Fasciotomy versus conservative treatment for compartment syndrome of the forearm following earthquakes

(Protocol)
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Fasciotomy versus conservative treatment for compartment syndrome of the forearm following earthquakes

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ABSTRACT

This is the protocol for a review and there is no abstract. The objectives are as follows:
To collate and appraise evidence for surgical management of closed compartment syndrome of the forearm following earthquakes and identify optimal treatment strategy.

For patients with closed compartment syndrome of the forearm, which is preferable to avoid development of necrosis and ischemic contracture; fasciotomy or conservative treatment?
BACKGROUND

The low incidence of forearm compartment syndrome makes it difficult to draw conclusions regarding optimal management and outcome. Diagnosis often combines clinical signs with compartment pressure monitoring and standard treatment includes early fasciotomy (Kalyani et al., 2011). Fractures of the distal end of the radius is the most common cause of forearm compartment syndrome in adults, whereas in children the most common cause is supracondylar fractures of the humerus (McQueen et al., 2000), (Kalyani et al., 2011). Soft tissue injuries not involving fractures have been reported to cause as much as 23% of forearm compartment syndromes (Elliott, Johnstone, 2003). Crush injuries are known to cause compartment syndromes (Reis, Better, 2005). The incidence of crush injuries following an earthquake is estimated to 3% to 20% (Gonzalez, 2005). Of all crush injuries, 74% affect the lower extremities, followed by upper extremities (10%) and trunk (9%) (Briggs, 2006).

Late fasciotomy in patients with compartment syndrome is a controversial approach, especially when not addressed within 12 hours after injury (Malinoski et al., 2004). Following an earthquake humanitarian surgical programs usually are set up after a few days. This means experiencing late effects of crush-injured limbs with compartment syndromes and muscle necrosis. The optimal surgical management at this stage needs to be defined. An estimated number of 2000-4000 amputations were done following the 2010 earthquake in Haiti (Handicap International, 2010). The number of fasciotomies is uncertain. In such circumstances, insuring quality of care is extremely challenging and outcome data, especially long-term outcomes, are difficult to collect as patients often do not return for follow-up and may be difficult to trace (Chu et al., 2011).

In this systematic review we will assess the evidence regarding surgical care of closed compartment syndrome of the forearm following earthquakes. Considering the limited number of earthquake-specific studies, all original research studies will be included - disregarded the context and we will not restrict searches by language or date.

Description of the condition

Patients with closed compartment syndrome of the forearm, defined as the portion of the upper limb between the elbow and the wrist

Description of the intervention

Fasciotomy of the forearm.

How the intervention might work

The role of fasciotomy has been well established in literature as a treatment for closed compartment syndrome of the forearm (Kalyani et al, 2011).

Why it is important to do this review

This systematic review aims at evaluating the effectiveness of fasciotomy as a way to prevent the development of ischemic contracture of the forearm in the specific setting following earthquakes.

OBJECTIVES

Primary objective

To collate and appraise evidence for surgical management of closed compartment syndrome of the forearm following earthquakes and identify the most effective treatment strategy.

Research questions
For patients with closed compartment syndrome of the forearm, which is preferable to avoid development of ischemic contracture - fasciotomy or conservative treatment? - early or late fasciotomy?

METHODS
Criteria for considering studies for this review
Types of studies
All types of published peer-reviewed scientific original research studies. Considering the limited number of earthquake-specific studies, all studies will be included - disregarded the context.

Types of participants
All studies concerning patients with closed compartment syndrome of the forearm will be included.

Types of interventions
Fasciotomy and conservative treatment (mannitol infusion, watchful waiting).

Types of outcome measures
Primary outcomes
- Ischemic contracture
Secondary outcomes
- Mortality
- Disabling pain
- Amputation
- Infection
- Septicemia

Search methods for identification of studies
We will search for all types of published original research studies. If needed we will ask authors of relevant studies to provide further information. We will not restrict searches by language, date or publication status.

Electronic searches
We will search the following electronic databases:

PubMed

The Cochrane Library:

Web of Science

SveMed+

Searching other resources
The reference list of included studies will be reviewed for additional published peer-reviewed scientific original research studies.
Data collection and analysis
We will use Review Manager 5.1 software to conduct the review. Multiple publications of the same study will be carefully reviewed in order to avoid double reporting of the same patients.

Selection of studies
Two authors (AÅ, MG) will assess titles or abstracts of all studies identified by the initial search and will exclude clearly non-relevant studies. We will obtain the full text of articles for potentially relevant studies and any studies with unclear methodology.

Two authors (AÅ, MG) will independently assess these studies to determine whether they meet the inclusion criteria for this review.

Articles will be included if they:
- Constitute original research (commentaries and letters will be included if they report original research findings). Case reports are excluded. We define a case report as an article describing data from one patient. If several case reports are contained in one article, this article will be included if more than one case is a closed compartment syndrome of the forearm.
- Discuss management of closed compartment syndrome of the forearm

We define a closed compartment syndrome as a compartment syndrome without an obvious open route to the fascia or muscle. Examples of such obviously open routes are open fractures, penetrating injury such as gun shot wounds, and peri-operative compartment syndromes, occurring during surgery of the forearm.

Compartment syndromes caused by injections, infusions, and snake bites will be included but excluded in sensitivity analyses.

Studies that present a mixture of injury entities will be considered for inclusion if data on patients with closed compartment syndrome of the forearm can be extracted separately, or data can be obtained from study authors, otherwise these studies will be excluded.

80% inter-rater agreement on the level of study inclusion or exclusion will be achieved before proceeding to the next stage in the review process.

Data extraction and management
Two authors (AÅ, MG) will independently extract the following information for each included study:
- Citation
- Research question/objective
- Study type
- Time frame (start of study period – end of study period)
- Study population (total number, age, sex)
- Setting
- Country
- Etiology
- Interventions
- Time from onset of symptoms to intervention
- Outcomes studied
- For each outcome measures of effect (RR, OR, SE, CI, and P-values) will be extracted as reported.

Assessment of risk of bias in included studies
Methodological quality of included studies will be assessed using the instrument developed by Cho et al in 1994 (Cho et al., 1994).

**Measures of treatment effect**

We will analyze dichotomous data for relative risk ratio (RR), odds ratios (OR), or absolute risks, as appropriate depending on how treatment effects are reported in included articles. We will calculate 95% confidence intervals for these measures of effect. Continuous outcomes will be compared using means.

**Unit of analysis issues**

We will perform analyses on two levels. If possible, individual patient data will be extracted from original studies and collated into one single dataset. In this analysis, the forearm will be the unit of analysis for the outcomes ischemic contracture, amputation, and infection. For mortality, disabling pain and septicemia the unit of analysis will be the patient.

We will also perform a meta-analysis on study level. In this analysis, each study arm will be the unit of analysis.

**Dealing with missing data**

We will contact the authors if additional information is required, such as individual patient data.

**Assessment of heterogeneity**

We expect a high degree of heterogeneity in included studies in terms of study designs, patients, interventions, and outcomes. Therefore, random coefficient models will be used in the analyses.

If a meta-analysis is not doable, and for studies excluded from the meta-analysis, a structured narrative review will be performed.

**Assessment of reporting biases**

Where we suspect the presence of reporting bias, we will attempt to contact study corresponding authors asking them to provide missing outcome data.

**Data synthesis**

STATA statistical software version 12 will be used for all statistical analyses. As described above, we will perform analyses on two levels. First, we will attempt to collate individual patient data into one single dataset. Depending on the relationship between dependent (outcome) and independent (management type or time to intervention, treating age, sex, and etiology as potential confounders) variables multiple linear or logistic regression models will be used. A 5% significance level and 95% confidence level will be applied.

For the meta-analysis, data will be summarized statistically if they are available, sufficiently similar and of sufficient quality. The unit of analysis will be study arms. For the meta-analysis of dichotomous outcomes we will use the most appropriate effect measure, depending on how effects are reported in articles, of an event occurring with 95% confidence intervals (CI) and control event rates for reporting dichotomous data. For the meta-analysis of continuous outcomes, if all studies reported the final outcome on the same scale, we will pool the mean differences between the treatment arms and compare to pooled mean differences of control arms using the mean difference method with 95% CI or using the standardized mean difference method with 95% CI otherwise. The results of meta-analysis for each outcome will be presented graphically as forest plots. If trials reported their continuous variables as medians with ranges, we will use that the mean is equal to the median value itself and estimated the standard deviation (SD) as a quarter of the range (samples ≤ 70) or range/6 (samples > 70) (Hozo et al., 2005). If neither ranges nor any other measure of
dispersion was reported, and it is impossible to estimate the mean and SD based on the published data, the corresponding continuous variables will excluded from the statistical pool.

**Subgroup analysis**
Subgroup analysis for mass casualties vs. routine clinical care, crush injury induced vs. non-crush induced compartment syndrome, early vs. late fasciotomy

**Sensitivity analysis**
If there are sufficient included studies we will re-analyze the results by excluding studies of compartment not caused by crush injury and studies of low methodological quality.

**DECLARATION OF INTEREST**
The authors declare no competing interests.
REFERENCES


APPENDICES

Appendix 1. Search strategy in PubMed

(Compartment Syndromes"[Mesh] AND "Forearm"[Mesh] AND "Fascia"[Mesh]) 44

(forearm OR arm) AND compartment syndrome 687

(forearm OR arm OR upper extremity) AND compartment syndrome

Limits: Published in the last 180 days 10

Appendix 2. Search strategy in Cochrane Library:

compartment syndrome AND (arm* OR forearm* OR upper extremity) 7

Appendix 3. Search strategy in Web of Science:

("compartment syndrome") AND (arm* OR forearm*) 336

Appendix 4. Search strategy in SveMed+

compartment syndrome AND upper extremity 6
Appendix 5. Data extraction form

Reviewer (AÄ/MG):
Study citation (Vancouver style):

Author contact details:

Study ID (initials + number e.g. AÄ1):

Confirm eligibility (included/excluded):

Reason for exclusion:

Correspondence required (with reason):

<table>
<thead>
<tr>
<th>Data to collect</th>
<th>Item</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Methods</strong></td>
<td></td>
<td></td>
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<tr>
<td>Study design</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Time frame (start of study period – end of study period)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Study participants</strong></td>
<td></td>
<td></td>
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<tr>
<td>Total number</td>
<td></td>
<td></td>
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<tr>
<td>Setting (including country)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Inclusion/exclusion criteria</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age (mean</td>
<td>measure of spread)</td>
<td></td>
</tr>
<tr>
<td>Females</td>
<td></td>
<td></td>
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<tr>
<td>Compartment syndrome etiology</td>
<td></td>
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<tr>
<td>Time from onset of symptoms to intervention</td>
<td></td>
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<tr>
<td>Time for follow up</td>
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</tbody>
</table>

If individual patient data are available, fill in dataset template on last page.

**Interventions**

<p>| Total number of intervention groups |         |
| Intervention 1                     |         |</p>
<table>
<thead>
<tr>
<th>Intervention 1 details (number of incisions, incision placement etc)</th>
<th></th>
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</thead>
<tbody>
<tr>
<td>Intervention 2</td>
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<tr>
<td>Intervention 2 details (number of incisions, incision placement etc)</td>
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<tr>
<td>Intervention 3</td>
<td></td>
</tr>
<tr>
<td>Intervention 3 details (number of incisions, incision placement etc)</td>
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</tbody>
</table>

### Outcomes

<table>
<thead>
<tr>
<th>Outcomes reported</th>
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<tbody>
<tr>
<td>Outcome n</td>
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</table>

<table>
<thead>
<tr>
<th>Type</th>
<th>Dichotomous</th>
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<tbody>
<tr>
<td>Continuous</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Definition</th>
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<tbody>
<tr>
<td>Unit of measurement</td>
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</table>

### Results

For outcome 1

<table>
<thead>
<tr>
<th>Sample size</th>
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<tbody>
<tr>
<td>Effect measure on group level (as reported in article)</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Treatment group</th>
<th>Control group</th>
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</thead>
<tbody>
<tr>
<td>Effect size</td>
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<tr>
<td>Standard error</td>
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<tr>
<td>Standard deviation</td>
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<tr>
<td>Confidence interval lower limit <em>(note confidence level here:  )</em></td>
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</tr>
<tr>
<td>Confidence interval upper limit</td>
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<tr>
<td>P-value</td>
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<tr>
<td>Effect measure comparison level (as reported in article)</td>
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<tr>
<td>Effect size</td>
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<tr>
<td>Confidence interval lower limit <em>(note confidence level here:  )</em></td>
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<tr>
<td>Confidence interval upper limit</td>
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<td>--------------------------------</td>
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<tr>
<td>Miscellaneou</td>
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<tr>
<td>Funding source</td>
<td></td>
</tr>
<tr>
<td>Key conclusion of study authors</td>
<td></td>
</tr>
<tr>
<td>References to other relevant studies</td>
<td></td>
</tr>
</tbody>
</table>

**Assessment of methodological quality (adapted from Cho et al. 1994)**

1. **Study design (choose 1 only)**
   - **Experimental, randomized:**
     - Placebo-controlled trial
     - Comparative trial, no placebo
     - Time series trial
     - Crossover trial
   - **Experimental, unrandomized:**
     - Placebo-controlled trial
     - Comparative trial, no placebo
     - Time series trial
     - Crossover trial
     - Natural experiment
   - **Nonexperimental:**
     - Cohort, prospective
     - Cohort, retrospective
     - Cross-sectional
     - Case-control
     - Case reports or case series
   - None of the above:

2. **What was the study question?**
   - Yes
   - Partial
   - No
   - Not applicable
   - Comments

3. **Was the study question sufficiently described?**

4. **Was the study design appropriate to answer the study question?**

5. **Were both inclusion and exclusion criteria specified? (If case study, check N/A.)**
<table>
<thead>
<tr>
<th></th>
<th>Question</th>
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<tbody>
<tr>
<td>6</td>
<td>For case studies only: Were patient characteristics adequately reported? (If not case study, check N/A.)</td>
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<td>7</td>
<td>Were subjects appropriate to the study question?</td>
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<td>8</td>
<td>Were control subjects appropriate? (If no controls were used, check No.)</td>
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<tr>
<td>9</td>
<td>Were subjects randomly selected from the target population?</td>
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<tr>
<td>10</td>
<td>If subjects were randomly selected, was the method of random selection sufficiently well described? (If subjects were not randomly selected, check N/A.)</td>
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<tr>
<td>11</td>
<td>If subjects were randomly allocated to treatment groups, was the method of random allocation sufficiently described? (If subjects were not randomly allocated, check N/A.)</td>
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<td>12</td>
<td>If blinding of investigators to intervention was possible, was it reported? (If not possible, check N/A.)</td>
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<td>13</td>
<td>If blinding of subjects to intervention was possible, was it reported? (If not possible, check N/A.)</td>
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<tr>
<td>14</td>
<td>Was measurement bias accounted for by methods other than blinding?</td>
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</table>
15 Were known confounders accounted for by study design? (If no known confounders, check N/A.)

16 Were known confounders accounted for by analysis? (If no known confounders, check N/A.)

17 Was there a sample size justification before the study?

18 Were post hoc power calculations or confidence intervals reported for statistically nonsignificant results?

19 Were statistical analyses appropriate?

20 Were the statistical tests stated?

21 Were exact values or confidence intervals reported for each test?

22 Were attrition of subjects and reason for attrition recorded?

23 For those subjects who completed the study, were results completely reported?

24 Do the findings support the conclusions?

**Individual patient data**

<table>
<thead>
<tr>
<th>Patient ID (Study ID + Number)</th>
<th>Sex</th>
<th>Age</th>
<th>Time from onset of symptoms to intervention</th>
<th>Intervention</th>
<th>Time for follow-up</th>
<th>Outcome 1</th>
<th>Outcome 2</th>
<th>Outcome 3</th>
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