CLINICAL INVESTIGATIONS

Effectiveness of Implant Therapy Analyzed in a Swedish Population: Early and Late Implant Loss

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Abstract: *Treatment outcomes in implant dentistry have been mainly assessed as implant survival rates in small, selected patient groups of specialist or university clinical settings. This study reports on loss of dental implants assessed in a large and randomly selected patient sample. The results were aimed at representing evaluation of effectiveness of implant dentistry. Using the national data register of the Swedish Social Insurance Agency, 4,716 patients were randomly selected. All had been provided with implant-supported restorative therapy in 2003. Patient files of 2,765 patients (11,311 implants) were collected from more than 800 clinicians. Information on patients, treatment procedures, and outcomes related to the implant-supported restorative therapy was extracted from the files. In total, 596 of the 2,765 subjects, provided with 2,367 implants, attended a clinical examination 9 y after therapy. Implant loss that occurred prior to connection of the supraconstruction was scored as an early implant loss, while later occurring loss was considered late implant loss. Early implant loss occurred in 4.4% of patients (1.4% of implants), while 4.2% of the patients who were examined 9 y after therapy presented with late implant loss (2.0% of implants). Overall, 7.6% of the patients had lost at least 1 implant. Multilevel analysis revealed higher odds ratios for early implant loss among smokers and patients with an initial diagnosis of periodontitis. Implants shorter than 10 mm and representing certain brands also showed higher odds ratios for early implant loss. Implant brand also influenced late implant loss. Implant loss is not an uncommon event, and patient and implant characteristics influence outcomes (ClinicalTrials.gov NCT01825772).*

KEY WORDS: endosseous dental implantation, implant-supported dental prosthesis, adverse effects, multivariate analysis, survival rate, treatment outcome.

Introduction

Restorative therapy using dental implants is considered a safe and predictable treatment procedure in edentulous and partially dentate patients (Jung et al. 2012; Pjetursson et al. 2012). The main outcome variable reported in longitudinal studies is the rate of implant survival, and data are based on the proportion and number of implants, while information on proportions of affected patients is rare (Berglundh et al. 2002). The documentation is also predominantly based on assessments made in small, selected patient groups (i.e., so-called convenience samples) (Tomasi and Derks 2012), and treatment was in most cases performed by clinicians in specialist or university clinical settings. Thus, treatment outcomes were mainly assessed in efficacy evaluations rather than appraisals of effectiveness (Berglundh and Giannobile 2013). It is important to adapt to recommendations on improvement of reporting on treatment outcomes (Tonetti and Palmer 2012) and to address the need for randomly selected and appropriately sized patient groups treated by different categories of clinicians.

The adult population in Sweden is provided with federal financial support for dental care, including implant-supported restorative therapy, which is administered by the Swedish Social Insurance Agency (SSIA, Försäkringskassan). In 2003, the federal subsidies increased for patients ≥65 y of

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age, resulting in a dominance of implant-supported restorative therapy among treatment procedures in this group of patients.

In this study, we report on loss of dental implants assessed in a large and randomly selected patient sample. The national data register of the SSIA provided unique access to a group of patients who had received implant-supported restorative therapy. The results were aimed at representing evaluation of the effectiveness of implant dentistry.

Materials and Methods

The study protocol was approved by the regional Ethical Committee, Gothenburg, Sweden (Dnr 290-10) and registered at ClinicalTrials.gov (NCT01825772). Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines were followed. The study consisted of an analysis of patient files and a clinical evaluation about 9 y after completion of implant-supported restorative therapy.

Study Sample

The patient material used in the present study has been previously described (Derks et al. 2014). Briefly, 4,716 subjects in 2 age groups (45–54 y and 65–74 y in 2003) provided with implant-supported restorative therapy in 2003 were randomly selected from the national data register of the SSIA. All subjects were contacted by letter and asked for consent to access their patient files. Name and social security number, unique to each individual, were used to identify all subjects.

Analysis of Patient Files

Documentation related to the implant-supported restorative therapy was requested from the respective dental clinicians of all consenting patients. All patient files were copied and subsequently returned. Reported information regarding patients, treatment procedures, and treatment outcomes was extracted from the patient files and entered into a database by 2 examiners (J.D. and M.L.). Patient data included information on history of diabetes, cardiovascular diseases, and periodontitis at the time of implant therapy. Patients were categorized as smokers if reported to be smoking at the time of implant therapy. All other patients, including former smokers, were categorized as nonsmokers. In addition, the frequency of recall visits following the completion of the implant-supported restorative therapy was assessed and categorized as "regular" if the patient had attended on an annual basis.

Clinicians involved in the treatment were categorized with regard to private or public dental clinical setting and general practitioner or registered specialist by the Swedish National Board of Health and Welfare at the time of treatment. For surgical treatment, specialists in oral/maxillofacial surgery and periodontics were considered, while prosthetic treatment involved specialists in prosthodontics, stomatognathic physiology, and periodontics.

Implants were categorized according to brand, as defined by implant system and provider. Implants were also grouped regarding length (<10 mm and ≥10 mm), diameter (<4 mm and ≥4 mm), and installation protocols (1-stage and 2-stage). Bone augmentation procedures, including ridge and sinus augmentation, and the use of prophylactic antibiotics were recorded. Implants were categorized according to jaw and anterior/posterior position. Anterior was defined as the region corresponding to tooth position canine to canine. Further categorization included type of prosthetic retention, design of suprastructure, type of connection, and prosthetic loading protocols. Loading was categorized as "early" if the supraconstruction was connected <4 wk after implant placement.

Clinical Evaluation

In total, 900 subjects, stratified for age, were randomly selected from the patient-file database and subsequently invited to a free-of-cost examination at a conveniently located dental clinic in Sweden about 9 y after therapy. The examinations were carried out by specialists in periodontics, predominantly by 2 investigators (J.D. and J.H.), and included clinical and radiographic assessments of the relevant implant regions.

Assessment of Implant Loss

If implant loss had occurred prior to connection of the supraconstruction, it was scored as an early implant loss. If the loss had occurred afterward, it was considered a late implant loss. Early implant loss was assessed in patient files by 2 examiners. Double assessments revealed an inter- and intraexaminer agreement of 1.0 (Cohen's unweighted κ). Late implant loss was recorded at the clinical examination.

Consequences of implant loss were noted as reported in patient files. Changes in treatment planning, placement of new implants, and noncontinuation of treatment were recorded for early implant loss. For late implant loss, placement of new implants, prosthodontic therapy, and partial or total loss of reconstructions were scored.

Data Analysis

Recorded data were expressed in mean values and frequency distributions. Frequencies of early and late implant loss were assessed on the implant and patient level (SPSS 21.0; SPSS, Inc., Chicago, IL, USA). To identify factors affecting the probability of implant loss, we used multiple logistic multilevel models (MLwiN 2.28; Center of Multilevel Modelling, University of Bristol, Bristol, UK). The hierarchical analyses included the patient at the higher level and the implant at the lower level. The logit function was applied to link the linear model with the probability of the binary event. Two models, one for "early loss" and one for "late loss," were built. The independent factors entered into the models were retrieved from the patient-file database. For the factor "implant brand," 4 groups were formed: 1) Straumann group implants (Basel, Switzerland), 2) Nobel Biocare group implants (Zurich, Switzerland), 3) Astra Tech group implants (Mölndal, Sweden), and 4) other. Brands representing less than 5% of all implants were collapsed into one group to facilitate the statistical analysis.

Models were built with the intercept as a random term. All variables were tested by the Wald test in a bivariate analysis. Significant factors were entered into a multiple model (fixed effect). Nonsignificant factors were removed backward until a final model was created containing only significant factors ($P < 0.05$). The intercept for each parameter was transformed into an odds ratio (OR), including a 95% confidence interval. Parameters were estimated using the Markov chain Monte Carlo method with 50,000 simulations.

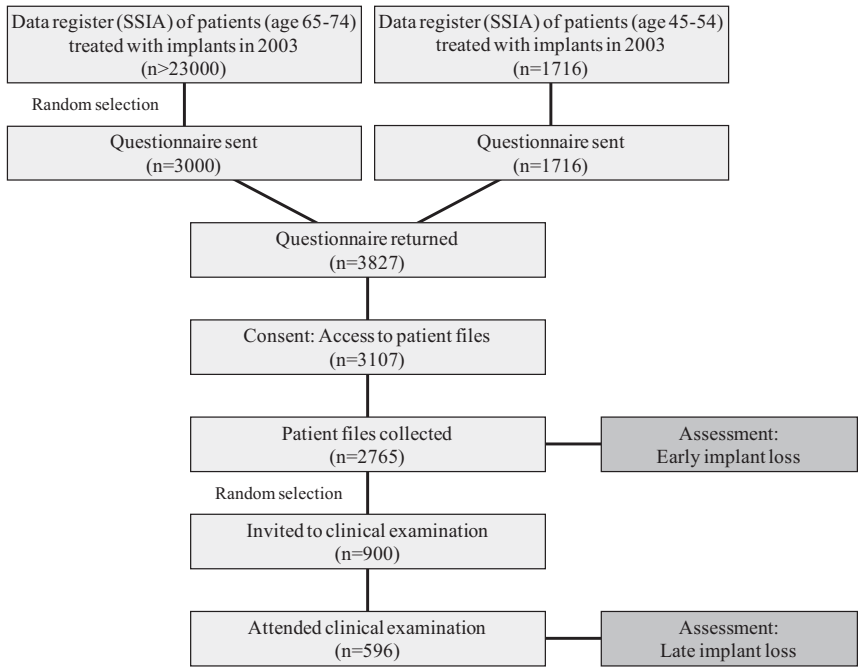
Results

Patient Sample

In total, 3,107 subjects gave their consent for access to patient files, of which the files of 2,765 patients were retrieved from more than 800 clinicians. The patient files covered a mean ± SD function time of 5.4 ± 2.2 y following implant therapy. Of 900 invited subjects, 596 attended the clinical examination (Fig.). Reasons for nonattendance were lack of interest (187 subjects), general health (68), unable to contact (30), and deceased (19). For the patients attending the clinical examination, a mean ± SD of 8.9 ± 0.8 y had passed since implant placement. Attending and nonattending subjects did not differ significantly in terms of age, sex, systemic disease, and therapy-related parameters (e.g., average number of implants per patient).

Table 1 describes patient-related data in terms of sex, general and dental health status, and implant-supported restorative therapy. Table 2 describes implant-related data. Three brands (termed Astra Tech, Nobel Biocare, and Straumann group of implants) represented 90% of all implants. Among Astra Tech group implants, 99.2% had a TiOblast surface; 98.7% of all Nobel Biocare group implants had a TiUnite surface; and 99.9% of all Straumann group implants had an SLA surface. Within the remaining 10% of "other" implants, the predominant brands were Biomet 3i (3.3% of all implants; Palm Beach Gardens, FL, USA), CrescoTi (1.7%; Kristianstad, Sweden), XiVE (1.3%; Mannheim, Germany), Frialit (1.3%; Mannheim, Germany), and Lifecore (1.2%; Burlington, MA, USA).

Figure.
Patient enrollment (n = number of patients)



Implant Loss

The analysis of patient files (n = 2,765) revealed that 121 subjects (4.4%) experienced early implant loss with a total of 154 implants (1.4%) lost (Table 3). Within this group, 102 patients lost 1, 10 lost 2, 4 lost 3, and 5 lost 4 implants. Of the 121 subjects affected by early implant loss, 76 (63%) underwent new implant placement procedures. Treatment planning had to be adjusted for 21 (17%). For 2 patients (2%), therapy was not continued after the early loss had occurred, and for 33 patients (27%), treatment was completed without renewed implant placement or changes in treatment planning.

Among the 596 patients examined clinically, 45 (7.6%) experienced implant loss, irrespective if it had occurred early or late. A total of 72 implants (3.0%) were lost. Twenty-five (4.3%) of the 596 patients experienced late implant loss, representing 46 implants (2.0%). Within this group, 13 patients lost 1, 8 patients lost 2, and 1 patient lost 3 implants. One patient lost 4 and 2 patients lost 5 implants each. Of the 25 patients affected by late implant loss, 6 (24%) underwent new implant placement procedures. For 8 patients (32%), new supraconstructions were produced. For 4 patients (16%), supraconstructions were modified, while for 5 subjects (20%), the whole supraconstruction was lost and not replaced. For 8 cases (32%), late implant loss had no impact on the prosthetic rehabilitation.

Early and late implant loss according to implant brands are described in the Appendix Table.

Table 4 shows the results of the multilevel analysis for the event "early loss." Of the significant factors identified in the bivariate analyses, 4 factors showed significantly higher odds ratios (ORs) for early loss in the final model: subjects with an initial diagnosis of periodontitis (OR, 3.3), smokers (OR, 2.3), implants <10 mm (OR, 3.8), and implant brand. Compared with Straumann group implants, Nobel Biocare group implants (OR, 1.9), Astra Tech group implants (OR, 2.1), and the category of "other" implants (OR, 7.8) presented with significantly higher odds ratios for early loss.

Table 1.
Patient-Related Information Retrieved from Patient Files

	Patient File Sample (n = 2,765)	Clinical Examination Sample (n = 596)
Female sex	54	55
Smoker	30	29
Diabetes	8	5
Myocardial infarction	2	2
Stroke	2	2
Periodontitis diagnosis	24	22
Prophylactic antibiotics at implant placement	86	84
Implants per patient, mean ± SD	4.1 ± 2.9	4.0 ± 2.8
Surgery		
General practitioner	22	21
Specialist	78	79
Prosthetics		
General practitioner	76	73
Specialist	24	27
Maintenance		
General practitioner	82	80
Specialist	14	17
None	4	3
Frequency of recall visits		
Regular (annual)	81	82
Irregular	19	18

All data are given in percentages unless otherwise noted.

Results of the multilevel analysis for "late loss" are also described in Table 4. The final model showed associations between late loss and implant brand. Straumann group implants were used as reference (OR, 1.0). Odds ratios for Nobel Biocare group implants and Astra Tech group implants were 6.1 and 5.2, respectively. For "other" implants (OR, 58.2), a significantly higher odds ratio was observed.

Discussion

In the present study, early and late occurring loss of dental implants were evaluated in a large and randomly selected patient sample. It was demonstrated that early implant loss occurred in 4.4% of patients, while 4.2% of the patients who were examined around 9 y after therapy presented with late implant loss. Taken together, 7.6% of the patients had lost at least 1 implant. In addition, multilevel analysis revealed higher odds ratios for early implant loss among smokers and patients with an initial diagnosis of periodontitis. Implants shorter than 10 mm and representing certain brands also showed higher odds ratios for early implant loss. Implant brand also influenced late implant loss. It is suggested that implant loss is not an uncommon event and that patient and implant characteristics influence outcomes.

The present study reports on a patient material, which in several aspects is different from that presented in most clinical studies on dental implant therapy. The national data register of the SSIA covers almost all individuals >20 y of age receiving dental care in public or private setting in Sweden. As the register also included patients exposed to restorative therapy using dental implants, the patient groups of the present study represent a random sample of the selected age categories of the population. In addition, the implant-supported restorative therapy in the present study was carried out by a large number of clinicians representing different clinical settings and training in the field. Thus, in contrast to previous publications on so-called convenience patient samples, the present study sample constitutes a true cohort. The evaluation also applies to everyday clinical practice and provides data on effectiveness rather than efficacy (Berglundh and Giannobile 2013).

Patients from 2 age groups were randomly selected for the present study. As stated above, in 2003, the federal subsidies for implant-supported restorative therapy increased for patients ≥65 y of age. A reference group of younger individuals (45–54 y) was also included in the study (Derks et al. 2014).

Table 2.
Implant-Related Information Retrieved from Patient Files

	Patient File Sample (n = 11,311 Implants)	Clinical Examination Sample (n = 2,367 Implants)
Implant brand		
Astra Tech group implants (Astra Tech Implant System)	19	19
Nobel Biocare group implants (Brånemark System, Replace Select)	41	40
Straumann group implants (Straumann Dental Implant System)	30	32
Other	10	9
Implant length		
<10 mm	9	9
≥10 mm	91	91
Implant diameter		
<4 mm	59	56
≥4 mm	41	44
Jaw		
Maxilla	58	60
Mandible	42	40
Position		
Anterior (canine-canine)	45	44
Posterior	55	56
Implant placement		
Immediate (same session as tooth extraction)	4	4
Healed ridge	96	96
Installation procedure		
1-stage	49	49
2-stage	51	51
Bone augmentation procedure	7	8
Loading		
Early/direct (<4 wk from implant placement)	7	5
Late (≥4 wk)	93	95
Retention of supraconstruction		
Screw retained	83	81
Cemented	16	19
Removable	1	0
Design of supraconstruction		
Single	10	12
Multiunit without cantilever	30	30
Multiunit with cantilever	60	58
Connection		
Single	10	12
Implant-implant	89	87
Implant-tooth	1	1

All data are given in percentages.

Table 3.
Implant Loss

	Early Loss (2,765 Patients, 11,311 Implants)	Late Loss (596 Patients, 2,367 Implants, Mean Function Time: 8.9 y)	Total Loss (596 Patients, 2,367 Implants, Mean Function Time: 8.9 y)
Patients affected	121 (4.4%) 10 patients unaccounted for	25 (4.2%)	45 (7.6%)[a]
Implants lost	154 (1.4%) 50 implants unaccounted for	46 (2.0%)[b] 2 implants unaccounted for	72 (3.0%) 2 implants unaccounted for

[a]Early and/or late loss.
[b]Early lost implants not considered for calculation of percentage.

Table 4.
Factors Associated with Early and Late Implant Loss: Multiple Multilevel Analysis

Early Loss (11,311 Implants, 2,765 Subjects)	Early Loss (% of Implants)	Odds Ratio	95% Confidence Interval	*P* Value
Periodontitis diagnosis				
No	1.0	1		
Yes	2.3	3.29	1.69–6.42	0.001
Smoking				
Nonsmoker	0.9	1		
Smoker	2.2	2.32	1.03–5.24	0.042
Implant length				
≥ 10 mm	1.2	1		
<10 mm	3.0	3.78	2.15–6.64	<0.001
Implant brand				
A	0.7	1		
B	1.3	1.94	1.02–3.69	0.043
C	1.5	2.10	1.03–4.30	0.042
D	3.5	7.79	3.69–16.47	<0.001
Late Loss after 8.9 y (2,367 Implants, 596 Subjects)	**Late Loss (% of Implants)**	**Odds Ratio**	**95% Confidence Interval**	***P* Value**
Implant brand				
A	0.5	1		
B	2.4	6.13	0.47–80.51	0.139
C	2.5	5.23	0.28–99.38	0.244
D	3.8	58.15	2.35–1435.92	0.012

Implant brands: A, Straumann implant group; B, Nobel Biocare implant group; C, Astra Tech implant group; D, other.

The findings on early implant loss presented in the current study disclosed that the proportion of affected patients was larger than that of early lost implants (4.2% vs. 1.4%). While similar results were presented in a multicenter study on implant loss performed in private clinics (Esposito et al. 2010), results from a study conducted in a university clinic revealed that early loss occurred in 0.7% of implants and 0.8% of patients (Bornstein et al. 2008).

The approach of a retrospective evaluation of early implant loss carried out in the present study was also applied by Alsaadi et al. (2007). They examined 2,004 patient files from a university clinic and reported that 258 implants (3.6%) in 178 patients (8.9%) were lost prior to or at abutment connection. Most cases (91%) had lost 1 or 2 implants. While the

data presented by Alsaadi et al. (2007) indicated larger proportions of early lost implants and affected patients than in the present study, a similar percentage of patients presenting with 1 or 2 lost implants was found in the 2 studies. The findings on higher odds ratios for smokers and implants with length <10 mm for early implant loss reported by Alsaadi et al. (2007) are consistent with results in the present study.

The multilevel analysis of implant-related factors on early implant loss in the present study showed that, in addition to implant length, implant brand influenced the outcome. Thus, Straumann group implants presented with a lower odds ratio for early implant loss than other implant brands. As the Straumann group implants in the present material had a 1-piece design that included both the intraosseous and transmucosal portions, the installation procedure for this implant type called for a nonsubmerged or so-called 1-stage technique. Other categories of implants, however, comprised 2 parts and were, hence, installed using either a 1- or a 2-stage (initially submerged) technique. The analysis of early implant loss in the present study failed to demonstrate significant differences between the 2 installation procedures. Reasons for the observed differences between implant brands with regard to early implant loss are not detectable from the current material. Factors related to implant design in combination with site preparation may be considered, as early implant loss indicates a failure in integration of the implant in bone tissue following implant installation.

The results from the analysis of patient-related factors in the present study revealed that an initial diagnosis of periodontitis had a higher odds ratio for early implant loss. While periodontitis is one of the most common diseases in humans and one of the main reasons for tooth loss, the susceptibility to the disease itself may not explain the higher odds ratio. The consequences of the progression of the disease, however, with advanced attachment and bone loss and, eventually, tooth loss result in an edentulous ridge with reduced dimensions. Reduced ridge dimensions may also reflect the use of implants with length <10 mm. In this context, it should be realized that differences in bone quality of the alveolar process between patients with and without periodontitis may not exist as studies on human bone samples failed to demonstrate differences between patient groups (Cecchinato et al. 2012; Lindhe et al. 2012).

The second part of the present investigation was based on findings made in a clinical examination performed on 596 of 900 invited patients at 9 y after therapy. The rate of attendance may be considered high, taking into account the age of the 2 patient groups (54–63 and 74–83 y, respectively, at the time of clinical examination) and the varying accessibility for patients to dental clinics in this nationwide project. The examination revealed that 2.0% of implants in 4.2% of the patients were lost during the 9 y after prosthesis connection. These findings indicate better outcomes in comparison with data reported in long-term studies in implant dentistry. Results from a systematic review revealed a mean total implant loss rate of 5.1% after 5 y and 6.9% after 10 y (Pjetursson et al. 2012). Most of the 32 studies included in the review represented 5-y outcomes, with early and late implant loss occurring in 2.4% and 2.7%, respectively. In addition, the patients in the review by Pjetursson et al. (2012) represented in most cases specialist or university clinical settings. The evaluations made in the present study on late implant loss did not disclose any differences in outcomes between clinical settings (i.e., public vs. private practice or general practitioner vs. registered specialist). Furthermore, no associations between late implant loss and patients with an initial diagnosis of periodontitis or presenting with irregular recall visits were found. This observation is not in agreement with data reported in a 10-y study on implant loss in different categories of patients (Roccuzzo et al. 2010). In addition, the finding that smoking was not associated with late implant loss is not in agreement with data presented in systematic reviews (Heitz-Mayfield and Huynh-Ba 2007; Strietzel et al. 2007).

The multilevel analysis in the present study disclosed that implant brand also influenced late implant loss. As was the case for differences between implant brands regarding early implant loss, the data from the present material did not provide explanations for the differences in late implant loss. In addition, there may be several reasons for late implant loss, such as progressive marginal bone loss, damages on the interface between the implant and the bone tissue, or harm to the implant, including implant fracture.

The present study also examined the consequences of early and late occurring implant loss. The findings indicate that for the individual patient, implant loss has a significant effect on the overall treatment outcome of implant-supported restorative therapy.

In summary, the present study reported on outcomes in implant dentistry assessed in a large and randomly selected patient sample representing effectiveness of the treatment procedures. Almost 8% of patients had lost ≥1 implants, and several patient- and implant-related factors influencing early and late occurring loss were detected.

Author Contributions

J. Derks, contributed to data analysis, drafted the manuscript; J. Håkansson, contributed to conception and design, critically revised the manuscript; J.L. Wennström and T. Berglundh, contributed to conception, design, and data analysis, drafted the manuscript; C. Tomasi and M. Larsson, contributed to data analysis, critically revised the manuscript. All authors gave final approval and agree to be accountable for all aspects of the work.

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