Use of resorbable implants for mandibular fixation: a systematic review

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CRD summary
This review concluded that there was some evidence concerning possible indications of resorbable fixation methods for mandibular fractures, but no conclusive evidence to indicate their effectiveness. Despite some concerns about the review and a risk that relevant studies were missed, the authors’ conclusions appear appropriate given the limitations of the included evidence.

Authors’ objectives
To evaluate the effectiveness of resorbable implants and indications for their use for treatment of mandibular fractures and osteotomies.

Searching
MEDLINE via PubMed, The Cochrane Library, DARE, NHS EED, HTA and American College of Physicians Journal Club were searched for studies published between January 1990 and October 2007; the authors stated that first-generation biomaterials were not in use until the early 1990’s. Search terms were reported. A Google internet search was performed to locate unpublished meta-analyses and systematic reviews. Reference lists of retrieved articles were searched for additional studies. Only studies published in English were included in the review.

Study selection
Clinical studies that assessed use of any type of resorbable implant for treatment of mandibular fractures of the angle, symphysis or subcondylar regions or mandibular osteotomy were eligible for inclusion in the review. Patients with risk factors such as alcohol or tobacco use were included. Participants were not restricted by age, but syndromic patients or those with combination fixation, bimaxillary osteotomies or cancer were excluded from the review. Computer simulation studies were excluded. Studies had to report sufficient data to assess outcomes that included morbidity or resorbable device success. Studies that focused on finite element analysis, distraction osteogenesis or laboratory biomechanical testing were excluded.

Most included studies used plates and screws for mandibular fixation; the rest used screws only. The most commonly used implant was made from 70% poly-L-lactic acid and 30% poly-D, L-lactic acid (PLLA 70/PDLLA 30). Other implants included those made from 100% PLLA (half of which used strength reinforced PLLA; SR-PLLA) and those made from 82% PLLA and 18% polyglycolic acid (PLLA82/PGA18). Studies involved 10 different implant manufacturers, which included LactoSorb, Walter Lorenz Surgical, Biofix and BioSorbFX. In most studies mean age of participants was not reported; where reported, mean age ranged from 23.1 to 32.1 years (range six months to 83 years). Most patients underwent open reduction and internal fixation (ORIF) for treatment of a mandibular fracture (type of fracture varied between studies) or bilateral split sagittal osteotomy (BSSO) for advancement. Forty-two percent of studies included patients other than those who underwent mandibular surgery. Mean follow-up ranged from three to 348 weeks. Reported outcomes included incidence of infections, foreign-body reactions, malocclusions, malunions and premature plate removals.

Studies were assessed for inclusion by two independent authors. Discrepancies were resolved through consensus.

Assessment of study quality
It was unclear whether the authors performed a formal assessment of study quality, but they discussed the quality of included studies with reference to dropout rates, outcome reporting, reporting of baseline patient characteristics, patient numbers and reporting of intraoperative techniques. The number of authors involved in performing this assessment was not reported.

Data extraction
Data were extracted independently by two reviewers. The numbers of events per treatment arm for each outcome were reported.
Methods of synthesis
Studies were combined in a narrative synthesis due to the presence of a high level of heterogeneity.

Results of the review
Nineteen studies (n=438) were included in the review; one was a randomised controlled trial (RCT). A total 326 patients were treated with plates and 112 were treated with screws alone. No studies reported dropout rates. Only five studies clearly reported their inclusion/exclusion criteria. Only four studies recorded individual patient data using a chart format. The RCT compared bioresorbable implants including titanium and the effects of bioresorbable implants alone could not be determined. The RCT included patients who required fixation of a variety of craniofacial structures.

Patients who received fixations that involved both plates and screws: There were 14 to 15 infections reported (eight studies, one of which did not report data clearly), two foreign-body reactions (reported in two studies of PLLA implants), seven malocclusions (in four studies), eight malunions (in three studies of PLLA 70/DLLA 30 implants) and eight to 10 premature removals (reported in six studies, one of which did not clearly report data). One patient required revisional surgery.

Patients who received fixations that involved screws only: There was one foreign body reaction and two malocclusions reported (in two studies).

Authors' conclusions
There was some evidence concerning possible indications of resorbable fixation methods for mandibular fractures, but no conclusive evidence to indicate their effectiveness.

CRD commentary
This review answered a clearly defined review question using a wide range of study designs. A number of appropriate sources were searched for relevant studies. Only studies published in English were included in the review, which suggested a risk of publication and language biases. Searches were limited to a specified time period and reasons for this were reported. Attempts were made to reduce reviewer risk and error during study selection and data extraction. It was unclear whether a formal assessment of study quality was applied and if so how many reviewers performed the assessment; the authors discussed the quality of the evidence and highlighted a number of important methodological limitations, which suggested that included data was not reliable. Only one study used a randomised controlled design and the rest used a mixture of prospective and retrospective designs. The studies varied greatly with respect to their populations, interventions and outcomes and so the authors’ use of a narrative synthesis appeared appropriate. The reporting of the review findings was not always clear with respect to outcome data and study design and there appeared to be some discrepancies between data in the text and tables with regard to patient numbers. Overall, despite some concerns about the review and the risk that relevant studies may have been missed, the authors’ conclusions appear appropriate given the limitations of the included evidence.

Implications of the review for practice and research
Practice: The authors did not state any implications for practice.

Research: The authors stated that further well-constructed randomised controlled trials of bioresorbable implants for mandibular fixation were required. Studies should be designed to separately investigate use of bioabsorbable and titanium plates for open reduction and internal fixation secondary to fractures in adults and children. Studies should use a minimum follow-up period of one year and when carried out in paediatric patients, should include a detailed analysis of cranial growth using cephalometric studies. All studies should record details of individual patient characteristics using specifically designed patient charts as used in previously published studies.

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