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Plate fixation versus conservative treatment of displaced midshaft clavicle fractures: Functional outcome and patients' satisfaction during a mean follow-up of 5 years

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ABSTRACT

Introduction: The aim of the present prospective clinical trial was to compare patient-oriented and surgeon-based outcomes after non-operative care with operative treatment of displaced midshaft clavicle fractures.

Patients/Methods: Between January 2009 and July 2011, 97 consecutive patients presenting with a midshaft clavicle fracture were prospectively recorded and included in this study. The patients were placed in either of the treatment groups on their own preference. They were then seen in outpatient clinic at two, six and 24 weeks were all endpoints were investigated and motivation of choice of treatment was noted. Study follow-up was continued until Augustus 2014, being the time point that long-term functional outcome was measured through a DASH score by letter.

Results: 97 patients were included in the functional outcome analysis. The mean DASH and Constant scores were significant better in the operative (90.9 ± 14.2 and 15.7 ± 17.2) than in the conservative treatment group at six weeks (78.7 ± 17.0 and 24.8 ± 16.7). There was a significant improvement in the Constant (95.9 ± 10.5 *versus* 94.5 ± 5.9) and DASH scores (8.8 ± 12.0 *versus* 7.1 ± 10.7) for both groups at 24 weeks but there was no significant difference in functional scores between the groups. Four patients developed a non-union, one patient in the operative and three patients in the conservative group. Overall complications were significantly higher in the operative group (31%) compared to the conservative group (9%) ($p < 0.001$). There was no significant difference in long-term functional outcome between the two treatment groups (5.2 ± 9.8 *versus* 2.5 ± 4.9 $p = 0.12$). Patient's satisfaction was higher in the operative than in the conservative group ($p < 0.04$).

Conclusion: Significant superior outcome scores were seen at six weeks for the operative group. However, at 24 weeks and 5-year follow-up no difference was seen in functional outcome scores for both treatment groups. Therefore, the challenge for the future is to better identify the subgroup of patients who might benefit from primary surgical intervention.

Introduction

Fractures of the clavicle account for 2.6–4% of all fractures. The vast majority (69–82%) of these fractures are located in the midshaft of the clavicle [1–3]. These midshaft clavicle fractures are caused by a direct axial compressive force to the shoulder after a sudden stop or fall and occur mostly in young active individuals. The treatment of clavicle fractures is, therefore, aimed at quickly restoring function of the upper extremity and preventing disability. Traditionally, midshaft clavicle fractures have been treated non-operatively, even when substantially displaced. This was based on early reports suggesting that clavicle non-unions are very rare [4,5]. However, decreased shoulder function due to clavicle shortening after non-operative fracture management has been reported [6].

There is, nowadays, a growing trend to treat displaced midshaft clavicle fractures with primary open reduction and plate fixation. Whether such treatment results in improved patient outcomes is

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debatable. There is limited evidence on the relative effectiveness of different methods of surgical intervention for treating acute fractures of the middle third of the clavicle and no consensus exist yet [7]. Therefore, the choice of treatment depends mostly upon the experience of the surgeon and is often not patient oriented.

The aim of the present prospective clinical trial was to compare patient-oriented and surgeon-based outcomes after non-operative care with operative treatment of completely displaced midshaft clavicle fractures.

Patients and methods

Between January 2008 and July 2010, all consecutive patients presenting with a new midshaft clavicle fracture at the emergency department of the Meander Medical Center (MMC), were prospectively recorded and included in this clinical trial. The MMC serves as a regional Level 2 trauma center. Our hospital treats an increasing number of emergency department patients of around 35,000 patients. The study was approved by the local medical ethics committee.

Patient selection

Inclusion criteria were: (1) a completely displaced midshaft fracture of the clavicle with no cortical contact between the proximal and distal fragment; (2) age between 16 and 70 years.

Exclusion criteria were: (1) fracture in the proximal or distal third of the clavicle; (2) pathological fracture (bony abnormalities at the side of the fracture); (3) open fracture; (4) fracture seen more than twenty-one days after the injury; (5) a significant ipsilateral upper extremity fracture.

Once identified as eligible for the study, patients were seen at the outpatient clinic within 5 days. They received detailed information from one experienced trauma surgeon regarding the advantages and disadvantages of the both operative and nonoperative treatment. After explanation of both therapeutic methods, the patients were placed in either the operative or non-operative group on their own preference.

Outcome measures

The primary outcome parameters were: (1) fracture union and (2) functional outcome measured using the "Disability of the Arm, Shoulder and Hand" (DASH) questionnaire [8] and the Constant shoulder questionnaire [9].

Secondary outcome parameters were: (1) complications; (2) return to work; and (3) motivation choice of treatment.

Long-term outcome parameters were: (1) functional outcome measured using the "Disability of the Arm, Shoulder and Hand" (DASH) questionnaire [9] and "visual analog scale" VAS [10] by letter; (2) complications; (3) residual complaints; (4) patients' satisfaction with treatment measured with an additional questionnaire by letter.

Interventions

Conservative treatment was performed with use of a standard sling for two weeks, only passive movements were allowed. After these two weeks, the patient was seen on the outpatient clinic and a course of physiotherapy for exercise and strengthening was carefully initiated. The full range of active motion was permitted after six weeks, and return to full activities was permitted after three months.

Surgery was performed within three weeks after injury. The procedure of applying the VA-LCP anterior locking compression plate was performed according to standard orthopaedic procedures [11]. A sling was used during the first two weeks postoperatively. The postoperative exercise protocol was similar to that in the non-operative group.

Fracture union

Union of the clavicle fracture was defined as complete cortical bridging between proximal and distal fragments. Symptomatic mal-union was defined as a patient with symptoms severe enough to warrant corrective osteotomy. Non-union was defined as the absence of radiographic union six months or longer after the injury.

Patients with non-union at six months who had symptoms of pain or mobility at the fracture site were offered secondary open reduction and anterior plate fixation [11]. Delayed union was defined as progression to union on three-dimensional CT at one year of follow-up in patients who had not healed by six months.

Follow-up

Following enrollment in the study, the patients were seen in outpatient clinic at two, six weeks, and at 6 months. The DASH and Constant shoulder scores were completed, motivation of choice of treatment was noted and radiographs were made.

Study follow-up was continued until May 2014, being the time point that long-term functional outcome was measured through a DASH score and VAS by letter combined with an letter were all adverse events were noted and divided into physical complaints (droopy shoulder, bump and/or asymmetry, scar, sensitive and/or painful fracture site, hardware irritation, incisional numbness), the need of operative procedure or additional medical treatment and patients' satisfaction with the chosen treatment.

Functional outcome

The Disabilities of the Arm, Shoulder and Hand (DASH) [8] scoring system was developed to assess the level of disability for any patient with any condition affecting the upper limb by covering domains including symptoms, physical function, social function and psychological function. The DASH is scored in two components: the disability/symptom questions (30 items, scored 1–5) and the optional high performance sport/music or work section (4 items, scored 1–5).

The Constant-Murley score [9] comprises both clinician-assessed physical examination findings and subjective patient-reported assessments. It consists of 14 items, with a total score of 0–100. The questionnaire consists of two parts: the subjective part measures pain during various activities: pain, activity level sleep affected, recreations/sport limitation, daily living limitations and arm positioning.

The objective part is completed by the surgeon and includes the following components: Range of motion, strength of abduction, external rotation and internal rotation. An additional questionnaire was used to assess functional impairment and clinical outcomes including: recovery of former function, such as time to return to previous activities (sport, manual labour), cosmetic appearance and patient satisfaction. The VAS is a self-rated health status using a visual analogue scale (VAS) recording the perception of the participant's current overall health state. The latter is ranged from 0 (the worst imaginable health state) to 100 (the best imaginable state) [10].

Complications

Complications were considered to exist if a subsequent surgical procedure was performed, if fixation failed or produced irritation