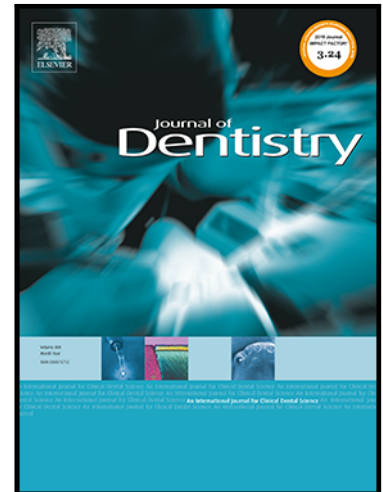


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Key Factors for a National Dental Implant Registry

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Declaration of competing interest

The authors declare that they have no conflict-of-interests.

Keywords: Dental implants; National registry; Key factors; Pilot study; Dental implant registry

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Introduction

Rehabilitation of oral function with implant-retained fixed or removable prosthetic restorations is an established treatment to replace teeth that are missing due to illness, injury, agenesis, surgery, periodontal disease, or other causes. Medical devices are categorized into classes I, IIa, IIb and III, based on their intended use and associated risks [1]. Dental implants are classified as class IIb devices. Thus, these must go through the conformity assessment conducted by notified bodies before they are placed on the market or put into service [1].

Globally, there is a considerable market for dental implants. In 2003, more than 220 commercial brands from about 80 producers were available [2], and new products have continuously entered the international market since then. In Europe, it is estimated that 5.5–6 million dental implants are sold annually [3]. Even if new products obtain CE (Communauté Européenne) approval [4], they may pass for clinical use without documentation from clinical trials or in vivo use.

Many studies on dental implants have been published [5]. The overall long-term implant survival is reported to be above 96% at 10 years of follow-up [6, 7]. However, implant failures do occur [8, 9]. There is a wide variety in design, surface characteristics and material composition, and due to the large variation, it is of great importance to identify implants with a high probability of complications and loss as early as possible. Within different specialties in medicine, implant registers are acknowledged tools to ensure overall high quality of treatment [10, 11].

Medical implant registries, some of which have existed for decades, enable systematic monitoring and analysis of treatment outcomes, identifying best practices and improving procedures to enhance overall patient care quality. The registries can identify unsatisfactory products and procedures, preventing the use of unsuitable implants, and thereby increase patient safety [11, 12]. By improving treatment quality and reducing the number of failed implants, the registries can lower the costs associated with revisions, benefiting both the healthcare system and the patients. This helps to standardize treatment procedures and outcomes, reducing variability in care and ensuring consistent treatment quality for all patients [12]. National dental implant registries may serve as a comprehensive database for documenting dental implant treatments, and health authorities may benefit from this when establishing guidelines. A national registry, implying a broader inclusion of clinics, operators, patients, and products, would enhance the generalizability and applicability of data. This would offer a more accurate representation of implants across groups of patients and clinical settings. Dental implant professionals have discussed the need, modalities, and design for national dental implant registries [13].

The aim of the study was to identify key factors when establishing a national dental implant registry by using experiences from relevant medical registries and by involving dental clinicians in a pilot study.

Material and methods

The project was initiated in 2015 by representatives from the Dental Biomaterials Adverse Reaction Unit at the Norwegian Research Centre (NORCE) and from the Department of Clinical Dentistry at the University of Bergen (UiB) in Norway.

An advisory board was also established, consisting of representatives from the Dental Biomaterials Adverse Reaction Unit, the Department of Clinical Dentistry at UiB, the Department of Maxillofacial Surgery at Haukeland University Hospital (HUS), the Norwegian Arthroplasty Register at HUS and the Nordic Institute of Dental Materials (NIOM).

Meetings were arranged with relevant Norwegian medical registries and the Norwegian Advisory Unit for Medical Quality Registries [14]. Relevant literature in biomedical databases was obtained. Furthermore, national dental implant registries worldwide were searched for.

A pilot study was conducted to explore methods for collecting data for a national registry for dental implants and to evaluate whether the information obtained was relevant and sufficient to reveal information that is important for a successful treatment with dental implants.

The pilot study

The pilot study, *Prospective registration of implant-retained oral rehabilitation* [15], was initiated in autumn 2017. The aim of the pilot study was to perform a prospective registration of all dental implants inserted or removed in five dental clinics in Western Norway. The pilot study was funded by the Norwegian Directorate of Health and was a collaboration between the Dental Biomaterials Adverse Reaction Unit (Project Manager), the Department of Clinical Dentistry (UiB), the Oral Health Centre of Expertise – Rogaland and representatives from the five clinics.

An initial meeting with the five participating clinics (three private and two public) was arranged in November 2017. The purpose of this meeting was to discuss methods for data registration, which data to be included and the duration of the registration period. In addition, principles related to ethics, protection of personal patient data and the procedures for collecting informed consent from the patients were discussed. As a result, it was decided to prepare both a paper-based and an electronic registration form for implant insertion and implant removal/loss, with a project period of 2 years.

The dataset covered information about the dental implants and details regarding insertion or removal procedures. Additionally, the lot number and/or catalogue number of the implant, and information about planned prosthodontic treatment, were included. If the dental implant treatment was entitled to cost reimbursement from The Norwegian Health Economics Administration [16], this was also registered.

From September 2018 to September 2020, a prospective registration of inserted or removed/lost dental implants in five dental clinics in Western Norway was performed. All patients with dental implants inserted or removed/lost during this period were invited to participate in the pilot study. A Norwegian identification number (11-digit) and a signed informed consent were required for inclusion to the study. Dentists performing implant surgery had advanced training in oral surgery. To follow a specific implant from insertion to removal or loss, both the implant site and the patient's 11-digit personal identification number, which is assigned to every citizen in Norway [17], were recorded. Furthermore, to calculate the lifespan of the specific implant, the dates of insertion and removal/loss were registered.

During the pilot project period, two follow-up meetings were arranged with the participating clinics. The meetings were set up to exchange experiences regarding registration routines.

After the registration period, representatives from the participating clinics were invited to discuss their experiences. Both the parameters included in the registration forms and the structure of the forms were discussed, and the registration forms were reviewed accordingly.

The work to establish a national dental implant registry was presented at both local and national meetings for dentists. Information and a scientific article [18] were published in the Norwegian Dental Journal. A report describing the project work was submitted to the funding authority, the Norwegian Directorate of Health [15]. The pilot study was submitted to the regional ethics committee in Norway (2017/2260) and approved by the Norwegian Centre for Research Data 17 December 2017 (ID: 56916).

Statistical methods

For descriptive purposes, in the pilot study, continuous variables were presented using mean values (with standard deviations), while categorical data were presented using frequencies and percentages. For the failure probabilities, one minus the ordinary Kaplan-Meier curves were presented. Cox regression models, with cluster robust standard errors adjusting the standard errors for multiple implants per patient, were applied. The results from the Cox regression were presented as hazard rate ratios (HR) with 95% confidence intervals and p-values. The computer package "R" (R

Foundation for Statistical Computing, Vienna, Austria) and Stata version 18 (StataCorp, TX, USA) were used for the statistical analyses.

Results

Only a few national dental implant registries were found. The Finnish Dental Implant Registry, with mandatory reporting for the dentists, was established in 1994 [19]. However, data collection ended in 2016 [20], and no later reports from the Finnish registry have been published.

In Sweden, the work towards a national dental implant quality registry started in 2005 and this work is ongoing [3, 13, 21, 22].

Work to establish a national registry in Norway, limited to dental implants at public hospitals, started in 1994. Registration started in 2003 [23], but was terminated in 2006 due to lack of funding.

In Australia, the Dental Implant Registry (DIR) was launched in 2013 and is operational. Registration is voluntary for both patients and dentists. Patients pay a fee to have their data registered, whilst registration is free for the dentists [24, 25]. A certificate is issued to the dental clinics that report to the registry.

A dental implant registry, with sufficiently detailed information to follow each single implant over time, operated by a commercial company, available in several countries, was identified [26].

There are several studies that present outcomes from registration of dental treatment with implants [5, 27-29] However, most of these registrations were confined to selected patient groups or clinics [5, 30, 31].

The pilot study

From September 2018 to September 2020, 1,326 dental implants were registered in a total of 781 patients (52.2% men, 47.8% women), with mean age 55.7 years (SD=16.6). Most of the implants (80.2%) were placed in the mandible. The total distribution was 19.8% in the incisor, 17.2% in the canine, 41.1% in the premolar and 21.9% in the molar position (Figure 1). Most patients (n=491, 62.3%) were registered with one implant, whilst 3 patients (0.4%) had 10 or more implants. A total of 551 (41.6%) of the registered implants were entitled to cost reimbursement from the Norwegian Health Economics Administration [16].

The estimated failure of implants one year after insertion was 2.9% (95% CI: 2.0-4.1). There was no difference in implant failure between males and females (HR=1.90, 95% CI: 0.86-4.19, $p=0.110$, Figure 2A), and there was no effect of age on the risk for failure (HR=0.90 per 10-year increase in age, 95% CI: 0.71-1.14, $p=0.384$). Most of the implants (85.0%) were of the Straumann brand. No

difference in failure was found between Straumann and the other brands (HR=0.79, 95% CI: 0.32-1.94, $p=0.603$, Figure 2B).

A request to the participating clinics revealed that approximately 60% of implants inserted during the period of the pilot were registered. The compliance varied between the clinics (41% to 97%).

Interviews revealed that dental secretaries or receptionists managed patient interactions and obtained informed consent from the patients. The primary reasons for implants not being included were deficient procedures and oversights by the clinical staff in obtaining consent. None of the patients who were asked for informed consent to participate, refused registration.

The data collection procedures varied across clinics. At most clinics, the registration was performed electronically. Some clinics assigned a dedicated staff member, thereby streamlining the process and reducing time.

Based on the discussion and subsequent collaboration with the participating clinicians, the registration forms used in the pilot study were revised, developed, and elaborated. In the revised forms, particular emphasis was placed on optimizing the relevance and precision of the dataset for dental implant treatment and failure (Figure 3). Moreover, to minimize the clinicians' workload, the dataset was designed for seamless integration with an electronic patient record system.

Discussion

Treatment with dental implants is a highly successful procedure, with high long-term implant survival rates [6,7]. Despite this, it is important to identify factors that influence the failure of this treatment. The characteristics of the implant are of importance, in addition to patient-related factors, surgical procedure and type of prosthetic [6, 32, 33]. Implant failure can lead to additional treatment procedures and financial costs for patients, dentists, and implant manufacturers.

Databases and registries for dental implants have been established in some countries [5]. Both the establishment and the maintenance of dental implant registries appear to be more complex compared to quality registries in other fields of medicine. Dental care in the adult population, including implant surgery, is primarily carried out in private dental clinics, using non-federated electronic patient record systems, which makes seamless data sharing and integration complicated. To follow inserted dental implants over time, including when treatment and follow-up are carried out in different clinics, it is essential to record a form of personal identification, in addition to the dates of insertion and failure/loss. Many countries have some sort of national identification number (e.g., the 11-digit number in Norway), which enables linkage to other registries and to patient-reported outcome measures (PROMs) [34].

The value of a registry is based on both the relevance and the quality of the data. A dental implant registry should include the most important factors influencing the survival/loss of the implants [6, 32, 35]. Based on the discussions with the clinicians participating in our pilot study, the structure of the registration was also considered to be essential. To ensure a high degree of reporting, it is important to design a dataset that is limited to the most important factors influencing the survival/loss of the implants. The pilot study was small and had too short follow-up for meaningful comparisons, e.g. of different brands of implants. However, the pilot indicates that such differences may be analysed in a national dental implant registry.

According to the European General Data Protection Regulation (GDPR), patients are required to give their informed consent for the collection and processing of any personally identifiable information [36]. As experienced in the pilot study, the moderate compliance was compromised by the lack of the patients' active consent, which was attributable to the procedures at the clinics, and not based on characteristics with the implants, patient, or clinician. The use of specially dedicated personnel with advanced training and follow-ups could improve these procedures. However, passive consent may lead to a higher participation rate, compared with active consent [37].

If the compliance to a registry is non-random (MNAR), bias in the results will appear. However, if missingness is random or completely random (MAR or MCAR) comparison of groups will still be adequate, even if overall prevalences are biased [38]. In a national registry we would expect that MNAR is unlikely.

Even though the Finnish registry was mandatory, the registry has experienced a decline in coverage in recent years [19, 20]. Coverage refers to the proportion of dental implants registered compared to the total number of implants installed.

In a busy clinical setting, the dentist may not prioritize registration to a registry, which would result in low reporting rates. Completeness of data is crucial. Design of the pilot study included to discuss this issue with the participating clinicians. The need-to-know principle should be enhanced to ensure a high completeness of the registered data. This was important when designing the revised dataset when establishing a national registry. Havelin et al. highlighted the motivational aspect of providing continuous updates and feedback to the operators/surgeons [39]. Information from the registry can be valuable in the surgeon's clinical work [39-41].

The privacy commitment for each individual surgeon is a fundamental element in the success of the Scandinavian arthroplasty registries [39].

Motivation to register can be maintained by introducing education programmes, publishing yearly reports, and arranging meetings. Co-operation with and support from relevant specialist associations is also essential.

Although reporting was mandatory, only 72% of reimbursed implants were documented in the final report from the Finnish registry [20]. There seem to be few possible sanctions when dentists do not follow directives for reporting. Making registration mandatory to receive reimbursement may lead to increased reporting. However, less than half of the implants in our pilot study met the criteria for cost reimbursement from the Norwegian Health Economics Administration [16]. Furthermore, in Norway treatment with dental implants may also be carried out by general practitioner dentists, but only specialists are obliged to submit requests for reimbursement. The voluntary Australian Dental Implant Registry (DIR) certifies participating clinics, thereby highlighting to both patients and colleagues that these clinics prioritize the quality of implant surgery [24]. This may motivate dentists to report.

In our pilot study, data collection was carried out using electronic forms, not integrated with the electronic patient record (EPR), which appeared time-consuming. Ideally, the collection of data in a registry should be integrated with the EPR. Moreover, a standardized clinical terminology system, such as SNOMED CT (Systematized Nomenclature of Medicine - Clinical Terms), would make it easier to structure the health information about each patient.

In Sweden, the work to establish a national quality registry for dental implants (SKRI) now involves automated extraction of information from dental records into the established "Swedish Quality Register for Caries and Periodontitis" [21]. A pilot study conducted in 2022-23 in two regions in southwest Sweden (Halland and Skåne) demonstrated the potential of these technical solutions [21]. National health registries can be successfully maintained by either specialist associations or healthcare providers [41]. Studies addressing national health registries emphasize the importance of financial support [41]. The Norwegian Dental Implant Registry [23] was terminated after three years due to the lack of funding. Registries operated and financed by implant companies involve conflicts of interest but may be a tool for the company to monitor and improve the quality of their own products. A national dental implant registry requires a high degree of independence and objectivity in data collection and analysis.

Integration of patient-reported outcome measures (PROMs) should also be considered. This includes assessing patient satisfaction, providing valuable insights into the overall success and patients' experiences of the dental implant procedure. In Norway, the registration of PROMs is one of the criteria to be acknowledged as a national quality registry [14].

Conclusions

This study adds insights into the establishment of a national dental implant registry. The pilot study highlighted the importance of careful planning, collaboration with clinicians, data collection solutions and compliance with data protection regulations. In a future national dental implant registry,

continuous work to maintain a high compliance is required. Moreover, it is essential to ensure that the variables recorded are both relevant and appropriate, adhering to a "need to know" rather than a "nice to know" principle. Finally, securing adequate funding and establishing sustainable operational mechanisms are key considerations for the successful implementation and maintenance of a registry.

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Figure captions

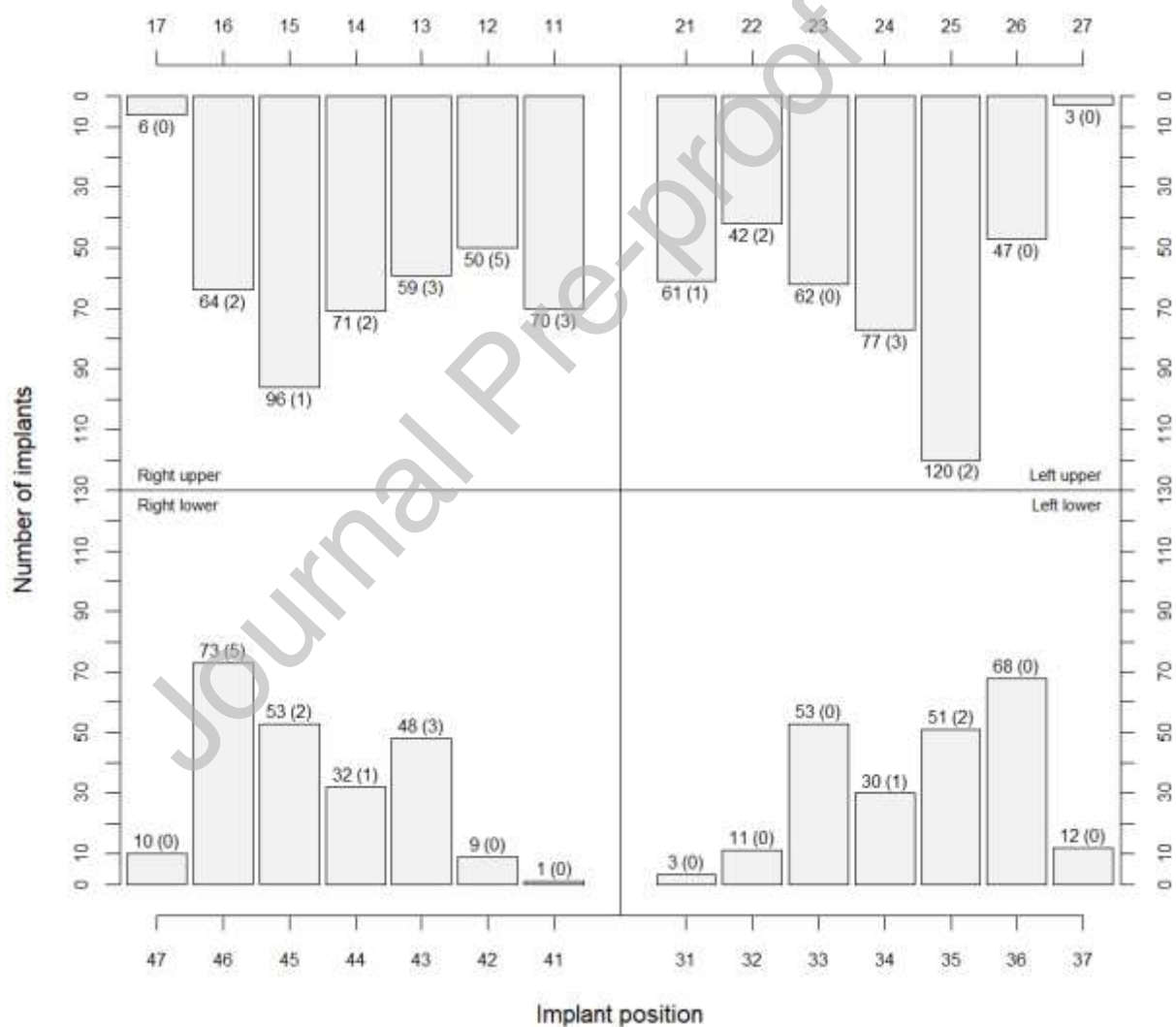


Figure 1: Number of inserted implants during the pilot project period, for different positions. The number of failed implants is marked in parentheses.

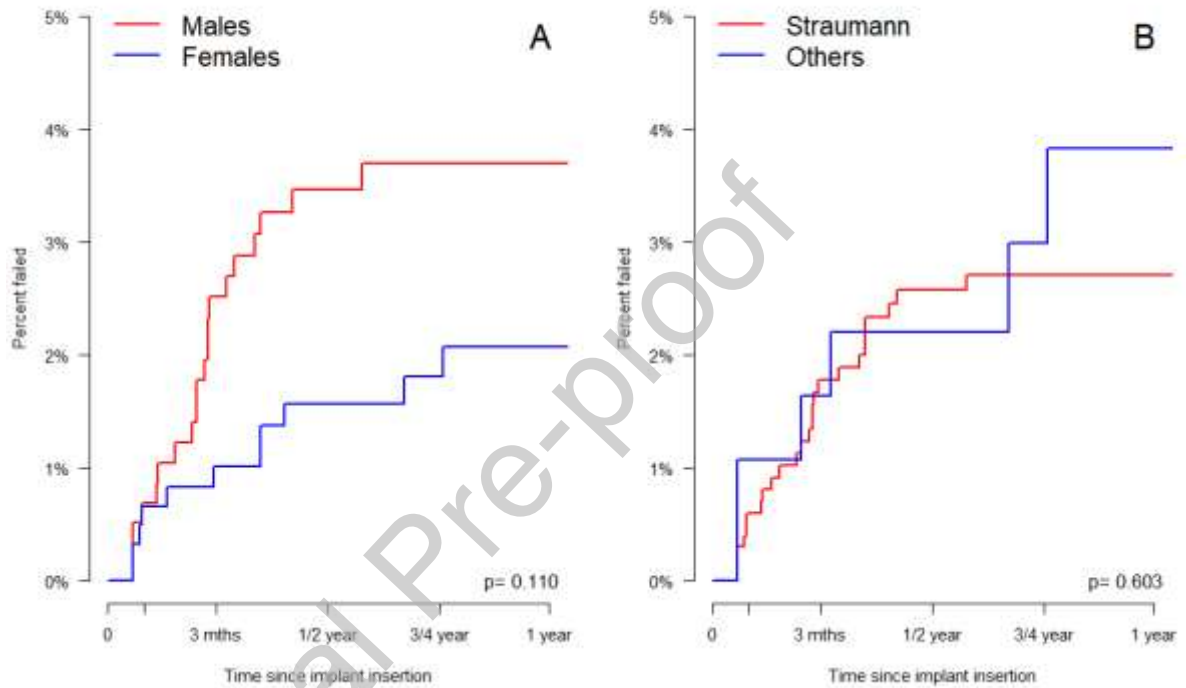


Figure 2: Failure probabilities for implants since time of insertion.

A: Males compared with females

B: Straumann implants compared with other brands

Patient
Personal identification number
Age
Gender
Health risk factors (general and local)
e.g., smoking habits and periodontal disease
Planned prosthetic restoration
Single crown
Fixed bridge (number of fixtures)
Removable prosthesis

Planned loading time
Implant
Implant position
Implant system / Brand name
Catalogue number / Lot number
Surgical procedure
Date of insertion
Antibiotic prophylaxis
Type, dose, duration
Bone Quantity / Quality
Reconstruction of jaw
Perioperative complications
Implant failure
Date of implant removal/loss
Reasons for implant removal/loss

Figure 3: Elements to be included in a dataset for dental implants.

Declaration of competing interest

The authors declare that they have no conflict-of-interests.