Maxillofacial traumatology and orthognathic surgery are major fields of oral and maxillofacial surgery. Internal rigid fixation systems, i.e. plates and screws, are used for fixation and stabilization of osteotomized or fractured bone segments. Plates and screws are generally made of titanium and are currently regarded as the golden standard. However, titanium devices also have disadvantages. They interfere with radiotherapy and imaging techniques. Besides, titanium implants have been associated with complications such as growth restriction and brain damage, infection, and possible mutagenic effects. A second intervention to remove the implants implies additional surgical discomfort, risks, and associated socio-economical costs. Biodegradable osteofixation systems have the possibility to degrade, thus preventing the need for a second intervention. Another advantage of biodegradable devices is their radiolucency, implying good compatibility with radiotherapy and imaging techniques. Since the introduction of biodegradable devices in 1966, the development of their mechanical properties and degradation characteristics has been extensive. Numerous in vitro, animal, and clinical studies have been published with positive as well as negative results. Despite the supposed advantages of biodegradable osteofixation devices, these systems did not replace the titanium systems and are currently applied in only limited numbers. The mechanical properties are less favourable and ultimate resorption has not been proven. Another significant factor of the limited use is the resistance by surgeons to modify their conventional, well experienced, treatment techniques. The major drawback for general use of biodegradable devices is the lack of clinical evidence. The general aim of this thesis was to establish the effectiveness and safety of biodegradable plates and screws to fix bone segments in the maxillofacial skeleton as a potential alternative to metallic ones.

Chapter 2 comprises a systematic review of the available literature to determine the clinical efficacy and safety of biodegradable devices compared with titanium devices in oral and maxillofacial surgery. A highly sensitive search in the databases of MEDLINE (1966-2005), EMBASE (1989-2005), and CENTRAL (1800-2005) was conducted to identify eligible studies. The relevance of studies was evaluated by a first selection based on title and abstract. Eligible studies were independently evaluated by two assessors using a quality assessment scale. The procedure revealed four methodologically ‘acceptable’ articles. Owing to the different outcome measures used in the studies, it was impossible to perform a meta-analysis. Therefore, the major effects regarding the stability and morbidity of fracture fixation using titanium and biodegradable fixation systems were qualitatively described. Firm conclusions regarding the fixation of traumatically fractured bone segments cannot be drawn due to the lack of controlled clinical trials. Regarding the fixation of bone segments in orthognathic surgery, only a few controlled clinical studies are available. There does not appear to be a significant short-term difference between titanium and biodegradable fixation systems regarding stability and morbidity. However, definite conclusions, especially with respect to the long-term performance of biodegradable fixation devices used in maxillofacial surgery, cannot be drawn.

Chapter 3 focuses on the mechanical characteristics of biodegradable versus titanium plates and screws. In chapter 3.1 the differences in maximum torque for 7 commercially available biodegradable and 2 commercially available titanium screw systems were investigated. Besides, the differences of maximum torque between ‘hand tight’ and break of the screws were investigated. Four oral and maxillofacial surgeons inserted 8 specimens of all 9 screw systems in polymethylmethacrylate (PMMA) plates. The surgeons were instructed to insert the screws as they would have done in the clinic (‘hand tight’). The data were recorded by a torque measurement meter. A PhD resident inserted 8 specimens of the same set of 9 screw systems until fracture occurred. The maximum applied torque was recorded likewise. The mean maximum torque of the 2 titanium screw systems was significantly higher than that of the 7 biodegradable screw systems. Besides, the mean maximum torque for ‘hand tight’ was significantly lower than for break regarding 2 biodegradable, and both titanium screw systems. Based on the results, we conclude that the 1.5- and 2.0 mm titanium screw systems still present the highest torque strength compared to the biodegradable screw systems. When there is an intention to use biodegradable screws, with regard to their mechanical characteristics, we recommend the use of 2.0 mm BioSorb FX, 2.0 mm LactoSorb or the 2.5 mm Inion CPS screws.

In chapter 3.2.1 and 3.2.2 relevant mechanical data is presented in order to simplify the selection of an osteofixation system for situations requiring immobilization in oral and maxillofacial surgery. Seven biodegradable and 2 titanium osteofixation systems (chapter 3.2.1) and the SonicWeld Rx biodegradable osteofixation system (chapter 3.2.2) were investigated. The SonicWeld Rx system uses an ultra-sound activated sonic electrode to insert the biodegradable pin into the borehole. As a result of the added ultra-sound energy, the thermoplastic biodegradable pin will melt, resulting in a flow of biodegradable polymers into the cortical bone layer and the cavities of the cancellous bone. At the same time the biodegradable plate and pinhead fuse. The plates and screws were fixed to 2 polymethylmethacrylate (PMMA) blocks to simulate bone segments. The plates and screws were subjected to tensile, side bending, and torsion tests. During tensile tests, the strength of the osteofixation system was monitored. The stiffness was calculated for the tensile, side bending, and torsion tests. The results were that the two titanium systems (1.5 mm and 2.0 mm) presented significantly higher tensile strength and stiffness compared to the 7 biodegradable systems (2.0 mm, 2.1 mm, and 2.5 mm) presented in chapter 3.2.1. The 2.0 mm titanium system revealed significantly higher side bending and torsion stiffness than the other 7 systems. Regarding the SonicWeld Rx biodegradable plates and screws (chapter 3.2.2), the tensile strength and stiffness as well as the side bending stiffness of that system presented up to 11.5 times higher mean values than the conventional biodegradable Resorb X system. The torsion stiffness of both systems presents similar mean values and standard deviations. Based on the results of the current study, it can be concluded that the titanium osteofixation systems were (significantly) stronger and stiffer than the biodegradable systems. The BioSorb FX,
LactoSorb, and Inion CPS 2.5 mm systems have high mechanical device strength and stiffness compared to the investigated biodegradable osteofixation systems. In addition, the results presented in chapter 3.2.2 yielded that the SonicWeld Rx system is an improvement in the search for a mechanically strong and stiff biodegradable osteofixation system. Future research should be done in order to find out whether the promising in vitro results can be transferred to the in situ clinical situation.

Chapter 4 comprises a randomized controlled trial regarding the effectiveness and safety of biodegradable plates and screws as a potential alternative to metallic ones. The multi-centre RCT was conducted from December 2006 to July 2009. Included were patients who underwent mandibular- and Le Fort I osteotomies and those with fractures of the mandible, maxilla, or zygoma. The patients were assigned to a titanium control-group (KLS Martin) or to a biodegradable test-group (Inion CPS). The primary outcome measure was ‘bone healing 8 weeks after surgery’. The Intention To Treat analysis (ITT) of 111 patients in the titanium group and 112 patients in the biodegradable group yielded a non-significant difference. In 25 patients (22%) who were included in the biodegradable group, the surgeon made the decision to switch to the titanium system per-operatively. Concerning most of the secondary outcome measures, the biodegradable system appeared to be non-inferior to the titanium system. In contrast, the handling characteristics showed a remarkable difference between both systems whereby biodegradable plates and screws were more difficult in use as compared to titanium plates and screws. Despite the ‘non inferior’ primary outcome result, the benefits of using biodegradable systems (less plate removal operations) should be demonstrated during a follow-up of minimally 5 years, especially when the large number of patients for whom it was per-operatively decided to switch from the biodegradable system to the conventional titanium system, are taken into account.

The main research outcomes are discussed and general conclusions are drawn in chapter 5. Based on the results of the RCT performed in this thesis, it is concluded that biodegradable plates and screws do not perform inferior to titanium regarding a follow-up period of 8 weeks. The high percentage of per-operative switches from biodegradable to titanium is a threat to a widespread acceptance of biodegradable plates and screws in the current treatment protocols and guidelines in maxillofacial surgery. The follow-up period of 1 year is expected to provide more clarity about the potential differences in plate removal operations and thus the potential gain in effectiveness in the treatment of fractures and osteotomies of the maxillofacial skeleton. The 1 year follow up results will also provide more information about the skeletal stability, biocompatibility, and resorption aspects of Inion CPS plates and screws.