Initial results of the Anser: A novel intramedullary device for fixation of midshaft clavicle fractures. An explorative case series

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The goals of this study are to evaluate the initial performance, safety and functional results of the Anser; A novel intramedullary device for fixation of midshaft clavicle fractures. The primary outcome measures will be union rate, complication...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bone and joint injuries
Study type	Interventional

Summary

ID

NL-OMON43088

Source
ToetsingOnline

Brief title
Results of the Anser Novel Device

Condition

- Bone and joint injuries
- Fractures

Synonym
Clavicle Fracture Collarbone Fracture

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,Isshoni BV,STW en MIT

Intervention

Keyword: Clavicle, Fixation, Fracture, Intramedullary

Outcome measures

Primary outcome

Pre-operatively base-line characteristics of the participating patients will be

noted. These base-line characteristics are:

• Age

• Gender

• BMI

• Dominant arm

• Occupation

• Trauma mechanism

• Medical history

• Medication

• Smoking

• SF-36 Questionnaire

• Sports (if yes; at what level? Recreational or professional)

• Robinson Classification

The primary outcome measures will be union rate, complication rate and

functional outcome scores.

Union is defined as a 2/3rd circumferential cortical bridging between medial and lateral fragments on both radiographs as determined by the treating surgeon and an independent radiologist. Complication is defined as any general or implant-related adverse effect intra- and postoperatively. Functional Outcome scores will be measured with using the Constant score and DASH score at the 6 weeks, 3, 6 and 12 months postoperative visits.

Secondary outcome

Secondary outcomes will be closed reduction rate, operative time, image-intensifier time, hospital stay, incision length, time to radiological union, pain, re-operation, health related quality of life and cosmetic satisfaction.

Closed reduction is defined as advancing the Anser through both lateral and medial fragments without opening the skin over the fracture site. Operative time and image-intensifier time will be measured in minutes. Hospital stay will be measured in days. Incision length will be measured using a tape measure at the 6 week outpatient clinic visit by an independent reviewer. Time to radiological union will be measured in weeks. Pain is assessed with a VAS pain 10-point scale (0 = no pain and 10 = extremely painful). Also participating patients are asked to note the type and amount of analgesics used. Re-operation is defined as any additional surgery after implantation of the Anser for any reason. Health related quality of life is assessed using the SF 36. The SF 36 is a validated questionnaire designed to measure health related quality of life. The cosmetic result after 6 weeks, 3 and 6 months, and 1 year is assessed using the VAS patient satisfaction score on a 0 (= very unsatisfactory) to 10 (= very

satisfactory) scale.

Study description

Background summary

Rationale & Background information

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 two features have been found to be poor predictors of outcome concerning non-unions, persistent posttraumatic symptoms and cosmetics in conservatively treated mid-shaft clavicle fractures. (MSCF). [3,4,5].
For this reason lately the tendency has been to surgically reduce and fixate MSCF. Currently the gold standard for these operations is fixation by using a (angle-stable) plate and screws. This method creates a rigid fixation of the fracture elements and aims for primary bone healing. It re-establishes and maintains the normal length and alignment of the clavicle. Patients are able to quickly start rehabilitating. There have been reports that plate fixation leads to better rates of union, less mal-unions and increased patient satisfaction in comparison to conservative therapy [6,7]. The downsides of this procedure are a large incision with subsequent scarring, neuropathy of the supraclavicular nerve and increased risk of infection. Hardware irritation necessitating a secondary operative intervention of 21-80% have been reported [8,9].

Another frequently used technique to reduce and align MSCF is applying intramedullary devices. These devices are rigid pins (Hagie, Knowles, Rockwood) (Zimmer Biomet), flexible pins such as titanium elastic nails (TEN) (Depuy/Synthes) or partially flexible devices such as the CRX Collarbone Pin (Sonoma Orthopedic Products).
The rigid and partially flexible devices aim for primary bone healing and require an inside-out open reduction operative technique which means loss of the fracture hematoma, increased risk of infection and scar over the fracture. It has produced a variety of results concerning functional outcomes and complication rates [10-12]. Millet et al. reports nonunion rates up to 8.6%. All Rockwood Pins are removed during a second intervention [10-12].

The TEN aims for secondary fracture healing by not evacuating the fracture hematoma with all its bone healing substances. Closed reduction rates are reported between 29-93% are reported [13,14] but are generally around 50-60% [15-20]. Good results have been reported using TEN concerning functional

outcomes and nonunion rates [21-23]. TEN is minimally invasive; it requires smaller incisions. Because of the flexibility of TEN it allows itself to follow the shape of the clavicle and re-align the fractured clavicle. The downside of TEN is that they do not protect the MSCF from secondary shortening and subsequently forming of a, possibly symptomatic, malunion. Secondary shortening >5mm is reported to be up to 37.5% [17,18,24]. Another negative feature of TEN is implant migration because the device is not fixated within the clavicle. This leads to revision rates described between 0-35.3% [16,22]. Hardware removal, in general, is performed after union in 100% of cases [14,15, 20-24].

The Anser is a novel device for the intramedullary fixation of the fractured clavicle aiming to combine the pros of both plate and intramedullary devices into one. Its goal is to reduce the clavicle and preserve its length in a minimally invasive manner. Its design consists of a flexible base pin fabricated from a titanium alloy that has the capabilities to follow the sigmoid-shaped intramedullary canal. The pin has a blunted tip to prevent perforation and a self-tapping screw thread to fixate within the bone on the medial side of the fracture. On the lateral side the base 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 lateral fixation is anchored by the lateral fixation device which screws itself into the cortical bone on the lateral side and at the same time fixes itself around the base pin in one of the previously mentioned indentations. This position is then secured by the endcap. To prevent friction on the implant during rotation of the clavicle around its axial axis during motion of the arm, the lateral fixation device will allow rotation around the base pin whilst continuing to secure its appropriate length. The system creates an intramedullary internal fixator. It is hypothesized that due to its design, in the majority of cases, does not need hardware removal, leading to a decline in re-operations and costs compared to the current devices used.

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Study objective

The goals of this study are to evaluate the initial performance, safety and functional results of the Anser; A novel intramedullary device for fixation of midshaft clavicle fractures.
The primary outcome measures will be union rate, complication rate and functional outcome scores.
Secondary outcomes will be closed reduction rate, operative time, image-intensifier time, hospital stay, incision length, time to radiological union, pain, re-operation, health related quality of life and cosmetic satisfaction.

Study design

Prospective consecutive post-market case series. Therapeutic study. 3 Dutch hospitals are involved which are the Radboud university medical center (RUMC), Rijnstate Arnhem (RA) and Admiraal de Ruyter Ziekenhuis Goes (AdR). RUMC is a Level 1 trauma center. RA and AdR are Level 2 trauma centers. Participating

departments will be those of Orthopedics and Trauma Surgery.
The primary outcome measures will be union rate, complication rate and functional outcome scores.
Secondary outcomes will be closed reduction rate, operative time, image-intensifier time, hospital stay, incision length, time to radiological union, pain, re-operation, health related quality of life and cosmetic satisfaction.
Follow up will be at 12 months. Early results will be reported after 3 months.

Intervention

The surgical technique for the Anser will be as described in the implant brochure. Patients are administered prophylactic antibiotics. With a general anesthetic, the patient is placed in a beach-chair position with the arm draped freely. The anatomic landmarks of the shoulder will be identified and marked. The image-intensifier in positioned in such a way that is possible to image the entire clavicle in two planes. The lateral entry point at the posterior aspect of the conoid process is identified. A stab incision is made and soft tissues are spread until the conoid process is in sight. The intramedullary canal opened using a pointed drill and tissue protector. The base pin is implanted using the pindriver or hand-held pindriver. Once the base pin reaches the fracture site closed reduction is attempted using percutaneous clamps. The base pin is passed through the medial fragment. The last centimeters towards the sterno-clavicular joint the hand-held pindriver is used. Once adequate grip is obtained the base pin is in place. Positioning of the base pin is checked using the image intensifier in two planes. With a cannulated tap the lateral cortex is prepared for the lateral fixation device. Placement of the lateral fixation device. Reduction of the checked and secured by placement of the endcap. The pin is cut flush to the endcap. Irrigation of the wound followed by closure of the skin. After coverage of the wound a sling is applied. Post-operatively an X-ray in two planes will be made.

Postoperatively, patients are given a sling but are encouraged to start with pain-dependent mobilization after 1 week and to discard the sling as soon as possible thereafter. Load bearing is not recommended before osseous consolidation. After 2 weeks passive guided exercises will be prescribed by a physical therapist. Patients are advised to take pain medication when necessary. The patient is requested to record - on a daily basis immediately following surgery - the pain experienced as well as the type and amount of analgesics used. Pain is assessed with a VAS pain 10-point scale (0 = no pain and 10 = extremely painful).

Study burden and risks

3 additional outpatient clinic visits. 2 x 2 additional X-rays. It is hypothesized less re-operations and less complications will occur compared to

the numbers described in current literature in which current fixation devices are used.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

• Displaced midshaft clavicle fracture Type 2A1 or 2B1 according to the Robinson Classification
• Age > 18 years, < 65 years
• < 7 days after trauma

Exclusion criteria

• All patients deemed not fit for surgery by the anesthesiologist
• All patients with nonunion or previous malunion
• Patients <18 years or > 65 years
• Possible noncompliant patients (eg, alcohol and drug addiction, dementia)
• Additional neurovascular injury
• Pathologic fractures

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-05-2017
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO Date:	26-09-2016
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	05-10-2016
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO	

Date:	24-01-2017
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	03-04-2017
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL57209.091.16