Protocol

Registry of Australian and New Zealand Dental Implant Devices and Procedures

Prepared by Dental Implant Registry Ltd ABN 89 636 372 248

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Chief Investigator:
Dr Steven Soukoulis
Periodontal Specialist
Dental Implant Registry
Ground floor
62 Greenhill Road
Wayville SA 5034
ABN 89 636 372 248

Research Advisor:
Emeritus Professor Alastair Goss
alastair.goss@adelaide.edu.au
0419 867 449

Abbreviations

CI
Chief Investigator

Course of Treatment (CoT)
The complete treatment plan delivered to the patient to restore (reconstruct) intraoral defects such as missing teeth, missing parts of teeth, and missing soft or hard structures of the jaw and palate. The CoT can be made up of several cycles of treatment including examination of a patient, assessment of their oral health, the planning of any treatment to be provided to that patient as a result of that examination and the dental implant intervention. The CoT groups together multiple Registrations.

Dental Graft
A soft tissue or bone graft used to replace missing or lost bone in the jaw.

HREC
Human Research Ethics Committee

Dental Prosthesis
A manufactured dental appliance used in the CoT Includes implants, crowns, bridges, dentures, abutments, occlusal and abutment screws, and Multi-Unit Abutments (MUA).

Implant Component
A component captured within the Dental Implant Registry. For example, a Dental Prosthesis, or Dental Graft.

MDS
Minimum Data Set

ODS
Optional Data Set

MUA
Multi-Unit Abutments

NHMRC
National Health and Medical Research Council

PIC
Patient Information Card. A government regulated informational card supplied to patients after an implant.

PIS
Patient Information Sheet. A document produced by DIR Ltd outlining the DIR including, its aim, function, consent methods and contact details. Provided to the patient during CoT Registration.

PMS
Practice Management Software. Software used by practices to store, sort and manage their data, including patient records, within their practice.

Registration
The record of data for when an Implant Component was used. Reflects only one type of Implant Item attached to a single tooth location. Multiple Registrations are grouped together under a CoT. For example, a single Registration records the details for either an Implant, or Abutment, or MUA, or Screw, or Graft.

Treating Party
Any entity that contributes towards the patients' health care (e.g. dental practitioners) and enters information against the Course of Treatment (CoT) record within the DIR.

Background

Dental implants are a treatment option used to replace teeth missing from the mouth.

Dental implant technology has been widely used for oral reconstruction in recent years. Dental implants provide an alternative solution for patients who are unsatisfied with traditional partial or full mouth dentures. [1] A robust dental implant prosthesis restores chewing function, has superior biomechanics and aesthetics, and facilitates efficient long-term care.[1]

The annual global dental implant market is estimated at around 12–18 million implants sold, representing more than one hundred commercial brands. [2] Dental implant usage is ever increasing; a range of reasonable projection estimates suggest that dental implant prevalence in the US alone could be as high as 23% by 2026. [3]

Anonymised data is sent to PwC Data Analytics from the top six prostheses suppliers to the Australian dental implant market in Australia which indicates 150,000 to 200,000 are implanted yearly within Australia. The total number of implants sold and implanted in patients in Australia and New Zealand is currently unknown.

Identification of dental implant system in undocumented patients is a major challenge for dentists due to the vast variety of tools and technologies that are used in dental care. It also takes a long time to identify the type of connection or length and diameter of implant. To obtain accurate and timely information, it is necessary to have a Dental Implant Registry (DIR). [4]

The identification of dental implant components can have a significant financial impact on the patient being treated due to additional x-rays required, dental practitioners time, laboratory work and outsourced identification services.

Each brand offers a number of different implants, with various macro- and micro-characteristics and material composition. In total, several hundred million patients have been provided with dental implants over the last decades. Few studies have been published representing long-term outcome of treatment performed in everyday practice representing a mixed patient population. Rapid development of new implants, surgical and prosthodontic materials and procedures and the introduction of these innovations to the clinic, with no or limited scientific evidence, are factors behind the initiative of an implant quality register. [2]

The Australia and New Zealand Dental Implant Registry (DIR) structure was established in 2016 by Chief Investigator Dr Steven Soukoulis, specialist periodontist in Adelaide South Australia, in consultation with other periodontal specialists in his field. In 2018 the already established Dental Implant Registry (DIR) commenced the collection of dental implant patient data.

The experience of Dr Soukoulis and fellow dental practitioner identified a lack of transparency between patients, dental practitioners, and laboratories about the type of implant components used. Patients can present to a dental clinic with unknown dental implant components, requiring replacement or repair, the identification can take hours, days, or weeks to identify, or may not be successfully identified. Using the incorrect instruments to remove the prosthetic implant components can mean that the prosthetic, and or implant, can be damaged. This can lead to further on costs for practitioners and patients.

The predominant use of dental implants is for dentoalveolar reconstruction following tooth loss. There are additional specialist areas of expertise for implants, including:

1. Following jaw resection and reconstruction for
   - Cancer
   - Cleft deformities

2. Extra alveolar implants
   - Zygomatic implants
   - Aural prostheses

This will be subject to subset registries.

Purpose and Objectives

- Confirm the endurance and long-term predictability of dental implants.
- Define dental practice and improve outcomes of dental implant procedures in Australia and New Zealand.
- Accurately identify implant components in a timely manner to both the patient and dental practitioner when an implant requires replacement or repair.
- Document Bone Grafting technique and usage.
- Document the demographic of patients requiring an Implant Component as part of their CoT.
- Document diagnostic characteristics of patients requiring an Implant Component as part of their CoT.
- Provide confidential data to individual dental practitioners of their dental implant procedures.
- Educate Australian and New Zealand dental practitioners in the most effective prosthetic and surgical techniques to achieve successful outcomes.
- Using research findings to engage device manufacturers and dental laboratories to improve manufacturing technique and processes to improve long term patient outcomes.
- Using anonymised research findings to inform regulatory bodies such as the TGA, about potential common adverse events arising from systemic failures related to an Implant Component or procedure.

Aims

Primary Aim

The primary aim of the Dental Implant Registry is to collect data to improve outcomes for patients receiving a dental implant component.

Secondary Aim

To facilitate the recruitment of participants into dental research and trials, and to establish a resource to facilitate further study into the risk factors for, and trajectory of, people requiring dental implants in Australia and New Zealand.

The ultimate vision of the DIR is to bring together dental practitioners, patients, and dental implant manufacturers to minimise potential complications such as infections, fractures or loosening of implant crowns or bridges. This paper describes the protocol for establishing the DIR.

Design

The DIR is a prospective and restrospective registry of patients receiving a dental implant component

The DIR will collect data for procedures using the following prosthesis types.

- Single Fixed Crown
- Implant Bridge (minimum of two teeth)
- Implant Supported denture
- Full Arch reconstructions (all teeth)
- Specialist indications (oncology)

See Appendix A, B, C, D, E

Separate sub registries will be developed for Surgically complex situations (i.e., oncology).

Participants

Inclusion criteria for participants are 1) receiving a dental implant component in primary or revision surgery in participating sites within Australia and New Zealand, and 2) aged 18 years and over.

Participating sites

Participating sites in the DIR primarily include private dental clinics, individual dental specialists, dental laboratories involved in the placement and manufacturing of dental Implant components, as well as universities and other academic institutions.

In Australia and New Zealand, dental implant procedures also take place in private hospitals and public hospitals, these organisations will be approached to participate.

A treating party can be a participating site, if they use a compatible application.

Site participation in the DIR is voluntary.

Finance

The establishment of the DIR is funded privately by Implant Registries Pty Ltd ACN 600 442 313 (Implant Registries) and through the sale of reporting, and through grants and, donations.

The DIR does not charge registration fees.

Further funding sources will be sought in the future.

Recruitment and consent methods

The DIR uses an opt-out method from which patients will be informed of the DIR prior to their treatment, through the provision of a Patient Information Sheet (PIS). Patients are given an opportunity to 'opt-out' if they wish, otherwise their information will be entered into the DIR.

The DIR is free for patients.

This method has been chosen to obtain the large dataset, accurately representing the sample of patients receiving a dental Implant Component. Due to the large scale and low-risk nature of data collected, the opt-out method is also used to reduce administrative burden on treating parties.

After the first completed registration within each CoT, the patient will be sent a Patient Information Sheet (PIS) via email or SMS directly from DIR. This serves as an additional provision of the PIS to ensure the patient receives the PIS, and we are not solely reliant on the Treating Party to provide this.

Additionally, participating Treating Parties have the option to provide the PIS via one or more methods:

- allow the patient to scan a QR code within the treating practitioner's site, and/or
- provided a printed hard copy to the patient.

The patient will receive an automated welcome email and a login prompt to setup their own online account if they wish to do so. The patient will be prompted to review and accept the 'terms and conditions of use' of the patient DIR platform before account registration. The patient online account allows the patient to view their own registration data and to provide real time permission to future treating dental practitioners to access their data record.

The patient can complete the withdrawal form and send to the DIR via email or post if they choose to withdraw from the DIR. If requested by the patient, their data will be removed or managed as requested on the withdrawal form.

Benefits and Risks to Patients

Patients will be able to use the patient portal anytime to view what dental implant components and materials they have received. This information can be shared with other

future treating dental practitioners if they choose to do so. This will help any future treating dental practitioners to identify the dental implant components used and therefore minimise potential complications such as infections, fractures or loosening of patient implant crowns or bridges.

Patients may benefit indirectly from findings obtained from the DIR.

Specifically, a major benefit from the DIR will be the ability to monitor quality of dental implant components used in treatment across Australia and New Zealand to ensure the delivery of the best possible health service to people requiring a dental implant. If issues are identified that may lead to a product recall, only de-identified information will be reported to the relevant regulatory bodies, such as the Therapeutic Goods Administration (TGA).

The DIR poses no foreseeable risk, harm, or discomfort to patients.

All data entered in the DIR contains identifiable patient and treating dental practitioner information (risk). Only anonymised data will be reported and published (minimise risk). Anonymised data reporting allows practices and dental practitioners to benchmark their results to enable a change in practice and potentially improve patient outcomes.

Data Collection

Data Form

The Implant and Abutment forms are completed at the time of procedure and entered in the DIR website/application or using paper form. DIR registrations take an average of 2-3 minutes to complete and on completion of registration a PDF digital patient implant card is created to keep on the patient's file.

If paper form is used, the forms are collated each month by the treating party and sent to the DIR via postage for data entry by the DIR administrator.

Minimum Data Set

Table 1 Key data elements in DIR MDS

Category	Key Data elements
Patient identifiers	Title, First name, Last name, Date of birth, Gender, Postcode, Email Address, Medicare number for Australian patients or the National Health Index number (NHI number) for New Zealand patients.
Patient demographic information	Country of residence
Baseline clinical data	Treating dental practitioner Name and APHRA code Date of treatment Hospital or clinic name Type of intervention Tooth identifier Implant component identification Prosthetic component identification Bone Grafting interventions

Optional Patient Collected Data

Baseline co-morbidities	Smoking status at time of procedure Immunocompromised status Diabetes Type 1 or Type 2 Taking antiresorptive medication for osteoporosis Chronic Inflammatory conditions Allergies

Identified Patient Data

The DIR collects and stores identified patient data to match patient procedures to track prosthesis history. The DIR will later link to the Australian National Death Index (NDI) to determine mortality status. Further research may also include data linkage.

Data Quality Management

The DIR will use a secure, web-based platform to enter and manage data. All users of the DIR database need to log in to the database through a login screen with a user email address and password. The database server is housed on Amazon Servers within Australia and the database is managed in an International Organization for Standardization (ISO) 27,001 certified environment.

The DIR will implement a number of strategies to ensure the quality, consistency and interpretability of data recorded. This will include strategies for data entry such as in-built logic checks to ensure data meets formatting and value requirements and validity, as well as quality assurance processes post data entry; such as routine cleaning and quality checks of data received in the database. Training, education, and ongoing liaison with participating sites will be provided to support high-quality data collection.

Patient confidentiality

All patient data will be managed in accordance with the Guidelines for the Protection of Privacy in the Conduct of Medical Research. Patient contact details will only be used for the purpose for which they were collected and will be stored securely and confidentially. Patients will not be identified in any reports, manuscripts or presentations derived from the DIR.

Treating Party confidentiality

Each treating party will only be able to review the results of their own procedures by requesting their data from the DIR in tabulated form. No individual dental practitioners or private practice will be identified in any reports produced.

Manufacturer Confidentiality

Manufacturers of prostheses will not be identified in any public reports produced by the DIR. Manufacturers can request reports of their own prostheses and of the general performance of their products in comparison to all other prosthesis manufacturers, but only when there is enough data to ensure other manufacturers cannot be identified. All reports requested by manufacturers will be supplied at a fee determined by the DIR.

Data usage restrictions

The data collected will only be used by the DIR for the purposes intended as outlined in this protocol.

Any data published in reports, papers and publications will be de-identified. Access to identifiable information is limited to authorised DIR staff and engaged biostatisticians.

Data Storage and Record Retention

The organisation contracted to manage DIR data has policies and procedures in place as well as software barriers to protect personal information. These include the use of codes, passwords, and encryption.

The paper forms used for data collection are destroyed once data has been entered into the DIR database. All data will be retained in accordance with good scientific practice.

All electronic data collected will be held for a minimum of 15 years after publication of any final reports and manuscripts.

Data Analysis

A biostatistician will be engaged to undertake data analysis.

Initial data analysis for the DIR will focus on descriptive analysis to provide aggregate summary information regarding cohort and implant characteristics. This data will provide the basis for reporting and feedback to participating sites as well as annual public reports. The DIR will also conduct analyses to provide performance metrics such as withdrawal rate and cumulative recruitment of participating sites.

When participant volume is sufficient, data analysis will occur. The DIR aims to link to the Australian National Death Index (NDI) to determine mortality status.

A fee free table formatted data extraction from the DIR can be supplied to dental practitioners. Dental practitioners and dental industry manufacturers can request ad-hoc reports at cost. This is an important feature because the DIR's primary purpose is to assist participating dental practitioners review their dental practice and use this information to drive improvements.

Governance

The DIR is operated by Implant Registries Pty Ltd ACN 600 442 313 ("Implant Registries"). Implant Registries appoints a Registrar to manage and oversee the technical operation and data integrity of the Dental Implant Registry. A DIR Steering Committee will provide governance oversight, strategic direction and ensure that agreed policies and procedures are adhered to. The Steering Committee will comprise of a key clinician group representative (dental specialist, laboratory technician, etc), DIR dental practitioners, dentistry-related peak bodies, and representatives of people with dental implants.

Research advisor Emeritus Prof. Alastair Goss will provide leadership of the DIR Steering Committee. The DIR Steering Committee will aim to have six members. CPI Steven Soukoulis will be a member.

Invitations will be sent to the Australian Dental Association (ADA), Therapeutic Goods Administration (TGA) and representation sought from a consumer.

The DIR Steering Committee will aim to be established within one year of ethics approval and aim to meet biannually.

A patient Advocacy Group will meet bi-annually. An invitation is sent by email to DIR participants to attend online. The group number varies dependant on whom responds and participant availability.

A Manufacturer steering committee will also be established to provide feedback. The Manufacturer Steering Committee will aim to meet yearly and will aim to have six attendees.

Invitations will be sent to the six largest volume manufacturers within Australia/New Zealand: Straumann, Southern Implants, Biohorizons, Dentsply, MIS and Neoss.

Statement of Compliance with NHMRC National Statement on Ethical Conduct in Human Research

The DIR will be conducted in accordance with the ethical principles that have their origin from the Declaration of Helsinki and are consistent with ICH/GCP. This study will comply with the National Health and Medical Research Council (NHMRC), National Statement on Ethical Conduct in Human Research [5].

References

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2. Björn Klinge, Mats Lundström, Måns Rosén, Kristina Bertl, Anna Klinge, Andreas Stavropoulos **Dental Implant Quality Register—A possible tool to further improve implant treatment and outcome** *Wiley Clinical Oral Implants Research* 23 April 2018 DOI: 10.1111/clr.13268

3. H.W. Elani, J.R. Starr, J.D. Da Silva, and G.O. Gallucci Trends in Dental Implant Use in the U.S., 1999–2016, and Projections to 2026 Journal of Dental Research, 2018 Dec; 97(13): 1424–1430.

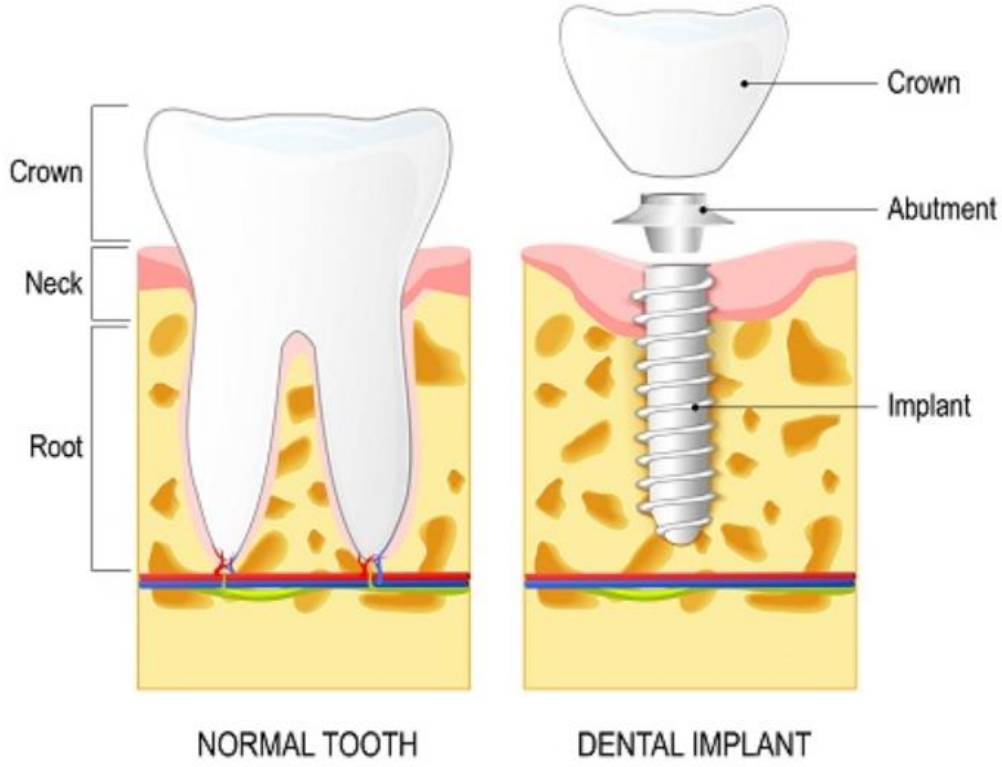
4. Roya Naemi, Majid Jangi, Hamid Reza Barikani, and Leila Shahmoradi **Design and Evaluation of Web-Based Dental Implant Registry (DIR) for Better Clinical Outcomes** *International Journal of Biomaterials.* v.2022; 2022 PMC8856821

5. National Health and Medical Research Council. National Statement on Ethical Conduct in Human Research (2007) – updated 2018; https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018

6. https://www.teeth.org.au/dental-implants Written by the Australian Dental Association, Nov 13, 2022

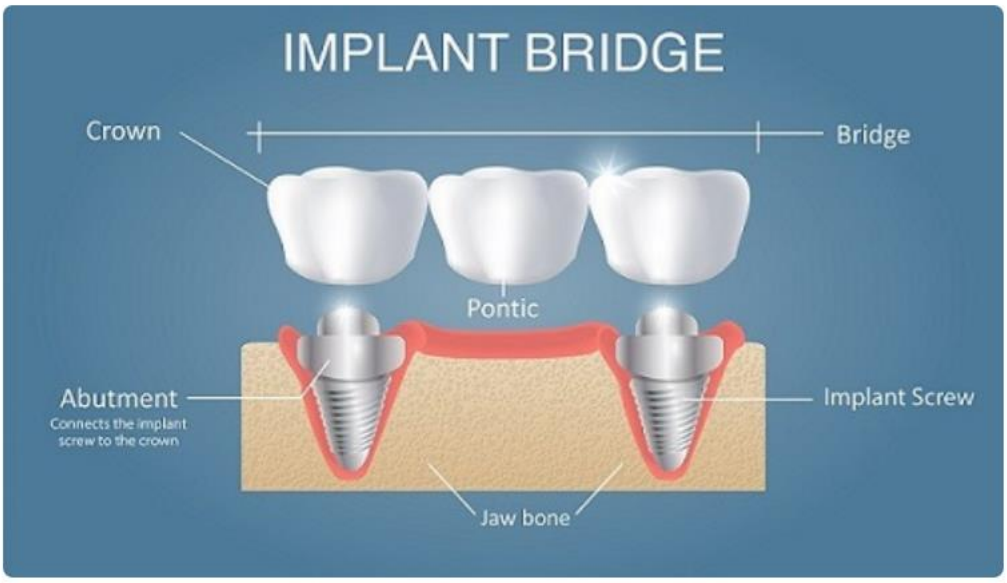
Appendix A – Implant Components Diagram – Example Single Fixed Crown

Sourced from https://www.teeth.org.au/dental-implants, Oral health information website created by the Australian Dental Association.[6]



Appendix B -Example Diagram - Implant Bridge

Sourced from https://www.teeth.org.au/dental-implants, Oral health information website created by the Australian Dental Association.[6]

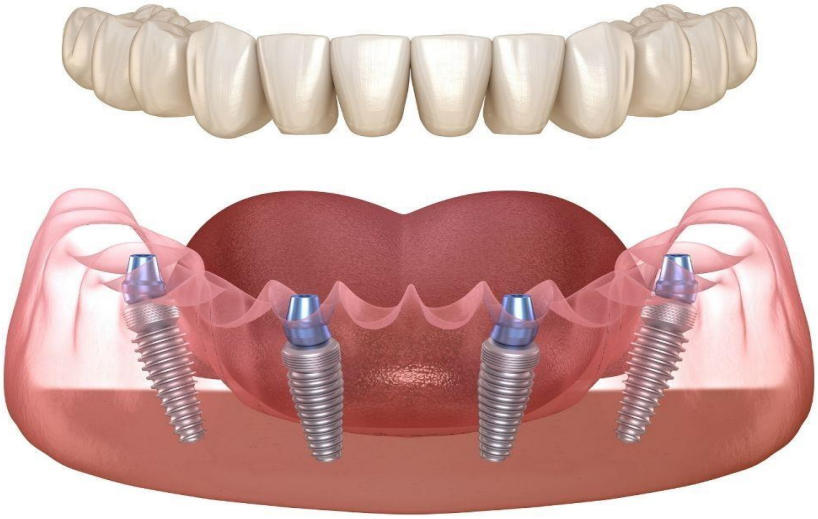


Appendix C –Example Diagram – Implant Supported Denture

Sourced from https://www.teeth.org.au/dental-implants, Oral health information website created by the Australian Dental Association.[6]

Appendix D –Example diagram – Full Arch Reconstructions (all teeth)

Sourced from https://www.shutterstock.com/image-illustration/mandibular-prosthesis-all-on-4-system-1627811641



Appendix E – Example diagram - Specialist Indications (Oncology)