

Treatment of Pediatric Diaphyseal Femur Fractures

Evidence-Based Clinical Practice Guideline

Adopted by:

The American Academy of Orthopaedic Surgeons Board of Directors
December 5, 2020

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Disclaimer

This Clinical Practice Guideline was developed 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 the 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 guideline.

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FDA Clearance

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2020 REPORT FOR THE UPDATE OF THE 2009 CLINICAL PRACTICE GUIDELINE ON THE TREATMENT OF PEDIATRIC DIAPHYSEAL FEMUR FRACTURE (REISSUED IN 2015)

This guideline is greater than 5 years old and is reviewed every five years. New studies have been published since this guideline was developed, however the AAOS has determined that these studies are not sufficient to warrant changing the guideline scope at this time. Due to the paucity of evidence and the relevance of the existing scope, this guideline was approved to be updated via the AAOS Rapid Update Methodology. The 2020 additions to this document are outlined below and reflect additions based on newly available evidence relevant to the original PICO questions and resulting guideline recommendations. Only the recommendations have been updated, and all other information (e.g. the methods, work group roster, recommendation rationales) remain that of the original 2009 guideline. For the full AAOS Clinical Practice Guidelines Rapid Update Methodology please visit: aaos.org/quality

OVERVIEW OF 2020 UPDATES TO THE 2009 ORIGINAL GUIDELINE

1. Addition of the Siddiqui, et al, 2008 study findings to the Early or Delayed Spica Casting recommendation.
2. Addition of the Ahmad, et al, 2015, Naseem, et al, 2015, and Soleimanpour, et al, 2013 study findings to the Elastic Intramedullary Nails recommendation.
3. Updated the strength of recommendation of the Elastic Intramedullary Nails recommendation based on new study findings.
 - a. Based on the new strength of evidence, the recommendation language was updated from '*Limited evidence supports the option for physicians to use flexible intramedullary nailing to treat children age five to eleven years diagnosed with diaphyseal femur fractures*' to '*Strong evidence supports the use of flexible intramedullary nailing to treat children age five to eleven years diagnosed with diaphyseal femur fractures.*'

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SUMMARY OF RECOMMENDATIONS

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

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

CHILD ABUSE

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

Strength of Recommendation: Strong ★★★★★

Description: Evidence from two or more “High” quality studies with consistent findings for recommending for or against the intervention.

INFANT FEMUR FRACTURE

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

Strength of Recommendation: Limited ★★★☆☆

Description: Evidence from two or more “Low” quality studies with consistent findings or evidence from a single “Moderate” quality study recommending for against the intervention or diagnostic or the evidence is insufficient or conflicting and does not allow a recommendation for or against the intervention.

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EARLY OR DELAYED SPICA CASTING

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

Strength of Recommendation: Moderate ★★★★★

Description: Evidence from two or more “Moderate” quality studies with consistent findings or evidence from a single “High” quality study for recommending for or against an intervention.

ELASTIC INTRAMEDULLARY NAILS

Strong evidence supports the use of flexible intramedullary nailing to treat children age five to eleven years diagnosed with diaphyseal femur fractures.

Strength of Recommendation: Strong ★★★★★

Description: Evidence from two or more “High” quality studies with consistent findings for recommending for or against the intervention.

ORIF PEDIATRIC FEMUR FRACTURES

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

Strength of Recommendation: Limited ★★★★★

Description: Evidence from two or more “Low” quality studies with consistent findings or evidence from a single “Moderate” quality study recommending for against the intervention or diagnostic or the evidence is insufficient or conflicting and does not allow a recommendation for or against the intervention.

PAIN CONTROL

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

Strength of Recommendation: Limited ★★★★★

Description: Evidence from two or more “Low” quality studies with consistent findings or evidence from a single “Moderate” quality study recommending for against the intervention or diagnostic or the evidence is insufficient or conflicting and does not allow a recommendation for or against the intervention.

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WATERPROOF CASTING

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

Strength of Recommendation: Limited ★★☆☆

Description: Evidence from two or more “Low” quality studies with consistent findings or evidence from a single “Moderate” quality study recommending for against the intervention or diagnostic or the evidence is insufficient or conflicting and does not allow a recommendation for or against the intervention.

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INTRODUCTION

OVERVIEW

This clinical practice guideline is based on a systematic review of published studies for the treatment of isolated diaphyseal femur fractures in children where children are defined as those not having reached skeletal maturity. This guideline aims to provide practice recommendations based on the best available evidence, highlight the limitations in the current literature, and suggest areas for future research.

This guideline was developed for all qualified and appropriately trained health care professionals involved in the management of glenohumeral joint osteoarthritis. It is intended as an information resource to guide decision making and assist developers of future practice guidelines and treatment recommendations.

GOALS AND RATIONALE

Clinical practice guidelines provide evidence-based treatment recommendations derived from a systematic review of the best current available evidence in the literature. The goal of this guideline is to summarize the areas where there is good evidence and poor evidence in the treatment of isolated diaphyseal femur fractures in children and identify areas where evidence of any kind is lacking. AAOS staff and the physician work group predetermined specific questions of interest for this patient population, systematically reviewed the currently available literature, and developed the current recommendations based on the strength or weaknesses of the results of this review.

This guideline was created as a tool to assist physicians, surgeons and other health care professionals that care for skeletally immature patients with isolated diaphyseal femur fractures in developing an understanding of levels of evidence that exist for a range of common diagnostic and treatment practices. It is by no means a replacement for appropriate clinical judgement regarding any specific treatment modality or procedure and each patient should be managed based on their needs and resources available to the individual healthcare provider.

INTENDED USERS

This guideline is intended to be used by orthopaedic surgeons and all qualified physicians managing pediatric patients. The treatment of pediatric diaphyseal femur fractures is based on informed decision making between the patient/guardian and the healthcare provider. Discussion of available nonsurgical and surgical treatments provides a thorough outline of all of the options so an informed decision can be made. Clinician input based on medical knowledge, conservative management and surgical experience as well as skill, all influence the successful identification of who will benefit from specific treatment options.

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

PATIENT POPULATION

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

BURDEN OF DISEASE

There are many components to consider when calculating the overall cost of treatment for pediatric femoral View background material and data summaries via the CPG [eAppendix](#)

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

INCIDENCE AND PREVALENCE

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

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

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

POTENTIAL BENEFITS, HARMS, AND CONTRAINDICATIONS

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

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

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METHODS

The methods used to perform this clinical practice guideline were employed to minimize bias and enhance transparency in the selection, appraisal, and analysis of the available evidence. These processes are vital to the development of reliable, transparent, and accurate clinical recommendations for management of Glenohumeral Joint Osteoarthritis. To view the full AAOS clinical practice guideline methodology please visit the [eAppendix](#) or <https://www.aaos.org/additonalresources/>.

The methods used to perform this systematic review were employed to minimize bias in the selection and summary of the available evidence.^{8,9} These processes are vital to the development of reliable, transparent, and accurate clinical recommendations for treating isolated diaphyseal femur fractures in children.

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

GUIDELINE UPDATE

The original guideline and systematic review were prepared by the AAOS Pediatric Diaphyseal Femur Fractures physician work group with the assistance of the AAOS Clinical Practice Guidelines Unit. Based on the current procedure for updating AAOS guidelines, the Medical Librarian ran an updated search to identify literature published after the original search for the 2007 guideline that could address and possibly change the original recommendations. The AAOS Committee on Evidence-Based Quality and Value in conjunction with the Department of Clinical Quality and Value then used the inclusion criteria from the original guideline to determine if any articles published after the final literature search date of the original guideline were relevant to the recommendations.

LITERATURE SEARCHES

The medical librarian conducted a comprehensive search of PubMed, Embase, and the Cochrane Central Register of Controlled Trials based on key terms and concepts from the systematic literature review development group's preliminary recommendations. Bibliographies of relevant systematic reviews were hand searched for additional references. The original guideline searched for all articles published up to October 1, 2008, the 2015 re-issued guideline searched for articles published up to November 27, 2013, and the 2020 updated guideline searched for all articles published up to April 6, 2020.

STUDY SELECTION CRITERIA

TYPES OF STUDIES

The original guideline development group developed *a priori* article selection criteria for the review. Specifically, to be included in the 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.

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

For the recommendation on waterproof cast liners only, the group 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 the group 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
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necessarily been correlated to function and risk of developing further problems.

The group 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, the group did not include the longer-term data). The group also excluded outcomes for study groups that did not have at least 10 patients.

When distinguishing between stable and unstable fractures, the group defined transverse and short oblique fractures as stable. The group 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, the group included the study in the evidence base of the recommendation whose age range included the study’s median patient age.

DEFINING THE STRENGTH OF THE RECOMMENDATIONS




Judging the strength of evidence is only a steppingstone towards arriving at the strength of a systematic literature review recommendation. The strength of recommendation (Table 1) also takes into account the quality, quantity, and the trade-off between the benefits and harms of a treatment, the magnitude of a treatment’s effect, and whether there is data on critical outcomes. Table 2 addresses how to interpret the strength of each recommendation.

VOTING ON THE RECOMMENDATIONS

The recommendations and their strength were voted on by the guideline development group members during the final meeting. If disagreement between the guideline development group occurred, there was further discussion to see whether the disagreement(s) could be resolved. Recommendations were approved and adopted in instances where a simple majority (60%) of the guideline development group voted to approve; Please see appendix for voting breakdown.

INTERPRETING THE STRENGTH OF EVIDENCE

Table 1. Strength of Recommendation Descriptions

Strength	Overall Strength of Evidence	Description of Evidence Quality	Strength Visual
Strong	Strong	Evidence from two or more “High” quality studies with consistent findings for recommending for or against the intervention.	
Moderate	Moderate	Evidence from two or more “Moderate” quality studies with consistent findings, or evidence from 1 a single “High” quality study for recommending for or against the intervention.	
Limited	Low or Conflicting Evidence	Evidence from two or more “Low” quality studies with consistent findings or evidence from a single “Moderate” quality study recommending for against the intervention or diagnostic or the evidence is insufficient or conflicting and does not allow a recommendation for or against the intervention.	

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Consensus	No Evidence	There is no supporting evidence. In the absence of reliable evidence, the systematic literature review development group is making a recommendation based on their clinical opinion.
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Table II. Clinical Applicability: Interpreting the Strength of a Recommendation

Strength of Recommendation	Patient Counseling (Time)	Decision Aids	Impact of Future Research
Strong	Least	Least Important, unless the evidence supports no difference between two alternative interventions	Not likely to change
Moderate	Less	Less Important	Less likely to change
Limited	More	Important	Change possible/anticipated
Consensus	Most	Most Important	Impact unknown

REVIEW PERIOD

The original draft of the guideline and evidence report were peer reviewed by an expert outside advisory panel that was nominated by the physician work group prior to the development of the guideline (eAppendix). 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. (eAppendix) 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.

After modifying the draft in response to peer review, the original guideline was subjected to a thirty-day period of “Public Commentary.” Commentators consist of members of the AAOS Board of Directors (BOD), members of the Council on Research, Quality Assessment, and Technology (CORQAT), members of the Board of Councilors (BOC), and members of the Board of Specialty Societies (BOS). Based on these bodies, up to 185 commentators had the opportunity to provide input into the development of this guideline. Of these, 12 returned public comments.

THE AAOS CLINICAL PRACTICE GUIDELINE APPROVAL PROCESS

This final clinical practice guideline draft must be approved by the AAOS Committee on Evidence-Based Quality and Value Committee, the AAOS Council on Research and Quality, and the AAOS Board of Directors. These decision-making bodies are described in the eAppendix. Their charge is to approve or reject its publication by majority vote.

REVISION PLANS

This clinical practice guideline represents a cross-sectional view of current treatment and may become outdated as new evidence becomes available. This clinical practice guideline will be revised in accordance with new evidence, changing practice, rapidly emerging treatment options, and new technology. This clinical practice guideline will be updated, re-issued, or withdrawn in five years.

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SYSTEMATIC LITERATURE REVIEW DISSEMINATION PLANS

The primary purpose of the present document is to provide interested readers with full documentation of the best available evidence for various procedures associated with the topic of this review. Publication of most systematic literature reviews is announced by an Academy press release, articles authored by the systematic literature review development group and published in the *Journal of the American Academy of Orthopaedic Surgeons*, and articles published in *AAOS Now*.

Selected clinical practice guidelines are disseminated by webinar, AAOS Online Learning, the Orthopaedic Video Theater (OVT), Media Briefings, and by distributing them at relevant Continuing Medical Education (CME) courses and at the AAOS Resource Center.

RECOMMENDATIONS

CHILD ABUSE

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

Strength of Recommendation: Strong ★★★★★

Description: Evidence from two or more “High” quality studies with consistent findings for recommending for or against the intervention.

RATIONALE:

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

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

In addition, the work group emphasizes that children who are not yet walking and sustain a femur fracture are at particular risk for 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

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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.

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INFANT FEMUR FRACTURE

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

Strength of Recommendation: Limited ★★☆☆

Description: Evidence from two or more “Low” quality studies with consistent findings or evidence from a single “Moderate” quality study recommending for against the intervention or diagnostic or the evidence is insufficient or conflicting and does not allow a recommendation for or against the intervention.

RATIONALE:

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

Supporting Evidence:

Two studies addressed this recommendation. One retrospective comparative 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.

EARLY OR DELAYED SPICA CASTING

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

Strength of Recommendation: Moderate



Description: Evidence from two or more “Moderate” quality studies with consistent findings or evidence from a single “High” quality study for recommending for or against an intervention.

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 High Quality 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 High quality study,²² with a mean patient age of 6 years old, but that addressed harms in children as young as 4 was also included to address this recommendation.

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Previously Published Systematic Reviews:

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

ELASTIC INTRAMEDULLARY NAILS

Strong evidence supports the use of flexible intramedullary nailing to treat children age five to eleven years diagnosed with diaphyseal femur fractures.

Strength of Recommendation: Strong ★★★★★

Description: Evidence from two or more “High” quality studies with consistent findings for recommending for or against the intervention.

2009 RATIONALE:

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

The high quality 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).

Two moderate quality studies^{24, 50} shows more rapid return to walking and school with flexible intramedullary nailing and one low quality 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 “limited” recommendation. Based on the advantages suggested, less adverse events and more rapid return to school, flexible intramedullary nailing is a treatment option for children five to eleven years diagnosed with diaphyseal femur fractures.

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

Patients over age 11 or with weight over 49 kg are at increased risk of a poor 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.

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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.

2020 Update Supporting Evidence:

Ahmad, I, Gilani, H. U. R, Rasool, K, Rasool A. Comparison of titanium elastic nailing vs hip spica cast in treatment of femoral shaft fractures in children between 6-12 years of age. *Pakistan Journal of Medical and Health Sciences*. 2015 January;9(2): 717-719.

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ORIF PEDIATRIC FEMUR FRACTURES

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

Strength of Recommendation: Limited ★★☆☆

Description: Evidence from two or more “Low” quality studies with consistent findings or evidence from a single “Moderate” quality study recommending for against the intervention or diagnostic or the evidence is insufficient or conflicting and does not allow a recommendation for or against the intervention.

RATIONALE:

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

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

Supporting Evidence:

One High Quality and four Low quality studies addressed this recommendation. The High Quality 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 Low quality studies, one investigated flexible nailing,²⁷ one investigated rigid trochanteric entry nailing,³⁸ one investigated near piriformis entry rigid nailing,^{38,40} and one investigated submuscular plating of comminuted fractures.⁴¹

The study of flexible 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

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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.

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.

PAIN CONTROL

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

Strength of Recommendation: Limited ★★☆☆

Description: Evidence from two or more “Low” quality studies with consistent findings or evidence from a single “Moderate” quality study recommending for against the intervention or diagnostic or the evidence is insufficient or conflicting and does not allow a recommendation for or against the intervention.

RATIONALE:

We identified one High quality study⁴⁵ of a hematoma block and one Low quality 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 Moderate Quality study⁴⁵ investigating a hematoma block and one Low quality case series⁴⁶ investigating a femoral nerve block addressed this recommendation. The High quality study compared patients who received a bupivacaine hematoma block after elastic nail fixation to patients who did not receive a hematoma block. Pain scale scores were not reported; however, patients who received a hematoma block received their first post-operative narcotic dose a mean of 5 hours later than patients in the control group (p = .008).

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

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.

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WATERPROOF CASTING

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

Strength of Recommendation: Limited ★★☆☆

Description: Evidence from two or more “Low” quality studies with consistent findings or evidence from a single “Moderate” quality study recommending for against the intervention or diagnostic or the evidence is insufficient or conflicting and does not allow a recommendation for or against the intervention.

RATIONALE:

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

We identified one High Quality 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 High Quality 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.

FUTURE RESEARCH

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

Specific trials which would be helpful include:

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

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

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