Intramedullary Distraction Devices for Lower-Limb Lengthening: Clinical Effectiveness and Guidelines
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Acknowledgments:

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About CADTH: CADTH is an independent, not-for-profit organization responsible for providing Canada’s health care decision-makers with objective evidence to help make informed decisions about the optimal use of drugs, medical devices, diagnostics, and procedures in our health care system.
Research Questions

1. What is the clinical effectiveness of intramedullary distraction devices for patients requiring lower-limb lengthening?

2. What are the evidence-based guidelines regarding the use of intramedullary distraction devices for lower-limb lengthening?

Key Findings

One randomized controlled trial and twenty-two non-randomized studies were identified regarding the clinical benefit and safety of intramedullary distraction devices for lower-limb lengthening in adults.

Methods

A limited literature search was conducted on key resources including MEDLINE, The Cochrane Library, University of York Centre for Reviews and Dissemination (CRD) databases, Canadian and major international health technology agencies, as well as a focused Internet search. Methodological filters were applied to limit retrieval to health technology assessments, systematic reviews, meta-analyses, randomized controlled trials, non-randomized studies, and guidelines. Where possible, retrieval was limited to the human population. The search was also limited to English language documents published between January 01, 2012 and April 11, 2017 year. Internet links were provided, where available.

Selection Criteria

One reviewer screened citations and selected studies based on the inclusion criteria presented in Table 1.

Table 1: Selection Criteria

<table>
<thead>
<tr>
<th>Population</th>
<th>Adults (≥ 18 years) with length deficiency or deformity in one or both legs who require lengthening procedures</th>
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<tbody>
<tr>
<td>Intervention</td>
<td>Intramedullary distraction (or distraction osteogenesis) devices for lower-limb (i.e., tibia and femur) lengthening  (e.g., PRECICE limb lengthening system, intramedullary skeletal kinetic distractor, Phenix M2 bone lengthening nail, Fitbone)</td>
</tr>
<tr>
<td>Comparator</td>
<td>Q1: External fixation devices (e.g., Taylor Spatial Frame); Physical therapy; No intervention</td>
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<td></td>
<td>Q2: No comparator</td>
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<tr>
<td>Outcomes</td>
<td>Q1: Clinical benefit (e.g., rate of lengthening, overall lengthening, range of motion, gait, pain, functional ability); Harms (e.g., femoral fissure, spontaneous bony section, transient palsy, pain, fracture, mechanical failure, poor bone formation, lengthening at an inappropriate rate, fat embolization, deep vein thrombosis, respiratory distress syndrome, equinus ankle deformity)</td>
</tr>
<tr>
<td></td>
<td>Q2: Evidence-based guideline recommendation regarding appropriate indications and use of intramedullary distraction for lower-limb lengthening</td>
</tr>
<tr>
<td>Study Designs</td>
<td>Health technology assessments, systematic reviews, meta-analyses, randomized controlled trials, non-randomized studies, evidence-based guidelines</td>
</tr>
</tbody>
</table>
Results

Rapid Response reports are organized so that the higher quality evidence is presented first. Therefore, health technology assessment reports, systematic reviews, and meta-analyses are presented first. These are followed by randomized controlled trials, non-randomized studies, and evidence-based guidelines.

One randomized controlled trial and twenty-two non-randomized studies were identified regarding the clinical benefit and safety of intramedullary distraction devices for lower-limb lengthening in adults. No relevant health technology assessments, systematic reviews, meta-analyses, or evidence based guidelines were identified.

Additional references of potential interest are provided in the appendix.

Health Technology Assessments

No literature identified.

Systematic Reviews and Meta-analyses

No literature identified.

Randomized Controlled Trials


Non-Randomized Studies

Active Comparators


No Comparator


Guidelines and Recommendations
No literature identified.
Appendix — Further Information

Previous CADTH Reports


   Available from: https://www.cadth.ca/limb-lengthening-achondroplasia

Non-Randomized Studies

Alternate Comparator


   Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4062798/


   PubMed: PM22143986

Case Series


   PubMed: PM25081825.


   PubMed: PM22009413.

Qualitative Studies


   PubMed: PM26688988

Review Articles

