

# The Reporting Quality of Randomized Controlled Trials in Orthodontics

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## Abstract

**Objectives:** Accurate trial reporting facilitates evaluation and better use of study results. The objective of this article is to investigate the quality of reporting of randomized controlled trials (RCTs) in leading orthodontic journals, and to explore potential predictors of improved reporting.

**Methods:** The 50 most recent issues of 4 leading orthodontic journals until November 2013 were electronically searched. Reporting quality assessment was conducted using the modified CONSORT statement checklist. The relationship between potential predictors and the modified CONSORT score was assessed using linear regression modeling.

**Results:** 128 RCTs were identified with a mean modified CONSORT score of 68.97% (SD = 11.09). The Journal of Orthodontics (JO) ranked first in terms of completeness of reporting (modified CONSORT score 76.21%, SD = 10.1), followed by American Journal of Orthodontics and Dentofacial Orthopedics (AJODO) (73.05%, SD = 10.1). Journal of publication (AJODO:  $\beta = 10.08$ , 95% CI: 5.78, 14.38; JO:  $\beta = 16.82$ , 95% CI: 11.70, 21.94; EJO:  $\beta = 7.21$ , 95% CI: 2.69, 11.72 compared to Angle), year of publication ( $\beta = 0.98$ , 95% CI: 0.28, 1.67 for each additional year), region of authorship (Europe:  $\beta = 5.19$ , 95% CI: 1.30, 9.09 compared to Asia/other), statistical significance (significant:  $\beta = 3.10$ , 95% CI: 0.11, 6.10 compared to non-significant) and methodologist involvement (involvement:  $\beta = 5.60$ , 95% CI: 1.66, 9.54 compared to non-involvement) were all significant predictors of improved modified CONSORT scores in the multivariable model. Additionally, median overall Jadad score was 2 (IQR = 2) across journals, with JO (median = 3, IQR = 1) and AJODO (median = 3, IQR = 2) presenting the highest score values.

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**Conclusion:** The reporting quality of RCTs published in leading orthodontic journals is considered suboptimal in various CONSORT areas. This may have a bearing in trial result interpretation and use in clinical decision making and evidence-based orthodontic treatment interventions.

**Keywords:** RCTs, Orthodontic journals, CONSORT, Jadad scale, Reporting quality.

## INTRODUCTION

The primacy of randomized controlled trials (RCTs) and systematic reviews (SRs) in providing evidence concerning the effectiveness of interventions is clear. However, a high proportion of trials have been exposed as being at high risk of bias leading to barren systematic reviews, the merits of which are contestable.<sup>1</sup> The integrity and relevance of an RCT hinges on its “internal validity,” which is predicated on a range of methodological characteristics. Internally valid trials may have a profound impact on clinical practice. Assessment of methodological quality and risk of bias is usually conducted directly from the published trial manuscript. It is therefore difficult to make a correct judgment on internal validity from poorly-reported studies. However, when trials at high risk of bias are viewed in isolation, they risk prompting inappropriate treatment; in systematic reviews, findings from these studies are likely to be overlooked.<sup>2</sup>

A variety of techniques have been used to assess the reporting and methodological quality of RCTs.<sup>3-8</sup> The CONSORT guidelines, a product of previous efforts have been developed and modified in an attempt to standardize the reporting of clinical trial with the ultimate objective to better inform health care decisions through the correct assessment of the quality of the existing evidence.<sup>3</sup> These guidelines cover 25 items relating to key facets of RCTs presenting a valuable framework for reporting and indirectly for research design.<sup>1</sup>

Despite widespread adoption of the CONSORT guidelines, there is abundant evidence of suboptimal reporting of RCTs throughout medicine and dentistry.<sup>6,9,10</sup> In particular, areas with incomplete reporting include inadequate randomization procedures including allocation concealment, lack of blinding and failure to account for loss to follow-up.<sup>3</sup> The upshot of these problems include incorrect evaluation and potentially biased estimates related to inadequate concealment<sup>11</sup> and lack of blinding, with the latter having been shown to result in inflated effect estimates of the order of 13%.<sup>12</sup> These aspects have also both been exposed as deficient in an assessment of dental journals.<sup>10</sup> These shortcomings were compounded by near universal failure to describe or account for protocol deviations and improper reporting of the results.<sup>10</sup>

The objectives of this study were therefore to get an updated assessment of the reporting quality of randomized controlled trials in orthodontics, by assessing a subset

of leading journals. In addition, the relationship between reporting quality and a range of variables were to be explored including: journal and region of publication, number and expertise of authors and prior provision of ethical approval.

## MATERIALS AND METHODS

Randomized controlled trials published in major orthodontic journals were included in the present study. The contents of the most recent 50 issues of the *American Journal of Orthodontics and Dentofacial Orthopedics* (AJODO), the *Angle Orthodontist* (Angle), the *European Journal of Orthodontics* (EJO) and the *Journal of Orthodontics* (JO) were electronically searched up to November 2013 by two authors (EL, DK). Only RCTs in human were eligible for inclusion. Initially the title and abstract was scanned; if randomization was apparent or the prospective nature of the study verified, the full text was accessed to clarify trial design. Terminology such as “random allocation,” “random assignment,” “randomly divided” or similar, were chosen as indicators of a randomized design.

The modified CONSORT checklist, reported by Tiruvoipati et al (2006)<sup>7</sup> was used for evaluation of the quality of reporting of the orthodontic RCTs. The checklist comprises of 30 questions related to items derived from the CONSORT guidelines. Information pertaining to the first item (title and abstract) was omitted as the authors are obliged to follow editorial or journal guidelines when reporting these aspects (e.g. word numbering limitations in titles or abstracts). The score per item ranged from 1 to 3, with a score of 1 indicating no description, 2 representing inadequate description and 3 reflecting adequate description. The scores for the 30 items were combined, and a percentage score calculated for each constituent trial. Non-applicable items did not receive any score. The maximum score for an RCT with adequate description for all items was 90, which corresponded to 100 percent. Similarly, a trial with 26 applicable items could receive a maximum score of 78, also equivalent to 100%.

In addition, the quality of the RCTs included was assessed according to the Jadad scale<sup>4</sup> incorporating questions regarding randomization, blinding and patient attrition. Fifty percent of the papers were scored independently by each of the two authors (EL, DK) to arrive to a

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