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# Subtalar Joint Arthroereisis

# Key Messages

#### What Is the Issue?

- The subtalar joint enables the inversion and eversion of the feet. Excessive movement of the subtalar joint can lead to painful foot conditions that may require surgical treatment in severe cases.
- Subtalar joint arthroereisis involves the insertion of an implant that limits excessive movement of the subtalar joint. It is considered a minimally invasive surgical procedure with a relatively fast healing period compared to alternative surgical procedures.
- While this procedure is commonly used for children with pes planus, it is becoming a more common treatment for adults with foot conditions. There is uncertainty as to whether subtalar joint arthroereisis can be effective for adults.

#### What Did We Do?

- We conducted a rapid review to identify, summarize, and critically appraise evidence regarding the clinical effectiveness and cost-effectiveness of subtalar joint arthroereisis for adults with pes planus (i.e., flatfoot, plantar fasciitis, and other foot conditions). Additionally, we aimed to identify, summarize, and critically appraise evidence-based guidelines regarding the use of subtalar joint arthroereisis for adults.
- An information specialist conducted a customized literature search, balancing comprehensiveness with relevancy, of multiple sources and grey literature on November 20, 2024.

#### What Did We Find?

- We identified 8 relevant studies (1 systematic review and 7 nonrandomized studies) that evaluated the clinical effectiveness of subtalar joint arthroereisis for adults with pes planus. Compared to baseline, the literature suggests that subtalar joint arthroereisis improves key clinical outcomes, such as overall foot and ankle condition, health-related quality of life, and pain relief (1 systematic review and 4 nonrandomized studies). One nonrandomized study found mixed results when comparing subtalar joint arthroereisis to lateral column lengthening for adults living with stage IIb adult-acquired flatfoot deformity.
- We also found 2 relevant nonrandomized studies regarding the clinical effectiveness of subtalar joint arthroereisis for adults with other foot conditions (i.e., reducible talotarsal joint dislocation and partial talotarsal joint instability). Compared to baseline, the literature suggests that subtalar joint arthroereisis improves the function of the foot and ankle,

# Key Messages

pain relief, and ability to perform activities of daily living in the long term for adults with partial talotarsal joint issues (1 nonrandomized study).

- For the studies in this report, sinus tarsi pain was the most reported adverse event and the cause of implant removal. Other adverse events included implant revision, surgical infection, stress fractures, insufficient deformity correction, reoccurrence of foot deformity, wound healing issues, and muscle and tendon complications (10 studies).
- Overall, there is uncertainty in the identified evidence due to risk of bias and methodological limitations.
- We did not identify relevant studies regarding the clinical effectiveness of subtalar joint arthroereisis for adults with plantar fasciitis. We also did not find any relevant cost-effectiveness studies or evidence-based guidelines regarding the use of subtalar joint arthroereisis for adults.

#### What Does This Mean?

- These results should be interpreted with caution. Most studies included in this report were of low-quality and limited to comparing before-andafter outcomes. Additionally, most studies did not account for the impact of confounding variables (e.g., obesity) and heterogeneity within and between treatment arms (e.g., implant sizes, adjunct procedures, and implant type). Comparative evidence from robust studies is needed before definitive conclusions regarding the clinical effectiveness of subtalar joint arthroereisis can be made.
- Future studies could consider evaluating the cost-effectiveness of subtalar joint arthroereisis with considerations of the implications of implant removals, as well as the clinical effectiveness of subtalar joint arthroereisis for individuals with plantar fasciitis. Given that subtalar joint arthroereisis is commonly provided in combination with other procedures, future research may also consider evaluating best practices with adjunctive treatments for adults with foot conditions.

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# **Abbreviations**

AOFAS	American Orthopaedic Foot & Ankle Society
BMI	body mass index
FADI	Foot and Ankle Disability Index
FAOS	Foot and Ankle Outcome Score
SF-36	Short Form (36) Health Survey
VAS	visual analogue scale
VAS-FA	visual analogue scale – foot and ankle

### **Research Questions**

- 1. What is the clinical effectiveness of subtalar joint arthroereisis for adults with plantar fasciitis?
- 2. What is the clinical effectiveness of subtalar joint arthroereisis for adults with pes planus?
- 3. What is the clinical effectiveness of subtalar joint arthroereisis for adults with other foot conditions?
- 4. What is the cost-effectiveness of subtalar joint arthroereisis for adults with plantar fasciitis?
- 5. What is the cost-effectiveness of subtalar joint arthroereisis for adults with pes planus?
- 6. What is the cost-effectiveness of subtalar joint arthroereisis for adults with other foot conditions?
- 7. What are the evidence-based guidelines regarding the use of subtalar joint arthroereisis for adults?

### **Context and Policy Issues**

#### What Is the Subtalar Joint?

Our feet use a complex mechanical system formed of many bones, joints, muscles, ligaments, and tendons that work together to support all steps of the human gait.<sup>1</sup> The foot can be divided into 3 regions: the hindfoot, midfoot, and forefoot.<sup>1</sup> In the hindfoot, the subtalar joint articulates the talus bone and calcaneus, and enables the inversion and eversion of the feet.<sup>1,2</sup>

Inversion, or pronation, refers to when feet roll inwards during motion.<sup>3,4</sup> Eversion, or supination, refers to when the foot rolls outward.<sup>3</sup> Abnormal eversion and inversion increases the risk of injury and can lead to painful conditions, such as pes planus and plantar fasciitis.<sup>3</sup>

#### What Is Pes Planus?

Pes planus involves the loss or absence of the longitudinal arch, which can present in combination with other foot deformities. Individuals with pes planus can be asymptomatic while others may experience pain along their foot.<sup>5,6</sup> Other symptoms include difficulties in footwear fitting, as well as impaired gait and function.<sup>5,7</sup> Pes planus can be congenital or acquired. In the first few years of life, pes planus is considered physiologically normal unless it is symptomatic.<sup>5</sup> Typically, pes planus in childhood spontaneously corrects itself, but in some cases, it may persist through or be acquired during adulthood.<sup>5</sup> Risk factors of acquired pes planus include age, obesity, diabetes, hypertension, and trauma.<sup>8,9</sup>

The severity of pes planus can be categorized into 4 stages: I, II (i.e., type a and type b), III, and IV.<sup>10</sup> Stage I, the least severe stage, indicates loss of the longitudinal arch and is typically managed using conservative treatment.<sup>10,11</sup> The additional stages increase in pain severity and foot deformity, moving beyond the loss of the longitudinal arch.<sup>10,11</sup> Stage II indicates hindfoot deformity with (type b) or without (type a) forefoot abduction and loss of the longitudinal arch.<sup>10,11</sup> Stage III indicates a hindfoot deformity, rigid forefoot abduction, and loss of the longitudinal arch.<sup>10,11</sup> Stage IV indicates rigid hindfoot valgus, rigid forefoot abduction, deltoid ligament compromise, and loss of the longitudinal arch.<sup>10,11</sup> A flexible deformity means the

absence of the deformity when there is no weight on the foot, whereas a rigid deformity indicates that the deformity is present regardless of weight on the foot.<sup>12</sup>

Individuals with symptomatic pes planus will typically start treatment with conservative strategies, such as activity modifications, stretching, and muscle strengthening exercises as well as supportive footwear, orthotics, and over-the-counter pain medications.<sup>5,6,13,14</sup> When conservative treatment is ineffective in relieving pain, surgical treatments can be considered, such as lateral column lengthening or Evan's osteotomy (which involves inserting a bone graft),<sup>15</sup> arthrodesis, and other types of osteotomies.<sup>5,6,11</sup>

#### What Is Plantar Fasciitis?

Individuals with plantar fasciitis experience inferior heel pain and local point tenderness near the plantar fascia.<sup>9,16</sup> The plantar fascia is a band of tissues that connects your heel bone to the base of your toes. It also supports the longitudinal arch of the foot.<sup>9,16</sup> It is believed that the etiology of plantar fasciitis is multifactorial.<sup>9</sup> Risk factors may include weight and obesity, diabetes, physical trauma, pes planus, and reduced ankle dorsiflexion.<sup>9</sup>

Individuals with plantar fasciitis most often experience heel pain when initiating walking (e.g., in the morning or after long periods of rest).<sup>9,16</sup> In severe cases, individuals may experience pain with any weight-bearing movement.<sup>16</sup> Treatments for individuals with plantar fasciitis include avoiding potential triggers, cushioned footwear, and addressing underlying conditions (e.g., symptomatic pes planus).<sup>9</sup> For more severe cases, more intensive treatments, such as glucocorticoid injections and surgical options, are available.<sup>9</sup>

#### What Is Subtalar Joint Arthroereisis?

Subtalar joint arthroereisis involves the surgical insertion of an implant in the subtalar joint to restore and maintain the physiologic alignment between the talus and calcaneus, while aiming to minimize pain and excessive pronation.<sup>4-6</sup> The procedure is reversible, considered minimally invasive, has a relatively fast healing period, and is seen to have lower risks and complications compared to more invasive surgical procedures, such as arthrodesis and osteotomies.<sup>4</sup> The procedure can be a standalone treatment or combined with other treatments.<sup>5</sup> There are 3 different types of implants used for subtalar joint arthroereisis, including axis-altering prosthesis, impact-blocking devices, and self-locking implants.<sup>5</sup> While they differ in design, all 3 types of implants are designed to limit subtalar joint movement.<sup>5</sup>

#### Why Is It Important to Do This Review?

The literature suggests that children and adolescents with pes planus benefit from subtalar joint arthroereisis, given their flexible skeletal structure and soft tissues that have yet to reach maturity.<sup>13,17</sup> This surgical procedure is becoming a more common treatment for adults, especially for those with pes planus.<sup>10</sup> However, there is uncertainty about the benefits and harms, cost-effectiveness, and best practices of subtalar joint arthroereisis in adults with foot conditions.

#### **Objectives**

The purpose of this rapid review is to summarize and critically appraise the evidence regarding the clinical effectiveness and cost-effectiveness of subtalar joint arthroereisis for adults with foot conditions, such as pes planus and plantar fasciitis. We also aimed to summarize and critically appraise evidence-based guidelines regarding the use subtalar joint arthroereisis in adults.

### **Methods**

An information specialist conducted a customized literature search, balancing comprehensiveness with relevancy, of multiple sources and grey literature on November 20, 2024. One reviewer screened citations and selected studies based on the inclusion criteria presented in <u>Table 1</u>, and critically appraised included publications using established critical appraisal tools.

<u>Appendix 1</u> presents a detailed description of methods and selection criteria for included studies.

Criteria	Description
Population	Adults with plantar fasciitis, pes planus, or other foot conditions
Intervention	Subtalar joint arthroereisis (may also be referred to as extraosseous talotarsal stabilization)
Comparator	Q1 to Q6: Standard of care, any treatment, no treatment Q7: Not applicable
Outcomes	Q1 to Q3: Clinical benefits (e.g., physical activity level, pain, function) and harms (e.g., adverse events) Q4 to Q6: Cost-effectiveness (e.g., cost per quality-adjusted life-year gained) Q7: Recommendations regarding best practices for subtalar joint arthroereisis
Study designs	Systematic reviews, randomized controlled trials, nonrandomized studies, economic evaluations, evidence-based guidelines
Publication date	Since January 1, 2014

#### Table 1: Selection Criteria

### Summary of Evidence

#### **Quantity of Research Available**

This rapid review includes a total of 10 relevant articles,<sup>10,11,13,18-24</sup> specifically 1 systematic review<sup>10</sup> and 9 nonrandomized studies.<sup>11,13,18-24</sup> Of the 10 studies, 8 articles addressed question 2,<sup>10,11,13,19,20,22-24</sup> while 2 articles addressed question 3.<sup>18,21</sup>

<u>Appendix 1</u> presents the PRISMA<sup>25</sup> flow chart of the study selection. Additional references of potential interest are provided in <u>Appendix 5</u>.

#### **Summary of Study Characteristics**

The summary of study characteristics is organized by research question. We did not identify any relevant articles for questions 1, 4, 5, 6, and 7; therefore, no summaries can be provided for these research questions. Additional details regarding the characteristics of included publications are provided in <u>Appendix 2</u>.

# Included Studies for Question 2: Clinical Effectiveness of Subtalar Joint Arthroereisis for Pes Planus

We identified a total of 8 relevant articles to question 2, specifically 1 systematic review<sup>10</sup> and 7 nonrandomized studies.<sup>11,13,19,20,22-24</sup>

#### Systematic Review

The systematic review by Baryeh and colleagues<sup>10</sup> was conducted in the UK and published in 2022. The review authors limited the eligibility criteria to nonrandomized studies, specifically cohorts and case series, that focused on adults with adult-acquired flatfoot.<sup>10</sup> The review had no search time frame limitations for their search strategy.<sup>10</sup> Relevant to this review, they investigated clinical outcomes before-and-after subtalar joint arthroereisis, including both isolated and adjunct procedures.<sup>10</sup> Baryeh and colleagues<sup>10</sup> reported on the following clinical outcomes:

- adverse events
- general health and quality of life using the Short Form (36) Health Survey (SF-36)
- overall foot and ankle condition using the American Orthopaedic Foot and Ankle Society (AOFAS) score and the Foot and Ankle Outcome Score (FAOS).

#### Nonrandomized Studies

Of the 7 nonrandomized studies, 2 studies evaluated the clinical effectiveness of subtalar joint arthroereisis and lateral column lengthening for adults with stage IIb adult flatfoot deformity.<sup>11,20</sup> Both studies measured clinical outcomes of subtalar joint arthroereisis before and after the procedure, specifically, adverse events, general health and quality of life (i.e., SF-36 score), overall foot and ankle condition (i.e., AOFAS score), and pain (visual analogue scale [VAS] score).<sup>11,20</sup> Additionally, both studies were conducted in Singapore.<sup>11,20</sup>

Silva et al. (2021)<sup>11</sup> conducted a retrospective cohort study. They included 72 adults (79 feet) who underwent treatment at a single centre between 2007 and 2013.<sup>11</sup> The researchers measured outcomes at 6- and 24-months postprocedure.<sup>11</sup> Subtalar joint arthroereisis was an adjunct procedure to Achilles tendon lengthening or gastrocnemius release (dependent on their clinical needs).<sup>11</sup> Participants who underwent a lateral column lengthening procedure also underwent a medializing calcaneal osteotomy, distraction osteotomy, flexor digitorum longus transfer, and either Achilles tendon lengthening or gastrocnemius release (dependent to AOFAS score, SF-36, and VAS, Silva and colleagues<sup>11</sup> compared changes in body mass index (BMI) within and between study groups at 24 months postprocedure. For this study, the mean age of individuals who underwent a subtalar joint arthroereisis was 46.3 years old, which did not significantly differ from those in the comparator group.<sup>11</sup> Further, individuals who underwent a subtalar joint arthroereisis procedure did not differ in sex and race or ethnicity to individuals who underwent a

Summary of Evidence

lateral column lengthening procedure. However, the lateral column lengthening had a statistically significantly higher BMI at baseline compared to the subtalar joint arthroereisis group.<sup>11</sup>

The study by Fang Junxian and colleagues<sup>20</sup> conducted a retrospective study that was published in 2015. They included 22 adults who underwent unilateral surgeries from a single centre.<sup>20</sup> All study participants received the same adjunctive procedures regardless of whether they underwent subtalar joint arthroereisis or lateral column lengthening (i.e., gastrocnemius recession, tibialis posterior insertion site debridement, and a calcaneal osteotomy).<sup>20</sup> Fang Junxian and colleagues<sup>20</sup> compared clinical outcomes at baseline and at follow-up at a minimum of 12 months postprocedure. For this study, the mean age of individuals who underwent a subtalar joint arthroereisis was 52.7 years old.<sup>20</sup> The study groups were comparable in age and sex.<sup>20</sup> While the study compared before-and-after outcomes for each treatment arm, the researchers did not conduct any statistical tests to compare the before-and-after scores between subtalar joint arthroereisis and lateral column lengthening.<sup>20</sup>

The remaining 5 nonrandomized studies relevant to question 2 compared the clinical effectiveness of subtalar joint arthroereisis from baseline.<sup>13,19,20,22-24</sup> Of which, 3 studies<sup>13,19,24</sup> measured adverse events postprocedure as clinical outcomes relevant to this review. Fu et al. (2024)<sup>13</sup> conducted their study in a hospital in Shanghai, and analyzed data of individuals who did not respond to 6 months of conservative treatment with no age limits.<sup>13</sup> Of 732 study participants, 223 were adults (i.e., the relevant population for this report).<sup>13</sup> Most adults (92.4%) in this study underwent an adjunct subtalar joint arthroereisis.<sup>13</sup> Saxena and colleagues<sup>24</sup> conducted a prospective study on 41 adults with symptomatic flexible pes planus in Poland.<sup>24</sup> The mean age of the study population was 53.3 years.<sup>24</sup> They measured the adverse events, specifically implant removals.<sup>24</sup> The study population had a mean follow-up of 6.5 years.<sup>24</sup> Bernasconi et al. (2022) conducted a single-centre, retrospective study in the UK.<sup>19</sup> They analyzed data from 21 adults (22 feet) with stage IIb adult-acquired flexible flatfoot deformity. For inclusion, adults must have follow-up data regarding adverse events at least 6 months postprocedure.<sup>19</sup> In addition to subtalar joint arthroereisis, study participants underwent medializing calcaneal osteotomy, flexor digitorum longus transfer, and spring ligament repair with or without cotton osteotomy.<sup>19</sup> The mean age of adults included in the study was 55.2 years old.<sup>19</sup>

Lewis et al. (2024)<sup>22</sup> and Ozan et al. (2015)<sup>23</sup> evaluated the impact of subtalar joint arthroereisis using a single centre, before-and-after study design. Lewis and colleagues<sup>22</sup> conducted a retrospective study involving 187 adults (212 feet) with Stage I pes planus who did not respond to 6 months of conservative treatment.<sup>22</sup> The mean age of study participants was 59.7 years, and the mean follow-up was 2.5 years.<sup>22</sup> The researchers compared postprocedure results from baseline, specifically foot and ankle condition using FAOS score and Foot and Ankle Disability Index (FADI), and quality of life using the EQ-5D-5L.<sup>22</sup> Lewis and colleagues<sup>22</sup> also measured adverse events (i.e., implant removal rate).<sup>22</sup> The study by Ozan and colleagues<sup>23</sup> compared the before-and-after outcomes of isolated subtalar joint arthroereisis on 16 adults (26 feet) with symptomatic flexible pes planus, specifically foot and ankle condition (i.e., AOFAS score) and pain (i.e., VAS score). The mean age was 24.5 years, and the mean follow-up is 15.1 months.<sup>23</sup>

# Included Studies for Question 3: Clinical Effectiveness of Subtalar Joint Arthroereisis for Other Foot Conditions

#### **Nonrandomized Studies**

We identified 2 nonrandomized studies published in 2023 relevant to question 3.18,21

Kolodziej and colleagues<sup>21</sup> conducted a single-centre, prospective, before-and-after study to evaluate the clinical effectiveness of extraosseous talotarsal stabilization (with the HyProCure implant) for adults with partial talotarsal joint instability. They included 41 adults (62 feet) who received the HyProCure implant from a surgical department in Poland between 2012 to 2015.<sup>21</sup> The mean age of participants was 46.4 years.<sup>21</sup> They measured the impact of extraosseous talotarsal stabilization on activity (i.e., the UCLA activity score, symptom-related activity scale score), function (i.e., Lower Extremity Functional Scale score), ability to partake in sports and exercise (i.e., sports frequency score, number of physical activity, and time on physical activity), and pain (i.e., VAS). The mean follow-up for study participants was 8.6 years.<sup>21</sup>

Agnew and colleagues<sup>18</sup> conducted a multicentre, retrospective, before-and-after study in the US.<sup>18</sup> Relevant to this review, they analyzed adverse event data (i.e., implant revision and implant removal rates) from 67 individuals who had subtalar joint arthroereisis, of which 53 (79.1%) were adults, with symptomatic talotarsal joint dislocation.<sup>18</sup> These adults received a standalone type II extraosseous talotarsal stabilization implant (HyProCure).<sup>18</sup> The median age is 41 years (ranging from 20 to 74 years). The mean follow-up was 7 years, 8 months, and 19 days.<sup>18</sup>

#### **Summary of Critical Appraisal**

Critical appraisal summaries are organized by research questions followed by study design. Additional details regarding the strengths and limitations of included publications are provided in <u>Appendix 3</u>.

#### **Clinical Effectiveness Literature on Adults With Pes Planus (Question 2)**

#### Systematic Review

Overall, the systematic review by Baryeh et al.<sup>10</sup> lacks rigour and is at a high risk of selection bias. The review authors did not describe established methods before its conduct or rationale for limiting their eligibility to case series and cohort studies. While Baryeh and colleagues<sup>10</sup> conducted a risk of bias assessment, they did not discuss or address the implications of their evidence assessment findings in their results and discussion. The review authors assessed some primary studies in their review as "some risk of bias" and "high risk of bias" in the areas of selection bias, performance bias, attrition bias, and detection bias of their assessment tool.<sup>10</sup> The findings could be misleading without a clear explanation of how they should be interpreted.

Moreover, the review authors limited inclusion to before-and-after studies.<sup>10</sup> Given the nature of before-andafter study designs, individual studies do not consider confounding variables, which may have implications for their results. Baryeh and colleagues<sup>10</sup> reported averages of relevant outcomes across included studies without performing a meta-analysis. Thus, these averages did not account for heterogeneity and effect sizes. Additionally, Baryeh and colleagues<sup>10</sup> did not conduct any tests for publication bias, and they did not state an intent to investigate sources of funding for included studies. It is unclear how confounding variables, bias, and funding may have affected the findings of their review.

#### **Nonrandomized Studies**

For question 2, all relevant nonrandomized studies clearly described the study objective and the main outcomes of interest.<sup>11,13,19,20,22-24</sup> Additionally, 5 studies detailed their inclusion and exclusion criteria,<sup>11,13,19,22,24</sup> and 2 studies did not.<sup>20,23</sup> Saxena and colleagues<sup>24</sup> did not describe the surgical process, unlike the other nonrandomized studies.

The included nonrandomized studies were mostly limited to before-and-after comparisons without comparative evidence against an alternative treatment.<sup>19,20,22-24</sup> Considering the nature of the included nonrandomized studies, this study design is at a greater risk of threats to internal validity, whereas a control group would have limited such threats. In addition, there are further internal validity concerns given that the investigators did not report whether they concealed treatment to researchers or study participants.<sup>11,13,19,20,22-24</sup> There was a minimal consideration of confounding variables and considerable heterogeneity across the studies and treatment arms within these studies.<sup>11,13,19,20,22-24</sup> For example, most studies differed in adjunct procedures, implant types, and implant sizes within study arms.<sup>11,13,19,20,22,24</sup> In addition, some studies included both isolated and adjunct procedures under the same treatment group.<sup>13,24</sup>

It appears that all nonrandomized studies used appropriate statistical methods and outcome measures.<sup>11,13,19,20,22-24</sup> However, the Lewis et al. study<sup>22</sup> used multiple outcome measures to assess foot condition, specifically pain and activity levels.<sup>22</sup> Their statistical analysis did not adjust for multiplicity,<sup>22</sup> and it increases the likelihood of favourable outcomes. Additionally, Lewis and colleagues<sup>22</sup> conducted unplanned comparative analysis to evaluate the impact of age and operative FAOS, FADI, and EQ-5D-5L scores on implant removal.

All nonrandomized studies for question 2 provided little to no description of individuals lost to follow-up or those excluded.<sup>11,13,19,20,22-24</sup> It is unclear how these individuals may have impacted their findings. The studies conducted by Silva et al.<sup>11</sup> and Bernasconi et al.<sup>19</sup> were adequately powered. The other nonrandomized studies that conducted statistical testing for outcome measures relevant for this report did not report whether they were adequately powered.<sup>13,20,22-24</sup>

Two studies measured the impact of subtalar joint arthroereisis and lateral column lengthening over the time intended for comparison.<sup>11,20</sup> The study by Fang Junxian et al.<sup>20</sup> did not use statistical methods to compare these 2 treatments. It is unclear if the subtalar joint arthroereisis and lateral column lengthening were comparable at baseline or if there was a clinically meaningful difference postprocedure. The same study provided minimal details about how they recruited the study population.<sup>20</sup> Hence, it is unclear how selection bias may have impacted their findings. Additionally, the study by Silva et al.<sup>11</sup> did not report their funding source. It is unclear if funding may have influenced their findings.

None of the nonrandomized studies for question 2 were conducted in Canada. Some studies provided minimal descriptions of their recruitment process.<sup>20,23,24</sup> For these studies, it is unclear as to whether their

study population is representative of their source population. It is also unclear how generalizable these studies are to other health settings, including those in Canada.

#### **Clinical Effectiveness Literature on Adults With Other Foot Conditions (Question 3)**

#### Nonrandomized Studies

The nonrandomized studies clearly described the researchers' hypothesis, outcomes of interest, the intervention of interest, and main findings.<sup>18,21</sup> When applicable, the researchers of both studies provided estimated of random variability and P values.<sup>18,21</sup> Both studies reported no conflicts of interest for authors and no funding sources that may have introduced bias and affected the reporting of study findings.<sup>18,21</sup>

The included nonrandomized studies were limited to before-and-after comparisons without comparative evidence against an alternative treatment.<sup>18,21</sup> Additionally, individuals involved in the study and participants had knowledge of the intervention. Both studies lack consideration of confounding variables that may have affected the findings of the study.<sup>18,21</sup> For both studies, the researchers did not describe individuals excluded from the study due to lack of follow-up data.<sup>18,21</sup> It is also unclear how excluded individuals differ from study participants, and how they may have affected the results. Hence, it is unclear to what extent the results can be attributed to the subtalar joint arthroereisis alone.

The study by Kolodziej and colleagues<sup>25</sup> used a variety of outcome measures to evaluate the impact of the intervention on function and activities of daily living. By using multiple outcome measures, the researchers may have increased the risk of finding a significant result.

Both studies were conducted outside of Canada.<sup>18,21</sup> It is unclear as to how their treatment facilities differ from health settings in Canada, and how applicable these findings are to adults living in Canada with foot conditions.

#### **Summary of Findings**

We summarized the results of relevant studies regarding the clinical effectiveness of subtalar joint arthroereisis for pes planus (question 2) and other foot conditions (question 3). No relevant evidence regarding the subtalar joint arthroereisis for plantar fasciitis was identified; therefore, no summary can be provided for question 1. Additionally, we did not find relevant economic evaluations or evidence-based guidelines; therefore, no summary of findings can be provided for questions 4 to 7.

<u>Appendix 4</u> presents additional details regarding the main study findings.

#### Clinical Effectiveness of Subtalar Arthroereisis for Pes Planus (Before-and-After Outcomes)

#### Foot and Ankle Condition

The systematic review by Baryeh and colleagues<sup>10</sup> found that subtalar joint arthroereisis improved AOFAS scores for adults with pes planus compared to baseline (P value not reported). These findings align with the Fang Junxian et al.<sup>20</sup> and Ozan et al.<sup>23</sup> studies, which reported a statistically significant improvement in AOFAS scores from baseline.

The systematic review by Baryeh and colleagues<sup>10</sup> also reported that subtalar joint arthroereisis significantly improved total FAOS scores for adults with pes planus compared to baseline.

#### Health-Related Quality of Life

The study by Lewis and colleagues<sup>22</sup> found a statistically significant improvement in EQ-5D-5L in adults who underwent a subtalar joint arthroereisis compared to baseline scores.

#### Pain

Compared to baseline, all studies that included the reporting of pain outcomes found a statistically significant decrease in pain due to pes planus after subtalar joint athroereisis.<sup>10,22,23</sup> However, some studies reported that subtalar joint arthroereisis caused pain postprocedure, including sinus tarsi pain and complex regional pain syndrome.<sup>10,13,19</sup> The prevalence of pain because of the procedure ranged from 0.6% to 57.1% of adults with pes planus.<sup>10,13,19</sup>

#### **Symptoms**

Lewis and colleagues also found an improvement of symptoms after subtalar joint arthroereisis for adults with pes plenus.<sup>22</sup> They measured and reported pain scores separately using a subcomponent of FAOS.<sup>22</sup>

#### Activities of Daily Living or Activity

The study by Lewis and colleagues found a statistically significant improvement in the ability to partake in activities for adults with pes planus after subtalar joint arthroereisis (as measured by a subcomponent of the FADI).<sup>22</sup> The same study found a statistically significant improvement in the ability to perform activities of daily living, as measured by a FAOS subcomponent.<sup>22</sup>

#### Adverse Events

#### Implant Removal and Revision

The prevalence of implant removals among adults with pes planus who underwent a subtalar joint arthroereisis varied across studies. It ranged from 7.6% to 48.1% of study participants.<sup>10,13,19,22-24</sup> Most studies reported sinus tarsi pain as the most common cause of implant removals for this population.<sup>10,13,19,22</sup> The study by Fu and colleagues reported that all individuals who had their implants removed experienced pain relief.<sup>13</sup>

#### Other Adverse Events and Complications

Studies reported adverse events and complications beyond pain and implant removals after subtalar joint arthroereisis for adults with pes planus. They reported the following complications:

- surgical infection (2 studies with rates ranging from 0.6% to 10% of study participants)<sup>10</sup>
- stress fracture (0.6% of feet from 1 systematic review)<sup>10</sup>
- insufficient foot correction (0.6% of feet from 1 systematic review)<sup>10</sup>
- recurrence of deformity (0.6% of feet from 1 systematic review and 3.8% of feet in a nonrandomized study)<sup>10</sup>
- Achilles tendon tension (0.85% of feet from 1 study)<sup>13</sup>

- peroneal spasm (0.85% of feet from 1 study)<sup>13</sup>
- wound healing issues (0.42% of cases from 1 study)<sup>13</sup>
- foreign body sensations (0.42% of cases from 2 study).<sup>13</sup>

# Clinical Effectiveness of Subtalar Joint Arthroereisis Versus Lateral Column Lengthening for Pes Planus

Of note, the Fang Junxian et al. study<sup>20</sup> does not use statistical methods to compare before-and-after scores between lateral column lengthening and subtalar joint arthroereisis (refer to <u>Table 7</u> for further study results).<sup>20</sup>

#### Foot and Ankle Condition

The study by Fang Junxian and colleagues<sup>20</sup> found subtalar joint arthroereisis and lateral column lengthening significantly improved the condition of the foot and ankle. Both procedures resulted in a statistically significant increase in AOFAS scores at follow-up compared to baseline.<sup>20</sup> Silva and colleagues<sup>11</sup> found that subtalar joint arthroereisis and lateral column lengthening increased AOFAS scores for the hindfoot and midfoot area at 6 and 24 months. Lateral column lengthening resulted in a statistically significant increase in AOFAS scores for the hindfoot area compared to subtalar joint arthroereisis at 24 months, which suggests that lateral column lengthening may result in greater sustained improvements in the hindfoot.<sup>11</sup> The authors did not find any significant differences between groups for AOFAS scores for all other comparisons (i.e., hindfoot at 6 or 24 months, midfoot at 6 months).

#### **General Health**

Fang Junxian and colleagues<sup>20</sup> found a statistically significant increase in the SF-36 general health subscale scores for subtalar joint arthroereisis and lateral column lengthening compared to baseline. These findings suggest that both procedures may improve overall health.<sup>20</sup>

#### Physical Health

Fang Junxian and colleagues<sup>20</sup> reported a statistically significant increase in physical function and role limitation (physical health) subscale scores of the SF-36 compared to baseline. Additionally, the study by Silva and colleagues<sup>11</sup> found an increase physical component summary of the SF-36 for subtalar joint arthroereisis and lateral column lengthening with no difference when comparing scores between treatments.<sup>11</sup> These results suggest that both procedures may improve physical health for people with stage IIb adult-acquired flatfoot.

#### Mental Health

Silva and colleagues<sup>11</sup> found an increase in SF-36 mental health component summary scores after subtalar joint arthroereisis and lateral column lengthening compared to baseline. However, there were no clinically meaningful differences between the treatments.<sup>11</sup> The study by Fang Junxian and colleagues<sup>20</sup> found a statistically significant increase in role limitation (emotional problems, subscale of SF-36) but no significant differences for emotional well-being (subscale of the SF-36) after subtalar joint arthroereisis compared to baseline.

#### **Social Function**

The study by Fang Junxian and colleagues<sup>20</sup> reported an increase in the SF-36's social functioning subscale scores after lateral column lengthening and subtalar joint arthroereisis compared to baseline. These findings suggest that both procedures can improve social function for people with stage IIb adult-acquired flatfoot.<sup>20</sup>

#### Energy

Fang Junxian and colleagues<sup>20</sup> reported a statistically significant increase in the SF-36 energy and fatigue subscale scores for subtalar joint arthroereisis and lateral column lengthening compared to baseline, which suggests both procedures can improve energy for people with stage IIb adult-acquired flatfoot.<sup>20</sup>

#### Pain

Fang Junxian and colleagues<sup>20</sup> found that, compared to baseline, both subtalar joint arthroereisis and lateral column lengthening significantly decreased pain caused by stage II adult-acquired flatfoot.<sup>20</sup> Lateral column lengthening and subtalar joint arthroereisis resulted in a statistically significant increase in SF-36 pain scores and a statistically significant decrease in VAS scores postprocedure compared to baseline.<sup>20</sup>

Silva and colleagues<sup>11</sup> found an improvement in VAS for midfoot and hindfoot pain, compared to baseline, in subtalar joint arthroereisis and lateral column lengthening groups at 6 and 24 months.<sup>11</sup> Compared to baseline, they found decreased VAS scores for the midfoot and hindfoot.<sup>11</sup> Lateral column lengthening resulted in statistically significantly lower midfoot VAS compared to subtalar joint arthroereisis at 24-months follow-up, but not 6-months follow-up. This suggests that lateral column lengthening results in better sustained pain relief in midfoot area.<sup>11</sup> However, there were no statistically significant differences between groups for the hindfoot area for either follow-up period.

#### Adverse Events

The Silva et al. study<sup>11</sup> found the lateral column lengthening group had fewer complications (4.4%, n = 2) than the subtalar joint arthroereisis group (20.6%, n = 7). For the lateral column lengthening group, the adverse events reported included wound breakdown and sural nerve entrapment. For subtalar joint arthroereisis, all implant removals were due to midfoot pain.<sup>11</sup> Silva and colleagues<sup>11</sup> reported that correction of flatfoot was maintained at 24 months despite removal. Fang Junxian and colleagues<sup>20</sup> found that lateral column lengthening group had no implant removals (i.e., bone graft); whereas the subtalar joint arthroereisis group had 4 (33.3% of participants in this study group) implant removals.

#### **Body Mass Index**

Silva and colleagues<sup>11</sup> found there was a statistically significant reduction in BMI for the lateral column lengthening group at 24 months postprocedure but not for the subtalar joint arthroereisis group.<sup>11</sup> Of note, individuals in the lateral column lengthening arm of the study had a significantly higher BMI at baseline than individuals who underwent a subtalar joint arthroereisis. Silva and colleagues<sup>11</sup> hypothesized that the lower complication rate in the lateral column lengthening allowed for reduced hospital stays and, thus, an earlier return to an active lifestyle.

# Clinical Effectiveness of Subtalar Joint Arthroereisis for Talotarsal Joint Issues (Before-and-after Outcomes)

The study by Kolodziej and colleagues<sup>21</sup> measured clinical outcomes, which are summarized in detail in <u>Table 8</u>. Relevant to this report, Agnew and colleagues<sup>18</sup> reported adverse events (<u>Table 9</u>).

#### Function and Activities of Daily Living

Kolodziej and colleagues<sup>21</sup> assessed the function of the foot and ankle, and activities of daily living before and after the subtalar joint arthroereisis using the UCLA activity score, Symptom-Related Activity Scale, and the Lower Extremity Functional Scale. The results were mixed: the Symptom-Related Ankle Activity Scale and Lower Extremity Functional Scale outcome measures showed a statistically significant improvement from baseline, whereas the UCLA activity score did not.<sup>21</sup>

#### Sports and Exercise

Compared to baseline, Kolodziej et al.<sup>21</sup> did not find any statistically significant differences for participants after subtalar joint arthroereisis regarding sport frequency score and number of physical activities.

#### Pain

Subtalar joint arthroereisis resulted in statistically significant reduction of pain caused by partial talotarsal joint instability in the long-term, as indicated by the lower mean VAS after the procedure.<sup>21</sup>

#### Adverse Events

Overall, Kolodziej et al. (2023)<sup>21</sup> reported 2 minor complications (4.9%) from subtalar joint arthroereisis.<sup>21</sup> One participant experienced persistent pain that limited their activities, and another participant experienced wound healing issues that self-resolved without negatively affecting activity and function. None of the participants had their implants removed.<sup>21</sup>

Agnew and colleagues<sup>18</sup> reported that 8 (15.1%) implants in their study experienced ongoing device issues. Within this category, they included a broad range of adverse events and complications, such as pain, stiffness, general discomfort, and ankle disability, that occurred postprocedure.<sup>18</sup> Additionally, 3 (4.5%) implants needed device revision surgery.<sup>18</sup> Of which, 2 implants from 1 adult (a bilateral case) received incorrect implant sizes; whereas the remaining case needed revision surgery as the patient believed their improvement had plateaued.<sup>18</sup>

### Limitations

#### Limited Comparative Studies and Poor-Quality Evidence

Most studies in this report evaluated the clinical effectiveness of subtalar joint arthroereisis for adults with pes planus and talotarsal joint issues using before-and-after outcomes.<sup>10,13,18,19,21-24</sup> Most studies lacked comparative evidence against an alternative treatment, randomization of study participants, detailed description of individuals lost to follow-up or excluded from the study, and consideration of confounding

variables.<sup>10,13,18-24</sup> It is possible that subtalar joint arthroereisis may have contributed to the positive findings of these studies, but the extent to which it can be attributed to the procedure alone remains unclear.

#### **Adjunct Procedures With Subtalar Joint Arthroereisis**

The nonrandomized studies conducted subtalar joint arthroereisis with other adjunct procedures for adults with indications of interest,<sup>11,13,19,20,22</sup> except for 2 studies.<sup>18,21</sup> Across these studies, adjunct procedures that may have been performed with subtalar joint arthroereisis include medializing calcaneal osteotomy, flexor digitorum longus, Achilles tendon lengthening, gastrocnemius release, tibialis posterior insertion site debridement, and other types of surgical procedures.<sup>10,11,13,19,22,24</sup> Some procedures were performed at the discretion of clinicians, dependent on clinical needs.<sup>11,13,19,22,24</sup> However, most nonrandomized studies did not account for the variations in procedures when applicable.<sup>11,13,19,22,24</sup> Additionally, 1 systematic review reported that the heterogeneity of adjunct procedures across included studies was a limitation of their review.<sup>10</sup>

Two nonrandomized studies evaluated the clinical effectiveness of subtalar joint arthroereisis in insolation,<sup>18,21</sup> with 1 study that reported on 1 relevant outcome for this report (i.e., adverse events).<sup>18</sup> These 2 studies provided limited insight into the procedure's clinical effectiveness for pes planus, and may be influenced by other factors, such as the staff (i.e., surgeons) and staff experience at facilities. Moreover, there are some concerns for risk of bias for both studies, including threats to both internal and external validity, and these methodological limitations restrict the potential to understand the true effects of isolated subtalar joint arthroereisis for adults with indications of interest.

#### Types of Implant and Implant Sizes for Subtalar Joint Arthroereisis

In addition to the adjunct procedures used, participants across studies may have differed in the type of implant and implant size used for subtalar joint arthroereisis. Of the 7 included nonrandomized studies, 4 used HyProCure implants.<sup>11,13,18,21</sup> The remaining nonrandomized studies did not specify the type of implant used for subtalar joint arthroereisis.<sup>19,20,22</sup> The systematic review by Baryeh and colleagues found that the studies included in their review varied widely in implant type.<sup>10</sup> It is unclear how the implant type may have affected the results.

#### Lack of Evidence for Adults With Plantar Fasciitis

We did not identify any studies regarding the clinical effectiveness of subtalar joint arthroereisis for adults with plantar fasciitis. Hence, it is unclear how effective subtalar joint arthroereisis is for this subpopulation.

#### Lack of Relevant Economic Evaluations and Guidelines

We did not identify any economic evaluations and evidence-based guidelines that met this report's eligibility criteria. Hence, it is unclear whether performing subtalar joint arthroereisis is cost-effective for adults with plantar fasciitis, pes planus, and other foot conditions. Additionally, the standard and best practices to perform subtalar joint arthroereisis for adults with foot conditions remains unclear.

#### **External Validity**

All studies in this report were conducted outside of Canada. Most studies performed specific procedures at a single facility.<sup>11,13,19,20,22</sup> It is unclear how these treatments and contexts align with facilities in Canada and how they apply to adults with pes planus or partial talotarsal joint instability living in Canada.

Additionally, most studies evaluated the clinical effectiveness of subtalar joint arthroereisis on adults with stage IIb adult-acquired flatfoot. It is unclear how generalizable these findings are to other stages of pes planus.

# **Conclusions and Implications for Decision- or Policy-Making**

#### **Summary of Evidence**

Subtalar joint arthroereisis involves surgically inserting an implant to limit excessive movement of the subtalar joint that may cause painful foot conditions.<sup>4-6</sup> We conducted a rapid review of the evidence on the clinical effectiveness and cost-effectiveness of subtalar joint arthroereisis for adults with foot conditions (e.g., plantar fasciitis, pes planus). We also searched for guidelines with recommendations for these populations. We identified 1 systematic review and 9 nonrandomized studies relevant to this report. Most of the evidence extracted from the included studies was from before-and-after study designs, which limits our ability to provide strong conclusions for questions where literature was identified.

Overall, the literature suggests that subtalar joint arthroereisis may provide adults with pes planus and flexible or reducible talotarsal dislocation with some clinical benefits over time. We did not identify any studies on adults with plantar fasciitis. Pain was a complication postprocedure and a common reason for implant removal. Rates of implant removal varied across studies, ranging from 0% to 48.1% of cases.<sup>10,11,13,19-21</sup> Other adverse events reported in the identified literature include device revision (the need for),<sup>10</sup> surgical infection,<sup>10</sup> stress fracture,<sup>10</sup> insufficient deformity correction,<sup>10</sup> reoccurrence of foot deformity,<sup>13,21</sup> wound healing issues,<sup>10</sup> and muscle and tendon complications.<sup>10,11,13,19,20,22</sup>

We found 8 relevant studies that evaluated the clinical effectiveness of subtalar joint arthroereisis for adults with pes planus (question 2).<sup>10,11,13,19,20,22-24</sup> The findings suggest that, compared to baseline, subtalar joint arthroereisis improves overall foot and ankle condition,<sup>22</sup> function (overall, physical, social),<sup>20</sup> energy,<sup>20</sup> health-related quality of life,<sup>22</sup> symptoms,<sup>22</sup> pain,<sup>10,20,22</sup> and ability to perform activities of daily living<sup>22</sup> for adults with pes planus. One comparative study found mixed results when comparing lateral column lengthening to subtalar joint arthroereisis procedures: the findings varied depending on the outcome, duration of follow-up, and aspect of the foot involved (i.e., midfoot versus hindfoot).<sup>11</sup>

We also identified 2 relevant studies that evaluated the clinical effectiveness of subtalar joint arthroereisis for adults with flexible or reducible talotarsal joint dislocation (question 3).<sup>18,21</sup> Compared to baseline, subtalar joint arthroereisis may improve function of the foot and ankle as well as pain outcomes.<sup>18</sup>

#### **Considerations for Interpreting Evidence**

These results should be interpreted with caution. The included systematic review lacked methodological rigour, given the absence of established methods before conduct, detailed reporting of processes, and consideration of risk of bias in reporting results.

The nonrandomized studies were mostly limited to comparing before-and-after clinical outcomes. Given the nature of these study designs, they are at high risk for internal bias (e.g., absence of randomization). Of the 9 nonrandomized studies, 6 studies<sup>11,13,19,20,22,24</sup> evaluated adjunct subtalar joint arthroereisis or had a portion of their study population consisting of adjunct subtalar joint arthroereisis. The systematic review also discussed the amount of heterogeneity in the included studies regarding adjunct procedures.<sup>10</sup> However, this may be consistent with how subtalar joint arthroereisis is used in clinical practice: the procedure is seldom performed in isolation, especially for adults.<sup>13,26</sup> Moreover, the American College of Foot and Ankle Surgeons found limited evidence that demonstrates the effectiveness of isolated subtalar joint arthroereisis for a stage IIb adult-acquired flatfoot deformity during the development of their consensus statements on the clinical management of pes planus.<sup>17</sup> Some literature suggests that isolated subtalar joint arthroereisis may be less successful in adults because their feet have matured and are less adaptable compared to the feet of children and adolescents.<sup>13,17</sup> Interestingly, the Agnew et al.<sup>18</sup> study included in this rapid review found no differences in outcomes between adults and children with talotarsal joint dislocation.

There was little to no consideration of confounding variables in the analysis or interpretation of findings for most studies in this review. For example, the literature suggests that obesity can increase the risk of sinus tarsi pain postprocedure in adults with pes planus.<sup>13</sup> Most studies in this report did not account for such factors in their analysis or report the demographics of their study population. The true clinical effects of subtalar joint arthroereisis remains unclear without accounting for confounding factors that may have influenced results. Additionally, high heterogeneity across studies, beyond adjunct procedure, may have also affected the findings. For example, the sizes and types of implants specific for subtalar joint arthroereisis varied within and across some studies. There is some literature to suggest that implant size and implant type can impact the success of subtalar joint arthroereisis.<sup>5,27,28</sup> Given the complexity of foot biomechanics, some researchers have begun evaluating the potential for customized implants as a potential solution to address the consequences of implant mismatch using computerized models.<sup>28</sup>

#### **Clinical Implications and Considerations for Future Research**

This rapid review may be used to understand how subtalar joint arthroereisis has been evaluated in the adult population. However, none of the studies in this report were conducted in Canada; therefore, it is unclear how generalizable these results are to health settings in Canada. In addition, robust and high-quality randomized studies are still needed to draw conclusions about the clinical effectiveness of subtalar joint arthroereisis in practice, especially studies that compare the intervention against a comparator, control for heterogeneity, and account for confounding variables. Future studies may ensure both treatment arms receive similar adjunct procedures and account for confounding variables, such as obesity, implant types, and implant size, in their analysis.

We did not identify any economic evaluations regarding subtalar joint arthroereisis. Bernasconi and colleagues<sup>19</sup> raised concerns about the potential financial burden of implant removals, which can cost as much as the implant itself. Future economic evaluations may consider implant removals when developing their models. We also did not identify any evidence-based guidelines regarding subtalar joint arthroereisis. Hence, there is a gap in the literature about best practices and treatment standards when using subtalar joint arthroereisis as treatment for adult foot conditions. Future studies may wish to consider evaluating best adjunctive treatments with subtalar joint arthroereisis for adults with pes planus given that it is typically given in combination with other treatments in clinical practice.

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### Appendix 1: Detailed Methods and Selection of Included Studies

Please note that this appendix has not been copy-edited.

An information specialist conducted a literature search on key resources including MEDLINE, the Cochrane Database of Systematic Reviews, the International HTA Database, the websites of health technology assessment agencies in Canada and major international health technology assessment agencies, as well as a focused internet search. The search approach was customized to retrieve a limited set of results, balancing comprehensiveness with relevance. The search strategy comprised both controlled vocabulary, such as the National Library of Medicine's MeSH (Medical Subject Headings), and keywords. Search concepts were developed based on the elements of the research questions and selection criteria. The main search concept was arthroereisis. Comments, newspaper articles, editorials, and letters were excluded. Retrieval was limited to the human population. The search was completed on November 20, 2024, and was limited to English-language documents published since January 1, 2014.

#### **Selection Criteria and Methods**

One reviewer screened citations and selected studies. In the first level of screening, titles and abstracts were reviewed and potentially relevant articles were retrieved and assessed for inclusion. The final selection of full-text articles was based on the inclusion criteria presented in <u>Table 1</u>.

#### **Exclusion Criteria**

Articles were excluded if they did not meet the selection criteria outlined in <u>Table 1</u>, were duplicate publications, or were published before 2014. Systematic reviews in which all relevant studies were captured in other more recent or more comprehensive systematic reviews were excluded. We identified another systematic review which had significant overlap in included primary studies as the systematic review included in this rapid review (Baryeh et al. study<sup>10</sup>), as well as a greater number of relevant studies included to this rapid review. However, we excluded this review considering comprehensiveness and the level of rigour between the systematic reviews and considerable overlap. Primary studies retrieved by the search were excluded if they were captured in 1 or more included systematic reviews. Guidelines with unclear methodology were also excluded.

#### **Critical Appraisal of Individual Studies**

The included publications were critically appraised by 1 reviewer using the following tools as a guide: A MeaSurement Tool to Assess systematic Reviews 2 (AMSTAR 2)<sup>29</sup> for the systematic review and the Downs and Black checklist<sup>30</sup> for nonrandomized studies. Summary scores were not calculated for the included studies; rather, the strengths and limitations of each included publication were described narratively.



#### Figure 1: Selection of Included Studies

### **Appendix 2: Characteristics of Included Publications**

#### Table 2: Characteristics of the Included Systematic Review

Study citation, country, funding source	Study design, Number of primary studies included	Population characteristics	Intervention and comparator	Relevant clinical outcomes, length of follow-up
Baryeh et al. (2022) <sup>10</sup> UK <b>Funding source:</b> The authors received no support for the research, authorship, and/or publication of the study.	Study Design: Systematic review of clinical and radiological outcomes from studies published from inception to December 2019. Included studies: 9 nonrandomized studies (case series or cohort studies)	Adults treated with subtalar joint arthroereisis for acquired flatfoot N = 167 adults (190 feet) Age, mean (SD): 47.4 (NR) years Sex: 2:1 ratio of female to male Bilateral surgery: NR Surgery on left foot: NR Ethnicity: NR BMI: NR Implant size: Varied across studies Implant type: Varied across studies	Intervention: Isolated or adjunct subtalar joint arthroereisis Comparator: Baseline	<ul> <li>Adverse events</li> <li>General health and quality of life (SF-36 score)</li> <li>Overall foot and ankle condition (AOFAS score and FAOS score)</li> <li>Pain (VAS-FA)</li> <li>Follow-up, mean (range): 31.9 (1.3 to 76.0) months</li> </ul>

AOFAS = American Orthopaedic Foot & Ankle Society; FAOS = Foot and Ankle Outcome Score; NR = not reported; SD = standard deviation; SF-36 = Short Form (36) Survey; VAS-FA = Visual Analogue Scale Foot and Ankle. Note: This table has not been copy-edited.

#### **Table 3: Characteristics of Included Nonrandomized Studies**

Study citation, country, funding source	Study design	Population characteristics	Intervention and comparator	Relevant clinical outcomes, length of follow-up
		Indication: Pes planus		
Fu et al. (2024) <sup>13</sup> China <b>Funding source:</b> Shanghai Jiao Tong University, Science and Technology of Shanghai Municipality, and Shanghai Municipal Commission of Economy and Informatization.	Single-centre retrospective study	People with pes planus, admitted to Shanghai Sixth People's Hospital from 2013 to 2015 who did not respond to 6 months of conservative treatment preoperatively. N = 508 Adults, n (%): 223 (43.9%) Age (adults): NR Sex (adults): 156 (69.9%) females	<ul> <li>Intervention: Isolated or adjunct subtalar joint arthroereisis</li> <li>18 feet (7.36%) were treated with an isolated procedure</li> <li>218 feet (92.37%) were treated with adjunct subtalar joint</li> </ul>	<ul> <li>Adverse events (i.e., sinus tarsi pain, implant removal)</li> <li>Follow-up: NR</li> </ul>

Study citation, country, funding source	Study design	Population characteristics	Intervention and comparator	Relevant clinical outcomes, length of follow-up
		Bilateral surgery (adults): NR Surgery on left foot (adults): 132 (59.1%) had implants inserted in their left foot Ethnicity (adults): NR BMI (adults), median (Q1, Q3): 22.9 (20.7, 25.4) kg/m <sup>2</sup> Implant size (adults): Varied across the study population Implant type (adults): HyProCure	arthroereisis. <b>Comparator:</b> NA	
Lewis et al. (2024) <sup>22</sup> Australia <b>Funding Source:</b> No funding received to support completing this study.	Single-centre, retrospective, before-and-after study	Adults with stage I flexible progressive collapsing foot deformity between 2010 and 2018, who did not respond to 6 months of non-operative treatment. N = 187 adults (212 feet) Age, mean (SD): 59.7(13.1) years Sex: 118 (63.1%) females Bilateral surgery: 26 feet (12.3%) Surgery on left foot = 126 (59.4%) implants were inserted in the left foot Ethnicity: NR BMI, mean (SD): 28.1 (4.3) kg/m <sup>2</sup> Implant size: 90.6% of cases used a 9 mm implant. Implant type: NR	Intervention: Adjunct subtalar joint arthroereisis. Of 212 feet, 133 (62.7%) also underwent Achilles tendon lengthening as part of the procedure Comparator: Baseline	<ul> <li>Adverse events (i.e., implant removal)</li> <li>Activity (FAOS subcomponent score)</li> <li>Activities of daily living (FAOS subcomponent score)</li> <li>Foot and Ankle condition (FAOS score, FADI score)</li> <li>Pain (FAOS subcomponent score, FADI subcomponent score)</li> <li>Quality of life (FAOS subcomponent score)</li> <li>Quality of life (FAOS subcomponent score)</li> <li>Symptoms (FAOS subcomponent score)</li> <li>Follow-up, mean (SD): 2.5 (1.3) years</li> </ul>
Bernasconi et al. (2022) <sup>19</sup> UK <b>Funding Source:</b> Authors received no financial support for the research, authorship,	Single-centre, retrospective, before-and-after study	Adults with stage IIb adult-acquired flexible flatfoot deformity (ICD 21.4) presenting to a single unit between July 2004 to January 2019 <b>N =</b> 21 adults (22 feet)	Intervention: Adjunct subtalar joint arthroereisis. All participants also underwent medializing calcaneal osteotomy, flexor	<ul> <li>Adverse events</li> <li>Follow-up: minimum 6 months postprocedure</li> </ul>

Study citation, country, funding source	Study design	Population characteristics	Intervention and comparator	Relevant clinical outcomes, length of follow-up
and/or publication of this article.		Age, mean (SD): 55.2 (2.4) years Sex: 11 (50%) females Bilateral surgery: NR Surgery on left foot: NR Ethnicity: NR BMI, mean (SD): 31.4 (1.1) kg/m <sup>2</sup> Implant size: Varied across study population. Implant type: NR	digitorum longus transfer, spring ligament repair with or without cotton osteotomy <b>Comparator:</b> NA	
Silva et al. (2021) <sup>11</sup> Singapore <b>Funding Source:</b> NR	Single-centre, retrospective cohort study	Adults with stage IIb acquired flatfoot deformity between January 2007 and 2013. <b>N</b> = 72 adults (79 feet) <b>Age:</b> The mean age for the intervention arm was 46.3 (SD 16.8) years. The mean age for intervention group was 46.9 (SD 25.1) years. <b>Sex:</b> 55 (76.4%) females <b>Bilateral surgery:</b> NR <b>Surgery on left foot:</b> NR <b>Race or ethnicity:</b> 61 (84.7%) adults were reported to be Chinese. <b>BMI:</b> The BMI at baseline significantly differed between the intervention and comparator groups. The mean BMI for the intervention group is 26.3 (SD 4.3) kg/m <sup>2</sup> . The mean BMI for the comparator group is 29.1 (SD 4.2) kg/m <sup>2</sup> . <b>Implant size:</b> Varied across the study population. <b>Implant type:</b> HyProCure Intervention and comparator groups	Intervention: Subtalar joint arthroereisis (HyProCure implant) adjunct to tendo- Achilles lengthening or gastrocnemius release (dependent on clinical findings) <b>Comparator:</b> Lateral column lengthening with medializing calcaneal osteotomy, distraction osteotomy, flexor digitorum longus transfer, and tendo-Achilles lengthening or gastrocnemius release (dependent on clinical findings)	<ul> <li>Adverse events</li> <li>BMI (at 24 months)</li> <li>Foot and ankle condition (AOFAS subcomponent score)</li> <li>Mental health (SF-36 subcomponent score)</li> <li>Physical function (SF-36 subcomponent score)</li> <li>Pain (VAS)</li> <li>Follow-up: 6 and 24 months after surgery</li> </ul>

Study citation, country, funding source	Study design	Population characteristics	Intervention and comparator	Relevant clinical outcomes, length of follow-up
		did not differ in sex, age, and race or ethnicity.		
Fang Junxian et al. (2020) <sup>20</sup> Singapore <b>Funding source:</b> No funding was received for the completion of the study.	Single-centre, retrospective cohort study	Adults with symptomatic adult-acquired flatfoot disease (stage IIb posterior tibial tendon dysfunction) N = 22 adults (22 feet) Subtalar joint arthroereisis, n (%): 12 (54.5%) Age (subtalar joint arthroereisis group), mean (SD): 52.7 (NR) years Sex: 13 (59.0%) females Unilateral surgery: all cases (100%) Surgery on left foot: 6 (27.2%) implants were done on the left foot Ethnicity: NR BMI: NR Implant size: Varied across the study population. Implant type: NR Intervention and comparator groups were comparable in age and sex.	Intervention: Adjunct subtalar joint arthroereisis <b>Comparators:</b> Baseline, adjunct lateral column lengthening All study participants had an endoscopic gastrocnemius recession, tibialis posterior insertion site debridement, and a medializing calcaneal osteotomy.	<ul> <li>Adverse events</li> <li>Energy (SF-36 subcomponent score)</li> <li>Foot and ankle condition (AOFAS score)</li> <li>Physical function (SF-36 subcomponent score)</li> <li>Role limitation from physical health and emotional problems (SF-36 subcomponent score)</li> <li>Pain (VAS score; SF-36 subcomponent score)</li> <li>General health (SF-36 subcomponent score)</li> <li>Follow-up: minimum of 12 months</li> </ul>
Saxena et al. (2016) <sup>24</sup> US <b>Funding Source:</b> First author received royalties from Arthrex for the implants used.	Prospective study	Adults treated for symptomatic flexible flatfoot between 1996 and 2012. N = 100 adults Age, mean (SD): 53.3 (14.7) years Sex: NR Bilateral surgery: NR Surgery on left foot: NR Ethnicity: NR BMI: NR Implant size: NR	<ul> <li>Intervention: Subtalar joint arthroereisis</li> <li>29 (27.9%) feet underwent adjunctive procedures, such as calcaneal osteotomy and posterior tibial tendon advancement.</li> <li>Comparator: NA</li> </ul>	<ul> <li>Adverse events (i.e., implant removals)</li> <li>Follow-up, mean (SD): 6.5 (3.2) years</li> </ul>

Study citation, country, funding source	Study design	Population characteristics	Intervention and comparator	Relevant clinical outcomes, length of follow-up
		Implant type: Varied across study population		
Ozan et al. (2015) <sup>23</sup> Turkey <b>Funding Source:</b> NR	Single-centre, before-and- after study	Adults with symptomatic flexible flatfoot deformity treated between 2011 and 2013, who did not respond to 6 months of conservative treatment. <b>N</b> = 16 adults (26 feet) <b>Age, mean (SD):</b> 24.5 (5.24) years <b>Sex:</b> 12 (75%) females <b>Bilateral surgery:</b> NR <b>Surgery on left foot:</b> 13 (50%) implants were inserted in the left foot. <b>Ethnicity:</b> NR <b>Implant size:</b> Varied across study population <b>Implant type:</b> BioPro Horizon	Intervention: Isolated subtalar joint arthroereisis Comparator: Baseline	<ul> <li>Foot and ankle condition (AOFAS score)</li> <li>Pain (VAS score)</li> <li>Follow-up, mean (SD): 15.1 (4.7) months</li> </ul>
		Indication: Other foot conditions		
Agnew et al. (2023) <sup>18</sup> US <b>Funding Source:</b> No funding was received for conducting this study.	Multicentre, retrospective, before-and-after study	Individuals with symptomatic, reducible talotarsal joint dislocation since 2009. N = 67 individuals (53 feet) Adults, n (%): 36 (53 feet) Age, median (range): 41 (20 to 74) years Sex (adults): 37 (69.8%) feet from female participants Bilateral surgery (adults), n (%): 17 (25.4%) Surgery on left foot (adults), n (%): 27 (50.9%) Ethnicity: NR BMI: NR Implant size: Varied across study	Intervention: Standalone type II extraosseous talotarsal stabilization implant (HyProCure and HyProCure II implants) Comparator: NA	<ul> <li>Adverse events (i.e., implant revision and removal)</li> <li>Follow-up (adults), mean (range): 7 years, 8 months, 19 days (5 years, 2 days to 12 years, 2 months, 7 days)</li> </ul>

Study citation, country, funding source	Study design	Population characteristics	Intervention and comparator	Relevant clinical outcomes, length of follow-up
		population. <b>Implant type:</b> HyProCure and HyProCure II		
Kolodziej et al. (2023) <sup>21</sup> Poland <b>Funding Source:</b> No external funding reported.	Single-centre, prospective, before-and-after study	Adults (> 18 years) with partial talotarsal joint instability between 2012 and 2015. N = 41 adults (62 feet) Age, mean (SD): 46.4 (15.6) years Sex: 36 (87.8%) females Bilateral surgery, n (%): 21 (51.2%) Surgery on left foot: NR Ethnicity: NR BMI, mean (SD): 24.2 (3.2) kg/m <sup>2</sup> Implant size: Varied across study population Implant type: HyProCure implant	Intervention: Extraosseous talotarsal stabilization. Comparator: Baseline	<ul> <li>Activity (UCLA Activity Score, Symptom-Related Activity Scale score)</li> <li>Function (Lower Extremity Functional Scale)</li> <li>Sports and Exercise (Sports Frequency score, number of physical activities, time on physical activity)</li> <li>Pain (VAS score)</li> <li>Follow-up, mean (range): 8.6 (7.3 to 10.3) years</li> </ul>

AOFAS = American Orthopaedic Foot & ankle Society; BMI = body mass index; FADI = Foot and Ankle Disability Index; FAOS = Foot and Ankle Outcome Score; ICD = international classification of diseases; NA = not applicable; NR = not reported; Q = quartile; SD = standard deviation; SF-36 = Short Form (36) Health Survey; VAS = visual analogue scale.

Note: This table has not been copy-edited.

# **Appendix 3: Critical Appraisal of Included Publications**

Please note that this appendix has not been copy-edited.

#### Table 4: Strengths and Limitations of the Systematic Review Using AMSTAR 2<sup>29</sup>

Strengths	Limitations			
Baryeh et a	al. (2022) <sup>10</sup>			
• The review authors described the population, intervention, and outcomes of interest in adequate detail, which was	<ul> <li>The report lacked an explicit statement about established methods before the conduct of the review.</li> </ul>			
<ul> <li>reflected in the inclusion criteria and research question.</li> <li>The review authors used a comprehensive search strategy and described included studies in adequate detail.</li> </ul>	<ul> <li>The review authors did not justify their inclusion and exclusion criteria or provide a list of excluded studies from full-text screening.</li> </ul>			
<ul> <li>The review authors performed study selection in duplicate.</li> <li>The report detailed the study selection process and justified</li> </ul>	<ul> <li>The report lacked details about review authors attempting to identify funding sources for the studies included in the review.</li> </ul>			
excluded studies from full-text screening through a PRISMA diagram.	<ul> <li>It is unclear whether review authors performed data extraction in duplicate.</li> </ul>			
<ul> <li>The review authors discussed the heterogeneity across studies (i.e., procedures done in tandem with subtalar joint arthroereisis, and types of implants).</li> </ul>	<ul> <li>The review authors calculated averages for outcomes with &gt; 1 relevant study. They did not conduct appropriate statistical methods that could have accounted for effect sizes (e.g., weighted averages)</li> </ul>			
<ul> <li>The review authors declared no potential sources of conflicts of interest.</li> </ul>	<ul> <li>The review authors conducted a risk of bias assessment using a tool devised by the Agency for Health care Research Quality (AHRQ). While the review authors shared the results of their critical appraisal through an infographic, they did not discuss the implications of the results of the risk of bias assessment.</li> </ul>			
	<ul> <li>The review authors did not perform assessments for publication bias. Hence, they did not discuss the likelihood and magnitude of the impact of publication bias on their findings.</li> </ul>			

AMSTAR 2 = A MeaSurement Tool to Assess systematic Reviews 2; PRISMA = Preferred Reporting Items for Systematic Reviews and Meta-analyses.

#### Table 5: Strengths and Limitations of Clinical Studies Using the Downs and Black Checklist<sup>30</sup>

Strengths	Limitations			
Fu et al.	(2024) <sup>13</sup>			
<ul> <li>The researchers clearly described the following: <ul> <li>the objective of the study</li> <li>the main outcomes</li> <li>inclusion and exclusion criteria</li> <li>the intervention of interest.</li> </ul> </li> <li>The researchers clearly reported the main findings of the study, all important adverse events, as well as the random variability in the data and P values when applicable.</li> </ul>	<ul> <li>The researchers used before-and-after study design, which lacks:</li> <li>o comparative evidence against an alternative treatment</li> <li>o randomization of study participants.</li> <li>The researchers and participants had knowledge of which treatment each participant had when measuring and analyzing the main outcomes.</li> <li>The researchers did not provide any details about the individuals who may have been evaluated from the study.</li> </ul>			
<ul> <li>It appears that researchers used appropriate statistical analysis.</li> </ul>	<ul> <li>The researchers do not report on follow-up time. It is unclear how this varied across participants.</li> </ul>			

Strengths	Limitations			
<ul> <li>It appears that researchers used appropriate outcome measures.</li> <li>The researchers recruited participants from the same population and over the same period.</li> <li>The researchers declared no conflicts of interest and reported sources of funding for the study.</li> <li>Compliance of study participants to the intervention is reliable given the nature of the procedure.</li> </ul>	<ul> <li>The study lacks thorough consideration of confounding variables. The main objective of the study was to investigate use trends vs. the evaluate effectiveness of the intervention.</li> <li>The researchers did not describe the characteristics of recruited participants excluded from the study, including those who may have been lost to follow-up.</li> <li>The researchers recruited study participants who received treatment from 1 hospital in China. The treatment and study population may not be generalizable to other facilities, especially those in Canada.</li> </ul>			
Lewis et a	al. (2024) <sup>22</sup>			
<ul> <li>The researchers clearly described the following: <ul> <li>the objective of the study</li> <li>the main outcomes</li> <li>the intervention of interest</li> <li>inclusion and exclusion criteria.</li> </ul> </li> <li>The researchers clearly reported the main findings of the study, as well as the random variability in the data and P values when applicable.</li> <li>It appears that the researchers used appropriate statistical tests to assess outcomes.</li> <li>The researchers assessed the impact of the participant's age on implant removals.</li> <li>It appears that researchers used appropriate outcome measures.</li> <li>All study participants were recruited from the same population and from the same period.</li> <li>The researchers declared no conflicts of interests and no specific sources of funding for this study.</li> <li>Compliance of study participants to the intervention is reliable given the nature of the procedure.</li> </ul>	<ul> <li>The researchers conducted a before-and-after study. The study lacked randomization of participants and comparative evidence against an alternative treatment.</li> <li>The researchers and participants had knowledge of which treatment each participant had when measuring and analyzing the main outcomes.</li> <li>The study has a small sample size. Of 187, 21 (28 feet) participants had preoperative scores available.</li> <li>The researchers reported on implant removals but did not provide information about other important adverse events (e.g., pain, infections).</li> <li>The researchers did not account for the impact of confounding variables.</li> <li>The outcome measures (FAOS, FADI, EQ-5D-5L) used to measure differences before-and-after overlap in outcomes of interest, such as pain and activity levels.</li> <li>The researchers did not describe individuals excluded from the study due to lack of follow-up data. It is unclear how they differ from participants included in the study.</li> <li>The researchers recruited participants from 1 institution in Australia. Hence, it is unclear if participants were representative of the treatment most patients receive. Additionally, the results may not be generalizable to other facilities, especially those in other countries.</li> <li>The researchers performed an unplanned comparative analysis (data dredging) between participants who had their implant removed vs. those who did not, specifically the impact of age and difference between preoperative and operative</li> </ul>			
Agnew et a	al. (2023) <sup>18</sup>			
The researchers clearly described the following:	• The researchers recruited a small sample size for the study.			
<ul> <li>the objective of the study</li> <li>the intervention of interest</li> </ul>	They did not conduct any calculations to ensure sufficient power to detect a clinically important effect.			
<ul> <li>o inclusion and exclusion criteria</li> </ul>	<ul> <li>The researchers excluded individuals with less than 5-years</li> </ul>			

Strengths	Limitations		
<ul> <li>the main findings of the study.</li> <li>The researchers reported random variability and P values in the data for the main outcomes.</li> <li>It appears that researchers used appropriate statistical tests.</li> <li>It appears that researchers used appropriate outcome measures.</li> <li>The researchers recruited all participants from the same population over the same period.</li> <li>The researchers declared no conflicts of interest and no sources of funding that may have biased the study.</li> <li>Compliance of study participants to the intervention is reliable given the nature of the procedure.</li> </ul>	<ul> <li>follow-up data. It is unclear how these individuals differ from the those included in the study.</li> <li>It is unclear whether individuals screened for participation is representative of the entire population from which they were recruited.</li> <li>The researchers recruited participants from 6 centres in the US. It is unclear how representative the staff, places, and facilities of what individuals receiving care in Canada would receive.</li> <li>Given the nature of the study design, the researchers could not randomize the participants into treatments. Authors and participants were aware of the interventions the participants received.</li> <li>The researchers do not account for varying follow-up periods between study participants.</li> </ul>		
Kolodziej et	t al. (2023) <sup>21</sup>		
<ul> <li>The researchers clearly described the following: <ul> <li>the objective and hypothesis of the study</li> <li>the intervention of interest</li> <li>inclusion and exclusion criteria</li> <li>the main findings of the study</li> </ul> </li> <li>The researchers reported random variability and P values in the data for the main outcomes.</li> <li>It appears that the researchers used appropriate statistical tests to assess the main outcomes.</li> <li>It appears that researchers used appropriate outcome measures.</li> <li>The researchers declared no conflicts of interest and no external sources of funding.</li> <li>The researchers reported important adverse events that may be a consequence of the intervention.</li> <li>Compliance of study participants to the intervention is reliable given the nature of the procedure.</li> </ul>	<ul> <li>The study has a small sample size. The study authors did not conduct a calculation to ensure the study had statistical power to detect a clinically significant outcome.</li> <li>The researchers conducted a before-and-after study without comparative evidence against other treatments. The study lacks randomization of participants and researchers and participants were aware of the interventions the participants received.</li> <li>The researchers do not consider and account for the impact of potential confounders on the study findings.</li> <li>The researchers do not account for the different lengths of follow-up between study participants.</li> <li>The researchers do not provide details regarding recruitment. Hence, it is unclear if study participants are representative of the entire population they were recruited from.</li> <li>The researchers do not describe individuals who were excluded due to lack of follow-up data. Hence, it is unclear how these individuals may differ from the study participants.</li> <li>It is unclear whether the study received internal funding to support study activities.</li> </ul>		
Bernasconi e	et al. (2022) <sup>19</sup>		
<ul> <li>The researchers clearly described the following: <ul> <li>the objective of the study</li> <li>the intervention of interest</li> <li>inclusion and exclusion criteria</li> <li>the main outcomes and findings of the study.</li> </ul> </li> <li>The researchers evaluated the impact of age, sex, weight, BMI, and height on radiographic outcomes through a</li> </ul>	<ul> <li>The researchers conducted a retrospective cohort study with before-and-after results. The study lacks randomization of study participants. Additionally, the researchers and participants had knowledge of which treatment each participant had when measuring and analyzing the main outcomes.</li> <li>The researchers do not account for differences in follow-up periods.</li> </ul>		

Strengths	Limitations
<ul> <li>regression analysis.</li> <li>The researchers reported simple outcome data and estimates of random variability in their results.</li> <li>The researchers screened eligibility in a representative sample of the entire population from which these individuals were recruited from.</li> <li>It appears that the researchers used appropriate statistical tests to assess the main outcomes.</li> <li>The compliance with the intervention is reliable given the nature of the procedure.</li> <li>The researchers recruited study participants from the same population and period.</li> <li>The researchers exceeded the minimum sample size they needed based on their calculations.</li> <li>The authors disclosed that some researchers are minority shareholders in a CT-related company.</li> <li>The researchers received no financial support for the study's conduct.</li> </ul>	<ul> <li>The researchers reported on sinus tarsi pain and implant removal, but it is unclear whether they attempted to measure other types of adverse events.</li> <li>The researchers excluded 8 individuals without weightbearing radiographs or are lacking radiographs. It is unclear how these individuals may have impacted the findings of the study.</li> <li>The study was conducted in a single centre in Poland. It is unclear how applicable these findings are to health settings in Canada.</li> </ul>
Silva et a	l. (2021) <sup>11</sup>
<ul> <li>the objective of the study</li> <li>the main outcomes and main findings of the study</li> <li>intervention of interest</li> <li>inclusion and exclusion criteria</li> <li>characteristics of individuals lost to follow-up.</li> <li>The researchers reported estimates of random variability for the main outcomes.</li> <li>The researchers reported all important adverse events because of the interventions.</li> <li>All individuals seen in the single centre within the same period (2007 to 2013) were eligible and screened for inclusion in the study.</li> <li>All participants had the same follow-up (6 and 12 months).</li> <li>It appears the researchers used appropriate statistical tests to assess main outcomes.</li> <li>It appears that the researchers used appropriate outcome measures.</li> <li>The researchers found that both treatment groups were comparable at baseline.</li> <li>The study had sufficient power to detect a clinically important effect.</li> <li>Compliance to the intervention is reliable given the nature of</li> </ul>	<ul> <li>The researchers did not provide P values for nonsignificant findings, as well as for comparisons between before-and-after results within treatment arms.</li> <li>The researchers conducted a retrospective nonrandomized study. Hence, they did not randomize participants.</li> <li>The researchers and participants had knowledge of which treatment each participant had when measuring and analyzing the main outcomes.</li> <li>It is unclear how the findings of this study conducted at a single institution in Singapore applies to individuals receiving care in Canada.</li> </ul>

Strengths	Limitations			
Fang Junxian	et al. (2020) <sup>20</sup>			
<ul> <li>The researchers clearly described the following:</li> <li>the objective of the study</li> <li>the techniques and processes followed for the intervention and comparators</li> </ul>	<ul> <li>The researchers conducted a retrospective longitudinal study comparing before-and-after findings for each treatment. The study lacks randomization of participants.</li> <li>Clinicians, researchers, and participants had knowledge of</li> </ul>			
<ul> <li>main outcomes and findings</li> <li>clinical characteristics of the study population.</li> <li>While the researchers didn't provide details on the exclusion criteria, the published report states that "there was no exclusion of patients from the study."</li> <li>The researchers reported P values.</li> <li>No study participants were lost to follow-up.</li> <li>It appears the researchers used reliable and accurate outcome measures.</li> <li>The researchers reported no conflicts of interest and no financial support to complete the study.</li> <li>Compliance to the intervention is reliable given the nature of the procedure.</li> </ul>	<ul> <li>which procedures each participants received.</li> <li>The researchers did not describe inclusion and exclusion criteria in detail.</li> <li>The study lacks thorough consideration of differences in preoperative scores.</li> <li>While the objective of the study was to compare the effectiveness of treatments, the researchers did not conduct any statistical tests to detect significant differences in outcome measures between treatment groups.</li> <li>The researchers reported on sinus tarsi pain and implant removal. It is unclear if they tracked other adverse events (e.g., infections).</li> <li>It is unclear how and what time frame authors recruited their study population. Hence, it is unclear if participants are representative of their source population.</li> <li>Study participants received treatment from a single centre. Hence, it is unclear if the staff, places, and facilities where participants were treated were representative of most treatment this population receives.</li> <li>The researchers performed an unplanned comparative analysis (data dredging between participants who had their implant removed vs. those who did not), specifically SF-36, AOFAS scores, and VAS scores.</li> <li>The researchers recruited a small sample size. It is unclear if the study had the statistical power to detect a clinically significant difference between groups.</li> </ul>			
	• The researchers did not conduct any tests to detect any clinically significant differences between the intervention and comparator.			
Saxena et a	al. (2016) <sup>24</sup>			
<ul> <li>The researchers clearly described the purpose of the study, the main outcomes, and inclusion and exclusion criteria.</li> <li>The researchers reported simple outcome data and estimates of random variability (i.e., standard deviations and ranges).</li> <li>It appears that the researchers used appropriate statistical methods to assess the main outcomes.</li> <li>No study participants withdrew from the study.</li> </ul>	<ul> <li>The intervention was not described in detail, including the surgical process. It is unclear how generalizable the findings are to other health settings.</li> <li>The study does not consider principal confounders that may have impacted findings.</li> <li>The study lacked randomization.</li> <li>Individuals involved in the study conduct and participants had</li> </ul>			

Strengths	Limitations			
<ul> <li>The researchers reported P values for main outcomes.</li> <li>No unplanned analysis occurred.</li> <li>The compliance to the intervention is reliable given the nature of the procedure.</li> <li>The main outcomes were accurate and reliable.</li> </ul>	<ul> <li>Not all adverse events were measured in the study. The researchers focused on implant removals.</li> <li>The researchers did not describe the recruitment process. Hence, it is unclear whether the study population is representative of the population they were recruited from. It is also unclear whether all participants were recruited from the same period or location.</li> <li>Individuals who did not have &gt; 2 years of follow-up data were excluded. It is unclear how these individuals may have been affected by the results.</li> <li>The researchers did not conduct any testing to ensure the study was adequately powered.</li> <li>The researchers reported no conflicts of interest. However, the first author of the study received royalties from an implant manufacturer, as stated in the financial disclosure section without further details on how or if this potential conflict of interest was mitigated.</li> </ul>			
Ozan et a	I. (2015) <sup>23</sup>			
<ul> <li>The researchers clearly described the purpose of the study, the main outcomes of interest, and the inclusion criteria.</li> <li>The intervention is clearly described, including the surgical process and implant type.</li> <li>The main findings of the study are clearly described. The researchers reported simple outcome data, P values, and estimates of random variability (i.e., range, standard deviation) for major findings.</li> <li>No data dredging was performed.</li> <li>It appears that the researchers conducted appropriate statistical tests to assess main outcomes.</li> <li>The compliance to the intervention is reliable given the nature of the procedure.</li> <li>It appears that the outcome measures were valid and accurate.</li> <li>The authors reported no conflicts of interest.</li> </ul>	<ul> <li>It is unclear whether the researchers had exclusion criteria for study participation.</li> <li>The researchers do not consider principal confounders that may have impacted study findings.</li> <li>The researchers did not report if study participants were lost to follow-up. It is unclear if this may have impacted study findings.</li> <li>The researchers reported the number of implant removal and pain as a result of the procedure, but they did not provide a comprehensive list of adverse events they measured.</li> <li>The researchers did not describe the recruitment process for this study. It is unclear if the study population is representative of the population they were recruited from.</li> <li>The study lacks randomization of study participants.</li> <li>Individuals involved in the study conduct and participants had knowledge of treatment.</li> <li>The researchers did not conduct a test to ensure the study was adequately powered.</li> <li>The researchers did not report if there was a source of funding for this study. It is unclear how this may have had an impact on their findings.</li> </ul>			

AOFAS = American Orthopaedic Foot & Ankle Society; BMI = body mass index; Version; FADI = Foot and Ankle Disability Index; FAOS = Foot and Ankle Outcome Score; SF-36 = Short Form (36) Health Survey; VAS = visual analogue scale.

### **Appendix 4: Main Study Findings**

# Table 6: Summary of Findings — Subtalar Joint Arthroereisis and Lateral Column Lengthening for Adults With Pes Planus From the Nonrandomized Study by Silva et al. (2021)<sup>11</sup>

	Baseline (mean score)			Follow-up at 6 months (mean score)			Follow-up at 24 months (mean score)		
Outcome measure	Subtalar joint arthroereisis	Lateral column lengthening	P value	Subtalar joint arthroereisis	Lateral column lengthening	P value	Subtalar joint arthroereisis	Lateral column lengthening	P value
AOFAS hindfoot	50.3 (SD 21.1)	52.2 (SD 21.6)	ns	75.3 (SD 18.6)	71.4 (SD 17.5)	ns	81.6 (SD 21.6)	86.4 (SD 17.3)	ns
AOFAS midfoot	47.6 (SD 26.0)	45.1 (SD 21.9)	0.21	74.0 (SD 24.2)	73.1 (SD 19.5)	0.15	81.1 (SD 20.6)	90.3 (SD 12.6)	< 0.001
SF-36 PCS	47.8 (SD 21.2)	48.3 (SD 19.2)	ns	57.3 (SD 20.0)	52.4 (SD 19.9)	ns	65.3 (SD 21.1)	65.2 (SD 23.3)	ns
SF-36 MCS	69.1 (SD 21.8)	75.3 (SD 20.3)	ns	76.6 (SD 19.9)	74.8 (SD 20.7)	ns	80.6 (SD 17.5)	79.1 (SD 19.5)	ns
VAS midfoot	4.8 (SD 3.7)	5.7 (SD 3.2)	ns	1.7 (SD 2.7)	1.5 (SD 2.2)	ns	1.3 (SD 2.4)	0.5 (SD 1.6)	< 0.001
VAS hindfoot	6.1 (SD 3.0)	5.6 (SD 3.3)	ns	2.6 (SD 2.9)	2.2 (SD 2.4)	ns	1.4 (SD 2.5)	1.2 (SD 2.6)	ns
BMIª	26.3 (SD 4.3)	29.1 (SD 4.2)	< 0.01	NA	NA	NA	26.8 (SD 4.5)	27.2 (SD 4.2)	ns
Adverse events⁵ [rate (%)]	NA	NA	NA	NA	NA	NA	7 (20.6) <sup>b</sup>	2 (4.4%) <sup>b</sup>	NA

AOFAS = American Orthopaedic Foot & Ankle Society; BMI = body mass index; MCS = mental component summary; NA = not significant; ns = not significant; PCS = physical component summary; SD = standard deviation; SF-36 = Short Form (36) Health Survey; VAS = visual analogue scale.

Notes: Bolded outcome measures indicate a statistically significant difference.

Silva and colleagues<sup>11</sup> did not report P values for any nonsignificant comparisons where P > 0.05, except for VAS midfoot score.

The study by Fang Junxian and colleagues<sup>20</sup> compared and reported before-and-after outcomes for the subtalar joint arthroereisis group and the lateral column lengthening group. However, they did not use any statistical methods to compare the scores of the subtalar joint arthroereisis group vs. the scores of the lateral column lengthening group. Therefore, the findings relevant to this report are the before-and-after results for the subtalar joint arthroereisis group and presented in the before-and-after outcomes tables. Of note, this study found that lateral column lengthening significantly improved the overall foot and ankle condition (AOFAS), general health (SF-36), role limitation from physical health (SF-36), energy (SF-23), emotional well-being (SF-36), and pain relief (VAS) compared to baseline.

<sup>a</sup>This outcome was only measured at 24 months.

<sup>b</sup>Adverse events were reported as a rate (% of cases) throughout the study. While it is reported under "follow-up at 24 months," these adverse events may have started before the 6-months or 24-months follow-up. Note: This table has not been copy-edited.

# Table 7: Summary of Findings — Subtalar Joint Arthroereisis for Pes Planus (Before-and-after Outcomes)

Study, study design	Baseline mean score	Follow-Up mean score	P value	Notes		
	Outcome measure: AOFAS score					
Baryeh et al. (2022), <sup>10</sup> SR	50.7 (NR)ª	81.4 (NR)ª	NA	Based on the findings of 5 included studies. Of which, 3 reported significant improvement at follow-up from baseline (P value < 0.001, < 0.00001, 0.0001).		
Fang Junxian et al. (2020), <sup>20</sup> NRS	54.9 (NR)	83.8 (NR)	0.004 <sup>b</sup>	_		
Ozan et al. (2015), <sup>23</sup> before-and-after study	52 (SD 6.6)	75 (SD 11.2)	0.0001 <sup>b</sup>	_		
	Outcome	e measure: EQ-5D-5L score	e			
Lewis et al. (2024), <sup>22</sup> before-and-after study	0.69 (SD 0.22)	0.82 (SD 0.14)	< 0.05 <sup>b</sup>	Of 187 participants, 21 had pre- and postoperative scores.		
	Outco	me measure: FAOS score				
Baryeh et al. (2022) <sup>10</sup> SR	42.6 (NR)	68.2 (NR)	< 0.05 <sup>b</sup>	Based on the findings of 1 included study.		
Lewis et al. (2024), <sup>22</sup> before-and-after study	—	_		Of 187 participants, 21 had pre- and postoperative scores.		
Pain	35.9ª (SD 17.2)	73.0ª (SD 16.6)	< 0.001 <sup>b</sup>	—		
Symptoms	71.8ª (SD 6.1)	81.9ª (SD 9.6)	< 0.001 <sup>b</sup>	—		
Activities of daily living	65.6ª (SD 14.6)	84.0ª (SD 11.0)	< 0.001 <sup>b</sup>	—		
Quality of life	26.6ª (SD 14.0)	47.8ª (SD 20.1)	0.001 <sup>b</sup>	_		
	Outco	me measure: FADI score				
Lewis et al. (2024), <sup>22</sup> before-and-after study	—	—	—	Of 187 participants, 21 had pre and postoperative scores.		
Pain	52.0 (SD 18.6)	22.4 (SD 16.9)	< 0.001 <sup>b</sup>	_		
Activity	49.8 (SD 22.0)	23.8 (SD 18.9)	< 0.001 <sup>b</sup>	—		
	Outco	me measure: SF-36 score				
Baryeh et al. (2022), <sup>10</sup> SR	NR	75.4	NA	—		
Fang Junxian et al. (2020), <sup>20</sup> NRS	_	_	—	_		
Physical function	40.3 (NR)	72.1 (NR)	0.006 <sup>b</sup>	_		
Role limitation (physical health)	16.1 (NR)	82.1 (NR)	0.001 <sup>b</sup>	_		
Role limitation (emotional problems)	38.1 (NR)	90.5 (NR)	0.006 <sup>b</sup>	_		
Energy fatigue	52.9 (NR)	64.3 (NR)	0.026 <sup>b</sup>	_		

Study, study design	Baseline mean score	Follow-Up mean score	P value	Notes
Emotional well-being	72.7 (NR)	77.1 (NR)	0.573	—
Social functioning	58.0 (NR)	96.4 (NR)	0.001 <sup>b</sup>	—
Pain	43.4 (NR)	83.4 (NR)	0.001 <sup>b</sup>	
General function	58.6 (NR)	66.8 (NR)	0.009 <sup>b</sup>	
	Outcon	ne measure: VAS-FA score		
Baryeh et al. (2022), <sup>10</sup> SR	61.6 (range 25 to 86)	83 (range 61 to 100)	< 0.0001 <sup>b</sup>	Based on the findings of 1 included study,
	Outco	ome measure: VAS score		
Baryeh et al. (2022), <sup>10</sup> SR	7.8 (NR)	2.8 (NR)	NA	Based on the findings of 3 included studies. Of which, 2 studies reported a significant difference (< 0.05 and 0.0001).
Fang Junxian et al. (2020), <sup>20</sup> NRS	7.6 (NR)	2.9 (NR)	0.002 <sup>b</sup>	—
Ozan et al. (2015), <sup>23</sup> before-and-after study	6.9 (SD 0.6)	4.1 (SD 1.4)	0.0001 <sup>b</sup>	_

AOFAS = American Orthopaedic Foot & Ankle Society; FA = foot and ankle; FAOS = Foot and Ankle Outcome Score; NA = not applicable; NR = not reported; SF-36 = Short Form (36) Health Survey; SR = systematic review; VAS = visual analogue scale; VAS-FA = visual analogue scale foot and ankle.

<sup>a</sup>Reported as a mean by the respective study.

<sup>b</sup>P < 0.05.

Note: This table has not been copy-edited.

# Table 8: Summary of Findings — Subtalar Joint Arthroereisis for Partial Talotarsal JointInstability (before-and-after study by Kolodziej et al. [2023]<sup>21</sup>)

Outcome measure	Baseline, mean (SD)	Follow-up, mean (SD)	P value					
Function and activities of daily living								
Lower Extremity Functional Scale	74.2 (23.7)	88.6 (15.3)	0.0006ª					
Symptom-Related Ankle Activity Scale	71.7 (20.0)	82.9 (18.7)	0.002ª					
UCLA Activity Score	6.02 (2.7) 6.09 (2.5)		0.787					
Sports and exercise								
Number of physical activities (per week)	1.95 (1.1)	1.83 (1.0)	0.37					
Sport Frequency score	2.1 (0.5)	2.1 (0.4)	0.11					
Time of physical activity (minutes per week)	153 (126.3) 170 (102)		0.15					
Pain								
VAS	4.6 (3.3)	0.9 (1.5)	< 0.0001ª					

SD = standard deviation; VAS = visual analogue scale.

Note: This table has not been copy-edited.

<sup>&</sup>lt;sup>a</sup>P value < 0.05.

Study, study design	Result	Notes		
Implant removal				
Baryeh et al. (2022), <sup>10</sup> SR	40 of 175 (22.9%) implants	<ul> <li>Based on 8 relevant studies involving 175 feet<sup>a</sup></li> <li>Of the 40 removals, the main causes include:</li> <li>Sinus tarsi pain for 28 feet (70%)</li> </ul>		
		<ul> <li>Routine postoperative protocol but were pain free for 8 feet (20%)</li> <li>Eixation failure for 1 foot (2.5%)</li> </ul>		
		3 implant removals had no reasons described (7.5%)		
Fu et al. (2024), <sup>13</sup> NRS	36 (15.3%) implants	Implant removals were caused by sinus tarsi pain that was not relieved by conservative treatment. After removal, all patients experienced pain relief. The most common cause of removal was sinus tarsi pain.		
Lewis et al. (2024), <sup>22</sup> before-and- after study	102 of 212 (48.1%) implants	Mean time for removal was 0.64 years (SD 0.41) postprocedure. Sinus tarsi pain or lateral hind foot pain was the reason for all implant removals. Lewis and colleagues found a statistically significant difference in age between participants who had their implant removed and those who did not.		
Agnew et al. (2023), <sup>18</sup> before-and- after study	2 of 53 (3.7%) implants⁵	_		
Kolodziej et al. (2023), <sup>21</sup> before- and-after study	0 of 41 adults⁵	—		
Bernasconi et al. (2022), <sup>19</sup> before- and-after study	4 of 21 (19.0%) adults	Implants were removed due to sinus tarsi pain.		
Silva et al. (2021), <sup>11</sup> NRS	7 of 31 (20.6%) adults	Implants were removed due to midfoot pain. For adults with removed implants, deformity correction was maintained at 24 months.		
Fang Junxian et al. (2020), <sup>20</sup> NRS	4 of 12 (33.3%) implants	All implants were removed because of sinus tarsi pain. They performed removals at a mean of 27 months after the intervention. Implant removal significantly improved all components of SF-26 (except for emotional being), AOFAS score, and VAS scores.		
Saxena et al. (2016), <sup>24</sup> NRS	23 of 103 (22.3%) implants	Most implants were removed at a mean of 12.9 months (SD 8.6) after the procedure.		
Ozan et al. (2015), <sup>23</sup> before-and- after study	3 of 26 (7.6%) implants	Of 3 implant removals, 2 were caused by sinus tarsi pain and 1 was caused by loss of deformity fixation.		
Pain				
Kolodziej et al. (2023), <sup>21</sup> before- and-after study	1 of 41 (2.4%) individuals experienced persistent pain <sup>ь</sup>	The individual experience pain up until their last follow-up (8 years from surgery), which also limited their activities.		
Bernasconi et al. (2022), <sup>19</sup> before- and-after study	12 of 21 (57.1%) adults experienced persistent sinus tarsi pain	_		

#### Table 9: Summary of Findings — Adverse Events or Complications

Study, study design	Result	Notes		
Baryeh et al. (2022), <sup>10</sup> SR	1 (0.6%) foot with complex regional pain syndrome	Based on 8 relevant studies involving 175 feet. <sup>a</sup>		
Baryeh et al. (2022), <sup>10</sup> SR	28 of 175 (16%) with sinus tarsi pain	Based on 8 relevant studies involving 175 feet. <sup>a</sup>		
Fu et al. (2024), <sup>13</sup> NRS	60 (25.42%) cases with sinus tarsi pain	Sinus tarsi pain was the most common complication and most common cause of implant removal. Of the 60 cases, 23 feet experienced symptom relief conservative treatment.		
Fang Junxian et al. (2020), <sup>20</sup> NRS	6 (27.3%) adults with sinus tarsi pain	—		
Ozan et al. (2015), <sup>23</sup> before-and- after study	3 of 26 (11.5%) feet with sinus tarsi pain	—		
Device revision				
Agnew et al. (2023), <sup>18</sup> before-and- after study	3 of 53 (5.6%) implants⁵	—		
Infection				
Baryeh et al. (2022), <sup>10</sup> SR	1 (0.6%) foot with surgical site infection	Based on 8 relevant studies.		
Fractures				
Baryeh et al. (2022), <sup>10</sup> SR	1 of 175 (0.6%) feet experienced a stress fracture	Based on 8 relevant studies.ª		
Insufficient foot correction				
Baryeh et al. (2022), <sup>10</sup> SR	1 of 175 (0.6%) feet experienced insufficient foot correct	Based on 8 relevant studies.ª		
	Recurrence of def	ormity		
Baryeh et al. (2022), <sup>10</sup> SR	1 of 175 (0.6%) feet experienced a reoccurrence of foot deformity	Based on 8 relevant studies.ª		
Ozan et al. (2015), <sup>23</sup> before-and- after study	1 of 26 (3.8%) feet	—		
Muscle and tendon complications				
Fu et al. (2024), <sup>13</sup> NRS	2 (0.85%) cases had Achilles tendon tension	—		
Fu et al. (2024), <sup>13</sup> NRS	2 (0.85%) cases had peroneal spasm	_		
Fu et al. (2024), <sup>13</sup> NRS	2 (0.85%) cases experienced decline in muscle strength	—		
Wound healing issues				
Fu et al. (2024), <sup>13</sup> NRS	1 (0.42%) case had poor wound healing	_		
Kolodziej et al. (2023), <sup>21</sup> before- and-after study	1 of 41 (2.4%) individuals with a wound healing issue <sup>b</sup>	"The issue self-resolved without any negative impact on the outcome."		

Study, study design	Result	Notes		
Other				
Fu et al. (2024), <sup>13</sup> retrospective cohort	1 (0.42%) case had a foreign body sensation	_		
Agnew et al. (2023), <sup>18</sup> before-and- after study	8 of 53 (15.1%) implants experienced "ongoing device related issues" <sup>b</sup>	For this study, this category includes pain, stiffness, general discomfort, feeling of weak ankle and instability, lack of correction or improvement, difficulty walking, difficulty wearing shoes, neuropathy, swelling, limited range of motion, and occasional feelings of cramps art night.		

NRS = nonrandomized study; SR = systematic review.

Note: Most studies in this table were conducted on adults with pes planus except for the Agnew et al. study<sup>18</sup> and the Kolodziej et al. study.<sup>21</sup>

<sup>a</sup>For the systematic review by Baryeh and colleagues,<sup>10</sup> a total of 8 studies were included. They had difficulties ascertaining whether complications were from the interest group in 1 study.

<sup>b</sup>The study was conducted on individuals with other foot conditions.

Note: This table has not been copy-edited.

## **Appendix 5: References of Potential Interest**

Please note that this appendix has not been copy-edited.

#### Nonrandomized Studies

#### Mixed Population (Includes Pediatric Population)

Stichnoth M, Luders KA, Hell AK, Stinus H. Comparative study of subtalar arthroereisis, medializing calcaneal osteotomy and the combination of both techniques for the treatment of symptomatic adult flatfeet. *J Foot Ankle Surg*. 2024 Oct 29;29:29. PubMed: PM39523149.

Jain A, Gupta G, Gupta A. Short Term Clinico-Radiological Outcome of Extra Osseous Talo-Tarsal Stabilization (EOTTS) in Flat Foot: An Indian Perspective. *Indian J Orthop*. 2022 Jan;56(1):94-102. PubMed: PM35070148.

#### Case Series

Mercun A, Kovacic B, Suhodolcan L, Drobnic M. Patient Outcomes Following Extra-Osseous Talo-Tarsal Stabilization for Foot Hyperpronation. J Foot Ankle Surg. 2022 Mar-Apr;61(2):318-322. PubMed: PM34600818.

#### **Guidelines and Recommendations**

#### Unclear Methodology

College of Chiropodists of Ontario. Subtalar Joint Arthroereisis Procedure. Accessed November 21 2024, <a href="https://www.cocoo.on.ca/pdf/guidelines/subtalar\_joint\_arthroereisis.pdf">https://www.cocoo.on.ca/pdf/guidelines/subtalar\_joint\_arthroereisis.pdf</a>.

#### Alternative Methods

Salga M, Gatin L, Deltombe T, et al. International Recommendations to Manage Poststroke Equinovarus Foot Deformity Validated by a Panel of Experts Using Delphi. Arch Phys Med Rehabil. 2023 03;104(3):372-379. PubMed: PM36030892.

#### **Review Articles**

Blue Shield of California. Subtalar Arthroereisis. Accessed November 21 2024, <u>https://www.blueshieldca.com/content/dam/bsca/en/provider/docs/medical-policies/Subtalar-Arthroereisis.pdf</u>.



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