

Influence of Prosthetic and Implant Therapy on Satisfaction and Quality of Life: A Systematic Literature Review. Part 1—Characteristics of the Studies

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Purpose: This study systematically searched the dental literature to identify and classify articles on the influence of prosthodontic and dental implant treatment on patient satisfaction and oral health–related quality of life according to their level of evidence.

Materials and Methods: A literature search was carried out for articles published between 1960 and February 2003 using an electronic key word search complemented by hand searching. The retrieved articles were subjected to inclusion and exclusion criteria. Only experimental studies were included; articles that did not focus on the effect of therapy on the patient were excluded from further processing. The levels of evidence of the articles were classified following the guidelines of the US Agency for Health Care Policy and Research. **Results:** A total of 207 publications were identified, of which 114 reports investigating 24,863 patients met the inclusion criteria. Data from the studies were analyzed using SPSS 9.0. Two thirds of the publications showed a low evidence level of III; most were conducted in patients who were edentulous or restored with complete dentures (59% of all studies). Mostly, nonstandardized, custom-made questionnaires (80%) were used. On average, 9 (SD 4.2) outcome variables were used within each trial, but clinical criteria were more often used than psychosocial criteria. The most frequently used questions concerned “chewing function” (86%), esthetics (77%), speech (68%), and general satisfaction (67%). Validated instruments, such as the Oral Health Impact Profile, were increasingly used in recent studies, which were also methodically more sufficient.

Conclusion: Few studies with high levels of evidence were found. Research in this field is still in a phase of development. *Int J Prosthodont* 2004;17:83–93.

Four basic parameters have been described to affect the outcome of prosthetic therapy^{1,2}: (1) biologic and physiologic parameters (health of oral structures, chewing ability, nutritional status, esthetics); (2) longevity and survival (of teeth, implants, restorations); (3) psychosocial parameters (treatment satisfaction, self-esteem, body image, quality of life); and (4) economic parameters (cost of fabrication and maintenance, indirect

cost). Clinical scientists in prosthodontics so far have primarily investigated variables from the first two categories. Patient-based outcomes, including psychosocial parameters and economic outcomes, have been neglected for many years and are only now becoming more popular. However, in recent years, interest in assessing the psychosocial outcomes of oral health and dental therapy has exploded.³

The purpose of this investigation was to identify the current literature on satisfaction and quality of life outcomes in dentistry using a thorough electronic and manual search. The collected literature was systematically reviewed, outcome variables and patient collectives were described, and the publications were classified according to established evidence criteria. It was hypothesized that the number of studies using patient-based outcomes is small and that the level of evidence of such studies is low.

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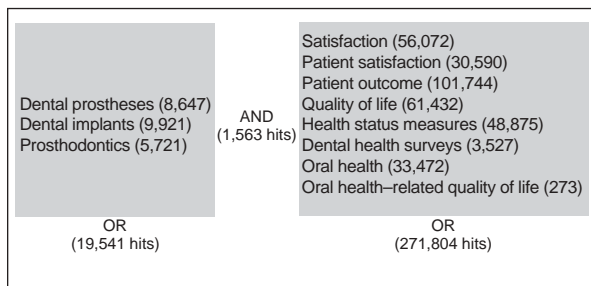


Fig 1 Strategy for the electronic search (limited to key words, Feb 2003).

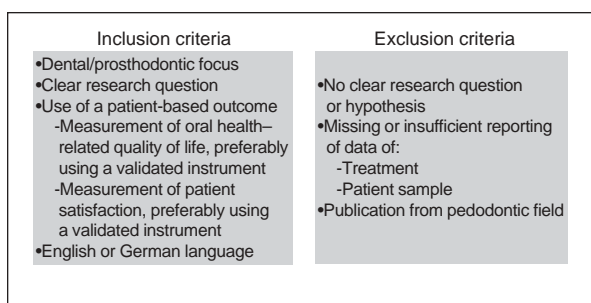


Fig 2 Inclusion and exclusion criteria.

Materials and Methods

Using the software Knowledge Finder (version 4.27, Aries Medical Knowledge), the dental literature from 1960 to February 2003 indexed in the following electronic databases was searched using the key word search strategy depicted in Figs 1 and 2:

- Cochrane Library
 - Cochrane Controlled Trial Register (CCTR)
 - Database of Abstracts of Reviews of Effectiveness (DARE)
- MEDLINE (Knowledge Finder)
- EMBASE (German Institute for Medical Documentation and Information [DIMDI] grips web search)
- 24 dental journals at "Ingenta" (ingenta.com)
- Online search of *Deutsche Zahnärztliche Zeitschrift* (zahnheilkunde.de)
- Online search of *International Poster Journal of Dentistry and Oral Medicine* (ipj.quintessenz.de)

The electronic search was completed February 28, 2003. The reference lists of the retrieved articles were screened for further references.

Inclusion/Exclusion Criteria and Level of Evidence

The primary focus of the search was on systematic reviews, Cochrane reviews, and meta-analyses of randomized controlled clinical trials, which used oral health-related quality of life (OHRQOL) or satisfaction as an outcome of prosthetic intervention (evidence level Ia). Then, randomized controlled trials (evidence level Ib), clinical trials without randomization (evidence level IIa), and other experimental studies (evidence level IIb) were considered. Since a large number of articles were retrospective, nonexperimental studies using OHRQOL outcomes (evidence level III) were also included. To reflect the whole range of publications in the field of patient outcomes in prosthodontics, theoretic and conceptual literature (evidence level IV) was also reviewed, but these publications were not included in the statistical evaluation of the data. The levels of evidence of the articles were classified following the guidelines of the US Agency for Health Care Policy and Research (AHCPR)⁴:

- Ia = evidence obtained from a meta-analysis of randomized controlled trials
- Ib = evidence obtained from at least one randomized controlled trial
- IIa = evidence obtained from at least one well-designed controlled study without randomization
- IIb = evidence obtained from at least one other type of well-designed quasiexperimental study
- III = evidence obtained from well-designed non-experimental studies, such as comparative, correlational, or case studies
- IV = evidence obtained from expert committee reports or opinions and/or clinical experiences of respected authorities

A number of studies used patient satisfaction with the clinical setting, practitioner, and patient management as the outcome. Since these did not evaluate the effect of therapy, they were excluded from further processing. Further exclusion criteria were insufficient description of the sample characteristics or the therapeutic intervention, and missing or unclear hypotheses (for a complete list, see Fig 2).

Sampling and Data Processing

All identified publications were obtained from the German Library of Medicine (Cologne) and were then independently reviewed by two of the authors, who also applied the exclusion criteria. Relevant publications were archived electronically, and all data were further processed using statistical software (SPSS 9.0).

Table 1 Classification of Level of Evidence of Publications Within Each Time Bracket

Year of publication	Level of evidence				Studies	
	Ib	Ila	Ilb	III	n	%
1960–1980	—	—	—	4	4	4
1981–1985	—	1	2	1	4	4
1986–1990	—	1	1	17	19	17
1991–1995	5	1	—	15	21	18
1996–2003	12	5	10	39	66	58
Total (n)	17	8	13	76	114	
Total (%)	15	7	11	67		100

Table 2 Mean No. of Patients in Studies by Year of Publication

Year of publication	Studies (n)	No. of patients per study		Range
		Mean	SD	
1960–1980	4	222	144	54–398
1981–1985	4	249	422	19–882
1986–1990	19	228	419	13–1,842
1991–1995	21	292	348	15–1,217
1996–2003	66	190	370	10–2,050
Total	114	218	368	10–2,050

SD = standard deviation.

Results

Two hundred seven publications were identified by the search, of which 114 were studies with a total of 24,863 patients. Thirty-seven publications were excluded from further processing because they did not meet inclusion criteria.^{2,5–39} A further 56 articles had a conceptual focus or dealt with theoretic discussions of satisfaction and quality of life issues in dentistry^{3,4,40–93} and were also excluded. The remaining 114 studies^{94–207} were filed electronically. Data such as the year of publication, origin (country), number and age of participants, type of prosthetic condition, and restoration were recorded. In addition, the evidence level was assessed and noted, as were the type (eg, questionnaire or interview) and number of patient-based measurements (eg, Oral Health Impact Profile [OHIP] or custom-made single-item measures of chewing ability or general satisfaction).

The number of studies using quality of life or satisfaction as outcomes have increased steadily over the last 40 years, with an almost exponential growth in the past decade (Table 1). However, a large number of those publications have methodologic shortcomings. About 67% of all publications only reached a low level of evidence (III; retrospective studies). A large portion were case-control studies; only 17 studies published since 1991 represent high levels of evidence.

Study Populations, Dental Status, and Therapeutic Strategies

The total of treated and examined patients in all studies that met inclusion criteria was 24,863. The mean number of subjects per study was 218 (standard deviation [SD] 368). While the variability in number of patients between studies was very large (range 10 to 2,050), there was little change over time in the mean number of subjects (Table 2).

The age of the study samples was reported inconsistently. In only 66 of the 114 studies was age reported in means with SDs. The mean age of all patients was 59 years (SD 9). The majority of the studies reported on completely edentulous subjects (59%); 19% used partially edentulous patients. The remainder of the studies (19%) used mixed samples. Close to 59% of the publications reported on prosthetic therapy for completely edentulous subjects; more than half also included implant-retained prosthetic devices (17 studies, 51%). Those publications surfaced after 1990, and their share increased to 61% between 1996 and 2003. Other therapeutic options were rarely investigated; no specific data were reported in four papers (Table 3).

Methodologic Characteristics

The number of outcomes used in clinical trials has increased markedly. After 1980, the mean number of

Table 3 Classification of Studies by Type of Treatment*

Year of publication	Implant restorations		Nonimplant restorations	
	n	%	n	%
1960–1980	—	—	4	100
1981–1985	1	25	3	75
1986–1990	7	37	12	63
1991–1995	12	57	9	43
1996–2003	38	61	24	39
Total	58	53	52	47

*Missing data in four cases.

Table 4 Mean No. of Clinical and Psychosocial Criteria Used in Identified Studies

Year of publication	No. of studies	All criteria	Clinical criteria	Psychosocial criteria
1960–1980	4	6.8	4.8	2.0
1981–1985	4	5.5	3.5	2.0
1986–1990	19	7.7	4.5	3.2
1991–1995	21	9.9	6.6	3.2
1996–2003	66	9.5	6.6	2.9
Total	114	9.0	6.0	3.0

Table 5 Frequency of Use of Evaluation Criteria in All Identified Studies

Criterion	Clinical	Psychosocial	n	%
1. Chewing function	x		98	86
2. Esthetics	x		88	77
3. Speech function	x		78	68
4. General satisfaction		x	76	67
5. Comfort	x		71	62
6. Technical quality of prosthesis	x		68	59
7. Fit/retention of prosthesis	x		67	59
8. Food choice	x		52	46
9. Social impact		x	49	43
10. Psychologic discomfort		x	46	40
11. Self-esteem		x	46	40
12. Pain	x		45	40
13. Ease of use	x		43	38
14. Activities		x	38	33
15. Adaptation		x	34	30
16. General health	x		28	25
17. Taste	x		27	24
18. Work role		x	24	21
19. Smell	x		24	21
20. General quality of life		x	10	9
21. Intimate relations		x	9	8
22. Cost		x	6	5

parameters was 6.8 (SD 3.4), whereas between 1996 and 2003 the number of criteria increased to 9.5 (SD 4.5). The increase has been mostly driven by the inclusion of psychosocial parameters used to assess quality of life and satisfaction with aspects of treatment (Table 4). The most important criteria were patient assessments of chewing function (86%), esthetics (77%), speech function (68%), and general satisfaction (67%) with prosthetic restorations. The effect of prosthetic therapy on intimate relations was

rarely assessed (8%). The least-used outcome was cost (5%; Table 5).

In the majority of the studies (82%), custom-made, rarely validated questionnaires were used. In five cases, the results of interview surveys were presented.^{96,98,129,136,141} By the late 1980s, validated instruments slowly surfaced. Among those, the Geriatric Oral Health Assessment Index (GOHAI¹⁰⁰), the Dental Impact Profile (DIP¹⁰¹), and the Subjective Oral Health Status Indicators (SOHSI¹¹⁹) had been

described. However, OHIP appears to be the most frequently used and best-documented instrument to date. Between 1990 and 2003, 13 studies using OHIP^{103–111,173,181,186,201} were published.

Levels of Evidence

The few studies that represented high levels of evidence (Ib) primarily focused on patient outcomes after restoration with mandibular implant prostheses. These publications (n = 17) were published after 1991. Most of them describe superior results of mandibular implant overdentures or fixed prostheses as opposed to conventional complete dentures.^{108,112,113,130,139,140,155,161,163,171,194,202} A number of randomized cross-over trials comparing different types of implant prostheses in the mandible^{102,165} and maxilla^{179,199} were also classified into the Ib category. Further trials with an evidence level of IIa also confirmed the results from the above-mentioned trials for implant restorations of the mandible^{110,118,123,137,197,201} and maxilla.¹⁵¹ Two further trials in the IIa classification report on implant restorations of partially edentulous jaws.^{127,193}

Discussion

This review attempted to identify published articles describing the effect of prosthetic therapy on elements of quality of life and patient satisfaction. Despite a thorough and systematic search, no systematic review or meta-analysis addressing this topic was found. Therefore, the focus of this article was to describe and summarize the characteristics of the studies published so far. The content and results of the studies will be part of a forthcoming manuscript.

History

Since the 1980s, interest in the use of patient-based outcome measures in dentistry, like OHRQOL, has steadily increased,³ which is reflected in a growing number of publications. This trend can also be observed in the medical field.⁹² There are several reasons for this development. The assessment of the patient perspective offers new opportunities for the improvement of health and dental care, which is also driven by the conceptual approach of patient-centered care.⁷¹ Further important aspects are consumerism in health care and the allocation of resources based on cost effectiveness of treatment modalities.^{28,34,87}

The evaluation of prosthetic therapy from the patient's perspective has mostly focused on effects at the oral level. More recently, authors have started to assess well-being in relation to the type of treatment, its

burden on the patient, and the economic cost. However, the number of methodologically sound, randomized clinical trials is small. The majority of the identified studies only reached an evidence level of III, somewhat limiting the value of their content. This point of view is shared by other authors.^{3,93} After 1991, a number of studies with an evidence level of Ib were published. This confirms that the quality of the conducted trials investigating the effect of prosthetic therapy on patient-based outcomes is improving and that properly defined research hypotheses are being used in such experimental studies.

Main Outcomes and Future Directions

The publications described in this review primarily demonstrate the negative effect of oral conditions and disease like complete edentulism and complete denture therapy on quality of life.^{97,100,104} While the predominant selection of this most disabling oral condition seems reasonable and medically justified, it also indicates the narrow spectrum of the conducted trials. A common denominator in the conducted trials seemed to be the use of broad questions of general satisfaction, supplemented by more specific items addressing chewing and speech function as well as comfort and esthetics.¹³⁴ These factors seemed to be regarded as the most relevant, and for some of them, this has been confirmed.¹²⁸ One problem of nonspecific, broad questions is the high number of false-positive responses; therefore, these types of questions should always be complemented by more specific items.^{42,144}

The simple measurement of satisfaction with a prosthetic rehabilitation falls short when assessing the effect of dental care on a person as a whole.²³ OHRQOL is a multidimensional idea that embraces this holistic perspective. It can be defined as a person's assessment of how functional, psychological, and social factors and pain/discomfort affect his or her well-being—in the context of oral health.²⁰⁸ The development of validated multi-item questionnaires for the measurement of OHRQOL has made significant progress in the past decade. However, this has also led to longer, more complex instruments. The inclusion of psychosocial effects is one of the characteristics of OHIP,¹⁰³ a validated multi-item questionnaire. The use of standardized questionnaires to some extent allows comparison between studies. Some studies have suggested that depending on their age and general health status, subjects assign different levels of importance to certain aspects of OHRQOL.^{105,119,159} However, for OHIP, the use of weighted item scores has no effect on the total score.^{21,74} Recent developments include attempts to modify (eg, shorten and revalidate) existing instruments.¹⁸¹

Regarding the type of restorations, a positive effect on OHRQOL has been reported for implant-retained overdentures^{108,110,112,113,130,140} as well as fixed prostheses.^{102,127} The effect of the technical correctness and quality of prosthetic restorations has been scarcely investigated. Three studies postulate a moderate positive and significant correlation between technical quality of dental prostheses and satisfaction/quality of life.^{115,148,158} Still, it remains unclear if prosthetic dental care has any effect on general health-related quality of life,^{29,106} and there is a lack of evidence for the efficacy of traditional fixed, combined-fixed, and removable prosthetic restorations.

Conclusion

The high number of publications from the area of general medicine illustrate that outcomes and quality of life research in general medicine has progressed at a much faster pace than in the dental field.^{49,92} Therefore, the state of the outcomes research in dentistry is not yet satisfactory. Methodically more refined studies are required to assess the effects of a broader spectrum of restorative therapeutic approaches on OHRQOL. While some encouraging results have been published, outcomes research in restorative and prosthetic dentistry is still in its early stages. It is hard to predict the pace at which further progress will be made. However, since improvement of OHRQOL has been demonstrated for some restorative options (eg, mandibular implant overdentures), it will be imperative to also demonstrate if these treatments are cost effective. This will give further rise to patient outcomes as one component in dental health economics.

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Literature Abstract

Effect of implant healing time on crestal bone loss of a controlled-load dental implant.

A successful implant treatment outcome requires that osseointegration be achieved and cervical bone height maintained. This study hypothesized that early application of a mechanical stimulus (decreased implant healing time) leads to increased bone formation and decreased crestal bone loss. The study design had internal controls, which assessed the healing bone's condition before loading, and external controls, which assessed the bone after loading. This design permits the following comparisons to be made: (1) loading vs no loading, comparing bone adaptation at the end of the implant period; (2) implant healing time (1, 2, or 4 months); and (3) length of implant healing time. An intraoral hydraulic device was used to control in vivo load and healing time quantitatively. There was a significant difference between loading and nonloading for 4 months of healing ($P = .008$), but not for 1 month ($P = .900$) or 2 months ($P = .360$). Crestal bone loss during loading for the 1-month healing group was slightly larger than for the unloaded controls. The 2- and 4-month groups had 2 times and 4 times as much bone loss as the external controls, respectively. The crestal bone of the loaded 1-month healing implants was radiographically denser and more opaque than in the other groups, indicating that loading at 1 month stimulates bone formation more effectively. Trabeculae appeared to orient along the long axis of the implant, matching the direction of loading, suggesting the adaptation occurred in response to the early loading. The tendency to such an adaptation pattern under functional loading decreased as the healing time increased. Mean elastic moduli were 7.3 GPa, 7.9 GPa, and 8.4 GPa for the 1-, 2-, and 4-month groups, respectively; consequently, early-healing bone is more compliant under functional loading. Loading and bioactivities of osteoblasts exert a synergistic effect on osseointegration that likely supports the hypothesis that early loading produces more favorable osseointegration.

Ko CC, Douglas WH, DeLong R, et al. *J Dent Res* 2003;82:585–591. **References:** 30. **Reprints:** Dr C. C. Ko, Minnesota Dental Research for Biomaterials and Biomechanics, Graduate School, University of Minnesota, Minneapolis, Minnesota 55455. e-mail: koxxx007@unm.ed —Myung W. Brian Chang, Lincoln, Nebraska