



**TREATMENT OF PEDIATRIC DIAPHYSEAL
FEMUR FRACTURES**

GUIDELINE AND EVIDENCE REPORT

**Adopted by the AAOS Board of Directors
June 19, 2009**

Endorsed by:



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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Summary of Recommendations

The following is a summary of the recommendations in the AAOS' clinical practice guideline, 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.

1. We recommend that children younger than thirty-six months with a diaphyseal femur fracture be evaluated for child abuse.
Level of Evidence: II
Grade of Recommendation: A
2. Treatment with a Pavlik harness or a spica cast are options for infants six months and younger with a diaphyseal femur fracture.
Level of Evidence: IV
Grade of Recommendation: C
3. We suggest 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.
Level of Evidence: II
Grade of Recommendation: B
4. 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.
Level of Evidence: V
Grade of Recommendation: Inconclusive
5. 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.
Level of Evidence: V
Grade of Recommendation: Inconclusive
6. When using the spica cast in children six months to five years of age, altering the treatment plan is an option if the fracture shortens greater than 2 cm.
Level of Evidence: V
Grade of Recommendation: C

7. 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.
Level of Evidence: V
Grade of Recommendation: Inconclusive
8. It is an option for physicians to use flexible intramedullary nailing to treat children age five to eleven years diagnosed with diaphyseal femur fractures.
Level of Evidence: III
Grade of Recommendation: C
9. Rigid trochanteric entry nailing, submuscular plating, and flexible intramedullary nailing are 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.
Level of Evidence: IV
Grade of Recommendation: C
10. We are unable to recommend for or against removal of surgical implants from asymptomatic patients after treatment of diaphyseal femur fractures.
Level of Evidence: IV
Grade of Recommendation: Inconclusive
11. We are unable to recommend for or against outpatient physical therapy to improve function after treatment pediatric diaphyseal femur fractures.
Level of Evidence: V
Grade of Recommendation: Inconclusive
12. Regional pain management is an option for patient comfort perioperatively.
Level of Evidence: IV
Grade of Recommendation: C
13. We are unable to recommend for or against the use of locked versus non-locked plates for fixation of pediatric femur fractures.
Level of Evidence: IV
Grade of Recommendation: Inconclusive
14. Waterproof cast liners for spica casts are an option for use in children diagnosed with pediatric diaphyseal femur fractures.
Level of Evidence: III
Grade of Recommendation: C

Work Group

**Mininder S. Kocher, MD, MPH,
Chair**

Children's Hospital
300 Longwood Ave
Orthopaedic Dept
Boston, MA 02115

Ernest L. Sink, MD, Co-Chair

The Children's Hospital
13123 East 16th Ave B060
Aurora, CO 80045

R Dale Blasier, MD

Dept of Orthopaedic Surgery
800 Marshall St Sturgis 363
Little Rock, AR 72202

Scott J. Luhmann, MD

St Louis Children's Hospital
One Children's Pl Ste 4S 20
Saint Louis, MO 63110

Charles T. Mehlman, DO, MPH

Children's Hospital Medical Center
3333 Burnet Avenue, MLC 2017
Cincinnati, Ohio 45229-3039

David M. Scher, MD

Hospital for Special Surgery
535 E 70th St 5th Fl
New York, NY 10021

Travis Matheney, MD

Children's Hospital Boston
Orthopedic Surgery
47 Joy Street
Boston, MA 02115

James O Sanders, MD

Department of Orthopaedics
Rehabilitation University of Rochester
601 Elmwood Avenue
Rochester NY 14642

Guidelines Oversight Chair:

William C. Watters, III MD

6624 Fannin #2600
Houston, TX 77030

Guidelines Oversight Vice-Chair:

Michael J. Goldberg MD

Children's Hospital and Regional
Medical Ctr.
4800 Sand Point Way NE #w7706
PO Box 5371
Seattle WA 98105-5371

Evidence-Based Practice Committee
Chair:

Michael Warren Keith, MD

2500 Metro Health Drive
Cleveland, OH 44109-1900

AAOS Staff:

Robert H. Haralson III, MD, MBA

AAOS Medical Director
6300 N River Road
Rosemont, IL 60018

Charles M. Turkelson, PhD

Director of Research and Scientific
Affairs

Janet L. Wies, MPH

Manager, Clinical Practice Guidelines

Patrick Sluka, MPH

Lead Research Analyst

Kristin Hitchcock

AAOS Medical Librarian

Peer Review

The following organizations participated in peer review of this clinical practice guideline:

American Academy of Pediatrics, Section on Orthopaedics

European Paediatric Orthopaedic Society

Orthopaedic Trauma Association

American Osteopathic Academy of Orthopedics

American Academy of Orthopaedic Surgeons (AAOS) Committees
Guidelines and Technology Oversight Committee (GTOC)
Evidence Based Practice Committee (EBPC)

For additional information concerning these processes and a complete list of individuals who participated in the peer review or public commentary processes of this document, please refer to the Appendices.

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I. 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. Insurance payers, governmental bodies, and health-policy decision-makers may also find this guideline useful as an evolving standard of evidence regarding treatment of diaphyseal femur fractures in pediatric patients.

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.

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 activities.^{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 whites¹ 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 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.

II. 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.

This 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 (Appendix I). When information from the literature was sparse or lacking, it was supplemented by the consensus opinion of the work group.

To develop this 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 (see Appendix II for a description of the AAOS bodies involved in the approval process)

PRELIMINARY RECOMMENDATIONS

The 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 Level II studies that addressed the recommendation, Level III and IV 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 $\geq 50\%$ (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.

LITERATURE SEARCHES

We searched for articles published up to October 1, 2008. Search strategies were reviewed by the 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 III.

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 IV provides details about the inclusion and exclusion of these studies.

JUDGING THE QUALITY OF EVIDENCE

The quality of evidence was rated using an evidence hierarchy and an accompanying checklist for RCTs. This evidence hierarchy is shown in Appendix V.

Randomized controlled trials were categorized as Level I studies, but the level of evidence was reduced by one level if there was a “No” or “Not Reported by Authors” to any of the following checklist questions:

- Was randomization stochastic? (i.e. at the time of assignment to groups, did all patients have an equal probability of being assigned to any given group)
- Was there concealment of the allocation to groups?
- Were the patients, caregivers, or evaluators blinded?

Downgrading of Level I studies was not cumulative. If a study had more than one of the methodological flaws listed above, it would only decrease by a single level. The downgrading of the formal level of evidence of a study indicates the discrepancy between claims of the study authors and the results of the critical appraisal process.

Non-randomized controlled trials and other prospective comparative studies were categorized as Level II studies. Retrospective comparative studies and case-control studies were initially categorized as Level III studies and case-series studies/reports were categorized as Level IV studies.

When comparative studies had only one group that was relevant to the recommendation, the data from these studies were considered as Level IV evidence.

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 VI.

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

Grade	Overall Quality of Evidence	Description of Evidence
A	Good Quality Evidence	More than one Level I study with consistent findings for or against recommending intervention.
B	Fair Quality Evidence	More than 1 Level II or III study with consistent findings or a single Level I study for or against recommending intervention.
C	Poor Quality Evidence	More than 1 Level IV or V study or a single Level II or III study for or against recommending intervention.
I	No Evidence or Conflicting Evidence	There is insufficient or conflicting evidence not allowing a recommendation for or against intervention.

Final grades were based upon preliminary grades assigned by AAOS staff, which took into account only the quality and quantity of the available evidence as listed in the table above. Work group members then modified the grade using the ‘Form for Assigning Grade of Recommendation (Interventions)’ shown in Appendix VII. This form, which is based on recommendations of the GRADE Work Group¹² requires the work group to consider the harms, benefits, and critical outcomes associated with a treatment. It also requires the work group to evaluate the applicability of the evidence. The final grade is assigned by the physician work group, which modifies the preliminary grade on the basis of these considerations.

CONSENSUS DEVELOPMENT

The recommendations and their grades were voted on using a structured voting technique. Voting on guideline recommendations was conducted using a secret ballot. Each member of the guideline work group either agreed (“yes”) or disagreed (“no”) with a guideline recommendation. Work group members were blinded to the responses of other members. Unanimous agreement was needed in order for a recommendation to pass. If voting was not unanimous, there was further discussion to see whether the disagreement(s) could be resolved. Up to three rounds of voting were held to attempt to resolve disagreements. If disagreements were not resolved following three voting rounds, no recommendation was adopted.

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

Table 2 AAOS Guideline Language

Guideline Language	Grade of Recommendation	Level of Evidence
<i>We recommend</i>	A	Level I
<i>We suggest</i>	B	Level II or III
<i>option</i>	C	Level IV or V
<i>We are unable to recommend for or against</i>	I	None or Conflicting

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 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 VIII). 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 IX) 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 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 final guideline draft 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. Descriptions of these bodies are provided in Appendix II.

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 Medicine 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 Orthopedic Surgeons and AAOS Now.

For selected guidelines, dissemination also includes developing a webinar, developing an Online Module for the Orthopedic 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.

III. RECOMMENDATIONS AND SUPPORTING DATA

RECOMMENDATION 1

We recommend that children younger than thirty-six months diagnosed with a diaphyseal femur fracture be evaluated for child abuse.

AAOS Level of Evidence: II

AAOS Grade of Recommendation: A

Figures relevant to this recommendation are: Figure 1

Tables relevant to this recommendation are: Table 3

RATIONALE

Our systematic review identified three level II 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 abuse⁷, so one must make every attempt to identify these patients. One of the studies² 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 Therefore, although the level of evidence for this recommendation is II, the work group feels that the substantial

harms associated with abuse, and the great benefit of recognizing it, warrant upgrading the grade of recommendation to A.

SUPPORTING EVIDENCE

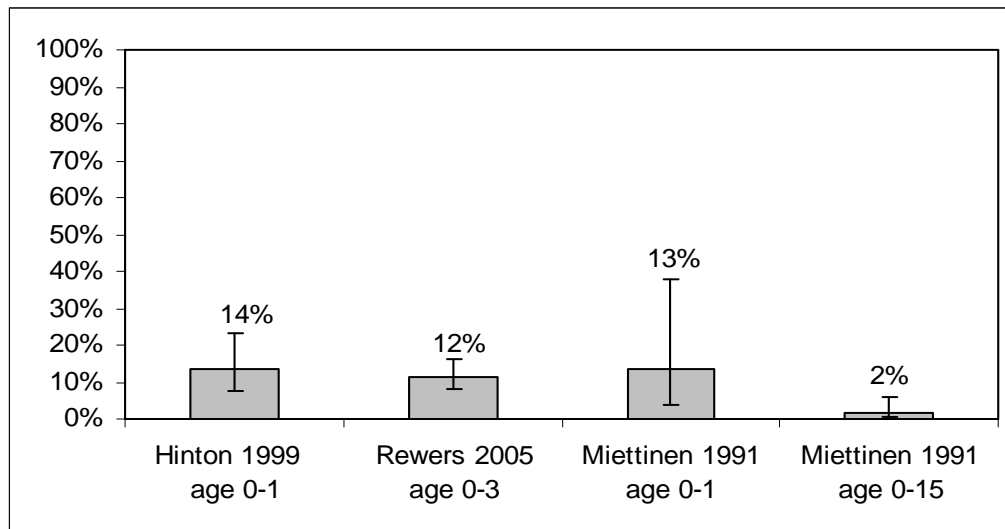
Three population-based studies reported data addressing this recommendation. Hinton et al.¹ used the Hospital Discharge Database of the Maryland Health Services Cost Review Commission from 1990-1996, Rewers et al.² used the Colorado Trauma Registry from 1998-2001, and Miettinen et al.¹⁶ used a medical 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

RECOMMENDATION 2

Treatment with a Pavlik harness or a spica cast are options for infants six months and younger with a diaphyseal femur fracture.

AAOS Level of Evidence: IV

AAOS Grade of Recommendation: C

Figures relevant to this recommendation are: Figure 2

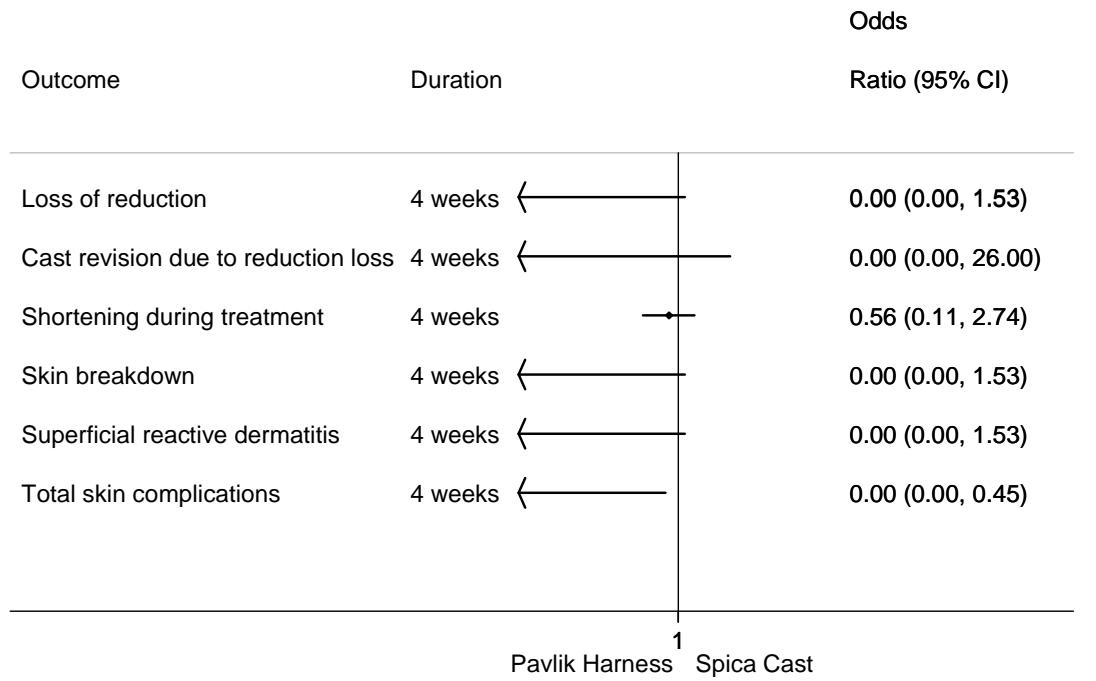
RATIONALE

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 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 study¹⁷ 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 X 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.

RECOMMENDATION 3

We suggest 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.

AAOS Level of Evidence: II

AAOS Grade of Recommendation: B

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 study²² 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 Level II studies addressed this recommendation. One study²⁰ included patients 2-10 years old, with 54% of the patients between ages 2-5. The other study¹⁹ included patients 9 months – 10 years old, with a mean age in both groups of 3.5 years.

One Level I 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

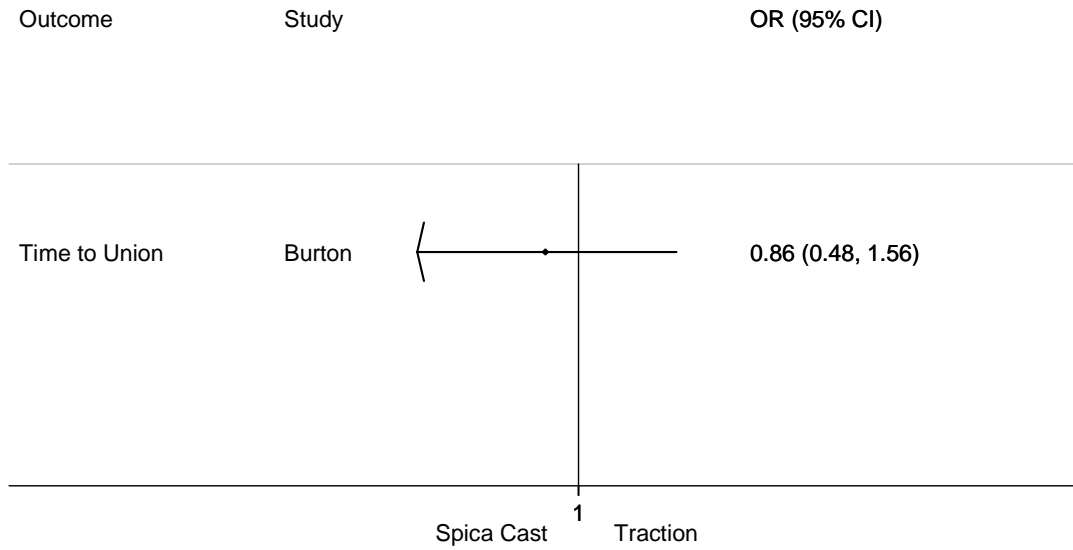
Table 4. Summary of Evidence

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

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

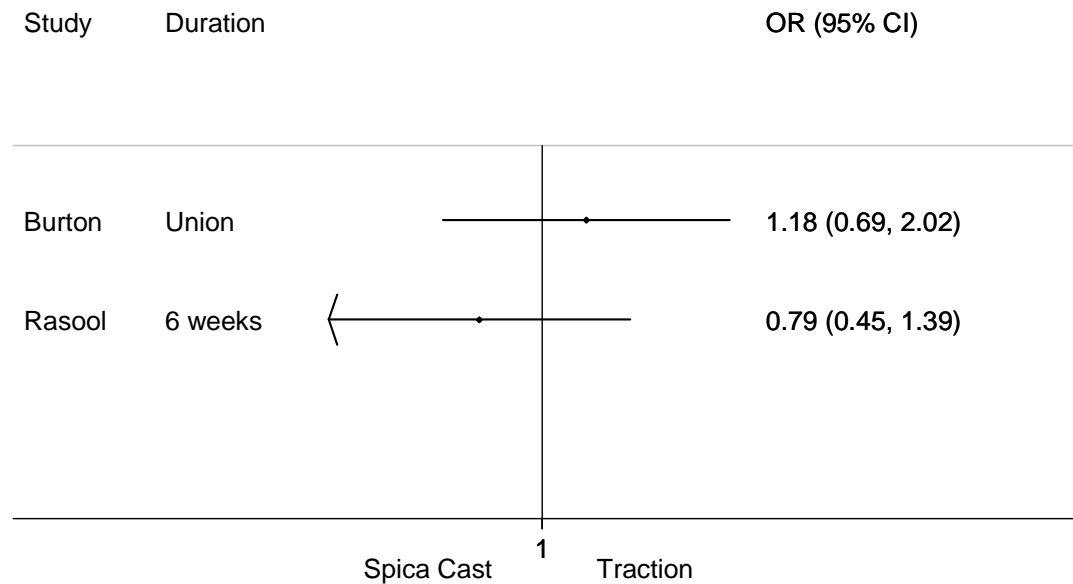
○ = result is not statistically significant nr = not reported t = traction

Figure 3. Time Immobilized (Time to Union)



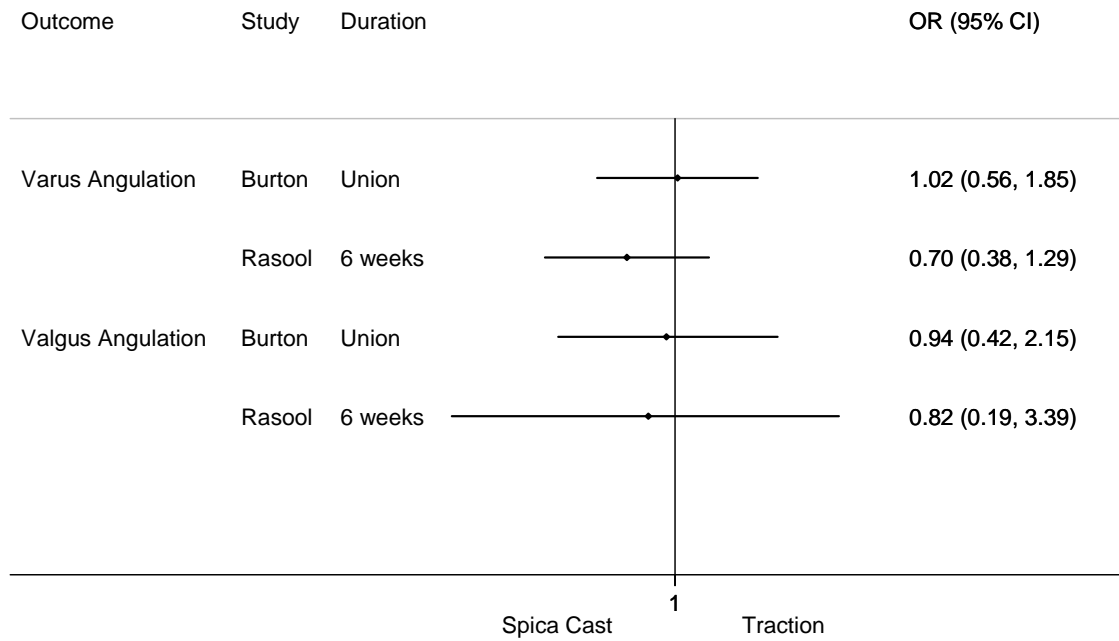
*Odds Ratio from ordered logistic regression (AAOS calculation)

Figure 4. Shortening



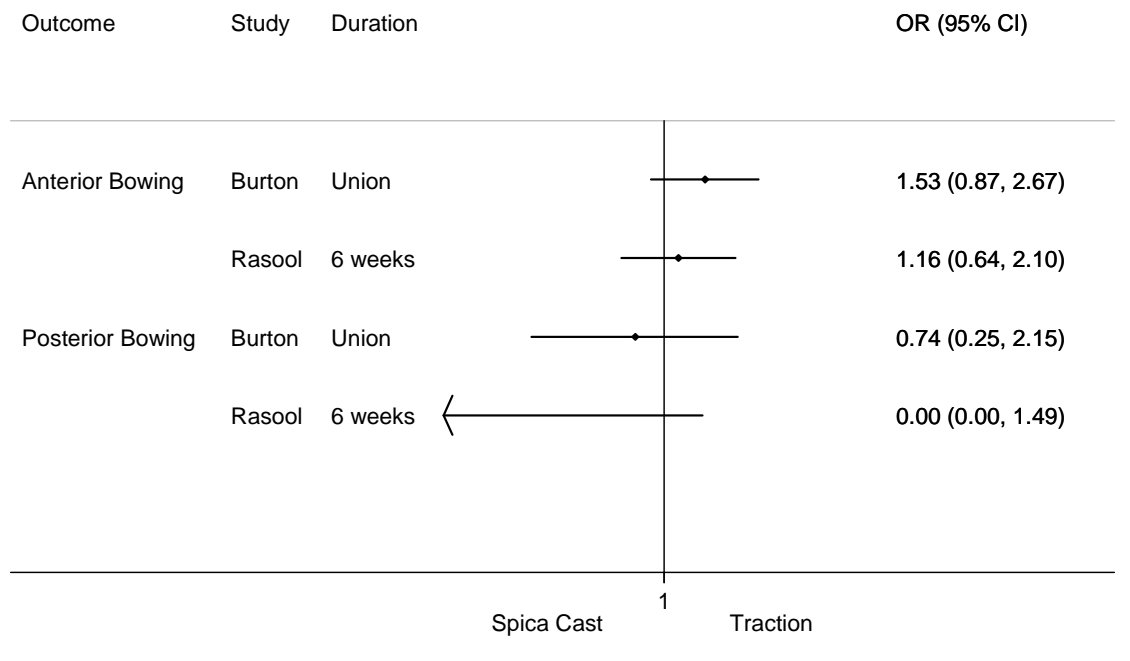
*Odds Ratios from ordered logistic regression (AAOS calculation)

Figure 5. Angulation



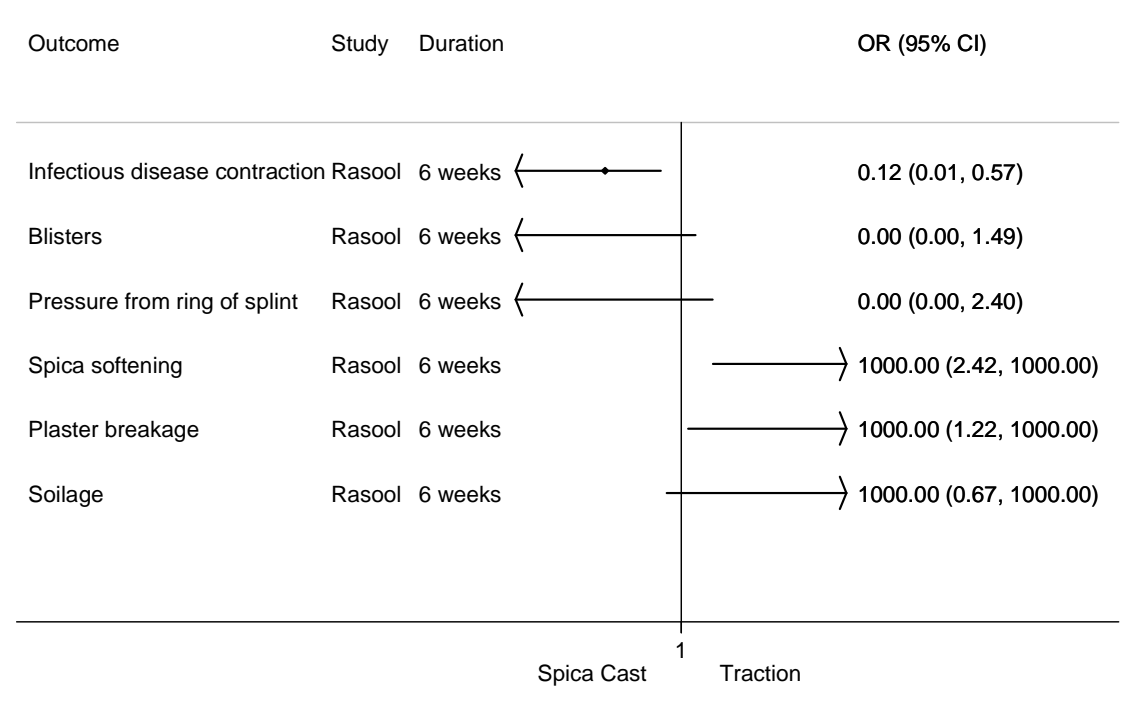
*Odds Ratios from ordered logistic regression (AAOS calculation)

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.

RECOMMENDATION 4

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.

AAOS Level of Evidence: V

AAOS Grade of Recommendation: Inconclusive

RATIONALE

Children between the ages of 6 months and 5 years who have femoral shortening greater than 2 cm are usually considered to be poor candidates for a spica cast. This is because of concern for overly aggressive reduction during cast application that can result in compartment syndrome once the cast is applied. This concern for compartment syndrome is in immediate spica casting, not delayed spica casting (traction followed by spica casting). Given that we found no studies specifically addressing whether spica casting should be utilized in this population, nor comparing spica casting to other treatment modalities, we can only say that the current available literature is insufficient to recommend for or against the use of spica casting when greater than 2 cm of femoral shortening is present

Careful clinical and radiographic follow-up during treatment is considered current “best medical practice.”

SUPPORTING EVIDENCE

No studies have addressed this recommendation.

RECOMMENDATION 5

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.

AAOS Level of Evidence: V

AAOS Grade of Recommendation: Inconclusive

RATIONALE

We found no studies that specifically addressed weight as a criterion for the use of spica casts in children. The work group cannot determine whether there is a maximum or minimum optimal weight range for the use of spica casting.

SUPPORTING EVIDENCE

No studies have addressed this recommendation.

RECOMMENDATION 6

When using the spica cast in children six months to five years of age, altering the treatment plan is an option if the fracture shortens greater than 2 cm.

AAOS Level of Evidence: V

AAOS Grade of Recommendation: C

RATIONALE

We found no data that addressed the claim that greater than 2 cm of shortening during the follow-up of spica casting for pediatric diaphyseal femur fracture should be addressed by changing the current treatment, e.g., exchanging or changing the cast or moving to another treatment. Due to the potential harms associated with excessive femoral shortening, the consensus of the AAOS work group is that altering the treatment plan is an option for treatment. The exact amount of shortening that may cause potential harm is unclear. The expert opinion of the work group was to alter the treatment plan if the shortening was greater than 2 cm.

SUPPORTING EVIDENCE

No studies have addressed this recommendation.

RECOMMENDATION 7

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.

AAOS Level of Evidence: V

AAOS Grade of Recommendation: Inconclusive

RATIONALE

We found no studies that specifically addressed this recommendation. There is insufficient evidence to support using any specific degree of malalignment or rotation as a criterion for changing the spica casting treatment plan.

SUPPORTING EVIDENCE

No studies have addressed this recommendation.

RECOMMENDATION 8

It is an option for physicians to use flexible intramedullary nailing to treat children age five to eleven years diagnosed with diaphyseal femur fractures.

AAOS Level of Evidence: III

AAOS Grade of Recommendation: C

Figures relevant to this recommendation are: Figure 8 - Figure 31

Tables relevant to this recommendation are: Table 5 - Table 10

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 Level I study²² 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).

One Level II study²⁴ shows more rapid return to walking and school with flexible intramedullary nailing and one Level III study²⁵ 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 Grade C. 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 outcome²⁷ 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 Level I study,²² five Level II studies^{24,28-31} and eight Level III studies^{25,26,32-37} addressed this recommendation. Level III studies are included in this recommendation because they examine treatments not compared in the Level I and II 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 Level IV study²⁷ 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. 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 6 on page 26.
- For summary of nonsignificant outcomes see Table 7 on page 27.
- For summary of Level I evidence see Table 8 on page30.
- For summary of Level II evidence see Table 9 on page 31.
- For summary of Level III evidence see Table 10 on page 33.

Table 6. Summary of Significant Outcomes with Level of Evidence

TREATMENT FAVORED				
	<i>Flexible Nails</i>	<i>External Fixation</i>	<i>Spica Cast</i>	<i>Traction (+ Casting)</i>
<i>Flexible Nails</i>	N/A	Loss of movement at knee (post-op)/III		Irritation at nail entry site/II
<i>External Fixation</i>	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
<i>Spica Cast</i>		Malunion/I Anterior/Posterior Angulation/I	N/A	
<i>Traction (+ Casting)</i>	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 7. Summary of Nonsignificant Outcomes with Level of Evidence

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

Table 7. Summary of Nonsignificant Outcomes with Level of Evidence (continued)

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

Table 7. Summary of Nonsignificant Outcomes with Level of Evidence (continued)

<i>Comparisons</i>	<i>External Fixation</i>	<i>Spica Cast</i>	<i>Traction + Casting</i>
<i>Spica Cast</i>	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 8. Summary of Level I Evidence

Author	Level of Evidence	n	Comparison	Outcome (follow-up duration)	Result
Wright	I	101	External Fixation vs. Early Spica Cast	Malunion (2 yr)	● ef
Wright	I	101		Malunion inc. rotation (2 yr)	○
Wright	I	101		Leg length discrepancy \geq 2 cm (2 yr)	○
Wright	I	101		Ant/post. angulation \geq 15° (2 yr)	● ef
Wright	I	101		Varus/valgus angulation \geq 10° (2 yr)	○
Wright	I	101		Rotational Malunion (2 yr)	○
Wright	I	101		Treatment alteration (2 yr)	○
Wright	I	101		Unacceptable loss of reduction (2 yr)	○
Wright	I	101		RAND overall (2 yr)	○
Wright	I	101		RAND physical subscale (2 yr)	○
Wright	I	101		Duration of treatment (n/a)	● sc
Wright	I	101		Behavioural Questionnaire (post-hosp)	○
Wright	I	101		Parent Satisfaction (2 yr)	○
Wright	I	101		Child Satisfaction (2 yr)	○
Wright	I	101		Refracture (2 yr)	○
Wright	I	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 9. Summary of Level II Evidence

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

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Table 9. Summary of Level II Evidence (continued)

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

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

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Table 10. Summary of Level III Evidence (continued)

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

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

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Table 10. Summary of Level III Evidence (continued)

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

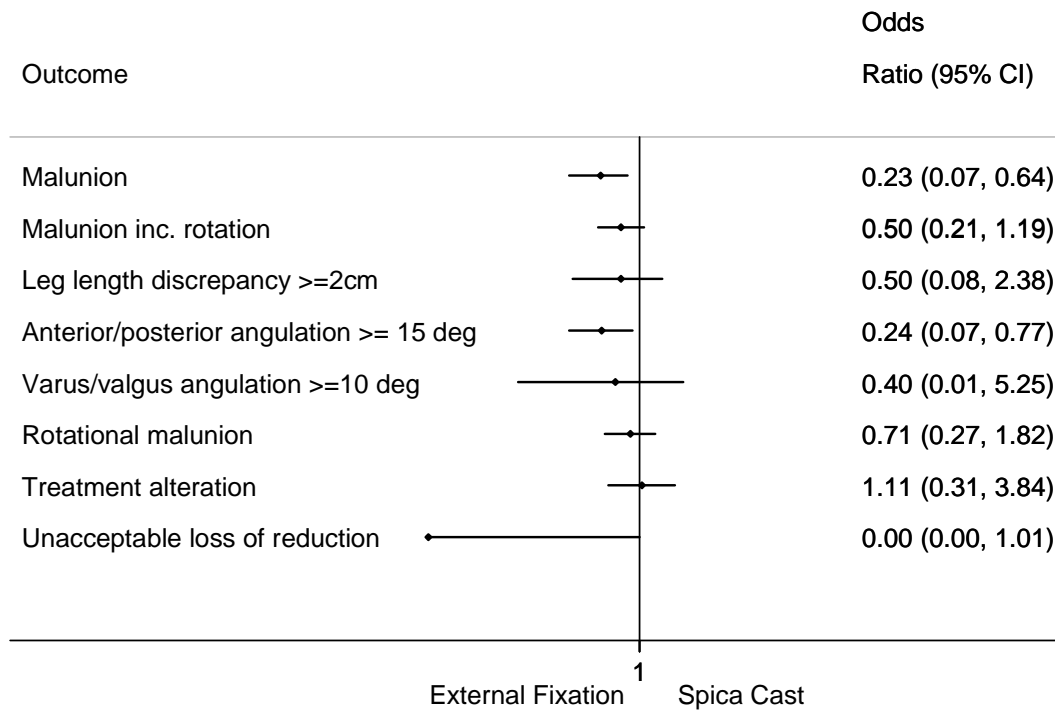


Figure 9. External Fixation vs. Spica Cast -continuous outcomes (Wright et al.²²)

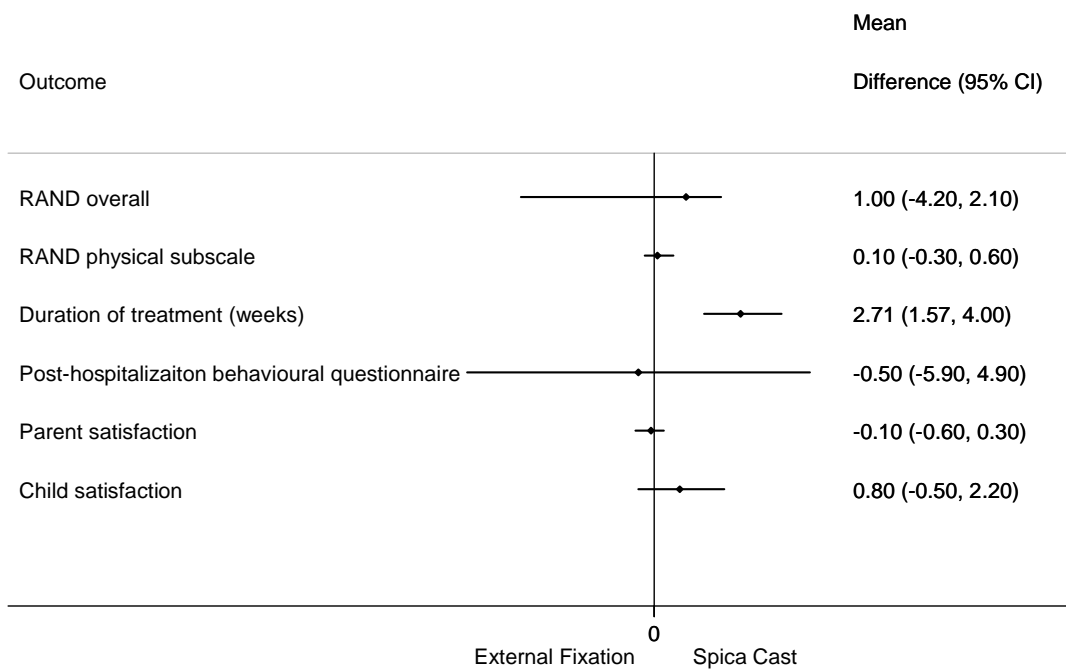


Figure 10. External Fixation vs. Spica Cast - Complications (Wright et al.²²)

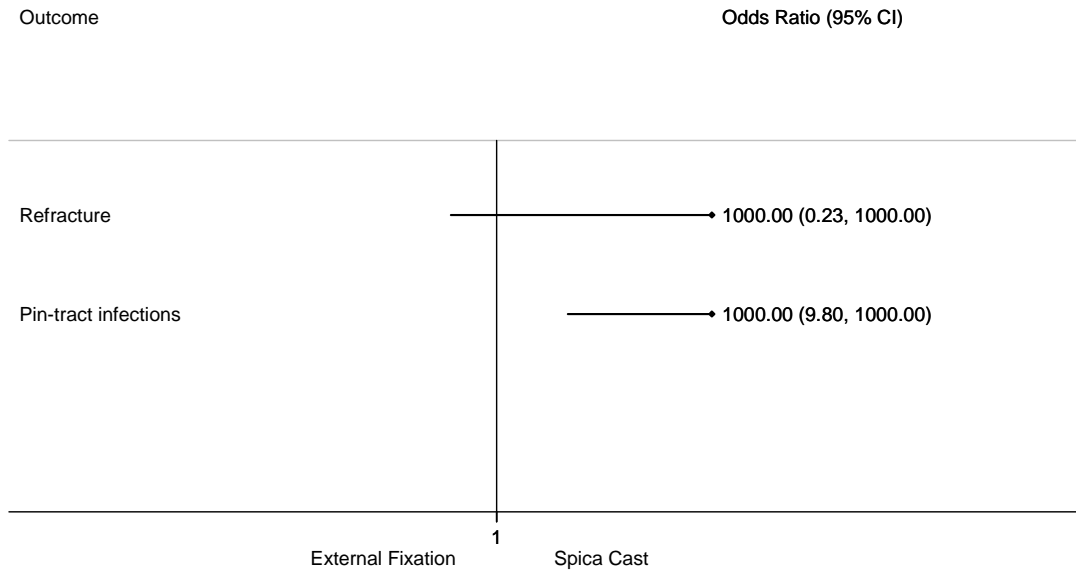


Figure 11. Dynamic vs. Static External Fixation (Domb et al.²⁸)

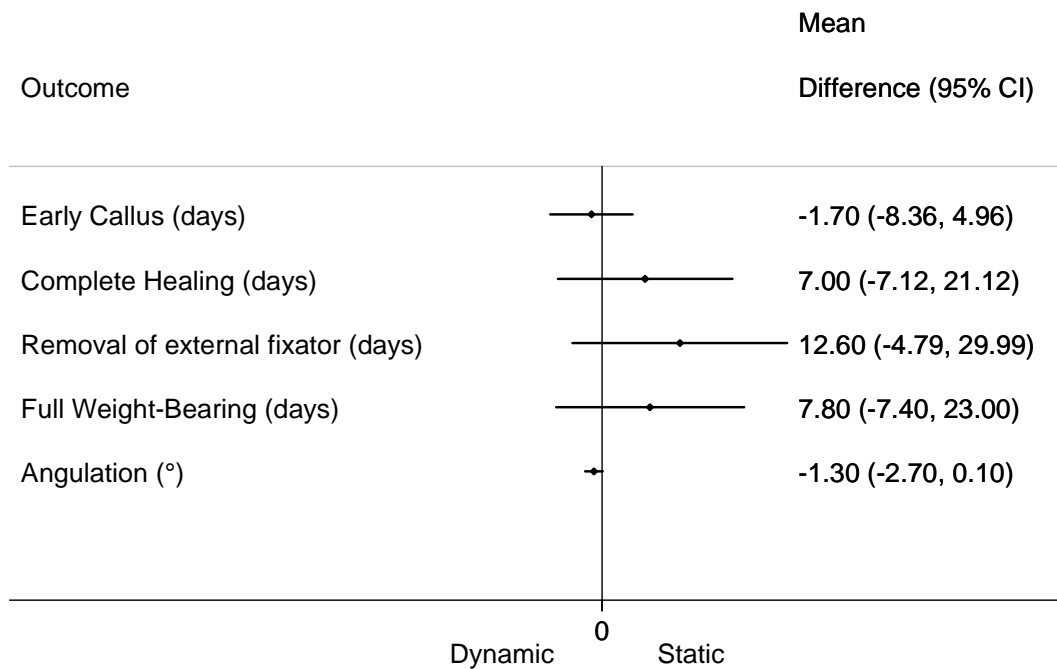


Figure 12. Traction & Cast vs. Flexible Nails –binary outcomes

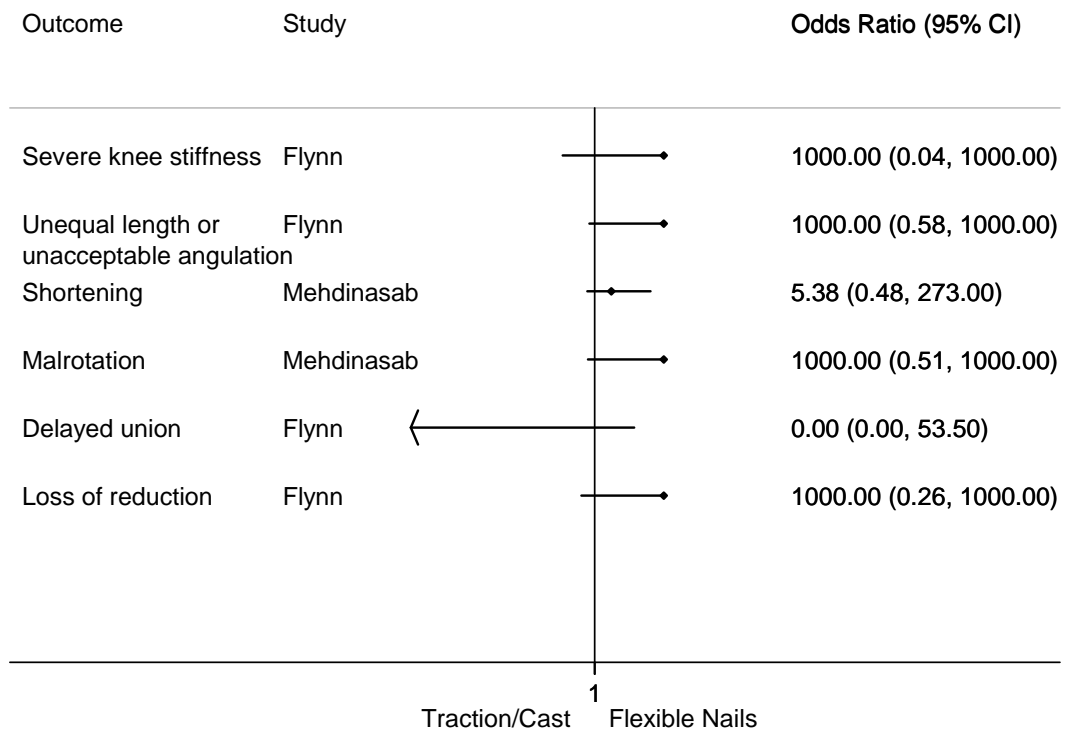


Figure 13. Traction & Cast vs. Flexible Nails – continuous outcomes

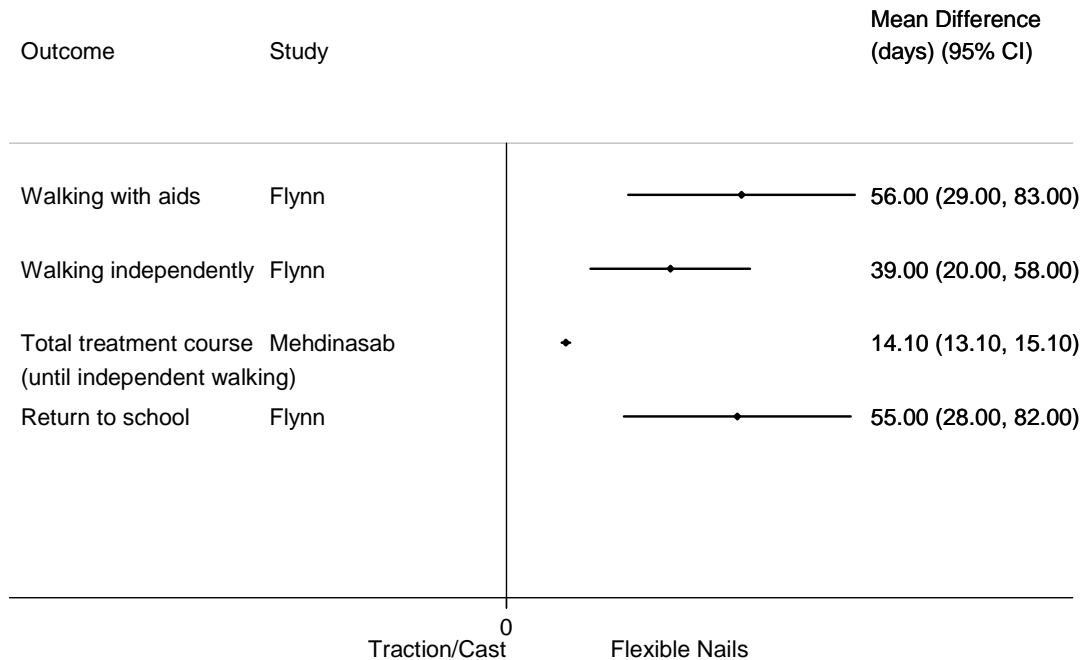


Figure 14. Traction & Cast vs. Flexible Nails - Complications

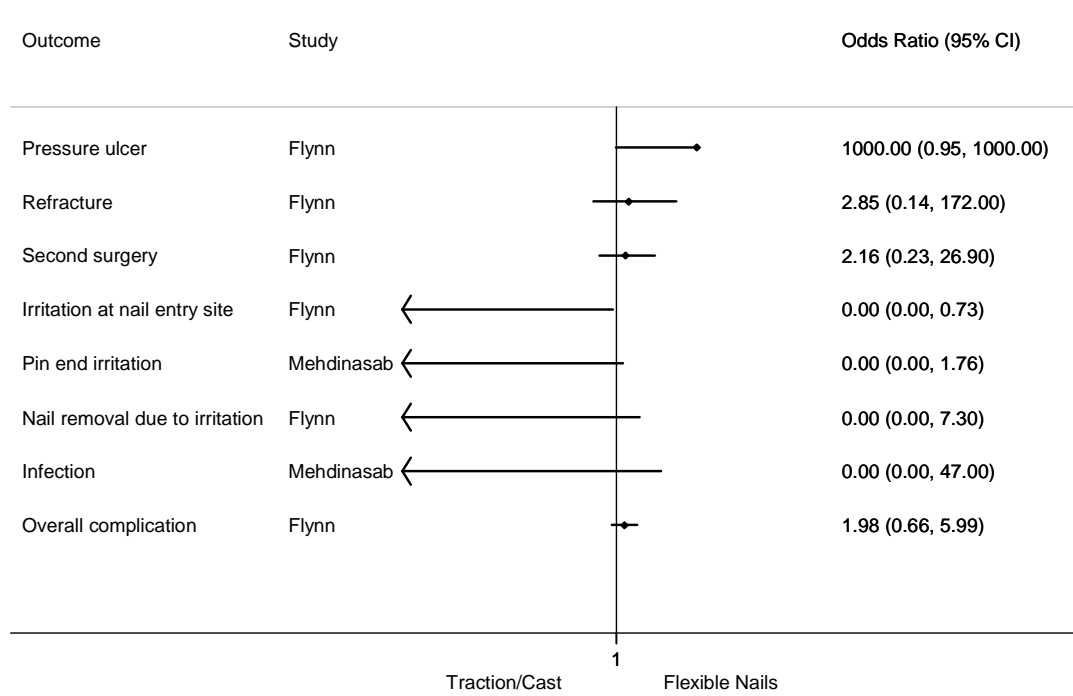


Figure 15. Early Spica Cast vs. Traction - continuous outcomes (Ali et al.³⁰)

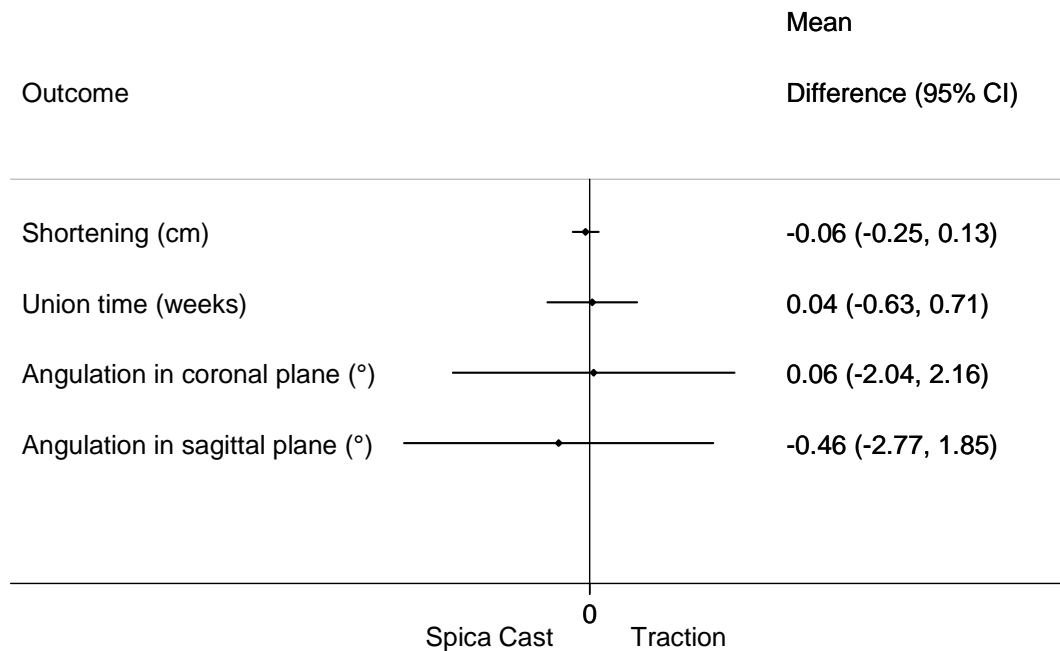


Figure 16. Early Spica Cast vs. Traction -Complications (Ali et al.³⁰)

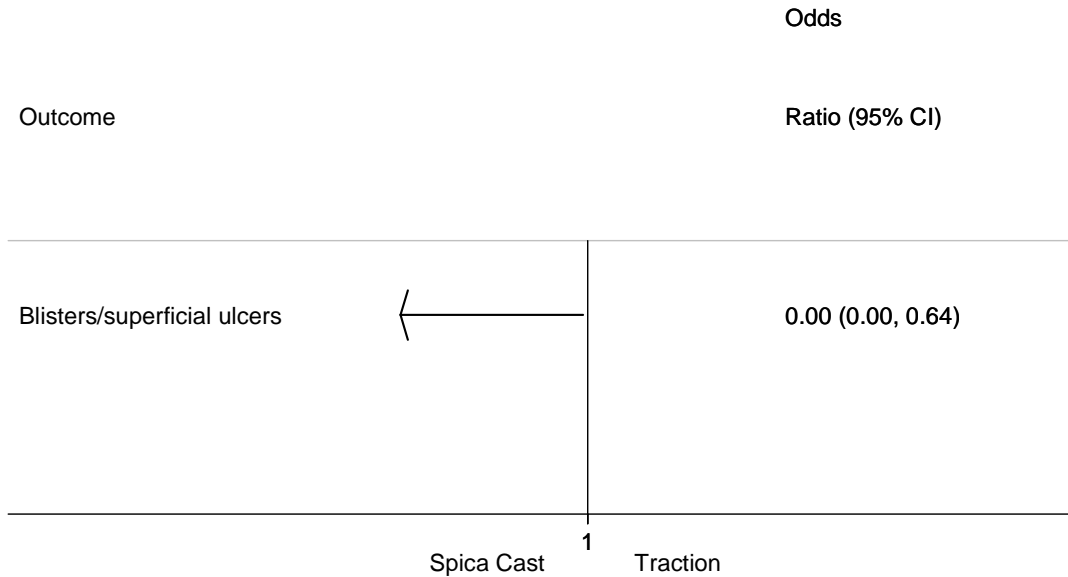


Figure 17. Early Pontoon Spica vs. Traction/Cast – Short-term Complications (Curtis et al.³¹)

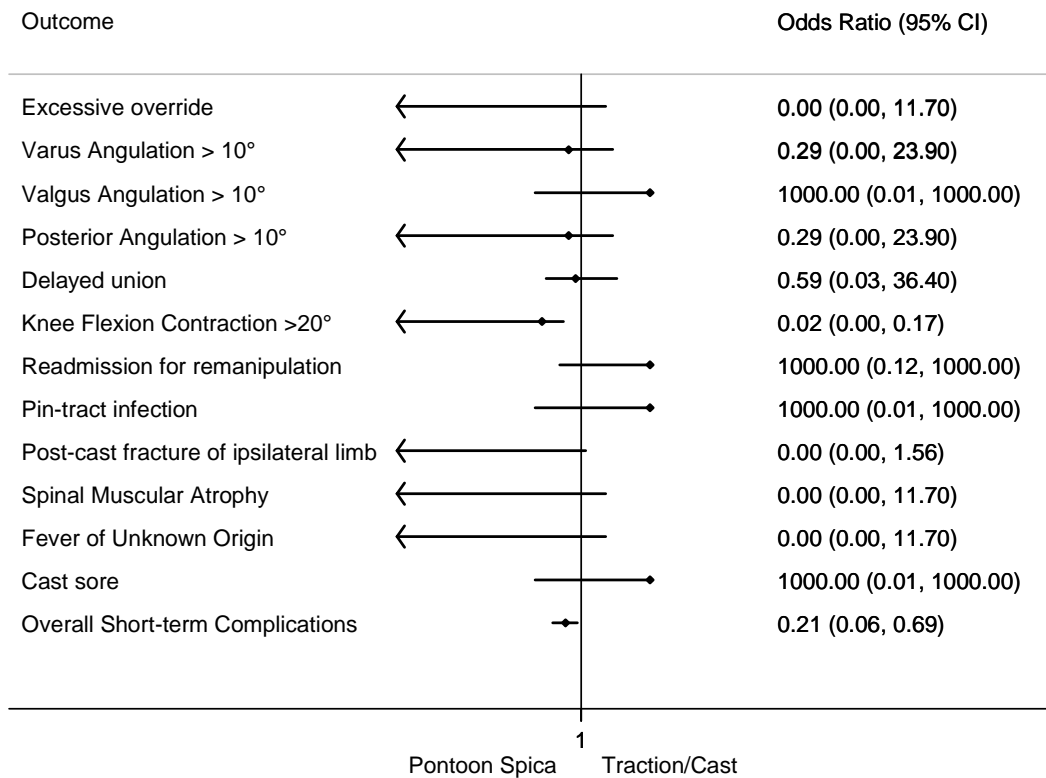


Figure 18. External Fixation vs. Traction & Cast - Treatment Length (Nork et al.³²)

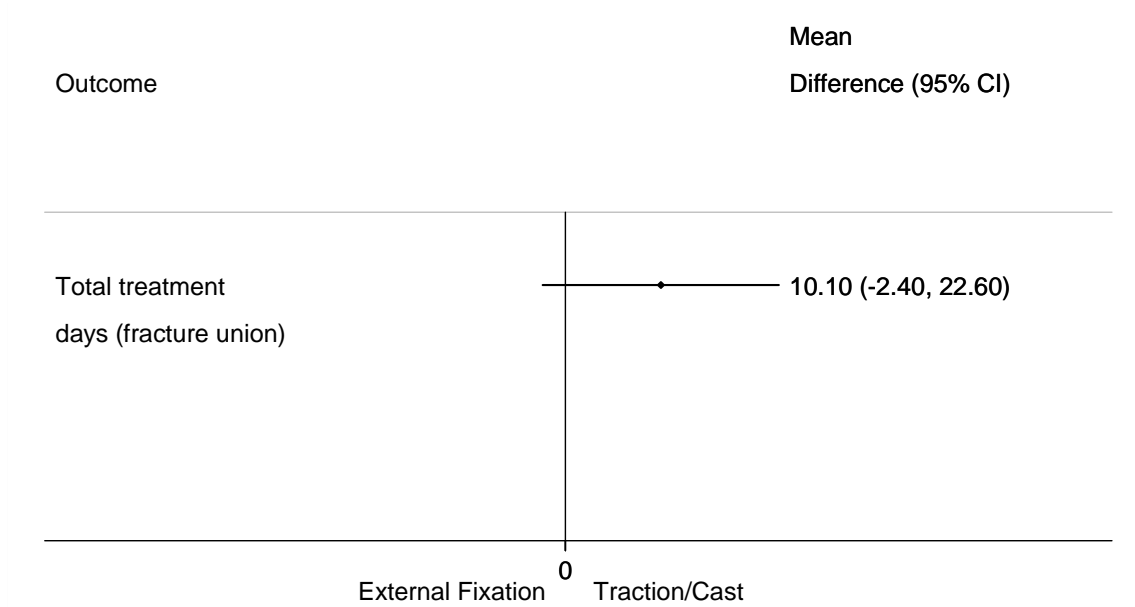


Figure 19. External Fixation vs. Traction & Cast – Complications (Nork et al.³²)

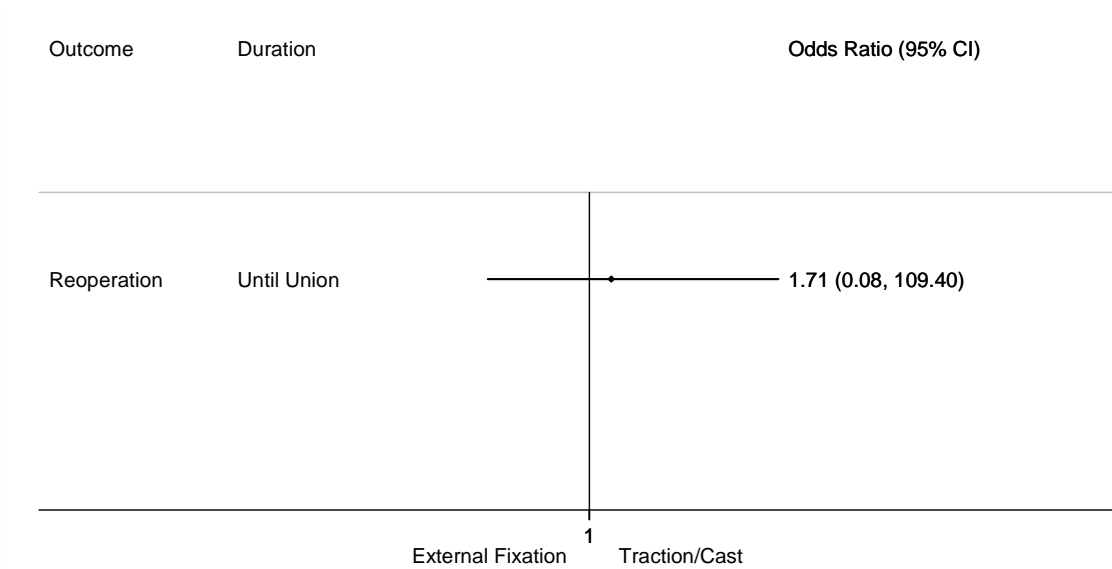


Figure 20. External Fixation vs. Traction - Treatment Length (Hedin et al.³⁴)

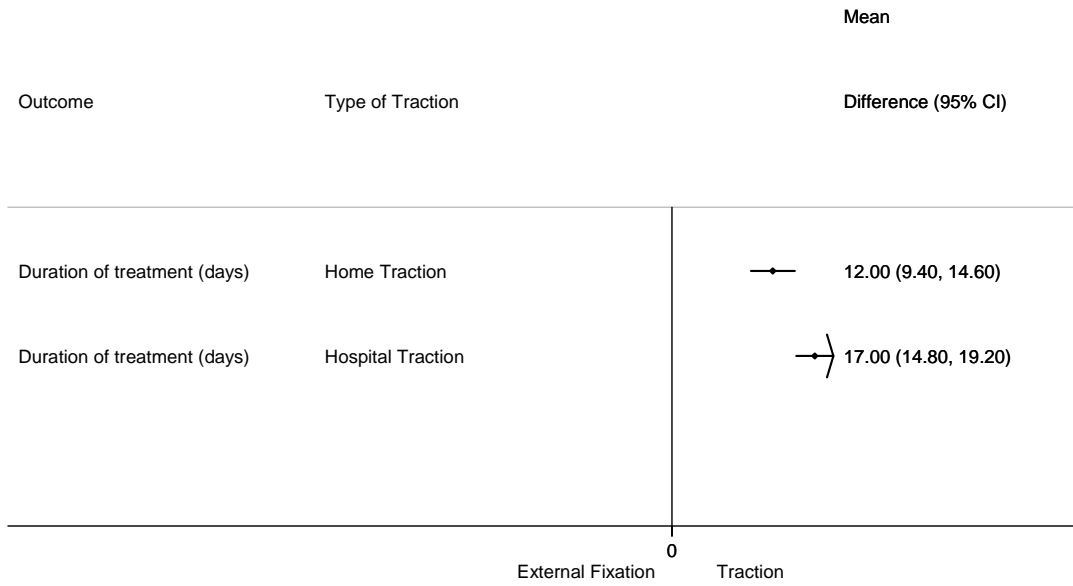


Figure 21. External Fixation vs. Traction - Patient Satisfaction (Hedin et al.³⁴)

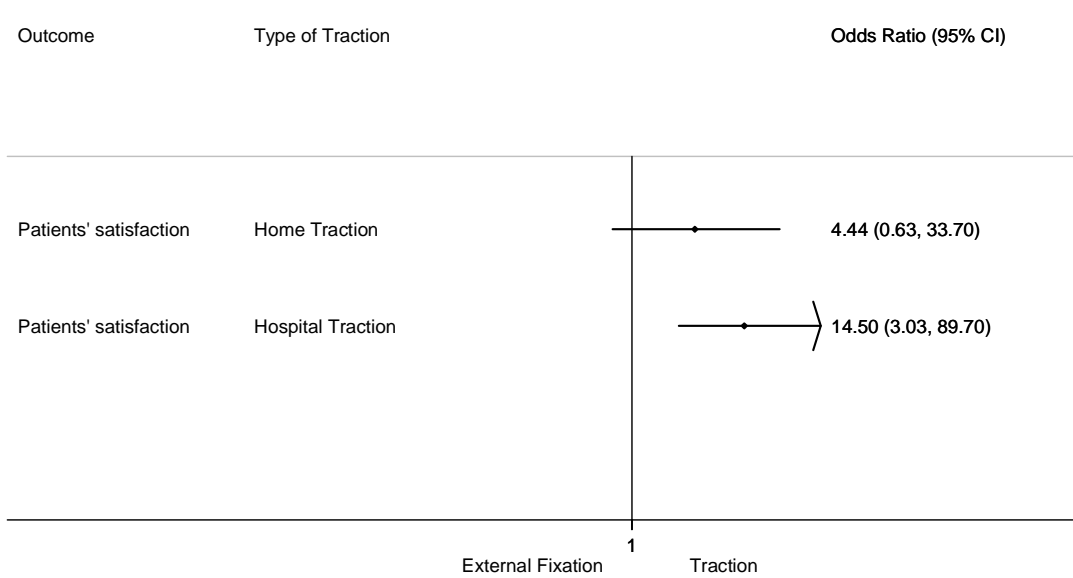


Figure 22. Flexible Nails vs. Traction & Cast - binary outcomes

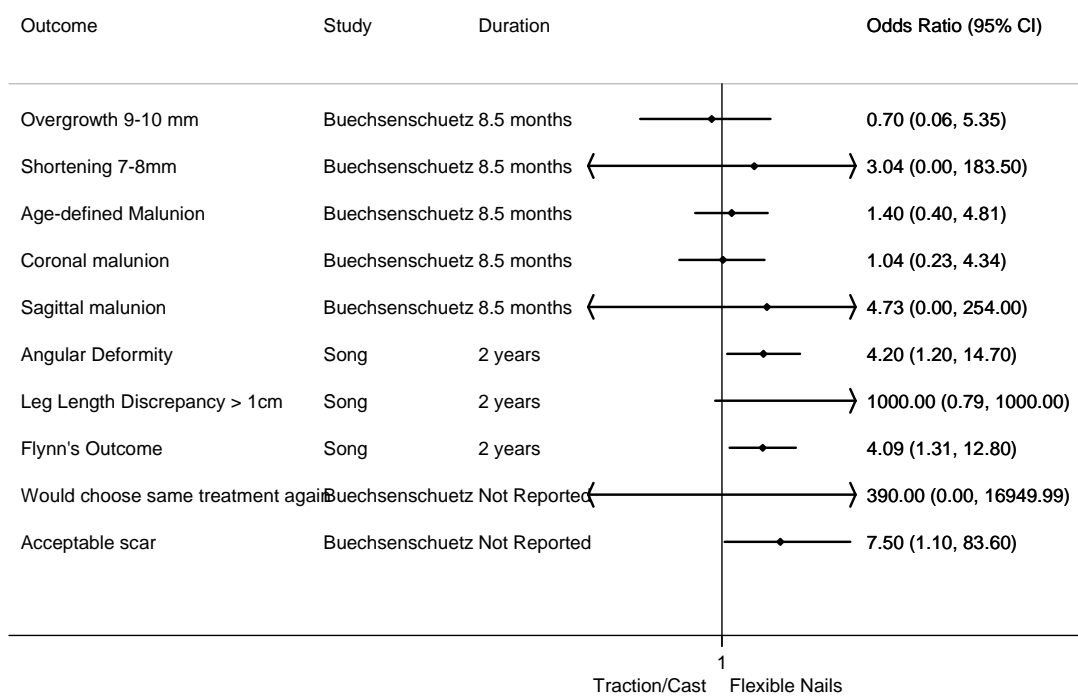


Figure 23. Flexible Nails vs. Traction & Cast -Leg Length Discrepancy (Song et al.³³)

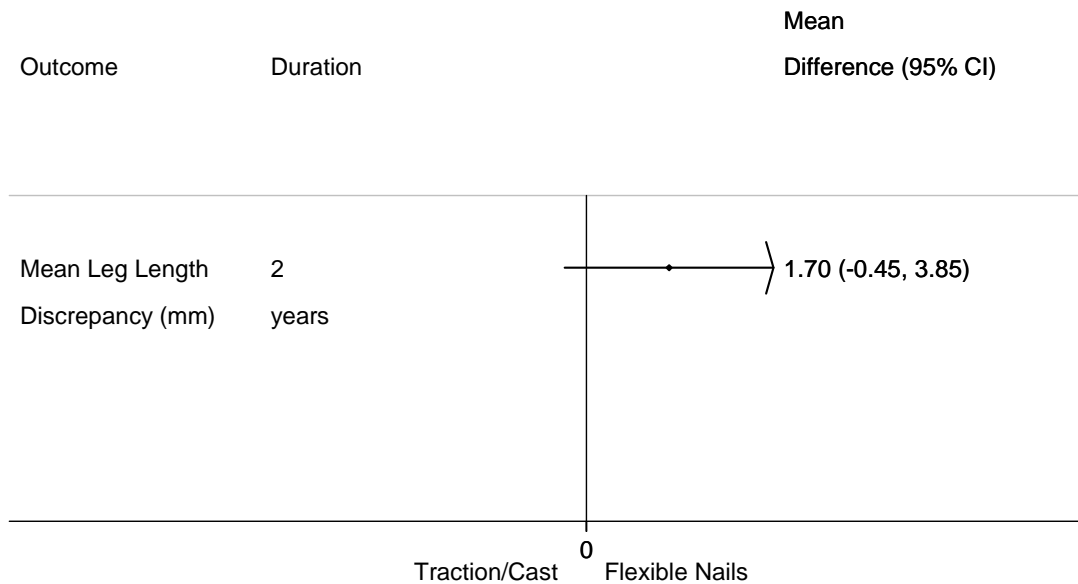


Figure 24. Flexible Nails vs. Traction & Cast - Major Complications

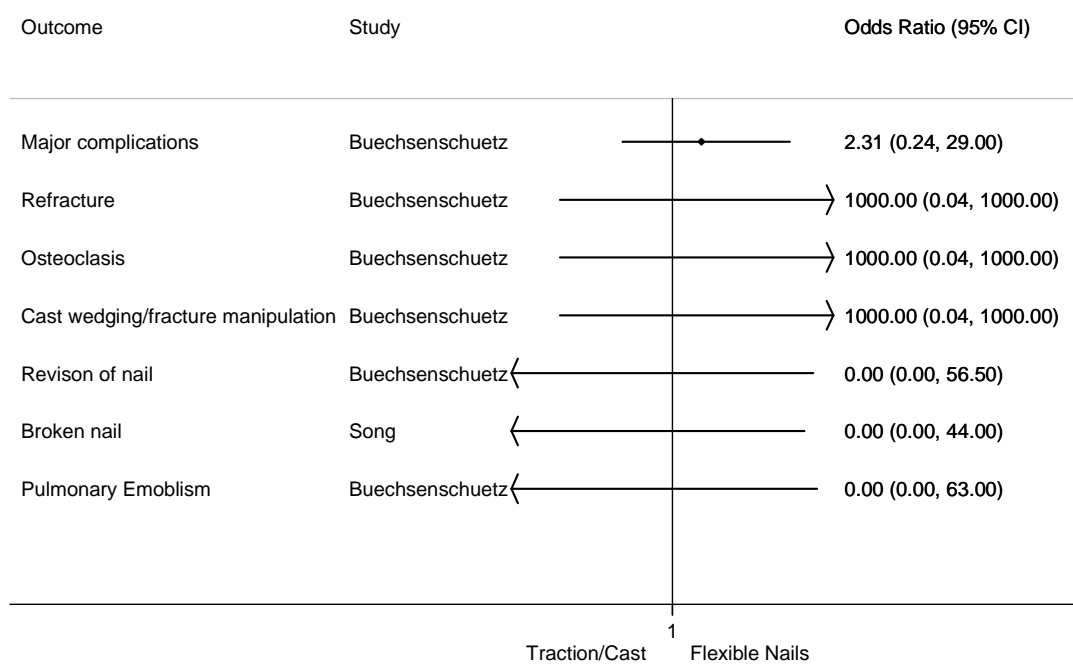


Figure 25. Flexible Nails vs. Traction & Cast - Minor Complications

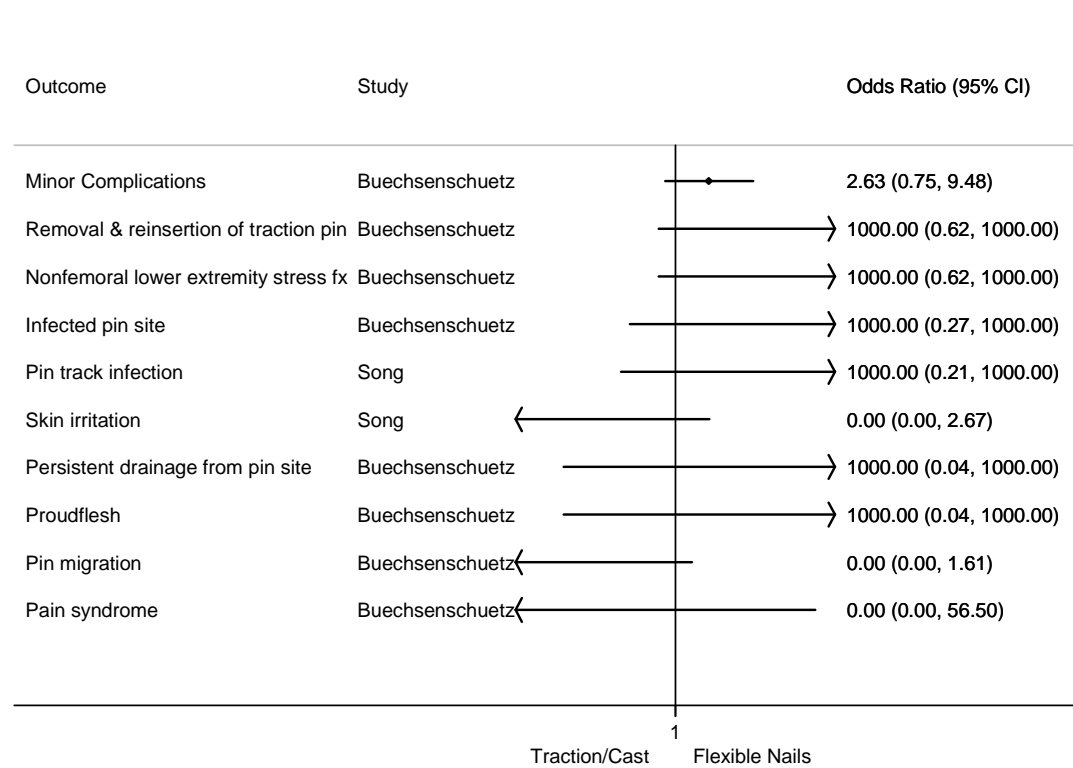


Figure 26. Titanium vs. Stainless Steel Flexible Nails – Complications (Wall et al.³⁷)

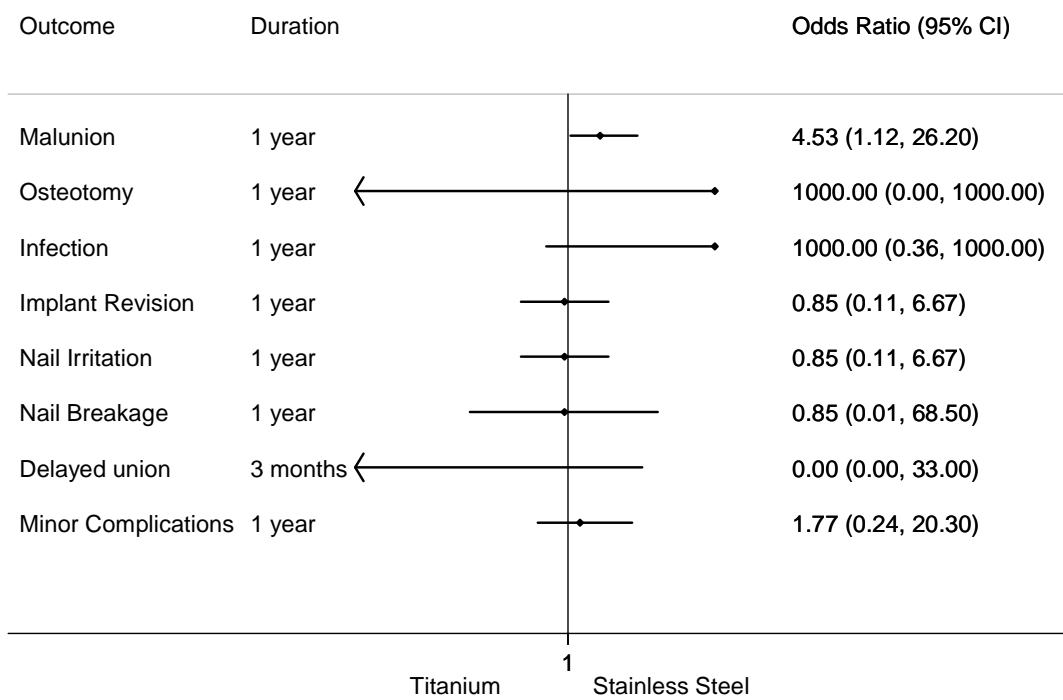


Figure 27. Immediate vs. Delayed Spica Cast - Complications (Rasit et al.³⁵)

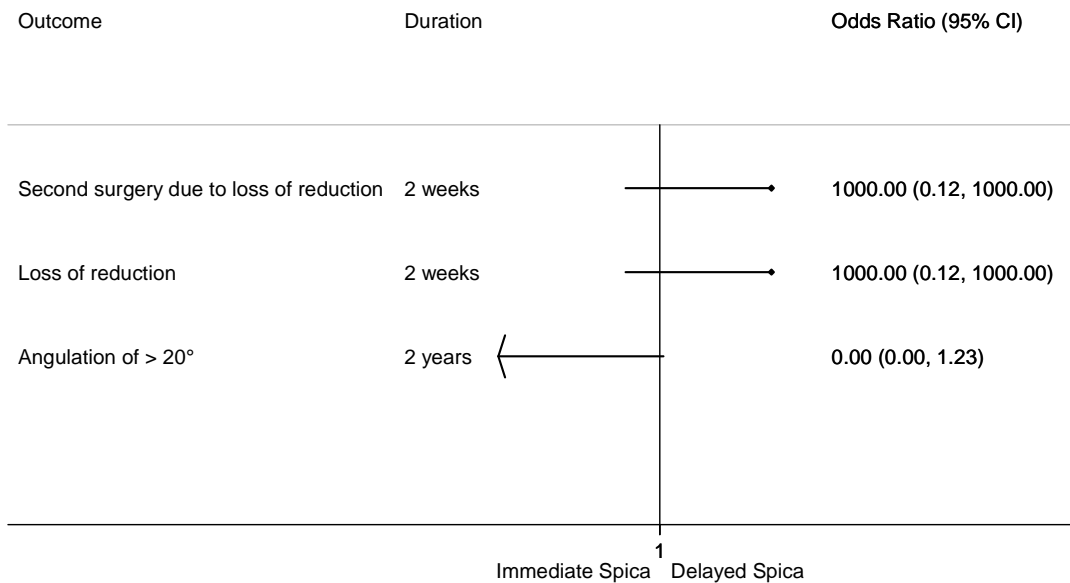


Figure 28. Early Intervention vs. Traction (Sturdee et al.³⁶)

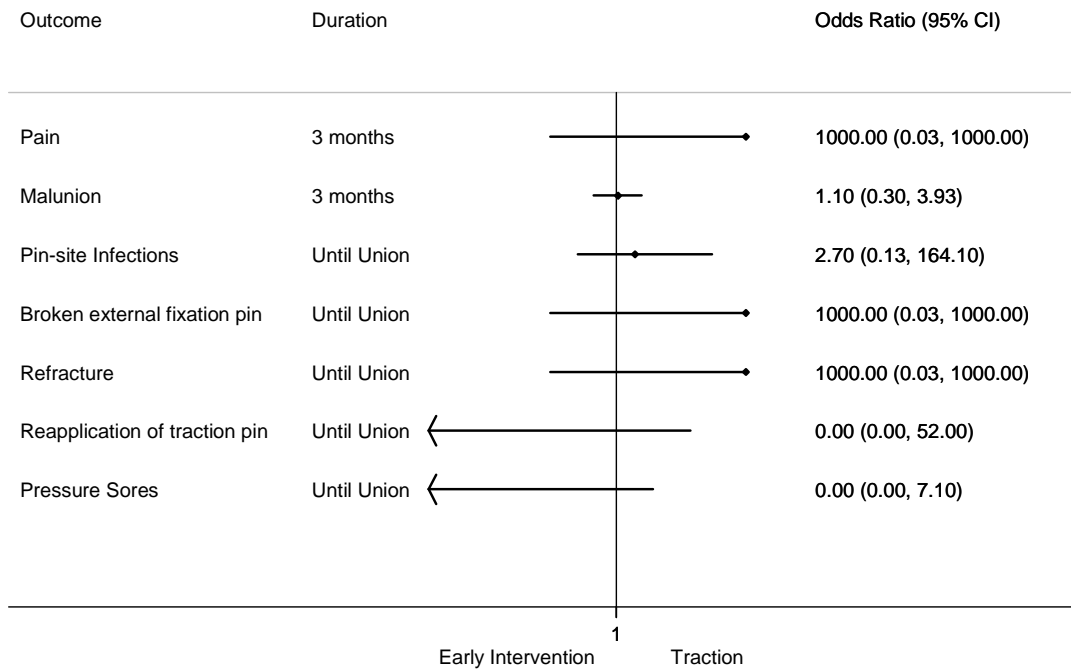
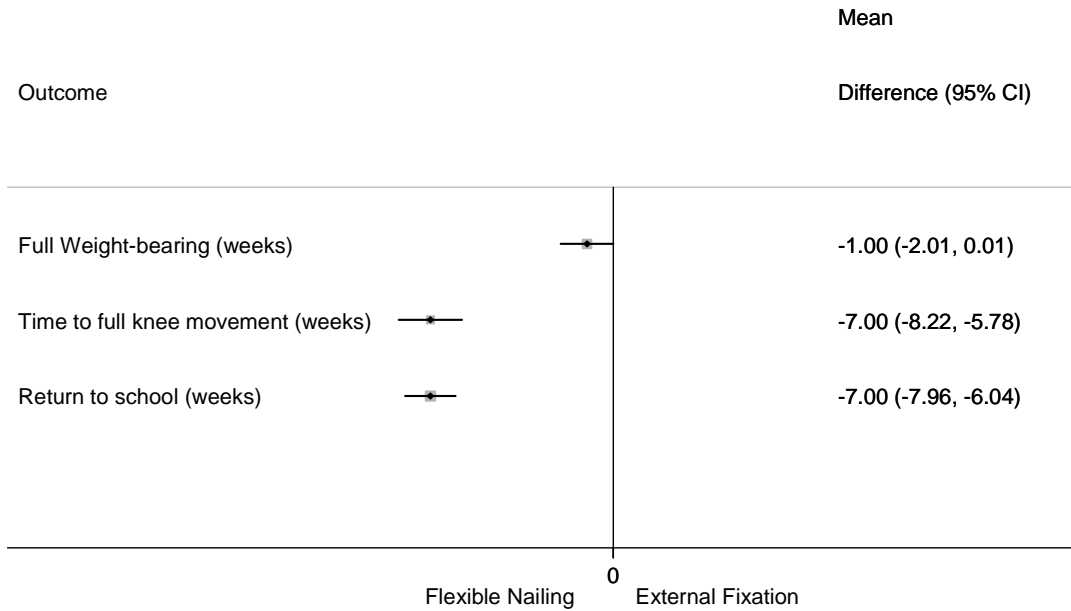


Figure 29. Flexible Nailing vs. External Fixation - Continuous Outcomes (Barlas et al. 2006²⁶)



*Standard deviations estimated from range

Figure 30. Flexible Nailing vs. External Fixation -Binary Outcomes (Barlas et al. 2006²⁶)

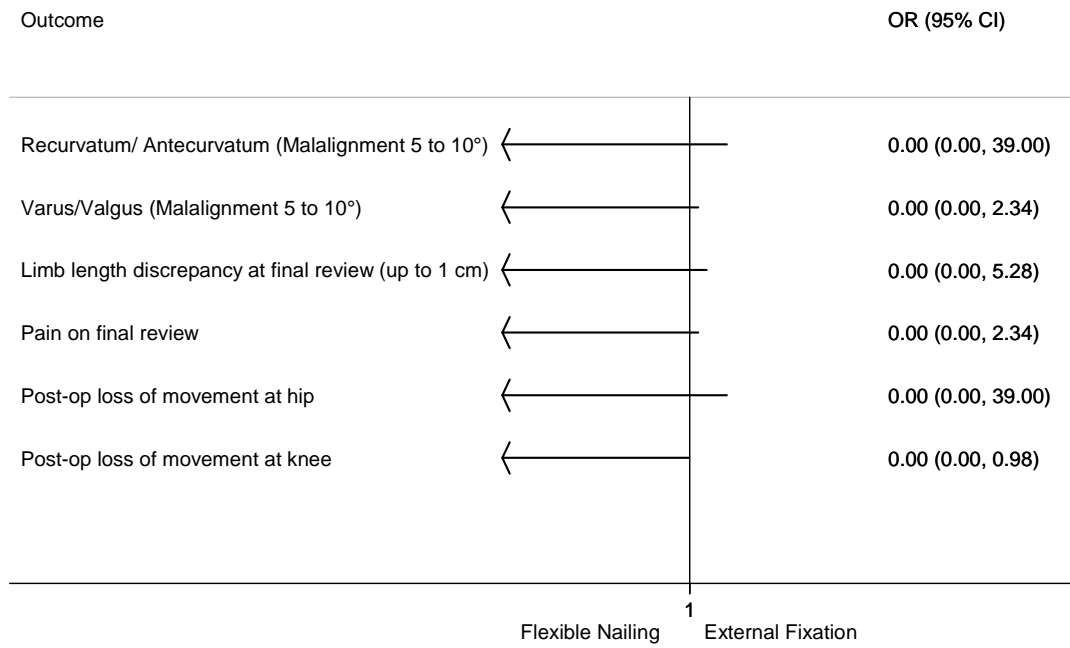
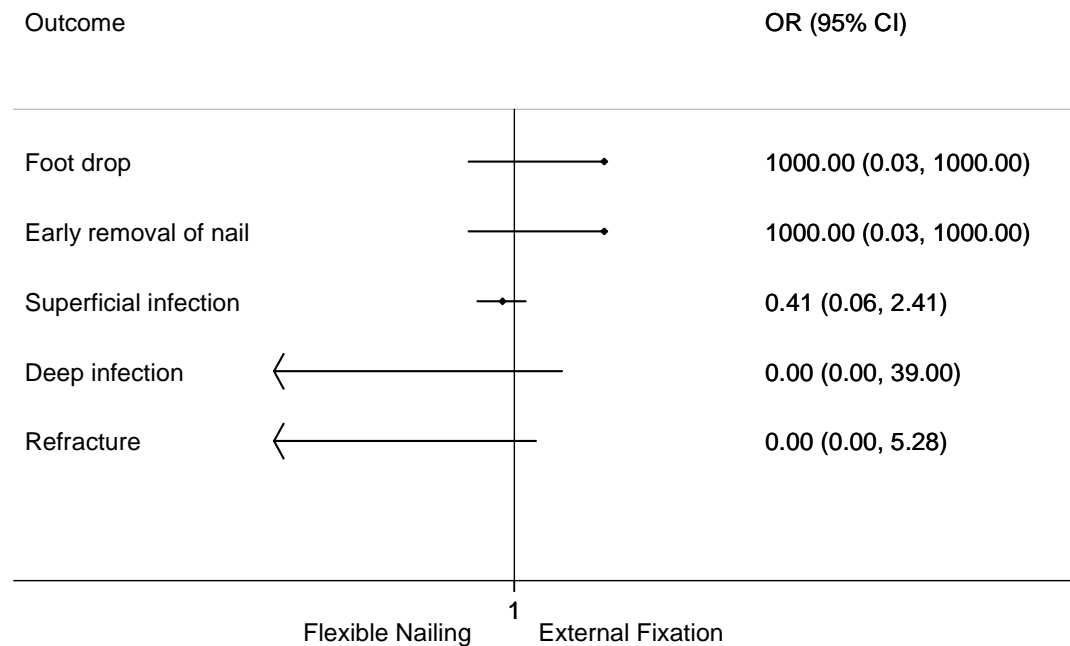


Figure 31. Flexible Nailing vs. External Fixation - Complications (Barlas et al. 2006²⁶)



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 review²³ concluded that flexible nails reduced the malunion and adverse event rate compared to external fixation, and that external fixation reduced the malunion 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.

RECOMMENDATION 9

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

AAOS Level of Evidence: IV

AAOS Grade of Recommendation: C

Figures relevant to this recommendation are: Figure 32 - Figure 34

Tables relevant to this recommendation are: Table 11- Table 15

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 Level IV 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 Level III and four Level IV studies addressed this recommendation. The Level III study³⁹ 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 Level IV 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 nailing²⁷ 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 11. Flexible Intramedullary Nailing and Patients' Weight

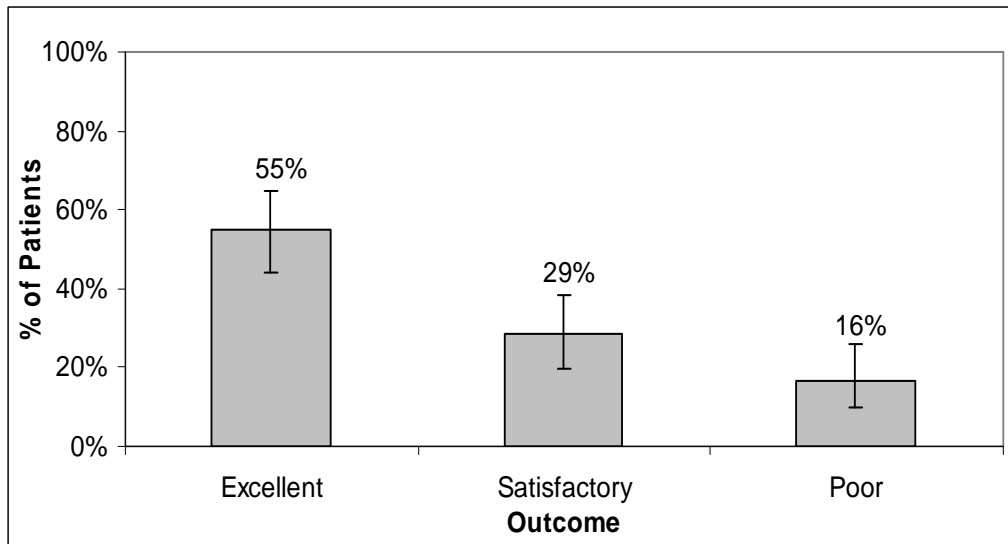
Treatment	n	Mean weight (excellent/satisfactory outcome)	Mean weight (poor outcome)	p-value
Titanium Elastic Nailing	222	39 kg (range 17 to 95.2)	54 kg (range 22.3 to 95.2)	0.003

Table 12. 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 13. 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%

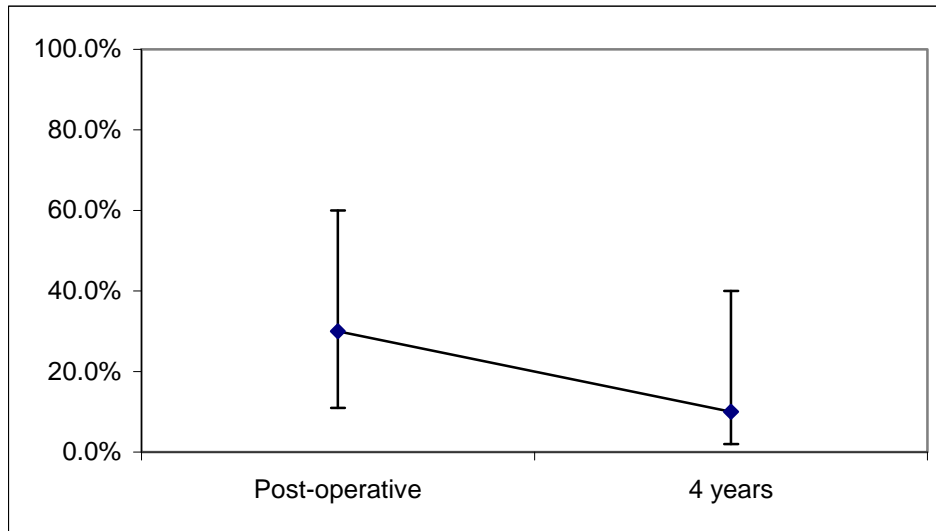
Table 14. Rigid Near Piriformis Entry Nailing Outcomes (Buford et al.³⁸)

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 15. Bridge Plating Outcomes (Agus et al.⁴¹)

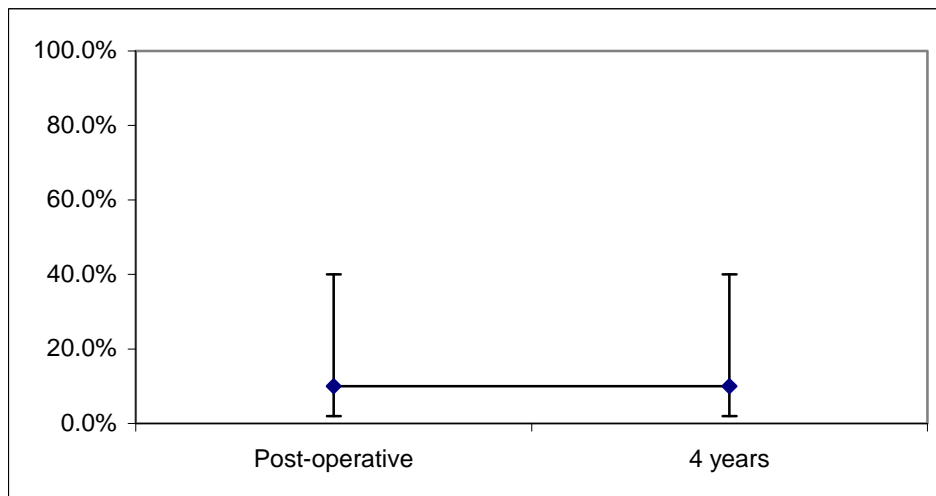
Outcome	Duration	n	Mean (95% CI)	%
Time to grade 2 callus (weeks)	n/a	10	9.1 (7.7, 10.5)	n/a
Complete radiographic healing time (weeks)	n/a	10	13.4 (11.4, 15.4)	n/a
Broken plates	4 years	10	n/a	0.0%
Refractures	4 years	10	n/a	0.0%
Femoral length inequality (cm)	4 years	10	0.6 (0.4, 0.8)	n/a
Increased 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 review²³ 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.

RECOMMENDATION 10

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

AAOS Level of Evidence: IV

AAOS Grade of Recommendation: Inconclusive

Tables relevant to this recommendation are: Table 16

RATIONALE

Certain devices used for managing pediatric diaphyseal femur fractures, such as external fixators, must be removed after fracture healing. However, other implants (e.g., flexible intramedullary nails, rigid intramedullary nails, and plates and screws) are often routinely removed after fracture healing in asymptomatic patients. The rationale for removal is to prevent future problems related to the implant such as pain, stress shielding of the bone, stress riser effects, chronic metal exposure, and difficulty with future surgeries from the implant. Although implant removal is typically a minor uncomplicated procedure, complications such as infection, hematoma, refracture, and anesthetic risks can occur. In addition, implant removal puts the patient and family through a second procedure.

We identified six level IV studies^{22,24,40,42-44} that presented data on implant removal after the management of pediatric femur fractures. We identified no studies that compared routine implant removal to implant retention, or that assessed the long-term implications of implant retention. Refractures occurred after external fixator removal. Complications were infrequent after removal of internal fixation but included refracture and hematoma.

Because of the limited pertinent data regarding routine implant removal versus implant retention after internal fixation of pediatric femur fractures, it was the consensus of the work group that routine implant removal cannot be advocated for or against.

SUPPORTING EVIDENCE

Six Level IV studies^{22,24,40,42-44} presented data regarding implant removal. These data are presented in Table 16. Other studies utilizing surgical implants did not report any outcomes regarding implant removal. No studies conducted follow-up longer than an average of 2.7 years. One study using rigid nailing reported no complications of implant removal. Of the three studies using flexible nailing, one reported no complications, one reported a refracture in one (2%) patient, and the third reported a hematoma in one (2%) patient. Of the two studies using external fixation, refracture occurred in 4% and 2% of patients, respectively.

Table 16. Implant Removal Complications

Study	Outcome	Duration	Treatment	Age	n	%
Kanellopoulos	Hardware removal	2.4 years	Rigid IM Nailing	14.4 years (11-16)	20	70%
Kanellopoulos	Complications of hardware removal	2.4 years	Rigid IM Nailing	14.4 years (11-16)	14	0%
Mazda	Hardware removal	2.6 years	Flexible IM Nails	9.5 years (6-17)	32	94%
Mazda	Early removal of hardware	5 months	Flexible IM Nails	9.5 years (6-17)	32	31%
Mazda	Complications/activity limitations caused by hardware removal surgery	2.6 years	Flexible IM Nails	9.5 years (6-17)	30	0%
Flynn**	Refracture after nail removal	1 year	Flexible IM Nails	10.2 years (6-16)	48	2%
Cramer	Hematoma after rod removal	2.7 years	Flexible IM Nails	8.5 years (5-14)	48	2%
Wright	Refracture after external fixator removal	2 years	External Fixation	6.5 years (4-10)	45	4%
Hedin 2003	Refracture after external fixator removal	1 year	External Fixation	8.1 years (3-15)	96	2%
Hedin 2003	Progressive bending at fracture site after removal*	1 year	External Fixation	8.1 years (3-15)	96	3%

* 2 of 3 patients with progressive bending had bilateral femoral fractures with below knee fracture on one

**In the Flynn study, some children had temporary reduction in function following nail removal

RECOMMENDATION 11

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

AAOS Level of Evidence: V

AAOS Grade of Recommendation: Inconclusive

RATIONALE

We found no evidence addressing the use of outpatient physical therapy as a means to improve patient function after treatment for a pediatric diaphyseal femur fracture.

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.

The work group is unable to recommend for or against the routine use of outpatient physical therapy. However, in keeping with current best medical practice in the absence of evidence, the decision to prescribe physical therapy as related to a specific individual, should be based on mutual communication between the treating physician and child's guardian.

SUPPORTING EVIDENCE

No studies addressed this recommendation.

RECOMMENDATION 12

Regional pain management is an option for patient comfort peri-operatively.

AAOS Level of Evidence: IV

AAOS Grade of Recommendation: C

Figures relevant to this recommendation are: Figure 35 - Figure 38

Tables relevant to this recommendation are: Table 17

RATIONALE

We identified one Level III study⁴⁵ of a hematoma block and one Level IV study⁴⁶ 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 Level III study⁴⁵ investigating a hematoma block and one Level IV case series⁴⁶ investigating a femoral nerve block addressed this recommendation. The Level III 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 Level IV 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

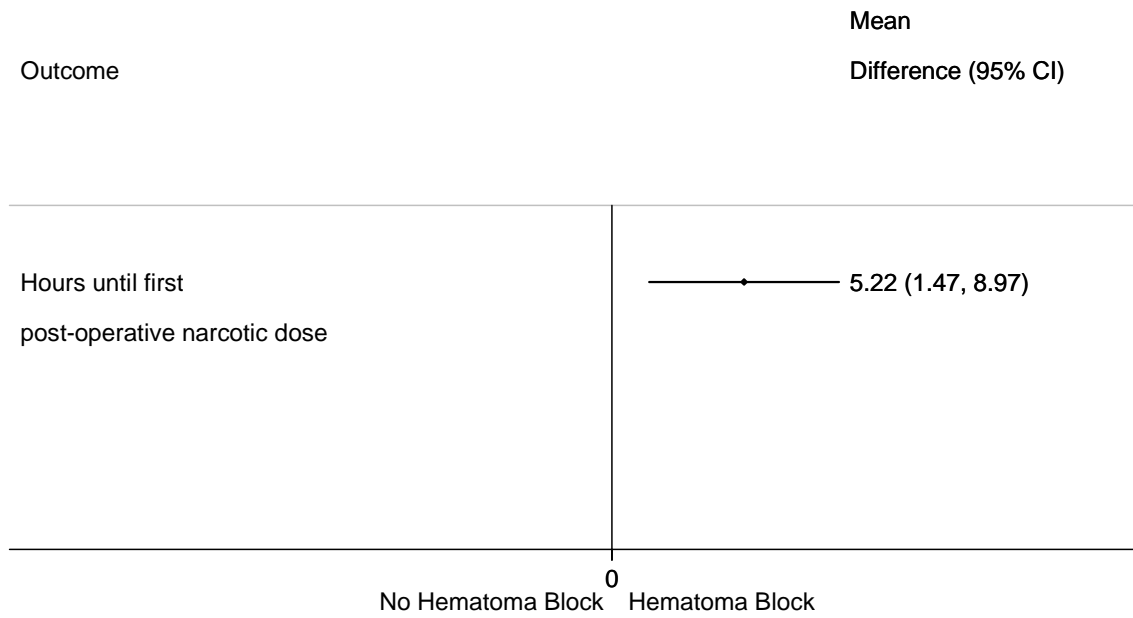


Figure 36. Hematoma Block vs. Control - Post-Operative Narcotic Requirement

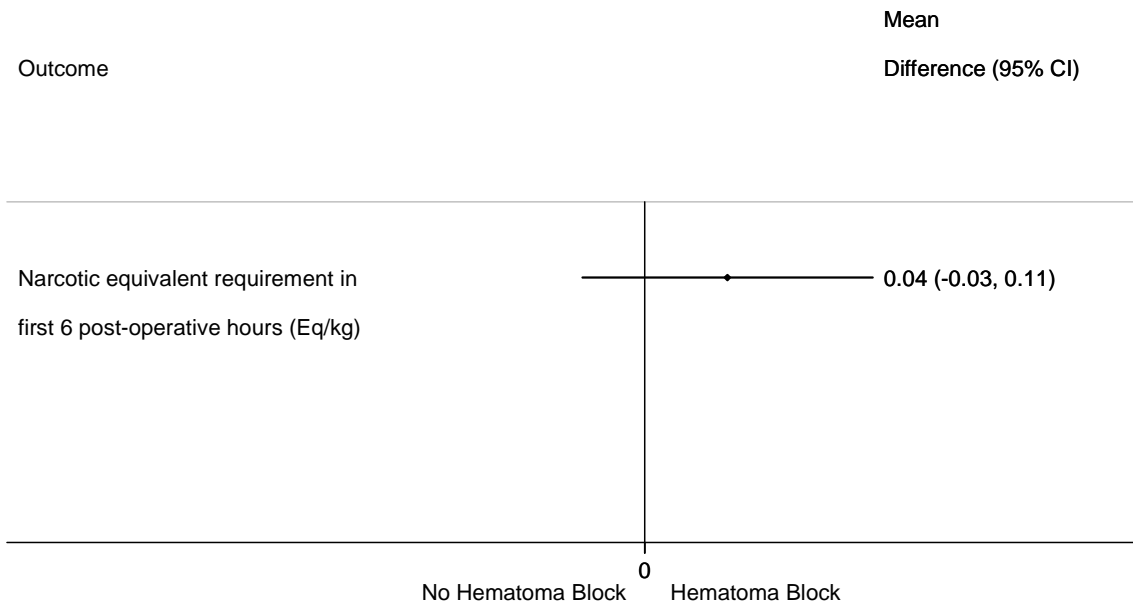


Figure 37. Hematoma Block vs. Control - Binary Outcomes

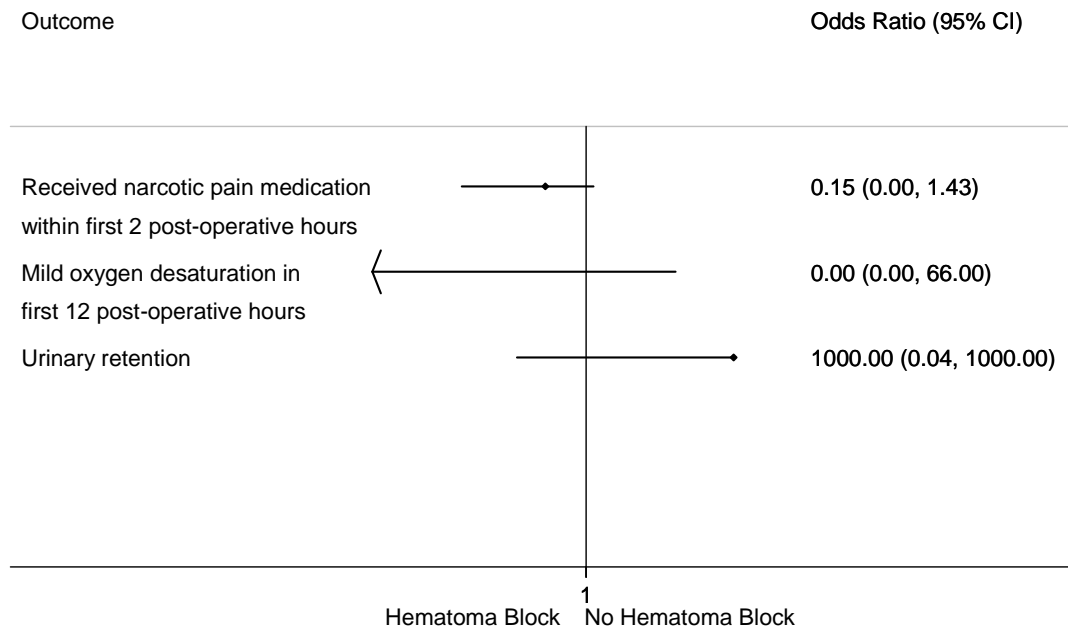
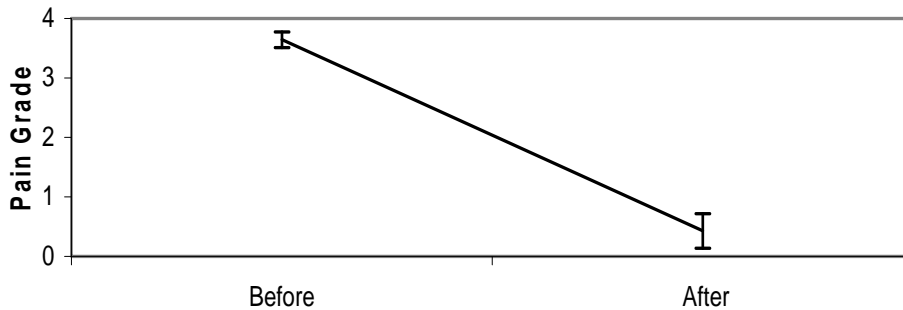


Figure 38. Femoral Nerve Block – Pain Relief



*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 review⁴⁷ 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.

RECOMMENDATION 13

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

AAOS Level of Evidence: Level IV

AAOS Grade of Recommendation: Inconclusive

There are no figures or tables relevant to this recommendation.

RATIONALE

There are no comparative studies investigating the use of locked and non-locked plates. One level IV study in this guideline used non-locked plates for the treatment of comminuted femur fractures but made no comparison to other treatment methods. In light of insufficient data, the work group is unable to make a recommendation.

SUPPORTING EVIDENCE

One study⁴¹ included in this guideline used plates for fixation of pediatric femur fractures. This study use non-locked plates. The age of patients in the study ranged from 9-14 years. Fractures healed in 13.4 weeks, on average. At long-term follow-up, mean femoral length inequality was 0.6 cm, mean torsion difference between limbs was 4.5°, 10% of patients had frontal plane angulation, and 10% of patients had sagittal plane angulation. The authors reported no other complications. The complete results of this study are presented under Recommendation 9.

RECOMMENDATION 14

Waterproof cast liners for spica casts are an option for use in children diagnosed with pediatric diaphyseal femur fractures.

AAOS Level of Evidence: III

AAOS Grade of Recommendation: C

Figures relevant to this recommendation are: Figure 39

RATIONALE

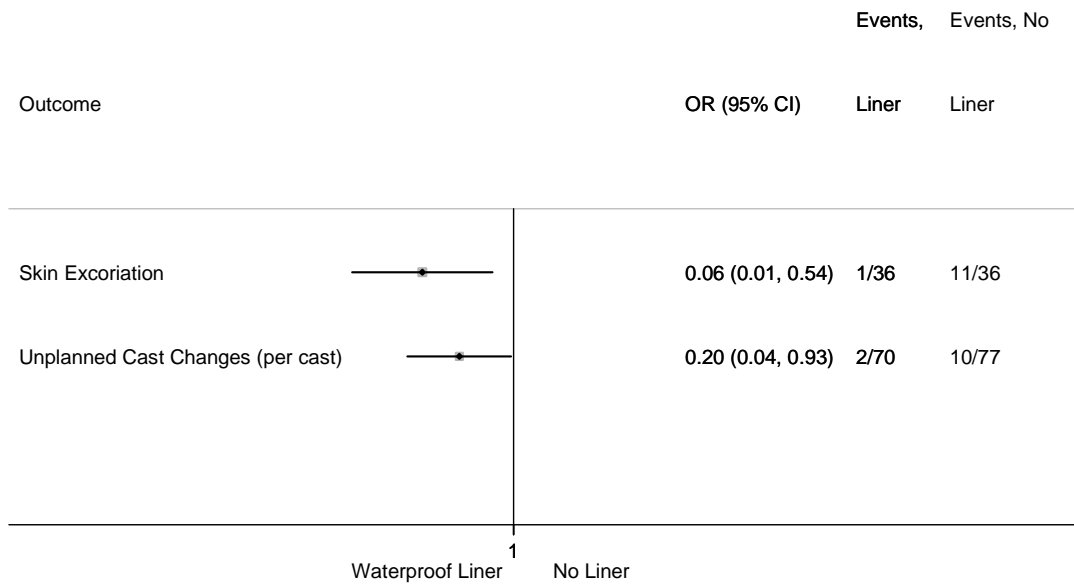
Waterproof cast liners are often used when applying a spica cast for the management of femur fractures in children in order to improve ease of care.

We identified one level III study⁴⁸ 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 Level III study⁴⁸ 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. Of 14 recommendations in this CPG, only 2 have level I or level II evidence available.

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.

IV.APPENDIXES

APPENDIX I WORK GROUP

Mininder S. Kocher, MD, MPH, Chair

Children's Hospital
300 Longwood Ave
Orthopaedic Dept
Boston, MA 02115

Ernest L. Sink, MD, Co-Chair

The Children's Hospital
13123 East 16th Ave B060
Aurora, CO 80045

R Dale Blasier, MD

Dept of Orthopaedic Surgery
800 Marshall St Sturgis 363
Little Rock, AR 72202

Scott J. Luhmann, MD

St Louis Children's Hospital
One Children's Pl Ste 4S 20
Saint Louis, MO 63110

Charles T. Mehlman, DO, MPH

Children's Hospital Medical Center
3333 Burnet Avenue, MLC 2017
Cincinnati, Ohio 45229-3039

David M. Scher, MD

Hospital for Special Surgery
535 E 70th St 5th Fl
New York, NY 10021

Travis Matheney, MD

Children's Hospital Boston
Orthopedic Surgery
47 Joy Street
Boston, MA 02115

James O Sanders, MD

Department of Orthopaedics
Rehabilitation University of Rochester
601 Elmwood Avenue
Rochester NY 14642

Guidelines Oversight Chair:

William C. Watters, III MD

6624 Fannin #2600
Houston, TX 77030

Guidelines Oversight Vice-Chair:

Michael J. Goldberg MD

Children's Hospital and Regional
Medical Ctr.
4800 Sand Point Way NE #w7706
PO Box 5371
Seattle WA 98105-5371

Evidence-Based Practice Committee Chair:

Michael Warren Keith, MD

2500 Metro Health Drive
Cleveland, OH 44109-1900

AAOS Staff:

Robert H. Haralson III, MD, MBA

AAOS Medical Director
6300 N River Road
Rosemont, IL 60018

Charles M. Turkelson, PhD

Director of Research and Scientific
Affairs

Janet L. Wies, MPH

Manager, Clinical Practice
Guidelines

Patrick Sluka, MPH

Lead Research Analyst

Kristin Hitchcock

AAOS Medical Librarian

APPENDIX II

AAOS BODIES THAT APPROVED THIS CLINICAL PRACTICE GUIDELINE

Guidelines and Technology Oversight Committee

The AAOS Guidelines and Technology Oversight Committee (GTOC) consists of sixteen AAOS members. The overall purpose of this Committee is to oversee the development of the clinical practice guidelines, performance measures, health technology assessments and utilization guidelines.

Evidence Based Practice Committee

The AAOS Evidence Based Practice Committee (EBPC) consists of ten AAOS members. This Committee provides review, planning and oversight for all activities related to quality improvement in orthopaedic practice, including, but not limited to evidence-based guidelines, performance measures, and outcomes.

Council on Research, Quality Assessment, and Technology

To enhance the mission of the AAOS, the Council on Research, Quality Assessment, and Technology promotes the most ethically and scientifically sound basic, clinical, and translational research possible to ensure the future care for patients with musculoskeletal disorders. The Council also serves as the primary resource to educate 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 areas of importance.

The Council is comprised of the chairs of the AAOS Biological Implants, Biomedical Engineering, Evidence Based Practice, Guidelines and Technology Oversight, Occupational Health and Workers' Compensation, Patient Safety, Research Development, and US Bone and Joint Decade committees. Also on the Council are the AAOS second vice-president, representatives of the Diversity Advisory Board, the Women's Health Issues Advisory Board, the Board of Specialty Societies (BOS), the Board of Councilors (BOC), the Communications Cabinet, the Orthopaedic Research Society (ORS), the Orthopedic Research and Education Foundation (OREF), and three members at large.

Board of Directors

The 17 member AAOS Board of Directors manages the affairs of the AAOS, sets policy, and determines and continually reassesses the Strategic Plan.

DOCUMENTATION OF APPROVAL

AAOS Work group Draft Completed	December 10, 2008
Peer Review Completed	January 31, 2009
Public Commentary Completed	April 30, 2009
AAOS Guidelines and Technology Oversight Committee	May 12, 2009
AAOS Evidence Based Practice Committee	May 11, 2009
AAOS Council on Research, Quality Assessment, and Technology	May 18, 2009
AAOS Board of Directors	June 19, 2009

APPENDIX III

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:

- PubMed (from 1966 through October 1, 2008)
- EMBASE (from 1966 through October 1, 2008)
- CINAHL (from 1982 through October 1, 2008)
- The Cochrane Central Register of Controlled Trials (through October 1, 2008)

This initial search (after removal of duplicates) yielded 1181 articles, of which 274 were retrieved and evaluated. The full search strategies are listed below.

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:

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:

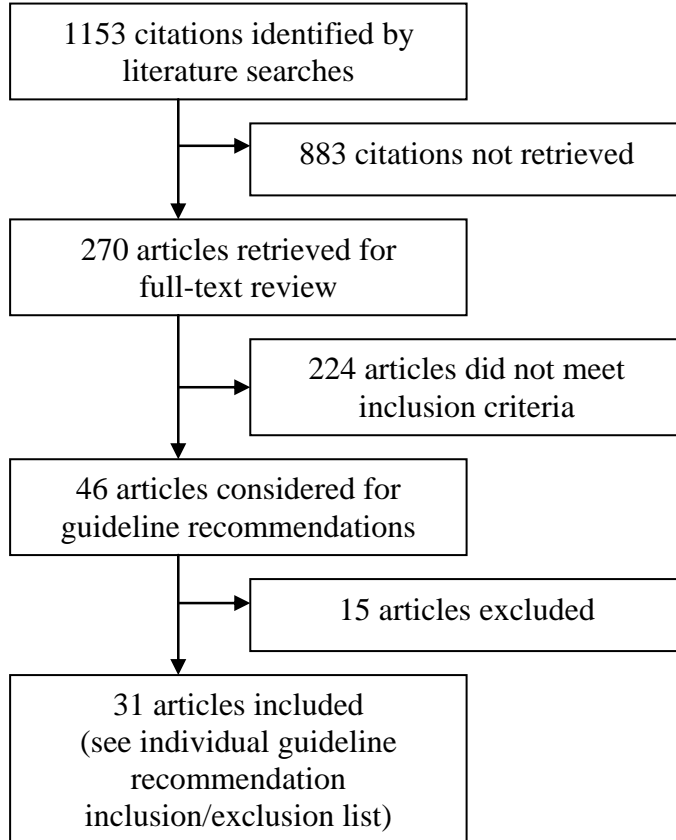
Cast AND (liner OR waterproof)

Cochrane Central Register of Controlled Trials was searched using the following strategy:

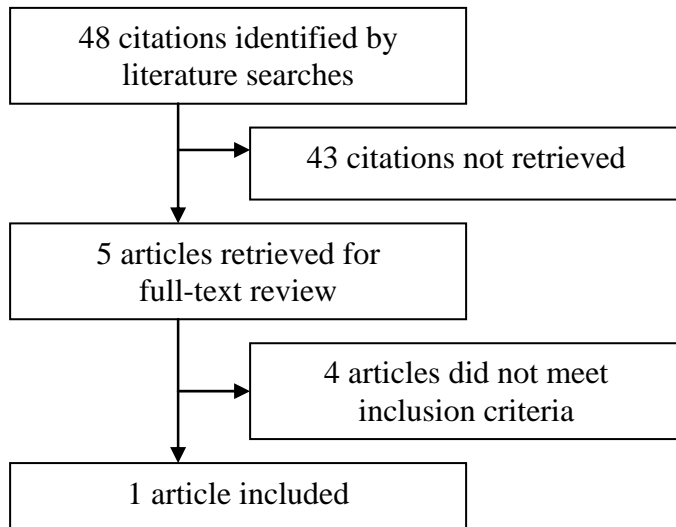
Cast AND (liner OR waterproof)

**APPENDIX IV
STUDY ATTRITION FLOWCHARTS**

ALL SEARCHES FLOWCHART



WATERPROOF CAST LINER SEARCH FLOWCHART



APPENDIX V LEVEL OF EVIDENCE

Levels of Evidence For Primary Research Question¹

	Types of Studies			
	Therapeutic Studies – Investigating the results of treatment	Prognostic Studies – Investigating the effect of a patient characteristic on the outcome of disease	Diagnostic Studies – Investigating a diagnostic test	Economic and Decision Analyses – Developing an economic or decision model
Level I	<ul style="list-style-type: none"> High quality randomized trial with statistically significant difference or no statistically significant difference but narrow confidence intervals Systematic Review² of Level I RCTs (and study results were homogenous³) 	<ul style="list-style-type: none"> High quality prospective study⁴ (all patients were enrolled at the same point in their disease with ≥ 80% follow-up of enrolled patients) Systematic review² of Level I studies 	<ul style="list-style-type: none"> Testing of previously developed diagnostic criteria on consecutive patients (with universally applied reference “gold” standard) Systematic review² of Level I studies 	<ul style="list-style-type: none"> Sensible costs and alternatives; values obtained from many studies; with multiway sensitivity analyses Systematic review² of Level I studies
Level II	<ul style="list-style-type: none"> Lesser quality RCT (e.g. < 80% follow-up, no blinding, or improper randomization) Prospective⁴ comparative study⁵ Systematic review² of Level II studies or Level I studies with inconsistent results 	<ul style="list-style-type: none"> Retrospective⁶ study Untreated controls from an RCT Lesser quality prospective study (e.g. patients enrolled at different points in their disease or <80% follow-up.) Systematic review² of Level II studies 	<ul style="list-style-type: none"> Development of diagnostic criteria on consecutive patients (with universally applied reference “gold” standard) Systematic review² of Level II studies 	<ul style="list-style-type: none"> Sensible costs and alternatives; values obtained from limited studies; with multiway sensitivity analyses Systematic review² of Level II studies
Level III	<ul style="list-style-type: none"> Case control study⁷ Retrospective⁶ comparative study⁵ Systematic review² of Level III studies 	<ul style="list-style-type: none"> Case control study⁷ 	<ul style="list-style-type: none"> Study of non-consecutive patients; without consistently applied reference “gold” standard Systematic review² of Level III studies 	<ul style="list-style-type: none"> Analyses based on limited alternatives and costs; and poor estimates Systematic review² of Level III studies
Level IV	Case Series ⁸	Case series	<ul style="list-style-type: none"> Case-control study Poor reference standard 	<ul style="list-style-type: none"> Analyses with no sensitivity analyses
Level V	Expert Opinion	Expert Opinion	Expert Opinion	Expert Opinion

1. A complete assessment of quality of individual studies requires critical appraisal of all aspects of the study design.
2. A combination of results from two or more prior studies.
3. Studies provided consistent results.
4. Study was started before the first patient enrolled.
5. Patients treated one way (e.g. cemented hip arthroplasty) compared with a group of patients treated in another way (e.g. uncemented hip arthroplasty) at the same institution.
6. The study was started after the first patient enrolled.
7. Patients identified for the study based on their outcome, called “cases”; e.g. failed total arthroplasty, are compared to those who did not have outcome, called “controls”; e.g. successful total hip arthroplasty.
8. Patients treated one way with no comparison group of patients treated in another way.

APPENDIX VI

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 VII
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 VIII PEER REVIEW PANEL

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

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 in 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 IX
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	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. There is an explicit link between the recommendations and the supporting evidence	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Given the nature of the topic and the data, all clinically important outcomes are considered	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. The guideline’s target audience is clearly described	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. The patients to whom this guideline is meant to apply are specifically described	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. The criteria used to select articles for inclusion are appropriate	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. The reasons why some studies were excluded are clearly described	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. All important studies that met the article inclusion criteria are included	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. The validity of the studies is appropriately appraised	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. The methods are described in such a way as to be reproducible.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. The statistical methods are appropriate to the material and the objectives of this guideline	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. Important parameters (e.g., setting, study population, study design) that could affect study results are systematically addressed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13. Health benefits, side effects, and risks are adequately addressed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14. The writing style is appropriate for health care professionals and patients	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15. The grades assigned to each recommendation are appropriate	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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:

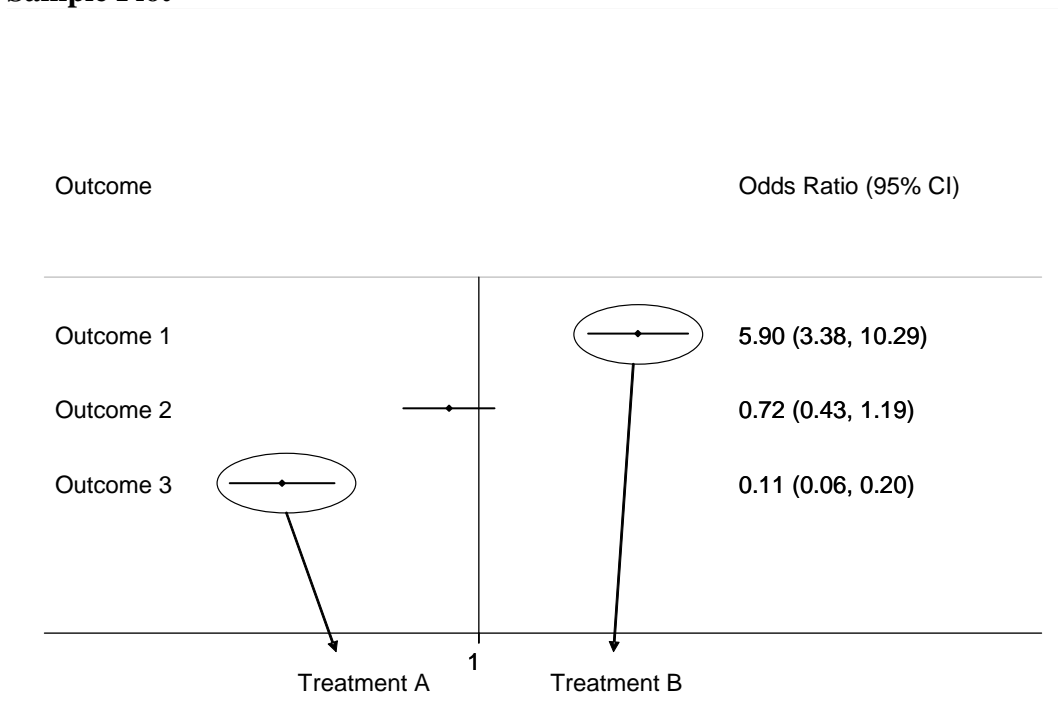
Please provide the reason(s) for your recommendation.

APPENDIX X INTERPRETING THE FOREST PLOTS⁴⁹



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 XI 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; McKesson 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 XII

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