

A systematic review of the incidence of biological and technical complications in implant dentistry reported in prospective longitudinal studies of at least 5 years

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Abstract

Objective: To systematically review the incidence of biological and technical complications in implant therapy reported in prospective longitudinal studies of at least 5 years.

Methods: A MEDLINE search was conducted for prospective longitudinal studies with follow-up periods of at least 5 years. Screening and data abstraction were performed independently by multiple reviewers. The types of complications assessed were as follows: implant loss, sensory disturbance, soft tissue complications, peri-implantitis, bone loss ≥ 2.5 mm, implant fracture and technical complications related to implant components and suprastructures.

Results: The search provided 1310 titles and abstracts, out of which 159 were selected for full-text analysis. Finally, 51 studies were included. Meta analysis of these studies indicated that implant loss prior to functional loading is to be expected to occur in about 2.5% of all implants placed in implant therapy including more than one implant and when routine procedures are used.

Implant loss during function occurs in about 2–3% of implants supporting fixed reconstructions, while in overdenture therapy $>5\%$ of the implants can be expected to be lost during a 5-year period. Few studies (41% of those included) reported data on the incidence of persisting sensory disturbance >1 year following implant surgery. Most of the studies that provided such data reported on the absence or a low incidence (1–2%) of this complication beyond this interval. A higher incidence of soft tissue complications was reported for patients treated with implants supporting overdentures. There is limited information regarding the occurrence of peri-implantitis and implants exhibiting bone loss ≥ 2.5 mm. Implant fracture is a rare complication and occurs in $<1\%$ of all implants during a 5-year period. The incidence of technical complications related to implant components and suprastructures was higher in overdentures than in fixed reconstructions.

Conclusion: Implant loss was most frequently described (reported in about 100% of studies), while biological complications were considered in only 40–60% and technical complications in only 60–80% of the studies. This observation indicates that data on the incidence of biological and technical complications may be underestimated and should be interpreted with caution.

Key words: complications; dental implants; longitudinal; prospective; systematic review

The outcome of implant therapy has been summarized in several recent reviews (Cochran 1996, Esposito et al. 1998, Fritz 1996, Fiorellini et al. 1998, Gotfredsen 1999, Mericske-Stern 1999, Van Steenberghe et al. 1999) and evaluations are often reported in success and survival rates. The interpretation of the results, however, relies on the concept that different investigators use similar criteria for implant success and survival. Variations in study design and study period, and an improper definition of the selection of patients are factors that may further affect the interpretation of data.

In a consensus report from the 3rd European Workshop on Periodontology (Wennström & Palmer 1999), recommendations and guidelines for the design of clinical trials in implant dentistry were presented. It was suggested that longitudinal studies on implants should have the character of a randomized clinical trial when a scientifically accepted standard reference exists. A longitudinal study including consecutive cases could be accepted in the absence of a proper control. In the consensus report it was further suggested that the follow-up period of an implant system should be at least 5 years. It was also stated that complications and patient satisfaction should be recorded during the evaluation period.

There are two categories of complication that occur in implant therapy: biological and technical (mechanical). 'Biological complications' refer to disturbances in the function the implant characterized by biological processes that affect the tissues supporting the implant. Implant loss is classified as a biological complication and can be distinguished into early and late losses. Biological complications also include reactions in the peri-implant hard and soft tissues, and the detection of such complications requires adequate clinical and radiographic examination methods.

'Technical complications' serve as a collective term for mechanical damage of the implant/implant components

and suprastructures. Brägger (1999) stated in a review paper that technical complications of implant components or prostheses frequently occur and that the incidence of some technical complications is specific for certain implant systems. In a comprehensive review on clinical complications (biological and technical) among implants, Goodacre et al. (1999) concluded that: 'variations in study design and reporting procedures limited the available data and therefore precluded proper analysis of certain complications'.

The objective of this systematic review was to describe the incidence of biological and technical complications in implant therapy reported in prospective longitudinal studies of at least 5 years.

Materials and methods

Study inclusion criteria

Type of studies

Prospective longitudinal studies with follow-up periods of at least 5 years were considered. Thus, cohort studies, controlled clinical trials and randomized controlled clinical trials were included in the review. Prospective studies reporting life-tables were analysed with respect to the proportion of patients/implants that were followed >5 years. Publications were excluded if less than 80% of the initial subject sample was examined at 5 years, or if breakdown of data corresponding to 5 years of observation could not be achieved.

Type of patients

Edentulous and partially edentulous patients restored with implant-supported reconstructions were included in the systematic review. The implant-supported reconstructions included single crowns, fixed partial bridges, fixed complete bridges and overdentures. The implants must have been in function >5 years. Prospective longitudinal studies of 5 years or

more analysing (1) implant therapy in conjunction with regenerative procedures including the use of grafts, (2) immediate placement of implants in extraction sockets and (3) implants subjected to early loading were also included in the review.

Type of complications recorded

Implant loss. An implant lost or removed before the prosthetic reconstruction was connected was regarded as an early loss and as being indicative of a lack of tissue integration. The number of implants representing early loss was related to the total number of implants placed and expressed as a percentage. All implants lost or removed during function, with the exception of fractured implants, were related to the total number of implants placed and to the number of implants followed during the observation period. Thus, two different percentages of implant loss during function were calculated. One proportion was related to the number of implants entering the study (number of implants lost during function divided by the number of implants entered) and the other proportion was calculated from the number of implants followed, so disregarding implants withdrawn during the monitoring period (number of implants lost during function divided by the number of implants followed plus the number of implants lost during function).

Sensory disturbance. Patients demonstrating persisting sensory disturbance >1 years after implant surgery.

Soft tissue complications. Symptoms from the peri-implant tissues, such as persisting pain, excessive swelling, hyperplasia requiring surgical therapy, fistula or suppuration, were regarded as complications. The number of events per patient during a 5-year period was calculated.

Peri-implantitis. The frequency of implants exhibiting symptoms of peri-implantitis according to the definitions made by Albrektsson & Isidor (1994)

was recorded. In addition to the direct information on peri-implantitis reported in the different studies, results from probing and attachment level assessments as well as radiographic examinations were analysed. Implants demonstrating the following features were scored as peri-implantitis: probing depth of >6 mm in combination with (2) bleeding on probing/suppuration and (2) attachment loss/bone loss of 2.5 mm. Studies in which data from probing assessments at all implants were lacking were scored as 'not analysed' (NA). If probing data were presented in terms of mean values and no frequency distributions were provided, the study was scored as 'not reported' (NR) for the occurrence of peri-implantitis.

Crestal bone loss. Implants demonstrating crestal bone loss of 2.5 mm over the entire 5-year period of monitoring were identified. Studies in which data from radiographic examinations were lacking were scored as NA. If data from radiographic examinations were presented as mean values and no frequency distributions were provided, the study was scored as NR for the detection of bone loss.

Implant fracture. The frequency of implants reported as fractured during the observation period was determined. If the implant fracture resulted in the removal of the implant, it was not included in the category 'implant loss'.

Implant components and connections. Technical complications related to the implant components and connections to the suprastructure, including screw loosening or fractures of screws, were counted and presented as the number of events per patient during a 5-year period due to the complexity of implant/suprastructure connections.

Suprastructures. Technical complications related to suprastructures, such as fracture or deformation, were documented and presented as the number of events per patient during a 5-year period.

Search strategy

A MEDLINE search (PubMed) was conducted, and work published in English until December 2001 was included in the systematic review. The following search terms were used: 'dental implants' AND 'cohort studies'; 'dental implants' AND 'case control studies'; 'dental implants' AND 'controlled clinical trials'; 'dental implants'

AND 'randomized controlled clinical trials'; 'dental implants' AND 'complications'; 'dental implants' AND 'clinical'; 'dental implants' AND 'longitudinal'; 'dental implants' AND 'prospective'. Additional search strategies included the terms 'failure', 'suppuration', 'peri-implantitis' and 'fracture'.

Manual searches included (1) bibliographies of previous reviews, (2) European Workshops in 1994, 1997 and 1999, (3) World Workshops in 1989 and 1996, and (3) the following journals: *Clinical Implant Dentistry & Related Research*, *Clinical Oral Implants Research*, *International Journal of Oral & Maxillofacial Implants*, *International Journal of Periodontics & Restorative Dentistry*, *Journal of Clinical Periodontology* and *Journal of Periodontology*.

Validity assessments

Titles and abstracts from the search were screened by two examiners (TB and LP). An appraisal form for data abstraction from full text articles was produced. Two independent reviewers (TB and BK) performed full-text analysis of selected studies of possible relevance against the inclusion criteria. Agreement between examiners and reviewers was determined by Kappa statistics.

Quantitative data synthesis

Weighted mean values and the 95% confidence interval (CI) were calculated for each type of complication and treatment procedure. The number and proportion of included studies providing information regarding the different types of complication were calculated.

Results

Study characteristics

Some 159 of the 1310 titles and abstracts that were screened by the two examiners were selected for further analysis. Substantial agreement was reached with the Kappa score 0.66 (95% CI, 0.59–0.73). In the case of titles and abstracts retrieved by only one screener, the publication was added for further analysis. Manual searching added four studies. Fifty-one studies remained after full-text analysis by the two reviewers. Five additional publications reported

data on subject samples included in the 51 studies. Such repeated reportings were grouped together. Thus, three of the five studies that reported 10 years of observations (Gunne et al. 1999, Steflik et al. 1995, Zarb & Schmitt 1991) (see Tables 2 and 3 later) were grouped together with their 5-year counterpart (Olsson et al. 1995, Koth et al. 1988, Zarb & Schmitt 1990a), while two of the five studies presenting the same patient material and study period but with different types of complication (Zarb & Schmitt 1990b,c) were reported together with their preceding publication (Zarb & Schmitt 1990a) (Table 2).

Several studies presented data from mixed treatment procedures (e.g. overdentures, fixed complete/partial bridges). Findings from such studies were analysed with respect to the number of patients, implants and complications in relation to each treatment procedure, and were reported separately. This resulted in a total of 56 study units distributed for each treatment procedure (Tables 1–6). Studies reporting mixed treatment procedures and in which breakdown of data for each treatment type could not be achieved were grouped into the category of treatment procedures that dominated in the study (Buser et al. 1997, De Bruyn et al. 1999, Hellem et al. 2001, Weber et al. 2000). The majority of the selected studies were longitudinal cohort studies and, in a few cases, controlled clinical trials and randomized controlled trials.

Of the 169 selected studies of possible relevance for the review following screening of titles and abstracts, 113 were excluded following full-text analysis. The main reasons for exclusion of publications were (1) retrospective design, (2) observation periods <5 years and (3) inability to perform breakdown of data corresponding to 5 years in studies reporting life tables.

The 51 studies (56 study units) that met the inclusion criteria are presented in Tables 1–6. Each table refers to a specific treatment group. The number of patients and implants included and the frequencies of complications occurring during the observation period are presented for each study and treatment group (Tables 1–6). In the 51 studies, representing 56 study units, 10 implant systems had been used. The Brånemark System (Nobel Biocare AB, Göteborg, Sweden)

Table 1. Overdentures

References	Patients/Implants			Complications								
	No. patients/ implants included	Implant system study period	No. patients/ implants followed >5 years	Implants lost before loading (%)	Implants lost during function (fractures excluded) (%)**	Persisting paresthesia >1 year (% patients)	Soft tissue compl (5 year incidence/patient)	Peri- implantitis (%)	Bone loss ≥2.5 mm fracture (%)	Implant (%)	Implant- connection (5 year incidence/patient)	Suprastructure (5 year incidence/ patient)
Bergendal & Engquist (1998)	49/115	Brånemark 3–9 years*	27/57 (mand./ max.)	2.6 (mand.)	11.3/12.3 (max.)	NR	NA	NA	NR	0	2.70	4.74
Buser et al (1997) (Mixed treatment procedures)	269/536	ITI 5 years	249/488 (mand./ max.)	0.4	0.9/1.0	NR	NR	0.8	NA	0.2	NA	NA
Cordioli et al (1997) (Overdent. on 1 impl.)	21/21	3i (different surfaces) 5 years	15/15 (mand.)	0	0	NR	0	0	6.7	NR	NR	1.0
Davis & Packer (1999)	25/52	Astra Tech 5 years	25/52 (mand.)	0	1.9/1.9	NR	NA	NA	0	3.8	3.84	3.40
Deporter et al (1999)	52/156	Endopore 5 years	46/134 (mand.)	NR	6.4/7.4	NR	0	0	NR	NA	NA	NA
Fartash et al (1996).	86/324	Bioceram, sapphire 3–12 years*	NR/282 (mand.)	2.2	8.3/9.5	0	0	NA	NR	NR	0.15	0.74
Gotfredsen & Holm (2000)	26/52	Astra Tech 5 years	25/50 (mand.)	1.9	0	NR	0.15	0	NR	0	3.15	3.50
Hemmings et al (1994)	25/68	Brånemark 3–9 years*	25/64 (mand.)	5.9	3.1/3.1	NR	0.1	1.6	NA	0	0.30	1.25
Jemt et al (1996)	133/510	Brånemark 5 years	–/213 (mand./ max.)	7.7 (max.) 1.8 (mand.)	20.0/25.3 (max.) 3.5/4.3 (mand.)	NR	NA	NA	NR	NR	NR	NR
Makkonen et al. (1997)	20/78	Astra Tech 5 years	NR/NR (mand.)	2.6	0	0	NR	0	0	0	0	0.15
Meijer et al. (2000) (RCT)	29/58 32/64	IMZ Brånemark 5 years	29/58 30/60 (mand.)	5.1 7.8	1.8/1.8 6.2/7.2	6.9 6.8	0.30 0.05	NR NR	8.9 8.3	0	0.45 0.05	1.45 2.05
Mericske-Stern et al. (1994)	39/78	ITI 5 years	33/66 (mand.)	0	1.3/1.5	NR	NR	1.5	NA	1.5	NA	NA
Naert et al. (1998, 1999) (RCT)	36/72	Brånemark 5 years	31/62 (mand.)	1.4	0	NR	2.0	NR	0	0	3.51	3.42
Smedberg et al. (1999)	20/86	Brånemark 6–7 years	14/72 (max.)	NR	16.3/16.3	NR	0.30	NA	0	0	6.64	1.01

Table 2. Continued

Patients/Implants				Complications								
References	No. patients/ implants included	Implant system study period	No. patients/ implants followed >5 years	Implants lost before loading (%)	Implants lost during function (fractures excluded) (%)*	Persisting paresthesia >1 year (% patients)	Soft tissue compl (5 year incidence/ patient)	Peri- implantitis (%)	Bone loss ≥2.5 mm (%)	Implant fracture (%)	Implant- connection components (5 year incidence/ patient)	Suprastructure (5 year incidence/ patient)
Makkonen et al (1997)	13/77	Astra Tech 5 years	NR/NR (mand.)	0	0	0	NR	1.3	1.3	0	0.08	0.15
Tinsley et al (2001)	21/104	Calcitek 5 years	21/79 (mand.)	0	0	NR	NA	NA	16.5	NR	0.24	0.62
Zarb & Schmitt (1990a,b,c,1991)	46/274	Brånemark 4–9 years* 5–10 years	46/262 (max. + mand.)	8.0	3.4/4.0	0	NR	NA	NA	0	1.09	0.22
Mean (SD)				2.73 (2.94)	3.76/4.05 (5.67)/(5.71)		0.21 (0.34)	1.00 (1.25)	7.00 (10.72)	0.20 (0.47)	0.25 (0.36)	0.56 (0.57)
Range				0–8.0	0–20.7/0–20.7		0–0.71	0–3.10	0–30.00	0–1.30	0–1.09	0–1.56
Weighted mean (SD)				2.16 (0.69)	2.71/3.42 (0.99)/(1.08)		0.19 (0.10)	0.71 (0.34)	3.78 (1.97)	0.08 (0.09)	0.19 (0.11)	0.54 (0.18)
95 % CI				1.80–2.52	2.20–3.23/ 2.86–3.99		0.12–0.26	0.44–0.98	2.41–5.14	0.03–0.12	0.13–0.26	0.42–0.66

NA, not analysed, NR, not reported.

*Data calculated corresponding to 5 years. **Calculated from number of implants lost in relation to: number entered/number known (followed + lost).

Table 3. Fixed partial dentures

Patients/Implants				Complications								
No. patients/ implants included	Implant system study period	No. patients/ implants followed >5 years	Implants lost before loading (%)	Implants lost during function (fractures excluded) (%)**	Persisting paresthesia >1 year (% patients)	Soft tissue compl (5 year incidence/patient)	Peri- implantitis (%)	Bone loss ≥2.5 mm (%)	Implant fracture (%)	Implant- connection components (5 year incidence/patient)	Suprastructure (5 year incidence/patient)	
References												
Behneke et al. (2000)	55/144	ITI (solid screw 5 years	47/94 (max. + mand).	0	4.4/5.3	NR	0.05	14.4	NR	0	0.27	0.15
Brägger et al. (2001)	45/103	ITI 5 years	45/103	0	0	NR	0	9.7	NA	1.9	0.22	0.24
De Leonardis et al. (1998)	33/70	Minimatic implants 5 years	32/68 (max.+ mand.)	0	0	NR	NR	0	0	0	NA	NA
Fartash & Arvidson (1997)	27/56	Bioceram- sapphire 7 –13 years	27/56 (max + mand.)	0	0.	0	0	NA	NR	1.8	NR	NR
Gotfredsen & Karlsson (2001)	50/133	Astra Tech 5 years Machined/ TiO–bl.	40/117 (max + mand.)	1.5	0.7/0.9	2.5	NR	NR	1.7	0	0.48	0.05

Jemt & Lekholm (1993)	67/259	Brånemark 5 years	60/NR (max. + mand.)	1.5	1.2/1.3	NR	0.16	NA	NR	1.8	0.12	0.54
Lekholm et al. (1994)	159/558	Brånemark 5 years	132/438 (max. + mand.)	3.6	2.9/3.7	3.8	0.08	NR	NR	0.46	0.17	0.24
Lekholm et al. (1999)	127/461	Brånemark 10 years	89/304 (max. + mand.)	3.9	3.3/4.7	1.8	NR	NA	NR	0.9	0.06	0.18
Mengel et al. (2001) (GAP pts)	5/36	Brånemark 5 years	5/34 (max. + mand.)	2.8	2.8/2.9	NR	NR	NR	NR	NR	NR	NR
Olsson et al. (1995) (5 years), Gunne et al. (1999) (10 years)	23/69	Brånemark 5 years 10 years	21/58 20/52 10 years (mand.)	1.4	10.1/10.8 (5 y) 10.1/11.9 (10 y)	19.0 10.0	NR	NR	NR	0	0.19 0.25	0.10 NR
Koth et al. (1988) (5 years), Steffik et al. (1995) (10 years)	17/28	Bioceram-sapphire 5 years 10 years	—/21 (5 years) —/17 (10 years) (mand.)	17.0	4.3/4.5 (0–5 y) 17.4 /23.5 (5–10 y)	NR	0	4.3	NR	NR	NA	NA
Weber et al. (2000) (Partial dentures + single crowns)	46/112	ITI (Hollow screw/cylinders) 5–6 years	40/106 (max. + mand.)	0	0.9/0.9	NR	0.8	0.9	0.9	2.6	NA	NA
Wyatt & Zarb (1998)	77/230	Brånemark 1–12 years (Mean 5.41 years)	77/221 (max. + mand.)	3.0	3.0/3.2	0	NA	NA	NA	0	0.50	0.32
Zarb & Schmitt (1993)	35/105	Brånemark 2.6–7.4 years (Mean 5.2 years)	35/101 (max. + mand.)	1.9	0	NR	NA	NA	NA	1.9	NR	0.17
Mean (SD)				2.68 (4.60) 0–17.9	2.40/2.73 (2.75)/(3.02) 0–10/0–10.8		0.16 (0.29) 0–0.80	5.86 (6.10) 0–14.4	0.87 (0.85) 0–1.70	0.94 (0.99) 0–2.60	0.25 (0.16) 0.06–0.50	0.22 (0.14) 0.05–0.54
Range				2.53 (0.62) 2.21–2.86	2.49/3.07 (0.52)/(0.64) 2.22–2.76/ 2.73–3.40		0.15 (0.07) 0.10–0.20	6.47 (1.39) 5.26–7.69	1.01 (0.19) 0.79–1.23	0.74 (0.24) 0.61–2.88	0.23 (0.05) 0.20–0.27	0.24 (0.04) 0.22–0.27
Weighted mean (SD)												
95 % CI												

NA, not analysed, NR, not reported.

*Data calculated corresponding to 5 years. **Calculated from number of implants lost in relation to: number entered/number known (followed + lost).

Table 4. Single tooth replacement

Patients/Implants			Complications								
No. patients/ implants included	Implant system study period	No. patients/ implants followed > 5 years	Implants lost before loading (%)	Implants lost during function (fractures excluded) (%)**	Persisting paresthesia >1 year (% patients)	Soft tissue compl (5 year incidence/patient)	Peri- implantitis (%)	Bone loss ≥2.5 mm (%)	Implant fracture (%)	Implant- connection components (5 year incidence/patient)	Suprastructure (5 year incidence/patient)
References											
Andersson et al (1998a)	Brånemark 5 years	49/55 (max.+ mand.)	0	1.5/1.8	NR	0.02	0	NR	0	0.04	0.10
Andersson et al (1998b)	Brånemark 5 years	35/35 (max.)	0	0	NR	0.11	0	NR	0	0	0.03
De Leonardis (1998)	Minimatic implants 5 years	30/30 (max.+ mand.)	0	0	NR	NR	3.3	0	0	NA	NA
Fartash & Arvidson (1997)	Bioceram- sapphire 7–13 years	7/7 (max.)	0	14.3/14.3	0	0	0	0	0	NR	NR
Henry et al. (1996)	Brånemark 5 years	75/86 (max.+ mand.)	0.9	1.9/2.3	0	0.14	0	NR	0	0.87	-0.2
Mericske-Sternal (2001)	ITI Solid screw 5 years	26/26 (max.+ mand.)	0	7.6/7.6	NR	0	0	3.8	0	0.23*	0.15*
Palmer et al (2000)	Astra Tech 5 years	14/14 (max.)	0	0	0	0	0	0	0	0	0.14
Scheller et al. (1998)	Brånemark 5 years	57/65 (max.+ mand.)	2.0	2.0/3.1	NR	0.09	0	NR	0	0.07	0.21
Mean (SD) Range			0.36 (0.73) 0–2.00	3.41/3.64 (5.06)/(4.99) 0–14.3/ 0–14.30		0.05 (0.06) 0–0.14	0.41 (1.17) 0–3.30	0.95 (1.90) 0–3.80	0 (0) 0	0.20 (0.34) 0–0.87	0.15 (0.08) 0.03–0.25
Weighted mean (SD) 95 % CI			0.76 (0.02) 0.55–0.97	2.06/2.50 (0.36) 1.43–2.69/ 1.81–3.19	(0.51)	0.08 (0) 0.06–0.09	0.31 (0.16) 0.06–0.56	1.28 (0.03) 0.78–1.78	0 (0) 0	0.30 (0.18–0.43)	0.17 0.14–0.19

NA, not analysed, NR, not reported.

*Data calculated from number of implants lost in relation to: number entered/number known (followed + lost).

Table 5. Immediate placement/Early loading

	Patients/Implants			Complications								
	No. patients/ implants included	Implant system study period	No. patients/ implants followed >5 years	Implants lost before loading (%)	Implants lost during function (fractures excluded) (%)**	Persisting paresthesia >1 year (% patients)	Soft tissue compl (5 year incidence/patient)	Peri- implantitis (%)	Bone loss ≥2.5 mm (%)	Implant fracture (%)	Implant- connection components (5 year incidence/patient)	Suprastructure (5 year incidence/patient)
References												
Becker et al. (1999)	40/49	Brånemark 5 years immediate placement + ePTFE membranes	25/29 (max. + mand.)	6.1	0	NA	NA	NA	NR	0	NA	NA
Ericsson et al. (2000)	16/88	Brånemark 5 years (early loading: 20 days)	13/72 (mand.)	0	0	0	0	0	NR	0	0	0
Polizzi et al. (2000)	143/264	Brånemark 5 years (immediate or 3–5 weeks healing following extr.)	86/163 (max. + mand.)	3.8	2.3/3.6	0	0.10	0	NR	0	NA	NA
Mean (SD)				3.30 (3.08)	0.77/1.20 (1.33)/(2.07)		0.05 (0.07)	0 (0)	– (–)	0 (0)	0 (0)	0 (0)
Range				0–6.10	0–2.30/0–3.60		0–0.10	0	–	0	0	0
Weighted mean (SD)				3.25 (1.32)	1.51/2.22 (0.77)/(1.24)		0.09 (0.03)	0 (0)	– (–)	0 (0)	0 (0)	0 (0)
95 % CI				1.75–4.75	0.64–2.39/ 0.82–3.62		0.05–0.13	0	–	0	0	0

NA, not analysed, NR, not reported.

*Data calculated corresponding to 5 years. **Calculated from number of implants lost in relation to: number entered/number known (followed + lost).

Table 6. Augmentation procedures

References	Patients/Implants			Complications								
	No. patients/ implants included	Implant system study period	No. patients/ implants followed >5 years	Implants lost before loading (%)	Implants lost during function (fractures excluded) (%)**	Persisting paresthesia >1 year (% patients)	Soft tissue compl (5 year incidence/ patient)	Peri- implantitis (%)	Bone loss ≥2.5 mm (%)	Implant fracture (%)	Implant- connection components (5 year incidence/ patient)	Suprastructure (5 year incidence/ patient)
Becker et al. (1999)	44/55	Brånemark 5 years dehiscences/ fenestrations + ePTFE membranes	26/33 (max. + mand.)	9.1	10.9/15.4	NA	NA	NA	NR	0	NA	NA
Buser et al. (1996)	9/12	ITI 5 years Ridge augm. EPTFE membranes	9/12 (max. + mand.)	0	0	0	0	0	25	0	NA	NA
Mean (SD)				4.55 (6.43)	5.45/7.70 (7.71)/(10.9)		0 (0)	0 (0)	25 (—)	0 (0)	—	—
Range				0–9.10	0–10.9/0–15.4		0	0	—	0		
Weighted mean (SD)				7.47 (3.49)	8.95/11.29 (4.17)/(6.81)		0 (0)	0 (0)	25 (—)	0 (0)	—	—
95 % CI				2.63–12.3	3.16–14.74/ 1.85–20.73		0	0	—	0		

NA, not analysed, NR, not reported.

**Calculated from number of implants lost in relation to: number entered/number known (followed + lost).

dominated and represented 28 of the studies, followed by ITI Dental Implant System (Straumann AG, Waldenburg, Switzerland) (eight studies) and Astra Tech Implants Dental System (Astra Tech AB, Mölndal, Sweden) (six studies). Bioceram sapphire (Kyocera, Japan) implants were used in three studies, while Calcitek (Calcitek Inc., Carlsbad, USA), Endopore (Innova Technologies Corp., Toronto, Canada), IMZ (Friedrichsfeld, Mannheim, Germany), Minimatic implants (Minimatic Implants Technology, Boca Raton, USA), Screw-Vent (Core Vent, Encino, USA) and 3i (Implant Innovation Inc., West Palm Beach, USA) implants were described in one study each.

The number of patients included in the 56 study units ranged from five to 269 and the number of implants per unit ranged from seven to 618. The overall dropout rate of patients and the number of withdrawn implants during the study periods were $11.0 \pm 13.7\%$ and $14.6 \pm 14.9\%$ respectively. The weighted mean values and 95% CI calculated for each type of complication and treatment group are presented in Table 7. The number of studies included for each treatment group is described and the number of studies reporting data in relation the different types of complication are presented in parentheses.

Complications (Table 7, weighted means)

Patient-based data on implant losses either prior to or during functional loading were not retrievable in sufficient numbers (less than 50%) from the studies reviewed. Hence, implant-based incidences are reported.

(1) Implants lost before loading

The frequency of implants lost before any prosthetic reconstruction was connected ranged from 2.16% to 2.53% for implants designated to support overdentures, fixed complete bridges and fixed partial dentures. The corresponding percentage for implants used in single-tooth replacement procedures was 0.76%. Larger proportions of losses were identified for implants in the group representing 'immediate placement following tooth extraction/early loading' (3.25%) and implants placed in conjunction with 'ridge augmentation procedures' (7.47%). In the two latter groups, however, the number of included

studies was only three and two respectively.

(2) Implants lost during function

Two different scores were calculated for the number of implants that were lost during function. One score (the lower value) was related to the number of implants entering the study. The second score (the higher value) was calculated from the number of implants that was accounted for; hence, implants withdrawn from the study were disregarded.

In the overdenture group, the rate of implants lost during function varied between 5.56% and 5.86%, while the proportions of lost implants were smaller in the groups with fixed complete and partial dentures (2.72–3.42%; complete) (2.49–3.07%; partial). For implants used in single-tooth replacement procedures and in conjunction with immediate placement/early loading, the two scores were 2.06–2.50% and 1.51–2.22% respectively. The two studies on implants lost during function in the ridge augmentation group reported considerably higher figures of 8.95–11.29%.

(3) Persisting sensory disturbance

Few of the studies (23 out of 56) reported on the incidence of persisting sensory disturbance >1 year following implant surgery (Tables 1–6). The number of patients exhibiting symptoms of sensory disturbance varied between 0 and 19. In 13 of the 23 studies providing information on this issue, no patients were identified with nerve disturbances. In the remaining 10 studies, eight publications reported sensory disturbance to occur in of about 1–2%; in two studies, this complication occurred in 6.9% and 19% of cases respectively.

(4) Soft tissue complications requiring therapy

Complications affecting the peri-implant tissues were expressed as the incidence per patient over a 5-year period. About 50% of the studies on overdentures, fixed complete and partial bridges reported on this type of complication. The patients in the overdenture group had a higher number of soft tissue complications than did patients carrying fixed reconstructions – 0.27 vs. 0.19 (complete) and 0.15 (partial). Smaller values were recorded for the single-tooth replacement group

and the immediate placement/early loading groups (0.08 and 0.09).

(5) Peri-implantitis

The frequency of implants exhibiting peri-implantitis varied between the different treatment groups. Studies on overdentures, fixed complete dentures and single-tooth replacement reported frequencies ranging from 0.31% to 0.71%, while the weighted mean value calculated for the treatment group of fixed partial dentures was 6.47%. In this context, it should be noted that data on peri-implantitis were only provided in 35–45% of the included studies on overdentures, fixed complete and fixed partial dentures. In the group of studies on single-tooth replacement, eight publications reported on data referring to presence/absence of peri-implantitis.

(6) Crestal bone loss

The percentage of implants demonstrating bone loss of 2.5 mm was greater in studies reporting on overdentures and fixed complete dentures than in studies including fixed partial dentures and single-tooth replacements (4.76% and 3.78% vs. 1.01% and 1.28%). Data regarding this type of complication were only provided in 20–50% of the included studies.

(7) Implant fracture

Fracture of implants was a rare complication and occurred in 0.08–0.74% of the implants used in overdentures, fixed complete and fixed partial dentures. No implant fractures were reported in studies on single-tooth replacement, immediate placement/early loading and ridge augmentation procedures. The percentage of the included studies that reported on the occurrence of implant fracture was high (ranging from 66% to 100%).

(8) Complications related to implant components

Implants supporting overdentures demonstrated a considerably higher incidence of complications related to implant components and connections to suprastructures than did implants used in fixed reconstructions (complete, partial and single tooth). The weighted mean 5-year incidence per patient was 1.56 for the overdenture group and, for the different treatment

Table 7. Weighted means and 95 % C.I. for all treatment groups. Number of included studies providing data ()

Treatment group	No. studies included	Implants lost before loading (%)	Complications							
			Implants lost during function (fractures excluded) (%)**		Soft tissue compl (5 year incidence/patient)	Peri-implantitis (%)	Bone loss ≥2.5 mm (%)	Implant fracture (%)	Implant-connection components (5 year incidence/patient)	Suprastructure (5 year incidence/patient)
			Low	High						
Overdentures	15	(13) 2.49 2.20–2.78	(15) 5.86 5.23–6.51	(15) 5.56 4.86–6.26	(8) 0.27 0.19–0.37	(7) 0.66 0.55–0.77	(6) 4.76 3.97–5.56	(10) 0.38 0.24–0.51	(9) 1.56 1.30–1.82	(11) 1.90 1.73–2.06
Fixed complete dentures	14	(14) 2.16 1.80–2.52	(14) 2.72 2.20–2.86	(14) 3.42 2.86–3.99	(7) 0.19 0.12–0.26	(6) 0.71 0.44–0.98	(8) 3.78 2.41–5.14	(12) 0.08 0.03–0.12	(9) 0.19 1.130–0.26	(9) 0.54 0.42–0.66
Fixed partial dentures	14	(14) 2.53 2.21–2.86	(14) 2.49 2.22–2.76	(14) 3.07 2.73–3.40	(7) 0.15 0.10–0.20	(5) 6.47 5.26–7.69	(3) 1.01 0.79–1.23	(12) 0.74 0.61–0.88	(9) 0.23 0.20–0.27	(9) 0.24 0.22–0.27
Single-tooth replacement	8	(8) 0.76 0.55–0.92	(8) 2.06 1.43–2.69	(8) 2.50 1.81–3.19	(7) 0.08 0.06–0.09	(8) 0.31 0.06–0.56	(4) 1.28 0.78–1.78	(8) 0 0	(6) 0.30 0.18–0.43	(6) 0.17 0.14–0.19
Immediate placement/ Early loading	3	(3) 3.25 1.75–4.75	(3) 1.51 0.64–2.39	(3) 2.22 0.82–3.62	(2) 0.09 0.05–0.13	(2) 0 0	(0)– 0 0	(3) 0 0	(1) – –	(1) – –
Augmentation procedures	2	(2) 7.47 2.63–12.3	(2) 8.95 3.16–14.74	(2) 11.29 1.85–20.73	(1) – –	(1) – –	(1)– 0 0	(2) 0 0	(0) – –	(0) – –
Reporting score (No.) (%)	56	54 96.4	56 100	56 100	32 57.1	29 51.8	22 39.3	47 83.9	34 60.7	36 64.3

**Calculated from number of implants lost in relation to: number entered/number known (followed + lost).

groups indicating fixed reconstructions, the values were 0.19, 0.23 and 0.30 respectively.

(9) Complications related to suprastructures

The incidence of complications occurring in suprastructures was about 4–10 times higher at implants used in overdenture therapy than at implants incorporated in fixed reconstructions. The weighted mean 5-year incidence for the overdenture studies was 1.90, while the corresponding values for the studies representing fixed complete and partial dentures and single-tooth replacement were 0.54, 0.24 and 0.17 respectively.

Technical complications related to implant components and suprastructures were reported in 60–75% of the studies included.

Discussion

In the present systematic review, a large number of longitudinal cohort studies were analysed with respect to complications in implant therapy. The main approach in the search was to identify studies of prospective design and with follow-up periods of at least 5 years. When titles and abstracts did not provide sufficient information regarding study design and duration, a full-text analysis of studies of possible relevance was carried out. The study design was not clearly defined in all publications and, if not stated in the text, the decision on whether the study was retrospective or prospective in character was made on baseline data, information on drop-outs/withdrawn implants and previous consecutive reports on the same patient material. A retrospective design and duration of <5 years were the main reasons for exclusion of publications. In studies not defining the study endpoint to 5 years for the entire cohort, life tables according to Cutler & Ederer (1958) and Kaplan & Meijer (1958) were frequently applied. Studies reporting results in life tables had to allow breakdown of data corresponding to 5 years in order to be included in the present review (Bergendal & Engquist 1998, Fartash et al. 1996, Hemmings et al. 1994, Wyatt & Zarb 1998, Zarb & Schmitt 1990a, b, c, 1993).

The term 'implant failure' was not included in the list of complications in

the present review because different definitions on failure were used in the studies. The intention of this systematic review was to evaluate features that, on the one hand, may be included in the suggested definitions of implant failure and, on the other hand, eventually result in the loss or removal of the implant. Implant loss was therefore analysed as one type of complication and was distinguished into those occurring prior to and those that took place after prosthesis installation. In this way, it became possible to detect the incidence of implants that were lost before functional loading. The calculated weighted mean values presented in Table 7 indicate that implant loss prior to loading occurs in about 2.5% of all implants placed, with the exception of single-tooth replacement therapy and immediate placement/early loading and ridge augmentation procedures.

The second category of implant loss, i.e. after loading, was presented by two values; one lower and one higher. The lower value was calculated according to Albrektsson & Isidor (1994) from the number of implants lost in relation to the total number of implants placed. The higher value, however, was computed from the number of implants that was accounted for, i.e. implants that either remained and/or were lost during the observation period. By using both values of implant loss during function, a realistic range of implant loss is obtained. It is evident from the meta-analysis that implants in overdenture therapy exhibited higher frequencies of (>5%) of implant loss during a 5-year function period than implants supporting fixed reconstructions (2–3%). The higher scores on implant loss during function found for overdentures are mainly related to implant loss occurring in the maxilla (Bergendal & Engquist 1998, Jemt et al. 1996, Smedberg et al. 1999). In the two studies on implants placed in conjunction with augmentation procedures and with a study duration of 5 years, the weighted mean frequencies of implant loss during function were 9–11%. Implant loss only occurred in one of the studies (Becker et al. 1999), while no implants were lost during the 5-year period in the other report (Buser et al. 1996). It is suggested that insufficient data exist on implant loss in implant therapy

combined with augmentation procedures and with a study duration of 5 years.

Few studies (41% of those included) reported data on the incidence of sensory disturbance persisting >1 year following implant surgery. In the studies that provided data, it was reported that such complications were absent or had a low incidence (1–2%). In one group of patients treated for partial edentulism in the posterior segment in the mandible and followed for 5 years (Olsson et al. 1995) and 10 years (Gunne et al. 1999), it was reported that four out of 21 patients after 5 years and that two of 20 patients after 10 years were concerned about sensory disturbance.

Data on soft tissue complications such as excessive swelling, hyperplasia requiring surgical therapy, fistula or suppuration were reported in <60% of the studies. The overall incidence of this type of complication expressed per patient over a 5-year period was about 0.1–0.3. A higher incidence was reported for patients treated with implants supporting overdentures.

Frequencies of implants exhibiting symptoms of peri-implantitis were analysed in only 29 of the 56 study units (52%). The majority of the 29 studies that provided information on peri-implantitis described findings made from probing assessments. Attachment level measurements were less frequently reported and the terms 'peri-implantitis' and 'peri-implant infection' were used in few studies. Consequently, the interpretation of data on the incidence of peri-implantitis is difficult, because of the inconsistency in the assessment procedures. The weighted mean frequencies presented in Table 7 varied between 0.31 and 0.71 for overdentures, fixed complete dentures and single tooth replacement. In the five studies reporting on peri-implantitis at implants supporting partial fixed dentures, the weighted mean was 6.47. This value was obtained from frequencies reported from three studies on the ITI system, one study on Bioceram and one study on Minimatic implants. In the other nine studies on partial fixed dentures, no data were provided (seven studies on Brånemark system, one study on Astra Tech and study on Bioceram respectively).

For diagnosis of peri-implantitis, it is recommended that the investiga-

tor combines data from probing and attachment level assessments (including bleeding/suppuration) and radiographic bone loss. There is limited information on frequencies of implants exhibiting bone loss of ≥ 2.5 mm. Information on this type of complication was provided in only 40% of the included studies. The weighted mean frequencies determined for implants supporting overdentures and fixed complete dentures were greater than those for implants in fixed partial dentures and in single-tooth replacements.

The technical complication implant fracture appears to be an undisputable variable. Hence, information was provided in 84% of the studies. In the assessments of the percentage of implants lost during function, all fractured implants were excluded. Thus, it was possible to distinguish between the frequencies of implant loss occurring for reasons other than implant fracture. From the data obtained in the present meta-analysis, it is evident that implant fracture is a rare complication and occurs in $<1\%$ of implants during a 5-year period. The highest incidence of implant fracture was found in the group representing partial fixed dentures. An implant fracture does not always result in the removal of the implant. For surgical and other reasons, the fractured implant may be left as 'sleeping'. Anticipating that all fractured implants are removed and considered as lost, the proportion of all implants lost during function as a result of implant fracture remains low (5–20%).

Technical complications related to implant components and suprastructures were more frequently reported than complications related to peri-implant tissues. Results from the meta-analysis revealed that implants supporting overdentures had a considerably higher incidence of complications related to implant components than was the case for implants used in fixed reconstructions. A similar observation was made regarding the incidence of complications occurring in suprastructures.

Conclusions

Within the limits of this systematic review considering only prospective longitudinal studies of at least five years duration, the following conclusions have been drawn:

- 1 Of the different categories of implant complications analysed in prospective studies of at least 5 years, implant loss was most frequently described (reported in 96–100% of the studies), while biological complications were considered in only 40–60% and technical complications in only 60–80% of the studies. Thus, the data on the incidence of biological and technical complications in this review should be interpreted with caution.
- 2 Patient-based data on implant losses either prior to or during functional loading were not retrievable in sufficient numbers (less than 20%) of relevant studies reviewed. In studies providing information on patient level regarding implant loss, no general pattern of cumulative losses within the same patient was detected. Implant-based incidences were analysed.
- 3 The incidence of implant loss prior to functional loading was threefold (2.5%) that of single-tooth replacement when multiple implants were placed for overdentures, fixed complete and partial reconstructions.
- 4 Implant loss during function occurred in 2–3% of implants supporting fixed reconstructions, while twice as many implants were lost in overdenture therapy during a 5-year period. A further analysis of the data on overdentures revealed that the highest frequencies of implant loss during function occurred in the maxilla.
- 5 Limited data exist on implant loss when implants are used in combination with immediate placement/early loading and augmentation procedures.
- 6 Few included studies (41%) reported data on the incidence of persisting sensory disturbance >1 year following implant placement. With the exception of one study with an incidence of $>10\%$, absence or a low incidence (1–3%) of this complication was reported.
- 7 The type of soft tissue complications requiring therapy varied between studies. The overall incidence expressed per patient was 0.1–0.3 in 5 years. A higher incidence was reported for patients treated with implants supporting/retaining overdentures.
- 8 There is limited information on the incidence of peri-implantitis and the occurrence of crestal bone loss of 2.5 mm in 5 years. The term 'peri-implantitis' was included in only a few studies.
- 9 The inability to use information on the incidence of peri-implantitis and the occurrence of crestal bone loss of 2.5 mm in 5 years resulted from the lack of data describing frequency distributions of (1) probing assessments and (2) radiographic bone loss.
- 10 Data on implant fracture were provided in 84% of the studies. In the first 5 years of function, implant fracture was a rare complication and occurred in less than 1% of all implants.
- 11 The incidence of technical complications related to implant components and suprastructures was higher in overdentures than in fixed reconstructions.

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