Mini-implants for orthodontic anchorage

Abstracted from

Antoszewska-Smith J, Sarul M, Łyczek J, Konopka T, Kawala B.

Effectiveness of orthodontic miniscrew implants in anchorage reinforcement during en-masse retraction: A systematic review and meta-analysis. *Am J Orthod Dentofacial Orthop* 2017; **151:** 440-455. doi: 10.1016/j.ajodo.2016.08.029. Review. PubMedPMID: 28257728.

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Question: What is the effectiveness of temporary intraoral skeletal anchorage devices compared to conventional anchorage augmentation during space closure by retraction of anterior teeth?

Data sources Pubmed, Embase, Cochrane Central Register of Controlled Trials and the Web of Science databases. Hand searches of the journals European Journal of Orthodontics, Journal of Orthodontics, Journal of Clinical Orthodontics, Seminars in Orthodontics, American Journal of Orthodontics & Dentofacial Orthopaedics and Angle Orthodontist.

Study selection Two reviewers independently selected studies. Randomised controlled trials (RCTs) and controlled clinical trials (CCTs) of orthodontic patients requiring extraction of the maxillary first premolars and closure of the spaces without anchorage loss were considered.

Data extraction and synthesis Data extraction and risk of bias assessment were carried out independently by two reviewers. Meta-analysis and sensitivity analysis were conducted.

Results Fourteen studies; seven RCTS and seven CCTs were included. In total 303 patients received TISADs with 313 control patients. Overall the quality of the studies was considered to be moderate. Overall the TISAD group had significantly less anchorage loss than the control group. On average, TISADs enabled 1.86mm more anchorage preservation than did conventional methods.

Conclusions The results of the meta-analysis showed that TISADs are more effective than conventional methods of anchorage reinforcement. The average difference of 2mm seems not only statistically but also clinically significant. However, the results should be interpreted with caution because of the moderate quality of the included studies. More high-quality studies on this issue are necessary to enable drawing more reliable conclusions.

Commentary

The objective of the systematic review by Antoszewska-Smith and colleagues[1] was to compare the effectiveness of orthodontic mini-implants (OMIs) as anchorage devices with conventional orthodontic anchorage methods in patients in need of space closure of extracted maxillary first premolars without losing molar anchorage. The difference in anchorage loss, ie mesial movement of the maxillary first molars, between these techniques was the primary outcome measure. For this commentary we assessed the quality of the systematic review. We used the AMSTAR and ROBIS tools to score respectively the methodological validity and the risk of bias in the systematic review.[2-5] These instruments were applied independently to this review by the two authors (RMR and LD) of this commentary.

The outcomes of our appraisals with the AMSTAR and ROBIS tools were summarised in Tables 1 and 2 and were assigned in complete agreement between both reviewers.

Table 1. AMSTAR scores for the systematic review by Antoszewska-Smith *et al*.[1]

AMSTAR questions	Scores
Q1. Was an 'a priori' design provided?	No
Q2. Was there duplicate study selection and data extraction?	Yes
Q3. Was a comprehensive literature search performed?	No
Q4. Was the status of publication (ie grey literature) used as an inclusion criterion?	No
Q5. Was a list of studies (included and excluded) provided?	No
Q6. Were the characteristics of the included studies provided?	Yes
Q7. Was the scientific quality of the included studies assessed and documented?	Yes
Q8. Was the scientific quality of the included studies used appropriately in formulating conclusions?	Can't answer
Q9. Were the methods used to combine the findings of studies appropriate?	No
Q10. Was the likelihood of publication bias assessed?	Yes
Q11. Was the conflict of interest included?	No

Table 2. Tabular presentation for ROBIS results for the systematic review by Antoszewska-Smith *et al.*[1]

Phase 1: Assessing relevance	Phase 2: Identifying concerns with the review process				Phase 3: Judging risk of bias
Does the question addressed by the review match the target question?	Domain 1. Study eligibility criteria	Domain 2. Identification and selection of studies	Domain 3. Data collection and study appraisal	Domain 4. Synthesis and findings	Risk of bias in the review
Not applicable, because we did not formulate a target question	☹	☹	?	☹	☹

(☹) = high risk of bias; ? = unclear risk of bias

Limitations of the systematic review

Table 3 presents the rationale for the AMSTAR and ROBIS scores and also lists additional limitations of the review. These issues are explained here.

Table 3. Limitations of the systematic review by Antoszweska-Smith *et al.*[1]

Item	Limitation
Prioritising of research questions and assessing whether the review was already done previously	Research questions were not prioritised. The authors did not report whether they assessed if the review was already conducted previously
Registration or publication of the protocol	A protocol was not published or registered
Pilot testing of research methods	Pilot testing of research methods was not reported
Eligibility criteria	Eligibility criteria were inadequate and reporting on these items was suboptimal
Information sources and search strategy	Grey literature and review articles were not screened. Investigators were not consulted on unknown or ongoing studies. The search strategy was not pilot tested
Study selection and data extraction	A list of excluded studies with rationale was not given
Risk of bias assessment	It was unclear whether all eligible studies in the meta-analyses measured the same outcomes and with the same test methods. A non-eligible study was included in two meta-analyses
Data synthesis	Can't answer
Quality of evidence	A validated instrument, eg GRADE, was not used to assess the quality of evidence
Adverse effects of interventions	Adverse effects of interventions were not assessed
Conflict of interest	Conflicts of interest were not reported by the authors

Prior to starting a systematic review investigators should (1) prioritise their research questions with pertinent stakeholders to assess whether their planned questions are necessary; [6] (2) assess whether the review has already been done previously. If so, authors should assess whether a new review is indicated, for example in the context of the limitations of the earlier review. The main text and the references of the review by Antoszewska-Smith and co-authors1 showed that they did not undertake such assessments. For example, they did not consider a recent Cochrane review by Jambi and co-workers[7] that asked similar research questions. We consulted the PROSPERO[8] register and various online protocol repositories,[9,10] but were unable to identify a protocol of the systematic review by Antoszewska-Smith and co-authors.[1] Not registering or publishing of protocols can introduce various biases such as selective reporting and publication of outcomes.[11] Pilot testing of any of the research methods was also not reported in our appraised review.

Carefully defined eligibility criteria permit the reproducibility of a review and reduce sources of medical uncertainties such as the variability in participants, interventions, comparators, outcomes etc. Numerous eligibility criteria in this review were either not defined or were incomplete. For example: (1) a definition of eligible controlled clinical trials was missing; (2) eligible characteristics for participants such as age, sex, and other demographic items were not given. Restrictions for the type of setting were also not reported; (3) reporting on both the interventions and comparators was suboptimal. For example, the characteristics of eligible interventions with OMIs and conventional anchorage methods were not defined; (4) An eligible duration of treatment was not reported; (5) A clear time point for measuring outcomes was also not defined. It was not reported whether closure of extraction spaces with or without paralleling

the roots was considered as the endpoint of treatment; (6) Eligible methods for measuring outcomes, eg model or cephalometric analyses were also not reported; (7) Language bias was a problem, because only articles reported in the English language were eligible

The authors screened a wide spectrum of electronic databases and also manually searched various pertinent journals and the references of included studies. However, they did not consult: (1) the Grey literature; (2) researchers and sponsors to obtain information on unknown or ongoing studies; (3) references of review articles on OMIs. The search strategy was probably sufficient, because it covered the same keywords as other systematic reviews on OMIs.[7,12] However, we do not know whether this search strategy was pilot tested and whether an information specialist with expertise in searching the biomedical literature was consulted to validate the search strategy. A list of excluded studies with the rationale for exclusion was also not reported. Not including such a list makes the reproducibility of the review impossible and also introduces study selection bias.[13]

For the assessment of the quality of the eligible controlled clinical trials studies, the reviewers applied the Newcastle-Ottawa scale. This instrument lacks comprehensive manuals with instructions for users, which has resulted in low reliability between reviewers.[14-16] To deal with these shortcomings, the Cochrane Bias Methods Group and the Cochrane Non-Randomised Studies Group developed a new tool for assessing risk of bias in non-randomised studies of interventions (ROBINS-I tool).[17] This instrument, previously known as the ACROBAT-NRSI tool[18] should have been used for the bias assessment in the eligible controlled clinical trials. The authors assigned the quality of evidence as moderate for both the included randomised controlled trials and the controlled clinical trials, but this score was based on test methods developed by the authors themselves. Instead, they should have implemented a validated instrument such as the GRADE approach for assessing the quality of evidence.[19]

It was unclear whether conducting meta-analyses was indicated, because definitions of eligible outcomes were underreported in the eligibility criteria and in the review as a whole. It was therefore unclear whether all studies included in the meta-analyses had measured the same outcomes and with the same test instruments. It was also unclear whether outcomes on failed OMIs were included in the intervention groups. This is important, because excluding these outcomes can seriously upgrade the effectiveness of these devices. The same issue applies to excluding outcomes on poor headgear collaborators from the comparator groups. The authors also included a non-eligible study[20] in two of the meta-analyses for a secondary outcome. The inclusion of this study is particularly problematic, because it skewed the meta-analysis on tipping of molars in favour of OMIs.

The authors of the appraised review did not assess any outcome on adverse effects of interventions. When considering the implementation of a new health technology, clinicians want to know both the benefits and the adverse outcomes of the intervention of interest. It is therefore mandatory in Cochrane reviews to assess the findings of at least one adverse effect as a primary outcome.

Competing interests can influence how research studies are designed, conducted and reported, which could divert outcomes away from the truth. In addition, it has been estimated that around 50% of the studies that involve researchers with conflicts of interests do not declare them.[21] Full transparency on the role of a sponsor or funder during any part of the review process is therefore key.[22] A statement on potential conflicts of interest was not included in the appraised review by Antoszewska-Smith and co-workers.[1]

Conclusions

Prior to applying the findings of a systematic review on a specific intervention to a patient, clinicians need to exclude numerous uncertainties. The assessment of the quality of the review is an initial step in this process. Quality assessments of systematic reviews are important as was explained in a recent investigation by Ioannidis.[23] He suggested that 'possibly the large majority of produced systematic reviews and meta-analyses are unnecessary, misleading, and/or conflicted'.[23] These three limitations were also found in the systematic review by Antoszewska-Smith and co-workers.[1] First, the review reported no information on potential conflicts of interests. Second, assessments with both the AMSTAR and ROBIS tools identified numerous limitations. These shortcomings could have been resolved either during the protocol phase or during the conduct and reporting of the review. Supplementary files published online should have expanded on many of the underreported items. A good collaboration between editors, peer-reviewers, and the authors of this review could also have significantly raised its quality. Now only a new unbiased review team can address these shortcomings in a new systematic review. Third, before developing and conducting a new review one should first assess whether addressing the current research questions is really necessary, because the effectiveness of non-moving implants for anchorage purposes is obvious and probably does not need further research. Clinicians and patients are possibly more interested in reviews that assess how displacements of OMIs and therefore anchorage loss can be avoided. Prioritising review questions with pertinent stakeholders is the first step when considering a new review.[6]

Practice point

- Critical appraisals with the AMSTAR and ROBIS tools conducted by two reviewers independently, identified numerous limitations in this systematic review. These shortcomings should be carefully weighed prior to implementing the findings of this low quality review to our patients
- Research on the obvious effectiveness of non-moving implants for anchorage purposes is probably not what patients and clinicians want. Prioritising review questions with pertinent stakeholders is indicated before designing and conducting a new review on orthodontic mini-implants and comparator interventions.

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