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Miniscrews Failure Rate in Orthodontics: Systematic Review and Meta-analysis.

Abstract

Introduction: Miniscrews in orthodontics have many clinical applications, however the literature has reported varying failure rates. All published studies in regard to miniscrew failure rate were systematically reviewed, meta-analysis of eligible studies undertaken to provide a more precise estimation of miniscrew failure rate and the possible risk factors were identified.

Methods: All relevant studies were identified through the Cochrane Database of Systematic Reviews, MEDLINE, Scopus and Ovid. The full-text of all clinical trials and cohort studies, published in English, which reported on the failure rate of miniscrews with diameter up to 2mm were obtained. Study selection, data extraction and risk of bias assessment were undertaken blindly and in duplicate. Miniscrew failure event rates and the relative risk factors with the corresponding 95% confidence intervals were calculated using the random-effects model. Subgroup and sensitivity analyses were performed.

Results: The included studies were 16 randomised clinical trials and 30 prospective cohort studies. Five studies were not included in the meta-analysis due to a lack of the statistical information needed to compute the effect sizes. 3250 miniscrews from 41 studies were pooled in a random-effect model. The overall failure rate was 13.5 % (95% CI, 11.5-15.9). Subgroup analysis showed that miniscrews 'diameter, length and design, patient age and jaw of insertion had minimal effect on miniscrew failure while the type of the gingivae and smoking had significant effect.

Conclusion: Miniscrews have an acceptably low failure rate. The findings should be interpreted with caution due to high-level of heterogeneity and unbalanced groups in the included studies. High quality RCTs with large sample sizes are required to support the findings of this review.

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Miniscrews Failure Rate in Orthodontics: Systematic Review and Meta-analysis.

Introduction

Orthodontic skeletal anchorage devices are used by orthodontists for a range of clinical applications. This includes molar distalisation, molar protraction, intrusion of incisors, intrusion of molars, crossbite or scissor bite correction and anchorage reinforcement [1-7](#). It was following Konami's publication in 1997 that orthodontic skeletal anchorage devices, as we know them today, were popularized [8](#).

Orthodontic skeletal anchorage devices can broadly be divided into two categories: osseointegrated implants such as mid-palatal implants [9](#) and onplants [10](#), and mechanically retained devices such as titanium mini-plates [11,12](#), zygomatic wires, and miniscrews [13,14](#). The use of miniscrews has increased in orthodontics due to their ease of insertion and removal, reasonable cost, biocompatibility and capability to withstand orthodontic forces [15,16](#). Publications regarding the mechanically-retained miniscrews increased dramatically from a few papers in the 1980s to above 5000 papers up until 2017, indicating a huge interest in skeletal anchorage. Unfortunately, the vast majority of these papers are case reports and biological science research with few clinical trials published.

Miniscrews should ideally remain stationary when orthodontic force is applied to be effective. Several factors contribute to the miniscrews' success which may be design related, patient related or clinician related factors. Age is a patient related factor with a higher failure rate reported in adolescents than adults as a result of the difference in the buccal plate thickness [17](#). Poor oral hygiene and smoking are further patient related risk factors that reduce the survival rate of miniscrews [18-20](#). Insertion site and type of the mucosa (keratinised and non-keratinised mucosa) are further patient related factors. In general, miniscrews have been reported to have a good success rate if inserted in the maxillary region and through keratinised gingivae [17,19,21](#).

With regard to miniscrew design factors, it has previously been concluded that miniscrews with a diameter between 1.1-1.6mm provide the best success rate [22](#). Similarly, miniscrews longer than 5-8mm are more stable than shorter ones [19,22](#). Clinician's experience, sterilization and asepsis, loading protocol [23](#), implant placement torque [24,25](#) and insertion angle [26](#) have all been implicated as clinician related factors that may significantly affect the survival of miniscrews.

Recent reviews investigated the effectiveness of all types of skeletal anchorage devices in anchorage provision in relation to conventional methods [7,27,28](#). However, the findings of these reviews were not specific to the most commonly used skeletal anchorage device, that is

mechanically-retained miniscrews. In this study, we performed a systematic review and meta-analysis of controlled and uncontrolled prospective clinical trials to provide a contemporary estimate the failure rate of miniscrews used in orthodontic treatment and their associated risk factors.

Methods

This review received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors. This systematic review was planned and reported accordingly with the preferred reporting items for systematic review and meta-analysis ²⁹ and Cochrane Guidelines for Systematic Reviews ³⁰. This review was registered with International prospective register of systematic reviews (PROSPERO, number CRD42017071441).

Criteria for included studies

The main research question was defined in PICO format (Table 1). The included studies in this systematic review were human controlled clinical trials and prospective cohort studies that were published in English till July 2017. There was no restriction in the search strategy about the starting date. Since the nature of this study was to aggregate the failure rates of miniscrews, no comparators were needed. Articles on miniscrews with a diameter greater than 2 mm, in vitro studies, animal studies, case reports and case series and review articles were excluded. In cases of unclear study design, the author was contacted twice for further information. If there was no response from the author, the study was excluded.

Search strategy

Controlled vocabulary and free text terms was used to allocate published, ongoing and unpublished studies. The vocabulary was updated following initial search, if necessary, so as to identify all studies to be considered in this review. The following databases were searched until 1st of July 2017 (Appendix 1): MEDLINE via PubMed, Cochrane Database of Systematic Reviews; Scopus and Ovid. Other bibliographic databases were also searched for ongoing and unpublished data including dissertation data, grey literature in Europe, clinical trial registry, ISRCTN registry, dissertation and theses dissemination as well as Google Scholar until July 2017. A manual search was also carried out in relevant orthodontic journals until July 2017. Reference lists of the included articles and other relevant systematic reviews to this topic were checked for any additional relevant literature and to include an additional controlled vocabulary and free text terms if present. The Cohen kappa statistic was used to assess the agreement between the two review authors.

Study selection and data extraction

Endnote reference manager software was used for duplicate removal. Relevant articles were identified first after reading their titles and abstracts. The full text of the potential articles was assessed for eligibility by two reviewers (FA & DB). With the potential difficulties encountered

with translating multiple articles into English, it was decided to only include articles presenting with a full text in English. However, this exclusion criterion was applied following the primary search so as to avoid bias in the search protocol.

One reviewer (FA) independently extracted study characteristics and outcomes using the customized data extraction form developed by Papadopoulos and his colleagues ⁷. The following information was included for each study: year of publication, setting, study design, number of miniscrews and their characteristics, success criteria, failure rate and handling of failure.

Assessment of risk bias in the included studies

Clinical trials were assessed for risk of bias using the Cochrane collaboration's tool ³⁰. Each included study was assessed in regard to the risk of bias in (1) random sequence generation; (2) allocation concealment; (3) blinding of outcome assessors; (4) incomplete outcome data; (5) selective reporting; and (6) other sources of bias. Each RCT was assigned an overall risk of bias, low risk if all key domains have low risk, high risk if more than one key domain has high risk, and unclear risk if more than one key domain has unclear risk.

Prospective cohort studies were assessed for risk of bias using the Newcastle-Ottawa Scale as suggested by the Cochrane Handbook for Systematic Reviews of Interventions ³¹. The Newcastle-Ottawa Scale assess the studies in the following three domains: (1) selection; (2) comparability; and (3) outcome. In case of disagreement between the two reviewers, a mutual decision through discussion was made. Again, The Cohen kappa statistic was used to assess the agreement between the two review authors.

Data synthesis and meta-analysis

To calculate the failure rate, the original outcome data were pooled in a random-effect model using the statistical software Comprehensive Meta-Analysis (Biostat Inc., Englewood, NJ, USA). The pooled estimate was computed from studies that reported similar intervention and outcomes. Failures of miniscrew implants were expressed as event rates with their 95% confidence intervals (CI).

Taking in consideration the methodological and statistical heterogeneity, a random-effects model was used to estimate all pooled estimates ³². The heterogeneity across the studies was assessed using the I² and Chi² test for heterogeneity (no heterogeneity =0%, low = 25-49%, moderate=50-74%, and high 75-100%. ³³.

Other analysis

Subgroup and stratified analyses were pre-planned and pre-specified (a priori) to explore the effect of miniscrews' length, diameter, age group, jaw, the study design (RCT or cohort) and sample size (100 TADs and more) pooled estimate. We also pre-planned to explore the effect of the miniscrew design, self-drilling miniscrews and non-self-drilling miniscrews that require pre-drilling pilot hole before insertion, on the pooled estimate. As planned, subgroup analyses were planned to be used for a minimum of five studies.

Assessment of publication bias

Publication bias was assessed by visual inspecting the funnel plot asymmetry [33](#). Moreover, two statistical methods were used to produce significance tests in order to recognize publication bias: Begg/ Mazumdar's method [34](#) and Egger's method [35](#).

Results

Study characteristics

There were 8636 hits from both electronic and manual searches. After duplicate removal, studies were screened and 7915 studies did not meet the inclusion criteria on the basis of title and abstract (Figure 1). Another 152 of the qualifying studies were excluded after their full texts were retrieved. This was because they were laboratory studies, retrospective studies, systematic reviews or not relevant to the review topic. The final sample was 46 studies that met the primary inclusion criteria. The included studies were 16 randomised clinical trials [36-51](#) and 30 prospective studies [24,52-80](#). Among the prospective studies there were three controlled trials (CCT), twenty-eight cohort study (PCS) and one split mouth cohort study. Five studies, two RCTs and three PCSs were not included in the meta-analysis due to a lack of the statistical information needed to compute the effect sizes [37,47,56,58,79](#). However, they were included in the quality assessment of the studies. The authors were contacted when necessary to obtain more information and, if no reply was received, the study was excluded.

The main characteristics of the 46 included studies which collectively included 3466 miniscrews are presented in table 2. In regard to study settings, 36 (78%) of the studies were based purely in university settings, while the other 10 studies took place in either private, hospital, mixed or unknown settings. Generally, the number of miniscrew used per participant ranged from 1 to 4 miniscrews and the average number per study was approximately 77 miniscrews. There was considerable variation between the manufacturer of the miniscrews used in the included studies and in the dimensions of the inserted miniscrews. The diameter of the inserted miniscrews ranged from 1.2 mm to 2 mm and their length from 5 mm to 15 mm. As presented, the recorded failure rate of miniscrews in the included studies also ranged from zero to 40.8%.

Risk of bias of included studies

The random sequence generation domain was assessed as adequate in 9 trials of the included RCTs while the remaining trials were assessed as having high risk of bias or unclear risk (Table 3). Allocation concealment domain was graded as having low risk of bias in five trials only and the rest of the studies were assessed as having unclear risk of bias or high risk of bias. The blinding of participants and personnel was not possible in the included trials due to the nature of orthodontic treatment. However, blinding of assessors was possible and was carried out in 6 trials, in the remaining ten studies either blinding was not performed or the reporting was not

adequate. There were no dropouts in the included trials or the dropouts were reported on. Therefore, all included trials were assessed as having low risk of bias. Selective bias domain was judged to have a low risk of bias in three trials. The remaining studies were judged to have unclear risk of bias because no information was reported to permit judgment. The summary judgment of risk of bias was assessed to be low in four trials only [36-39](#). The remaining trials were judged to have overall high risk of bias after assessment all six domains was performed [40-51](#).

With regard to the quality assessment of prospective cohort studies, the vast majority of the these studies had medium quality according to the Newcastle-Ottawa Scale [24,52-76](#) (Table 4). Three studies were judged to have high quality [77-79](#) and one study was judged to have low quality [80](#).

Overall miniscrews failure rate (Primary outcomes)

Out of 46 studies, the primary outcome of this review i.e. failure rate of miniscrews, was reported in 41 studies. Data of 3250 miniscrews were extracted and pooled in a random-effect model. The pooled failure rate was 13.5 % (95% CI, 11.5-15.9, P= 0.001, I²= 57.1%) (Figure 2).

Data of 1391 miniscrews extracted from 30 studies that included less than 100 miniscrews for each study were pooled in a random-effect model. The failure rate of 12.5% (95% CI, 9.7-16.1, P=0.001, I²=60.23%) was comparable to the summary points estimates of the effect size of all the studies. Data from the 11 studies where each study included more than 100 mini-screws were then analysed in a random-effect model, the total number of mini-screws placed was 1893. The failure rate was 14.3 % (95%CI, 11.5-17.7, P=0.027, I²=71.5%). Similarly, in studies where more than 100 miniscrews were placed, the rate did not differ considerably from the estimates of the effect size of the main analysis.

Assessment of the miniscrew failure risk factors (Secondary outcomes)

Miniscrews diameter and length were reported in more studies than any factor except for the location (maxilla or mandible). Diameter, length, age, jaw of insertion, smoking status and type of soft tissue were investigated (Table 5). Associated factors with miniscrews failure were assessed in planned subgroup analysis if possible.

Influence of study design on the estimating of failure rate was assessed (Figure 3). Fifteen RCTs that included 876 mini-screws were pooled in one random-effect model as a part of the sensitivity analysis. Their failure rate was 13.5 % (CI 95%, 10.1-17.9, Q=31.5 P=0.001,

$I^2=55.6\%$). Interestingly, this was equal to the pooled failure rate (13.5%, CI 95%, 11.0-16.4, $Q=76.54$, <0.001 , $I^2=67.34\%$) of the 26 PCSs that included 2374 miniscrews,

Influence of miniscrew design and length on the estimating of failure rate was also assessed (Figure 4 and 5). The length of 8mm was used as a cut-off point to assess the effect of length of miniscrew on the failure rate. The failure rate of the long miniscrews ($> 8\text{mm}$) (8.3%, 95% CI, 3.1 -20.2, $Q=15.2$, $DF=5$, $P=0.009$, $I^2=67.2\%$) and the failure rate for the short miniscrews was 12.7% (95% CI, 10.5-15.4, $Q=47.26$, $P=0.007$, $DF=26$, $I^2=44.9\%$).

Data from 11 studies that used non-self-drill miniscrews and 10 studies that used self-drill miniscrews were pooled. Miniscrews failure rate was 14.9 % (95% CI, 10.4-20.8, $Q=20.7$, $DF=8$, $P=0.008$, $I^2=88.9\%$) in the non-self-drill miniscrews group which was not significantly different from the estimate effect in the self-drill miniscrews (14.2%, 95% CI, 5.6-31.8, $Q=51.57$, <0.001 , $I^2=71.41\%$).

Only one study 54 evaluated the association between smoking and miniscrews failure rate and included 110 miniscrews. 73 miniscrews were placed in non-smokers, 18 miniscrews for light smokers (≤ 10 cigarettes/day) and the rest for heavy smokers (≥ 10 cigarettes/day). The failure rates were 9.5%, 11% and 57.8% respectively. Moreover, one trial ⁴³ reported on the influence of type of gingivae at insertion site. 32 miniscrews were included in the study, those were placed in keratinized tissue (11 miniscrews) showed no failure, 4 out of 21 miniscrews (19%) that were placed in non-keratinized tissue failed.

Publication bias analysis

Figure 6 shows a funnel plot of studies where the effect sizes were plotted against standard error. The vertical line represents the weighted mean effect size estimate. As one would expect, studies with a smaller sample size and large sampling error would scatter toward the bottom of the funnel plot. If publication bias is not present, the data points would normally be expected to be distributed symmetrically around the mean effect size estimate. In this current meta-analysis, the shape of the inverted funnel-plot was asymmetrical between the right and the left sides of the plot meaning that there was absence of smaller sized studies towards the right side of the plot. Therefore, a considerable publication bias due to a failure of including studies with small effect sizes seems likely in this meta-analysis. Furthermore, Both Begg's test (Kendall's $\tau_a=-0.34535$, $P=.00131$) and Egger's test (-1.789, 95% CI, -2.70- -0.874, $P=0.00017$) suggested that publication bias may be present in this meta-analysis.

Discussion

This systematic review included 16 clinical trials and 30 prospective cohort studies, mostly where the miniscrews were used to reinforce orthodontic anchorage. The majority of the included trials were judged as having a high risk of bias. In most of these trials, randomisation and allocation concealment procedures were either inadequate or reported incompletely. The quality of most of prospective cohort studies was medium. This can be attributed to the fact that most of included cohort studies did not include a comparison group, thus, they had a lower score in the Newcastle-Ottawa Scale.

The meta-analysis estimated the miniscrews failure rate to be 13.5% (95% CI, 11.5-15.9). Sensitivity analysis, after excluding small studies, showed almost similar pooled failure rate (14.3%) to the overall estimate effect indicating adequate robustness of the results. This finding differed slightly from the failure rate previously reported by Papageorgiou and colleagues ⁷ who reported a failure rate of 13.5 % (95% CI, 11.5-15.8). The difference between the two estimates might have resulted from including additional studies in our meta-analysis [38,42,55,59,60,77,78](#). Secondly, we excluded retrospective studies, studies with unclear design or studies in language other than English that had been included in the previous meta-analysis ⁸⁰.

Associated factors with miniscrew failure were assessed in subgroup analyses. It appeared from the findings of this meta-analysis that miniscrews with diameter smaller than 1.3 mm had lower failure rate (10.7%, 95% CI, 7.6-15) when compared with miniscrews with diameter of 1.4-1.6 mm (13.6%, 95% CI, 10.3-17.1) and diameter of 1.7-2 mm (14.4%, 95% CI, 8.8-23.5). However, the number of included miniscrews with small diameter was 450 while the included miniscrews with medium diameter were 1586 and the ones with large diameter were 391. This variation in sample size between the included miniscrews and the heterogeneity may have influenced the conclusiveness of the findings. Papageorgiou and colleagues ⁷ found comparable failure rates for miniscrews of small and large diameter: 10.9 % (95% CI, 7.7-15.3) and 14.3 % (95% CI, 7.4-25.8) respectively. However, they found that miniscrews with medium diameter had failure rate of 12.7% (95% CI, 8.1-19.3). Lim and his team conducted two retrospective studies and found that the miniscrew diameter had no significant effect on the success of miniscrew ^{81,82}. Furthermore, the difference between large and medium size diameter was minimum, approximately 0.8%. This was proven in previous study as a diameter greater than about 1.6 mm seems to confer no significant benefit as wide miniscrews are associated with higher risk of root contact than narrow miniscrews ²²

The miniscrews in this meta-analysis were subdivided into short ($\leq 8\text{mm}$) and long ($> 8\text{mm}$) group. Most of the studies used short miniscrews (Table 5). The failure rate of short miniscrews was 14.1 % (95% CI, 12.7-15.7) which is much larger than the failure rate of long miniscrews (8.3%, 95% CI, 3.1 -20.2). It is at the discretion of the clinician to consider this difference clinically significant or not but theoretically, longer miniscrews should have a lower failure rate as they offer better mechanical retention in the bone than shorter miniscrew. Lim et al. ⁸² found higher failure rate (25%) with miniscrews of 6 mm or less, whereas miniscrews longer than 6mm had lower failure rate ($<12\%$). This could be due to the significant heterogeneities in the subgroup analysis, thus, this finding is not conclusive and it should be interpreted with caution. Furthermore, in this review an arbitrary cut-off point of 8mm to assess the effect of length of miniscrew on the failure rate, was adopted; hence, the possibilities of the overlap of the findings on either side of the cut-off point is high i.e. those miniscrews with 7.9mm or less will be included in the short group. It is acknowledged that this cut-off point carries weak specificity on the pooled estimate.

The design of the miniscrews was compared in a small number of included studies and did not have any effect on the failure rate according to our findings. The failure rate of self-drilling miniscrews was 14.2 % (95% CI, 5.6-31.8) and for the non-self-drilling was 14.9% (95% CI, 10.4-20.8). Similar finding was reported by Papageorgiou et al. ⁷ for the non-self-drilling miniscrews (17.7 %, 95% CI, 5.1-44.9) but was significantly lower in self-drilling group (7.7%, 95% CI, 4.8-12.0). This discrepancy might be due to the fact that we extracted the data of miniscrews design from 9 studies compared to 3 studies in Papageorgiou and team review ⁷, this might have influenced the estimation of the failure rate. Moreover, this could be due to the significant heterogeneities in the subgroup analysis, thus, this finding is not conclusive and it should be interpreted with caution. Interestingly, Chen et al. (2008) in their retrospective study found that self-drilling miniscrews had higher failure rate (33%) when compared with non-self-drilling (10%) ⁸³, though this difference was not significant.

Age is a patient related factor with a higher failure rate in adolescents than adults potentially as a result of the difference in the buccal plate thickness ¹⁷. In this review, most studies recruited a mix of young (≤ 18 years) and adult patients (> 18 years). The failure rate of miniscrews placed in younger patients was 8.6 % (95%, CI, 4.7-15.1) which is lower than the failure rate reported by Papageorgiou and colleagues ⁷ who found that the failure rate in patients younger than 20 years was 12.6 (95% CI, 6.4-23.3). The difference between the two estimates was not significant and could be the result of the variation in the included studies between the two meta-

analyses. Similarly, the failure rate of miniscrews placed in adults according to our analysis was 11.2% (95% CI, 6.6-18.7) compared to 15.5 % (95% CI, 11.2-21.0) in Papageorgiou and team review ⁷. In contrary, retrospective studies ^{82,84} showed that older patients had higher failure rate probably due to smoking and compromised periodontium in adult patients. On the other hand, these findings may simply be a function of sample size, as there were more miniscrews inserted in younger participants than adults.

In our analysis the failure rate of miniscrews placed in the maxilla was 11.0% (95% CI, 8.8-13.7) while the failure rate of those placed in the mandible was 16.5% (95% CI, 11.6-22.7). The higher failure rate in the mandible may be caused by the greater bone density, the availability of cortical bone around the miniscrews, and the narrow vestibule compared with the maxilla ⁸⁴. However, it is important to consider the significant degree of heterogeneities in the subgroup analysis during interpretation of the data.

Data regarding to the effect of smoking on the failure rate of miniscrews was extracted from only one study ⁵⁴ in our review and it appears that smoking has a negative effect on miniscrew stability although there is very limited data to support this.

The type of mucosa was investigated in only one study ⁴³. They found that 11 miniscrews placed in the keratinized tissue had no failures. Although many clinicians advise placing miniscrews in keratinized tissue, this advice was led by retrospective studies rather than prospective studies ⁵⁴.

Limitations of the study

The above interpretation of the findings should be read with caution due to the significant heterogeneity ($Q=86.34$, $P= 0.001$, $I^2= 57.1\%$) between the studies. This is to be expected because the included studies had different designs, sample sizes and methods.

Inspection of the funnel plot and statistically significant Egger's test and Begg's test suggested that publication bias is likely to be present. This is expected because the included studies in this meta-analysis were only in English and not all of the included trials were meta-analysed because the authors did not report data on failure rate of miniscrew. Additionally, the asymmetry in the funnel plot may have raised due to true methodological and statistical heterogeneity or just a chance. It is worth noting that the funnel plot is able to indicate the presence of the publication bias but it cannot explain the reasons for the asymmetry ^{83,85}.

Conclusion

- The included studies in this meta analysis were a mix of clinical trials that mostly had a high risk of bias and prospective cohort studies with mostly moderate quality.
- The failure rate of miniscrews was modest (13.5%, 95% CI, 11.5-15.9) which suggests that miniscrews are clinically reliable.
- Subgroup analysis showed that with the possible exception of smoking and type of mucosal insertion, the assessed risk factors had very minor effects on miniscrew survival. However, the subgroup analysis should be interpreted with caution due to high-level heterogeneity and unbalanced and small groups.
- High quality RCTs with large sample sizes are required to support the findings of this review.

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List of captions

Figures

Figure 1- Flow chart of the selection of studies

Figure 2 Forest plot of overall miniscrews failure rate (random-effect model)

Figure 3 Forest plot of according to the study design (random-effect model)

Figure 4. Forest plot of according to miniscrews design (random-effect model)

Figure 5. Forest plot of according to miniscrews length (random-effect model)

Figure 6 Funnel plot of studies included in the meta-analysis

Tables

Table 1- PICO format

Table 2 Characteristics of included studies

Table 3 Risk of bias assessment of the included RCTs

Table 4 Risk of bias assessment of included cohort studies using Newcastle-Ottawa Scale (NOS)

Table 5 Summary of miniscrews failure associated factors Final 03 Aug

Appendix

Appendix 1. Search strategy for miniscrews failure rate systematic review.