

# **The National Dental Practice-Based Research Network Dental Implant Restoration Registry: A Protocol for a Prospective Observational Study of Dental Implant Outcomes in Community Practice Settings**

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# The National Dental Practice-Based Research Network Dental Implant Restoration Registry: A Protocol for a Prospective Observational Study of Dental Implant Outcomes in Community Practice Settings

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## Abstract

**Background:** Dental implants are a widely used therapeutic option for tooth replacement; however, biological and prosthetic complications may compromise implant success. While prior research has largely focused on academic or specialty settings, data on implant outcomes in community dental practices remain limited.

**Objective:** This study aims to establish a national registry within the National Dental Practice-Based Research Network (PBRN) to evaluate the incidence and factors associated with biological and prosthetic complications following implant therapy in community practice settings.

**Methods:** This prospective, observational cohort study will enroll approximately 1550 patients receiving implant restorations from 150 practitioners across six regional PBRN nodes. A total of 2,000 implant restorations will be longitudinally monitored over three years. Clinical, implant, and prosthetic characteristics will be recorded at baseline, with annual follow-up visits collecting data on complications, implant failures, prosthetic issues, and patient-reported outcomes. Digital radiographs will be centrally reviewed for peri-implant bone changes, emergence angle, and prosthetic fit. The primary outcome is the incidence of biological and prosthetic complications. Secondary analyses will evaluate patient-centered outcomes and identify risk factors for complications. Advanced statistical models, including multilevel mixed-effects regression and time-to-event analyses, will be employed to account for clustering and censored data.

**Conclusions:** This registry will generate robust, real-world evidence on implant-related complications and their predictors in community practice. The findings will enhance clinical decision-making, support personalized risk assessment, and ultimately improve patient outcomes in implant dentistry.

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## Original Manuscript

## The National Dental Practice-Based Research Network Dental Implant Restoration Registry: A Protocol for a Prospective Observational Study of Dental Implant Outcomes in Community Practice Settings

*Short title:* Dental Implant Restoration Registry Protocol

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## Abstract

**Background:** Dental implants are a widely used therapeutic option for tooth replacement; however, biological and prosthetic complications may compromise implant success. While prior research has largely focused on academic or specialty settings, data on implant outcomes in community dental practices remain limited.

**Objective:** This study aims to establish a national registry within the National Dental Practice-Based Research Network (PBRN) to evaluate the incidence and factors associated with biological and prosthetic complications following implant therapy in community practice settings.

**Methods:** This prospective, observational cohort study will enroll approximately 1550 patients receiving implant restorations from 150 practitioners across six regional PBRN nodes. A total of 2,000 implant restorations will be longitudinally monitored over three years. Clinical, implant, and prosthetic characteristics will be recorded at baseline, with annual follow-up visits collecting data on complications, implant failures, prosthetic issues, and patient-reported outcomes. Digital radiographs will be centrally reviewed for peri-implant bone changes, emergence angle, and prosthetic fit. The primary outcome is the incidence of biological and prosthetic complications. Secondary analyses will evaluate patient-centered outcomes and identify risk factors for complications. Advanced statistical models, including multilevel mixed-effects regression and time-to-event analyses, will be employed to account for clustering and censored data.

**Conclusions:** This registry will generate robust, real-world evidence on implant-related complications and their predictors in community practice. The findings will enhance clinical decision-making, support personalized risk assessment, and ultimately improve patient outcomes in implant dentistry.

## Keywords (MeSH terms)

Dental Implants; Dental Prosthesis; Dentures, Implant-Supported; Oral Health; Prospective Studies

## Introduction

Dental implants have become a standard treatment modality for rehabilitating partially and fully edentulous patients worldwide. The global dental implant market, valued at approximately \$9 billion in 2025 with an estimated 5 million implants placed annually, is projected to experience steady growth due to rising patient demand and advances in implant technologies [1]. While dental implants have demonstrated long-term success in many cases, they are not free from complications associated with various factors, including treatment planning, patient-related issues, surgical and prosthetic execution, material failure, and lack of maintenance [2-5].

The longitudinal survival rates of osseointegrated dental implants range between 90-96.2% after 5 years [2-5]. However, these figures may not fully capture the rates of peri-implant disease and health. Biological and prosthetic complications can interfere with the health of the peri-implant tissues and the function and aesthetics of implant restorations [6]. Peri-implant diseases are classified into peri-implant mucositis (inflammation restricted to the peri-implant mucosa) and peri-implantitis (characterized by peri-implant bone loss). The prevalence of peri-implant mucositis and peri-implantitis varies widely, with reported ranges of 19–65% and 1–47%, respectively, and meta-analyses estimating weighted mean prevalences of 43%-63% for mucositis and 22%-25% for peri-implantitis [7-12]. Prosthetic complications, such as screw loosening, fractures, chipping, and decementation, pose significant clinical challenges in implant dentistry. Their prevalence ranges from 10% to 16% during mid-term follow-up, influenced by prosthetic design and materials [13-15].

The current body of literature on biologic and prosthetic complications is limited by small studies primarily conducted in European academic and specialty settings [4, 16, 17]. Many of these studies have been retrospective and may not accurately represent community practice settings. The National Dental Practice-Based Research Network (PBRN) Dental Implant Restoration Registry aims to address these knowledge gaps by creating an implant registry to record implant and prosthetic procedures and characteristics and any complications in community practice settings. The primary objective of this study is to quantify the incidence of biological and prosthetic complications in dental implants over a 3-year period. Secondary objectives are to assess risk factors associated with implant complications, develop a risk assessment tool for implant complications, and evaluate patient-reported outcomes related to implant therapy.

## Methods

### Study design and setting

This study is a prospective, observational cohort designed to evaluate outcomes of dental implant restorations over a three-year follow-up period in community practice settings. It will be conducted across approximately 150 dental practices across the United States. Eligible practitioners, who are members of the National Dental Practice-Based Research Network (PBRN) from all six Regional Nodes and provide dental implant restorative therapy, will be invited to participate. The study protocol has been reviewed by the Network's Practitioner Executive Committee. The funding agency and the IRB also reviewed and approved the protocol (version 6 November 11, 2024). This study protocol is reported following the reporting guidelines for protocols and for observational studies [18, 19].

The National Dental PBRN is a collaborative, nationwide initiative funded by the National Institute of Dental and Craniofacial Research (NIDCR) that engages dental practitioners from a broad range of community settings across the United States in conducting clinical research relevant to routine dental care [20, 21]. The Network integrates academic researchers with everyday clinical practitioners to accelerate the translation of research findings into real-world dental practice, improve oral health care, and generate robust, practice-relevant evidence.

### Study population

Participants inclusion criteria are patients with planned receipt of dental implant restoration(s) from a participating practice, age 18 or 19 years or older (depending on the regional node), and available for the duration of the study. Exclusion criteria include inability to comply with study procedures or provide informed consent. Each enrolled patient can contribute more than one implant if multiple implants will be restored at the baseline visit.

### Recruitment and retention

Practitioners will recruit and enroll their patients during the prosthetic phase of implant therapy. The Network's Regional Coordinators will assist practitioners in implementing the study protocol and monitoring recruitment progress. Strategies to enhance recruitment include regular communication with participating practitioners, provision of recruitment materials, offering continuing education credits for study participation, and periodic recruitment progress reports to motivate practitioners. Patient retention will be promoted through reminder emails or text messages for follow-up visits and surveys, and flexible scheduling of follow-up visits. A modest payment incentive will be provided to participants for their involvement in the study.

### Study Schedule of Assessments

The study timeline includes a baseline visit (prosthesis insertion) for enrollment, consent, and baseline data collection, followed by annual follow-up visits at 1, 2, and 3 years ( $\pm 30$  days to  $+150$  days from target date).

### Data collection procedures and variables

All study data will be collected electronically using secure, web-based forms accessible via tablets, smartphones, or computers. Practitioners will enter clinical examination and procedural data through electronic case report forms (CRFs) at baseline and during each annual follow-up visit. Radiographs taken as part of routine clinical care at baseline (prosthesis placement) and at each follow-up visit will be uploaded by practitioners to a secure centralized electronic repository. Separately, enrolled participants will complete electronic surveys following the baseline visit and at each annual follow-

up interval.

### Patient-Completed Surveys

Participants will provide self-reported demographic data, including age, sex, race, ethnicity, insurance type, education level, household income, and residential environment. They will also report on general health status and behaviors, including medical conditions, allergies, medication use, and tobacco product usage (cigarettes, cigars, smokeless tobacco, and electronic nicotine delivery systems). Oral health-related data will include measures of oral health-related quality of life (OHRQoL) and symptoms of dry mouth.

OHRQoL will be assessed using 10 items with responses on a 4-point Likert scale (“Never,” “Sometimes,” “Always,” and “Not sure”). Items will query functional limitations (e.g., restrictions in eating and difficulty with chewing or speaking), pain or discomfort during eating or oral hygiene, medication use for dental pain, social impacts, and satisfaction with dental appearance and implant-supported prostheses. Dry mouth symptoms will be assessed with four questions covering frequency of dry mouth diagnosis, difficulty swallowing, oral dryness during meals, and burning tongue sensations.

At each annual follow-up, participants will update their health status, medication and tobacco use, and will re-complete the OHRQoL questions.

### Practitioner-Completed Clinical Research Forms

Practitioners will complete standardized electronic CRFs at baseline and each follow-up visit to capture comprehensive patient, implant, and prosthesis-level data.

- *Patient-level clinical data:* At baseline, practitioners will assess and record the participant’s overall oral health, detailed periodontal status (health, gingivitis, periodontitis stage and progression) around natural teeth, the presence and extent of peri-implant disease in existing implants, routine dental maintenance history (frequency of maintenance visits in the prior 12 months), and parafunctional habits (e.g., bruxism, occlusal guard use).

- *Implant-level characteristics:* For each study implant, practitioners will document the reason for tooth loss at the implant site, implant brand, length and diameter, timing of placement in relation to extraction, results of bone and soft tissue grafting, and any early healing complications.

- *Peri-implant mucosal characteristics:* Practitioners will document their assessments of peri-implant soft tissue (bleeding on probing, presence of purulence, deepest probing depth and location, mucosal recession and its extent, width of keratinized mucosa), patient-reported pain at the implant site (with pain characteristics), and radiographic evaluation of bone levels.

- *Prosthetic characteristics:* Data will be captured on prosthetic connection type, temporary prosthesis use and timing, final prosthesis type (fixed or removable), retention method, material, occlusal scheme, classification of opposing dentition, number of units and pontics, cantilever presence, abutment and cement types, seating and fit, and the presence and location of open contacts.

At each follow-up, CRFs will be used to record changes in periodontal and peri-implant status, occurrences of peri-implant disease or other complications, updates on implant survival (removal and reason), patient-reported pain, and radiographic bone loss. Practitioners will also document any biologic or prosthetic complications (e.g., screw loosening or fracture, prosthesis or abutment misfit, loss of retention, chipping or fracture of restorative materials, cement remnants, and adverse events) as well as management procedures and outcomes.

### Radiographic Measurement for the Assessment of Bone Level and Prosthetic Fit

Radiographs obtained at baseline (prosthetic placement) and at annual follow-up visits (1, 2, and 3

years) will be used to quantify peri-implant bone levels and evaluate the fit of implant-supported prostheses. Calibrated evaluators will measure bone levels and prosthetic fit using NIH ImageJ software [22] following a standardized protocol, with annotated images and measurements securely saved and uploaded to the study database.

Alveolar bone levels will be measured at the mesial and distal surfaces of each study implant as the linear distance from the implant platform to the most coronal bone-implant contact visible on the radiograph. Since images will originate from different clinical systems with varying resolutions, measurements will be recorded in pixels initially and converted to millimeters using implant-specific geometry parameters (implant length or diameter) to standardize measurements across images.

Radiographs will also be examined for gaps at the implant–abutment and abutment–prosthesis interfaces, with fit discrepancies recorded as a dichotomous variable. The emergence angle will be measured mesially and distally, using the implant platform as the vertex and lines drawn along the implant’s long axis and the gingival contour of the abutment or prosthesis, to assess prosthetic design and potential biomechanical risk factors.

### **Data management and monitoring**

All data will be entered directly into the electronic data capture system, which includes built-in quality control checks. All radiographs will be anonymized and reviewed centrally for quality assurance. Two independent and calibrated evaluators, blinded to clinical data and each other’s measurements, will perform radiographic measurements. Discrepancies exceeding predefined thresholds will prompt involvement of a third adjudicator, who will conduct an independent assessment. All measurement data and marked images will be stored in a centralized repository.

Data will be encrypted for transmission to the coordinating center and stored on password-protected computers. Unique study codes will be used for participants to maintain confidentiality. The data management team will perform regular data quality checks and generate reports on missing data, inconsistencies, and protocol deviations. Research coordinators will support practitioners in resolving data inconsistencies and minimizing missing data whenever possible.

The study team will implement a clinical site monitoring plan to ensure the quality and integrity of the data collected. The monitoring strategy will include both remote and on-site monitoring, regular quality control assessments, and ongoing monitoring of protocol adherence. These procedures will maintain high standards of data quality and ensure that study conduct is compliant with all applicable human subjects research and regulatory requirements.

Although the study is observational, participant safety will remain a priority. Safety monitoring will focus on unanticipated problems involving risks to participants, including unanticipated problems that meet the definition of a serious adverse event. All reported events will be followed by the study team until resolution or stabilization. The Principal Investigator will be responsible for overall study oversight, including monitoring and assessment of adverse events and unanticipated problems, and ensuring data integrity and adherence to the approved study protocol.

### **Dissemination and data sharing**

Results from this study will be disseminated through multiple channels, including publication in peer-reviewed scientific journals, presentation at national and international dental conferences, dissemination to Network practitioners through newsletters and webinars, and public release of findings through press releases and the Network website. Authorship will be determined according to the International Committee of Medical Journal Editors (ICMJE) guidelines. The Network acknowledges the efforts of all participating practitioners by listing them as a group author in primary publications. De-identified participant-level data and statistical code will be made available after the publication of primary study results in the PBRN’s website, consistent with NIH policy [23].

## Statistical Considerations

### Sample size

Approximately 1550 patients will be enrolled to achieve a sample of 2000 implants. This sample size was determined based on anticipated complication rates of 10-15% over 3 years, the desire to detect differences in complication rates as small as 5% between groups, accounting for clustering of implant restorations within patients and practitioners, and allowing for up to 20% loss to follow-up. The sample size provides 80% power to detect clinically meaningful differences in complication rates between subgroups, with a two-sided alpha of 0.05.

### Statistical analysis plan

The study's primary outcomes will be the incidence of biologic and prosthetic complications occurring over the three-year follow-up period. *Biologic complications* will be defined according to the following criteria:

- *Peri-implant mucositis*: Presence of bleeding on probing (BoP) and/or purulent exudate around the implant without concomitant radiographic bone loss.
- *Peri-implantitis*: Radiographic peri-implant bone loss will be calculated by comparing the bone level at each annual follow-up to the baseline measurement, with bone loss defined as a negative change in millimeters.
- *Implant failure*: Documented implant loss or planned removal, as reported by practitioners during follow-up.

*Prosthetic complications* will include any event compromising the esthetics or function of the implant restoration. These complications encompass screw loosening or fracture, structural fractures, resin or porcelain fractures, loss of retention, abutment or implant misfit, and other adverse prosthetic events captured via practitioner-completed data forms.

*Patient-centered outcomes* are critical components in evaluating the overall success of dental treatments. Secondary outcomes will include patient-reported measures of satisfaction with implant esthetics and function, as well as OHRQoL.

Descriptive statistics will be presented to summarize baseline characteristics and outcome variables. A study flow diagram will illustrate the number of participants at each stage of the study, including reasons for exclusion, loss to follow-up, and other participant dispositions following reporting guidelines [18, 19]. Incidence and prevalence rates of biologic and prosthetic complications will be estimated per implant and per year of follow-up. The primary analysis will use multilevel mixed-effects models to account for clustering of implant restorations within patients and practitioners. Time-to-event analyses will be conducted for complication-free survival. Multivariable regression models incorporating patient characteristics, implant-specific factors, prosthetic details, and behavioral variables will be estimated to identify predictors of biologic and prosthetic complications. Subgroup analyses will explore effect modification by implant and prosthesis type and patient demographics. Missing data will be handled using multiple imputation techniques. Sensitivity analyses will be conducted to assess the impact of missing data and loss to follow-up on the study conclusions.

### Ethical Considerations

The study will be conducted in accordance with the International Conference on Harmonisation guidelines, the Code of Federal Regulations on the Protection of Human Subjects (45 CFR Part 46), and the NIDCR Clinical Terms of Award. Institutional Review Board approval will be obtained from the National Dental PBRN Central IRB at the University of Alabama at Birmingham, with local context review by the local IRBs from each regional node. Any modifications to the protocol that

may impact the conduct of the study or patient safety will be submitted for IRB approval before implementation. Protocol amendments will be communicated to all participating sites and investigators.

Informed consent will be obtained verbally at the prosthetic placement visit by trained personnel who have completed study protocol and human subjects research training. The consent process will include a thorough explanation of the study procedures, risks, and benefits and will be documented in the electronic data capture system. Patients will have the opportunity to ask questions before providing consent. Participant confidentiality will be maintained through the use of unique study codes, data encryption, and password-protected storage. Access to identifiable information will be restricted to authorized study personnel on a need to know basis. The principal investigator and study statisticians will have access to the final dataset. Other investigators may request access to de-identified data after the completion of the primary analyses.

All investigators will disclose any potential conflicts of interest related to the study. These will be reviewed by the institutional conflict of interest committee and managed appropriately.

## Discussion

This study protocol describes a large-scale, prospective observational study of dental implant complications in community practice settings. By leveraging the National Dental Practice-Based Research Network, this study will provide valuable real-world data on the incidence and risk factors of biological and prosthetic complications associated with dental implants.

The strengths of this study include its prospective design, large sample size, and diverse patient population from community practices across the United States. These factors will enhance the generalizability of the findings and provide a more accurate representation of implant outcomes in real-world settings compared to previous studies conducted in academic or specialty clinics. Limitations of the study include its observational nature, which precludes causal inferences, and the potential for variability in clinical practices among participating dentists. However, this variability also reflects the reality of community-based dental care and enhances the external validity of the findings.

The results of this study have the potential to significantly impact clinical practice by informing evidence-based recommendations for implant therapy, risk assessment, and complication prevention. The establishment of a national implant registry will create opportunities for future targeted studies on specific complications identified through this research. This study protocol outlines a comprehensive approach to addressing the current knowledge gaps in dental implant and prosthetic outcomes in dental practice settings. The findings will contribute to improved patient care and inform clinical decision-making in implant dentistry.

## Acknowledgements

Opinions and assertions contained herein are those of the authors and are not to be construed as necessarily representing the views of the respective organizations or the National Institutes of Health. An Internet site devoted to the network is located at <http://NationalDentalPBRN.org>. All CRFs for this protocol are publicly available at <https://www.nationaldentalpbrn.org/recruiting-ongoing-upcoming-completed>

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## Conflicts of Interest

The authors declare that they have no conflicts of interest related to this work. There has been no financial or personal relationship that could inappropriately influence or bias the content of this work.

## Data Availability

The data that support the findings of this study are available from the corresponding author upon reasonable request.

## Author Contributions

**Barton, Danyelle:** Data Curation, Investigation, Methodology, Project Administration, Validation, Writing - Review & Editing; **Cochran, David:** Investigation, Methodology, Supervision, Writing - Review & Editing; **Cunha-Cruz, Joana:** Conceptualization, Formal Analysis, Funding Acquisition, Investigation, Methodology, Project Administration, Supervision, Visualization, Writing - Original Draft, Writing - Review & Editing; **Fahimipour, Farahnaz:** Conceptualization, Investigation,

Methodology, Writing - Review & Editing; **Funkhouser, Ellen**: Data Curation, Formal Analysis, Methodology, Validation, Writing - Review & Editing; **Geurs, Nicolaas C**: Conceptualization, Funding Acquisition, Investigation, Methodology, Project Administration, Supervision, Writing - Review & Editing; **Gilbert, Gregg H**: Funding Acquisition, Investigation, Methodology, Writing - Review & Editing; **Johnson, James D**: Investigation, Methodology, Writing - Review & Editing; **Kaur, Maninder**: Conceptualization, Investigation, Methodology, Writing - Review & Editing; **Smith, Ning**: Data Curation, Formal Analysis, Methodology, Validation, Writing - Review & Editing; **Waiwaiole, Lisa**: Investigation, Methodology, Writing - Review & Editing; **Startley, Sarah J**: Investigation, Methodology, Writing - Review & Editing.

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## Supplementary Files

## Multimedia Appendixes

We are providing the protocol with NIDCR Program Officers' review comments and edits as proof of peer-review process of a protocol for a funded observational study. Please keep it as a confidential document, for the editor appreciation only.

URL: <http://asset.jmir.pub/assets/426c891774e00e7fa054b82fdd98a79d.pdf>