Results of the Anser Clavicle Pin for treatment of Midshaft Clavicle Fractures

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The goals of this study are to evaluate the union rate, patient satisfaction and functional results of the Anser Clavicle Pin in a larger cohort then approved in the study, Anser; A novel intramedullary device for fixation of midshaft clavicle...

Ethical review	Approved WMO
Status	Completed
Health condition type	Bone disorders (excl congenital and fractures)
Study type	Interventional

Summary

ID

NL-OMON52512

Source
ToetsingOnline

Brief title
Results of the Anser Clavicle Pin

Condition

- Bone disorders (excl congenital and fractures)

Synonym
clavicle fracture, collarbone break

Research involving
Human

Sponsors and support

Primary sponsor: Rijnstate Ziekenhuis
Source(s) of monetary or material Support: Isshoni BV,STW

Intervention

Keyword: Clavicle, Fixation, Fracture, Intramedullary

Outcome measures

Primary outcome

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 months and 1 year 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, return to work, health related quality of life and cosmetic satisfaction.

Closed reduction is defined as advancing the Anser Clavicle Pin 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 patient satisfaction result after 6 weeks, 3 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

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.
An explorative study including 20 patients has been approved by our institutional review board. An interim analysis after the inclusion of 10 patients shows no intra- or peri-operative complications and adequate callus formation in all 3 weeks post-operatively. 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.

Study objective

The goals of this study are to evaluate the union rate, patient satisfaction and functional results of the Anser Clavicle Pin in a larger cohort then approved in the study, Anser; A novel intramedullary device for fixation of midshaft clavicle fractures. (CMO 2016-2428) Furthermore the indications for using the Anser Clavicle Pin will be broadened.
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, return to work, health related quality of life and cosmetic satisfaction.

Study design

Prospective case series. Therapeutic study with medical device. A multicenter trial
with at least 7 Dutch hospitals involved which are Rijnstate Arnhem (RA), UMCG (UG), Radboudumc (RUMC), Diakonessenhuis Utrecht (DIA) and Zuyderland Medisch Centrum (ZMC), Haga Ziekenhuis (HAG) and Noordwest Ziekenhuisgroep (NWZ). UG, RUMC, HAG and NWZ are Level 1 trauma centers. RA, DIA, ZMC are Level 2 trauma centers. Participating departments will be those of Orthopaedic and
Trauma Surgery.

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 tubercle is identified. A stab incision is made and soft tissues are spread until the conoid tubercle is in sight. The intramedullary canal opened using the 4mm Anser Drill Bit and Anser Drill Guide. The Anser Clavicle Pin is implanted using the Universal Pin Driver or Anser Manual Pin Driver. Once the Anser Clavicle Pin reaches the fracture site closed reduction is attempted. The Anser Clavicle Pin is passed through the medial fragment in a drilling or oscilating manner. The last centimeters towards the sterno-clavicular joint the Anser Manual Pin Driver is used. Once adequate grip is obtained the Anser Clavicle Pin is in place. Positioning of the Anser Clavicle Pin is checked using the image intensifier in two planes. With a cannulated Anser Tap the lateral cortex is prepared for the Anser Lateral Fixation Device. Placement of the Anser Lateral Fixation Device. Reduction of the checked and secured by placement of the Anser Endcap. The Anser Clavicle Pin is cut flush to the Anser Endcap. Irrigation of the wound followed by closure of the skin. After coverage of the wound a sling is applied. Post-operatively the fluoroscopic images will be saved.

Study burden and risks

During the explorative case series with the Anser we did not identify any intra- or perioperative complications. Participation in this study can lead to a decline in complication rates, a higher patient satisfaction than those reported in literature using current devices and a decline in re-interventions for hardware removal. One additional outpatient clinic at 1 year post-operatively is added to the standard of care and two visits (6 weeks and 3 months) will be extended by 10 minutes due to the administration of the outcome

scores.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

• Displaced midshaft clavicle fracture Type 2B or 2C according to the Robinson Classification
• Age >= 18 years,
• Surgery <=4 weeksafter trauma

Exclusion criteria

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

Study design

Design

Study phase:	3
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	04-06-2021
Enrollment:	100
Type:	Actual

Medical products/devices used

Generic name:	Anser Clavicle Pin
Registration:	No

Ethics review

Approved WMO

Date:	22-10-2020
Application type:	First submission

Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	11-01-2021
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	08-02-2021
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	22-03-2021
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	20-04-2022
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	NL63003.091.17