# Clavicle fractures may be conservatively treated with acceptable results – a systematic review

Ilija Ban[1, 2], Ulrik Branner[1], Kim Holck[1], Michael Krasheninnikoff[1] & Anders Troelsen[1]


## ABSTRACT

**INTRODUCTION:** The optimal treatment of acute, displaced midshaft clavicle fractures is controversial. Despite lack of compelling evidence towards superior results after primary surgery, it seems that more and more patients are treated surgically. The aim of this study was to investigate which treatment modality should be preferred in this population according to current literature.

**METHOD:** Randomized trials and prospective cohort studies comparing different treatment modalities for acute, displaced midshaft clavicle fracture in adults, published in English from 1966 to August 2011 were sought via an electronic database search (MEDLINE).

**RESULTS:** Five studies with a total of 365 patients were identified. All fractures were described as midshaft fractures with complete displacement of their bony parts. Overall, the functional outcome (measured with the Constant score) was better in the surgically treated groups than in the conservatively treated groups. Likewise, union rates were higher in the surgical groups than in the conservative groups. Overall, complication rates were close to 30% in the surgically treated groups compared with 47% in the conservatively treated groups.

**CONCLUSION:** Surgical treatment of acute, displaced midshaft clavicle fractures with a plate yields a better functional outcome and lower mal- and nonunion rates than conservative treatment. However, the clinical relevance of the observed functional benefits are questionable as is the use of the shoulder outcome scores frequently employed to assess the functional outcome of clavicle fracture treatment. When operative treatment is preferred, the number needed to treat to avoid a nonunion is high.


Pioneering research on clavicle fractures done in the 1960s [1, 2] made conservative treatment the treatment of choice for clavicle fractures for more than three decades (**Figure 1**). Over the past 15 years, several publications focusing on fracture subgroups, functional outcome and fracture nonunion have suggested that surgical treatment should play a greater role in primary treatment of acute, displaced clavicle fractures than previously assumed [3-6]. The past five years have therefore seen a major shift towards primary surgical treatment of acute, displaced midshaft clavicle fractures. This shift has occurred despite a lack of compelling evidence of superior results from surgery, and probably as a result of the theoretical advantages offered by modern plate-fixation techniques. Concern has been raised that primary surgical intervention may lead to overtreatment and one study has suggested that nine operations of acute, displaced, midshaft clavicle fractures are required to prevent one nonunion [7]. Furthermore, no study has validated any of the most commonly used shoulder scores on patients with clavicle fractures [8], which adds to the controversial nature of any interpretation of outcome results based on shoulder scores.

FIGURE 1

Conservatively treated clavicle fracture healing with malunion.

Controversy clearly exists, and the purpose of this study was to investigate which treatment modality is to be preferred for acute, displaced midshaft clavicle fractures in adults on the basis of a systematic literature review that focusing on functional outcome and fracture heeling.

### Facts on clavicle fractures

Clavicle fractures are typically seen in young males (approximately 70% of cases are males) with a mean age close to 30 years [5, 6]. A direct trauma to the shoulder as a result of contact sport or a vehicle accident is the most common mechanism of injury. Clavicle fractures are a frequent injury and represent somewhere between 5% and 10% of all fractures seen in orthopaedics [6]. Close to 70% of all clavicle fractures are localized to the middle third of the clavicle and most of these fractures (approximately 70%) are displaced. Open fractures and fractures with associated neurovascular injury are rare [6].

Three main classification systems are used: the

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1) Clinical Orthopaedic Research, Department of Orthopaedics, Hvidovre Hospital
2) Department of Orthopaedics, Slagelse Hospital

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Allman classification [9], the Orthopaedic Trauma Association (OTA) classification and the Edinburgh classification [6]. In addition to the anatomic site, the last two classification systems also describe the complexity of the fracture.

### Treatment modalities

Midshaft clavicle fractures are treated both conservatively and surgically.

Conservative treatment consists of immobilization either by a simple sling or a figure-of-eight bandage in combination with analgesics. A study by Anderson et al showed no functional or cosmetic difference between the two techniques, except that the simple sling caused less discomfort [10]. The same study showed that neither technique was able to reduce a displaced fracture. The bandage is removed once the acute pain resides, typically in few weeks, and if the fracture unites, full range of motion is almost achieved after six weeks [7].

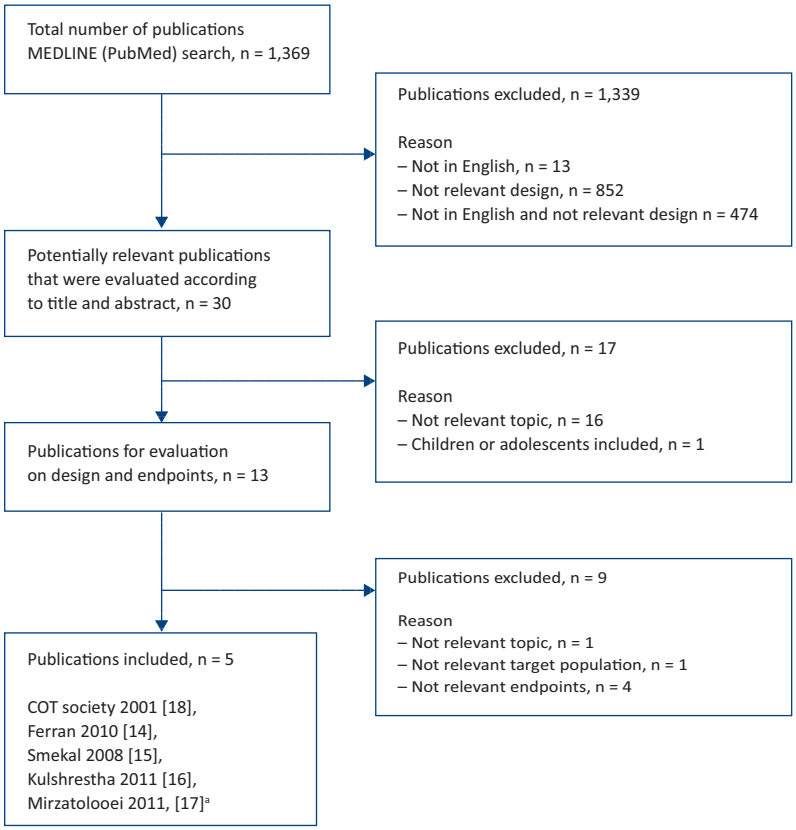
Surgical treatments have consisted of a wide variety of experimental and established techniques. The use of external fixators and Kirschner wires is associated with profound complications and is not recommended as primary treatment for closed midshaft fractures [7]. Plate fixation and intramedullary fixation are the most commonly used devices. Plate implants have evolved from conventional reconstruction plates – which have been associated with deformation at the fracture site [7] – to contemporary pre-contoured locking plates. The latter have advantageous biomechanical properties [11] and low complication rates in the elderly [12]. Like plates, intramedullary devices have evolved over time from simple K-wires and smooth pins to elastic nails and pins with locking possibilities.

The goal of surgery is to improve the functional outcome, avoid non-union and symptomatic mal-union by achieving close-to-anatomic reduction. Rigid fixation should be obtained with the chosen technique in order to facilitate early mobilization. Weight bearing of the operated upper extremity is usually not allowed for the first six postoperative weeks.

It is generally acknowledged that undisplaced midshaft clavicle fractures should be treated conservatively. Regarding acute, displaced fractures, an ongoing debate in the literature shows that there is no consensus concerning the optimal choice of treatment.

FIGURE 2

Algorithm of search strategy results.




COT = Canadian Orthopaedic Trauma Society
a) Identified via related articles in PubMed and subsequently included.

## METHOD

We aimed to identify all randomized trials and prospective cohort studies comparing different treatment modalities for acute, displaced midshaft clavicle fracture in adults.

We performed a search in MEDLINE (PubMed).

### Search strategy

MEDLINE was searched for references published from 1966 to the present using the following MeSH terms ("Clavicle/injuries"(MeSH) OR "Clavicle/radiography" (MeSH) OR "Clavicle/surgery"(MeSH)) AND ("Fracture, Bone"(MeSH) OR "Fracture Fixation, Intramedullary" (MeSH) OR "Fracture Fixation"(MeSH)). A selection was done according to methodology (clinical trials and randomized clinical trials) and language (English).

The main author (IB) screened the extracted references by revising their titles and abstracts and retrieved the full text article if the selection criteria were met.

### Selection criteria

We identified articles that met the following criteria:

1. Methodology: prospective cohort or randomized clinical trials
2. Language: English literature
3. Target population: adults with an acute midshaft clavicle fracture

TABLE 1

Study characteristics.

| Study | Method | No. of patients (♂/♀) | No. of LTF | Mean age, years | Fracture | Interventions | Endpoints[a] |
|---|---|---|---|---|---|---|---|
| COT society, 2007 | RCT | 132 (87/24) | 21 | 35.5 | Completely displaced | Internal plate fixation (n = 67) or simple sling (n = 65) | Constant and DASH score<br>Union and complication rates |
| Ferran et al, 2010 | RCT | 32 (27/5) | 0 | 29.1 | Completely displaced and shortened | Internal plate fixation (n = 15) or intramedullary fixation (n = 17) | Constant and Oxford shoulder score<br>Union and complication rates |
| Smekal et al, 2008 | RCT | 68 (52/8) | 8 | 37.7 | Completely displaced[b] | Intramedullary fixation (n = 33) or simple sling (n = 35) | Constant and DASH score<br>Union and complication rates |
| Mirzatolooei, 2011 | RCT | 60 (41/9) | 10 | 33.4 | Completely displaced and comminuted | Internal plate fixation (n = 31) or simple sling (n = 29) | Constant and DASH score<br>Union and complication rates |
| Kulshrestha et al, 2011 | pCS | 73 (67/6) | 5 | 32 | Completely displaced[b] | Internal plate fixation (n = 45) or simple sling (n = 28) | Constant score<br>Union and complication rates |

LTF = patients lost to follow-up; pCS = prospective cohort study; RCT = randomized clinical trial.
a) Only endpoints relevant to this article are mentioned. b) Fractures further subclassified.

4. Intervention: all conservative and surgical treatments
5. Primary outcome: the Constant score and reports on heeling and non-union
6. Secondary outcome: reports on complications.

The choice to use the Constant score in the selection criteria rests on the fact that despite the lack of proper validation [8], the score is recommended by the The European Society for Surgery of the Shoulder and Elbow (ESSSE) for the evaluation of injuries of the shoulder before and after treatment [13]. Further, the Constant score is widely accepted and recognized as being superior to alternative scores [13].

### Data collection

The included articles were evaluated independently by two of the authors (IB and UB). Plain data on patient demographics, type of intervention and endpoints were registered. In case of discrepancies, a third reviewer was consulted.

## RESULTS

### Literature search

The MEDLINE search was performed in August 2011. A total of 1,369 references were initially identified. After selection according to methodology and language, 30 references were extracted. Of these, 17 were excluded by revision of their titles and abstracts due to design or irrelevant topic. The remaining 13 potentially relevant publications were fully evaluated according to our selection criteria, and of these four were included. Four of the nine excluded publications were excluded because the Constant score had not been used for assessment of the functional outcome (purpose-made, unvalidated functional outcome evaluations were used). See **Figure 2**.

During the writing process, a recent publication was identified via related articles in PubMed and subsequently included.

### Study characteristics

**Table 1** describes the included studies and their outcomes. All studies were available in full text.

### Population

The total number of included patients in all five studies was 365 with a total of 44 patients lost to follow-up. One of the included studies described inclusion of a single adolescent (age: 13 years) [14]. The remaining included patients were described as adults (Table 1) with an acute, midshaft clavicle fracture. The percentage of male participants varied from 66% to 92%. The length of follow-up ranged from 12 to 24 months (**Table 2**).

### Fracture type

Midshaft fractures with complete displacement of the bony parts were used as inclusion criterion in all studies. A specific fracture classification was used in two studies [15, 16]. The fractures in the study by Ferran et al [14] had to be shortened as well as displaced, and in the study by Mirzatolooei et al [17], only comminuted fractures were included. None of the two last mentioned studies used a specific fracture classification. The study by the Canadian Orthopaedic Trauma Association [18] did not mention fracture classification or degree of comminution.

Because of the different methods used for describing the fractures in the five studies, it is not possible to compare the severity of the fractures treated except that they were all displaced.

### Interventions

Four studies [15-18] compared conservative treatment

TABLE 2

Results of functional outcome.

| Study | Constant score | Difference in score[a] | Follow-up time (months) | Other functional assessments |
|---|---|---|---|---|
| COT society, 2007 | Significantly higher Constant score in plate group than in simple sling group | 6 | 12 | Results of DASH score correlates with results of Constant score |
| Ferran et al, 2010 | Higher Constant score in intramedullar nail group than in plate group Not significant | 3,4 | 12 | Results of Oxford shoulder score correlates with results of Constant score |
| Smekal et al, 2008 | Significantly higher Constant score in intramedullar nail group than in simple sling group | 4,2 | 24 | DASH score higher in intramedullar nail group than in sling group at all times during first 24 weeks. Significant difference during first 18 weeks |
| Mirzatolooei, 2011 | Significantly higher Constant score in plate group than in simple sling group | 11 | 12 | Results of DASH score correlates with results of Constant score |
| Kulshrestha et al, 2011 | Significantly higher Constant score in plate group than in simple sling group | 5 | 18 | |

a) Difference in Constant score at the end of follow-up.

to operative intervention, and one study [14] compared two different operative interventions. Four of the studies [14-15,17-18] were randomized controlled trials and one study [16] a prospective cohort study. See **Table 3**.

Pooling of the data showed that a total of 156 patients had been treated with plate fixation, 159 patients had been treated conservatively and 50 patients had been treated with intramedullary nail fixation. Four different plate implants [14, 16-18] and two different nail implants [14, 15] had been used. A simple sling had been used in all four studies [15-18] reporting on result of conservative treatment.

**Functional outcome**

All five studies had used functional outcome to evaluate the results of their interventions (Table 1). Three different outcome scores had been used. All five studies had used the Constant score [19] for primary assessment of functional outcome. Supplemental to the Constant score, the patient-reported DASH score [20] had been used in three studies and the patient-reported Oxford Shoulder Score [21] in one study.

The results of functional assessment are outlined in Table 2.

The Constant scores were significantly higher at measure points in the surgical group in all of the four studies that compared surgical treatment to conservative treatment [15-18]. A difference in the Constant score of ten points or more has been considered clinically relevant [22]. The study performed by the Canadian Orthopaedic Trauma Association [18] reported a difference at the one-year follow-up of approximately ten points in favour of plate fixation; however, a graphic presentation in the same manuscript demonstrates a difference in mean Constant score of only six points. The only study that reported a difference in mean Constant score of more than ten points in favour of plate fixation was Mirzatolooei et al [17], who reported a difference of 11 points at the one-year follow-up.

Ferran et al [14] compared intramedullary nailing to plate fixation. They found higher Constant scores in the nailing group at all measure points during follow-up than in the plate fixation group; however, the scores were only 3.4 points higher at the one-year follow-up (not statistically significant).

**Fracture union**

All five studies reported union rates. The definition of union was similar in all studies: radiographic evidence of bony bridging. Nonunion was reported in four of the five studies and, likewise, the definition of nonunion was similar: lack of radiographic consolidation with clinical symptoms (pain and fracture motion). The time of assessment of nonunion differed from study to study. One study defined nonunion at 12 months [18], whereas the other three studies defined nonunion at six months [16-18]. Delayed union was only defined in one study and described as union after six months [15].

The reports of nonunion and delayed union are outlined in Table 3.

Three studies reported 100% union in all those of their patients who underwent surgical intervention [14-16]. The Canadian Orthopaedic Trauma Association [18] reported a slightly lower union rate of 97% in their plate-fixation group (one non-union was actually not operated, but kept in the surgical group according to the "intention-to-treat" principle). Mirzatolooei et al [17] reported one nonunion in the plate fixation group due to infection, leaving an overall union rate at 96%.

Union in the conservatively treated groups was overall lower than in the surgery treated groups. The Canadian Orthopaedic Trauma Association [18] and Smekal et al [15] reported similar union rates in their

sling group with union rates of 86% and 90%, respectively. The lowest union rate in the sling group was 68%, which was reported by Kulshrestha et al [16], whereas with 96%, Mirzatolooei et al [17] reported the highest union rate in any sling group.

### Complications

Nonunion is not accounted for as a complication in this section because it is discussed above.

Table 3 outlines the number of complications related to the included studies.

Pooling data from all studies, we found an overall complication rate for plate fixation of 29% (43/146), but the rate ranged from 14% [16] to 47% [14]. The majority of complications were related to prominent hardware causing soft tissue irritation (approximately 26% of all plate-related complications). Wound infection (16%) and hardware failure (16%) were other frequent complications.

In the group of intramedullary nailing, the complication rate ranged from 24% [14] to 30% [15] with an overall complication rate of 28% (13/47). As in the plate group, the majority of complications were soft tissue irritation caused by hardware protrusion (62%, eight of 13), which in all cases required minor surgical intervention. Hardware failure accounted for 23% (3/13) of all nail-related complications. No infections occurred.

The overall complication rate in the conservative group was 47% (60/128). Symptomatic malunion was the predominant complication seen in the conservatively treated group where it accounted for 67% (40/60) of the complications. Eleven of the 40 symptomatic malunions were reported to have undergone further treatment. The second most common complication related to the conservative group was transient neurological deficits (17%, 10 of 60) – with persistent neurological deficit reported in three cases (5%).

The overall rate of hardware removal was 14% in the plate group. All plates removed seemed to be related to some sort of complication, mostly hardware prominence, hardware failure and infection. The overall rate of hardware removal was 82% in the intramedullary nailing group. In one study, all nails were removed [14].

## DISCUSSION

Though the statistically significantly higher Constant scores favoured surgical intervention over conservative treatment, only one study found a difference of more than ten points [17]. Based on measurements obtained from subjects with healthy shoulders, the literature acknowledges that a difference of more than ten points on the Constant score is clinically relevant [22]. Some methodological problems prevail in these studies, and, in particular, a skewed (almost statistically significant) gender distribution and patients lost to follow-up add controversy to the interpretation of differences in func-

TABLE 3

Plate fixation.

| Study | Intervention | No. of patients[a] | Constant score, mean (SD) | No. of nonunion (delayed union) | No. of complications | | |
|---|---|---|---|---|---|---|---|
| | | | | | overall[b] | symp. malunion | hardware removal |
| COT society, 2007 | LCDCP | 44 | | | | | |
| | Reconstruction plate | 15 | | | | | |
| | Precontoured plate | 4 | 96 ± 1 | 2 | 21 | 0 | 8 |
| | Other plate | 4 (5) | | | | | |
| Ferran et al, 2010 | LCDCP | 15 | 88.7 ± 9.1 | 0 | 7 | 0 | 8 |
| Mirzatolooei, 2011 | Reconstruction plate | 29 (3) | 89.8 | 1 | 9 | 4 | 2 |
| Kulshrestha et al, 2011 | Reconstruction plate | 45 (2) | 95 (93 – 97)[c] | 0 | 6 | 2 | 4 |
| Total | | 156 (10) | | 3 | 43 | 6 | 22 |
| *Conservative treatment* | | | | | | | |
| COT society, 2007 | Simple sling | 65 (16) | 90 ± 2 | 7 | 24 | 9 | – |
| Smekal et al, 2008 | Simple sling | 35 (5) | 93.7 ± 6.0 | 3 (6) | 5 | 2 | – |
| Mirzatolooei, 2011 | Simple sling | 31 (7) | 78.8 | 1 | 21 | 19 | – |
| Kulshrestha et al, 2011 | Simple sling | 28 (3) | 90 (85 – 92)[c] | 8 | 10 | 10 | – |
| Total | | 159 (31) | | 19 (6) | 60 | 40 | |
| *Intramedullay nail* | | | | | | | |
| Ferran et al, 2010 | Intramedullary nail | 17 | 92.1 ± 6.0 | 0 | 4 | 0 | 17 |
| Smekal et al, 2008 | Intramedullary nail | 33 (3) | 97.9 ± 1.7 | 0 (1) | 9 | 0 | 25 |
| Total | | 50 (3) | | 0 (1) | 13 | 0 | 42 |

LCDDP = limited contact dynamic compression plate; SD = standard deviation.

a) In parentheses, the number of patients lost to follow-up. b) Nonunion not included. c) Given as median (interquartile range).

**KEY-POINTS ON CLAVICLE FRACTURES**

Clavicle fractures are a frequent injury.

The functional outcome (Constant score) is better after surgical treatment of displaced midshaft fractures than after conservative treatment.

Union rates are higher and complication rates lower after surgical treatment than after conservative treatment.

The difference in functional outcome may not be clinically relevant.

tional outcome scores in the largest randomized trial to date [3]. It remains questionable whether the reported differences in Constant score or the other validated functional outcome scores used in the included studies reflects the true level of disability of patients with clavicle fractures. There is therefore a need for validation of the conventional shoulder scores in patients with clavicle fractures.

The reported results of functional benefit in favour of surgical intervention compared with conservative treatment at early stages (< 12 months) of follow-up may have a significant impact on the patients' work and social lives. This issue has not yet been clarified, and a cost-benefit analysis would have to be included to establish such impact.

Nonunion and malunion have been the two topics most discussed when it comes to clavicle fractures. Reported rates of nonunion in conservatively treated clavicle fractures have ranged from close to negligible (< 1%) [1, 2] too as high as 15% [23]. A meta-analysis based on 22 studies reported a nonunion rate for displaced midshaft fractures of 15.1% [24]. Our findings seem to support that nonunion is not an insignificant complication as we found an overall nonunion rate of 15% in the conservatively treated group. An overall 2% nonunion rate was found in the plating group, and this number seems to be in agreement with the 2% reported on displaced clavicle fractures in the meta-analysis mentioned above [24].

Previously considered of only radiographic interest [1], malunion has attracted much interest in recent literature. Reports on displaced, conservatively treated fractures have showed that approximately 30% of patients with malunion are dissatisfied with their overall result [23]. Our results suggest that 31% of all conservatively treated patients developed symptomatic malunion, but the finding did not correlate with a worse functional outcome in any of the studies. However, two of the included studies [15, 18] found an association between fracture displacement/shortening and DASH scores at the end of follow-up, but whether these patients had symptomatic malunion or not is not mentioned.

Khan et al [7] quote an analysis suggesting that 3.3 patients with a displaced, midshaft clavicle fracture have to undergo surgical intervention with plating to avoid one nonunion or symptomatic malunion, whereas nine fractures have to be fixed to prevent one nonunion. It has not yet been clarified what potential effect malunion has on functional outcome scores following midshaft clavicle fractures. Given this uncertainty, a number needed to treat (NNT) analysis has been used to advocate that overtreatment is taking place when plate fixation is preferred.

Increasing age, female gender, smoking and comorbidities have been identified as risk factors of nonunion in displaced midshaft clavicle fractures [25]. Furthermore, focus on high-risk patients could yield a lower NNT when plate fixation is preferred.

Risk of hardware removal seems to be largely neglected in the overall discussions that compare surgical intervention to conservative treatment. High removal rates were found, especially in the nailing group in our study. None of the studies reported whether hardware removal was accompanied by complications or not, but patients with clavicle fractures have to be informed of the relatively high risk of undergoing a second operation.

The simple sling has been preferred over the figure-of-eight bandage since the study by Andersen et al in 1987 [10]. However, that study was based on relative few patients in a heterogenic population of both adolescents and adults. The superior role of the simple sling is therefore controversial.

## CONCLUSION

Drawing on the highest level of evidence in the current literature, it can be concluded that surgical treatment of acute, displaced midshaft clavicle fractures with a plate yields better functional outcome and lower mal- and nonunion rates than conservative treatment. However, the clinical relevance of the observed functional benefits are questionable as is the use of shoulder outcome scores frequently employed to assess the functional outcome of clavicle fracture treatment. Development of a functional outcome score validated for assessment of clavicle fracture treatment is warranted. When operative treatment is preferred, the NNT to avoid a nonunion is high. Future treatment algorithms should pay specific attention to patients at high risk of non-union as these patients may benefit the more from operative treatment. More information on the potentially negative influence of malunion on the functional outcome is needed to refine treatment strategies. The current literature does not make definite recommendations regarding what treatment strategy should be preferred. However, given the lack of evidence that primary surgical treatment yields superior results, and

since over treatment may occur, clavicle fractures may best be treated conservatively.

**CORRESPONDENCE:** *Ilija Ban,* Klinisk Ortopædkirurgisk Forskning, Ortopædkirurgisk Afdeling, Hvidovre Hospital, 2650 Hvidovre, Denmark.
E-mail: ilija.ban@gmail.com

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