Surgical Technique ANSER Clavicle Pin Set
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Introduction

Features and benefits
The ANSER Clavicle Pin Set is an intramedullary fixation device, intended for fixation of mid-shaft clavicular fractures, mal-unions and non-union of the clavicle. The ANSER Clavicle Pin Set aims to become an intramedullary internal fixator that restores and preserves the anatomical length and alignment of the fractured clavicle in a minimally invasive manner.

The ANSER Clavicle Pin Set is intended to be used by Orthopaedic surgeons in an Operation Room.

Fractures of the clavicle are common, comprising up to 5% of all fractures in adults [1]. Most clavicle fractures are localized at the level of the mid-diaphyseal third [2]. Because of the specific sigmoid shaped anatomy and muscle insertions the majority of these fractures are displaced and/or shortened. These fractures have been found to be predictors of poor outcomes concerning non-unions, persistent posttraumatic symptoms and cosmetics in conservatively treated mid-shaft clavicle fractures. (MSCF). [3,4,5].

Several current treatment options exist, such as plate fixation and other types of intramedullary fixation devices, that are generally associated with good outcomes however also have their own specific drawbacks. The ANSER is a novel intramedullary fixation device, of which the design aims to combine the advantages of current treatment options’.

The ANSER Clavicle Pin Set is a device for the intramedullary fixation of the fractured clavicle aiming to combine the pros of both plate and intramedullary devices into one.

The goal of the ANSER Clavicle Pin Set is to reduce the clavicle and preserve its length in a minimally invasive manner. Its design consists of the flexible ANSER Clavicle flexible Pin fabricated from a titanium alloy. The ANSER Clavicle Pin has a blunted tip to prevent perforation with screw thread to fixate within the bone on the medial side of the fracture.

On the lateral side the ANSER Clavicle Pin has a plurality of indentations that allow the surgeon to decide on the correct length of the clavicle and the pin intra-operatively. The ANSER has a one-size-fits-all principle. This means no extensive instrument sets, which simplifies the procedure.

The outside of the ANSER Lateral Fixation Device screws itself into the cortical bone of the lateral fracture element. At the same time it positions itself around the ANSER Clavicle Pin in one of the previously mentioned indentations. This position is then secured by the ANSER End Cap.

To prevent possible friction and loosening of the implant during rotation of the clavicle around its axial axis while moving the arm, the ANSER Lateral Fixation Device will allow rotation around the ANSER Clavicle Pin whilst continuing to secure its appropriate length.

The system is an intramedullary internal fixator.

The design of the ANSER is expected to reduce the need for hardware removal, which in turn may lead to a decline in re-operations and costs compared to the current treatment options available.
Overall, the expected benefits of the ANSER include:

- Intramedullary device
- Minimally invasive
- Restoration and maintenance of length and alignment of the fractured clavicle
- Low risk of perforation because of a blunt tip
- Prevents secondary shortening and migration, because of fixation in both fracture elements
- Low infection risk
- Low risk of complications
Set description

The ANSER Clavicle Pin Set consists of the following components:

<table>
<thead>
<tr>
<th>REF</th>
<th>Name</th>
<th>Contents</th>
<th>Qty.</th>
</tr>
</thead>
<tbody>
<tr>
<td>ANS-301S</td>
<td>ANSER Clavicle Pin Set</td>
<td>ANSER Clavicle Pin</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>ANSER Lateral Fixation Device</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>ANSER End Cap</td>
<td>1</td>
</tr>
</tbody>
</table>

The ANSER Instrument Set contains the following:

<table>
<thead>
<tr>
<th>REF</th>
<th>Instrument</th>
<th>Image</th>
<th>Functions</th>
<th>Qty.</th>
</tr>
</thead>
<tbody>
<tr>
<td>ANS-201</td>
<td>ANSER Pin Adapter</td>
<td></td>
<td>Insertion of the clavicle pin with a power tool</td>
<td>1</td>
</tr>
<tr>
<td>ANS-202</td>
<td>ANSER Manual Pin Driver</td>
<td></td>
<td>Manual insertion of the clavicle pin</td>
<td>1</td>
</tr>
<tr>
<td>ANS-203</td>
<td>ANSER Tap</td>
<td></td>
<td>Tapping thread for the lateral fixation device</td>
<td>1</td>
</tr>
<tr>
<td>ANS-204</td>
<td>ANSER Lat. Fix. Device Inserter</td>
<td></td>
<td>Insertion of the lateral fixation device</td>
<td>1</td>
</tr>
<tr>
<td>ANS-205</td>
<td>ANSER End Cap Inserter</td>
<td></td>
<td>Application of the end cap</td>
<td>1</td>
</tr>
<tr>
<td>310.401</td>
<td>Drill Bit*</td>
<td></td>
<td>Connected to a power tool to drill a hole in the cortex to provide access to the medullary canal</td>
<td>1</td>
</tr>
<tr>
<td>95-186.01</td>
<td>Drill Guide*</td>
<td></td>
<td>Guide the drilling with the drill bit and protect the surrounding tissue</td>
<td>1</td>
</tr>
<tr>
<td>713.30.05</td>
<td>Large Forceps*</td>
<td></td>
<td>Reposition the fracture elements percutaneously</td>
<td>2</td>
</tr>
<tr>
<td>40-892-32</td>
<td>Pin Cutter*</td>
<td></td>
<td>Cut the pin to length</td>
<td>1</td>
</tr>
<tr>
<td>ANS-401</td>
<td>ANSER Tray</td>
<td></td>
<td>Facilitate cleaning, sterilization, transportation, and presentation of the instruments</td>
<td>1</td>
</tr>
</tbody>
</table>
**Intended Use**
Intramedullary fixation of mid-shaft clavicle fractures in order to restore and maintain the anatomical position of the clavicle and facilitate osteosynthesis.

**Indications**
Indications for the ANSER Clavicle Pin include skeletally mature patients suffering from mid-shaft clavicular fractures.

**Contraindications**
Contraindications include:

- Patients suffering from (severe) osteoporosis
- Patients who are not fit for surgery
- Patients with non-union or mal-union
- Patients who are not skeletally mature
- Possible non-compliant patients (e.g. due to alcohol and drug addiction, dementia)
- Additional neurovascular injury
- Pathologic fractures
Surgical Technique

1. The patient is positioned in beach chair position.

2. Prophylactic antibiotics are given: cephalosporine, e.g. KEFZOL®. (Sterile natriumcefazoline), 2 g i.v.
3. Identification and marking of the anatomic landmarks.
4. Positioning of the fluoroscopy.
5. Determine and mark the entry position and exact location for skin incision using fluoroscopy: posterolaterally, just medial of the AC joint at the location of the posterior conoid tubercle.

6. Disinfection and sterile draping.
7. Incise the skin and subcute at the previously determined position. Identify the posterior conoid tubercle.

[Images of surgical technique]

[Diagram of surgical technique]

[Diagram of anatomical landmarks]
8. Use a 4mm Drill Bit with the Drill Guide to open the cortex into the medullary canal of the lateral fracture element. Make sure the opening is done in the middle or slightly under the equator of the posterior conoid tubercle.

![Image of a drill opening the cortex](image1)

9. Use the Universal pin driver or ANSER Pin Adapter to place the flexible ANSER Clavicle Pin into the lateral fracture element. Check position using fluoroscopy in two planes.

![Image of a flexible pin being placed](image2)

10. Advance the ANSER Clavicle Pin until the fracture site.

![Image of an advanced pin](image3)

11. Reposition the fracture elements and align them percutaneously using the Large Forceps.

<table>
<thead>
<tr>
<th>Warning</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proper alignment of the fracture parts before traversing the fracture site with the ANSER Clavicle Pin is of utmost importance. Failure to align the fragments may lead to disastrous complications such as penetration of the subclavian artery or the lung. See Warnings section for relevant anatomy.</td>
</tr>
</tbody>
</table>
12. Slowly drive or oscillate the ANSER Clavicle Pin into medial bone fragment.

13. Check the position of the ANSER Clavicle Pin by using fluoroscopy in two planes.
14. If closed reduction fails make a small incision over the fracture site and slowly drive or oscillate the ANSER Clavicle Pin into medial bone fragment.
15. Manually drive the ANSER Clavicle Pin towards the SC joint using the ANSER Manual Pin Driver until good grip is acquired.

**Pre-caution:** While inserting the medial fixation make sure to keep pushing the pin forward in order to avoid destruction of the self-tapped thread.

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Equivalent intramedullary implants have a reported risk of hardware failure. The risk exists that the pin may plastically deform or break due to peak loading. The risk exists also during surgery. Do not exceed in forcing (pushing or rotation) during surgery.

16. Check the position of the ANSER Clavicle Pin by using fluoroscopy in two planes.
17. Prepare the lateral fragment for the ANSER Lateral Fixation Device using the Tap.

**Pre-caution:** While tapping make sure to keep pushing the ANSER Tap forward in order to avoid destruction of the tapped thread.
18. Tapping should continue until the black marker is close to the opening of the cortex on the posterior conoid tubercle. This ensures that a functional thread is created that facilitates proper placement of the ANSER Lateral Fixation Device.

19. Insert the ANSER Lateral Fixation Device over the ANSER Clavicle Pin using the ANSER Lateral Fixation Device Inserter.

Be aware that if the ANSER Clavicle Pin section protruding from the clavicle is severely bent the resulting friction may rotate the Pin further into the bone while applying the ANSER Tap (step 17 & 18). Adjust or replace the ANSER Clavicle Pin if necessary.
A black engraved marker on the ANSER Lateral Fixation Device Inserter indicates where the distal end of the ANSER End Cap will be located in relation to the ANSER Lateral Fixation. The marker may be used to identify the amount of implant protrusion (and accessibility of the Anser End Cap).

Avoid, if possible, using multiple insertion attempts during placement of the ANSER Clavicle Pin medial fixation in the medial fragment (step 15) and placement of the ANSER Lateral Fixation Device (step 19) in order to prevent weakening/destruction of the (self-) tapped threaded interfaces.

20. Check the reposition of the fracture elements and, when ascertained of the correct position, place the ANSER End Cap using the ANSER End Cap Inserter. An audible “click” helps confirm correct placement of the ANSER End Cap.

If placing the End Cap (step 20) is hard or impossible to do, the ANSER Lateral Fixation Device may be damaged or incorrectly positioned. Check that the “legs” are straight and correctly placed in the grooves of the ANSER Lateral Pin. Adjust or replace the ANSER Lateral Fixation Device if necessary.
ANSER Lateral Fixation Device legs should be straight (as shown in the figure).

The tip of the ANSER Lateral Fixation Device legs should be positioned inside a groove of the ANSER Clavicle Pin.

21. Placing of the ANSER End Cap secures the repositioned fracture elements at the appropriate length. To prevent friction and loss of reduction the ANSER Lateral Fixation Device and ANSER End Cap can freely rotate about the ANSER Clavicle Pin.
22. Cut the ANSER Clavicle Pin at the level of the ANSER End Cap using the Pin Cutter.
23. Wash out the surgical field and close the wound.
**Warnings**

- Avoid, if possible, using multiple insertion attempts during placement of the ANSER Clavicle Pin medial fixation in the medial fragment (step 15) and placement of the ANSER Lateral Fixation Device (step 19) in order to prevent weakening/destruction of the (self-) tapped threaded interfaces.

- Be aware that if the ANSER Clavicle Pin section protruding from the clavicle is severely bent the resulting friction may rotate the Pin further into the bone while applying the ANSER Tap (step 17 & 18). Adjust or replace the ANSER Clavicle Pin if necessary.

- If placing the End Cap (step 20) is hard or impossible to do, the ANSER Lateral Fixation Device may be damaged or incorrectly positioned. Check that the “legs” are straight and correctly placed in the grooves of the ANSER Lateral Pin. Adjust or replace the ANSER Lateral Fixation Device if necessary.

- Equivalent intramedullary implants have a reported risk of hardware failure. The risk exists that the pin may plastically deform or break due to peak loading. The risk exists also during surgery. Do not exceed in forcing (pushing or rotation) during surgery.

- Proper alignment of the fracture parts before traversing the fracture site with the ANSER Clavicle Pin is of utmost importance. Failure to align the fragments may lead to disastrous complications such as penetration of the subclavian artery or the lung.

① ANSER Lateral Fixation Device legs should be straight (as shown in the figure).

② The tip of the ANSER Lateral Fixation Device legs should be positioned inside a groove of the ANSER Clavicle Pin.
Magnetic Resonance Imaging

Torque, Displacement and Image Artifacts according to ASTM F 2213-06, ASTM F 2052-06e1 and ASTM F2119-07
Non-clinical testing of worst case scenario in a 3 Tesla (T) MRI system did not reveal any relevant torque or displacement of the construct for an experimentally measured local spatial gradient of the magnetic field of 3.69 T/m. The largest image artifact extended approximately 169 mm from the construct when scanned using the Gradient Echo (GE). Testing was conducted on a 3 T MRI system.

Radio-Frequency-(RF-)induced heating according to ASTM F2182-11a
Non-clinical electromagnetic and thermal testing of worst case scenario lead to peak temperature rise of 9.5 °C with an average temperature rise of 6.6 °C (1.5 T) and a peak temperature rise of 5.9 °C (3 T) under MRI Conditions using RF Coils (whole body averaged specific absorption rate [SAR] of 2 W/kg for 6 minutes [1.5 T] and for 15 minutes [3 T]).

Pre-caution
The above mentioned test relies on non-clinical testing. The actual temperature rise in the patient will depend on a variety of factors beyond the SAR and time of RF application. Thus, it is recommended to pay particular attention to the following points:

- It is recommended to thoroughly monitor patients undergoing MR scanning for perceived temperature and/or pain sensations.
- Patients with impaired thermoregulation or temperature sensation should be excluded from MRI scanning procedures.
- Generally, it is recommended to use a MR system with low field strength in the presence of conductive implants. The employed specific absorption rate (SAR) should be reduced as far as possible.
- Using the ventilation system may further contribute to reduce temperature increase in the body.

Implant Removal

1. The patient is positioned in beach chair position.
2. Prophylactic antibiotics are given: cephalosporine, e.g. KEFZOL®. (Sterile natriumcefazoline), 2 g i.v.
3. Identification and marking of the anatomic landmarks and scar.
4. Disinfection and sterile draping.
5. Excise the scar and incise the subcute.
6. Identify the ANSER End Cap and remove using pliers
7. Use the ANSER Lateral Fixation Device Inserter to remove the ANSER Lateral Fixation Device.
8. Use pliers or reverse drill to remove the ANSER Clavicle Pin.
9. Wash out the surgical field and close the wound.
References

Literature
15. Braun KF, Siebenlist S, Sandmann GH, Martetschläger F, Kraus T, Schrödl C, Kirchhoff C, Neumaier M. Functional results following titanium elastic-stable intramedullary nailing (ESIN) of mid-

**Figures**

The following sources have been used for the figures shown in the surgical steps.

**Figure**
Step 1 & 5: Beach chair positions

Final bullet under warnings: Thorax figures

All other figures

**Source**
Retrieved from AO Surgery Reference website
https://www2.aofoundation.org/wps/portal/surgery

Retrieved from Evocates Online website
https://online.epocrates.com/home

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