Surgical Versus Conservative Treatments for Displaced Midshaft Clavicular Fractures

A Systematic Review of Overlapping Meta-Analyses

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Abstract: Multiple meta-analyses have been performed to compare surgical and conservative interventions for treating displaced midshaft clavicular fractures. But conclusions are discordant.

The purposes of current study were (1) to conduct a systematic review of meta-analyses comparing surgical and conservative interventions for the treatment of displaced midshaft clavicular fractures, (2) to help decision makers interpret and choose among discordant meta-analyses, and (3) to provide treatment recommendations through the best available evidence.

We searched the Cochrane library, PubMed, and EMBASE databases to identify meta-analyses comparing surgical and conservative treatments for the displaced midshaft clavicular fractures. Two investigators independently scanned titles and abstracts to exclude irrelevant articles and identify meta-analyses that met the eligibility criteria. The methodological quality of the meta-analysis was independently assessed by the two investigators using the Oxford Centre for Evidence-based Medicine Levels of Evidence and the Assessment of Multiple Systematic Reviews (AMSTAR) tool. The Jadad decision algorithm was applied to determine which of the included studies provided the best available evidence.

Six meta-analyses met the eligibility criteria in this systematic review. AMSTAR scores ranged from 5 to 10. The Jadad decision-making tool suggests that the highest quality review should be selected based on the publication characteristics of the primary trials, the methodology of the primary trials, the language restrictions, and whether analysis of data on individual patients was included in the study. As a result, we selected a high-quality Cochrane review.

This systematic review of overlapping meta-analyses comparing surgical and conservative treatments suggests that surgical treatment provides a lower rate of overall treatment failure and a better functional outcome, but is associated with more implant-related complications. Hence, treatment should be individualized, with careful consideration of the advantages and disadvantages of each treatment method and of patient preferences.

Abbreviations: AMSTAR = Assessment of Multiple Systematic Reviews, RCT = Randomized clinical trial.

INTRODUCTION

Clavicle fractures are common, with an overall incidence of 36.5 – 64 per 100,000 people every year.1,2 The most common site of fracture is the midshaft of the clavicle, which accounts for 80% of all clavicle fractures. Conservative treatments are widely used and are recommended for midshaft clavicular fractures, with rates ranging from 0.03% to 5.9%.1,3 However, the outcome of conservative treatment is not as favorable as once thought and there has been a growing trend to treat these fractures surgically.4 The best treatment for displaced midshaft clavicle fractures remains a topic of debate.

Numerous clinical studies, including many prospective, randomized controlled trials (RCTs), have been published to compare surgical and conservative treatments.5–9 On the basis of the proliferation of clinical studies, multiple authors have conducted systematic reviews and meta-analyses comparing surgical and conservative treatments.10–16 However, the results of the overlapping meta-analyses have been discordant in their findings regarding the postoperative outcomes. For example, a meta-analysis by Kong et al17 showed surgical treatment leads to a higher risk of postoperative complications. However, McKee et al11 and Xu et al16 concluded that both operative and conservative treatments can achieve a similar incidence of complications.

The purposes of this systematic review were: (1) to conduct a systematic review of meta-analyses comparing surgical and conservative interventions for the treatment of displaced midshaft clavicular fractures, (2) to help decision-makers interpret and choose among discordant systematic reviews, and (3) to provide treatment recommendations through the best available evidence.

MATERIALS AND METHODS

Literature Search

We searched the PubMed, Cochrane library, and EMBASE databases up to February 2015. The following key words were used for the searches: meta-analysis or systematic review; clavicle or clavicular; fracture. The references for each of these citations were also manually screened to ensure that no studies were missed.

Eligibility Criteria

We aimed to identify all meta-analyses or systematic review comparing surgical and conservative treatments for
displaced midshaft clavicular fractures. The exclusion criteria were: (1) non-English language articles; (2) meta-analysis was not performed; and (3) meetings abstract.

Selection of Studies
Two investigators independently scanned titles and abstracts to exclude irrelevant articles and identify meta-analyses that met the eligibility criteria. We resolved discrepancies between investigators by consulting a third review investigators. Then two authors independently extracted data for the included meta-analyses. The following information relating to key characteristics of the meta-analyses were extracted: date of literature search, search database, date of publication, number of included trials, design of included studies, software use, and I² statistic value.

Assessment of Methodological Quality
Two investigators independently assessed the methodological quality of the included meta-analyses using the Oxford Centre for Evidence-based Medicine Levels of Evidence18 and the Assessment of Multiple Systematic Reviews (AMSTAR) tool.19 AMSTAR was chosen because of its reported inter-rater reliability, construct validity and feasibility. AMSTAR uses 11 items to assess which review methods are unbiased19,20 and are extensively applied.21,22 Then the total scores for every article were calculated.

Application of Jadad Decision Algorithm
The Jadad decision algorithm was used to guide interpretation of discordant meta-analyses.21 Discordance among meta-analyses as described by Jadad et al21 derive from the following six reasons: clinical question, study selection and inclusion, data extraction, assessment of study quality, assessment of the ability to combine studies, and statistical methods for data synthesis.23 It was independently applied by two authors, whose results were compared to most robustly determine which of the included meta-analyses proposed a guide through the currently best available evidence.

RESULTS
Search Results
The initial search found 316 abstracts. Six meta-analyses met the eligibility criteria in this systematic review (Figure 1).

Search Methodology
Only one study17 reported the publication language was restricted as English, and no language restriction were applied.
Most studies comprehensively searched databases. All of the included studies searched Medline or PubMed. There was heterogeneity as to whether meta-analyses also included searches of Embase, Cochrane library, OVID, and Google scholar (Table 3).

**Study Quality and Validity**

Only one meta-analysis specially included Level I evidence; four studies included evidence of Levels I to II; and one study included evidence of Levels I and III (Table 4). One Cochrane review reported the GRADE was used in their article. AMSTAR scores were assessed for each study and ranged from 5 to 10, with a median of 7.2 (Table 5). The Cochrane review by Lenza et al was assessed as the most highest quality study.

**Heterogeneity Assessment**

All meta-analyses performed statistical heterogeneity analysis and reported $I^2$ statistic value. Of the six meta-analyses, three meta-analyses performed subgroup analyses based on the surgical method (Table 4). Table 6 summarized the $I^2$.

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**TABLE 1. General Description of the Characteristics of Each Meta-Analysis**

| Authors          | Journal                                   | Date of Last Literature Search | Date of Publication | No. of Included Studies | No. of Included RCTs |
|------------------|-------------------------------------------|--------------------------------|----------------------|-------------------------|----------------------|
| McKee et al 2012 | Journal of Bone and Joint Surgery Am      | 2010                           | April, 2012          | 6                       | 6                    |
| Lenza et al 2013 | Cochrane Database of Systematic Reviews   | December, 2012                 | June, 2013           | 8                       | 8                    |
| Liu et al 2013   | International Orthopaedics               | December, 2011                 | August, 2013         | 8                       | 5                    |
| Xu et al 2013    | European Journal of Orthopaedic Surgery and Traumatology | June, 2012 | August, 2013 | 4                       | 4                    |
| Kong et al 2014  | Archives of orthopaedic and trauma surgery | January, 2014                  | November, 2014       | 6                       | 6                    |
| Xu et al 2014    | Journal of Shoulder and Elbow Surgery     | February, 2013                 | February, 2014       | 7                       | 7                    |

**TABLE 2. Primary Studies Included in Meta-Analyses**

| Authors          | Smith 2000 | COTS 2007 | Witzel 2007 | Figueiredo 2008 | Koch 2008 | Judd 2009 | Smekal 2009 | Chen 2011 | Mirzatolouei 2011 | Virtanen 2012 | Robinson 2013 |
|------------------|------------|-----------|-------------|----------------|-----------|-----------|-------------|-----------|------------------|--------------|--------------|
| McKee et al 2012 | +          | +         | +           | +               | +         | +         | +           | +         | +                | +            | +            |
| Lenza et al 2013 | +          | +         | +           | +               | +         | +         | +           | +         | +                | +            | +            |
| Liu et al 2013   | +          | +         | +           | +               | +         | +         | +           | +         | +                | +            | +            |
| Xu et al 2013    | +          | +         | +           | +               | +         | +         | +           | +         | +                | +            | +            |
| Kong et al 2014  | +          | +         | +           | +               | +         | +         | +           | +         | +                | +            | +            |
| Xu et al 2014    | +          | +         | +           | +               | +         | +         | +           | +         | +                | +            | +            |

**TABLE 3. Search Methodology Used by Each Study**

| Authors          | Restriction of Publication Language | Restriction of Publication Status | PubMed | Medline | Embase | Cochrane Library | OVID | Google scholar | Others |
|------------------|-------------------------------------|----------------------------------|--------|---------|--------|------------------|------|---------------|--------|
| McKee et al 2012 | No                                  | NA                               | +      | +       | +      | +                |      | +             | +      |
| Lenza et al 2013 | No                                  | No                               | +      | +       | +      | +                |      | +             | +      |
| Liu et al 2013   | No                                  | NA                               | +      | +       | +      | +                |      | +             | +      |
| Xu et al 2013    | No                                  | NA                               | +      | +       | +      | +                |      | +             | +      |
| Kong et al 2014  | Yes                                 | NA                               | +      | +       | +      | +                |      | +             | +      |
| Xu et al 2014    | No                                  | NA                               | +      | +       | +      | +                |      | +             | +      |

NA = Not Available.
statistic value for each outcome of included meta-analyses. Heterogeneities for the majority of outcomes were acceptable.

Results of Jadad Decision Algorithm

The Jadad decision algorithm was applied to determine which of the six included studies provided the best available evidence. Figure 2 showed the all outcomes of included meta-analyses. Given that the selection criteria were not accordant among included meta-analyses, the Jadad algorithm suggests that the highest-quality review should be selected based on the publication characteristics of the primary trials, the methodology of the primary trials, the language restrictions, and whether analysis of data on individual patients was included in the study. As a result, we selected a high-quality Cochrane review (Figure 3). This Cochrane review concluded that 'Limited evidence is available from randomised controlled trials on the relative effectiveness of surgical versus conservative treatment for acute middle third clavicle fractures. Treatment options must be chosen on an individual patient basis, after careful consideration of the relative benefits and harms of each intervention and of patient preferences.'

### DISCUSSION

Although several meta-analyses have been published for the treatment of displaced midshaft clavicular fractures, they still reached different conclusions. Such discordance causes difficulties for decision makers (including clinicians, policymakers, researchers and patients, depending on the context) who rely on these meta-analyses to help them make choices among alternative interventions when experts and the results of trials disagree. Jadad et al summarized the potential sources of discordance among meta-analyses and provided a decision tool which summarizes the process for identifying and resolving causes of discordance.

According to the Jadad model, the Cochrane review by Lenza et al was selected in this systematic review. Lenza et al found that surgical intervention was superior to conservative treatment in DASH questionnaire, constant score, symptomatic malunion, overall treatment failure, deformity and/or asymmetry, asymptomatic malunion, stiffness/restricted of range of shoulder movement, number of patients return to sport activities, and time to return to previous activities. There were no differences between surgical and conservative

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**TABLE 4. Methodological Information for Each Included Study**

| Authors       | Design of Included Studies | Level of Evidence | Software | GRADE | Subgroup Analysis |
|---------------|---------------------------|-------------------|----------|-------|-------------------|
| McKee et al 2012 | RCT                       | Level I           | Revman   | No    | No                |
| Lenza et al 2013 | RCT                       | Level II          | Revman   | Yes   | Yes               |
| Liu et al 2013 | RCT or CCT                | Level III         | Revman   | No    | No                |
| Xu et al 2013  | RCT                       | Level II          | Revman   | No    | Yes               |
| Kong et al 2014| RCT                       | Level II          | Stata    | No    | Yes               |
| Xu et al 2014  | RCT                       | Level II          | Stata    | No    | Yes               |

CCT = controlled clinical trial, RCT = Randomized clinical trial.

**TABLE 5. AMSTAR Criteria for Each Included Study**

| Items                                                                 | McKee et al 2012 | Lenza et al 2013 | Liu et al 2013 | Xu et al 2013 | Kong et al 2014 | Xu et al 2014 |
|-----------------------------------------------------------------------|-------------------|-------------------|----------------|--------------|----------------|--------------|
| 1. Was an a priori design provided?                                    | 0                 | 1                 | 0              | 0            | 0              | 0            |
| 2. Was there duplicate study selection and data extraction?           | 1                 | 1                 | 1              | 1            | 1              | 1            |
| 3. Was a comprehensive literature search performed?                   | 0                 | 1                 | 1              | 1            | 1              | 1            |
| 4. Was the status of publication (ie grey literature) used as an inclusion criterion? | 1                 | 1                 | 1              | 1            | 1              | 1            |
| 5. Was a list of studies (included and excluded) provided?            | 0                 | 1                 | 0              | 0            | 0              | 0            |
| 6. Were the characteristics of the included studies provided?         | 1                 | 1                 | 1              | 1            | 1              | 1            |
| 7. Was the scientific quality of the included studies assessed and documented? | 1                 | 1                 | 0              | 1            | 1              | 1            |
| 8. Was the scientific quality of the included studies used appropriately in formulating conclusions? | 1                 | 1                 | 0              | 1            | 1              | 1            |
| 9. Were the methods used to combine the findings of studies appropriate? | 1                 | 1                 | 0              | 1            | 1              | 1            |
| 10. Was the likelihood of publication bias assessed?                   | 0                 | 0                 | 0              | 0            | 0              | 1            |
| 11. Was the conflict of interest stated?                               | 1                 | 1                 | 1              | 1            | 1              | 1            |
| Total scores                                                          | 7                 | 10                | 5              | 6            | 7              | 8            |
treatments in function, UCLA score, pain, symptomatic non-union, early mechanical failure, unsightly scar, total of cosmetic problems, asymptomatic nonunion, skin and nerve problems (incisional numbness), refracture, and total of adverse events. Conservative treatment was superior to surgical intervention in hardware irritation and/or prominence, infection and/or dehiscence, and hardware irritation requiring removal. However, because these results were based on evidence from the RCTs with high risk of bias, Lenza et al. concluded that the evidence is insufficient to indicate whether surgical or conservative treatment is best for treating displaced midshaft clavicular fractures. Treatment should be individualized, with careful consideration of the relative advantages and disadvantages of each intervention and of patient preferences.

This conclusion is consistent with the finding by Robinson et al. They performed a multicenter RCT involving 200 patients and do not support the routine use of primary surgical fixation for displaced midshaft clavicular fractures in adults.

Robinson et al. found that open reduction and plate fixation provides a lower rate of nonunion and a better functional outcome, but increased implant-related complications. When comparing with nonoperative treatment, routine primary surgical treatment not only exposed an unacceptably high number of patients to the risks of surgery, but also increased economic burden of hospital costs. They think treatment should be chosen based on an individual patient, after consideration of expectations of treatment, each patient’s age, and activity level.

There are limitations to our study. First, we only included English language studies. Although we searched for as many meta-analyses as possible, it is possible that we have omitted non-English language trials. Second, meta-analyses included and analyzed lower quality RCTs. The evidence was of low quality overall as the result of methodological flaws including lack of adequate allocation concealment and failure to blind the outcome assessor in the majority of trials.

### TABLE 6. $I^2$ Statistic Value of Each Variable in Each Meta-Analysis

| Items                                                   | McKee 2012 | Lenza 2013 | Liu 2013 | Xu 2013 | Kong 2014 | Xu 2014 |
|---------------------------------------------------------|------------|------------|----------|----------|-----------|---------|
| Function                                                |            | 85%        |          |          |           | –       |
| DASH questionnaire                                      | 80%        |            | 91%      |          |           | –       |
| Constant score                                          | 72%        | –          |          | 67%      | –         | –       |
| UCLA score                                              | –          |            |          |          |           | –       |
| SANE score                                              | –          |            |          |          |           | –       |
| L’Insalata score                                        | –          |            |          |          |           | –       |
| Pain                                                    | –          |            |          |          |           | –       |
| Nonunion                                                | 0%         | 0%         | 0%       | 0%       | 0%        | –       |
| Symptomatic nonunion                                    | 0%         | 0%         | 0%       | 0%       | 0%        | –       |
| Malunion                                                | 0%         | 0%         | 0%       | 0%       | 0%        | –       |
| Symptomatic malunion                                    | 0%         |            |          |          |           | –       |
| Nonunion and symptomatic malunion                       | 0%         |            |          |          |           | –       |
| Delayed union                                           |            | 29%        |          |          |           | –       |
| Early mechanical failure                                |            | 0%         |          |          |           | –       |
| Overall treatment failure                               |            | 0%         |          |          |           | –       |
| Deformity and/or asymmetry                              |            | 0%         |          |          |           | –       |
| Hardware irritation and/or prominence                    |            | 0%         |          |          |           | –       |
| Unsightly scar                                          |            | 0%         |          |          |           | –       |
| Total of cosmetic problems                              |            | 0%         |          |          |           | –       |
| Asymptomatic nonunion                                   |            | 0%         |          |          |           | –       |
| Asymptomatic malunion                                   |            | 0%         |          |          |           | –       |
| Infection and/or dehiscence                             |            | 0%         |          |          |           | –       |
| Hardware irritation requiring removal                    |            | 0%         |          |          |           | –       |
| Skin and nerve problems (incisional numbness)           |            | 0%         |          |          |           | –       |
| Neurological complication                               |            | 0%         |          |          |           | –       |
| Stiffness/restricted of range of shoulder movement       |            | 0%         |          |          |           | –       |
| Refracture                                              |            | 0%         |          |          |           | –       |
| Refractures or implant failure                          |            | 0%         |          |          |           | –       |
| Surgery intervention                                    |            | 0%         |          |          |           | –       |
| Total of adverse events                                 |            | 0%         |          |          |           | –       |
| Dissatisfaction                                         |            | 0%         |          |          |           | –       |
| Outcomes dissatisfaction                                 |            | 0%         |          |          |           | –       |
| Appearance dissatisfaction                               |            | 0%         |          |          |           | –       |
| Number of patients return to sport activities           |            | 0%         |          |          |           | –       |
| Time to return to previous activities                   |            | 0%         |          |          |           | –       |
| Item                          | McKee 2012 | Lenza 2013 | Liu 2013 | Xu 2013 | Kong 2014 | Xu 2014 |
|------------------------------|------------|------------|----------|---------|-----------|---------|
| Function                     |            |            |          |         |           |         |
| DASH questionnaire           |            |            |          |         |           |         |
| Constant score               |            |            |          |         |           |         |
| UCLA score                   |            |            |          |         |           |         |
| Pain                         |            |            |          |         |           |         |
| Nonunion                     |            |            |          |         |           |         |
| Symptomatic nonunion         |            |            |          |         |           |         |
| Malunion                     |            |            |          |         |           |         |
| Symptomatic malunion         |            |            |          |         |           |         |
| Nonunion and symptomatic malunion |      |            |          |         |           |         |
| Delayed union                |            |            |          |         |           |         |
| Early mechanical failure     |            |            |          |         |           |         |
| Overall treatment failure    |            |            |          |         |           |         |
| Deformity and/or asymmetry   |            |            |          |         |           |         |
| Hardware irritation and/or prominence |      |            |          |         |           |         |
| Unsightly scar              |            |            |          |         |           |         |
| Total of cosmetic problems   |            |            |          |         |           |         |
| Asymptomatic nonunion        |            |            |          |         |           |         |
| Asymptomatic malunion        |            |            |          |         |           |         |
| Infection and/or dehiscence  |            |            |          |         |           |         |
| Hardware irritation requiring removal |      |            |          |         |           |         |
| Skin and nerve problems (incisional numbness) |      |            |          |         |           |         |
| Neurological complication    |            |            |          |         |           |         |
| Stiffness/restricted range of shoulder movement |      |            |          |         |           |         |
| Refracture                   |            |            |          |         |           |         |
| Refractures or implant failure |          |            |          |         |           |         |
| Surgery intervention         |            |            |          |         |           |         |
| Total of adverse events      |            |            |          |         |           |         |
| Dissatisfaction              |            |            |          |         |           |         |
| Outcomes dissatisfaction      |            |            |          |         |           |         |
| Appearance dissatisfaction   |            |            |          |         |           |         |
| Number of patients return to sport activities |      |            |          |         |           |         |
| Time to return to previous activities |      |            |          |         |           |         |

FIGURE 2. Results of each included meta-analysis.
CONCLUSIONS

This systematic review of overlapping meta-analyses comparing surgical and conservative treatments suggests that surgical treatment provides a lower rate of overall treatment failure and a better functional outcome, but is associated with more implant-related complications that are not seen in association with conservative treatment. Hence, treatment should be individualized, with careful consideration of the advantages and disadvantages of each treatment method and of patient preferences.

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