JSES International 4 (2020) 272–279

Contents lists available at ScienceDirect

JSES International

journal homepage: www.jsesinternational.org

Functional outcomes, union rate, and complications of the Anser Clavicle Pin at 1 year: a novel intramedullary device in managing midshaft clavicle fractures

Paul Hoogervorst, MD [a,*], Peer Konings, MD [b], Gerjon Hannink, PhD [c], Micha Holla, MD, PhD [a], Wim Schreurs, MD, PhD [a], Nico Verdonschot, Eng, PhD [a,d], Albert van Kampen, MD, PhD [a]

[a] Department of Orthopaedic Surgery, Radboud University Medical Center, Nijmegen, The Netherlands
[b] Department of Trauma and Orthopaedic Surgery, Rijnstate Ziekenhuis, Arnhem, The Netherlands
[c] Department of Operating Rooms, Radboud University Medical Center, Nijmegen, The Netherlands
[d] Department of Biomechanical Engineering, University of Twente, Enschede, The Netherlands

ARTICLE INFO

Keywords:
Clavicle
fracture
intramedullary
fixation
functional outcomes
complications

Level of evidence: Level IV; Case Series; Treatment Study

Background: Surgical management of displaced midshaft clavicle fractures in adults leads to better union rates, improved early functional outcomes, and increased patient satisfaction compared with nonoperative treatment. However, both intramedullary fixation and plate osteosynthesis are subject to a specific array of disadvantages and complications. The Anser Clavicle Pin is a novel intramedullary device designed to address these disadvantages and complications. The aim of this study was to evaluate the union rate, functional outcomes, and complications of the Anser Clavicle Pin at 1-year follow-up.

Methods: A prospective explorative case series including 20 patients with displaced midshaft clavicle fractures was performed in 2 hospitals. The primary outcomes were union rate, functional outcomes (Constant-Murley score and Disabilities of the Arm, Shoulder and Hand score), and complications. The secondary outcomes were closed reduction rate, operative time, image-intensifier time, hospital stay, incision length, time to radiologic union, postoperative pain reduction, reoperation rate, health-related quality-of-life score, and patient satisfaction.

Results: There was a 100% union rate. The Constant-Murley score at 1 year was 96.7 (standard deviation [SD], 5). The Disabilities of the Arm, Shoulder and Hand score was 5.1 (SD, 10). There were no infections, neuropathy of the supraclavicular nerve, or hardware irritation requiring removal of hardware. Three device-related complications (15%) occurred, including plastic deformation, protrusion, and hardware failure. The satisfaction score was 8.9 (SD, 1) on the visual analog scale at the 1-year follow-up.

Conclusion: Managing displaced midshaft clavicle fractures with the Anser Clavicle Pin results in a 100% union rate and excellent functional outcomes and patient satisfaction. It has a low non–device-related complication rate, and the device-related complications that occurred in this series may be prevented in the future.

Midshaft clavicle fractures are common fractures with an incidence of 59.3 per 100,000 person-years, comprising up to 5% of all fractures in adults.[12,28] In recent years the incidence of clavicle fractures has increased, and the operative treatment of these fractures has risen disproportionately.[19,24] The reasons for the increase in operative management may be multiple reports stating that surgical treatment in adults leads to better union rates, improved early functional outcomes, and increased patient satisfaction.[19,21,29,30,33,36,38,41,43]

Currently, the gold standard of surgical management of the midshaft clavicle fracture is open reduction–internal fixation by means of plates and screws. A plethora of different plate types (dynamic compression plate, limited contact dynamic compression plate, locking compression plate, precontoured, reconstruction) and locations (superior, anterior) have been described. Some of the advantages of open reduction–internal fixation with a plate-and-screw construct include restoration of the anatomy and thus the length of the clavicle, improved union rates, and early pain

This study was approved by the Commissie Mensgebonden Onderzoek Arnhem-Nijmegen Institutional Review Board (2016-2428) and the Dutch health care inspectorate (Inspectie voor de Gezondheidszorg [IGZ], VGR1014867).

* Corresponding author: Paul Hoogervorst, MD, Department of Orthopaedics, Radboud University Medical Center, PO Box 9101, 6500, HB Nijmegen, The Netherlands.

E-mail address: paul.hoogervorst@radboudumc.nl (P. Hoogervorst).

https://doi.org/10.1016/j.jseint.2020.01.002

reduction and start of rehabilitation.[3,19,22,33,37,41,43] Disadvantages include large incisions, risk of infection, hardware failure, damage to the supraclavicular nerve, and hardware irritation requiring removal during a secondary intervention.[10,19,21,33,37,41,43]

Other techniques manage these fractures by means of an intramedullary device such as the Sonoma Crx (Arthrex, Naples, FL, USA), Rockwood pin (DePuy Synthes, Warsaw, IN, USA), Hagie pin (Smith & Nephew, Memphis, TN, USA), Knowles pin (Zimmer Biomet, Warsaw, IN, USA), or Titanium Elastic Nails (TENs) DePuy Synthes, Warsaw, IN, USA or Stryker, Kalamazoo, MI, USA. The advantages of these devices are that they are minimally invasive, and have low rates of infection and good union rates. However, these devices also have their specific array of disadvantages such as hardware prominence, protrusion, telescoping, migration, wound breakdown, and in case of TENs, an almost 100% need for removal during a secondary intervention.[1,8,14,15,17,20,25-27,34,40]

The Anser Clavicle Pin (BAAT Medical BV, Hengelo, The Netherlands) is a novel intramedullary device aiming to result in excellent functional outcomes, union rates, and patient satisfaction in surgically managed patients with midshaft clavicle fractures. It is designed to address the disadvantages of the current techniques with the goal to lower health care costs and societal burden by reducing the need for secondary interventions, such as hardware removal. The aim of this first-in-human study was to evaluate the union rate, functional outcomes, and complications of the Anser Clavicle Pin.

Materials and methods

A prospective explorative case series was performed in 2 Dutch hospitals (Radboud University Medical Center, Nijmegen, and Rijnstate Ziekenhuis, Arnhem). A maximum of 20 patients was allowed to participate. Before the start of the study, the research protocol was registered in The Netherlands Trial Registry (NTR NL 6097). Written informed consent was obtained from all participants. This study was monitored by an independent monitor.

The inclusion criteria were (1) midshaft clavicle fracture type 2A2 or 2B1 according to the Robinson classification, (2) age between 18 and 65 years, and (3) surgery within days 10 days after trauma. The exclusion criteria were (1) patients deemed unfit for surgery by the anesthesiologist, (2) patients with nonunion or previous malunion, (3) patients younger than 18 years or older than 65 years, (4) possibly noncompliant patients (eg, alcohol and drug addiction or dementia), (5) patients with additional neurovascular injury, and (6) patients with pathologic fractures.

The authors and treating physicians were not involved in data collection. All preoperative and postoperative data were collected by designated independent reviewers in both hospitals and stored in an electronic data capture system (Castor EDC, Amsterdam, The Netherlands).[2] Preoperative characteristics of the participating patients were collected, including age, sex, body mass index, medical history, medications, American Society of Anesthesiologists classification, dominant side, occupation, trauma mechanism, smoking status, health-related quality-of-life questionnaire (Short Form 36 [SF-36]) score, participation and level of sports, and fracture classification according to the Robinson classification.

The primary outcomes included union rate, functional outcome as measured by the Constant-Murley score (CMS) and Disabilities of the Arm, Shoulder and Hand (DASH) score, and complications at 1-year follow-up. Union was defined as a two-thirds circumferential cortical bridging between the medial and lateral fragments on both the anteroposterior and 15° caudocranial radiographs as determined by 3 independent radiologists. Complications were defined as any general or implant-related intraoperative or postoperative adverse events that occurred during follow-up. Explicit inquiries during follow up were made regarding infection, hardware irritation, and neuropathy of the supraclavicular nerve.

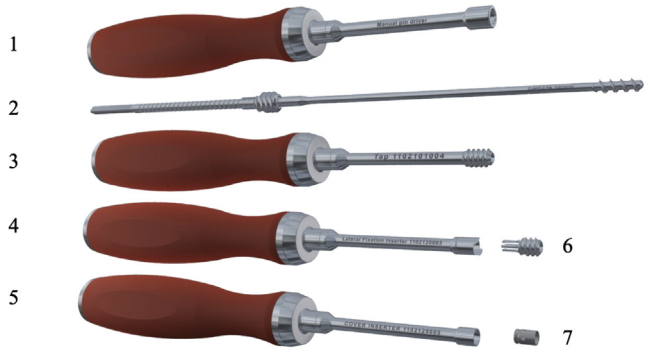

Figure 1 Anser Clavicle Pin and instruments (BAAT Medical BV): (1) Anser Manual Pin Driver, (2) Anser Clavicle Pin (including Anser Lateral Fixation Device), (3) Anser Tap, (4) Anser Lateral Fixation Device Inserter, (5) Anser Endcap Inserter, (6) Anser Lateral Fixation Device, and (7) Anser Endcap.

The secondary outcomes recorded were the closed reduction rate, operative time (in minutes), image-intensifier time, length of hospital stay, incision length, time to radiologic union, postoperative pain reduction (on a visual analog scale [VAS], 0-10), reoperation rate, SF-36 questionnaire score, and patient satisfaction (on a VAS, 0-10).

Follow-up was scheduled at 1, 3, and 6 weeks and 3, 6, and 12 months in the outpatient clinic. All visits included a standardized clinical evaluation and registration of complications. Radiographs were taken immediately after surgery and at 1, 3, and 6 weeks, until radiographic union had occurred. The CMS and DASH score were recorded during the 6-week, 3-month, 6-month, and 1-year postoperative visits. Patient satisfaction was recorded during the 6-week, 3-month, 6-month, and 1-year visits. At 6 months and 1 year, the patients were asked to complete the SF-36 questionnaire. Descriptive statistics were used to summarize the data. For the analysis of the CMS, DASH score, and SF-36 score over time, linear mixed models were used. Statistical analyses were performed using R (version 3.6.0; R Foundation for Statistical Computing, Vienna, Austria).

Surgical technique and rehabilitation protocol

The Anser Clavicle Pin is based on the premise that midshaft clavicle fractures do not need absolute stability but do need to be realigned and kept at length until union has occurred. It is flexible, so it can follow the biplanar sigmoid-shaped intramedullary canal of the clavicle, and is rigid enough to withstand the forces across the clavicle. It is anchored on both sides of the fracture, maintaining the reduction and preventing implant migration and secondary shortening. To prevent loss of fixation and hardware failure, the technology allows for rotational freedom of the fracture elements within its design. A rendering of the Anser Clavicle Pin and instruments used is shown in Figure 1.

All surgeons were trained during a cadaveric instructional course or by the surgeon (P.K.) with the most experience using the Anser Clavicle Pin. The surgical technique is described in detail in Supplementary Appendix S1. In short, after the induction of general anesthesia and the administration of prophylactic antibiotics, the patient was positioned in the beach-chair configuration and prepared and draped with the arm free. Anatomic landmarks of the shoulder were identified and marked. The image intensifier was positioned so that adequate views of the clavicle in 2 directions could be obtained. The posterolateral entry point at the posterior conoid tubercle was identified, and an incision through skin and

Table I
Patient data and baseline characteristics

Patient No.	Sex	Age, yr	Height, cm	Weight, kg	BMI	Dominant side	Injured side	Trauma mechanism	Robinson classification	Sports	Occupation	ASA class	Smoking
1	M	34	177	76	24	R	L	Direct	2B1*	Gym	Accountant	1	No
2	M	60	190	80	22	L	R	FOOSH	2B1*	—	Carpenter	1	No
3	M	47	180	82	25	R	R	FOOSH	2B1*	Gym	Active military	1	No
4	F	60	170	77	27	R	R	FOOSH	2B2	Cycling	Secretary	1	No
5	M	49	182	87	26	R	L	Direct	2B1*	Gym	Manager	1	No
6	M	48	188	90	25	R	R	FOOSH	2A2	CrossFit†	Active military	1	No
7	M	35	176	72	23	R	R	FOOSH	2B2	ATB	Designer	1	Yes
8	F	20	166	75	27	R	R	FOOSH	2B1	—	Student	1	No
9	M	55	179	87	27	R	L	Direct	2B1	Gym	Bus driver	1	No
10	M	56	178	103	33	L	L	Direct	2B1*	Cycling	Teacher	2	No
11	M	43	178	80	25	R	L	Direct	2B2	Motocross	Mechanic	1	No
12	M	44	196	91	24	R	R	FOOSH	2B1*	Cycling	Manager	1	No
13	M	26	182	75	23	R	L	FOOSH	2B1*	Soccer	Therapist	1	No
14	M	23	173	63	21	R	L	Direct	2B1	Triathlon	Student	1	No
15	M	51	190	95	26	R	L	Direct	2B2	Cycling	Engineer	1	No
16	M	62	190	90	25	R	L	Direct	2B1	Cycling	Entrepreneur	1	No
17	M	31	186	88	25	R	R	Direct	2B1	Rugby	Active military	1	No
18	M	51	180	80	25	R	R	FOOSH	2B1*	Equestrianism	Sculptor	1	No
19	M	37	180	70	22	R	R	FOOSH	2B1	ATB	Administrator	1	No
20	M	25	183	80	24	R	R	FOOSH	2B1*	Running	Furniture maker	1	No

M, male; *F*, female; *BMI*, body mass index; *R*, right; *L*, left; *FOOSH*, fall on outstretched hand; *ATB*, all-terrain bike; *ASA*, American Society of Anesthesiologists.
* With butterfly fragment.
† Semiprofessional.

subcutaneous tissue was made. After visual identification of the posterior conoid tubercle, the intramedullary canal was opened using a 4.0-mm drill and the Anser Clavicle Pin was advanced into the lateral fragment using the universal pin driver or Anser Manual Pin Driver (BAAT Medical BV) until it reached the fracture site. Closed reduction was attempted using percutaneous large pointed reduction clamps. If this was not possible, a small incision over the fracture site was made to facilitate direct reduction and visual confirmation. The Anser Clavicle Pin was then advanced into the medial fragment in an oscillating manner. At the last centimeters toward the sternoclavicular joint and subchondral plate, the Anser Manual Pin Driver was used until adequate grip and fixation were obtained. With a cannulated Anser Tap (BAAT Medical BV), the lateral cortex was prepared and the Anser Lateral Fixation Device (BAAT Medical BV) was placed. Reduction and the length of the clavicle were once more checked and then secured by placing the Anser Endcap (BAAT Medical BV). The Anser Clavicle Pin was then cut flush with the Anser Endcap. The wound was irrigated and closed. After the wound was dressed, the arm was placed in a sling for comfort.

Postoperatively, patients were encouraged to start with pain-dependent mobilization after 1 week and to discard the sling as soon as possible thereafter. Load bearing was not recommended until osseous consolidation had occurred. After 2 weeks, passive guided exercises were initiated by a physical therapist.

Results

Between May 2017 and April 2018, 20 patients (18 men and 2 women) were enrolled in this prospective case series. Table I provides an overview of included patient characteristics. The mean age at the time of surgery was 42.2 years (standard deviation [SD], 13.1 years). Mean recorded body mass index was 25 (SD, 2.5). A total of 15 Robinson type 2B1 fractures were included, of which 9 included a butterfly fragment (Fig. 2). Four fractures were classified as Robinson type 2B1 fractures during enrollment but, intraoperatively, a comminuted zone was observed; they were thus retrospectively classified as Robinson type 2B2 fractures (Fig. 3). One Robinson 2A2 fracture was included. Eighteen clavicle fractures were vertically displaced more than 100% of the shaft's width, one fracture was vertically displaced 50%-100%, and one fracture was vertically displaced 0%-50%. Most patients participated in cycling and gym workouts at an amateur level. Almost half of the patients had high—physical demand occupations for their upper extremities, including 3 active military members, a bus driver, a carpenter, a sculptor, a mechanic, and a furniture maker.

Nineteen patients were classified as American Society of Anesthesiologists class 1. One patient indicated tobacco use.

Primary outcomes

A 100% union rate was found at the 1-year follow-up. Adequate callus formation was seen in all but 1 of the cases at 6 weeks, as was radiographic consolidation at the 3-month follow-up evaluation. The remaining fracture underwent consolidation at between 3 and 6 months postoperatively. The CMS increased from 81.0 (SD, 14; range, 55-100) at 6 weeks to a mean of 96.7 (SD, 5; range, 83-100) at the 1-year follow-up (Fig. 4). The DASH score improved from 17.9 (SD, 16; range, 2-49) at 6 weeks to a mean of 5.1 (SD, 10; range, 0-29) at the 1-year follow-up (Fig. 3). No infections or neuropathy of the supraclavicular nerve were recorded during follow-up. Of 18 patients with the Anser Clavicle Pin in situ at 1-year follow-up, 1 reported minimal hardware irritation at the posterolateral entry point not requiring hardware removal. One non—device-related adverse event was recorded—a thromboembolic process of the subclavian vessels for which temporary anticoagulant therapy with apixaban was initiated. At the 1-year follow-up, a CMS of 96.0, DASH score of 1.6, and VAS satisfaction score of 8 were recorded for this particular patient. Three device-related complications occurred in our series. One pin was not

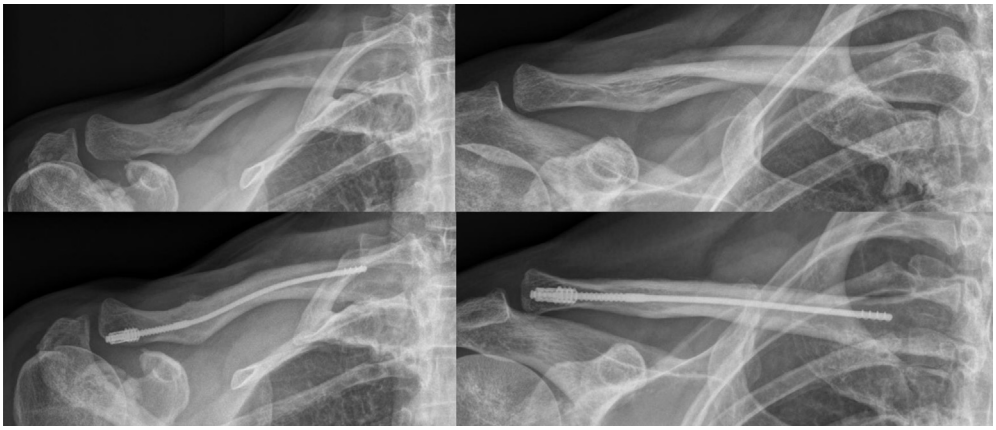

Figure 2 Example of Robinson type 2B1 fracture managed with Anser Clavicle Pin. The *bottom row* shows 3-month follow-up images.

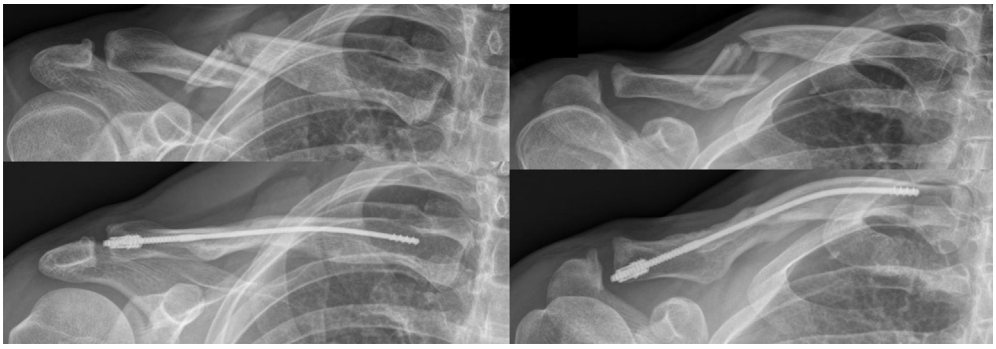

Figure 3 Example of Robinson type 2B2 fracture managed with Anser Clavicle Pin. The *bottom row* shows 3-month follow-up images.

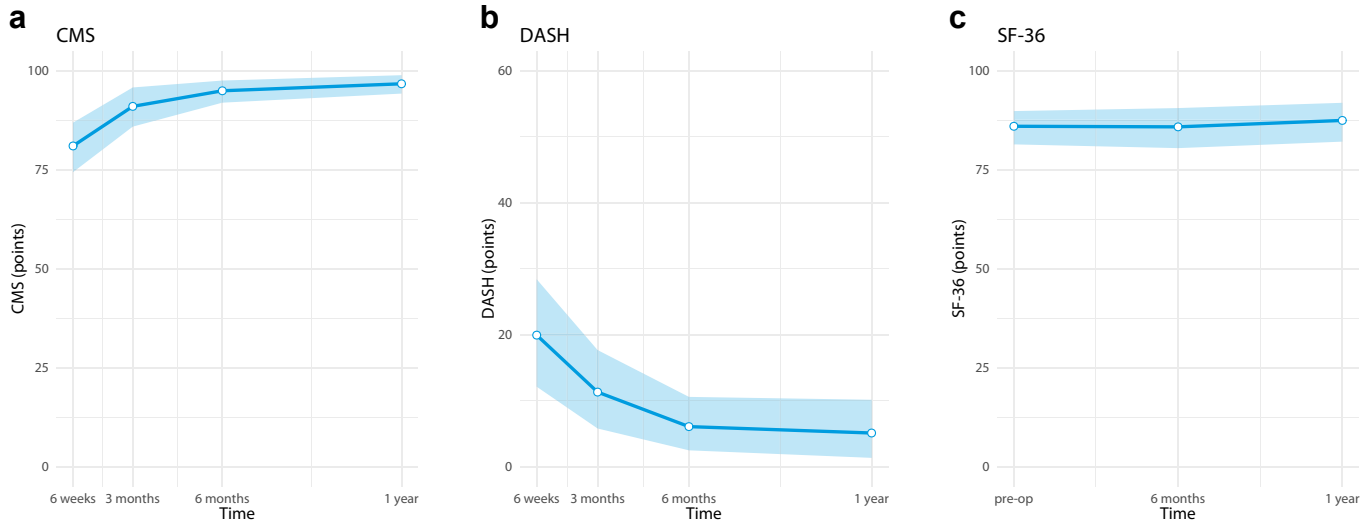

Figure 4 (**a**) Mean Constant-Murley score (*CMS*) with 95% confidence intervals at different follow-up moments (n = 18 at 6 weeks, n = 18 at 3 months, n = 17 at 6 months, and n = 17 at 1 year). (**b**) Mean Disabilities of the Arm, Shoulder and Hand (*DASH*) score with 95% confidence intervals at different follow-up moments (n = 17 at 6 weeks, n = 18 at 3 months, n = 15 at 6 months, and n = 17 at 1 year). (**c**) Mean Short Form 36 (*SF-36*) scores with 95% confidence intervals preoperatively (*pre-op*) and at 6 months and 1 year of follow-up. (n = 19 preoperatively, n = 15 at 6 months, and n = 18 at 1 year).

advanced far enough in the medial fragment, leading to plastic deformation of the pin. The patient declined the possibility of revision because it did not bother him and the fracture united without complications and resulted in a CMS of 100, DASH score of 0, and VAS satisfaction score of 10 at the 3-month and 1-year postoperative follow-up assessments. One pin was not adequately fixed into the posterolateral cortex, therefore allowing secondary shortening and causing hardware irritation requiring hardware removal. At the 1-year follow-up, the patient reported a CMS of 99.0 and VAS satisfaction score of 10. The third device-related complication was hardware failure at 4 weeks, which required revision surgery. A superiorly located plate was placed, and the fracture went on to unite without any complications. This patient was excluded from further analysis. Both of the hardware removal procedures were uncomplicated.

Table II
Outcome (secondary outcome) measures with Anser Clavicle Pin

Patient No.	Days to surgery	OR time, min	Fluoroscopy time, s	Closed reduction	incision length, cm*	Complication	Union	Neuropathy of suprascapular nerve at 12 mo	Hardware irritation at 12 mo
1	11	38	43	No	5		Yes	No	Minimal
2	12	49	34	No	8		Yes	No	No
3	12	45	34	No	7		Yes	No	No
4	8	45	19	No	7		Yes	No	No
5	9	30	13	No	8		Yes	No	No
6	3	40	27	No	9		Yes	No	No
7	5	45	61	No	7		Yes	No	No
8	3	61	66	No	7		Yes	No	No
9	6	35	33	No	7		Yes	No	No
10	5	45	25	No	6		Yes	No	No
11	9	42	36	No	—		Yes	No	No
12	8	30	34	No	6	Plastic deformation of Anser Clavicle Pin	Yes	No	No
13	5	50	25	No	8	Thromboembolism of subclavian vessels	Yes	No	No
14	5	37	17	No	6		Yes	No	No
15	6	35	58	No	5		Yes	No	No
16	7	67	83	No	6		Yes	No	No
17	3	80	48	No	6		Yes	—	—
18	6	27	15	No	6		Yes	No	No
19	6	30	15	No	9	Inadequate lateral fixation†	Yes	No	NA
20	3	29	14	No	—	Hardware failure†	Yes‡	NA	NA

OR, operating room; *NA*, not applicable.
* Combined posterolateral and anterior incisions.
† Removal of hardware required.
‡ After open reduction–internal fixation with plate.

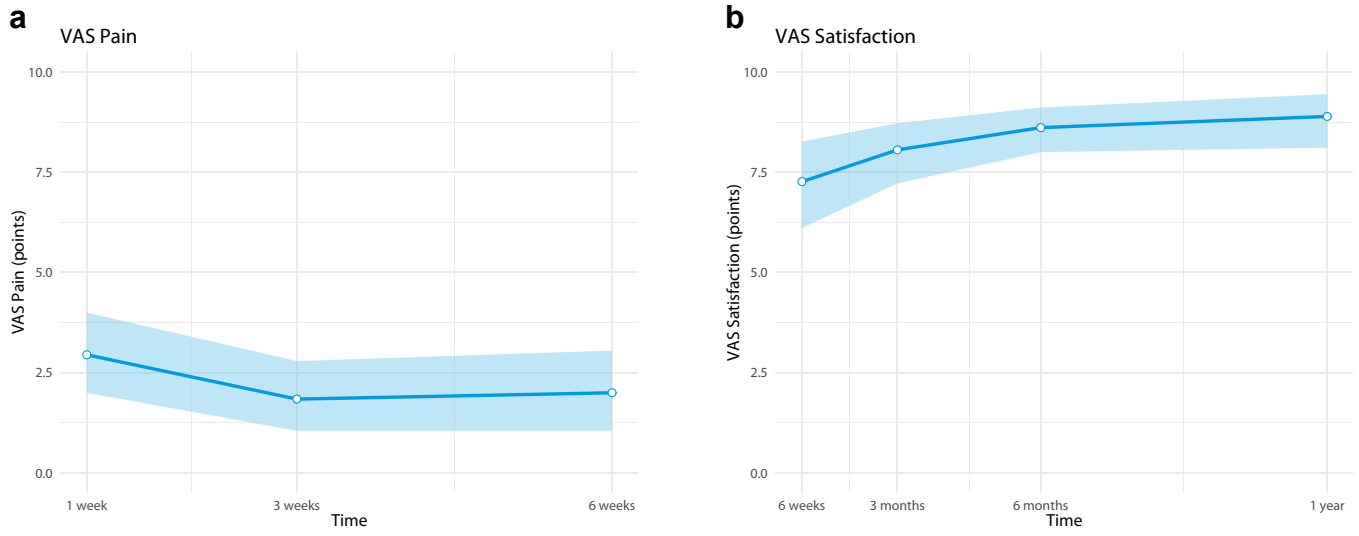

Figure 5 (**a**) Mean visual analog scale (*VAS*) score for pain with 95% confidence intervals at 1 week (n = 19), 3 weeks (n = 19), and 6 weeks (n = 19) postoperatively. (**b**) Mean VAS score for satisfaction with 95% confidence intervals at different follow-up moments (n = 19 at 6 weeks, n = 18 at 3 months, n = 18 at 6 months, and n = 18 at 1 year).

Secondary outcomes

Secondary outcomes are shown in Table II. The mean time to surgery was 6.6 days (SD, 2.9 days; range, 2-12 days). The mean surgical time was 43.0 minutes (SD, 13.6 minutes; range, 27-80 minutes). The mean fluoroscopy time was 35 seconds (SD, 19.6 seconds; range, 13-83 seconds). All but 1 patient stayed in the hospital for 1 day. The remaining patient was admitted for 3 days for unrelated medical reasons. In all patients, a small accessory incision was made over the fracture site to aid in reduction and adequate advancement of the Anser Clavicle Pin. The mean length of the 2 incisions combined was 6.8 cm (SD, 1.2 cm; range, 5-9 cm). Postoperatively, the Anser Clavicle Pin led to a quick reduction in the pain score, from 3.0 (SD, 2.3; range, 0-8) at 1 week to 2.0 (2.3, range 0-7) at 6 weeks (Fig. 4). The VAS satisfaction score increased from 7.3 (SD, 2; range, 2-10; n = 19) at 6 weeks to 8.9 (SD, 1; range, 4-10; n = 18) at the 1-year follow-up (Fig. 5). At 6 weeks, 15 patients had returned to work. At the 1-year follow-up, 1 patient had not returned to work, which was not a sequela of the clavicle fracture or its treatment. The health-related quality-of-life assessment using the SF-36 showed a return to preoperative baseline scores (86; 95% confidence interval [CI], 81-91) at both the 6-month (86; 95% CI, 81-91) and 1-year (88; 95% CI, 82-93) follow-up evaluations (Fig. 4).

Discussion

In this study, we aimed to evaluate the union rate, functional outcomes, and complications of the Anser Clavicle Pin. We found a 100% union rate and excellent functional outcome scores as measured by the CMS and DASH score. Union rates of displaced midshaft clavicle fractures between 90% and 100% are reported when managed surgically with either plate or intramedullary fixation.[10] The mean CMS when using the Anser Clavicle Pin is in line with the scores reported in a systematic review by Zhu et al,[45] who found CMS values of 93.8 at 1-year follow-up using intramedullary fixation and 89.3 using plate fixation. At 6 months' follow-up, Xiao et al[42] reported CMS values of 92.6 using intramedullary fixation and 87.2 using plate fixation. These scores fall well within the minimal clinically important difference of 10 and should be regarded as similar.[31] Chen et al[4] reported a DASH score at 6 months' follow-up of 6.6 when using intramedullary TENs and a score of 15 when using plate fixation. The DASH score after management with the Anser Clavicle Pin at 6 months' follow-up was similar, at 6.1 (SD, 8), further improving to 5.1 (SD, 10) at 1-year follow-up.

Infection rates for plate and intramedullary fixation range from 0%-36% and occur significantly more often when using plate fixation.[10] No infections were recorded when using the Anser Clavicle Pin. Neuropathy of the supraclavicular nerve may be one of the most commonly under-reported complications associated with plate fixation of the displaced midshaft clavicle fracture. Because there was the possibility of an accessory incision over the fracture site using the present device, it was decided before the start of the study to actively record the occurrence of this specific complication. No sensory deficits of the supraclavicular nerve were recorded with the Anser Clavicle Pin at 1-year follow-up. Of 18 patients with the Anser Clavicle Pin in situ at the 1-year follow-up, 1 reported minimal hardware irritation at the posterolateral entry point not requiring removal. This rate seems to be lower than the rate of hardware irritation caused by the TEN, which is often reported to be higher than 20% and up to 61%.[1,5,6,8-10,13,16,18,23,32,35,39,40] The reduction in hardware irritation is likely inherent to the design of the Anser Clavicle Pin allowing it to be placed in a retrograde fashion from the posterolateral clavicle, where it is minimally prominent and covered by more soft tissues than a TEN that is placed in an antegrade fashion just lateral to the sternoclavicular joint.

Three device-related complications were reported. In 1 patient, the Anser Clavicle Pin was plastically deformed. This is most likely caused by insufficient advancement of the pin into the medial fragment resulting in a less stable fracture and longer lever arm of the medial fragment on the pin. This complication may be prevented in the future by advancing the Anser Clavicle Pin far enough into the medial fragment. The second complication was hardware irritation at the posterolateral clavicle due to inadequate placement and thus fixation of the lateral fixation device into the cortex of the posterior conoid process. This allowed for secondary shortening and hardware irritation necessitating removal of hardware. This complication may be prevented in the future by adequately securing the lateral fixation device into the cortex. Our finding of 1 case of hardware irritation requiring hardware removal is substantially lower than the rates reported for plate osteosynthesis (38%) and intramedullary fixation (73%)[10] and would theoretically lead to a more cost-effective approach to the surgical management of midshaft clavicle fractures. The last complication consisted of hardware failure of the Anser Clavicle Pin. After review of the available radiographs in this patient, it seems that the fracture was reduced and fixed in a distracted position. This would have increased the forces on the device, resulting in its failure. This complication may be prevented in the future by ascertaining oneself that the clavicle is not lengthened during the procedure. Furthermore, the rehabilitation protocol in our study allowed for early mobilization. When in doubt, a transition to a more restricted rehabilitation protocol could be considered to prevent hardware failure. According to Hussain et al,[11] intramedullary fixation is 20.2 minutes faster than plate osteosynthesis. The studies reporting on intramedullary fixation used for this comparison reported a mean operating room time between 35.6 minutes (SD, 5.5 minutes)[44] and 53.2 minutes (SD, 25.8 minutes).[1] In our study, a mean operating room time of 43.0 minutes (SD, 13.6 minutes) was recorded. This time could be reduced further by increased experience and lowering of the threshold for making the accessory incision over the fracture site. In our study, the accessory incision did not seem to influence the union rate or cause neuropathy of the supraclavicular nerve. The added benefit of the accessory incision is that it allows for direct visualization of the fracture site and therefore safe pin advancement. Furthermore, it may be cosmetically more pleasing than 4 stab incisions, not in line, used for percutaneous reduction maneuvers.[7] During our series, it was noted that, most likely because of the delay until intervention, adequate closed reduction and advancement of the Anser Clavicle Pin were difficult. This could possibly be improved by earlier intervention (<3 days after trauma). This case series confirms that the Anser Clavicle Pin allows for early and adequate pain reduction and thus early rehabilitation, as well as return to baseline health-related quality of life at 6 months' follow-up.

A potential limitation is that one of the authors is involved in the development and commercialization of the Anser Clavicle Pin. The fact that this prospective case series has a registered protocol to which we adhered reduces the risk of reporting bias. This potential limitation is further mitigated by the data collection by designated independent reviewers and independent study monitoring. Another potential limitation of this study is the small sample size. The institutional review board and Dutch health care inspectorate (Inspectie voor de Gezondheidszorg [IGZ]) did not permit us to include more patients.

In summary, in this first-in-human prospective case series of 20 patients, the Anser Clavicle Pin has an excellent union rate, functional outcomes, and patient satisfaction when used in the management of displaced midshaft clavicle fractures. It has a low non–device-related complication rate, and the device-related complications that occurred in this series may be prevented in the future. The low rate of reintervention and absence of hardware removal owing to hardware irritation could positively impact the associated morbidity and economic and societal burden.

To confirm the present findings, a larger case series is necessary, followed by a comparison to other intramedullary fixation devices and/or plate osteosynthesis in a randomized controlled trial that includes a cost-effectiveness analysis.

Conclusion

Managing displaced midshaft clavicle fractures with the Anser Clavicle Pin results in an excellent union rate, functional outcomes, and patient satisfaction. It has a low non–device-related complication rate, and the device-related complications that occurred in this series can be prevented in the future.

Acknowledgments

The authors thank Ruben Scholten and Thijs Nijenhuis for collecting all preoperative and postoperative patient data.

Disclaimer

This study received funding from Stichting Technologie en Wetenschap (STW) Takeoff Grant 14475.

Paul Hoogervorst is the inventor of the Anser Clavicle Pin and is a stakeholder in a company involved in its commercialization.

The other authors, their immediate families, and any research foundations with which they are affiliated have not received any financial payments or other benefits from any commercial entity related to the subject of this article.

Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.jseint.2020.01.002.

References

1. Andrade-Silva FB, Kojima KE, Joeris A, Silva JS, Mattar R. Single, superiorly placed reconstruction plate compared with flexible intramedullary nailing for midshaft clavicular fractures: a prospective, randomized controlled trial. J Bone Joint Surg Am 2015;97:620–6. https://doi.org/10.2106/JBJS.N.00497.
2. Castor EDC. Castor Electronic Data Capture [online]. 2019. Available at: https://castoredc.com.
3. Canadian Orthopaedic Trauma Society. Nonoperative treatment compared with plate fixation of displaced midshaft clavicular fractures. A multicenter, randomized clinical trial. J Bone Joint Surg Am 2007;89:1–10. https://doi.org/10.2106/JBJS.F.00020.
4. Chen Y-F, Wei H-F, Zhang C, Zeng B-F, Zhang C-Q, Xue J-F, et al. Retrospective comparison of titanium elastic nail (TEN) and reconstruction plate repair of displaced midshaft clavicular fractures. J Shoulder Elbow Surg 2012;21:495–501. https://doi.org/10.1016/j.jse.2011.03.007.
5. Frigg A, Rillmann P, Perren T, Gerber M, Ryf C. Intramedullary nailing of clavicular midshaft fractures with the titanium elastic nail: problems and complications. Am J Sports Med 2009;37:352–9. https://doi.org/10.1177/0363546508328103.
6. Fuglesang HFS, Flugsrud GB, Randsborg PH, Oord P, Benth J, Utvåg SE. Plate fixation versus intramedullary nailing of completely displaced midshaft fractures of the clavicle. Bone Joint J 2017;99B:1095–101. https://doi.org/10.1302/0301620X.99B8.BJJ20161318.R1.
7. Fuglesang HFS, Oksum MA, Wikeroy AKB. Mini-invasive intramedullary fixation of displaced midshaft clavicle fractures with an elastic titanium nail. JBJS Essent Surg Tech 2018;8:e16. https://doi.org/10.2106/jbjs.st.18.00001.
8. Govindasamy R, Kasirajan S, Meleppuram JJ, Thonikadavath F. A retrospective study of titanium elastic stable intramedullary nailing in displaced mid-shaft clavicle fractures. Rev Bras Ortop 2017;52:270–7. https://doi.org/10.1016/j.rboe.2016.07.005.
9. Hartmann F, Hessmann MH, Gercek E, Rommens PM. Elastic intramedullary nailing of midclavicular fractures. Acta Chir Belg 2008;108:428–32. https://doi.org/10.1080/00015458.2008.11680255.
10. Houwert RM, Smeeing DP, Ahmed Ali U, Hietbrink F, Kruyt MC, van der Meijden OA. Plate fixation or intramedullary fixation for midshaft clavicle fractures: a systematic review and meta-analysis of randomized controlled trials and observational studies. J Shoulder Elbow Surg 2016;25:1195–203. https://doi.org/10.1016/j.jse.2016.01.018.
11. Hussain N, Sermer C, Prusick PJ, Banfield L, Atrey A, Bhandari M. Intramedullary nailing versus plate fixation for the treatment displaced midshaft clavicular fractures: a systematic review and meta-analysis. Sci Rep 2016;6:34912. https://doi.org/10.1038/srep34912.
12. Huttunen TT, Launonen AP, Berg HE, Lepola V, Fellander-Tsai L, Mattila VM. Trends in the incidence of clavicle fractures and surgical repair in Sweden: 2001-2012. J Bone Joint Surg Am 2016;98:1837–42. https://doi.org/10.2106/JBJS.15.01284.
13. Jubel A, Andermahr J, Prokop A, Lee JI, Schiffer G, Rehm KE. Treatment of midclavicular fractures in adults. Early results after rucksack bandage or elastic stable intramedullary nailing. Unfallchirurg 2005;108:707–14. https://doi.org/10.1007/s00113-005-0970-8.
14. Jubel A, Andermahr J, Schiffer G, Rehm KE. Die Technik der intramedullären Osteosynthese der Klavikula mit elastischen Titannägeln [Technique of intramedullary osteosynthesis of the clavicle with elastic titanium nails]. Unfallchirurg 2002;105:511–6. https://doi.org/10.1007/s00113-001-0386-z.
15. Jubel A, Andermahr J, Schiffer G, Tsironis K, Rehm KE. Elastic stable intramedullary nailing of midclavicular fractures with a titanium nail. Clin Orthop Relat Res 2003:279–85. https://doi.org/10.1097/00003086-200303000-00037.
16. Kadakia AP, Rambani R, Qamar F, McCoy S, Koch L, Venkateswaran B. Titanium elastic stable intramedullary nailing of displaced midshaft clavicle fractures: a review of 38 cases. Int J Shoulder Surg 2012;6:82–5. https://doi.org/10.4103/0973-6042.102557.
17. Keihan Shokouh H, Naderi MN, Keihan Shokouh M. Treatment of midshaft clavicular fractures with elastic titanium nails. Trauma Mon 2014;19:e15623. https://doi.org/10.5812/traumamon.15623.
18. Kettler M, Schieker M, Braunstein V, König M, Mutschler W. Elastic Stable Intramedullary Nailing (ESIN) of displaced midclavicular fractures with titanium nails. Aktuelle Traumatol 2005;35:303–7. https://doi.org/10.1055/s-2005-865953.
19. Kong L, Zhang Y, Shen Y. Operative versus nonoperative treatment for displaced midshaft clavicular fractures: a meta-analysis of randomized clinical trials. Arch Orthop Trauma Surg 2014;134:1493–500. https://doi.org/10.1007/s00402-014-2077-6.
20. Kraus TM, Martetschlager F, Schrodl C, Siebenlist S, Ganslmeier A, Kirchhoff C, et al. Die elastisch stabile intramedulläre Osteosynthese der diaphysären Klavikulafraktur: Offene vs. geschlossene Reposition [Elastic stable intramedullary nailing of clavicular midshaft fractures: comparison of open vs closed fracture reduction]. Unfallchirurg 2013;116:102, 104-8. https://doi.org/10.1007/s00113-011-2059-x.
21. Lenza M, Faloppa F. Conservative interventions for treating middle third clavicle fractures in adolescents and adults. Cochrane Database Syst Rev 2016;12:CD007121. https://doi.org/10.1002/14651858.CD007121.pub4.
22. Lenza M, Faloppa F. Surgical interventions for treating acute fractures or nonunion of the middle third of the clavicle. Cochrane Database Syst Rev 2015:CD007428. https://doi.org/10.1002/14651858.CD007428.pub3.
23. Lu CC, Liu PC, Huang SH, Hsieh CH, Tien YC, Chien SH. Complications and technical pitfalls of titanium elastic nail fixation for midclavicular fractures. Orthopedics 2014;37:e377–83. https://doi.org/10.3928/01477447-20140401-60.
24. McKee RC, Whelan DB, Schemitsch EH, McKee MD. Operative versus nonoperative care of displaced midshaft clavicular fractures: a meta-analysis of randomized clinical trials. J Bone Joint Surg Am 2012;94:675–84. https://doi.org/10.2106/JBJS.J.01364.
25. Mueller M, Burger C, Florczyk A, Striepens N, Rangger C. Elastic stable intramedullary nailing of midclavicular fractures in adults: 32 patients followed for 1-5 years. Acta Orthop 2007;78:421–3. https://doi.org/10.1080/17453670710014013.
26. Mueller M, Rangger C, Striepens N, Burger C. Minimally invasive intramedullary nailing of midshaft clavicular fractures using titanium elastic nails. J Trauma 2008;64:1528–34. https://doi.org/10.1097/TA.0b013e3180d0a8bf.
27. Narsaria N, Singh AK, Arun GR, Seth RRS. Surgical fixation of displaced midshaft clavicle fractures: elastic intramedullary nailing versus precontoured plating. J Orthop Trauma 2014;15:165–71. https://doi.org/10.1007/s10195-014-0298-7.
28. Nowak J, Holgersson M, Larsson S. Can we predict long-term sequelae after fractures of the clavicle based on initial findings? A prospective study with nine to ten years of follow-up. J Shoulder Elbow Surg 2004;13:479–86. https://doi.org/10.1016/j.jse.2004.01.026.
29. Rehn CH, Kirkegaard M, Viberg B, Larsen MS. Operative versus nonoperative treatment of displaced midshaft clavicle fractures in adults: a systematic review. Eur J Orthop Surg Traumatol 2014;24:1047–53. https://doi.org/10.1007/s00590-013-1370-3.
30. Robertson GA, Wood AM. Return to sport following clavicle fractures: a systematic review. Br Med Bull 2016;119:111–28. https://doi.org/10.1093/bmb/ldw029.
31. Roy JS, MacDermid JC, Woodhouse LJ. Measuring shoulder function: a systematic review of four questionnaires. Arthritis Rheum 2009;61:623–32. https://doi.org/10.1002/art.24396.
32. Saha P, Datta P, Ayan S, Garg AK, Bandyopadhyay U, Kundu S. Plate versus titanium elastic nail in treatment of displaced midshaft clavicle fractures: a comparative study. Indian J Orthop 2014;48:587–93. https://doi.org/10.4103/0019-5413.144227.
33. Smeeing DPJ, van der Ven DJC, Hietbrink F, Timmers TK, van Heijl M, Kruyt MC, et al. Surgical versus nonsurgical treatment for midshaft clavicle fractures in patients aged 16 years and older: a systematic review, meta-analysis, and comparison of randomized controlled trials and observational studies. Am J Sports Med 2017;45:1937–45. https://doi.org/10.1177/0363546516673615.
34. Smekal V, Irenberger A, Struve P, Wambacher M, Krappinger D, Kralinger FS. Elastic stable intramedullary nailing versus nonoperative treatment of displaced midshaft clavicular fractures-a randomized, controlled, clinical trial. J Orthop Trauma 2009;23:106–12. https://doi.org/10.1097/BOT.0b013e318190cf88.
35. van der Meijden OA, Houwert RM, Hulsmans M, Wijdicks FJ, Dijkgraaf MG, Meylaerts SA, et al. Operative treatment of dislocated midshaft clavicular fractures: plate or intramedullary nail fixation? A randomized controlled trial. J Bone Joint Surg Am 2015;97:613–9. https://doi.org/10.2106/jbjs.n.00449.
36. Wang J, Meng XH, Guo ZM, Wu YH, Zhao JG. Interventions for treating displaced midshaft clavicular fractures: a Bayesian network meta-analysis of randomized controlled trials. Medicine (Baltimore) 2015;94:e595. https://doi.org/10.1097/md.0000000000000595.
37. Wang XH, Cheng L, Guo WJ, Li AB, Cheng GJ, Lei T, et al. Plate versus intramedullary fixation care of displaced midshaft clavicular fractures: a meta-analysis of prospective randomized controlled trials. Medicine (Baltimore) 2015;94:e1792. https://doi.org/10.1097/md.0000000000001792.
38. Wang XH, Guo WJ, Li AB, Cheng GJ, Lei T, Zhao YM. Operative versus nonoperative treatment for displaced midshaft clavicle fractures: a meta-analysis based on current evidence. Clinics (Sao Paulo) 2015;70:584–92. https://doi.org/10.6061/clinics/2015(08)09.
39. Wang YC, Fu YC, Chou SH, Liu PC, Tien YC, Lu CC. Titanium Elastic Nail versus plate fixation of displaced midshaft clavicle fractures: a retrospective comparison study. Kaohsiung J Med Sci 2015;31:473–9. https://doi.org/10.1016/j.kjms.2015.07.008.

40. Wijdicks FJ, Houwert M, Dijkgraaf M, de Lange D, Oosterhuis K, Clevers G, et al. Complications after plate fixation and elastic stable intramedullary nailing of dislocated midshaft clavicle fractures: a retrospective comparison. Int Orthop 2012;36:2139–45. https://doi.org/10.1007/s00264-012-1615-5.
41. Woltz S, Krijnen P, Schipper IB. Plate fixation versus nonoperative treatment for displaced midshaft clavicular fractures: a meta-analysis of randomized controlled trials. J Bone Joint Surg Am 2017;99:1051–7. https://doi.org/10.2106/jbjs.16.01068.
42. Xiao H, Gao H, Zheng T, Zhao J, Tian Y. Plate fixation versus intramedullary fixation for midshaft clavicle fractures: meta-analysis of complications and functional outcomes. J Int Med Res 2016;44:201–15. https://doi.org/10.1177/0300060515621638.
43. Xu J, Xu L, Xu W, Gu Y, Xu J. Operative versus nonoperative treatment in the management of midshaft clavicular fractures: a meta-analysis of randomized controlled trials. J Shoulder Elbow Surg 2014;23:173–81. https://doi.org/10.1016/j.jse.2013.06.025.
44. Zehir S, Akgul T, Zehir R. Results of midshaft clavicle fractures treated with expandable, elastic and locking intramedullary nails. Acta Orthop Traumatol Turc 2015;49:13–7. https://doi.org/10.3944/aott.2015.14.0070.
45. Zhu Y, Tian Y, Dong T, Chen W, Zhang F, Zhang Y. Management of the mid-shaft clavicle fractures using plate fixation versus intramedullary fixation: an updated meta-analysis. Int Orthop 2015;39:319–28. https://doi.org/10.1007/s00264-014-2655-9.