# The Reporting of Randomized Controlled Trials in Prosthodontics

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**Purpose:** This article evaluates the reporting of randomized controlled trials (RCT) in prosthodontics, excluding endosseous implant-based prosthetics. **Materials and Methods:** Reports of RCTs published to the end of 2000 in any language were identified using a multilayered search strategy. The Cochrane Oral Health Group specialized register, Medline, and personal libraries were searched. Three researchers appraised the articles independently using guidelines following Jadad and CONSORT, complemented with an evaluation of the appropriateness of the reported statistics. **Results:** Ninety-two reports of RCTs were evaluated, covering a wide spectrum of study hypotheses, topics, and issues within various prosthodontic domains. The interrater agreements on appraisal criteria were relatively high, with median kappa values ranging between 0.65 and 0.79. The reports were in general of poor methodologic quality. Randomization and procedures for concealment allocation were not described in 70% of the articles. The methods used to generate the random allocation sequence were not mentioned in 82%. The methods used to implement the random allocation sequence, clarifying whether it was concealed until all interventions were assigned, was not mentioned in 94%. Reporting who generated allocation sequence, who enrolled patients, and who assigned participants to groups was not reported in 7%. Reasons for withdrawals were not given in 23% of the reports. No attempt at blinding was reported in 72%. Statistical analysis was not described in 6% of the papers, while these analyses were assessed as appropriate for 75%, unclear in 12%, and inappropriate in 7%. **Conclusion:** Few RCTs in prosthodontics are reported in accordance with contemporary guidelines for adequate reporting of trials. *Int J Prosthodont 2002;15:230–242.*

Prosthodontics is a specific discipline within dental education, treatment, and research, and several definitions of the discipline have existed throughout the 20th century.[1] One recent definition is "The discipline of dentistry concerned with the consequences of congenital absence or acquired loss of oral tissues on appearance, stomatognathic function, comfort, and local and general health of the patient, and with the methods for, and assessment if more good than harm is done by, inserting artificial devices made from alloplastic materials to change these conditions."[1]

An essential characteristic of prosthetic treatment is that it to a large extent is a practical application of biomaterials and biomechanical principles to solve individual patients' problems. Accordingly, significant research interest in prosthodontics is directed toward development and evaluation of new techniques, treatment modalities, and biomaterials with varying physical and chemical properties. It is critical that the clinical studies used to test the often marginal improvements of these new developments are designed and carried out with maximum chances of detecting a potential increased effectiveness of a new intervention in comparison with alternative interventions or no treatments.

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Different study designs are applied to evaluate the magnitude of gains attributed to therapeutic interventions. A randomized controlled trial (RCT) is the most scientifically sound method to detect small therapeutic gains, as long as it has been properly designed to minimize bias (systematic error).[2] Essential elements are needed in an RCT for universal acceptance, eg, correct randomization and allocation concealment that minimizes bias in treatment allocation, as well as presentation of estimates of minimum sample size.[3]

The methodology of RCTs and the reporting of RCTs show considerable variation in medicine[4,5] and in dentistry.[6] It is therefore important to assess the characteristics of an RCT before changing clinical practice. Several meta-analyses based on RCTs and clinical controlled trials have been presented on various topics in prosthodontics,[7–11] and a register of RCTs published in US prosthodontic journals has also been reported.[12] However, the methodologic quality of these papers has not been critically appraised. The reporting of RCTs and research in general is frequently incomplete. Ideally, the report of an RCT needs to convey to the reader enough relevant information to permit an informed judgment of internal and external validity. The Consolidated Standards of Reporting Trials (CONSORT) statement checklist offers guidance regarding appraising the quality of reported RCTs.[13]

A quality assessment of RCTs reporting interventions using endosseous oral implants has been published elsewhere.[14] The aim of the present investigation was to evaluate the reporting of other RCTs within the discipline of prosthodontics, excluding trials involving endosseous oral implants.

## Materials and Methods

### *Literature Search*

A literature search strategy appropriate for a Cochrane systematic review was undertaken.[15] The Cochrane Oral Health Group specialized register was searched using the key words ([Dental AND Prosthetic] OR Denture). In February 2001, this database contained more than 10,000 controlled clinical trials, RCTs, and related material published on oral health (http://www.cochrane-oral.man.ac.uk/). Trials included in this register are identified either by hand searching or from various databases including Medline and Embase. Twenty-seven journals were and are being hand searched by the Oral Health Group. PubMed was independently searched for RCTs and using the "related articles" feature. Two authors' personal indexed databases containing over 3,000 and 1,500 references on topics related to prosthodontics were also searched. Bibliographies of RCTs and relevant review articles[7–12] were checked for study reports outside the hand-searched journals. RCTs were also identified through correspondence and personal contacts with experts in the field. The present search was not restricted to the English language and was limited to RCTs published through the end of 2000.

### *Assessment of Reports*

All prospective clinical trials including the use of the term random, randomized, randomly, or randomization in context with allocation of a therapeutic intervention were defined as RCTs. An evaluation form consisting of seven items was designed to assess the characteristics of the RCTs' study design and statistical analyses (Fig 1). The form was based on criteria originally developed by Jadad.[16] However, calculations of a composite score as an indication of trial quality were not carried out, since such scoring has been shown to be inconsistent.[17] The adequacy of the description of the randomization and allocation concealment procedures was appraised relative to the CONSORT recommendations.[13] The country of origin, funding source, setting of the study, and RCT design were also recorded. Other methodologic issues, such as the relevance of the hypothesis tested, the choice of outcome measures, and the interpretation of results, were not evaluated, since these are difficult to quantify objectively. Articles were evaluated only for the information that they contained, and no additional reference or information was sought from the authors. Papers were not appraised if they described trials including fewer than five patients (split-mouth and cross-over designs) or fewer than 10 patients (parallel study design).

Four assessors, three clinical researchers and one statistician, evaluated independently the RCTs in a nonblinded setting. Each article was assessed in depth by at least two clinical researchers. The statistician evaluated all articles for the appropriateness of the statistical analysis and recorded any reason why statistical analyses were incorrectly performed. The characteristics of each article were finalized in a consensus meeting by the three clinical researchers. In case of inability to reach consensus, the dental statistician was consulted to make the final judgment.

## Results

### *Literature Search*

Ninety-two RCTs within the discipline of prosthodontics were identified.[18–109] All identified RCTs were published in English, except one in French.[108] This paper was excluded, as the same findings were presented in

Completion date: Reviewer:
Author _____ Year of publication _____
Journal _____ Country _____

| Funding source | | Setting | | Study design | |
|---|---|---|---|---|---|
| Commercial | ❑ | University | ❑ | Parallel | ❑ |
| Independent | ❑ | Nonuniversity | ❑ | Split mouth | ❑ |
| Unclear | ❑ | Unclear | ❑ | Cross over | ❑ |

Is the sample size ≥ 10 (≥ five for split-mouth and cross-over studies)?
No STOP HERE
Yes Continue to complete form

A) Was a power or sample size calculation described?
0 No/Not mentioned
1 Yes, but not confirmed by calculation
2 Yes, confirmed

B) Description of method used to generate random allocation sequence, allocation concealment and implementation, and who generated, enrolled, and assigned participants to groups
0 Not mentioned
1 Inadequate or includes reference to another paper
2 Partially adequate
3 Adequate

C) Were inclusion/exclusion criteria clearly defined?
0 No 1 Yes

D) Was reason for withdrawal specified by study group?
0 No/Not mentioned 1 Yes, or not applicable as no withdrawals

E) Were the control and treatment groups comparable at entry for important prognostic factors?
0 No 1 Unclear 2 Yes

F) Was there any attempt at blinding (for example, independent assessor)?
0 No 1 Yes

G) Was the statistical analysis appropriate?
0 No 1 Unclear 2 Yes

**Fig 1** Data collection form.

an English paper.[81] Another paper included only four patients, and this paper was also excluded.[109] Thus, 90 articles remained and were appraised for characteristics of the study design and statistical analysis (Table 1).

The large majority of the RCTs appeared in the six English-language journals that are limited to prosthodontics (n = 61), especially in the *Journal of Prosthetic Dentistry* (n = 43 papers). Nine papers appeared in the *Journal of Oral Rehabilitation,* six in *The International Journal of Prosthodontics,* and one each in the *Journal of Prosthodontics, Clinical Oral Implants Research,* and the *European Journal of Prosthodontics and Restorative Dentistry*. Three papers were identified in medical journals, and the remaining 26 papers were in general dental journals.

### *Interrater Agreements*

The judgment of the observers based on trial reports showed a general high percentage agreement for funding, setting, design, and items A to F, ranging from 76% to 100% between raters 1 and 2, from 70% to 97% between raters 1 and 3, and from 48% to 95% between raters 2 and 3 (Table 2). Kappa values were also generally high, with the comparison between raters 1 and 2 ranging from 0.47 to 1.00, with a median value of 0.79, and perfect agreement on one of the nine criteria. The kappa values between raters 1 and 3 ranged from 0.46 to 0.97, with a median value of 0.72, and between raters 2 and 3 from 0.19 to 0.91, with a median value of 0.65. Nearly all disagreement could be attributed to reading errors or to differences in interpretation of the published material and were solved during a consensus meeting. Exceptions were lack of general agreement on the reporting of adequate comparison of important variables of the sample groups at study entry, as well as complete description of all the important and relevant inclusion and exclusion criteria.

**Table 1** Characteristics of Reported RCTs in Prosthodontics (n = 90)

| Reference | Funding | Setting | Study design | No. of patients | Power calculation | Randomization description (see Fig 2) | Incl/excl criteria | Withdrawal described | Compared at entry | Blinding attempt |
|---|---|---|---|---|---|---|---|---|---|---|
| **1. Resin-bonded bridges** | | | | | | | | | | |
| 18 | Independent | University | Parallel | 24 | Not mentioned | Inadequate | Clear | Yes | No | No |
| 19 | Commercial | University | Parallel | 175 | Not mentioned | Partially adequate | Unclear | No | No | No |
| 20 | Commercial | University | Parallel | 175 | Not mentioned | Partially adequate | Unclear | No | No | No |
| 21 | Commercial | University | Parallel | 175 | Not mentioned | Partially adequate | Clear | No | No | No |
| 22 | Independent | University | Parallel | 183 | Not mentioned | Partially adequate | Unclear | Yes | Unclear | No |
| 23 | Independent | University | Parallel | 183 | Not mentioned | Partially adequate | Unclear | No | No | No |
| 24 | Independent | University | Parallel | 183 | Not mentioned | Inadequate | Unclear | No | No | No |
| 25 | Independent | University | Uncertain | 183 | Not mentioned | Inadequate | Unclear | No | No | No |
| 26 | Independent | University | Parallel | 183 | Yes, unconfirmed | Partially adequate | Unclear | No | No | No |
| 27 | Independent | University | Parallel | 77 | Not mentioned | Inadequate | Clear | No | No | No |
| **2. Fixed partial dentures** | | | | | | | | | | |
| 28 | Independent | University | Parallel | 24 | Not mentioned | Partially adequate | Clear | No | Yes, verified | No |
| 29 | Commercial | University | Split mouth | 30 | Not mentioned | Partially adequate | Clear | Yes | Uncertain | Yes |
| 30 | Commercial | University | Parallel | 47 | Not mentioned | Inadequate | Unclear | Yes | Yes, verified | No |
| 31 | Independent | Nonuniversity | Split mouth | 630 | Not mentioned | Inadequate | Clear | No | Uncertain | Yes |
| 32 | Independent | Nonuniversity | Split mouth | 604 | Not mentioned | Inadequate | Unclear | No | No | No |
| 33 | Independent | Nonuniversity | Split mouth | 604 | Not mentioned | Inadequate | Clear | No | No | No |
| 34 | Independent | University | Split mouth | 22 | Not mentioned | Inadequate | Unclear | Yes | Uncertain | Yes |
| 35 | Commercial | University | Split mouth | 23 | Not mentioned | Inadequate | Clear | Yes | Uncertain | Yes |
| 36 | Commercial | University | Parallel | 30 | Not mentioned | Inadequate | Clear | No | No | No |
| 37 | Commercial | University | Parallel | 30 | Not mentioned | Inadequate | Clear | No | Yes, verified | Yes |
| 38 | Commercial | University | Split mouth | 60 | Not mentioned | Partially adequate | Unclear | No | Uncertain | Yes |
| 39 | Independent | Nonuniversity | Parallel | 61 | Not mentioned | Inadequate | Clear | No | No | No |
| **3. Single crowns** | | | | | | | | | | |
| 40 | Independent | Nonuniversity | Split mouth | 18 | Not mentioned | Inadequate | Unclear | Yes | Uncertain | No |
| 41 | Independent | University | Cross over | 12 | Not mentioned | Partially adequate | Clear | Yes | Uncertain | Yes |
| 42 | Commercial | Nonuniversity | Parallel | 77 | Not mentioned | Partially adequate | Unclear | No | No | Yes |
| 43 | Commercial | University | Parallel | 24 | Yes, unconfirmed | Inadequate | Clear | No | No | Yes |
| 44 | Commercial | University | Parallel | 24 | Not mentioned | Inadequate | Clear | No | No | Yes |
| 45 | Independent | University | Parallel | 12 | Not mentioned | Inadequate | Unclear | Yes | Uncertain | Yes |
| 46 | Commercial | Unclear | Parallel | 90 | Not mentioned | Partially adequate | Clear | Yes | No | Yes |
| **4. Denture fabrication** | | | | | | | | | | |
| 47 | Independent | University | Parallel | 25 | Not mentioned | Inadequate | Unclear | Yes | No | No |
| 48 | Commercial | University | Parallel | 67 | Yes, confirmed | Partially adequate | Clear | No | Yes, verified | Yes |
| 49 | Commercial | University | Parallel | 67 | Yes, confirmed | Partially adequate | Unclear | No | Yes, verified | Yes |
| 50 | Independent | University | Parallel | 70 | Not mentioned | Inadequate | Unclear | No | No | No |
| 51 | Independent | University | Parallel | 34 | Not mentioned | Not mentioned | Unclear | No | No | No |
| 52 | Independent | University | Parallel | 34 | Not mentioned | Partially adequate | Clear | No | No | No |
| 53 | Independent | University | Parallel | 37 | Not mentioned | Not mentioned | Unclear | No | No | No |
| 54 | Independent | University | Parallel | 52 | Not mentioned | Not mentioned | Unclear | No | No | No |
| 55 | Independent | University | Parallel | 36 | Not mentioned | Not mentioned | Unclear | No | No | Yes |
| 56 | Independent | University | Parallel | 48 | Not mentioned | Partially adequate | Unclear | No | No | No |
| 57 | Independent | University | Parallel | 52 | Not mentioned | Not mentioned | Unclear | No | No | No |
| 58 | Independent | University | Parallel | 53 | Not mentioned | Inadequate | Unclear | No | No | No |

*Continued*

**Table 1** *Continued*

| Reference | Funding | Setting | Study design | No. of patients | Power calculation | Randomization description (see Fig 2) | Incl/excl criteria | Withdrawal described | Compared at entry | Blinding attempt |
|---|---|---|---|---|---|---|---|---|---|---|
| 59 | Independent | University | Parallel | 64 | Not mentioned | Partially adequate | Clear | Yes | No | No |
| 60 | Independent | Unclear | Parallel | 22 | Not mentioned | Inadequate | Unclear | Yes | No | No |
| 61 | Independent | University | Parallel | 28 | Not mentioned | Inadequate | Unclear | Yes | No | Yes |
| 62 | Independent | University | Cross over | 10 | Not mentioned | Inadequate | Unclear | Yes | Uncertain | No |
| 63 | Independent | University | Cross over | 10 | Not mentioned | Inadequate | Unclear | Yes | Uncertain | Yes |
| 64 | Independent | University | Parallel | 22 | Not mentioned | Inadequate | Clear | No | No | No |
| 65 | Commercial | University | Split mouth | 54 | Not mentioned | Inadequate | Clear | No | Uncertain | No |
| **5. Denture adhesives** | | | | | | | | | | |
| 66 | Independent | University | Cross over | 32 | Not mentioned | Inadequate | Unclear | Yes | Uncertain | No |
| 67 | Commercial | University | Cross over | 25 | Not mentioned | Inadequate | Unclear | Yes | Uncertain | No |
| 68 | Commercial | Nonuniversity | Cross over | 26 | Not mentioned | Inadequate | Clear | Yes | Uncertain | Yes |
| 69 | Commercial | University | Cross over | 32 | Not mentioned | Inadequate | Unclear | Yes | Uncertain | No |
| **6. Denture hygiene** | | | | | | | | | | |
| 70 | Commercial | University | Parallel | 35 | Not mentioned | Inadequate | Clear | Yes | Yes, verified | Yes |
| 71 | Independent | University | Cross over | 43 | Not mentioned | Inadequate | Unclear | No | Uncertain | No |
| 72 | Independent | University | Cross over | 80 | Not mentioned | Inadequate | Unclear | No | Uncertain | Yes |
| 73 | Commercial | University | Cross over | 18 | Not mentioned | Inadequate | Clear | No | Uncertain | Yes |
| 74 | Commercial | University | Parallel | 78 | Not mentioned | Inadequate | Clear | No | Yes, verified | Yes |
| 75 | Commercial | University | Parallel | 83 | Not mentioned | Inadequate | Clear | No | No | Yes |
| 76 | Commercial | Nonuniversity | Cross over | 14 | Not mentioned | Inadequate | Unclear | Yes | Uncertain | Yes |
| 77 | Independent | University | Parallel | 150 | Not mentioned | Inadequate | Clear | Yes | Yes, verified | Yes |
| 78 | Commercial | Nonuniversity | Parallel | 305 | Yes, unconfirmed | Partially adequate | Clear | Yes | Yes, verified | No |
| 79 | Commercial | University | Parallel | 40 | Not mentioned | Inadequate | Clear | Yes | Yes, verified | Yes |
| 80 | Independent | University | Parallel | 23 | Yes, unconfirmed | Inadequate | Unclear | No | No | No |
| 81 | Independent | University | Parallel | 50 | Not mentioned | Partially adequate | Clear | No | No | Yes |
| 82 | Independent | Nonuniversity | Parallel | 36 | Not mentioned | Partially adequate | Clear | Yes | Yes, verified | Yes |
| 83 | Commercial | University | Parallel | 33 | Not mentioned | Partially adequate | Clear | Yes | No | No |
| 84 | Commercial | University | Parallel | 59 | Not mentioned | Inadequate | Clear | Yes | Yes, verified | Yes |
| 85 | Commercial | Unclear | Parallel | 24 | Not mentioned | Inadequate | Clear | Yes | No | Yes |
| **7. Denture use** | | | | | | | | | | |
| 86 | Independent | Nonuniversity | Parallel | 14 | Yes, confirmed | Adequate | Clear | Yes | Yes, verified | Yes |
| 87 | Independent | University | Parallel | 95 | Not mentioned | Inadequate | Unclear | No | No | No |
| **8. Overdenture use** | | | | | | | | | | |
| 88 | Independent | University | Split mouth | 49 | Yes, unconfirmed | Partially adequate | Clear | Uncertain | Uncertain | No |
| 89 | Independent | University | Parallel | 74 | Not mentioned | Inadequate | Clear | Yes | Yes, verified | No |
| 90 | Independent | University | Parallel | 74 | Not mentioned | Inadequate | Unclear | No | Yes, verified | No |
| 91 | Independent | University | Parallel | 74 | Not mentioned | Inadequate | Clear | Yes | Yes, verified | No |
| 92 | Independent | University | Parallel | 74 | Not mentioned | Inadequate | Unclear | No | Yes, verified | No |
| 93 | Independent | University | Parallel-2 | 19 | Not mentioned | Inadequate | Clear | No | No | No |
| 94 | Independent | University | Parallel-3 | 30 | Not mentioned | Inadequate | Unclear | Yes | Yes, verified | No |
| 95 | Independent | University | Parallel-3 | 34 | Not mentioned | Inadequate | Clear | No | Yes, verified | No |
| **9. Removable partial dentures** | | | | | | | | | | |
| 96 | Independent | University | Parallel | 38 | Not mentioned | Inadequate | Unclear | Yes | No | No |
| 97 | Independent | University | Cross over | 22 | Not mentioned | Not mentioned | Unclear | Yes | Uncertain | Yes |
| 98 | Independent | Nonuniversity | Parallel | 134 | Not mentioned | Inadequate | Clear | Yes | Yes, verified | No |
| 99 | Independent | Nonuniversity | Parallel | 118 | Not mentioned | Inadequate | Unclear | Yes | Yes, verified | No |

*Continued*

**Table 1** *Continued*

| Reference | Funding | Setting | Study design | No. of patients | Power calculation | Randomization description (see Fig 2) | Incl/excl criteria | Withdrawal described | Compared at entry | Blinding attempt |
|---|---|---|---|---|---|---|---|---|---|---|
| 100 | Commercial | University | Cross over | 8 | Not mentioned | Inadequate | Clear | Yes | Uncertain | Yes |
| 101 | Independent | University | Cross over | 25 | Not mentioned | Inadequate | Unclear | No | Uncertain | No |
| **10. Removable partial dentures vs blade implants** | | | | | | | | | | |
| 102 | Independent | Nonuniversity | Parallel | 218 | Not mentioned | Inadequate | Unclear | Yes | Yes, verified | No |
| 103 | Independent | Nonuniversity | Parallel | 228 | Not mentioned | Inadequate | Unclear | No | Yes, verified | No |
| 104 | Independent | Nonuniversity | Parallel | 232 | Not mentioned | Inadequate | Unclear | Yes | Yes, verified | No |
| 105 | Independent | Nonuniversity | Parallel | 232 | Not mentioned | Inadequate | Unclear | Yes | Yes, verified | No |
| 106 | Independent | Nonuniversity | Parallel | 272 | Yes, unconfirmed | Adequate | Clear | Yes | Yes, verified | No |
| **11. Maxillofacial prosthetics** | | | | | | | | | | |
| 107 | Independent | University | Parallel | 25 | Not mentioned | Inadequate | Clear | Yes | No | No |

### *Study Methodology Assessment*

The results of the methodologic assessment of RCTs are summarized in Table 1. Nine study reports described that a sample size calculation had been carried out,[26,43,48,49,78,80,86,88,106] although the actual figures were given in only three papers.[48,49,86] The results regarding adequacy of randomization and allocation concealment are presented in Fig 2. In 68 (76%) reports, no information regarding these procedures was provided, besides the inclusion of some variant of the term random.

One rater assessed the appropriateness of the statistical analysis. Of 90 reports, five (6%) included no statistical analysis,[27,34,35,52,84] and in four of these a statistical analysis should have been conducted.[27,34,35,84] In 68 of the remaining papers, the statistical analysis was assessed as appropriate (75%); it was unclear if it was appropriate or not in 11 (12%), and it was inappropriate in six (7%). In three of these, the analysis failed to take the "paired" design into account.[40,62,65] In the other three papers,[43,44,88] the analysis failed to take the clustering of the sites within crowns (or patients) into account, with two papers[43,44] saying that they had confirmed the independence of the sites within crowns by a statistical test; however, this analysis was considered inappropriate. This problem of considering sites/teeth/crowns independently without taking into account the clustering of these sites within patients occurred in a further eight study reports. These were judged as appropriate statistical analyses, as there was not too much difference between the number of sites and the number of patients. Thus, the analysis ignoring the clusters would probably not have influenced the results and conclusions in these study reports.

### *Prosthodontics Domains*

A general characteristic of the study reports was a great diversity of study aims, topics, choice of statistical units, and techniques. A post hoc search classification of the identified RCTs according to clinical domain was attempted. Eleven groups were identified, each with a range of different aims and topics. Three groups described issues related to fixed prostheses, seven related to removable prostheses, and one group was limited to maxillofacial prosthetics (n = 1).[107] The three groups related to fixed prostheses were labeled "resin-bonded bridges" (n = 10),[18–27] "fixed partial dentures" (n = 12),[28–39] and "crowns" (n = 7).[40–46] The last group was limited to trials involving only single crowns. Among the seven groups related to removable prostheses, five focused on dentures and were titled

**Table 2** Percent Agreement, Kappa Values, Standard Errors (SE), and 95% Confidence Intervals (CI) Assessing Interexaminer Reliability

| | Rater 1 vs 2 (n = 35) | | | | Rater 1 vs 3 (n = 61) | | | | Rater 2 vs 3 (n = 64) | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | % | κ | SE | CI | % | κ | SE | CI | % | κ | SE | CI |
| Funding | 94 | 0.85 | 0.10 | 0.66, 1.00 | 97 | 0.91 | 0.06 | 0.78, 1.00 | 95 | 0.83 | 0.07 | 0.70, 0.97 |
| Setting | 91 | 0.73 | 0.14 | 0.36, 1.00 | 97 | 0.82 | 0.13 | 0.57, 1.00 | 91 | 0.77 | 0.09 | 0.60, 0.94 |
| Design | 97 | 0.95 | 0.05 | 0.85, 1.00 | 97 | 0.97 | 0.04 | 0.89, 1.00 | 95 | 0.91 | 0.05 | 0.80, 1.00 |
| Sample size calculation | 100 | 1.00 | NA | NA | 95 | 0.65 | 0.19 | 0.29, 1.00 | 95 | 0.61 | 0.16 | 0.31, 0.92 |
| Inclusion | 86 | 0.72 | 0.11 | 0.50, 0.94 | 82 | 0.64 | 0.10 | 0.45, 0.83 | 63 | 0.29 | 0.10 | 0.09, 0.49 |
| Withdrawal | 80 | 0.60 | 0.13 | 0.34, 0.86 | 72 | 0.46 | 0.10 | 0.26, 0.66 | 52 | 0.19 | 0.07 | 0.05, 0.33 |
| Baseline balance | 76 | 0.47 | 0.15 | 0.19, 0.76 | 70 | 0.49 | 0.09 | 0.31, 0.66 | 48 | 0.21 | 0.07 | 0.07, 0.34 |
| Blinding | 97 | 0.94 | 0.06 | 0.83, 1.00 | 90 | 0.79 | 0.08 | 0.64, 0.95 | 86 | 0.70 | 0.09 | 0.52, 0.88 |


**Fig 2** Description of the randomization procedures in 90 study reports in prosthodontics according to the recommendations in the CONSORT statement.[13,117]

"denture fabrication" (n = 19),[47–65] "denture adhesives" (n = 4),[66–69] "denture hygiene" (n = 17),[70–85] "denture use" (n = 2),[86,87] and "overdenture use" (n = 8).[88–95] The two other groups were studies related to "removable partial dentures" (n = 6)[96–101] and one group consisting of a single longitudinal trial that compared "removable partial dentures versus blade implants" (n = 5).[102–106]

*Resin-bonded bridges.* Ten papers reported findings from four clinical trials, all with a parallel study design. The most recent was a small study from Hong Kong that compared anterior cantilever versus fixed-fixed bridges.[18] The others were a slightly larger trial from the US that compared the effect of preparation design on posterior bridges[27] and two large longitudinal studies from the Netherlands, one limited to posterior bridges[19–21] and one focused on both anterior and posterior bridges.[22–26] These two studies included effects of operator, preparation design, surface treatment, and cement. Only one paper reported on power calculation,[26] but this was not verified in the report.

*Fixed partial dentures.* Eight studies, four using parallel designs[28,30,36,37,39] and four with a split-mouth design,[29,31–35,38] were described in 12 reports. None of the papers reported power calculations of sample size. A trial done by the US Veterans Administration was markedly larger than the others, as it included 630 patients.[31–33] The reports varied in respect to description of inclusion and exclusion criteria, description of withdrawals, comparison at study entry,

and attempts at blinding, but none included a satisfactory description of all these aspects. The range of issues evaluated were pontic soft tissue surgery,[28] temporization aspects,[29,36,37] cements over 17 months[38] and 10 years,[39] and alloys over 3 years,[34,35] 5 years,[33] 6 years,[30] and 10 years.[31,32]

*Crowns.* The seven papers displayed great diversity regarding study aims, funding (three commercial, three independent), setting (university, nonuniversity, and unclear), design (parallel, split mouth, and cross over), and sample sizes. Also, the methodologic characteristics varied greatly, with no study demonstrating outstanding characteristics. An attempt at blinding of the study participants was described in six of the seven reports. The topics investigated were comparisons of temporary cements,[46] desensitizing agents,[42] effect of cements over the short term,[43–45] and cast alloys observed over 2 months[41] and over 2 years.[40]

*Denture fabrication.* Although this group included the highest number of reports, 10 of these originate from one single trial initiated in 1969 in Kentucky.[51–59,110] This study included originally two parallel arms, each with 32 patients, and results were reported after several months,[59] 5 years,[54,56–58] 10 years,[53,55] and 20 years.[51,52] In spite of the initially well-designed and adequately reported publication,[110] only three of the follow-up papers make any mention of the original randomization scheme.[52,56,59] Among the remaining RCT reports, a wide range of aspects were evaluated: method used for maxillomandibular relationship record,[51–59] choice of denture material,[47,64] selection of impression material,[60] placement of artificial teeth on denture,[64] wear of artificial teeth,[48–50,65] and differences among resilient liners.[61,62] The trial on wear of denture teeth over 3 years also included power calculations,[48,49] but apart from this study, none of the reports demonstrated any high methodologic standard.

*Denture adhesives.* A characteristic of these four studies[66–69] is that they were very similar in study design, ie, they all used a cross-over design and patient-centered outcomes on evaluating the adhesiveness of two[68] to five[67] adhesives. There was no mention of power calculations in any study, but the number of participants ranged between 25 and 32. The appraisal of relevant inclusion and exclusion criteria, as well as relevant variables for comparison at entry, caused some divergence among the study assessors.

*Denture hygiene.* Several subgroups could be identified under this topic, but the demarcation between these was difficult to define. Focus was on comparing denture hygiene instruction,[77] denture disinfectants for extraoral use,[70–74,76,80] use of antimicrobial mouthrinses,[74,75] or comparison of interventions toward manifest denture-related candidosis.[78–85] The outcome measures were improvement in denture hygiene,[70,72] bacteria count,[71,73–76] or mycologic count.[71,75,76,78–85] These outcomes were in some studies supplemented with clinical intraoral examinations.[71,73,75,78–85] The reports on denture-related candidosis that were also commercially funded were of higher methodologic quality compared to the remaining reports on RCTs in prosthodontics.

*Denture use.* This topic comprised one very well-designed but small US study appraising the effects of diet on the prosthesis-supporting mucosa over 10 days,[86] while one study from the Netherlands compared relining versus new dentures among 95 elderly patients.[87]

*Overdenture use.* This topic was only reported by independent university studies from the Netherlands.[88–95] One split-mouth study compared dental materials to restore 155 roots under overdentures over a 4-year period.[88] More general aspects of the use of overdentures with or without magnetic attachments on 74 patients were described in four reports over a 4.5-year period.[89–92] A small study involving 19 patients in a parallel design evaluated the effects of two oral hygiene regimens over 2 years.[93] The same aspects were also reported in two papers in an 18-month parallel study originally comprising 34 patients.[94,95]

*Removable partial dentures.* This group comprises a large US Veterans Administration parallel study comparing denture designs in 134 individuals.[98,99] The other papers reported on three small cross-over studies that compare the effects of specific design details on the periodontium,[100,101] and choice of optimal impression material.[97] A slightly larger Australian trial compared titanium versus cobalt-chromium partial dentures in two parallel arms, each with 19 patients, over 2 years.

*Removable partial dentures versus blade implants.* This group consists of five reports on one single longitudinal study started by the US Veterans Administration in the mid-1970s.[102–106] Great efforts had apparently been made to ensure the quality of the study methodology and management, including criteria development, calibration, clinician training, pilot studies, etc. Unfortunately, the treatment modality had become obsolete by the time the papers appeared in print.

*Maxillofacial prosthetics.* One single RCT was identified, where the adhesiveness of different adhesives for extraoral silicone materials was compared on the participants' underarms.[107]

## Discussion

The rationale for carrying out the present study was to identify and appraise the quality of science that is available to back up claims of therapeutic superiority of interventions in prosthodontics. Such claims can of course be based on various study designs, eg, prospective or retrospective cohort studies, cross-sectional studies, or case-control studies, but these study designs are prone to bias to a much larger extent than RCTs.[111] Thus, the RCT design is regarded as the gold standard to establish reliable conclusions about the effectiveness of interventions, especially if it is assumed that possible differences between alternative interventions are small. If the aims are instead to report prognosis or panoramas of different treatment outcomes or patient managements, then other study designs are considered more appropriate.[112] Findings from a well-designed RCT are also much easier to interpret statistically compared to any other study design because bias and confounding are reduced.

A well-reported RCT can also enable future meta-analyses and thus increase the confidence of study results, clarify possible reasons for heterogeneity of results from similar studies, and even improve chances of publication in spite of negative findings. A consideration of the presently identified RCT reports is that studies that become published usually are biased toward positive and "encouraging" results (publication bias).[113] This is due to the fact that "uninteresting" information is less likely to reach the publication stage, especially if the study design is of mediocre methodologic quality.

The proportion of study reports that included power calculations and estimation of minimum or adequate sample sizes was very low. This is not satisfactory, because sample size calculation estimates the minimal number of patients needed to detect a significant difference among groups to be compared. If the number of subjects included in a study is too small, clinically important effects caused by different interventions may not be detected.[114,115] Such studies are scientifically useless and thereby unethical in their use of patients and other resources.

External validity or generalizability is the precision and extent to which it is possible to generalize the results of one study to other settings. External validity is relevant to making treatment decisions. It is very important to know whether withdrawals or exclusions of study participants occurred and from which group (attrition bias), since this may result in a systematic error that leads to an incorrect estimate of the treatment effectiveness. For instance, patients may drop out because of intervention side effects or be deliberately excluded by an investigator because of alleged protocol deviation. Slightly fewer than half of the trials (48%; n = 43) described the reason for withdrawals or reported no withdrawals at all. Also, clearly defined inclusion and exclusion criteria will help the reader to decide if the results of a trial are applicable to his or her own population of patients. Moreover, clearly described groups—identical apart from the treatment so that any difference in outcome is attributable to the intervention—need to be demonstrated in the paper.[116]

The independent scoring by three assessors resulted in an initial relatively high agreement, and a subsequent consensus meeting solved most of the individual interpretation differences. Exceptions were the criteria used for exclusion and inclusion of participants, as well as important variables that were compared in the sample groups at study entry. The reason for the discrepancy of opinions on the reported adequacy among the assessors may be due to their different backgrounds, ie, a prosthodontist, an oral surgeon, and a periodontist. It is probable that subject content knowledge influences opinions about what are considered clear and unclear descriptions of patient characteristics. While, eg, age, gender, and socioeconomic background are common patient descriptors in many medical and dental studies, more important descriptors of, eg, patients with overdentures, can be medication, caries activity, xerostomia, etc. It is important to point out that the inclusion and exclusion criteria and sample group characteristics prior to commencing a trial are not meant to be made as limiting as possible. Rather, this information is necessary for the reader to evaluate if the study is valid and if the results can be applicable to his or her own patients.

When clinical judgment is needed, personal preferences of the investigators may intrude. This problem can be prevented if those assessing treatment outcomes are unaware of the treatment each patient received. Blinding is not always possible, but some precautions should be taken to minimize bias, such as the use of independent assessors for measuring outcomes. Only 36% (n = 33) of the assessed RCTs described some sort of blinding procedure of the patient, the investigator giving the intervention, the investigator in charge of assessing the outcomes, and/or the data analysts.

Although the material for comparison among the journals was small, a clear difference was noted in the quality of reports, in that the three papers published in the medical journals[78,79,81] were of general better quality than the average. It is obvious that not only the

authors, but also the editor and reviewers are responsible for adequate reporting and that major improvements in the quality of reporting can be obtained by adherence to stricter criteria for publishing. To improve the quality of reporting of RCTs, unified guidelines developed by a panel of investigators and editors have been made available (the CONSORT statement).[13,117] An increasing number of medical and dental journals have adopted these recommendations for publishing RCTs. A general description of CONSORT is that the study information should be presented in a structured manner and in full detail, so that *(1)* the study can be replicated, and *(2)* the reader can appraise whether the findings are likely to be reliable.

Loss of oral soft and hard tissues leads to an extensive variation of possible morphologic and functional results, which many patients experience as a problem. Today, the clinician can select from a battery of technical solutions and biomaterials to attempt to resolve this problem. A traditional classification of issues in prosthodontics is into fixed, removable, maxillofacial, and implant domains. From a research point of view, this classification is of little importance because the selection of statistical units, treatment outcomes, blinding, chance variation, and bias are identical. On the other hand, because of this diversity of possible research issues within the broad classification of prosthodontics, it is unreasonable to assume that all RCTs need to adopt similar study designs. Rather, the optimal strategy for choice of RCT design may vary depending on topic or issue, study aim, and purpose. The present article shows what study designs other investigators have employed, and may thereby hopefully give some guidance in this respect.

As in the present paper, the quality of the reporting is often used as an indicator of the quality of the study design. It is acknowledged that in some cases there may be a difference between the quality of the presentation and how the study was actually conducted. However, under-reporting of high-quality RCTs is more rare than are trials with inadequate methodologic procedures.[116] Moreover, some papers refer to additional information about the study design in previous publications with shorter observation times. However, for a reader to make an informed judgment regarding internal and external validity of the trials, complete information about important methodology issues needs to be clearly presented.[13] Whether the RCTs are of poor quality or it is the reporting of these RCTs that is poor remains speculative, but is has been suggested that these two factors are related.[118]

The result of this investigation causes concern, since it points out the lack of sound evidence on a number of common procedures in prosthodontics, eg, differences between impression materials, alloys, cements, occlusal adjustments, ceramics, temporization, etc. Moreover, the number of actual RCTs is low, and the methodologic quality of the reporting of these trials seems highly variable. The methodologic quality varied to some extent depending on prosthetic domain (Table 1), with the best reports being commercially funded studies on topics related to denture hygiene and published in oral medicine and medical journals.[70–85]

Thus, in conclusion, there seem to be multiple areas within prosthodontics where well-designed and reported RCTs may document therapeutic gains of new materials, techniques, and procedures compared to traditional interventions.

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*Literature Abstract*

## Oral squamous cell carcinoma of the mandibular region: A survival study.

Oral squamous cell carcinomas (SCC) of the mandibular region present the lowest survival rates of the whole oral cavity. The purpose of the study was to evaluate the prognostic significance of several diagnostic and therapeutic variables in the survival rates of these carcinomas. Forty-nine patients with oral cancers were treated with primary site surgery that involved mandibular resection in all cases. Thirty-one patients underwent postoperative adjuvant radiotherapy. Overall mean survival time and 5-year survival rate were 56.5 months and 44%, respectively. Patients in stages III and IV showed a statistically significantly ($P$ = .01) lower survival rate than those in stage II, and positive surgical margins had an adverse effect on survival ($P$ = .03). No differences were found between patients treated by marginal or segmental mandibulectomy. Among the prognostic predictors studied, only the status of the surgical resection margin and tumor stage affected the prognosis for SCC of the mandibular region. Tumor site was not associated with prognosis but was related to the probability that surgical margins were involved.

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