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Systematic Review and Meta-analysis
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Skeletal stability following bioresorbable versus titanium fixation in orthognathic surgery: a systematic review and meta-analysis

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Abstract. Despite developments in bioresorbable fixation over recent decades, controversy remains regarding skeletal stability following the use of this material in orthognathic surgery. This systematic review and meta-analysis investigated evidence from the international literature from studies comparing skeletal stability between bioresorbable and titanium fixation in orthognathic surgery. Key words were searched in MEDLINE, Embase, and Cochrane Library, and relevant journals and reference lists were searched for additional material, up to January 2017. Study quality was assessed with the Newcastle–Ottawa scale. The meta-analysis was performed using RevMan software. Ten cohort studies were included. The meta-analysis showed no statistically significant difference between bioresorbable and titanium fixation (SMD (95% CI)) for maxillary horizontal relapse (maxillary advancement 0.09 (−0.16 to 0.33); maxillary setback −0.04 (−0.64 to 0.56)), maxillary vertical relapse (maxillary elongation 0.15 (−0.31 to 0.61); maxillary impaction −0.30 (−1.10 to 0.50)), mandibular horizontal relapse (mandibular advancement 0.16 (−0.72 to 1.03); short-term mandibular setback −0.33 (−0.82 to 0.15)), and mandibular angular relapse (mandibular clockwise rotation −0.39 (−0.79 to 0.00); mandibular counter-clockwise rotation 0.14 (−0.37 to 0.66)). However, after mandibular setback, titanium fixation showed significantly less relapse in the long-term (0.97 (0.47 to 1.47)). With regard to skeletal stability, bioresorbable fixation is comparable to titanium fixation when used in maxillary setback and mandibular clockwise rotation; however titanium fixation may be preferable in mandibular setback. Further high-quality studies are needed to draw more definitive conclusions.

Key words: bioresorbable; titanium; fixation; orthognathic surgery; skeletal stability.

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Immobilization of the bone segments is one of the essential prerequisites for the healing of osteotomies. Internal fixation with titanium plates and screws has been accepted as the 'gold standard' in orthognathic surgery to achieve immobilization. While titanium fixation has the advantages of good mechanical and handling properties[1,2], a disadvantage of this material is the long time it may remain in situ. Furthermore, if left in situ, removal of the titanium plates and screws may be required for several possible reasons[3], such as palpability of the Plates[4,5], sensitivity to temperature stimuli, interference with electromagnetic and ionizing radiation[6–8], titanium particles in overlying soft tissues and regional lymph nodes[9–11], induced growth restriction, and mutagenic effects[12,13], which have been verified in many studies over the past few decades.

These limitations of titanium fixation brought about the development of bioresorbable fixation, which reduces or prevents the need for second surgery to remove the plates and screws. However, bioresorbable fixation is not used widely in orthognathic surgery due to controversy regarding skeletal stability.

Several cohort studies have compared skeletal stability between bioresorbable and titanium fixation in orthognathic surgery, suggesting that bioresorbable fixation is a comparable alternative in terms of skeletal stability. A previous systematic review of this topic included 15 comparative studies and five randomized controlled trials, but did not analyze the results of surgery according to the different types of procedure (maxillary or mandibular surgery) or the direction of movement (advancement or setback)[14]. Since the tendency to relapse is greater for certain procedures, it is inappropriate to compare the operative results without accounting for the types and directions of the surgery. Moreover, this previous review included studies that used different reference landmarks as outcome indicators and failed to synthesize data to obtain quantitative results.

The present systematic review and meta-analysis, based on the current international literature, was conducted to compare the effects on skeletal stability of bioresorbable fixation versus titanium fixation in orthognathic surgery, according to the different types of surgery and directions of movement.

Materials and methods

Information sources and search methods

A review protocol was implemented in which two reviewers independently performed the study inclusion and data extraction procedures and the risk of bias assessment. Cohen's kappa statistic was used to assess the level of agreement between the two reviewers. Any disagreement was resolved through consultation with another reviewer.

A search of the literature was performed using the MEDLINE (from 1946 to January 6, 2017), Embase (from 1974 to January 6, 2017), and Cochrane Library (from inception to January 6, 2017) databases, including conference abstracts and dissertations. The search strategy combined medical subject heading (MeSH) terms with free-text words. The main search terms were 'bioresorbable', 'titanium', 'fixation', and 'orthognathic surgery'. Relevant journals and the reference lists of articles included in the review were also searched for additional material. After the initial electronic search, the titles and abstracts of the records identified were screened, following which the full texts of relevant articles were retrieved. There were no unclear or missing data in these articles.

Study selection

The study inclusion criteria were set according to the PICOS format: (1) the population (P) comprised all patients, without limitation on sex or race, aged 16–45 years, who were treated with orthognathic surgery; the surgery types and directions included maxillary advancement, maxillary setback, maxillary elongation, maxillary impaction, mandibular advancement (mandibular clockwise rotation), and mandibular setback (mandibular counter-clockwise rotation). (2) The intervention (I) group patients received bioresorbable fixation during surgery. (3) The control (C) group patients received titanium fixation during surgery. (4) The outcome indicators (O) included maxillary horizontal, maxillary vertical, mandibular horizontal, and mandibular angular follow-up relapse of reference landmarks and angles. (5) The study type (S) included randomized controlled trials, clinical controlled trials, and cohort studies.

The study exclusion criteria were as follows: (1) duplicate publication; (2) patients with maxillofacial fractures. A flow diagram of the study inclusion process is given in Fig. 1.

Assessment of methodological quality

As all of the studies included were cohort studies, the Newcastle–Ottawa scale was employed to assess the risk of bias[15]. The star system was applied to assess each study based on three broad perspectives: selection of the study groups, comparability of the groups, and ascertainment of the outcome of interest.

Data extraction

Data were extracted from the studies using a form. The following data were collected: the first author and year of publication; the country where the study was conducted; study type; number of participants in the intervention (bioresorbable/Bio) and control (titanium/Ti) groups; group allocation; sex (% male) of the participants; mean age; surgery types and directions; lateral cephalometric reference landmarks; duration of follow-up.

Statistical analysis

The analysis was conducted using Review Manager software (RevMan version 5.3; The Nordic Cochrane Centre, Copenhagen, Denmark, 2014). To evaluate heterogeneity, the proportion of between-study inconsistency was estimated with the I^2 statistic. If $I^2 > 50\%$ and $P < 0.10$, the causes were analyzed. The random-effects model was adopted for meta-analysis when heterogeneity was high ($I^2 > 50\%$), otherwise the fixed-effects model was used. The standardized mean difference (SMD) with 95% confidence intervals (CI) was calculated. This study used the SMD instead of the mean difference, due to the different time points of follow-up among studies; this is in accordance with the Cochrane guidelines. The level of statistical significance of this test was set at $p < 0.1$ (two-tailed Z-test). A sensitivity analysis was also conducted by omitting each study in turn, in order to evaluate the effect of the individual studies on the overall SMD. Since the number of studies included did not exceed 10, publication bias was not assessed.

The GRADE system (GRADE Working Group, 2004) was applied to describe the quality of the evidence and strength of clinical recommendations[16]. This quality rating includes categories of high, moderate, low, and very low.

Results

Identification and characteristics of the studies

Following the screening and selection process, a total of 10 articles reporting 10 cohort studies were included[17–26]. Four of