Reporting quality of randomized controlled trials published in prosthodontic and implantology journals

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Reporting quality of randomized controlled trials published in prosthodontic and implantology journals

Running head: Reporting quality of RCTs in prosthodontics and implantology

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SUMMARY The purpose of this study was to examine the reporting quality of randomized controlled trials (RCTs) published in prosthodontic and implantology journals. Thirty issues of 9 journals in prosthodontics and implant dentistry were searched for RCTs, covering the years 2005-2012: *The Journal of Prosthetic Dentistry, Journal of Oral Rehabilitation, The International Journal of Prosthodontics, The International Journal of Periodontics & Restorative Dentistry, Clinical Oral Implants Research, Clinical Implant Dentistry & Related Research, The International Journal of Oral & Maxillofacial Implants, Implant Dentistry and Journal of Dentistry*. The reporting quality was assessed using a modified CONSORT statement checklist. Data were analyzed using descriptive statistics followed by univariable and multivariable examination of statistical associations (α=0.05). A total of 147 RCTs were identified with a mean CONSORT score of 69.4 (SD = 9.7). Significant differences were found among journals with the Journal of Oral Rehabilitation achieving the highest score (80.6, SD= 5.5) followed by Clinical Oral Implants Research (73.7, SD= 8.3). Involvement of a statistician/methodologist was significantly associated with increased CONSORT scores. Overall, the reporting quality of RCTs in major prosthodontic and implantology journals requires improvement. This is of paramount importance considering that optimal reporting of RCTs is an important prerequisite for clinical decision-making.

KEYWORDS: randomized clinical trials, prosthodontics, dental implants

Introduction

Reliable evidence is more likely consequent to sound design and methodology (1, 2). Among the various study designs the randomized controlled trial (RCT) is considered as the "gold standard" for assessing the effectiveness and safety of medical interventions. Nevertheless, RCTs are also prone to inadequacies and there is a substantial body of evidence in the biomedical literature, which indicates that the quality of many RCTs is suboptimal (3-6).

Accurate and transparent reporting of RCTs is prerequisite for the assessment of their internal validity and the clinical translation of their results (7). In an effort to improve and standardize reporting of RCTs the CONSORT (Consolidated Standards of Reporting Trials) guidelines were developed by the CONSORT group and are continuously being updated. The main CONSORT document consists of 25 items and sets standards on how and what should be included in an RCT report (2).

The CONSORT guidelines have been endorsed by over 580 journals (8) and there is evidence of a positive impact on RCT reporting (9). In dentistry reporting quality of RCTs has been assessed in a number of general and dental specialty journals (10-18), indicating that there is room for improvement. However, there is a lack of studies comparatively evaluating the completeness of reporting of recently published RCTs in prosthodontic and implantology using the CONSORT guidelines (2).

Therefore, the primary objective of this study was to evaluate the completeness of reporting of RCTs in prosthodontic and implantology journals using the CONSORT statement. A secondary aim was to identify factors associated with better reporting of RCTs**.**

Materials and methods

Four dental journals with emphasis on prosthodontics (*The International Journal of Prosthodontics, Journal of Oral Rehabilitation, The Journal of Prosthetic Dentistry, The International Journal of Periodontics & Restorative Dentistry*), 4 dental implantology journals (*Clinical Implant Dentistry & Related Research, Clinical Oral Implants Research, Implant Dentistry, The International Journal of Oral & Maxillofacial Implants*) and 1 general dental journal with a predilection for prosthodontics (*Journal of Dentistry*) were included in the study. The selected journals had the highest impact factors of prosthodontic and implant dentistry journals based on 2009 data.

The contents of 30 issues of each journal from June 2012 backwards were searched for RCTs on humans. Supplemental issues were included in the search, but were not counted as an issue. Initially the abstract was read and any trials that were clearly RCTs were included. Other articles that used

terminology in the title or abstract such as “prospective”, “comparative”, “efficacy” or an indication was given that a comparison of treatment groups was assessed prospectively, were further investigated to examine whether randomization was implemented. Studies that did not involve humans and studies, where it was concluded that no true randomization was implemented, were excluded. Screening and selection of studies were conducted independently by two authors (DK, SNP).

The information extracted from each article included journal and year of publication, region of publication (Europe, Americas or other region, based on the first author), ethical approval, statistical significance of main finding, number of authors, involvement of a statistician or methodologist, and whether the study was single- or multicenter. Involvement of a statistician or methodologist was ascertained by checking author affiliations (public health or epidemiology departments were considered as providing statistical assistance), author degrees (where provided), and information in the methods or acknowledgement sections of each paper.

A modified CONSORT checklist as presented by Tiruvoipati *et al*. (6) was used to evaluate the reporting completeness of RCTs. This checklist has 30 questions related to the CONSORT items excluding the first item of the CONSORT checklist (title and abstract), since the authors have to follow the instructions of the journal in preparing the abstract. The given score per item ranged from 1 to 3, with 1=no description, 2=inadequate description and 3=adequate description. The scores for the 30 items were added, and a percentage score was calculated for each trial, whereas non- applicable items were not scored. A trial with adequate descriptions (score 3) for all items would receive a score of 90. All scores were converted to a percentage scale and therefore a score of 90 was equivalent to 100% in the percentage scale. When non-applicable items were identified (for example inability to blind the treatment provider) only the applicable items were considered for the calculation of the percentages. Therefore, a trial with only 28 applicable items, but adequate descriptions (score 3) for these, would receive a maximum score of 84, corresponding to a percentage of 100%.

Each RCT was also scored using the Jadad scale (19), allocating trials a score between zero (very poor) and five (rigorous). The Jadad scale includes three questions and each one of them is answered with either yes (1 point) or no (no point): (1) “Is the study described as randomized?”; (2) “Is the study described as double blinded?”; (3) “Is there a description of withdrawals and dropouts?”. Two additional points, to reach a maximum score of 5, are given (i) if the method of randomization is clearly described and appropriate or (ii) if the method of blinding is clearly described and appropriate. One or

two points are subtracted if the method of randomization or the method of blinding is described, but is inappropriate.

Each included RCT was scored independently by 2 authors (DK, SNP), and subsequently results were compared and modified in order to arrive to a mutually agreed score. Discrepancies between the 2 authors (DK, SNP) were resolved by discussion. Before data extraction, a calibration exercise was performed between the two authors responsible for it (DK, SNP) with 80 randomly selected studies. Inter-rater agreement was evaluated for all extracted data with Cohen's kappa and any disagreements were resolved with discussion.

Statistical Analysis

Descriptive statistics were calculated for the modified CONSORT scores and tabulated by trial characteristics. The modified CONSORT scores were approximately normally distributed. Data were analyzed through linear regression modeling; univariable analysis was utilized to determine articles' characteristics associated with the modified CONSORT scores, whereas multivariable analysis was employed to adjust for possible confounders. A two-tailed P-value of 0.05 was considered statistically significant with a 95% confidence interval. Analyses were performed with the STATA® version 13.0 software (Stata Corporation, College Station, Texas, USA).

Results

From the 3667 articles that were originally screened 3520 were excluded for not adhering to the inclusion criteria, leaving 147 RCTs for detailed assessment (Appendix 1). Inter-rater agreement was found to be excellent (kappa 0.88, 95% CI: 0.87-0.89). The included RCTs reported on a wide selection of topics ranging from surgical implant procedures and techniques, survival of implants and prostheses, biological responses, clinician's perspective of esthetics and patient satisfaction.

Table 1 displays the 147 RCTs tabulated by their characteristics. The journals contributing with the most RCTs were *Clinical Oral Implants Research* (31.3%), followed by *The International Journal of Oral and Maxillofacial Implants* (16.3%) and *Journal of Dentistry* (14.3%). The majority of RCTs originated from Europe (58.5%), were approved by an ethical committee (72.1%) and reported statistically significant findings (59.2%). Concerning the number of authors, most RCTs included four to six authors (64.6 %), whereas a statistician/methodologist was involved in 37.4% of the RCTs. Finally, the majority of RCTs were a multi-center effort (71.4 %).

Table 2 displays the scores for all items on the modified CONSORT checklist. Description of pre-study sample size calculation was absent in the majority of the trials (64.0%). No description of the random number generation was also evident in 32.7% of the trials. Allocation concealment was not reported in 61.9% of the studies, whereas details of personnel involved in sequence allocation, enrollment, and assignment were not described in 51.0% of those. Blinding of participants and treatment providers was not reported in 36.7% and 37.4% of the sample respectively. No description of blinding of assessors and analysts reached 61.9% and 89.8% respectively. Absence of a flow chart describing patient numbers at different stages of a study was apparent in 76.9% of the sample. Trial limitations and generalizability of the trial results were not reported in 55.8% and 52.4 % of the studies respectively.

The modified CONSORT scores per study characteristic are presented in Table 3. The highest modified CONSORT score was found for the *Journal of Oral Rehabilitation* (80.6%), which, however, contributed only 2 RCTs, followed by the *Clinical Oral Implants Research* (73.7%). The highest modified CONSORT scores chronologically were found in the years 2010-2011. Increased CONSORT scores were also found for RCTs with ethical approval and RCTs with involvement of a statistician/methodologist.

Table 4 presents the results of the univariable and multivariable linear regression analyses. In the univariable analysis, the journal of publication and the involvement of a statistician/methodologist were significantly associated with the CONSORT scores. Similar associations were observed in the multivariable analysis.

Table 5 displays the Jadad scores for the 147 RCTs tabulated by journal. The median Jadad scores ranged from 1.0 (*Journal of Prosthetic Dentistry*) to 3.5 (*Implant Dentistry*).

Discussion

In this study the reporting quality of RCTs in the fields of prosthodontics and implant dentistry was assessed using a modified CONSORT statement (6) and the Jadad scale (19). The mean modified CONSORT scores ranged from 60.9% to 80.6 % among the journals included in the study, a finding similar to the scores reported in medical journals (6,20). The Jadad score ranged from 1.0 to 3.5; this finding is comparable to other fields in medicine (6). Although all quality score scales have inherent limitations and caution should be used when evaluating reporting quality, the overall score indicates that there is room for improvement.

Pre-study sample size calculation is an important part of designing a trial, and guards against underpowered trials that may result in waste (21-24). In the present study 64.0% of the RCTs did not report sample size calculation at all, while, 8.2% of them reported it inadequately. Chan and Altman (25) reported that 73% of the 519 medical trials published in PubMed in December 2000 did not report sample size calculation. It seems that problematic reporting of pre-study sample size calculations in RCTs is a common finding in the literature (11, 14, 26-30). Trials with insufficient sample size can be considered unethical, wasteful (21-24) and less credible compared to trials of sufficient size.

The reporting of the randomization process should, ideally, include details about both the methods used to generate the random allocation sequence and any restrictions used during the process. Terms such as “patients were randomly assigned” or “two groups were formed at random” are considered inadequate. The current study showed that the generation of the unpredictable allocation sequence was reported inadequately in 11.6% of the cases or not at all in 32.7% of the cases. Altman and Dore (31) studied 80 medical trials published in four leading medical journals and concluded that in 30% of trials there was no clear evidence that the groups had been randomised.

In dentistry, Montenegro *et al*. (15) found that only 17% of the trials published in periodontal journals reported the randomization process adequately. Koletsi *et al*. (32) found that from 112 clinical trials in the orthodontic literature labeled as RCTs, only 29.5% were indeed identified as RCTs based on clear descriptions of appropriate random number generation.

Allocation concealment ensures that neither the investigators nor the patients know which treatment the next patient will be allocated to and guards against confounding. Although allocation concealment is always feasible, the results showed that 61.9% of the included RCTs did not report allocation concealment at all, while 17.7% of them reported it inadequately. These results are in accordance with previous studies; Pandis *et al*. (18) reported 22% adequacy in reporting allocation

concealment among dental journals and Montenegro *et al*. (15) only 7% among three periodontal journals.

Another key element in RCT reporting is the description of blinding. Blinding is important to the validity of a trial, as it prevents performance and detection bias, and protects the sequence after allocation. Often the concepts of allocation concealment and blinding are confused. Blinding is especially important for subjective outcomes (e.g. pain scores), as these are more prone to bias. Blinding of the patients and the treatment providers may not always be possible, however, blinding of the assessors and the analysts is (33, 34). The results of this study showed that blinding of the various groups was not reported at all in 36.7% to 89.8% of the cases. Pandis *et al*. (18) using a similar scale reported adequate description of blinding in RCTs published in leading dental journals in the range of 0 to 26%.

Statistical methods used for data analysis were not described in 6.1% whereas 59.2% of the RCT reports provided an adequate description. These results are similar to a previous assessment in dentistry, which reported that 3% of the studies provided no description and 51% provided adequate description of statistical methods (18). Analyses should be pre-specified and ideally described in the trial protocol. Pre-specification allows for the assessment of selective reporting and data driven analysis which can be misleading. A common statistical pitfall is the conduct of multiple tests, which leads to increased type I error (false positive) that can be misleading when associated with selective reporting. It is recommended that subgroup analyses should be pre-specified and kept to the minimum (35, 36). The results of the present study showed that 30.6% of the trials did not describe how this issue was handled, while 34.0% of the reports described it adequately. Pocock *et al*. (37) studied 45 medical trials published in three high impact factor medical journals and they reported that multiple endpoints were analyzed without being pre-specified as primary endpoints.

Finally, in the present study 6.1% and 80.2% of the trials lacked complete description of estimates and confidence intervals, respectively. Previous studies found inadequate results' reporting in leading medical journals (37). Pandis *et al*. (18) found that dental trials also suffered from problematic reporting in this area of interest, with lack of description in 3% and 80% of the studied trials and adequate description in 62% and 20% of them for the complete reporting of the results and for the reporting of confidence intervals respectively. Reporting of estimates and confidence intervals facilitates interpretation in relation to clinical importance. P-values and statistical significance are based on arbitrary cut-off points (i.e. 0.05) and are sensitive to sample size and variance. Small P-

values are often misinterpreted as showing a clinically important effect and vice versa as trivial and clinically unimportant differences can be statistically significant when sample size is large and variance is small (38).

This study is not free of limitations. A limitation might be that the scoring of trials is always susceptible to some degree of subjectivity. Nevertheless, considerable efforts were made to compensate for inter-rater subjectivity by calibration exercises before study commencement and strict adherence to applied CONSORT guidelines. RCT assessment was limited to high impact factor prosthetic journals and therefore published RCTs in lower impact factor journals or even non-published RCTs were excluded. However, we believe that the selected journals constitute a representative or best case scenario sample of the reporting status in the specialty. It should be, also, underlined that incomplete reporting of trials does not necessarily infer low quality of conducting or false methodology (39). Researchers might have designed and conducted a study ideally, but they might have omitted reporting accurately all stages and aspects of their trial due to, for instance, space limitations. Even though RCTs are pivotal for evidence-based dentistry and medicine, they are not free of shortcomings. It is important that they are designed properly, implemented and reported well.

Numerous journals have adopted the CONSORT guidelines and very few have implemented active compliance. The American Journal of Orthodontics and Dentofacial Ortopedics, for instance, has recently implemented a novel approach which includes assessment of compliance at the editorial level and specific recommendations for the authors in order to improve RCT reporting. A preliminary study indicated that this approach has increased dramatically reporting quality (40). In addition the journal has recently adopted a structured report which diverges from the standard IMRaD (Introduction, Methods, Results, Discussion) structure and includes 17 subheadings that lead the report (41). Similar initiatives have been proposed elsewhere (42). The results of the present study indicate that adherence to the CONSORT statement of RCTs in major prosthodontic and implantology journals can be improved.

Conflict of interest

No funding was obtained for the current study. No conflict of interest declared.

Tables

Table 1. Characteristics of the 147 included randomized controlled trials

Characteristic	Category	N	%
Journal	Clin Implant Dent Relat Res	13	8.8
	Clin Oral Implants Res	46	31.3
	Implant Dent	4	2.7
	Int J Oral Maxillofac Implants	24	16.3
	Int J Periodontics Restor Dent	15	10.2
	Int J Prosthodont	20	13.6
	J Dent	21	14.3
	J Oral Rehabil	2	1.4
	J Prosthet Dent	2	1.4
Year	2007	4	2.7
	2008	12	8.2
	2009	13	8.8
	2010	41	27.9
	2011	42	28.6
	2012	35	23.8
Continent	Europe	86	58.5
	Americas	30	20.4
	Asia/Other	31	21.1
Ethics committee approval	No	41	27.9
	Yes	106	72.1
Statistical significance of main finding	No	60	40.8
	Yes	87	59.2
Number of authors	<4	35	23.8
	4- 6	60	40.8
	6≤	52	35.4
Statistician/methodologist involvement	No	92	62.6
	Yes	55	37.4
Number of centers	Single-center	42	28.6
	Multicenter	105	71.4

Table 2. Distribution of consensus scores for the items in the modified CONSORT checklist (n=147)

Item	No description – n (%)	Inadequate – n (%)	Adequate – n (%)
1.Justification for the trial for the trial	15 (10.2)	16 (10.9)	116 (78.9)
2.Explicit definition of eligibility criteria	9 (6.1)	26 (17.7)	112 (76.2)
3.Detailed description of setting/location of recruitment and data collection	21 (14.3)	27 (18.4)	99 (67.3)
4.Details of intervention studied	0 (0.0)	14 (9.5)	133 (90.5)
5.Clear statement of hypothesis or objectives	2 (1.4)	29 (19.7)	116 (78.9)
6.Identification and definition of outcome measures	2 (1.4)	24 (16.3)	121 (82.3)
7.Description of pre-study sample size calculation	94 (63.9)	12 (8.2)	41 (27.9)
8.Description of the generation of unpredictable allocation sequence	48 (32.7)	17 (11.6)	82 (55.8)
9.Details of any restriction used in randomization	85 (57.8)	13 (8.8)	49 (33.3)
10.Description of allocation concealment	91 (61.9)	26 (17.7)	30 (20.4)
11.Details of personnel involved in sequence allocation, enrollment, and assignment	75 (51.0)	35 (23.8)	37 (25.2)
12.Details of blinding of participants	54 (36.7)	9 (6.1)	84 (57.1)
13.Details of blinding of treatment providers	55 (37.4)	4 (2.7)	88 (59.9)
14.Details of blinding of assessors	91 (61.9)	18 (12.2)	38 (25.9)
15.Details of blinding of analysts	132 (89.8)	6 (4.1)	9 (6.1)
16.Details of measurement of success of blinding	143 (97.3)	1 (0.7)	3 (2.0)
17.Description of statistical methods	9 (6.1)	51 (34.7)	87 (59.2)
18.Flow chart describing patient numbers at different stages	113 (76.9)	6 (4.1)	28 (19.1)
19.Clear description of protocol deviations	55 (37.4)	19 (12.9)	73 (49.7)
20.Description of dates of recruitment	89 (60.5)	8 (5.4)	50 (34.0)
21.Details of follow-up	12 (8.2)	17 (11.6)	118 (80.3)
22.Description of baseline characteristics	19 (12.9)	64 (43.5)	64 (43.5)
23.Reporting of intention-to-treat principle	135 (91.8)	3 (2.0)	9 (6.1)
24.Complete reporting of results	9 (6.1)	16 (10.9)	122 (83.0)
25.Reporting of confidence intervals	118 (80.3)	2 (1.4)	27 (18.4)
26.Multiple testing and corrections	45 (30.6)	52 (35.4)	50 (34.0)
27.Description of side effects/adverse effects	33 (22.5)	19 (12.9)	95 (64.6)
28.Trial limitations and weaknesses	82 (55.8)	31 (21.1)	34 (23.1)
29.External validity of trial results	77 (52.4)	49 (33.3)	21 (14.3)
30.Literature review	1 (0.7)	9 (6.1)	137 (93.2)

Table 3. Modified CONSORT scores of the 147 included randomized controlled trials

Characteristic	Category (N)	Mean	SD
Journal	Clin Implant Dent Rel Res (n=13)	64.1	5.8
	Clin Oral Implants Res (n=46)	73.7	8.3
	Implant Dent (n=4)	65.8	4.5
	Int J Oral Maxillofac Implants (n=24)	71.0	10.6
	Int J Periodontics Restor Dent (n=15)	60.9	9.3
	Int J Prosthodont (n=20)	68.0	10.9
	J Dent (n=21)	69.3	7.5
	J Oral Rehabil (n=2)	80.6	5.5
	J Prosthet Dent (n=2)	62.2	12.6
Year	2007 (n=4)	70.0	11.4
	2008 (n=12)	64.8	10.1
	2009 (n=13)	67.0	11.9
	2010 (n=41)	70.5	10.0
	2011 (n=42)	70.5	8.6
	2012 (n=35)	69.1	9.5
Country	Europa (n=86)	69.6	10.1
	Americas (n=30)	69.8	8.8
	Asia/Other (n=31)	68.4	9.6
Ethics committee approval	No (n=41)	67.5	10.0
	Yes (n=106)	70.1	9.5
Statistical significance of main finding	No (n=41)	70.1	9.7
	Yes (n=106)	68.9	9.7
Number of authors	<4 (n=35)	70.4	9.8
	4≤n< 6 (n=60)	68.9	10.0
	≤6 (n=52)	69.2	9.4
Statistician/methodologist involvement	No (n=92)	68.4	8.3
	Yes (n=55)	71.1	11.5
Number of centers	Single-center (n=42)	68.3	9.1
	Multicenter (n=105)	69.8	9.9
	Total (n=147)	69.4	9.7

SD, standard deviation.

Table 4. Univariable and multivariable linear regression-derived coefficients (β) and 95% Confidence Intervals (CIs) for modified CONSORT score as dependent variable for the 147 included randomized controlled trials

		Univariable analysis			Multivariable analysis		
		β	95% CI	P	β	95% CI	P
Journal							
	Clin Implant Dent Relat Res	3.21	(-3.53,9.95)	0.35	2.75	(-3.96,9.46)	0.42
	Clin Oral Implants Res	12.76	(7.47,18.05)	<0.001	12.42	(7.08,17.76)	<0.001
	Other	7.72	(-0.06,15.51)	0.05	8.37	(0.62,16.11)	0.04
	Int J Oral Maxillofac Implants	10.08	(4.23,15.94)	0.001	10.21	(4.27,16.15)	0.001
	Int J Prosthodont	7.11	(1.04,13.19)	0.02	6.37	(0.28,12.46)	0.04
	J Dent	8.26	(2.25,14.28)	<0.01	8.21	(2.12,14.32)	<0.01
Year							
		0.64	(-0.57,1.85)	0.30	0.55	(-0.66,1.75)	0.37
Country							
	Europe	1.21	(-2.82,5.25)	0.55			
	America	1.39	(-3.54,6.32)	0.56			
	Asia/Other	Baseline (reference)					
Ethics committee approval							
	No	Baseline (reference)					
	Yes	2.56	(-0.95,6.07)	0.15	0.42	(-3.02,3.86)	0.81
Statistical significance of main finding							
	No	1.17	(-2.05,4.39)	0.47			
	Yes	Baseline (reference)					
Number of authors							
	<4	1.44	(-2.66,5.53)	0.49			
	4-6	Baseline (reference)					
	6≤	0.26	(-3.38,3.91)	0.87			
Statistician/ methodologist involvement							
	No	Baseline (reference)					
	Yes	2.77	(-0.48,6.01)	0.09	3.44	(0.29,6.59)	0.03
Number of centers							
	Single-center	Baseline (reference)					
	Multicenter	1.54	(-1.96,5.04)	0.39			

Table 5. Descriptive statistics for the Jadad score of the 147 included RCTs by journal

Journal (n)	Median	IQR
Clin Implant Dent Relat Res (n=13)	3.0	1.0
Clin Oral Implants Res (n=46)	3.0	1.0
Implant Dent (n=4)	3.5	2.0
Int J Oral Maxillofac Implants (n=24)	3.0	2.0
Int J Periodontics Restor Dent (n=15)	2.0	1.0
Int J Prosthodont (n=20)	2.0	1.0
J Dent (n=21)	3.0	0.0
J Oral Rehabil (n=2)	3.0	2.0
J Prosthet Dent (n=2)	1.0	2.0

IQR, interquartile range (Q3-Q1).

Appendix 1. List of scored papers

ID	Year	Journal	Year	Issue(volume)	First Author	Jadad	CONSORT	CONSORT %
18	2012	Clin Oral Implants Res	2012	23(5)	Sisti A	4	67	74.4
22	2012	Clin Oral Implants Res	2012	23(5)	Canullo L	4	58	64.4
30	2012	Clin Oral Implants Res	2012	23(5)	Van Assche N	3	66	73.3
31	2012	Clin Oral Implants Res	2012	23(5)	Quirynen M	3	65	72.2
32	2012	Clin Oral Implants Res	2012	23(5)	Chongcharoen N	3	66	73.3
38	2012	Clin Oral Implants Res	2012	23(4)	Trombelli L	5	69	76.7
46	2012	Clin Oral Implants Res	2012	23(4)	Krennmair G	2	60	66.7
47	2012	Clin Oral Implants Res	2012	23(4)	Romano M	5	61	67.8
48	2012	Clin Oral Implants Res	2012	23(4)	Elsyad M	3	73	81.1
58	2012	Clin Oral Implants Res	2012	23(3)	Lorenzo R	5	83	92.2
78	2012	Clin Oral Implants Res	2012	23(2)	Hammerle C	5	76	84.4
79	2012	Clin Oral Implants Res	2012	23(2)	Urban T	3	63	70.0
143	2011	Clin Oral Implants Res	2011	22(11)	den Hartog L	5	75	83.3
155	2011	Clin Oral Implants Res	2011	22(10)	Cordaro L	3	70	77.8
162	2011	Clin Oral Implants Res	2011	22(10)	Enkling N	3	67	74.4
173	2011	Clin Oral Implants Res	2011	22(8)	Karabuda Z	3	71	78.9
175	2011	Clin Oral Implants Res	2011	22(8)	Galindo-Moreno P	3	58	64.4
182	2011	Clin Oral Implants Res	2011	22(7)	Sakalioglu U	2	54	60.0
193	2011	Clin Oral Implants Res	2011	22(6)	van Brakel	2	61	67.8
201	2011	Clin Oral Implants Res	2011	22(6)	Nissan J	2	54	60.0
202	2011	Clin Oral Implants Res	2011	22(6)	Bressan E	1	55	61.1
209	2011	Clin Oral Implants Res	2011	22(5)	Jokstad A	5	80	88.9
211	2011	Clin Oral Implants Res	2011	22(5)	Chackartchi T	3	63	70.0
222	2011	Clin Oral Implants Res	2011	22(5)	Heberer S	3	58	64.4
234	2011	Clin Oral Implants Res	2011	22(4)	Mardas N	4	79	87.8
239	2011	Clin Oral Implants Res	2011	22(3)	Heitz-Mayfield L	5	69	76.7
241	2011	Clin Oral Implants Res	2011	22(3)	Rickert D	4	65	72.2
252	2011	Clin Oral Implants Res	2011	22(3)	Alsabeeha N	3	74	82.2
272	2011	Clin Oral Implants Res	2011	22(1)	Tan W	3	64	71.1
278	2011	Clin Oral Implants Res	2011	22(1)	Galucci G	4	70	77.8
298	2010	Clin Oral Implants Res	2010	21(12)	Felice P	5	81	90.0
302	2010	Clin Oral Implants Res	2010	21(11)	Van Der Bilt A	1	53	58.9
304	2010	Clin Oral Implants Res	2010	21(11)	Van de Velde T	3	66	73.3
309	2010	Clin Oral Implants Res	2010	21(11)	Urban T	3	61	67.8
313	2010	Clin Oral Implants Res	2010	21(11)	Koch F	3	64	71.1
318	2010	Clin Oral Implants Res	2010	21(9)	Pineiro A	2	59	65.6

343	2010	Clin Oral Implants Res	2010	21(7)	Degidi M	5	73	81.1
344	2010	Clin Oral Implants Res	2010	21(7)	Mardas N	4	72	80.0
373	2010	Clin Oral Implants Res	2010	21(5)	Elsyad M	3	68	75.6
374	2010	Clin Oral Implants Res	2010	21(5)	Zembic A	4	69	76.7
377	2010	Clin Oral Implants Res	2010	21(5)	Thone-Muhling M	3	59	65.6
381	2010	Clin Oral Implants Res	2010	21(5)	Pelegrine A	2	60	66.7
426	2010	Clin Oral Implants Res	2010	21(2)	Park J-C	4	76	84.4
428	2010	Clin Oral Implants Res	2010	21(2)	Jofre J	2	64	71.1
431	2010	Clin Oral Implants Res	2010	21(1)	Sanz M	3	69	76.7
444	2010	Clin Oral Implants Res	2010	21(1)	Canullo L	4	61	67.8
467	2012	Clin Implant Dent Relat Res	2012	14(s1)	Al-Zubeidi M	2	59	65.6
503	2012	Clin Implant Dent Relat Res	2012	14(2)	Enkling N	3	49	54.4
509	2012	Clin Implant Dent Relat Res	2012	14(1)	Lindgren C	2	58	64.4
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521	2012	Clin Implant Dent Relat Res	2012	14(1)	Enkling N	2	50	55.6
534	2011	Clin Implant Dent Relat Res	2011	13(3)	Wenneberg A	4	69	76.7
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634	2009	Clin Implant Dent Relat Res	2009	11(3)	Mericske-Stern R	2	60	66.7
649	2009	Clin Implant Dent Relat Res	2009	11(1)s	Canullo L	3	59	65.6
695	2008	Clin Implant Dent Relat Res	2008	10(1)	Guncu G	3	55	61.1
726	2007	Clin Implant Dent Relat Res	2007	9(1)	Hall J	3	56	62.2
819	2012	Int J Oral Maxillofac Implants	2012	27(2)	Wohlfahrt J	4	70	77.8
823	2012	Int J Oral Maxillofac Implants	2012	27(2)	Ramel C	4	63	70.0
873	2011	Int J Oral Maxillofac Implants	2011	26(6)	Taguchi T	2	55	61.1
946	2011	Int J Oral Maxillofac Implants	2011	26(3)	Krennmair G	1	47	52.2
948	2011	Int J Oral Maxillofac Implants	2011	26(3)	Canullo L	4	67	74.4
949	2011	Int J Oral Maxillofac Implants	2011	26(3)	Fung K	4	66	73.3
972	2011	Int J Oral Maxillofac Implants	2011	26(2)	Heberer S	2	53	58.9
975	2011	Int J Oral Maxillofac Implants	2011	26(2)	De Kok I	2	62	68.9
989	2011	Int J Oral Maxillofac Implants	2011	26(1)	Salihoglu U	2	55	61.1
998	2011	Int J Oral Maxillofac Implants	2011	26(1)	Pieri F	5	71	78.9
1022	2010	Int J Oral Maxillofac Implants	2010	25(6)	Jofre J	4	65	72.2
1078	2010	Int J Oral Maxillofac Implants	2010	25(4)	Merli M	5	85	94.4
1099	2010	Int J Oral Maxillofac Implants	2010	25(3)	van Kesteren C	2	60	66.7
1213	2009	Int J Oral Maxillofac Implants	2009	24(5)	Aimetti M	3	63	70.0
1278	2009	Int J Oral Maxillofac Implants	2009	24(2)	Prosper L	5	80	88.9
133	200	Int J Oral Maxillofac Implants	200	23(5)	Covani U	3	58	64.4

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1339	2008	Int J Oral Maxillofac Implants	2008	23(5)	Cannizzaro G	5	79	87.8
1347	2008	Int J Oral Maxillofac Implants	2008	23(5)	Shahidi P	3	60	66.7
1373	2008	Int J Oral Maxillofac Implants	2008	23(4)	Schropp L	3	56	62.2
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1408	2008	Int J Oral Maxillofac Implants	2008	23(2)	Morneburg T	2	57	63.3
1469	2007	Int J Oral Maxillofac Implants	2007	22(5)	Oates T	2	57	63.3
1478	2007	Int J Oral Maxillofac Implants	2007	22(5)	Testori T	5	78	86.7
1515	2012	Implant Dent	2012	21(3)	Gadallah A	5	65	72.2
1547	2012	Implant Dent	2012	21(3)	Gadallah A	4	56	62.2
1719	2010	Implant Dent	2010	19(2)	Basha A	2	57	63.3
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1918	2012	J Dent	2012	40(5)	de Sousa Barbosa R	2	54	60.0
1967	2012	J Dent	2012	40(1)	West N	4	79	87.8
1980	2011	J Dent	2011	39(s3)	Moffa E	3	58	64.4
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2006	2011	J Dent	2011	39(11)	Kitasako Y	4	65	72.2
2015	2011	J Dent	2011	39(10)	Ren Y-F	3	58	64.4
2038	2011	J Dent	2011	39(7)	Huth K	4	69	76.7
2042	2011	J Dent	2011	39(7)	Nelson-Filho P	3	63	70.0
2043	2011	J Dent	2011	39(7)	Shen P	3	70	77.8
2056	2011	J Dent	2011	39(5)	Wirsching E	2	53	58.9
2114	2010	J Dent	2010	38(12)	Meireles S	5	70	77.8
2122	2010	J Dent	2010	38(12)	Huth K	3	67	74.4
2125	2010	J Dent	2010	38(11)	Hyde T	5	66	73.3
2131	2010	J Dent	2010	38(11)	Pan S	3	62	68.9
2173	2010	J Dent	2010	38(7)	Syrek A	3	54	60.0
2181	2010	J Dent	2010	38(6)	dos Santos M	3	64	71.1
2184	2010	J Dent	2010	38(6)	Banerjee A	3	58	64.4
2189	2010	J Dent	2010	38(6)	Mcdonald E	3	58	64.4
2219	2010	J Dent	2010	38(3)	Emami E	2	64	71.1
2252	2010	J Dent	2010	38s3	Mason S	3	52	57.8
2253	2010	J Dent	2010	38s3	Maggio B	2	63	70.0
2352	2011	J Prosthet Dent	2011	106(1)	Burns D	2	64	71.1
2424	2010	J Prosthet Dent	2010	104(6)	Damodara E	0	48	53.3
2616	2011	J Oral Rehab	2011	38(10)	Nilsson H	2	69	76.7
2759	2010	J Oral Rehab	2010	37(7)	Kimoto S	4	76	84.4
2852	2012	Int J Prosth	2012	25(4)	Gjengedal H	2	53	58.9

2865	2012	Int J Prosth	2012	25(3)	Stober T	2	53	58.9
2867	2012	Int J Prosth	2012	25(3)	Sagirkaya E	2	63	70.0
2868	2012	Int J Prosth	2012	25(3)	Volpato Sanita P	3	70	77.8
2886	2012	Int J Prosth	2012	25(2)	Elsyad M	2	54	60.0
2887	2012	Int J Prosth	2012	25(2)	Machado de Andrade I	1	49	54.4
2947	2011	Int J Prosth	2011	24(4)	Zicari F	3	72	80.0
2993	2011	Int J Prosth	2011	24(1)	Cehreli M	2	62	68.9
3007	2010	Int J Prosth	2010	23(6)	Larsson C	0	49	54.4
3030	2010	Int J Prosth	2010	23(4)	Cune M	0	52	57.8
3055	2010	Int J Prosth	2010	23(3)	Klat-amnuay S	3	79	87.8
3060	2010	Int J Prosth	2010	23(2)	Kimoto S	4	76	84.4
3086	2009	Int J Prosth	2009	22(6)	Sailer I	2	57	63.3
3120	2009	Int J Prosth	2009	22(4)	Walton J	4	78	86.7
3126	2009	Int J Prosth	2009	22(4)	Pradies G	2	62	68.9
3143	2009	Int J Prosth	2009	22(3)	Cannulo L	3	69	76.7
3148	2009	Int J Prosth	2009	22(3)	Haim M	2	57	63.3
3219	2008	Int J Prosth	2008	21(4)	Berg E	2	58	64.4
3221	2008	Int J Prosth	2008	21(4)	Luthardt R	2	50	55.6
3298	2007	Int J Prosth	2007	20(5)	Naumann M	2	61	67.8
3330	2012	Int J Periodontics Restorative Dent	2012	32(4)	Cardaropoli D	4	67	74.4
3347	2012	Int J Periodontics Restorative Dent	2012	32(3)	Riza Certin A	0	51	56.7
3351	2012	Int J Periodontics Restorative Dent	2012	32(3)	Griffiths G	1	56	62.2
3358	2012	Int J Periodontics Restorative Dent	2012	32(2)	Jankovic K	2	60	66.7
3361	2012	Int J Periodontics Restorative Dent	2012	32(2)	Margossian P	3	57	63.3
3377	2012	Int J Periodontics Restorative Dent	2012	32(1)	Cordaro L	2	73	81.1
3381	2011	Int J Periodontics Restorative Dent	2011	31(6)	Froum S	2	59	65.6
3448	2011	Int J Periodontics Restorative Dent	2011	31(2)	Rasperini G	1	50	55.6
3504	2010	Int J Periodontics Restorative Dent	2010	30(3)	Rasperini G	1	57	63.3
3515	2010	Int J Periodontics Restorative Dent	2010	30(2)	Wu S-Y	0	51	56.7
3535	2009	Int J Periodontics Restorative Dent	2009	29(6)	Trammel K	3	49	54.4
3579	2009	Int J Periodontics Restorative Dent	2009	29(2)	Haghighati F	0	44	48.9
3589	2009	Int J Periodontics Restorative Dent	2009	29(1)	Cardaropoli D	2	47	52.2
3607	2008	Int J Periodontics Restorative Dent	2008	28(5)	Merli M	2	59	65.6
3619	2008	Int J Periodontics Restorative Dent	2008	28(4)	Jung R	1	42	46.7

References

1. Juni P, Altman DG, Egger M. Systematic reviews in health care: assessing the quality of controlled clinical trials. BMJ. 2001;323:42–46.
2. Moher D, Hopewell S, Schulz KF, Montori V, Gøtzsche PC, Devereaux PJ *et al.* CONSORT 2010 Explanation and Elaboration: updated guidelines for reporting parallel group randomised trials. BMJ. 2010;340:c869.
3. Schulz KF, Chalmers I, Grimes DA, Altman DG. Assessing the quality of randomization from reports of controlled trials published in obstetrics and gynecology journals. JAMA. 1994;272:125–128.
4. Moher D, Jadad AR, Nichol G, Penman M, Tugwell P, Walsh S. Assessing the quality of randomized controlled trials: an annotated bibliography of scales and checklists. Control Clin Trials. 1995;16:62–73.
5. Balasubramanian SP, Wiener M, Alshameeri Z, Tiruvoipati R, Elbourne D, Reed MW. Standards of reporting of randomized controlled trials in general surgery: can we do better? Ann Surg. 2006;244:663–667.
6. Tiruvoipati R, Balasubramanian SP, Atturu G, Peek GJ, Elbourne D. Improving the quality of reporting randomized controlled trials in cardiothoracic surgery: the way forward. J Thorac Cardiovasc Surg. 2006;132:233–240.
7. Glasziou P, Altman DG, Bossuyt P, Boutron I, Clarke M, Julious S *et al*. Reducing waste from incomplete or unusable reports of biomedical research. Lancet. 2014;383:267–276.
8. *The CONSORT Website.* CONSORT endorsers-journals. http://www.consortstatement.org/about-consort/consort-endorsement/consort-endorsers journals/.
9. Turner L, Shamseer L, Altman DG, Schulz KF, Moher D. Does use of the CONSORT Statement impact the completeness of reporting of randomised controlled trials published in medical journals? A Cochrane review. Cochrane Database Syst Rev. 2012;doi: 10.1186/2046-4053-1-60.
10. Antczak AA, Tang J, Chalmers TC. Quality assessment of randomized control trials in dental research. II. Results: Periodontal research. J Periodontal Res. 1986;21:315–321.
11. Prihoda TJ, Schelb E, Jones JD. The reporting of statistical inferences in selected prosthodontic journals. J Prosthod.1992;1:51–56.
12. Dumbrigue HB, Jones JS, Esquivel JF. Control of bias in randomized controlled trials published in prosthodontic journals. J Prosthet Dent. 2001;86: 592–596.

13. Esposito M, Coulthard P, Worthington HV, Jokstad A. Quality assessment of randomized controlled trials of oral implants. Int J Oral Maxillofac Implants. 2001;16:783–792.
14. Jokstad A, Esposito M, Coulthard P, Worthington HV. The reporting of randomized controlled trials in prosthodontics. Int J Prosthodont. 2002;15:230–242.
15. Montenegro R, Needleman I, Moles D, Tonetti M. Quality of RCTs in periodontology. A systematic review. J Dent Res. 2002;81:866–870.
16. Sjögren P, Halling A. Quality of reporting randomised clinical trials in dental and medical research. Br Dent J. 2002;192:100–103.
17. Harrison JE. Clinical trials in orthodontics II: Assessment of the quality of American Journal of Dentistry, Vol. 21, No. 1, February, 2008 reporting of clinical trials published in three orthodontic journals between 1989 and 1998. J Orthod. 2003;30:309–315.
18. Pandis N, Polychronopoulou A, Eliades T. An assessment of quality characteristics of randomised control trials published in dental journals. J Dent. 2010;38:713–721.
19. Jadad AR, Moore RA, Carroll D, Jenkinson C, Reynolds DJ, Gavaghan DJ *et al.* Assessing the quality of reports of randomized clinical trials: is blinding necessary? Control Clin Trials. 1996;17:1–12.
20. Moher D, Jones A, Lepage L. Use of the CONSORT statement and quality of reports of randomized trials: a comparative before-and-after evaluation. JAMA. 2001;285:1992–1995.
21. Al-Shahi Salman R, Beller E, Kagan J, Hemminki E, Phillips RS, Savulescu J *et al*. Increasing value and reducing waste in biomedical research regulation and management. Lancet. 2014;383:176–185.
22. Chan AW, Song F, Vickers A, Jefferson T, Dickersin K, Gøtzsche PC *et al.* Increasing value and reducing waste: addressing inaccessible research. Lancet**.** 2014;383:257–266.
23. Ioannidis JP, Greenland S, Hlatky MA, Khoury MJ, Macleod MR, Moher D *et al.* Increasing value and reducing waste in research design, conduct, and analysis. Lancet. 2014;383:166–175.
24. Macleod MR, Michie S, Roberts I, Dirnagl U, Chalmers I, Ioannidis JP *et al.* Biomedical research: increasing value, reducing waste. Lancet. 2014;383:101–104.
25. Chan AW, Altman DG. Epidemiology and reporting of randomised trials published in PubMed journals. Lancet. 2005;365:1159–1162.
26. Hujoel PP, Baab DA, DeRouen TA. The power of tests to detect differences between periodontal treatments in published studies. J Clin Periodontol. 1992;19:779–784.
27. Gunsolley JC, Elswick RK, Davenport JM. Equivalence and superiority testing in regeneration clinical trials. J Periodontol. 1998;69:521–527.

28. Lesaffre E, Garcia Zattera MJ, Redmond C, Huber H, Needleman I. Reported methodological quality of split-mouth studies. J Clin Periodontol. 2007;34:756–761.

29. Lempesi E, Koletsi D, Fleming PS, Pandis N. The reporting quality of randomized controlled trials in orthodontics. J Evid Based Dent Pract. 2014;14:46–52.

30. Fleming PS, Lynch CD, Pandis N. Randomized controlled trials in dentistry: common pitfalls and how to avoid them. J Dent. 2014;42:908–914.

31. Altman DG, Dore CJ. Randomisation and baseline comparisons in clinical trials. Lancet. 1990;335:149–153.

32. Koletsi D, Pandis N, Polychronopoulou A, Eliades T. What's in a title? An assessment of whether randomized controlled trial in a title means that it is one. Am J Orthod Dentofacial Orthop. 2012;141:679–685.

33. Schulz KF, Chalmers I, Altman DG. The landscape and lexicon of blinding in randomized trials. Ann Intern Med. 2002;136:254–259.

34. Savović J, Jones HE, Altman DG, Harris RJ, Jűni P, Pildal J *et al*. Influence of reported study design characteristics on intervention effect estimates from randomized, controlled trials. Ann Intern Med. 2012;157:429–438.

35. Pandis N. Multiplicity 1: subgroup analyses. Am J Orthod Dentofacial Orthop. 2013;143:439–441.

36. Sun X, Ioannidis JP, Agoritsas T, Alba AC, Guyatt G. How to use a subgroup analysis: users' guide to the medical literature. JAMA. 2014;311:405–411.

37. Pocock SJ, Hughes MD, Lee RJ. Statistical problems in the reporting of clinical trials. A survey of three medical journals. New Eng J Med. 1987;317:426–432.

38. Rothman KJ. Six persistent research misconceptions. J Gen Intern Med. 2014;29:1060–4.

39. Soares HP, Daniels S, Kumar A, Clarke M, Scott C, Swann S *et al.* Bad reporting does not mean bad methods for randomised trials: observational study of randomised controlled trials performed by the Radiation Therapy Oncology Group. BMJ. 2004;328:22–24.

40. Pandis N, Shamseer L, Kokich V, Fleming PS, Moher D. Implementation of a strategy to improve adherence to the CONSORT guidelines by a dental specialty journal. J Clinical Epidemiology pii: S0895-4356(14)00114-0. doi: 10.1016/j.jclinepi.2014.04.001. [Epub ahead of print]

41. Guidelines for Randomised Clinical trials. http://www.ajodo.org/content/authorinfo#idp1848752

42. Altman DG. Making research articles fit for purpose: structured reporting of key methods and findings. Trials. 2015 Feb 20;16(1):53. doi:10.1186/s13063-015-0575-7