

Systematic Review of Randomized Controlled Trials Comparing Efficacy of Crossed Versus Lateral K-wire Fixation in Extension Type Gartland Type III Supracondylar Fractures of the Humerus in Children

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SUMMARY

Supracondylar fractures of the humerus occur frequently in children and account for approximately 70% of all elbow fractures. The aim of this systematic review is to critically appraise randomized controlled trials in the literature comparing the outcome of surgical treatment of extension type Gartland III supracondylar fractures using either a cross pin configuration or lateral pins only for fixation in terms of the stability of fixation and the incidence of encountered complications. Only 4 randomized trials were found over the past 10 years. These were reviewed according to the CONSORT 2010 check list. No study found any significant statistical difference in terms of loss of reduction between the two groups, suggesting similar stability of both constructs. There is currently, however, no Level 1 evidence comparing the outcome of crossed pinning versus lateral entry pinning in extension type Gartland III supracondylar fracture. Additionally, the current highest level evidence discussed above has limitations ranging from small sample size to insufficient data on clinical outcome. Therefore we cannot draw any firm conclusions on the above evidence. We suggest that future RCTs take into account the recent evidence on fixation by including three lateral pins and larger diameter pins in their cohorts.

Key words: systematic review, randomized controlled trial, K-wire fixation, supracondylar fractures, humerus, children

BACKGROUND

Supracondylar fractures of the humerus occur frequently in children, making up approximately 70% of all elbow fractures [1-3] with a peak incidence in the age range of 5-8 years [4,5].

These fractures are classified as extension or flexion patterns according to the presumed mechanism of injury and resulting pattern of fracture, with extension type fractures by far the most common accounting for 97-99% of all supracondylar fractures [6,7]. Extension type fractures are subclassified according to the Gartland classification [4], which has in recent times been modified to account for a larger spectrum of radiographic appearance [8,9].

Within this classification, a type III fracture is defined as one in which there is complete displacement of the distal fragment with no apparent cortical continuity. As a result of displacement at the time of injury and/or subsequent swelling, these fractures are at high risk of associated neurovascular compromise [5,10].

The prevalence of displaced supracondylar humeral fractures presenting with vascular compromise has been reported to be as high as 12- 20% [11-14]. Neurological deficit present shortly after the injury presents at a similar frequency of 10-20% [3,14-16]. However, the majority of nerve injuries are neurapraxias, which usually resolve spontaneously at an average of 3 months [17-19].

Treatment of uncomplicated and undisplaced type I and II fractures is mostly non-operative [20]. Although there are occasional reports in the literature of successful treatment of Gartland III fractures using closed reduction and Plaster of Paris application or traction, the mainstay of treatment for type III fractures is percutaneous pinning after open or closed reduction of the fracture [20-26].

There exists some controversy, however, on the pattern of percutaneous pinning of type III fractures. Medial and lateral entry pins in a crossed configuration and lateral entry only pins are the two most commonly employed techniques [26]. While other techniques, such as the posterior intrafocal wire, have been described [27], their use is not widely practiced.

The ulnar nerve at the cubital tunnel is at risk from medial pin placement and iatrogenic injury to the ulnar nerve is frequently reported in the literature [28], with some authors reporting rates as high as 15% with crossed pin configuration [29]. A recent systemic review by Brauer also reported a five times higher rate of iatrogenic ulnar nerve injury in studies with crossed pin configuration as opposed to lateral pins alone [26].

Crossed pin fixation, however, has been shown to be a more stable construct in biomechanical studies,

especially when tested in axial rotation [28,30,31], and data presented from the above systematic review is that the probability of residual deformity or loss of reduction is 58% lower than with lateral pin entry alone [26]. The strength of this evidence is questionable, and the author makes note of the potential for significant confounding bias with the retrospective nature of the studies reviewed, most of which had collected their data over long time periods.

The debate, nevertheless, continues and proponents of lateral entry pins point to a recent body of evidence which states that the use of 3 lateral entry pins confers stability almost equal to that of crossed pins [32-34].

Brauer's review is the only one presented in the literature in the last 10 years, and as pointed out by the author, the results have to be interpreted with caution because of the limited number of prospective, case-controlled studies with appropriate randomization reviewed in the study.

The aim of this review is to critically appraise randomized controlled trials in the literature comparing the outcome of surgical treatment of extension type Gartland III supracondylar fractures, using either a cross pin configuration or lateral pins only for fixation in terms of the stability of fixation and the incidence of encountered complications.

MATERIAL AND METHODS

The search was conducted using Ovid SP (vide infra: Search Strategy) in July 2011. The population in question was children, who are defined according to the OVID SP search engine as those aged 0-18 years. Regarding the planned Inclusion criteria, all articles comparing crossed and lateral pins as the two modalities of fixation for extension type Gartland type III supracondylar fractures were included in the study irrespective of the surgical approach used.

The planned primary outcome measure was loss of fixation or reduction as dictated by the mean change in the Baumann's angle and humerocapitellar angle (radiological evaluation). Secondary outcome measures included iatrogenic ulnar nerve injury, loss of carrying angle and the range of movement in the elbow. These outcome measures were chosen as they were the most commonly utilised in the body of literature to date [26].

A minimum 6 weeks of follow-up was required to include the studies as union is rapid in this well-vascularised area and hence loss of reduction (rather than subsequent deformity due to altered growth associated with physeal injury), if it is to occur, will happen within this time frame.

Search Strategy

Ovid MEDLINE(R) (1948 – July 2011) was the chosen search engine.

The search was carried out using the Key words shown in Table 1. These were selected as the most relevant terms with respect to the research question. The option 'Map Term to Subject Heading' was chosen.

The keyword 'distal humerus' was chosen over the term 'supracondylar' to conduct the search as it yielded more specific subject headings. Selected and exploded subject headings included; 'Humeral Fracture', 'Elbow Joint', 'Fracture Fixation, Internal'. The subject heading 'distal humerus' was selected as a key word (search 1).

The keywords 'k-wire' and 'pins' were used rather than using 'fixation' or 'internal fixation' as they did yield more related subject headings. Selected and exploded subject headings included; 'Bone Wires', 'Fracture Fixation, Internal', 'Orthopaedic Fixation Devices', 'Humeral Fractures', 'Fracture Fixation', 'Fracture Bone and Elbow Joint'. The subject heading 'k-wire' was selected as a key word (search 2).

The subject heading 'supracondylar', the subject heading 'crossed' and the subject heading 'lateral' were selected as key words only and searched for (mp. search as Keyword)

The five conducted searches were finally combined with 'AND' and the search was limited by articles in 'English Language', 'Humans', 'All Child (0-18 years)' and the publication year 2001 – Current.

Twenty-two articles were displayed. Abstracts were reviewed and only studies utilizing and comparing both crossed and lateral k-wire fixation as modalities of treatment of Gartland type III supracondylar fractures, irrespective of the surgical technique, were included.

Eleven studies met the inclusion criteria. Two biomechanical studies conducted on synthetic composite humeri and synthetic bone models respectively were excluded, as they were not conducted on humans, leaving 9 studies to review.

To ensure the adequacy of the search for the relevant articles, further broader searches were conducted using the above search terms proposed in Table 1:

- Search 1 and 2 combined using 'AND' with the subject heading 'Gartland' as a key word. The search was limited using the same criteria as above. This revealed 3 more relevant articles.
- Search 1 and 2 combined using 'AND' with the subject heading 'supracondylar' as a key word and the subject heading 'wires' as a key word. This search did not reveal any more relevant articles than the original search.
- Search 1 and 2 combined using 'AND' with the subject heading 'supracondylar' as a key word and the subject heading 'pinning'. This search revealed 2 more relevant articles

A total of 14 articles were identified related to the topic since 2001. During that period, 3 randomized trials were done [35-37]. Reference review of the relevant articles revealed a further randomized trial [38].

RESULTS

Only 4 randomized trials were found over the past 10 years. These were reviewed according to the CONSORT 2010 check list.

Following our review, the study by Tripuraneni K et al. was found to be a prospective comparative study and the study by Foad et al. is of limited external validity [36,38].

The study by Tripuraneni et al is perceived initially as a randomized trial by virtue of its title. Although the author initially describes block randomization, the equal number of patients recruited to each group raises the possibility of bias. In addition to the fact that there was no allocation concealment or blinding, the author reveals in the methodology that although patients were randomized preoperatively the final decision for the choice of crossed or lateral entry pinning was up to the treating surgeon's intraoperative evaluation. The operating surgeon abandoned crossed pinning if intraoperative ulnar nerve examination demonstrated it subluxed anteriorly. At the same time, patients in the lateral entry pinning group were on occasion treated with an additional medial pin. The rationale behind this approach was neither mentioned by the author nor was it mentioned in the methodology.

Regarding this study as a prospective comparative study, there are further limitations:

Tab. 1. Proposed search terms

Fracture site	Fixation	Age	Classification
Supracondylar	K-wire fixation /wires	Children	Gartland
Supracondylar	Internal fixation	Children	Gartland
Supracondylar	Pinning	Children	Gartland
Distal Humerus	Internal fixation	Children	Gartland
Distal Humerus	K-wire fixation / wires	Children	Gartland
Distal Humerus	Pinning	Children	Gartland

- No clear inclusion or exclusion criteria
- No defined primary and secondary outcome measures
- No sample size calculation
- Small sample size in each group (crossed pinning: 20, lateral entry pinning: 20), and further reduction with 7 patients failing to return for follow-up after pin removal
- Baseline/pre-treatment demographics are not disclosed.

The author concludes there was no statistically significant difference in complication rates, range of motion, and radiographic alignment (mean change in Baumann's angle: 0.3 degrees in each group, mean change in humerocapitellar angle: 0.5 degrees in each group).

As a prospective comparative study, the results of this study have to be interpreted with caution. In addition to the above limitations, each group was a mix of both treatment modalities and the author analysed the results according to 'intention to treat groups' (crossed pinning group: 4 with 2 lateral pins / 1 medial pin and 1 with 3 lateral pins, Lateral entry group: 1 patient had 2 lateral / 1 medial pin). Moreover 5 patients had Gartland type II fractures and the extent of displacement is unknown.

The author, however, presents an interesting technique for the avoidance of ulnar nerve injury, where the ulnar nerve is palpated intraoperatively adjacent to the medial epicondyle and if it was felt that the nerve was easily subluxed anteriorly, medial pin placement was abandoned. In addition to this, any inserted medial pins were checked with a nerve stimulator as described by Wind et al [39].

The authors reported only one case of neurological complications, describing it as an "ulnar neuritis" which resulted in paraesthesia and clawing but resolved after 7 months. They noted that this particular patient did not have intra-operative nerve excitability, but did not mention if any of the other inserted medial pins had and if any pins were removed if this occurred. This information would have been useful to ascertain the rate of ulnar nerve injury as nerve stimulation is not routinely carried out in other centres.

The study by Foead et al. was found to have a significant flaw in its design, which we believe limits the external validity of the proposed results [38]. The authors did not carry out any baseline radiological assessments post-fixation and they presumed that all fractures were fixed with "perfect reduction" based on intra-operative imaging alone, and did not take any measurements to support this. The measured "loss of fixation" could therefore have been due to malreduction rather than reflection of the stability of the fixation achieved.

For determining outcome, the authors used the carrying angle of the uninjured arm as their control. While this may be useful in identifying prognosis and outcome related to a particular patient, it is not suitable for examining two techniques of fixation. A perfect form of fixation would maintain the position of the fracture during healing, regardless of the initial position. Therefore a fracture fixed in a slightly varus position will maintain that position. The authors, however, made the assumption that any change in alignment was due wholly to loss of reduction during the healing process and not in any part due to the initial fixation. Although this may be true, it lacks supporting evidence, and cannot be assumed.

In addition, there are several other limitations of the study:

- No defined primary and secondary outcome measures
- No sample size calculation
- Not known whether there was any statistically significant difference regarding pre-treatment demographics of both groups, including age, sex and fracture pattern.
- Non-computerised sequence generation for randomization, possibility of bias is high considering there was no allocation concealment or blinding
- All patients were operated on by an orthopaedic trainee under the supervision of one of the authors of the paper. There may have been a spectrum of technical skill and this might have been reflected in the high incidence of iatrogenic ulnar nerve injury (12.72%), which occurred in 5 cases of the cross pinning group and 2 cases of the lateral entry pinning group. The occurrence of the latter is much less likely and this relatively high incidence in lateral entry wires has not been commented upon by the author.

The author concludes that according to the clinical and radiological parameters of both groups (loss of carrying angle, loss of Baumann's angle and elbow range of movement), no statistically significant difference was found in the coronal and sagittal plane alignments after treatment with the two methods of pin fixation. However, based on the above limitations the authors' conclusion cannot be considered.

Table 2 below shows comparison between the two remaining randomized control trials by Gaston et al. and Kocher et al. [35,37] according to the CONSORT Check List 2010 (appendix 1).

According to the above assessment against the CONSORT check list 2010, the study by Gaston et al. and Kocher et al. are level 2 evidence studies.

The outcomes were similar in both studies. However, the radiological definition of loss of reduction

Tab. 2. Comparison between the two remaining randomized control trials by Gaston et al [35] and Kocher et al [37] according to the CONSORT Check List 2010 (appendix 1)

Study	Gaston et al.	Kocher et al.
Trial Design	Prospective RCT	Prospective RCT
Participants		
Inclusion criteria	Skeletal immaturity and a closed, Gartland III supracondylar fracture treated within 24 hours of the injury.	3-10 years old, completely displaced Gartland III supracondylar fracture treated within 48 hours of the injury
Exclusion criteria	Skeletal maturity, open fracture, inadequate perioperative radiographs and inadequate follow-up	Age <3y and >10y, open fracture, fracture requiring open reduction, fracture requiring neurovascular exploration, floating elbow injury, bilateral supracondylar fracture, previous ipsilateral elbow fracture
Intervention		
Technique	Crossed Pinning versus Lateral entry Pinning	Crossed Pinning vs. Lateral entry alone pinning
Sufficient details to allow replication of the procedure	No	Yes
Operating surgeon	6 paediatric fellowship-trained orthopaedic surgeons were divided into 2 treatment arms, 3 in each group.	Ten different full-time paediatric orthopaedic surgeons, all of whom had post-residency training in paediatric orthopaedic surgery
Pin size	Not Stated	Children ≤20 kg were treated with 1.6-mm k-wires and children >20 kg were treated with 2 mm pins
Medial incision over the medial Epicondyle	No	Yes
Elbow extended to < 90° at the time of medial pin insertion to avoid injury to an anteriorly subluxating ulnar n	Yes	Yes
Standard postoperative regime	Yes, pin removal at mean 27 days.	Yes, pin removal at 3-4 weeks
Outcome measures		
Defined 1ry and 2ry measures	No	No
Radiological Evaluation of loss of Reduction	Change in Baumann's angle of 6 degrees Change in humerocapitellar angle of 10 degrees. Derived from 2 SDs above the mean difference of intraobserver panel measurements	Baumann's angle (defined according to criteria reported by Skaggs [40]) No displacement: Change in Baumann angle of <6° Mild displacement: change 6-12° Major displacement: change >12°. Change in Humerocapitellar angle not defined
Radiological assessment	A panel of an attending pediatric orthopaedist, chief orthopaedic resident and a junior orthopaedic resident. Intraobserver reliability assessed	Unknown
Clinical Evaluation		
Ulnar nerve injury	Yes	Yes
Loss of carrying angle	No	Yes
Elbow Range of movements	No	Yes
Time of assessment	Unknown	3-4 week and at 3 month
Sample size calculation	Yes, post-hoc	Yes, pre-hoc
Sufficient numbers recruited in each group to detect statistically significant differences between the two techniques?	Yes	Yes
Randomization		
Sequence generation	Based on day of presentation to the emergency room and the on-call physician of the day	random number generator provided values kept in a sealed envelope open following closed red
Allocation concealment	No	Sealed envelope used and opened in theatres after closed reduction
Blinding	No	No
Statistical methods		
Statistical design	Adequate methodology (Wilcoxon Rank-sum test: detects difference between dependent groups and continuous non-parametric data)	Adequate methodology (Student t-test for dependent sample: continuous non-parametric data. Fisher exact test used to
Methods for additional and subgroup Analysis	Yes	No

Tab. 2 (cont). Comparison between the two remaining randomized control trials by Gaston et al [35] and Kocher et al [37] according to the CONSORT Check List 2010 (appendix 1)

Results			
Participants flow including cross overs	Yes	Yes	
	Crossovers not analysed as per initial group (intention-to-treat)	Crossovers excluded	
Flow chart	No	No	
Recruitment			
Dates defining period of Recruitment	Yes (12 months)	Yes (18 months)	
Dates defining period of follow up	Not stated	Yes	
Baseline data			
Pre-treatment demographics	Both groups were similar with respect to age, fracture displacement, timing of surgery, associated fractures and vascular injuries		No statistically significant differences between the two groups with respect to age, sex, fracture displacement, and the NV status
Type of fracture	Gartland III supracondylar fracture		Gartland III supracondylar fractures
Numbers analysed			
Number of patients	121		217
Number of patient eligible	104		153
Agreed to participate	104		66
Crossed Pinning	57		24
Lateral entry Pinning	47		28
Further Exclusion	None		5 underwent open reduction 4 surgeon added pin to configuration 2 fracture deemed Type II on review 2 pin configuration not as protocol 1 inadequate preoperative NV examination
Number of crossovers	4 converted to cross pinning group		None
Mean age			
Crossed Pinning	5.7 y		5.7 y
Lateral entry pinning	6.2 y		6.1 y
Outcomes and Results			
Change in Baumann's angle (deg)			
Crossed Pinning	2.9		5.4
Lateral entry Pinning	3.7		5.8
Results statistically significant	No (p=0.54)		No (p=0.401)
Loss of reduction:	Change in Baumann's of >6 deg	Change in humero-capitellar >10 deg	As per criteria noted above
Crossed Pinning	18%	28%	0 major, 1 mild
Lateral entry Pinning	25%	25%	0 major, 6 mild
Results statistically significant	No (p=0.32)	No (p=0.76)	No (p=0.107)
Change in Humero capitellar angle (deg)			
Crossed Pinning	5.1		6.5
Lateral entry Pinning	4.8		6.2
Results statistically significant	No (p=0.76)		No (p=0.206)
Loss of carrying angle			
Crossed Pinning	Not reported		7.2 degrees
Lateral entry Pinning			7.3 degrees
Results statistically significant			No
Iatrogenic ulnar nerve injury	2 cases with medial pin group		None
	1 tenting of the nerve with incomplete recovery at 3/12 f/u		
	1 pin indenting the nerve at 90 of elbow flexion: complete recovery at 3/12		

was not identical and the study by Kocher does not define loss of reduction as measured by the humero-capitellar angle. Despite this neither study found any significant statistical difference in terms of loss of reduction between the two groups, suggesting similar stability of both constructs.

Although there is a reasonable description of the surgical technique in the paper by Gaston, it is not so

comprehensive as to allow identical replication of the technique, particularly with regard to the configuration of the lateral pins. In Kocher's paper, however, the method of fixation is adequately described.

One factor which we feel reduces the external validity of Gaston's study is that those patients in the lateral only pin group who had a third pin inserted medially for stability were analysed as to their initial

group on an intention-to-treat principle. Although this number was small (5), it may have had an effect on the overall statistical confidence.

Kocher's study had both concealment of allocation and blinding of the operator to the intervention until the closed reduction had been carried out under fluoroscopic guidance. The numbers recruited, however, were small.

Gaston's study however did not have allocation concealment or blinding of the intervention, but randomised the treatment based on the day of presentation of each patient. The operating surgeon on that day was specifically chosen due to their preference and skill for that particular treatment. This meant that fracture randomisation was maintained while at the same time ensuring that the technique employed was the one which the surgeon was most comfortable with.

DISCUSSION

The aim of all of the above studies was to compare stability achieved following crossed pinning versus lateral entry pinning technique for Gartland Type III extension supracondylar humerus fractures.

Previous biomechanical studies have shown the crossed pin fixation pattern to be a more stable construct [28,31,33]. However, neither the study by Gaston or Kocher revealed any statistical significance in radiological outcome. Gaston et al. provide several reasons that the biomechanical models do not simulate the fracture mechanics accurately, and identify that in one biomechanical study the lateral pins were in parallel rather than divergent configuration [31]. Divergence has been shown to be superior in terms of stability by more recent biomechanical studies, which have attributed the strength of divergent pins to the increased purchase in both the medial and lateral columns [30,33,34].

There were no iatrogenic ulnar nerve injuries in Kocher's study, but two occurred in the study by Gaston. This may be because the method of medial pin placement in Gaston's did not involve direct visualisation of the nerve in a mini-open technique. The author's nevertheless defend their technique by evidence from the exploration of the two iatrogenic nerve injuries which established that in both cases there was no direct penetration of the nerve. Their study, however, included 5 patients who underwent open reduction in the crossed pin group, in which case visualisation of the ulnar nerve would have been possible and perhaps were it not for this small cohort the incidence of nerve injury may have been higher. It is, however, likely that the study population was insuffi-

cient to identify any differences in iatrogenic nerve injury, and certainly the power calculations for each study were performed primarily to identify radiological outcomes, with nerve injury as secondary outcome measures.

Gaston et al. have a more robust study design in our view, with the operating surgeon performing the procedure they are most proficient and comfortable with rather than required to perform a less familiar technique as may have been the case in the study by Kocher. It must be noted that the ultimate goal in both studies is to see how well each technique would perform given ideal fixation, and not the collective ability of a group of surgeons of mixed skill to achieve fixation given two randomised techniques.

Factors that have not been elaborated on in the above studies are the effect of pin size or number of inserted lateral entry wires. Recent evidence from several sources implementing three lateral pins suggests that fixation is superior to two lateral pins and biomechanically equal to that of crossed pins [33, 35]. With regard to pin size, evidence from synthetic models has shown that large diameter pins (1.6 mm) provided significantly increased stability compared to small diameter pins (1.25 mm) in all four pin configurations tested [41]. In clinical studies large pin sizes were found to improve the radiographic sagittal alignment at final follow-up without an increased rate of infection or ulnar nerve palsy [42].

One limitation of Gaston's study is that clinical outcome was not recorded, and although Kocher's study did record clinical outcome, it did not show, nor was it sufficiently powered to show, any statistical difference between the two groups.

CONCLUSION

There is currently no Level 1 evidence comparing the outcome of crossed pinning versus lateral entry pinning in extension type Gartland III supracondylar fracture. Additionally, the current highest level evidence discussed above has limitations ranging from small sample size to insufficient data on clinical outcome. Therefore we cannot draw any firm conclusions on the above evidence.

We suggest that future RCTs take into account the recent evidence on fixation by including three lateral pins and larger diameter pins in their cohorts. Larger patient numbers would increase study power and therefore increase the likelihood of detecting any significant differences in iatrogenic ulnar nerve injury, clinical outcome and complications including cubitus varus.

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