AAOS
American Academy of Orthopaedic Surgeons

TREATMENT OF PEDIATRIC DIAPHYSEAL FEMUR FRACTURES EVIDENCE-BASED CLINICAL PRACTICE GUIDELINE

Adopted by the American Academy of Orthopaedic Surgeons Board of Directors

June 12, 2015

OrthoGuidelines

2015 REPORT FOR THE REISSUE OF THE 2009 CLINICAL PRACTICE GUIDELINE ON THE TREATMENT OF PEDIATRIC DIAPHYSEAL FEMUR FRACTURES

"This guideline is greater than 5 years old and is reviewed every five years. New studies have been published since this guideline was developed, however the AAOS has determined that these studies are not sufficient to warrant changing the guideline at this time. The information contained in this guideline provides the user with the best evidence available at the time this guideline was published."

OVERVIEW OF 2015 UPDATES TO THE 2009 ORIGINAL GUIDELINE

1) Addition of the Shemshaki, et al, 2011 study findings to Elastic Intramedullary Nails.
2) Updated strength of recommendation language to match current AAOS guideline language (see Grading the Recommendations).
3) Removed "inconclusive" recommendations due to lack of evidence (see Appendix XI)

For a user-friendly version of this clinical practice guideline, please visit the AAOS OrthoGuidelines Web-Based App at:
http://www.orthoguidelines.org

Disclaimer
This Clinical Practice Guideline was developed by an AAOS physician volunteer Work Group based on a systematic review of the current scientific and clinical information and accepted approaches to treatment and/or diagnosis. This Clinical Practice Guideline is not intended to be a fixed protocol, as some patients may require more or less treatment or different means of diagnosis. Clinical patients may not necessarily be the same as those found in a clinical trial. Patient care and treatment should always be based on a clinician's independent medical judgment, given the individual patient's clinical circumstances.

Disclosure Requirement
In accordance with AAOS policy, all individuals whose names appear as authors or contributors to Clinical Practice Guideline filed a disclosure statement as part of the submission process. All panel members provided full disclosure of potential conflicts of interest prior to voting on the recommendations contained within this Clinical Practice Guidelines.

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FDA Clearance
Some drugs or medical devices referenced or described in this Clinical Practice Guideline may not have been cleared by the Food and Drug Administration (FDA) or may have been cleared for a specific use only. The FDA has stated that it is the responsibility of the physician to determine the FDA clearance status of each drug or device he or she wishes to use in clinical practice.

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I. SUMMARY OF RECOMMENDATIONS

The original guideline on the Treatment of Pediatric Diaphyseal Femur Fractures (PDFF) was the third guideline developed by the AAOS in-house. It had fourteen recommendations of varying strengths. However, per current AAOS policy, all recommendations in the original guideline identified as "inconclusive" were removed from this 2015 reissue (see Appendix XI for a full list of the inconclusive recommendations that were removed). Based on the current procedure for updating AAOS guidelines, the Medical Librarian ran a preliminary search to identify literature that could address and possibly change the original recommendations. The AAOS Evidence-Based Medicine Unit then used the inclusion criteria from the original guideline to determine if any articles published after the final literature search date of the original guideline were relevant to the original recommendations.

The following is a summary of the recommendations in the AAOS' clinical practice guideline on the Treatment of Pediatric Diaphyseal Femur Fractures (PDFF). This summary does not contain rationales that explain how and why these recommendations were developed nor does it contain the evidence supporting these recommendations. All readers of this summary are strongly urged to consult the full guideline and evidence report for this information. We are confident that those who read the full guideline and evidence report will also see that the recommendations were developed using systematic evidence-based processes designed to combat bias, enhance transparency, and promote reproducibility. This summary of recommendations is not intended to stand alone.

Strength of Recommendation Descriptions

Strength	Overall Strength of Evidence	Description of Evidence Strength	Strength Visual
Strong	Strong	Evidence from two or more "High" strength studies with consistent findings for recommending for or against the intervention.	
Moderate	Moderate	Evidence from two or more "Moderate" strength studies with consistent findings, or evidence from a single "High" quality study for recommending for or against the intervention.	
Limited	Low Strength Evidence or Conflicting Evidence	Evidence from two or more "Low" strength studies with consistent findings **or** evidence from a single study for recommending for or against the intervention or diagnostic test or the evidence is insufficient or conflicting and does not allow a recommendation for or against the intervention.	
Consensus*	No Evidence	There is no supporting evidence. In the absence of reliable evidence, the work group is making a recommendation based on their clinical opinion. Consensus recommendations can only be created when not establishing a recommendation could have catastrophic consequences.	

CHILD ABUSE
Strong evidence supports that children younger than thirty-six months with a diaphyseal femur fracture be evaluated for child abuse.

Grade of Recommendation: Strong 

INFANT FEMUR FRACTURE
Limited evidence supports treatment with a Pavlik harness or a spica cast for infants six months and younger with a diaphyseal femur fracture, because their outcomes are similar.

Grade of Recommendation: Limited 

EARLY OR DELAYED SPICA CASTING
Moderate evidence supports early spica casting or traction with delayed spica casting for children age six months to five years with a diaphyseal femur fracture with less than 2 cm of shortening.

Grade of Recommendation: Moderate 

ELASTIC INTRAMEDULLARY NAILS
Limited evidence supports the option for physicians to use flexible intramedullary nailing to treat children age five to eleven years diagnosed with diaphyseal femur fractures.

Grade of Recommendation: Limited 

ORIF PEDIATRIC FEMUR FRACTURES
Limited evidence supports rigid trochanteric entry nailing, submuscular plating, and flexible intramedullary nailing as treatment options for children age eleven years to skeletal maturity diagnosed with diaphyseal femur fractures, but piriformis or near piriformis entry rigid nailing are not treatment options.

Grade of Recommendation: Limited 

PAIN CONTROL
Limited evidence supports regional pain management for patient comfort peri-operatively.

Grade of Recommendation: Limited 

WATERPROOF CASTING
Limited evidence supports waterproof cast liners for spica casts are an option for use in children diagnosed with pediatric diaphyseal femur fractures.

Grade of Recommendation: Limited 

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Table of Contents

List of Tables

List of Figures

II. INTRODUCTION

OVERVIEW

This clinical practice guideline presents the results of a systematic review of published studies on the treatment of isolated diaphyseal femur fractures in children, where children are defined as those not having reached skeletal maturity. In addition to providing practice recommendations, this guideline also highlights gaps in the literature and areas that require future research.

This guideline is intended to be used by all appropriately trained surgeons and all qualified physicians considering treatment of isolated diaphyseal femur fractures in children. It is also intended to serve as an information resource for decision makers and developers of practice guidelines and recommendations.

GOALS AND RATIONALE

The purpose of this clinical practice guideline is to help improve treatment based on the current best evidence. Current evidence-based practice (EBP) standards demand that physicians use the best available evidence in their clinical decision making. To assist in this decision making, this clinical practice guideline consists of a systematic review of the available literature on the treatment of isolated diaphyseal femur fractures in children. The systematic review detailed herein includes evidence published from 1966 through October 1, 2008 and demonstrates where there is good evidence, where evidence is lacking, and what topics future research must target in order to improve the treatment of children with isolated diaphyseal femur fractures. AAOS staff and the Pediatric Diaphyseal Femur Fractures physician work group systematically reviewed the available literature and subsequently wrote the following recommendations based on a rigorous, standardized process.

Musculoskeletal care is provided in many different settings by many different providers. We created this guideline as an educational tool to guide qualified physicians through a series of treatment decisions in an effort to improve the quality and efficiency of care. This guideline should not be construed as including all proper methods of care or excluding methods of care reasonably directed to obtaining the same results. The ultimate judgment regarding any specific procedure or treatment must be made in light of all circumstances presented by the patient and the needs and resources particular to the locality or institution.

INTENDED USERS

This guideline is intended to be used by orthopaedic surgeons and all qualified physicians managing pediatric patients. Typically, orthopaedic surgeons will have completed medical training, a qualified residency in orthopaedic surgery, and some may have completed additional sub-specialty training.

Treatment of pediatric diaphyseal femur fractures is based on the assumption that decisions are predicated on guardian and physician mutual communication with discussion of available treatments and procedures applicable to the individual patient. Once the patient's guardian has been informed of available therapies and has discussed

these options with his/her child's physician, an informed decision can be made. Clinician input based on experience with both conservative management and surgical skills increases the probability of identifying patients who will benefit from specific treatment options.

This guideline is not intended for use as a benefits determination document.

PATIENT POPULATION

This document addresses the treatment of isolated diaphyseal femur fractures in children who have not yet reached skeletal maturity. The guideline provides information on pediatric patient management after diagnosis of a diaphyseal femur fracture. This guideline is not intended for use in pediatric patients who present with additional coexisting injuries that require formal surgical intervention or other life-threatening conditions that take precedence over the treatment of the diaphyseal femur fracture.

INCIDENCE

The annual rate of children who present with femoral shaft fracture has been estimated at 19 per 100,000.[1] Boys have a higher risk of fracture than girls and this is consistent with participation of boys in sporting activites.[1,2]

PREVALENCE

Diaphyseal femur fractures account for 1.4%[3] to 1.7%[4] of all pediatric fractures.

BURDEN OF DISEASE

There are many components to consider when calculating the overall cost of treatment for pediatric femoral fracture.[5] The main considerations for patients and third party payers are the relative cost and effectiveness of each treatment option. But hidden costs for pediatric patients must also be considered. These costs include the additional home care required for a patient, the costs of rehabilitation and of missed school for the patient, child care costs if both parents work, and time off of work required by one or both parents to care for the pediatric patient.[6]

ETIOLOGY

The primary cause of diaphyseal femur fracture in children varies by age groups but includes falls, motor-vehicle accidents, and sports injuries.[1] In addition, the Cincinnati Children's Hospital Medical Center states, "In children less than one year of age, child abuse is the leading cause of femoral fractures and abuse remains a significant concern in toddlers up to about five years of age."[7]

RISK FACTORS

Occurrences of pediatric diaphyseal femur fractures are higher in boys than in girls in all age groups.[1,2] This literature also suggests that the primary mechanism of fracture is age-related, including falls and child abuse for younger children, falls, motor vehicle-pedestrian, bicycle, and motor-vehicle collisions for school age children and motor-vehicle or sports related accidents in teenagers.

One study suggests increased risk of fracture for blacks over whites[1] and one study suggests no difference by race/ethnicity.[2] Both studies suggest that lower socioeconomic conditions also increase fracture risk.

EMOTIONAL AND PHYSICAL IMPACT OF PEDIATRIC DIAPHYSEAL FEMUR FRACTURES

The prolonged loss of mobility and absence from school often associated with the treatment of pediatric diaphyseal femur fractures can lead to adverse physical, social, and emotional consequences for the child as well as the child's family. Treatments that minimize the child's length of immobilization and time out of school are therefore desirable.

POTENTIAL BENEFITS, HARMS, AND CONTRAINDICATIONS

Invasive and operative treatments are associated with known risks. Contraindications vary widely based on the treatment administered. Therefore, discussion of available treatments and procedures applicable to the individual patient rely on mutual communication between the patient's guardian and physician, weighing the potential risks and benefits for that patient.

Further, the age groups referred to in the specific recommendations are general guides. Obviously, additional factors may affect the physician's choice of treatment including but not limited to associated injuries the patient may present with as well as the individual's comorbidities, skeletal maturity, and/or specific patient characteristics including obesity. The individual patient's family dynamic will also influence treatment decisions; therefore, treatment decisions made for children who border any age group should be made on the basis of the individual. Decisions will always need to be predicated on guardian and physician communication with discussion of available treatments and procedures applicable to the individual patient. Once the patient's guardian has been informed of available therapies and has discussed these options with his/her child's physician, an informed decision can be made. Clinician input based on experience increases the probability of identifying patients who will benefit from specific treatment options.

III. METHODS

This clinical practice guideline and the systematic review upon which it is based evaluate the effectiveness of treatments for isolated pediatric diaphyseal femur fractures. This section describes the methods used to prepare this guideline and systematic review, including search strategies used to identify literature, criteria for selecting eligible articles, grading the evidence, data extraction, methods of statistical analysis, and the review and approval of the guideline. The methods used to perform this systematic review were employed to minimize bias in the selection and summary of the available evidence.[8,9] These processes are vital to the development of reliable, transparent, and accurate clinical recommendations for treating isolated diaphyseal femur fractures in children.

To develop the original guideline, the work group initially met in an introductory meeting on April 5, 2008, to establish the scope of the guideline and systematic review. Upon completion of the systematic review the work group participated in a two-day recommendation meeting on November 8 and 9, 2008, at which the final recommendations were written and voted on. The resulting draft guidelines were then peer-reviewed, subsequently sent for public commentary, and then sequentially approved by the AAOS Evidence Based Practice Committee, AAOS Guidelines and Technology Oversight Committee, AAOS Council on Research, Quality Assessment, and Technology, and the AAOS Board of Directors.

GUIDELINE REISSUE

The original guideline and systematic review were prepared by the AAOS Pediatric Diaphyseal Femur Fractures physician work group with the assistance of the AAOS Clinical Practice Guidelines Unit. Based on the current procedure for updating AAOS guidelines, the Medical Librarian ran an updated search to identify literature published after the original search for the 2007 guideline that could address and possibly change the original recommendations. The AAOS Evidence-Based Medicine Unit then used the inclusion criteria from the original guideline to determine if any articles published after the final literature search date of the original guideline were relevant to the recommendations. The resulting reissue draft was then sequentially approved by the AAOS Committee on Evidence Based Quality and Value, the AAOS Council on Research and Quality and the AAOS Board of Directors (see Appendix I).

PRELIMINARY RECOMMENDATIONS

The original work group began work on this guideline by constructing a set of preliminary recommendations. These recommendations specify [what] should be done in [whom], [when], [where], and [how often or how long]. They function as questions for the systematic review, not as final recommendations or conclusions. Simulated recommendations are almost always modified on the basis of the results of the systematic review. These recommendations also form the guideline's scope and guide the searches for literature. These *a priori* simulated recommendations are inviolate in that, once specified, they cannot be modified, they must all be addressed by the systematic review, and the relevant review results must be presented in the final guideline. The *a priori* and inviolate nature of the preliminary recommendations combats bias.

STUDY SELECTION CRITERIA

TYPES OF STUDIES

We developed *a priori* article selection criteria for our review. Specifically, to be included in our systematic reviews an article had to be a report of a study that:

- Evaluated a treatment for isolated pediatric diaphyseal femur fracture.
- Was a full article published in the peer reviewed literature.
- Was an English language article published after 1965.
- Was not a cadaveric, animal, or in vitro study.
- Was not a retrospective case series, medical records review, meeting abstract, unpublished study report, case report, historical article, editorial, letter, or commentary.
- Was the most recent report of a study or the report with the largest number of enrolled patients in a study with multiple publications.
- Enrolled ≥ 10 patients in each of its study groups.
- Enrolled a patient population of at least 80% of patients with a diaphyseal femur fracture and were not skeletally mature (closure of proximal and distal femoral growth plates).
- Reported quantified results.
- Enrolled patients without the following conditions
  - subtrochanteric fractures, supracondylar femur fractures, physeal fractures, open fractures, compound fractures, pathologic fractures, or multiple lower extremity fractures.
  - co-existing abdominal or neurological injuries requiring surgical intervention (the physician work group chair and co-chair determined whether an article met inclusion criteria in cases when studies reported insufficient detail to determine whether co-existing injuries required surgical intervention).
  - osteogenesis imperfecta, cerebral palsy, myelodysplasia (spina bifida), metabolic bone diseases, or skeletal dysplasia.

When examining primary studies, we analyzed the best available evidence regardless of study design. We first considered the randomized controlled trials identified by the search strategy. In the absence of two or more RCTs, we sequentially searched for prospective controlled trials, prospective comparative studies, retrospective comparative studies, and prospective case-series studies. Only studies of the highest level of available evidence were included, assuming that there were 2 or more studies of that higher level. For example, if there were two high quality studies that addressed the recommendation, moderate, low, and very low quality studies were not included.

For the recommendation on waterproof cast liners only, we considered for inclusion studies that included patients with conditions other than diaphyseal femur fractures

because the complications potentially avoided by using waterproof liners are not specific to diaphyseal femur fractures.

The Pediatric Diaphyseal Femur Fracture physician work group requested that the AAOS guidelines unit capture surrogate outcome measures if the study inclusion criteria were met. For this patient population, children, surrogate outcomes are often used because patients' communication skills are limited or not yet developed. Surrogate outcome measures are laboratory measurements or another physical sign that are used as substitutes for clinically meaningful end points that measure directly how a patient feels, functions, or survives.[10] In order for a surrogate measure to be valid, it must be in the causal pathway between the intervention and the outcome and it must demonstrate a large, consistently measurable association with the outcome.[10]

The main surrogate measures we considered were radiographic measures, such as those indicating a malunion of the fracture. It should be noted that generally accepted definitions of malunion have not necessarily been correlated to function and risk of developing further problems.

We only considered an outcome if ≥ 50% (80% for case series) of the patients were followed for that outcome (for example, some studies reported short-term outcomes data on nearly all enrolled patients, and reported longer-term data on only a few patients. In such cases, we did not include the longer-term data). We also excluded outcomes for study groups that did not have at least 10 patients.

When distinguishing between stable and unstable fractures, we defined transverse and short oblique fractures as stable. We defined comminuted and long oblique fractures as unstable.

When the age range of patients in a study overlapped the target age range of two or more recommendations, we included the study in the evidence base of the recommendation whose age range included the study's median patient age.

ORIGINAL AND UPDATED LITERATURE SEARCHES

The updated guideline searched for articles published up to November 27, 2013. The original guideline searched for articles published up to October 1, 2008. Search strategies were reviewed by the original work group prior to conducting the searches. All literature searches were supplemented with manual screening of bibliographies of all publications retrieved. We also searched the bibliographies of recent systematic reviews and other review articles for potentially relevant citations. A list of potentially relevant studies, not identified by the literature search, was also provided by the work group members. Three such studies met the inclusion criteria. We conducted one recommendation-specific search for primary articles on waterproof cast liners. For the entire guideline, thirty-two primary studies were included and two hundred forty-three studies were excluded.

SEARCH FOR RCTS AND OTHER STUDY DESIGNS

To identify primary studies for this guideline, we searched four electronic databases; PubMed, EMBASE, CINAHL, and The Cochrane Central Register of Controlled Trials. The search strategies we used are provided in Appendix II.

We used a previously published search strategy [11] to identify relevant randomized controlled trials. In the absence of relevant RCTs, we modified the search strategy to identify studies of other designs.

The study attrition diagram in Appendix I provides details about the inclusion and exclusion of these studies.

DATA EXTRACTION

Data elements extracted from studies were defined in consultation with the physician work group. Three reviewers completed data extraction independently for all studies. Disagreements were resolved by consensus and by consulting the work group. Evidence tables were constructed to summarize the best evidence pertaining to each preliminary recommendation. The elements extracted are shown in Appendix IV.

GRADING THE RECOMMENDATIONS

Following data extraction and analyses, each guideline recommendation was assigned a preliminary grade that was based on the total body of evidence available using the following system:

Table 1. Grade of Recommendation Description

Strength	Overall Strength of Evidence	Description of Evidence Strength	Strength Visual
Strong	Strong	Evidence from two or more "High" strength studies with consistent findings for recommending for or against the intervention.	
Moderate	Moderate	Evidence from two or more "Moderate" strength studies with consistent findings, or evidence from a single "High" quality study for recommending for or against the intervention.	
Limited	Low Strength Evidence or Conflicting Evidence	Evidence from two or more "Low" strength studies with consistent findings **or** evidence from a single study for recommending for or against the intervention or diagnostic test or the evidence is insufficient or conflicting and does not allow a recommendation for or against the intervention.	
Consensus*	No Evidence	There is no supporting evidence. In the absence of reliable evidence, the work group is making a recommendation based on their clinical opinion. Consensus recommendations can only be created when not establishing a recommendation could have catastrophic consequences.	

Each recommendation was constructed using the following language which took into account the final grade of recommendation.

Table 2 AAOS Guideline Language

Guideline Language	Strength of Recommendation
Strong evidence supports that the practitioner should/should not do X, because…	Strong
Moderate evidence supports that the practitioner could/could not do X, because…	Moderate
Limited evidence supports that the practitioner might/might not do X, because…	Limited
In the absence of reliable evidence, it is the ***opinion*** of this work group that…*	Consensus*

STATISTICAL METHODS

We calculated, where applicable, odds ratios (OR) for dichotomous data and mean differences for continuous data.

When published studies only reported the median, range and size of the trial, we estimated their means and variances according to a published method.[13]

We used StatXact for the calculation of exact odds ratios confidence intervals for dichotomous data. All other calculations were performed using STATA 10.0 (StataCorp LP, College Station, Texas). We used the Wilson score method to calculate confidence intervals for proportions.[14] For ordinal data, we used ordinal logistic regression to calculate odds ratios. Ordinal logistic regression produces proportional odds ratios, which assumes that the odds ratio is the same between each pair of outcome groups (lowest category vs. all higher categories, lowest two categories vs. all higher categories, etc.).

PEER REVIEW

The original draft of the guideline and evidence report were peer reviewed by an expert outside advisory panel that was nominated by the physician work group prior to the development of the guideline (Appendix VI). In addition, the physician members of the AAOS Guidelines and Technology Oversight Committee and the Evidence Based Practice Committee provided peer review of the draft document. Peer review was accomplished using a structured peer review form. (Appendix VII) We forwarded the draft guideline to a total of thirty-three reviewers and eleven returned reviews. The disposition of all non-editorial peer review comments was documented and accompanied this guideline through the public commentary and the following approval process.

PUBLIC COMMENTARY

After modifying the draft in response to peer review, the original guideline was subjected to a thirty day period of "Public Commentary." Commentators consist of members of the AAOS Board of Directors (BOD), members of the Council on Research, Quality Assessment, and Technology (CORQAT), members of the Board of Councilors (BOC),

and members of the Board of Specialty Societies (BOS). Based on these bodies, up to 185 commentators had the opportunity to provide input into the development of this guideline. Of these, 12 returned public comments.

THE AAOS GUIDELINE APPROVAL PROCESS

Following peer review, the 2009 CPG was approved by the AAOS Guidelines and Technology Oversight Committee, the AAOS Evidence Based Practice Committee, the AAOS Council on Research, Quality Assessment and Technology, and the AAOS Board of Directors.

The 2015 Guideline Reissue was approved by the AAOS Committee on Evidence Based Quality and Value, the AAOS Council on Research and Quality and the AAOS Board of Directors. Descriptions of these bodies are provided in Appendix I.

REVISION PLANS

This guideline represents a cross-sectional view of current treatment and will become outdated when more sophisticated tests, more objective assessments, and more rigorous differential diagnoses are possible. Linkage to other disorders, genetic diagnosis, and occupational and human factors literature will contribute to our understanding of pediatric diaphyseal femur fractures.

Because of the pediatric population, changing medical reimbursement practices by all payors, and the high level of interest in this topic, the guideline will be revised in accordance with changing practice, rapidly emerging treatment options, new technology, and new evidence. This guideline will be revised or withdrawn in five years in accordance with the standards set forth by the National Guidelines Clearinghouse.

GUIDELINE DISSEMINATION PLANS

Dissemination of the guideline is coordinated by the vice-chair of physician work group and the AAOS Evidence Based Quality and Value Coordinator. Dissemination efforts vary by guideline. Publication of most guidelines is announced by an Academy press release and corresponding articles authored by the vice chair and published in the Journal of the American Academy of Orthopaedic Surgeons and AAOS Now.

For selected guidelines, dissemination also includes developing a webinar, developing an Online Module for the Orthopaedic Knowledge Online website, producing a Radio Media Tour and producing Media Briefings. The guideline is also distributed at the AAOS Annual Meeting in various venues such as Academy Row and Committee Scientific Exhibits. It will also be distributed at applicable Continuing Medical Education (CME) courses and the AAOS Resource Center.

Other dissemination efforts outside the Academy will include submission of the guideline to the National Guideline Clearinghouse and distribution at other medical specialty societies' meetings.

IV. **RECOMMENDATIONS AND SUPPORTING DATA**

CHILD ABUSE

Strong evidence supports that children younger than thirty-six months with a diaphyseal femur fracture be evaluated for child abuse.

Grade of Recommendation: Strong ★★★★

Figures relevant to this recommendation are: Figure 1
Tables relevant to this recommendation are: Table 3

RATIONALE

Our systematic review identified three high quality population-based studies that identified femur fractures in children caused by child abuse from three different registries. Two of these studies[1,2] reported 14% and 12% of the fractures were the result of abuse in children zero to one year old and zero to three years old, respectively. The third study reported that only two (2%) of the fractures were caused by abuse among children zero to 15 years old, which would correspond to 13% if both of these fractures occurred in children zero to one year old.

The work group recognizes that the most important elements in evaluating a child for abuse are a complete history and physical exam with attention to the signs and symptoms of child abuse. The work group defines "evaluating" a child for abuse however, as not only these routine elements, but also including direct communication with the patient's pediatrician or family doctor, consultation with the child abuse team at institutions where this may be available, and selective ordering of a skeletal survey by the orthopaedist *when considered appropriate by the treating physician*. In cases of possible child abuse, these professionals can add valuable input, based on experience, which increases the probability of identifying patients who may be at increased risk.[15]

In addition, the work group emphasizes that children who are not yet walking and sustain a femur fracture are at particular risk for abuse[7], so one must make every attempt to identify these patients. One of the studies[2] reports 48 of 49 child abuse-related femur fractures occurred in the less than three year old age group. This author found that in 332 femur fractures in children 0-3 years of age forty-eight of them were due to abuse. Accordingly, there were 451 children, four to twelve years of age, who had femur fractures and only one child in this age group was confirmed as abused. There were no cases of child abuse identified in the thirteen to seventeen year old age group. The work group acknowledges that this study is not exclusively reporting data on shaft fractures and has isolated the data specific to shaft fracture in the following data tables. However, the study does illustrate the need to focus on the patients who are less than three years old.

Estimates of child abuse suggest that the incidence is underreported and the consequences of missing it result in serious complications including death.[2]

SUPPORTING EVIDENCE

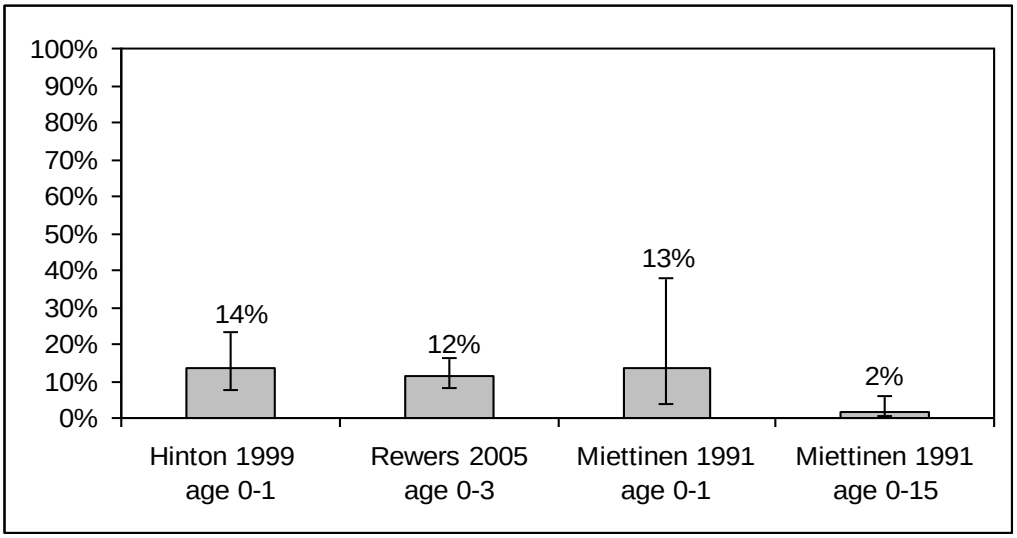
Three population-based studies reported data addressing this recommendation. Hinton et al.[1] used the Hospital Discharge Database of the Maryland Health Services Cost Review Commission from 1990-1996, Rewers et al.[2] used the Colorado Trauma Registry from 1998-2001, and Miettinen et al.[16] used a medical information register for University Central Hospital in Kuopio, Finland from 1976-1985.

Table 3. Incidence of Diaphyseal Femur Fractures Caused by Child Abuse

Study	Age Group	Fractures	Fractures Caused by Child Abuse	% of Fractures Caused by Child Abuse
Miettinen	0-15 yrs.	114	2	2%
Rewers	0-3 yrs.	243	28	12%
Miettinen	0-1 yr.	15	Not Reported specific to this age group*	Up to 13%
Hinton	0-1 yr.	73	10	14%

* The authors of this study, Miettinen H., Makela E. A., and Vainio J. (1991), actually reported 2 cases of child abuse in 114 patients, one boy and one girl, 0-15 years of age. While they reported the incidence by age and gender, the authors did not report the distribution by cause of injury. For this calculation, the assumption was therefore made that both cases of child abuse that were reported, occurred in the 0-1 year old age group.

Figure 1. Incidence of Diaphyseal Femur Fractures Caused by Child Abuse



*AAOS computed the 95% Confidence Intervals from published data

INFANT FEMUR FRACTURE

Limited evidence supports treatment with a Pavlik harness or a spica cast for infants six months and younger with a diaphyseal femur fracture, because their outcomes are similar.

Grade of Recommendation: Limited ★★☆☆

Figures relevant to this recommendation are: Figure 2

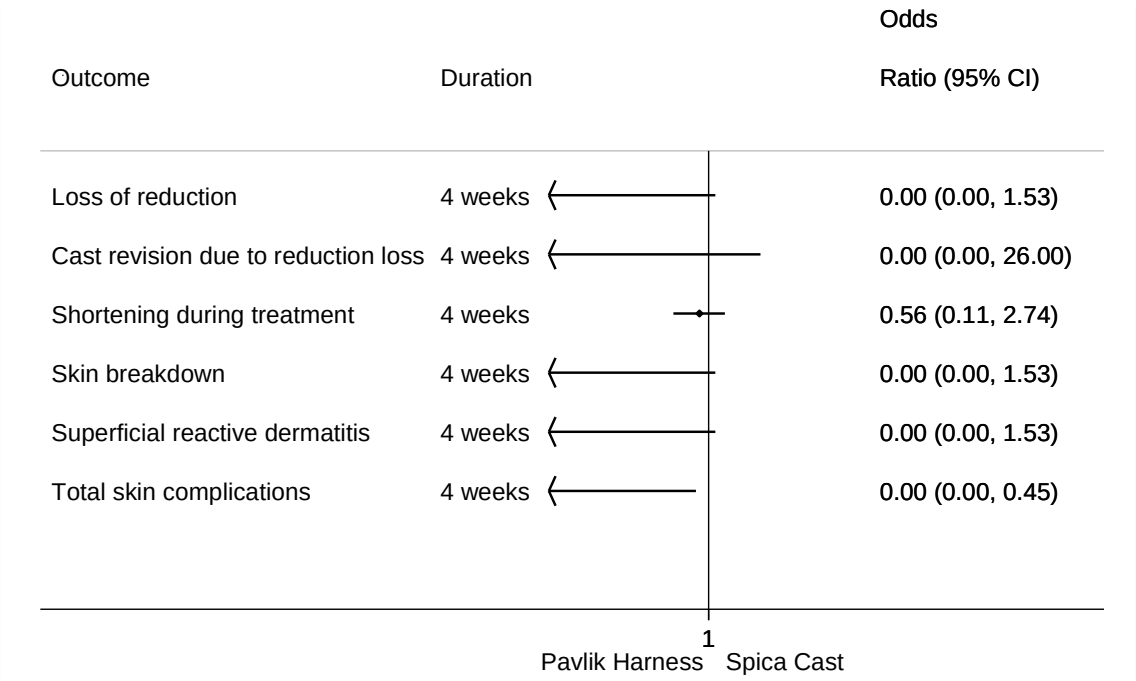
RATIONALE

The first 6 months of a child's life is a time of most rapid growth. Because of this, rapid healing of diaphyseal femur fractures and post-fracture skeletal remodeling is maximal. Hence spontaneous, complete correction after fracture healing is expected. Due to the rapid union and complete remodeling, treatment of diaphyseal femur fractures centers on assuring ease of patient care and minimizing treatment complications. Both Pavlik harnesses and spica casts result in good outcomes with minimal complications. In the studies we reviewed, the only identifiable difference between these two treatments was more frequent skin complications in the spica cast group. Because this is a minor and correctable issue that does not cause long-term problems or disability, either type of treatment is an option.

SUPPORTING EVIDENCE

Two studies addressed this recommendation. One retrospective comparative study[17] compared the Pavlik harness to a spica cast, and one case series examined Pavlik harnesses.[18] The case series reported that all 16 patients achieved stable union by 5 weeks in a Pavlik harness. In the comparative study, the spica cast group had significantly more skin complications ($p<.01$) than the Pavlik harness group, but there were no other statistically significant differences between groups. The Pavlik harness group was significantly younger ($p=.028$), with an average age of 3.6 months versus an average age of 6.5 months in the spica cast group.

Figure 2. Pavlik Harness vs. Spica Cast



Note on figures: Appendix contains information on how to interpret forest plots such as the one above as well as explanations of symbols used in this guideline's figures and tables.

EARLY OR DELAYED SPICA CASTING

Moderate evidence supports early spica casting or traction with delayed spica casting for children age six months to five years with a diaphyseal femur fracture with less than 2 cm of shortening.

Grade of Recommendation: Moderate 

Figures relevant to this recommendation are: Figure 3 - Figure 7
Tables relevant to this recommendation are: Table 4

RATIONALE

Two studies compared the use of early spica casting with traction followed by spica casting. There were significantly more infections in the traction group and more spica softening and plaster breakage in the early spica group.[19] There were no statistically significant differences between the treatment groups in time to union, femoral shortening, malalignment, or malrotation.[19,20]

Based on the summary of evidence, we did not find conclusive evidence that one modality of treatment (spica casting or traction) was superior and no studies compared flexible nails to spica casting in this age group. We suggest using early spica casting for social and economic considerations, specifically in relative ease of care and decreased length of hospital stay.[21] While the work group suggests early spica for children in this age group, traction may be appropriate in some cases. This recommendation does not suggest against the use of traction. In keeping with current best medical practice, we further suggest careful clinical and radiographic follow-up during the course of treatment.

In addition, no trial has specifically examined children in the age group of 4-5 years. A third study[22] indicates that in children as young as four more malunions occur with spica casting than with external fixation. Treatment decisions made on children who border any age group should be made on the basis of the individual. Until further research clarifies the possible harms associated with any treatment in this age group, decisions will always need to be predicated on guardian and physician mutual communication with discussion of available treatments and procedures applicable to the individual patient. Once the patient's guardian has been informed of available therapies and has discussed these options with his/her child's physician, an informed decision can be made. Clinician input based on experience increases the probability of identifying patients who will benefit from specific treatment options.

SUPPORTING EVIDENCE

Two High Quality studies addressed this recommendation. One study[20] included patients 2-10 years old, with 54% of the patients between ages 2-5. The other study[19] included patients 9 months – 10 years old, with a mean age in both groups of 3.5 years.

One High quality study,[22] with a mean patient age of 6 years old, but that addressed harms in children as young as 4 was also included to address this recommendation. (See Recommendation 8)

Summary of Evidence

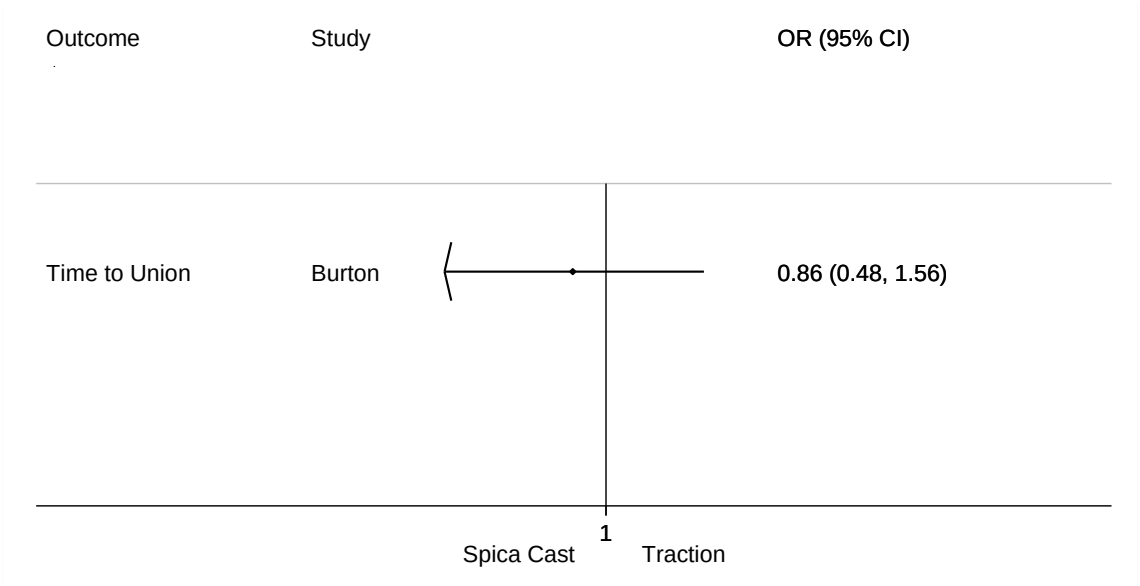
Table 4. Summary of Evidence

Author	Level of Evidence	n	Comparison	Outcome (follow-up duration)	Result
Burton	High	183	Spica Cast vs. Traction	Time to Union (n/a)	○
Burton	High	183		Shortening (at Union)	○
Rasool	High	170		Shortening at (6 wk)	○
Burton	High	183		Varus angulation (at Union)	○
Rasool	High	170		Varus angulation (6 wk)	○
Burton	High	183		Valgus angulation (at Union)	○
Rasool	High	170		Valgus angulation (6 wk)	○
Burton	High	183		Anterior Bowing (at Union)	○
Rasool	High	170		Anterior Bowing (6 wk)	○
Burton	High	183		Posterior Bowing (at Union)	○
Rasool	High	170		Posterior Bowing (6 wk)	○
Rasool	High	170		Infectious disease contraction (6 wk)	● sc
Rasool	High	170		Pressure from ring of splint (6 wk)	○
Rasool	High	170		Blisters (6 wk)	○
Rasool	High	170		Spica softening (6 wk)	● t
Rasool	High	170		Plaster breakage (6 wk)	● t
Rasool	High	170		Soilage (6 wk)	○

● = result is statistically significant n/a = not applicable sc = spica cast

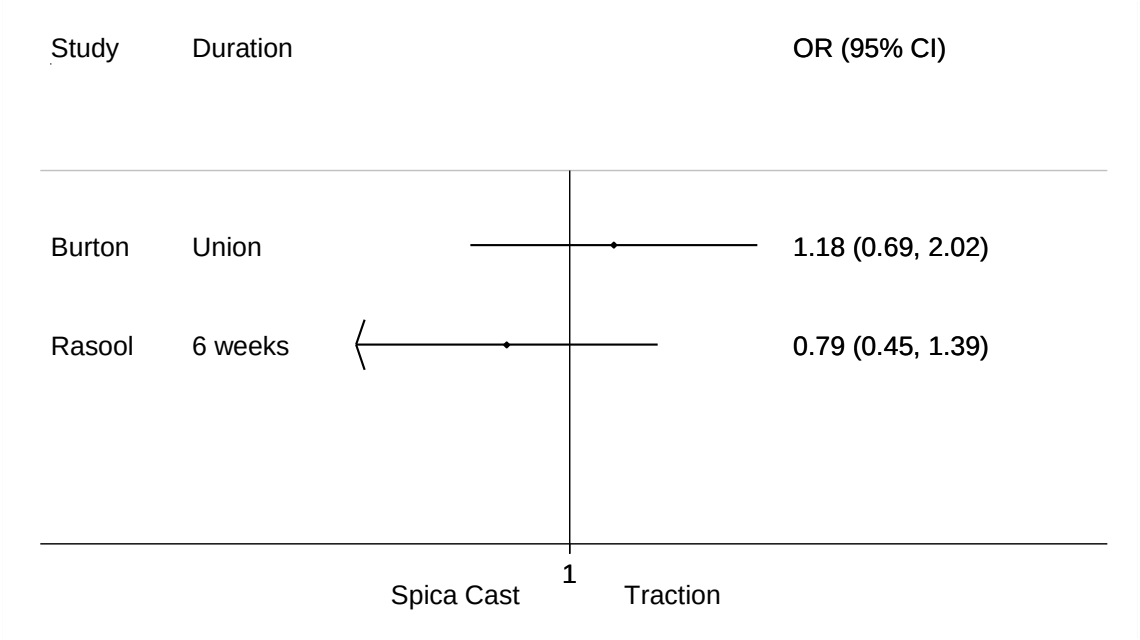
○ = result is not statistically significant nr = not reported t = traction

Figure 3. Time Immobilized (Time to Union)



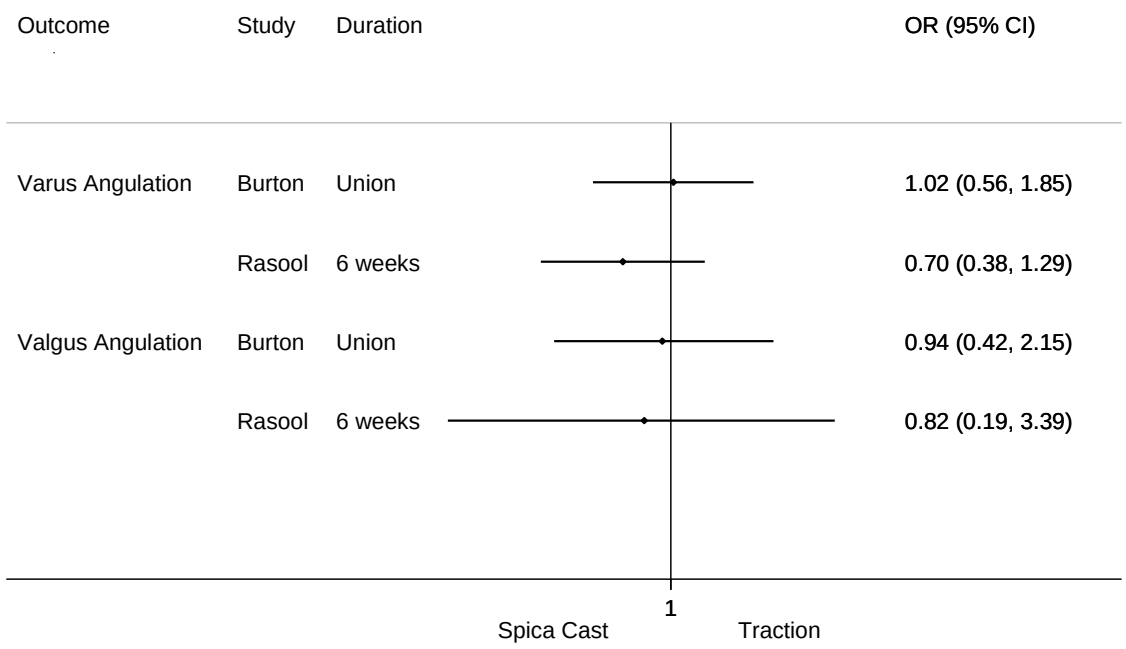
*Odds Ratio from ordered logistic regression (AAOS calculation)

Figure 4. Shortening



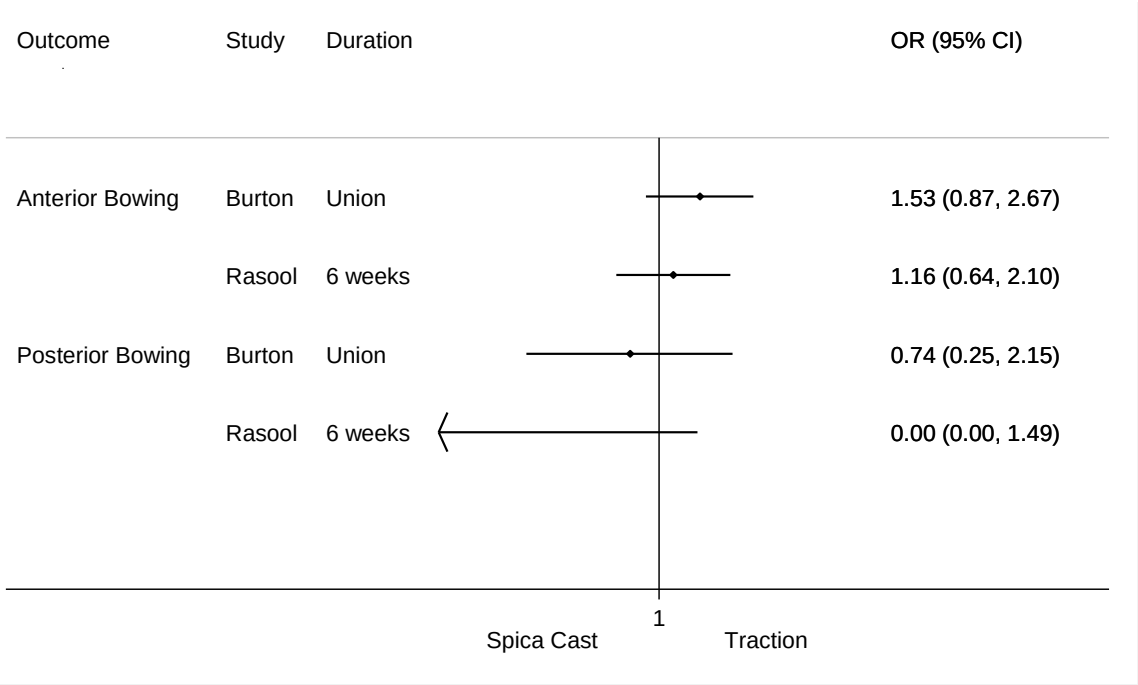
*Odds Ratios from ordered logistic regression (AAOS calculation)

Figure 5. Angulation



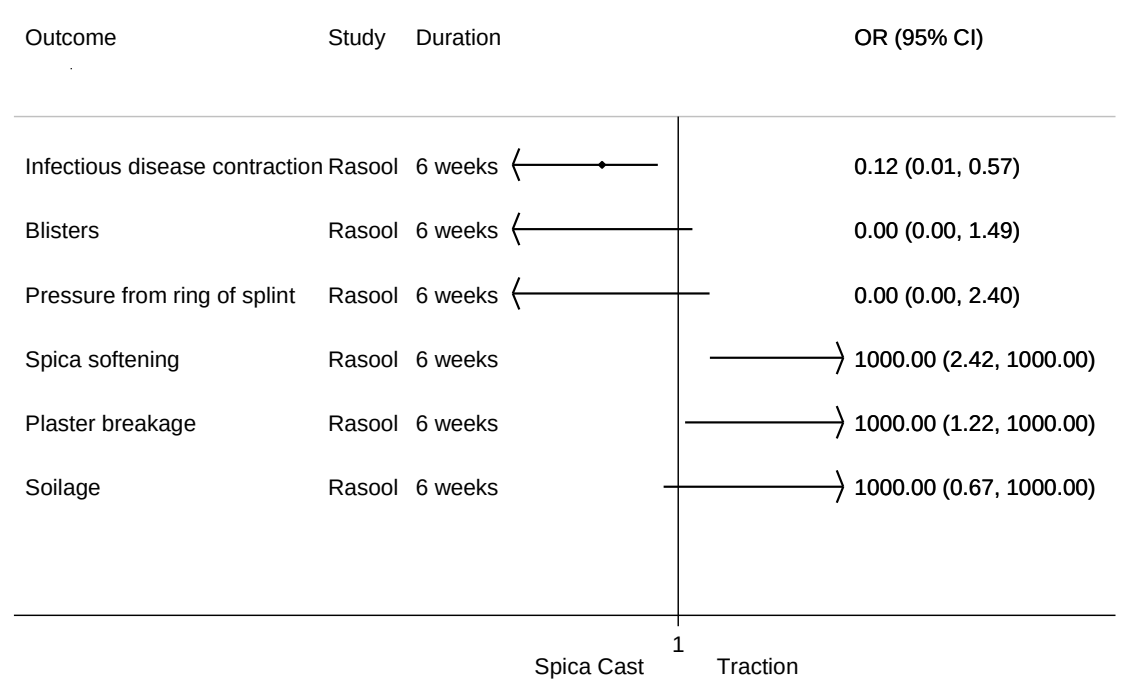
*Odds Ratios from ordered logistic regression (AAOS calculation)

Figure 6. Bowing



*Anterior Bowing Odds Ratios from ordered logistic regression (AAOS calculation)

Figure 7. Complications



PREVIOUSLY PUBLISHED SYSTEMATIC REVIEWS

Two previous systematic reviews[21,23] concluded that early spica casting was associated with shorter inpatient hospital stays and fewer adverse events than traction. Both of these reviews, however, were not specific to the population of interest for this recommendation, so we did not include them in our systematic review.

ELASTIC INTRAMEDULLARY NAILS

Limited evidence supports the option for physicians to use flexible intramedullary nailing to treat children age five to eleven years diagnosed with diaphyseal femur fractures.

Grade of Recommendation: Limited 

Figures relevant to this recommendation are: Figure 8 - Figure 31
Tables relevant to this recommendation are: Table 6 - Table 11

RATIONALE

There are few statistically significant differences between treatments in healing of the fracture. The evidence reviewed included ten studies that examined one hundred varying outcomes. Of these one hundred outcomes twenty-one were significant. There were no studies that directly compared flexible nails to spica casting. When flexible nails were compared to external fixation and traction plus casting, nine outcomes were significant favoring flexible nails, one significant outcome favored external fixation and one significant outcome favored traction plus casting. (Please refer to Tables 6 and 7 below.)

The high quality study[22] found to address this recommendation compared external fixation to spica casting. External fixation was favored over spica casting for malunions, including anterior/posterior angulation. Twelve other outcomes for this comparison had non-significant results.

In summary, the overall body of evidence considered for this recommendation indicates that there are few significant outcomes when all comparisons are considered. Further, important comparisons have not been investigated (spica casting and flexible nails).

Two moderate quality studies[24, 50] shows more rapid return to walking and school with flexible intramedullary nailing and one low quality study[25] illustrates less associated hospital costs when compared to traction and casting. The ability to mobilize the patient, return them to school rapidly, and suggested decrease in hospital costs leads the work group to suggest flexible intramedullary nailing over traction followed by casting. There is evidence that flexible intramedullary nailing has less adverse events and more rapid return to school than external fixation in both stable and unstable fractures.[26]

In making this recommendation, the work group acknowledges that they are including their expert opinion and they have therefore, downgraded the Grade of this Recommendation to a “limited” recommendation. Based on the advantages suggested, less adverse events and more rapid return to school, flexible intramedullary nailing is a treatment option for children five to eleven years diagnosed with diaphyseal femur fractures.

There is currently insufficient literature in specially designed pediatric rigid intramedullary nails and bridge plating for inclusion in the current guideline.

Patients over age 11 or with weight over 49 kg are at increased risk of a poor outcome[27] with flexible intramedullary nailing. The mean weight between patients with a poor outcome and those with an excellent or satisfactory outcome was significant, but weight was not independent of age and had a sensitivity of only 59% in predicting poor outcomes.

SUPPORTING EVIDENCE

One High quality study,[22] six moderate quality studies[24,28-31, 50] and eight low quality studies[25,26,32-37] addressed this recommendation. Low quality studies are included in this recommendation because they examine treatments not compared in the high and moderate quality studies. The average age of the patients enrolled in these studies was 4-11 years but ten studies included patients outside of this range.

One very low quality study[27] addressed the issue of patient weight as a criterion for the use of flexible nailing in this age group by comparing the weight of patients with an excellent or satisfactory outcome to the weight of patients with a poor outcome. Sixty percent (60%) of the patients in this study were less than 11 years old. The 15 kg difference in mean weight between patients with a poor outcome and those with an excellent or satisfactory outcome was statistically significant according to the author's calculations (p=.003). Moreover, using a cut-off point of 49 kg, heavier patients were about five times more likely than lighter patients to have poor outcomes. However, the investigators found that weight did not independently predict a poor outcome when age was also included in a logistic regression model. The investigators also found that the weight cut-off point had 78.5% specificity and 59% sensitivity for detecting a poor outcome.

Table 5. Summary of Updated Findings for Titanium Elastic Nailing

Study	Quality	N	Comparison	Outcome	Author p-value	Result
Shemshaki,H.R., 2011	Moderate	46	TEN vs. Traction + spica casting	Hopital Stay (days)	<0.001	TEN
				Time to start walking with aids(days)	<0.001	TEN
				Time to start walking independently (days)	<0.001	TEN
				Time to return to school (days)	<0.001	TEN
				Knee range of motion (degrees)	0.078	NS
				Malunion	0.117	NS
				Infection	0.117	NS
				Parent satisfaction-excellent	0.003	TEN

Table 6. Flexible Intramedullary Nailing and Patients' Weight

Treatment	n	Mean weight (excellent/satisfactory outcome)	Mean weight (poor outcome)	p-value
Titanium Elastic Nailing	222	39 kg (range 17 to 95.2)	54 kg (range 22.3 to 95.2)	0.003

Summary of Evidence:

For summary of significant outcomes see Table 7 on page 23.
For summary of nonsignificant outcomes see Table 8 on page 24.
For summary of High quality evidence see Table 9 on page27.
For summary of High Qualityevidence see Table 10 on page 28.
For summary of High Quality evidence see Table 11 on page 30.

Table 7. Summary of Significant Outcomes with Level of Evidence

TREATMENT FAVORED

	Flexible Nails	***External Fixation***	***Spica Cast***	***Traction (+ Casting)***
Flexible Nails	N/A	Loss of movement at knee (post-op)/III		Irritation at nail entry site/II
External Fixation	Time to full knee movement/III Return to school/III	N/A	Duration of treatment/I Pin-tract infections/I	Duration of treatment/III Duration of treatment/III
Spica Cast		Malunion/I Anterior/Posterior Angulation/I	N/A	
Traction (+ Casting)	Walking with aids/II Walking independently/II Walking independently/II Return to school/II Angular deformity/III Flynn's outcome/III Acceptable scar/III	Patient satisfaction/III	Blisters/superficial ulcers/II Knee flexion contraction/II Overall short-term complications/II	N/A

*Number of outcomes examined: 100
**Number of significant outcomes: 21
***Number of studies:10
****Number of nonsignificant outcomes:
Flexible nails: 49
External fixation: 26
Spica cast: 27
Traction and casting: 56

Table 8. Summary of Nonsignificant Outcomes with Level of Evidence

Comparisons	*External Fixation*	*Spica Cast*	*Traction + Casting*		
Flexible Nails	Full Weight bearing (n/a)/III Re/antecurvatum malalignment 5 to 10 degrees (nr)/III Varus/valgus malalignment 5 to 10 degrees (nr)/III Limb length discrepancy up to 1 cm (final review)/III Pain (final review)/III Loss of movement at hip (post-op)/III Foot drop (nr)/III Early removal of nail (nr)/III Superficial infection (nr)/III Deep Infection (nr)/III Refracture (nr)/III	No studies	Severe knee stiffness (1 yr)/II Unequal length or unacceptable angulation (6 mo)/II Shortening (6 mo)/II Malrotation (6 mo)/II Delayed union (1 yr)/II Loss of reduction (1 yr)/II Pressure ulcer (1 yr)/II Refracture (1 yr)/II Second Surgery (1yr)/II Pin end irritation (6 mo)/II Nail removal due to irritation (1 yr)/II Infection (6 mo)/II Overall complications (1 yr)/II	Overgrowth 9-10 mm (8.5 mo)/III Shortening 7-8 mm (8.5 mo)/III Age-defined malunion (8.5 mo)/III Coronal malunion (8.5 mo)/III Sagittal malunion (8.5 mo)/III Leg length discrepancy > 1cm (2 yr)/III Would choose same treatment (nr)/III Mean leg length discrepancy (2 yr)/III Major complications (8.5 mo)/III Refracture (8.5 mo)/III Osteoclasis (8.5 mo)/III Pulmonary embolism (8.5 mo)/III	Minor complications (nr)/ III Remove/reinsert traction pin (nr)/III Nonfemoral lower ext. stress fx. (nr)/III Infected pin site (nr)/III Pin track infection (2 yr)/III Skin irritation (2 yr)/III Persistent drainage from pin site (nr)/III Proudflesh (nr)/III Pin migration (nr)/III Pain syndrome (nr)/III Cast wedging/fx. manipulate (8.5 mo)/III Revision of nail (8.5 mo)/III Broken nail (2 yr)/III

Table 8. Summary of Nonsignificant Outcomes with Level of Evidence (continued)

Comparisons	*External Fixation*	*Spica Cast*	*Traction + Casting*
External Fixation	N/A	Malunion inc. rotation (2 yr)/I Leg length discrepancy ≥ 2 cm (2 yr)/I Varus/valgus angulation ≥ 10° (2 yr)/I Rotational Malunion (2 yr)/I Treatment alteration (2 yr)/I Unacceptable loss of reduction (2 yr)/I RAND overall (2 yr)/I Duration of treatment (n/a)/I Behavioural Questionnaire (post-hosp)/I Parent Satisfaction (2 yr)/I Child Satisfaction (2 yr)/I Refracture (2 yr)/I	Total treatment days until union/III Reoperation (until union)/III Patient Satisfaction/III

Table 8. Summary of Nonsignificant Outcomes with Level of Evidence (continued)

Comparisons	*External Fixation*	*Spica Cast*	*Traction + Casting*
Spica Cast	N/A	N/A	Shortening (1 yr)/II Union time (n/a)/II Coronal angulation (1 yr) /II Sagittal angulation (1 yr)/II Excessive override (3 mo)/II Varus angulation > 10° (3 mo/II) Valgus angulation > 10° (3 mo)/II Posterior angulation > 10° (3 mo)/II Delayed union (3 mo)/II Readmission for manipulation (3 mo)/II Pin-tract infection (3 mo)/II Post-cast fracture of ipsi. limb (3 mo)/II Spinal muscular atrophy(3 mo)/II Fever of unknown origin (3 mo)/II Cast sore (3 mo)/II

*Number of outcomes examined: 100
**Number of significant outcomes: 21 (See Table 6)
***Number of studies:10
****Number of nonsignificant outcomes:
Flexible nails: 49
External fixation: 26
Spica cast: 27
Traction and casting: 56

Table 9. Summary of High Quality Evidence

Author	Level of Evidence	n	Comparison	Outcome (follow-up duration)	Result
Wright	High	101	External Fixation vs. Early Spica Cast	Malunion (2 yr)	● ef
Wright	High	101		Malunion inc. rotation (2 yr)	○
Wright	High	101		Leg length discrepancy ≥ 2 cm (2 yr)	○
Wright	High	101		Ant/post. angulation ≥ 15° (2 yr)	● ef
Wright	High	101		Varus/valgus angulation ≥ 10° (2 yr)	○
Wright	High	101		Rotational Malunion (2 yr)	○
Wright	High	101		Treatment alteration (2 yr)	○
Wright	High	101		Unacceptable loss of reduction (2 yr)	○
Wright	High	101		RAND overall (2 yr)	○
Wright	High	101		RAND physical subscale (2 yr)	○
Wright	High	101		Duration of treatment (n/a)	● sc
Wright	High	101		Behavioural Questionnaire (post-hosp)	○
Wright	High	101		Parent Satisfaction (2 yr)	○
Wright	High	101		Child Satisfaction (2 yr)	○
Wright	High	101		Refracture (2 yr)	○
Wright	High	101		Pin-tract infections (2 yr)	● sc

● = result is statistically significant n/a = not applicable ef = external fixation

○ = result is not statistically significant nr = not reported sc = spica cast

Table 10. Summary of Moderate Quality Evidence

Author	Level of Evidence	n	Comparison	Outcome (follow-up duration)	Result
Domb	Moderate	49	Dynamic vs. Static External Fixation	Early Callus (n/a)	○
Domb	Moderate	49		Complete Healing (n/a)	○
Domb	Moderate	49		Removal of external fixator (n/a)	○
Domb	Moderate	49		Full weight bearing (n/a)	○
Domb	Moderate	49		Angulation (nr)	○
Flynn	Moderate	83	Traction and cast vs. Flexible Nails	Severe knee stiffness (1 yr)	○
Flynn	Moderate	83		Unequal length or unacceptable angulation (6 mo)	○
Mehdinasab	Moderate	66		Shortening (6 mo)	○
Mehdinasab	Moderate	66		Malrotation (6 mo)	○
Flynn	Moderate	83		Delayed union (1 yr)	○
Flynn	Moderate	83		Loss of reduction (1 yr)	○
Flynn	Moderate	83		Walking with aids (n/a)	● fn
Flynn	Moderate	83		Walking independently (n/a)	● fn
Mehdinasab	Moderate	66		Walking independently (n/a)	● fn
Flynn	Moderate	83		Return to school	● fn
Flynn	Moderate	83		Pressure ulcer (1 yr)	○
Flynn	Moderate	83		Refracture (1 yr)	○
Flynn	Moderate	83		Second surgery (1 yr)	○
Flynn	Moderate	83		Irritation at nail entry site (1 yr)	● t/c
Mehdinasab	Moderate	66		Pin end irritation (6 mo)	○
Flynn	Moderate	83		Nail removal due to irritation (1 yr)	○
Mehdinasab	Moderate	66		Infection (6 mo)	○
Flynn	Moderate	83		Overall complications (1 yr)	○

● = result is statistically significant n/a = not applicable fn = flexible nails

○ = result is not statistically significant nr = not reported t/c = traction and cast

(*continued next page*)

Table 10. Summary of Moderate Quality Evidence (continued)

Author	Level of Evidence	n	Comparison	Outcome (follow-up duration)	Result
Ali	Moderate	66	Early spica cast vs. traction	Shortening (1 yr)	○
Ali	Moderate	100		Union time (n/a)	○
Ali	Moderate	66		Coronal angulation (1 yr)	○
Ali	Moderate	66		Sagittal angulation (1 yr)	○
Ali	Moderate	100		Blisters/superficial ulcers (until union)	● sc
Curtis	Moderate	91	Early pontoon spica cast vs. traction, then spica cast	Excessive override (3 mo)	○
Curtis	Moderate	91		Varus angulation > 10° (3 mo)	○
Curtis	Moderate	91		Valgus angulation > 10° (3 mo)	○
Curtis	Moderate	91		Posterior angulation > 10° (3 mo)	○
Curtis	Moderate	91		Delayed union (3 mo)	○
Curtis	Moderate	91		Knee flexion contraction > 20° (3 mo)	● psc
Curtis	Moderate	91		Readmission for manipulation (3 mo)	○
Curtis	Moderate	91		Pin-tract infection (3 mo)	○
Curtis	Moderate	91		Post-cast fracture of ipsi. limb (3 mo)	○
Curtis	Moderate	91		Spinal muscular atrophy(3 mo)	○
Curtis	Moderate	91		Fever of unknown origin (3 mo)	○
Curtis	Moderate	91		Cast sore (3 mo)	○
Curtis	Moderate	91		Overall short-term complication (3 mo)	● psc

● = result is statistically significant n/a = not applicable sc = spica cast

○ = result is not statistically significant nr = not reported psc = (pontoon) spica cast

Table 11. Summary of Low Quality Evidence

Author	Level of Evidence	n	Comparison	Outcome (follow-up duration)	Result
Nork	Low	29	External fixation vs. traction and cast	Total treatment days (until union)	○
Nork	Low	29		Reoperation (until union)	○
Hedin 2004	Low	59	External fixation vs. home traction	Duration of treatment (n/a)	● t
Hedin 2004	Low	66		Patient satisfaction (nr)	○
Hedin 2004	Low	59	External fixation vs. hospital traction	Duration of treatment (n/a)	● t
Hedin 2004	Low	66		Patient satisfaction (nr)	● ef
Buechsensc.	Low	71	Flexible nails vs. traction and cast	Overgrowth 9-10 mm (8.5 mo)	○
Buechsensc.	Low	71		Shortening 7-8 mm (8.5 mo)	○
Buechsensc.	Low	71		Age-defined malunion (8.5 mo)	○
Buechsensc.	Low	71		Coronal malunion (8.5 mo)	○
Buechsensc.	Low	71		Sagittal malunion (8.5 mo)	○
Song	Low	51		Angular deformity (2 yr)	● fn
Song	Low	51		Leg length discrepancy > 1cm (2 yr)	○
Song	Low	51		Flynn's outcome (2 yr)	● fn
Buechsensc.	Low	43		Would choose same treatment (nr)	○
Buechsensc.	Low	43		Acceptable scar (nr)	● fn
Song	Low	51		Mean leg length discrepancy (2 yr)	○
Buechsensc.	Low	71		Major complications (8.5 mo)	○
Buechsensc.	Low	71		Refracture (8.5 mo)	○
Buechsensc.	Low	71		Osteoclasis (8.5 mo)	○
Buechsensc.	Low	71		Cast wedging/fx. manipulate (8.5 mo)	○
Buechsensc.	Low	71		Revision of nail (8.5 mo)	○
Song	Low	51		Broken nail (2 yr)	○
Buechsensc.	Low	68		Pulmonary embolism (8.5 mo)	○

● = result is statistically significant n/a = not applicable t = traction ef = external fixation

○ = result is not statistically significant nr = not reported fn = flexible nails

(*continued next page*)

Table 11. Summary of Low Quality Evidence (continued)

Author	Level of Evidence	n	Comparison	Outcome (follow-up duration)	Result
Buechsensc.	Low	71	Flexible nails vs. traction and cast	Minor complications (nr)	○
Buechsensc.	Low	71		Remove/reinsert traction pin (nr)	○
Buechsensc.	Low	71		Nonfemoral lower ext. stress fx. (nr)	○
Buechsensc.	Low	71		Infected pin site (nr)	○
Song	Low	51		Pin track infection (2 yr)	○
Song	Low	51		Skin irritation (2 yr)	○
Buechsensc.	Low	71		Persistent drainage from pin site (nr)	○
Buechsensc.	Low	71		Proudflesh (nr)	○
Buechsensc.	Low	71		Pin migration (nr)	○
Buechsensc.	Low	71		Pain syndrome (nr)	○
Wall	Low	104	Titanium vs. stainless steel flexible nail	Malunion (1 yr)	● ss
Wall	Low	104		Osteotomy (1 yr)	○
Wall	Low	104		Infection (1 yr)	○
Wall	Low	104		Implant revision (1 yr)	○
Wall	Low	104		Nail irritation (1 yr)	○
Wall	Low	104		Nail breakage (1 yr)	○
Wall	Low	104		Delayed union (3 mo)	○
Wall	Low	104		Minor complications (1 yr)	○
Rasit	Low	40	Immediate vs. delayed spica cast	2nd surgery/loss of reduction(2 wk)	○
Rasit	Low	40		Angulation > 20° (2 wk)	○
Sturdee	Low	56	Early intervention vs. traction	Pain (3 mo)	○
Sturdee	Low	56		Malunion (3 mo)	○
Sturdee	Low	56		Pin-site infections (until union)	○
Sturdee	Low	56		Broken external fixation pin (until union)	○
Sturdee	Low	56		Refracture (until union)	○
Sturdee	Low	56		Reapplication of traction pin (until union)	○
Sturdee	Low	56		Pressure sores (until union)	○

● = result is statistically significant n/a = not applicable ss = stainless steel

○ = result is not statistically significant nr = not reported

(*continued next page*)

Table 11. Summary of Low Quality Evidence (continued)

Author	Level of Evidence	n	Comparison	Outcome (follow-up duration)	Result
Barlas	Low	40	Flexible nailing vs. external fixation	Full weight bearing (n/a)	○
Barlas	Low	40		Time to full knee movement (n/a)	● fn
Barlas	Low	40		Return to school (n/a)	● fn
Barlas	Low	40		Re/antecurvatum malalignment 5° to 10° (nr)	○
Barlas	Low	40		Varus/valgus malalignment 5° to 10° (nr)	○
Barlas	Low	40		Limb length discrepancy, up to 1 cm (final review)	○
Barlas	Low	40		Pain (final review)	○
Barlas	Low	40		Loss of movement at hip (post-op)	○
Barlas	Low	40		Loss of movement at knee (post-op)	● ef
Barlas	Low	40		Foot drop (nr)	○
Barlas	Low	40		Early removal of nail (nr)	○
Barlas	Low	40		Superficial infection (nr)	○
Barlas	Low	40		Deep infection (nr)	○
Barlas	Low	40		Refracture (nr)	○

● = result is statistically significant n/a = not applicable fn = flexible nailing

○ = result is not statistically significant nr = not reported ef = external fixation

Figure 8. External Fixation vs. Spica Cast - binary outcomes (Wright et al.[22])

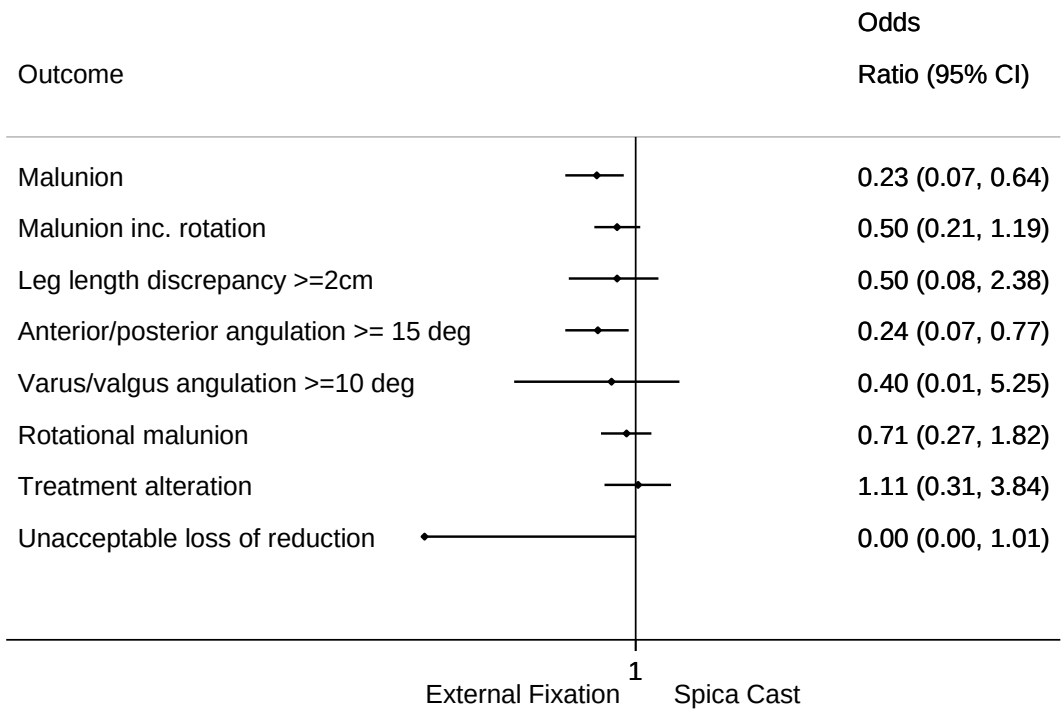


Figure 9. External Fixation vs. Spica Cast -continuous outcomes (Wright et al.[22])

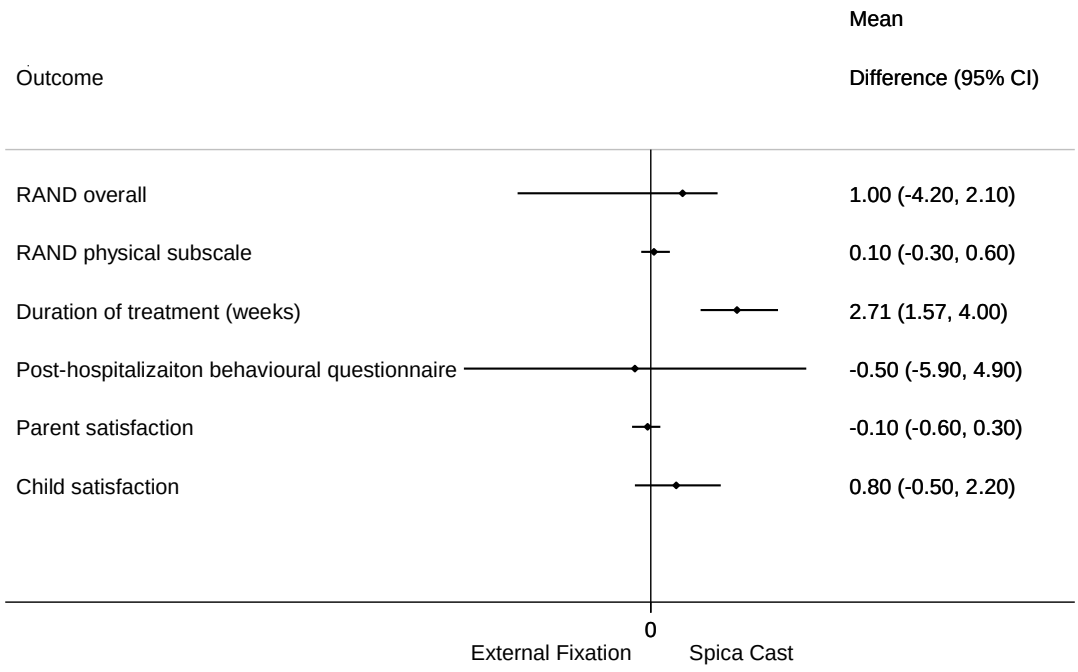


Figure 10. External Fixation vs. Spica Cast - Complications (Wright et al.[22])

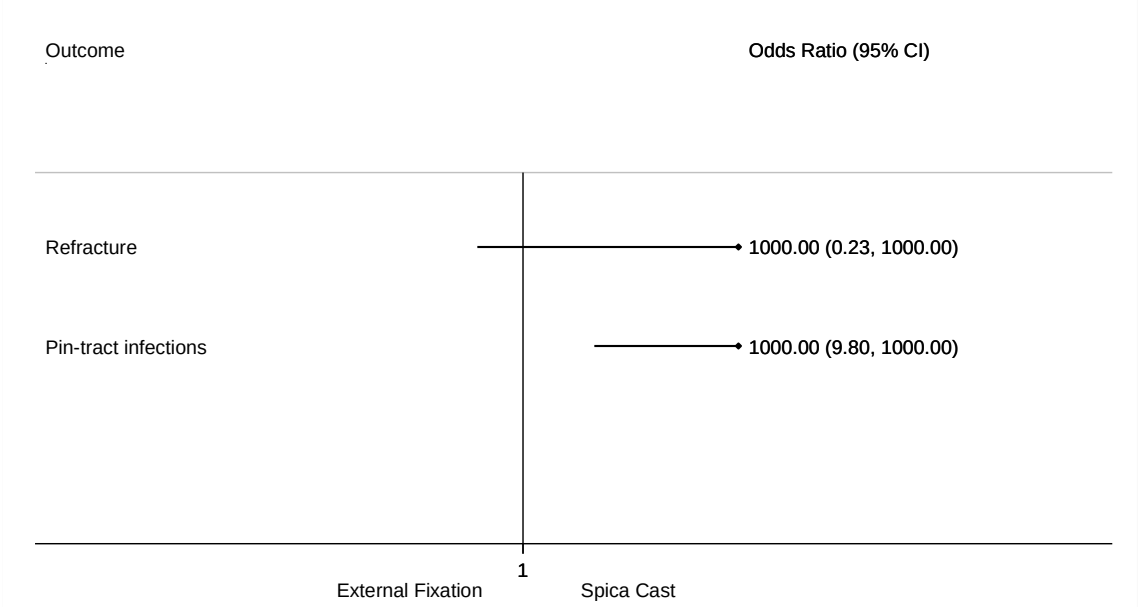


Figure 11. Dynamic vs. Static External Fixation (Domb et al.[28])

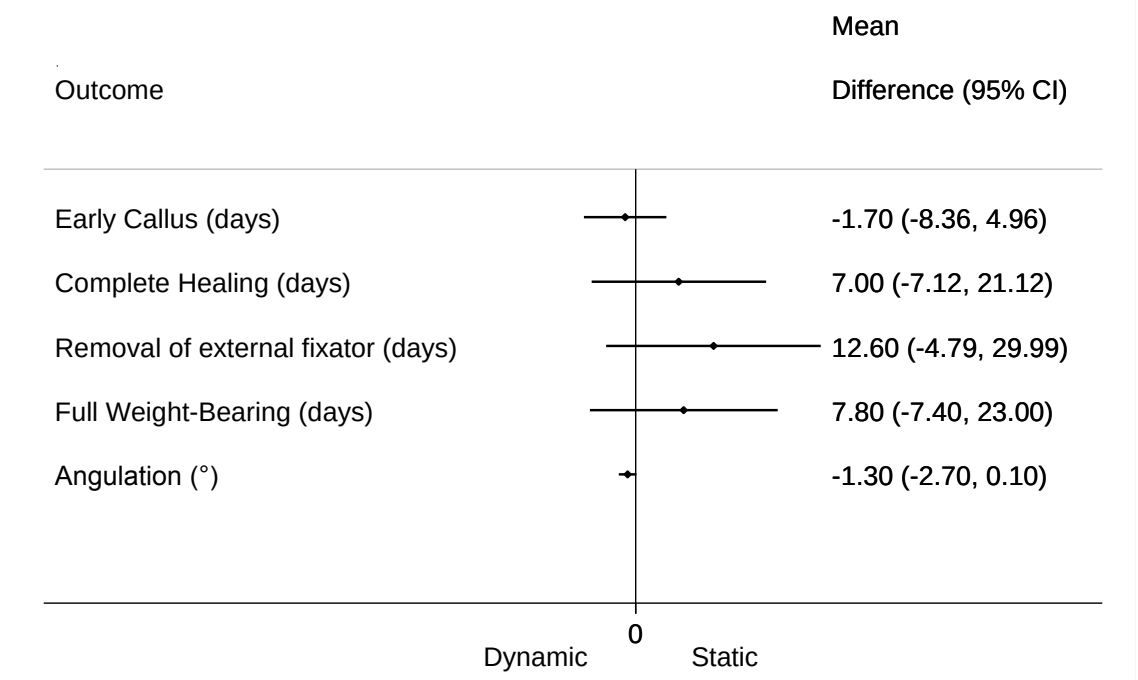


Figure 12. Traction & Cast vs. Flexible Nails –binary outcomes

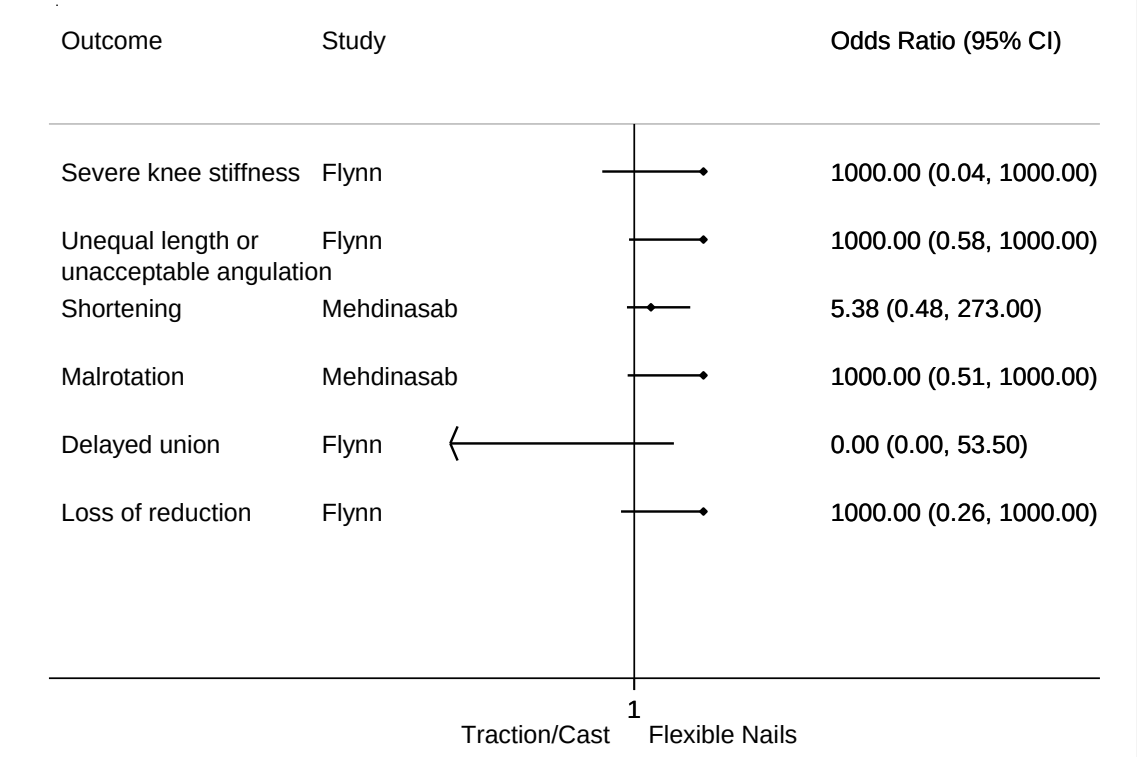


Figure 13. Traction & Cast vs. Flexible Nails – continuous outcomes

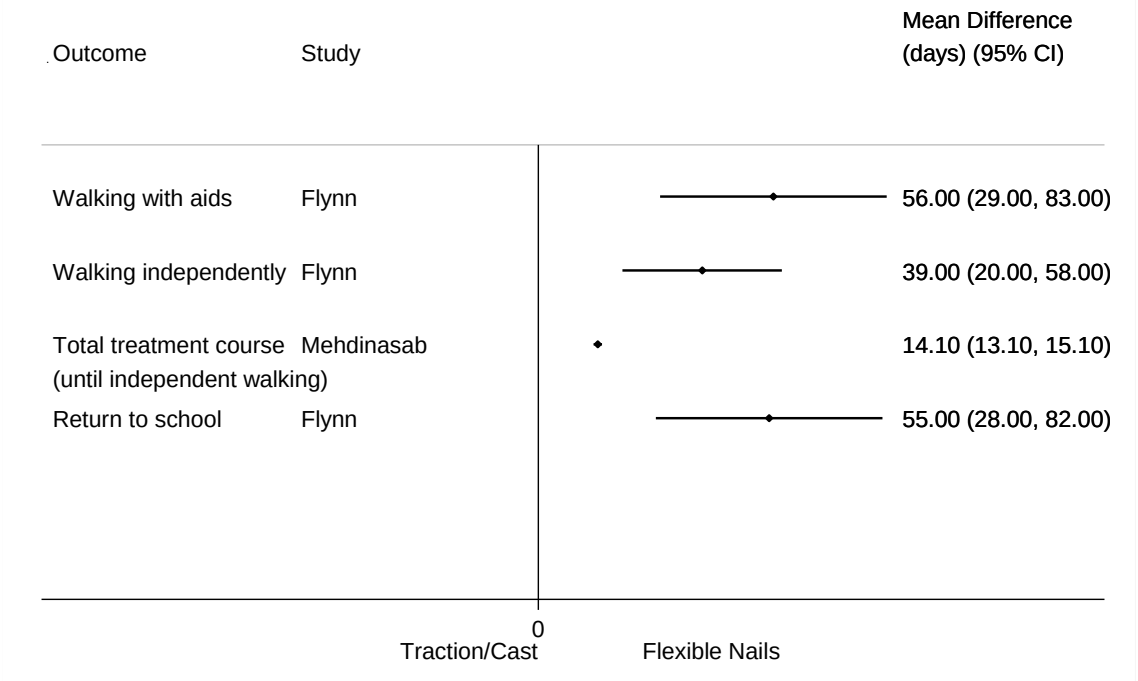


Figure 14. Traction & Cast vs. Flexible Nails - Complications

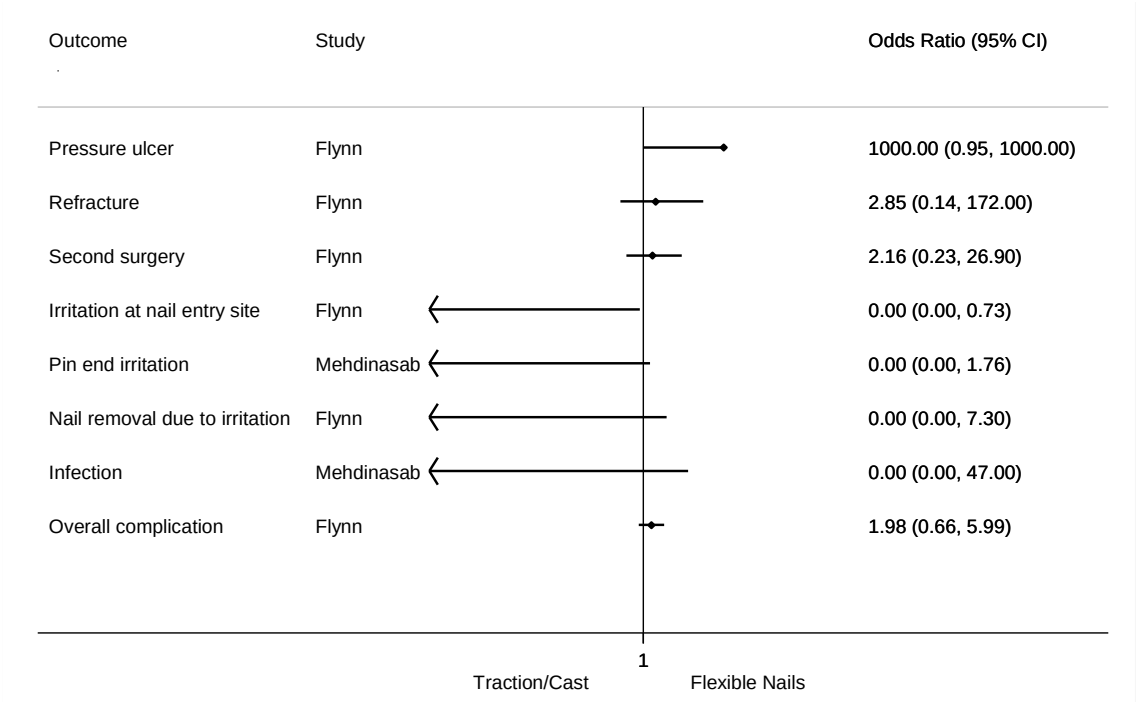


Figure 15. Early Spica Cast vs. Traction - continuous outcomes (Ali et al.[30])

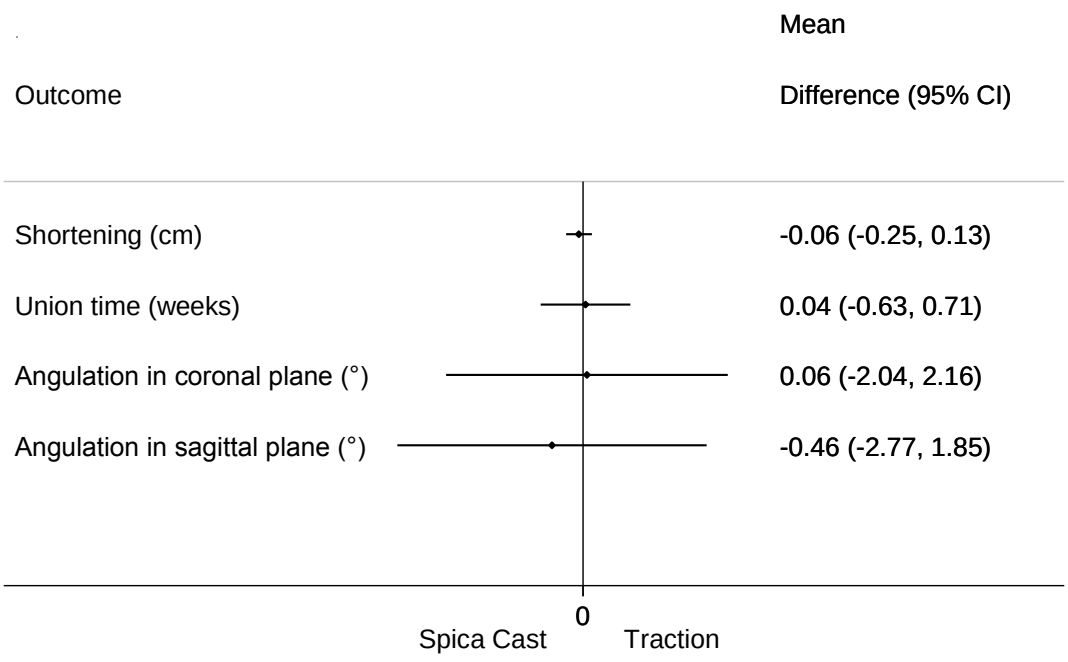


Figure 16. Early Spica Cast vs. Traction -Complications (Ali et al.[30])

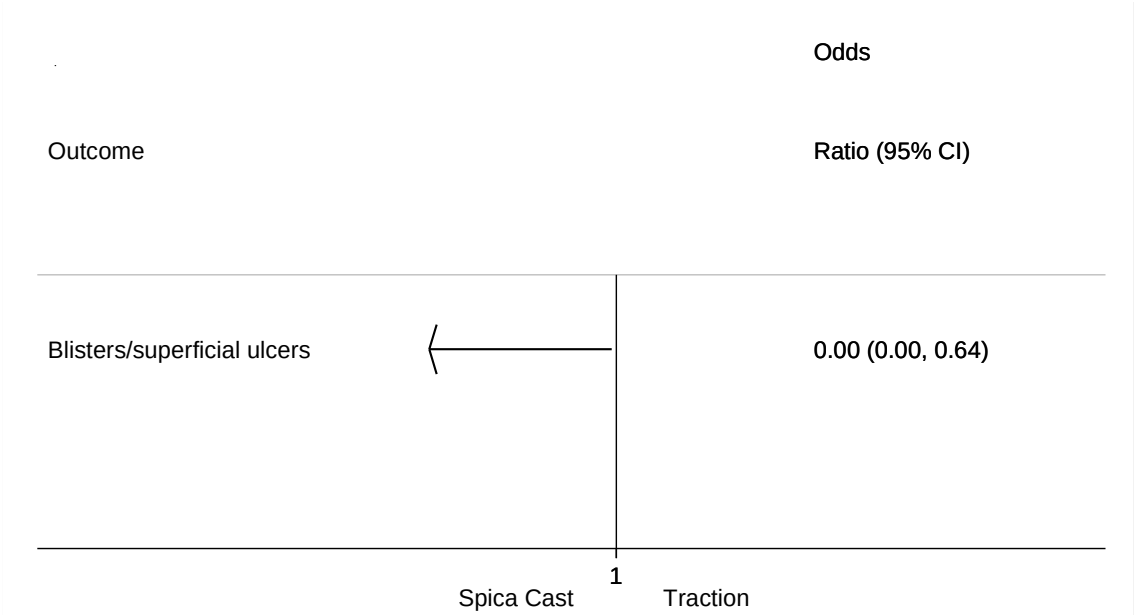


Figure 17. Early Pontoon Spica vs. Traction/Cast – Short-term Complications (Curtis et al.[31])

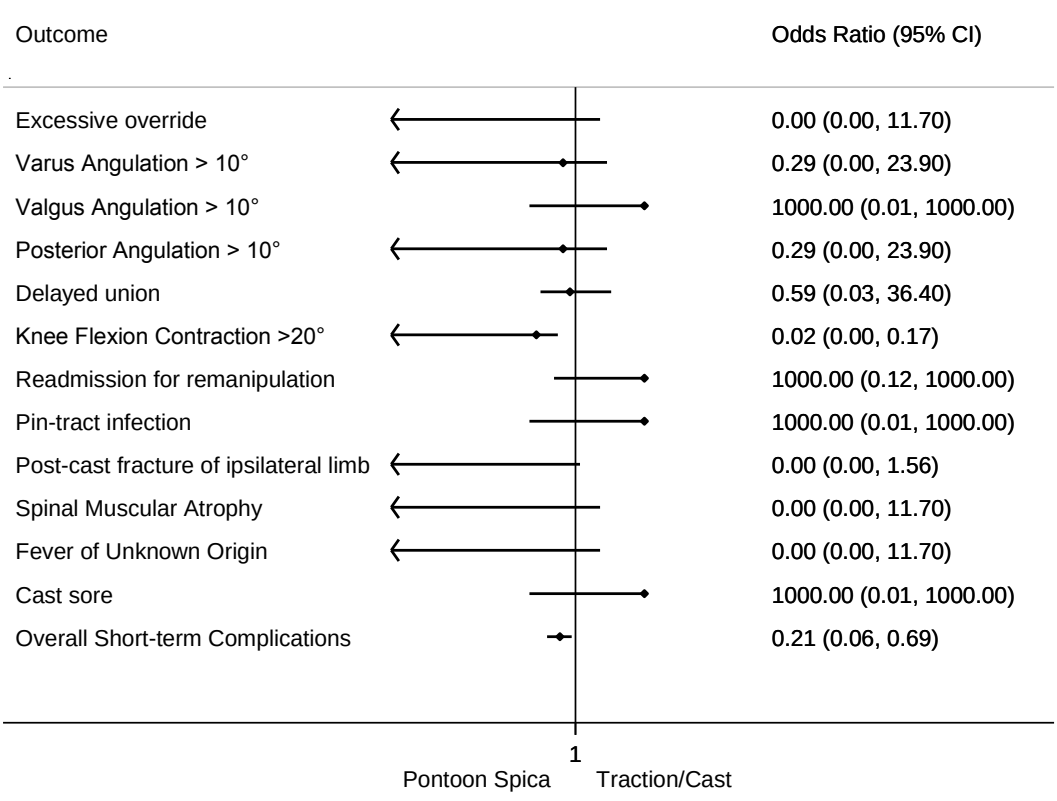


Figure 18. External Fixation vs. Traction & Cast - Treatment Length (Nork et al.[32])

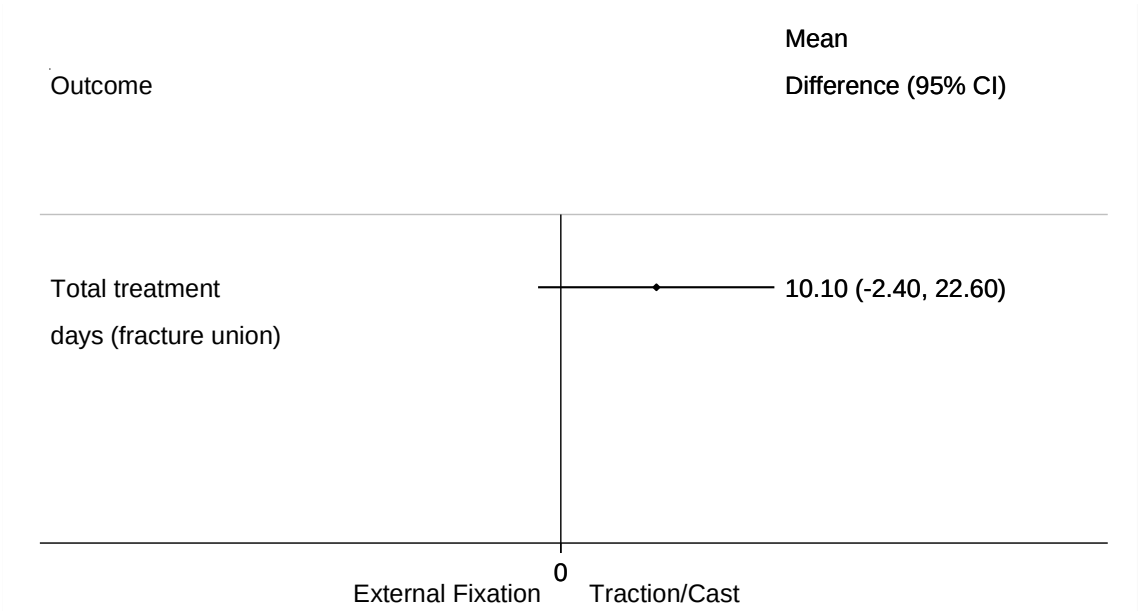


Figure 19. External Fixation vs. Traction & Cast – Complications (Nork et al.[32])

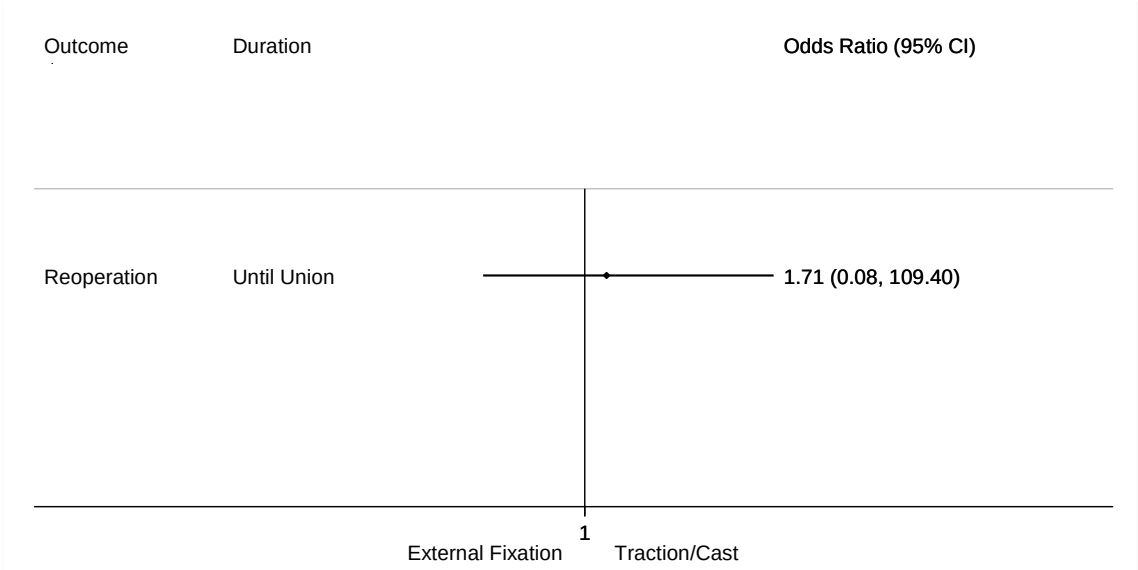


Figure 20. External Fixation vs. Traction - Treatment Length (Hedin et al.[34])

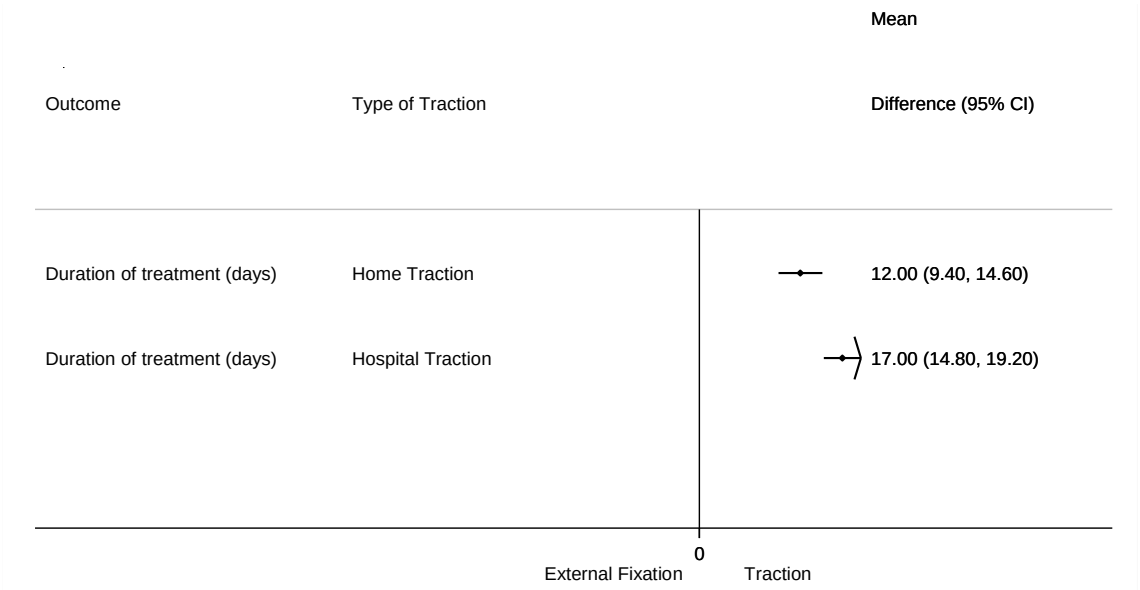


Figure 21. External Fixation vs. Traction - Patient Satisfaction (Hedin et al.[34])

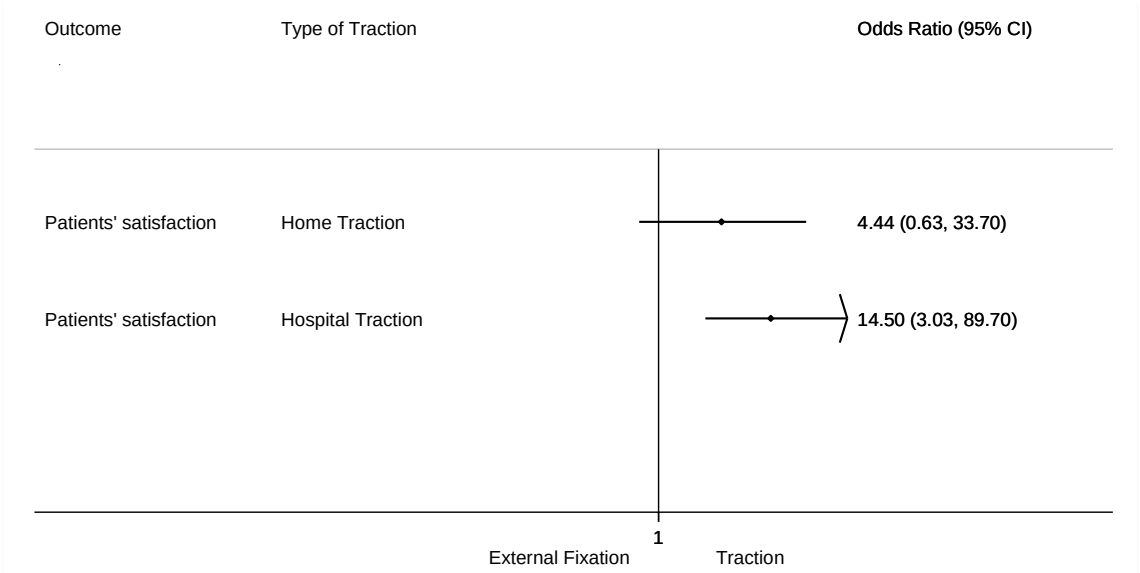


Figure 22. Flexible Nails vs. Traction & Cast - binary outcomes

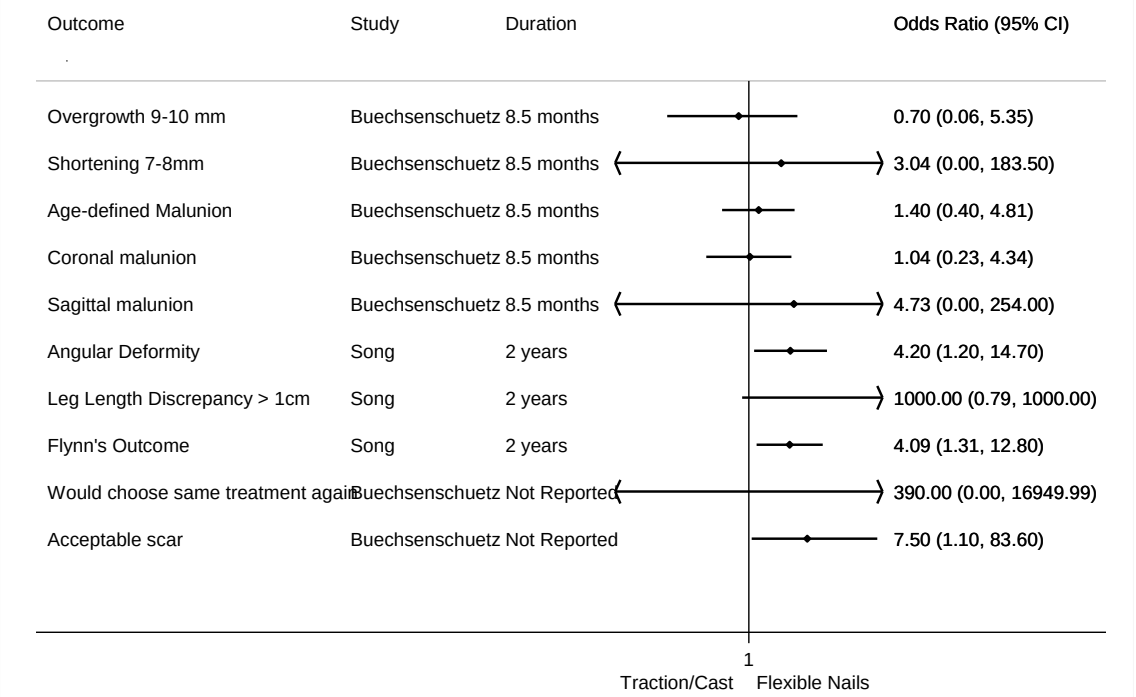


Figure 23. Flexible Nails vs. Traction & Cast -Leg Length Discrepancy (Song et al.[33])

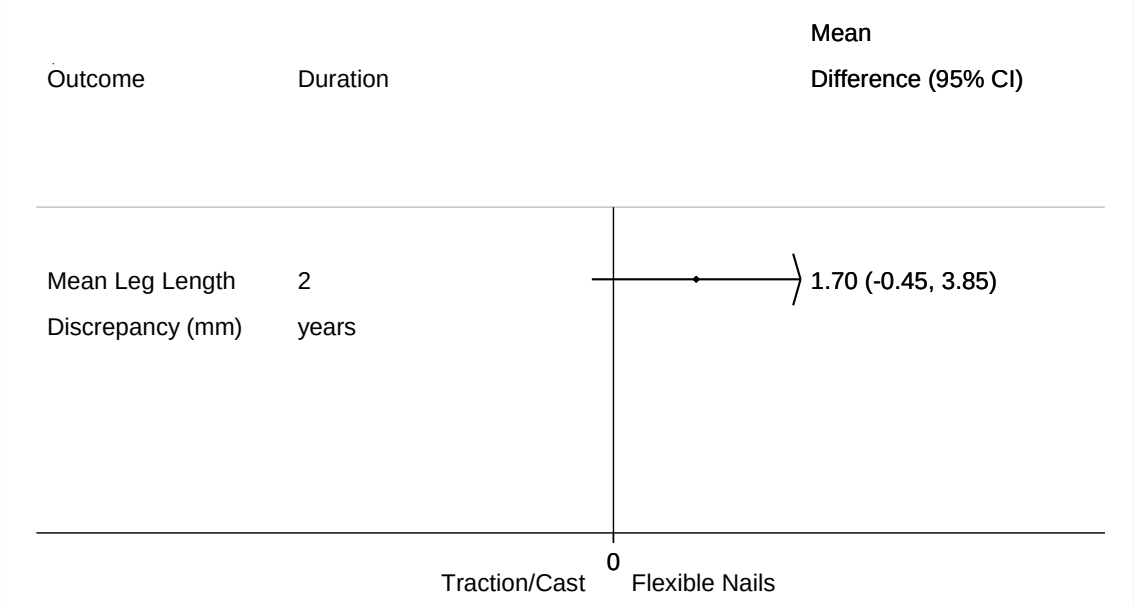


Figure 24. Flexible Nails vs. Traction & Cast - Major Complications

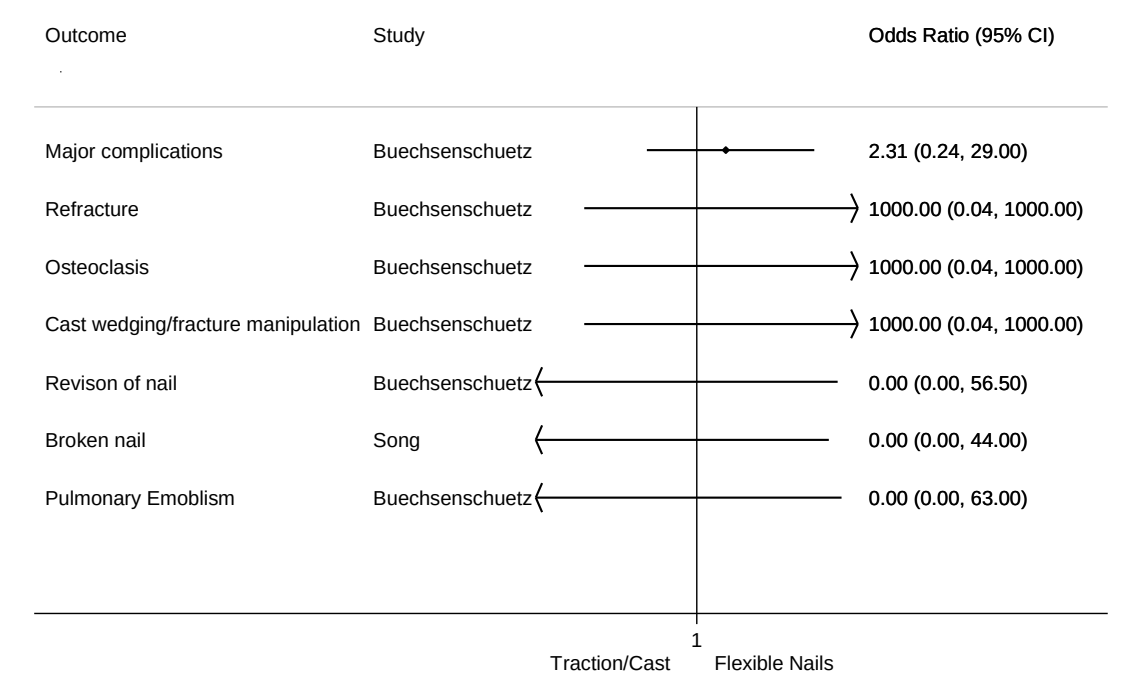


Figure 25. Flexible Nails vs. Traction & Cast - Minor Complications

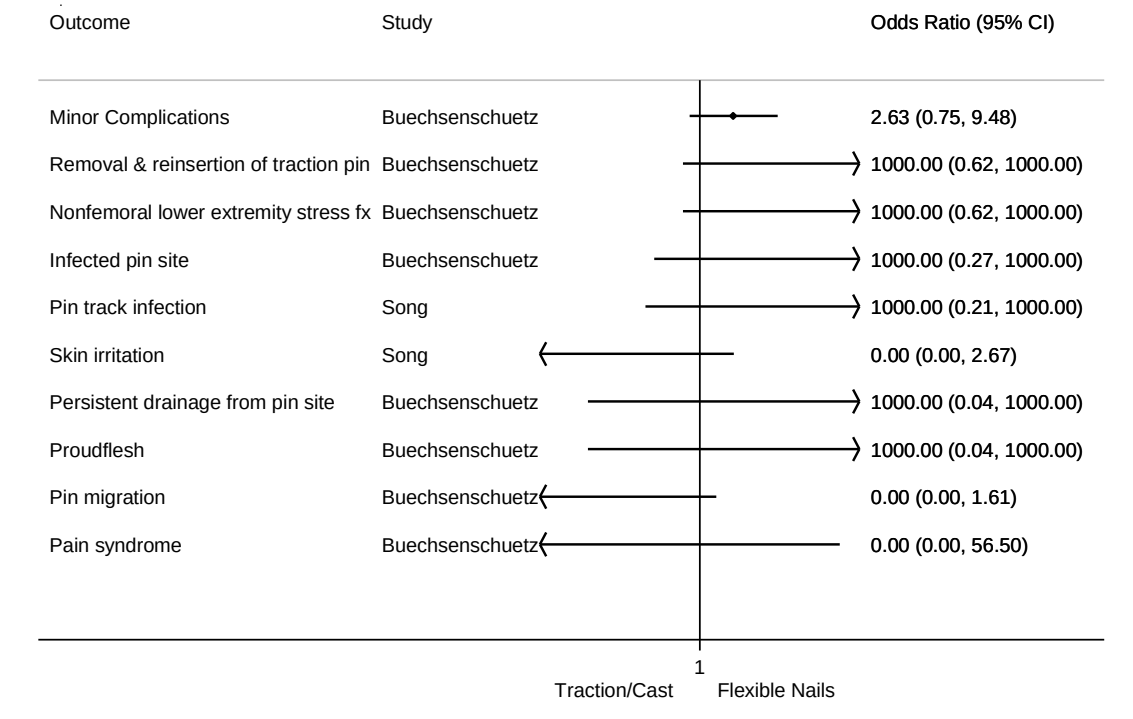


Figure 26. Titanium vs. Stainless Steel Flexible Nails – Complications (Wall et al.[37])

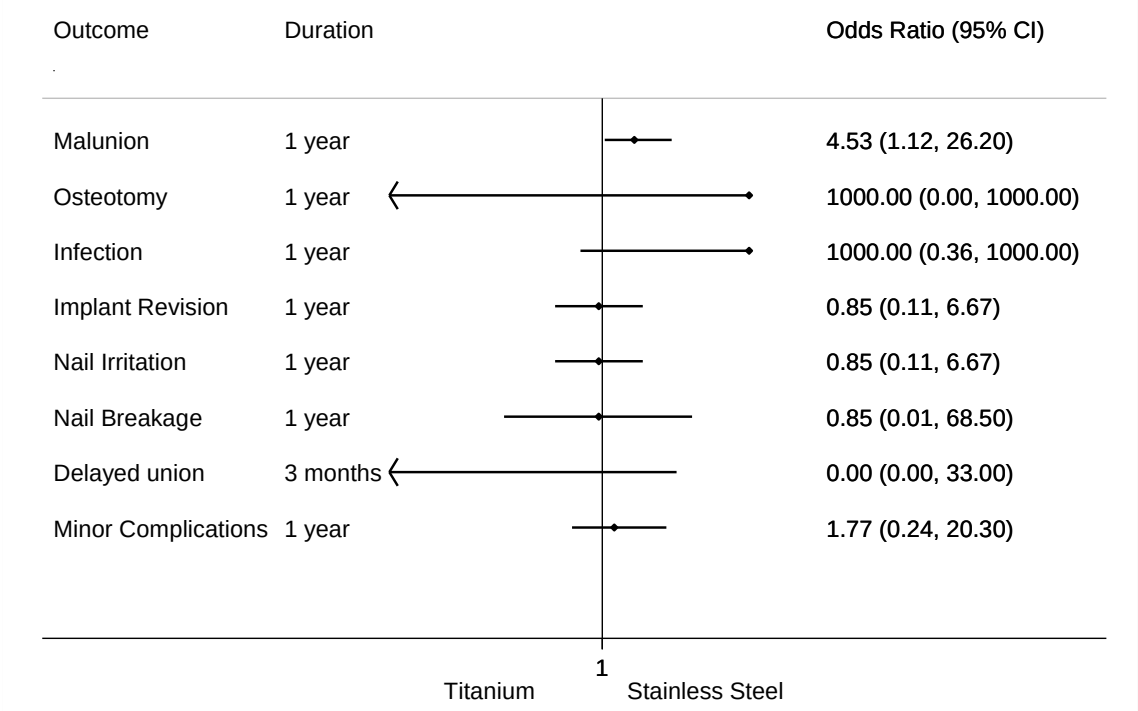


Figure 27. Immediate vs. Delayed Spica Cast - Complications (Rasit et al.[35])

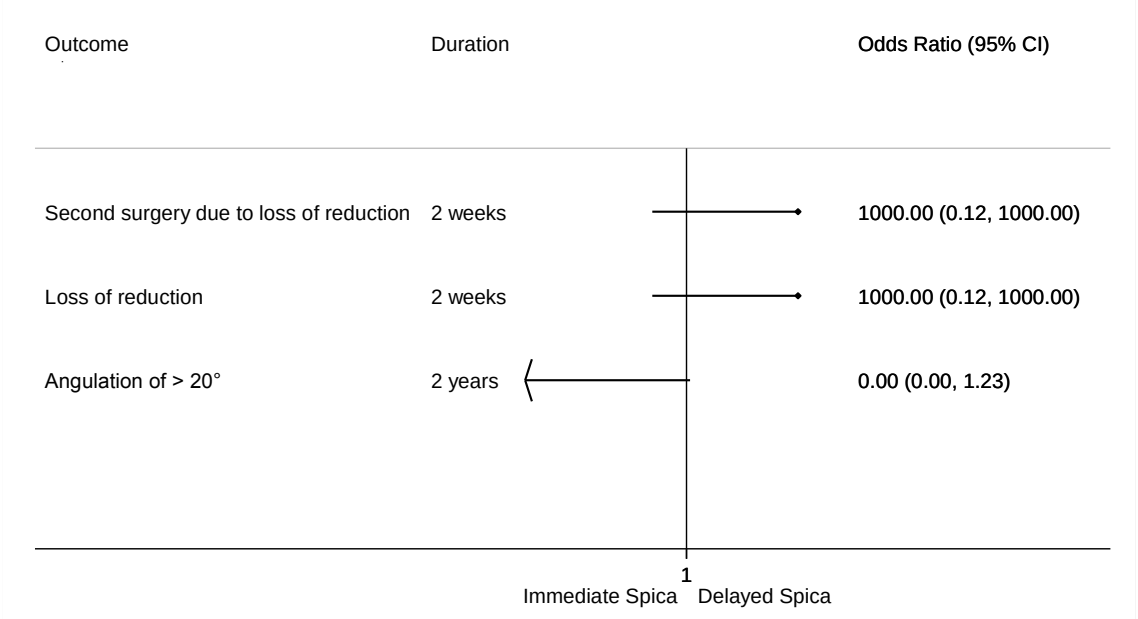


Figure 28. Early Intervention vs. Traction (Sturdee et al.[36])

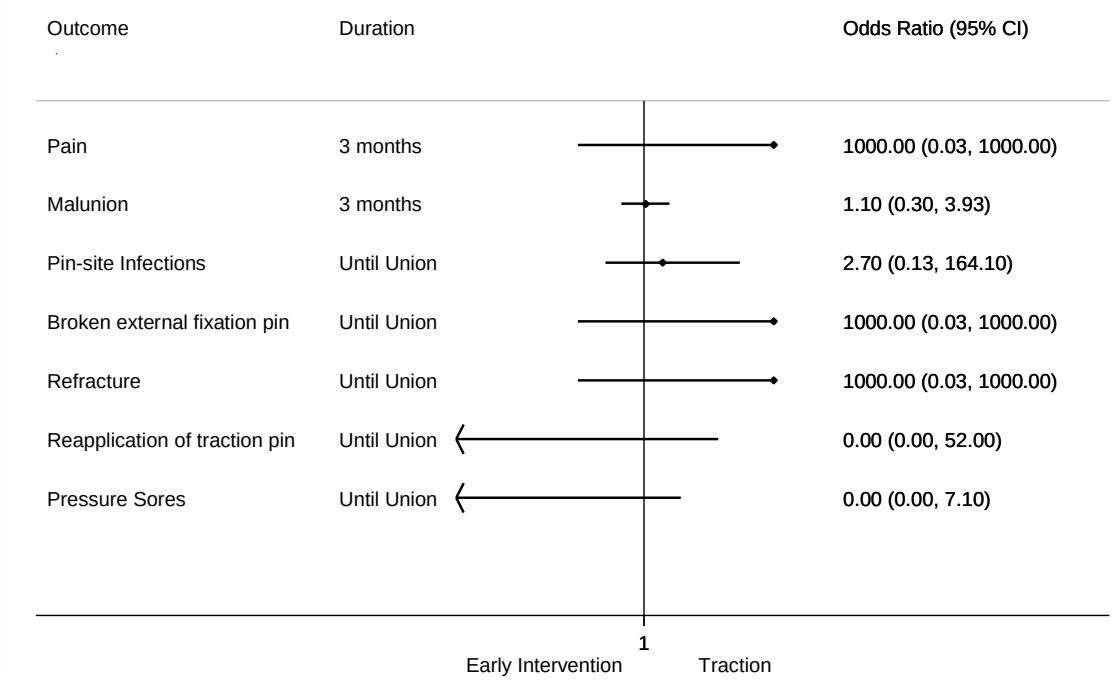
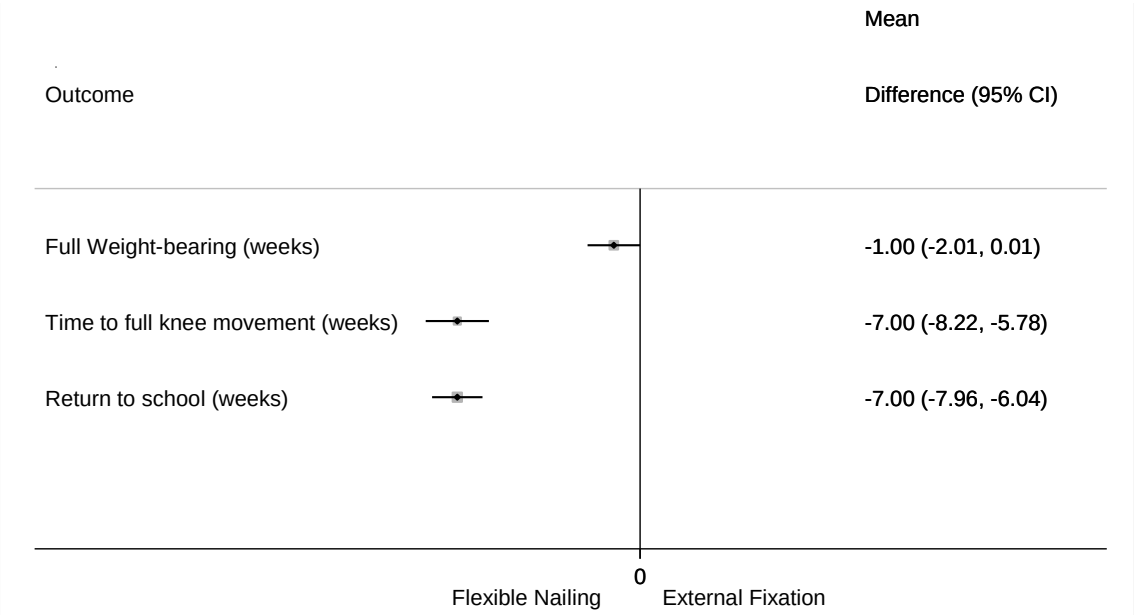


Figure 29. Flexible Nailing vs. External Fixation - Continuous Outcomes (Barlas et al. 2006[26])



*Standard deviations estimated from range

Figure 30. Flexible Nailing vs. External Fixation -Binary Outcomes (Barlas et al. 2006[26])

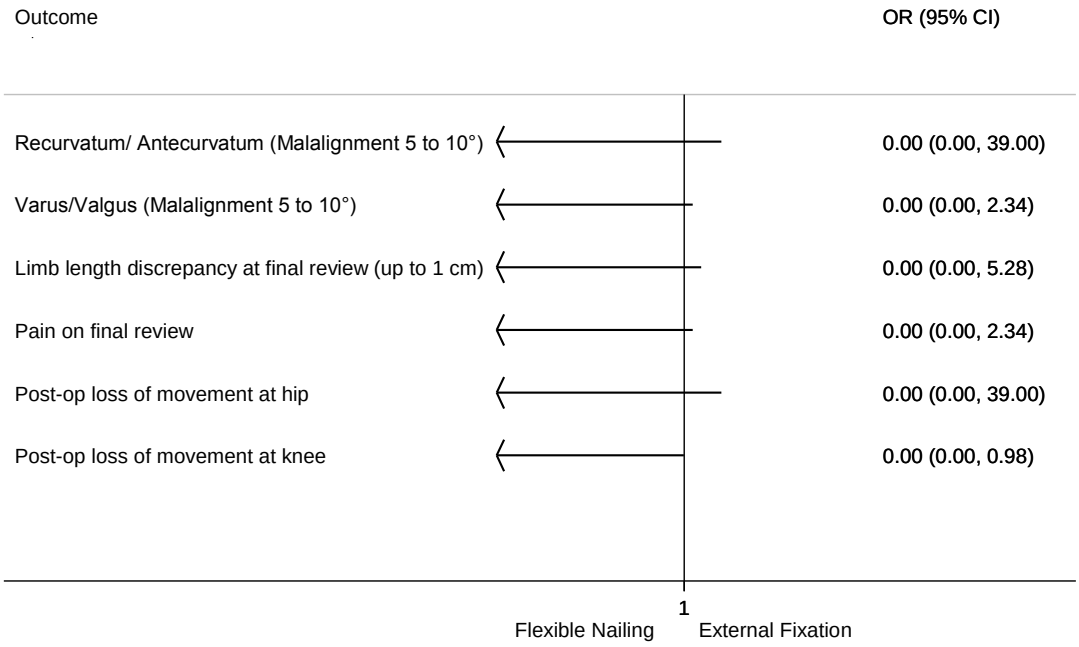
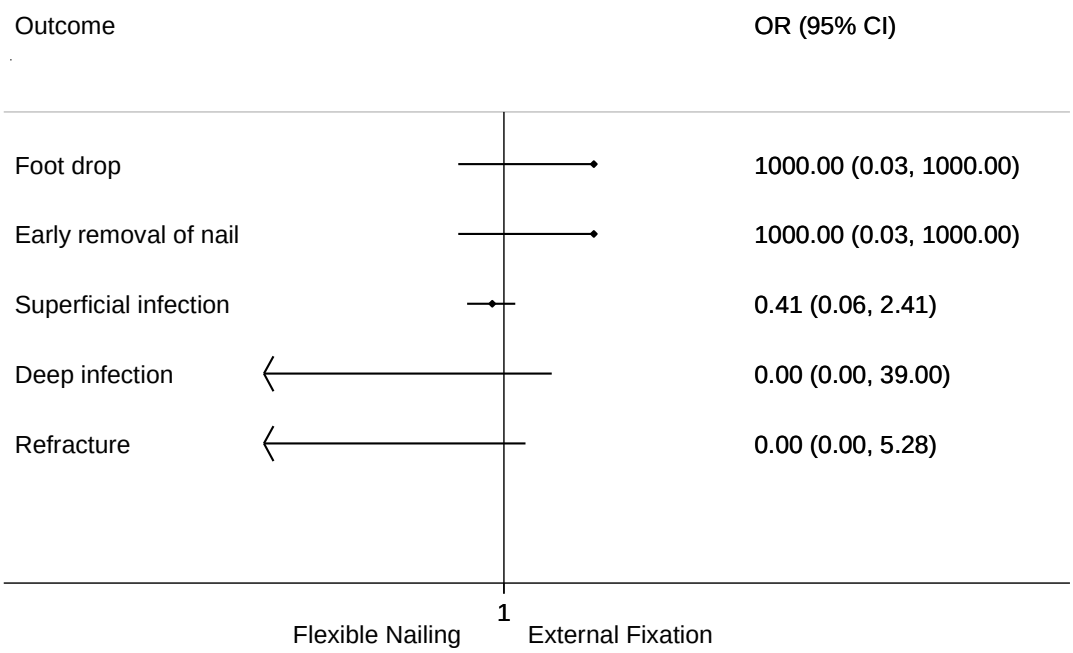


Figure 31. Flexible Nailing vs. External Fixation - Complications(Barlas et al. 2006[26])



PREVIOUSLY PUBLISHED SYSTEMATIC REVIEWS

Two previous systematic reviews[21,23] concluded that early spica casting was associated with shorter inpatient hospital stays and fewer adverse events than traction. One review[23] concluded that flexible nails reduced the malunion and adverse event rate compared to external fixation, and that external fixation reduced the maluion rate compared to early spica casting. This review also concluded that dynamic external fixation had a lower total adverse event rate compared to static external fixation, and that operative treatment reduced the malunion and total adverse event rates compared to nonoperative treatment. Both of these reviews, however, were not specific to the population of interest for this recommendation, so we did not include them in our systematic review.

ORIF PEDIATRIC FEMUR FRACTURES

Limited evidence supports rigid trochanteric entry nailing, submuscular plating, and flexible intramedullary nailing as treatment options for children age eleven years to skeletal maturity diagnosed with diaphyseal femur fractures, but piriformis or near piriformis entry rigid nailing are not treatment options.

Grade of Recommendation: Limited ★★☆☆

Figures relevant to this recommendation are: Figure 32 - Figure 34
Tables relevant to this recommendation are: Table 12- Table 16

RATIONALE

Skeletally immature patients are at increased risk for avascular necrosis of the femoral head when piriformis or near piriformis fossa entry nails are used. The rate of this potentially devastating complication is at least 4%.[38] Every effort should be made to decrease the risk of avascular necrosis.

Fracture patterns that compromise post-reduction stability (i.e. axial and / or angular stability) as well as heavier patients may stimulate the surgeon to choose rigid trochanteric entry nailing or submuscular plating over flexible intramedullary nailing. One Low quality study demonstrated a five times higher risk of poor outcomes for flexible nailing in patients whose weight met or exceeded 49 kg (108 lbs).[27] In the expert opinion of the work group, external fixation is another option in the older patient with an unstable fracture pattern, but its significantly higher complication rates, as demonstrated in other age groups,[23,26] make it less desirable than rigid trochanteric entry nailing or submuscular plating.

SUPPORTING EVIDENCE

One High Quality and four Low quality studies addressed this recommendation. The High Quality study[39] compared nonoperative treatment, mainly traction and cast bracing, to closed intramedullary nailing. Of the 20 patients (21 fractures) in the operative group, 16 were treated with piriformis entry rigid nailing. There was a statistically significant difference in favor of intramedullary nailing for two outcomes, time to healing and malunion. There were no other statistically significant differences between the two groups.

Of the four Low quality studies, one investigated flexible nailing,[27] one investigated rigid trochanteric entry nailing, [38] one investigated near piriformis entry rigid nailing,[38,40] and one investigated submuscular plating of comminuted fractures.[41]

The study of flexible nailing[27] also compared the weight of patients with an excellent or satisfactory outcome to the weight of patients with a poor outcome. Forty percent (40%) of the patients in this study were at least 11 years old. The 15 kg difference in mean weight between patients with a poor outcome and those with an excellent or satisfactory

outcome was statistically significant according to the author's calculations (p=.003). Moreover, using a cut-off point of 49 kg, heavier patients were about five times more likely than lighter patients to have poor outcomes. However, the investigators found that weight did not independently predict a poor outcome when age was also included in a logistic regression model. The investigators also found that the weight cut-off point had 78.5% specificity and 59% sensitivity for detecting a poor outcome.

Table 12. Flexible Intramedullary Nailing and Patients' Weight

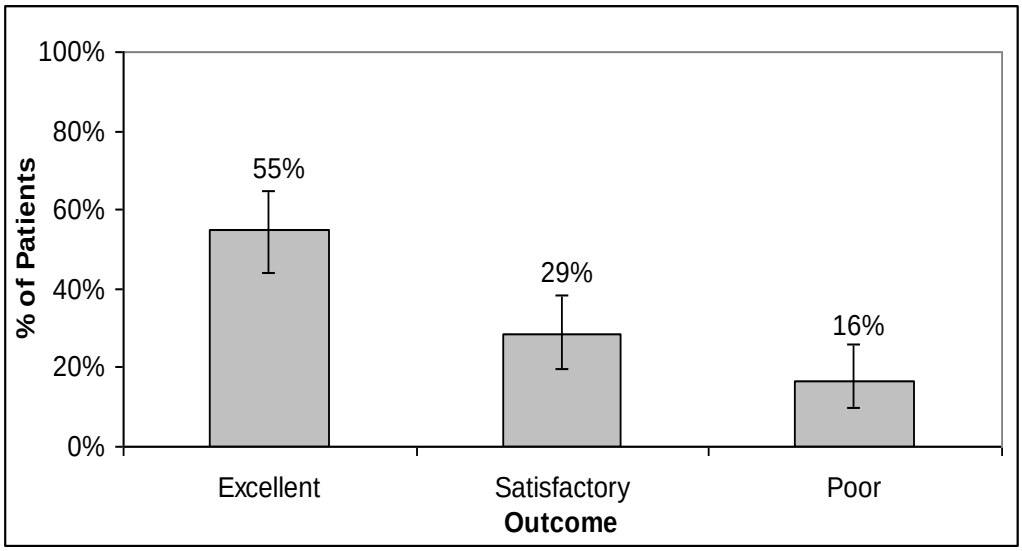
Treatment	n	Mean weight (excellent/satisfactory outcome)	Mean weight (poor outcome)	p-value
Titanium Elastic Nailing	222	39 kg (range 17 to 95.2)	54 kg (range 22.3 to 95.2)	0.003

Table 13. Traction vs. Piriformis Entry Rigid Nailing (Herndon et al.[39])

Outcome	Duration	n	Mean Difference (95% CI)	% (Traction)	% (Rigid Nails)	Favors
Healing (weeks)	(<1 to 7 yrs. follow up)	44	1.5 (0.5, 2.5)	n/a	n/a	IM Nailing
Malunion			n/a	29.0%	0.0%	IM Nailing
Shortening >2cm				20.8%	0.0%	N/S
Varus >10°				12.5%	0.0%	N/S
Valgus >10°				4.2%	0.0%	N/S
Anterior angle >20°				8.3%	0.0%	N/S
Pressure sore				4.2%	0.0%	N/S
Pin track infection				4.2%	0.0%	N/S
Limp				8.3%	0.0%	N/S
Second Surgery				8.3%	0.0%	N/S
Growth plate arrest				0.0%	0.0%	N/S

*N/S = no significant difference

Figure 32. Titanium Elastic Nailing Outcomes Among Age 11+ (Moroz et al.[27])



* AAOS computed the 95% confidence intervals from published data

Table 14. Rigid Trochanteric Entry Nailing Outcomes (Kanellopoulos et al.[40])

Outcome	Duration	n	Mean	%
Secondary Healing	n/a	20	9 weeks (8-13)	n/a
Weight Bearing (full)	6 weeks	20	n/a	80%
Full Range of Motion	6 weeks	20	n/a	100%
Return to Preinjury Activity	29 months	20	n/a	100%
Limp	29 months	20	n/a	0%
Delayed or Nonunion	13 weeks	20	n/a	0%
Deep infections	29 months	20	n/a	0%
Hip Osteonecrosis	29 months	20	n/a	0%

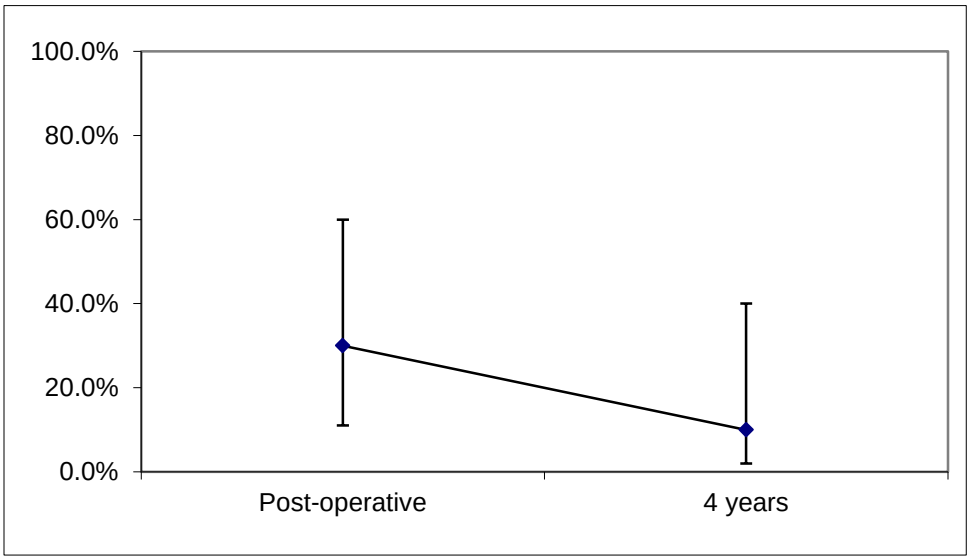
Table 15. Rigid Near Piriformis Entry Nailing Outcomes (Buford et al.[38])

Outcome	Duration	n	Mean	%
Time to healing	n/a	54	6 weeks	n/a
Gait disturbance	20 months	54	n/a	0%
Hip pain	20 months	54	n/a	0%
Significant leg length discrepancies	20 months	54	n/a	0%
Nonunion	20 months	54	n/a	0%
Infection	20 months	54	n/a	0%
Subclinical avascular necrosis	20 months	54	n/a	4%
Postoperative nerve palsies	20 months	54	n/a	0%
Acetabular dysplasia	20 months	54	n/a	0%
Refracture through nail site	20 months	54	n/a	2%

Table 16. Bridge Plating Outcomes (Agus et al.[41])

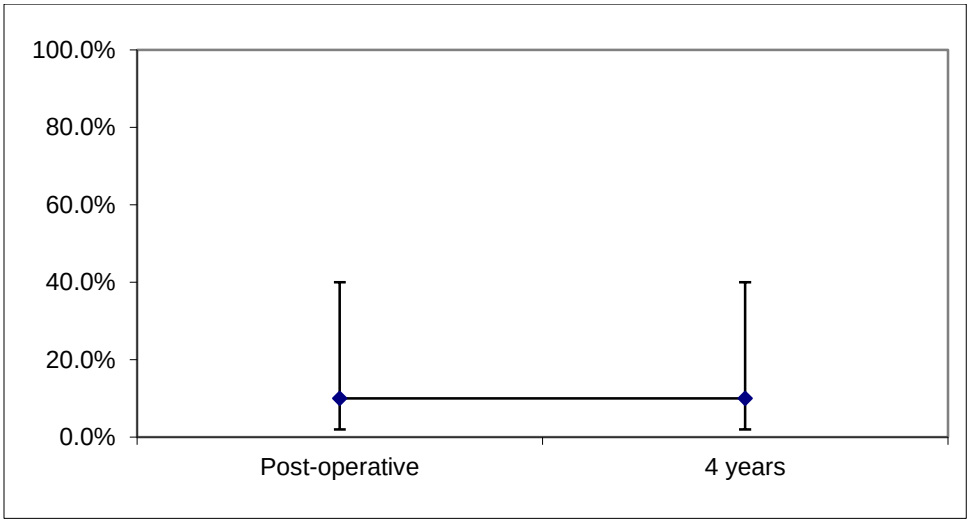
Outcome	Duration	n	Mean (95% CI)	%
Time to grade 2 callus (weeks)	n/a	10	9.1 (7.7, 10.5)	n/a
Complete radiographic healing time (weeks)	n/a	10	13.4 (11.4, 15.4)	n/a
Broken plates	4 years	10	n/a	0.0%
Refractures	4 years	10	n/a	0.0%
Femoral length inequality (cm)	4 years	10	0.6 (0.4, 0.8)	n/a
Increased torsion	4 years	10	n/a	50.0%
Decreased torsion	4 years	10	n/a	50.0%
Torsion diff b/w injured/uninjured limb (absolute value)	4 years	10	4.5° (0, 9.7)	n/a
Limp	4 years	10	n/a	0.0%

Figure 33. Bridge Plating - Percentage of Patients with Frontal Plane Angulation (Agus et al.[41])



*AAOS computed the 95% confidence intervals from published data

Figure 34. Bridge Plating -Percentage of Patients with Sagittal Plane Angulation (Agus et al.[41])



* AAOS computed the 95% confidence intervals from published data

PREVIOUSLY PUBLISHED SYSTEMATIC REVIEWS

A previous systematic review[23] concluded that intramedullary nailing resulted in fewer malunions and adverse events than traction or subsequent casting. This review, however, was not specific to the population of interest for this recommendation, so we did not include it in our systematic review.

PAIN CONTROL

Limited evidence supports regional pain management for patient comfort peri-operatively.

Grade of Recommendation: Limited ★★☆☆

Figures relevant to this recommendation are: Figure 35 - Figure 38
Tables relevant to this recommendation are: Table 17

RATIONALE

We identified one High quality study[45] of a hematoma block and one Low quality study[46] of a femoral nerve block, both of which were effective at reducing pain. In the expert opinion of the work group, the risks associated with regional pain management, such as femoral nerve neuritis and the complications associated with epidural anesthesia in lower extremity fractures (missed compartment syndrome), are less than with oral or IV systemic medicines.

SUPPORTING EVIDENCE

One Moderate Quality study[45] investigating a hematoma block and one Low quality case series[46] investigating a femoral nerve block addressed this recommendation. The High quality study compared patients who received a bupivacaine hematoma block after elastic nail fixation to patients who did not receive a hematoma block. Pain scale scores were not reported; however, patients who received a hematoma block received their first post-operative narcotic dose a mean of 5 hours later than patients in the control group ($p = .008$).

In the Low quality case series, the authors reported that the nerve block was effective at reducing pain (Figure 38). The onset of analgesia occurred in 8.0 ± 3.5 minutes. The pain scale used in this study ranges from 0 (calm, no spontaneous pain or during handling, radiographs, or traction installation) to 4 (child is crying, major tachycardia (>60% normal rate in consideration to age) and high blood pressure, handling impossible). Table 17 lists the complications in this study.

Figure 35. Hematoma Block vs. Control - Time until First Post-Operative Narcotic Dose

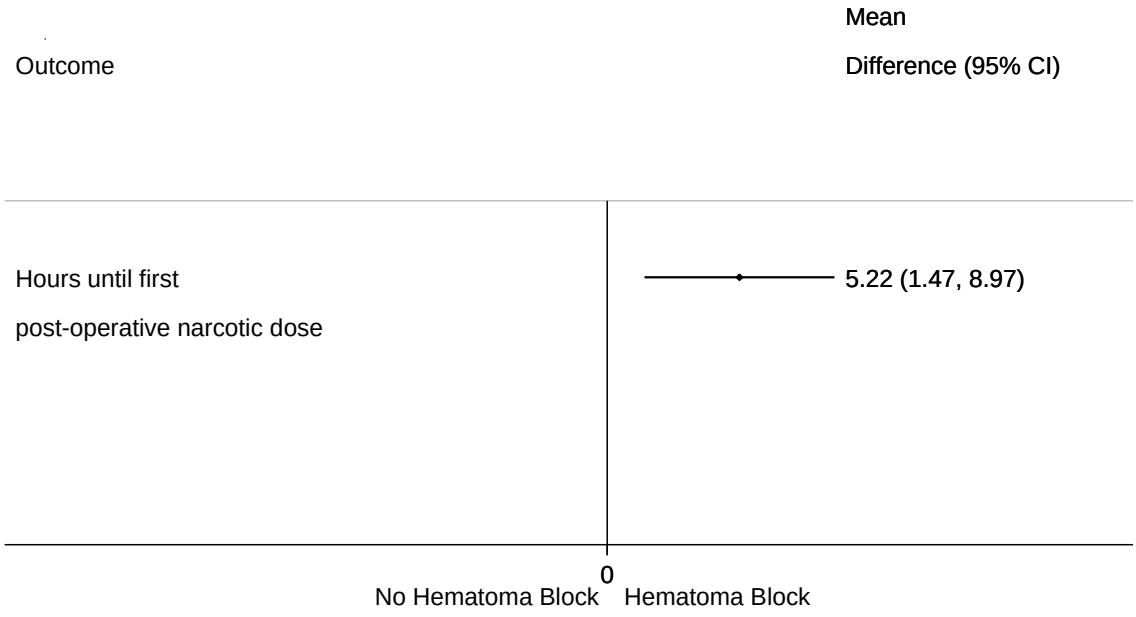


Figure 36. Hematoma Block vs. Control - Post-Operative Narcotic Requirement

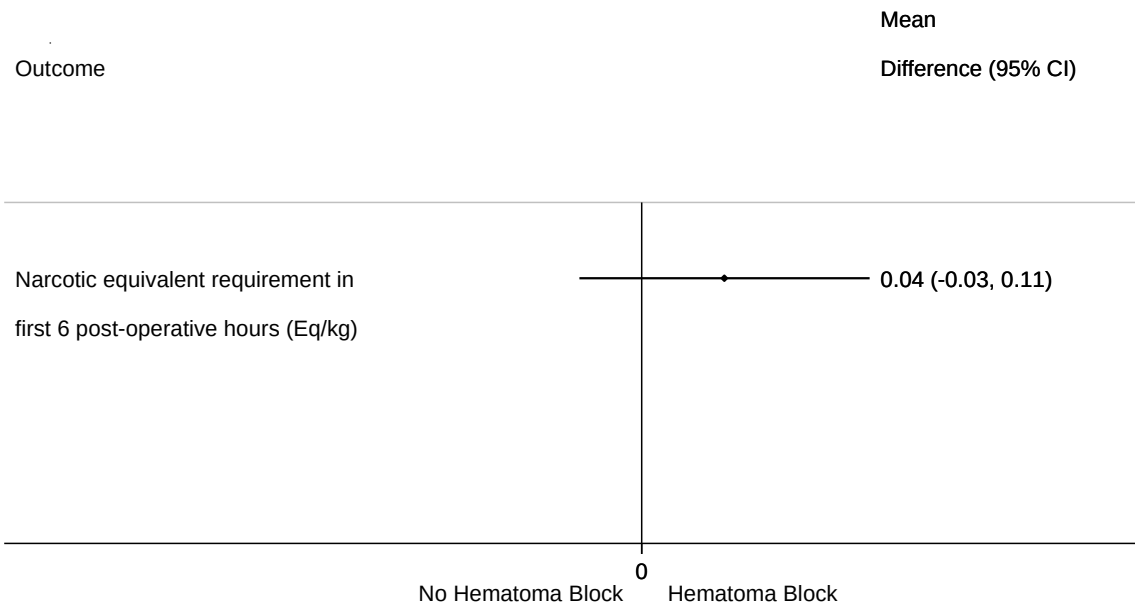


Figure 37. Hematoma Block vs. Control - Binary Outcomes

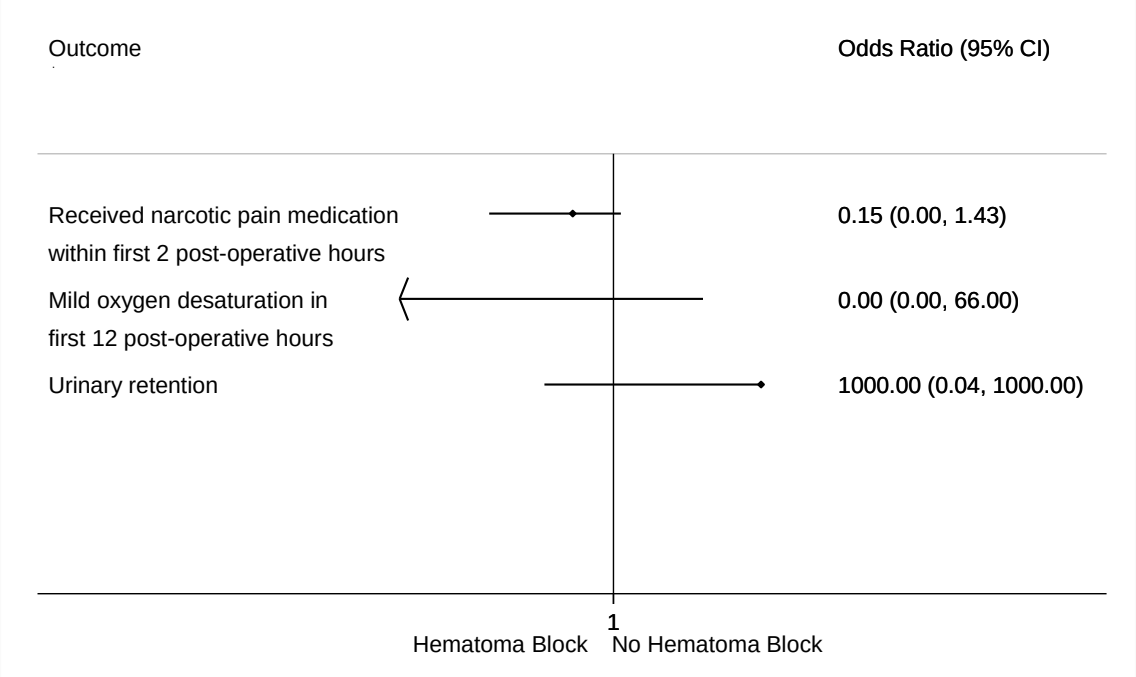
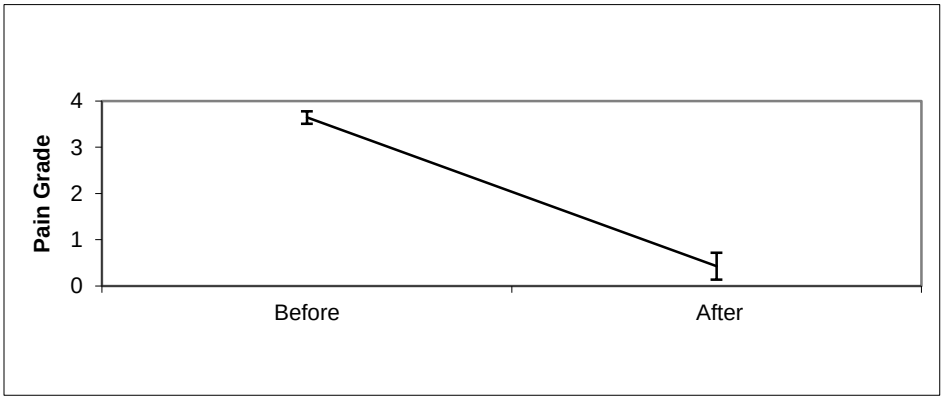


Figure 38. Femoral Nerve Block – Pain Relief



*p<.001 (AAOS calculation); AAOS computed the 95% confidence intervals from published data

Table 17. Femoral Nerve Block Complications

Outcome	n	%
Failed block	14	7%
Femoral artery puncture		7%
ECG changes		0%
Seizure		0%
Respiratory Rate Abnormality		0%
Adverse Sequelae		0%
Neurologic Abnormality (at discharge)		0%

PREVIOUSLY PUBLISHED SYSTEMATIC REVIEWS

A previous systematic review [47] concluded that femoral nerve block effectively reduces pain in children with femoral shaft fractures. Although the stated subject of this systematic review was children, two of the three included studies included adults. Therefore, we did not include it in our systematic review.

WATERPROOF CASTING

Limited evidence supports waterproof cast liners for spica casts are an option for use in children diagnosed with pediatric diaphyseal femur fractures.

Grade of Recommendation: Limited ★★☆☆

Figures relevant to this recommendation are: Figure 39

RATIONALE

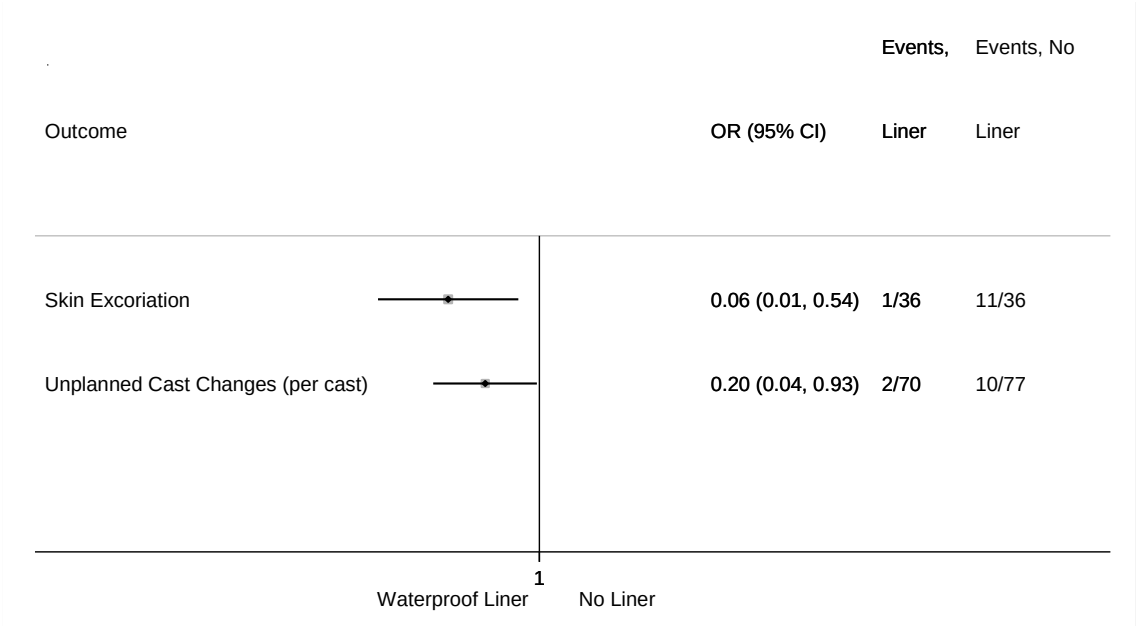
Waterproof cast liners are often used when applying a spica cast for the management of femur fractures in children in order to improve ease of care.

We identified one High Quality study[48] that addressed the use of waterproof liners in spica casts. Use of a waterproof liner was associated with significantly fewer skin problems and unexpected cast changes. However, in this study spica casts were used for the management of developmental dysplasia of the hip, not specifically for diaphyseal femur fractures. In addition, other outcomes such as impact on family and financial considerations were not studied. Waterproof liners may make cast care easier for the family, thus decreasing the overall impact of treatment on family functioning. Cast liners add increased cost to overall management. Nevertheless, the patient ages were similar to the patient ages for spica cast management of diaphyseal femur fractures and the findings should be able to be extrapolated. The overall benefit in terms of skin problems, unplanned cast changes, and ease of care for the family likely obviates the increased costs from the use of waterproof cast liners in the expert opinion of the physician work group.

SUPPORTING EVIDENCE

One High Quality study[48] addressed this recommendation. In this study, however, hip spica casts were applied to treat conditions other than diaphyseal femur fractures, such as developmental dysplasia. The study compared the use of hip spica casts with and without a waterproof liner. The use of a waterproof liner was associated with significantly fewer occurrences of skin excoriation and unplanned cast changes.

Figure 39. Waterproof Liner vs. No Waterproof Liner



Future Research

The quality of scientific data regarding the management of femur fractures in children is clearly lacking. Controversy exists regarding the optimal management of pediatric femur fractures. A multitude of treatment options exist including Pavlik harness, spica casting, traction, external fixation, flexible intramedullary nailing, rigid intramedullary nailing, and bridge plating. Properly designed randomized clinical trials comparing treatment options are necessary to determine optimal treatment. These trials would benefit from being multicenter trials in terms of accrual of patients and external validity.

Specific trials which would be helpful include:

1. Delayed spica casting versus immediate spica casting for femur fractures in children 6 months – 6 years old.
2. Flexible intramedullary nailing versus immediate spica casting for femur fractures in children 5 and 6 years old, and even children younger than 5-6 years of age.
3. External fixation versus bridge plating versus elastic nails versus rigid trochanteric nails for length unstable femur fractures in children 6 years old – skeletal maturity.
4. Flexible intramedullary nailing versus rigid intramedullary nailing versus bridge plating for femur fractures in children 6 years old – skeletal maturity.

Intermediate outcome measures are often used in studies regarding pediatric femur fractures such as radiographic parameters. Functional outcome measures and later development of osteoarthritis are difficult to measure and have a long time course. However, the relationship between commonly accepted radiographic measures of malunion and functional outcome or later development of problems is not clear. Further research to validate accepted radiographic standards of malunion would be extremely valuable. Also the inclusion of family function outcomes may improve recommendations

for those younger patients that may either get intramedullary nailing versus immediate spica casting.

V. **APPENDIXES**

APPENDIX I
AAOS BODIES THAT APPROVED THE 2015 GUIDELINE REISSUE

This final guideline draft must be approved by the AAOS Committee on Evidence Based Quality and Value, the AAOS Council on Research and Quality, and the AAOS Board of Directors. These decision-making bodies are invited to provide comments during the review process for consideration by the work group but are not designated to modify the contents of the guideline. Their charge is to approve or reject its publication by majority vote.

Committee on Evidence Based Quality and Value - April 18, 2015

The committee on Evidence Based Quality and Value (EBQV) consists of twenty AAOS members who implement evidence-based quality initiatives such as clinical practice guidelines (CPGs) and appropriate use criteria (AUCs). They also oversee the dissemination of related educational materials and promote the utilization of orthopaedic value products by the Academy's leadership and its members.

Council on Research and Quality – May 8, 2015

The Council on Research and Quality promotes ethically and scientifically sound clinical and translational research to sustain patient care in musculoskeletal disorders. The Council also serves as the primary resource for educating its members, the public, and public policy makers regarding evidenced-based medical practice, orthopaedic devices and biologics, regulatory pathways and standards development, patient safety, occupational health, technology assessment, and other related important errors.

The Council is comprised of the chairs of the committees on Biological Implants, Biomedical Engineering, Occupational Health and Workers' Compensation, Patient Safety, Research Development, U.S. Bone and Joint Decade, and chair and Appropriate Use Criteria and Clinical Practice Guideline section leaders of the Evidence Based Quality and Value committee. Also on the Council are the second vice-president, three members at large, and representatives of the Diversity Advisory Board, Women's Health Issues Advisory Board, Board of Specialty Societies (BOS), Board of Councilors (BOC), Communications Cabinet, Orthopaedic Research Society (ORS), Orthopedic Research and Education Foundation (OREF).

Board of Directors – June 5, 2015

The 17 member Board of Directors manage the affairs of the AAOS, set policy, and oversee the Strategic Plan.

The 2009 CPG was approved by the AAOS Guidelines and Technology Oversight Committee, the AAOS Evidence Based Practice Committee, the AAOS Council on Research, Quality Assessment and Technology, and the AAOS Board of Directors

APPENDIX II
LITERATURE SEARCHES

The search for eligible literature began with a search of the following databases on May 8, 2008, and updated on October 6, 2008, and November 27, 2013:

- PubMed (from 1966 through November 27, 2013)
- EMBASE (from 1966 through November 27, 2013)
- CINAHL (from 1982 through November 27, 2013)
- The Cochrane Central Register of Controlled Trials (through November 27, 2013)

The original search (after removal of duplicates) yielded 1181 articles, of which 274 were retrieved and evaluated. The full search strategies are listed below. The updated search conducted in November 2013 yielded an additional 384 articles published after the original search.

All literature searches were supplemented with manual screening of bibliographies in publications accepted for inclusion into the evidence base. In addition, the bibliographies of recent systematic reviews and other review articles were searched for potentially relevant citations.

GENERAL SEARCH

PubMed was searched using the following strategy:
(diaphyseal OR diaphysis OR shaft OR diaphysial) AND fracture AND (femur OR femoral OR thigh) NOT "comment"[Publication Type] NOT "editorial"[Publication Type] NOT "letter"[Publication Type] NOT "Addresses"[Publication Type] NOT "News"[Publication Type] NOT "Newspaper Article"[Publication Type] AND (("1966/1/1"[EDat]:"2008/10/01"[EDat]) AND (Humans[Mesh]) AND (English[lang]) AND ((infant[MeSH] OR child[MeSH] OR adolescent[MeSH])))

EMBASE was searched using the following strategy:
(diaphyseal OR ('diaphysis'/exp OR 'diaphysis') OR shaft OR diaphysial) AND ('fracture'/exp OR 'fracture') AND (('femur'/exp OR 'femur') OR femoral OR ('thigh'/exp OR 'thigh')) AND ([article]/lim OR [review]/lim) AND [english]/lim AND [humans]/lim AND ([infant]/lim OR [child]/lim OR [adolescent]/lim) AND [embase]/lim AND [1966-2008]/py

CINAHL was searched using the following strategy:
(diaphyseal OR diaphysis OR shaft OR diaphysial) AND fracture AND (femur OR femoral OR thigh)

Cochrane Central Register of Controlled Trials was searched using the following strategy:
(diaphyseal OR diaphysis OR shaft OR diaphysial) AND fracture AND (femur OR femoral OR thigh)

WATERPROOF CAST LINER SEARCH

A search for literature pertaining to cast liners began with a search of the following databases on August 6, 2008, and updated on October 7, 2008, and November 27, 2013:

PubMed was searched using the following strategy:
cast AND (liner OR waterproof)

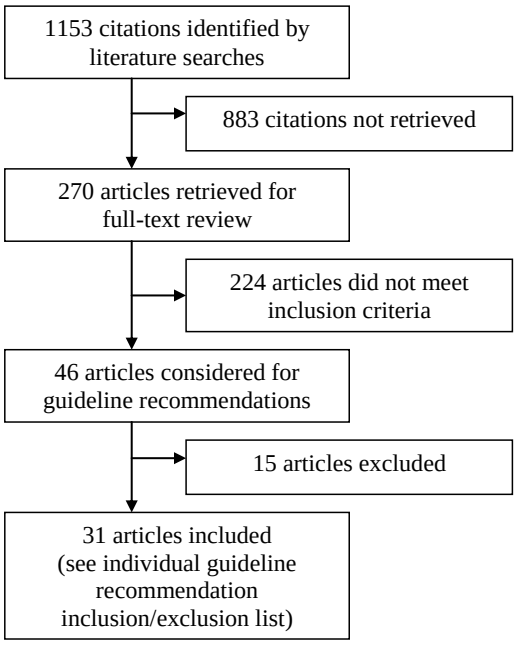
EMBASE was searched using the following strategy:
cast AND (liner OR waterproof) AND [english]/lim AND [humans]/lim AND [embase]/lim

CINAHL was searched using the following strategy:
Cast AND (liner OR waterproof)

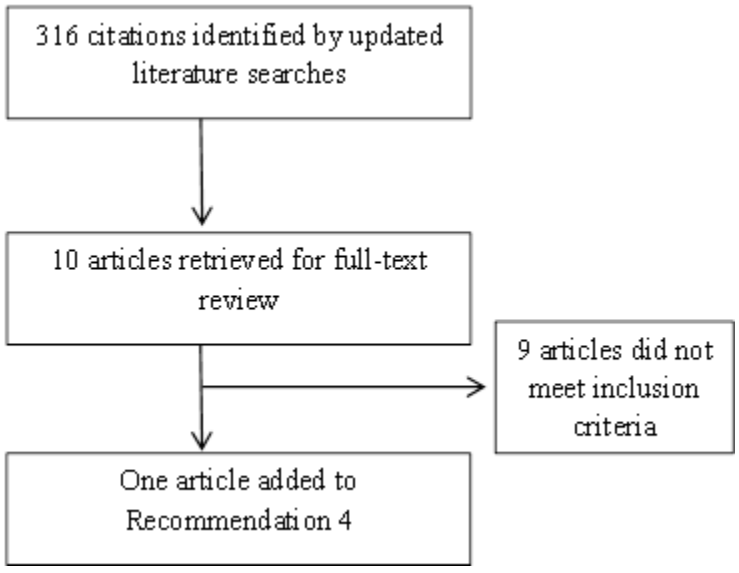
Cochrane Central Register of Controlled Trials was searched using the following strategy:
Cast AND (liner OR waterproof)

APPENDIX III
STUDY ATTRITION FLOWCHARTS

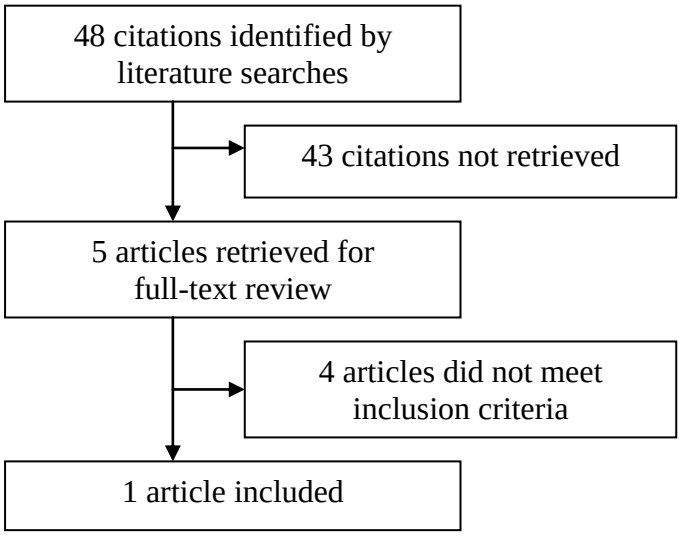
ORIGINAL 2008 LITERATURE SEARCH FLOWCHART



UPDATED 2013 LITERATURE SEARCH FLOWCHART



WATERPROOF CAST LINER SEARCH FLOWCHART



APPENDIX IV
DATA EXTRACTION ELEMENTS

The data elements below were extracted into electronic forms in Microsoft® Excel from published studies. The extracted information includes:

Study Characteristics (for all relevant outcomes in a study)

- methods of randomization and allocation
- use of blinding (patient, caregiver, evaluator)
- funding source/conflict of interest
- duration of the study
- number of subjects and follow-up percentage
- experimental and control groups
- *a priori* power analysis

Patient Characteristics (for all treatment groups in a study)

- patient inclusion/exclusion criteria
- age
- weight
- surgical complications
- adverse events

Results (for all relevant outcomes in a study)

- duration at which outcome measure was evaluated
- mean value of statistic reported (for dichotomous results)
- mean value of measure and value of dispersion (for continuous results)
- statistical test p-value

APPENDIX V
FORM FOR ASSIGNING GRADE OF RECOMMENDATION (INTERVENTIONS)

GUIDELINE RECOMMENDATION_____

PRELIMINARY GRADE OF
RECOMMENDATION:_____

STEP 1: LIST BENEFITS AND HARMS

Please list the benefits (as demonstrated by the systematic review) of the intervention

Please list the harms (as demonstrated by the systematic review) of the intervention

Please list the benefits for which the systematic review is not definitive

Please list the harms for which the systematic review is not definitive

STEP 2: IDENTIFY CRITICAL OUTCOMES

Please circle the above outcomes that are critical for determining whether the intervention is beneficial and whether it is harmful

Are data about critical outcomes lacking to such a degree that you would lower the preliminary grade of the recommendation?

What is the resulting grade of recommendation?

STEP 3: EVALUATE APPLICABILITY OF THE EVIDENCE

Is the applicability of the evidence for any of the critical outcomes so low that substantially worse results are likely to be obtained in actual clinical practice?

Please list the critical outcomes backed by evidence of doubtful applicability:

Should the grade of recommendation be lowered because of low applicability?

What is the resulting grade of recommendation?

STEP 4: BALANCE BENEFITS AND HARMS

Are there trade-offs between benefits and harms that alter the grade of recommendation obtained in STEP 3?

What is the resulting grade of recommendation?

STEP 5 CONSIDER STRENGTH OF EVIDENCE

Does the strength of the existing evidence alter the grade of recommendation obtained in STEP 4?

What is the resulting grade of recommendation?

NOTE: Because we are not performing a formal cost analyses, you should only consider costs if their impact is substantial.

APPENDIX VI
PEER REVIEW PANEL FOR THE ORIGINAL 2009 GUIDELINE

Participation in the AAOS peer review process does not constitute an endorsement of this guideline by the participating organization.

Peer review of the draft guideline is completed by an outside Peer Review Panel. Outside peer reviewers are solicited for each AAOS guideline and consist of experts in the guideline's topic area. These experts represent professional societies other than AAOS and are nominated by the guideline Work Group prior to beginning work on the guideline. For this guideline, five outside peer review organizations were invited to review the draft guideline and all supporting documentation. All five societies participated in the review of the Treatment of Pediatric Diaphyseal Femur Fractures guideline draft and four consented to be listed as a peer review organization in this appendix. One organization did not give explicit consent that the organization name could be listed in this publication. The organizations that reviewed the document and consented to publication are listed below:

American Academy of Pediatrics, Section on Orthopaedics

European Paediatric Orthopaedic Society

Orthopaedic Trauma Association

American Osteopathic Academy of Orthopedics

Individuals who participated in the peer review of this document and gave their consent to be listed as reviewers of this document are:

James Breivis, MD, San Francisco, CA
Blair C. Filler MD, Los Angeles, CA
J. Eric Gordon MD, St. Louis MS
Michael Heggeness MD, Houston, TX
Harvey Insler MD, Erie, PA
John Kirkpatrick MD, Jacksonville, FL
Pierre Lascombes MD, Nancy France
David A. Podenswa MD, Dallas, TX
Charles A Reitman MD, Houston, TX
Debra K. Spatz, D.O, Prince Frederick, MD

Again, participation in the AAOS guideline peer review process does not constitute an endorsement of the guideline by the participating organizations or the individuals listed above.

PUBLIC COMMENTARY FOR ORIGINAL 2009 GUIDELINE

A period of public commentary follows the peer review of the draft guideline. If significant non-editorial changes are made to the document as a result of public commentary, these changes are also documented and forwarded to the AAOS bodies that approve the final guideline. Public commentators who gave explicit consent to be listed in this document include the following:

Participation in the AAOS guideline public commentary review process does not constitute an endorsement of the guideline by the participating organizations or the individual listed nor does it is any way imply the reviewer supports this document.

Jeffrey Anglen MD, Indianapolis, IN
Howard R. Epps MD, Houston TX
M. Bradford Henley MD MBA, Seattle WA
William C McMaster MD, Orange, CA
Jack R. Steel MD, Huntington WV

J. Mark Melhorn MD, Wichita, KS on behalf of:
The American Academy of Disability Evaluating Physicians

APPENDIX VII
STRUCTURED PEER REVIEW FORM

Reviewer Information:

Name of Reviewer_____
Address_____
City_____ State_____ Zip Code_____
Phone _____Fax _____
E-mail_____

Specialty Area/Discipline: _____
Work setting: _____
Credentials: _____

May we list you as a Peer Reviewer in the final Guidelines? ☐ Yes ☐ No

Are you reviewing this guideline as a representative of a professional society? ☐ Yes ☐ No

If yes, may we list your society as a reviewer of this guideline? ☐ Yes ☐ No

Reviewer Instructions
Please read and review this Draft Clinical Practice Guideline and its associated Technical Report with particular focus on your area of expertise. Your responses are confidential and will be used only to assess the validity, clarity, and accuracy of the interpretation of the evidence. If applicable, please specify the draft page and line numbers in your comments. Please feel free to also comment on the overall structure and content of the guideline and Technical Report.

If you need more space than is provided, please attach additional pages.
Please complete and return this form electronically to weis@aaos.org or fax the form back to Jan Weis at (847) 823-9769.

Thank you in advance for your time in completing this form and giving us your feedback. We value your input and greatly appreciate your efforts. Please send the completed form and comments by **Month, Day, Year**

	Please indicate your level of agreement with each of the following Statements, by placing an "X" in the appropriate box.			
	Very much agree	**Moderately agree**	**Moderately disagree**	**Very much disagree**
1. The recommendations are clearly stated	☐	☐	☐	☐
2. There is an explicit link between the recommendations and the supporting evidence	☐	☐	☐	☐
3. Given the nature of the topic and the data, all clinically important outcomes are considered	☐	☐	☐	☐
4. The guideline's target audience is clearly described	☐	☐	☐	☐
5. The patients to whom this guideline is meant to apply are specifically described	☐	☐	☐	☐
6. The criteria used to select articles for inclusion are appropriate	☐	☐	☐	☐
7. The reasons why some studies were excluded are clearly described	☐	☐	☐	☐
8. All important studies that met the article inclusion criteria are included	☐	☐	☐	☐
9. The validity of the studies is appropriately appraised	☐	☐	☐	☐
10. The methods are described in such a way as to be reproducible.	☐	☐	☐	☐
11. The statistical methods are appropriate to the material and the objectives of this guideline	☐	☐	☐	☐
12. Important parameters (e.g., setting, study population, study design) that could affect study results are systematically addressed	☐	☐	☐	☐
13. Health benefits, side effects, and risks are adequately addressed	☐	☐	☐	☐
14. The writing style is appropriate for health care professionals and patients	☐	☐	☐	☐
15. The grades assigned to each recommendation are appropriate	☐	☐	☐	☐

COMMENTS

Please provide a brief explanation of both your positive and negative answers in the preceding section. If applicable, please specify the draft page and line numbers in your comments. Please feel free to also comment on the overall structure and content of the guideline and Technical Report

OVERALL ASSESSMENT

Would you recommend these guidelines for use in practice? (check one)

Strongly recommend _____

Recommend (with provisions or alterations) _____

Would not recommend _____

Unsure _____

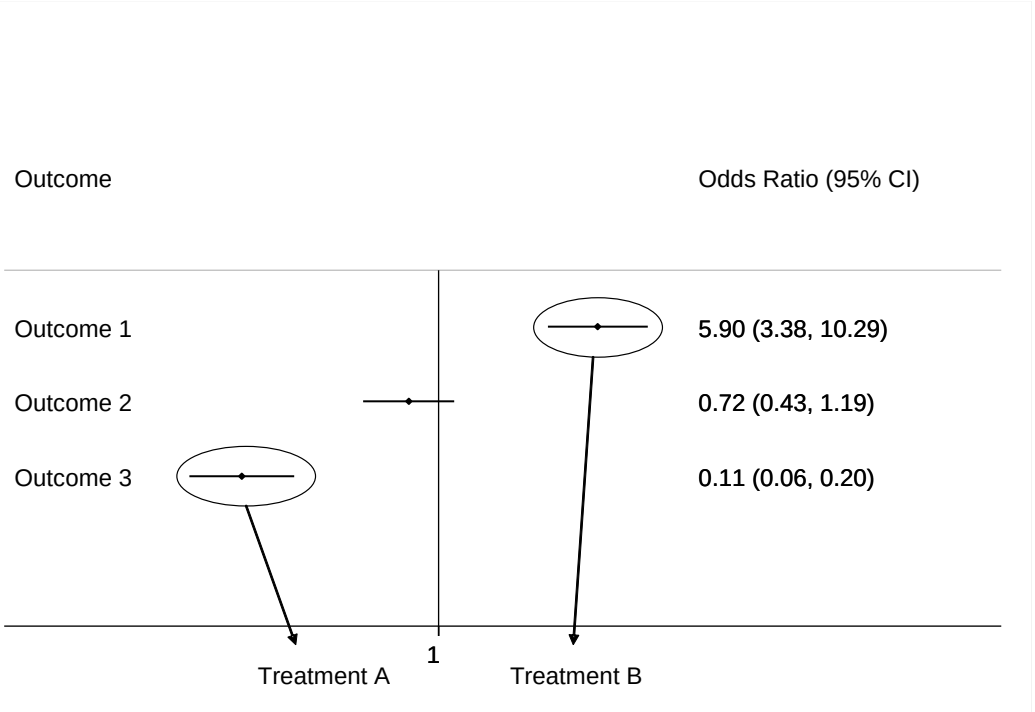
COMMENTS:
Please provide the reason(s) for your recommendation.

APPENDIX VIII
INTERPRETING THE FOREST PLOTS[49]

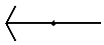
Throughout the guideline we use descriptive diagrams or forest plots to present data from studies comparing the differences in outcomes between two treatment groups. In this guideline there are no meta-analyses (combining results of multiple studies into a single estimate of overall effect), so each point and corresponding horizontal line on a sample plot should be viewed independently. In the example below, the odds ratio is the effect measure used to depict differences in outcomes between the two treatment groups of a study. In other forest plots, the point can refer to other summary measures (such as the mean difference or relative risk). The horizontal line running through each point represents the 95% confidence interval for that point. In this graph, the solid vertical line represents "no effect" where the Odds Ratio, OR, is equal to one. When mean differences are portrayed, the vertical line of no effect is at zero.

For example, in the figure below the odds of a patient experiencing Outcome 1 are 5.9 times greater for patients who received Treatment B than for patients who received Treatment A.. This result is statistically significant because the 95% Confidence Interval does not cross the "no effect" line. In general, the plots are arranged such that results to the left of the "no effect" line favor Treatment A while results to the right favor Treatment B. In the example below, the odds ratio for Outcome 1 favors Treatment B, the odds ratio for Outcome 3 favors Treatment A, and the odds ratio for Outcome 2 does not favor either treatment because the 95% CI crosses the "no effect" line (i.e. the difference is not statistically significant).

Sample Plot



DESCRIPTION OF SYMBOLS USED IN FIGURES AND TABLES

Symbol	Description
OR	Odds Ratio = The odds in Group B divided by the odds in Group A, where the odds is the probability of the outcome occurring divided by the probability of the outcome not occurring.
95% CI	95% Confidence Interval = A measure of uncertainty of the point estimate: if the trial were repeated an infinite number of times, then the 95% CI calculated for each trial would contain the true effect 95% of the time.
	An arrow in a forest plot indicates that the 95% confidence interval continues beyond the range of the graph.
○	An open circle in a Summary of Evidence Table indicates that the result is not statistically significant.
● fn	A filled-in circle in a Summary of Evidence Table indicates that the result is statistically significant in favor of the listed treatment (in this example, in favor of fn = flexible nails)

APPENDIX IX
CONFLICT OF INTEREST

All members of the AAOS work group disclosed their conflicts of interest prior to the development of the recommendations for this guideline. Conflicts of interest are disclosed in writing with the American Academy of Orthopaedic Surgeons via a private on-line reporting database and also verbally at the recommendation approval meeting. Members of all AAOS Work Groups are required to disclose their conflicts of interest at the same level and depth of detail as the AAOS Board of Directors.

AAOS DISCLOSURE PROGRAM INFORMATION

R Dale Blasier, MD (Little Rock, AR): 4 (Synthes); 7 (Synthes). Submitted on: 04/23/2008.

Michael J Goldberg, MD: 2 (Journal of Pediatric Orthopedics; Journal of Children's Orthopaedics). Submitted on: 12/11/2007.

Mininder S Kocher, MD (Boston, MA): 1 (Pediatric Orthopaedic Society of North America); 5A (Biomet; Regen Biologics; Smith & Nephew); 7 (CONMED Linvatec); 9 (Saunders/Mosby-Elsevier). Submitted on: 05/27/2008.

Scott J Luhmann, MD (Saint Louis, MO): 4 (Medtronic Sofamor Danek; Stryker); 5A (Medtronic Sofamor Danek); 7 (Medtronic Sofamor Danek). Submitted on: 08/05/2008.

Travis Matheney, MD (Boston, MA): (n). Submitted on: 10/29/2008

Charles T Mehlman, DO (Cincinnati, OH): 2 (Journal of Bone and Joint Surgery - American; Journal of Orthopaedics and Traumatology; Journal of Pediatric Orthopedics; Saunders/Mosby-Elsevier; Wolters Kluwer Health - Lippincott Williams & Wilkins; eMedicine (Orthopaedic Surgery); Journal Children's Orthopaedics (EPOS); The Orthopod (JAOAO); The Spine Journal (NASS)); 5B (Stryker); 7 (DePuy, A Johnson & Johnson Company; Medtronic Sofamor Danek; National Institutes of Health (NIAMS & NICHD); Synthes; University Cincinnati); 8 (Eli Lilly; Zimmer). Submitted on: 04/08/2008.

James O Sanders, MD (Rochester, NY): 7 (Medtronic Sofamor Danek; K2M); 8 (Abbott; Biomedical Enterprises). Submitted on: 07/30/2008.

David M Scher, MD (New York, NY): 1 (American Academy for Cerebral Palsy and Developmental Medicine; Pediatric Orthopaedic Club of New York); 2 (Hospital for Special Surgery Journal). Submitted on: 03/28/2008.

Ernest L Sink, MD (Aurora, CO): 1 (Pediatric Orthopaedic Society of North America); 2 (Orthopedics); 4 (Biomet); 5B (Biomet). Submitted on: 04/15/2008.

William Charles Watters III, MD: 1 (North American Spine Society; Work Loss Data Institute); 2 (The Spine Journal); 5A (Stryker; Intrinsic Therapeutics; MeKessen Health Care Solutions). Submitted on: 10/09/2007 at 08:09 PM and last confirmed as accurate on 04/23/2008.

Disclosure Items: (n) = Respondent answered 'No' to all items indicating no conflicts. 1=Board member/owner/officer/committee appointments; 2= Medical/Orthopaedic Publications; 3= Royalties; 4= Speakers bureau/paid presentations;5A= Paid consultant; 5B= Unpaid consultant; 6= Research or institutional support from a publisher; 7= Research or institutional support from a company or supplier; 8= Stock or Stock Options; 9= Other financial/material support from a publisher; 10= Other financial/material support from a company or supplier.

APPENDIX X

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Ref Type: Electronic Citation

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APPENDIX XI

INCONCLUSIVE RECOMMENDATIONS REMOVED FROM UPDATED GUIDELINE

The recommendations listed below were published in the original 2009 guideline, but removed from the 2015 reissue due to a lack of evidence.

- We are unable to recommend for or against early spica casting for children age six months to five years with a diaphyseal femur fracture with greater than 2 cm of shortening.

- We are unable to recommend for or against patient weight as a criterion for the use of spica casting in children age six months to five years with a diaphyseal femur fracture.

- We are unable to recommend for or against using any specific degree of angulation or rotation as a criterion for altering the treatment plan when using the spica cast in children six months to five years of age.

- We are unable to recommend for or against removal of surgical implants from asymptomatic patients after treatment of diaphyseal femur fractures.

- We are unable to recommend for or against outpatient physical therapy to improve function after treatment pediatric diaphyseal femur fractures.

- We are unable to recommend for or against the use of locked versus non-locked plates for fixation of pediatric femur fractures.