroup came up with recommendations for the Board to consider the benefits of requiring a minimum hours CE courses, requiring hand's on courses, restoring a certain number of implants before surgically placing them, and mentorships. Specialty recognition was not the focus of this workgroup.

Furthermore, Dr. Recker communicated something to the affect that no evidence exists suggesting a General Dentist is any more of a threat to the public than a specialist. If we are comparing apples to apples, then I would think that a failed implant could be considered as harmful to a person. Any complication for that matter could be considered as harmful, so in

order to minimize the possibility of causing harm, we have to focus on minimizing complications. As many specialists in support of SB835 will attest, they spend a disheartening amount of time treating the complications of some General Dentists and have plenty of cases where they genuinely thought the patient would have had a better outcome had they treated the patient in the first place.

I've attached a study that was published in the respected Journal of the American Dental Association. The conclusion of this study reported their "results suggest that implant survival and success rates in general dental practices may be lower than those reported in the studies conducted in academic or specialty settings." Dr. Recker may find reasons why this study may not pass legal muster, but it is a published body of evidence.

This is why specialty recognition as stated in SB835 matters. As hard as it is to admit, well intentioned General Dentists can sometimes take on a complex situation and not realize that they're not equipped to safely negotiate their patient through the process. The board of dentistry does what it can to regulate with the intention of minimizing potentially harmful outcomes. The public needs to have laws like SB835 to facilitate making more informed decisions about whether to seek treatment from a generalist or a specialist.

Very Respectfully,

Normund K. Auzins, D.D.S.
President, Oregon Society of Oral & Maxillofacial Surgeons
President, Multnomah County Dental Society

Memorandum

To: OBD Dental Implant Safety Workgroup Members & OBD Board Members

From: Stephen Prisby, OBD Executive Director

Date: September 12, 2017

Re: Dental Implant Safety Workgroup Initial Meeting

The OBD identified dental implant complications and the subsequent complaints during strategic planning in 2016 as a significant problem in Oregon, ultimately memorialized in the OBD's 2017-2020 Strategic Plan. At the April 21, 2017 Board Meeting, the OBD established an ad hoc Committee named the "Dental Implant Safety Workgroup" per ORS 679.280, to research, review and discuss dental implants, complications and the resulting investigations with the goal of advising the OBD on what should be the most effective actions in protecting the public and educating dentists regarding dental implants. Thank you for serving on this important Workgroup.

My role is clear, to carry out the Board's directives, fulfill our statutory mission and protect Oregonians, in areas regarding dental health, that are described in the Dental Practice Act.

I want to assure the dental community, citizens of our state and Board members that I believe consumer protection should be an integral component regarding the recommendations from this Workgroup and Board actions on the subject of dental implant safety.

The work and recommendations will also inform other state boards of dentistry, and from what I understand, our state is at the forefront of addressing this patient safety issue in a proactive and meaningful manner.

I am optimistic that your collective experience and expertise along with feedback from the dental community will culminate in some actionable and practical recommendations to the Board, which is due in a report, no later than the October 19, 2018 Board Meeting.

Attached is the agenda for the inaugural meeting and other documents for the Workgroup to consider and review.

DENTAL IMPLANT SAFETY WORKGROUP

At the April 21, 2017 Board Meeting, the OBD established an ad hoc committee named the "Dental Implant Safety Workgroup" per ORS 679.280, to research, review and discuss dental implants, complications and the resulting investigations with the goal of advising the OBD on what should be the most effective action in protecting the public and educating dentists regarding dental implants.

The Dental Implant Safety Workgroup is being created because during strategic planning in 2016, the OBD identified dental implant complications and the subsequent complaints as a significant problem in Oregon. This was ultimately addressed in the OBD's 2017-2020 Strategic Plan, which was ratified on August 19, 2016.

The Dental Implant Safety Workgroup, which shall be comprised of three current OBD Board Members; one or two may be the Chair/Co-Chair. The Workgroup shall also include up to two OBD staff members. Two positions will be reserved for the ODA on this Workgroup. A position on this Workgroup will also be reserved for the OHSU School of Dentistry

Oregon licensed dentists who are familiar with placing implants have also been invited to participate. As of June 20, 2017, 25 licensees have submitted interest forms to serve on this Workgroup.

This Workgroup will seek relevant information on the training of dental students as it relates to dental implants. Staff shall also survey regional testing agencies regarding this topic, to provide feedback to this Workgroup as directed by the Chairs. Staff shall also survey other state dental boards, regarding how they regulate dental implants.

The Co-Chairs of this Workgroup shall consult with the OBD's Executive Director in approving additional members to this Workgroup from those interested dentists that are not ODA appointees. The Workgroup shall not exceed 12 members. All Workgroup members will be assigned voting rights on relevant work, and a simple majority of those present at a meeting will approve Workgroup actions.

Current OBD Board Members are always invited to attend OBD Committee/Workgroup meetings, whether they are assigned to that Committee/Workgroup or not. Only the initial three OBD Board Members assigned to this Workgroup will have voting rights.

Workgroup members shall be reimbursed for transportation costs to and from these meetings, limited to reimbursement for mileage as long as the Workgroup members complete the required reimbursement forms. It is anticipated that some of the work will be done through email, and possibly teleconferences as well. Board members attending Workgroup meetings will be reimbursed as they normally are when they participate in Board business. All Workgroup meetings will be at the OBD's office or conference room at 1500 SW. 1st Ave., Portland, Or 97201 and will be public meetings.

This Workgroup shall be charged with producing a final report with observations and recommendations to the Board no later than the October 2018 Board Meeting.

The Co-Chairs shall consult with the Executive Director regarding any facet of the Workgroup and the Co-Chairs shall retain the authority to unilaterally make any modifications they see fit, to facilitate the intended outcome of providing the Board a final report with respect to its purpose.

Thank you to all of the dentists who submitted interest forms for serving on the Workgroup. The Workgroup's meetings will be public meetings and if its work ultimately leads to any rule changes, the OBD adheres to a transparent and public rulemaking process where all interested parties will have the opportunity to share their opinions on any proposed rule changes.

The 12 person Roster of the Dental Implant Safety Workgroup includes:

OBD Board Members
Co-Chair Dr. Gary Underhill
Co-Chair Dr. Julie Ann Smith
Dr. Todd Beck

OBD Staff Members
Dr. Paul Kleinstub
Dr. Daniel Blickenstaff

ODA Designees
Dr. S. Shane Samy
Dr. Normund Auzins

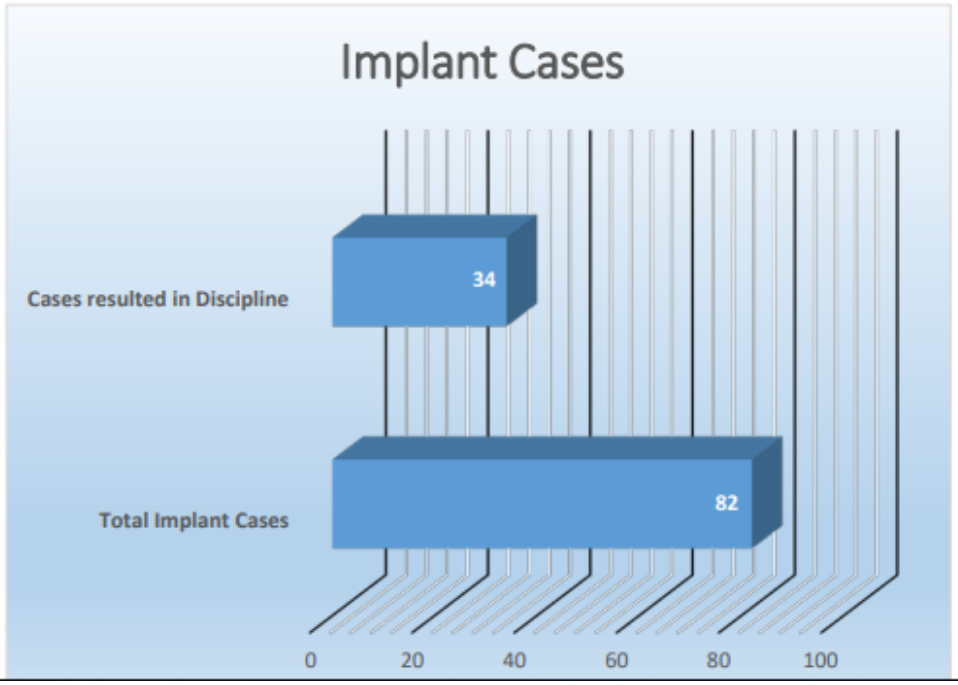
OHSU School of Dentistry
Dr. James Katancik

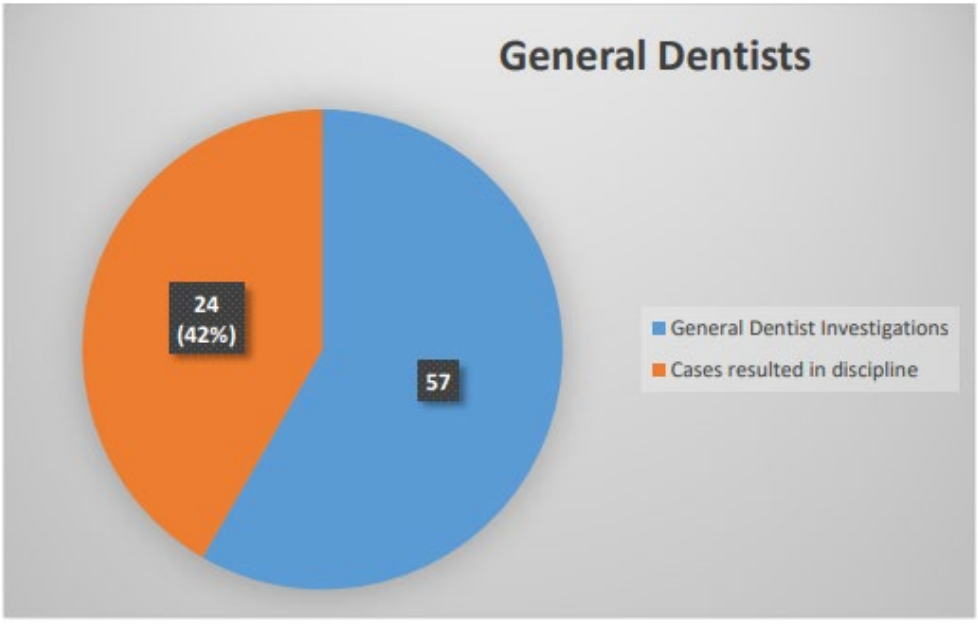
Appointed Licensees
Dr. Cyrus Javadi
Dr. Duy Anh Tran
Dr. Russell Lieblick
Dr. Donald Nimz

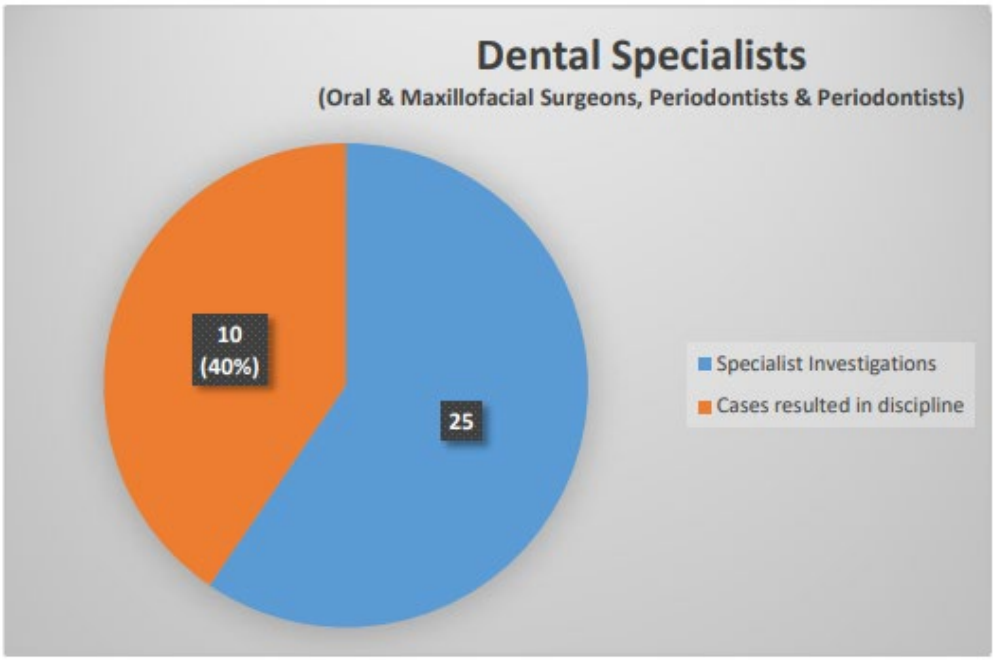
All Board, Committee and Workgroup meetings are noticed following the Secretary of States' rules and procedures. The OBD encourages feedback from the dental community on oral health care issues important to you. ■

General Information

The Oregon Board of Dentistry (OBD) between February 2014 and August 2017 investigated 82 dental implant cases. Of those 82 cases, 34 (41%) resulted in Disciplinary Action.




General Dentists
24
(42%)
57
General Dentist Investigations
Cases resulted in discipline


Dental Specialists
(Oral & Maxillofacial Surgeons, Periodontists & Periodontists)
10
(40%)
25
Specialist Investigations
Cases resulted in discipline

ADA CE Program ARTICLE 1

COVER STORY

Outcomes of implants and restorations placed in general dental practices

A retrospective study by the Practitioners Engaged in Applied Research and Learning (PEARL) Network

John D. Da Silva, DMD, MPH, ScM; Julie Kazimiroff, DDS, MS; Athena Papas, DMD, PhD; Frederick A. Curro, DMD, PhD; Van P. Thompson, DDS, PhD; Donald A. Vena, BS; Hongyu Wu, MPH; Damon Collie, MSHS; Ronald G. Craig, DMD, PhD; for the Practitioners Engaged in Applied Research and Learning (PEARL) Network Group

ABSTRACT

Objectives. The authors conducted a study to determine the types, outcomes, risk factors and esthetic assessment of implants and their restorations placed in the general practices of a practice-based research network.

Methods. All patients who visited network practices three to five years previously and underwent placement of an implant and restoration within the practice were invited to enroll. Practitioner-investigators (P-Is) recorded the status of the implant and restoration, characteristics of the implant site and restoration, presence of periimplant pathology and an esthetic assessment by the P-I and patient. The P-Is classified implants as failures if the original implant was missing or had been replaced, the implant was mobile or elicited pain on percussion, there was overt clinical or radiographic evidence of pathology or excessive bone loss (> 0.2 millimeter per year after an initial bone loss of 2 mm). They classified restorations as failures if they had been replaced or if there was abutment or restoration fracture.

Results. The authors enrolled 922 implants and patients from 87 practices, with a mean (standard deviation) follow-up of 4.2 (0.6) years. Of the 920 implants for which complete data records were available, 64 (7.0 percent) were classified as failures when excessive bone loss was excluded from the analysis. When excessive bone loss was included, 172 implants (18.7 percent) were classified as failures. According to the results of univariate analysis, a history of severe periodontitis, sites with preexisting inflammation or type IV bone, cases of immediate implant placement and placement in the incisor or canine region were associated with implant failure. According to the results of multivariate analysis, sites with preexisting inflammation (odds ratio [OR] = 2.17; 95 percent confidence interval [CI], 1.41-3.34]) or type IV bone (OR = 1.99; 95 percent CI, 1.12-3.55) were associated with a greater risk of implant failure. Of the 908 surviving implants, 20 (2.2 percent) had restorations replaced or judged as needing to be replaced. The majority of P-Is and patients were satisfied with the esthetic outcomes for both the implant and restoration.

Conclusions. These results suggest that implant survival and success rates in general dental practices may be lower than those reported in studies conducted in academic or specialty settings.

Practical Implications. The results of this study, generated in the private general practice setting, add to the evidence base to facilitate implant treatment planning.

Key Words. Implant therapy; implant treatment outcomes; practice-based research.
JADA 2014;145(7):704-713.

doi:10.14219/jada.2014.27

Deciding whether to perform endodontic therapy followed by placement of a post and core and restoration or to extract the tooth and replace it with an implant-supported restoration is a common situation encountered in general dental practices. However, few studies have been conducted in private general practices to help guide the clinician when making these decisions. Most studies pertaining to the outcome of endodontic or implant therapy have been performed in academic or specialty settings and usually have not included the restorative outcome. Therefore, the results of endodontic and implant treatment outcome studies conducted in academic or specialty settings may not be entirely applicable to situations

faced in general dental practices.

To address the need for outcome studies conducted in general practices, the Practitioners Engaged in Applied Research and Learning (PEARL) Network, a practice-based research network (PBRN) composed mainly of general dentists within the greater northeastern United States,[1] conducted two large but separate comparative retrospective outcome studies regarding primary endodontic and implant therapy. We conducted this study in patients visiting dental practices affiliated with the PEARL Network. The PEARL Network was one of three dental PBRNs established in 2005 with a seven-year grant from the National Institute of Dental and Craniofacial Research. Failure in both studies was determined from the patient's perspective (PEARL studies are patient centered) and included restorative failures. PEARL has reported on the three- to five-year outcomes of 1,312 primary endodontic and restorative procedures performed in PEARL practices. After a mean follow-up of 3.9 years, 3.3 percent of all primary endodontically treated teeth were extracted, 2.2 percent underwent re-treatment, 3.6 percent elicited pain on percussion and 10.6 percent exhibited periapical radiolucencies, for a combined failure rate of 19.1 percent.[2] An additional 13.9 percent of teeth experienced restorative failures.[3] These results are in stark contrast to the failure rate of less than 5 percent five years after endodontic therapy reported in academic studies[4,5] and in studies involving the use of insurance databases.[6]

As is the case with endodontic outcome studies, dental implant outcome studies have been conducted mainly by specialists in academic settings. Iqbal and Kim[7] conducted a systematic review and meta-analysis of 34 implant outcome studies and reported three- to five-year success rates in excess of 95 percent for single-unit implants. However, the results of this systematic review and meta-analysis are difficult to apply to general dental practices because these studies were conducted primarily in specialist or academic settings, were limited to implant survival, involved the use of varying definitions of implant success or failure, and did not include patient-centered outcomes or restorative outcomes.

To address the need for implant outcome studies conducted in private general dental practices, we evaluated the three- to five-year outcomes and risk factors associated with success or failure of implants and their restorations within the general dental practices of the PEARL Network. The intent of this study was to add to the evidence base to facilitate implant treatment planning decisions faced in general practices and was designed to parallel the aforementioned PEARL endodontic outcomes study. The hypothesis tested was that the three- to five-year survival rates, success rates or both of implants and their restorations placed in general private practices would be lower than those reported in studies conducted in specialist or academic settings. The specific aims of the study were to characterize the types of implants and implant-supported restorations placed within the PEARL Network; to determine the outcome of implants and their restorations, including factors associated with success and failure; and to assess the patient's and practitioner's perceptions of the esthetic outcome of both the implant and restoration.

METHODS

Study population and inclusion and exclusion criteria. The institutional review board at New York University School of Medicine, New York City, reviewed and approved the research protocol. All patients visiting participating PEARL practices for maintenance or recall appointments or for active dental care were eligible for enrollment if they had received an endosseous dental implant and restoration in the practice within the previous three to five years (calculated from the date of implant placement). The implant could be root-form or cylindrical in design and fabricated from commercially pure titanium or titanium alloy. The implant could have been placed surgically by the site practitioner-investigator (P-I), by another practitioner in the P-I's practice or by a specialist to whom the patient had been referred. However, the P-I must have restored the implant. In the case of multiple implant-supported restorations, we included the implant placed earliest within the three- to five-year period (that is, it became the index implant). Only adults 21 years or older and able to understand and sign a letter of informed consent were enrolled in the study.

Excluded from the study were mini implants that supported interim prostheses, zygomatic implants, implants placed solely for orthodontic anchorage or to support maxillofacial prostheses, press-fit implants and blade-form supraperiosteal or subperiosteal implants. We also excluded patients undergoing active orthodontic therapy.

Data recorded. The figure depicts the sequence of data collection. After recording demographic data, which included the patient's age and race and ethnicity, the P-I determined whether the index implant was present. If present, he or she performed a clinical examination to determine whether the implant was mobile, elicited pain on percussion, had been replaced and the reason for replacement (that is, peri-implantitis, implant fracture or other), or needed to be replaced. In addition, the P-I determined whether the peri-implant tissues exhibited inflammation, bleeding or suppuration. He or she also recorded whether the implant-supported restoration had been replaced or needed to be replaced and the reason for replacement (abutment fracture, abutment screw fracture, crown fracture or nonretentive restoration).

ABBREVIATION KEY. **CRA:** Clinical research associate. **PBRN:** Practice-based research network. **PEARL:** Practitioners Engaged in Applied Research and Learning. P-**I:** Practitioner-investigator.

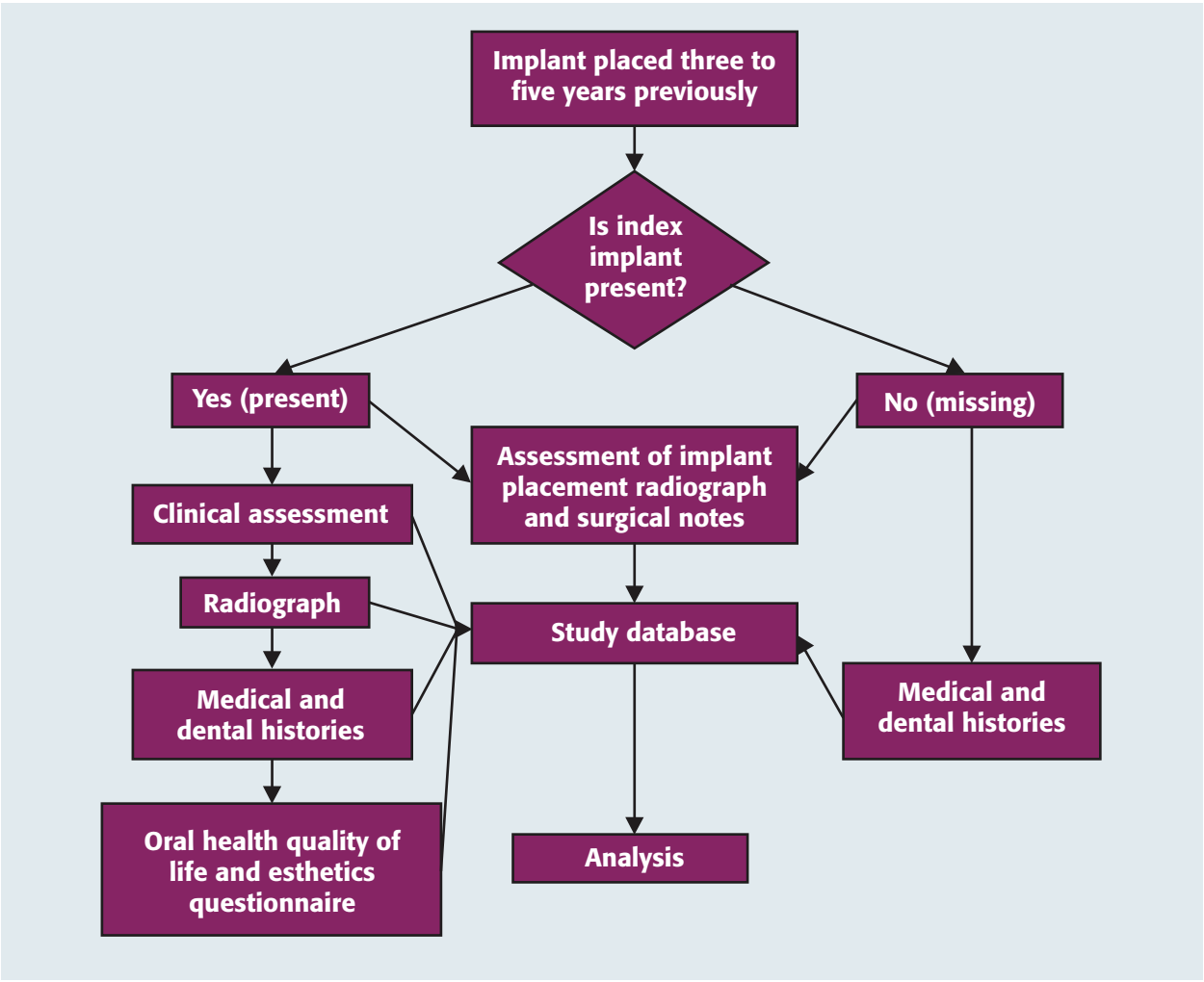


Figure. Data collection flowchart.

We asked the P-I to rank the overall esthetics of the implant by using a 5-point scale and to record any specific esthetic deficiencies of the peri-implant tissues with regard to color, presence of gingival inflammation, presence of interproximal tissues, root eminence or osseous contour. We also asked the P-I to rank the overall esthetics of the implant-supported restoration by using a 5-point scale and to record any specific esthetic deficiencies of the restoration with regard to size, contour, shape or translucency.

The P-I or a staff member obtained a periapical radiograph of the index implant, and the P-I recorded the presence of any radiographically visible pathology. Both the immediate postinsertion radiograph and the study enrollment radiograph were sent to the PEARL administrative center where two of us (F.A.C. and R.G.C.) measured radiographic bone loss independently by using the following formula:

bone loss (in millimeters) =
actual implant length (mm)/radiographic length (mm)
× radiographic bone loss (mm)

For all index implants, the P-I recorded the following: the site of implant placement; an assessment of bone quality by means of the criteria of Lekholm and Zarb;[8] whether a bone graft had been placed before implant placement; the use of antibiotics at the time of implant placement (including the type and duration of use); whether occlusal loading of the implant was conventional or delayed; whether the implant was placed immediately after tooth extraction or was delayed until the site had healed; whether the implant surgery was single stage or two stage; and who performed the implant surgery (the site P-I, another general dentist, a periodontist or an oral surgeon). He or she also recorded the implant design (cylindrical or root-form/tapered), implant

dimensions (height and width), surface characteristics, manufacturer, type of restoration and whether the restoration was cemented or screw retained.

The P-I recorded the following from the patient's medical and dental histories: smoking history (including whether he or she was a current or former smoker and cumulative pack-years); history of periodontitis and its severity; evidence of bruxism; history of diabetes (including type and glycemic control); diagnosis of osteoporosis and bisphosphonate use; and, for women, menopausal and hormone-replacement therapy status.

We asked each patient to complete a questionnaire independently of the P-I; he or she ranked both the peri-implant tissue and restoration esthetics by using a 5-point scale (1 = extremely satisfied, 5 = extremely dissatisfied).

All participating PEARL practices submitted data electronically to the PEARL Data Coordinating Center (The EMMES Corporation, Rockville, Md.) by using a proprietary data capture software program (AdvantageEDC, The EMMES Corporation). Source documents, worksheets and case report forms remained with the dental practice until the conclusion of the study. PEARL Network P-Is were trained and underwent calibration regarding all aspects of the study protocol by using a Web-based training module. Once online training was completed, a certified PEARL clinical research associate (CRA) visited the practice to initiate the study, review case report forms and ensure staff members' competency in using the AdvantageEDC software. CRAs also were available by telephone or e-mail to respond to questions regarding the protocol, to monitor sites for data quality assurance and to close out the study. Each practice also received a chairside reference guide that included questions regarding inclusion and exclusion criteria (to be checked off) and the sequence of data collection.

Statistical analysis. We enrolled one implant per participant; therefore, the unit of analysis was the patient, not the implant. The primary outcome variable was the presence or absence of the index implant and restoration. The following secondary dependent variables defined implant failure: the presence of bone loss in excess of 0.2 mm per year after an initial loss of 2.0 mm, presence of implant mobility or pain on percussion, or presence of overt clinical or radiographic peri-implant pathology. Secondary dependent variables that defined restoration failure were abutment fracture or restoration fracture.[9-11]

We used logistic regression to evaluate the relationship between the dependent variables and the following independent variables: the site of implant placement, bone quality, whether a bone graft had been placed, the use of antibiotics at the time of implant placement, whether the implant was placed immediately after tooth extraction or placement was delayed, the specialty status of the surgeon, implant design and dimensions, type of restoration and whether the restoration was cemented or screw retained. Additional independent variables in the regression analysis were the patient's sex, age, race and ethnicity, smoking history, medical status, history of periodontitis and bruxism.

We powered the study by assuming a 95 percent implant success rate to detect a doubling of risk associated with binary, relatively nonskewed covariates. Factors significant at the $P \leq .10$ level in the univariate setting were included in the multivariate model, with a backward elimination at $P \leq .05$ for variable selection.

RESULTS

Study population. From Sept. 8, 2010, to April 10, 2012, 922 patients were enrolled in the study from 87 sites (range, 1-125 participants per site) in 25 states. The mean (standard deviation [SD]) age of participants was 61.4 (12.2) years, of whom 396 (43.0 percent) were male and 526 (57.0 percent) were female. The ethnic composition of the study population was as follows: 45 were Hispanic (4.9 percent), 835 were not Hispanic (90.6 percent) and 42 (4.6 percent) were of unknown ethnicity. With regard to race, 773 of the patients (83.8 percent) were white, 80 (8.7 percent) were African American, two (0.2 percent) were Hawaiian or Pacific Islander, 50 (5.4 percent) were Asian, four (0.4 percent) were Native American and 13 (1.4 percent) were of unknown racial background.

Implant characteristics and outcome. The mean (SD) time from implant placement to study enrollment was 4.2 (0.6) years. The most common reason for implant placement was a fractured tooth (299 participants [32.6 percent]), followed by endodontic failure (230 participants [25.1 percent]), edentulous space of unknown cause (149 participants [16.2 percent]), advanced periodontitis (106 participants [11.6 percent]), advanced caries (98 participants [10.7 percent]), a site with a congenitally missing tooth (24 participants [2.6 percent]) and trauma (12 participants [1.3 percent]). Most implants (519 [56.5 percent]) were placed by the P-I, followed by 201 (21.9 percent) placed by a periodontist, 187 (20.4 percent) placed by an oral surgeon and 12 (1.3 percent) placed by another general dentist. Six hundred sixty-one implants (71.9 percent) were placed conventionally in edentulous sites, and 258 (28.1 percent) were placed immediately after tooth extraction.

The study results showed no differences in the frequency of implant placement in the maxillary or mandibular arch. However, on the basis of the site of tooth replacement, implants were placed most frequently in the mandibular molar region (30.1 percent), followed by the maxillary premolar area (21.2 percent), maxillary molar area (15.1 percent) and maxillary incisor area (13.3 percent). The least number of implants were placed in the mandibular canine (1.2 percent) and incisor (2.9 percent) regions. Practitioners prescribed antibiotics for 781 of 919 patients (85 percent) at implant placement; 15 of these patients (1.9 percent) received antibiotics only at

TABLE 1

Implants, manufacturers and surface modifications.

IMPLANT	SURFACE MODIFICATION	NO. OF IMPLANTS	PERCENTAGE OF IMPLANTS
Nobel Biocare, Zürich	Electrochemical oxidation	309	33.6
ITI Dental Implant System and Straumann SLA, Institut Straumann, Basel, Switzerland	Blasted, acid etched, plasma sprayed	166	18.1
Brånemark Integration, Göteborg, Sweden	Machined, acid washed	121	13.2
Zimmer Dental, Carlsbad, Calif.	Blasted, acid washed	92	10.0
Biomet 3*i*, Palm Beach Gardens, Fla.	Acid etched, electrochemical oxidation	73	7.9
Keystone, Burlington, Mass.	Acid etched, electrochemical oxidation	30	3.3
Astra Tech (now Dentsply), Mölndal, Sweden	Blasted, acid etched	15	1.6
BioHorizons, Birmingham, Ala.	Blasted, laser etched	13	1.4
Mega'gen, Gangnam-gu, Seoul, Korea	Blasted, acid etched	13	1.4
Bicon Dental Implants, Boston	Grit blasted, acid etched or electrochemical oxidation	9	1.0
Core-Vent (Paragon) (discontinued), Sulzer Medica, Zürich	Blasted	5	0.5
MIS Implant Technologies, Fair Lawn, N.J.	Sand blasted, acid etched	2	0.2
Steri-Oss (discontinued), Nobel Biocare	Acid etched, laser treatment	2	0.2
Other	Not applicable	69	7.5
TOTAL	Not applicable	**919**	**99.9***

* Percentage does not total 100 because of rounding; in addition, data for one implant were missing.

TABLE 2

Reasons for implant failure, with and without excessive bone loss.*

REASON FOR IMPLANT FAILURE	NO. (%) OF IMPLANTS	95% CONFIDENCE INTERVAL
Excessive Bone Loss Not Considered		
Missing	12 (1.3)	0.6-2.0
Replaced	8 (0.9)	0.3-1.5
Present but not in function	18 (2.0)	1.1-2.9
Peri-implantitis	9 (1.0)	0.3-1.6
Other	17 (1.8)	1.0-2.7
TOTAL	**64** (7.0)	5.3-8.6
Excessive Bone Loss Considered		
Missing	12 (1.3)	0.6-2.0
Replaced	8 (0.9)	0.3-1.5
Present but not in function	18 (2.0)	1.1-2.9
Peri-implantitis or excessive bone loss	127 (13.8)	11.6-16.0
Other	7 (0.8)	0.2-1.3
TOTAL	**172** (18.7)	16.2-21.2

* As defined by Albrektsson and colleagues.[11]

the time of surgery, 195 (25.0 percent) received antibiotics for five days after surgery and 571 (73.1 percent) received antibiotics for six to 14 days after surgery. Bone grafts had been placed in 283 of the implant placement sites (30.8 percent). At the time of placement, type III bone was the most common bone type present (38.3 percent), followed by type II bone (32.3 percent), type I bone (18.8 percent) and type IV bone (10.7 percent).

Table 1 presents the manufacturers and surface characteristics of the implants. A total of 673 (73.2 percent) root-form and 246 (26.8 percent) cylindrical-form implants from more than 24 implant manufacturers were placed. The most commonly placed implants were from Nobel Biocare (Zürich), followed by Institut Straumann (Basel, Switzerland), Brånemark Integration (Göteborg, Sweden), Zimmer Dental (Carlsbad, Calif.) and Biomet 3*i* (Palm Beach Gardens, Fla.).

Table 2 presents the number of implants that failed and the reasons for failure, analyzed both with and without bone loss in excess of Albrektsson and colleagues'[11] criteria for implant success. Of the 920 implants enrolled in the study for which we had complete data records, 64 (7.0 percent) were classified as failures when excessive bone loss was not considered in the analysis. When we included excessive bone loss in the analysis, 172 implants (18.7 percent) were classified as failures.

Table 3 presents the results of the univariate analysis of risk factors for implant failure, including evidence of excessive bone loss. Participants with a history of severe periodontitis, sites with preexisting inflammation or type IV bone, immediate versus delayed implant placement, and placement in an incisor or a canine region versus a premolar or molar region were associated with an increased risk of implant failure. We found that the following variables were not associated with implant failure: smoking, diabetes mellitus, nocturnal bruxism, postsurgical use of antibiotics, whether the implant supported a single-unit or multiunit restoration, and specialty status

of the implant surgeon.

The results of the multivariate analysis showed that preexisting inflammation or implants placed in type IV bone significantly increased the risk of failure. The odds ratio for implant failure at sites with preexisting chronic inflammation (that is, sites with root canal failure, fractured roots or advanced periodontitis versus sites with congenitally missing teeth, acute trauma or coronal caries) was 2.17 (95 percent confidence interval [CI], 1.41-3.34). The odds ratio for failure of implants placed in type IV bone was 1.99 (95 percent CI, 1.12-3.55).

TABLE 3

Univariate analysis of risk factors for implant failure.

RISK FACTOR	ODDS RATIO	95% CONFIDENCE INTERVAL	*P* VALUE	OVERALL *P* VALUE
Smoking Status				.96
Current	1.00			
Former	0.91	0.48-1.73	.78	
Never	0.93	0.51-1.70	.81	
Diabetes Mellitus				.93
No	1.00			
Yes	1.03	0.57-1.85		
History and Severity of Periodontitis				.17
None	1.00			
Mild	1.13	0.70-1.82	.62	
Moderate	1.05	0.69-1.61	.81	
Severe	2.09	1.09-3.99	.03	
Sleep Bruxism				.40
No	1.00			
Yes	0.84	0.56-1.26	.40	
Implant Site With Preexisting Inflammation*†				.0001
No	1.00			
Yes	2.29	1.49-3.51	.0001	
Assessment of Bone Quality*				.01
Type I	1.00			
Type II	0.81	0.49-1.32	.39	
Type III	0.92	0.57-1.48	.73	
Type IV†	2.12	1.20-3.75	.01	
Clinician Performing Implant Surgery				.23
Oral surgeon	1.00			
General dentist	1.19	0.77-1.83	.43	
Periodontist	0.82	0.48-1.41	.47	
Antibiotic Used After Surgery				.87
Yes	1.00			
No	1.04	0.65-1.65	.87	
Implant Placement*				.04
Conventional	1.00			
Immediate	1.45	1.02-2.07	.039	
Site of Implant Placement*				.04
Molar	1.00			
Premolar	1.15	0.78-1.70	.47	
Incisor or canine	1.71	1.13-2.60	.01	
Index Implant Supports				.69
Single-unit restoration	1.00			
Multiunit restoration	1.09	0.71-1.70	.69	

* Included in the multivariate logistic regression analysis.
† Variable found to be associated with implant failure in multivariate analysis.

Restoration characteristics and outcome. Most implants (838 of 919 [91.2 percent]) were loaded conventionally, 63 (6.9 percent) received immediate occlusal loading and 18 (2.0 percent) received early occlusal loading. The mean (SD) time from implant placement to restoration loading was 166.1 (114.8) days. Seven hundred sixty-eight implants (83.6 percent) supported a single-unit restoration. (After the first 263 implants were enrolled, the eligibility criteria were amended to allow multiunit implants.) Of the remaining 151 implants, 75 (49.7 percent) supported two-unit restorations; 27 (17.9 percent) supported three-unit restorations; 28 (18.5 percent) supported four-unit restorations; six (4.0 percent) supported five-unit restorations; eight (5.3 percent) supported six-unit restorations; five (3.3 percent) supported seven-unit restorations; and two (1.3 percent) supported eight-unit restorations. Most restorations (852 [93.1 percent]) were cement retained, and 63 (6.9 percent) were screw retained (data were missing for five implants). Eight hundred fifty-three restorations (93.2 percent) were porcelain fused to metal, 53 (5.8 percent) were porcelain and ceramic and nine (1.0 percent) were metal and acrylic. Of the 908 surviving implants, 20 (2.2 percent) had restorations that had been replaced or were judged as needing to be replaced, for an implant restoration survival rate of 97.8 percent.

TABLE 4

Participant and practitioner-investigator assessments of implant and restoration esthetics.

RESPONSE	PERI-IMPLANT TISSUE APPEARANCE		RESTORATION APPEARANCE	
	No. of Respondents	Percentage of Respondents	No. of Respondents	Percentage of Respondents
Participant				
1. Extremely satisfied	507	58.3	573	66.0
2. Satisfied	271	31.2	243	28.0
3. Neutral opinion	54	6.2	31	3.6
4. Dissatisfied	24	2.8	11	1.3
5. Extremely dissatisfied	13	1.5	10	1.2
TOTAL	**869**	**100**	**868**	**100.1***
Practitioner-Investigator				
1. No deficiencies	765	84.3	757	83.4
2. Very minor deficiencies	112	12.3	124	13.7
3. Mild deficiencies	25	2.8	22	2.4
4. Moderate deficiencies	5	0.6	4	0.4
5. Major deficiencies	1	0.1	1	0.1
TOTAL	**908**	**100.1***	**908**	**100**

* Percentage does not total 100 because of rounding; in addition, data were missing for some participants.

Esthetic assessment of implant and restoration. Both the participant and P-I responded independently to a questionnaire about the esthetic outcome of the implant and restoration. As shown in Table 4, the majority of participants reported being "extremely satisfied" or "satisfied" with the esthetics of the peri-implant tissue and the restoration. P-Is assessed the esthetics of the implant and surrounding periodontal tissues and of the restoration by using a 5-point scale that ranged from "no deficiencies" to "major deficiencies." The majority of P-Is reported either "no deficiencies" or "very minor deficiencies" for peri-implant tissues and the restoration. P-Is also reported specific perceived deficiencies in the implant and restoration esthetics. The presence of gingival inflammation, loss of the interproximal papilla and gingival recession were the implant deficiencies recorded most frequently. Concerns regarding the restoration contour were the most frequently recorded deficiency for implant-supported restorations.

DISCUSSION

The objective of this study was to determine the three- to five-year success and survival rates for implants and their restorations placed in a dental PBRN and to compare these results with those reported for implant outcome studies conducted in specialty or academic settings. We should point out the primary outcome in our study was the presence or absence of the implant or restoration as a measure of implant or restoration survival. Secondary outcomes—pain on percussion, implant mobility, implant nonfunction, presence of clinical or radiographic evidence of overt peri-implant pathology with and without excessive crestal bone loss—as defined by Albrektsson and colleagues[11] were intended to be measures of implant success. We felt that the stringent criteria used in this study to define success would be of major interest to clinicians for use during treatment planning. We also should note that we analyzed only one implant per participant to avoid the effect of clustered implant failures in a single participant, which occurs frequently when several implants are assessed per participant.[12]

After a mean time to follow-up of 4.2 years and with excessive bone loss excluded, we found that 64 of 920 implants for which we had complete data records were failures, for a 93.0 percent success rate. Twenty of the 920 implants were missing or had been replaced, for a 97.8 percent survival rate. When we included excessive bone loss in the analysis, the results showed that 172 implants were failures, for an 81.3 percent success rate. We acknowledge that some of the implants with excessive bone loss or with peri-implant pathology may represent failing or ailing implants amenable to treatment, and researchers have questioned the use of bone levels as a criterion for success.[13] Nonetheless, success rates in this study are lower than those reported generally in implant outcome studies conducted in specialist or academic settings.

One of the most comprehensive analyses of implant survival is a systematic review and meta-analysis conducted to determine whether differences in outcomes existed between restored endodontically treated teeth and single-unit implant-supported restorations.[7] Inclusion criteria for single-unit implants included the following: reports of trials with greater than 10 units published between 1981 and 2005; a follow-up period of more than one year; and both the manufacturer's implant system used and number of participants stated clearly. The researchers included 55 studies in the implant group, with 99 to 1,007 implants per study and a mean follow-up of five years.

At the three-year follow-up, the study results showed a 95.7 percent survival rate (95 percent CI, 94.4-97.0) for the implant group.[7] At five years' follow-up, the researchers found a 95.8 percent survival rate (95 percent CI, 94.4-97.2) in the implant group. If all studies had been

examined for survival rates at the last follow-up examination, the 55 implant studies (follow-up range, 12 to 144 months) would have had a survival rate of 96.0 percent (95 percent CI, 95.2-96.8).[7]

Investigators in a second systematic review and meta-analysis compared the outcomes of primary endodontic therapy, tooth extraction and replacement with a single-unit implant-supported restoration or three-unit fixed partial dental prostheses.[5] They included 46 reports regarding implant outcomes published between 1966 and 2006 with a minimum of two years' follow-up. The investigators defined implant success as being present and in function without overt pathology and reported it separately from implant survival, which they defined as being present at follow-up. At four to six years' follow-up, single-unit implants had a 97 percent success rate (95 percent CI, 96-98) and a 97 percent survival rate (95 percent CI, 95-98).[5]

Authors of a 2012 review of prospective and retrospective outcome studies compared implant- and tooth-supported fixed partial dental prostheses and single-unit crowns for which follow-up was at least five years.[14] They reported a 94.5 percent survival rate (95 percent CI, 92.0-96.2) for 465 implant-supported single-unit crowns from 12 studies and a 95.2 percent survival rate (95 percent CI, 92.7-96.8) for 1,384 fixed dental prostheses from 17 studies.[14] The survival rate for implants was high in these studies; however, the results of our study suggest that success rates in general dental practices were lower than those reported in studies conducted primarily in specialist and academic settings.

The results of our univariate analysis showed that several factors were associated with implant failure, including severe periodontitis, sites with preexisting inflammation or type IV quality bone, immediate implant placement and placement into incisor or canine regions versus molar or premolar regions (Table 3). Investigators in several implant outcome studies reported that previous or present periodontitis was associated with an increased risk of implant failure,[15-19] a risk that can be decreased with successful periodontal treatment and maintenance therapy.[20] Although only 28 percent of the implants in our study were placed immediately after tooth extraction, immediate placement was associated with an increased risk of failure. In contrast, researchers in other studies did not report different outcomes for immediate and delayed implant placement.[21-24] However, in one systemic review and meta-analysis, Quirynen and colleagues[25] questioned whether sufficient well-designed outcome studies existed to answer this question.

The anatomical site of implant placement has been associated with implant failure. In a case series of 1,387 implants supporting single-unit crowns, Levin and colleagues[26] reported the highest rate of survival (96.2 percent) at follow-up of up to six years in the maxillary premolar region. Alsaadi and colleagues[27] conducted a retrospective analysis of 1,514 implants in 412 participants, the results of which showed that more failures occurred in the maxilla than in the mandible and more occurred in the posterior maxilla than in any other sextant.

After the multivariate analysis in our study, only sites with preexisting inflammation or type IV quality bone versus type I quality bone were a risk factor for implant failure. Alsaadi and colleagues[28] questioned whether implants should be placed in sites with inflammation due to root canal failure, fractured roots or advanced periodontitis, and the results of our study suggest an increased risk of failure in such sites. However, several investigators suggested that implants can be placed in sites with periapical pathology without a decrease in survival rates compared with those for implants placed in sites without periapical pathology[22,29]; this might suggest the presence of a subtle procedure-dependent variable such as the degree of site debridement before implant placement.

Implants placed in sites with type IV quality bone have been reported to be at an increased risk of implant failure,[27,30,31] a finding confirmed by the results of our study. Type IV bone consists of minimal cortical and trabecular bone, factors that can compromise initial implant stability and long-term bone-to-implant contact, thus increasing the risk of implant failure.[8,21,30]

Most implants (83.6 percent) in our study supported single-unit restorations, and most (93.1 percent) were cement retained. In addition, most restorations (93.2 percent) were porcelain fused to metal. Of the surviving 908 implants, 20 had implant-supported restorations that had been replaced or were judged as needing to be replaced, for a 2.2 percent failure rate. These results compare favorably with results of a systematic review and meta-analysis, which showed an estimated five-year survival rate of 94.5 percent (95 percent CI, 91.8-96.3) for 465 implant-supported single-unit crowns from 12 studies.[32]

Implant therapy has become accepted as a predictable treatment option for the replacement of missing teeth. As a consequence, the focus of research has shifted from function and long-term survival outcomes to an increasing interest in esthetic outcomes, including patient-centered outcomes.[13,33,34] Accordingly, we included a questionnaire to assess the perceived esthetic outcome of both implant and restoration. As presented in Table 4, both P-Is and participants reported a high degree of satisfaction with the implants and restorations. Of note, participants reported being "satisfied" or "extremely satisfied" with both the implant (89.5 percent) and restoration (94.0 percent), while P-Is reported either "no deficiencies" or "very minor deficiencies" for both the implant (96.6 percent) and restoration (97.1 percent).

One should consider several limitations when analyzing the results of this study. We enrolled patients of PEARL Network practices, a PBRN whose members

(that is, P-Is) are screened before membership to ensure that they have no license limitations to practice. In addition, most P-Is are located in the northeastern United States. Most of these dentists have established practices in suburban communities with patient populations reflective of the ethnic and racial composition of those communities. Therefore, the results of this study may not reflect the United States population at large.

In addition, the retrospective design of the study resulted in recruitment of participants who received implant therapy three to five years previously. It is possible that patients who were not satisfied with the care received left the practices and those who remained were satisfied with the care, which could be a potential source of bias. In that event, our results may underestimate negative implant and restorative outcomes. Also, because of the sample size, our study was not designed to determine differences in success rates between different implant manufacturers and implant surface characteristics; rather, our objective was to provide an estimate of implant outcomes in private general practices and patient-associated risk factors.

Finally, when evaluating the results of retrospective studies involving the use of patient records data, we should keep in mind that the types, extent and quality of clinical data entered into patients' records were not standardized because the procedures performed predated the study. To deal with this challenge, we developed the data entry items in collaboration with the PEARL executive committee, a group of general practitioners whose responsibilities include study development. This ensured that the items requested from P-Is and patients conformed to those usually recorded in private practice. In addition, data entered by means of the AdvantageEDC software were screened for inconsistent entries, and PEARL CRAs followed up with the practices regarding the resulting queries. A measure of the effectiveness of this strategy is that we had complete records for 920 of the 922 patients enrolled in the study.

CONCLUSIONS

We conducted a retrospective study of the three- to five-year outcomes of 922 implants and their restorations in 87 practices of the PEARL Network. Of the 920 implants for which we had complete data records, 64 (7.0 percent) were classified as failures when excessive bone loss was excluded. When excessive bone loss was included, 172 (18.7 percent) were classified as failures. Of the surviving 908 implants, 20 had restorations that had been replaced or were judged as needing replacement, for a 2.2 percent failure rate. According to the results of multivariate analysis, sites with preexisting inflammation (OR = 2.17; 95 percent CI, 1.42-3.34) or type IV bone (OR = 1.99; 95 percent CI, 1.12-3.55) were at greater risk of implant failure. The majority of P-Is and patients were satisfied with the esthetic outcomes for both the implant and restoration. These results suggest that implant success rates in general practices may be lower than those reported in studies conducted in academic or specialist settings. ■

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