

ORTHODONTIC EVIDENCE:

PROBLEMS AND SOME SOLUTIONS



PADHRAIG FLEMING



ORTHODONTIC EVIDENCE:

PROBLEMS AND SOME SOLUTIONS



PADHRAIG FLEMING



TAURANGA 2019



Treatment Duration

Adult Orthodontics

Retention

Growing Wiser

Functional Appliances

Orthodontic Research Practice



Development of a core outcome set for orthodontic trials using a mixed-methods approach: protocol for a multicentre study

Riki Yoshida^{1,2}, Kevin O'Brien³, Anna Juhl⁴, Zoe Markman⁵, Philip Benson⁶, Fiorella B. Colomo Salazar⁷ and Padraig S. Fleming²

ORTHODONTIC EVIDENCE

- EVIDENCE: WHY WE NEED IT
- EVIDENCE AND DECISION-MAKING (IN GENERAL)
- EVIDENCE IN ORTHODONTICS
- HOW EVIDENCE AFFECTS WHAT I SAY, PLAN AND DO
- THE ORTHODONTIC EVIDENCE WE LACK
- HOW TO IMPROVE OUR EVIDENCE



ORTHODONTIC JOURNALS



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OPEN SCIENCE

ros.royalsocietypublishing.org

Research



Modelling science
trustworthiness under
publish or perish pressure

David Robert Grimes^{1,2}, Chris T. Bauch³ and
John P. A. Ioannidis^{4,5,6,7,8}

Scientific publication is immensely important to the scientific endeavour. There is, however, concern that rewarding scientists chiefly on publication creates a perverse incentive, allowing careless and fraudulent conduct to thrive, compounded by the predisposition of top-tier journals towards novel, positive findings rather than investigations confirming null hypothesis.

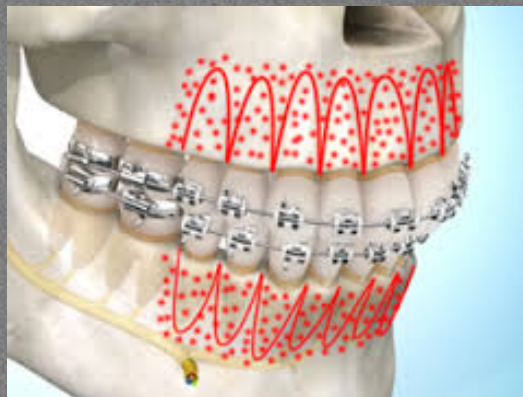
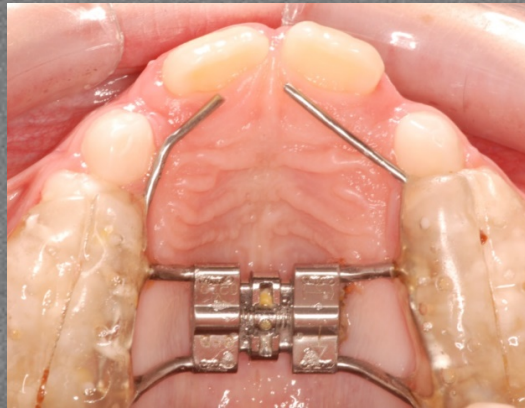
WHY RESEARCH?

To **benefit patients** by providing effective and safe treatments

Therefore, we must produce results that can be both trusted and useful



HOW DO WE MAKE DECISIONS?



HOW DO WE MAKE DECISIONS?

DECISION-MAKING



- OBJECTIVES
- PROCESS



EXPERIENCE



EVIDENCE



ENVIRONMENT

EVIDENCE



A closed mouth

A wise head

Irish Proverb



EVIDENCE

EXPERIENCE

EXPERIENCE

- EXPERTS/COLLEAGUES
- PATIENTS
- INDUSTRY

- BIAS



- FOUNDATIONS

ORIGINAL ARTICLE

AJO-DO

Attitudes, awareness, and barriers toward evidence-based practice in orthodontics

Asha Madhavji,^a Eustaquio A. Araujo,^b Ki Beom Kim,^c and Peter H. Buschang^d
St Louis, Mo, and Dallas, Tex

Table VII. Percentage of respondents to the state to age groups, involvement in teaching, and hav

	Age* ($P < 0.001$)		
	≤ 40 y	41–60 y	≥ 61 y
Colleague advice	24%	12%	9%
Expert advice	32%	35%	36%
Clinical journals	15%	26%	29%
Literature reviews	18%	13%	11%
Other	11%	14%	15%
Total	100%	100%	100%

* $P < 0.05$.

ENVIRONMENT



EVIDENCE



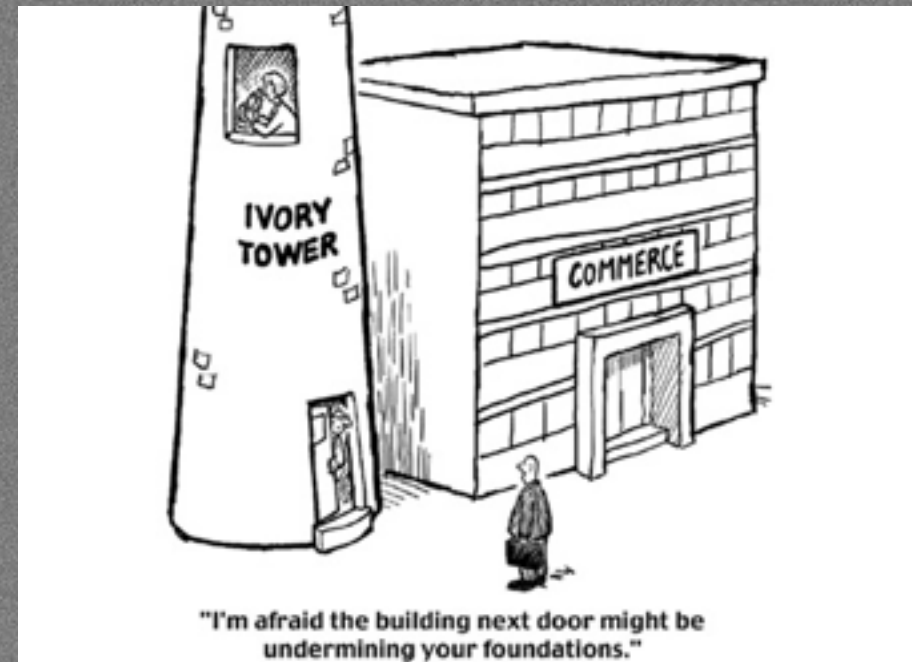
OCTOBER 15, 2018

WHO PAYS THE PIPER? AN INFLUX
OF KEY OPINION LEADERS

ENVIRONMENT

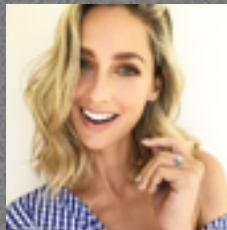
SALES AND MARKETING

INDUSTRY?



Have Selfies Ruined the Smile?

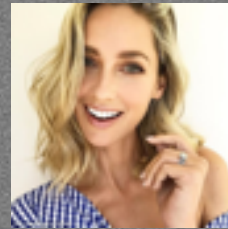
By Rina, Executive Editor | June 16, 2017



Instagram

facebook





Instagram

facebook



GREAT EXPECTATIONS ...



PREDICTABLE

WHAT
WORKS?

OR

WHAT MIGHT
WORK?

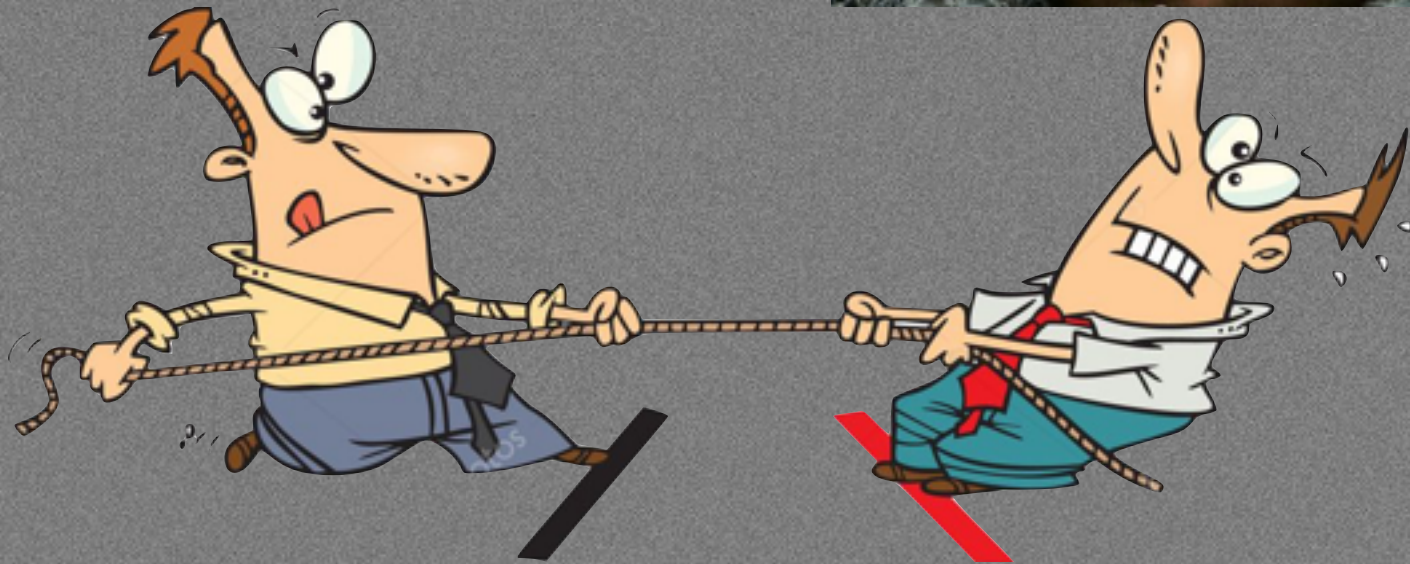
We are told these days that every medical consultation is the meeting of two experts. We are experts in health care provision but the patient is also an expert. . . in their own condition. The patients' wishes therefore, are an extremely important consideration when planning a course of treatment. Patients often select an orthodontist, based on the opinion they gather either from their circle of friends or perhaps peer group advice and possibly based on their insurance coverage. In a survey conducted recently, the friendliness of the staff was rated to have an 86.9% influence on patient's office visits and interestingly the educational qualifications and the prestige of affiliated educational institutions were rated much lower. These superficial ways of selecting medical or dental care makes patients extremely vulnerable to the 'power of advertising'.

HOW DO WE KNOW WE ARE DOING RIGHT?

- EVIDENCE

"A FOOL THINKS HIMSELF TO BE WISE, BUT A WISE MAN KNOWS HIMSELF TO BE A FOOL."

WILLIAM SHAKESPEARE



RESEARCHER OR CLINICIAN ???

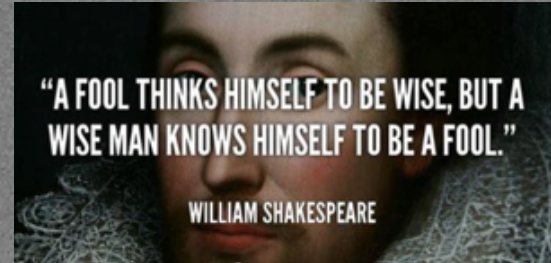
An orthodontic registry: Producing evidence from existing resources

James L. Vaden,^a Christopher S. Riolo,^b and Michael L. Riolo^c
Cookeville, Tenn, Seattle, Wash, and Detroit, Mich

PREDICTABLE

WHAT WORKS?

hospitals unless there is evidence to support their clinical efficacy. The Federal Drug Administration does not allow drugs to be used unless these drugs have been tested and proven to have a predictable value for the patient. Why are there not similar safeguards in orthodontics? A registry would help the specialty to improve its performance on 2 fundamental levels. (1) On an individual level, a registry will enhance each clinician's understanding of his or her performance. (2) On the population level, a registry will facilitate the establishment of a standard of care for the many problems being treated.^{12,13}

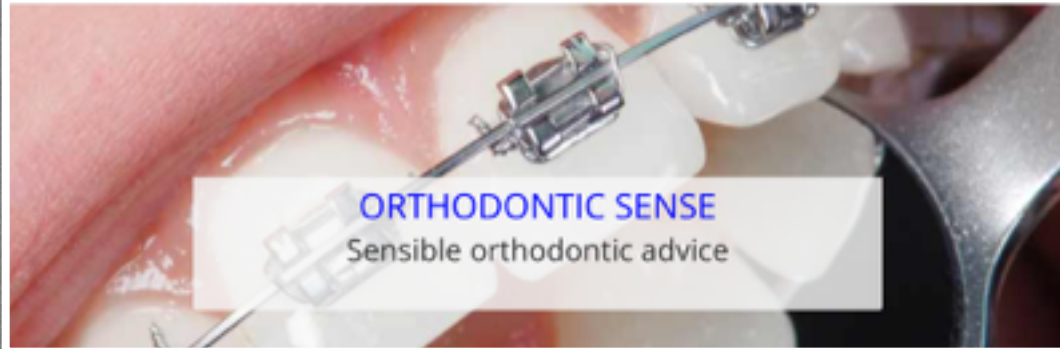


ORTHODONTIC SENSE: FOR PATIENTS



Orthodontic Sense

[Home](#) [Orthodontic Treatment](#) [Types of brace](#) [FAQs](#) [🔍](#)



ORTHODONTIC SENSE
Sensible orthodontic advice



Professor Kevin O'Brien

I work at the University of Manchester. I carry



Dr Padhraig Fleming

I work at Queen Mary's University London. My best known research



Professor Susan Cunningham

I work at University College, London. I carry



Professor Zoe Marshman

I work at the University of Sheffield. I carry out

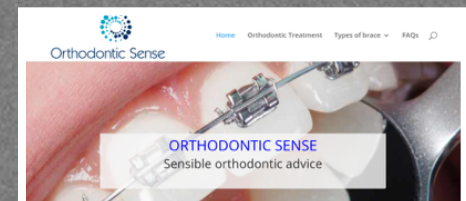
ORTHODONTIC SENSE: FOR PATIENTS

Sensible advice about orthodontic treatment

Our aim is to give you balanced information about all different aspects of orthodontic treatment. We hope that this will help you decide whether treatment is right for you, allow you to understand what the likely effects of treatment will be and give you a good idea of what you will experience during treatment.

We also highlight claims made about orthodontic treatment that are not all that they seem and are perhaps not supported by evidence.

Our aim is to give you the right information to help you to decide what is best for your teeth and/or your children's teeth.



ORTHODONTIC SENSE: FOR PATIENTS

Lingual Braces

A lingual brace is fixed to the inside surface of the teeth (on the tongue side). They are usually made especially for your mouth, from impressions taken by your orthodontist / dentist using moulds.

What are the advantages of a lingual brace?

Appearance

In general, lingual braces cannot be seen by other people, unless they look inside your mouth.

Fewer white / brown marks on teeth visible, after the braces are removed

If you have any brace, your oral hygiene and brushing must be excellent. If plaque sits on the teeth and is not removed by brushing, you can get areas of early tooth decay, which appear as white or brown marks. These can still occur with lingual braces, but would be less visible than with braces fitted to the outside surface of the teeth.

Will my treatment be different if I choose a lingual brace, compared with a metal or a white fixed brace?

Cost

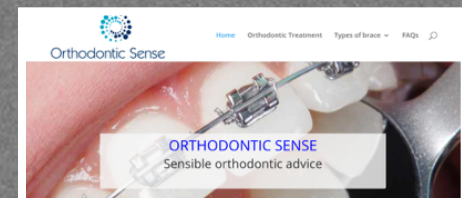
Lingual braces are more expensive than metal and ceramic braces. They are not offered within the National Health Service in the U.K. and are not provided by all orthodontists.

Treatment appointment time

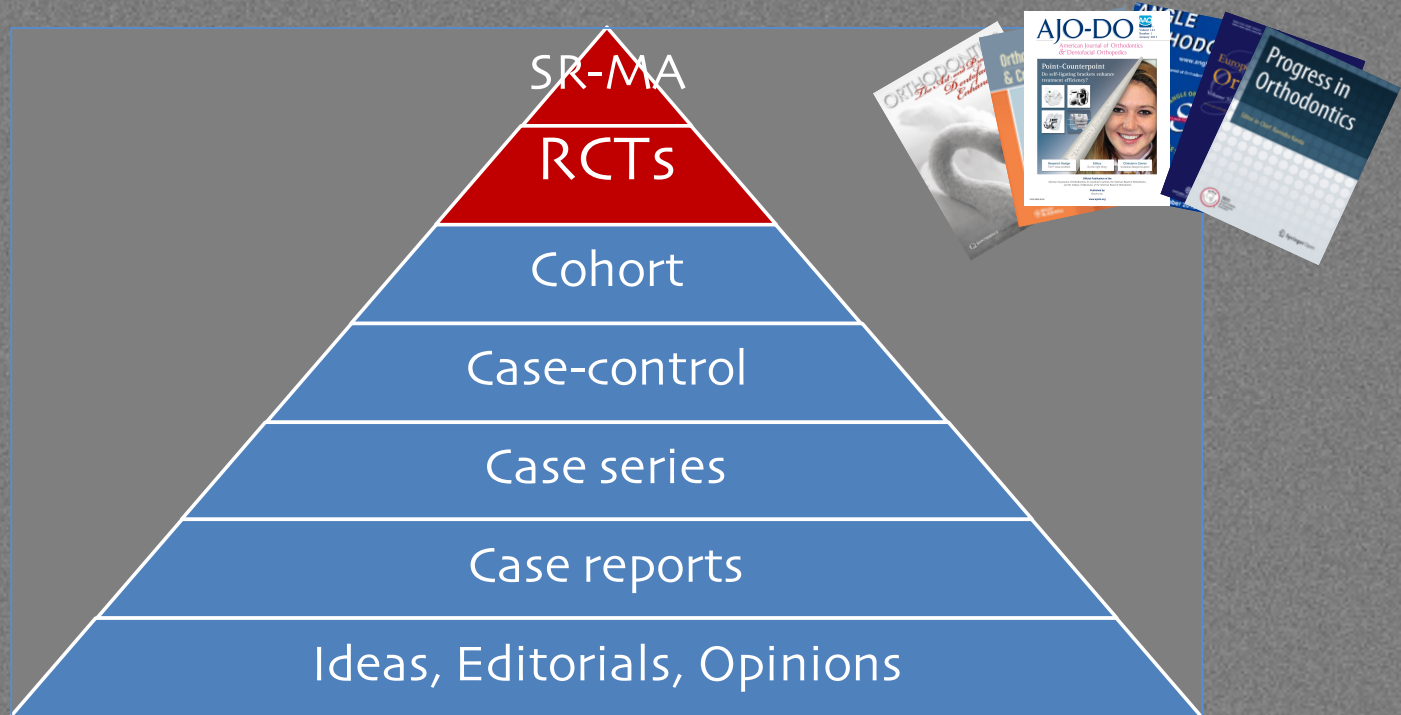
Lingual braces are more difficult to place and adjust. Therefore, your appointments might take longer.

Overall treatment time

There is no definitive evidence on the differences in treatment time based on whether the braces are on the inside or outside surface of the teeth. However, most orthodontists would suggest that treatment with lingual braces may take longer. Your orthodontist will be able to let you have an estimate of the time that your treatment may take.



HOW SHOULD WE MAKE DECISIONS?



• BIAS

• FOUNDATIONS

WHAT ARE WE PRODUCING?



Early treatment for Class II Division 1 malocclusion with the Twin-block appliance: A multi-center, randomized, controlled trial

Kevin O'Brien, Jean Wright, Frances Conboy, Priscilla Appelbe, Linda Davies, Ivan Connolly, Laura Mitchell, Simon Littlewood, Nicola Mandall, David Lewis, Jonathan Sandier, Mark Hammond, Stephen Chadwick, Julian O'Neill, Catherine McDade, Mojtaba Oskoue, Badri Thiruvengkatchari, Michael Read, Stephen Robinson, David Birnie, Alison Murray, Iain Shaw, Nigel Harradine, and Helen Worthington
Manchester, United Kingdom

Outcomes in a 2-phase randomized clinical trial of early Class II treatment

J. F. Camilla Tulloch, BDS, FDS, DOrth,* William R. Proffit, DDS, PhD,* and Ceib Phillips, PhD, MPH*
Chapel Hill, NC

Early class III protraction facemask treatment reduces the need for orthognathic surgery: a multi-centre, two-arm parallel randomized, controlled trial

Nicky Mandall, Richard Cousley, Andrew DiBiase, Fiona Dyer, Simon Littlewood, Rye Mattick, Spencer J. Nute, Barbara Doherty, Nadia Stivaros, Ross McDowall, Inderjit Shargill & Helen V. Worthington

Is early class III protraction facemask treatment effective? A multicentre, randomized, controlled trial: 15-month follow-up

Nicky Mandall, Andrew DiBiase, Simon Littlewood, Spencer Nute, Nadia Stivaros, Ross McDowall, Inderjit Shargill, Helen Worthington, Richard Cousley, Fiona Dyer, Rye Mattick & Barbara Doherty

A randomized clinical trial to compare three methods of orthodontic space closure

V. Dixon, M. J. F. Read, K. D. O'Brien, H. V. Worthington and N. A. Mandall
University Dental Hospital of Manchester, UK

THE GOOD ...



- GROWTH MODIFICATION
- FIXED APPLIANCE MECHANICS
- TREATMENT DECISIONS
- EXPECTATIONS/CONSENT

- EXPECTATIONS/CONSENT

WHAT ARE WE PRODUCING?

The Reporting Quality of Randomized Controlled Trials in Orthodontics

Evangelia Lempesi, DDS, MSc^{a,b}, Despina Koletsi, DDS, MSc^{a,b,*},
Padhraig S. Fleming, BDent Sc. (Hons.), MSc, PhD, FDS (Orth.), FHEA^c, and
Nikolaos Pandis, DDS, MS, dr med dent, MSc, DLSHTM^{d,e}

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:

- LESS THAN 1 RCT PER JOURNAL

- REPORTING

JOURNAL OF EVIDENCE-BASED DENTAL PRACTICE

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.

WHAT ARE WE PRODUCING?

Randomized Controlled Trial

- ☐ Comparative assessment of treatment efficacy and adverse effects during nonextraction orthodontic treatment of Class I malocclusion patients with direct and indirect bonding: A parallel randomized clinical trial

Kübra Yıldırım, Banu Sağlam-Aydinatay

p26-34.e1

Published in issue: July 2018

[Full-Text HTML](#) | [PDF](#)

Systematic Review

- ☐ Scoping review of systematic review abstracts about temporomandibular disorders: Comparison of search years 2004 and 2017

Donald J. Rinchuse, Charles S. Greene

p35-46.e9

Published in issue: July 2018

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Original Articles

- ☐ Accuracy of clear aligners: A retrospective study of patients who needed refinement

Orfeas Charalampakis, Anna Iliadi, Hiroshi Ueno, Donald R. Oliver, Ki Beom Kim

p47-54

Published in issue: July 2018

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- ☐ Retrospective evaluation of treatment time and efficiency of a predictable cantilever system for orthodontic extrusion of impacted maxillary canines

Maciej Iancu Potrubacz, Claudio Chimentì, Laura Marchione, Michele Tepedino

p55-64

Published in issue: July 2018

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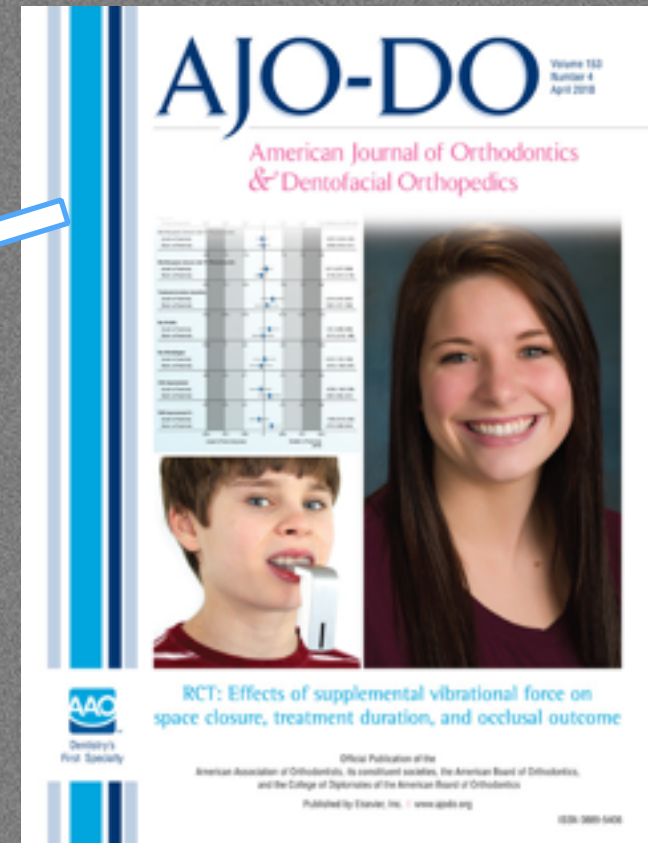
- ☐ Sleep disordered breathing in children seeking orthodontic care

Ashok K. Rohra Jr., Catherine A. Demko, Mark G. Hans, Carol Rosen, Juan Martin Palomo

p65-71

Published in issue: July 2018

[Full-Text HTML](#) | [PDF](#) | [Supplemental Materials](#)



WHAT ARE WE PRODUCING?

- Childhood body mass index is associated with early dental development and eruption in a longitudinal sample from the Iowa Facial Growth Study

Christina L. Nicholas, Kevan Kadavy, Nathan E. Holton, Teresa Marshall, Andrew Richter, Thomas Southard

p72-81

Published in issue: July 2018

[Full-Text HTML](#) | [PDF](#)

- Impact of altered gingival characteristics on smile esthetics: Laypersons' perspectives by Q sort methodology

Panchali Batra, Anika Daing, Imam Azam, Ragini Miglani, Ashu Bhardwaj

p82-90.e2

Published in issue: July 2018

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- Three-dimensional evaluation of craniofacial characteristics related to mandibular asymmetries in skeletal Class I patients

Guilherme Thiesen, Maria Perpétua Mota Freitas, Eustáquio A. Araújo, Bruno Frazão Gribel, Ki Beom Kim

p91-98

Published in issue: July 2018

[Full-Text HTML](#) | [PDF](#)

- Correlation between midline deviation and condylar position in patients with Class II malocclusion: A cone-beam computed tomography evaluation

Gina Della Roque-Torres, Priscila Dias Peyneau, Eliana Dantas da Costa, Frab Noberto Bóscolo, Solange Maria de Almeida, Luciano Wagner Ribeiro

p99-107

Published in issue: July 2018

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- Effects of acid etching and calcium chloride immersion on removal torque and bone-cutting ability of orthodontic mini-implants

Tae-Ho Jang, Jae-Hyun Park, Won Moon, Jong-Moon Chae, Na-Young Chang, Kyung-Hwa Kang

p108-114

Published in issue: July 2018

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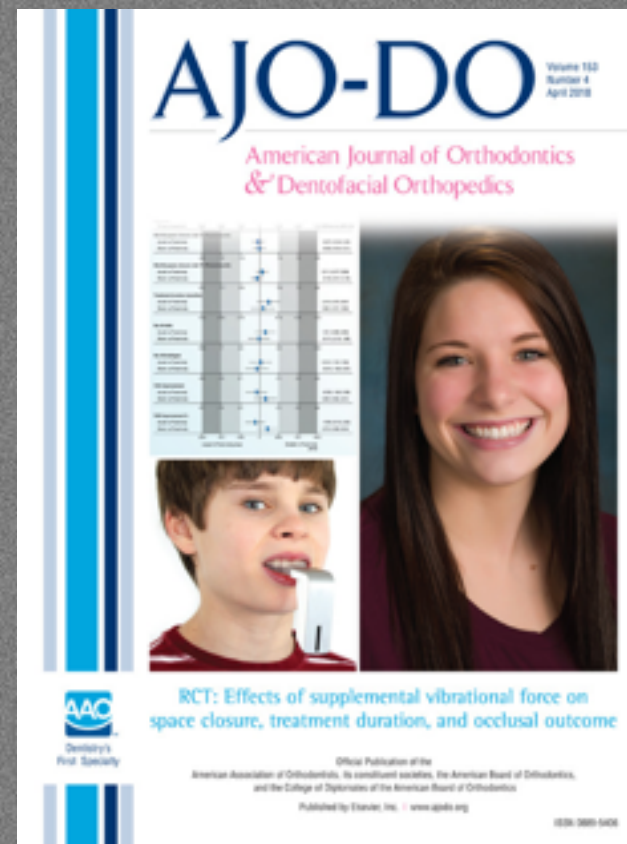
- Effects of lactoferrin on bone resorption of midpalatal suture during rapid expansion in rats

Ye Cheng, Jianfeng Sun, Zeyuan Zhou, Jie Pan, Shujuan Zou, Jianwei Chen

p115-127

Published in issue: July 2018

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WHAT ARE WE PRODUCING?

Case Report

- ☐ **Conventional surgical-orthodontic approach with double-jaw surgery for a patient with a skeletal Class III malocclusion: Stability of results 10 years posttreatment**

Susana Maria Deon Rizzato, Luciane Macedo de Menezes, João Julio da Cunha Filho, Susiane

Allgayer

p128-139

Published in issue: July 2018

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Techno Bytes

- ☐ **Hybrid approach for automatic cephalometric landmark annotation on cone-beam computed tomography volumes**

Jesús Montúfar, Marcelo Romero, Rogelio J. Scougall-Vilchis

p140-150

Published in issue: July 2018

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Continuing Education

- ☐ **July 2018:154(1)**

Allen H. Moffitt

p151.e1-151.e2

Published in issue: July 2018

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In Memoriam

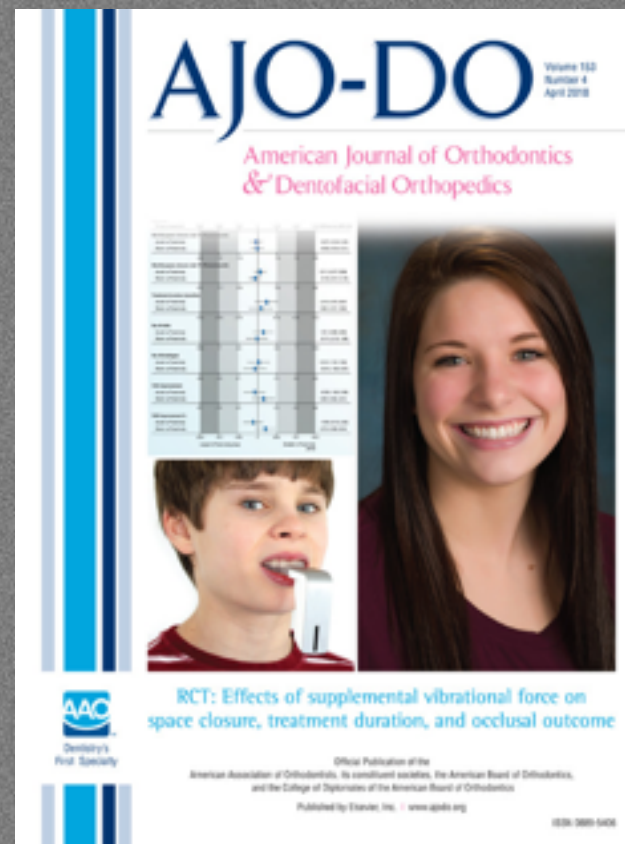
- ☐ **Ellen A. BeGole, 1934-2018**

Hans Wellens

p152-153

Published in issue: July 2018

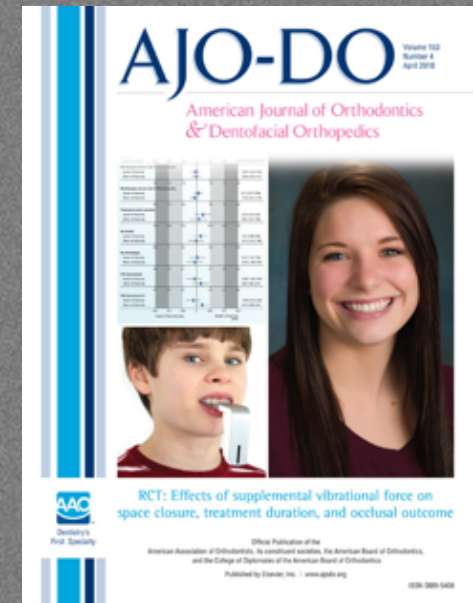
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ADVERTISEMENTS IN ORTHODONTIC JOURNALS



Article(s) Unpublished studies, expert opinion



LIVAS ET AL. (2015. ANGLE ORTHOD.

RESEARCH PRACTICE

Research: increasing value, reducing waste 5

Reducing waste from incomplete or unusable reports of biomedical research

Paul Glasziou, Douglas G Altman, Patrick Bossuyt, Isabelle Boutron, Mike Clarke, Steven Julious, Susan Michie, David Moher, Elizabeth Wager

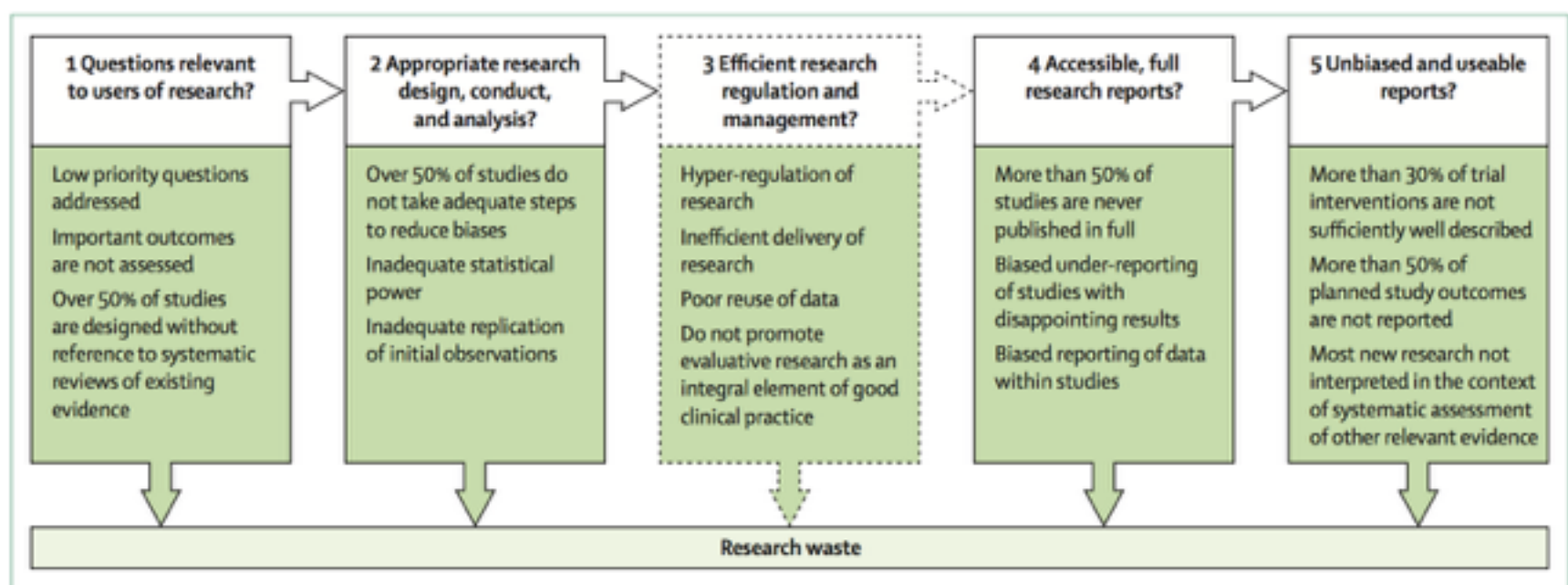
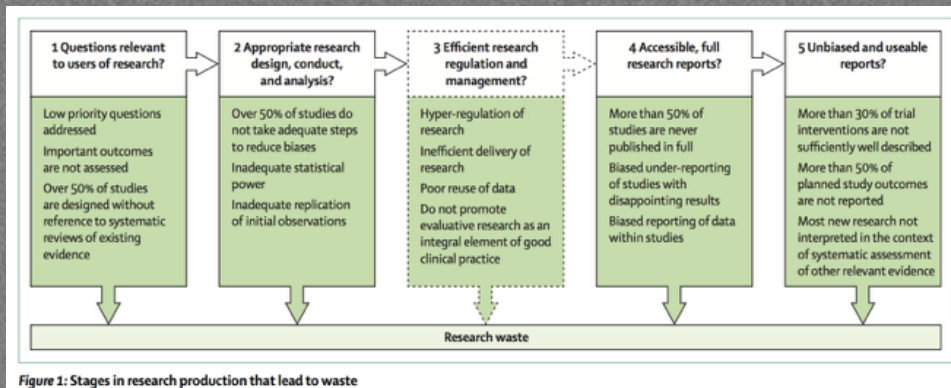


Figure 1: Stages in research production that lead to waste

RESEARCH WASTE



Chalmers and Glasziou¹³ estimated in 2009 that 85% of research funding was being avoidably wasted across the entire biomedical research range (eg, clinical, health services, and basic science). Evidence of the extent and avoidability of waste in research production at each stage of the authors' four stage model has grown, and has



100%

50% UNPUBLISHED

50%

50% POORLY-REPORTED

25%

50% MAJOR DESIGN FLAWS

12.5%

Chalmers and Glasziou¹³ estimated in 2009 that 85% of research funding was being avoidably wasted across the entire biomedical research range (eg, clinical, health services, and basic science). Evidence of the extent and avoidability of waste in research production at each stage of the authors' four stage model has grown, and has



12.5%

- 170 BILLION DOLLARS ANNUAL
- GDP KUWAIT



Chalmers and Glasziou¹³ estimated in 2009 that 85% of research funding was being avoidably wasted across the entire biomedical research range (eg, clinical, health services, and basic science). Evidence of the extent and avoidability of waste in research production at each stage of the authors' four stage model has grown, and has

RESEARCH WASTE: ORTHODONTICS

- QUALITY
- FOCUS/CORRECT QUESTIONS?
- DUPLICATION OF EFFORT
- OUTCOMES OF SPECIFIC STUDIES

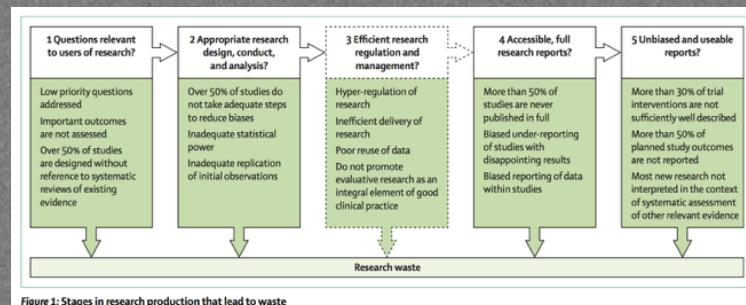


Figure 1: Stages in research production that lead to waste



SYSTEMATIC REVIEWS

- PRECISE ESTIMATES
 - RESOLUTION OF EFFECTIVENESS CONTROVERSIES
-
- RELIANT ON DATA FROM PRIMARY STUDIES
 - META-ANALYSIS A KEY ELEMENT

SYSTEMATIC REVIEWS IN MEDICINE



Journal of Clinical Epidemiology 67 (2014) 754–759

Journal of
Clinical
Epidemiology

Systematic reviews published in higher impact clinical journals were of higher quality

Padhraig S. Fleming^{a,*}, Despina Koletsi^b, Jadbinder Seehra^c, Nikolaos Pandis^d

Objectives: To compare the methodological quality of systematic reviews (SRs) published in high- and low-impact factor (IF) Core Clinical Journals. In addition, we aimed to record the implementation of aspects of reporting, including Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) flow diagram, reasons for study exclusion, and use of recommendations for interventions such as Grading of Recommendations Assessment, Development and Evaluation (GRADE).

Study Design and Setting: We searched PubMed for systematic reviews published in Core Clinical Journals between July 1 and December 31, 2012. We evaluated the methodological quality using the Assessment of Multiple Systematic Reviews (AMSTAR) tool.

Results: Over the 6-month period, 327 interventional systematic reviews were identified with a mean AMSTAR score of 63.3% (standard deviation, 17.1%), when converted to a percentage scale. We identified deficiencies in relation to a number of quality criteria including delineation of excluded studies and assessment of publication bias. We found that SRs published in higher impact journals were undertaken more rigorously with higher percentage AMSTAR scores (per IF unit: $\beta = 0.68\%$; 95% confidence interval: 0.32, 1.04; $P < 0.001$), a discrepancy likely to be particularly relevant when differences in IF are large.

Conclusion: Methodological quality of SRs appears to be better in higher impact journals. The overall quality of SRs published in many Core Clinical Journals remains suboptimal. © 2014 Elsevier Inc. All rights reserved.

SYSTEMATIC REVIEWS IN MEDICINE

THE MILBANK QUARTERLY

A MULTIDISCIPLINARY JOURNAL OF POPULATION HEALTH AND HEALTH POLICY

[Explore this journal >](#)

Original Investigation

The Mass Production of Redundant, Misleading, and Conflicted Systematic Reviews and Meta-analyses

JOHN P.A. IOANNIDIS 

First published: 13 September 2016 [Full publication history](#)

- CORRECT QUESTIONS?
- DUPLICATION OF EFFORT
- FOCUS



SYSTEMATIC REVIEWS IN ORTHODONTICS

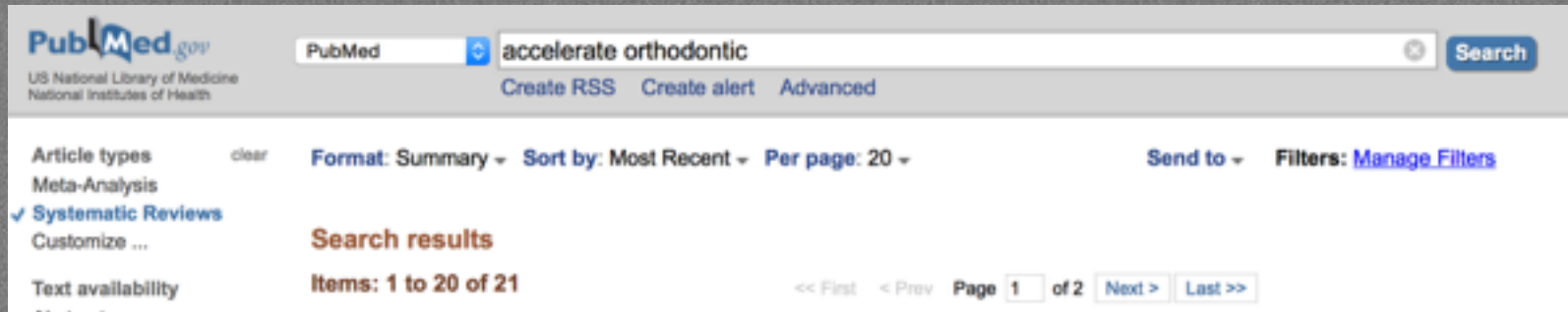
EDITORIAL

Systematic reviews – professional masochism or important process?

- ASKING THE RIGHT QUESTIONS
- 'LOW HANGING FRUIT'



WASTE: SRs AND FADS



- INSUFFICIENT EVIDENCE, FURTHER HIGH-QUALITY RCTs REQUIRED

- PREMATURE, FURTHER PRIMARY RESEARCH BEFORE SYSTEMATIC REVIEW



A black and white photograph of Usain Bolt, a Jamaican sprinter, celebrating a victory. He is wearing a white athletic singlet with a Jordan brand logo on the right chest and a bib that reads "London 2012" and "BOLT". He is holding a white object, possibly a medal or a piece of chalk, in his right hand and has his left arm raised in a celebratory gesture. His face is contorted in a shout or cry of triumph.

**YOU ONLY GET OUT
WHAT YOU PUT IN..**

QUALITY OF THE EVIDENCE: MEDICINE



Journal of Clinical Epidemiology 78 (2016) 34–42

Journal of
Clinical
Epidemiology

High quality of the evidence for medical and other health-related interventions was uncommon in Cochrane systematic reviews

Padhraig S. Fleming^{a,*}, Despina Koletsi^b, John P.A. Ioannidis^{c,d,e,f}, Nikolaos Pantis^{g,h}

Objectives: To appraise the quality of evidence in systematic reviews (SRs) within the Cochrane Database of Systematic Reviews (CDSRs) across diverse topics and to explore the relationship between the strength of evidence using Grades of Recommendation, Assessment, Development, and Evaluation (GRADE) and the probability that authors would interpret that an intervention may be of value.

Study Design and Setting: We evaluated the SRs published on the CDSR from January 1, 2013, to June 30, 2014. Two authors identified relevant SRs by independent searching of the Cochrane register. We further focused on SRs that incorporated tables with GRADE [summary of findings (SoF)]. Data were extracted independently by two authors. The quality of the evidence for the first listed primary outcome in SoF tables in each review and reasons for upgrade or downgrade were recorded.

Results: Overall, 1,394 SRs were identified. Of these, 608 (43.6%) incorporated GRADE. Within these reviews, only 13.5% ($n = 82$) reported a high quality and 30.8% ($n = 187$) a moderate quality of evidence for the first listed primary outcome, whereas 31.7% ($n = 193$) had low level and 24% ($n = 146$) had very low level of evidence. High quality of evidence was more common in updated compared to new reviews and in pharmacologic than other types of interventions. Even when all outcomes listed in the SoFs were considered, only 116/608 (19.1%) of SRs had at least one outcome with high quality of evidence. Overall, only 4.1% (25/608) of SRs incorporating GRADE in SoF tables had high quality of evidence, allied both to significant results and a favorable interpretation of the intervention by the reviewers.

Conclusion: Evidence of high quality is uncommon for medical and health-related interventions assessed with GRADE within the CDSR, and favorable evidence of high quality is even more uncommon. © 2016 Elsevier Inc. All rights reserved.

QUALITY OF THE EVIDENCE: DENTISTRY

	Non-Cochrane	Cochrane	Total
	N (%)	N (%)	N (%)
High	1 (2)	0 (0)	1 (1)
Moderate	10 (20)	9(22)	19 (21)
Low	24 (48)	22(54)	46 (51)
Very low	15 (30)	10 (24)	25 (27)
Total	50 (100)	41 (100)	91 (100)

• 1%: HIGH QUALITY !!!

• PANDIS ET AL. (2015): PLoS ONE

SYSTEMATIC REVIEWS: ORTHODONTICS VS MEDICINE

The evidence from systematic reviews and meta-analyses published in orthodontic literature. Where do we stand?

Despina Koletsi*, Padhraig S. Fleming**, Theodore Eliades*** and Nikolaos Pandis****,*****

*Department of Orthodontics, University of Athens, Greece and Private Practice, Athens, Greece, **Barts and The London School of Medicine and Dentistry, Queen Mary University of London, UK, ***Clinic of Orthodontics and Paediatric Dentistry, University of Zurich, Switzerland, ****Department of Orthodontics and Dentofacial Orthopedics, Dental School/Medical Faculty, University of Bern, Switzerland, *****Private Practice, Corfu, Greece

Correspondence to: Despina Koletsi, Department of Orthodontics, University of Athens, Thivon 2, Goudi, Athens 11527, Greece. E-mail: d.koletsi@gmail.com

Summary

Aim: To analyse meta-analyses included in systematic reviews (SRs) published in leading orthodontic journals and the Cochrane Database of Systematic Reviews (CDSR) focusing on orthodontic literature and to assess the quality of the existing evidence.

Materials and methods: Electronic searching was undertaken to identify SRs published in five major orthodontic journals and the CDSR between January 2000 and June 2014. Quality assessment of the overall body of evidence from meta-analyses was conducted using the Grading of Recommendations Assessment, Development and Evaluation working group (GRADE) tool.

Results: One hundred and fifty-seven SRs were identified; meta-analysis was present in 43 of these (27.4 per cent). The highest proportion of SRs that included a meta-analysis was found in Orthodontics and Craniofacial Research (6/13; 46.1 per cent), followed by the CDSR (12/33; 36.4 per cent) and the American Journal of Orthodontics and Dentofacial Orthopaedics (15/44; 34.1 per cent). Class II treatment was the most commonly addressed topic within SRs in orthodontics ($n = 18/157$; 11.5 per cent). The number of trials combined to produce a summary estimate was small for most meta-analyses with a median of 4 (range: 2–52). Only 21 per cent ($n = 9$) of included meta-analyses were considered to have a high/moderate quality of evidence according to GRADE, while the majority were of low or very low quality ($n = 34$; 79.0 per cent).

Conclusions: Overall, approximately one quarter of orthodontic SRs included quantitative synthesis, with a median of four trials per meta-analysis. The overall quality of evidence from the selected orthodontic SRs was predominantly low to very low indicating the relative lack of high quality of evidence from SRs to inform clinical practice guidelines.

- 27% HAVE M/A VS 63% IN MEDICINE
- 4 STUDIES PER M/A VS 15 IN MEDICINE

RCTs IN ORTHODONTICS: THE GOOD

Early treatment for Class II Division 1 malocclusion with the Twin-block appliance: A multi-center, randomized, controlled trial

Kevin O'Brien, Jean Wright, Frances Conboy, Priscilla Appelbe, Linda Davies, Ivan Connolly, Laura Mitchell, Simon Littlewood, Nicola Mandall, David Lewis, Jonathan Sandler, Mark Hammond, Stephen Chadwick, Julian O'Neill, Catherine McDade, Mojtaba Oskoue, Badri Thiruvengkatchari, Michael Read, Stephen Robinson, David Birnie, Alison Murray, Iain Shaw, Nigel Harradine, and Helen Worthington
Manchester, United Kingdom



Outcomes in a 2-phase randomized clinical trial of early Class II treatment

J. F. Camilla Tulloch, BDS, FDS, DOrth,* William R. Proffit, DDS, PhD,* and Ceib Phillips, PhD, MPE*
Chapel Hill, NC

Is early class III protraction facemask treatment effective? A multicentre, randomized, controlled trial: 15-month follow-up

Nicky Mandall, Andrew DiBiase, Simon Littlewood, Spencer Nute, Nadia Stivaros, Ross McDowall, Inderjit Shargill, Helen Worthington, Richard Cousley, Fiona Dyer, Rye Mattick & Barbara Doherty

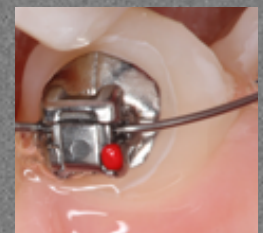
Early class III protraction facemask treatment reduces the need for orthognathic surgery: a multi-centre, two-arm parallel randomized, controlled trial

Nicky Mandall, Richard Cousley, Andrew DiBiase, Fiona Dyer, Simon Littlewood, Rye Mattick, Spencer J. Nute, Barbara Doherty, Nadia Stivaros, Ross McDowall, Inderjit Shargill & Helen V. Worthington

A randomized clinical trial to compare three methods of orthodontic space closure

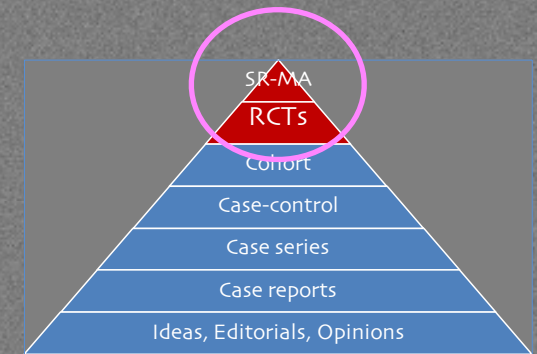
V. Dixon, M. J. F. Read, K. D. O'Brien, H. V. Worthington and N. A. Mandall
University Dental Hospital of Manchester, UK

- GROWTH MODIFICATION
- FIXED APPLIANCE MECHANICS



RESEARCH INFORMING MY PRACTICE?

- UNQUESTIONABLY:
 - SAY
 - DECIDE
 - DO
 - USE





GROWTH MODIFICATION

- FUNCTIONAL APPLIANCE THERAPY:
 - TEMPORARY ACCELERATION
 - NO/NEGLIGIBLE SUSTAINED SKELETAL EFFECT
 - RARELY SUGGEST 2-PHASE TREATMENT
 - EFFECTIVENESS AND EFFICIENCY

• EFFECTIVENESS AND EFFICIENCY

• EFFECTIVENESS AND EFFICIENCY

Early treatment for Class II Division 1 malocclusion with the Twin-block appliance: A multi-center, randomized, controlled trial

Kevin O'Brien, Jean Wright, Frances Conboy, Priscilla Appelbe, Linda Davies, Ivan Connolly, Laura Mitchell, Simon Littlewood, Nicola Mandall, David Lewis, Jonathan Sandler, Mark Hammond, Stephen Chadwick, Julian O'Neill, Catherine McDade, Mojtaba Oskoue, Badri Thiruvengkatachari, Michael Read, Stephen Robinson, David Birnie, Alison Murray, Iain Shaw, Nigel Harradine, and Helen Worthington
Manchester, United Kingdom

Outcomes in a 2-phase randomized clinical trial of early Class II treatment

J. F. Camilla Tulloch, BDS, FDS, DOrth,^a William R. Proffit, DDS, PhD,^a and Ceib Phillips, PhD, MPH^a
Chapel Hill, NC



GROWTH MODIFICATION



- PROTRACTION HEADGEAR:
 - LIMITED SUSTAINED SKELETAL EFFECT
 - INFLUENCED BY VERTICAL DIMENSION

• INFLUENCED BY VERTICAL DIMENSION

Early class III protraction facemask treatment reduces the need for orthognathic surgery: a multi-centre, two-arm parallel randomized, controlled trial

Nicky Mandall, Richard Cousley, Andrew DiBiase, Fiona Dyer, Simon Littlewood, Rye Mattick, Spencer J. Nute, Barbara Doherty, Nadia Stivaros, Ross McDowall, Inderjit Shargill & Helen V. Worthington



Is early class III protraction facemask treatment effective? A multicentre, randomized, controlled trial: 15-month follow-up

Nicky Mandall, Andrew DiBiase, Simon Littlewood, Spencer Nute, Nadia Stivaros, Ross McDowall, Inderjit Shargill, Helen Worthington, Richard Cousley, Fiona Dyer, Rye Mattick & Barbara Doherty



GROWTH MODIFICATION



- PROTRACTION HEADGEAR:
 - OCCLUSAL CORRECTION
 - REDUCED SUBJECTIVE NEED FOR SURGERY

- REDUCED SUBJECTIVE NEED FOR SURGERY

Table 4 Statistically significant effects of PFG compared with the CG at DC2 and those maintained at DC3 (in bold).

	PFG DC2 (degrees)	PFG DC3 (degrees)
SNA	1.1	0.7
SNB	-1.5	-0.7
ANB	2.6	1.4
Maxilla rotation	4.4 down and backwards	4.1 down and backwards
Functional occlusal plane		
Rotation	4.5 up and forwards	2.8 up and forwards
MM angle	1.6	0.4
L/MdP	-3.7	-0.8
Overjet (mm)	4.1	2.5
% weighted PAR (difference between PFG improvement and CG worsening)	40.8	29.4

FIXED APPLIANCES: ARCHWIRES

- ARCHWIRE SELECTION: EQUIVOCAL
- NO IDEAL SEQUENCE
- NiTi NO EVIDENCE OF SUPERIORITY/INFERIORITY

Which orthodontic archwire sequence? A randomized clinical trial

N. A. Mandall*, C. Lowe**, H. V. Worthington*, J. Sandler***, S. Derwent, M. Abdi-Oskoueï* and S. Ward*



Initial arch wires used in orthodontic treatment with fixed appliances

Yan Wang¹, Chang Liu¹, Fan Jian¹, Grant T McInerney¹, Declan T Miller¹, Joy Hickman¹, Wenli Lai¹



FIXED APPLIANCES: MECHANICS



- SPACE CLOSURE: NiTi COILS AND ELASTOMERIC CHAIN SIMILAR AND SUPERIOR TO ALTERNATIVES
- NO EVIDENCE CONCERNING TIMING OF EXTRACTIONS
- LACEBACKS: MOVE TEETH BUT DON'T ALTER ANCHORAGE BALANCE

A randomized clinical trial to compare three methods of orthodontic space closure

V. Dixon, M. J. F. Read, K. D. O'Brien, H. V. Worthington and N. A. Mandall
University Dental Hospital of Manchester, UK

The effectiveness of laceback ligatures:
A randomized controlled clinical trial

R. Irvine and S. Power
Royal Bournemouth Hospital, Bournemouth, UK
F. McDonald
Guy's, King's and St Thomas' Dental Institute, London, UK



FIXED APPLIANCES: BRACKET CHOICE



- BRACKET TYPE
 - MODE OF LIGATION: LITTLE/NO DIFFERENCE
 - CUSTOMISATION: NO DIFFERENCE
 - SLOT SIZE : NO DIFFERENCE

RANDOMIZED CONTROLLED TRIAL

AJO-DO

Comparison of maxillary arch dimensional changes with passive and active self-ligation and conventional brackets in the permanent dentition: A multicenter, randomized controlled trial

Padhraig S. Fleming,^a Robert T. Lee,^b Valeria Marinho,^c and Ama Johal^d

J Dent Res. 2017 Dec;96(13):1498-1504. doi: 10.1177/0022034517720913. Epub 2017 Jul 25.

Orthodontics with Customized versus Noncustomized Appliances: A Randomized Controlled Clinical Trial.

Penning EW¹, Peerlings RHJ², Govers JDM³, Rischen RJ³, Zinad K¹, Bronkhorst EM⁴, Breuning KH⁵, Kuliers-Jaatsman AM¹.

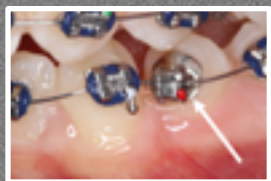
A randomized clinical trial of the effectiveness of 0.018-inch and 0.022-inch slot orthodontic bracket systems: part 1—duration of treatment

Yassir A Yassir^a, Ahmed M El-Angbawi^a, Grant T McIntyre^a, Gavin F Revie^a,

Self-Ligating Brackets in Orthodontics

A Systematic Review

Padhraig S. Fleming^a; Ama Johal^b



FIXED APPLIANCES: BRACKET CHOICE



- BRACKET TYPE
 - PRESCRIPTION
 - NO DIFFERENCE: LOCALLY???

Roth versus MBT: does bracket prescription have an effect on the subjective outcome of pre-adjusted edgewise treatment?

Bopelo Moesi*, Fiona Dyer and Philip E. Benson***

FIXED APPLIANCES: BRACKET CHOICE



- BRACKET TYPE
 - PRESCRIPTION
 - NO DIFFERENCE: LOCALLY???

FIXED APPLIANCES: BRACKET CHOICE



- Inverted MBT on right central ($+6^\circ$)
- MBT on left central (-6°)
- Roth on both laterals



FIXED APPLIANCES: AUXILIARIES

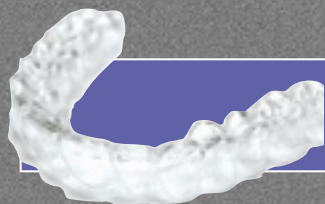


- TRANS-PALATAL ARCH: MINIMAL BENEFIT
- NANCE PALATAL ARCH: USEFUL BUT LABOURED
- MINI-IMPLANTS AND LOCAL VARIATIONS

Effectiveness of 3 methods of anchorage reinforcement for maximum anchorage in adolescents: A 3-arm multicenter randomized clinical trial

Jonathan Sandler,^a Alison Murray,^b Badri Thiruvengadachari,^c Rodrigo Gutierrez,^d Paul Speight,^e and Kevin O'Brien^f





ORTHODONTIC RETENTION



- FIXED VS REMOVABLE
- LONGER-TERM IMPACT
- PATIENT-BASED OUTCOMES

• PATIENT-BASED OUTCOMES

RANDOMIZED CONTROLLED TRIAL



AJO-DO

Effectiveness of bonded and vacuum-formed retainers: A prospective randomized controlled clinical trial

Niamh O'Rourke,^a Hussein Albeedh,^a Pratik Sharma,^a and Ama Johal^b
London, United Kingdom

RANDOMIZED CONTROLLED TRIAL



AJO-DO

Effects of fixed vs removable orthodontic retainers on stability and periodontal health: 4-year follow-up of a randomized controlled trial

Dalia Al-Moghrabi,^a Ama Johal,^b Niamh O'Rourke,^c Nikolaos Denos,^d Nikolaos Pandis,^e Cecilia Gonzales-Marin,^f and Padhraig S. Fleming^g
London, United Kingdom, Riyadh, Saudi Arabia, Bern, Switzerland, and Corfu, Greece



OTHER AUXILIARIES



- VIBRATIONAL STIMULI: NO
- SURGICAL ACCELERATION: ESSENTIALLY NO

Surgical adjunctive procedures for accelerating orthodontic treatment (Review)

Fleming PS, Fedorowicz Z, Johal A, El-Anbawi A, Pandis N

Research Report: Clinical

Supplemental Vibrational Force During Orthodontic Alignment: A Randomized Trial

N.R. Woodhouse^{1,2}, A.T. DiBiase¹, N. Johnson³, C. Slipper³, J. Grant³,
M. Alsalhi¹, A.N.A. Donaldson¹, and M.T. Colbourne¹

Journal of Dental Research
2015, Vol. 94(2), 480-488
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New posts

AcceleDent advertising is judged to breach a UK advertising code

👤 Kevin O'Brien 📅 July 5, 2018 📁 Recent posts 💬 4 Comments

You may remember that sometime ago I posted about Damon advertising the the UK advertising code. It now appears that AcceleDent have done the same. I have done an extra post for this week. (Visited 1,595 times, 203 visits today)

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RCTs IN ORTHODONTICS: OUR FOCUS

- There is insufficient evidence to support the use of self-ligating fixed orthodontic appliances over conventional appliance systems or vice versa.
- SLBs do not confer particular advantage with regard to subjective pain experience.
- There is insufficient evidence suggesting that orthodontic treatment is more or less efficient with SLBs.



CONCLUSIONS

The self-ligating bracket systems used in this trial neither improved the efficiency of fixed appliance orthodontic treatment nor resulted in fewer treatment

technology. To date published prospective trials into these systems have considered alignment efficiency during the initial stages of treatment; torque expression in the upper labial segment; pain experience; and the efficiency of appliance manipulation. By and large the clinical promise of these systems has not been reflected in the outcomes of these controlled clinical trials.

SLBs: MASS PRODUCTION OF RCTs



tion of the mandibular incisors. Although wide individual variation was seen in mandibular incisor proclination in both samples, the overall arch-length reduction might also reflect forward movement of the first molars.

SCOTT 2008

Conclusion – The anticipated translation and buccal bone modeling using active or passive SLBs could not be confirmed. Because of the large interindividual variation, a patient-specific analysis seems to be mandatory as individual factors like pre-treatment teeth inclination and occlusion influenced the treatment of patients.

CATTANEO 2011

thus, the stability of the therapy was not investigated. Buccal expansion in the mandibular arch is highly unpredictable and can be influenced by various factors, including anatomy of the underlying structures, inclination of the molars, and architecture of the oral musculature.¹⁰ On the other hand, the tentative argument that stainless steel wires with larger cross section

PANDIS 2011

It is not surprising that bracket type does not have a significant influence on treatment efficiency. Treatment efficiency is the product of many mechanical and biologic factors. It is unlikely that any 1 factor is responsible for the rate of tooth movement. The biology of tooth movement is a complex and highly coordinated process at the cellular, molecular, and genetic levels. Individual variation undoubtedly has a fundamental underlying role in tooth movement and treatment efficiency.

WONG 2010

Conclusions

WONG 2013

- No differences were found in the amount of space closure between three different bracket/archwire combinations.
- The largest factor in determining the rate of tooth movement is probably the individual patient response to any applied force.

Both active and passive closure methods using upper canine retraction have proven effective. No statistical differences were found between their rates of movement (Table 2). Significant individual variation was found in the rates of tooth movement, with some individuals reaching twice as much displacement as

MEZOMO 2011

SOCIAL MEDIA-BASED PLANNING

One of the most predictable things in life is there will be change. You are better off if you can have a say in the change. But you are ignorant or naïf

FAKE NEWS

- Bias?



RESEARCH FOCUS

RESEARCH

Open Access



Clinical evaluation of marketed orthodontic products: are researchers behind the times? A meta-epidemiological study

Jadbindar Seehra^{1*}, Nikolaos Pandis² and Padhraig S. Fleming³

Abstract

Background: The role of marketing and industry in the treatment decisions of orthodontists has received increasing attention in recent years with clinical research typically undertaken subsequent to established use of these devices and often failing to confirm the promise of manufacturers' claims. This meta-epidemiological study was undertaken to assess the proportion of clinical trials in orthodontics evaluating commercially marketed products and to evaluate the direction of the results of these studies.

Methods: Electronic searching was undertaken to identify randomized controlled trials (RCTs) published over a 5-year period (1 January 2012 to 31 December 2016). Data obtained included the type of marketed intervention, direction of effect and declaration of both industry sponsorship and conflict of interest.

Results: Eighty-four RCTs published in 23 scientific journals were included with the highest percentage in the *American Journal of Dentofacial Orthopedics* (AJO-DO) (23.8%), followed by the *European Journal of Orthodontics* (EJO) (14.3%), *Journal of Orthodontics* (JO) (10.7%) and *Angle Orthodontist* (AO) (10.7%). Overall, 45% (38/84) of clinical trials assessed involved analysis of marketed products after their introduction. Interventions to improve oral health or circumvent the risk of iatrogenic damage, such as white spot lesions, were most commonly assessed (15.8%), with the relative merits of non-surgical adjuncts (14.1%) and other orthodontic auxiliaries (13.1%) also frequently evaluated. In 44% of RCTs, a positive effect of the marketed intervention was not reported. Industry sponsorship of the research was declared in 9.5% RCTs. No significant associations between the direction of the effect and both declaration of industry sponsorship ($p = 0.56$) and conflict of interest ($p = 0.96$) were detected. Moreover, for marketed and non-marketed products, no significant associations for both declaration of industry sponsorship ($p = 0.44$) and conflict of interest ($p = 0.28$) were found.

Conclusions: Almost half of orthodontic clinical trials over the past 5 years involve analysis of marketed products after their introduction. The results highlight a potential source of waste in orthodontic research emanating from existing approaches to licensing and marketing of orthodontic products.

RESEARCH GAPS: FUNDAMENTAL QUESTIONS

Always keep your
eye on the ball



Unless that ball
is the sun.



RESEARCH

Open Access

Clinical evaluation of marketed orthodontic products: are researchers behind the times? A meta-epidemiological study

Jadbindar Seehra^{1*}, Nikolaos Pandis² and Padhraig S. Fleming³



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More than straight teeth[™]



RESEARCH GAPS: FUNDAMENTAL QUESTIONS

- EXTRACTION VS NON-EXTRACTION
- DURATION OF GROWTH MODIFICATION
- APPOINTMENT INTERVALS: FIXED APPLIANCES
- PRACTICE-BASED RESEARCH



RESEARCH

Open Access



Collaboration in orthodontic clinical trials: prevalence and association with sample size and funding

D. Al-Moghrabi^{1,2}, A. Tsihlaki¹, N. Pandis^{3,4} and P. S. Fleming^{1*}



Abstract

Background: To assess patterns of research collaboration in orthodontics and possible relationships with sample size and funding status.

Methods: Orthodontic randomised and non-randomised controlled clinical trials published between 2013 and 2017 were identified through electronic searching. The nature of collaboration, author institutions, study setting, sample size, and funding status were assessed. Linear and logistic regression analyses were applied.

Results: Of 1153 studies, 217 met the selection criteria. The majority of studies were authored by university academics (86%), were conducted in a single centre (71.9%) and in at least one university hospital (68.2%). The number of practice-based trials (10.1%), as well as the involvement of specialist practitioners (5.2%) in co-authorship, was limited. Multi-centred studies within a single country were associated with a significantly larger sample size compared to single-centred trials ($P = 0.00$; 95% confidence interval [CI] 33.59, 106.93). However, authorship collaboration either nationally (odds ratio [OR] 2.37; 95% CI 0.85, 6.57) or internationally across different continents (OR 5.54; 95% CI 0.62, 49.52) did not translate into increased funding.

Conclusions: Most orthodontic studies were undertaken in university hospital settings within a single country. Collaboration is common in orthodontics but involvement of practice settings remains limited, suggesting a need for stimulation of practice-based research and research partnerships.



• NIKOLAOS PANDIS

RCTs IN ORTHODONTICS

RCTs IN ORTHODONTICS: PROBLEMS

Design

Execution

Publication

- DESIGN
- CONDUCT
- REPORTING

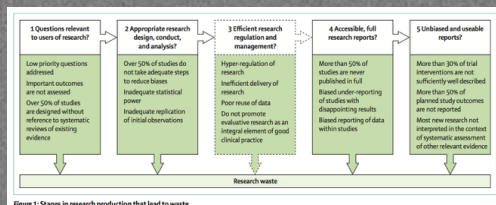


Figure 1: Stages in research production that lead to waste



RCTs IN ORTHODONTICS: DESIGN

Sample size in orthodontic randomized controlled trials: are numbers justified?

Despina Koletsi*, Nikolaos Pandis** and Padhraig S. Fleming***

*Department of Orthodontics, School of Dentistry, University of Athens, Greece, **Department of Orthodontics and Dentofacial Orthopedics, Dental School/Medical Faculty, University of Bern, Switzerland, and ***Barts and The London School of Medicine and Dentistry, Institute of Dentistry, Queen Mary University of London, UK.

SUMMARY Sample size calculations are advocated by the Consolidated Standards of Reporting Trials (CONSORT) group to justify sample sizes in randomized controlled trials (RCTs). This study aimed to analyse the reporting of sample size calculations in trials published as RCTs in orthodontic speciality journals. The performance of sample size calculations was assessed and calculations verified where possible. Related aspects, including number of authors; parallel, split-mouth, or other design; single- or multi-centre study; region of publication; type of data analysis (intention-to-treat or per-protocol basis); and number of participants recruited and lost to follow-up, were considered. Of 139 RCTs identified, complete sample size calculations were reported in 41 studies (29.5 per cent). Parallel designs were typically adopted ($n = 113$; 81 per cent), with 80 per cent ($n = 111$) involving two arms and 16 per cent having three arms. Data analysis was conducted on an intention-to-treat (ITT) basis in a small minority of studies ($n = 18$; 13 per cent). According to the calculations presented, overall, a median of 46 participants were required to demonstrate sufficient power to highlight meaningful differences (typically at a power of 80 per cent). The median number of participants recruited was 60, with a median of 4 participants being lost to follow-up. Our finding indicates good agreement between projected numbers required and those verified (median discrepancy: 5.3 per cent), although only a minority of trials (29.5 per cent) could be examined. Although sample size calculations are often reported in trials published as RCTs in orthodontic speciality journals, presentation is suboptimal and in need of significant improvement.

RCTs: CONDUCT AND REPORTING

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American Journal of Orthodontics and Dentofacial Orthopedics

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The American Journal of Orthodontics & Dentofacial Orthopedics is the number 8 journal in **Dentistry, Oral Surgery & Medicine** according to total citations received. Of 89 journals in the dental literature, the AJO-DO ranks 14th for the number of current articles published. This is a testament to the Journal's significant relevance in the field.

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[Systematic Review and Meta-analysis Guidelines](#)

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RCTs: CONDUCT AND REPORTING



CENTENNIAL SPECIAL ARTICLE

100 Years AJO-DO

The CONSORT Statement: Application within and adaptations for orthodontic trials

Nikolaos Pandis,^a Padhraig S. Fleming,^b Sally Hopewell,^c and Douglas G. Altman^d
Bern, Switzerland, Corfu, Greece, London and Oxford, United Kingdom, and Paris, France

High-quality randomized controlled trials (RCTs) are an integral part of evidence-based medicine. RCTs are the bricks and mortar of high-quality systematic reviews, which are important determinants of health care policy and clinical practice. For published research to be used most effectively, investigators and authors should follow the guidelines for accurate and transparent reporting of RCTs. The consolidated standards of reporting trials (CONSORT) statement and its extensions are among the most widely used reporting guidelines in biomedical research. CONSORT was adopted by the *American Journal of Orthodontics and Dentofacial Orthopedics* in 2004. Since 2011, this *Journal* has been actively implementing compliance with the CONSORT reporting guidelines. The objective of this explanatory article is to highlight the relevance and implications of the various CONSORT items to help authors to achieve CONSORT compliance in their research submissions of RCTs to this and other orthodontic journals. (*Am J Orthod Dentofacial Orthop* 2015;147:663-79)

RCTs/SRs: SUBHEADINGS

SYSTEMATIC REVIEW

AJO-DO

Self-etch primers and conventional acid-etch technique for orthodontic bonding: A systematic review and meta-analysis

Padhraig S. Fleming,^a Ama Johal,^b and Nikolaos Pandis^a
London, United Kingdom, Cusfy, Greece, and Bern, Switzerland

Introduction: The use of self-etch primers has increased steadily because of their time savings and greater simplicity; however, overall benefits and potential disadvantages and harms have not been assessed systematically. In this study, we reviewed randomized controlled trials to assess the risk of attachment failure, bonding time, and demineralization adjacent to attachments between 1-stage (self-etch) and 2-stage (acid etch) bonding in orthodontic patients over a minimum follow-up period of 12 months. **Methods:** Data sources were electronic databases including MEDLINE, EMBASE, the Cochrane Oral Health Group's Trials Register, and CENTRAL, without language restrictions. Unpublished literature was searched on ClinicalTrials.gov, the National Research Register, and Pro-Quest Dissertation Abstracts and Thesis database. Authors were contacted when necessary, and reference lists of the included studies were screened. Search terms included randomized controlled trial, controlled clinical trial, random allocation, double-blind method, single-blind method, orthodontics, self-etch, SEP, primer, and bonding agent. Randomized clinical trials directly comparing self-etch and acid-etch primers with respect to the predefined outcomes and including patients with full-arch, fixed, and bonded orthodontic appliances (not banded) with follow-up periods of at least 12 months were included. Using predefined forms, 2 authors undertook independent data extraction with conflict resolution by the third author. Randomized clinical trial quality assessment based on the Cochrane Risk of Bias tool was also used. **Results:** Eleven studies met the inclusion criteria; 6 were excluded because of a high risk of bias. In total, 1721 brackets bonded with acid-etch and 1723 with self-etch primer techniques were included in the quantitative synthesis. Relatively low statistical and clinical heterogeneity was observed among the 5 randomized clinical trials ($n = 3444$ brackets) comparing acid-etch with self-etch primers. A random effects meta-analysis demonstrated a tendency for a higher risk of failure (odds ratio, 1.36; 95% CI, 0.99-1.83; $P = 0.06$) with self-etch primers. A small but statistically significant time saving was also associated with the self-etch primer technique (weighted mean difference, 23.2 seconds per bracket; 95% CI, 20.7-25.8; $P < 0.001$). There was insufficient evidence to assess the effect of bonding modality on demineralization rates. **Conclusions:** There is weak evidence indicating higher odds of failure with self-etch primer than acid-etch over 12 months in orthodontic patients, and there is strong evidence that a self-etch primer is likely to result in a modest time savings (8 minutes for full bonding) compared with acid etch. **Funding:** No funding was received for this review. (Am J Orthod Dentofacial Orthop 2012;■: 83-95)

group dissolves and removes calcium ions from hydroxyapatite, becoming incorporated in the network before the primer polymerizes, neutralizing the acid.

The proposed advantages of SEPs include reduced chair-side time, although this is tempered by the requirement for judicious priming before bonding procedures to minimize the risk of failure²; reduced sensitivity to moisture; and reduced inventory requirements. However, although the performance of SEPs has been compared with conventional acid-etch (AE) techniques in randomized controlled trials, a comparison of these techniques in the context of a systematic review has not been undertaken.

OBJECTIVES

The aims of this study were therefore to compare 1-step and 2-step bonding procedures with respect to attachment failure rates and time taken to place attachments.

MATERIAL AND METHODS

Protocol and registration

The protocol for a systematic review of SEPs was registered on the National Institute of Health Research Database (www.crd.york.ac.uk/PROSPERO, Protocol: CRD42011001601).

Eligibility criteria

The following selection criteria were applied for the review.

1. Study design: randomized and controlled clinical trials, with split-mouth designs included.
2. Participants: patients with full-arch, fixed, and bonded orthodontic appliances.
3. Interventions: SEPs were used to prepare tooth surfaces before bonding the orthodontic attachments in the intervention sample. The control group's appliances were bonded with the conventional, 2-step AE technique.
4. Exclusion criteria: studies using banded attachments and those involving follow-up periods of less than 12 months were omitted from the review.
5. Outcome measures: the main outcome measure was first-time bond failure with both bonding systems. Secondary outcome measures included time required to place individual brackets and decalcification. The attachment failures with each enamel preparation technique were recorded. When available, the time taken for failures to occur was also recorded. The time taken to place attachments with each technique and the presence of demineraliza-

tion adjacent to the bonded attachments were noted, in addition to the severity of each lesion.

Information sources, search strategy, and study selection

The following electronic databases were searched: MEDLINE (1966 to July 2011; Appendix), EMBASE (1980 to July 2011), Cochrane Oral Health Group's Trials Register (March 2011), Cochrane Central Register of Controlled Trials (CENTRAL, The Cochrane Library Issue 2, 2011). Language restrictions were not applied. Unpublished literature was searched electronically by using ClinicalTrials.gov (www.clinicaltrials.gov) and the National Research Register (www.controlled-trials.com) with the term "orthodontic" and "bond." In addition, the Pro-Quest Dissertation Abstracts and Thesis database was searched (www.lib.umi.com/dissertations) by using "orthodontic" and "bond." Conference proceedings and abstracts were also accessed when possible. Authors were contacted to identify unpublished or ongoing clinical trials and to clarify data as required. Reference lists of the included studies were screened for relevant research.

Assessment of research for inclusion in the review, assessment of risk of bias, and extraction of data were performed independently and in duplicate by 2 investigators (P.S.F. and A.J.) who were not blinded to the authors or the results of the research. Disagreements were resolved by discussion and consultation with the third author (N.P.).

Data items and collection

A data extraction form was developed to record study design, observation period, participants, interventions, outcomes, and outcome data of interest, including risk of failure of attachments, time taken to place attachments, and severity of demineralization when applicable.

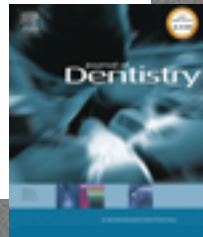
Risk of bias/quality assessment in individual studies

Seven criteria were analyzed to grade the risk of bias inherent in each study, including random sequence generation, allocation concealment, blinding of participants and personnel, blinding of assessors, incomplete outcome data, selective reporting of outcomes, and other potential sources of bias. An overall assessment of risk of bias (high, unclear, low) was made for each included trial by using the Cochrane Collaboration risk of bias tool. Studies with at least 1 criterion designated to be at high risk of bias were regarded as having a high risk of bias overall and excluded from the meta-analysis.

RCTs IN ORTHODONTICS: REPORTING

The use of tailored subheadings was successful in enhancing compliance with CONSORT in a dental journal

Despina Koletsi^{a,*}, Padhraig S. Fleming^{b,c}, Rolf G. Behrents^c, Christopher D. Lynch^d, Nikolaos Pandis^{c,e}



Objectives: Efforts to enhance the reporting of clinical trials have intensified in recent years with automated strategies and editorial involvement showing promise in improving compliance with accepted guidelines. This study aimed to evaluate the effectiveness of a concerted approach to adherence to CONSORT (CONsolidated Standards Of Reporting Trials) guidelines in a dental journal.

Materials and methods: Following the publication of an exemplar clinical trial on the American Journal of Orthodontics and Dentofacial Orthopedics (AJO-DO) website and related changes to the author guidelines, trial submissions were required to follow a standard format incorporating subheadings mirroring the CONSORT guidelines. Compliance with CONSORT was assessed in initial submissions over a 30-month period. Reporting was compared to submissions of randomized controlled trials (RCTs) which did not include subheadings over the same period.

Results: Seventy-one RCTs were submitted to the AJO-DO from January 2014 to June 2016, 49 with subheadings and 22 without. Most CONSORT items (e.g. random sequence generation, allocation concealment and blinding) were more frequently adequately reported when RCTs were submitted with inclusion of subheadings. Overall, reporting quality of the submitted RCTs was 15.2% higher with use of the subheadings format (95%CI: 10.5, 20.0; $p < 0.001$) with a mean overall score of 87.3%.

Conclusion: Enhanced compliance of submitted RCTs was found with use of a bespoke approach to trial presentation utilizing CONSORT item subheadings. The improvement in initial submissions is particularly encouraging as this arose without input either from peer reviewers or journal editors. This simple approach may have wider applicability.

RCTs IN ORTHODONTICS: REPORTING

Design

Execution

Publication



CONSORT guidelines AJODO:
Dramatic improvement in
reporting quality of published **RCTs**

CLINICIAN- OR PATIENT- CENTRED?



Results: Overall 220 RCTs involving 409 outcomes (257 primary and 152 secondary) were identified. Measures of disease activity were most commonly assessed as both primary (n = 91, 35%) and secondary outcomes (n = 59, 39%). Quality of life and functional measures were rarely considered as primary outcome domains. Overall, 182 (44%) outcomes were primarily clinician-focused, 140 (34%) were patient-centered, while 22% (n = 87) were both patient- and clinician- focused.

Conclusions: There is an undue emphasis on technical, clinician-centered outcomes within dental research common to all specialty areas. Development and adoption of core outcome sets representing the minimum set of data that should be obtained within a dental clinical trial would assist in addressing this issue.

Orthodontic trial outcomes: Plentiful, inconsistent, and in need of uniformity?

A scoping review

Aliki Tsiachlari,^a Kevin O'Brien,^b Ama Johal,^a and Padhraig S. Fleming^a

London and Manchester, United Kingdom

Introduction: The selection of appropriate outcomes that matter to both patients and operators is increasingly appreciated, with core outcome sets in clinical trials gaining in popularity. The first step in core outcome set development is the generation of a list of possible important outcomes based on a scoping literature review. Moreover, outcome heterogeneity is known to detract from the findings of systematic reviews and meta-analyses. The aim of this study was to identify the range of outcome domains and specific outcome measures in contemporary orthodontic research. **Methods:** Multiple electronic databases were searched from December 31, 2012, to December 31, 2016, to identify clinical trials of orthodontic interventions, with no language restrictions. Abstracts, eligible full texts, and reference lists were screened, and all reported primary and nonprimary outcomes and methods of measurement were recorded. **Results:** The search identified 1267 abstracts, of which 189 full-text articles were retrieved, and 164 studies were included in the analysis. A total of 54 outcomes were identified and categorized into 14 outcome domains. The most frequently measured outcomes were patient-reported pain, periodontal health, tooth angulation/inclination changes, and treatment duration, followed by rate of tooth movement and skeletal changes. Outcomes that followed the overall course of treatment were assessed in only 14 studies. **Conclusions:** Patient perspectives are increasingly being accounted for in orthodontic trials; however, there is little consistency in outcome selection among them. The identified list of outcomes will be used to inform a ranking exercise with service users and providers to establish an agreed core outcome set for future orthodontic clinical trials. (Am J Orthod Dentofacial Orthop 2018;153:797-807)

RELEVANT OUTCOMES

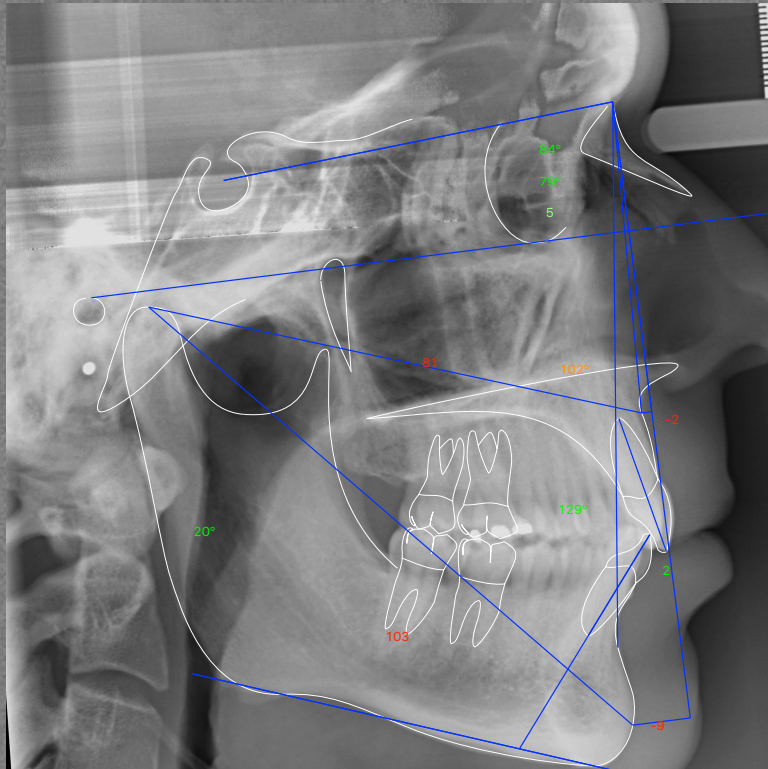


Table II. Comparison of morphologic characteristics of the patients treated with mini-implants (G1) and without (G2) at T1

	G1 (n = 18)		G2 (n = 18)		P value	Significance
	Mean	SD	Mean	SD		
Skeletal measurements						
SNA (°)	82.67	2.57	80.45	3.6	0.3243	NS
SNB (°)	78	3.82	76.67	2.22	0.3512	NS
ANB (°)	4.67	2.38	4.67	1.68	1	NS
Go-Gn-SN (°)	30.78	6.92	31.28	7.09	0.8318	NS
UFH (N-ANS) (mm)	48.94	2.5	51.56	1.89	0.0013	*
LFH (ANS-Me) (mm)	67.44	4	64.78	4.17	0.0585	NS
UFH/LFH (%) (mm)	72.94	6.38	80.1	7.03	0.003	*
PFH (S-Go) (mm)	75.44	7.01	75.94	4.68	0.8031	NS
TAFH (N-Me) (mm)	116.11	4.1	116.44	3.63	0.7979	NS
PFH/TAFH (%)	65.47	5.04	65.23	5.38	0.8939	NS
Pog-Sv (mm)	64	8.03	59	5.71	0.0393	*
Dental measurements						
U1-SN (°)	113	7.19	115.83	4.16	0.1595	NS
IMPA (°)	98.56	6.81	104.72	9.52	0.0327	*
U1-L1 (°)	112.67	9.13	103.22	7.26	0.0016	*
U6-PP (mm)	21.78	1.06	21.44	1.89	0.5189	NS
U6-Sv (mm)	50.56	5.88	44.44	4.42	0.0013	*
L6-MP (mm)	32	2.66	31	3.46	0.3385	NS
L6-Sv (mm)	50.78	6.94	44.78	5.08	0.0059	*
U1-Sv (mm)	80.22	6.86	76.44	3.73	0.0501	NS
L1-Sv (mm)	75.44	6.91	71.44	4.68	0.051	NS
Soft-tissue measurements						
G-Sn-Pg (°)	18.67	6.53	19.33	3.94	0.7134	NS
Nasolabial angle (°)	92.11	10.69	103.44	16	0.0182	*
Labiomental angle (°)	114.33	19.31	109.78	21.31	0.5062	NS
Sv-Ni (mm)	98.67	6.63	97.11	2.93	0.372	NS
E-line-Ls (mm)	1.39	1.84	-0.11	1.57	0.0129	*
E-line-Li (mm)	5.83	2.47	4	1.46	0.0114	*
E-line-Ss (mm)	-9.39	0.76	-9.38	1.45	0.973	NS
E-line-Si (mm)	-3	2.54	-3.44	1.2	0.5197	NS

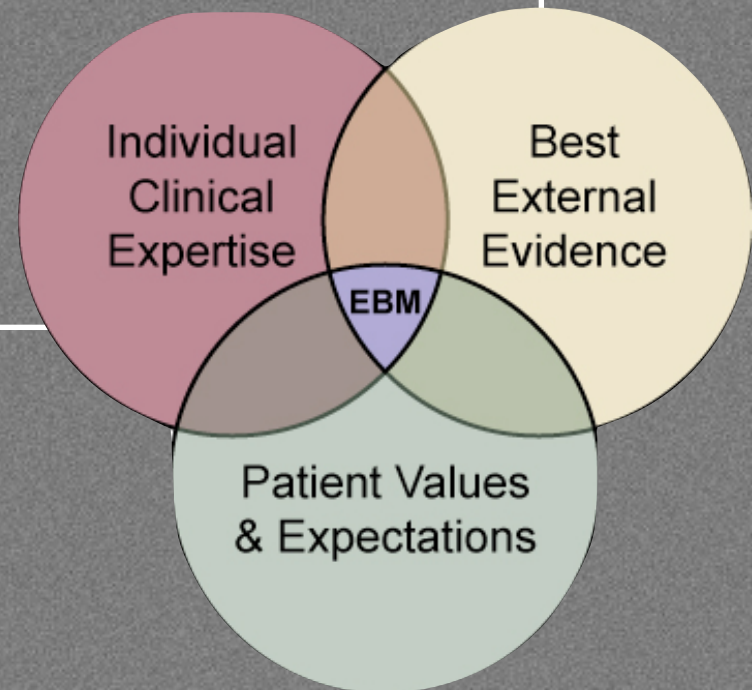
NS, Not significant; * $P < 0.05$; † $P < 0.01$.

• UPADHYAY ET AL. (2008): 27 CEPHALOMETRIC OUTCOMES

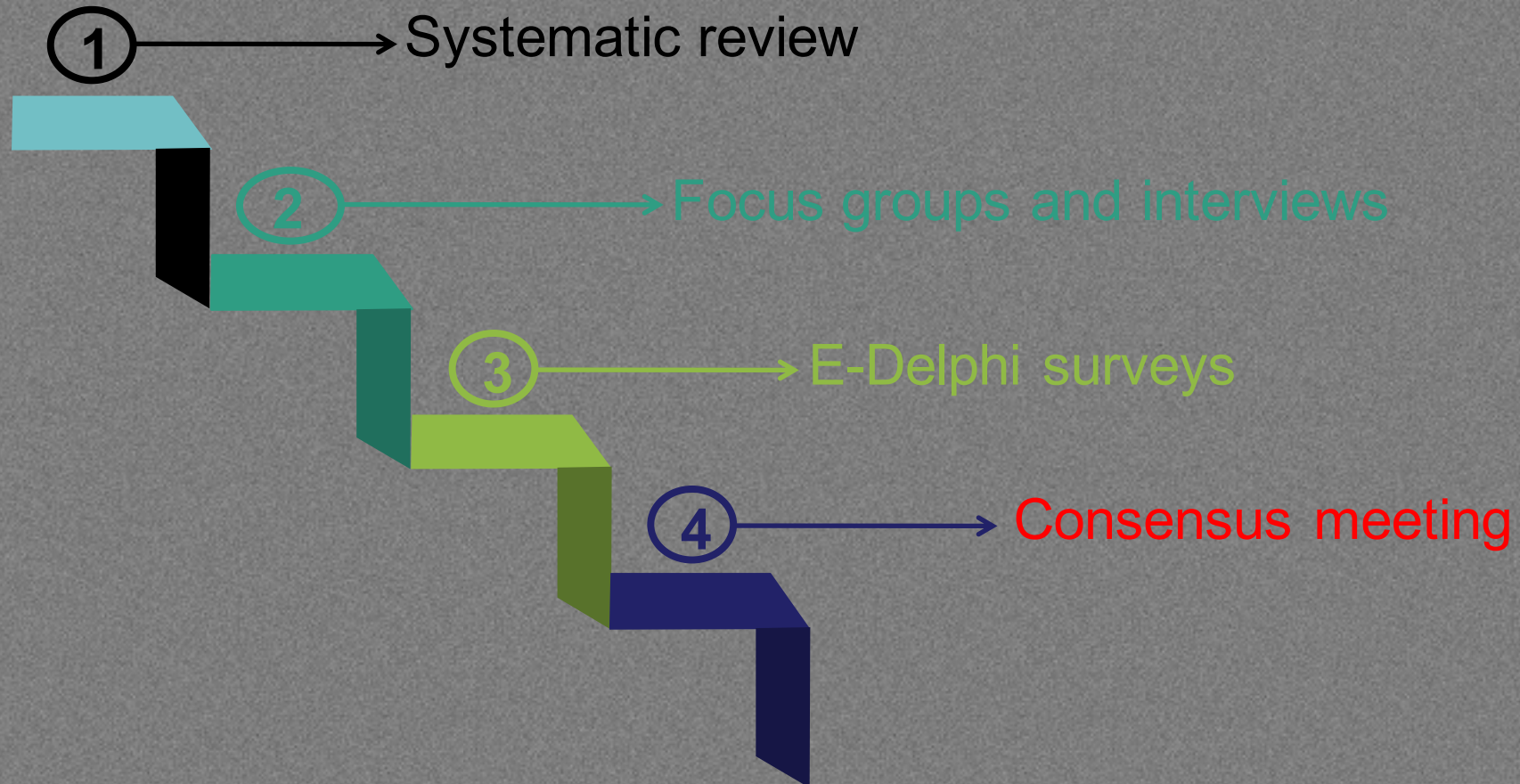
CORE OUTCOME SET

- AGREED STANDARDISED SET OF OUTCOMES
- MEASURED AS A MINIMUM IN CLINICAL TRIALS

- RELEVANT
- LESS HETEROGENEITY
- ENABLE META-ANALYSIS



COS DEVELOPMENT



STUDY PROTOCOL

Open Access



Development of a core outcome set for orthodontic trials using a mixed-methods approach: protocol for a multicentre study

Aliki Tsichlaki^{1*} , Kevin O'Brien², Ama Johal¹, Zoe Z. Marshman³, Philip P. Benson³, Fiorella B. Colonio Salazar^{3,4} and Padhraig S. Fleming¹

Abstract

Background: Orthodontic treatment is commonly undertaken in young people, with over 40% of children in the UK needing treatment and currently one third having treatment, at a cost to the National Health Service in England and Wales of £273 million each year. Most current research about orthodontic care does not consider what patients truly feel about, or want, from treatment, and a diverse range of outcomes is being used with little consistency between studies. This study aims to address these problems, using established methodology to develop a core outcome set for use in future clinical trials of orthodontic interventions in children and young people.

Methods/design: This is a mixed-methods study incorporating four distinct stages. The first stage will include a scoping review of the scientific literature to identify primary and secondary outcome measures that have been used in previous orthodontic clinical trials. The second stage will involve qualitative interviews and focus groups with orthodontic patients aged 10 to 16 years to determine what outcomes are important to them. The outcomes elicited from these two stages will inform the third stage of the study in which a long-list of outcomes will be ranked in terms of importance using electronic Delphi surveys involving clinicians and patients. The final stage of the study will involve face-to-face consensus meetings with all stakeholders to discuss and agree on the outcome measures that should be included in the final core outcome set.

Discussion: This research will help to inform patients, parents, clinicians and commissioners about outcomes that are important to young people undergoing orthodontic treatment. Adoption of the core outcome set in future clinical trials of orthodontic treatment will make it easier for results to be compared, contrasted and combined. This should translate into improved decision-making by all stakeholders involved.

Trial registration: The project has been registered on the Core Outcome Measures in Effectiveness Trials (COMET) website, January 2016.

Keywords: Core outcome set, Orthodontics, Mixed-methods, Delphi

STUDY PROTOCOL

Open Access



Development of a core outcome set for orthodontic trials using a mixed-methods approach: protocol for a multicentre study

Aliki Tsichlaki^{1*} , Kevin O'Brien², Ama Johal¹, Zoe Z. Marshman³, Philip P. Benson³, Fiorella B. Colonio Salazar^{3,4} and Padhraig S. Fleming¹

- RELEVANT
- LESS HETEROGENEITY
- ENABLE META-ANALYSIS

The evidence from systematic reviews and meta-analyses published in orthodontic literature. Where do we stand?

Despina Koletsis*, Padhraig S. Fleming**, Theodore Eliades*** and Nikolaos Pandis****

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Summary

Aim: To analyse meta-analyses included in systematic reviews (SRs) published in leading orthodontic journals and the Cochrane Database of Systematic Reviews (CDSR) focusing on orthodontic literature and to assess the quality of the existing evidence.

Materials and methods: Electronic searching was undertaken to identify SRs published in five major orthodontic journals and the CDSR between January 2000 and June 2014. Quality assessment of the overall body of evidence from meta-analyses was conducted using the Grading of Recommendations Assessment, Development and Evaluation working group (GRADE) tool.

Results: One hundred and fifty-seven SRs were identified; meta-analysis was present in 43 of these (27.4 per cent). The highest proportion of SRs that included a meta-analysis was found in Orthodontics and Craniofacial Research (6/13; 46.1 per cent), followed by the CDSR (12/33; 36.4 per cent) and the American Journal of Orthodontics and Dentofacial Orthopaedics (15/44; 34.1 per cent). Class II treatment was the most commonly addressed topic within SRs in orthodontics (n = 18/157; 11.5 per cent). The number of trials combined to produce a summary estimate was small for most meta-analyses with a median of 4 (range: 2–52). Only 21 per cent (n = 9) of included meta-analyses were considered to have a high/moderate quality of evidence according to GRADE, while the majority were of low or very low quality (n = 34; 79.0 per cent).

Conclusions: Overall, approximately one quarter of orthodontic SRs included quantitative synthesis, with a median of four trials per meta-analysis. The overall quality of evidence from the selected orthodontic SRs was predominantly low to very low indicating the relative lack of high quality of evidence from SRs to inform clinical practice guidelines.

RESEARCH PRIORITIES

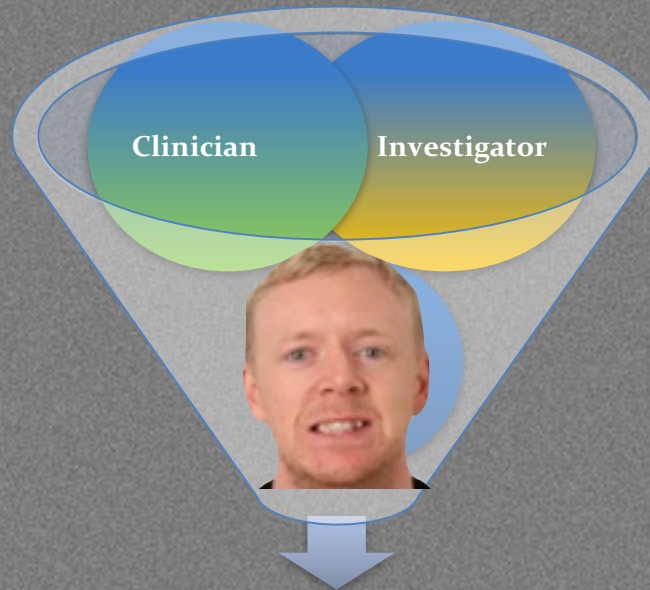
I'm not sure what the future holds but I do know that I'm going to be positive.

Nicole Kidman

“ quote fancy

RESEARCH PRIORITIES

- FUNDAMENTAL QUESTIONS
- KEY OUTCOMES



- PATIENT-BASED PRACTICE AND RESEARCH

RESEARCH PRIORITIES

GUEST EDITORIAL

AJO-DO

An orthodontic registry: Producing evidence from existing resources

James L. Vaden,^a Christopher S. Riolo,^b and Michael L. Riolo^c
Cookeville, Tenn, Seattle, Wash, and Detroit, Mich



WHAT WORKS BEST ..
AND FOR WHO ..

PREDICTABILITY

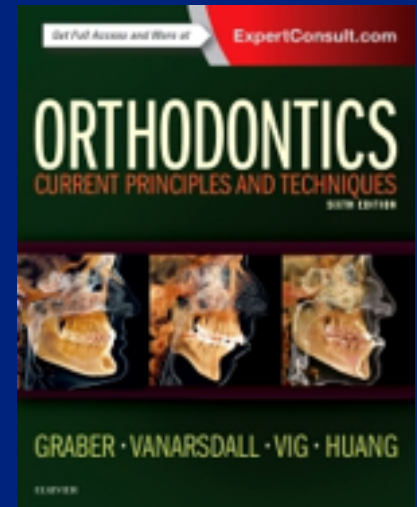
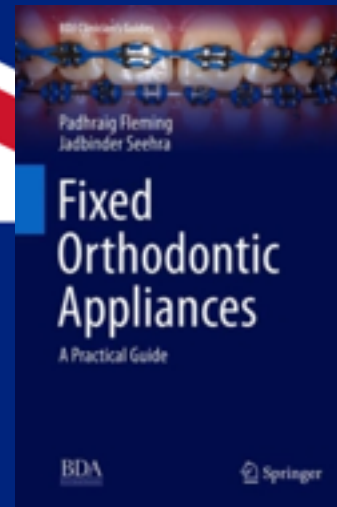
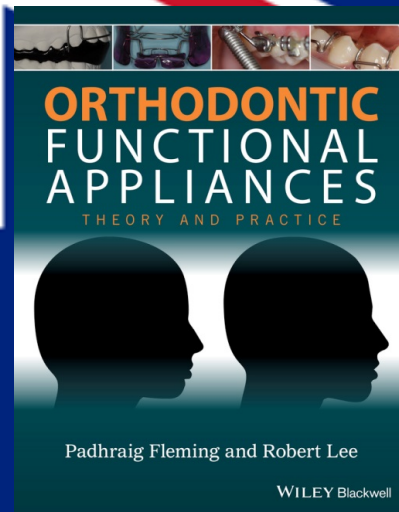
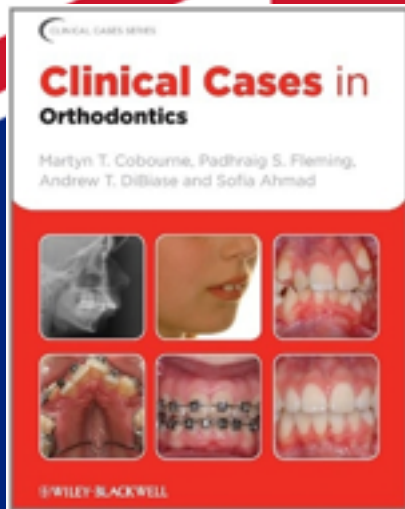




CONCLUSIONS

- EXPERIENCE AND RESEARCH CHANGE PRACTICE
- IMPROVING ALL THE TIME: VOLUME AND RELEVANCE
- RESEARCH FOCUS: KEY QUESTIONS

MY FUTURE: WORK



THANK YOU



WE DON'T HAVE THE ANSWERS ..

Sunset in Enniscrone:
August 2018

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ORTHODONTICS- DO WHAT WORKS
(OR AT LEAST WHAT WE THINK WORKS) ...





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