

CASE REPORT

Clavicle anatomical osteosynthesis plate breakage – failure analysis report based on patient morphological parameters

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Abstract

Clavicle fracture reported incidence is about 5% of fractures in adult; among them, those located in the middle third of the shaft represent more than 80% from the total of cases. Due to the special morphological and biomechanical constraints of the clavicle, several methods for restoring morphological integrity in these fractures are described, including conservative, non-surgical treatment. The last 10 years of clinical studies in the field have favored the surgical treatment for selected cases; several osteosynthesis implants are in use – mostly anatomical plates with specific advantages and documented complications. A failed anatomical clavicle plate was explanted and analyzed after a protocol using stereomicroscopy, scanning electron microscopy and energy dispersive spectrometry. Based on the computed tomography (CT) scan determination of patient morphological parameters, a finite elements analysis of the failure scenario was completed. The failure analysis has proved that the plate breakage had occurred in the point of maximal elastic stress and minor deformation. The clinical implication is that no hole should remain free of screw during clavicle plate fixation and the implant should be chosen based on patient morphological parameters. In comminuted clavicle fracture, anatomic bridging with locked plate technique may lead to implant failure due to increase of the stress in the midshaft area. Thorough knowledge of anatomy and morphology of complex bones like the clavicle is necessary. Modern osteosynthesis anatomical implants are still to be improved.

Keywords: midshaft clavicle fracture, anatomic plates, complications, failure analysis.

Introduction

Clavicle fracture reported incidence is about 5% of fractures in adult; among them, those located in the middle third of the shaft represent more than 80% from the total of cases. Due to the special morphological and biomechanical constraints of the clavicle, several methods for restoring morphological integrity in these fractures are described, including conservative, non-surgical treatment [1]. The last 10 years of clinical studies in the field have favored the surgical treatment for selected cases. Whenever there is a displacement – usually postero-superior – combined with angulation and shortening of the shaft, or the fracture pattern is comminuted, or contains a vertical fragment, the surgical treatment is indicated in order to obtain anatomical reduction and good shoulder function results [2].

Surgical treatment for displaced middle shaft clavicle fractures include plate fixation (pre-contoured, blocked or un-blocked), intramedullary fixation or various combinations of the above mentioned; among the implants, there are special devices (as Mennen plate) or complementary suture techniques, all of them in the effort to obtain a good fracture reduction and a good primary stability. The reported outcomes of these techniques include reasonable good results as well as complications [3, 4]. Among the complications, non-union and implant failure are the most feared. Variable rates for these complications are reported; however, there is an agreement

that for displaced middle shaft clavicle fractures surgical treatment offers better results, in order to reduce non-union rate (from 10–15% to 2%) [4] and to improve functional scores. Factors related to higher complications rate were described; among them age, degree of fracture displacement, female gender and fracture comminution [4]. Frequently, the lack of osseous contact at fracture site, as in transverse fracture patterns may cause complications in the fracture healing process and overall recovery. Concerning the amount of implant failures, there are not many publications in the literature [5, 6] especially related to the complex morphology of the clavicle.

Our study starts from a series of clinical observations with documented early failure of an anatomically contoured implant; in one case, the implant was retrieved and an anatomical-biomechanical analysis of the failure mechanism was performed.

Patient, Materials and Methods

The case study implicates a 28-year-old male with a documented comminuted fracture in the middle third of the clavicle, with an intermediary fragment inferiorly located, displacement and shortening of the shoulder of 2 cm. Considering the age, the level of physical activity and fracture pattern a surgical treatment was indicated and performed. Open reduction and osteosynthesis with blocked anatomically precontoured plate, in a bridging fashion was performed; in addition, two special sutures

(FiberWire No. 2, Arthrex®) were added to connect the intermediary fragment to the main bone shaft (Figure 1a). For the first three weeks, the shoulder was immobilized in a sling; after three weeks, he started passive mobilization and progressively regained its shoulder mobility. At six weeks, during daily living activities, he felt a sudden onset of pain and completely lost shoulder function. Clinical examination revealed complete breakage of the implant (Figure 2a). As a special notice, the intermediary fragment was solidary with montage during breakage. Surgery was advised; the implant was retrieved and a complete analysis was initiated (Figure 3, a and b). The fracture was reduced and a new reconstruction plate was implanted. The patient resumed his previous activities at four months; at two years follow-up, the shoulder function is completely restored.

The explant analysis followed a established protocol begun with a complete macroscopic examination, stereomicroscopic images (Olympus SZX7) of failure area were obtained; the breakage was located right in the middle of screw hole and no material inhomogeneities were noted (Figure 3b). The scanning electron microscopy (SEM, ESEM Philips XL 30 TMP) documented that there were no structural inhomogeneities in failure area (Figure 4).

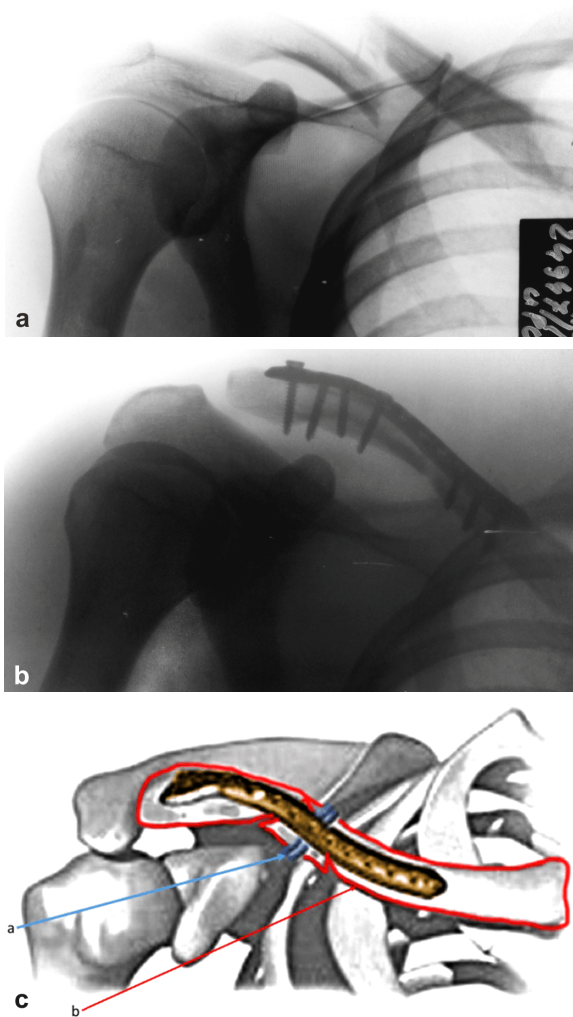


Figure 1 – (a) X-ray: comminuted fracture of the clavicle with intermediary fragment; (b) Postoperative X-ray with reduction and bridging osteosynthesis with anatomical contoured locked plate; (c) Surgical principle – bridging the fracture interval (anatomical plate and additional FiberWire No. 2 cerclage fixation).

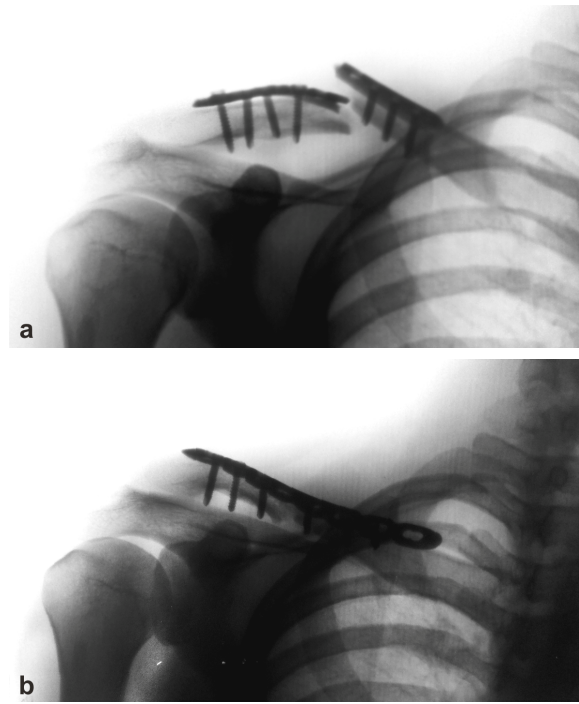


Figure 2 – (a) X-ray: implant failure with subsequent plate breakage; (b) X-ray postoperative control after revision.

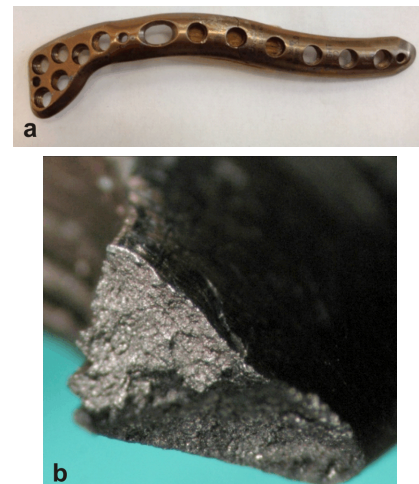


Figure 3 – (a) Breakage of the plate – the arrows shows the area where the plate failed; (b) Stereomicroscopy image of the failure area (12.5×) revealing the fractured area. The observed surface had no severe plastic deformation marks, the fracture direction was almost perpendicular on the surface and this one remained relatively regular, resulting that the implant breakage was fragile-type.

Energy dispersive spectrometry (EDS) was next completed in the plate examination. The main purpose of these examinations was to check the material composition and see if they are in agreement with manufacturer reports. In this respect, metallographic specimens were harvested and sampled; it has been proved that the implant was within standards. In addition, microstructure characteristics, possible defects as well as structural inhomogeneity were analyzed. The complete analysis confirms plate composition – titanium as well as screw composition – Ti-Al-V; no structural inhomogeneity was noted.

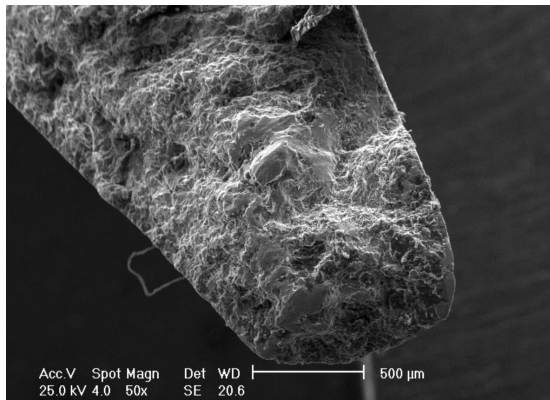


Figure 4 – Scanning electron microscopy images of the failure area with magnified detail of failure; at 50× magnification, the analysis revealed a homogenous structure in the fracture zone; impurities or other compounds are absent, leading to the conclusion that the fracture occurred due to some external factors.

In order to check the hypothesis of failure of the anatomical plate due to morphological constraints, the mode of breakdown was experimentally tested through a computer-simulated load analysis. The finite elements analysis was performed as a structural analysis using ANSYS 12 software (ANSYS Inc., PA, USA). A tetrahedral mesh model with 2 mm size elements was created from the patient morphological parameters of the shoulder girdle (Figures 5 and 6). The DICOM files from the patients computed tomography (CT) scans were initially imported in MIMICS 10.1 (Materialise Inc., Leeuwen, Belgium) – the reconstructed three-dimensional (3D) model from two-dimensional (2D) data was further refined for anatomical and geometric accuracy using Geomagic Studio 9 (3D System Inc., USA) (Figure 7).

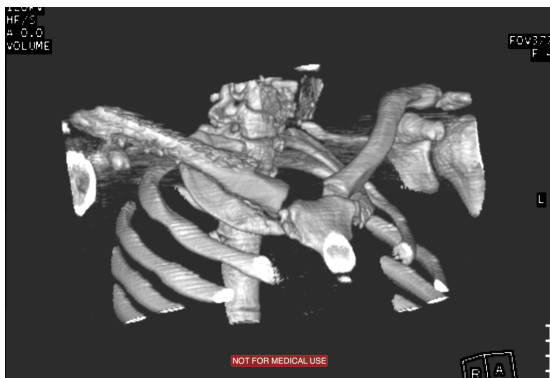


Figure 5 – 3D rendering of the shoulder girdle is developed from the 2D DICOM dataset acquired from the patient CT (MIMICS software allows reconstruction of exact anatomy of the patient, allowing further experimentation on a real case-based scenario).

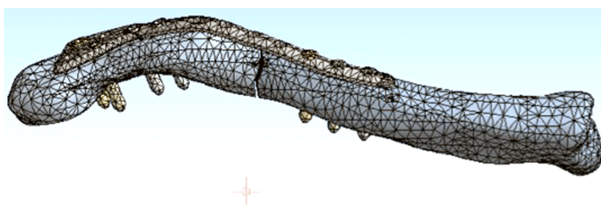


Figure 6 – Structure discretization – a mathematical model of the patient clavicle is created from 2 mm tetrahedral elements in MIMICS software filtered after the previous step of 3D rendering.

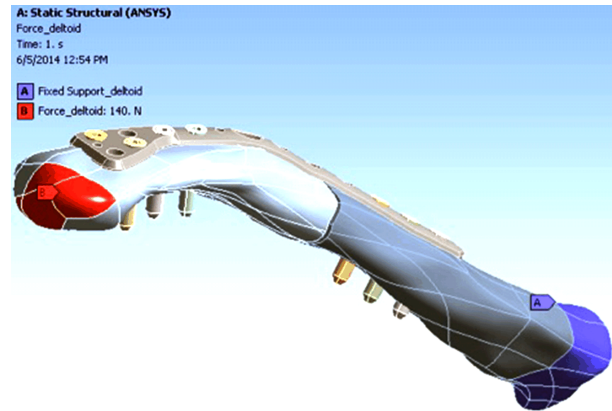


Figure 7 – Boundary limit established after refinement of the morphological 3D model in Geomagic Studio software; ANSYS software applied simulation of forces were applied on the reconstructed patient model.

The anatomical positioning of the implant is also important; the plate was placed on the superior surface of the clavicle, according to recommended surgical guidelines. The force transmitted during a fall on the arm is directed through the head of the humerus mainly to the scapula (Figure 8a). There is no apparent transmission of the biomechanical load to the clavicle. The applied force to the clavicle is only through direct contact with the acromion process. Two components of the axial force can be described F_y and F_z that will tend to move the scapula upwards and backwards, away from the clavicle, with a tendency to dislocation rather than fracture. Only in those cases when the outstretched arm is in the coronal plane relative to the body, is it possible that the force component F_x will be sufficient to produce compression forces in the clavicle shaft and subsequent fracture. Recent biomechanical studies confirm that with upwards and backwards movement of the scapula, the force transferred from the attached ligaments and muscles is enough to produce clavicular bending. Two types of loading conditions were used – axial compression F_x and inferior bending (F_y and F_z). In contrast, Figure 8b shows that with an effort to the arm it is possible for the entire force to be transmitted along the clavicular axis in different angles, so that three perpendicular components F_x , F_y and F_z form along and perpendicular to the axis of the clavicle. Even if F_x is zero, when muscles are activated, both F_y and F_z are variable purely along the clavicular axis. In an attempt to be as close as *in vivo* scenarios, two simulations were completed: one regarding the deltoid muscle activation and the second regarding the major pectoralis muscle. During examination, an overall distribution of equivalent elastic stress at 300 N anterior deltoid activation was utilized. The simulation image confirms a uniform distribution with only one peak at the level of the breakage point. At the breakage point, stress value was close to 67.9 N, comparing to the minimum-recorded tensile forces of 5.85 N. The total deformation has a 1 mm value and it was maximum at the acromial clavicle end and minimum at the sternal clavicle end (Figure 9a); at breakpoint site, the initial deformation was between 0.25304 and 0 mm (Figure 9b). When interpreting these results, we should take into account the fact that titanium plates leads to less stress shielding due to the elastic modulus close to that of the bone. On the other hand, the

biomechanical load is higher in locked plate configuration, which is our case.

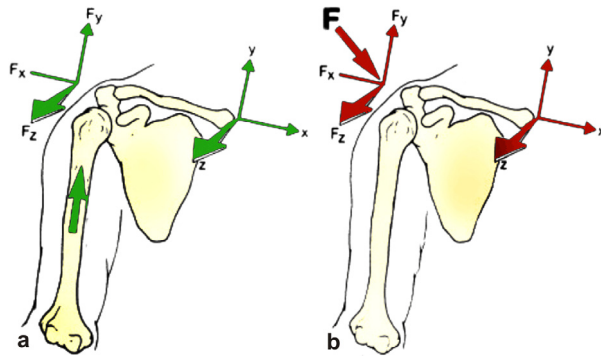


Figure 8 – (a) The impact force vector F is directed along the humerus when falling on the outstretched arm. (b) The impact force vector F associated with a direct shock on the shoulder has three components along the clavicle. In vivo, there is an important effect related to muscular forces, so, validated simulation protocols take into account deltoid and major pectoralis activation [7].

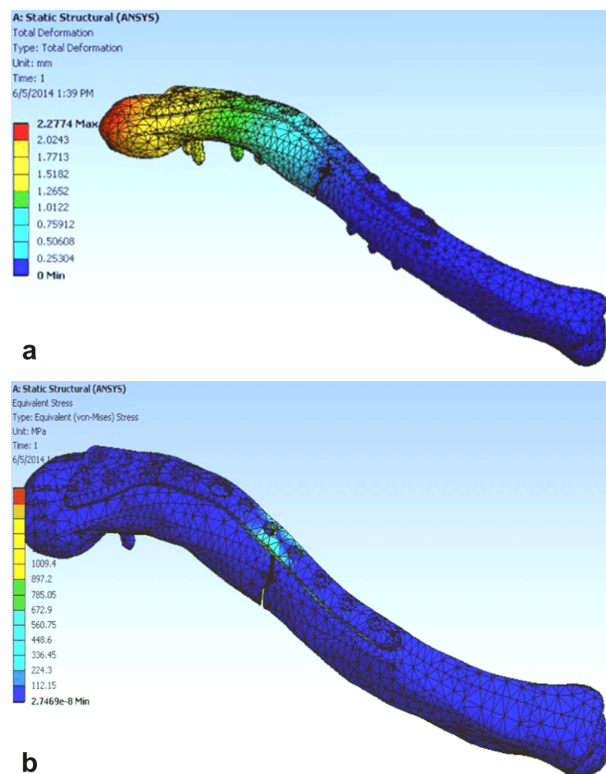


Figure 9 – (a) Total deformation of the implanted assembly, at maximum load in ANSYS 12 software simulation; (b) At 300 N, the force of the pectoralis muscle produces also tensions sent into the anatomical implant.

The distribution graph in the plate presented in Figure 10 indicates two logical elements: the equivalent tensions increase as the load value increases and their distribution shows a maximum in the aperture proximity due to the load intensification edges. The problem is that, due to the special morphology of the clavicle, load values in this area are higher than the yield limits over 100 N loads. The overpassing of the yield limit would result in plate breakage. Taking into account the implant dimensions, material and the anchorage modality it would be useful

the patient restriction in order to decrease the possibility for him to develop forces more than 100 N. The equivalence of the 100 N force developed by the patient is carrying of an item heavier than 9 kg or traction–pushing of heavy objects.

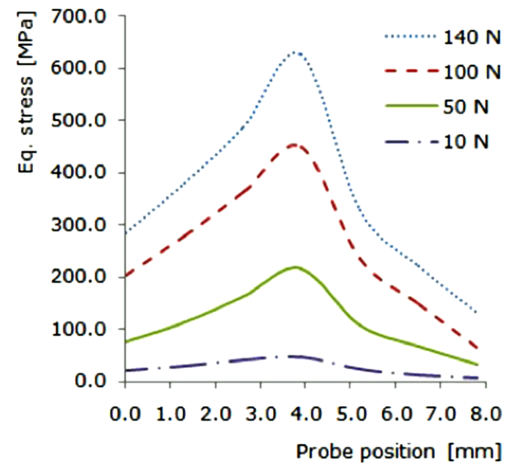


Figure 10 – Plate tension distribution graph in the plate at the four loading forces in the patient model (showing a normal distribution and characteristics).

Discussion

Functionally, the clavicle actions mainly as a point of muscle attachment. Some of the early literature suggested that with good repair of the muscle, the only functional consequences of surgical removal of the clavicle are limitations in heavy overhead activity and that its function as a support [8] is therefore less important. This concept seems to be supported by the relatively good function of persons with congenital absence of the clavicle. However, others have found that anatomical modifications of the clavicle in adulthood have an overwhelming effect on shoulder function [9].

The biomechanical behavior of the clavicle remained less well understood until recent studies [10]. This is probably due to the complex anatomy, such as the complicated attachments of multiple ligaments and muscles, which make the measurement of muscle forces acting during real life scenarios nearly impossible. However, as the major supporting structure for the shoulder, the clavicle is positioned under two frequent loading modes: bending and compressive loads [11]. Clavicle fractures are the most frequent cited fractures of the shoulder with most of them located in the midshaft; this is related to the morphological features of the bone. Bachoura *et al.* [12] represented a model of the clavicle constructed around two inverse curves enabling the bone to absorb stress; segmentation into areas based on the biomechanical centers of rotation of the two described curves define one short lateral area and two wide – middle and intermediate – segments. Osteosynthesis anatomical implants on the market are designed using statistical data from such studies; unfortunately, individual anatomy is far more complex. Some companies produce plate options: superior medial, superior distal, inferior medial and inferior distal. Superior plates are available in left and right for precise contour, pre-contoured to reduce need for additional intraoperative contouring and what is more important,

with reconstruction-like plate segments to aid additional modeling if necessary [13].

Currently, the anatomical indications for surgical treatment in clavicle fracture are well established: displacement over 100%, shortening more than 2 cm and presence of a vertical *zed* fragment [14, 15]. The goals of osteosynthesis – surgical fixation of the bone, are to prevent nonunion development, to decrease the time of immobilization and to restore shoulder function by restoring clavicle morphology. Surgical treatment is based on utilization of different implants to achieve clavicle fixation [16]. Two main groups of implants are used: extramedullary devices as plates and intramedullary devices as nails. Intramedullary fixation in clavicle fracture is a relatively new concept and it was developed based on its presumed advantages: smaller incisions, lesser muscular stripping during approach, closed reduction with fracture hematoma's preservation. As its use begun to expand, its disadvantages were revealed; among them: less mechanical rotational stability, less anatomical reduction, irradiation for both patient and medical personal and frequent implant breakage [15]. Extramedullary fixation is the most used treatment in clavicle fracture. Several facts are well known and already admitted in this type of treatment: the fixation depends on fracture pattern, maximum fixation strength is obtained when six screws are used (three medial and three lateral), additional fixation is needed in comminuted fractures (wires cerclage or screws), additional autograft may be considered [6, 17]. However, some issues are still on debate; among them best positioning of the plate. Robertson *et al.*, in a paper from 2008 [18], recommended an anterior–inferior placement of the plate for better results. Still, the anterior–superior positioning is mostly used [19].

For achieving extramedullary fixation, several types of plates are used. Low-contact compression plates are strong but bulky, difficult to accommodate to the clavicle anatomy and may cause soft tissue irritation. Reconstruction plates are easier to contour but offer less mechanical strength [18, 20]. Repeated bending of the plate – during surgery, in order to achieve a better fitting to the bone – may affect mechanical strength. In addition, it is time consuming and based on surgeon experience and patience. Pre-contoured anatomical plates do not require additional bending; having a lower profile, they cause less irritation issues while maintaining good mechanical strength. However, the choice for the plate is not easy; in a study from 2007, Huang *et al.* [21] documented that the shape of the plate can accommodate mostly of superior contour of clavicle in male but not in female. Therefore, choosing the right plate is not an easy job. It may prolong the surgery time because we should fit the plate to individual size and shape characteristics. This is why there are papers that recommend preoperative 3D printing of fracture for making plate choice easier and more effective [22]. Operative treatment is not free of complications; rates as about 27% are reported [23].

Among them, implant failure is reported. Failure of the implants usually occurs in the first three postoperative months. Its reported frequency is between 1% and 4% of the cases [24]. The type of fixation in cases, which used plate fixation, is rigid; even more, in cases when blocked plate is used. During stress, the plate may bend or break.

When talking about modes of implant failure at least two possibilities can be taken into account: a mechanical or a biological mode [25]. The biological mode is usually related to poor bone quality, frequent in elderly people; also, when the failure site is located at bone–screw interface, a biological mode of failure may be implied. In the mechanical mode of failure, usually a bending stress on the bone is transmitted to the implant and generates a failure located at the screw–plate junction. We suspected in our case a complex type of mechanical failure. The failure analysis protocol of implants that was performed [26] showed no structural inhomogeneities of the implant. In order to support our hypothesis, a load analysis was conducted; during it, forces acting over clavicle have been examined and impact over anatomical plate osteosynthesis was evaluated.

In our case, the breakage point was right in the middle of the three holes free of screws – because of the fracture pattern, it was not possible a screw insertion in the intermediary bone fragment without the risk for further damage. Therefore, the unobstructed holes in this bridging technique created a zone of minimal resistance, in the area free of screws, which induced plate breakage right in its middle point. It may be hypothesized that an appropriate plate should not have unobstructed holes at all. Monocortical screws or obturators placed in the free holes may enhance mechanical plate integrity and prevent its failure.

Also, the specific distribution of tension forces due to the morphological characteristics of the area in which the fracture occurred (midshaft, turning point between the two anatomical curves of the clavicle), may had a significant impact on the failure scenario. In our case, for a comminuted midshaft clavicle fracture, with 100% displacement, 2 cm shortening and presence of an intermediary fragment osteosynthesis with pre-contoured plate was recommended. Because of the fracture pattern, a bridging technique was used, in order to protect the intermediary fragment for further comminution. An additional fixation of the intermediary fragment was achieved with two sutures with FiberWire No. 2. This additional fixation method has proven to be effective; at the moment of implant breakage, the intermediary fragment was healed to the medial side, so convert the comminuted fracture into a common two fragments fracture. This additional fixation may be safely used in case of comminution cases [27].

We may presume that, during daily living activities, the tension stress was uniformly distributed through entire clavicle and plate, as in the finite elements analysis modeling performed. Such computer-aided techniques are currently more utilized for validation of novel surgical techniques [7]. As distribution of stress was uniform and the deformation was close to minimum in the failure area, it may be presumed that the oblong, unobstructed hole was a point of weakness from where the failure started. Therefore, the bridging technique may be related to complications like implant breakage. To prevent this unfortunate events plate strength should be enhanced. A feasible method to do that is using an appropriate technique; in this case, a suitable technique means that less – or none if possible – holes remain unobstructed. We may use monocortical screws or simple obturators for the holes in order to protect the comminuted fragment for further damage and enhance plate strength.

On the other hand, we should take into account that reconstruction of every comminuted clavicle fracture is a challenge. The appropriate type of plate, the appropriate surgical technique and rehabilitation protocol should be used. Recent publications recommend a careful preoperative planning in clavicle midshaft fractures but strong clinical evidence still favor plate fixation [28].

✉ Conclusions

In comminuted clavicle fracture, anatomical bridging locked plate technique may cause implant failure due to increase of the stress in free holes area. Thorough knowledge of anatomy and morphology of complex bones like the clavicle is necessary for surgical reconstruction. Modern anatomical implants are still to be ameliorated with regard to the specific morphology of the patient – one important development may be related to 3D printing of such implants.

Conflict of interests

The authors declare that they have no conflict of interests.

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