Elastic Stable Intramedullary Nail for Paediatric Femoral Fractures

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Author(s): Akilapa O

Introduction

Femoral shaft fractures are relatively rare but severe injuries in children that frequently require hospital admissions and prolonged rehabilitation. These fractures account for less than two percent of all paediatric fractures and have an annual incidence of approximately 19 per 100,000 [1-4]. The injuries are more common in boys, especially during the toddler years and early adolescence [5-8]. The mechanism of injury varies from simple falls to high energy trauma e.g. road traffic accidents [9].

Treatment of these fractures can be broadly divided into non-surgical and surgical interventions. Non-surgical interventions include pavlik harness, skeletal traction, immediate or delayed application of a hip spica or functional cast bracing. Options for surgical stabilization include elastic intramedullary nails, rigid intramedullary nailing, plating and external fixation. The choice of treatment depends on the age and weight of the child, fracture pattern and social circumstances.

Flexible intramedullary nailing is a rapidly emerging technique of femoral shaft fracture fixation in children. It involves the insertion of one or more stainless steel or titanium elastic nails into the medullary canal to provide stable fixation. The fixation is not rigid but allows enough stress at the fracture site to encourage abundant callus formation and promote healing. Its major advantage is that the entry point for the nails spares the growth plate and avoids unwanted complications like growth arrest or osteonecrosis. Its primary limitation relates to the lack of rigid fixation, which makes it unsuitable for fracture patterns that have a tendency to shorten or angulate. Its use is also limited in the heavier child that weighs more than 50kg.

The evidence supporting the use of flexible intramedullary for treatment of femoral shaft fractures in children is limited. There is a paucity of robust studies that have compared its efficacy with other methods of intervention such as hip spica, rigid intramedullary nailing or external fixation[10,11,12]. The aim of this review is to compare the efficacy of elastic stable intramedullary nail fixation with other interventions (Hip spica, External Fixation, Rigid intramedullary Nails etc) for treating femoral shaft fractures in children. The research question is simple; “Should flexible intramedullary nailing become the gold standard for treating femoral shaft fractures in children”?

Methods

ELIGIBILITY CRITERIA

Study design

This review includes all randomised and quasi-randomised controlled trials (where the method of allocation can be predicted; e.g. by alternation, date of birth or hospital number) that directly compared the efficacy of elastic stable intramedullary nails with other interventions (e.g. hip spica, rigid nails or external fixation) for treatment of femoral shaft fractures in children.

Participants

Participants eligible for inclusion in this review are children and adolescents who are yet to attain skeletal maturity with femoral shaft fractures. Children with pathological fractures or metabolic bone diseases were excluded.

Interventions

This review includes all trials assessing the efficacy of flexible intramedullary nails by direct comparison with other interventions (e.g. traction, hip spica, external fixation, plate fixation, rigid intramedullary nail) for treating femoral shaft fractures in children.

Outcomes

Outcome data from trials included in this review had to be relevant and measured with validated instruments. Data relating to treatment efficacy and adverse events were specifically sought after. Functional outcomes like the Paediatric Outcome Data Collection Instrument (PODCI) [13, 14], and Activity Scale for Kids (ASK) [15] were considered relevant primary outcome measures.

Clinician reported outcomes like malunion (varus, valgus or rotational) and leg-length discrepancy were also considered relevant primary outcome measures. Complications such as deep infections, compartment syndrome, nerve injury, non-union, and re-fractures were also deemed essential to be reported as primary...
outcome measures.

SEARCH STRATEGY
Relevant randomised and quasi-randomised controlled trials, with no language restrictions, up to 2nd of October 2011 were searched for electronically and manually by the following search strategy.
I conducted an electronic search of Ovid MEDLINE(R) 1948 to September Week 3 2011. The Medline search strategy was a combination of Medical Subject Heading (MeSH) terms as well as relevant keywords to identify as many eligible studies as possible. To optimize the retrieval of randomised controlled trials, I combined my subject specific search strategy with the Cochrane Highly Sensitive Search Strategy for identifying randomised trials in MEDLINE: sensitivity and precision maximizing version (2008 revision)[16].
A detailed outline of the search strategy is shown in Figure 1.
I also conducted an electronic search of Ovid EMBASE (R) 1980 to 2011 Week 39 using a similar strategy as the one adopted in the Medline search by modifying the search terms to EMTREE compatible keywords as necessary.
I also searched the Cochrane Central Register of Controlled Trials (Issue 3 of 4, Jul 2011) to identify any randomised controlled trials that the Medline or Embase electronic strategy may have failed to retrieve.
I searched manually through the reference list of the papers identified from the electronic search strategy to retrieve more papers.
I did not seek after information from grey literature e.g. proceedings of scientific meeting or conferences or libraries of unpublished studies due to time and resource constraints.

DATA COLLECTION
I developed a data extraction sheet based on a prototype provided by the Cochrane Consumer and Communication Review Group’s data extraction template[17]. This was not pilot tested because of the very small number of studies included in this review. The information extracted relate to the study design and duration, participants number and demographics, specific interventions, outcome and time points collected and reported and a detailed analysis of the results. The sample data extraction form is attached as Appendix 1.

ASSESSMENT OF METHODOLOGICAL QUALITY
I assessed the methodological quality of the included studies with the Cochrane Collaboration’s tool for assessing the risk of bias[18].The tool assesses the risk of bias as a result of the randomisation process, pre- allocation disclosure of assignment, blinding of participants, personnel and outcome assessors and handling of the results. A copy of the tool is included as Appendix 2.

DATA SYNTHESIS
Data compiled from the studies included in this review was summarised by a narrative synthesis.

Results

Study Selection
The Medline electronic search strategy retrieved 29 studies. Two of these were randomised controlled trial with relevant patient population, interventions, comparators and outcome measures (PICO) as stated a priori in the eligibility criteria [19,20]. Excluded studies included 12 randomised controlled trials with irrelevant PICO, 4 review articles, 4 prospective, non-randomised cohort studies and 2 case series. Other studies excluded include a biomechanical study (1), duplicate study (1) and a technical report (1). There was no abstract available for two studies. The Embase search strategy retrieved one hundred and nine articles in total. Only one of the articles that fulfilled the eligibility criteria was unique[21] and included to the other two Medline studies
The electronic search of the Cochrane Central Register of Controlled Trials (CENTRAL) did not retrieve any additional randomised trials. Manual search of the bibliographies of articles retrieved electronically did not yield any additional trials.

Shemshaki and his colleagues reported that they conducted a randomised controlled trial to compare the efficacy of hip spica and flexible intramedullary nails in the treatment of femoral shaft fractures in children. The study design proposed was appropriate as randomised controlled trials are most appropriate for testing the efficacy of interventions especially in a comparative sense. The eligibility criteria were explicitly reported and highlighted the fact that the results of this study would only be applicable to children between the ages of six and twelve years old with simple fractures of the femoral shaft. The rationale behind the age restriction was not stated but this may be related to the authors’ conviction (as stated in the introduction) that the use of titanium elastic nails is limited to school aged children. The exclusion of extremely comminuted fractures, metabolic bone disorders or children with neuromuscular disorders was a rational attempt to
eliminate known confounders with significant prognostic implications on both treatment types. The authors’ attempted to justify the sample size by reporting a power calculation based on the perceived minimum clinically important difference between groups in a time related entity which was not explicit. The basis for which 5 days was derived as the “minimal expected difference between the two groups” was not clearly reported. It is reasonable to assume that the calculation was based on the reported primary outcome which was length of hospital stay. The authors also provided access to the study protocol as registered on an online clinical trials resource (www.clinicaltrials.gov). The protocol was submitted about six months after enrolment had been completed making it difficult to objectively assess compliance with their methodology. The protocol should have been published prior to commencement of the enrolment process to inspire more confidence in the methodological rigour and transparency.

The method of random sequence generation was not comprehensively reported. The authors utilized “random allocation software” which was not provided or referenced in the report. Furthermore, the authors reported in their study protocol online that the study was “Non-randomised” which directly conflicts with the print version of events. The authors did not report any attempt to shield personnel or participants from the allocation sequence if indeed there was any. Overall it is reasonable to conclude that the study had an unclear if not significant risk of selection bias based on these inconsistencies. Methodological studies have shown that the estimate of the size of treatment effect in studies with unclear reporting of allocation concealment or inadequate concealment were exaggerated by about 18 percent (Confidence interval 5 to 29%) more that trials in which allocation concealment was adequate [22].

The nature of the interventions made it impractical to blind the participants and personnel to the treatment arms. Empirical studies have reported that lack of blinding in randomized trials tend to exaggerate the treatment effect by nine percent on average [23]. The authors reported both interventions in sufficient detail to allow replication and made reference to the literature where appropriate. Surgery was performed by a single surgeon. This limits the external validity of the study as success or failure of the procedure is hugely dependent on the technical expertise of a single novice or expert and may not reflect the range of expertise in a broader setting. The authors did not report in print version of the study whether the outcome assessor(s) was blinded. The published study protocol though, reported blinding of the outcome assessor. The lack of adequate reporting makes it difficult to make any inferences as to the effectiveness of blinding of the outcome assessor(s) if indeed this was done.

The authors reported that all forty six patients that were enrolled completed the study. There was no mention of loss to follow up at any of the proposed post operative outcome assessment at two, four, twelve and twenty four weeks. The single outcome data table did not report the timing of outcome assessments. Overall, the risk of attrition bias is low. The authors reported the primary and secondary outcomes as documented in the study protocol. The fact that the protocol was not published before commencement of the trial makes it difficult to ascertain if indeed the outcomes reported were the outcomes desired a priori. The risk of selective reporting bias is unclear. Overall, this “randomised” trial had an unclear risk of selection bias as revealed in the inconsistencies between the protocol and the published study. The risk of performance bias was also unclear as there was no evidence of blinding of outcomes assessors. The study protocol reported the use of blinded outcome assessors but the authors did not report that in print. The risk of attrition bias was low and the risk of reporting bias was unclear.

Bar-on and colleagues conducted a prospective, randomised study to compare the efficacy of the flexible intramedullary nail with external fixation. The study design was appropriate to answer the research question. The eligibility criteria were explicit. The age restriction from five to fifteen years makes the results of the study applicable only to children within the same age bracket. The rationale of including children who may have attained skeletal maturity (fifteen year olds) in this study was not justified. This would have been very relevant as the use of flexible nails is generally limited to skeletally immature children. The inclusion of children with Gustilo I or II open fractures and Winquist I and II comminuted fractures is reasonable as none of these are absolute contraindications to the use of both interventions and their inclusion makes results more generalisable. The authors’ did not justify their sample size (Ten fractures in each treatment arm) with a power calculation. This makes it difficult to objectively conclude whether or not the study was adequately powered and not inherently prone to Type II errors. The relatively small numbers suggest that this study was underpowered.

The authors did not report the method of random sequence generation and allocation concealment. This
falls short of the standards recommended for the reporting of randomised controlled trials [23] and makes it very difficult to assess the risk of selection bias. Methodological studies have shown that inadequate generation of allocation sequences tend to be associated with biased intervention effects [24]. Furthermore, a pooled analysis of seven methodological studies found that effect estimates from trials with unclear reporting or inadequate allocation concealment were on average more beneficial than trials with adequate allocation concealment [22].

The nature of the interventions made it impractical to blind the participants and personnel to the treatment arms. The authors did not report the interventions in sufficient detail to allow replication. This raises questions as to whether treatment options were standardized and as such amenable to comparison. The authors gave some detail relating to the technical expertise of the surgeons involved. This is particularly useful in assessing external validity of the study and its generalisability to a wider population. The authors did not report any attempt to blind the outcome assessor. Overall, the risk of performance bias in this study was unclear.

The authors did not report that any patients were lost to follow up. The risk of attrition bias in this study is low.

The authors reported a number of outcomes but did not place any emphasis on a primary outcome. The results section highlighted parameters such as average duration of operations, mean fluoroscopy time and recovery milestones such as return to full weight bearing, full range of motion and school. It was difficult to assess the risk of selective reporting bias as there was no study protocol available. I could not find the research protocol through relevant search engines [25] or clinical trials registry [26] for comparison with the published report. The authors did not mention any changes in protocol. The outcome measures reported appeared relevant to the research question posed by the authors.

The results appeared to have been analysed without the use of inferential statistics. No probability values (p values) were reported alongside parameters such as duration of operation and mean fluoroscopy times thus reflecting tendencies or trends rather than statistically significant differences between groups. The strength of an adequately powered and rigorously conducted randomisation process to detect genuine statistical differences between groups cannot be overemphasized.

Overall, this randomised trial had an unclear risk of selection bias due to lack of reporting of the sequence generation and methods used to conceal allocations. The risk of performance bias was high as there was no evidence of blinding of outcomes assessors. The risk of attrition bias was low and the risk of reporting bias was unclear.

Hsu [21] 2008, Quasi-Randomised Trial

Hsu and colleagues conducted a prospective clinical trial to compare the efficacy of elastic intramedullary nailing (EIN) with dynamic skeletal traction spica casting (DSTSC) in the management of femoral shaft fractures in children. The authors reported that participants were assigned to treatment by flipping a coin in order to reduce selection bias. This method of sequence generation although systematic is not randomised. Coin flipping might in principle result in similar groups but the technique itself is not necessarily just a matter of chance. The most obvious inherent weakness in this method is that concealing the allocation schedule is usually impossible, which allows foreknowledge of the intervention assignment among personnel recruiting participants into the study, and biased allocations. Hence the risk of selection bias is high.

The eligibility criteria was explicitly reported and to some extent justifiable. The exclusions on the basis of missing data (four patients) are reasonable if it preceded assignment to interventions otherwise an intention to treat analysis should have been adopted. The authors attempted to validate their sample size (26 in EIN group, 25 in DSTSC group) by reporting a power calculation based on anticipated effect sizes between intervention groups in terms of length of hospital stay and cost. The enrolment process achieved the desired sample size of twenty five participants in each group hence the study was adequately powered.

The impracticality of blinding participants and personnel to the interventions is a recurring theme. Blinding of Outcome assessors on the other hand is quite practical. The authors reported that three outcome assessors were involved but did not report any attempt or constraints to blinding. The interventions were described in sufficient detail to allow replication with appropriate references to the literature. Overall, the risk of performance bias is unclear due to inadequate reporting.

The authors reported on quite a few outcomes. The primary outcome was length of hospital stay which is a reasonable parameter for the assessment of efficacy of two interventions. A huge confounder was the lack of adequate funding as patients in the elastic nail group had delayed interventions (due to cost) which reflected in the length of hospital stay. It is logical to interpret the differences in length of stay between
groups with extreme caution although it was reported as statistically significant (p<0.05). The authors did not report any loss to follow up hence it is reasonable to assume that the risk of attrition bias was low. The risk of selective reporting bias is unclear as I had no access to the study protocol.

Discussions and conclusion

IMPLICATIONS FOR BEST CLINICAL PRACTICE
The aim of this review is to compare the efficacy of elastic stable intramedullary nail fixation with other interventions (Hip spica, External Fixation, Rigid intramedullary Nails etc) for treating femoral shaft fractures in children.

The systematic search of the literature identified three trials[19, 20, 21] (two randomized controlled trials and a quasi-randomised) that directly compared the efficacy of titanium elastic nails with other interventions for treating femoral shaft fractures.

FLEXIBLE NAILS VERSUS HIP SPICA
Shemshaki and his colleagues attempted to validate the use of titanium elastic nails over the traditional hip spica. The study reported shorter hospital stay (p<0.001), shorter time to start walking (p<0.001) and earlier return to school (p<0.001) in the cohort of children treated with flexible nails.

The validity of these results and applicability to the wider population has to be interpreted within the context of the systematic biases as reported earlier. The study had an unclear risk of selection bias, a high risk of performance bias (no blinding) and a low risk of attrition bias.

Although, the study adds strength to the body of evidence that have compared elastic nails with the spica cast[10], its results have to be interpreted with some caution. The size of treatment effect may have been exaggerated (unclear risk of selection bias) and may not be consistent across rigorous studies.

FLEXIBLE NAILS VERSUS EXTERNAL FIXATOR
Bar-on and colleagues conducted a prospective, randomised study to compare the efficacy of the flexible intramedullary nail with external fixation. The study reported shorter duration of operation and mean fluoroscopy times in the External Fixator (No p values). It also reported that the flexible intramedullary nail group attained the recovery milestones (walking) much earlier than the external fixator group

The results of the study have to be interpreted within the context of its unclear risk of selection bias, high risk of performance bias and low risk of attrition bias. The strength of recommendation on the basis of the aforementioned is weak.

FLEXIBLE NAILS VERSUS THE DYNAMIC SKELETAL TRACTION SPICA
Hsu and colleagues conducted a prospective clinical trial to compare the efficacy of elastic intramedullary nailing (EIN) with dynamic skeletal traction spica casting (DSTSC) in the management of femoral shaft fractures in children.

The authors attempted to validate the use of a cheaper yet equally effective intervention (DSTSC) for treatment of femoral shaft fractures. The study showed longer hospital stays and higher costs were associated with the EIN. There were no significant differences in radiological outcomes or complication rates.

The results of the study have to be interpreted with extreme caution as there was a high risk of selection bias inherent in the study design (quasi-randomised) as well as a high risk of performance bias due to lack of blinding.

DIRECTIONS FOR FUTURE RESEARCH
The research question posed at the beginning of this review states “Should flexible intramedullary nails become the gold standard of treatment of femoral shaft fractures?”. This review has shown that there’s very little evidence available to emphatically answer that question. Future research efforts have to be directed towards conducting more rigorous randomised controlled trials comparing the flexible nails with other interventions most especially the rigid intramedullary nails as their indications appear to overlap.

The indications for the use of flexible nails are expanding and there’s an increasing trend towards its use in pre-school children (3 to 5 year olds). At the moment, there’s no randomised controlled trial published in the literature evaluating its efficacy in this age group.

References

4. Kocher MS, Sink EL, Blasier RD: Treatment of
25. www.pubmed.com accessed on 5th of October 2011
Illustrations

Illustration 1

Medline Search Strategy

<table>
<thead>
<tr>
<th>Snr</th>
<th>SEARCH TERMS</th>
<th>RESULTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>exp Femoral Fractures/</td>
<td>25362</td>
</tr>
<tr>
<td>2</td>
<td>Fractures, Bone/</td>
<td>42896</td>
</tr>
<tr>
<td>3</td>
<td>Fracture Healing/</td>
<td>7653</td>
</tr>
<tr>
<td>4</td>
<td>Fracture Fixation/</td>
<td>15461</td>
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<tr>
<td>5</td>
<td>2 or 3 or 4</td>
<td>59964</td>
</tr>
<tr>
<td>6</td>
<td>Femur/</td>
<td>27110</td>
</tr>
<tr>
<td>7</td>
<td>5 and 6</td>
<td>1024</td>
</tr>
<tr>
<td>8</td>
<td>(Femoral Fracture* or (Femur adj3 Fracture*)) inv</td>
<td>6806</td>
</tr>
<tr>
<td>9</td>
<td>1 or 7 or 8</td>
<td>28084</td>
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<tr>
<td>10</td>
<td>exp Infant/</td>
<td>863199</td>
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<tr>
<td></td>
<td>exp Child/</td>
<td></td>
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<tr>
<td>---</td>
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</tr>
<tr>
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<td>13</td>
<td>(Infant or Child or Pediatric or Psediatric) tw</td>
<td></td>
</tr>
<tr>
<td>14</td>
<td>10 or 11 or 12 or 13</td>
<td></td>
</tr>
<tr>
<td>15</td>
<td>Randomised Controlled Trial pt</td>
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</tr>
<tr>
<td>16</td>
<td>Controlled Clinical Trial pt</td>
<td></td>
</tr>
<tr>
<td>17</td>
<td>Randomised ab</td>
<td></td>
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<tr>
<td>18</td>
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<td></td>
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<td>19</td>
<td>Clinical trials as Topic ab</td>
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</tr>
<tr>
<td>20</td>
<td>Randomly ab</td>
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</tr>
<tr>
<td>21</td>
<td>Trial</td>
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<td>24</td>
<td>22 not 23</td>
<td>68,4382</td>
</tr>
<tr>
<td>25</td>
<td>9 and 14 and 24</td>
<td>29</td>
</tr>
</tbody>
</table>
Illustration 2

Flow Chart depicting selection process for studies included in this review

Total number of identified Studies (138)
(29 from MEDLINE, 109 from EMBASE, 0 from (CENTRAL + Manual search))

- Review of Abstracts
  - Studies with irrelevant PICO (106)
  - Studies with relevant PICO (3)

- 3 Full text articles retrieved
  - Review of Full text articles
  - 3 studies included 17, 18, 11
### Illustration 3

**Characteristics of included studies**

<table>
<thead>
<tr>
<th>Study Design</th>
<th>Patient Demographics</th>
<th>Intervention</th>
<th>Outcome</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shemshaki 19, RCT</td>
<td>46 Children(6-12yr olds), Iran Enrolled Feb 2009- Jan 2010(2 groups of 23 randomised to Hip spica or Titanium elastic nails (TEN) Inclusions; Simple femoral fractures in 6-12yr olds Exclusions; comminuted fractures, neuromuscular dx metabolic bone disease, pathological fractures.</td>
<td>TEN: Single Surgeon, Standardised Technique, Retrograde insertion of flexible nails Hip Spica: 3wks Traction + 4 wks Hip Spica, + Physiotherapy</td>
<td>Primary: Length of Hospital stay Secondary: Time to walking, Parents’ satisfaction Time off school</td>
<td>TEN group had: Shorter Hospital Stay(p&lt;0.001) Shorter time to walking (p&lt;0.001) Earlier return to school (p&lt;0.001) in comparison to Spica group No significant difference in infection or malunion rates between groups.</td>
</tr>
<tr>
<td>Bar-on 20, RCT</td>
<td>19 Children(20 fractures), Israel 2 groups of 10 randomised to External fixation(EF) or Flexible intramedullary nail(FIN) Inclusions; 5- 15yr olds with simple or mildly comminuted (Winquist I or II)or open(Gustilo I or II) femoral shaft fractures</td>
<td>FIN; Stainless steel or Titanium inserted closed and retrograde in most cases EF: Orthofix/AO Fixator</td>
<td>Duration of Operation Mean Fluoroscopy time Return to Full WB Return to FROM School</td>
<td>Duration of operation was longer in the FIN group (74 mins) vs EF group (56 mins). No p values given Mean Fluoroscopy Time was longer in the FIN grp (2.6 mins)vs EF grp(1.4mins). No p values given. Earlier return to full weight bearing, full range of movement and school in the FIN group.</td>
</tr>
<tr>
<td>Study Design</td>
<td>Patient Demographics</td>
<td>Intervention</td>
<td>Outcome</td>
<td>Results</td>
</tr>
<tr>
<td>--------------</td>
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</tr>
<tr>
<td>Hsu 21, Q-RCT</td>
<td>51 Children(5 -12yr olds), Philippines Quasi-Random (2 groups(26,25) randomised to Dynamic Skeletal Traction Spica Casting (DSTSC) or Elastic intramedullary nails (EIN) Inclusions; Simple femoral shaft fractures Exclusions; Multiple fractures, Open fractures(Gustilo II/III), pathological fractures, neurological disease, incomplete data</td>
<td>EIN; Standardized Technique, Retrograde insertion DSTSC: + Traction force of 3.5- 5.5kg for 3-4 wks Residual component of system removed after 8-10wks</td>
<td>3 Assessors (Not blinded) Primary: Hospital stay Total Cost Secondary: Radiological outcomes Complication rates</td>
<td>EIN group had longer hospital stay vs DSTSC(p=0.015) Total Costs were higher in the EIN group vs DSTSC(p=0.001) No significant difference in radiological outcomes or complication rates.</td>
</tr>
</tbody>
</table>
Illustration 4

Appendix

Appendix 1.

DATA EXTRACTION FORM
Study credentials
Study ID:
Citation + Contact Details:
Review Author:
Source of funding/Conflict of Interest:

ELIGIBILITY:
Eligible (Yes/No):
Rationale (PICO Summary):

STUDY CHARACTERISTICS
Study Design:
Total Study Duration:
Risk of bias:

PARTICIPANTS:
Size:
Setting:
Diagnostic criteria:
Age/Sex:
INTERVENTIONS:
Total number of intervention groups.
Details of Intervention (Explicit enough for duplication):

OUTCOMES
Primary Outcome (+Time collected + Reported):
Definition of Outcome/Diagnostic Criteria:
Unit of Measurement/Scales:
Secondary Outcomes:

RESULTS:
Number of participants in each intervention group:
Primary Outcome of Interest:
Sample size:
Loss to follow up:
Summary Data:
  Continuous, Mean (S.D):
  Dichotomous: 2 X 2 Tables:
Estimate of Effect + Confidence Interval + P value:
Subgroup Analyses:

CONCLUSION/COMMENTS (Study Author):
CONCLUSION/COMMENTS (Review Author):
Appendix 2

The Cochrane Collaboration’s tool for assessing risk of bias

<table>
<thead>
<tr>
<th>Domain</th>
<th>Support for judgement</th>
<th>Review authors’ judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Selection bias.</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Random sequence generation.</td>
<td>Describe the method used to generate the allocation sequence in sufficient detail to allow an assessment of whether it should produce comparable groups.</td>
<td>Selection bias (biased allocation to interventions) due to inadequate generation of a randomised sequence.</td>
</tr>
<tr>
<td>Allocation concealment.</td>
<td>Describe the method used to conceal the allocation sequence in sufficient detail to determine whether intervention allocations could have been foreseen in advance of, or during, enrolment.</td>
<td>Selection bias (biased allocation to interventions) due to inadequate concealment of allocations prior to assignment.</td>
</tr>
</tbody>
</table>
**Performance bias.**

| **Blinding of participants and personnel** | Describe all measures used, if any, to blind study participants and personnel from knowledge of which intervention a participant received. Provide any information relating to whether the intended blinding was effective. | Performance bias due to knowledge of the allocated interventions by participants and personnel during the study. |
| **Assessments should be made for each main outcome (or class of outcomes).** |

**Detection bias.**

| **Blinding of outcome assessment** | Describe all measures used, if any, to blind outcome assessors from knowledge of which intervention a participant received. Provide any information relating to whether the intended blinding was effective. | Detection bias due to knowledge of the allocated interventions by outcome assessors. |
| **Assessments should be made for each main outcome (or class of outcomes).** |
### Attrition bias.

<table>
<thead>
<tr>
<th>Incomplete outcome data</th>
<th>Assessments should be made for each main outcome (or class of outcomes).</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Describe the completeness of outcome data for each main outcome, including attrition and exclusions from the analysis. State whether attrition and exclusions were reported, the numbers in each intervention group (compared with total randomized participants), reasons for attrition/exclusions where reported, and any re-inclusions in analyses performed by the review authors.</td>
</tr>
<tr>
<td></td>
<td>Attrition bias due to amount, nature or handling of incomplete outcome data.</td>
</tr>
</tbody>
</table>

### Reporting bias.

<table>
<thead>
<tr>
<th>Selective reporting</th>
<th>State how the possibility of selective outcome reporting was examined by the review authors, and what was found.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Reporting bias due to selective outcome reporting.</td>
</tr>
</tbody>
</table>

**Other bias.**

<table>
<thead>
<tr>
<th>Other sources of bias.</th>
<th>State any important concerns about bias not addressed in the other domains in the tool. If particular questions/entries were pre-specified in the review’s protocol, responses should be provided for each question/entry.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Bias due to problems not covered elsewhere in the table.</td>
</tr>
</tbody>
</table>
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