Patient with recurrent fracture of osteosynthetic plate-association with the composition of osteosynthetic material and its fractographical study: a case report

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Case Report

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Abstract

Background

This case report deals with a twice reoperated patient with right clavicle fracture at the same position within 5 months. The report was divided in to three parts.

Case presentation

In the first part the description of both injuries and the methods of their treatment are provided: i) The patient suffered a fracture of the right clavicle which was fixed using Ti LCP-SCP plate (Locking Compression Plate - Superior Clavicle Plate). ii) Another accident occurred after five months which resulted with the refracture of the right clavicle and bending of the osteosynthetic material requiring the reoperation of the patient again using the Ti LCP-SCP plate iii) After seven months, the patient arrived at the hospital indicating the pain in the right clavicle, whereas the fracture of the osteosynthetic material was detected. This last fracture was fixed again with Ti LCP-SCP plate in combination with two lag screws cross sectionally positioned.

Conclusion

Whereas second and third parts are focused on the complex evaluation of osteosynthetic material and the tissue observations of this medical case. The second part is focused on the evaluation of the osteosynthetic material and a its fractographical study. The third part of the case report is devoted to the microscopic analysis of the metal particles found in tissues in positions of the contacts with osteosynthetic material.

Background

Fractures of the clavicle incidence is 2.6–5% of all fractures in adults [1]. The majority (69–82%) of fractures occur in the mid-shaft of the clavicle, followed by 12–26% in the lateral part and 2–6% in the medial part [2–5]. The middle part of the collarbone is fragile, because there are no muscular or ligamentous attachments, so it does not have support unlike the medial and lateral parts, which are firmly fixed. [6]. The most frequent injury mechanism is a direct fall on the shoulder. Fractures are often sustained during sports activities or traffic accidents [4]. In the past, the surgical treatment has only been recommended in case of open fracture, vascular bundle injury and floating shoulder. Conservative therapy still predominates; however, the trend has moved towards surgical stabilization of selected fractures including significant shortening (more than 2 centimeters), dislocation of more than full bone width, and the appearance of a transverse z-shaped (zed) fragment [6, 7, 8]. There are several options for osteosynthesis - plate fixation [6, 9, 10] or intramedullary fixation (pin [9, 10], threaded k-wires or elastic nails [11–13]).

Intramedullary osteosynthesis requires smaller incision to reduce the fracture and just a point incision for insertion of pin or elastic nail from the medial or lateral end of the clavicle. However, a higher rate of implant failure has been reported with pin fixation and it is a technique which is not appropriate for all types of fractures [8]. Plate fixation with precontoured LCP-SCP plates made to copy the S-shaped clavicle have gained popularity recently [6]. Plate fixation requires broader tissue dissection and therefore there's a higher risk of injury to surrounding structures (i.e. superior clavicular nerves) which is one of the main disadvantages. Another is implant prominence given the lack of subcutaneous tissue in some patients [14, 15]. The implant failure most commonly occurs in the first three months postoperatively. The frequency of intramedullary implants failure is between 3,5- 6% [16–18] and plate failure between 1% and 4% of the cases [19]. The plate fixation is very rigid, especially the locked plate and under stress the plate may bend or even fracture.

There are at least three main reasons for implant failure that can be considered: a biological, mechanical and implant composition (structural abnormalities, surface integrity, corrosion). The biological is mainly due to poor bone quality, prevalent in elderly patients; and the predominant failure site is the bone–screw interface. From the mechanical point of view, the bending stress is transmitted to the plate and usually results in a failure at the screw–plate interface. Clavicle is subjected to two main loading modes: bending and compressive loads [20]. Because of the characteristic anatomy of the clavicle, the load values in the mid-shaft area could be after osteosynthesis higher than the yield limits loads [21, 22]. To reduce the forces, it is optimal to combine plate osteosynthesis with additional fixation.

For comminuted fracture interfragmentary screw fixation is recommended before cerclage wiring [23]. In opposite, the holes free of screws in the bridging technique could create a problem. They are the weak point due to reduced cross-sectional area in this part and the plate is therefore prone to breakage in this part. Monocortical screws or obturators placed in the free holes may enhance mechanical plate integrity and prevent its failure. But if you fill the holes, there will be an unavoidable interaction between the screws and the plate, leading to wear and corrosion fatigue [24]. Ideally, therefore, the plate would not have unnecessary holes above the comminution zone.

Surface integrity of the implant is crucial because it typically becomes the initiation point for plate fracture. The damaged surface might be the result of careless surgical techniques, wear and tear (repeated dynamic loading, wear at component junctions) or faulty manufacturing. Every and any type of surface defect, e.g., pitting, fretting, fatigue cracking, or crevicing, is a weak point and is at high risk of corrosion, which further increases the implant failure risk. To identify the breaking mechanisms of osteosynthesis implants in more detail, analyses of extracted implants are necessary. Investigations such as stereomicroscopy and scanning electron microscopy are some of the methods which can contribute to identifying the causes leading to implants failure.

Case Presentation

A 43-year-old man, without chronic disease, BMI 25.5, non-smoker, working as a technician.

In October 2018 the man suffered right clavicle fracture after motorbike accident. Locally the skin was unaffected and the extremity was without neurocirculatory deficit. X-rays showed comminution fracture Allman I with three small interfragments, shortening 20 mm and typical dislocation (Figure 1A). Patient was indicated for surgical treatment. Open reduction and internal fixation using LCP-SCP (6-hole, 2.7/3.5 mm) was performed (Figure 1B). Postoperatively the patient was without complications, the wound healed by primary intention. After additional 4 weeks of brace fixation rehabilitation with low load was started and gradually increased up to full load, according to pain, by week 10 post surgery.

In March 2019 the patient suffered another injury to the clavicle after he fell from a bicycle. X-ray examination revealed angulation of the plate with underlying refracture of collarbone (Figure 2A) and patient was admitted for reosteosynthesis. Extraction of damaged osteosynthetic material, resection of nonunion, reosteosynthesis with LCP-SCP (8-holes) and spongioplasty with ChronOS ®(synthetic β -tricalcium phosphate bone void filler) was performed (Figure 2B). Two weeks of brace fixation and another two weeks in arm sling were indicated after the occurrence of exanthema in the wound area on day 14 postoperatively. This was treated locally as suspected contact dermatitis with good response and regression within two weeks. Five weeks postoperatively rehabilitation without load was initiated. In long term, however patient was complaining of subtle pain in collarbone area after increased load and exercise despite good healing progress on X-ray follow-ups.

In October 2019, while tightening the wheel, patient felt a sudden snap in the area of the right clavicle and because of pain progression he visited our clinic. Locally pain, swelling and crepitus at the fracture site was discovered and X-ray revealed refracture of the clavicle and a broken osteosynthetic plate. (Figure 3A). Extraction of the plate, decortication, reosteosynthesis with LCP-SCP, 7-holes) and spongioplasty with a graft from iliac crest was performed (Figure 3B). The wound healed by primary intention and eight weeks postoperatively rehabilitation with low load only was started while sling fixation continued. EMG was performed for ongoing paresthesia of right-hand fingers with no pathological findings. Follow up CT of right clavicle was performed in November 2020 (Figure 3C). Rehabilitation gradually increased to full load. In February 2021 on follow up the fracture was radiologically healed and patient was released from our care.

Results And Discussion

characterization of removed implants

Explanted osteosthetic materials have been thoroughly analysed to determine the reason of their damage. In Figure 4 both cases of the damaged Ti plates, bended (Figure 4A) and the broken (Figure 4B), are depicted. The material of both examined plates corresponds to the standard for surgical implants [20].

Defects in both plates occurred in similar locations of the plate, as can be seen from the Figure 4. A critical point of the plates is narrowing positions – combined hole, exactly the part for cortical screw

insertion. The fracture, two parts of the bone shown in Figure 4B, is located under the hole, and thus it is assumed that the stress load was concentrated to this area. Cyclic loading applied during the movements of the patient, caused a crack initiation and its further gradual propagation.

Kanchanomai et al studied fatigue fracture of a locking compression plate fixed across a transverse fracture and the cracks were detected near the hole in the middle of the plate [21]. As well as Sedmak and Čolić studied crack propagation in orthopedic Ti plates and experimental and numerical evaluation of stress-strain state showed that the maximal stress values have been located in the area of the hole [23].

The detail of the bended Ti plate (Figure 4A) in the narrowed position of the hole is shown in Figure 5A. More surface defects are visible but the one marked by yellow rectangle was indicated as the point of crack initiation. The SEM image of this crack is shown in Figure 5B, whereas no inclusion nor impurity causing the crack initiation and propagation were found.

The detail of the broken plate showed in Figure 4B, was also subjected to a fractographic analysis on the stereomicroscope and SEM. Stereomicroscopic observation (Figure 6A) showed the presence of the striation lines what is the typical mark of fatigue fracture. This observation allowed us to explain the fracture mechanism of the plate. The osteosynthetic material fracture was not caused by the overload, but the cyclic loading caused the crack initiation, and its slow propagation. The presence of the striation lines was proved using SEM technique as evidenced in Figure 6B.

Microscopic analysis and histology

Due to the frequent occurrence of black pigmentation around the implants, tissue that was in direct contact with the osteosynthetic material was analysed. The evaluation focused on the presence of micron metal-based particles that could be released from the osteosynthetic material. Tissue samples were immersed in 10% formalin. After dehydration with alcohol-xylene and automatic paraffin embedding they were cut as blocks into thin sections of 2-4 µm, which were stretched on slides in a water bath. These sections were deparaffinised in xylene and alcohol and were not stained. A scanning electron microscope (SEM) Explorer 4 analyser (Thermo Fisher) was used to analyse all samples. The samples were analysed using a maximum accelerating voltage of 20 keV and a spot size of 57.6%. The characterization of morphology, size and determination of the elemental composition of detected solid particles using energy dispersive X-ray spectroscopy (EDS) detector was investigated.

Results of microscopic analysis

According to SEM-EDS analysis, the composition of the osteosynthetic materials used was mainly based on Ti-V-Al (Nb).

Table1: The composition and size distribution of the detected particles in soft tissue and soft tissue with bone.

Elements	bent plate			broken plate		
	Soft tissue	Soft tissue with bone	Size Distribution [µm]	Soft tissue	Soft tissue with bone	Size Distribution [µm]
Ti (V, Nb, Al)	51	7	0.36-15.25	55	34	0.35-36.97
Fe (Cr, Ni)	8	1	0.46-8.72	5	5	0.44-3.40
Fe	3	16	0.54-3.44	2	4	0.62-1.60
W	47	-	0.16-4.17	1	3	0.30-0.80
Ba	2	5	0.30-0.75	-	2	2.65-4.19
Zn	-	1	0.39-0.39	-	-	-

The composition of the detected particles in soft tissue and soft tissue with bone showed the same composition as the composition of osteosynthetic materials (Table1). The presence of particles based on Fe, Cr, Ni, Ba, Zn and W could be caused by contamination from tools during the operation. Particles were also detected in size bellow 1 µm.

Results of histology

At the same time, histological analysis was performed. Tissue from the bent plate area showed a ligament's stroma with necrosis, with black pigment deposits, and hemorrhages. Furthermore, the presence of very significant fibroproduction was identified. Tissue from the broken plate area showed a stromal fragment with accented fibroproduction, hemorrhage and dispersive round cell lymphoplasmocytic infiltration. In both cases, according to histological findings, inflammation was demonstrated at the site of contact with the implant. Publications on pathological changes in tissues surrounding the plates after their surgical removal are quite common [28, 29].

One study has reported a connective tissue without inflammation [30]. On the other hand several other studies have reported the presence of connective tissue with moderate chronic inflammation [29, 31]. Pigmented deposits in the tissues were also mentioned in different studies and have been reported to be titanium and other metal particles [32]. Their presence may also cause variable degenerative changes in the surrounding tissues according to Kim et al. [33].

Conclusion

The collarbone was morphologically designed to break easily and dislocate in a typical direction. The middle part of the clavicle is the locus minoris resistentiae and is affected by torsional, bending and compressive forces. In the case we studied, the fracture of the osteosynthetic material was not caused by

overload, but the cyclic loading in the hole without the fixing screw caused the crack to initiate and to propagate slowly. The risk of refraction was subsequently reduced by surgical technique, by a good reduction and combination of plate osteosynthesis with lag screws. The use of screws in a vertical plane reduces the bending load and thus can reduce the risk of the plate failure (bending or breakage). In the postoperative phase, load reduction will also help. LCP-SCP with lateral extension are more resistant to strength than LCP-SCP without lateral extension, but in both cases fractures and cracks appeared in the same place - in the combined hole, in the part for the cortical screw, which is the thinnest in cross section. The fracture origin of the titanium-based LCP-SCP plate is affected by the stress intensification at the position of the plate screw hole above the bone fracture.

From the chemical analysis, it is clear that also during healing, particles are likely to be released from the implants and a subsequent inflammatory reaction occurs around the osteosynthetic plate in the surrounding tissue. Due to the frequency of complications associated with refraction of modern anatomical implants for osteosynthesis, their study leading to continuous improvement is a significant benefit.

Declarations

Ethical Approval: The study was approved by the Institutional Ethics Committee of University Hospital Ostrava, number 317/2019. The study was performed complying with the Declaration of Helsinki, good clinical practice, and applicable regulatory requirements. Informed consent was obtained from all participants prior to the initiation of any procedures.

Consent to Participate: Written informed consent was obtained from all participants before the initiation of any procedure.

Consent to Publish: The informed consent included the consent of the participants with anonymous publication of obtained data.

Availability of data and materials: The datasets used and analyzed during the current research are available from the corresponding author on request.

Competing interests: The authors declare that they have no competing interests.

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K.C.; visualization, K.C., J.V. and P.M.; supervision, J.V.; project administration, K.C. and P.M.; language correction, T.S. All authors have read and agreed to the published version of the manuscript.

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References

1. (2007) Nonoperative Treatment Compared with Plate Fixation of Displaced Midshaft Clavicular Fractures. *Canadian Orthopaedic Trauma Society* 89:1–10. <https://doi.org/10.2106/JBJS.F.00020>
2. Postacchini F, Gumina S, De Santis P, Albo F (2002) Epidemiology of clavicle fractures. *Journal of Shoulder and Elbow Surgery* 11:452–456. <https://doi.org/10.1067/mse.2002.126613>
3. Nowak J, Mallmin H, Larsson S (2000) The aetiology and epidemiology of clavicular fractures. *Injury* 31:353–358. [https://doi.org/10.1016/S0020-1383\(99\)00312-5](https://doi.org/10.1016/S0020-1383(99)00312-5)
4. Robinson CM (1998) Fractures of the clavicle in the adult: Epidemiology and Classification. *The Journal of Bone and Joint Surgery* 80:476–484. <https://doi.org/10.1302/0301-620X.80B3.8079>
5. Nordqvist A, Petersson C (1994) The incidence of fractures of the clavicle. *Clinical Orthopaedics and Related Research* 300:127–132
6. Basamania C (2006) Clavicle Fractures and Sternoclavicular Injuries. *Clinical Sports Medicine* 265–273. <https://doi.org/10.1016/B978-032302588-1.50030-0>
7. Zlowodzki M, Zelle BA, Cole PA, et al. (2005) Treatment of Acute Midshaft Clavicle Fractures: Systematic Review of 2144 Fractures. *Journal of Orthopaedic Trauma* 19:504–507. <https://doi.org/10.1097/01.bot.0000172287.44278.ef>
8. (2009) Vertical Fragment in Adult Midshaft Clavicle Fractures: An Indicator for Surgical Intervention. *Orthopedics* 32:01477447-20090818-06. <https://doi.org/10.3928/01477447-20090818-06>
9. Kwak-Lee J, Ahlmann ER, Wang L, Itamura JM (2014) Analysis of Contoured Anatomic Plate Fixation versus Intramedullary Rod Fixation for Acute Midshaft Clavicle Fractures. *Advances in Orthopedic Surgery* 2014:1–7. <https://doi.org/10.1155/2014/518310>
10. Šimek J, Šmejkal K, Frank M, et al. (2020) Operační léčba zlomeniny diafýzy klíční kosti – prospektivní randomizovaná studie. *Acta chirurgiae orthopaedicae et traumatologiae Cechoslovaca* 87:101–107
11. Grassi FA, Tajana MS, D'Angelo F (2001) Management of Midclavicular Fractures: Comparison between Nonoperative Treatment and Open Intramedullary Fixation in 80 Patients. *The Journal of Trauma: Injury, Infection, and Critical Care* 50:1096–1100. <https://doi.org/10.1097/00005373-200106000-00019>
12. Katras T, Baltazar U, Rush DS, et al. (2001) Subclavian Arterial Injury Associated with Blunt Trauma. *Vascular Surgery* 35:43–50. <https://doi.org/10.1177/153857440103500108>

13. Mueller M, Rangger C, Striepens N, Burger C (2008) Minimally Invasive Intramedullary Nailing of Midshaft Clavicular Fractures Using Titanium Elastic Nails. 64:1528–1534.
<https://doi.org/10.1097/TA.0b013e3180d0a8bf>
14. Formaini N, Taylor BC, Backes J, Bramwell TJ (2013) Superior Versus Anteroinferior Plating of Clavicle Fractures. Orthopedics 36. <https://doi.org/10.3928/01477447-20130624-20>
15. Toogood P, Coughlin D, Rodriguez D, et al. (2014) A biomechanical comparison of superior and anterior positioning of precontoured plates for midshaft clavicle fractures. American journal of orthopedics: Belle Mead, N.J. 43:226–231
16. Smekal V, Irenberger A, Attal RE, et al. (2011) Elastic stable intramedullary nailing is best for midshaft clavicular fractures without comminution: Results in 60 patients. Injury 42:324–329.
<https://doi.org/10.1016/j.injury.2010.02.033>
17. Ferran NA, Hodgson P, Vannet N, et al. (2010) Locked intramedullary fixation vs plating for displaced and shortened mid-shaft clavicle fractures: A randomized clinical trial. Journal of Shoulder and Elbow Surgery 19:783–789. <https://doi.org/10.1016/j.jse.2010.05.002>
18. Judd DB, Pallis MP, Smith E, Bottoni CR (2009) Acute operative stabilization versus nonoperative management of clavicle fractures. American journal of orthopedics: Belle Mead, N.J. 38:341–345
19. Navarro RA, Gelber JD, Harrast JJ, et al. (2016) Frequency and complications after operative fixation of clavicular fractures. Journal of Shoulder and Elbow Surgery 25:e125-e129.
<https://doi.org/10.1016/j.jse.2015.11.065>
20. Iannolo M, Werner FW, Sutton LG, et al. (2010) Forces across the middle of the intact clavicle during shoulder motion. Journal of Shoulder and Elbow Surgery 19:1013–1017.
<https://doi.org/10.1016/j.jse.2010.03.016>
21. Marinescu R, Antoniac VI, Stoia DI, Laptoiu DC (2017) Clavicle anatomical osteosynthesis plate breakage - failure analysis report based on patient morphological parameters. Romanian Journal of Morphology and Embryology 58:593–598
22. Frydryšek K, Michenková Š, Pleva L, et al (2021) Mechanics of Screw Joints Solved as Beams Placed in a Tangencial Elastic Foundation. Appl Sci 11(12), 5616, <background-color:#CFBFB1;uvertical-align:super;><https://doi.org/10.3390/app11125616></background-color:#CFBFB1;uvertical-align:super;>
23. Shin S-J, Do N-H, Jang K-Y (2012) Risk factors for postoperative complications of displaced clavicular midshaft fractures. Journal of Trauma and Acute Care Surgery 72:1046–1050.
<https://doi.org/10.1097/TA.0b013e31823efe8a>
24. Proverbio E, Bonaccorsi LM (2019) Microstructural Analysis of Failure of a Stainless Steel Bone Plate Implant. ASM Failure Analysis Case Histories: Medical and Biomedical Devices.
<https://doi.org/10.31399/asm.fach.med.c9001579>
25. (2014) ISO 5832-11:2014 (E) Implants for surgery – Metallic materials: Part 11: Wrought titanium 6-aluminium 7-niobium alloy

26. Kanchanomai C, Phiphobmongkol V, Muanjan P (2008) Fatigue failure of an orthopedic implant – A locking compression plate. *Engineering Failure Analysis* 15:521–530.
<https://doi.org/10.1016/j.engfailanal.2007.04.001>
27. Sedmak A, Čolić K (2019) Fracture and Fatigue Behaviour of Implants Made of Ti Alloys. *Procedia Structural Integrity* 23:45–50. <https://doi.org/10.1016/j.prostr.2020.01.061>
28. Schliephake H, Lehmann H, Kunz U, et al. (1993) Ultrastructural findings in soft tissues adjacent to titanium plates used in jaw fracture treatment. *Int J Oral Maxillofac Surg* 22: 20–25
29. Katou F, Andoh N, Motegi K, et al (1996) Immuno-inflammatory responses in the tissue adjacent to titanium miniplates used in the treatment on mandibular fractures. *J Cranio-Maxillofac Surg* 24: 155–162
30. Zaffe D, Bertoldi C, Consolo U (2003) Element release from titanium devices used in oral and maxillofacial surgery. *Biomaterials* 24: 1093–1099
31. Langford RJ, Frame JW (2002) Tissue changes adjacent to titanium plates in patients. *J Cranio-Maxillofac Surg* 30: 103–107
32. Meningaud JP, Poupon J, Bertrand JCh, et al. (2001) Dynamic study about metal release from titanium miniplates in maxillofacial surgery. *Int J Oral Maxillofac Surg* 30: 185–188
33. Kim YK, Yeo HH, Lim SC (1997) Tissue response to titanium plates: a transmission electron microscopy study. *J Oral Maxillofac Surg* 55: 322–326

Figures

Figure 1

A) input X-ray; comminuted fracture of the right clavicle, Allman I.; B) X-ray postoperative photo, osteosynthesis with LCP-SCP plate.

Figure 2

A) The deformation of the plate, refracture of the clavicle; B) Refracture of the clavicle and plate; condition after re-osteosynthesis of LCP-SCP plate, ChronOs spongioplasty.

Figure 3

A) The refracture of the clavicle and a broken osteosynthetic plate B) X-ray- after decortication, reosteosynthesis with a plate; C) 3D reconstructions-healing in good position, advanced reparative changes.

Figure 4

A) LCP SCP with lateral extension B) Fixation with Ti plate – bent plate, C) LCP SCP without lateral extension D) Fixation with Ti plate – broken plate.

Figure 5

A) the crack visible on the bending site of the Ti plate; B) magnification of the crack detected on SEM.

Figure 6

A) the crack visible on the bending site of the Ti splint; B) magnification of the crack detected on SEM.