WHAT IS A CLINICAL PRACTICE GUIDELINE?

Clinical Practice Guideline

A clinical practice guideline is a series of recommendations created to inform clinicians of best practices, based on best available evidence.
GOALS AND RATIONALE OF A CLINICAL PRACTICE GUIDELINE

- Improve treatment based on current best evidence
- Guides qualified physicians through treatment decisions to improve quality and efficiency of care
- Identify areas for future research

CPG recommendations are not meant to be fixed protocols; patients’ needs, local resources, and clinician independent medical judgement must be considered for any specific procedure or treatment.
WHAT IS EVIDENCE-BASED MEDICINE?

Evidence-Based Medicine is a Combination of:

- Individual Clinical Experience
- Best External Evidence
- Patient Values and Expectations
WHAT IS EVIDENCE-BASED MEDICINE?

Evidence-Based Medicine

Evidence-based medicine is the conscientious, explicit, and judicious use of current best evidence from clinical care research in the management of individual patients

Haynes, Sackett et al, 1996 Transferring evidence from research into practice
Sacket et al, 1996, BMJ EBM: what it is and isn't
IOM STANDARDS FOR DEVELOPING TRUSTWORTHY GUIDELINES

- Establish Transparency
- Management of Conflict of Interest
- Guideline Development Group Composition
- Clinical Practice Guideline-Systematic Review Intersection
- Establish Evidence of Foundations for and Rating Strength of Recommendations
- Articulation of Recommendations
- External Review
- Updating

Approved!
1. Select CPG Topic

2. Assemble Work Group Members (WG)

3. WG formulates PICO questions, set inclusion criteria at Introductory Meeting

4. Literature Review and Appraisal
   AAOS staff methodologists, in conjunction with work group (WG) members, review and appraise literature

5. Final Meeting
   WG meets in-person to:
   - Review quality appraisals and evidence tables
   - Assign grade/rating for each recommendation based on evidence
   - Develop final recommendations
   - Construct risk/harms statements
   - Define future research needs

6. Review Periods
   Peer Review and Public Comment review periods

7. Approval Process

8. Communication, Dissemination, and Implementation
FORMULATING PICOs

“P” = Patient Population

“I” = Intervention or variable of Interest

“C” = Comparison

“O” = Outcome
INCLUSION/EXCLUSION CRITERIA

Standard inclusion criteria include:

- Must study humans
- Must be published in English
- Must be published in or after 1966
- Can not be performed on cadavers

Work group members define additional exclusion criteria based on PICO question
LITERATURE SEARCHES

- Databases used:
  - PubMed
  - EMBASE (Excerpta Medica database)
  - Cochrane Central Register of Controlled Trials

- Search using key terms from work group’s PICO questions and inclusion criteria

- Secondary manual search of the bibliographies of all retrieved publications for relevant citations

- Recalled articles evaluated for inclusion based on the study selection criteria
BEST EVIDENCE SYNTHESIS

- Include only highest quality evidence for any given outcome if available

- If there are fewer than two occurrences of an outcome of this quality, the next lowest quality is considered until at least two occurrences have been acquired.
<table>
<thead>
<tr>
<th>STRENGTH</th>
<th>OVERALL STRENGTH OF EVIDENCE</th>
<th>STRENGTH VISUAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>STRONG</td>
<td>Two or more HIGH Strength Studies with consistent findings</td>
<td>★★★★★</td>
</tr>
<tr>
<td>MODERATE</td>
<td>1 HIGH OR 2 MODERATE strength studies with consistent findings</td>
<td>★★★★☆</td>
</tr>
<tr>
<td>LIMITED</td>
<td>One or more LOW strength studies and/or only 1 MODERATE strength study with consistent findings or evidence from a single, or the evidence is insufficient, or conflicting</td>
<td>★★★☆☆</td>
</tr>
<tr>
<td>CONSENSUS</td>
<td>Expert opinion (no studies) No supporting evidence in the absence of reliable evidence. Work group is making a recommendation based on their clinical opinion</td>
<td>★☆☆☆☆</td>
</tr>
</tbody>
</table>
# TRANSLATING RECOMMENDATIONS IN A CPG

<table>
<thead>
<tr>
<th>STRENGTH OF RECOMMENDATION</th>
<th>PATIENT COUNSELING TIME</th>
<th>DECISION AIDS</th>
<th>IMPACT OF FUTURE RESEARCH</th>
</tr>
</thead>
<tbody>
<tr>
<td>Strong</td>
<td>Least</td>
<td>Least important, unless the evidence supports no difference between two alternative interventions</td>
<td>Not likely to change</td>
</tr>
<tr>
<td>Moderate</td>
<td>Less</td>
<td>Less important</td>
<td>Less likely to change</td>
</tr>
<tr>
<td>Limited</td>
<td>More</td>
<td>More</td>
<td>Possible / Anticipates</td>
</tr>
<tr>
<td>Consensus</td>
<td>Most</td>
<td>Most Important</td>
<td>Impact unknown</td>
</tr>
</tbody>
</table>
ASSESSING QUALITY OF EVIDENCE

All included studies undergo a quality assessment

Each study’s design is evaluated for risk of bias and receives a final quality grade, depending on the number of study design flaws

Study quality tables are made available to the work group in the final data report and the final publication of the guideline/systematic review
RESULTS OF QUALITY ASSESSMENT: ORIGINAL 2008 STUDY ATTRITION FLOWCHART

- 1153 citations identified by literature searches
  - 883 citations not retrieved
  - 270 articles retrieved for full-text review
    - 224 articles did not meet inclusion criteria
    - 46 articles considered for guideline recommendations
      - 15 articles excluded
      - 31 articles included
UPDATED 2013
STUDY ATTRITION FLOWCHART

316 citations identified by updated literature searches

10 articles recalled from abstract review

One article added to recommendation 4

9 articles did not meet inclusion criteria
UPDATED 2020
STUDY ATTRITION FLOWCHART

442 abstracts reviewed by search performed on April 16, 2020

110 articles recalled from abstract review

332 articles did not meet inclusion criteria

One article added to recommendation 3
Three articles added to recommendation 4

106 articles did not meet inclusion criteria
WATERPROOF CAST LINER: STUDY ATTRITION FLOWCHART

48 citations identified by literature searches

5 articles retrieved for full-text review

43 citations not retrieved

4 articles excluded

1 articles included
VOTING ON THE RECOMMENDATIONS

Recommendations and recommendation strengths voted on by work group during final meeting

Approved and adopted by simple majority (60%) when voting on every recommendation

If disagreement, further discussion to whether the disagreement could be resolved
# GUIDELINE LANGUAGE STEMS

<table>
<thead>
<tr>
<th>GUIDELINE LANGUAGE STEMS</th>
<th>STRENGTH OF RECOMMENDATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Strong evidence supports that the practitioner should/should not do X, because...</td>
<td>STRONG</td>
</tr>
<tr>
<td>Moderate evidence supports that the practitioner could/could not do X, because...</td>
<td>MODERATE</td>
</tr>
<tr>
<td>Limited evidence supports that the practitioner might/might not do X, because...</td>
<td>LIMITED</td>
</tr>
<tr>
<td>In the absence of reliable evidence, it is in the opinion of this guideline work group that...</td>
<td>CONSENSUS</td>
</tr>
</tbody>
</table>
PEER REVIEW

- Guideline draft sent for peer review to external experts
- Comments and draft of responses reviewed by work group members
- Recommendation changes required a majority vote by work group
- A detailed report of all resulting revisions is published with the guideline document
PUBLIC COMMENT

Following peer review modifications, CPG undergoes public commentary period

Comments are solicited from:

AAOS Board of Directors
AAOS Council on Research and Quality
AAOS Committee on Evidence-Based Quality and Value
AAOS Board of Councilors
AAOS Board of Specialty Societies

200 commentators have the opportunity to provide input
The work group is charged with:

- Review of data summaries
- Final recommendation language
- Rationale and risk/harm construction
- Future research
TREATMENT OF PEDIATRIC DIAPHYSEAL FEMUR FRACTURES
CLINICAL PRACTICE GUIDELINE OVERVIEW

- Based on a systematic review of published studies
- Addresses the treatment of isolated diaphyseal femur fractures in children who have not yet reached skeletal maturity.
- Highlights limitations in literature and areas requiring future research
- Trained physicians and surgeons are intended users

- Guideline greater than 5 years old and is reviewed very five years.
- New studies were published.
- Not sufficient to warrant changing scope of guideline.
- Due to paucity of evidence and relevance of existing scope, guideline was approved via the AAOS Rapid Update Methodology.
- New additions based on newly available evidence relevant to original PICO questions and resulting guideline recommendations.
- Only recommendations were updated. All other information (e.g., methods, work group roster, recommendation rationales) remain that of original 2009 guideline.
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 ★★★★
INFANT FEMUR FRACTURE

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

Strength of Recommendation: Limited ★★★★☆
EARLY OR DELAYED SPICA CASTING

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

Strength of Recommendation: Moderate ★★★★☆
ELASTIC INTRAMEDULLARY NAILS

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

Strength of Recommendation: Strong 🌟🌟🌟🌟
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 ★★★★★
PAIN CONTROL

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

Strength of Recommendation: Limited ⭐⭐⭐
WATERPROOF CASTING

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

Strength of Recommendation: Limited ★★★☆☆
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.
FUTURE RESEARCH

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.
FUTURE RESEARCH

• 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.
PLEASE CITE CLINICAL PRACTICE GUIDELINE AS:

American Academy of Orthopaedic Surgeons Evidence-Based Clinical Practice Guideline on the Treatment of Pediatric Diaphyseal Femur Fractures  
http://www.orthoguidelines.org/topic?id=1015. Published December 5, 2020
TREATMENT OF PEDIATRIC DIAPHYSEAL FEMUR FRACTURES
CASE STUDY

Isolated pediatric femoral shaft fractures occur at an annual rate of 19 per 100,000 and represent the most frequent pediatric orthopaedic injury requiring hospitalization. The treatment of these fractures is dictated by various factors. The orthopaedic surgeon caring for these fractures must take into account the patient's age, weight, family circumstances, and fracture pattern to determine the best treatment options. The cost for these various treatment options can also come into consideration.

The treatment options available for pediatric femoral diaphyseal fractures include: Pavlik harnessing, Spica casting, traction with subsequent casting, external fixation, intramedullary flexible or rigid nailing, and plating (locked and unlocked methods). The desire for early mobilization in order to allow for earlier return to school for the patient, decrease in the burden of home bound children on the families, and decrease the duration of hospitalization has prompted the use of surgical intervention over non-surgical interventions.
TREATMENT OF PEDIATRIC DIAPHYSEAL FEMUR FRACTURES
CASE STUDY

While the vast majority of pediatric femoral fractures will progress to union without complications, the advantages and disadvantages of the available treatments must be weighed carefully when determining the best option for each patient, particularly when considering patients that are on the borders of either weight or the general age groupings. The American Academy of Orthopaedic Surgeons Clinical Practice Guideline: Treatment of Pediatric Diaphyseal Femur Fractures provides the current evidence based guidelines to help guide the practitioner when treating these injuries.
**HISTORY AND PHYSICAL**

A 3-year-old male is brought into the trauma bay after being hit by a motor vehicle while he was walking on a sidewalk. His only complaint on arrival is of thigh and abdominal pain. He had no loss of consciousness. His triage vital signs are BP 96/68, HR 209, RR 30, O2 Saturation 99%, weight 15kg. The patient is treated as per advanced trauma life support (ATLS) protocol by the general surgery trauma service with orthopaedic consultation.

On physical examination, he has superficial abrasions over the abdomen without peritoneal signs or deep tenderness. He has tenderness to palpation over the left upper thigh with soft compartments and intact pulses. The remainder of the physical exam is benign.
X-rays of the pelvis and left thigh as well as CT of the abdomen and pelvis reveal a left proximal third femur fracture with displacement and > 2cm of shortening, and a left pelvic wing subtle plastic deformity. This image shows the presentation x-ray. The soft tissues of the abdomen and pelvis on CT are negative.
**TREATMENT**

The AAOS clinical guideline groups treatment of pediatric femur fractures into four categories based on age: 0 to 6 months treat with Pavlik harnessing, 6 months to 5 years treat with Spica casting, 5 years to 11 years treat with flexible nailing, 11 years to skeletal maturity treat with trochanteric entry rigid nail, plating or flexible nailing. Treatment is not solely based on the patient’s age, but should also consider patient’s weight, and family dynamics. Considering all of the treatment recommendations, a diaphyseal femur fracture with >2cm of shortening in the 6 months to 5 year age group has no supporting evidence. The amount of acceptable shortening remains controversial. No studies were identified in the literature specifically addressing whether spica casting should be utilized in this population or comparing spica casting with other treatment modalities.
TREATMENT

The patient is admitted to the pediatric intensive care unit and placed in Buck’s traction pending definitive orthopaedic treatment. The following morning, the patient is deemed stable to undergo Spica casting of his left femur fracture. The Spica cast is applied without difficulty. During the afternoon on the day of cast application, the patient develops tachycardia and increasing abdominal pain that prompts a repeat abdominal CT scan. The repeat CT scan shows focal thickening and peritoneal enhancement with free fluid and air in the terminal ilium. At this point, the Spica cast is removed and he is taken to the OR by trauma surgery for exploratory laparotomy and is found to have a 1cm jejunal injury that requires repair along with an appendectomy. The patient is returned to the PICU for postoperative recovery and Buck’s’ traction is reinitiated.
On the next hospital day, the patient is again cleared to return to the OR for femur fracture stabilization via external fixator. His pelvis is stable to exam under anesthesia. His hospital course is complicated by abdominal wound dehiscence requiring operative debridement and IV antibiotics. His pin sites and thigh remain benign during this time and the parents are instructed on pin site care, which is initiated on POD 6. He is discharged on POD 12 to home with follow up 1 week later in the orthopaedic clinic. He is discharged with a wheelchair for protected weight bearing.
POST HOSPITALIZATION

The patient is seen in clinic one week after discharge without complaints. He has normal GI function. His pin sites are benign, and x-rays demonstrate maintained alignment and interval callus formation. He is seen one month later and there are no problems. He is now walking on the leg. X-rays demonstrate sufficient callus present for ex-fix removal, which is performed that week. He was to follow-up post external fixator removal, but the family has not returned for follow-up. He has been seen in the primary care clinic since removal of the external fixator without leg complaints or documentation of significant leg length discrepancy and is now almost 3 years out from injury.
DISCUSSION

While the AAOS clinical practice guideline for the treatment of pediatric diaphyseal femur fractures outlines current evidence-based treatment options, there remains a plea for additional scientific research in this area to improve the available recommendations. This case highlights a number of the management and treatment options for pediatric femur fractures.

First, higher energy injuries can result in additional bony and soft tissue injuries not initially noted in early presentation. ATLS recommends secondary and tertiary evaluations to prevent missing these injuries. It is important to communicate this with families and to be cognitive and vigilant that they may exist. Appropriate and timely communications with families and other treating services has the potential to improve time to diagnosis and treatment.
DISCUSSION

In this situation, the initial decision to treat the child with the femur fracture was based on the age less than 5 years. However, with the evolution of peritoneal signs and persistent abnormal vitals, the initial treatment plan needed to be modified to be able to have access to the abdomen and still have bony stabilization. In children, as with adults, external fixators can provide initial stabilization as well as definitive treatment.

Spica casting remains an option for treatment of isolated femur fractures in children less than 5. Shortening and angulation can be accepted, as there remains extensive remodeling potential in this age group. The precise extent of allowable shortening or deformity remains unanswered. Open plating and flexible nailing, although less commonly performed in this age group, also remain options to the treating surgeon if dictated by the clinical scenario and are within the armamentarium of that treating surgeon’s expertise and training.
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  - (Strong, Moderate, Limited, Consensus)
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- Access to full recommendation & rationale
- Links to references (PubMed)
Search across all CPG and AUC Via a Single Keyword Search
References provided for each recommendation


Links to PubMed
Appropriate Use Criteria Tool

Indication Profile

Symptom Severity
- Mild Symptoms
- Moderate Symptoms
- Severe Symptoms

American Society of Anesthesiologist's (ASA) Status (co-morbidities)
- ASA 1
- ASA 2
- ASA 3

Identifiable Factors that Negatively Affect Healing
- Present
- Absent

Identifiable Factors that Negatively Affect Outcome
- Present
- Absent

Tear Size and Retraction: Southern California Orthopaedic Institute (SCOI) Classification (Snyder Classification)
- C1: Small, complete tear
- C2: Moderate tear

Procedure Recommendations

Click Procedure of Interest to View Interactive Literature Reviewer

- Repair: 8
- Non-Operative: 8
- Partial Repair and/or Debridement: 4
- Reconstruct: 4
- Arthroplasty: 1

Print
PUBLISHED CLINICAL PRACTICE GUIDELINES

- Acute Compartment Syndrome
- Anesthesia and Analgesia in TJA (Endorsement)
- Anterior Cruciate Ligament Injuries
- Carpal Tunnel Syndrome
- Distal Radius Fractures
- Glenohumeral Joint Osteoarthritis
- Hip Fractures in the Elderly
- Limb Salvage or Early Amputation
- Osteoarthritis of the Hip
- Osteoarthritis of the Knee (Arthroplasty)
- Osteoarthritis of the Knee (Non-Arthroplasty)
- Osteochondritis Dissecans
- Pediatric Developmental Dysplasia of the Hip in infants up to Six Months
- Pediatric Diaphyseal Femur Fractures
- Pediatric Supracondylar Humerus Fractures
- Periprosthetic Joint Infections
- Prevention of Orthopaedic Implant Infections in Patients Undergoing Dental Procedures
- Psychosocial Factors Influencing Trauma Recovery
- Rotator Cuff Injuries
- Surgical Site Infections
- VTE Disease in Patients Undergoing Elective Hip & Knee Arthroplasty
- Tranexamic Acid in Total Joint Arthroplasty (Endorsement)
- Treatment of Metastatic Carcinoma of the Femur (Endorsement)
- Use of Imaging Prior to Referral to a Musculoskeletal Oncologist (Endorsement)

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