

# Protocol for a systematic review of the incidence of infection in operative vs non-operative management of Seymour fractures in children and adolescents

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## Protocol

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# Abstract

Background Seymour fractures are open, displaced juxta-epiphyseal fractures of the distal phalanx, with an overlying nail bed laceration that occur in children and adolescents with an open physis. This fracture occurs rarely, but its potential consequences are clinically significant. Due to anatomical particulars and proximity to the growth plate, this open fracture may result in soft tissue infection and osteomyelitis, leading to growth arrest and persistent mallet deformity. At present, there is no consensus as to the optimal management of Seymour fractures. The objective of this study will be to systematically evaluate the existing evidence to establish whether operative or non-operative management of Seymour fractures is associated with a lower incidence of infection.

Methods We designed and registered a study protocol for a systematic review of comparative and observational studies. A comprehensive literature search will be conducted (from 1966 to present) in MEDLINE, EMBASE, CINAHL, Cochrane Library and Google Scholar databases. Grey literature will be identified through searching Open Grey and dissertation databases using an exhaustive search strategy. All clinical studies examining the management of Seymour fractures in children & adolescents will be included, comparing operative and non-operative groups. Operative management will be defined as formal washout and soft tissue debridement prior to reduction, whether in the emergency department or operating theatre. Non-operative management refers to washout without surgical debridement. Primary outcome measures will be the incidence of superficial and deep infection. Secondary outcomes will include adverse events such mal-union, non-union, need for re-operation, physeal disturbance, nail dystrophy/atrophy. Two independent reviewers will screen all citations, full-text articles, and abstract data. Conflicts will be resolved through discussion. The study methodological quality (or bias) will be appraised using an appropriate tool. A narrative synthesis will be performed and if two or more studies with comparable design and reporting the same outcome are identified, data will be pooled for comparative analysis.

Discussion This review will provide robust evidence for the management of Seymour fractures, based on a cumulation of existing studies. Due to the rarity of this fracture pattern, included studies are expected to be mainly observational and prone to bias; however, there is value in summarising the evidence, assessing its risk of bias and performing meta-analysis where possible to guide clinicians.

Registration PROSPERO CRD42020153726

## Background

Seymour fractures are displaced, open fractures of the juxta-epiphyseal region of the distal phalanx,<sup>(1)</sup> with an overlying nail bed laceration, that occur in skeletally immature individuals. While this fracture pattern was first described by Seymour in 1966<sup>(1)</sup> the exact definition is not unanimous; the majority of sources (2–11) define it as an open injury however several sources also include a closed injury (12, 13).

Seymour's original description of the fracture did not specifically comment on the presence or absence of nailbed injury, and thus the definition is subject to interpretation.

Additionally, some sources identify a similar injury pattern in adults and include this in their definition. (14) Radiologically, these can be fractures of the epiphysis (Salter-Harris types I and II) or metaphyseal fractures just distal to the physis. Salter-Harris III-V are generally not included in the definition as these either cross the epiphyseal plate or would not cause the same displacement or clinical pseudo-mallet deformity.(3) Clinically, they may mimic a mallet type injury due to the insertion points of the flexor digitorum profundus and the opposing extensor tendon – causing a deformity where the shaft of the distal phalanx is flexed and the epiphysis remains extended (12)

## **Disease burden, morbidity in general**

The incidence of Seymour fractures has never been reported, such is the rarity of the fracture pattern. More broadly speaking, the annual occurrence of a phalangeal fracture is 2.7% in children.(15) Seymour fractures most commonly occur in younger children, with a reported mean age of 8.7 years(16) The most common mechanism is a crush or sporting injury.(4)

While these are rarely occurring fractures, the clinical impact and consequences of them are significant. Despite appearing as a potentially insignificant injury, these fractures are high-risk for complications and cause a disproportionately large amount of morbidity.

## **Consequences of infection in Seymour fractures**

Owing to several factors, this fracture pattern is high risk for infection(12, 16). Late presentation or lack of intervention may result in infection, growth arrest and persistent mallet deformity of the distal phalanx(10). Reyes reported a 45% overall infection rate with a 36% occurrence of osteomyelitis with presentation > 24 hours post injury. (16) The risk of infection is higher than in other open fractures of the distal phalanx due to the characteristic soft tissue injury with this fracture pattern. The nail plate is avulsed, and interposed soft tissue, the germinal matrix of the nail complex, may be present in the fracture site, leading to contamination of the fracture site.(17) In turn, an infection in the juxta-epiphyseal region of bone can lead to physeal arrest.

These injuries are also high risk for non-union(12). In the same vein, this is postulated to be due to their unique anatomical considerations; In a juxta-epiphyseal fracture such as this, the extensor tendon inserts onto the proximal segment of the fracture and the flexor tendon to the distal one(1, 17), so forces across the fracture oppose union(11). Any interposed nail bed as previously described, can also prevent union. (16)

A growth arrest of the distal phalanx, whether caused by infection or malunion has the potential to alter the normal arcade of finger lengths and result in cosmetic deformity.(10)

## **Current practice**

A range of different management options have been reported in a variety of different settings(5, 16). These range from manipulation and splint to formal washout, debridement and percutaneous Kirshner wire fixation. These interventions may take place in the emergency department (5) or the operating theatre (3, 16) under local anaesthetic (ring block) (5) or general anaesthesia (3, 16). The current practice in the management of Seymour fractures varies significantly amongst different surgeons and centres.

The rationale for conservative management is based on the original article by Seymour, due to high rates of post-operative infections.(1, 18) Seymour found a higher infection rate (40% vs 20%) in operative vs non-operative management of these fractures(1). This said, in Seymour's original study, perioperative antibiotics were not given nor did 'formal debridement' occur, as described by more recent studies.(3)

The rationale for formal operative management is based on principles of the management of an open fracture and is a more widely accepted practice in more recent years. (3, 7, 12, 13, 17)

Nonetheless, with a paucity of evidence informing the management of these fractures, equipoise exists.

## **Hypothesis/aims**

We hypothesize that Seymour fractures that undergo formal debridement, washout and reduction have lower infection rates and are at lower risk of malunion. This systematic review aims to summarise the best available evidence for the management of Seymour fractures in the acute setting. We aim to determine the optimal treatment for these injuries and determine whether the incidence of complications, in particular that of infection is higher amongst operative or non-operative treatment groups. This review will be directly applicable to the clinical care of these injuries and will provide higher level evidence for their management. This is of clinical relevance, in a fracture pattern that is high risk for complications, which may be avoided when managed with appropriate care.(5, 16)

## **Research question**

In children and adolescents who sustain Seymour fractures, is operative (formal soft tissue debridement and washout plus fixation) management associated with a reduced incidence of infection when compared to washout and reduction alone?

## **Materials And Methods**

### **General methods**

This protocol has been registered with the PROSPERO international prospective register of systematic reviews (registration number CRD42020153726) and will be reported adhering to the Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P) 2015 statement(19). The PRISMA-P checklist for this study is included as an additional file (Additional file 1).

The final review will be reported following the PRISMA statement and the Meta-Analysis of Observational Studies in Epidemiology (MOOSE) guidelines(20).

# Study eligibility criteria

Studies will be selected according to participants, condition or outcome(s) of interest, and study design.

## Study designs

We will include randomized controlled trials (RCT) and controlled observational studies assessing the management of Seymour fractures. We expect the majority of studies to be retrospective or prospective observational studies (cohort or case-control) with a comparative group. We will also include non-comparative studies e.g. case series, although series of less than 3 patients and case reports will be excluded). Study protocols will also be excluded.

## Participants

We will include studies examining the management of Seymour fractures children and adolescents, where these are persons aged under 18 years with open physal plates. Studies reporting adults (aged over 18) or any persons with fused epiphyseal plates will be excluded, as will patients without radiological confirmation of a juxta-epiphyseal fracture.

Patients who were delayed in presenting to hospital services will be excluded, where delayed is defined as presentation after 48 hours. Patients whose initial debridement was delayed later than 48 hours will also be excluded as this cohort preludes to a significant risk of infection regardless of subsequent management (16).

## Interventions

We will classify the interventions described in studies according to the broad categories of 'operative' vs 'non-operative' management.

Operative management will be defined as a formal washout, debridement of soft tissues and either splinting or Kirshner wire fixation, open reduction and internal fixation or a combination of approaches. Non-operative management will be defined as washout and splint in the emergency department, without an operative debridement of tissue. Washout, soft tissue debridement and splinting in the emergency department will also be considered as operative management.

The use, choice and modality of antibiotics will be examined.

'Initial' operative management will be defined as operative intervention within 48 hours. Data on patients with a delayed presentation of more than 48 hours will be excluded.

## Comparator

We aim to review this information to compare operative vs conservative management of acute Seymour fractures, where operative management is defined as any procedure involving a debridement and open reduction, whether in the emergency department or operating theatre.

Within the operative group, a subgroup comparison will be conducted, examining emergency department vs operating theatre management of the manipulation and splint and nail bed repair and splint cohorts. If reported, usual care such as antibiotics, pain relief and immobilisation technique will be examined in addition.

## **Outcome measures**

The primary outcome will be the proportion of patients in operative vs non-operative groups who incur a soft tissue or bony infection. Soft tissue infection is defined as those with characteristic signs of skin and subcutaneous tissue infection (erythema, warmth, purulence). Bony infection (osteomyelitis) is defined as those that had signs of infection combined with radiographic evidence of focal bony lysis or cortical loss or a periosteal reaction.

Secondary outcomes will include other adverse events such as mal-union, non-union, need for re-operation, physal disturbance, nail dystrophy/atrophy (all as defined by the study in question).

Patient reported outcome measures will be analysed where reported.

Mal-union, non-union will be assessed up to one year; nail growth and physal disturbance will be assessed with a minimum follow up of 3-months post injury.

## **Setting**

Studies performed in the hospital and emergency department setting will be included. Studies performed in a primary care setting will be excluded.

## **Language**

No limitations will be imposed on language.

## **Information sources**

The primary source of literature will be a structured search of the following major electronic databases: Ovid MEDLINE; EMBASE (Ovid SP); CINAHL (Cumulative Index to Nursing and Allied Health Literature), Google Scholar and the Cochrane Library (Cochrane Database of Systematic Reviews, Cochrane Central Register of Controlled Trials [CENTRAL], Cochrane Methodology Register), in collaboration with a medical research librarian. PROSPERO will be searched for ongoing or recently completed systematic reviews.

## **Additional search methods (grey literature)**

The secondary source of potentially relevant material will be a search of the grey or difficult to locate literature, including Open Grey and dissertation databases (e.g. Open Access Theses and Dissertations) We will hand-search and screen the reference lists of included studies, relevant reviews, national clinical practice guidelines or other relevant documents to identify cited articles not already in our list of included studies. Content experts and authors who are prolific in the field will be contacted. The

literature searches will be designed and conducted by the review team which includes two experienced health information specialists.

## **Search strategy**

The search strategy used will include a range of text words as well as Medical Subject Headings (MeSH) terms related to 'Seymour fractures' and 'juxta-epiphyseal fractures.' The draft search strategy for MEDLINE is presented in Additional file 2. These search terms will be adapted for use with other bibliographic databases.

No restrictions will be placed on the timing of publication. The search will be performed in English and translations will be sought for articles published in other languages. No restriction will be placed on publication status (i.e. unpublished studies will be included).

## **Selection of studies**

Once the text and MeSH searches have been combined, duplicates will be removed using EndNote (Clarivate Analytics, Boston, MA, USA). Citations will also be managed using this software.

The collated reference list of studies meeting the inclusion criteria will be searched to identify additional relevant studies. Two independent researchers (AK and GN) will screen titles and abstracts for eligibility against a pre-defined list of inclusion and exclusion criteria. This process will be carried out using Rayyan (21), a bespoke web and mobile app for systematic reviews. At this stage, any reference deemed eligible for inclusion by either reviewer will be included. Two reviewers (AK and GN) will then screen the full text of potentially relevant articles for eligibility. Reasons for exclusion will be recorded where applicable.

Where disparity occurs between references, consensus will be sought, and all remaining articles will be read in full before a decision on inclusion is made. If disagreements remain between the screening authors, the texts will be screened by a third author (LC).

The bibliography of the final included studies will be screened to check for additional publications that may be relevant. The search results, including abstracts, full-text articles, and record of the reviewer's decisions will be recorded first in Rayyan(21) and then in a pre-defined data collection sheet in Microsoft Excel (Microsoft Corporation, 2018).

## **Data extraction and management**

Two reviewers (AK and GN) will collect data independently and in duplicate using a pre-defined electronic data extraction form.

The data collection process will be in keeping with the Cochrane Handbook of Systematic Reviews of interventions. (22)

The following data will be extracted: first authors; year of publication; study design; inclusion & exclusion criteria; number of patients; method of diagnosis; age; sex; relevant medical history; mechanism; time

since injury; digit involved; type of intervention, (debridement, fixation, anaesthesia); duration of intervention; specialty performing intervention; location of intervention (theatre or A&E); antibiotic regimen; time to first antibiotic; analgesic regimen and primary and secondary outcomes.

Where authors provide data on outcomes based on acute vs chronic presentation, we will extract only the data for the acute setting. If authors report on adult patients, these will not be included in the analysis, if the data is clearly distinguishable.

In addition, the statistical analysis models and outcome measures used will be noted. Divergences will be resolved by consensus or with a third reviewer (LC) if needed.

## **Dealing with missing data**

Where relevant, study authors will be contacted if data relevant to the systematic review are missing in the study report. Where authors fail to reply after first contact or after one reminder, the missing data will be acknowledged, and we will proceed with the analyses.

## **Assessment Of Risk Of Bias Of Included Studies**

We expect that most included studies will be observational rather than randomised studies. As such, the risk of bias will be assessed at the study level of all included studies. This will be performed independently and in duplicate by two review authors (AK and GN) using the ROBINS-I tool (Risk Of Bias In Non-randomised Studies of Interventions)(23). If any randomised trials are found and of relevance, we will assess these according to the Cochrane Collaboration Risk of Bias assessment tool(22). We will assess bias for cohort and case-control studies across the following domains: selection bias, attrition bias, detection bias, reporting bias, confounding and other types of bias. According to specific criteria available in the ROBINS-I tool(23), the two reviewers will categorize the bias as “unclear risk of bias,” “low risk of bias,” “moderate risk of bias”, “serious risk of bias,” and “critical risk of bias.” Disagreements between the review authors will be resolved by consensus or with a third reviewer where necessary. A narrative summary of the risk of bias of the included studies will be performed, which will be supported by a figure and table showing the results of the critical appraisal. Results of ROBINS-I tool will be used in a sensitivity analysis to ensure that studies judged to be a “serious” or “critical” risk of bias do not affect the robustness of our results in any subsequent meta-analysis.

## **Data analysis and synthesis**

To answer the review question of whether operative management of Seymour fractures is associated with a reduced incidence of infection or bony malunion, the data from each paper will be used to build evidence tables providing an overall description of included studies. The tables will contain data including study characteristics, context, population, outcomes and findings for each included study. This will be accompanied by a narrative synthesis of the data.

Clinical and methodological heterogeneity will be assessed across each study in operative vs non-operative management (24). This will determine whether it may be feasible to perform a meta-analysis. If possible we will perform a random effects meta-analysis(24). Data from studies with differing study designs will not be pooled together. We will present the results as a pooled estimate for each of the primary outcomes comparing operative and non-operative management as relative risk and 95% confidence intervals. The results of this will be presented in a forest plot.

Heterogeneity will be assessed visually by examining the overlap of confidence intervals in the forest plot. We will quantify statistical heterogeneity by estimating the variance between studies using the  $I^2$  statistic which examines the variance between studies to produce a percentage score of between 0 and 100% which will be interpreted as per the Cochrane handbook(22). Tau squared and chi-squared tests will also be applied where a P value of  $< 0.05$  is considered statistically significant for heterogeneity.(24)

A summary of findings table will be created for the primary outcome measure. We will rate the overall quality of evidence of these outcomes using the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) Working Group methodology(25). Each critical outcome's quality of evidence is rated, taking into consideration five defined criteria (risk of bias and limitations of design, consistency of analysed studies and their results, directness, precision, and publication bias) that may lead to grading down, and three criteria (large effect, dose-response, and opposing bias and confounders) that may lead to grading up. (26, 27)

## Further analysis

If it is not possible to combine the data in the above manner, then we will determine the crude incidence estimates of infection (number of infections/sample size) along with the 95% confidence intervals for operative vs non-operative management for each study. If feasible and appropriate, incidence data will be used to perform a meta-analysis of proportions. A forest plot may be produced to show the pooled effect of findings.

Subgroup analysis will be performed for healing and complication rates amongst different age groups, provided the data sets are sufficient.

## Meta-bias

Publication bias will be investigated, and a funnel plot will be generated for each meta-analysis containing 10 or more studies. Depending on the number of included studies in the review, we will undertake a sensitivity analysis to ensure the robustness of our results. We anticipate that the systematic review will identify studies judged to be at high or very high risk of bias and we will perform a sensitivity analysis where these are excluded.

## Discussion

While the hand is the most frequently injured part of a child's body, Seymour fractures are relatively uncommon injuries (28). While we can ascertain certain aetiological details from studies, review articles and case series(5, 11, 12, 17), the paucity of evidence due to the rarity of this fracture pattern leads to controversy as to the optimal type and setting of treatment.

We hope to identify the treatment setting and modality that offers the best outcome for Seymour fractures in a comparison of several studies, and therefore provide clinicians with information to choose the optimal treatment plan for these rare fractures. Our conclusions will be based on validated methodology, including a quality of evidence and quality of reporting appraisal for each study.

## **Limitations**

Due to the relative infrequency of this injury we expect a lack of high-quality evidence and likely significant bias in the reported results. We also expect the small number of studies to limit the potential for meta-analysis of studies although we will continue to proceed with a narrative review in this instance. When summarising the results for this infrequently yet highly important clinical problem this systematic review will aid help guide clinicians in improving the management of these high-risk injuries.

## **Abbreviations**

A&E	Accident and Emergency
CENTRAL	Cochrane Central Register of Controlled Trials
CINAHL	The Cumulative Index to Nursing and Allied Health Literature
EMBASE	Excerpta Medica Database
GRADE	Grade of Recommendations, Assessment, Development and Evaluation
MA	Massachusetts
MEDLINE	Medical Literature Analysis and Retrieval System Online
MeSH	Medical Subject Headings
MOOSE	Meta-Analysis of Observational Studies in Epidemiology
PRISMA	Preferred Reporting Items for Systematic Review and Meta-Analysis
PRISMA-P	Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols
PROSPERO	International prospective register of systematic reviews
RCTs	Randomised controlled trials
ROBINS-I	Risk of Bias In Non-randomized Studies - of Interventions
USA	United States of America

## Declarations

### Ethics approval and consent to participate

Not applicable.

### Consent for publication

Not applicable.

### Availability of data and materials

Not applicable.

## Competing interests

The authors declare they have no competition interests.

## Funding

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## Author contributions

AK GN and LC designed the search strategy and methodology. AK wrote the protocol. All authors revised and approved the final manuscript. AK and LC conceived the project and design of the study.

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