A PROSPECTIVE STUDY OF TITANIUM ELASTIC NAILING SYSTEM FOR INTRAMEDULLARY FIXATION OF MID-CLAVICULAR FRACTURES.

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INTRODUCTION

Fractures of the clavicle are common injuries with an incidence of 5-10% of all fractures (1,2). Eighty percent of all fractures involve the middle third of the clavicle (3,4). The cause of injury is mostly an indirect trauma such as a fall on the shoulder or on the extended arm. Midclavicular fractures are generally managed conservatively, e.g. with a figure-of-eight-bandage. Imminent perforation of the skin, impending or existing neurovascular compromise and the floating shoulder represent absolute indications for operative treatment. Gross displacement of fracture fragments, as well as non-unions, are seen as relative indications for surgical fixation. Plate osteosynthesis is the gold standard for operative treatment, but higher complication rates have been described with this technique in comparison to conservative management (5,6). Recently, a number of publications described the technique of minimally-invasive osteosynthesis using titanium elastic nail system (TENS). The reported advantages are early functional recovery and a rapid return to daily activities. The complication rate has been reported to be low (7,8,9). The aim of the present study was the evaluation of the operative technique and the functional and re-integrative results after titanium elastic

MATERIALS AND METHODS

Patients

We prospectively reviewed a consecutive series of 20 patients with midclavicular fractures that were treated with TENS between March 2012 and January 2014. Patients with type 2A2 fractures (angled fractures) and type 2B1 type fractures (simple fractures) according to the Robinson classification (10) were included in this study. Comminuted fractures were excluded. Nine patients were male and one was female. The average age was 32.5 years (range 20 to 60 years). The typical mechanism of injury was an indirect trauma on the shoulder. Most injuries resulted from traffic accidents (n = 12), or a fall from a height (n= 8). Fourteen patients suffered a 2A2-type fracture with a cranial displacement of the medial fragment due to the pull of the sternocleidomastoid muscle. 2B1-type fractures were seen in 6 cases. Ten patients were treated surgically because of major displacement of the fracture fragments which is a relative indication for surgery. The average displacement was 1.5 diaphyseal width and the clavicular shortening ranged from one to 3.5 cm. All patients with relative indications for surgical fixation were young adults and had high demands on their shoulder function.
**Operative technique**

The Titanium Elastic Nailing (TEN) System was used. These nails are also used for the management of diaphyseal fractures of long bones in children. For the operation the patient is placed in the supine position. At the sternal end of the clavicle, a skin incision of 2 cm is made parallel to the clavicle. The anterior cortex is opened with an awl about 1.5 cm lateral to the sternoclavicular joint. A TEN (average diameter 2.5 mm) is inserted and advanced to the fracture site. Subsequently, the fracture is reduced in a closed manner. If closed reduction is not possible, a 1-2 cm skin incision at the level of the fracture site is made for open or semi-open fracture reduction. Reduction is maintained provisionally with a small reduction forceps. The nail is subsequently advanced across the fracture into the lateral fragment with gentle rotational movements. Care must be taken that the implant is not advanced too laterally in order to avoid penetration into the acromioclavicular joint. Fluoroscopic control is therefore mandatory. The medial end of the nail is cut and the overlying skin is sutured. Postoperatively, intravenous 1 g taxim iv BD was used for a week after which tab. taxim o 200 mg BD was used for a week. After surgery, early physical therapy with a limitation of abduction of 90° is commenced for the first 3 to 4 weeks. Assessment of the patients' shoulder function according to the Constant-Murley-Score (11) and radiologic evaluation of fracture healing were done. Time to functional recovery was assessed as well.

**3. RESULTS**

The operative treatment was performed an average of 6 days after trauma (range: from 2 to 15 days). None of the patients had any associated injury or co-morbidities. Constant Murley scoring system [figure 1] was used for functional outcome. Functional results according to the Constant Murley score were fair [figure 2]. The score averaged 95.3 ± 3.9 points. A complete consolidation of all fractures was observed radiologically after 12 weeks. Non-union was not observed. The period of disability in the whole patient population was 22 ± 9 days. Minor complications were observed in five patients. In one case the TEN was removed early due to skin irritation, 5 months after the operative treatment. Afterwards, all patients were without complaints. There were no infections observed in our series. Post-operative period was uneventful in other cases.

**4. DISCUSSION**

Traditionally, midclavicular fractures have been treated conservatively. Rowe (3) and Neer (1) in the sixties recommended non-operative treatment, because they observed a very small number of non-unions. Conservative treatment subsequently became the standard procedure for the management of non-displaced as well as for displaced midclavicular fractures. Also, more recent studies (12) observed good functional and radiographical results after non-operative treatment. The indications for operative treatment were limited to (imminent) skin perforation and associated neurovascular lesions (13). The results regarding the outcome of conservative treatment of displaced midclavicular fractures nowadays, however, are seen in a more differentiated manner and they are controversially discussed. Wick et al. (14) and Eskola et al. (15) observed high rates of non-union, shoulder pain and poor functional results when the fracture had healed with shortening of more than 2 cm. These findings were confirmed by Lazarides et al. (16) and by Hill (17). These studies favour operative treatment of displaced midclavicular fractures by describing high rates of good and excellent results. The standard procedure for osteosynthesis is plate fixation using small fragment DCP or reconstruction plate (14). Although plate fixation provides adequate stability, Rowe et al. (3) and Bronz et al. (18) described complications like non-union, refracture or loosening of implants. Similar complications have been described with intramedullary pinning (3). Grassi et al. experienced infections, non-union, refractures and hardware-related problems after operative treatment with 2.5 mm Kirschner-wires (8). Minimally invasive TENs was established as an alternative to plate fixation. Jubel et al. (9) showed that the correction of clavicular shortening is a prerequisite of good functional outcome. They did not observe non-union or poor postoperative outcome. In this study, intramedullary nailing provided anatomical reduction and early functional recovery in all patients. Patients today have high expectations of the functional outcome. They expect rapid and pain-free functional recovery following a fracture. In contrast to conservative treatment, minimally invasive techniques can fulfill these objectives with a reduced risk of complications (6). As a result, the mean period of disability is short. The advantages of intramedullary fixation [TENS] over extramedullary fixation [plate osteosynthesis] are

1. Minimal damage to soft tissue, periosteum and neurovascular structures
2. TENs can remodel according to anatomic structure of a bone without losing its rigidity and strength.
3. Implant exit can be done as an outpatient procedure without the need for anaesthesia.

Thus in TENs fixation the soft tissue damage is very less, the strength and rigidity of the nail is not sacrificed even when its contoured and implant exit is minimally invasive and cosmetically advantageous.
**Constant Shoulder Score**

**Clinician's Name:**

**Patient's Name:**

Answer all questions, selecting just one unless otherwise stated.

During the past 4 weeks...

1. **Pain**
   - Severe
   - Moderate
   - Mild
   - None

2. **Activity Level (check all that apply)**
   - Unrestricted daily
   - Full Recreation/Sport
   - Full Work

3. **Arm Positioning**
   - Up to Wrist
   - Up to Xiphoid
   - Up to Neck
   - Up to Top of Head
   - Above Head

4. **Strength of Abduction (Pounds)**
   - 0
   - 1-5
   - 6-10
   - 11-24
   - 25-49
   - 50-100
   - >100

**Range of Motion**

5. **Forward Flexion**
   - 31-60 degrees
   - 61-90 degrees
   - 91-120 degrees
   - 121-150 degrees
   - 151-180 degrees

6. **Lateral Elevation**
   - 31-60 degrees
   - 61-90 degrees
   - 91-120 degrees
   - 121-150 degrees
   - 151-180 degrees

7. **External Rotation**
   - Hand behind Head, Elbow forward
   - Hand behind Head, Elbow back
   - Hand to top of Head, Elbow forward
   - Hand to top of Head, Elbow back
   - Full Elevation

8. **Internal Rotation**
   - Lateral Thigh
   - Buttock
   - Lumbar-lumbar junction
   - Waist (L3)
   - T12 Vertebra
   - Intercostal (T7)

**The Constant Shoulder Score is:**

**Grading the Constant Shoulder Score**

- 30 Poor
- 21-30 Fair
- 11-20 Good
- >11 Excellent

**FIGURE 1**

**CASE 1**

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<th>PRE OPERATIVE</th>
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**CASE 2**

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We have taken up this study to gain a deeper understanding of results and problems associated with this procedure, to evaluate the functional outcome after fixation of displaced clavicular fractures with titanium elastic nailing.

5. CONCLUSION

The data of this study demonstrate that operative treatment of displaced midclavicular fractures with TENS results in a good functional outcome and anatomical reduction. This technique provides more rapid free movement of the shoulder and an earlier return to daily activities than the conservative treatment. In comparison with plate fixation, the procedure is less invasive and requires smaller incisions. In comminuted fractures that are at risk of telescoping, plate fixation however remains the procedure of first choice.

6. REFERENCES


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