Dissertation

Comparison of TriLock Bridging Plates with conventional Bridging Plates in the context of complex mandibular reconstruction

submitted by

Dr. med. univ. Dr. med. dent.
Gernot Ernst STEYER

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Division of Oral and Maxillofacial Surgery

under the Supervision of

Research Professor Priv.-Doz. Dr. med. univ. Dr. med. dent. Dr. scient. med.
Jürgen WALLNER

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Declaration of Academic Integrity

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Graz, 17.01.2026 Gernot Ernst Steyer e.h.

I dedicate this dissertation to the most important people in my life, my beloved wife Elisabeth and our two wonderful children, Gerald Ernst and Elina Gloria, who always promote me and made this work feasible.

Throughout my life, I have received tremendous support from my parents, for which I am deeply grateful.

Disclosures

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practice humility

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Colleagues who contributed to this dissertation and to the realization of this project:

Univ.-Prof. Priv.-Doz. DDr. Wolfgang Zemann
Head of Division of Oral and Maxillofacial Surgery, Clinic for Dental Medicine and Oral Health, Medical University Graz

Research Prof. Priv.-Doz. DDDr. Jürgen Wallner
First Deputy Head of Division of Oral and Maxillofacial Surgery, Clinic for Dental Medicine and Oral Health, Medical University Graz

Priv.-Doz. DDDr. Michael Schwaiger
Second Deputy Head of Division of Oral and Maxillofacial Surgery, Clinic for Dental Medicine and Oral Health, Medical University Graz

ao. Univ.-Prof. Dr. Stephan Spendel
First Deputy Head of Division of Plastic, Aesthetic and Reconstructive Surgery, Medical University Graz

OA Dr. Mauro Pau
Division of Oral and Maxillofacial Surgery, Clinic for Dental Medicine and Oral Health, Medical University Graz

DDr. Marcus Rieder
Division of Oral and Maxillofacial Surgery, Clinic for Dental Medicine and Oral Health, Medical University Graz

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Abbreviations and Definitions

AAOMS	American Association of Oral and Maxillofacial Surgeons
ASTM	American Society for Testing and Materials
BRONJ	Bisphosphonate Related Osteonecrosis of the Jaw
CBCT	cone-beam computed tomography
CI	confidence interval
CRF	case report form
CT	computed tomography
DCIA bone flap	Deep circumflex iliac artery bone flap
DRKS	Deutsches Register Klinischer Studien
G	grading
HR	hazard ratio
ICU	intensive care unit
ID	identification number
IQR	interquartile ranges
MCS	mental component summary
MMF	maxillomandibular fixation
MRONJ	Medication Related Osteonecrosis of the Jaw
MUG	Medical University Graz
NYHA	New York Heart Association
ONJ	osteonecrosis of the jaw
OPG	orthopantomogram
ORIF	Open Reduction and Internal Fixation
ORN	Osteoradionecrosis
PCS	physical component summary
PEG	Percutaneous Endoscopic Gastrostomy-tube
POC	point of care
PSI	patient specific implant
QoL	Quality of Life
R	resection margin
SF-36	short form 36
TNM	tumour, node, metastasis
UICC	Union for International Cancer Control
2D	2-dimentional
3D	3-dimentional

Abstract

This study aims to compare two different osteosynthesis plate systems in the context of complex mandibular reconstruction with regard to their safety, applicability, the surgeon's satisfaction, as well as the Quality of Life of the patients affected, with a postoperative follow-up period of one year per patient. It was conducted at the Medical University of Graz, Clinic for Dental Medicine and Oral Health, Division of Oral and Maxillofacial Surgery, between 2019 and 2024 and was set as a prospective, single-blinded, randomized controlled clinical trial. 40 patients included were randomly assigned to either the intervention group (MODUS 2 Mandible TriLock Bridging Plate System: n = 20) or the control group (MODUS 2.5 Locking Reconstruction Plate System: n = 20). The results were evaluated using multiple assessments at determined time points, including clinical and radiographic complication rates, intraoperative usability assessment by the surgeons and patient-reported Quality of Life.

The primary outcome measures were assessed over a 12-month postoperative follow-up period (at 2, 3, 6, 9, and 12 months) and overall the use of the intervention plate was associated with a significantly decreased risk of complications (HR 0.36, 95% CI 0.14-0.95) in the categories examined, such as *plate exposure*, *plate removal*, *infection*, *non-unification of the mandibular bone*. There was no event of *plate fracture* or *plate and screw migration* neither in the intervention group nor in the control group.

The secondary outcome measures showed significantly improved intraoperative usability of the intervention plate in most categories (*intraoperative adaptability to the bone*, *time to adapt the plate to the bone*, *range of plates*, *range of screws*, *trimming of the plate* and *contouring of the plate*) examined (Wilcoxon signed-rank test: $p < 0.05$), only *range of drill holes* did not show significant differences ($p=0.066$). The time required for trimming and adapting the plate was less in the intervention group compared to the control group (Wilcoxon rank sum test, $p = 0.447$).

Quality of Life improved over time in both groups, with higher scores in the intervention group at the measurement times 6 and 12 months postoperatively.

For complex mandibular reconstruction, the examined novel grid-structured plates generate fewer complications and offer improved intraoperative usability compared to the conventional reconstruction plate system.

Zusammenfassung

Ziel dieser Studie war es zwei unterschiedliche Osteosyntheseplattensysteme bei komplexen Unterkieferrekonstruktionen zu vergleichen hinsichtlich ihrer Sicherheit, Anwendbarkeit, Zufriedenheit der Operateure sowie der Lebensqualität der betroffenen Patienten. Jeder Patient wurde postoperativ ein Jahr nachbeobachtet. Die Studie wurde zwischen 2019 und 2024 an der Universitätsklinik für Zahnmedizin und Mundgesundheit der Medizinischen Universität Graz, Abteilung für Mund-, Kiefer- und Gesichtschirurgie, als prospektive, einfachblinde, randomisierte, kontrollierte klinische Studie durchgeführt. Die 40 eingeschlossen Patienten wurden entweder der Interventionsgruppe (MODUS 2 Mandible TriLock Bridging Plate System: n = 20) oder der Kontrollgruppe (MODUS 2.5 Locking Reconstruction Plate System: n = 20) zugeteilt. Die Ergebnisse wurden anhand verschiedener Kriterien zu bestimmten Zeitpunkten evaluiert, darunter die klinische und radiologische Komplikationsrate, die intraoperative Beurteilung der Anwendbarkeit durch die Operateure und die patientenevaluierte Lebensqualität. Die primären Endpunkte wurden über einen postoperativen Nachbeobachtungszeitraum von 12 Monaten (nach 2, 3, 6, 9 und 12 Monaten) erfasst. Insgesamt zeigte das Osteosyntheseplattensystem der Interventionsgruppe ein signifikant verringertes Komplikationsrisiko (HR 0.36, 95 % CI 0.14-0.95) in den untersuchten Kategorien wie *freiliegende Platte*, *Plattenentfernung*, *Infektion* und *fehlende Knochenheilung*. Weder in der Interventionsgruppe noch in der Kontrollgruppe traten *Plattenbruch* oder *Platten- und Schraubenbewegungen* auf. Die sekundären Endpunkte zeigten eine signifikant verbesserte intraoperative Anwendbarkeit in den meisten der untersuchten Kategorien (*intraoperative Adaptation der Platte an den Knochen*, *erforderliche Zeit zur Plattenanpassung*, *verfügbare Plattenvarianten*, *Schraubenposition*, *Plattenzuschnitt* und *Plattenkonturierung*) (Wilcoxon-signed-rank test: $p < 0.05$). Lediglich das *Angebot der Bohrlöcherpositionen* zeigte keinen signifikanten Unterschied ($p = 0.066$). Der Zeitaufwand für das Zuschneiden und Anpassen der Platte war in der Interventionsgruppe geringer als in der Kontrollgruppe (Wilcoxon-rank sum test, $p = 0{,}447$). Die Lebensqualität verbesserte sich im Zeitverlauf in beiden Gruppen, wobei die Werte in der Interventionsgruppe höher waren zu den Messzeitpunkten 6 und 12 Monate postoperativ. Bei komplexen Unterkieferrekonstruktionen zeigen die neuartigen, gitterstrukturierten Platten weniger Komplikationen und eine verbesserte intraoperative Anwendbarkeit, im Vergleich zu dem etablierten Rekonstruktionsplattensystem.

Introduction

General introduction

The present study was conducted at the Medical University of Graz (MUG), Clinic for Dental Medicine and Oral Health, Division of Oral and Maxillofacial Surgery, between 2019 and 2024 and was set as a prospective, single-blinded, randomized controlled clinical trial. Two different osteosynthesis plate systems used in complex mandibular reconstruction surgery were compared with each other with regard to their safety, applicability, the surgeon's satisfaction, as well as the Quality of Life (QoL) of the affected patients, with a follow-up period of one year per patient. The results were evaluated through multiple assessments of complication rates, an intraoperative evaluation of usability by the surgeons and a patient-reported assessment of Quality of Life over time at determined points in times.

Graz, with approximately 300.000 inhabitants, is Austria's second-largest city. The University Hospital serves as a tertiary care hospital, serving the Styrian region and parts of the neighbouring federal states with about 1.5 million inhabitants in total. All interventions and follow-up assessments were conducted at the University's facilities, providing a consistent and high-quality framework for study documentation.

The responsibilities of the Division encompasses the entire spectrum of Oral and Maxillofacial Surgery. Due to the wide range of surgical procedures, a wide variety of symptoms are diagnosed and patients treated in clinical practice every day. Surgical procedures are often necessary as part of medical treatment. For this purpose, the clinical division has access not only to modern techniques, equipment, and infrastructure, but also to a dedicated inpatient unit.

As the recruited patients of this present study, patients present themselves in our clinic with complex medical conditions often. Hence we have a very good interdisciplinary cooperation with other disciplines, clinics and practicing specialists.

Various diseases such as severe trauma, osteonecrosis or tumour resection can lead to residual mandibular continuity defects. These defects cause functional and aesthetic impairment for the affected patients and so reduce the Quality of Life. To avoid this a reconstruction of the defect in originally condition, containing diverse treatment approaches, is aspired (Fernandes & Yetzer, 2013; Wallner et al., 2022).

Large defects can cause functional problems in speech, swallowing, mastication or breathing for the patient (Kakarala et al., 2018; Quadri & McMullen, 2023). In combination with aesthetic impairment and therefrom resulting restrictions even in everyday life, a loss of Quality of Life consists either temporary, postoperative or maybe permanent (Woliansky et al., 2023).

The ideal reconstruction of a segmental defect of the mandible aims to restore the height and width of the missing part anatomically, restores soft tissue and replaces the missing dentition so the reconstructed mandible has the meant form and so can withstand the forces acting on it during function (Schrag et al., 2006; Wong, R. C. W. et al., 2009). The main goals that surgeons have to achieve with their therapies are an anatomical restitution, immobilization, the prevention of an infection and rehabilitation of the function (Singh et al., 2012).

Currently a wide range of mandibular reconstruction plates are available in various designs, differing in both, structural thickness and the materials used. But there is no universally accepted gold standard for the optimal design or geometric configuration of these devices at present despite the crucial role of these reconstruction plates in reconstructive mandibular surgery (Ferreira et al., 2015; Rahimov & Farzaliyev, 2011; Singh et al., 2012). This lack of consensus underscores the continued need for broad biomechanical and clinical investigations.

Although technological advances have enabled the fabrication and commercial availability of modern, patient-specific, computer-guided plates, clinical practice is currently still predominantly based on conventional, manually contoured plates shaped intraoperatively by the surgeon (Pfister et al., 2024; Rendenbach et al., 2017). As these traditional plates are versatile and easily accessible, they are unfortunately associated with a relatively high incidence of postoperative complications. These complications include, among others, exposure of the plate by soft tissue, postoperative infections, and mechanical failures such as plate fractures (Falci et al., 2021; Seemann et al., 2010). These unfavourable consequences demonstrate a significant challenge to both surgical success and patient morbidity.

To get over these limitations associated to conventional plating systems, technological advances in the design and manufacturing of mandibular reconstruction plates have led to the development of precontoured bridging plate systems. These precontoured plates are engineered to more closely replicate the natural anatomical curvature and morphology of the mandibular segments they are intended to stabilize, thereby improving fit and reducing intraoperative

manipulation (Duttenhoefer et al., 2017; Probst et al., 2012). A notable example of this innovation is the MODUS 2 Mandible TriLock Bridging Plate System (Medartis AG, Basel, Switzerland). This system offers a comprehensive selection of anatomically pre-formed plates tailored to specific regions of the mandible, including the body, angle, and condylar regions. A distinctive feature of this system is its unique grid-like plate body design, which is intended to minimize the amount of implanted metal, potentially reduces soft tissue irritation, and promotes improved biomechanical behaviour (Peters et al., 2020).

The clinical efficacy and practicality of the MODUS 2 Mandible TriLock Bridging Plate System were pre-evaluated in a retrospective clinical study involving 25 patient cases. The reported results were positive, demonstrating satisfactory intraoperative handling and a remarkably low complication rate compared to existing literature on mandibular plate systems (Schwaiger et al., 2018). However, the methodological limitations of this study must be considered, including its retrospective nature and the lack of a randomized control group, which limits the validity and generalizability of the conclusions. These factors require the conduct of further prospective, controlled studies with larger patient cohorts to validate these initial results and provide more reliable clinical evidence for the use of this plate system (Gielisch et al., 2023; Schwaiger et al., 2018).

Following the excellent preparatory work in our division, this topic can be continued and further important aspects can be taken into account by this latest investigations.

Specific introduction

The mandible

The mandible is the largest and strongest bone in the human skull and the only one moveable. It has a U-shaped form, houses the lower teeth, and articulates with the maxillary teeth and temporal bone. This bone is divided into the following anatomical structures: respectively the left and right condyles, coronoid processes, ascending rami, angles, bodies and the symphysis (Hatcher, 2022; Kidwai & Lu, 2022).

When planning therapy and in reconstruction, important structures such as vessels, nerves, teeth, muscles and the temporomandibular joints must be taken into account because changes in anatomy or unintentional injuries can lead to serious consequences in rehabilitation for the patients affected (Schrag et al., 2006). Changes in shape or position can significantly affect the appearance of the face, as well as its functions such as eating, speaking, and breathing (Al-Moraissi et al., 2015; Probst et al., 2023).

Acquired defects resulting from external forces in trauma mainly arise from the front, side, or bottom act on the mandible causing the arch to bend up. At the point of force application, tensile stress and fractures occur in the corpus region on the inside, in the colla regiones tensile stress and fractures occur on the outside (Hausamen, 2012). Natural forces can act on the mandible from swallowing, chewing, or biting and have the effects of tension/compression, shear, torsion, and bending on the jaw. In detail the deformation of the mandibular body while loading can be described as a combination of sagittal bending, torsion and lateral transverse bending. The mechanical load capacity and forces acting on the mandible and on the osteosynthesis material are complex and not yet fully understood (Wong, R. C. W. et al., 2009).

These forces must be taken into account during the reconstruction of the mandible, but are also crucial for the loading of the corresponding osteosynthesis material (Bede et al., 2019; Meyer et al., 2007).

Diseases causing large mandible defects

- **Tumour disease**

Cancer of the oral cavity is a common malignancy not only in developing countries but also in developed countries. The most common histology we see is the squamous cell carcinoma with main aetiology factors such as alcohol, tobacco and a poor oral hygiene. Less frequently tumours arise from salivary glands, epithelium, connective tissue, lymphoid tissue, or even metastasis from distant tumours (Montero & Patel, 2016). Clinical examination, radiographic imaging and histological sampling is crucial for diagnosis (Abati et al., 2020; Fedele, 2009). Despite an easy self-examination and physical examination patients in our clinic often present with a processed stage of their disease or a very late referral from other specialist.

Formerly large segmental defects of the mandible were often not reconstructed and led to malocclusion, mandibular deviation and aesthetic impairment (He et al., 2011).

Nowadays, depending on location and size, the most common treatment is surgical resection and reconstruction with a microvascular graft, often in combination with a neck dissection and postoperative adjuvant therapy such as radiotherapy and/or chemotherapy. Depending on the size of the defect, primary closure is not always possible and reconstruction using microvascular flaps is required. Then different types of tissue such as soft tissue or bone must be replaced. To keep it in the correct place appropriate osteosynthesis material is essential. For adequate ventilation of the patient, a temporary tracheotomy is often required. Since food intake may be impaired by surgical and postoperative adjuvant therapy in some cases the insertion of a Percutaneous Endoscopic Gastrostomy-tube (PEG) is necessary (Kerawala et al., 2016; Palme et al., 2004).

The coordination of the treatment plan takes place within an interdisciplinary tumour-board. The correct classification of tumour stages is important, for this the TNM-classification (tumour, node, metastasis) is used. Numbers following the letters provide more precise information about the extent of the tumour (T0-4), the number and location of involved lymph nodes (N0-3), and the presence or absence of distant metastases (M0 and M1). Tx/Bx/Mx is used if it can’t be assessed, Tcis stands for the pre-stage named carcinoma in situ. The grading describes the degree of differentiation of the cells, here also numbers (G1-4) or Gx (no

assessing) are used for a more precise description. Staging of oral cavity cancer is performed according to the UICC-TNM (Union for International Cancer Control) classification of malignant tumours, which describes the anatomical extent of the disease in relation to the primary tumour, the presence of regional lymph node metastases, and distant metastases with organ involvement (German Guideline Program in Oncology, 2021).

The treatment plan depends on the location, size of the primary tumour, the patient's general condition, the expected treatment-related morbidity and the expected treatment success. The goal is to achieve permanent or at least as long-lasting locoregional tumour control with minimal functional or aesthetic impairment. The most important functions to be preserved or to be restored are breathing, speech, chewing and swallowing. The treatment should be generally carried out in accordance with the recent guidelines (Montero & Patel, 2016).

In squamous cell carcinoma a microscopic resection margin of 5 mm around the tumour is recommended according to the guidelines. To achieve an in-sano resection with a minimum microscopic margin of 5 mm around the tumour, a macroscopic margin of at least 10–15 mm around the visible tumour is required during surgery, as shrinkage of the soft tissue occurs in the removal. The deep margin is determined by preoperative imaging and intraoperative palpation (Wong, T. & Wiesenfeld, 2018).

- **Osteonecrosis of the jaw**

Bone is constantly being remodelled due to a balance between osteoclasts, that remove old bone material, and osteoblasts, that build new bone matrix. Disruptions to this process by external or internal factors can lead to functional impairment and thus to the development of osteonecrosis (Golu et al., 2023). Osteonecrosis of the jaw (ONJ) is a serious condition that manifests as necrotic bone lesions that are exposed to the oral cavity or can be accessed through an intraoral or extraoral fistula in the maxillofacial region. It lasts for eight weeks at least without responding to appropriate treatment. ONJ is more common in the mandible but can also affect both jaws. Patients suffer from pain, inflammation, and suppuration (Anastasilakis et al., 2021).

There are different stagings regarding clinical or radiographic aspects with corresponding step-by-step therapy plans. These stadium classifications can describe eighter the time course,

whether it is acute or chronic, or the clinical presentation, whether it is asymptomatic, infected, involves bone sequestration, or pathological fractures, etc., or the extend, whether it is superficial or deep-reaching. Treatment recommendations range from medical therapy only, through debridement and local therapy, to extensive reconstructions (Golu et al., 2023).

At the early 2000s, there were first descriptions of osteonecrosis of the jaw associated with the use of bisphosphonates (Durie et al., 2005; Marx, 2003). Since then, a lot of research was done at this field, different types were described and staging systems have been developed. Initially osteonecrosis of the jaw was associated with the drug administration of predominantly bisphosphonates and referred to as BRONJ (Bisphosphonate Related Osteonecrosis of the Jaw). Only later the acronym MRONJ (Medication Related Osteonecrosis of the Jaw) was introduced, as this takes more account of other causative medications also (Bedogni et al., 2024; Ruggiero et al., 2014).

According to Brzak osteonecrosis of the jaw is a condition where bone cells die due to various causes. These can be classified as follows:

Avascular osteonecrosis with a partial or complete loss of blood supply

Medication related osteonecrosis of the jaw (MRONJ): Osteonecrosis associated with the use of antiresorptive drugs

Osteoradionecrosis (ORN) mostly in patients with malignoma that received a radiation therapy

Traumatic osteonecrosis caused by physical, chemical, or thermal bone trauma

Non-traumatic osteonecrosis associated with infections, neoplasms, some autoimmune diseases, etc.

idiopathic osteonecrosis developed without an obvious etiological cause

The most common types seen are the MRONJ and the ORN (Lončar et al., 2023).

- Medication related osteonecrosis of the jaw (MRONJ)

As described in the updated American Association of Oral and Maxillofacial Surgeons (AAOMS) position paper, antiresorptive medication (bisphosphonates and monoclonal antibodies) and antiangiogenic medication are primarily responsible for MRONJ. Patients

affected show an exposed bone for longer than 8 weeks and have no history of radiation therapy. Treatment goals are the prioritization and support of continued oncologic treatment and the preservation of Quality of Life. Different stages are known (0-3) with a step-by-step therapy (Ruggiero et al., 2014).

- Osteoradionecrosis of the jaw (ORN)

Osteoradionecrosis of the jaw is considered a subgroup of ONJ. It is defined as exposed, irradiated bone that fails to heal within three months without evidence of persistent or recurrent tumours (Golu et al., 2023). It is a feared skeletal late complication of radiotherapy in head and neck cancer and proceeds and finally leads to a significant morbidity and a negative impact on Quality of Life (Fritz et al., 2024).

- **Severe mandibular trauma**

Mandible trauma arises from mechanical forces primarily. We can separate blunt force trauma (surface remains intact) from penetrating forces (destruction of external and internal tissues). If the elastic limit of the bone is exceeded directly or indirectly simple fractures, multiple fractures or fractures with loss of bone will occur (Horch, 2007).

About 65-70% of all craniomaxillofacial fractures affect the mandible. Large forces or combinations with other injuries as part of polytrauma often lead to multiple fractures of the mandible (Hausamen, 2012). The aetiology of maxillofacial trauma is constantly changing and varies according to socioeconomic status cultural characteristics, geographical location and the age of the patients affected. Causes of severe mandibular trauma include traffic accidents, accidental falls, assaults, occupational accidents or sporting injuries (Khan et al., 2022).

While conservative fracture treatment used to dominate long time ago even in the adult patients, nowadays contemporary methods and steadily new inventions led to surgical treatment predominately. Not only form and occlusion, but the entire function and aesthetics are the goal of rehabilitation and this in a way most possible atraumatic and caring about surrounding tissues. This was achieved by the permanent development of osteosynthesis material (Luhr, 2000; Sauerbier et al., 2008).

The clinical examination can show crepitation, dislocation due to contraction of the muscle or abnormal mobility as signs of a fracture. With existing teeth a malocclusion may be noticed. Lesions of nerves can cause hyposensitivity, lesions of vessels can cause haematoma or swelling. The radiographical diagnostic includes 2D (e.g. orthopantomogram) or 3D (e.g. computed tomography scan) imaging. To find the correct reduced position, occlusion can help in the dentulous area, in the edentulous patient this is very difficult and error-prone (Serebrakian et al., 2017).

The surgical procedure as consensus nowadays is the Open Reduction and Internal Fixation (ORIF) with osteosynthesis (Bera & Tiwari, 2022).

For fracture fixation we separate load-bearing and load-sharing osteosynthesis. Load-bearing osteosynthesis (mostly reconstruction plates) can bear all of the functional load of the mandible, which protects the bone from forces during healing. They are used in comminuted fractures, defect fractures, in cases of extreme atrophy or the lack of dental support (Serebrakian et al., 2017). Results can be enhanced by the use of locking screws, so these plates function as internal fixators (Herford & Ellis, 1998). In contrast, load-sharing osteosynthesis (mostly miniplates) refers to a fixation where the functional load is distributed between the osteosynthesis material and the bone. This requires sufficient bony support at the fracture site and cannot be used in comminuted fractures or defect fractures (Serebrakian et al., 2017).

In craniomaxillofacial surgery the maxillomandibular fixation (MMF) is a fundamental principle in the treatment and therapy of injuries that affect the jaws because it provides a stable base for restoring facial form and function. It rebuilds the patient’s premorbid occlusion assisting in the ORIF of defects (Coletti et al., 2007).

Osteosynthesis material

First reports of orthopaedic implants being used dates back to the end of the 18th century. Iron wires were initially used for internal fixation, followed by open reduction and internal fixation. Crucial to the success was the development of Joseph Lister's antiseptic system of wound treatment. The first internal fixation using plate and screws was described by Carl Hansmann in Hamburg in 1858. Among his first 15 documented fracture treatments with plates were also 2 mandibular fractures (Hernigou & Pariat, 2016). The first developments of plate systems worked just as retainers. This increased the fracture gaps and also led to necrosis when both fracture ends were held apart by the plates. By plates possessing long and slotlike holes developed by Collins, Eggers and Roosth the fracture ends could be approximated after the screws were inserted. This modification was to become the compression plate (Sauerbier et al., 2008). Plate osteosynthesis has revolutionized oral and maxillofacial surgery and made a three-dimensional reconstruction possible, from fracture treatment over orthodontic surgery, surgery of craniofacial deformities, to reconstructive procedures. Previously the jaws were immobilized rigid for weeks using dental splints and patients required an exclusively liquid diet. This led to further stress for the patient in addition to the actual affection (Luhr, 2000). Plates need to be adopted precise to the bone to prevent changes in the alignment of the segments but by locking screws to the plate this achieves stability and the plate does not need to contact the bone in all areas. So Locking-plate-and-screw-systems function as internal fixators. Additionally, it allows for fewer screws per segment. (Herford & Ellis, 1998).

There are to distinguish two types of osteosynthesis plates: on the one hand load-bearing and on the other hand load-sharing plates. Load-bearing plates can bear all of the functional load of the bone, which protects from forces during healing, while load-sharing plates refer to a fixation where functional load is distributed between the plate and the bone and requires a sufficient bony support (Serebrakian et al., 2017). However, excessive loading of bone grafts and osteosynthesis material often lead to plate fractures, screw loosening and bone loss, which can potentially lead to a pathological fracture of the mandible (Wong, R. C. W. et al., 2009).

In certain cases, the lag-screw technique can be used instead of plate osteosynthesis, because it ensures a good interfragmentary compression and restoration of the premorbid anatomical alignment of the fracture fragments. When inserting these long screws, care must always be

taken to consider the positional relationship of the inferior alveolar nerves in order not to injure them (Rao et al., 2019).

Titanium is well-proven and the typically material used in osteosynthesis systems, but occasionally, for example due to infection, it has to be removed again in a subsequent surgical procedure. Plates made of resorbable material can be used in certain indications or in growing children and adolescents (Agnihotry et al., 2017; Filinte et al., 2015).

Another distinction concerns the adaptation to the bone: plates can be conventionally bent intraoperatively, can have a pre-formed shape that allows for a simpler intraoperative adaption, and preoperatively planned and manufactured customized plates (Schwaiger et al., 2018).

Below an overview of the preparatory work is shown that is often performed in cases with large mandibular defects to increase the intraoperative reconstruction accuracy (Fig. 1):

Using three-dimensional imaging datasets, such as CT- or CBCT-scans, a 3D printer can be used to create a plastic model of the bone. This can be studied from all directions at leisure without any soft tissue getting in the way. The osteosynthesis material can then be carefully and precisely bent. Time is of the essence. Once the plate has the correct shape, it can also be trimmed preoperatively and sterilized for use in the planned surgical procedure, or it can be adjusted to the needed length intraoperatively.

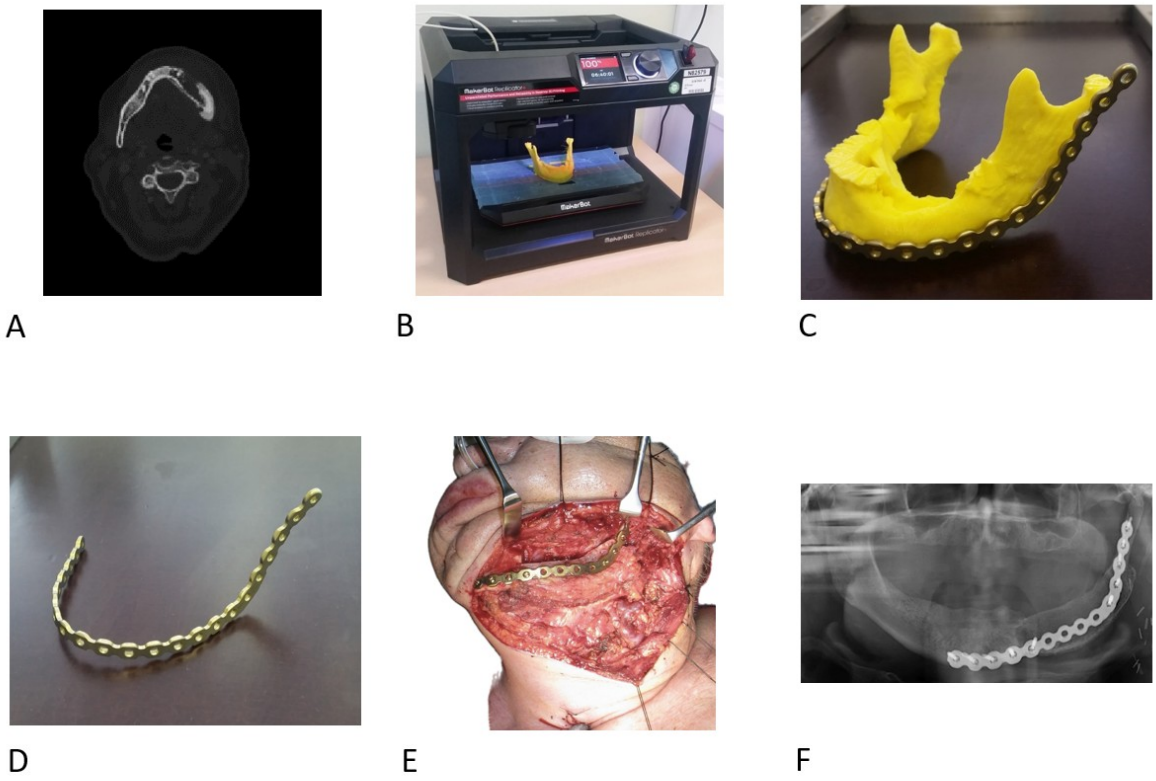


Fig. 1 *Preparatory work and clinical application as it is performed at the Division of Oral and Maxillofacial Surgery Graz, demonstrating mandibular reconstruction using the Modus 2.5 locking reconstruction plate. (A) The 3D data from the CT scan serves as the basis for the production of a model of the lower jaw, (B) which is manufactured using a 3D printer. (C) After studying the model precisely (D) the plate is adapted and after sterilisation (E) intraoperatively used. (F) The postoperative OPG showing the reconstruction with the used plate in situ.*

Quality of Life

Quality of Life (QoL) describes a complex construct of the individual's subjective assessment of the effects of diseases or treatment on physical, psychological, social and general well-being. To assess Quality of Life, precise and validated measurement instruments are used, consisting of self-report questionnaires designed to evaluate the impact of a pathology and its treatment on the patient's Quality of Life (Warshavsky et al., 2019). Historically, the outcomes of biomedical treatments, rather than the individual's Quality of Life, have been the primary outcome measures in medical and health research however more recently research has increasingly focused on the patient's Quality of Life, and the use of Quality of Life assessments has increased a lot. Not yet a standard has established for the questionnaires in the field of Quality of Life in medical studies so various questionnaires are used. Different questionnaires examine different aspects and the period of the survey also plays an important role (Haraldstad et al., 2019). We have to consider that a patient's assessment of Quality of Life is dynamic and often changing over time (Warshavsky et al., 2019).

The SF-36 Health Survey is a multi-purpose, short-form health survey. Thirty six questions divided in eight scales measure the patient’s physical and mental health. This questionnaire is not aimed at any specific age, disease, or treatment group. It has proven useful for comparing general and specific population groups and to differentiate between the burden of disease and the health benefits of different treatments. The translation into several languages made it internationally applicable and comparable in multicentre studies, so it has been established for decades now (Hays & Morales, 2001; Ware & Gandek, 1998).

The individuals are asked to fill out the questionnaire by themselves, available in both paper and computer formats, which will take a couple of minutes, then it will be scored by the examiner. Scores range from 0 to 100 for each domain, with a higher score defining a more favourable health status. The eight subscales consist of the sum scores of the assigned items (Patel, 2007).

The questionnaire with the 36 questions and the corresponding tick box options used in this study can be found in the appendix.

The eight sections:

- physical functioning
- physical role functioning
- bodily pain
- general health perceptions
- vitality (energy and fatigue)
- social role functioning
- emotional role functioning
- general mental health

Following Ware and Gandek the following questions can be assigned to the respective scales:

physical functioning (10 items: 3, 4, 5, 6, 7, 8, 9, 10, 11, 12), physical role functioning (4 items: 13, 14, 15, 16), bodily pain (2 items: 21, 22), general health perceptions (5 items: 1, 33, 34, 35, 36), vitality (4 items: 23, 27, 29, 31), social role functioning (2 items: 20, 32), emotional role functioning (3 items: 17, 18, 19), mental health (5 items: 24, 25, 26, 28, 30), a single item (2) additionally asks about the current state of health compared to one year ago.

Two summary measures can be constructed: the physical component summary (PCS) for self-perceived physical health and the mental component summary (MCS) for self-perceived mental health. To the PCS three scales contribute most (physical functioning, physical role functioning and bodily pain), to the MCS three scales contribute most (social role functioning, emotional role functioning and mental health), noteworthy correlations with both components are seen in three scales (vitality, general health perceptions and social role functioning) (Ware & Gandek, 1998).

Cases of this study

Two cases of this study demonstrating exemplary complex mandibular defects. Case one, assigned to the intervention group, treated using MODUS 2 Mandible TriLock Bridging Plate, case two, assigned to the control group, treated using MODUS 2.5 Locking Reconstruction Plate.

- **Case 1 (intervention group)**

A 51-year-old patient presented to our clinic with a squamous cell carcinoma in the right mandible. He was referred from another clinic where the initial examinations took place. There was a positive smoking and alcohol history, no secondary diagnoses relevant to surgery and no evidence of distant metastases. Based on the clinical and radiographic findings, the surgery was performed with a large mandibular resection and a microvascular reconstruction using a DCIA-bone flap (Deep Circumflex Iliac Artery) fixed with a MODUS 2 Mandible TriLock Bridging Plate including an ipsilateral neck dissection. In the area of the transplant locking-screws were used.

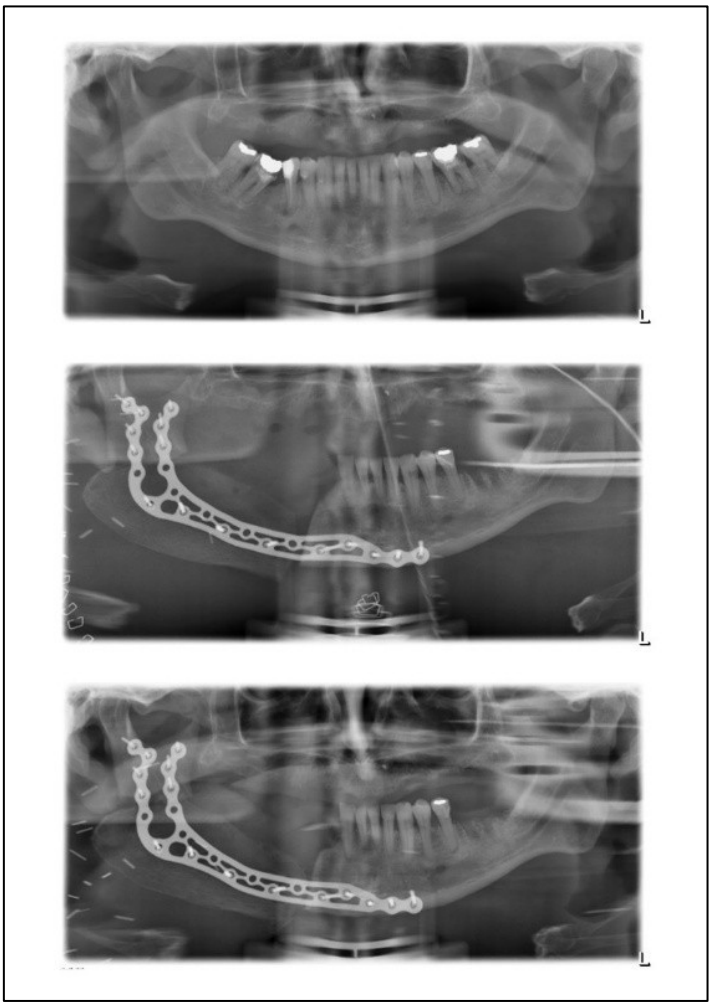


Fig. 2: *The x-ray images (orthopantomogram) show the progression over time. The first image shows the preoperative initial situation. The second image shows the inpatient stay after resection of the tumour, neck dissection and microvascular reconstruction, with still remaining nasogastric tube. The third image shows the final follow-up visit with the 12 months postoperative situation after healing.*

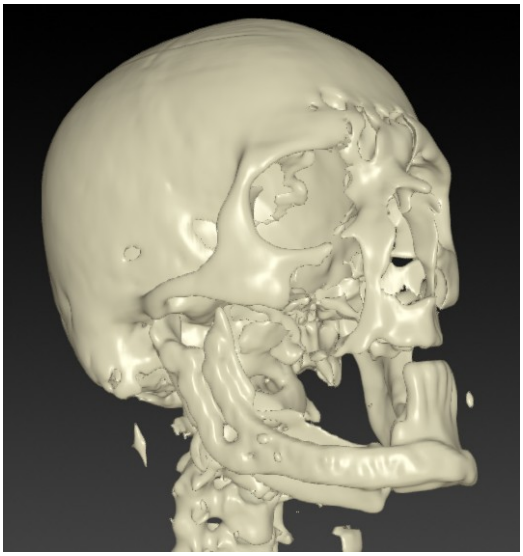


Fig. 3: *3D reconstruction of the postoperative situation with Modus 2 Mandible TriLock Bridging Plate System ready for the oral rehabilitation and further medical interventions.*

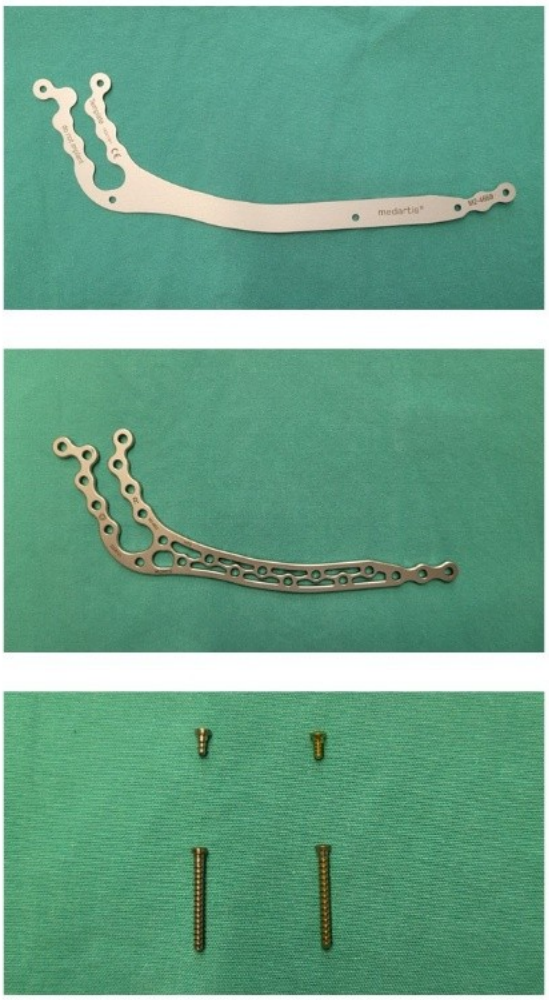


Fig. 4: *The following images show the items used intraoperatively including (1) template, (2) plate and (3) associated locking-screws on the left side and non-locking-screws on the right side.*

- **Case 2 (control group)**

A 36-year-old woman presented to our clinic with an extended osteoradionecrosis on the left side. There is a history of multiple tumour diseases with corresponding radiotherapy in the head and neck area, initially treated by the Division of Otorhinolaryngology of the Medical University of Graz. Based on the clinical and radiographic findings, the surgery was performed with a mandibular resection and a microvascular reconstruction using a scapular flap fixed with a MODUS 2.5 Locking Reconstruction Plate. Locking screws were used in the area of the transplant.

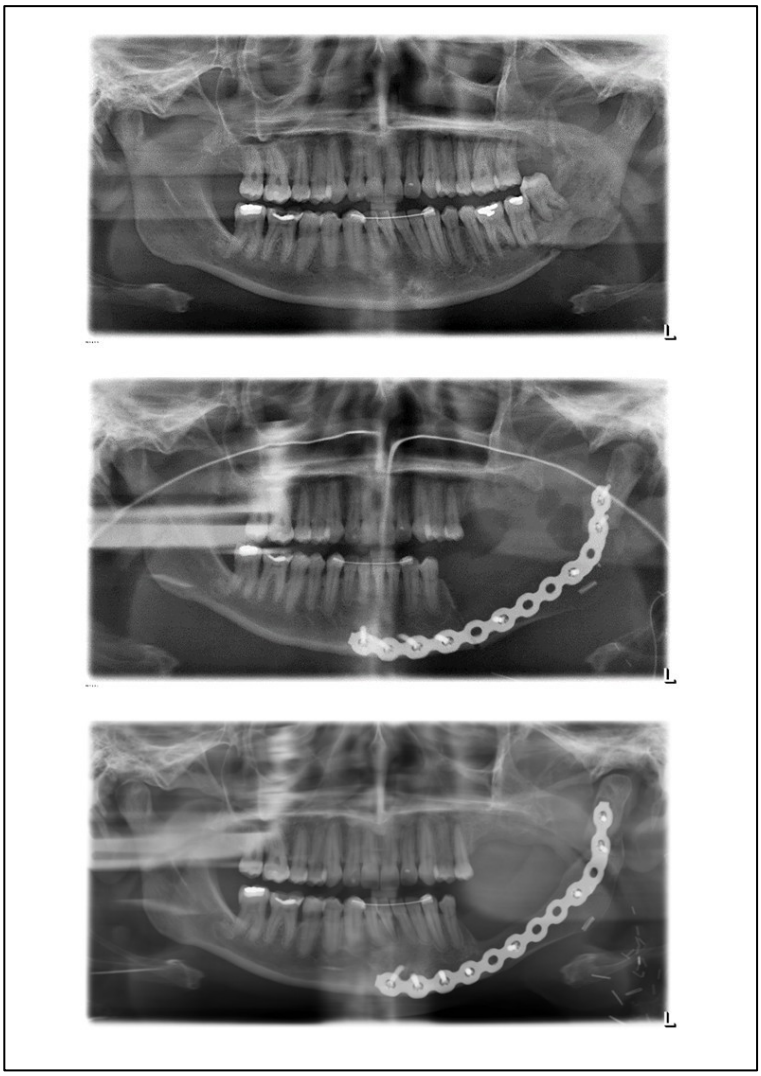


Fig 5: *The x-ray images (orthopantomogram) show the progression over time. The first image shows the preoperative initial situation with osteoradionecrosis. The second image shows the inpatient stay after mandible resection and reconstruction, with still remaining nasogastric tube. The third image shows the final follow-up visit with the 12 months postoperative situation after healing.*

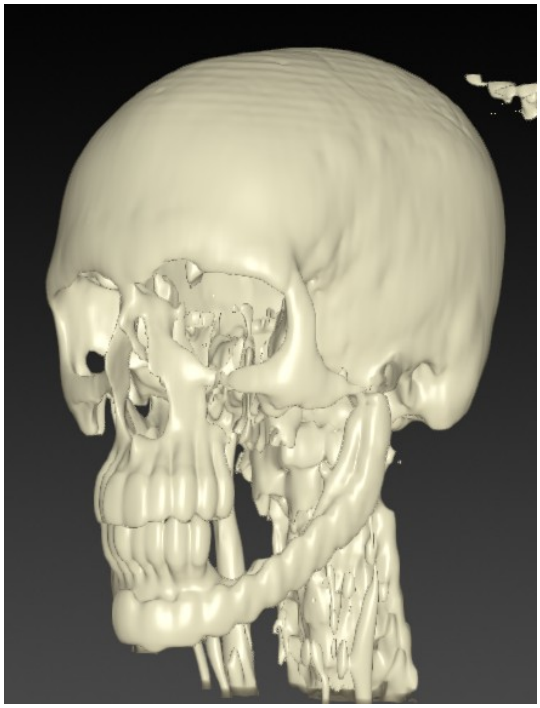


Fig. 6: *3D reconstruction of the postoperative situation with Modus 2.5 Locking Reconstruction Plate System.*

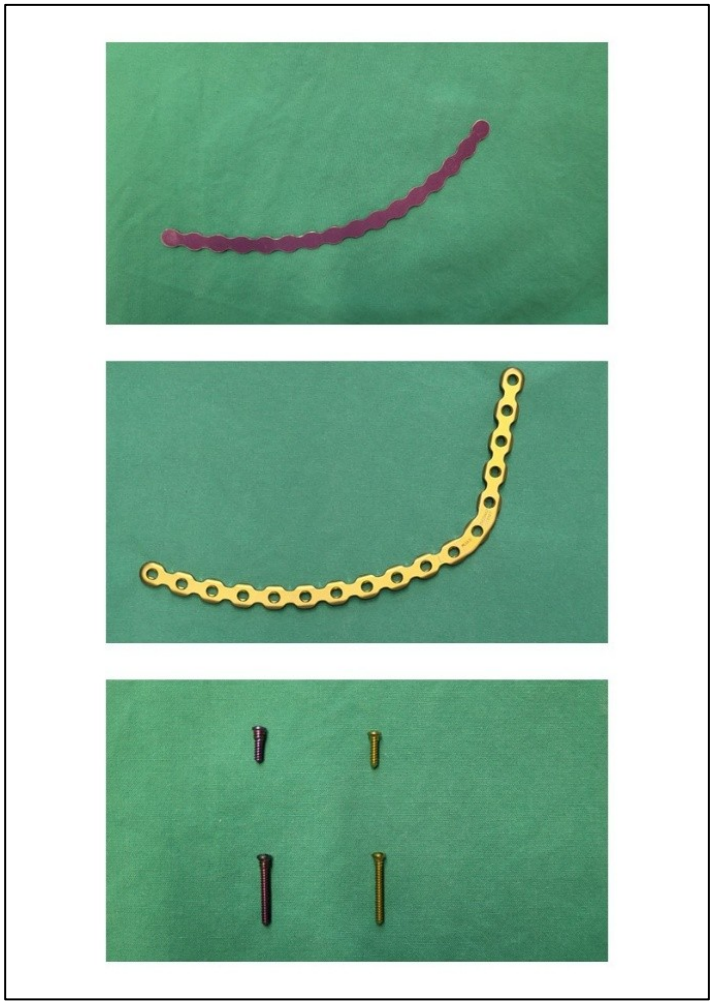


Fig. 7: *The following images show the items used intraoperatively including (1) template, (2) plate and (3) associated locking-screws on the left side and non-locking-screws on the right side.*

Justification of the research question

There are currently a variety of different osteosynthesis plate systems for mandibular reconstruction. Each of these systems has specific advantages and disadvantages, but to date there is no universally accepted gold standard in terms of design or geometry.

In general, the following three groups are distinguished (Schwaiger et al., 2018):

- conventional bendable plates
- pre-shaped plates, with appended bendable elements
- patient specific customized plates

As a practicing surgeon, one wants a system that is simple to use, precise in application, causes no complications does not require a long preparatory work and is affordable even in a high number of cases.

The mandible has a complex structure with a complicated movement pattern. The more it is important to have a sufficient treatment with stable conditions and few complications (Bede et al., 2019). The intraoperative precise adaption of the plate to the bone is a delicate and time-consuming process that can have a high inaccuracy (Bousleiman et al., 2012).

Osteosynthesis-plates are associated with a relatively high incidence of postoperative complications, not limited to plate exposure, infection, and/or fractures (Kakarala et al., 2018)

Even though nowadays modern technologies allows for patient-specific manufacturing of plates, manually formed plates are still the most commonly used fixation device so far (Abdulrazaq & Riyadh, 2019).

So further research in the field of mandibular plate systems is crucial. Apart retrospective clinical studies evaluating the clinical outcomes and intraoperative applicability of the MODUS 2.0 TriLock Bridging Plate System, to the author's knowledge of this study so far no further clinical studies have been conducted to investigate typical clinical parameters associated with the use of reconstruction plates. To ensure the highest level of evidence for the clinical application of MODUS 2.0 TriLock Bridging Plates, a prospective, single-blind, randomized, controlled trial is needed.

Aim of the study

The aim of this study is to provide a meaningful comparison of two different mandibular reconstruction plate systems with regard to defined clinical parameters.

- Primary aim

The primary aim is to compare the MODUS 2 Mandible TriLock Bridging Plate, *Medartis AG, Basel, Switzerland* (intervention group) with the MODUS 2.5 Locking Reconstruction Plate, *Medartis AG, Basel, Switzerland* (control group) regarding postoperative complications in a 12 months period.

- Secondary aims

The secondary aims are to compare these two plate systems regarding the intraoperative applicability and the patients' postoperative Quality of Life.

Hypotheses

Primary Null-hypothesis

- There will be no difference in the frequency and type of complications (safety) between the two plate systems.

Secondary Null-hypothesis

- There will be no difference in usability between the two plate systems
- There will be no difference in operating time between both plate systems
- There will be no difference in the duration of the inpatient stay
- There will be no difference in the patients' Quality of Life

Novelty value

Previous retrospective studies with small numbers of patients and/or the lack of a control group suggest a benefit for the surgeon and a benefit for the patient in terms of applicability and postoperative complications, but no prospective randomized controlled studies or data are currently available.

Material and Methods

Study design

This study was conducted as a prospective, single-blinded, single-center, randomized controlled trial with an allocation ratio of 1:1, comparing outcomes between two parallel groups.

In the Division of Oral and Maxillofacial Surgery at the Medical University of Graz, Austria, Europe, the MODUS 2 Mandible TriLock Bridging Plate, *Medartis AG, Basel, Switzerland* (intervention group) was used in parallel to the well-established MODUS 2.5 Locking Reconstruction Plate, *Medartis AG, Basel, Switzerland* (control group) during the study period from 2019 - 2024. The study involved 40 patients (male and female) distributed evenly in two groups (intervention group and control group) undergoing mandibular reconstruction and plate insertion, with a follow-up period of 12 months per patient from the insertion date to the final follow-up appointment.

Not only objective data but even so subjective data from the surgeons and subjective data from the patients were collected by questionnaires at determined timepoints.

Ethical approval

This study was first submitted to the Ethics Committee of the Medical University of Graz and was approved for the protocol and patient consent (31-158 ex 18/19).

German Clinical Trials Register

This monocentric study set in Graz, Austria, was registered at the DRKS – Deutsches Register Klinischer Studien and classified as a prospective study with the ID DRKS00017312.

Legal principles

In addition to the Declaration of Helsinki, the following guidelines and laws (in their current versions) had to be observed when conducting the study (e.g.): Medical Devices Act (MPG), EN 14155, ICH GCP Guideline, EU Directives 90/385/EEC, 93/42/EEC, 98/79/EC, etc.

The osteosynthesis material used in this study

Both bridging plate systems were used following standard surgical techniques by experienced oral and maxillofacial surgeons.

Control group

Patients assigned to the control group received the well established MODUS 2.5 Locking Reconstruction Plate, *Medartis AG, Basel, Switzerland*. As many years of experience at our division and the literature shows, this plate system has demonstrated favorable long-term outcomes, including relatively low rates of plate exposure, plate breakage, and pseudarthrosis compared to many other available systems. As a result it has become a widely used device in numerous clinical centers. These plates are made of commercially pure titanium grade 4, according to the standard specification for unalloyed titanium for surgical implant applications of the American Society for Testing and Materials (ASTM F67) and have a thickness of 2.5mm. They are available in different lengths, can additionally easily be trimmed at each hole and can be bent both, over the edge and over the plane. Different designs are used for different areas like the mandibular anterior region or the mandibular angle region. There are left-sided plates and right-sided plates. Templates allow you to determine the ideal curvature and length of the plate. The corresponding screws are available in different diameter and lengths for monocortical or bicortical use and are available as locking- or non-locking-screws additionally. Because of these aforementioned characteristics the plates can be used as load-bearing-plates and also as stand-alone-plates to bridge a continuity defect.

Tbl. 1: *The different MODUS 2.5 Locking Reconstruction Plates that could be used in this study:*

M-4560		straight 16 holes
M-4564		left angled 12 holes horizontally 5 holes vertically
M-4566		right angled 12 holes horizontally 5 holes vertically
M-4572		left angled 17 holes horizontally 5 holes vertically
M-4574		right angled 17 holes horizontally 5 holes vertically
M-4580		double angled 4 holes vertically 17 holes horizontally 4 holes vertically

M-4582		double angled 5 holes vertically 18 holes horizontally 5 holes vertically
M-4584		double angled 5 holes vertically 19 holes horizontally 5 holes vertically
non-locking screws		diameter 2,5 mm lenght 10mm-20mm diameter 2,8mm length 10mm-18mm
locking-screws		diameter 2,5 mm lenght 10mm-20mm diameter 2,8mm length 10mm-16mm

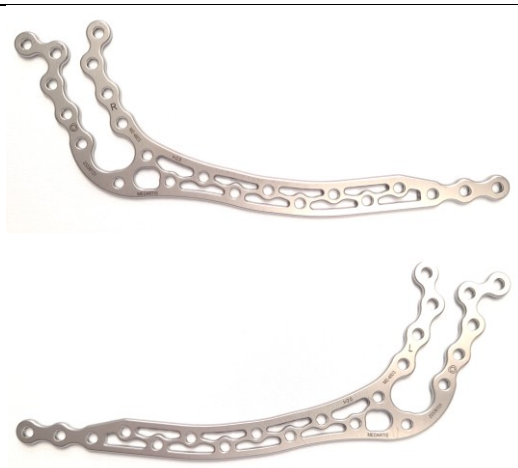
Intervention group

The intervention group was treated with the novel MODUS 2 TriLock Bridging Plate, *Medartis AG, Basel, Switzerland*, a further developed and successor model of the MODUS 2.5 Locking Reconstruction Plate System. It is a certified medical product completely authorized for a regular patient use. These novel plate system is made of commercially pure titanium (ASTM F67) grade 2 (semi-regide and therefor malleable), but in contrast to other devices features a reduced thickness of 2.0mm only.

The design in particular aims to provide a simplified adaptability while ensuring enhanced stability due to its grid like structure. Additionally it features an anatomically pre-shaped design and a customizable ramus section with bendable elements. The preformed bendable centrepiece contains cross-struts arranged in the vertical plane that were developed to ensure improved

vertical load distribution, however allows bending over the plane only and trimming in specific terminal areas only. Out of four different models the right one for the individual procedure can be selected for use in the mandibular anterior region or for the use in the mandibular angle area. Respectively short and long versions are available. The plates for mandibular angle region can be used as well in the left as in the right sides. Here too templates allow to determine the ideal curvature and position of the plate and the corresponding screws are available in different diameter (2,0mm, 2,3mm and 2,5mm) and lengths for mono- or bicortical use and are available as locking- or non-locking screws additionally.

Tbl. 2: *The different MODUS 2 TriLock Bridging Plates that could be used in this study:*

M2-4603		double-sided 13 holes horizontally 4+5 holes vertically
M2-4633		double-sided 17 holes horizontally 4+5 holes vertically
M2-4601		17 holes horizontally

M2-4635		2+3 holes vertically 17 holes horizontally 2+3 holes vertically
non-locking screws		diameter 2,0 mm lenght 4mm-19mm diameter 2,3mm length 5mm-19mm
locking-screws		Diameter 2,0mm Length 5mm-15mm diameter 2,3mm length 7mm-19mm diameter 2,5mm length 7mm-19mm

Randomization

Group assignment to the intervention group and control group respectively was performed by Randomizer for Clinical Trials® software (Version 2.1.0, Institute for Medical Informatics, Statistics and Documentation, Medical University of Graz, Austria). A random sequence was created with an 1:1 allocation using random block sizes of 2, 4 or 6 individuals to assign subjects to each group. This process was conducted by an individual not included in the patient recruitment, treatment or evaluation. Subjects were blinded to their treatment allocation to ensure responses remained unbiased and objective.

Outcome measurements

Primary outcomes

The primary outcomes were defined as the postoperative complications regarding the insertion of mandibular reconstruction plates over a follow-up period of 12 months.

The primary outcomes were measured using the following defined clinical and radiographic parameters: *plate fracture*, *plate exposure*, *plate removal*, *plate or screw migration* and *infection*. Patients had to attend precisely to the scheduled follow-up appointments with a permitted tolerance of +/- 1 week for each appointment.

As part of the precisely defined follow-up plan, medically necessary radiographic examinations were performed to obtain information about bone healing, implant dislocation, and plate fractures. Therefore the study protocol provides the following periods:

OPG (Orthopantomogram) preoperatively, first postoperatively within 2 weeks, following 2 months -, 3 months -, 6 months -, 9 months - and 12 months postoperatively.

CBCT/CT scan 3, 6 and 12 months postoperatively.

Secondary outcomes

The secondary outcomes were defined as the intraoperative usability and satisfaction of the surgeon on the one hand and the patient's progress in Quality of Life on the other hand.

The intraoperative usability of the plate system and satisfaction of the surgeon was assessed based on defined parameters using a custom-designed feedback questionnaire directly postoperatively. This questionnaire is attached to the appendix.

Following topics were collected using a 5-point Likert scale with a range from 1 (very poor), over 2 (poor), 3 (moderate), 4 (good), to 5 (excellent): *intraoperative adaptability to the bone, range of plates, range of drill holes, range of screws, trimming of the plate, contouring of the plate*. Additionally taken was the intraoperative time needed to adapt the plate to the bone (recorded on a stopwatch).

Quality of Life was assessed using the well-established SF-36 questionnaire at three defined time points (preoperatively, after 6 and after 12 months).

Implementation

A Case Report Form (CRF) was created for each individual. At every follow-up examination the form was entered and completed accordingly during the study period.

Timeline of patients' visits:

1 Preoperative screening

2 Surgery

3 Inpatient stay

4 Follow up-visit 1 (1 month postoperatively)

5 Follow up-visit 2 (2 months postoperatively)

6 Follow up-visit 3 (3 months postoperatively)

7 Follow up-visit 4 (6 months postoperatively)

8 Follow up-visit 5 (9 months postoperatively)

9 Follow up-visit 6 (12 months postoperatively)

The outpatient follow-up examinations took place in the clinical unit of the Division of Oral and Maxillofacial Surgery. Members of the study team reviewed the subjects closely according to clinical parameters. Six follow-up examinations were conducted.

Inclusion Criteria

For the patient recruitment to this study all of the following three points of the inclusion criteria had to be appropriate:

(1) The subject requires a mandibular reconstruction with a reconstruction plate in case of
   - expanded osteonecrosis of the jaw with segmental mandibular resection, or
   - malignant tumour disease including segmental resection of the lower jaw, or
   - severe mandibular trauma that included segmental reconstruction of the lower jaw.

(2) The subject is aged between 18-85 years.

(3) The subject has willingly given written informed consent.

Exclusion Criteria

The patient had to be excluded if one of the following points would applicable:

(1) Within the preoperative anaesthetic assessment the NYHA score was collected. If the subject was scored NYHA IV he/she had to be excluded.
(2) The subject suffered from a severe mandibular trauma which could be treated with miniplates only.
(3) A mandibular tumour resection would be performed without a segmental resection.
(4) A mandibular resection in osteonecrosis of the jaw would be performed without a segmental resection.
(5) The subject presented in the preoperative anaesthetic assessment with a limited anaesthesiologic fitness so that a surgery with mandibular reconstruction would not be feasible.
(6) The subject had not willingly given written informed consent.
(7) The subject was pregnant.
(8) The patient was minor.
(9) If there were any contraindications according to the instruction for use of the used plates such as
    - Pre-existing or suspected infection at or near the implantation site
    - Known allergies and/or hypersensitivity to implant materials
    - Inferior or insufficient bone quality to securely anchor the implant
    - Patients who were incapacitated and/or uncooperative during the treatment phase
    - Blocking of cranial sutures/growth plates with plates and screws
    - Not intended for use in direct contact with the dura mater and the central nervous system

Each patient allocated a current number and an attendant study code. Furthermore the patient was anonymous relatable by these numbers.

At the day of surgery the following data has been collected from the surgeon

- Determination of plate that has been used additionally further completion of the indication for the treatment (inclusion criteria) as the location, if a microvascular transplant was used or a stand-alone plate
- Time to adapt plate to the bone
- Postoperative surgeon's questionnaire (see below)

At the determined time points for the postoperatively follow-ups data were collected by a clinical and radiographic examination as described above.

At three times (initial point at the screening preoperative, intermediate at the follow-up visit 4 and final at the follow-up visit 6) each subject had to fill in the SF-36 questionnaire to assess the patient-related health status through time.

Statistical analysis

A power-analysis was performed to determine the number of patients required for this clinical trial comparing the rate and type of complications (nominal variable). Based on previous clinical results we assume a postoperative complication rate of 16% for the MODUS 2.0 Trilock Bridging Plate System (Schwaiger et al., 2018). A complication rate of 25% is assumed for the MODUS 2.5 Locking Bridging Plate System (Gielisch et al., 2023). With a power of 0.8 and a significance level of 0.05, a total sample of 630 patients was required, these are 315 subjects per group.

Statistically significant difference in Chi-square test with Alpha= 0.05 and Power von 0.8 (complication rate 16% and 25%), Odds ratio= 1,75

Since it is not realistic to recruit such a large number of patients in our clinic, this clinical study was designed as a pilot study.

The sample size was defined according (Noether et al., 1987) and the probability that a patient in the intervention group would outperform a patient in the control group on parameters of the primary outcome measures was set at $P(X>Y) = 0.75$. To get a power of 0.80 in a two-sided alpha of 0.05, the required sample size per group was calculated to be 21 patients (Wilcoxon rank-sum test).

Interim evaluations and reports were conducted to assess the performance of the systems used.

In an event of clear statistical superiority of one of the two plating systems in terms of outcome measures as the postoperative Quality of Life or complication rate, the study protocol provided for an early termination.

Statistical analysis were performed anonymous using R software (version 4.1.3, R Foundation for Statistical Computing, Austria)

Categorical variables were specified as absolute numbers and relative frequencies, continuous variables were specified as medians and interquartile ranges (IQR). The differences in the intraoperative usability and adaptability (primary outcomes) between the intervention and control groups were assessed using the Wilcoxon rank-sum test. Concerning complications in both groups, a time-to-event analysis was performed, where time-to-event was defined as the time between surgery and the occurrence of a primary complication. To demonstrate the probability of complications occurring, cumulative risk curves were calculated and displayed using the Kaplan-Meier estimator, with cumulative risk represented as 1 – "probability of no complications occurring". Those patients who were lost while the 12 months follow-ups were censored. A Cox proportional hazards regression model was computed, with a hazard ratios (HR) and their 95% confidence intervals (CI). Differences in the Quality of Life between the intervention group and the control group were assessed with the Wilcoxon rank sum test again. Differences within the group over time were assessed with the Wilcoxon signed rank test. Alpha was set to 0.05.

Data Management

The patient data collected for this study was safely stored in a locked cupboard in the office located at the Medical University Graz accessibly only for the author of this thesis. Printed data for each patient as Informed Consent, Case Report Form, SF-36 Questionnaire, Postoperative Questionnaire and X-rays were accurate stored in folders and digitised safed on a password-protected data medium. Microsoft Excel® was used to process patient data and were anonymised prior to the statistical analyses.

Results

Forty-two patients were screened and a total number of forty patients (n = 40) were included in the study and randomly assigned to either the intervention group (MODUS 2 Mandible TriLock Bridging Plate System: n = 20) or the control group (MODUS 2.5 Locking Reconstruction Plate System: n = 20) i.e. an allocation ratio of 1:1. Two patients were lost after screening, one died and another one did not attend any more. According to the inclusion criteria all these patients underwent a major mandibular reconstruction using one of the previously mentioned plate systems. The period for recruitment was from August 2019 to May 2023. The first patient enrolled was in August 2019 and the final patient follow-up (*follow-up 6*, 12 months postoperatively) took place in May 2024. The study participation lasted 12 months per subject including inpatient stay and outpatient follow-up care. The clinical characteristics of the 40 randomized patients were comparable in the intervention and control group (Table 3).

The median age for the full cohort at the time of recruitment was 65,4 years, for the intervention group 66.7 years (range 40.7-83.1) and for the control group 62.5 years (range 22.9-83.3) respectively.

The gender distribution for the full cohort was 22 male (55%) and 18 female (45%), showing the same distribution in both subgroups with 11 male (55%) and 9 female (45%) .

The frequency of diagnoses was distributed across the full cohort as follows: tumours were the most common with 19 patients (47,5%), followed by osteonecrosis with 11 patients (27,5%) and finally trauma with 10 patients (25%). The intervention group showed 8 (40%) patients with tumour, 7 patients (35%) with trauma and 5 patients (25%) with osteonecrosis. The control group also showed tumour as the most frequent diagnose with 11 (55%) patients, however a different order of the following diagnosis with 6 (30%) osteonecrosis cases and 3 (15%) trauma cases.

The length of defects were considerably longer in the intervention group with 8.5cm (range 7.3-10) than in the control group with 7cm (range 6-10), being 8cm (6-10) for the full cohort. However this was not applicable for 10 patients of the trauma subgroup where no resection was performed.

In both subgroups resections were performed almost exclusively in the lateral region, and these were distributed fairly evenly between the left and right sides. For the full cohort resections were performed on the lateral left side in 15 patients (50%) and on the lateral right side in 14 patients (46.6%), only one resection (3,3%) in the median. The intervention group showed 6 patients (20%) with a resection on the left side and equivalent on the right side, one (3,3%) was performed in the median. In the control group 9 resections (30%) were performed on the lateral left side, 8 (26,6%) on the lateral right side and none in the median.

The duration of the inpatient stay for the full cohort was in median 18 days. From the full cohort 26 patients had to stay at the intensive care unit (ICU) postoperatively in median for 3 days.

The inpatient stay in the intervention group (16 days) was in median 3,5 days shorter than in the control group (19,5 days), but there were no differences in the median length of patients who needed to stay at the intensive care unit (ICU) with 3 days. The mean time from inclusion to the study to surgery took 4,7 days.

Data from all patients were analysed for the primary and secondary outcome, but in total five patients were lost during the 12-month postoperative follow-up period (Fig. 8). In the intervention group three subjects were lost: one subject after one month (the patient did not attend to the appointment and was no longer contactable), one subject after three months (the patient did not attend to the appointment and was no longer contactable), one subject after nine months (the patient moved to another county and was treated in another hospital, but no data were available for further evaluation). In the control group two subjects were lost during the 12-month follow-up period: one subject after three months (the patient moved to another county and was treated in another hospital, but no more data were available), one subject after six months (the plate had to be removed because of postoperative plate exposure and due to an infection, no further surgery could be performed at this time).

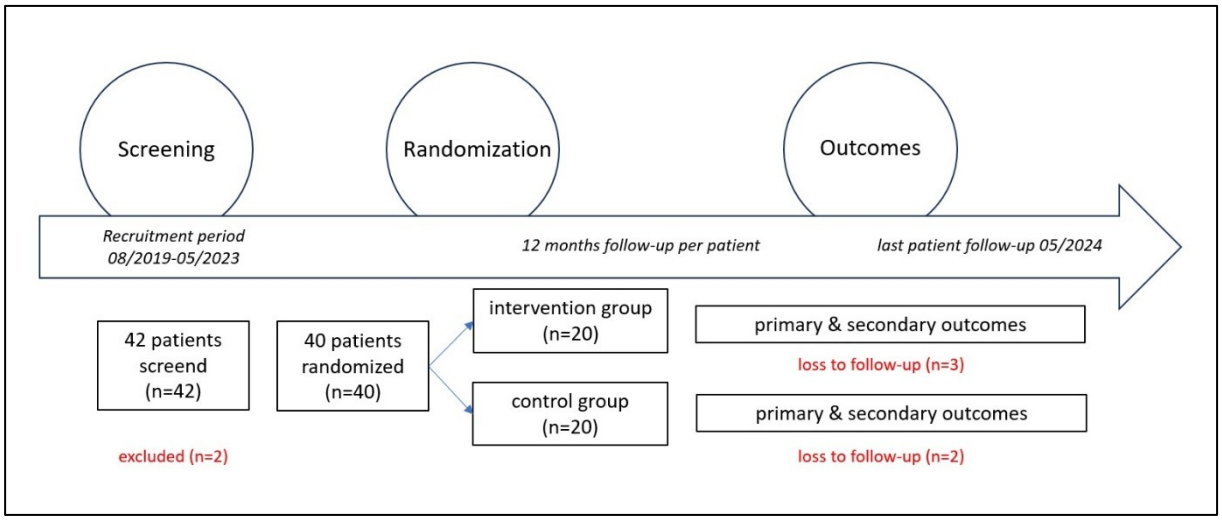


Fig. 8: *Diagram showing the study process. Forty-two patients were screened, out of that forty patients randomized to eighter the intervention group or the control group and outcomes collected over a 12 months follow up period. Modified after Steyer* (Steyer et.al., 2025)

Osteosynthesis material used

Intervention group:

From the 20 MODUS 2 Mandible TriLock Bridging Plates used, eleven were type M2-4603, six M2-4633, two M2-4635 and one M2-4601. The number of screws used was in median 13 of which were in median four locking screws (in cases of resection mostly used in the area of the transplant). Trimming of the plates: the three plates used for the anterior corpus area and only one plate for the angle area were not trimmed. All the other plates used, were trimmed eighter at the vertical or horizontal bendable elements, or both. Over all the anterior vertical bendable elements were trimmed by 0-4 holes respectively, the dorsal vertical bendable elements by 1-5 holes respectively and the horizontal bendable elements by 0-2 holes respectively.

Control group:

For the 20 MODUS 2.5 Locking Reconstruction Plates used in the control group nine were left angled (M-4572), eight right angled (M-4574), two double angled short (M-4580) and one double angled long (M-4582). The length was in median 13 holes, the screws used with a median of 10, of which were in median three locking screws (in cases of resection mostly used in the area of the transplant). Trimming of the plates: none of the plates used stayed in it's original length. The double angled plates were trimmed by 7 and 8 holes respectively. The left and right angled plates were trimmed by 1-9 holes respectively.

Primary outcomes

- **Postoperative complications**

Primary outcome measures were assessed over a 12-month postoperative follow-up period (at 2, 3, 6, 9, and 12 months) and included clinical and radiological outcomes such as:

1. plate fracture
2. plate exposure
3. plate removal
4. plate and screw migration
5. infection
6. non-unification of the mandibular bone

In total 20 patients (50%) had at least one of the previously mentioned postoperative complications, six patients (30%) in the intervention group and 14 patients (70%) in the control group. Once happened, it was very likely, that the complication occurred in several follow ups.

Nine patients with complications had more than one complication (up to 5 complications within the 6 Follow-Up visits).

With six patients the intervention group experienced fewer complications with cases of *plate exposure* than the control group with eight.

Six patients of the control group were affected by an *infection*. No infections were found in the intervention group.

Most complications could be brought under control with appropriate conservative therapy and the majority of patients kept their plates, but one patient in the control group required a *plate removal* after 6 months due to plate exposure and infection.

There was no event of *plate fracture* or *plate and screw migration* neither in the intervention group nor in the control group. Three cases in both groups showed a radiographical *non-unification of the mandibular bone* but did not show any instability in the clinical examination.

Overall the use of the intervention plate was associated with a significantly decreased risk of complications (HR 0.36, 95% CI 0.14-0.95) (Fig. 9).

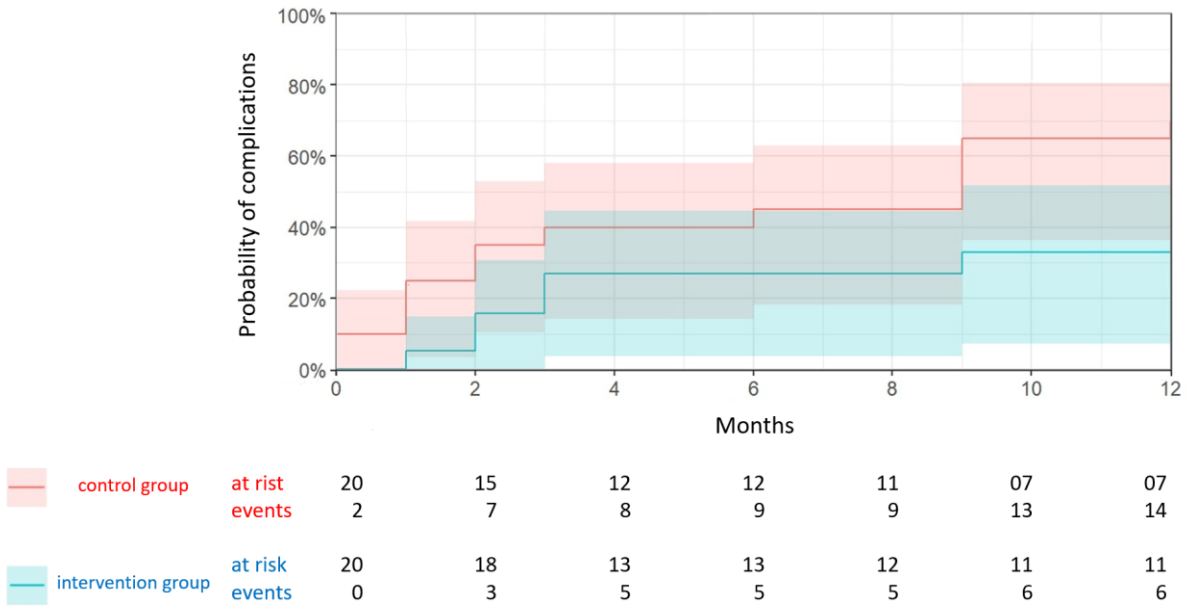


Fig. 9: *Probability of complications over time. Comparison between intervention and control group. HR is from a Cox proportional hazards regression model.*
Modified after Steyer (Steyer et.al., 2025)

Secondary outcomes

- **Intraoperative usability and satisfaction of the surgeon**

Values collected via the custom-designed surgeon feedback questionnaire to assess the surgeon's satisfaction on the intraoperative usability.

The categories examined were:

1. Intraoperative adaptability to the bone
2. Time to adapt plate to the bone
3. Range of plates
4. Range of drill holes
5. Range of screws
6. Trimming of the plate
7. Contouring of the plate

The so assessed intraoperative usability was mainly significant better in the intervention group compared to the control group across most evaluated categories. *Intraoperative adaptability to the bone*, *time to adapt the plate to the bone*, *range of plates*, *range of screws*, *trimming of the plate* and *contouring of the plate* were all significantly better in the intervention group ($p<0.05$), just the category *range of drill holes* ($p=0.066$) did not show significant differences. In any category there was no treatment rated as *very poor* in the intervention group or in the control group respectively, but the control group treatment was judged as *poor* multiple times (Tbl. 3).

	Intervention group (n=20)	Control group (n=20)	p-value
Adaptability to the bone, median (IQR)	4 (4-4)	3 (3-3.25)	p<0.001
Time to adapt the plate to the bone, median (IQR)	4 (3.75-4)	3 (2-4)	p=0.001
Range of plates, median (IQR)	4 (4-4)	3 (3-4)	p=0.002
Range of drill holes, median (IQR)	4 (3-4)	3 (3-4)	p=0.066
Range of screws, median (IQR)	4 (4-4)	3 (3-4)	p=0.013
Trimming of plate, median (IQR)	4 (3.75-4)	3 (3-4)	p=0.024
Contouring of plate, median (IQR)	4 (3-4)	3 (3-4)	p=0.036

Table 3: *Intraoperative usability of intervention and control group using p-values from Wilcoxon rank sum test.*

Comparing the respective subgroups of the two groups, as described above, the evaluation of the questionnaires to the surgeons showed the following results in percent:

The *intraoperative adaptability to the bone* was rated in the intervention group as "excellent" in 5%, as "good" in 75%, as "moderate" in 20%, there were no treatments rated as "poor" or "very poor". In the control group 25% were rated as "good", 65% as "moderate" and 10% as "poor". No treatment was rated "excellent" or "very poor".

The *time to adapt the plate to the bone* was rated in the intervention group as "excellent" in 10%, as "good" in 65%, as "moderate" in 25%, there were no treatments rated as "poor" or "very poor". In the control group 30% were rated as "good", 40% as "moderate", 30% as "poor" and no treatments were rated as "excellent" or "very poor".

The *range of plats* was rated in the intervention group as "excellent" in 15%, as "good" in 70%, as "moderate" in 15%, there were no treatments rated as "poor" or "very poor". In the control group 5% were rated as "excellent", 30% were rated as "good" and 65% as "moderate". No treatments were rated as "poor" or "very poor".

The *range of drill holes* was rated in the intervention group as "excellent" in 5%, as "good" in 55%, as "moderate" in 40%, no treatment was rated as "poor" or "very poor". In the control group 5% were rated as "excellent", 25% as "good", 65% as "moderate" and 5% as "poor". No treatment was rated "very poor".

The *range of screws* was rated in the intervention group as “excellent” in 10%, as “good” in 75%, as “moderate” in 15% and no treatment was rated as “poor” or “very poor”. In the control group 5% were rated as “excellent”, 40% as “good”, 55% as moderate and likewise the other group no treatment was rated “poor” or “very poor”.

The *trimming of the plate* was rated in the intervention group as “excellent” in 5%, as “good” in 70% and as “moderate” in 25%. No treatment was rated as “poor” or “very poor”. In the control group 45% were rated as “good”, 35% as “moderate”, 20% as “poor” and no treatment was rated as “excellent” or “very poor”.

Contouring of the plate was rated in the intervention group as “good” in 70% and as “moderate” in 30%. No treatment was rated as “excellent”, “poor” or “very poor”. In the control group 40% were rated as “good”, 45% as “moderate”, 15% as “poor” and no treatment was rated as “excellent” or “very poor”.

The *time* required for trimming and adapting the plate was less in the intervention group (IQR) with 14.0 (11.3-17.0) minutes compared to the control group with 15.0 (12.8-17.3) minutes (Wilcoxon rank sum test, p = 0.447).

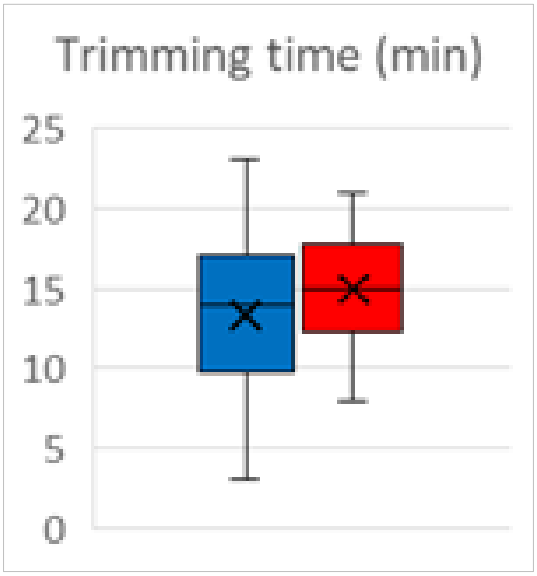


Fig. 11: *Time required for trimming and adapting the plate.*

Patient's Quality of Life

The patients' Quality of Life was assessed preoperatively as a baseline and compared to assessments at follow-up visit 4 (6 months postoperatively) and at follow-up visit 6 (12 months postoperatively) using the SF-36 questionnaire to evaluate the surgical impact on the overall well-being (Tbl. 4-6).

Screening (t=0 before surgery, baseline)		
	Intervention group (n=20)	Control group (n=20)
Physical functioning	30.0 (23.8-40.0)	32.5 (23.8-76.3)
Role limitations due to physical health	0.0 (0.0-50.0)	12.5 (0.0-31.3)
Role limitations due to emotional problems	16.7 (0.0-100.0)	16.7 (0.0-41.7)
Energy	40.0 (36.3-45.0)	45.0 (25.0-50.0)
Emotional well-being	50.0 (43.0-56.0)	56.0 (47.0-64.0)
Social functioning	50.0 (37.5-53.1)	37.5 (25.0-50.0)
Pain	32.5 (22.5-45.0)	32.5 (20.0-45.0)
General health	30.0 (28.8-50.0)	30.0 (25.0-47.5)
Health change	25.0 (0.0-50.0)	37.5 (18.8-50.0)

Tbl. 4: *The patients' Quality of Life assessed preoperatively.*

Follow-up visit 4 (t=6 month postoperatively)		
	Intervention group (n=18)	Control group (n=18)
Physical functioning	57.5 (45.0-83.8)	55.0 (50.0-67.5)
Role limitations due to physical health	100.0 (56.3-100.0)	75.0 (50.0-75.0)
Role limitations due to emotional problems	100.0 (100.0-100.0)	100.0 (41.7-100.0)
Energy	62.5 (50.0-70.0)	55.0 (50.0-73.8)
Emotional well-being	70.0 (61.0-79.0)	64.0 (60.0-80.0)
Social functioning	75.0 (53.1-75.0)	56.3 (40.6-62.5)
Pain	55.0 (45.0-65.0)	55.0 (47.5-55.0)
General health	60.0 (46.3-72.5)	47.5 (30.0-65.0)
Health change	62.5 (50.0-75.0)	62.5 (50.0-75.0)

Tbl. 5: *The patients' Quality of Life assessed at follow-up visit 4 (6 months postoperatively).*

Follow-up visit 6 (t=12 month postoperatively)		
	Intervention group (n=17)	Control group (n=18)
Physical functioning	85.0 (70.0-95.0)	70.0 (61.3-88.8)
Role limitations due to physical health	100.0 (100.0-100.0)	100.0 (75.0-100.0)
Role limitations due to emotional problems	100.0 (100.0-100.0)	100.0 (66.7-100.0)
Energy	80.0 (55.0-85.0)	80.0 (56.3-88.8)
Emotional well-being	76.0 (68.0-80.0)	74.0 (68.0-80.0)
Social functioning	75.0 (62.5-87.5)	62.5 (62.5-75.0)
Pain	77.5 (55.0-100.0)	60.0 (55.0-77.5)
General health	60.0 (45.0-75.0)	50.0 (40.0-63.8)
Health change	75.0 (50.0-75.0)	75.0 (50.0-75.0)

Tbl. 6: *The patients' Quality of Life assessed at follow-up visit 6 (12 months postoperatively).*

The baseline values were comparable in both groups. Quality of Life improved significantly over time compared to preoperative baseline values. At the 6- and 12-month follow-ups, patients in the intervention group had scores as high or even higher than those in the control group for all measured dimensions.

Figure 12 shows the dimension of the Quality of Life as baseline before surgery, postoperative at follow-up visit 4 (6-months postoperatively), and at follow-up 6 visit (12-months postoperatively) for the intervention group and control group. Chart showing median per Quality of Life dimension stratified by type of treatment at different time points. Two patients per group missing for the 6-month follow-up. Three patients in the intervention group and two patients in the control group missing for the 12-month follow-up.

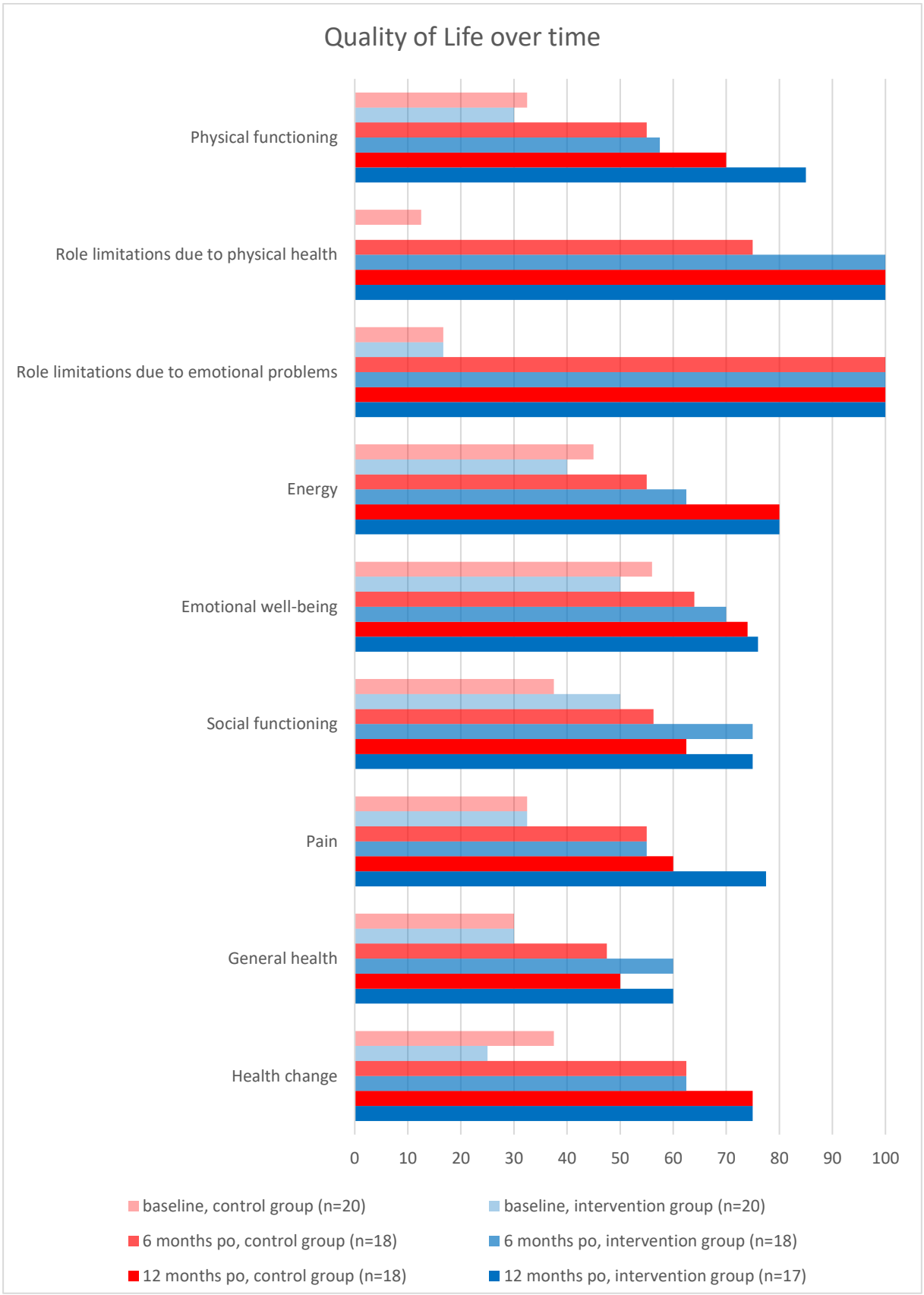


Fig. 12: *Quality of Life over time, modified after Steyer* (Steyer et.al., 2025)

Discussion

General management of severe mandibular defects

For large and severe acquired defects in the mandibular region rehabilitation is crucial. Important aspects include restoring the aesthetics as well as restoring functional aspects as the ability to masticate, speak and breath properly, so the patients can be reintegrated into their social environment postoperatively soon (Fernandes & Yetzer, 2013; Kakarala et al., 2018). Furthermore an intraoperative wrong shaped mandible can impair the natural occlusion and lead to an atypical or modified position of the temporomandibular joint (Azuma et al., 2014). Occlusal forces are divided into swallowing, chewing, and maximum bite forces. The measured values can vary considerably, depending on age, gender, and measurement methods. However, it can be shown that patients after mandibular reconstruction experience a massive reduction in biting force, which can amount to up to three-quarters of the force (Wong, R. C. W. et al., 2009). This can be temporary during the healing phase, but also permanent, depending on the extent of the therapy and any subsequent procedures. A complete oral rehabilitation is not always possible.

These forces on the bone generated by the muscles of mastication, as described above, must be bearded by the osteosynthesis material in the case of reconstruction. However, osteosynthesis material must not only break, it must also not loosen, as it can happen for example when the bone around the screws is resorbed due to improper force transmission (Bede et al., 2019).

Over and beyond psychosocial impairment and a loss of Quality of Life make postoperative lives difficult for those affected (Warshavsky et al., 2019)

For the rehabilitation in severe defects the use of fixation systems in oral and maxillofacial surgery is essential for stabilizing bone segments (Panesar & Susarla, 2021). Advances in medicine have enabled further developments in the field of osteosynthesis material and in the field of microvascular surgery in recent decades. These systems are routinely used in reconstructive procedures nowadays to bridge bone defects and have become an established method for the reconstruction of the mandible. If possible immediate reconstruction will provide the best aesthetic and function result (Disa & Cordeiro, 2000; Sauerbier et al., 2008).

The current gold standard for the reconstruction of extensive mandibular continuity defects involves the use of microvascular bone grafts, which allow for both, structural restoration and functional rehabilitation of the mandible, however in certain clinical situations – particularly in patients with severely compromised general health, advanced stage disease or contraindications to prolonged surgical procedures – bone graft reconstruction may not be feasible or ethically justifiable due to the elevated perioperative risk and limited potential for recovery. In such cases the application of a load-bearing stand-alone reconstruction plate represents a viable alternative for bridging the osseous defect but poses major challenges to the material and design of the osteosynthesis material (Merema et al., 2020; Zwetyenga et al., 2002). Future advancements in biomaterials and patient-specific implant design may further enhance the mechanical performance and long-term outcomes of such non-bony reconstructive strategies.

Different systems have individual advantages and disadvantages as well as challenges in terms of handling, adaptability, and geometry. A crucial factor in selecting the optimal osteosynthesis material for the respective case is its ability to ensure stable, load-bearing bone fixation while minimizing postoperative complications (Bianchi et al., 2010). Additionally the surgeon's preference is strongly influenced according the training and experience, furthermore the ease of intraoperative handling of the plate system and the familiarity with the application of the materials plays a significant role in the selection process of osteosynthesis materials (Sobrero et al., 2024). Of course, costs and existing infrastructure can also play a decisive role (Filinte et al., 2015). Today we distinguish three different types of application in the plate-systems for acquired continuity defects of the mandible: bendable plates, preformed plates, and individually and patient-specifically manufactured plates (Schwaiger et al., 2018).

This present study aimed to prospectively compare the intraoperative usability, complication rates, and patients' Quality of Life between two different load-bearing fixation systems: the novel Modus 2.0 TriLock bridging plate system (intervention group), a plate that can be counted among the group of preformed plates and the standard Modus 2.5 locking reconstruction plate system (control group), a plate that can be counted among the group of bendable plates. The goal was to evaluate their effectiveness in improving surgical and patient outcomes.

Assessment of the performed treatment

The two groups examined in this study are highly comparable. Of the 42 recruited study participants, 40 were enrolled, evenly distributed between the intervention and control groups, each consisting of 20 patients. A slight dropout rate at any time over the study period as we see it in our studies often is common. Reasons for this in this study, as described above, included the death of a patient after recruitment, missed appointments and failure to contact the patient, or relocation to other counties where the subsequent therapy was taken over and affected both groups at similar times during the study period.

The patients' average age at the time of surgery was comparable, as was their gender distribution. Regarding diagnoses, tumour was the most frequent diagnosis, both overall and in each of the two groups. Although the order of the other diagnoses, osteonecrosis and trauma, differed slightly, it was essentially the same.

The resections were not only approximately the same length in both groups but were also performed with equal frequency on the left and right sides.

The average length of the inpatient stay was slightly shorter in the intervention group and so was the number of patients in need for intensive care postoperatively. If intensive care was required during this postoperative hospital stay, the length of stay at the ICU was the same in both groups. However, the duration of the inpatient stay and a need for intensive care are caused multifactorial.

Assessment of the osteosynthesis material

A wide range of different plates is currently available for the treatment of mandibular defects, differing in both, structural thickness and the materials used. Despite the critical role of these plates, there is at the moment no universally accepted gold standard for the optimal design or geometric configuration of these devices. This lack of consensus underscores the continued need for comprehensive biomechanical and clinical investigations.

Taking it to detail, there are advantages and disadvantages to every osteosynthesis-system.

Miniplates require a minimal surgical approach and, due to the smaller amount of osteosynthesis material, have a lower rate of postoperative complications such as plate exposure

or infection (Cohen et al., 2025; Falci et al., 2021). However, in cases of multi-fragmentary or wide-span defects (e.g. panfacial trauma), continuity defects (e.g., after ablative tumour surgery), or when there is no dental support in an edentulous area, a load-bearing plate, thus a reconstruction plate, is required, because the defect results in new biomechanical movements and intermediate fragments are susceptible to move in mastication (Cohen et al., 2025).

To be effective, the plates must be well adapted to the bone. There must be no space between the plate and the bone, because this could lead to a shift of a fragment when tightening the screws. This can be improved by using locking screws in reconstruction plates, as the plate doesn't have to fit perfectly in all areas, while the fragments are still held in the correct position (Herford & Ellis, 1998; Yang et al., 2015).

Precise intraoperative adaption of the plate to the bone requires long-time practice and a good spatial imagination of the surgeon. In the literature a bone plate distance of less than 1 mm is described as very good or normal precise (Wurm et al., 2018).

According to Martola et al., a principal reason for plate fractures is the residual stresses generated through plate bending during surgery, which may affect the mean stress in fatigue loading (Wong, R. C. W. et al., 2009). Reconstruction plates show a good success rate, nevertheless a factor increasing postoperative complications is defect size; segmental defects are commonly smaller in trauma than iatrogenic created after ablative tumour resection (Bede et al., 2019). Bending can be facilitated through preoperative planning and preparatory work. Rapid prototyping allows pre-contouring a plate on a 3D-printed model based on radiographic images. This serves as a visual aid that can be viewed closely from all angles without soft tissue getting in the way, allowing the plate to be bent without distraction, precisely and calmly (Fowell et al., 2015; Wurm et al., 2018). Adapting preformed plates, that contour the average morphology of the mandibular, seems intraoperatively to be faster and easier in handling than conventional plates, so there is no need for an extensive bending to achieve the correct fit. This reduces fatigue fractures of the plates (Probst et al., 2012). The thickness of the osteosynthesis plate appears to increase the operating time and the complication rate (Pfister et al., 2024). We were able to show that what was expected was true. The pre-shaped design and the thin grid-like structure of the MODUS 2 Mandible TriLock Bridging Plate System were expected to improve intraoperative usability, like a more effortless and therefore faster adaptation of the plate to the bone. In this study the plate adaptation in the intervention group was in mean one

minute faster than in the control group. This objective results reflect quite well the subjective perception of the surgeons. In the questionnaire they stated the time to adapt the plate to the bone significantly better in the intervention group. In a multi hour taking operation, one might think that this small time saving is insignificant. However, when many small time savings add up over the innumerable steps, a reduction in the overall operating time can certainly be achieved for the patient to benefit.

Improvements in CAD/CAM developed customized patient specific plates that are milled from titanium. These plates do not require intraoperatively trimming or bending. Therefore they save time and the premorbid mandibular contour can be recreated most accurately (Kakarala et al., 2018). Despite these advantages, these systems are sometimes rarely used because preparatory work is long-lasting, complex and costly (Wurm et al., 2018). If the surgical plan changes intraoperatively, a rapid adjustment to the new situation is not possible. Such a situation could be, for example, the change in defect size or the change in the resection position. Sometimes the bone density is insufficient to anchor a screw. In that case, the screw must be positioned a screw hole few millimeters away. But in case of a non-changeable plate its screw holes can no longer be bent into a different position then.

The size of the planned resection may changes intraoperatively because no resection has been achieved in sano yet. In addition to the radiological and clinical assessment, visual and palpatory, frozen section diagnostics are of great importance to achieve a resection in sano in tumour surgery. Assessment of the tumour margin appears to be so important because positive margins are strongly associated with locoregional recurrence and mortality. Positive resection margins (described in the supplementary classification of TNM as R1 and higher) contribute to decisions regarding the implementation of adjuvant therapy (Agaimy et al., 2012; Urken et al., 2023).

No matter to which system of osteosynthesis you decide for, as well as conventionally and preformed reconstruction plates, patient specific plates seem sufficiently stable for mandible reconstruction in severe defects (Bera & Tiwari, 2022; Rendenbach et al., 2017). Boyd defined success as a reconstruction that does not have to be removed (Boyd, 1995).

Assessment of surgical satisfaction and complications

The fixation system used in the intervention group (MODUS 2 Mandible TriLock Bridging Plate System) in the present study offered significant advantages in reducing clinical complications such as infection, plate exposure or plate fracture. With a hazard ratio of 0.36 the time-to-event analysis showed a significantly improved outcome compared to the control group, representing a 64% reduction in the risk of complications in the intervention group.

A number of studies on mandibular reconstruction report complications as plate exposure rates ranging from 3.7% to 38%, and plate fracture rates from 0% to 26%, with long time follow-up periods ranging from 180 days to 67 months (Blackwell & Lacombe, 1999; Chepeha et al., 2008; Fanzio et al.; Gielisch et al., 2023; Head et al., 2003).

The same plate system as used in the intervention group of this study was specifically evaluated in two other studies reporting relatively low plate exposure rates, ranging from 8% to 17%, and fracture rates from 0% to 4% (Chepeha et al., 2008; Peters et al., 2020; Schwaiger et al., 2018).

We found a plate fracture rate of 0% in both groups. However, observed plate exposure rates of 20% in our intervention group and plate exposure rates of 45% in our control group respectively. Considering this, the plate exposure rate in the control group was twice as high as in the intervention group.

Regarding postoperative infections, a total of six infections (30%) occurred in the control group, while no infections occurred in the intervention group. The literature reports an overall infection rate varying from 3% to 30% regardless of the plating system used (Odom & Snyder-Warwick, 2016; Wood et al., 2018). Surgical site infections are commonly recognized as being closely associated with various plate-related complications. Disruption in the normal wound healing cascade can impair tissue regeneration, increase the probability of infection and leads to a higher plate exposure rate (Shah et al., 2024). Therefore, higher infection rates in the control group could have contributed to the higher rate of plate exposures observed in this study. No definitive explanation could be determined for why both the infection and plate exposure rates in the control group were higher. It appears that the plates in the intervention group tend to cause less postoperative mechanical tissue irritation and infection, resulting in lower plate exposure during the follow-up period. This is likely related to the plate geometry, particularly the reduced plate thickness of the system, which leads to less mechanical tissue irritation.

As the plate design can affect the success of the treatment (Pfister et al., 2024).

The intraoperative handling of the plate systems showed that the intervention group had shorter trimming times and better intraoperative assessments than the control group.

The data collected from the custom-designed surgeon feedback questionnaire to assess the surgeon's satisfaction showed that the surgeons observed a statistically significant improvement in handling in the intervention group in six out of seven categories (intraoperative adaptability to the bone, time to adapt the plate to bone, range of plates, range of screws, trimming of the plate and contouring of the plate). Only in one category (range of drill holes) no significant differences were found between the two groups.

In addition to the intraoperative handling aspects analysed above, the surgeons reported their subjective experiences with the respective fixation systems:

so the control group demonstrated a higher degree of adaptability due to their design and less complex geometry. This allowed for plate contouring and adjustment in multiple planes and directions. Especially in the management of extensive defects and in cases characterized by altered, non-physiological anatomy an increased flexibility in plate adaption is particularly important as seen, for example, in complex reconstructions with microsurgical free flaps.

In contrast the plates used in the intervention group showed an improved bone fitting, primarily attributable to their pre-shaped design and geometry, which closely follows the physiological anatomy of the mandible. This anatomical alignment led to the perception of a markedly reduced distance between the plate and the bone. It can be assumed that this improved fit contributed to the lower rate of plate exposure observed in the intervention group, as a more precise adaptation to the bone may reduce mechanical stress and minimize disturbances in the wound-healing process (Davies et al., 2021).

Based on these findings, it may be concluded that the plates used in the intervention group are particularly advantageous for defects of small to moderate size and for standardized clinical situations, where an extensive degree of intraoperative plate flexibility is not essential.

For the surgeon it is important that the osteosynthesis material used can be easily and effectively adapted to the specific situation. This involves easy bending the plate in all dimensions so that there is no significant indifference to the bone, which could cause postoperative problems such as wound healing defects or pain caused by too much tension in the soft tissue (Shah et al.,

2024). One challenge is to have a minor approach. The aim is to avoid unnecessary damage to surrounding tissue by overly large approaches (Cohen et al., 2025). The bone fragments or the remaining bone with the graft should remain in their original or premorbid position. Wang et al showed that there are three common types of undesired reconstruction as improper temporomandibular joint position, insufficient alveolar bone height or unsatisfactory mandible formation (Wang et al.). To restore the original mandible position, in the case of a resection, in our division we first exactly bend the plate and fix it temporary with non-locking screws in the proximal and distal fragments of the originally mandible. The screws and plate are then removed and the resection performed. Before the graft is inserted, the plate is permanently fixed in the previously determined position usually, if possible, with bicortical screws, and the graft is fitted into the existing gap. This ensures the correct positioning of the proximal and distal bone fragments relative to each other and a precise fit of the graft. To fix the fragment in a rotationally stable manner, more than one screw is required and for the reasons mentioned above, we use locking-screws in these areas.

The widespread use of reconstruction plates is based on their load-sharing and load-bearing qualities. In microvascular bone grafting, the reconstruction plate assumes the function of load-bearing during the bone healing phase and load-sharing after sufficient bone regeneration. The same principle applies in severe and multifragmentary trauma. While healing, the plate is load-bearing, then load-sharing. In the edentulous jaw which has no occlusal support the plate is also load-bearing. When used as a standalone plate, the load-bearing function persists (Cohen et al., 2025; Merema et al., 2020; Rendenbach et al., 2017).

Intraoperative bending makes the plates immediately available. Specific shapes of conventional plates allow a good adaptability of the different regions of the mandible. However, bending the plates correctly requires a long term practice and good spatial awareness. Furthermore, osteosynthesis material should never be bent back and forth, as this can weaken the material and eventually cause fracture immediately or later (Rahimov & Farzaliyev, 2011).

In some cases, it is advisable to pre-bend the osteosynthesis plates used. This saves time during surgery and allows for more detailed study of the structures. A 3D printer is used to create a plastic model from 3D data sets, such as a CT or CBCT scan. This model has the exact shape the surgeon will encounter intraoperatively. The plate can be bent and tested. Once the surgeon

is satisfied with the shape, it is sterilized and prepared for intraoperative use (Davies et al., 2021; Rendenbach et al., 2017).

Nowadays, it's also possible to produce patient-specific implants (PSI) eighter directly at the point-of-care (POC) such as hospitals, or outsourced to an external manufacturer. Here too CT or CBCT scans serve as the basis. The length and position are determined virtually and manufactured accordingly. This enables a precise fit. However, if unexpected changes occur intraoperatively e.g. if there is more to resect than planned, or if the position of the planned hole cannot be set on this position, problems can occur because the implant cannot be adjusted further. In-house production of patient-specific implants require less lead time in production than an outsourcing process but in return is in need of know-how and corresponding resources (Fowell et al., 2015; Maintz et al., 2024; Subash et al., 2023).

In summary, surgeons prefer materials that are easy and quick to process, but at the same time are sufficiently stable to absorb the large forces that occur, cause few side effects or postoperative complications, adapt precisely, and give the surgeon enough flexibility to react individually during the operation.

Assessment of the Quality of Life

Self-assessment questionnaires for Quality of Life provide information about the impact of a pathology and its treatment on the patient's Quality of Life. Scores can be influenced by various factors, such as comorbidities, treatment modalities, or postoperative complications. After very complex procedures, these scores can be unexpectedly high. Despite similarly complex procedures and postoperative courses, two different patients often have very different outcomes (Warshavsky et al., 2019). The patient's assessment appears to be dynamic and changeable across time and situations (Cella, 1994). Therefore in the current study the patients' health status was assessed at three times throughout the study period using the established SF-36 questionnaire. Every subject completed the questionnaire first before the operation, then again 6 months postoperatively, and finally after a follow-up period of 12 months.

In both treatment groups an increase in Quality of Life was observed over time after complex mandibular reconstruction. In medicine, changes in the Quality of Life scores can be used as measurement of the effectiveness of certain treatments (Kaukola et al., 2015).

An increase in these values reflects improved well-being and thus indicates the success of the therapy as we see it in our study. Initially only a slight change after a 6-month interval, followed by a significant increase in values, can probably be explained by the healing process or by the fact that the patients have become accustomed to and adapted to the new situations.

In all Quality of Life categories, the intervention group achieved scores at least as high as those of the control group. The data collected six and 12 months after surgery can be considered comparable in any Quality of Life category to existing data from the healthy German norm population in both study groups, however, it should be noted, that the preoperative Quality of Life scores were lower in both groups and significantly below those of the healthy German norm population.

The Quality of Life scores of the German norm population are based on a study from 2013 as part of the German Health Survey and Examination Survey for Adults, in which a total of 8152 participants took part (Ellert & Kurth, 2013)

Comparing the two groups, the intervention group showed slightly higher Quality of Life scores, which may resulted from the fact that a lower frequency of complications during the follow-up period occurred.

A direct comparison of the Quality of Life outcomes observed in this study with those reported in existing literature was not conducted as the considerable heterogeneity of disease conditions within the study population would have introduced substantial variability and potential bias, thereby compromising the accuracy and interpretability of the results. Such comparisons would not have yielded meaningful or scientifically robust conclusions regarding the effectiveness of the surgical interventions or the plate systems applied.

The observed improvement in Quality of Life clearly underscores the positive impact and significant clinical relevance of reconstructive surgery on patients' overall health, functional recovery, and psychosocial well-being, regardless of the plate system used. These results emphasize that, in addition to the technical aspects of reconstruction, the restoration of form and function plays a crucial role in improving daily activities, social integration, and long-term satisfaction with the treatment outcome. Furthermore, the findings demonstrate that reconstructive surgery is an essential component of comprehensive patient care and contributes

significantly to the physical rehabilitation and emotional resilience of individuals with severe craniofacial or mandibular defects.

Limitations of the research topic

One of the limitations is the number of patients recruited. Although Graz is the second-largest city in Austria, it is still a relatively small country. The number of patients and cases is correspondingly low. This also results in a limitation of this study: the limited number of patients included. A larger sample size would likely result in a greater precision and significance of the collected data, especially with regard to the comparison of the two plate systems used. However, achieving a significantly larger sample size represents a substantial challenge at the Division of Oral and Maxillofacial Surgery Graz. Such an increase of the sample size would likely take years, possible even decades, if conducted as a single centre study; alternatively a multicentre study would be necessary to achieve a statistically reliable number of patients within a reasonable period of time and to increase the generalisability of the results. The time period chosen in this study ensured that the same surgeons were involved, thus avoiding bias in the questionnaires administered to the surgeons and in their surgical skills. Furthermore the heterogeneity of the studied patient groups with severe mandibular defects represents a limitation. This heterogeneity results from the diversity of underlying diagnoses, including severe trauma, tumour diseases and osteonecrosis of the jaw, and consequently leads to different clinical outcomes and additional therapies. Although this variability potentially represents an additional confounding factor, it simultaneously reflects the real patient population and the clinical care reality in craniomaxillofacial surgery. Thus, the composition of the study population contributes to ensuring the practical relevance and transferability of the study results to everyday clinical practice. To avoid these limitations, future research must target a larger, multicenter sample to improve the robustness and generalizability of the results of this important research question.

The two compared groups with large mandible defects represent a heterogeneous group due to patients with different diagnoses (severe trauma, tumour diseases and osteonecrosis of the jaw) and therefor also different clinical pictures. However this reflects the usual patient collective and everyday life of the Oral and Maxillofacial Surgery.

Direct comparison of the compared plate systems by the author

Although the plates in the intervention group showed a lower level of complications, allowed for better intraoperative assessment, and led to equivalent or even higher postoperative Quality of Life than the plates in the control group, the plate system has some drawbacks.

The most considerable limitation of the system lies in its limited ability to allow bending in the plane and torsional adaptation of the plate body.

This lack of mechanical flexibility proves particularly critical in clinical situations where the original anatomy of the mandible has been substantially altered during surgery and complex multidirectional plate modifications are required. Such requirements frequently arise during the stabilization and integration of extensive microsurgical bone grafts following segmental mandibular resections or in large scale secondary reconstruction procedures.

Microvascular bone grafts are typically surrounded by a considerable volume of surrounding soft tissue, which often results in a reconstructed contour that deviates markedly from the standard mandibular anatomy. In these circumstances, the ability to finely adapt the osteosynthesis plate to the newly formed anatomy is essential to ensure accurate alignment and optimal biomechanical stability. The limited flexibility of the system used in the intervention group may probably result in suboptimal or unplanned outcomes, unintentionally performed plate cuttings and not predictable postoperative complications. Conversely, the pre-shaped plates used in the intervention group show clear advantages in clinical cases with medium-sized mandibular defects – where the anatomical configuration is largely preserved.

Examples include load-bearing osteosynthesis in extensive traumatic fractures or defect situations where the remaining bone segments still provide partial structural support. In such cases, the geometry of the mandible closely corresponds to the standard anatomical form which aligns precisely with the pre-shaped plate construct. This alignment allows the surgeon to position the plate quickly and accurately with minimal intraoperative adjustments and thereby reducing time of the surgery and technical complexity.

In summary, the pre-contoured plate system used in the intervention group represents an efficient and time-saving solution for osteosynthesis of mandibular defects limited to approximately one segment, where the anatomical integrity of the jaw is largely preserved. It offers favorable intraoperative handling characteristics and is associated with a lower rate of

technical complications. In contrast, more extensive defects - particularly those with non-viable or structurally damaged bone tissue resulting from oncological resections or prior radiotherapy - may be better treated with a more adaptable osteosynthesis system, such as the one used in the control group. This system allows for individualized plate contouring and three-dimensional adaptation to complex anatomical reconstructions.

Conclusion

The two investigated bridging plate systems (MODUS 2 Mandible TriLock Bridging Plate System and MODUS 2.5 Locking Reconstruction Plate System) clearly improved the patients' overall health status from preoperatively at baseline to a 12-month postoperatively condition, comparable to that of the normal population.

In terms of complication we found no event of *plate fracture* or *plate and screw migration* in both groups. *Infection* rates were comparable to other reconstruction plate systems. There were fewer events of *plate exposure* in the intervention group than in the control group. Radiographical *non-unifications of the mandibular bone* were seen in three cases out of forty, but none with an instability in the clinical examination. Postoperatively complications could be brought under control with appropriate conservative therapy and all plates stayed in vivo, except one in the control group in a 12-month follow up period.

The Intraoperative satisfaction of the surgeons with the plate system was nowhere rated in the worst category on a 5-point scale in either group. However, the intervention group achieved significantly better results in 6 of the 7 categories examined (*intraoperative adaptability to the bone, time to adapt plate to the bone, range of plates, range of screws, trimming of the plate and contouring of the plate*). No significance was found in the category *range of drill holes*. Intraoperative handling and patients' Quality of Life after a 12-month follow-up, confirming the system's suitability for the clinical use. Both systems operate similarly, the intraoperatively handling is comparable, both support the use of locking and non-locking screws. Various plates are available for different regions of the mandible and different length to bridge the respective defect. The preformed geometry of the plate efficiently supports and facilitates the fit of the plate to the bone, however, this shape does not allow for adjustments in plane or torque, which can limit the adaptability of the plate in some cases.

The investigated device MODUS 2 Mandible TriLock Bridging Plate System demonstrated safe and reliable outcomes. In particular, the plate system seems to provide the most suitable use in bone defects up to a moderate size when the pre-shaped geometry of the plate most efficiently supports the plate-to-bone fitting. However, the system's limitations in the flexibility of plate adaptation should be carefully considered in cases involving long size defects in complex reconstructions, as the grid-structure does not allow an adjustment in plane or torquing the plate. The choice between the Modus 2.0 TriLock bridging plate system (intervention group) and the

Modus 2.5 locking reconstruction plate system (control group) should be based on the specific needs of each case, weighing the observed easier use and lower complication rates, observed in the intervention group, against the control group's higher flexibility in the bone to plate adaptation. This choice has to be individually made separately for each reconstruction case depending on the bone defect size, the defect morphology and the planned surgical procedure. Which of the two plating systems the surgeon chooses will vary from case to case based on individual preferences and the specific requirements of the respective clinical scenario.

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Appendix

SF-36 Questionaire

SF-36 Fragebogen

1. Wie würden Sie Ihren Gesundheitszustand im allgemeinen beschreiben?

❍$_1$ Ausgezeichnet ❍$_2$ Sehr gut ❍$_3$ Gut ❍$_4$ Weniger gut ❍$_5$ Schlecht

2. *Im Vergleich zum vergangen Jahr*, wie würden Sie Ihren derzeitigen Gesundheitszustand beschreiben?

❍$_1$ Derzeit viel besser
❍$_2$ Derzeit etwas besser
❍$_3$ Etwa wie vor einem Jahr
❍$_4$ Derzeit etwas schlechter
❍$_5$ Derzeit viel schlechter

3. *Sind Sie durch Ihren derzeitigen Gesundheitszustand* bei folgenden Tätigkeiten *eingeschränkt*? Wenn ja, wie stark?

	Ja, stark eingeschränkt	Ja, etwas eingeschränkt	Nein, nicht eingeschränkt
a. anstrengende Tätigkeiten, z.B. schnell laufen, schwere Gegenstände heben, anstrengenden Sport treiben	❍$_1$	❍$_2$	❍$_3$
b. mittelschwere Tätigkeiten, z.B. einen Tisch verschieben, staubsaugen, kegeln, Golf spielen	❍$_1$	❍$_2$	❍$_3$
c. Einkaufstaschen heben oder tragen	❍$_1$	❍$_2$	❍$_3$
d. mehrere Treppenabsätze steigen	❍$_1$	❍$_2$	❍$_3$
e. einen Treppenabsatz steigen	❍$_1$	❍$_2$	❍$_3$
f. sich beugen, knien, bücken	❍$_1$	❍$_2$	❍$_3$
g. mehr als 1 Kilometer zu Fuß gehen	❍$_1$	❍$_2$	❍$_3$
h. mehrere Straßenkreuzungen weit zu Fuß gehen	❍$_1$	❍$_2$	❍$_3$
i. eine Straßenkreuzung zu Fuß weit gehen	❍$_1$	❍$_2$	❍$_3$
j. sich baden oder anziehen	❍$_1$	❍$_2$	❍$_3$

4. Hatten Sie in den vergangenen 4 Wochen aufgrund Ihrer körperlichen Gesundheit irgendwelche Schwierigkeiten bei der Arbeit oder anderen alltäglichen Tätigkeiten im Beruf bzw. zu Hause?

a. Ich konnte nicht so lange wie üblich tätig sein	❍1 ja	❍2 nein
b. Ich habe weniger geschafft als ich wollte	❍1 ja	❍2 nein
c. Ich konnte nur bestimmte Dinge tun	❍1 ja	❍2 nein
d. Ich hatte Schwierigkeiten bei der Ausführung	❍1 ja	❍2 nein

5. Hatten Sie in den vergangenen 4 Wochen aufgrund seelischer Probleme irgendwelche Schwierigkeiten bei der Arbeit oder anderen alltäglichen Tätigkeiten (z.B. weil Sie sich niedergeschlagen oder ängstlich fühlten)?

a. Ich konnte nicht so lange wie üblich tätig sein	❍1 ja	❍2 nein
b. Ich habe weniger geschafft als ich wollte	❍1 ja	❍2 nein
c. Ich konnte nicht so sorgfältig wie üblich arbeiten	❍1 ja	❍2 nein

6. Wie sehr haben Ihre körperliche Gesundheit oder seelische Probleme in den vergangenen 4 Wochen Ihre normalen Kontakte zu Familienangehörigen, Freunden, Nachbarn oder zum Bekanntenkreis beeinträchtigt?

❍1 überhaupt nicht ❍2 etwas ❍3 mäßig ❍4 ziemlich ❍5 sehr

7. Wie stark waren Ihre Schmerzen in den vergangenen 4 Wochen?

❍1 Keine Schmerzen
❍2 Sehr leicht
❍3 Leicht
❍4 Mäßig
❍5 Stark
❍6 Sehr stark

8. Inwieweit haben die Schmerzen Sie in den vergangenen 4 Wochen bei der Ausübung Ihrer Alltagstätigkeiten zu Hause und im Beruf behindert?

❍1 überhaupt nicht ❍2 etwas ❍3 mäßig ❍4 ziemlich ❍5 sehr

9. In diesen Fragen geht es darum, wie Sie sich fühlen und wie es Ihnen in den vergangenen 4 Wochen gegangen ist. (Bitte kreuzen Sie in jeder Zeile das Feld an, dass Ihrem Befinden am ehesten entspricht)

Wie oft waren Sie in den vergangenen 4 Wochen...	immer	meistens	Ziemlich oft	manch-mal	selten	nie
a. ... voller Schwung?	❍1	❍2	❍3	❍4	❍5	❍6
b. ... sehr nervös?	❍1	❍2	❍3	❍4	❍5	❍6
c. ...so niedergeschlagen, dass Sie nichts aufheitern konnte?	❍1	❍2	❍3	❍4	❍5	❍6
d. ... ruhig und gelassen?	❍1	❍2	❍3	❍4	❍5	❍6
e. ... voller Energie?	❍1	❍2	❍3	❍4	❍5	❍6
f. ... entmutigt und traurig?	❍1	❍2	❍3	❍4	❍5	❍6
g. ... erschöpft?	❍1	❍2	❍3	❍4	❍5	❍6
h. ... glücklich?	❍1	❍2	❍3	❍4	❍5	❍6
i. ... müde?	❍1	❍2	❍3	❍4	❍5	❍6

10. Wie häufig haben Ihre körperliche Gesundheit oder seelische Probleme in den vergangenen 4 Wochen Ihre Kontakt zu anderen Menschen (Besuche bei Freunden, Verwandten usw.) beeinträchtigt?

❍1 immer ❍2 meistens ❍3 manchmal ❍4 selten ❍5 nie

11. Inwieweit trifft jede der folgenden Aussagen auf Sie zu?

	Trifft ganz zu	Trifft weitgehend zu	Weiß nicht	Trifft weitgehend nicht zu	Trifft überhaupt nicht zu
a. Ich scheine etwas leichter als andere krank zu werden	❍1	❍2	❍3	❍4	❍5
b. Ich bin genauso gesund wie alle anderen, die ich kenne	❍1	❍2	❍3	❍4	❍5
c. Ich erwarte, dass meine Gesundheit nachläßt	❍1	❍2	❍3	❍4	❍5
d. Ich erfreue mich ausgezeichneter Gesundheit	❍1	❍2	❍3	❍4	❍5

Postoperative Questionaire

Comparison of TriLock Bridging Plates with conventional Bridging plates in the context of mandibular reconstruction

Postoperative Questionnaire

Surgeon _____ Date: _____

Surgery: _____ Plate: _____

Patient ID : _____

1.

Intraoperative adaptability to the bone	1 Very poor	2 poor	3 moderate	4 good	5 excellent

2.

Time to adapt plate to the bone	1 Very poor	2 poor	3 moderate	4 good	5 excellent

3.

Range of Plates	1 Very poor	2 poor	3 moderate	4 good	5 excellent

4.

Range of drill holes	1 Very poor	2 poor	3 moderate	4 good	5 excellent

5.

Range of screws	1 Very poor	2 poor	3 moderate	4 good	5 excellent

6.

Trimming of the plate	1 Very poor	2 poor	3 moderate	4 good	5 excellent

7.

Contouring of the plate	1 Very poor	2 poor	3 moderate	4 good	5 excellent