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CADTH RAPID RESPONSE REPORT: REFERENCE LIST

ApiFix Scoliosis System for the Management of Adolescent Idiopathic Scoliosis: Clinical Effectiveness and Guidelines

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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.

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Questions or requests for information about this report can be directed to **requests@cadth.ca**

Research Questions

1. What is the clinical effectiveness of the ApiFix scoliosis system for the treatment of adolescent idiopathic scoliosis?
2. What are the evidence-based guidelines regarding the appropriate use of the ApiFix scoliosis system for the treatment of adolescent idiopathic scoliosis?

Key Findings

No relevant clinical evidence was identified regarding the ApiFix scoliosis system for the treatment of adolescent idiopathic scoliosis. In addition, no relevant evidence-based guidelines were identified.

Methods

A limited literature search was conducted on key resources including Medline via OVID, 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. No filters were applied to limit the retrieval by study type. Where possible, retrieval was limited to the human population. The search was also limited to English language documents published between January 1, 2014 and February 12, 2019. 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

Population	Children and Adolescents with Adolescent Idiopathic Scoliosis
Intervention	ApiFix scoliosis system
Comparators	Q1: Scoliosis instrumentation and spinal fusion; Vertebral body tethering Before and after ApiFix Q2: No comparator
Outcomes	Q1: Clinical effectiveness (e.g., amount of correction achieved, whether correction is maintained, halting clinical progression of scoliosis, need for further surgery); safety (e.g., of the device and of the surgical procedure; both short and long term) Q2: Guidelines for patient selection (e.g. age for use, degree of curvature), guidelines for the use of the device/system
Study Designs	Health technology assessments, systematic reviews, meta-analyses, randomized controlled trials, non-randomized studies, evidence-based guidelines

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.

No relevant health technology assessments, systematic reviews, meta-analyses, randomized controlled trials, non-randomized studies, or evidence-based guidelines were identified regarding the ApiFix scoliosis system for the treatment of adolescent idiopathic scoliosis.

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

No literature identified.

Non-Randomized Studies

No literature identified.

Guidelines and Recommendations

No literature identified.

Appendix — Further Information

Non-Randomized Studies

Alternative Population – Alternative Scoliosis Etiologies

1. Rosenfeld S, Schlechter J, Smith B. Achievement of guided growth in children with low-tone neuromuscular early-onset scoliosis using a segmental sublaminar instrumentation technique. *Spine Deform*. 2018;6(5):607-613. PubMed: PM30122398

2. Jayaswal A, Kandwal P, Goswami A, et al. Early onset scoliosis with intraspinal anomalies: management with growing rod. *Eur Spine J*. 2016;25(10):3301-3307. PubMed: PM27072552

Intervention Insufficiently Described

3. Wall EJ, Reynolds JE, Jain VV, et al. Spine growth modulation in early adolescent idiopathic scoliosis: two-year results of prospective US FDA IDE pilot clinical safety study of titanium clip-screw implant. *Spine Deform*. 2017;5(5):314-324. PubMed: PM28882349

Clinical Trials

4. Apifix. NCT02200302: Safety and effectiveness evaluation of the minimal invasive deformity correction (MID-C) system in adolescent idiopathic scoliosis (AIS) (MID-C). *ClinicalTrials.gov*. Bethesda (MD): U.S. National Library of Medicine; 2017: https://clinicaltrials.gov/ct2/show/NCT02200302. Accessed 2019 Feb 15.

5. Apifix. NCT03519321: Minimal invasive deformity correction (MID-C) system for early onset scoliosis. *ClinicalTrials.gov*. Bethesda (MD): U.S. National Library of Medicine; 2018: https://clinicaltrials.gov/ct2/show/NCT03519321. Accessed 2019 Feb 15.

6. Apifix. NCT03071471: Feasibility evaluation study of the MID-C device (MID-C). *ClinicalTrials.gov*. Bethesda (MD): U.S. National Library of Medicine; 2017. https://clinicaltrials.gov/ct2/show/NCT03071471. Accessed 2019 Feb 15.

7. Apifix. NCT03071445: Feasibility study of MID-C for AIS (MID-C). *ClinicalTrials.gov*. Bethesda (MD): U.S. National Library of Medicine; 2017. https://clinicaltrials.gov/ct2/show/NCT03071445?term=NCT03071445&rank=1. Accessed 2019 Feb 15.

Review Articles

8. Floman Y, Burnei G, Gavriliu S, et al. Surgical management of moderate adolescent idiopathic scoliosis with ApiFix: a short peri- apical fixation followed by post-operative curve reduction with exercises. *Scoliosis*. 2015;10:4. PubMed: PM25685175

9. Odent T, Ilharreborde B, Miladi L, et al. Fusionless surgery in early-onset scoliosis. *Orthop Traumatol Surg Res*. 2015;101(6 Suppl):S281-288. PubMed: PM26386889