

Development and Clinical Evaluation of MatrixMANDIBLE Subcondylar Plates System (Synthes)

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Abstract

In this article, authors report the different steps of development and clinical validation of MatrixMANDIBLE Subcondylar Plates (Synthes, Soletta, Switzerland), a specialized osteosynthesis system developed by Synthes during the past 4 years. Between 2009 and 2013, a total of 62 patients were treated for subcondylar and condylar neck fractures via a preauricular or retromandibular/transparotid approach. The MatrixMANDIBLE Subcondylar Plates System consists of a Trapezoidal Plate, a three-dimensional (3D) 4-hole 1.0-mm plate for smaller fracture areas, the Lambda Plate, a 7-hole 1.0-mm linear plate which mimics the two miniplates technique, and the Strut Plate, a 3D 1.0-mm plate with great versatility of employment. All devices satisfy the principles of a functionally stable osteosynthesis as stated by Champy et al. None of the plates broke and no macroscopic condylar displacement was noted on radiological follow-up. Clinical and functional parameters assessed at 6 months postoperative (mandibular range of motion, pain, dental occlusion) were almost restored. MatrixMANDIBLE Subcondylar Plates System (Synthes) has proved to provide sufficient mechanical stiffness and anatomically accurate fracture reduction to avoid major postoperative drawbacks of subcondylar and condylar neck fractures.

Keywords

- ▶ subcondylar
- ▶ osteosynthesis
- ▶ internal rigid fixation
- ▶ condylar plate

Fractures of the mandibular condyle still account for a significant amount of all mandibular fractures, according to recent clinical reviews from 25 to 45%.^{1,2} In a randomized study in 2005,³ Loukota et al divided condylar fractures into head fractures (8%), neck fractures (32%), and subcondylar fractures (60%). Despite controversies between functional or surgical indications,^{4–8} treatment's aims must be functional restoration with a mouth opening > 40 mm, absence of pain during function, preservation of mandibular excursions, and restoration of occlusion with facial symmetry.⁹ Open reduction and internal rigid fixation (ORIF) in subcondylar and condylar neck fractures has become the standard option, owing to technical progresses in osteosynthesis methods (three-dimensional [3D]-shaped condylar plates) and introduction of endoscopic-

assisted procedures.^{10–12} Although encouraging biomechanical and clinical data, ORIF of condylar fractures is still prone to complications, such as plate bending and screws loosening, resulting in inadequate stability, at a rate of 4 to 20%.^{13–16} Authors report their personal clinical experience in plating technique of subcondylar and condylar neck fractures using specific MatrixMANDIBLE Subcondylar Plates System (Synthes, Soletta, Switzerland), a specialized osteosynthesis system developed during the past 4 years.

Materials and Methods

Data were collected between 2009 and 2013 with a mean of 12 patients treated per year and a total of 62 patients, with an

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age range of 17 to 63 years and a male:female ratio of 3:1. Pathogeneses of fractures were road accidents (48%), fist-fights (26%), accidental falls (16%), and sport traumas (10%). ORIF was performed in severely displaced/dislocated subcondylar and condylar neck fractures with dental malocclusion or vertical reduction of the ramus height, monolateral or bilateral condylar fractures, and isolated or complex mandibular/facial fractures. Exclusion criteria were total edentulism of one or both alveolar ridges and severe comorbidities. To reach the condyle area, the preauricular (25 cases) and the retromandibular/transparotid (37 cases) extraoral approaches were used, depending on the height of the fracture line (high-neck, low-neck, subcondylar fractures). Patients had at least 6 and 36 months maximum of follow-up period (with a mean follow-up of 21 months), consisting of clinical and radiographic evaluations. Clinical parameters monitored in the postoperative period were stability of occlusion, measurement of maximum interincisal distance, protrusion, laterotrusion, and mandibular deviation on mouth opening, persistence of pain during function, or chronic infection. Postoperative radiographic assessment included panoramic radiographs or computed tomographic scan. During 2009 and 2010, ORIF of subcondylar and condylar neck fractures were performed using two 4-hole 1.0-mm miniplates with monocortical screws, one plate placed parallel to the condylar axis along the posterior border of the ramus and the other parallel to the sigmoid notch, as stated by different authors in the literature.^{15,17-26} At the beginning of 2010, a new plating device for condylar fractures was introduced, the MatrixMANDIBLE Subcondylar Trapezoidal Plate (Synthes), a 4-hole 1.0-mm plate precontoured to fit the convex anatomy of the subcondylar region that progressively replaced the two miniplates technique in the surgical practice (►Figs. 1 and 2). At the end of 2010, another plate design was presented, the MatrixMANDIBLE Subcondylar Lambda Plate (Synthes), a 7-hole 1.0-mm plate which mimicked the two miniplates technique, with a straight segment parallel to the posterior border of the ramus and an anterior curved arm aligned to the sigmoidal notch (►Figs. 3 and 4). From 2010 to 2013, these two condylar plating systems were both used in subcondylar and condylar neck fractures, addressing a great variety of fractures with some differences according to specific indications. With its particular design, the Lambda Plate could address a large fracture area, although needing wider exposition through a retromandibular/transparotid approach.



Fig. 1 Displaced subcondylar fracture in a complex facial fracture.

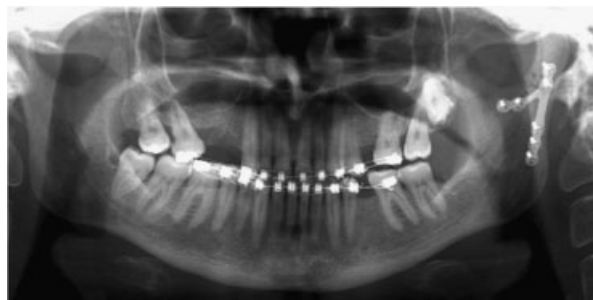


Fig. 2 Anatomic restoration of subcondylar region through a Trapezoidal Plate.



Fig. 3 Severely dislocated subcondylar fracture: lost relation between condyle and glenoid fossa with malocclusion.



Fig. 4 Accurate anatomic fracture reduction and rigid fixation through a Lambda Linear Plate.

Linear holes arrangement in the cranial segment of the plate facilitated fixation of high-neck condylar fractures with small condylar fragments. The feasibility of bending both arms or cut some holes allowed an easy anatomic adaptation to the fracture area. On the contrary, the reduced size of the Trapezoidal Plate allowed placement using different surgical approaches (preauricular or retromandibular/transparotid). The specific design easily fit the convex anatomy of the subcondylar region but its position was limited by the neck width. In 2013, a new condylar plate design, the Matrix-MANDIBLE Subcondylar 1.0 mm Strut Plate (Synthes) was introduced. With its particular plate design, the newly developed condylar device proved to have great versatility of employment and became the system of primary choice in authors' surgical practice (► Figs. 5 and 6). The Strut Plate was designed according to the two miniplates concept: the straight 3-hole segment has to be parallel to the posterior border of the ramus, aligned with the condylar head, while the 2-hole segment follows the rim of the sigmoid notch. Moreover, its size smaller than the Lambda Plate allowed placement through all surgical approaches. Its lightly curved profile and the possibility of bending the superior holes independently allowed a comfortably adaptation to the anatomy of the condylar neck and subcondylar region.

Results

Postoperative clinical and radiological results were generally comparable using all kinds of condylar device. The operation time for ORIF of the condylar fractures ranged variably, between 60 and 120 minutes, depending on the surgical approach and the degree of condylar displacement/dislocation. No anatomic misalignment of the fracture was observed or no plate fracture occurred in the follow-up period. Postoperative wound healing complications were observed in 25% of patients (16 patients): temporary salivary leakage through the surgical wound was observed in 10 patients who received



Fig. 5 Subcondylar fracture with displacement: loss of vertical dimension and open bite.



Fig. 6 Reduction and fixation using a Strut Plate: restoration of ramus height and occlusion.

a retromandibular/transparotid approach, healed with sterile compressive dressings. Six patients developed postoperative infections (four patients who received a preauricular approach and two patients who received a retromandibular/transparotid approach); the most common isolated pathogen was *Staphylococcus epidermidis* and infections were treated with irrigations and antibiotics systemic administration. Screw loosening was observed in three patients who developed postoperative infections: the screws were removed but nonetheless fracture healing and bone consolidation were complete in all cases. Clinical and functional evaluation revealed a mean maximal mouth opening of 41 mm at 6 months follow-up period (minimum value 35 mm, maximum 48 mm); mandibular protrusion and laterotrusion were almost normal (a mean value of 5 mm at 6 months postoperatively) with a slight lateral deviation to the fractured side on maximum mouth opening (1–2 mm) in 12 of the 62 patients. Although a transient slight malocclusion in the immediate postoperative period in 11 patients, which disappeared with functional elastics therapy, pretraumatic occlusion was generally restored. Despite initial pain during function, at mean follow-up period, it generally disappeared. A total of 18 patients (11 who received the retromandibular/transparotid and 7 who received the preauricular approach) suffered from transient facial nerve palsy, of both the frontal branch and the zygomatic one, which spontaneously disappeared in a mean time of 3 to 4 weeks, probably due to wider surgical fields or retractors' soft tissues compression.

Discussion

A proper surgical treatment of condylar neck and subcondylar fractures is mandatory to avoid long-term severe drawbacks, such as asymmetry, growth deficiency involving the orbit, the maxilla and the mandible if occurring during childhood, temporomandibular joint (TMJ) dysfunction with pain, malocclusion with retrognathia, open bite, reduced protrusion and laterotrusion, or fibrous or osseous ankylosis. The treatment outcome of condylar neck and subcondylar

fractures has gained considerably from ORIF.^{6,27-30} Nevertheless, internal rigid fixation has to be sufficient stable to fulfil the principles of functionally stable osteosynthesis as stated by Champy et al.³¹⁻³³ The osteosynthesis device has to be rigid enough to withstand physiologic masticatory forces applied on the condylar region and the plate design has to fit the strain pattern occurring in the condylar region during function: tensile strain lines along the rim of the sigmoid notch and compressive strain lines along the posterior border of the ramus, parallel to the condylar axis.²⁶ The use of a single straight 4-hole miniplate, placed vertically, aligned to the condylar axis, where the bone of the ramus is thickest, is not adequate.^{8,14,16,34-40} It neither respects the principle of functionally stable osteosynthesis nor prevents secondary displacement with fracture line diastasis along the sigmoid notch and plate fracture. It has been clearly demonstrated both clinically and experimentally.^{15,16,20,23,34,36,41-46} Even the alternative solutions advocated by some authors^{6,14,47-52} of a more rigid plate or a more solid fixation by means of bicortical screws or dynamic compression plate lead to treatment failure.^{41,53,54} Moreover, the use of heavy plates is usually not applicable to the small condylar segment. The two 4-hole miniplates technique with monocortical screws has proved to be the most reliable and functionally stable osteosynthesis procedure for condylar neck and subcondylar fractures and is considered the standard practice.^{15,17-26} Wagner et al in 2002 experimentally proved its biomechanical superiority.⁴² The anterior plate is placed along the tensile strain lines following the rim of the sigmoid notch and protects the posterior plate from mechanical strains. The posterior plate, fixed along the condylar axis at the posterior border of the ramus and almost strain free, retains the reduced correct position in the frontal and horizontal planes and prevents slippage or rotation of the condylar fragment. However, it could be sometimes difficult to insert four screws in the smaller condylar segment and can be particularly challenging in minimally invasive approaches to the condylar fracture. In the effort to overcome these limitations, specially designed 3D plates have been proposed and are available. Square and rectangular 3D plates were introduced by Farm-and et al in the 1990s for condylar fractures treatment^{55,56} as the best mechanical compromise to ensure primary stabilization of condylar fractures. They were resumed in 2006 by Meyer et al⁴³ as a 3D rectangular plate (Profile 2.3, Leibinger, Freiburg, Germany). Unlike the two miniplates technique, 3D plates seemed to improve osteosynthesis stability thanks to the mechanical connection between the two plate's arms. Moreover, their smaller size can avoid excessive soft tissue stripping during surgery and improves handling in minimally invasive surgical approaches. However, the square and rectangular plate geometry grossly respects the two miniplates concept in withstanding masticatory forces and partially satisfies the principles of functionally stable osteosynthesis as stated by Champy et al.³¹⁻³³ The anterior arm being parallel to the posterior one, it does not sufficiently support the tensile strains that develop parallel to the boundary of the sigmoid notch. An incorrect transmission of forces may derive.²⁶ Several solutions have been proposed in the literature to

overcome these problems. In 2007, Meyer et al introduced the 3D 4/9-hole trapezoidal osteosynthesis plate (Modus TCP 2.0 Medartis, Basel, Switzerland) fixed with 2.0 monocortical screws, specifically designed to improve plate biofunctionality in stabilizing subcondylar and condylar neck fractures.⁵⁷ Owing to this plate's shape modification, the anterior plate arm could follow as close as possible the tensile strains developing along the rim of the sigmoid notch, while the posterior arm could parallel the posterior border of the ramus with its compressive strain lines. Meyer et al published the results of an experimental protocol: standardized subcondylar fractures were produced on fresh dentate human mandibles, stabilized with either a 4- or a 9-hole 3D Trapezoidal Plate and loaded into a test bench reproducing maximum static biting forces. Results were evaluated by visual analysis of the macroscopic fracture line displacement and photoelastimetric analysis of the pre- and postsurgical strain patterns. No macroscopic fracture displacement was noted; the preoperative strain pattern in the subcondylar area, disrupted by the produced fracture, was perfectly restored by the 3D Trapezoidal Plate owing to a physiologic transmission of forces. The biomechanical required principles of functionally stable osteosynthesis were satisfied. The 3D design improves mechanical stability and needs minimal soft tissue stripping. Moreover, unlike the two miniplates technique, only two monocortical screws, both in the 4- and 9-hole plates, are necessary in the fractured condyle. The two different 4- or 9-hole variations allow adaptation to various situations: common subcondylar and high-neck fractures for the 4-hole plate, whose size respects the mean condylar neck width; comminuted, low-neck, and subcondylar fractures for the 9-hole plate, which allows greater adaptation to particular situations (poor bone quality, poor primary reduction, multiple fractures lines) and some bending possibilities. First in 2007 and then in 2011, Lauer et al^{58,59} presented their delta-shaped condylar miniplate (Modus Trauma 2.0 Condylus Fragment Plate, Medartis, Freiburg, Germany) and the Trilock Delta Condyle Trauma Plate (Medartis) fixed with 2.0 mm monocortical screws. The Delta Plate was initially tested in biomechanical and clinical studies confirming it could sufficiently neutralize tension and compression forces and produce great stability, combined with the advantage of a smaller plate.⁵⁷⁻⁶⁰ In the effort to further ameliorate results, a locking system was introduced, the Trilock Delta Condyle Trauma Plate. Resembling an external fixture, it makes thorough plate bending superfluous because intimate plate adaption to the bone contour is no longer necessary, preventing from excessive stripping. Its greater primary stability across the fracture gap reduces micromovements and screws loosening. In an experimental study with porcine hemimandibles,⁵⁹ the biomechanical behavior of Delta Plate and Trilock Delta Condyle Trauma Plate was compared with the two miniplates system. Results revealed generally better performances of the Delta System, and of the locking system in particular, compared with the two miniplates technique. Authors report their experience in the treatment of subcondylar and condylar neck fractures using the Synthes MatrixMANDIBLE Subcondylar Plates System. Introduced in 2010 and gradually enriched through years, it consists of

implants specifically designed for fractures of the subcondylar and condylar neck region to address different fracture patterns. All devices satisfy the principles of functionally stable osteosynthesis as stated by Champy et al^{31–33}: the plate's anterior arm has to perfectly follow the tensile strain lines along the rim of the sigmoid notch and acts as a tension resisting plate; the plate's posterior arm has to be located along the axis of the condyle neck, free from any harmful bending strain, and essentially maintains the reduction preventing slippage or rotation of the condylar fragment. The thickness of all plates in the system is 1.0 mm, complying with the thickness of the plate proposed by Seemann et al.⁶¹ Moreover, the 3D shape of the Trapezoidal and Strut Plates with their connection arms provides greater internal stability and more optimal leverage. The 7-hole 1.0-mm Lambda Plate gives the possibility to address a large fracture area through a wide extraoral access. With its 2-hole linear cranial segment and the feasibility of bending both anterior and posterior arms or cutting some holes it allows a greater anatomic adaptation. The Trapezoidal and the Strut Plate merge both the 3D plate concept and the two miniplates technique. The 4-hole 1.0-mm Trapezoidal Plate stabilizes a smaller fracture area but does not need excessive soft tissues stripping. It is precontoured to adapt to the convexity of the condylar neck and subcondylar region but the neck width can be a position limiting factor. After the introduction of the 4-hole 1.0-mm Strut Plate this plate has been widely used in various different situations owing to its greater versatility. Its reduced size allows for employment through different extraoral approaches with minimal soft tissues dissection. It has a precontoured curved profile to anatomically fit the fracture area, which can be further improved by a considerable bending chance.

Conclusion

Clinical data collected by the authors and the widely studied biomechanical background in the literature suggest that Synthes Subcondylar Plate System fulfils the principles of a functionally stable osteosynthesis and is suitable for ORIF of subcondylar and condylar neck fractures. The wide range of plate designs allows adequate stabilization of different fracture patterns although the 4-hole 1.0-mm Strut Plate proves greater versatility. A further clinical long-term evaluation is mandatory to determine the plates' behavior in vivo.

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