2026 Clinical Practice Guidelines on the Screening and Management of Clubfoot in Children

30 March 2026

Annex. Evidence Summaries

Table of Contents

GUIDELINE QUESTION 1: Should routine screening for foot deformities (e.g., clubfoot) be conducted for all newborns by primary care providers, such as midwives, nurses, pediatricians, and family physicians?

Research Question: Among all newborns, how effective and safe is routine screening for foot deformities compared with no routine screening when conducted by primary care providers (e.g., midwives, nurses, pediatricians, family physicians) on the early detection of foot deformities (e.g., clubfoot)?	
Population	Among all newborns
Intervention / Treatment	Routine screening for deformities conducted by primary care providers (e.g., midwives, nurses, pediatricians, family physicians)
Comparator	No routine screening
Outcomes	• Early detection of foot deformities (e.g., clubfoot) • Overdiagnosis/labeling
Subgroups (if any)	Not applicable
Methods	Observational studies; randomized controlled trials (RCTs); systematic reviews (SRs) of observational studies/diagnostic accuracy studies

Evidence Reviewer: Hannah Haile P. Almenario, MD, MPM
Date of Last Search: June 03, 2025

Statement of the Evidence

Among all newborns, routine screening by primary care providers may result in an increase in early detection of foot deformities. It may have little to no effect on functional outcomes, recurrence of foot deformities, or treatment complexity but the evidence is very uncertain.
The overall certainty of evidence is VERY LOW.

Review Methods

A comprehensive and systematic search of local and internal databases was done from database inception until June 03, 2025 through MEDLINE, Cochrane CENTRAL, HERDIN, and clinicaltrials.gov using the combined MeSH and free-text searches on newborn, clubfoot, talipes equinovarus, screening, early referral, and primary care providers. Only studies with the outcome of early detection, overdiagnosis, or labeling of foot deformities were included. The references of included studies were also hand searched to identify additional studies that may not have appeared in the database search. No language restrictions were applied. Additional search was done for unpublished studies through communications with authors or known researchers. Full search strategy is presented in Table Q1.2. The methodological quality of the included studies was assessed using the Newcastle-Ottawa Scale (NOS), Quality Assessment of Diagnostic Accuracy Studies 2 (QUADAS-2), or adaptations from previous systematic reviews, as applicable and appropriate, and the certainty of evidence was determined using the Grading, Recommendation, Assessment, Development, and Evaluations (GRADE) framework. A review of international guidelines on clubfoot was also conducted.

Recommendations from Other Groups

A summary of recommendations for CTEV screening is presented in Table Q1.1. While these guidelines highlight the lack of evidence to determine the optimal timing of screening, they uniformly recommend that newborns be examined at birth. Physical examination should be performed to identify any non-correctible deformities, enabling timely detection of CTEV and appropriate referral.

Annex Table Q1.1. Summary of Recommendations from Other Groups

Group or Agency	Recommendation	Strength of Recommendation Certainty/Quality of Evidence
NHS	All newborn babies are examined after birth and this examination should include an assessment for foot deformities. All newborn babies should have full passive ankle/foot range of movement (ROM) checked at birth. If the baby with a foot deformity has a full ROM this is classed as FULLY CORRECTABLE and is therefore normal. No referral is required as no intervention is needed. Inability to achieve full passive ankle/foot ROM is classed as NOT FULLY CORRECTABLE. ALL newborn feet that are NOT FULLY CORRECTABLE require a referral to paediatric physiotherapy as soon as possible.	No GRADE recommendation
American Academy of Pediatrics	The evaluation of a newborn with a clubfoot deformity involves a thorough general examination to determine overall health and development, exclude syndromes and neurologic conditions (eg, spina bifida, arthrogryposis, limb formation anomalies), and provide a focused examination of the foot and limb. Examination of all joints for range of motion and stability, including the hips, is important, as is examination of lower extremities for equal length and symmetry. The severity of a newborn foot deformity is determined more by the foot's flexibility than by its appearance. Newborn foot deformities that can be easily manipulated into an overcorrected position are considered positional rather than true clubfoot deformities.	-
Dutch guidelines	Clinical Question 3: What is the optimal method to be used for the diagnosis and classification of a clubfoot? • Use physical examination to establish a clubfoot diagnosis; • Do not use standard radiological examination; radiological examination should only be used when there are doubts about the diagnosis, or when there is a lack of progression of the foot correction, or if there is a recurrence; • Use both the Diméglio and the Pirani score as classification systems in order to obtain sufficient long-term data for both classification systems.	Because there is international consensus on defining the deformities in clubfoot, a systematic literature analysis was not required. Instead, authoritative standard works in orthopedics were used (Hefti 2007, Herring 2007).

Ongoing Studies and Research Gaps

There are currently no ongoing studies directly evaluating the safety and effectiveness of routine screening for foot deformities by primary care providers compared to no screening. Given the higher prevalence of clubfoot and the increased burden of neglected cases in low-income countries, this remains an important gap in the evidence. Future research should prioritize this area to better inform public health policy and optimize early management strategies.

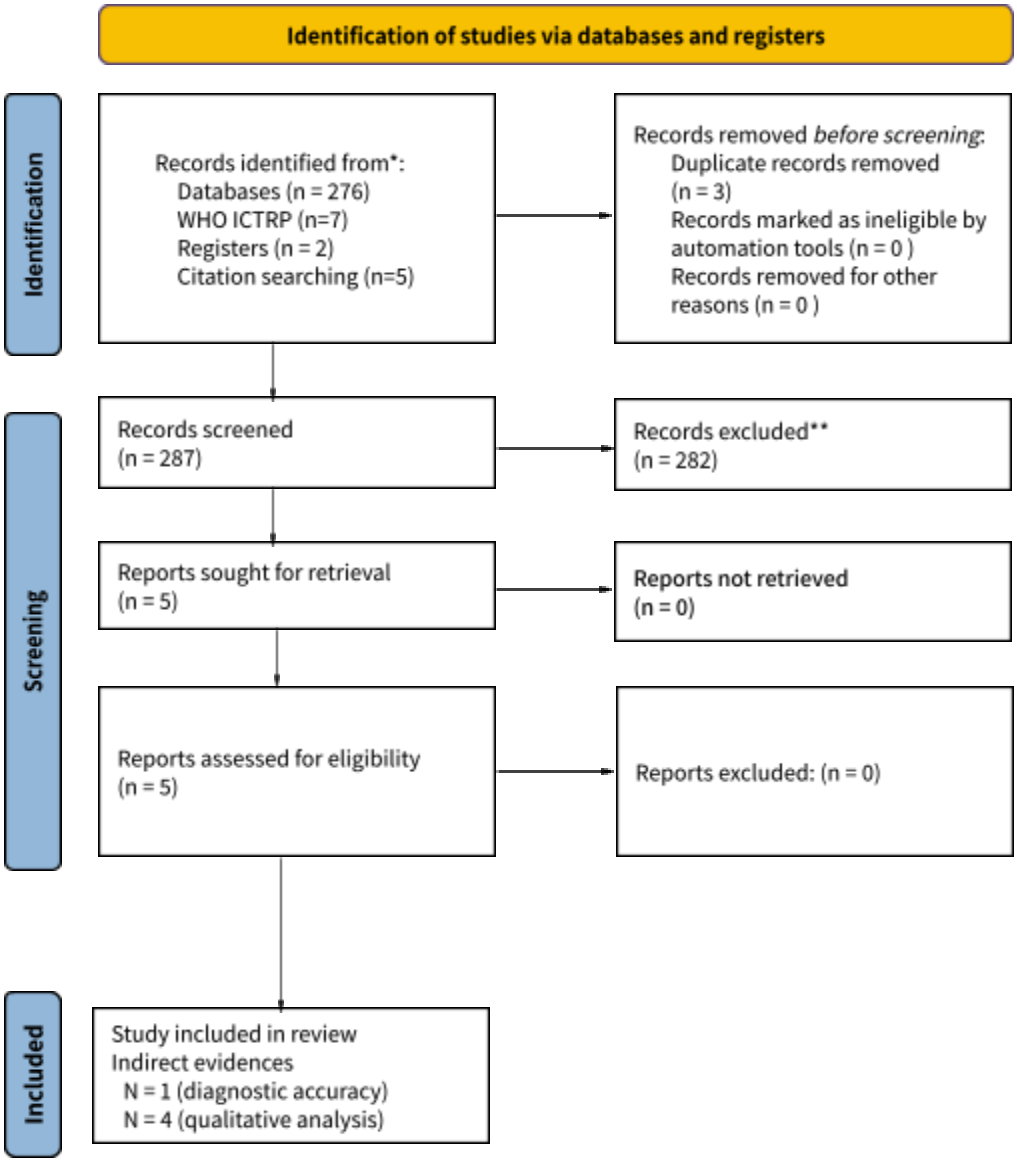
Search Strategy

Annex Table Q1.2. Search Strategy (as of June 3, 2025).

Database	Search strategy / Search terms	Date and time of search	RESULTS	
			Yield	Eligible
MEDLINE	("Infant, Newborn"[Mesh] OR "Infant"[Mesh] OR "newborn*" OR "neonat*" OR "infant*" OR "baby" OR "babies") AND ("Foot Deformities, Congenital"[Mesh] OR "Clubfoot"[Mesh] OR "Musculoskeletal Abnormalities"[Mesh] OR "clubfoot" OR "club foot" OR "talipes equinovarus" OR "foot deformit*" or "congenital foot anomaly" OR "idiopathic clubfoot" OR "atypical clubfoot" OR "neuromuscular clubfoot" OR "syndromic clubfoot") AND ("Mass Screening"[Mesh] OR "Early Diagnosis"[Mesh] OR "Physical Examination"[Mesh] OR "Preventive Health Services"[Mesh] OR "referral and consultation"[Mesh] OR "referral" OR "consultation" OR "early referral" OR "screen*" OR "screening program*" OR "early detect*" OR "early diagnosis" OR "routine check*" OR "neonatal examination" OR "newborn assessment" OR "physical exam*" OR "well baby check" OR "pediatric screening") AND ("Primary Health Care"[Mesh] OR "Health Personnel"[Mesh] OR "Pediatricians"[Mesh] OR "Nurses"[Mesh] OR "Midwifery"[Mesh] OR "primary care provider*" OR "midwives" OR "midwifery" OR "nurses" OR "family doctor*" OR "family physician*" OR "pediatrician*" OR "health worker*" OR "general practitioner*" OR "community health worker")	3 Jun 2025	253	0
CENTRAL	("Infant, Newborn"[Mesh] OR "Infant"[Mesh] OR "newborn*" AND "neonate" OR "infant" OR "baby" OR "babies") AND ("Foot Deformities, Congenital"[Mesh] OR "Clubfoot"[Mesh] OR "Musculoskeletal Abnormalities"[Mesh] OR "clubfoot" OR "club foot" OR "talipes equinovarus" OR "foot deformity*" or "congenital foot anomaly" OR "idiopathic clubfoot" OR "atypical clubfoot" OR "neuromuscular clubfoot" OR "syndromic clubfoot") AND ("Mass Screening"[Mesh] OR "Early Diagnosis"[Mesh] OR “Referral and consultation”[Mesh] OR "Physical Examination"[Mesh] OR "Preventive Health Services"[Mesh] OR “early referral” OR "screening program*" OR "early detection" OR "early diagnosis" OR "routine check" OR "neonatal examin" OR "newborn assessment" OR "physical exam*" OR "well baby check" OR "pediatric screening")	3 Jun 2025	23	0

Database	Search strategy / Search terms	Date and time of search	RESULTS	
			Yield	Eligible
WHO ICTRP	("clubfoot" or "clubfoot deformity" or "talipes equinovarus" or "foot deformity") and ("screening" or "referral" or "physical examination" or "diagnosis")	3 Jun 2025	7	0
HERDIN	("clubfoot" or "clubfoot deformity" or "talipes equinovarus" or "foot deformity") and ("screening" or "referral" or "physical examination" or "diagnosis")	3 Jun 2025	0	0
Clinicaltrials.gov	("clubfoot" or "clubfoot deformity" or "talipes equinovarus" or "foot deformity") and ("screening" or "referral" or "physical examination" or "diagnosis")	3 Jun 2025	2	0
Medrix and Biorxiv	("clubfoot" or "clubfoot deformity" or "talipes equinovarus" or "foot deformity") and ("screening" or "referral" or "physical examination" or "diagnosis")	3 Jun 2025	0	0

PRISMA Flow Diagram



Annex Figure Q1.1. PRISMA flow diagram.

Included Studies

Characteristics of Included Studies

Annex Table Q1.3. Study characteristics.

Author/Year	Study design	Country	Number of patients	Intervention group(s)	Control	Outcomes	Remarks
Sadhi, 2024	Cross-sectional	Malaysia	1214 newborn feet screened by non-orthopedic trained personnel	Screened with structured questionnaire	Screened without structured questionnaire	Diagnostic accuracy	INDIRECT Both groups screened for foot deformities
Khan, 2021	Longitudinal observational cohort (secondary data)	Bangladesh	93 children	Complying to the Ponseti treatment method	N/A	Functional outcomes (standing, walking, squatting, running)	INDIRECT Effectiveness of linked management
Van Schelven, 2022	Systematic review and meta-analysis	International	2987 idiopathic clubfoot	Treated by Ponseti method with recurrence or clubfoot deformity	N/A	Prognostic factors	INDIRECT Effectiveness of linked management
Kardm, 2023	Retrospective cohort	Saudi Arabia	89 children with CTEV	Different management options for clubfoot	N/A	Demographic profile Recurrence rate	INDIRECT Effectiveness of linked management
Dim 2023	Prospective, cohort (single-arm)	Nigeria	67 children with CTEV	Corrective manipulation and subsequent management	N/A	Factors associated with >/10 more castings to achieve correction	INDIRECT Effectiveness of linked management

Quality Assessment of Included Studies

Annex Table Q1.4. Quality of included studies for diagnostic accuracy (QUADAS-2).

Study ID	Patient selection	Index Test	Reference Standard	Flow and Timing	Patient selection	Index Test	Reference Standard	Overall
Sahdi 2024	Low	Low	High	Low	Low	Low	Low	Moderate

Annex Table Q1.5. Quality of included studies for observational study NOS).

Study ID	D1	D2	D3	D4	D5	D6	D7	D8	Overall
Khan 2021	★	☆	★	★	☆	★	★	☆	5/9 Serious
Kardm 2023	★	☆	★	★	☆	★	☆	★	5/9 Serious
Dim 2023	☆	☆	★	★	☆	★	★	★	4/9 Serious

D1 (Representativeness of the exposed cohort); D2 (selection of non-exposed cohort); D3 (ascertainment of exposure); D4 (outcome not present at start); D5 (control for confounders); D6 (assessment of outcomes); D7 (follow-up long enough); D8 (adequacy of follow-up)

Annex Table Q1.6. Overall quality of included studies for prognosis (Adapted Cochrane Prognostic RoB Tool).

Study ID	Selection	Detection	Attrition	Reporting	Overall*
Van Schelven 2022	Moderate	Serious	Moderate	Serious	Serious

*Synthesized risk of bias overall judgment as reported by the authors of the systematic review across 34 included studies.

GRADE Evidence Profile table

Annex Table Q1.7. GRADE Evidence Profile.

Question: Should routine screening for foot deformities (e.g., clubfoot) be conducted for all newborns by primary care providers, such as midwives, nurses, pediatricians, and family physicians?

Sensitivity	1.00 (95% CI: 0.15 to 1.00)
Specificity	1.00 (95% CI: 0.99 to 1.00)

Prevalences	0.2%	2%	5%

Outcome (Structured Screening)	№ of studies (№ of patients)	Study design	Factors that may decrease certainty of evidence					Effect per 1,000 patients tested			Test accuracy CoE
			Risk of bias	Indirectness	Inconsistency	Imprecision	Publication bias	pre-test probability of 0.2%	pre-test probability of 2%	pre-test probability of 5%	
True positives (patients with clubfoot)	1 studies 612 patients	cross-sectional (cohort type accuracy study)	serious[a]	serious[b]	not serious	not serious	none	2 (0 to 2)	20 (3 to 20)	50 (8 to 50)	⨁⨁◯◯ Low[a,b]
False negatives (patients incorrectly classified as not having clubfoot)								0 (0 to 2)	0 (0 to 17)	0 (0 to 42)	
True negatives (patients without clubfoot)	1 studies 612 patients	cross-sectional (cohort type accuracy study)	serious[a]	serious[b]	not serious	not serious	none	998 (988 to 998)	980 (970 to 980)	950 (941 to 950)	⨁⨁◯◯ Low[a,b]
False positives (patients incorrectly classified as having clubfoot)								0 (0 to 10)	0 0 to 10)	0 (0 to 9)	

Explanations

a. Orthopedic experts were unblinded to results of the house officers
b. All newborns were routinely screened, only differing in the screening structure

Annex Table Q1.8. GRADE Evidence Profile.

Sensitivity	0.66 (95% CI: 0.09 to 0.99)
Specificity	0.94 (95% CI: 0.92 to 0.96)

Prevalences	0.2%	2%	5%

Outcome (Unstructured Screening)	№ of studies (№ of patients)	Study design	Factors that may decrease certainty of evidence					Effect per 1,000 patients tested			Test accuracy CoE
			Risk of bias	Indirectness	Inconsistency	Imprecision	Publication bias	pre-test probability of 0.2%	pre-test probability of 2%	pre-test probability of 5%	
True positives (patients with clubfoot)	1 studies 602 patients	cross-sectional (cohort type accuracy study)	serious[a]	serious[b]	not serious	not serious	none	1 (0 to 2)	13 (2 to 20)	33 (5 to 50)	⨁⨁◯◯ Low[a,b]
False negatives (patients incorrectly classified as not having clubfoot)								1 (0 to 2)	7 (0 to 18)	17 (0 to 45)	
True negatives (patients without clubfoot)	1 studies 602 patients	cross-sectional (cohort type accuracy study)	serious[a]	serious[b]	not serious	not serious	none	940 (918 to 957)	923 (901 to 940)	895 (874 to 911)	⨁⨁◯◯ Low[a,b]
False positives (patients incorrectly classified as having clubfoot)								58 (41 to 80)	57 (40 to 79)	55 (39 to 76)	

Explanations

a. Orthopedic experts were unblinded to results of the house officers
b. All newborns were routinely screened, only differing in the screening structure

Annex Table Q1.9. GRADE Evidence Profile.

Question: Should routine screening for foot deformities (e.g., clubfoot) be conducted for all newborns by primary care providers, such as midwives, nurses, pediatricians, and family physicians?

Certainty assessment							Impact	Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations			
Functional outcomes									
1	non-randomised studies	serious[a]	not serious	very serious[b]	serious[c]	none	A longitudinal study in Bangladesh (n=93) reported that by age five, 100% of children treated with the Ponseti method for clubfoot could perform all key functional tasks (standing, squatting, walking, and running), up from 16% at baseline. The study did not involve or describe routine screening by primary care providers	⨁◯◯◯ Very low[a,b,c]	
Recurrence									
18	non-randomised studies	serious[d]	not serious	very serious[b]	serious[c]	none	Most included studies did not find a significant association between later treatment (>3 months) and recurrence of clubfoot, except for one study (Willis et al., 2009).	⨁◯◯◯ Very low[b,c,d]	
Treatment complexity (Number of casts >/10)									
1	non-randomised studies	serious[e]	not serious	very serious[b]	serious[f]	none	A study of 67 children (mean age 31.6 months) treated with the Ponseti method, found callosity (OR = 8.87, 95% CI: 1.08–73.20) and high Pirani score (OR = 3.49) were significantly associated with needing ≥10 casts. Older age showed a modest non-significant effect (OR = 1.03, 95% CI: 0.99–1.07).	⨁◯◯◯ Very low[b,e,f]	

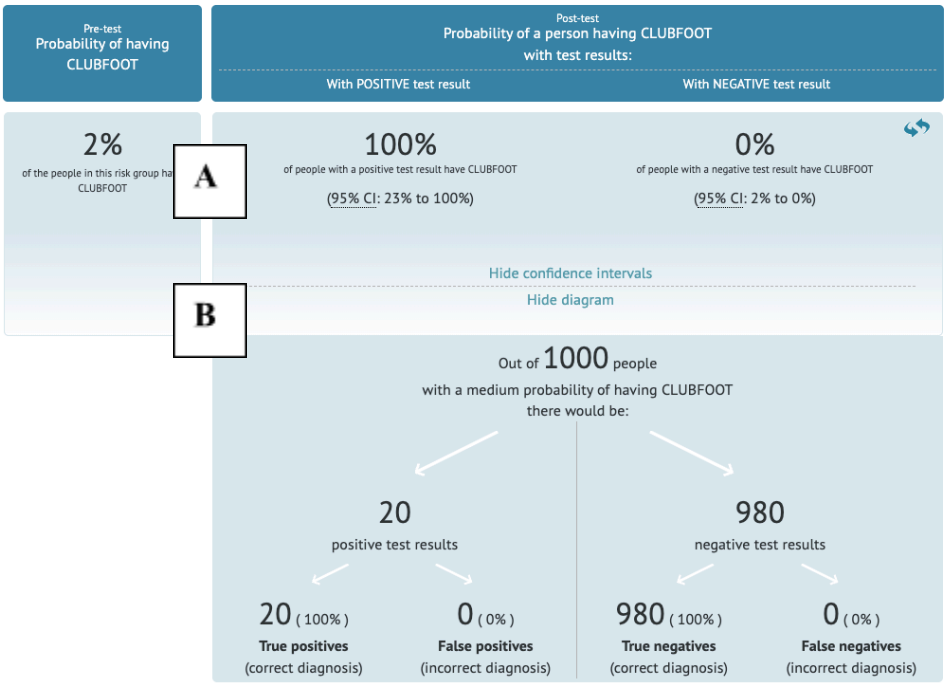
CI: confidence interval

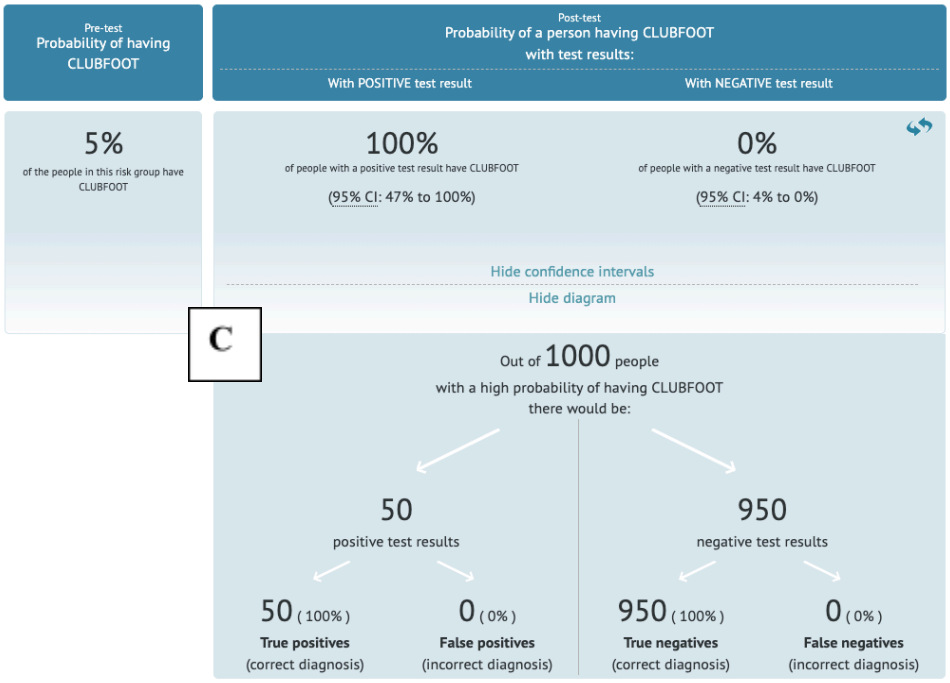
Explanations

a. Lack of control group, high exclusion rate, and no adjustment for confounders. Outcomes were assessed descriptively without blinding or standardized measurement validation.
b. Assessed treatment outcomes, not the effect of routine screening by primary care providers.
c. Absence of effect estimates, confidence intervals
d. Most studies had at least one high-risk domain, especially in detection (e.g., self-reported brace adherence) and reporting (e.g., lack of multivariable adjustment)
e. Absence of adjustment for confounders and unblinded outcome assessment
f. Wide confidence interval, small sample size

GRADE Evidence Interactive SOF Profile

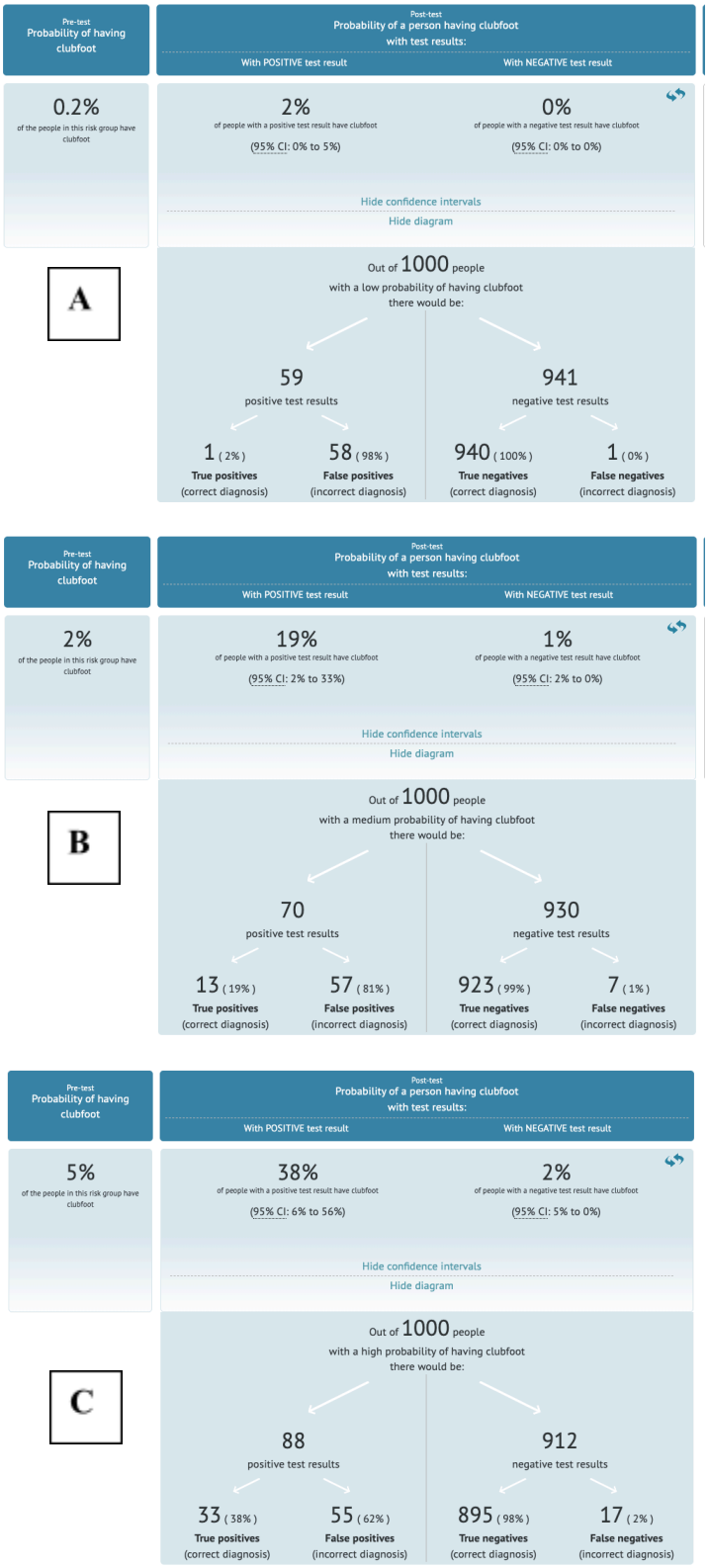
Structured Screening





Annex Figure Q1.2. Interactive SOF profile for structured screening with pre-test probability of A) 0.2% B) 2% C) 5%.

Unstructured Screening



Annex Figure Q1.3. Interactive SOF profile for unstructured screening with pre-test probability of A) 0.2% B) 2% C) 5%.

GUIDELINE QUESTION 2: Should the Ponseti method be used instead of conservative non-Ponseti methods to improve clinical and functional outcomes among infants with clubfoot?

Research Question: Among infants with clubfoot, how effective is the Kite method or French functional method compared to Ponseti method in reducing adverse events, relapse/recurrence rates, and improving clinical and functional outcomes?	
Population	Infants with congenital talipes equinovarus (clubfoot)
Intervention / Treatment	Ponseti method
Comparator	French functional method and Kite method
Outcomes	Relapse requiring surgery, safety (adverse events), treatment/correction rate, final functional outcomes, recurrence of deformity, Pirani score improvement, and complications
Subgroups (if any)	Children; neonates
Methods	Observational studies; randomized controlled trials (RCTs); systematic reviews (SRs) of observational studies/diagnostic accuracy studies

Evidence Reviewers: Miguel Gaston M. Agcaoili, RND, and Aldrich Ivan Lois D. Burog, MD, MSc (cand.)
Date of Last Search: July 26, 2025

Statement of the Evidence

Ponseti method vs. French functional method
Among children with idiopathic clubfoot:

- Ponseti method (PM) may reduce relapse requiring surgery but the evidence is very uncertain (very low certainty of evidence).
- PM may have little to no effect on correction rates, but the evidence is very uncertain (very low certainty of evidence).
- PM compared with the French functional method may improve final functional outcomes (very low certainty of evidence), but the evidence is very uncertain.
- PM may increase Pirani scores (improvement) but the evidence is very uncertain (very low certainty of evidence).
- The PM may make little to no difference in terms of relapse rate but the evidence is very uncertain.

The overall certainty of the evidence is **very low**.

Ponseti method vs. Kite method
Among children with idiopathic clubfoot treated conservatively:

- Ponseti method (PM) probably results in lesser relapse requiring surgery (moderate certainty) and likely results in an increase in correction rates (moderate certainty evidence).
- PM may make little to no difference in terms of relapse rates and may improve Pirani scores, but the evidence is very uncertain. Its effect on complication rates is also uncertain.

The overall certainty of the evidence is **very low**.

Review Methods

A systematic search of electronic databases was conducted from July 7 to 26, 2025, to find relevant studies to the research question, including MEDLINE (via Pubmed), Scopus, Web of Science, CINAHL (Cumulative Index to Nursing and Allied Health Literature) Ultimate, HERDIN (Health Research and Development Information Network), and ClinicalTrials.gov. medRxiv was also utilized to identify preprints. Citation searching from initially included studies and hand searching were also performed. Medical Subject Headings (MeSH) and free-text terms were used to increase search sensitivity, including “Infant,” “Child,” “Pediatrics,” “neonate,” “newborn,” “clubfoot,” “club feet,” “Talipes Equinovarus,” “Kite's method,” “Kite method,” “Kite Technique,” “French functional method,” “French method,” “French physical therapy,” “French functional (physiotherapy) method,” “French functional treatment,” “French functional therapy,” “Ponseti method,” “Ponseti’s method,” “Ponseti’s technique,” “Ponseti technique,” and “Ponseti manipulation.” Boolean operations were utilized to structure the search strategy. No filters were used across all databases. The complete search strategy for this evidence summary is reflected in Appendix 1.

Studies comparing the Ponseti method (PM) with the Kite method (KM) and/or the French functional method (FFM) among infants with clubfoot in inpatient or outpatient settings were eligible for inclusion. RCTs were prioritized among study designs, but in the absence of RCTs, cohort or case-control studies were considered for inclusion. The prioritized outcomes of interest were need for surgery, safety (adverse events), treatment success/correction rate, final functional outcomes, recurrence of deformity/relapse rate, Pirani score improvement, and complications.

Studies on stakeholder values, preferences, acceptability, equity, and feasibility were obtained through a systematic search and supplementary free-text searches. Additional data were gathered during consensus panel discussions.

Quality of RCTs was assessed using the Cochrane RoB 2 tool. Cohort studies were assessed using the ROBINS-I tool. Visualizations of the risk-of-bias assessments were generated using the robvis (Risk-Of-Bias VISualization) application. The certainty of the body of evidence for each outcome was assessed using the Grading of Recommendation, Assessment, Development, and Evaluation (GRADE) approach, with results summarized in GRADE Evidence Profiles. RevMan 5.4 was used to generate forest plots.

Recommendations from Other Groups

Annex Table Q2.1. Summary of recommendations from other groups.

Group or agency	Recommendation	Strength of Recommendation and Certainty of Evidence
British Society of Children's Orthopaedic Surgery	Regarding the treatment of idiopathic clubfoot deformity in infants and children up to walking age, the Ponseti technique should be the first-line treatment.	Strength of recommendation. Quality of evidence not reported.
Dutch Orthopedic Association	• Treat primary clubfoot with the standard Ponseti method. • Do not use plaster casting according to the Kite method. • Do not use synthetic plaster casts but Plaster of Paris for the Ponseti method. • Only carry out surgery for primary treatment for idiopathic clubfoot as described in the standard Ponseti method.	Strong recommendation*, very low quality of evidence. **GRADE definition. Indicates that most patients should receive the intervention, clinicians can adopt it as standard care, and policy-makers can use it as a benchmark; benefits clearly outweigh harms.*
ANAES	For treatment by serial casting followed by application of a brace, a plaster cast made by the Ponseti technique, combined if necessary with Achilles tendon tenotomy, reduces the rate of surgical posteromedial soft-tissue release compared to the use of Kite casts.	Grade C* **ANAES definition. A grade C guideline is based on studies of a lower level of evidence, e.g., case-control studies or case series.*

No practice guideline recommendation was retrieved related to FFM.

Ongoing Studies and Research Gaps

No ongoing studies were identified comparing PM, KM, and FFM through database searching. Limited RCTs comparing PM and KM were identified, with some showing a high risk of bias. No RCTs were identified comparing PM and FFM. Multiple observational studies were retrieved comparing PM and FFM, although serious methodological limitations were observed.

There is little to no evidence on resource implications, stakeholder values, preferences, acceptability, and equity and feasibility for KM and FFM. No relevant studies were retrieved in the Philippines comparing these conservative methods.

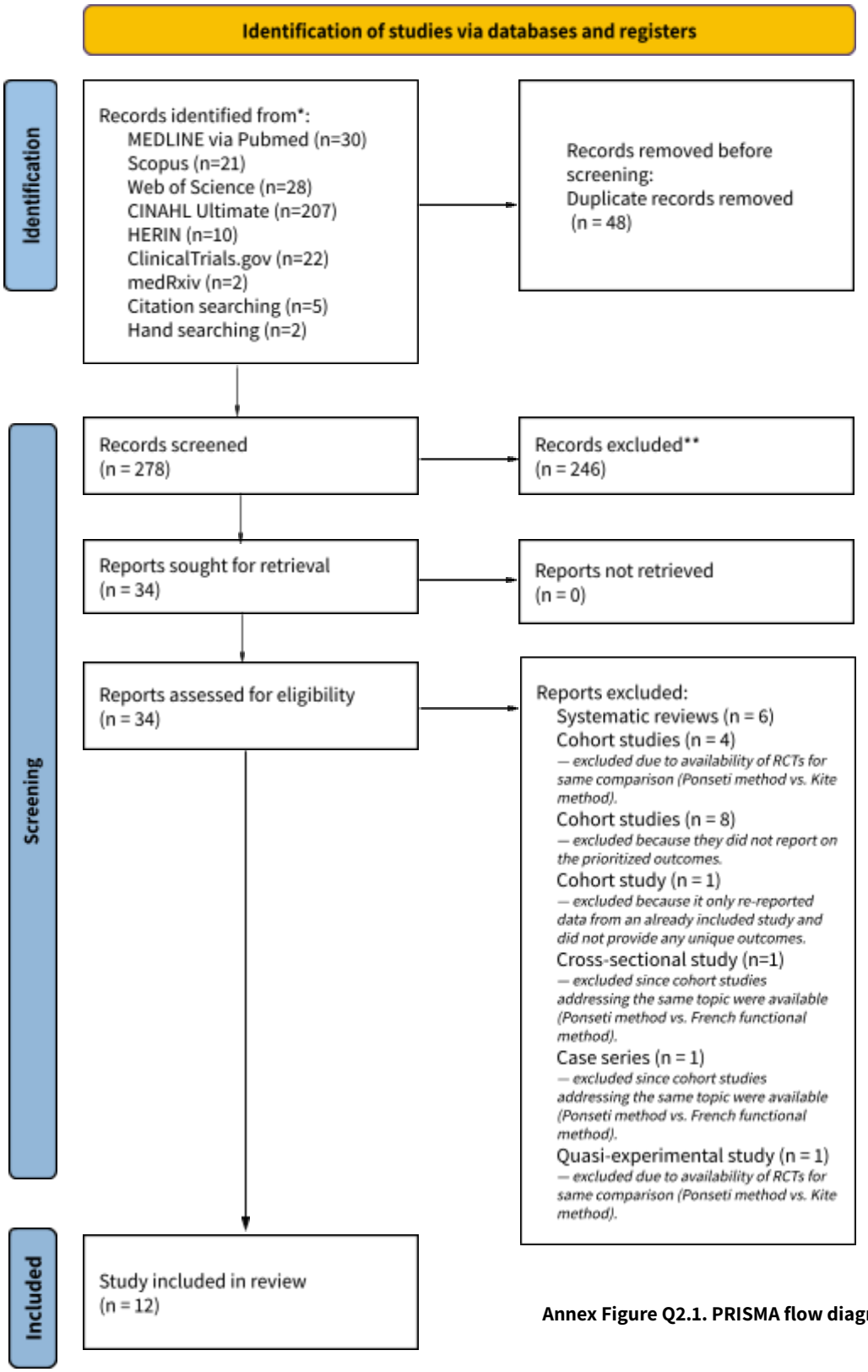
Search Strategy

Annex Table Q2.2. Search Strategy (as of July 26, 2025).

Database and Register	Syntax	Date of Search	Yield
MEDLINE via PubMed	((("Infant"[MeSH]) OR ("Child"[MeSH]) OR ("Pediatrics"[MeSH]) OR (infant*[tiab]) OR (child*[tiab]) OR (pediatric*[tiab]) OR (neonate*[tiab]) OR (newborn*[tiab])) AND (("clubfoot"[MeSH]) OR ("club foot"[tiab]) OR (clubfoot[tiab]) OR (clubfeet[tiab]) OR ("club feet"[tiab]) OR ("Talipes Equinovarus"[tiab]))) AND ((("Kite's method"[tiab]) OR ("Kite method"[tiab]) OR ("Kite Technique"[tiab])) OR (("French functional method*"[tiab]) OR ("French method"[tiab]) OR ("French physical therapy*"[tiab]))) AND (("Ponseti method"[tiab]) OR ("Ponseti's method"[tiab]) OR ("Ponseti's technique"[tiab]) OR ("Ponseti technique"[tiab]) OR ("Ponseti manipulation"[tiab]))	July 7, 2025	30
Scopus	(((TITLE-ABS(infant*) OR TITLE-ABS(child*) OR TITLE-ABS(pediatric*) OR TITLE-ABS(neonate*) OR TITLE-ABS(newborn*)) AND (TITLE-ABS("clubfoot") OR TITLE-ABS("club foot") OR TITLE-ABS(clubfoot) OR TITLE-ABS(clubfeet) OR TITLE-ABS("club feet") OR TITLE-ABS("Talipes Equinovarus"))) AND ((TITLE-ABS("Kite's method") OR TITLE-ABS("Kite method") OR TITLE-ABS("Kite Technique")) OR (TITLE-ABS("French functional method*") OR TITLE-ABS("French method") OR TITLE-ABS("French physical therapy*"))) AND (TITLE-ABS("Ponseti method") OR TITLE-ABS("Ponseti's method") OR TITLE-ABS("Ponseti's technique") OR TITLE-ABS("Ponseti technique") OR TITLE-ABS("Ponseti manipulation")))	July 7, 2025	21
Web of Science	(((TS=(infant*) OR TS=(child*) OR TS=(pediatric*) OR TS=(neonate*) OR TS=(newborn*)) AND (TS=("clubfoot") OR TS=("club foot") OR TS=(clubfoot) OR TS=(clubfeet) OR TS=("club feet") OR TS=("Talipes Equinovarus"))) AND ((TS=("Kite's method") OR TS=("Kite method") OR TS=("Kite Technique")) OR (TS=("French functional method*") OR TS=("French method") OR TS=("French physical therapy*"))) AND (TS=("Ponseti method") OR TS=("Ponseti's method") OR TS=("Ponseti's technique") OR TS=("Ponseti technique") OR TS=("Ponseti manipulation")))	July 7, 2025	28
CINAHL Ultimate	((TI infant* OR AB infant* OR TI child* OR AB child* OR TI pediatric* OR AB pediatric* OR TI neonate* OR AB neonate* OR TI newborn* OR AB newborn*) AND (TI "clubfoot" OR AB "clubfoot" OR TI "club foot" OR AB "club foot" OR TI clubfeet OR AB clubfeet OR TI "club feet" OR AB "club feet" OR TI "Talipes Equinovarus" OR AB "Talipes Equinovarus") AND ((TI "Ponseti method" OR AB "Ponseti method" OR TI "Ponseti's method" OR AB "Ponseti's method" OR TI "Ponseti technique" OR AB "Ponseti technique" OR TI "Ponseti manipulation" OR AB "Ponseti manipulation") OR (TI "Kite method" OR AB "Kite method" OR TI "Kite technique" OR AB "Kite technique") OR (TI "French functional method" OR AB "French functional method" OR TI "French functional treatment" OR AB "French functional treatment" OR TI "French functional therapy" OR AB "French functional therapy" OR TI "French physiotherapy" OR AB "French physiotherapy" OR TI "French method" OR AB "French method")))	July 7, 2025	207

Database and Register	Syntax	Date of Search	Yield
HERDIN	Clubfoot	July 7, 2025	10
Clinical Trials Gov	clubfoot AND (Ponseti OR "Ponseti method" OR "Ponseti technique" OR Kite OR "Kite method" OR "Kite technique" OR French OR "French functional method" OR "French method" OR "French physiotherapy")	July 7, 2025	22
medRxiv	clubfoot AND (Ponseti OR Kite OR "French functional method")	July 7, 2025	2
Citation searching	N/A	July 25, 2025	6
Hand searching	“Ponseti” “French method” “Kite method”	July 26, 2025	1
		Total Yield	**327**

PRISMA Flow Diagram



Annex Figure Q2.1. PRISMA flow diagram.

Included Studies

Characteristics of Included Studies

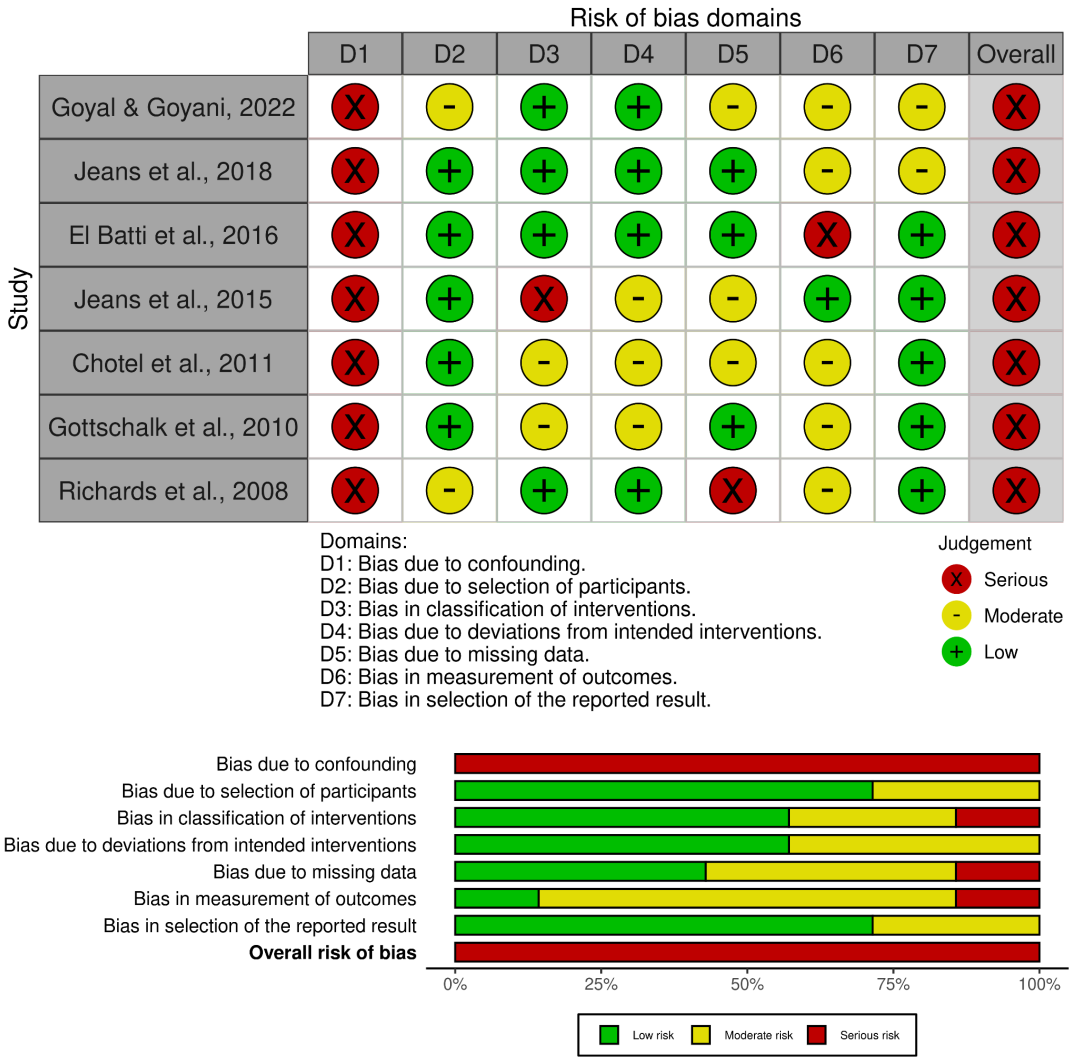
Annex Table Q2.3. Characteristics of Included Studies for Ponseti method vs. French functional method.

Author, Year	Study design	Country	Healthcare Setting	Number of patients	Population	Outcomes Measured
Goyal & Goyani, 2022	Prospective cohort study	India	Hospital-based clinics	60 patients (90 clubfeet)	• Infants aged ≤3 months • Diagnosed with idiopathic clubfoot, • Did not receive prior treatment	• Correction rate • Recurrence rate • Pirani score improvement
Jeans et al., 2018	Prospective cohort study	United States of America	Hospital-based clinics	175 patients (263 clubfeet)	Infants diagnosed with idiopathic clubfoot	• Correction rate
El Batti et al., 2016	Retrospective cohort study	France	Hospital-based clinics	79 patients (100 clubfeet)	• Infants with idiopathic congenital clubfoot • Untreated at presentation	• Final clinical outcome • Correction rate
Jeans et al., 2015	Prospective cohort study	United States of America	Hospital-based clinics	181 patients (276 idiopathic clubfeet)	• Infants with idiopathic congenital clubfoot • Untreated at presentation	• Correction rate
Chotel et al., 2011	Retrospective cohort study	France	Hospital-based clinics	146 patients (219 clubfeet)	• Consecutive idiopathic clubfeet • <1 month of age	• Final clinical outcome • Correction rate • Relapse requiring surgery
Gottschalk et al., 2010	Prospective cohort study	United States of America	Hospital-based clinics	33 patients (40 clubfeet)	Infants diagnosed with idiopathic clubfoot	• Correction rate
Richards et al., 2008	Prospective cohort study	United States of America	Hospital-based clinics	256 patients (386 clubfeet)	• Untreated idiopathic clubfoot • Infants aged <3 months	• Correction rate • Recurrence rate • Final clinical outcome • Relapse requiring surgery

Annex Table Q2.4. Characteristics of Included Studies for Ponseti method vs. Kite method.

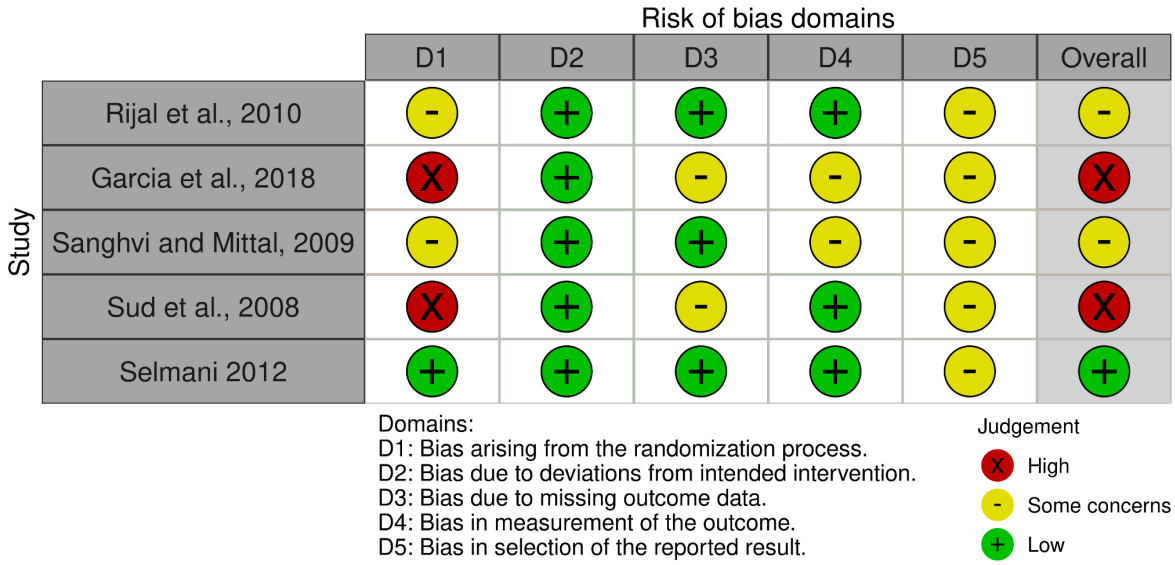
Author, Year	Study design	Country	Healthcare Setting	Number of patients	Population	Outcomes Measured
Garcia et al., 2018	Randomized controlled trial	Brazil	Hospital-based clinics	100 patients (126 clubfeet)	• Idiopathic congenital clubfoot • Age ≤12 months • Either unilateral or bilateral deformities	• Correction rate
Selmani 2012	Randomized controlled trial	Albania	Hospital-based clinics	100 patients (150 clubfeet)	• Classical idiopathic clubfeet • Age <3 months • No prior conservative or operative treatment	• Correction rate • Relapse rate • Relapse requiring surgery
Rijal et al., 2010	Randomized controlled trial	Nepal	Hospital-based clinics	50 patients (60 clubfeet)	• Children <2 years old with idiopathic congenital clubfoot • No prior treatment	• Pirani score improvement
Sanghvi and Mittal, 2009	Randomized controlled trial	India	Not explicitly reported, although author affiliations are from a tertiary care facility	42 patients (64 clubfeet)	Infants with idiopathic clubfoot	• Correction rate • Relapse rate • Relapse requiring surgery
Sud et al., 2008	Randomized controlled trial	India	Hospital-based clinics	45 patients (67 clubfeet)	• Infants <3 months old with idiopathic clubfoot (5–90 days) • No prior treatment	• Correction rate • Relapse rate • Relapse requiring surgery

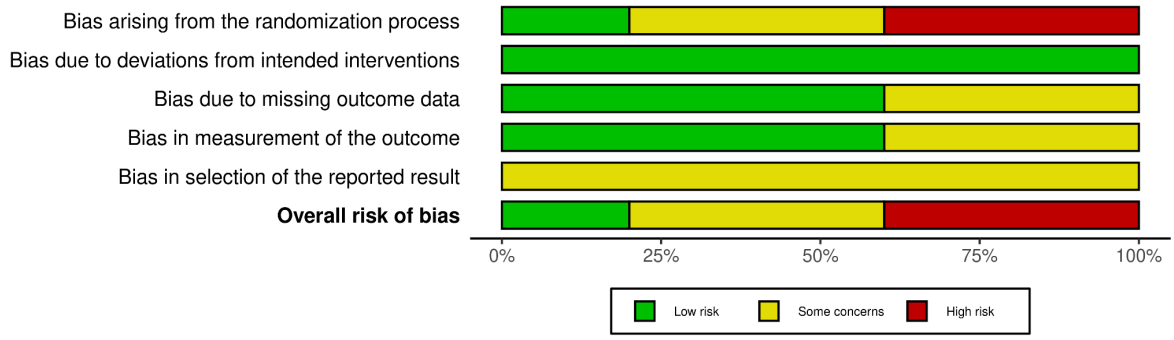
Quality Assessment of Included Studies



Annex Figure Q2.2. Quality assessment of included studies for randomized trials using ROBINS-I for Ponseti method vs. French functional method.

Annex Figure Q2.3. Quality assessment of included studies for randomized trials using the Risk of Bias 2 Tool for the Ponseti method vs. Kite method. – (not sure sa placement nito)





Annex Figure Q2.4. Quality assessment of included studies for randomized trials using ROBINS-I for Ponseti method vs. French functional method.

GRADE Evidence Profile table

Annex Table Q2.5. GRADE Evidence Profile.

Author(s): Miguel Gaston M. Agcaoili, RND, and Aldrich Ivan Lois D. Burog, MD, MSc (cand.)
Question: Should Ponseti method be used compared to Kite method method for infants with idiopathic clubfood?
Setting: Hospital-based clinics
Bibliography:

1. Sud, A., Tiwari, A., Sharma, D., & Kapoor, S. (2007). Ponseti's vs. Kite's method in the treatment of clubfoot-a prospective randomised study. *International Orthopaedics*, *32*(3), 409–413. https://doi.org/10.1007/s00264-007-0332-y
2. Rijal, R., Shrestha, B. P., Singh, G. K., Singh, M., Nepal, P., Khanal, G. P., & Rai, P. (2010). Comparison of Ponseti and Kite's method of treatment for idiopathic clubfoot. *Indian Journal of Orthopaedics*, *44*(2), 202–207. https://doi.org/10.4103/0019-5413.61941
3. Sanghvi, A., & Mittal, V. (2009). Conservative Management of Idiopathic Clubfoot: Kite versus Ponseti Method. *Journal of Orthopaedic Surgery*, *17*(1), 67–71. https://doi.org/10.1177/230949900901700115
4. Selmani, E. (2012). Is Ponseti's method superior to Kite's for clubfoot treatment? *European Orthopaedics and Traumatology*, *3*(3), 183–187. https://doi.org/10.1007/s12570-012-0116-8
5. Garcia, L. C., De Jesus, L. R., De Oliveira Trindade, M., Filho, F. C. G., Pinheiro, M. L., & De Sá, R. J. P. (2018). EVALUATION OF KITE AND PONSETI METHODS IN THE TREATMENT OF IDIOPATHIC CONGENITAL CLUBFOOT. *Acta Ortopédica Brasileira*, *26*(6), 366–369. https://doi.org/10.1590/1413-785220182606183925

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	ponseti method	Kite method	Relative (95% CI)	Absolute (95% CI)		
Relapse requiring surgery (follow-up: range 2.07 years to 3.02 years)												
3	randomised trials	serious[a]	not serious	not serious	not serious	none	14/142 (9.9%)	45/139 (32.4%)	**RR 0.30** (0.17 to 0.52)	**227 fewer per 1,000** (from 269 fewer to 155 fewer)	⊕⊕⊕◯ Moderate[a]	CRITICAL
Correction rate (follow-up: range 1.8 years to 3.3 years)												
4	randomised trials	serious[c]	not serious	not serious	not serious	none	179/213 (84.0%)	141/209 (67.5%)	**RR 1.20** (1.08 to 1.35)	**135 more per 1,000** (from 54 more to 236 more)	⊕⊕⊕◯ Moderate[a]	CRITICAL
Relapse rate (follow-up: range 1 to 3 years)												
3	randomised trials	serious[e]	not serious	not serious	serious[f]	none	20/136 (14.7%)	23/110 (20.9%)	**RR 0.67** (0.39 to 1.14)	**69 fewer per 1,000** (from 128 fewer to 29 more)	⊕⊕◯◯ Low[e,f]	CRITICAL

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	ponseti method	Kite method	Relative (95% CI)	Absolute (95% CI)		
Pirani score improvement (follow-up: mean 2.5 months)												
1	randomised trials	serious[g]	not serious	not serious	very serious[h]	none	4.7	3.34	-	MD **1.36 Pirani score points higher** (0.32 higher to 2.4 higher)	⊕◯◯◯ Very Low[g,h]	CRITICAL
Complications (follow-up: mean 2.5 months)												
1	randomised trials	serious[i]	not serious	not serious	very serious[h]	none	2/30 (6.7%)	3/34 (8.8%)	**RR 0.76** (0.14 to 4.22)	**21 fewer per 1,000** (from 76 fewer to 284 more)	⊕◯◯◯ Very Low[h,i]	CRITICAL

CI: confidence interval; **MD:** mean difference; **RR:** risk ratio

Explanations

a. All three studies were judged at serious risk of bias because of their non-randomized design, reliance on parent or clinician treatment choice, lack of blinding of outcome assessors, and incomplete follow-up.
b. Downgraded for imprecision due to modest sample sizes, limited number of events, and wide confidence intervals in some analyses.
c. Two trials were assessed as high risk of bias due to issues such as lack of allocation concealment, inadequate blinding of participants and assessors, and incomplete outcome reporting. Two other trials were judged as having some concerns, primarily because of unclear reporting of randomization procedures, absence of a pre-specified protocol or trial registration, and potential selective outcome reporting, although other domains were considered at low risk.
d. Downgraded for imprecision and possible publication bias because all four included trials were small and not prospectively registered.
e. One trial was assessed as low risk of bias, with adequate reporting of randomization and follow-up procedures. One trial was judged as having some concerns due to unclear reporting of randomization and the absence of a pre-specified protocol. One trial was assessed as high risk of bias because of systematic allocation to treatment groups and incomplete outcome reporting.
f. Downgraded for imprecision due to small sample sizes and wide confidence intervals crossing the line of no effect in all three included trials.
g. Unclear allocation concealment, no published protocol, and absence of trial registration.
h. Small sample size.
i. Unclear allocation concealment, no protocol or registration, some concerns on reporting.

Annex Table Q2.6. GRADE Evidence Profile.

Author(s): Miguel Gaston M. Agcaoili, RND, and Aldrich Ivan Lois D. Burog, MD, MSc (cand.)
Question: Should Ponseti method be used compared to French functional method for infants with idiopathic clubfood?
Setting: Hospital-based clinics
Bibliography:

1. Jeans KA, Karol LA, Erdman AL, Stevens WR. Functional outcomes following treatment for clubfoot. J Bone Joint Surg Am. 2018;100(23):2015–23. Available from: https://doi.org/10.2106/jbjs.18.00317
2. Goyal RK, Goyani RK. Comparative study of Ponseti method versus French functional method in the treatment of idiopathic clubfoot. J Popul Ther Clin Pharmacol. 2022;29(4):4953–7. Available from: https://doi.org/10.53555/vzszh024
3. Batti SE, Solla F, Clément J, Rosello O, Oborocianu I, Chau E, Rampal V. Initial treatment of congenital idiopathic clubfoot: prognostic factors. Orthop Traumatol Surg Res. 2016;102(8):1081–5. Available from: https://doi.org/10.1016/j.otsr.2016.07.012
4. Jeans KA, Erdman AL, Jo C, Karol LA. A longitudinal review of gait following treatment for idiopathic clubfoot: gait analysis at 2 and 5 years of age. J Pediatr Orthop. 2016;36(6):565–71. Available from: https://doi.org/10.1097/bpo.0000000000000515
5. Chotel F, Parot R, Seringe R, Berard J, Wicart P. Comparative study: Ponseti method versus French physiotherapy for initial treatment of idiopathic clubfoot deformity. J Pediatr Orthop. 2011;31(3):320–5. Available from: https://doi.org/10.1097/bpo.0b013e31820f77ba
6. Gottschalk HP, Karol LA, Jeans KA. Gait analysis of children treated for moderate clubfoot with physical therapy versus the Ponseti cast technique. J Pediatr Orthop. 2010;30(3):235–9. Available from: https://doi.org/10.1097/bpo.0b013e3181d3cba8
7. Richards BS, Faulks S, Rathjen KE, Karol LA, Johnston CE, Jones SA. A comparison of two nonoperative methods of idiopathic clubfoot correction: the Ponseti method and the French functional (physiotherapy) method. J Bone Joint Surg Am. 2008;90(11):2313–21. Available from: https://doi.org/10.2106/jbjs.g.01621

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Ponseti method	French functional method	Relative (95% CI)	Absolute (95% CI)		
Relapse requiring surgery (follow-up: range 4.2 years to 5.4 years)												
3	non-randomised studies	serious[a]	not serious	not serious	not serious	none	121/502 (24.1%)	124/379 (32.7%)	**RR 0.70** (0.56 to 0.88)	**98 fewer per 1,000** (from 144 fewer to 39 fewer)	⊕◯◯◯ Very Low[a]	CRITICAL
Correction rate (follow-up: range 1 years to 10.2 years)												
4	non-randomised studies	serious[b]	serious[c]	not serious	serious[d]	none	607/744 (81.6%)	463/630 (73.5%)	**RR 1.06** (1.00 to 1.12)	**44 more per 1,000** (from 0 fewer to 88 more)	⊕◯◯◯ Very low[b,c,d]	CRITICAL
Final functional outcome: Good and excellent results (follow-up: range 4.2 years to 6 years)												

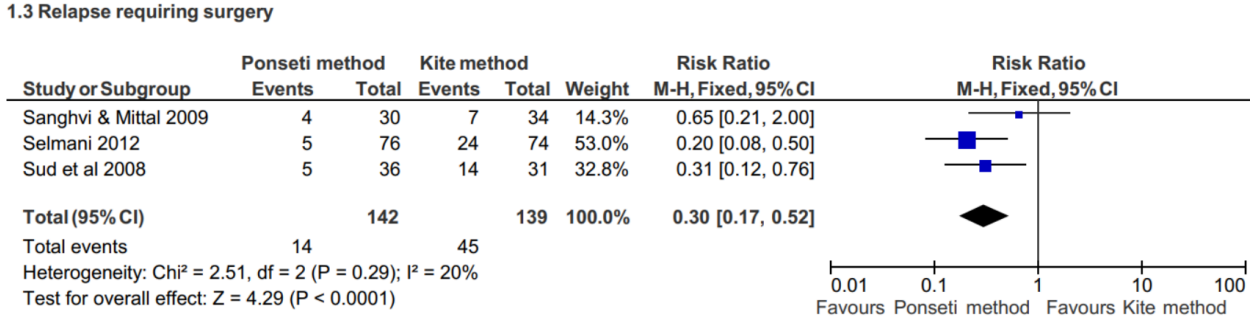
Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Ponseti method	French functional method	Relative (95% CI)	Absolute (95% CI)		
3	non-randomised studies	serious[e]	very serious[f]	not serious	serious[g]	none	337/425 (79.3%)	214/282 (75.9%)	**RR 1.09** (1.01 to 1.18)	**68 more per 1,000** (from 8 more to 137 more)	⊕◯◯◯ Very low[e,f,g]	CRITICAL
Relapse rate (follow-up: range 1 years to 4.2 years)												
2	randomised trials	serious[h]	serious[i]	not serious	very serious[j]	none	42/158 (26.6%)	97/297 (32.7%)	**RR 0.89** (0.65 to 1.21)	**36 fewer per 1,000** (from 114 fewer to 69 more)	⊕◯◯◯ Very low[h,i,j]	CRITICAL
Pirani score improvement (follow-up: mean 1 years)												
1	non-randomised studies	serious[k]	not serious	not serious	very serious[l]	none	4.1	4.7	-	MD **0.6 points higher** (0.46 higher to 0.74 higher)	⊕◯◯◯ Very low[k,l]	CRITICAL

CI: confidence interval; **MD:** mean difference; **RR:** risk ratio

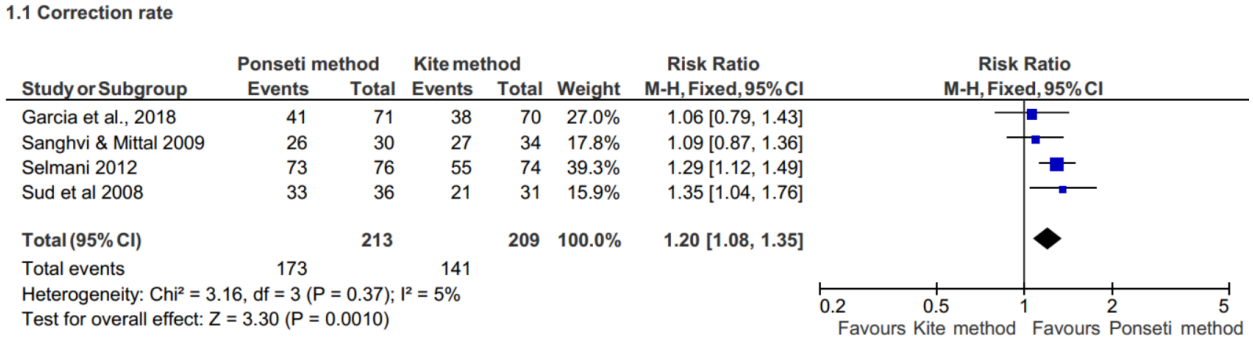
Explanations

a. All three studies were judged at serious risk of bias because of their non-randomized design, reliance on parent or clinician treatment choice, lack of blinding of outcome assessors, and incomplete follow-up.
b. Two trials were assessed as high risk of bias due to issues such as lack of allocation concealment, inadequate blinding of participants and assessors, and incomplete outcome reporting. Two other trials were judged as having some concerns, primarily because of unclear reporting of randomization procedures, absence of a pre-specified protocol or trial registration, and potential selective outcome reporting, although other domains were considered at low risk.
c. Substantial heterogeneity across follow-ups (I^2 = 74%) downgraded for inconsistency.
d. Correction rate effect estimate is borderline (RR 1.06 [1.00–1.12]) with fragility and small samples leading to imprecision.
e. One study with systematic allocation and incomplete outcome reporting.
f. Very serious inconsistency (I^2 = 90%)
g. Small sample sizes with fragile CI (RR 1.09 [1.01–1.18]) leading to imprecision.
h. Unclear allocation concealment and no published protocol.
i. Inconsistency with subgroup differences (I^2 = 68%).
j. Wide CI (0.65–1.21).
k. Unclear allocation concealment and no protocol
l. Single small RCT (N = 90), single-center, and limited events.

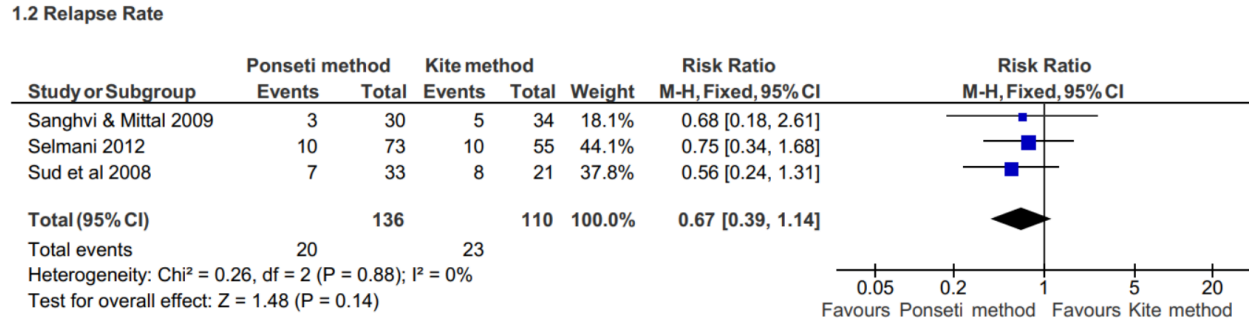
Forest Plots



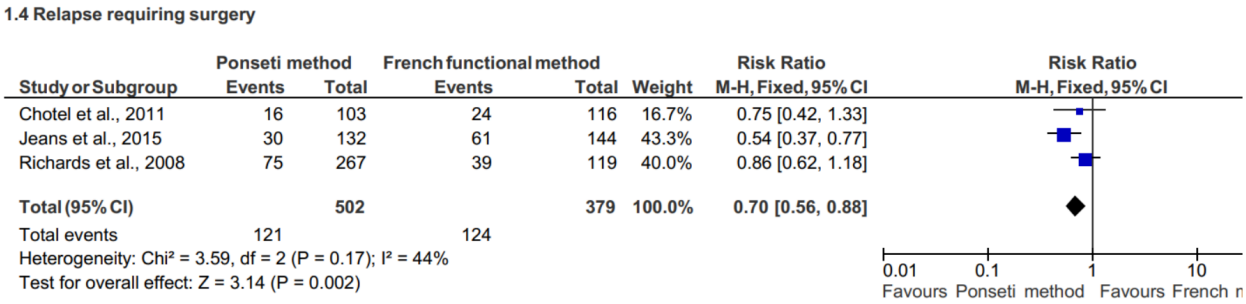
Annex Figure Q2.5. Forest plot for relapse requiring surgery (Ponseti vs. Kite)



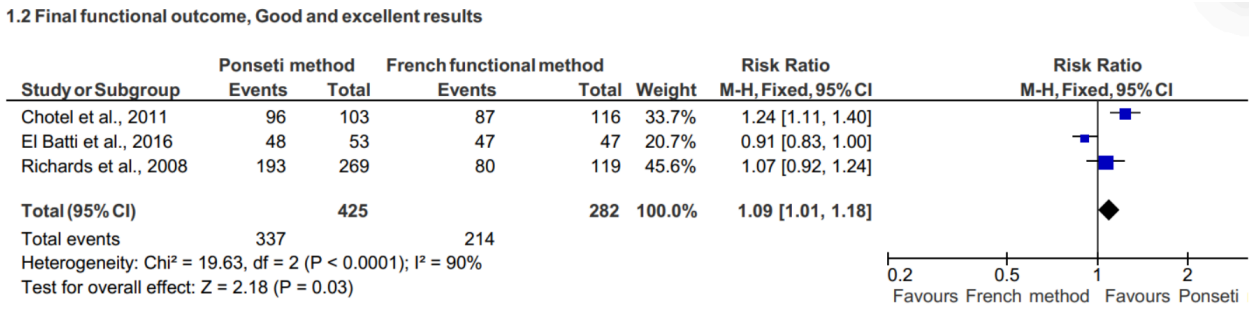
Annex Figure Q2.6. Forest plot for correction rate (Ponseti method vs. Kite method)



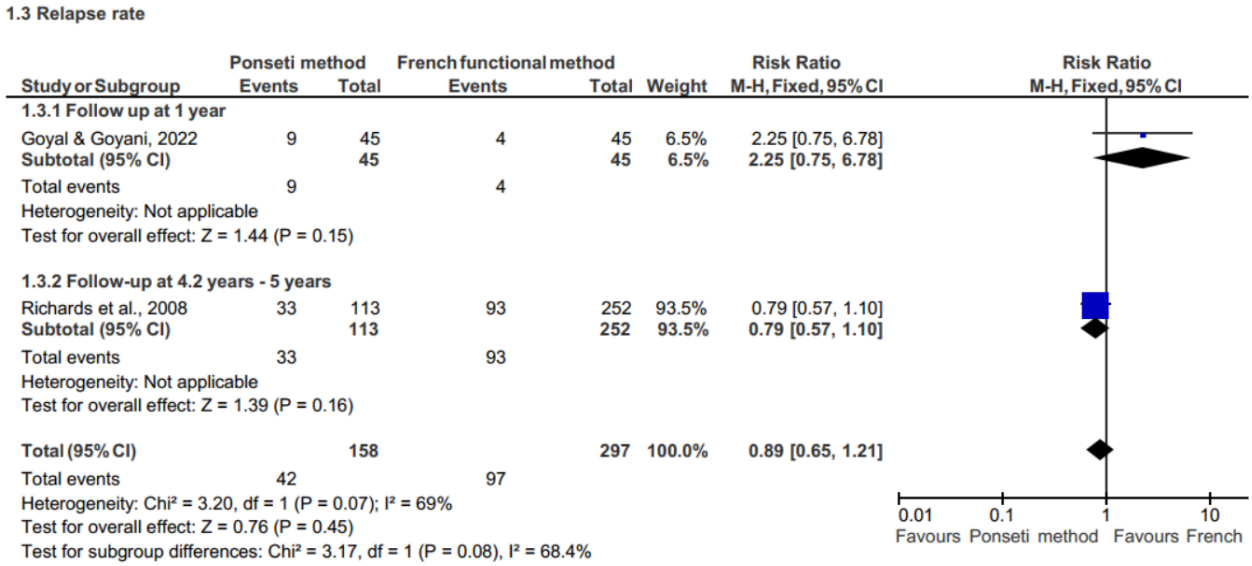
Annex Figure Q2.7. Forest plot for relapse rate (Ponseti vs. Kite)



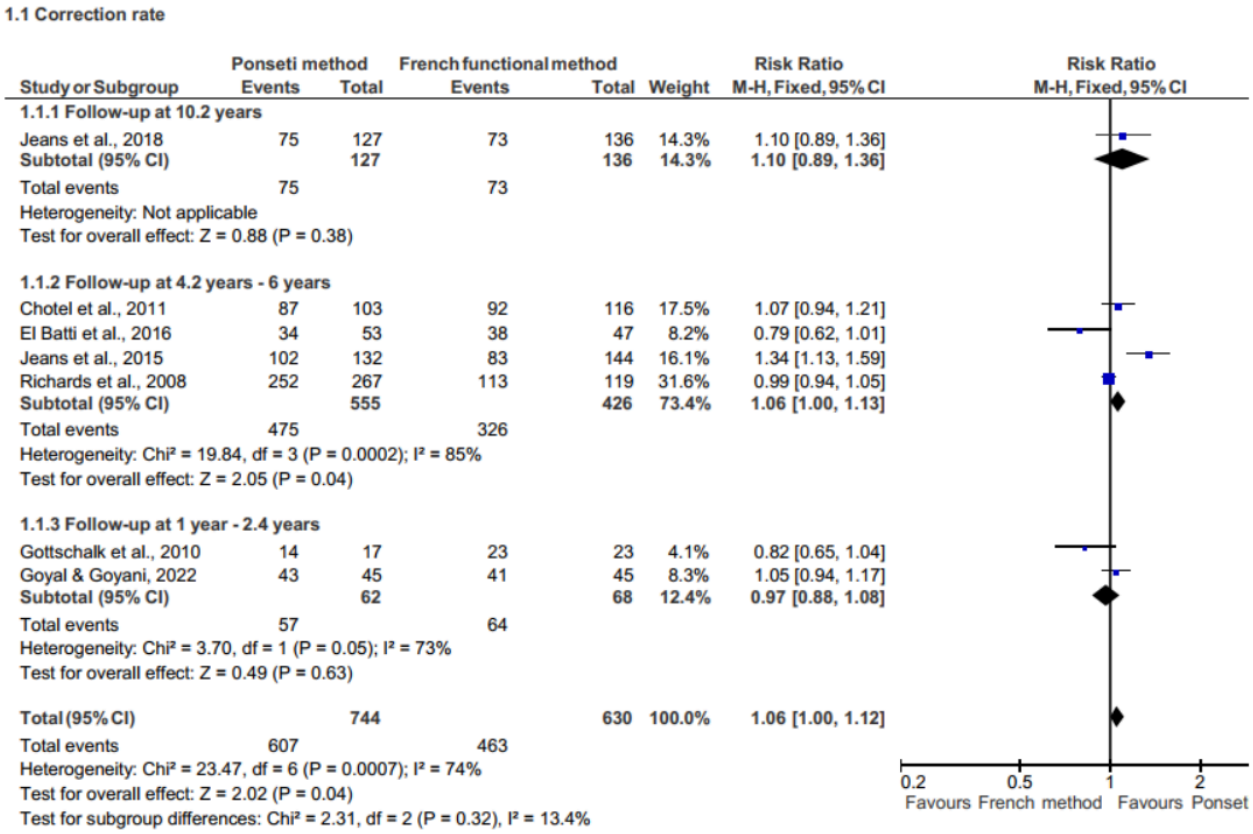
Annex Figure Q2.8. Forest plot for relapse requiring surgery (Ponseti method vs. French functional method)



Annex Figure Q2.9. Forest plot for Excellent + Good categories, Ghanem-Seringe score (Ponseti method vs. French functional method)



Annex Figure Q2.10. Forest plot for relapse rate (Ponseti method vs. French functional method)



Annex Figure Q2.11. Forest plot for correction rate (Ponseti method vs. French functional method)

GUIDELINE QUESTION 3: Should we implement structured parental education and compliance strategies as part of conservative management (e.g., Ponseti method) in children with idiopathic clubfoot?

In children with idiopathic clubfoot, how effective is structured parental education and other strategies compared with no structured education/strategies to improve compliance on reducing relapse, treatment failure, and improving treatment success as part of conservative management (e.g., Ponseti method)?	
Population	children with idiopathic clubfoot
Intervention / Treatment	structured parental education and compliance strategies as part of conservative management
Comparator	Non-structured parental education and compliance strategies
Outcomes	to improve compliance on reducing relapse, treatment failure, and improving treatment success as part of conservative management (e.g., Ponseti method)
Subgroups (if any)	Adults; adolescents; children
Methods	RCTs; systematic reviews of RCTs

Evidence Reviewers: Ericka Louise C. Gilo, RN; Aldrich Ivan Lois D. Burog, MD, MSc (cand.)
Date of Last Search: June 03, 2025

Statement of the Evidence

Among children with idiopathic clubfoot managed with the Ponseti method, structured parental education and compliance strategies *may* reduce recurrence and modestly improve Pirani scores (low certainty). These interventions *may also* enhance caregiver self-efficacy, understanding of the bracing protocol, and brace application skills, although the certainty of this evidence is very low. Reported brace compliance was slightly higher in intervention groups, but findings were inconclusive and based on very low certainty evidence. No evidence on potential harms was identified.

Overall, the certainty of evidence is very low.

Review Methods

A comprehensive and systematic search of both local and international databases was conducted to identify relevant studies, with the last search performed on June 03, 2025. The databases searched included MEDLINE (via PubMed), Cochrane Central Register of Controlled Trials (CENTRAL), HERDIN (Health Research and Development Information Network), SCOPUS, CINAHL (Cumulative Index to Nursing and Allied Health Literature) ClinicalTrials.gov., and WHO ICTRP (International Clinical Trials Registry Platform). Preprints were also searched using Medrxiv.org and Biorxiv.

A combination of Medical Subject Headings (MeSH) and free-text terms was used to maximize search sensitivity. The search terms included variations of the condition and intervention of interest, such as "clubfoot," "talipes

equinovarus," "Ponseti method," "bracing," "compliance," "adherence," and "parental education." Boolean operators (AND, OR) were used to systematically combine terms and broaden the search strategy across databases.

No search filters were applied for study design. This decision was made in consideration of the nature of the intervention, which focused on educational strategies targeting parental engagement and adherence. Educational interventions are often evaluated using diverse methodologies beyond randomized controlled trials, including quasi-experimental designs, cohort studies, and mixed-methods approaches. Applying filters for clinical trials or RCTs could have excluded potentially relevant and informative studies, particularly those assessing process outcomes, implementation strategies, or qualitative components of parent-focused interventions. No date and language restrictions were also applied to ensure a comprehensive review.

Recommendations from Other Groups

Annex Table Q3.1. Summary of recommendations from other groups.

Group/Agency	Recommendation	Strength of Recommendation & Certainty of Evidence
Ponseti International Association (PIA, 2015)	Recommends caregivers receive training through counseling, hands-on demonstration, and clear guidance on brace use, relapse risk, and ongoing follow-up as part of routine Ponseti care.	*Good practice statement* (Not formally graded)
British Society for Children's Orthopaedic Surgery (BSCOS, 2021)	Advises that parents be given information (verbal, leaflets, online) about casting, tenotomy, brace wear, as well as clear out-of-hours contact and well-trained staff.	*Consensus-based recommendation (Not graded)*

Ongoing Studies and Research Gaps

This evidence review identified several important gaps in the current literature. First, there is a lack of randomized controlled trials; existing evidence is limited to observational and pre–post studies, which are highly susceptible to bias. None of the included studies reported on potential harms or unintended consequences of the interventions, such as increased caregiver burden or implementation challenges. Additionally, process outcomes such as parental understanding, self-efficacy, and skills were only measured immediately post-intervention, leaving uncertainty about the long-term sustainability and impact of these changes.

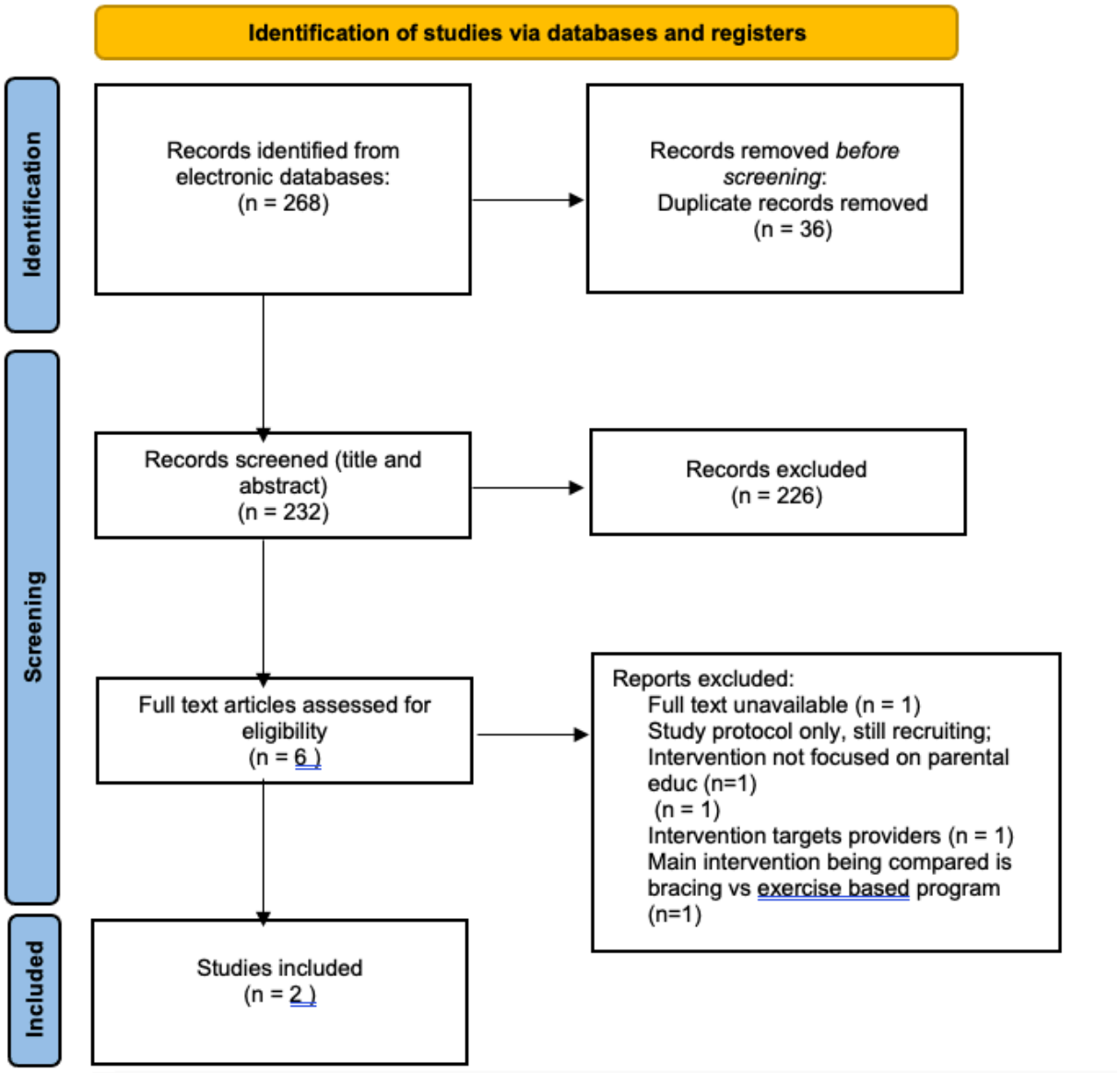
Another key limitation is the absence of standardized, validated outcome measures across studies, particularly for assessing parental knowledge and adherence. This hinders comparability and limits the strength of conclusions that can be drawn. Generalizability is also a concern, as both studies were conducted in single-center settings within specific cultural or institutional contexts, which may not reflect broader populations or low-resource settings. Finally, no economic evaluations were identified, leaving a gap in understanding the cost-effectiveness and feasibility of implementing such educational programs at scale.

Search Strategy

Annex Table Q3.2. Search Strategy (as of June 3, 2025).

Database	Search strategy / search terms	Date and time of search	Results	
			Yield	Eligible
MEDLINE	("Clubfoot"[Mesh] OR "idiopathic clubfoot" OR "talipes equinovarus") AND ("Parents"[Mesh] OR "Caregivers"[Mesh] OR parent* OR caregiver* OR family*) AND ("Health Education"[Mesh] OR "Patient Education as Topic"[Mesh] OR education OR training OR program* OR instruct* OR session* OR intervention* OR "compliance strategy" OR "educational support" OR "parent education program") AND ("Ponseti method" OR "Ponseti technique" OR "conservative treatment")	June 03, 2025 10:33 AM	71	3
SCOPUS	(TITLE-ABS-KEY ("idiopathic clubfoot" OR "talipes equinovarus" OR clubfoot)) AND (TITLE-ABS-KEY (parent* OR caregiver* OR family*)) AND (TITLE-ABS-KEY (education OR training OR program* OR instruct* OR session* OR intervention* OR "compliance strategy" OR "educational support" OR "parent education program")) AND (TITLE-ABS-KEY ("Ponseti method" OR "Ponseti technique" OR "conservative treatment"))	June 03, 2025 09:56 AM	77	4
COCHRANE LIBRARY	("idiopathic clubfoot" OR "talipes equinovarus" OR clubfoot) AND (parent* OR caregiver* OR family*) AND ("parental education" OR education OR instruct* OR train* OR program* OR session* OR intervention* OR "compliance strategy" OR "educational support" OR "parent education program") AND ("Ponseti method" OR "Ponseti technique" OR "conservative treatment")	June 03, 2025 08:25 PM	8	2
CINAHL	(MH "Clubfoot" OR "idiopathic clubfoot" OR "talipes equinovarus") AND (MH "Parents" OR MH "Caregivers" OR parent* OR caregiver* OR family*) AND (MH "Health Education" OR MH "Patient Education" OR education OR training OR program* OR instruct* OR session* OR intervention* OR "compliance strategy" OR "educational support" OR "parent education program") AND ("Ponseti method" OR "Ponseti technique" OR "conservative treatment")	June 03, 2025 09:20 AM	34	1
HERDIN	clubfoot	June 03, 2025 09:56 AM	10	0
ClinicalTrials.gov	(clubfoot OR "talipes equinovarus") AND ("parental education" OR education OR training OR "compliance strategy" OR adherence) AND ("Ponseti Method" OR "ponseti technique")	June 03, 2025 06:41 PM	2	0
WHO ICTRP	("clubfoot" OR "talipes equinovarus")	June 03, 2025 06:41 PM	21	1
Medrxiv.org and Biorxiv	("clubfoot" OR "talipes equinovarus")	June 03, 2025 06:41 PM	45	0
	TOTAL		**268**	**11**

PRISMA Flow Diagram



Annex Figure Q3. PRISMA flow diagram.

Included Studies

Annex Table Q3.3. Characteristics of included studies.

Author, Year	Study design	Country	Number of patients	Population	Intervention Group(s)	Control	Outcomes
Seegmiller et al., 2016	One group pre and post interventio n study	USA	30	Children with idiopathic clubfoot, bracing phase	Two session **Structured educational bracing program** for parents of children with idiopathic clubfoot **The bracing educational program** employs educational materials (use of a educational brochure, “teach back” method, and doll for skills demonstration) and consists of two visits with a health practitioner, occurring at the third and final casting appointments	Within the same group (no external control group)	(1) Parental self-efficacy for bracing protocol adherence, (2) Parental understanding of the importance of bracing protocol adherence (3) Skills improvement in brace application Tool: Self designed survey and questionnaire
Morin et al., 2014	Retrospect ive comparati ve study	USA	6 (104 idiopathic clubfeet)	Infants with idiopathic clubfoot	**communication protocol** as an adherence strategy The **communication protocol** first includes an educational handout for the initial clubfoot visit, and employed several communication techniques during the course of treatment: - brace wear issues explored non judgementally - use of praise - avoiding yes/no questions, and exploring brace wear problems at each visit - Refraining from using negatively worded statements - use of frequent positive affirmations - culturally sensitive	Historical control group (100 patients/ 138 idiopathic clubfeet)	(1) Pirani scores (2) rate of recurrence (3) caregiver reported brace compliance

Quality Assessment of Included Studies

Annex Table Q3.4. Quality Assessment of Included Studies using the ROBINS – I Tool.

Study	Bias due to confounding	Bias in selection of participants	Bias in classification of interventions	Bias due to deviations from intended interventions	Bias due to missing data	Bias in measurement of outcomes	Bias in selection of reported result	Overall Risk of Bias	Remarks
Seegmiller et al., 2016	Serious (no control group, small sample)	Moderate (clinic-based recruitment)	Low (intervention clearly defined)	Low (no protocol deviations reported)	Low (complete data reported)	Serious (subjective, self-reported outcomes)	Moderate (no protocol registered)	Serious	Lacks a control group; subjective outcomes raise concerns despite complete data reporting.
Morin et al., 2014	Serious (baseline differences, historical design)	Moderate (historical vs. current cohort)	Low (intervention and control well-defined)	Moderate (retrospective design, unclear adherence)	Low (outcomes reported for all participants)	Moderate (some objective, but unblinded)	Moderate (no protocol registered)	Serious	Uses historical control; potential baseline differences and unblinded outcome assessment.

GRADE Evidence Profile table

Annex Table Q3.5. GRADE Evidence Profile.

Author(s): Ericka Gilo
Question: Structured parental education and compliance strategies as part of conservative management compared to Non-structured parental education and compliance strategies for improving compliance on reducing relapse, treatment failure, and improving treatment success as part of conservative management (e.g., Ponseti method) in children with idiopathic clubfoot
Setting: Pediatric orthopedic clinics in high-income countries (USA and Canada); outpatient hospital-based care
Bibliography:

1. Seegmiller L, Rebecca Burmeister, Paulsen-Miller M, Morcuende J. Bracing in Ponseti Clubfoot Treatment: Improving Parental Adherence Through an Innovative Health Education Intervention. Orthop Nurs. 2016 Mar;35(2):92–7.
2. Morin ML, Hoopes DM, Szalay EA. Positive Communication Paradigm Decreases Early Recurrence in Clubfoot Treatment. J Pediatr Orthop. 2014 Mar;34(2):219–22.

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	structured parental education and compliance strategies as part of conservative management	Non-structured parental education and compliance strategies	Relative (95% CI)	Absolute (95% CI)		
Recurrence of deformity (follow-up: range 12 months to 24 months)												
1	non-randomised studies	serious[a]	not serious	not serious	serious[b]	none	2/69 (2.9%)	25/100 (25.0%)	**RR 0.11** (0.03 to 0.44)	**223 fewer per 1,000** (from 243 fewer to 140 fewer)	⊕⊕◯◯ Low[a,b]	CRITICAL
Pirani score improvement (follow-up: range 12 months to 24)												
1	non-randomised studies	serious[c]	not serious	not serious	serious[d]	none	169	0	-	MD **0.5 higher** (0.21 higher to 0.79 higher)	⊕⊕◯◯ Low[c,d]	CRITICAL
Parental self - efficacy for adherence												
1	non-randomised studies	very serious[e]	not serious	not serious	serious[d]	none	30	0[f]	-	**0.67 higher** (0.49 higher to 0.81 higher)	⊕◯◯◯ Very low[d,e]	CRITICAL
Parental understanding of importance of adherence												

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	structured parental education and compliance strategies as part of conservative management	Non-structured parental education and compliance strategies	Relative (95% CI)	Absolute (95% CI)		
1	non-randomised studies	very serious[e]	not serious	not serious	serious[d]	none	21/30 (70.0%)	0/0[g]	not estimable	**-- per 1,000** (from 510 more to 850 more)[h]	⨁◯◯◯ Very low[d,e]	CRITICAL
Skills in brace application												
1	non-randomised studies	very serious[e]	not serious	not serious	serious[d]	none	25/30 (83.3%)	0/0[f]	not estimable[i]	**-- per 1,000** (from 650 more to 840 more)[h]	⨁◯◯◯ Very low[d,e]	CRITICAL
Care giver reported brace compliance (follow-up: range 12 months to 24 months)												
1	non-randomised studies	serious[a]	not serious	not serious	serious[d]	none	62/69 (89.9%)	80/100 (80.0%)	**RR 1.12** (0.95 to 1.32)	**96 more per 1,000** (from 40 fewer to 256 more)[h]	⨁◯◯◯ Very low[a,d]	CRITICAL

CI: confidence interval; **MD:** mean difference; **RR:** risk ratio

Explanations

a. Retrospective, non-concurrent historical control, possible confounding.
b. Small sample; wide CI though favors benefit.
c. Retrospective, historical control; nonrandomized; outcome assessed by treating team (possible measurement bias).
d. Small total sample size, Wide confidence interval relative
e. Single-group pre-post; no control; self-report; high potential for social desirability bias.
f. One-group pre–post study. No concurrent control group
g. One-group pre–post study. No control group; reported proportion reflects post-intervention response only.
h. Single-group pre-post study; effect reported as proportion strongly agreeing that bracing is critical. No baseline comparison or control group.
i. One-group pre–post study; effect reported as proportion improved in brace application skill. No control group; absolute effect and 95% CI reflect single-group estimate.

GUIDELINE QUESTION 4: Should locally produced braces, compared to commercial (branded) braces, be used in patients with idiopathic clubfoot?

Research Question: Among patients with idiopathic clubfoot, how effective are locally produced braces compared with commercial (branded) braces in reducing recurrence of deformity and improving outcomes such as brace adherence, caregiver satisfaction, and long-term function?	
Population	patients with idiopathic clubfoot
Intervention/ Treatment	locally produced braces (e.g., Steenbeek braces)
Comparison	commercial (branded) braces
Outcomes	• reduction in recurrence of deformity • improvement in brace adherence • improvement in caregiver satisfaction • improvement in long-term function
Subgroups (if any)	Not applicable
Methods	RCTs; systematic reviews of RCTs; non-randomized studies of interventions (NRSIs)

Evidence Reviewers: Howell Henrian G. Bayona, MSc, RSLP, Aldrich Ivan Lois D. Burog, MD, MSc (cand.)
Date of Last Search: 11 June 2025 (updated 24 Jun 2025)

Statement of the Evidence

Newer dynamic or branded braces may reduce non-compliance, recurrence, and skin complications compared to traditional braces, though evidence is very uncertain. Recurrence was mainly linked to poor compliance rather than brace type, and one study found no functional differences between brace designs. Overall certainty of evidence is very low due to bias and study limitations.

Review Methods

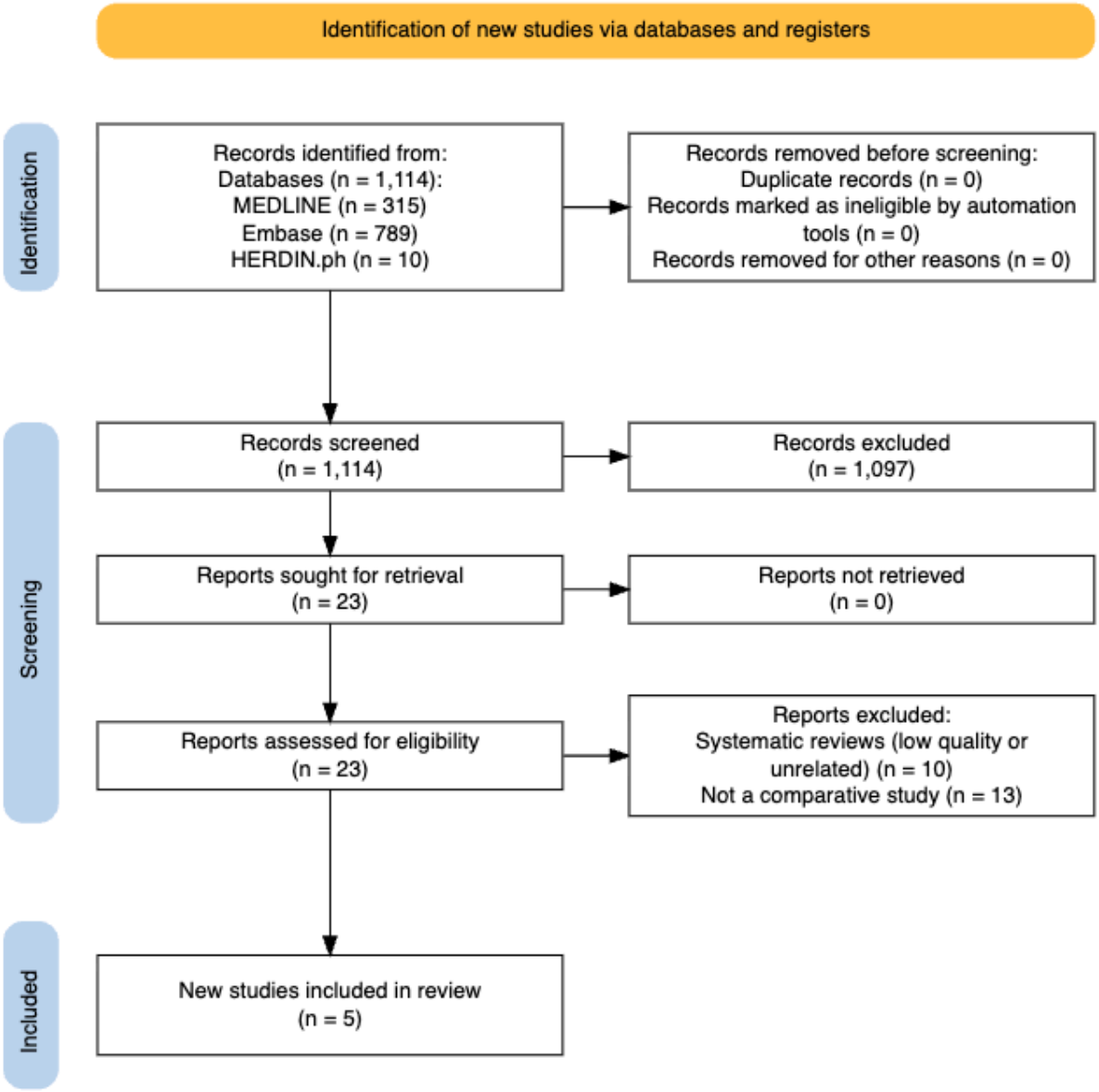
A systematic search was done for published studies from date of database inception until June 24, 2025 on MEDLINE via PubMed, Embase, and HERDIN.ph. The detailed search strategy combined MeSH and free text search terms related to 'clubfoot' and 'foot abduction braces'. References of systematic reviews and clinical practice guidelines related to the topic were checked for additional studies. Eligible studies for this evidence synthesis were randomized controlled trials (RCTs) or non-randomized studies of interventions (NRSIs) comparing the outcomes of locally produced FABs with commercially-available, branded FABs. Locally produced FABs were defined as any bar-connected brace or foot abduction orthosis that can be easily manufactured or produced by an orthotist, uses accessible materials (e.g., aluminum), and does not require hard plastics. Commercial or branded foot abduction braces are professionally manufactured, standardized orthotic devices (e.g., Dennis Browne bar, Mitchell-Ponseti brace) designed to maintain clubfoot correction after casting, typically produced by medical device companies and sold at higher cost. Outcomes of interest include reduction in recurrence of deformity, brace adherence, caregiver satisfaction, and improvement in long-term function. Risk of bias was assessed using the ROBINS-I tool. The certainty in the effect estimates were rated using the GRADE approach.

Search Strategy

Annex Table Q4.1. Search Strategy (as of June 24, 2025).

Database	PICO	No	Search terms
Medline via PubMed (06/24/25)	Population	1	"Clubfoot"[Mesh] OR "idiopathic congenital talipes equinovarus"[Title/Abstract] OR CTEV [Title/Abstract] OR "idiopathic clubfoot"[Title/Abstract]
	Intervention	2	"Foot Abduction Brace*"[Title/Abstract] OR "Orthotic Devices"[MeSH] OR "orthoses"[Title/Abstract] OR "Steenbeek"[Title/Abstract] OR "Mitchell-Ponseti"[Title/Abstract] OR “Denis Browne Bar”[Title/Abstract] OR “Dobbs Dynamic Bar”[Title/Abstract]
		3	**#1 AND #2**
	Limit: Systematic reviews only	4	#3 AND (meta-analysis[Filter] OR review[Filter] OR systematicreview[Filter])
Embase (06/24/25)	Population	1	Clubfoot/exp OR 'idiopathic congenital talipes equinovarus':ti,ab OR CTEV:ti,ab OR 'idiopathic clubfoot':ti,ab
	Intervention	2	'Foot Abduction Brace*':ti,ab OR 'Orthotic Devices'/exp OR orthoses:ti,ab OR Steenbeek:ti,ab OR Mitchell-Ponseti:ti,ab OR 'Denis Browne Bar':ti,ab OR 'Dobbs Dynamic Bar':ti,ab
		3	**#1 AND #2**
	Limit: EMBASE articles only	4	#3 AND [embase]/lim NOT ([embase]/lim AND [medline]/lim)
	Limit: including only published articles, articles in press, short survey, reviews	5	#4 AND ('article'/it OR 'article in press'/it OR 'review'/it OR 'short survey'/it)
HERDIN.ph (06/24/25)		**1**	**clubfoot**

PRISMA Flow Diagram

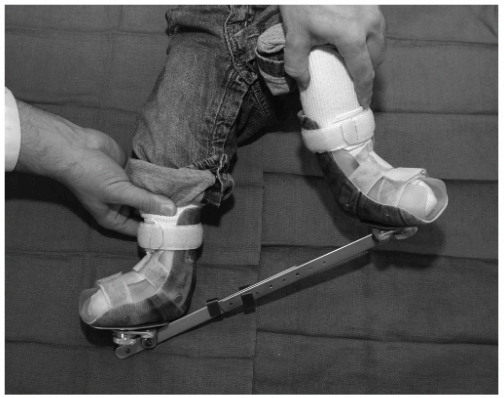


Annex Figure Q4.1. PRISMA Flow Diagram.

Included and Excluded Studies

Characteristics of Included Studies

Annex Table Q4.2. Characteristics of Included Studies (Chen 2007).

Population	n=28 patients (49 clubfeet) **Inclusion criteria:** Treated with a dynamic foot abduction orthosis after clubfoot correction using the Ponseti method. **Characteristics:** ● Mix of clubfoot types: 18 idiopathic clubfeet (31 feet), 2 complex idiopathic clubfeet (4 feet), 5 myelodysplasia (8 feet), and 3 syndromic (6 feet) ● 18 of these 28 patients had initially been prescribed the traditional foot abduction brace but were switched to the dynamic orthosis due to skin blistering and/or parental noncompliance. The remaining 10 patients started directly with the dynamic orthosis ● Mean age at the start of casting at the institution was 16.1 weeks (range, 1.0–77.1 weeks). ● 75% of patients had bilateral clubfeet, and 25% had unilateral clubfeet.	
Intervention	**Newly designed dynamic foot abduction orthosis (n=28)** ● also referred to as an articulating foot abduction orthosis ● dynamic bar allowing active movement (flexion and extension) of each leg in a single plane. ● Soft, custom-molded Duraflex interface placed inside a solid ankle-foot orthosis (AFO) for a custom fit to minimize skin blistering ● Secured with Velcro straps instead of laces and buckles for easier application ● quick-release mechanism in the middle of the bar to allow easy detachment/reattachment when placing a child in a high chair or car seat ● The feet are positioned in 70 degrees of external rotation (clubfoot) or 30 degrees (normal foot, if unilateral) and neutral dorsiflexion ● The brace was prescribed for full-time wear for 3 months, followed by part-time (night and nap time) use until the age of 4 years	 **FIGURE 1.** A 3-month-old boy in the dynamic foot abduction orthosis illustrating the ability to flex and extend the knees while using the orthosis.
Control	**Traditional FAB connected to Denis Browne bar (n=51)** ● The study primarily used a historical comparison by drawing on the authors' previously reported experience with the traditional foot abduction brace (Dobbs et al., 2004[20]).	

	• The traditional brace was described as open-toed, high-top, straight-last shoes attached in external rotation to a Denis Browne bar • This traditional brace had reported noncompliance rates of 41% and skin blistering rates of 23.5% in the comparison study
Outcomes	**Mean duration of follow-up:** 29 months, with a range of 24 to 36 months **Outcome 1: Compliance** • defined as not wearing the brace for the prescribed number of hours • 2/28 in Dobbs brace vs. 21/51 in traditional **Outcome 2: Recurrence of clubfoot deformity (or relapse)** • documented by age at recurrence, severity (Dimeglio grading system), and additional treatment needed. • 1/28 in Dobbs brace vs. 16/51 in traditional **Outcome 3: Complications** • particularly skin blistering • 1/28 in Dobbs brace vs. 11/51 in traditional
Notes	**Design:** case-control study (using a historical control group) **Aim:** to assess the results of a newly designed dynamic foot abduction orthosis in terms of (1) parental compliance and (2) effectiveness in preventing recurrent clubfoot deformities. **Setting:** Washington University School of Medicine in St Louis, St Louis Children's Hospital, and St Louis Shriners Hospital for Children, St Louis, Missouri

Annex Table Q4.3. Characteristics of Included Studies (Garg 2009).

Population	n=115 children Loss to follow-up: n=8/65 (12.3%) **Inclusion criteria:** Infants with idiopathic clubfoot were enrolled. Not treated surgically elsewhere, with prior manipulation and casting allowed Both groups were corrected initially with the Ponseti method **Exclusion criteria:** children with neuromuscular disorders, genetic syndromes, arthrogryposis previous surgery for clubfoot (including Achilles tenotomy)

	Characteristics: <u>Group 1: newly designed dynamic FAB (Dobbs brace) (n=58)</u> 43/57 male (75.4%) Mean age at the start of treatment: 2.7 months. <u>Group 2: standard orthosis with Denis-Browne bar (n=57)</u> Historical control group identified from clubfoot center treatment records immediately preceding the initiation of the dynamic brace, with identical inclusion and exclusion criteria 36/57 (63.2%) Mean age at the start of treatment was 1.9 months.	
Intervention	**Group 1: newly designed dynamic foot abduction orthosis (Dobbs brace)** ● dynamic bar allowing motion of each foot in the sagittal plane while maintaining abduction ● combines a custom-molded solid ankle foot orthosis (AFO) made of thin copolymer thermoplastic with a molded inner boot of Duraflex and a dorsum pringle pad ● https://www.dobbsbrace.com/ ● the dynamic bar can also be attached to Markell straight last shoes (http://www.markellshoe.com) or Mitchell clubfoot sandals (http://www.mdorthopaedics.com), as utilized by Ponseti in Iowa. ● Worn 23 hours for 3 months (removed only when bathing or stretching); reduced to night-time brace wear until 4 years	 **Fig. 3** Currently used model of the dynamic foot abduction orthosis. The foot piece is identical to the study brace. The dynamic bar has been modified in its weight and dimensions but has the same range and mobility as the dynamic bar used in the study group
Control	**Group 2: standard orthosis with Denis-Browne bar** ● standard orthosis consisted of straight last shoes connected to a Denis Browne bar ● Worn 23 hours for 3 months (removed only when bathing or stretching); reduced to night-time brace wear until 4 years	 **Fig. 1** Traditionally used foot abduction brace composed of shoes connected to a Denis Brown bar
Outcomes	**Follow-up duration:** Both groups were followed for an average of 2 years. ● The study group had an average follow-up of 21.1 months (range 12.2–32 months). ● The control group had an average follow-up of 29.0 months (range 10.1–72.1 months)	

	Outcome 1: Compliance with the post-correction foot abduction bracing. ● Defined as family-reported brace wear as instructed for 12 months following deformity correction. ● 47/58 (81%) in experimental were compliant; ● 21/57 (47%) in control group were compliant **Outcome 2: Recurrence of deformity** ● Diagnosed based on clinical evaluation ○ 11/58 (19%) in experimental group; all corrected with repeat casting and manipulation, 1 child needing tenotomy ■ 4/47 (8.5%) were compliant with bracing; 7/11 (63.6%) not compliant ○ 22/57 (39%) in control group **Outcome 3: Need for surgery** ● Achilles tenotomy: ○ 93/97 feet in experimental; ○ 89/92 feet in control ● Posteromedial soft tissue release: ○ 5/57 in control ■ 3/36 (8.3%) non compliant with bracing underwent surgery; 2/21 (9.5%) who were compliant with bracing underwent surgery; all elected for surgery despite initial recommendation for nonsurgical treatment ○ 0/58 in experimental **Outcome 4: Complications** ● Defined as any skin condition of the lower limb developing during bracing that required a cessation of bracing for healing. ● 2/58 in experimental; 11/57 in control The need for surgical soft tissue release (specifically posteromedial release). ◦ Clubfoot severity, determined by the number of casts required for correction
Notes	**Design:** case-control **Aim:** to test the hypothesis that a dynamic foot abduction orthosis would result in improved compliance, fewer skin complications, and fewer recurrences of deformity in children with clubfeet treated with the Ponseti method **Setting:** Washington University Orthopaedics and Shriners Hospital for Children, St. Louis, MO, USA

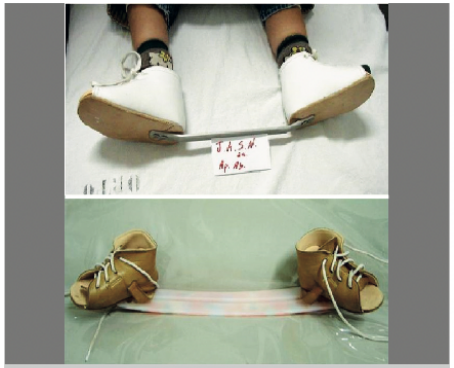
Annex Table Q4.4. Characteristics of Included Studies (Hemo 2011).

Population	n=38 children **Inclusion criteria:** Idiopathic clubfoot treated in the institution from beginning Followed up for at least 2 years (between 2002-2006) **Exclusion criteria:** Children initially treated elsewhere Atypical clubfoot **Characteristics:** 19/38 (50%) bilateral clubfoot; 30/38 (78.9%) males Mean age at treatment initiation: 1.7 weeks (range 1-12 weeks) The two groups were equal in severity at the beginning of treatment. There were no differences between the two groups in age (P = 0.4) or Pirani score (P = 0.382) at presentation, nor in the number of casts used (P = 0.089)
Intervention	Families were offered both brace options and were free to select the brace type they preferred, forming two groups: 21 children chose the DB brace and 17 chose the Mitchell brace **Group 1: Mitchell brace (aka Ponseti brace) (n=17)** MD Orthopaedics, Wayland, Iowa, USA This brace includes detachable shoes and soft silicone AFO-type inserts Treated by 2 senior orthopedic surgeons 1 dedicated physiotherapist FAB applied 23 hours for 3 months, then brace time gradually reduced Instructions: 20 hrs uninterrupted wear after 3 months, 18 hrs after 6 months, only night-time use from 1 year of age to 3-4 yrs
Control	**Group 2: Traditional simple brace attached to Denis-Browne bar (n=21)** Includes pre-walking shoes attached to a Denis-Browne bar Instructions: 20 hrs uninterrupted wear after 3 months, 18 hrs after 6 months, only night-time use from 1 year of age to 3-4 yrs
Outcomes	**Follow-up period:** mean 44 months (range 24-88 mos) Parents asked about brace use every quarter for year 1 or age at which bracing was discontinued **Outcome 1: Compliance with the post-corrective bracing protocol.** • parents of both brace groups reported having fully complied with the treatment instructions for the first 2 years. Most of the parents reported difficulties with bracing due to sleeping problems, which was the reason for non-compliance beyond the second year

	Outcome 2: Functional scores ● Using tool by Ezra et al[9]; incorporating different parameters such as ankle and subtalar motion, heel and forefoot position during standing, gait pattern, shoe type worn, functional limitations, pain and parental satisfaction ● No differences between groups in the last follow-up visit ● The final functional score was 138 for the Mitchell group and 139.8 for the DB group (P = 0.544) **Outcome 3: Radiographs** ● Radiographs taken after 2 years; followed protocol in which wooden rectangle is taped to plantar aspect of the foot for standardization; both antero-posterior (AP) view and lateral view in maximum dorsiflexion ● mean AP talocalcaneal angles were 29.8° (±6.6°) for the Mitchell group and 28° (±4.7°) for the DB group (P = 0.146) ● mean lateral talocalcaneal angles in maximal dorsiflexion were 32.4° (±8.2°) for the Mitchell group and 35.55° (±8.1°) for the DB group (P = 0.262) **Outcome 4: Complications** ● Parents asked about any problems during bracing period such as blistering, sleeping problems, dislodgment of the foot from the brace ● No actual rates reported; Most of the parents reported difficulties with bracing due to sleeping problems, which was the reason for non-compliance beyond the second year. Both groups stated that they would recom- mend the same brace that they had selected to others.
Notes	**Design:** NRSI, families chose which brace they preferred; retrospective review of charts for outcomes **Aim:** to compare compliance and treatment outcome using two brace designs; to determine whether added components of the newer device (Mitchell brace) and its claimed increased comfort would improve treatment outcome as measured by compliace with the brace protocol, clinical, radiological results **Setting:** Department of Pediatric Orthopedic Surgery, Dana Children's Hospital, Tel Aviv, Israel

Annex Table Q4.5. Characteristics of Included Studies (Lara 2017).

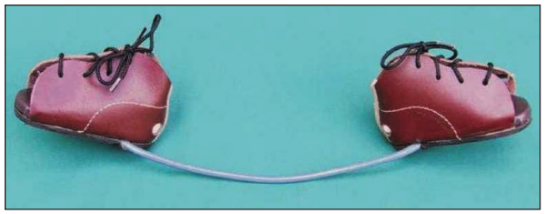
Population	n=28 patients (43 feet) **Inclusion criteria:** Children with idiopathic congenital clubfeet Used abduction orthotics for a minimum of 2 years **Exclusion criteria:** Patients who did not adhere to device use or dropped out of treatment **Characteristics:** Group 1 (traditional Denis-Browne): n=16; 24 clubfeet; 12/16 male; 8/16 bilateral; 15/24 Dimeglio III (severe); time of use mean 3.52 years (range 2-5

	years) Group 2 (Dobbs dynamic device): n=12; 19 clubfeet; 9/12 male; 7/12 bilateral; 10/19 Dimeglio III (severe); time of use mean 2.62 years (range 2-4 years) Both groups not significantly different in terms of Dimeglio score distribution	
Intervention	**Group 1: Traditional Denis-Browne type device (n=16, 24 clubfeet)** Traditional device consists of open-toe high-top boots connected by a fixed bar Unaffected foot maintained with external rotation 30-40°, affected foot in 60°–70° with 10-15° dorsiflexion Distance between feet same as distance between child's shoulders Worn 23 hrs per day for first 4 months, then 12 hrs / night for 3-4 years Weekly lectures explaining method were given to the family before appointments If deformity recurs while abduction device is being used, treatment is reinitiated and a new series of plaster casts is placed until the deformity is completely corrected; if necessary, tenotomy of the calcaneal tendon is done	 **Figure 1.** Denis Browne type device.
Control	**Group 2: Dobbs dynamic orthotic device** Provides independent flexion-extension to each leg, allowing for movement in a single plane, which aims to offer greater comfort and less restriction The affected foot is held at the same degrees of external rotation and dorsiflexion as the traditional device (60°–70° external rotation, 10-15° dorsiflexion) With central release mechanism, ensuring easy handling in daily activities Worn 23 hrs per day for first 4 months, then 12 hrs / night for 3-4 years Weekly lectures explaining method were given to the family before appointments If deformity recurs while abduction device is being used, treatment is reinitiated and a new series of plaster casts is placed until the deformity is completely corrected; if necessary, tenotomy of the calcaneal tendon is done	 **Figure 2.** Dobbs type device.
Outcomes	The average time the orthotics were used was 3.52 years for Group 1 (traditional) and 2.62 years for Group 2 (dynamic). The maximum time was 5.0 years	

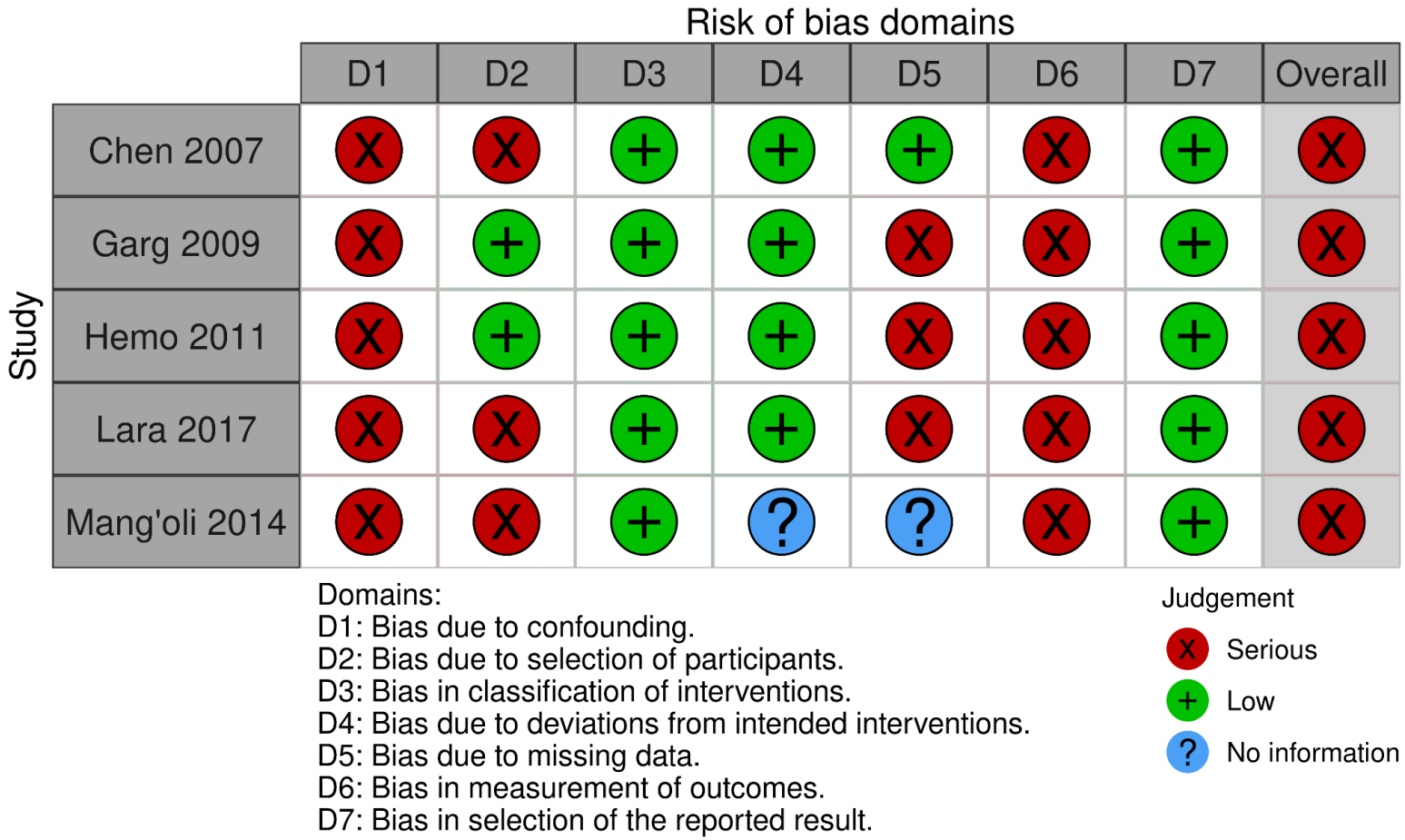
	for Group 1 and 4.0 years for Group 2 **Outcome 1: Recurrence** ● defined as the return of initial CCF deformities after treatment ● Group 1: 2/24 feet (8.3%) or 2/16 children (12.5%) ● Group 2: 1/19 feet (5.3%) or 1/12 children (8.3%) ● In both groups the recurrences were equinus, cavus, adduct but less acute form than the initial deformity; underwent repeat serial plaster casting and bracing **Outcome 2: Complications** ● No complications in either group
Notes	**Design:** NRSI, retrospective analysis of medical records **Aim:** to analyze and compare effectiveness of 2 types of abduction orthotics (Dennis-Browne/traditional vs. Dobbs/dynamic) in maintaining deformity correction and preventing recurrence of idiopathic congenital clubfoot **Setting:** Treated children at an outpatient foot and ankle clinic at the Hospital Universitario de Taubate, Sao Paulo Brazil

Annex Table Q4.6. Characteristics of Included Studies (Mang'oli 2014).

Population	n=223 (361 clubfeet) **Inclusion criteria:** Registered Clubfoot Care for Kenya (CCK) members Had used an SFAB for at least 6 months Willing to participate and consent **Characteristics:** Mean age at enrolment: 23 months Male-to-female ratio: 2:1 No data on clubfoot severity

Intervention	Steenbeek foot abduction brace (SFAB), which is locally made in Kenya at a low cost (< USD 10) Mean duration of SFAB wear: 18 mos (range: 6 to 28)	 **Figure 2)** *The Steenbeek foot abduction brace*
Control	No internal comparison group using a different brace type Findings on noncompliance and complications were compared to a previous study (Chen 2017) that had examined traditional Dennis Brown braces and newer, more expensive child-friendly braces	
Outcomes	**Follow-up period:** monthly, then every 3 months, then every 6 months until 4 years of age (routinely collected data in the CCK program in Kenya) **Outcome 1: Tolerability** ● defined as the absence of visible discomfort of the child when the brace was applied ● 208/223 (93.5%) **Outcome 2: Compliance** ● defined as consistent brace use for ≥ 6 months ● Noncompliance in 33/223 (14.8%) with SFAB ● Compared to 21/51 (41%) in traditional Dennis-Browne brace and 2/28 (7.1%) in newer brace **Outcome 3: Complications** ● defined as any skin lesion to the lower limb resulting from brace use ● 11/223 (5%) with SFAB: skin bruising and pressure sores on feet ● 12/51 (23.5%) with traditional Dennis-Browne braces, 2/28 (7.1%) in newer brace **Outcome 4: Outcome** ● defined as progress observed in the correction of the foot deformity compared with the previous two visits ● 179/190 (94%) who complied with brace showed improvement in foot deformity correction ● vs. 17/33 (53%) who had been noncompliant	
Notes	**Design:** cross-sectional study (retrospective review of routinely collected data); compared to rates in other study **Aim:** to investigate the acceptance, tolerability, compliance, complications, and outcomes of the Steenbeek foot abduction brace (SFAB) within the Clubfoot Care for Kenya (CCK) program **Setting:** Four health institutions in Kenya providing clubfoot services in both urban and rural settings; January to June 2014	

Quality Assessment of Included Studies



Annex Figure Q4.2. Quality assessment of included studies for (add description).

Annex Table Q4.7.Quality assessment of included studies.

Author Year	Confounding	Selection	Classification of interventions	Deviations from interventions	Missing data	Outcome measurement	Reporting	Overall ROB
Chen 2007	SERIOUS	SERIOUS	LOW	LOW	LOW	SERIOUS	LOW	SERIOUS
	Historical control group was used and not concurrent groups; cannot ensure balance in prognostic factors	18/28 patients in Dobbs group initially were switched from traditional brace due to non-compliance	Brace type received was recorded, well described	No issues	No issues	Given that some patients switched to a different type of brace, compliance data based on parental report may have been biased; outcome assessors not blinded to type of brace	No issues	Due to confounding, selection, measurement bias
Garg 2009	SERIOUS	LOW	LOW	LOW	SERIOUS	SERIOUS	LOW	SERIOUS
	Historical control group was used; dynamic brace group benefited from improved education and support process with brace wear, introducing systematic	no evidence that participants were selected based on characteristics observed after the start of intervention, which would introduce selection bias	Brace type received was recorded, well described	No issues	8/16 (12.3%) of children lost to follow up in the experimental group	Compliance was defined as "family-reported brace wear," a subjective measure prone to reporting bias, particularly given the increased support and communication provided to the	No issues	Due to confounding selection, measurement bias, missing data

Author Year	Confounding	Selection	Classification of interventions	Deviations from interventions	Missing data	Outcome measurement	Reporting	Overall ROB
	different in patient management					dynamic brace group; assessors unblinded		
Hemo 2011	SERIOUS	LOW	LOW	LOW	SERIOUS	SERIOUS	LOW	SERIOUS
	Self-selection introduces significant confounding, as parental preferences likely correlate with motivation, socioeconomic status, perceptions of comfort, which can influence compliance; less affluent families tended to choose DB brace	no evidence that selection into the study was based on post-intervention characteristics related to the outcomes	Mitchell brace and the traditional Denis Browne bar brace were distinct and clearly defined intervention types	Both groups were treated by the same senior orthopedic surgeons and a dedicated physiotherapist who offered "unlimited access to information and was available to address whatever problems they encountered"	Did not report actual rates of complications; but stated that some children experienced sleeping problems, irritability due to brace use	Functional scores assessed by unblinded assessors; compliance assessed using parental questionnaires	No issues	Due to confounding, missing data, outcome measurement bias
Lara 2017	SERIOUS	SERIOUS	LOW	LOW	SERIOUS	SERIOUS	LOW	SERIOUS
	Unspecified method of assignment; substantial	explicitly excluded patients "who did not	traditional Denis-Browne and Dobbs dynamic device,	both groups received consistent patient education through	systematic exclusion of patients who "did not adhere	Recurrence was defined as the "return of initial CCF deformities	No issues	Due to confounding, selection bias, measurement

Author Year	Confounding	Selection	Classification of interventions	Deviations from interventions	Missing data	Outcome measurement	Reporting	Overall ROB
	potential for unmeasured confounding factors, such as clinician preference, socioeconomic influences	adhere to device use or who dropped out of treatment (did not return for outpatient follow-up)	are distinct and were clearly defined	"weekly lectures explaining method"	to device use or dropped out of treatment" represents a significant amount of missing data for the broader eligible population	after treatment", which is a clinical assessment susceptible to detection bias, as assessors (clinicians) would be aware of the brace type; “no complications” in either group may be due to highly compliant participants		bias, and missing data
Mang’oli 2014	SERIOUS	SERIOUS	LOW	NO INFORMATION	NO INFORMATION	SERIOUS	LOW	SERIOUS
	Lacks internal comparison group; used historical data with different population and setting;	no data on clubfoot severity provided; study only included prevalent users of the brace, potentially excluding patients who experienced early failures,	the Steenbeek foot abduction brace (SFAB), is a clearly defined, locally made device	not possible to assess "deviations from intended interventions" in a comparative context (i.e., whether deviations were unbalanced between intervention groups)	does not provide specific information on loss to follow-up or the extent of missing data from enrollment onwards for these patients. The inclusion criterion of having used the SFAB for at least 6 months may	tolerability ("absence of visible discomfort"), compliance ("consistent brace use"), and "progress observed in the correction of the foot deformity" are largely subjective assessments;	No issues	Due to confounding, selection, measurement bias

Author Year	Confounding	Selection	Classification of interventions	Deviations from interventions	Missing data	Outcome measurement	Reporting	Overall ROB
		severe complications, or early non-compliance.			also mask early dropouts who would represent missing data	clinicians and parents both unblinded		

GRADE Evidence Profile table

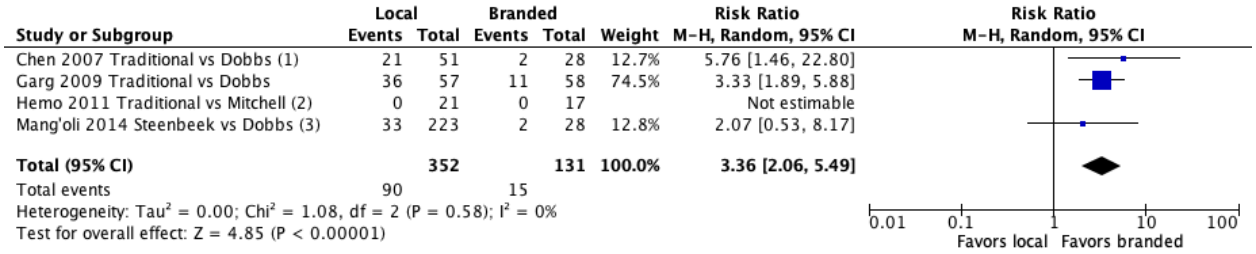
Annex Table Q4.8. Screening with enhanced care compared to usual care for maternal depression for mothers of at-risk infants under 6 months of age.

Author(s): HHGBayona
Question: Locally produced braces compared to commercial (branded) braces in patients with idiopathic clubfoot?
Setting: Outpatient; Philippines

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	locally produced braces	commercial (branded) braces	Relative (95% CI)	Absolute (95% CI)		
Brace non-compliance												
4	non-randomised studies	serious	serious	not serious	not serious	none	90/352 (25.6%)	15/131 (11.5%)	**RR 3.36** (2.06 to 5.49)	**270 more per 1,000** (from 121 more to 514 more)	⊕◯◯◯ Very low	CRITICAL
Recurrence of deformity / relapse												
3	non-randomised studies	serious	serious	not serious	not serious	none	40/132 (30.3%)	13/105 (12.4%)	**RR 2.43** (1.13 to 5.23)	**177 more per 1,000** (from 16 more to 524 more)	⊕◯◯◯ Very low	CRITICAL
Complications (assessed with: skin blistering)												
4	non-randomised studies	serious	serious	not serious	not serious	none	33/347 (9.5%)	4/126 (3.2%)	**RR 3.99** (1.44 to 11.03)	**95 more per 1,000** (from 14 more to 318 more)	⊕◯◯◯ Very low	CRITICAL
Total functional score (follow-up: range 44 months to 88 months; assessed with: Ezra scale)												
1	non-randomised studies	serious	not serious	not serious	not serious	none	No differences between children who used branded (Mitchell-Ponseti brace) or traditional brace in terms of final total functional score. The final functional score was 138 for the Mitchell group and 139.8 for the traditional group (P=0.544).				⊕◯◯◯ Very low	CRITICAL

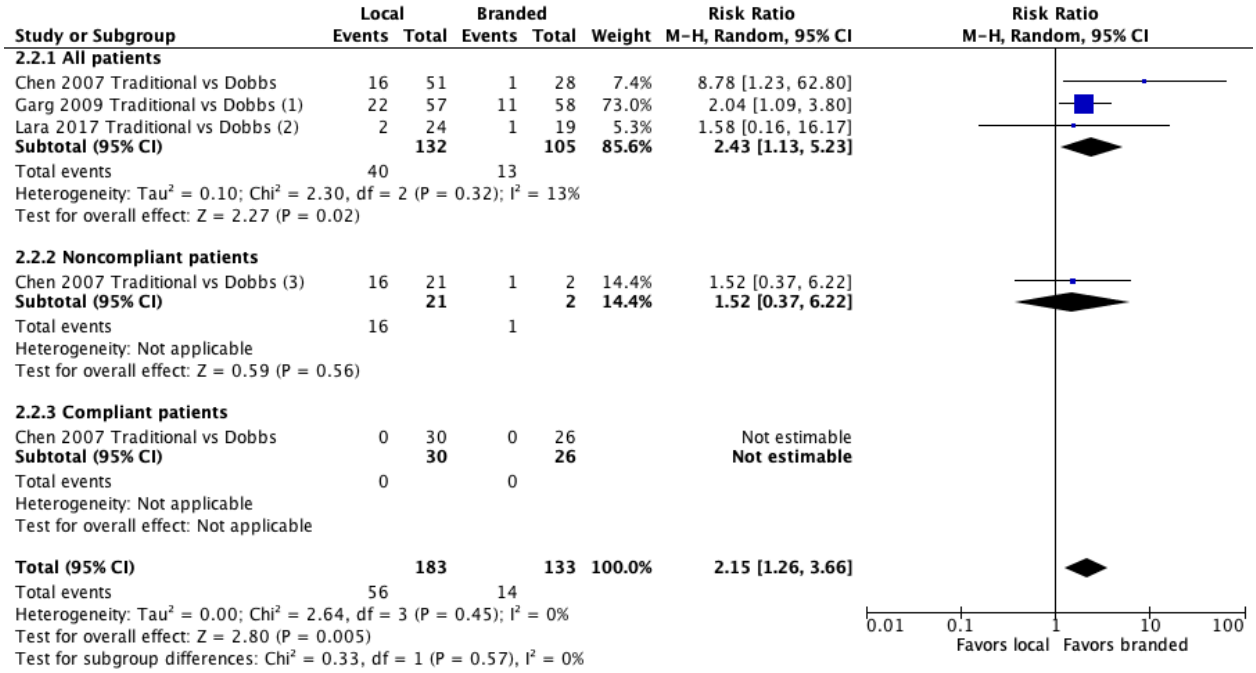
CI: confidence interval; **RR:** risk ratio

Forest plots



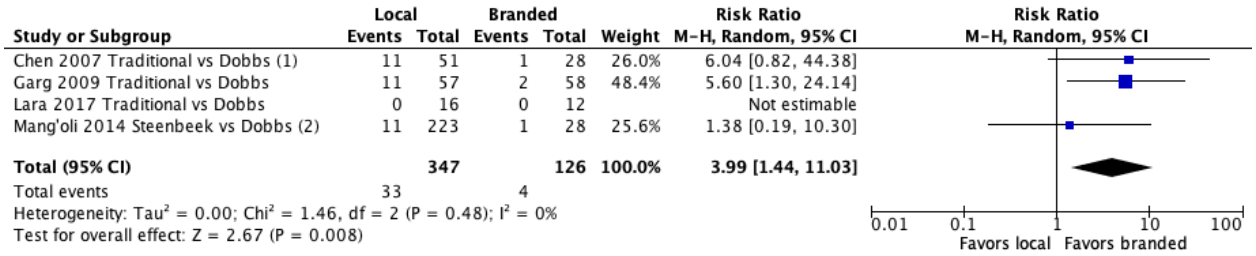
Footnotes
(1) used historical control group
(2) Full compliance for first 2 years based on parent report only; some difficulties noted but no figures
(3) Mean duration of use: 18 mos (range 6–28); used historical control group

Annex Figure Q4.3. Brace non-compliance / non-adherence.



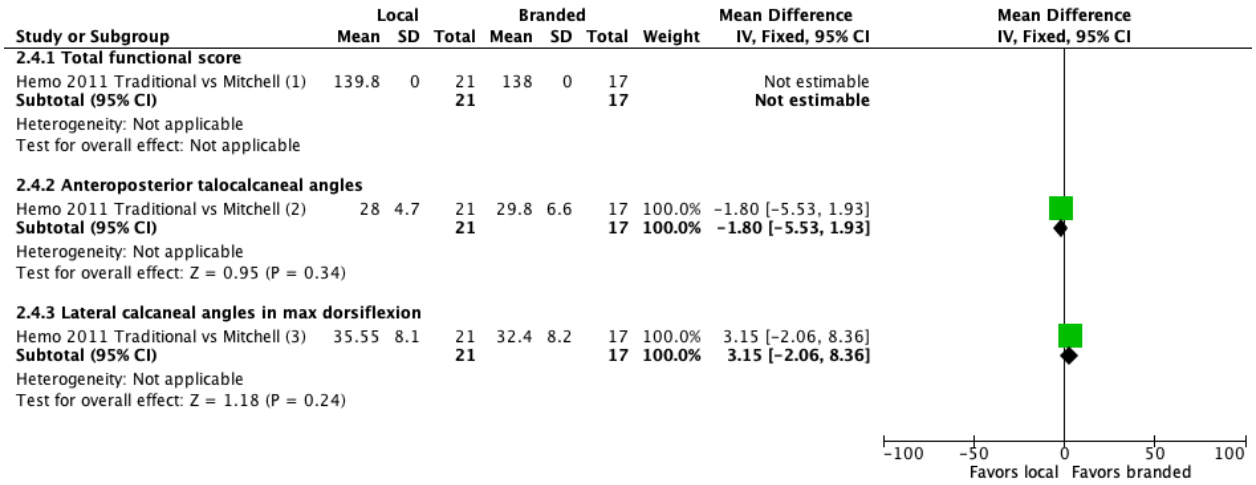
Footnotes
(1) Branded group: 4/47 (8.5%) were compliant with bracing; 7/11 (63.6%) not compliant
(2) excluded data from children who are non compliant
(3) 1 recurrence in branded group due to skin breakdown from improper application of orthosis

Annex Figure Q4.4. Recurrence of deformity / relapse.



Footnotes
(1) skin blistering
(2) skin bruising and pressure sores; rates for newer brace taken from another study

Annex Figure Q4.5. Complications.



Footnotes
(1) P=0.544
(2) P=0.146
(3) P=0.262

Annex Figure Q4.6. Functional scores and radiographic outcomes.

GUIDELINE QUESTION 5: Should infants with idiopathic clubfoot undergo casting within 4 weeks of birth or diagnosis as part of initial conservative (non-surgical) management?

Research Question: Among infants with idiopathic clubfoot, how effective is casting initiated within 4 weeks of birth or diagnosis compared with casting initiated after 4 weeks on improving outcomes as part of initial conservative (non-surgical) management?	
Population	infants with idiopathic clubfoot
Intervention/ Treatment	casting initiated within 4 weeks of birth
Comparison	casting initiated after 4 weeks of birth
Outcomes	improving outcomes as part of initial conservative (non-surgical) management
Subgroups (if any)	None
Methods	RCTs; systematic reviews of RCTs; non-randomized studies of interventions (NRSIs)

Evidence Reviewers: Howell Henrian G. Bayona, MSc, RSLP, Aldrich Ivan Lois D. Burog, MD, MSc (cand.)
Date of Last Search: 11 June 2025 (updated 24 Jun 2025)

Statement of the Evidence

The available evidence suggests that the Ponseti method is generally effective and safe for infants with clubfoot, but initiating treatment early (<1 month vs. later) may result in more cases of unsuccessful initial correction, increased relapse risk, require more casts, complications (cast slippage, blisters) and lower clubfoot severity scores after treatment. Given very low certainty of evidence, conclusions remain highly uncertain and further high-quality comparative studies are needed.

Review Methods

A systematic search was done for published studies from date of database inception until June 24, 2025 on MEDLINE via PubMed, Embase, and HERDIN.ph. The detailed search strategy combined MeSH and free text search terms related to 'clubfoot' and 'casting.' References of systematic reviews and clinical practice guidelines related to the topic were checked for additional studies. Eligible studies for this evidence synthesis were randomized controlled trials (RCTs) or non-randomized studies of interventions (NRSIs) comparing the outcomes of infants who received casting within the first 4 weeks after birth or diagnosis and those treated beyond 4 weeks. Outcomes of interest for this review include relapse rates, successful correction, complications, and long-term function. Risk of bias was assessed using the ROBINS-I tool. The certainty in the effect estimates were rated using the GRADE approach.

Ongoing Studies and Research Gaps

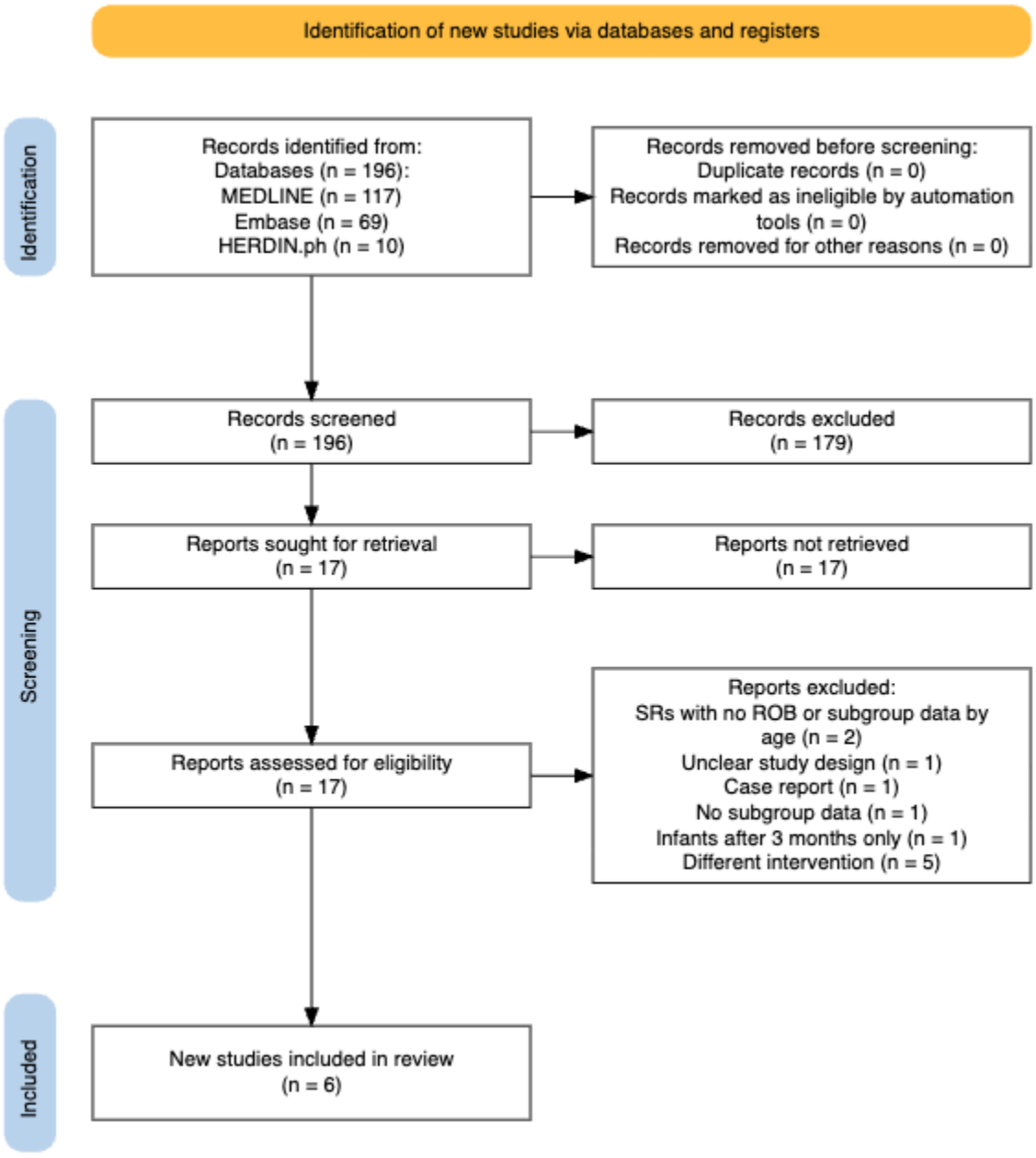
No ongoing studies were found. More comparative studies are needed, specifically in assessing long-term functional outcomes in infants.

Search Strategy

Annex Table Q5.1. Search strategy and yield (as of June 24, 2025).

Database	PICO	No	Search terms	Yield
Medline via PubMed (06/24/25)	Population	1	"Clubfoot"[Mesh] OR "idiopathic congenital talipes equinovarus"[Title/Abstract] OR CTEV [Title/Abstract] OR "idiopathic clubfoot"[Title/Abstract]	4,358
	Intervention	2	"cast"[Title/Abstract] OR "casts"[Title/Abstract] OR "casts, surgical"[MeSH Terms] OR "casting"[Title/Abstract]	72,153
	Population	3	"infant"[Title/Abstract] OR "infants"[Title/Abstract]	500,121
		4	**#1 AND #2 AND #3**	**117**
Embase (06/24/25)	Population	1	Clubfoot/exp OR 'idiopathic congenital talipes equinovarus':ti,ab OR CTEV:ti,ab OR 'idiopathic clubfoot':ti,ab	8,110
	Population	2	'infant':ti,ab OR 'infants':ti,ab	577,832
	Intervention	3	'casting':ti,ab	23,003
		4	**#1 and #2 and #3**	**69**
HERDIN.ph		**1**	**clubfoot**	**10**

PRISMA Flow Diagram



Annex Figure Q5.1. PRISMA Flow Diagram.

Included Studies

Characteristics of Included Studies

Annex Table Q5.2. Study characteristics (Alves 2009).

Population	No. of children: n=68 No. of clubfeet: n=102 4 Portuguese hospitals Children with uncorrected clubfeet, undergone previous tenotomy (considered as a non-operative treatment) Excluded children with clubfeet secondary to any other cause and those with previous posteromedial or posterior release **Subgroups:** ● Group I (< 6 mos): n=50 children (33 boys, 17 girls); 77 clubfeet; mean age at treatment 22.4 days (range: 1–171 days); 8 with previous casting ● Group II (> 6 mos): n=18 children (14 boys, 4 girls); 25 clubfeet, mean age at treatment 402.8 days (range, 180–924 days); all with previous nonoperative treatment, including percutaneous Achilles tenotomy in three feet; 11 with proposed posteromedial release
Intervention	**Ponseti method:** ● manipulation and casting performed by an orthopedic surgeon, often assisted by a nurse or another knowledgeable orthopedic professional. ● Plaster of Paris casts; removed in hospital with scissors or a cast knife, avoiding saws to prevent child distress or injury ● Correction involved addressing the cavus by supinating and gently abducting the forefoot, gradually abducting the foot under the talus, and applying counterpressure against the lateral aspect of the talar head. Approximately 70° of abduction was aimed for with three to eight progressive serial casts. ● "accelerated" Ponseti protocol (i.e., changing casts every 5 days)applied for some patients ● Percutaneous Achilles tenotomy done local anesthesia if residual equinus persisted after 60° to 70° of abduction, followed by immobilization in a final cast for 3 weeks. ● A foot abduction orthosis (FAO), consisting of a Dennis Browne bar and straight last shoes; shoes set to 70° of external rotation for bilateral clubfoot, or 70° for the affected foot and 40° to 45° for the normal foot in unilateral cases. ● FAO 23 hours per day for the first 3 months, then at night and during naps. Initially, 3 years of bracing were recommended, but this was extended to 4 to 5 years of age to prevent recurrences
Control	None
Outcomes	**Follow-up duration:** ≥ 30 mos (mean 41.4 mos [range 30-61]) **Outcome 1: Successful initial correction rates** (defined as “corrected” when it was clinically possible to obtain at least 15° of dorsiflexion, 70° of abduction, a neutral or slightly valgus heel, and a

	straight lateral foot border) ● Group I: 77/77 (100%) feet ● Group II: 25/25 (100%) feet **Outcome 2: Number of tenotomies performed** ● Group I: 65/77 feet (84.4%) ● Group II: 20/25 feet (80%) **Outcome 3: Relapse rate** (defined as later loss of dorsiflexion, varus of the heel, or dynamic supination) ● Relapses in children younger than 2 years were treated with recasting and rebracing. ● For older children, recasting and rebracing or recasting and tibialis anterior transference were offered. ● Radiographs were taken for relapses after 2 years of age to confirm the presence of the third cuneiform ossific nucleus before TAT ● Brace intolerance was identified as a reason for relapse ● Group I: 6/77 clubfeet (7.8%) ● Group II: 2/25 clubfeet (8%) **Outcome 4: Number of casts required to achieve correction** ● Group I: mean 5.3 casts (range 4-8) ● Group II: mean 4.3 casts (range 3-7) **Outcome 5: Need for posteromedial release** ● Group I: 0/77 feet (0%) ● Group II: 0/25 feet (0%) **Outcome 6: Need for tibialis anterior transference** ● Group I: 4/77 (5.2%) ● Group II: 1/25 (11.1%) **Outcome 7: Adverse effects / complications** ● Group I: 1/77 (1.3%) feet with rocker bottom deformity - recasted, repeat tenotomy; 1 blister due to cast; 2 blisters due to FAO ● Group II: 0/25 (0%) feet no complications
Notes	Retrospective review ◦ The study is classified as a Level II, prognostic study

Annex Table Q5.3. Study characteristics (Colburn 2003).

Population	**Number of infants:** 34 (n=14 w/o previous Ponseti treatment; n=12 boys) **Number of clubfeet:** 57 (n=24 w/o previous Ponseti treatment) Infants with congenital idiopathic talipes equinovarus (clubfoot) Age at treatment onset 9.2 days (range: 7-15) Most with (n=23) bilateral clubfeet Referred from other centers or maternity unit, after failure of or incomplete correction w/ other treatment (n=10/34) Excluded congenital syndromes/neuromuscular conditions or reducible deformity Age at baseline range 1-6 days; mean Demeglio score 11.2 (severe)
Intervention	**A. Ponseti method (n=14)** ● Gentle stretching and mobilization ● serial manipulations, ● Casting by well-molded thinly padded plastic casts (changed every 5-7 days) ● Percutaneous Achilles tenotomy as needed when full abduction of the foot of the talus achieved ● Straight-last shoes with a foot abduction bar (60-70° external rotation; worn 23 hrs/day) **B. Ponseti method done after other treatment attempts (n=20)** ● Manipulation ● Castings (non-Ponseti)
Control	None
Outcomes	**Follow-up duration:** 22.9 mos (range: 12-32 mos) **Outcome 1. Successful correction** (defined as ankle-joint dorsiflexion > 10°, plantigrade foot w/o heel varus; Dimeglio score) ● corrected w/ casting alone ○ 3/24 feet (12.5%); 13/33 feet (39.4%) ○ 2/14 infants (21.4%); 7/20 infants (35%) ● corrected w/ casting and Achilles tenotomy ○ 21/24 feet (87.5%); 17/33 feet (51.5%) ○ 12/14 infants (85.7%); 11/20 infants (55%) **Outcome 2. Relapses / recurrence requiring retreatment** ● 4/14 infants or 6/57 feet, all due to non-compliance with bracing; repeat serial mobilization and casting done **Outcome 3. No. of casts required before tenotomy** ● 4.8 avg. casts [range: 3-14])

	Outcome 4. No. of posteromedial release surgery required ● 0/24 feet (0%) ● 0/12 infants (0%)
Notes	USA (California) Retrospective case series

Annex Table Q5.4. Study characteristics (Iltar 2010).

Population	**Number of infants:** 29 **Number of clubfeet:** 40 Infants with congenital idiopathic talipes equinovarus (clubfoot) Mostly males (n=22; 75.9%) Mostly unilateral cases (n=18; 62%) n=4 with complex clubfood deformities, primarily casted then referred elsewhere for surgery Initial mean Demeglio score 15 (very severe; range 9-19) Initial mean Pirani score 5 (range 3-6) Group 1 (≤ 30 days): 19/29 (65.52%) Group 2 (30 days to 12 months): 10/29 (34.48%)
Intervention	**Ponseti method** ● Serial casting 1x weekly, w/ evaluation, manipulation, recasting; performed by surgeon ● Achilles tenotomy done if midfoot Pirani scores indicated correction and external rotation of 15° ● Last cast applied with ankle in 10° dorsiflexion, w/ mild external rotation of the hind foot; maintained for 3 weeks ● Abduction brace with boot with an open and an open heel w/o longitudinal arch support, w/ Denis Browne bar, positioned with foot 60° to 75° abduction; measured before tenotomy in preparation for the brace ● Family taught how to apply the brace and correct brace usage to prevent relapse ● In first 3 months, cast applied for full day (23 hrs)
Control	None
Outcomes	**Follow-up duration:** monthly, until 2 yrs old; mean 34 months (range 20-47) **Outcome 1. Clubfoot severity**

	(Pirani scores and Dimeglio scores; assessed by same surgeon; averaged if bilateral clubfeet case) ● Pirani scoring system: 6 signs of contracture ○ Midfoot - curved lateral border, medial creases, position of the lateral margin of the talar head) ○ Hindfoot - posterior creases, rigid equinus, varus heel ○ Grade I (score < 5) = benign; Grade II (score 5-9) = moderate; Grade III (score 10-14) = severe; Grade IV (score 15-20) = very severe ● Newborn group: ○ Dimeglio score: 15 (9-19) initial, 5 (4-7) final ○ Pirani score: 5 (3-6) initial, 1 (0.5-2) final ● Older infants (1-12 months) ○ Dimeglio score: 14 (9-18) initial, 4 (4-5) final ○ Pirani score: 5 (3-6) initial, 1 (0.5-1.5) final **Outcome 2. Relapses** ● 2/40 feet (5%) in 2/29 infants (6.9%) - both stopped brace use in the 19th and 24th months; 3 reduced brace wear to < 6 hrs/day for 2 months, but increased usage after warning for potential relapse; both unilateral, non complex cases **Outcome 3. No. of casts required for correction** ● 5 avg. casts [range: 3-11]) **Outcome 4. No. of complications** ● Overall: 4/29 (13.8%) ● Poor compliance: 2/18 in newborns (11.1%); 3/11 in older infants (27.3%) ○ 3 cases where grandparents convinced parents to remove brace (primary school education only) ● Other complications (unspecified if this occurred in the older or younger group) ○ Rocker-bottom deformity: 1/29 (3.4%) - corrected w 3 casts in clubfoot position, Ponseti continuation, tenotomy ○ Local allergic dermatitis: 3/29 (10.3%) - needed 3-5 days break before recasting ○ Circulation problems or bleeding: 0/29 (0%) ○ Ingrown nail: 1/29 (3.4%) ○ Dermal abrasion: 1/29 (3.4%) **Outcome 5: Relapse** ● 4/40 feet; 2/29 infants
Notes	Aim: to elucidate the influence of time (newborn period or later) at which Ponseti cast therapy is initiated for the treatment of clubfoot Setting: Ankara, Turkey (May 2005 - September 2007)

Annex Table Q5.5. Study characteristics (Liu 2018).

Population	**Number of infants:** total 90 infants **Number of clubfeet:** total 131 clubfeet **Grouping:** The 90 children (131 clubfeet) were divided into 3 groups according to the age at initiation of treatment: ● Group I: Initial treatment age younger than 28 days (30 cases, 43 feet). ● Group II: Age more than 28 days but less than 3 months (36 cases, 56 feet). ● Group III: Age more than 3 months but less than 6 months (24 cases, 32 feet). **Inclusion criteria:** Infants with idiopathic clubfeet treated with Ponseti method (finished the whole protocol) First presented in the hospital at age < 6 mos Had at least 4 years of post-treatment follow-up No preterm infants (mean gestation age 39.4 wks [range 37-41 weeks] at birth) **Exclusion criteria:** With postural, syndromic, and neurological clubfeet Previous treatment before referral Lost to follow-up at the institution before reaching 4 years of age Lost or incomplete data; or declined to participate. **Characteristics:** Males: Group I = 25/30 (83%); Group II = 29/36 (81%); Group III = 18/24 (75%) Unilateral cases: Group I = 17/30 (57%); Group II = 16/36 (44%); Group III = 16/24 (67%) Mean age at treatment onset: Group I = 13 days (2-27); Group II = 47 days (29-90); Group III = 4.5 mos (3-6) Mean initial Pirani score: Group I = 4.8 (0.9); Group II = 4.3 (1.1); Group III = 4.3 (0.7) Mean Dimeglio score: Group I = 14 (3.5); Group II = 13 (3.1); Group III = 13 (2.7)
Intervention	**Ponseti method:** ● **Protocol:** Strictly adhered to protocol, performed by single orthopedist ● **Casting:** Long leg cast applied after the first evaluation in the outpatient clinic. Casts were removed by a special technician, and parents were not recommended to remove them. ● **Percutaneous Achilles Tenotomy:** Indicated if ankle dorsiflexion was less than 15° and the foot abducted to 60–70° without pronation after the last cast. ● **Post-PAT cast:** A long-leg cast was applied for 3 weeks after the tenotomy. ● **Foot Abduction Orthosis (FAO) / Bracing:** After full correction, an FAO was prescribed. ● **Brace protocol:** Full-time use for the first 3 months, then 16 to 18 hours until 2 years old, then 14 to 16 hours until 4 years old

	• **Relapse Management:** treated with repeated manipulation and casting with or without PAT, followed by the use of the foot-abduction brace. Wearing of the brace was required for an additional year after the removal of the last cast in relapsed cases identified at older than 4 years of age. • **Tibialis Anterior Tendon Transfer (TATT):** Performed in children with dynamic supination of the forefoot during the swing phase of gait
Control	The primary comparison was among the three age groups (Group I, II, III) regarding treatment-related and prognosis-related variables. Variables compared included presentation age, initial Pirani and Dimeglio score, casts required, PAT rate, initial correction rate, compliance rate, relapse rate, ankle dorsiflexion after treatment, final Dimeglio score, and International Clubfoot Study Group (ICFSG) score. Propensity score matching was used for further analysis to adjust for potential confounding factors like gender, bilaterality, initial Pirani/Dimeglio scores, number of casts, PAT, brace compliance, and relapse.
Outcomes	**Follow-up duration:** mean 5 years (range 4-8 yrs) **Outcome 1: Initial correction rate / successful correction** • considered achieved when the foot has reached the targeted abduction (60-70° without pronation) through serial casting, even if residual equinus (dorsiflexion less than 15°) remains and requires a tenotomy • Group I = 22/30 (73.3%) or 33/43 feet (76.7%) • Group II = 33/36 (91.7%) or 51/56 feet (91.1%) • Group III = 20/24 (83.3%) or 26/32 feet (81.3%) **Outcome 2: Recurrence/relapse rates** • Defined as recurrence of any component of the deformities including adductus, varus, cavus, and equinus requiring further intervention, including either repeated manipulation and casting or surgical intervention • Group I = 7/30 (23.3%) or 14/43 feet (32.6%) • Group II = 4/36 (11.1%) or 6/56 feet (10.7%) • Group III = 2/24 (8.3%) or 2/32 feet (6.3%) **Outcome 3: Number of casts required before tenotomy** • Group I = 4.5 ± 1.6; Group II = 3.7 ± 1.2; Group III = 4.2 ± 1.4 **Outcome 2: Brace non-compliance** • Defined as not wearing brace for ≥ 75% of prescribed hours, parent-report • Odds for relapse associated with non-compliance: OR 3.3 • no influence of age at initiation of treatment on brace adherence among 3 groups • Group I = 5/30 (16.7%) or 8/43 feet (18.6%) • Group II = 6/36 (16.7%) or 10/56 feet (17.7%)

	• Group III = 6/24 (25.0%) or 6/32 feet (18.8%) **Outcome 4: Complications** • Cast slippage: 3/30 (10%) cases (4/43 feet) in Group I only • Rocker bottom deformity: 0 • Skin necrosis or ulcer: 0 • Neurovascular compromise post-tenotomy: 0 **Outcome 5: Clubfoot severity** • Assessed using ICFSG score; used to evaluate the outcome of clinical evaluation in terms of foot morphology, function, and radiology • Group I = 4.9 ± 1.6; Group II = 3.9 ± 2.2; Group III = 6.8 ± 1.1 (significantly worse vs. Group I and II) • Presentation age was only factor predictive of final clinical outcome **Outcome 6: Tenotomy rate** • Group I = 28/30 (93.3%) infants, 40/43 (93.0%) feet • Group II = 29/36 (80.6%) infants, 46/56 (82.1%) feet • Group III = 22/24 (91.7%) infants, 28/32 (87.5%) feet
Notes	A retrospective study evaluating clinical outcomes with different ages at the onset of Ponseti management for clubfoot. Aim: to assess whether age at start of treatment influences number of casts, tenotomies, correction rates, recurrence rates, ankle dorsiflexion after treatment, final clubfoot severity (Dimeglio score and International Clubfoot Study Group [ICFSG] score) Attrition rate: 61/188 (32.4%) lost to follow-up due to poor brace adherence (mean wearing time of 11 mos)

Annex Table Q5.6. Study characteristics (Zanardi 2019).

Population	**Number of infants:** 52 **Eligibility criteria:** Infants consecutively treated for idiopathic congenital clubfeet Born full-term (gestation ≥ 37 weeks) No previous clubfoot treatment or formal physiotherapy prior to walking age **Exclusion criteria:** postural deformities, benign feet (Dimeglio grade I), non-idiopathic clubfoot, any other conditions that could delay motor development (e.g., orthopedic, immobilization), lack of adherence to treatment protocol, underwent casts or interventions for relapses before independent ambulation **Characteristics (Ponseti group only, n=26):** Mostly males (21/26, 80.7%) Mostly bilateral cases (17/26, 65.4%) Mean age at beginning of treatment: 26.4 days (SD 10.8) Clubfoot severity (Mean Dimeglio score): 13.3 (SD 3.2)
Intervention	**Ponseti method:** Treatment done by single orthopedic surgeon with 10 years experience in managing clubfoot, following local protocols Weekly manipulation and above-knee casting until complete abduction was achieved Percutaneous Achilles tenotomy done if foot could not be dorsiflexed to 15° Foot abduction brace applied after last cast: worn 23 hrs/day x 3 mos, reduced gradually to 12 hrs/day, then at night and during naps from walking age to 4-5 yrs old No formal physical therapy was provided to prior to walking age
Control	Factors investigated for their influence on milestone achievement included sex, severity at presentation (DimS), laterality (unilateral versus bilateral), and need for tenotomy
Outcomes	**Follow-up duration:** mean 48 mos (SD 14) **Outcome 1: mean age to achieve gross motor milestones** ● Parents record age at which child achieved pull-to-standing, cruising, independent ambulation (10 steps w/o support); parent report validated by physician or physiotherapist observation at each clinic visit ● Pull to stand: 9.8 mos (SD 1.5) ● Cruising: 11.3 mos (SD 1.4) ● Independent walking: 14.3 mos (SD 1.6); all patients walking by 18 mos

	Outcome 2: number of infants needing tenotomy ● n=22/26 infants, 84.6% ● Age at tenotomy: 77 days (SD 12) **Outcome 3: successful initial correction** ● n=26/26 infants 100% Dimeglio score ● *Relapse rate not assessed*
Notes	Prospective cohort study; only the Ponseti group was used for this evidence synthesis Study setting: January 2011 to December 2015; two institutes in Italy Aim: to evaluate gross motor milestones in 2 groups of clubfoot patients – treated with Ponseti method or French physiotherapy

Annex Table Q5.7. Study characteristics (Zionts 2014).

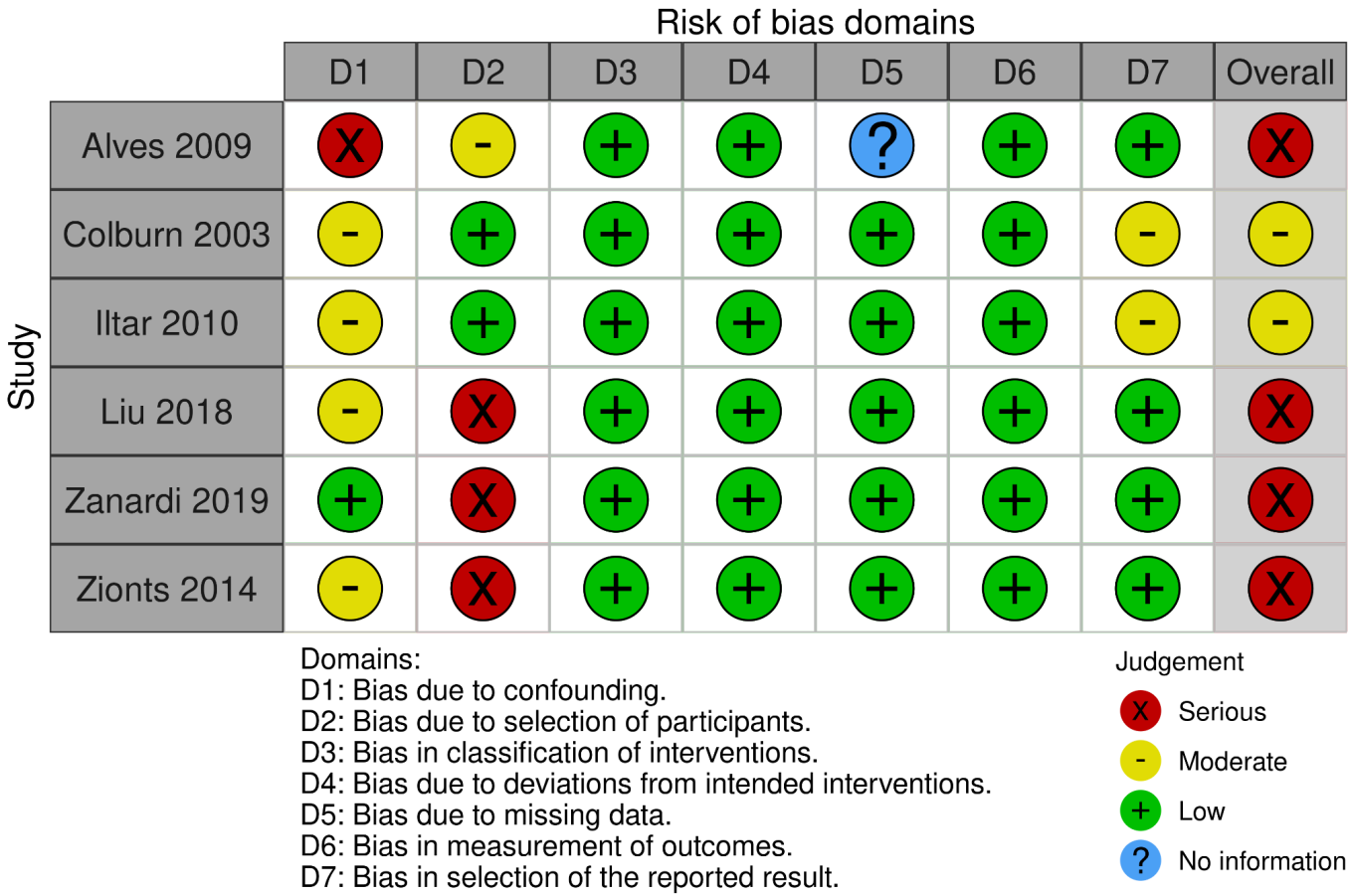
Population	**Number of infants:** 94 infants **Inclusion criteria:** Infants with idiopathic clubfoot who were full term at birth No more than 3 mos of age at the start of treatment No prior outside treatment Followed for a minimum of 24 mos **Exclusion criteria:** Gestational age < 37 wks; age > 3 mos at start of treatment; prior outside treatment; mild or positional deformity, orthopaedic problems other than clubfoot that might affect motor development; patients lost to follow-up prior to reaching twenty-four months at the institution; infants with a mild deformity (Diméglio Grade I) were also excluded because their treatment was usually less extensive and often differed from the standard Ponseti method **Characteristics:** Mean age at start of treatment 4.1 ± 2.4 wks (range 0.7 to 11.7) 68/94 (72%) were male and 26 (28%) were female. 50 (53%) had bilateral involvement, and among unilateral cases, 25 (57%) had the left foot affected. 22 (23%) patients had a first-degree relative with clubfoot. Deformity severity: 76 (81%) patients had Diméglio Grade II (moderate) or Grade III (severe) deformity, and 18 (19%) had Grade IV (very severe) deformity
Intervention	**Ponseti method:** ● **Manipulation:** serial manipulation weekly

	• **Casting:** Casting at the forefoot, midfoot, and subtalar components of the deformity; casts applied at weekly intervals using semi-rigid fiberglass material (3M Scotchfast Soft Cast Casting) • **Percutaneous Achilles (heel-cord) tenotomy:** required to address any remaining equinus and provide final correction if there was less than 15° of dorsiflexion when the foot achieved 70° of abduction relative to the thigh; done in the operating room under sedation • **Post-tenotomy cast:** Worn for 3 weeks after the tenotomy. • **Foot abduction orthosis (brace):** After the last cast, infants were fitted with a Mitchell-Ponseti (MP) brace. • **Brace regimen:** 23 hours a day for 3 mos, followed by night and naptime use until the child is at least 4yo; parents were generally instructed to perform heel-cord stretching exercises before applying the brace • **Relapse management:** series of 1-3 manipulations and casts, followed by the resumption of bracing. • No formal physical therapy was provided prior to walking.
Control	None

Outcomes	**Follow-up duration:** mean duration of follow-up was 15.8 ± 5.5 months
	
	Outcome 1: mean age to achieve gross motor milestones
	• Age at which infants achieved independent walking
	  ○ Mean age 14.5 ± 2.6 mos (range 10-22)
	  ○ 90% of patients were walking by 18 months
	• Based on parent report, validated by infant observation during clinic visit by physician; defined as taking 10 steps or more without assistance; recorded to the nearest month
	• Influence of patient factors (sex, bilaterality, severity, family history) on walking age
	  ○ Factor that had the greatest influence on the mean age at walking was the severity of deformity
	  ○ Patients with an initial diagnosis of a moderate or severe clubfoot deformity began walking more than one month sooner than the patients whose deformity was classified as very severe (14.2 months compared with 15.8 months; p = 0.03)
	• Influence of treatment factors (number of casts, tenotomy need, brace noncompliance, early relapse) on walking age
	  ○ Patients who experienced a relapse before learning to walk began walking nearly two months later than those who did not relapse (15.9 months compared with 14.2 months; p = 0.04)
	  ○ No significant influence: number of casts used prior to tenotomy, the need for heel-cord tenot- omy, and noncompliance with brace use
	
	Outcome 2: Number of casts needed to obtain initial correction
	• Mean 5.5 casts (range 3-12)
	• mean number of casts prior to tenotomy: 5.6 ± 1.7 casts
	
	Outcome 3: Noncompliance with bracing
	• Defined as failure to use the brace as prescribed.
	• 21/94 (22.3%) non compliance rate prior to onset of walking

	Outcome 4: Relapse rate ● Defined as the reappearance of any of the components of the clubfoot deformity requiring further treatment. ● 14/94 (14.9%), managed with a series of one to three manipulations and casts, followed by the resumption of bracing **Outcome 5: Clubfoot severity** ● Graded at initial presentation using the Diméglio scale. For bilateral cases, the greater of the two Diméglio scores was used; Grade I = 0-4 pts (mild); Grade II = 5-9 (moderate); Grade III = 10-14 (severe); Grade IV = 15-20 (very severe) **Outcome 6: Heel-cord tenotomy** ● 89/94 (95%) **Outcome 7: Initial correction of the deformity** ● 94/94 (100%)
Notes	Setting: July 2006 to August 2011; California, USA Aim: to determine age at which infants with idiopathic clubfoot treated with Ponseti method begin to walk; to evaluate influence of sex, bilaterality, severity of deformity, early relapse on achievement of independent walking

Quality Assessment of Included Studies



Annex Figure Q5.2. ____

Annex Table Q5.8. Risk of Bias using ROB1

Author Year	Confounding	Selection	Classification of interventions	Deviations from interventions	Missing data	Outcome measurement	Reporting	Overall ROB
Alves 2009	SERIOUS	MODERATE	LOW	LOW	UNCLEAR	LOW	LOW	SERIOUS
	2 groups not matched for previous treatment or clubfoot severity; older group had prior nonoperative treatment	Included patients w/ uncorrected clubfeet and previous tenotomy	Ponseti method clearly defined	similar protocol followed; non-compliance with bracing was an outcome of interest rather than deviation	No info	Outcomes were objectively defined	No selective reporting of results	Due to baseline confounding and selection bias
Colburn 2003	MODERATE	LOW	LOW	LOW	LOW	LOW	LOW	MODERATE
	Included either new to Ponseti or had prior non-Ponseti treatments; overall success rate presented by combining both groups	evaluated consecutive infants presenting at their institution within a specific age range (1 day to 6 months), and excluded specific conditions. Follow-up	Adhered to the Ponseti method protocol	non-compliance with bracing was an outcome of interest rather than deviation	No info; follow-up 23 months but unclear whether some were lost to follow-up or had missing outcome data	Success criteria were objectively defined (ankle dorsiflexion, plantigrade foot, no heel varus), and the Dimeglio scale was used for severity.	No selective reporting of results	Due to initial patient heterogeneity regarding previous treatment and the lack of clarity on missing data

Author Year	Confounding	Selection	Classification of interventions	Deviations from interventions	Missing data	Outcome measurement	Reporting	Overall ROB
		commenced from the start of Ponseti treatment, aligning with the "new user" principle for observational studies						
Iltar 2010	MODERATE	LOW	LOW	LOW	LOW	LOW	MODERATE	MODERATE
	Both age groups did not differ significantly in terms of Initial Pirani and Dimeglio scores, although it is unclear whether both groups were balanced in terms of other characteristics (e.g., bilateral involvement, comorbidities)	Appropriate inclusion criteria; only 2/31 cases lost to follow-up	Ponseti method strictly followed; all treated with tenotomy	No deviations noted	No issues	Standardized scoring systems (Pirani, Dimeglio, ICFSG) were used	Only data on Pirani and Dimeglio scores per subgroup were available; other data not subgrouped	Due to moderate risk of bias related to confounding and reporting of data.
Liu 2018	MODERATE	SERIOUS	LOW	LOW	LOW	LOW	LOW	SERIOUS

Author Year	Confounding	Selection	Classification of interventions	Deviations from interventions	Missing data	Outcome measurement	Reporting	Overall ROB
	Unmeasured confounding cannot be entirely ruled out; some attempt to control for confounding by doing propensity score matching for several covariates, and by showing no significant difference in initial clubfoot severity between the age groups	significant portion of initially treated patients (61/188 lost to follow-up, 16/188 still under treatment due to relapse) were excluded from the analysis because they did not complete the full protocol or 4 years of follow-up	Ponseti method was strictly followed and all cases were treated by a single orthopedist	compared outcomes based on the age at initiation of the Ponseti method. Non-compliance with bracing and relapse were treated as outcome of interest	For the included cohort of 90 children (131 feet), complete information was collected in their database	Standardized scoring systems (Pirani, Dimeglio, ICFSG) were used, and outcomes like casts and relapse rates were clearly defined and assessed consistently by a single orthopedist	clearly stated its objectives and reported results transparently for all planned outcomes and analyses	due to the selection bias in participant inclusion
Zanardi 2019	LOW	SERIOUS	LOW	LOW	LOW	LOW	LOW	SERIOUS
	No previous clubfoot treatment; most participants had higher clubfoot severity and number of	excluded patients who experienced relapses before achieving independent ambulation	Ponseti protocol was clearly described and applied by experienced teams at their respective institutions	Relapses were treated as an outcome	prospectively enrolled and followed all 52 infants, and parental reports of milestones were verified by physicians	Gross motor milestones (pull-to-standing, cruising, independent ambulation) were recorded by parents and validated by	No selective reporting of results	Due to selection bias

Author Year	Confounding	Selection	Classification of interventions	Deviations from interventions	Missing data	Outcome measurement	Reporting	Overall ROB
	bilateral cases, which may affect motor development negatively					medical staff, with parental recall reliability considered accurate		
Zionts 2014	MODERATE	SERIOUS	LOW	LOW	LOW	LOW	LOW	SERIOUS
	compared their Ponseti cohort's walking age to historical data from healthy infants, which carries inherent confounding risks from unmeasured factors	12 patients excluded for not completing 24 months of follow-up; given that some of these patients had brace noncompliance and relapses, their exclusion could have biased observed effects on walking age	Ponseti method was consistently applied by a single surgeon and clearly described, including manipulation, casting, tenotomy, and bracing.	Noncompliance with bracing and relapse were analyzed as factors influencing the outcome (walking age)	For the included 94 patients, walking age data were collected via parental report and physician observation, suggesting high completeness for this cohort	Walking age was recorded to the nearest month based on parental report, verified by physician observation. Parental recall reliability for milestones is noted to be accurate.	reported all relevant findings regarding walking age and its influencing factors without indication of selective reporting	Due to selection bias from excluding patients with incomplete follow-up)

GRADE Evidence Profile table

Annex Table Q5.9. GRADE Evidence Profile

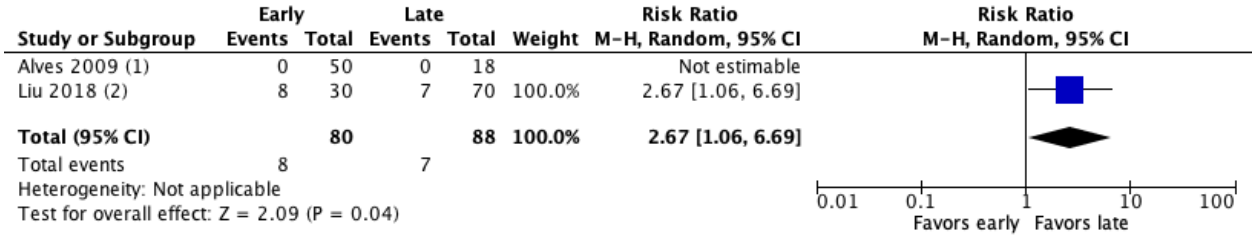
Author(s): HHGBayona
Question: Casting within 4 weeks of birth or diagnosis as part of initial conservative (non-surgical) management compared to casting > 4 weeks for infants with idiopathic clubfoot
Setting: Outpatient; Philippines

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	casting within 4 weeks	casting > 4 weeks	Relative (95% CI)	Absolute (95% CI)		
Rate of unsuccessful initial correction (follow-up: range 30 months to 8 years; assessed with: deformity reduction sufficient for non-surgical management and bracing)												
2	non-randomised studies	serious	serious	not serious	not serious	none	8/80 (10.0%)	7/88 (8.0%)	**RR 2.67** (1.06 to 6.69)	**133 more per 1,000** (from 5 more to 453 more)	⊕◯◯◯ Very low	CRITICAL
Rate of relapse / recurrence of deformity (follow-up: range 30 months to 8 years; assessed with: varied criteria (e.g., loss of dorsiflexion, dynamic supination, or noncompliance with bracing))												
2	non-randomised studies	serious	not serious	not serious	serious	none	14/107 (13.1%)	9/95 (9.5%)	**RR 1.96** (0.78 to 4.88)	**91 more per 1,000** (from 21 fewer to 368 more)	⊕◯◯◯ Very low	CRITICAL
Number of casts before tenotomy												
2	non-randomised studies	serious	not serious	not serious	serious	none	Infants treated in the first month required more casts than those treated later (Liu 2018: 4.5 ± 1.6 vs. 3.7 ± 1.2; Alves 2009: 5.3 ± 0.9 vs. 4.3 ± 1.2, NS).				⊕◯◯◯ Very low	CRITICAL
Need for tenotomies (follow-up: range 30 months to 8 years)												
2	non-randomised studies	serious	not serious	not serious	not serious	none	105/120 (87.5%)	94/113 (83.2%)	**RR 1.09** (0.98 to 1.22)	**75 more per 1,000** (from 17 fewer to 183 more)	⊕◯◯◯ Very low	CRITICAL
Need for posteromedial release (follow-up: range 30 months to 61 months)												
1	non-randomised studies	serious	not serious	not serious	not serious	none	0/77 (0.0%)	0/25 (0.0%)	not estimable		⊕◯◯◯ Very low	CRITICAL

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	casting within 4 weeks	casting > 4 weeks	Relative (95% CI)	Absolute (95% CI)		
Need for tibialis anterior transference (follow-up: range 30 months to 61 months)												
1	non-randomised studies	serious	not serious	not serious	not serious	none	4/77 (5.2%)	1/25 (4.0%)	**RR 1.30** (0.15 to 11.09)	**12 more per 1,000** (from 34 fewer to 404 more)	⊕◯◯◯ Very low	CRITICAL
Complications: brace non-compliance (follow-up: range 20 to 8 years)												
2	non-randomised studies	serious	not serious	not serious	serious	none	7/48 (14.6%)	15/81 (18.5%)	**RR 0.78** (0.34 to 1.77)	**41 fewer per 1,000** (from 122 fewer to 143 more)	⊕◯◯◯ Very low	CRITICAL
Complications: other (follow-up: range 30 months to 8 years; assessed with: cast slippage, blisters)												
2	non-randomised studies	serious	not serious	not serious	not serious	none	8/120 (6.7%)	0/113 (0.0%)	**RR 7.36** (0.95 to 56.98)	**0 fewer per 1,000** (from 0 fewer to 0 fewer)	⊕◯◯◯ Very low	CRITICAL
Independent walking (follow-up: range 10 months to 48 months; assessed with: age at which child can walk 10 steps without support)												
2	non-randomised studies	serious	not serious	not serious	not serious	none	Children treated with the Ponseti method achieved pull-to-stand at 9.8 ± 1.5 months, cruising at 11.3 ± 1.4, and walking at 14.3 ± 1.6 months (Zanardi 2019), while early-treated infants walked **2.4 months later** than healthy controls (14.5 ± 2.6 vs. 12.1 ± 1.8 months; p < 0.001), with relapses adding a further **1.7-month delay** (Zionts 2014).				⊕◯◯◯ Very low	CRITICAL
Clubfoot severity (follow-up: range 30 months to 8 years; assessed with: ICFSG score, Dimeglio score, or Pirani score)												
2	non-randomised studies	serious	not serious	not serious	not serious	none	Liu 2018 found no difference in final Dimeglio scores across treatment ages (<1 mo: 4.3 ± 1.3; 1–3 mo: 4.1 ± 0.8; 3–6 mo: 4.1 ± 0.6), while ICFSG scores were best for 1–3 mo (3.9 ± 2.2) compared to <1 mo (4.6 ± 1.4) and 3–6 mo (6.3 ± 1.1), all within good–excellent range. Iltar 2010 reported better Dimeglio scores for treatment at 1–12 mo (mean 4) versus <1 mo (mean 5), and in infants with ≥8 cm foot length (mean 4) versus <8 cm (mean 5).				⊕◯◯◯ Very low	CRITICAL

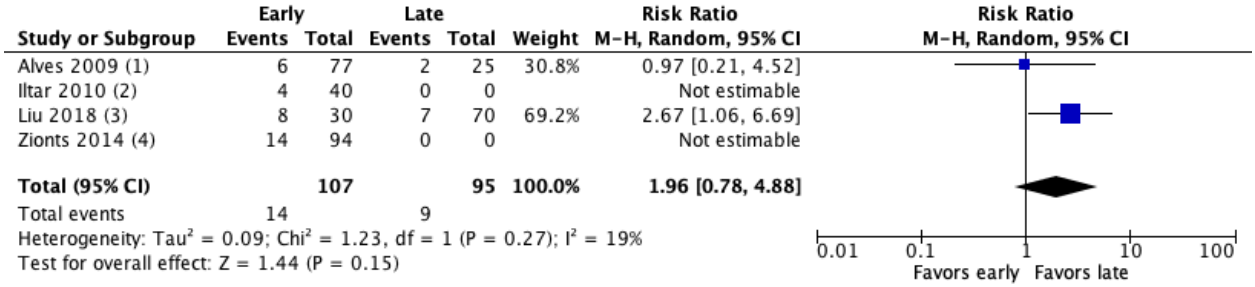
CI: confidence interval; **RR:** risk ratio

Forest plots



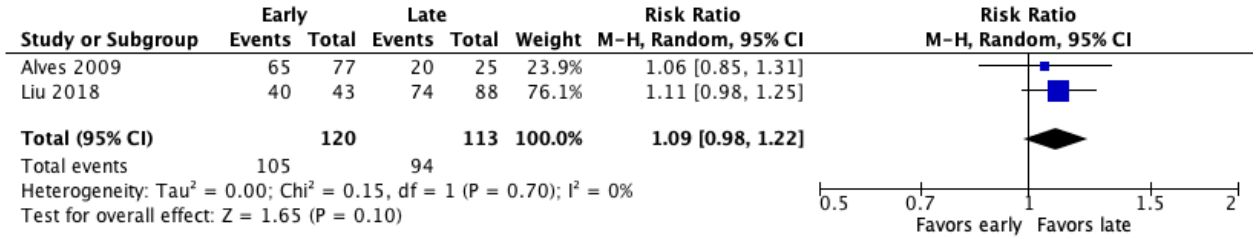
Footnotes
(1) < 6 mo (mean age 22.4 days) vs > 6 mos (mean age 402.8 days)
(2) < 28 days (mean age 13 days) vs. > 28 days (combined 1–3 mo and 3–6 mo)

Annex Figure Q5.3. Unsuccessful initial correction.



Footnotes
(1) < 6 mo (mean age 22.4 days) vs > 6 mos (mean age 402.8 days)
(2) 2/29 infants; mean age 59 days (65.5% < 1 mo old); both due to brace use stoppage
(3) < 28 days (mean age 13 days) vs. > 28 days (combined 1–3 mo and 3–6 mo)
(4) 14/94 (14.9%) relapse rate; managed with 1–3 manipulations and casts

Annex Figure Q5.4. Relapse rate *(pooled estimates only consider NSRIs).*



Annex Figure Q5.5. Need for tenotomies.

Study or Subgroup	Early Events	Early Total	Late Events	Late Total	Weight	Risk Ratio M-H, Random, 95% CI
Alves 2009 (1)	0	77	0	25		Not estimable
Colburn 2003 (2)	0	24	0	0		Not estimable
Total (95% CI)		**77**		**25**		**Not estimable**
Total events	0		0			

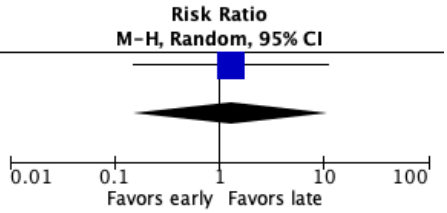
Heterogeneity: Not applicable
Test for overall effect: Not applicable

Footnotes
(1) 68 infants; age 22.4 days for "early" group, 402.8 days for "late" group
(2) 0/12 infants w/o previous Ponseti treatment; mean age 9.2 days

Annex Figure Q5.6. Need for posteromedial release.

Study or Subgroup	Early Events	Early Total	Late Events	Late Total	Weight	Risk Ratio M-H, Random, 95% CI
Alves 2009	4	77	1	25	100.0%	1.30 [0.15, 11.09]
Total (95% CI)		**77**		**25**	**100.0%**	**1.30 [0.15, 11.09]**
Total events	4		1			

Heterogeneity: Not applicable
Test for overall effect: Z = 0.24 (P = 0.81)



Annex Figure Q5.7. Need for tibialis anterior transference.

Study or Subgroup	Early Events	Early Total	Late Events	Late Total	Weight	Risk Ratio M-H, Random, 95% CI
1.7.1 Other complications						
Alves 2009 (1)	4	77	0	25	14.9%	3.00 [0.17, 53.86]
Liu 2018 (2)	4	43	0	88	14.8%	18.20 [1.00, 330.63]
Subtotal (95% CI)		**120**		**113**	**29.8%**	**7.36 [0.95, 56.98]**
Total events	8		0			

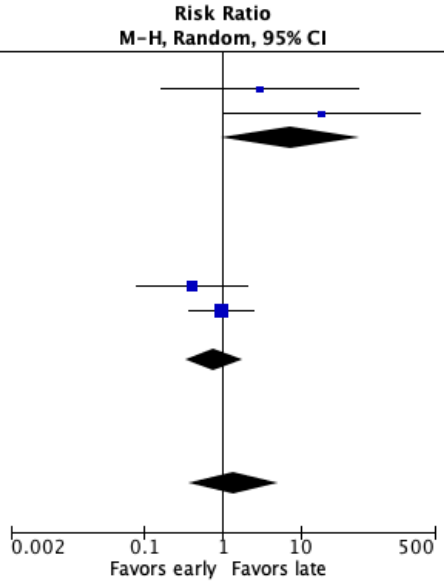
Heterogeneity: $Tau^2 = 0.00$; $Chi^2 = 0.75$, df = 1 (P = 0.39); $I^2 = 0\%$
Test for overall effect: Z = 1.91 (P = 0.06)

1.7.2 Brace noncompliance						
Iltar 2010	2	18	3	11	29.2%	0.41 [0.08, 2.07]
Liu 2018	5	30	12	70	41.1%	0.97 [0.38, 2.52]
Zionts 2014 (3)	21	94	0	0		Not estimable
Subtotal (95% CI)		**48**		**81**	**70.2%**	**0.78 [0.34, 1.77]**
Total events	7		15			

Heterogeneity: $Tau^2 = 0.00$; $Chi^2 = 0.82$, df = 1 (P = 0.37); $I^2 = 0\%$
Test for overall effect: Z = 0.60 (P = 0.55)

Total (95% CI)		**168**		**194**	**100.0%**	**1.38 [0.37, 5.16]**
Total events	15		15			

Heterogeneity: $Tau^2 = 0.87$; $Chi^2 = 6.05$, df = 3 (P = 0.11); $I^2 = 50\%$
Test for overall effect: Z = 0.48 (P = 0.63)
Test for subgroup differences: $Chi^2 = 3.99$, df = 1 (P = 0.05), $I^2 = 74.9\%$



Footnotes
(1) 1 rocker bottom deformity; 1 blister due to cast; 2 blisters due to brace
(2) 4 cast slippage
(3) 21/94 infants (22.3%) non compliant prior to onset of walking

Annex Figure Q5.8. Complications ***(pooled estimates only consider NSRIs).***

GUIDELINE QUESTION 6: Should percutaneous tenotomy be performed among those eligible following completion of Ponseti casting among patients with idiopathic clubfoot?

Research Question: Among patients with idiopathic clubfoot who are eligible (by Pirani score (e.g., >1 Hindfoot score)) after completion of Ponseti casting, how effective is performing percutaneous tenotomy compared with not performing tenotomy in achieving successful correction, reducing relapse, and improving long-term functional outcomes?	
Population	patients with idiopathic clubfoot who are eligible (by Pirani score (e.g., >1 Hindfoot score)) after completion of Ponseti casting
Intervention/ Treatment	percutaneous tenotomy
Comparison	Nonperformance of percutaneous tenotomy, or Z lengthening (open tenotomy), White Slide percutaneous lengthening
Outcomes	• Successful correction • Improvement in hindfoot Pirani score • Increase in ankle dorsiflexion • Increase in length of Achilles tendon • Residual deformity after initial treatment completion • Recurrence/relapse requiring further intervention • Time to achieve full correction • Gait function and mobility at follow-up • Long-term foot function (strength, flexibility, endurance) • Ankle/foot range of motion at follow-up (beyond dorsiflexion) • Health-related quality of life (HrQOL) for the child and family • Adverse events related to anesthesia/analgesia
Subgroups (if any)	None
Methods	RCTs; systematic reviews of RCTs; non-randomized studies of interventions (NRSIs)

Evidence Reviewers: Anna Angelica Macalalad Josue, MD, MSc (cand.); Aldrich Ivan Lois D. Burog, MD, MSc (cand.)
Date of Last Search: Sept 1, 2025

Statement of the Evidence

- Among patients with clubfoot who are eligible after completion of Ponsetti casting, PERCUTANEOUS TENOTOMY
  - may increase the possibility of successful correction
  - may result in improvement in hindfoot Pirani score
  - May result increase in ankle dorsiflexion
  - Increase in length Achilles heel tendon

- Late tenotomy may reduce the probability of relapse or recurrence, compared to no tenotomy
- We are uncertain if percutaneous tenotomy has any effect on residual deformity as measured by Demiglio score.

- We are uncertain whether initial percutaneous tenotomy has any effect on the probability of relapse or recurrence
- No evidence on the effect of percutaneous tenotomy on gait function and mobility at follow up, long term foot function (strength, flexibility, endurance), HrQOL for the child and family, Adverse events related to anesthesia/analgesia

Review Methods

A comprehensive literature search was conducted to identify studies examining percutaneous Achilles tenotomy in the management of idiopathic clubfoot. The following search terms were employed: clubfoot, clubfeet, congenital talipes equinovarus, CTEV, idiopathic clubfoot, percutaneous tenotomy, Achilles tendon release, needle tenotomy, heel cord tenotomy, Ponseti technique, serial manipulation and casting, equinus correction, hindfoot deformity management. Database searches included MEDLINE via PubMed, Cochrane Central Register of Controlled Trials, Embase, CINAHL, and specialized orthopedic literature repositories. No restrictions were applied regarding publication date, study methodology, or language of publication. Additional searches were performed in trial registries including ClinicalTrials.gov and WHO International Clinical Trials Registry Platform. The final search was completed on September 1, 2025. Studies lacking relevant outcome measures were excluded from analysis. Systematic reviews were identified using methodological search filters and evaluated with the AMSTAR2 assessment tool. High-quality systematic reviews were supplemented by searching for recent randomized controlled trials, which were critically appraised using the ROBUST RCT evaluation framework. The certainty of evidence was determined through GRADE methodology.

Recommendations from Other Groups

Annex Table Q6.1. Summary of Recommendations from Other Groups.

Group or Agency	Recommendation	Strength of Recommendation/ Certainty/Quality of Evidence
Dutch Orthopaedic Association, 2017	If possible, the Achilles tendon tenotomy is to be carried out under local anesthetics	No mention

Ongoing Studies and Research Gaps

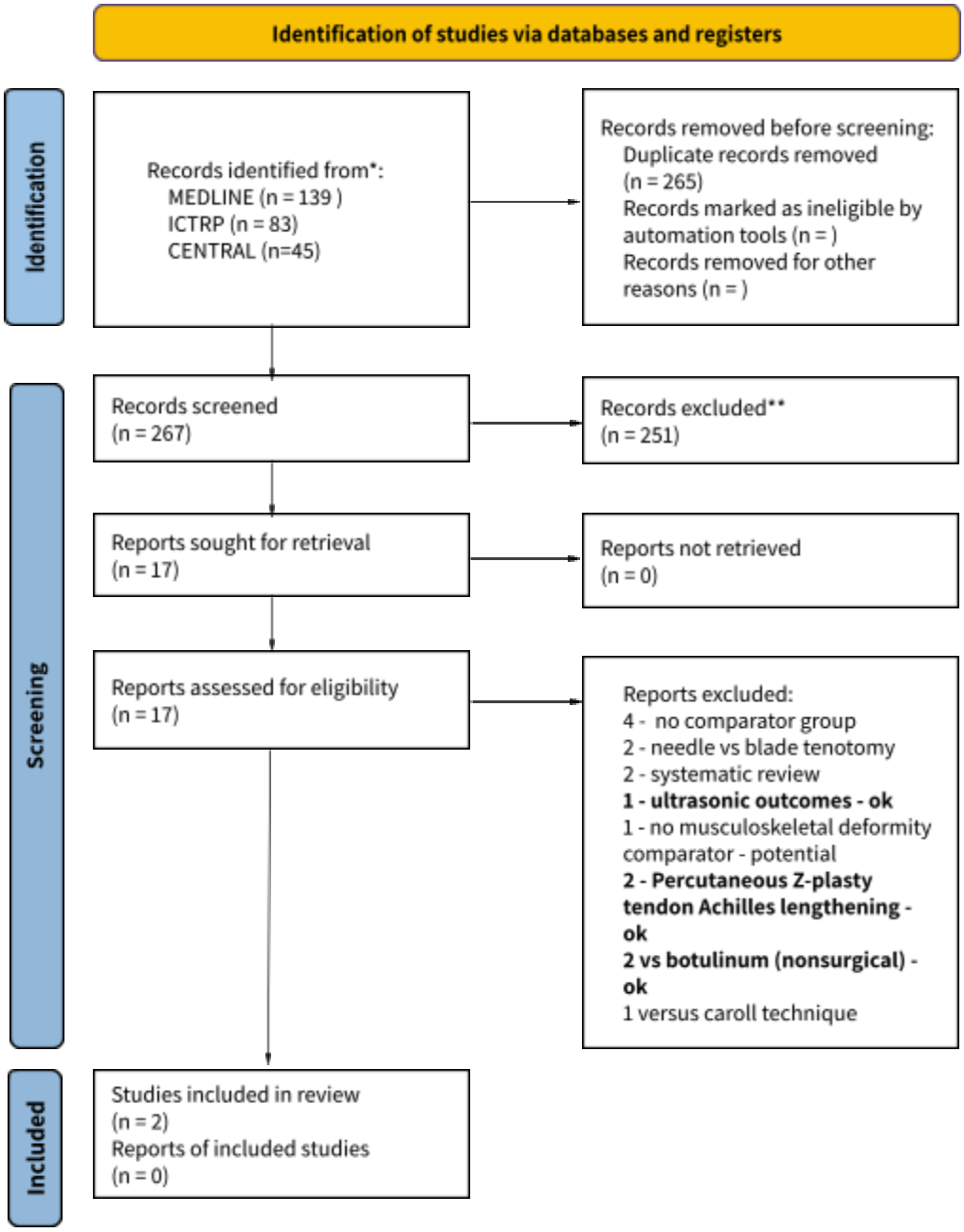
There are no studies comparing the effect of percutaneous tenotomy on gait function and mobility at follow up, long term foot function (strength, flexibility, endurance), HrQOL for the child and family as well as adverse events.

Search Strategy

Annex Table Q6.2. Search Strategy (as of September 1, 2025, MEDLINE).

Search number	Query	Sort By
25	#24 AND #15	138
24	#16 OR #17 OR #18 OR #19 OR #20 OR #21 OR #23	1,000
23	"Tenotomy"[Majr]	727
21	Blind tenotomy[Title/Abstract]	37
20	Office-based tenotomy	3
19	Closed tenotomy[Title/Abstract]	128
18	Needle tenotomy[Title/Abstract]	66
17	Percutaneous tendon release[Title/Abstract]	1
16	percutaneous tenotomy[Title/Abstract]	136
15	#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14	3,713
14	primary clubfeet[Title/Abstract]	68
13	essential clubfeet[Title/Abstract]	13
12	isolated clubfeet[Title/Abstract]	4
11	congenital clubfeet[Title/Abstract]	82
10	idiopathic clubfeet[Title/Abstract]	184
9	("Clubfoot/surgery"[Mesh] OR "Clubfoot/therapy"[Mesh])	2,509
8	Equinovarus deformity[Title/Abstract]	260
7	Essential clubfoot[Title/Abstract]	68
6	Isolated clubfoot[Title/Abstract]	43
5	Primary clubfoot[Title/Abstract]	7
4	Congenital clubfoot[Title/Abstract]	593
3	idiopathic clubfoot[Title/Abstract]	509
2	Talipes equinovarus[Title/Abstract]	997
1	Congenital talipes equinovarus[Title/Abstract]	461

PRISMA Flow Diagrams



*Consider, if feasible to do so, reporting the number of records identified from each database or register searched (rather than the total number across all databases/registers).

**If automation tools were used, indicate how many records were excluded by a human and how many were excluded by automation tools.

Source: Page MJ, et al. BMJ 2021;372:n71. doi: 10.1136/bmj.n71.

Annex Figure Q6. PRISMA Flow Diagram.

Included Studies

Characteristics of Included Studies

Annex Table Q6.3. Study characteristics.

Author Year	Study Design	Country	Number of Patients	Population	Intervention Group(s)	Control	Outcomes
Chandirasegaran 2019	Prospective observational study	Malaysia	27 patients (50 clubfeet)	Idiopathic clubfoot patients <3 months old, mean age 2 months	Percutaneous Achilles tendon tenotomy (n=25 feet)	Casting alone (n=25 feet)	- Hindfoot Pirani score- Ankle dorsiflexion measurement Achilles tendon length (ultrasonography) Achilles tendon thickness (ultrasonography)
Cao 2025	Retrospective cohort study	USA	791 patients (1,184 clubfeet)	Untreated idiopathic clubfoot patients <3 months old, mean age 17 days at treatment initiation	Initial heel cord tenotomy (n=826 feet)	No initial tenotomy (n=358 feet)	- Need for additional procedures Clinical outcomes (Richards classification) Number of casts to achieve correction Bracing compliance

Notes:

- All studies focused on idiopathic clubfoot treatment using the Ponseti method
- Follow-up periods varied: Chandirasegaran (6 weeks post-correction), Cao (minimum 2 years), Niki (27 months mean), Pedrotti (long-term, mean 9.8 years post-surgery)
- Outcome measures included both clinical assessments and imaging findings (ultrasonography)
- Study designs ranged from prospective observational to retrospective cohort studies

Quality Assessment of Included Studies

Annex Table Q6.4. Quality Assessment of Included Studies (New Castle Ottawa Scale)

Author Year	Study design	Selection				Comparability	Outcome		
		Representativeness of the exposed cohort	Selection of the non-exposed cohort	Ascertainment of exposure	Demonstration that outcome of interest was not present at start of study	Comparability of cohorts based on the design or analysis controlled for confounders	Assessment of outcome	Was follow-up long enough for outcomes to occur	Adequacy of follow-up of cohorts
Chandirasegaran 2019	Prospective observational study	★	★	★	★	★	★	★	★
Cao 2025	Retrospective cohort study	★	★	★	★	-	-	★	-
Niki 2013	Prospective observational study	★	★	★	★	-	-	★	-
Pedrotti 2024	Cross-sectional observational study								

GRADE Evidence Profile table

Annex Table Q6.5. GRADE Evidence Profile table.

Question: Percutaneous tenotomy compared to no tenotomy for idiopathic clubfoot who are eligible after completion of Ponseti casting

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	percutaneous tenotomy	no tenotomy	Relative (95% CI)	Absolute (95% CI)		
Successful correction (no tenotomy vs initial tenotomy) (assessed with: as described by Richards et al)												
1	non-randomised studies	not serious	not serious	not serious	not serious	none	549/826 (66.5%)	280/358 (78.2%)	**OR 1.85** (1.09 to 3.13)	**87 more per 1,000** (from 14 more to 136 more)	⊕⊕◯◯ Low	CRITICAL
Successful correction (no tenotomy vs late tenotomy) (assessed with: Successful correction (no tenotomy vs initial tenotomy))												
1	non-randomised studies	not serious	not serious	not serious	not serious	none	280/358 (78.2%)	98/184 (53.3%)	**OR 3.02** (1.52 to 6.00)	**242 more per 1,000** (from 101 more to 340 more)	⊕⊕◯◯ Low	
Recurrence/relape requiring further intervention (additional procedure) (no tenotomy vs initial tenotomy)												
1	non-randomised studies	not serious	not serious	not serious	not serious	none	300/826 (36.3%)	147/358 (41.1%)	**OR 1.22** (0.97 to 1.53)	**49 more per 1,000** (from 7 fewer to 105 more)	⊕⊕◯◯ Low	
Recurrence/relape requiring further intervention (additional procedure) (no tenotomy vs late tenotomy)												
1	non-randomised studies	not serious	not serious	not serious	not serious	none	180/184 (97.8%)	147/358 (41.1%)	**OR 0.015** (0.006 to 0.041)	**400 fewer per 1,000** (from 406 fewer to 383 fewer)	⊕⊕◯◯ Low	
Residual deformity after initial treatment completion (Demiglio score)												
1	non-randomised studies	not serious	not serious	not serious	not serious	none	826	358	-	MD **2 higher** (8.97 lower to 12.97 higher)	⊕⊕◯◯ Low	
Improvement in hindfoot Pirani score (assessed with: %)												
1	non-randomised studies	not serious	not serious	not serious	not serious	none	25	25	-	MD **32.94 % higher** (26.36 higher to 39.52 higher)	⊕⊕◯◯ Low	

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	percutaneous tenotomy	no tenotomy	Relative (95% CI)	Absolute (95% CI)		
Increase in ankle dorsiflexion (assessed with: degrees)												
1	non-randomised studies	not serious	not serious	not serious	not serious	none	25	25	-	MD **36.6 degrees higher** (31.45 higher to 41.75 higher)	⊕⊕◯◯ Low	
Increase in length of Achilles tendon (cm) (assessed with: ultrasound in cm)												
1	non-randomised studies	not serious	not serious	not serious	not serious	none	25	25	-	MD **0.2 cm higher** (0.15 higher to 0.25 higher)	⊕⊕◯◯ Low	CRITICAL

CI: confidence interval; **MD:** mean difference; **OR:** odds ratio

GUIDELINE QUESTION 7: Should outpatient percutaneous tenotomy be offered as an alternative to operating room-based tenotomy in patients with clubfoot?

Research Question: Among patients with clubfoot, what is the efficacy and safety of outpatient percutaneous tenotomy as an alternative to operating room-based tenotomy in terms of achieving successful correction and minimizing complications?	
Population	Patients with clubfoot
Intervention/ Treatment	Outpatient-based percutaneous tenotomy
Comparison	OR-based percutaneous tenotomy
Outcomes	Efficacy and Safety outcomes Critical: Proportions with complications, Proportion with repeat tenotomy
Subgroups (if any)	N/A
Methods	RCTs; systematic reviews of RCTs

Evidence Reviewers: Aldrich Ivan Lois D. Burog, MD, MSc (cand); Anna Angelica Macalalad-Josue, MD, MSc (cand)
Date of Last Search: September 5, 2025

Statement of the Evidence

Among infants with idiopathic clubfoot, outpatient-based percutaneous Achilles tenotomy may be an alternative to operating room–based procedures, as it appears to result in similar rates of complications and repeat tenotomy. On the other hand, the effects remain very uncertain, as the available evidence is limited to small observational studies with wide confidence intervals, making it difficult to rule out either benefit or harm. The overall certainty of the evidence is very low.

Review Methods

A systematic literature search was conducted from database inception until 05 September 2025 to identify relevant studies. The following databases were searched: MEDLINE (via PubMed), Cochrane Library, and Google Scholar, using a combination of MeSH terms and free-text keywords related to the population and intervention of interest. The main search terms included: “clubfoot,” “congenital talipes equinovarus,” “Achilles tenotomy,” “percutaneous tenotomy,” “outpatient,” “clinic-based,” “operating room,” “theatre,” and “local anesthesia,” “general anesthesia.”

In addition, clinical trial registries such as ClinicalTrials.gov and the WHO International Clinical Trials Registry Platform (ICTRP) were searched for ongoing or unpublished studies. Bibliographies of relevant articles and systematic reviews were also screened for additional eligible studies. No language restrictions were applied. The detailed search strategy is provided in Appendix 7.

Eligibility criteria: Studies were included if they enrolled patients with clubfoot (idiopathic or syndromic) undergoing percutaneous Achilles tenotomy, compared outpatient/clinic-based procedures (typically under local

anesthesia) against operating room (OR)-based procedures (under general anesthesia, sedation, or mini-open approaches), and reported on efficacy or safety outcomes. Outcomes of interest included:

- Critical outcomes: proportion of patients with complications (e.g., infection, bleeding, neurovascular injury), and need for repeat tenotomy.
- Important outcomes: recurrence rates, readmission rates, procedure-related adverse events, caregiver satisfaction, and resource use (time, cost, separation from caregiver)

Both randomized controlled trials and comparative observational studies were considered eligible for inclusion in this review, while case series without a comparator were excluded from the main synthesis but used to provide contextual insights where appropriate. Screening of titles, abstracts, and full texts was conducted independently by two reviewers, who also performed data extraction using a standardized collection form. To evaluate methodological quality, we applied the Cochrane Risk of Bias 1.0 (RoB1) tool or the ROBUST-RCT instrument for randomized trials, and the Newcastle–Ottawa Scale (NOS) for non-randomized comparative studies.

The findings from included studies were primarily summarized narratively. Where studies were sufficiently similar in terms of design, interventions, and outcomes, pooled analyses were undertaken; in cases where heterogeneity was substantial, results were reported descriptively. The certainty of the evidence for each outcome was assessed using the GRADE framework, taking into account potential limitations such as risk of bias, inconsistency, indirectness, imprecision, and publication bias. No explicit thresholds for minimal clinically important differences (MCIDs) or ignorable levels of benefit or harm were identified in the literature, and the Steering Committee did not establish outcome-specific thresholds for this review.

Recommendations from Other Groups

Annex Table Q7.1. Summary of Recommendations from Other Groups.

Group or Agency	Recommendation	Strength of Recommendation/ Certainty/Quality of Evidence
British Society of Children's Orthopaedic Surgery Consensus Statements Gelfer Y, Davis N, Blanco J, Buckingham R, Trees A, Mavrotas J, Tennant S, Theologis T. Attaining a British consensus on managing idiopathic congenital talipes equinovarus up to walking age. Bone Joint J. 2022 Jun;104-B(6):758-764. doi: 10.1302/0301-620X.104B6.BJJ-2021-1687.R1. PMID: 35638218; PMCID: PMC9948433.	33) The primary tenotomy should be performed under local anaesthesia, however GA may be considered for children over the age of six months or at the discretion of the surgeon. 34) The tenotomy should be performed by a trained paediatric orthopaedic surgeon or under the direct supervision of such a surgeon. 35) There must be adequate access to a paediatric orthopaedic surgeon so that the tenotomy can be performed in a timely fashion, with no long waits in cast for surgeon availability. 36) An environment with facilities allowing for paediatric resuscitation should be available; this would normally be in a clinic environment within a hospital or health centre. 37) The tenotomy should be a complete tenotomy of the Achilles tendon, performed percutaneously, using as small a blade as possible, and under a sterile environment.	NA

Group or Agency	Recommendation	Strength of Recommendation/ Certainty/Quality of Evidence
American Academy of Pediatrics AAP Cady R, Hennessey TA, Schwend RM. Diagnosis and Treatment of Idiopathic Congenital Clubfoot. Pediatrics. 2022 Feb 1;149(2):e2021055555. doi: 10.1542/peds.2021-055555. PMID: 35104362; PMCID: PMC9645716.	The Ponseti Treatment Method Careful and complete use of the Ponseti method leads to optimal results. The method consists of 3 phases of treatment: manipulation and casting, tenotomy, and bracing. ● The first phase involves manipulation and weekly serial above-knee casting performed by an individual trained in the technique. This phase typically lasts for 5 to 8 casts. It is not necessary to initiate treatment in the newborn nursery. Treatment can start anytime in the neonatal period, ideally the first 1 to 3 weeks. ● **In the second phase, after all of the elements of the deformity except equinus have been corrected, a percutaneous Achilles tenotomy is performed under local anesthesia by a surgeon in the clinic, which eliminates the perioperative risk of general anesthesia and concerns about anesthetic neurotoxicity in the infant.** ● **Some surgeons prefer to perform the tenotomy in the operating room under general anesthesia, particularly in older children.** ● A final cast is placed immediately after the tenotomy and worn for 3 weeks. Ninety percent of infants with clubfoot require a tenotomy	

Search Strategy

Annex Table Q7.2. Search strategy and yield (15 August 2020 5:27 PM) per database.

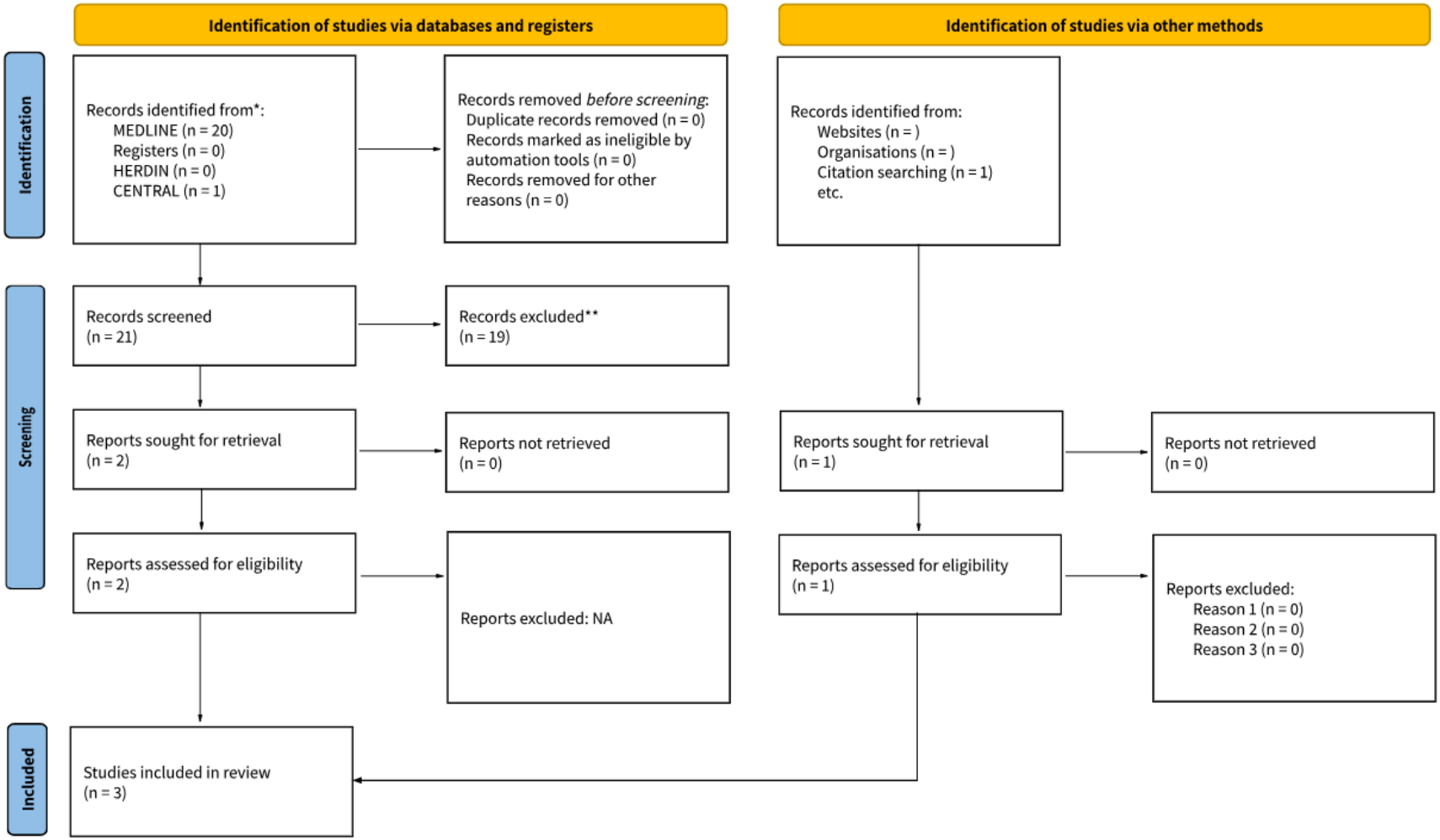
Database	Search Strategy / Search Terms	Date and Time of Search	Results	
			Yield	Eligible
Medline	(("Achilles Tendon"[Mesh] OR "Achilles tendon" OR tendoachilles OR "Achilles tenotomy" OR "percutaneous tenotomy" OR tenotomy) AND ("Ambulatory Care"[Mesh] OR outpatient OR "clinic-based" OR "office-based" OR "day care" OR "ambulatory setting" OR "outpatient clinic")) AND (((((systematic review*[Title]) OR (meta analys*[Title])) OR (metaanalys*[Title])) AND ((((((((search*[Title]) OR (strateg*[Title])) OR (filter[Title/Abstract])) OR (filters[Title/Abstract])) OR (retrieve*[Title])) OR (identif*[Title])) OR (locat*[Title])) OR (find*[Title])) OR ((indexing[Title] OR indexed[Title]))))) OR ((review*[Title]) AND (((search*[Title]) OR (review*[Title])) OR (filter*[Title]))))	05 September 2025 9:21:07 pm	6	1
MEDLINE	((("Achilles Tendon"[Mesh] OR "Achilles tendon" OR tendoachilles OR "Achilles tenotomy" OR "percutaneous	05 September 2025	3	0

Database	Search Strategy / Search Terms	Date and Time of Search	Results	
			Yield	Eligible
	tenotomy" OR tenotomy) AND ("Ambulatory Care"[Mesh] OR outpatient OR "clinic-based" OR "office-based" OR "day care" OR "ambulatory setting" OR "outpatient clinic")) AND (("Achilles Tendon"[Mesh] OR "Achilles tendon" OR tendoachilles OR "Achilles tenotomy" OR "percutaneous tenotomy" OR tenotomy) AND ("Operating Rooms"[Mesh] OR "operating room" OR theatre OR "surgery center" OR "operating theatre" OR "surgical suite" OR "hospital-based"))) AND ((((((((((randomized controlled trial[Publication Type]) OR (controlled clinical trial[Publication Type])) OR (randomized[Title/Abstract])) OR (placebo[Title/Abstract])) OR (drug therapy [sh])) OR (randomly[Title/Abstract])) OR (trial[Title/Abstract])) OR (groups[Title/Abstract])) NOT (animals [mh] NOT humans [mh]))	9:24:28 pm		
MEDLINE	((("Clubfoot"[Mesh] OR clubfoot OR "congenital talipes equinovarus" OR CTEV)) AND (("Achilles Tendon"[Mesh] OR "Achilles tendon" OR tendoachilles OR "Achilles tenotomy" OR "percutaneous tenotomy" OR tenotomy) AND ("Ambulatory Care"[Mesh] OR outpatient OR "clinic-based" OR "office-based" OR "day care" OR "ambulatory setting" OR "outpatient clinic"))) AND (("Achilles Tendon"[Mesh] OR "Achilles tendon" OR tendoachilles OR "Achilles tenotomy" OR "percutaneous tenotomy" OR tenotomy) AND ("Operating Rooms"[Mesh] OR "operating room" OR theatre OR "surgery center" OR "operating theatre" OR "surgical suite" OR "hospital-based"))	05 September 2025 9:24:28 pm	6	2
MEDLINE	(((("Clubfoot"[Mesh] OR clubfoot OR "congenital talipes equinovarus" OR CTEV)) AND (("Achilles Tendon"[Mesh] OR "Achilles tendon" OR tendoachilles OR "Achilles tenotomy" OR "percutaneous tenotomy" OR tenotomy) AND ("Ambulatory Care"[Mesh] OR outpatient OR "clinic-based" OR "office-based" OR "day care" OR "ambulatory setting" OR "outpatient clinic"))) AND (("Achilles Tendon"[Mesh] OR "Achilles tendon" OR tendoachilles OR "Achilles tenotomy" OR "percutaneous tenotomy" OR tenotomy) AND ("Operating Rooms"[Mesh] OR "operating room" OR theatre OR "surgery center" OR "operating theatre" OR "surgical suite" OR "hospital-based"))) AND (((((systematic review*[Title]) OR (meta analys*[Title])) OR (metaanalys*[Title])) AND ((((((((search*[Title]) OR (strateg*[Title])) OR (filter[Title/Abstract])) OR (filters[Title/Abstract])) OR (retrieve*[Title])) OR (identif*[Title])) OR (locat*[Title])) OR (find*[Title])) OR ((indexing[Title] OR indexed[Title]))))) OR ((review*[Title]) AND (((search*[Title]) OR (review*[Title])) OR (filter*[Title]))))) - Schema: all	05 September 2025 9:19:20 pm	0	0

Database	Search Strategy / Search Terms	Date and Time of Search	Results	
			Yield	Eligible
MEDLINE	((((("Clubfoot"[Mesh] OR clubfoot OR "congenital talipes equinovarus" OR CTEV)) AND (("Achilles Tendon"[Mesh] OR "Achilles tendon" OR tendoachilles OR "Achilles tenotomy" OR "percutaneous tenotomy" OR tenotomy) AND ("Ambulatory Care"[Mesh] OR outpatient OR "clinic-based" OR "office-based" OR "day care" OR "ambulatory setting" OR "outpatient clinic"))) AND (("Achilles Tendon"[Mesh] OR "Achilles tendon" OR tendoachilles OR "Achilles tenotomy" OR "percutaneous tenotomy" OR tenotomy) AND ("Operating Rooms"[Mesh] OR "operating room" OR theatre OR "surgery center" OR "operating theatre" OR "surgical suite" OR "hospital-based"))) AND (((((systematic review*[Title]) OR (meta analys*[Title])) OR (metaanalys*[Title])) AND (((((((((search*[Title]) OR (strateg*[Title])) OR (filter[Title/Abstract])) OR (filters[Title/Abstract])) OR (retrieve*[Title])) OR (identif*[Title])) OR (locat*[Title])) OR (find*[Title])) OR ((indexing[Title] OR indexed[Title]))))) OR ((review*[Title]) AND (((search*[Title]) OR (review*[Title])) OR (filter*[Title]))))	05 September 2025 9:19:35 pm	0	0
MEDLINE	((("Clubfoot"[Mesh] OR clubfoot OR "congenital talipes equinovarus" OR CTEV)) AND (("Achilles Tendon"[Mesh] OR "Achilles tendon" OR tendoachilles OR "Achilles tenotomy" OR "percutaneous tenotomy" OR tenotomy) AND ("Operating Rooms"[Mesh] OR "operating room" OR theatre OR "surgery center" OR "operating theatre" OR "surgical suite" OR "hospital-based"))) AND (((((systematic review*[Title]) OR (meta analys*[Title])) OR (metaanalys*[Title])) AND (((((((((search*[Title]) OR (strateg*[Title])) OR (filter[Title/Abstract])) OR (filters[Title/Abstract])) OR (retrieve*[Title])) OR (identif*[Title])) OR (locat*[Title])) OR (find*[Title])) OR ((indexing[Title] OR indexed[Title]))))) OR ((review*[Title]) AND (((search*[Title]) OR (review*[Title])) OR (filter*[Title])))) - Schema: all	05 September 2025 9:19:15 pm	0	0
HERDIN	(clubfoot OR "congenital talipes equinovarus" OR CTEV) AND (("Achilles tenotomy" OR "percutaneous tenotomy" OR tenotomy) AND (outpatient OR "clinic-based" OR "office-based" OR "ambulatory care" OR "day care")) AND (("Achilles tenotomy" OR "percutaneous tenotomy" OR tenotomy) AND ("operating room" OR theatre OR "surgery center" OR "hospital-based" OR "surgical suite"))	05 September 2025 9:43:15 pm	0	0

Database	Search Strategy / Search Terms	Date and Time of Search	Results	
			Yield	Eligible
CENTRAL	(clubfoot OR "congenital talipes equinovarus" OR CTEV) AND ("Achilles tenotomy" OR "percutaneous tenotomy" OR tenotomy) AND ((outpatient OR "clinic-based" OR "office-based" OR "ambulatory care" OR "day care") OR ("operating room" OR theatre OR "surgery center" OR "hospital-based" OR "surgical suite"))	05 September 2025 9:45:15 pm	5	1

PRISMA Flow Diagram



Annex Figure Q7.1 PRISMA Flow Diagram.

Included Studies

Characteristics of Included Studies

Annex Table Q7.3. Study characteristics.

Author, Year	Study design	Country	Number of patients	Population	Intervention Group(s)	Control	Outcomes
Agius et al., 2018	Retrospective comparative study	New Zealand	40 patients (59 feet)	Idiopathic clubfoot, Ponseti method	Outpatient percutaneous Achilles tenotomy under local anaesthesia (26 feet)	OR-based tenotomy under general anaesthesia (33 feet)	Recurrence, complications, functional outcome
Tühanioğlu et al., 2018	Retrospective comparative study	Turkey	57 patients (85 feet)	Idiopathic clubfoot	Outpatient percutaneous Achilles tenotomy under local anaesthesia (47 feet)	OR-based tenotomy under general anaesthesia (38 feet)	Recurrence, complications
Hedrick et al., 2018	Retrospective comparative study	USA	382 patients (563 feet)	Idiopathic clubfoot	Outpatient percutaneous Achilles tenotomy under local anaesthesia (140 patients)	OR-based tenotomy under general anaesthesia (242 patients)	Complications, hospital expenses

Quality Assessment of Included Studies

Annex Table Q7.4. Methodological Quality Assessment of Included Retrospective Comparative Studies (Selection, Comparability, and Outcome Domains)

Author, Year	Study design	Selection	Comparability	Outcome	Overall assessment	Remarks
Agius et al., 2018	Retrospective comparative study	++++	+	++	Moderate	somewhat limited by surgeon-dependent allocation and low parental survey response rate.
Tuhanioğlu et al., 2018	Retrospective comparative study	++++	+	+++	Low to Moderate	
Hedrick et al., 2018	Retrospective comparative study	++++	++	++	Low	multicentre cost analysis is strongest due to large sample size and multicentre design.

Agius et al., 2018 (New Zealand study)

- This was a retrospective comparison of outpatient versus theatre-based Achilles tenotomy that also included parental satisfaction surveys.
- The exposed cohort consisted of consecutive infants treated at one hospital, while the comparison group was drawn from the same population but managed by a different surgeon, raising some concern for selection bias.
- Exposure was clearly ascertained from surgical and hospital records, and all patients started without prior correction of clubfoot.
- The investigators accounted for demographic factors such as sex, severity, ethnicity, and deprivation index, but did not adjust for compliance or surgeon experience.
- Outcomes were measured through clinical follow-up, although blinded assessment was not reported.
- All patients had at least two years of follow-up, but the completeness of parental satisfaction survey responses was limited by a low response rate (32%).
- Overall, the study was judged to have a moderate risk of bias.

Tuhanioğlu et al., 2018 (Turkey study)

- This retrospective evaluation compared 57 patients undergoing achillotomy under local versus general anaesthesia.
- The cohorts were consecutive cases from a tertiary hospital, and both exposed and non-exposed groups were drawn from the same population.
- Exposure was documented from surgical records, and all patients were free of prior correction at baseline.
- Groups were comparable in age, sex, and laterality, and statistical analyses were conducted, although no adjustment was made for other potential confounders such as brace compliance or severity scoring.
- Outcomes were based on clinical follow-up records without blinding.
- The mean follow-up was 28 months, which was adequate, and although 26 patients were excluded due to prior treatment or loss to follow-up, the remaining cohort had acceptable completeness.
- The overall risk of bias was considered low to moderate.

Hedrick et al., 2018 (US multicentre cost analysis)

- This retrospective chart review included 382 patients across three high-volume referral hospitals, comparing Achilles tenotomy performed in the clinic versus the operating room.

- Both exposed and non-exposed cohorts were drawn from hospital settings, although they were not always from the same source populations, leaving some possibility of selection bias.
- Exposure was identified using surgical records and billing codes, and all patients entered the study without prior correction.
- The study controlled for key variables including age, laterality, and number of casts, with stratified analyses performed.
- Outcomes, including complications and costs, were assessed from objective hospital records.
- Follow-up focused only on perioperative outcomes and did not include long-term recurrence, although completeness was high within the perioperative window.
- This study was judged to have a low risk of bias.

GRADE Evidence Profile

Annex Table Q7.5. GRADE Evidence Profile.

Author(s): ADB; AMJ
Question: Outpatient percutaneous tenotomy be offered as an alternative compared to operating room-based tenotomy in patients with clubfoot?
Setting: worldwide
Bibliography:

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	outpatient percutaneous tenotomy be offered as an alternative	operating room-based tenotomy	Relative (95% CI)	Absolute (95% CI)		
Repeat Tenotomy												
2	non-randomised studies	serious[a]	not serious	not serious	serious[b]	none	4/270 (1.5%)	12/441 (2.7%)	**OR 0.60** (0.14 to 2.65)	**11 fewer per 1,000** (from 23 fewer to 42 more)	⊕◯◯◯ Very low[a,b]	CRITICAL
Proportion with complications												
3	non-randomised studies	serious[a]	not serious	not serious	serious[b]	none	2/73 (2.7%)	1/72 (1.4%)	**OR 3.13** (0.32 to 30.80)	**28 more per 1,000** (from 9 fewer to 289 more)	⊕◯◯◯ Very low[a,b]	CRITICAL

CI: confidence interval; **OR:** odds ratio

Explanations
a. due to allocation by surgeon preference, lack of blinding in outcome assessment, and incomplete parental survey responses
b. serious imprecision because of small sample sizes, few events, and very wide confidence intervals spanning both potential benefit and harm

Summary of Findings for outpatient percutaneous tenotomy be offered as an alternative Versus operating room-based tenotomy for patients with clubfoot?

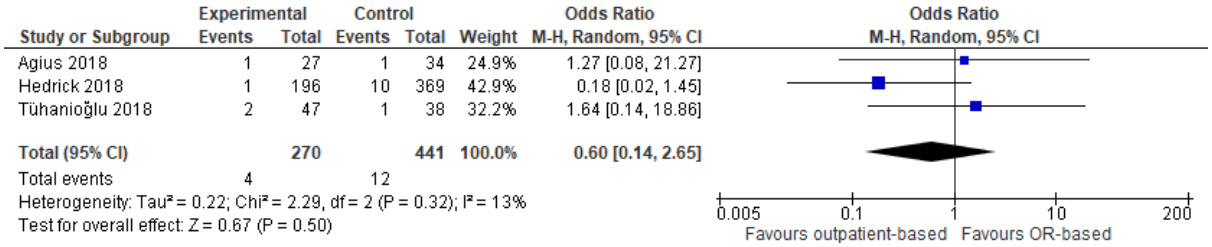
Outcome and follow-up	Patients (studies), N	Relative effect (95% CI)	Absolute effects (95% CI)			Certainty	What happens
			operating room-based tenotomy	outpatient percutaneous tenotomy be offered as an alternative	Difference		
Repeat Tenotomy	711 (2 non-randomised studies)	**OR = 0.60** (0.14 to 2.65)	27 per 1,000	**17 per 1,000** (4 to 69)	**11 fewer per 1,000** (from 23 fewer to 42 more)	⊕◯◯◯ Very low[a,b]	Outpatient percutaneous tenotomy be offered as an alternative may reduce/have little to no effect on Repeat Tenotomy but the evidence is very uncertain.
Proportion with complications	145 (3 non-randomised studies)	**OR = 3.13** (0.32 to 30.80)	14 per 1,000	**42 per 1,000** (4 to 303)	**28 more per 1,000** (from 9 fewer to 289 more)	⊕◯◯◯ Very low[a,b]	Outpatient percutaneous tenotomy be offered as an alternative may increase/have little to no effect on proportion with complications but the evidence is very uncertain.

CI: confidence interval; **OR:** odds ratio

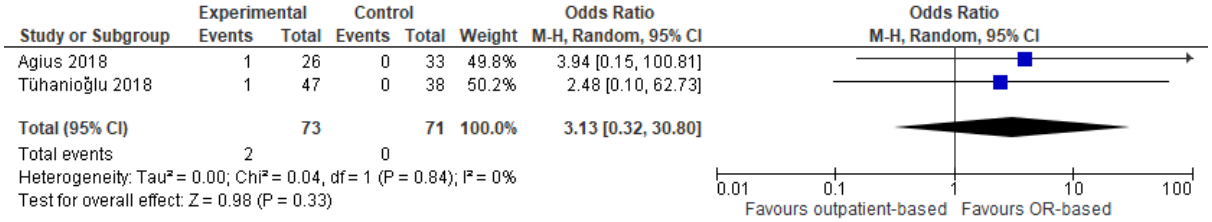
a. due to allocation by surgeon preference, lack of blinding in outcome assessment, and incomplete parental survey responses

b. serious imprecision because of small sample sizes, few events, and very wide confidence intervals spanning both potential benefit and harm

Forest Plots



Annex Figure Q7.2. Forest plot of comparison: 1 Outpatient-based versus OR-based Percutaneous Tenotomy, outcome: 1.1 Proportion with complications.



Annex Figure Q7.3.Forest plot of comparison: 1 Outpatient-based versus OR-based Percutaneous Tenotomy, outcome: 1.2 Proportion with Repeat Tenotomy.

GUIDELINE QUESTION 8: Should children with clubfoot who are older than 4 years undergo casting (e.g., Ponseti method or other casting techniques) or proceed directly (i.e., outright) to surgical management?

Research Question: Among children with clubfoot older than 4 years, how effective is casting (e.g., Ponseti method with percutaneous tenotomy or other casting techniques) compared with proceeding directly to surgical management in improving foot correction, functional outcomes, and reducing complications?	
Population	Children with clubfoot older than 4 years old
Intervention/ Treatment	Casting (e.g., Ponseti method with percutaneous tenotomy or other casting techniques)
Comparison	Surgical management (surgical means gradual correction using Ilizarov, open posterior medial release, limited releases, and lengthening)
Outcomes	Foot correction, functional outcomes, reduction in complications
Subgroups (if any)	None
Methods	RCTs, systematic reviews; non-randomized studies of intervention (NRSIs)

Evidence Reviewers: Jayson M. Villavicencio, MD; Aldrich Ivan Lois Burog MD, MSc (cand)
Date of Last Search: July 5, 2025

Statement of the Evidence

- There was no direct evidence found comparing casting versus direct surgery among children with clubfoot older than four years old.
- Among older children with neglected clubfoot, we are uncertain whether Ponseti method increases or decreases the success and recurrence rate compared to surgery.
- In terms of safety, we are also uncertain if Ponseti method increases or decreases the complication rate compared to surgery.
- We found no evidence on the outcomes of long-term foot function (strength, flexibility, endurance), health-related quality of life, gait function and mobility at follow-up, long-term durability of correction, and residual deformity.

The overall certainty of the evidence is very low.

Review Methods

A comprehensive and systematic search of local and internal databases was done (with date of last search: July 05, 2025) from database inception through MEDLINE, CENTRAL, HERDIN, Google scholar, and clinicaltrials.gov using the combined MeSH and keywords search on clubfoot, talipes equinovarus, neglected clubfoot, casting, Ponseti method, surgery, posteromedial release, Turco surgery, Kite's surgery, and Ilizarov . No filter was used due to paucity of randomized controlled trials. There were no studies found direct to the population (children with clubfoot and older than 4 years old) and comparator of interest (surgery). The references of included studies were

also hand searched to identify additional studies that may not have appeared in the database search. No language restrictions were applied. Additional search was done for unpublished studies through communications with authors or known researchers. Full search strategy is presented in Annex Table Q8.2. We used the Joanna Briggs Institute (JBI) to assess the quality of the studies involved.

Recommendations from Other Groups

Annex Table Q8.1. Summary of Recommendations from Other Groups.

Group or Agency	Recommendation	Strength of Recommendation/ Certainty/Quality of Evidence
British Society of Children's Orthopaedic Surgery[32]	• No direct recommendation on the use of Ponseti method for neglected clubfoot or clubfoot in the older children. • The Ponseti casting method is the gold standard treatment for clubfoot in the UK.	NA-
American Academy of Pediatrics[33]	• No direct recommendation on the use of Ponseti method for neglected clubfoot or clubfoot in the older children. • Ponseti method has become the standard for the treatment of clubfoot.	-NA
Dutch Orthopedic Association[34]	• No direct recommendation on the use of Ponseti method for neglected clubfoot or clubfoot in the older children. • Treat primary clubfoot with the standard Ponseti method. Only carry out surgery for primary treatment for idiopathic clubfoot as described in the standard Ponseti method.	-NA

Ongoing Studies and Research Gaps

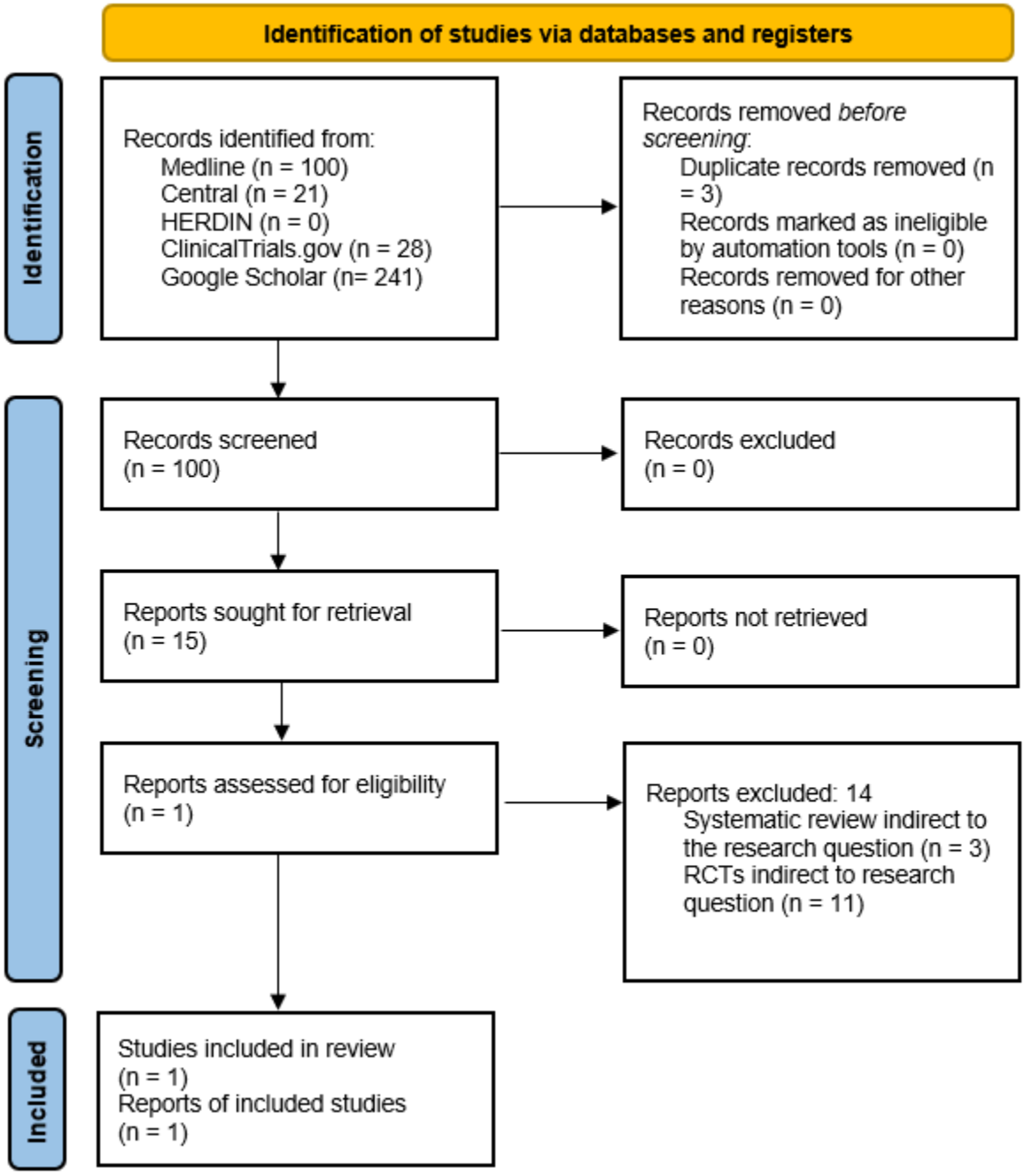
There are no ongoing studies comparing casting with surgery for older children with clubfoot. There were several research gaps identified in the review of the evidence for this clinical question. The most significant is the lack of high-quality evidence comparing casting with surgery for clubfoot, particularly for children older than 4 years old. Randomized studies evaluating these procedures were focused on infants and toddlers under 2 years old, with the assumption that older children have reduced malleability and poorer outcomes with conservative treatment. There's insufficient data on the age cut-offs where casting may become inadequate. There was also a lack of standardization in casting protocols for older children. Studies don't consistently define optimal casting duration, force application, tenotomy timing, or modification of traditional Ponseti techniques for older age groups. Most studies focus on radiographic correction and measurements rather than other important outcomes such as patient-reported functional outcomes, long-term quality of life, activity, and patient/parent satisfaction comparing casting versus surgical approaches in this older age group.

Search Strategy

Annex Table Q8.2. Search Strategy (as of July 5, 2025).

Database	Search Strategy / Search Terms	Date and Time of Search	Results	
			Yield	Eligible
Medline	("clubfoot"[MeSH Terms] OR "clubfoot"[All Fields] OR ("talipes"[All Fields] AND "equinovarus"[All Fields]) OR "talipes equinovarus"[All Fields] OR "clubfoot"[MeSH Terms] OR ("clubfoot"[MeSH Terms] OR "clubfoot"[All Fields] OR "clubfeet"[All Fields]) OR "clubfoot"[MeSH Terms]) AND ("neglect"[All Fields] OR "neglected"[All Fields] OR "neglectful"[All Fields] OR "neglecting"[All Fields] OR "neglects"[All Fields] OR (("older"[All Fields] OR "olders"[All Fields]) AND "child*"[All Fields])) AND ("casted"[All Fields] OR "casting"[All Fields] OR "castings"[All Fields] OR "casts"[All Fields] OR (("ponseti"[All Fields] OR "ponseti s"[All Fields]) AND ("method s"[All Fields] OR "methods"[MeSH Terms] OR "methods"[All Fields] OR "method"[All Fields] OR "methods"[MeSH Subheading])) OR (("ponseti"[All Fields] OR "ponseti s"[All Fields]) AND "methods"[MeSH Terms]))	July 05, 2025 11:00AM	100	0
CENTRAL	#1 MeSH descriptor: [Clubfoot] explode all trees #2 Neglected #3 Casting #4 Ponseti method #5 #1 OR #2 #6 Surgery #7 Surgical treatment #8 #6 OR #7 #9 #3 AND #4 #10 #5 AND #9	July 05, 2025 11:30AM	21	0
ClinicalTrials.gov	Clubfoot AND Casting OR Ponseti Method	July 05, 2025 12:30 PM	28	0
HERDIN	Clubfoot	July 05, 2025 12:45 PM	7	0
Google Scholar	Clubfoot AND Casting OR Ponseti Method AND Surgery	July 05, 2025 1:00 PM	241	0

PRISMA Flow Diagram



Annex Figure 8.1. PRISMA Flow Diagram.

Included Studies

Characteristics of Included Studies

Annex Table Q8.3. Study characteristics.

Author Year	Study design	Country	Number of patients (feet)	Population (all with congenital clubfoot)	Intervention Group	Control	Outcomes
Mehtani 2018	Case series	India	41 (73)	3.1 mean age	Ponseti method	-	Pirani, Dimeglio, Ankle dorsiflexion, success rate
Sinha 2016	Case series	India	30 (41)	3.02 years mean age	Ponseti method	-	Pirani, Dimeglio, ankle dorsiflexion, radiological assessment, success rate
Faizan 2014	Case series	India	19 (28)	2.7 years mean age	Ponseti method	-	Pirani, Dimeglio, ankle dorsiflexion, success rate
Ayana 2014	Case series	Ethiopia	22 (32)	4.4 years mean age	Ponseti method	-	Pirani, Dimeglio, success rate
Qureshi 2013	Case series	Pakistan	50	1.64 years mean age	Ponseti method	-	Pirani, Dimeglio, success rate
Hassan 2013	Case series	Egypt	20 (30)	1.59 years mean age	Ponseti method	-	Pirani, Dimeglio, ankle dorsiflexion, success rate
Banskota 2013	Case series	Nepal	36 (55)	7.4 years mean age	Ponseti method	-	Pirani, Dimeglio, ankle dorsiflexion, success rate
Verna 2012	Case series	India	37 (55)	2.06 years mean age	Ponseti method	-	Pirani, ankle dorsiflexion, success rate
Yagmurlu 2011	Case series	Turkey	27 (31)	1.76 years mean age	Ponseti method	-	Dimeglio, success rate
Khan 2010	Case series	India	21 (25)	8.9 years mean age	Ponseti method	-	Dimeglio, Ankle dorsiflexion, success rate
Spiegel 2009	Case series	Nepal	171 (260)	-	Ponseti method	-	Pirani, Ankle dorsifexion, success rate
Lourrenco 2007	Case series	Brazil	17 (24)	3.9 years mean age	Ponseti method	-	Ankle dorsiflexion, success rate
Fadel 2021	Case series	Somalia	24 (37)	10.3 years mean age (5-15)	Ilizarov external fixator	-	Treatment success, complications

Author Year	Study design	Country	Number of patients (feet)	Population (all with congenital clubfoot)	Intervention Group	Control	Outcomes
Aslani 2023	Cross-sectional	Iran	47 (56)	7.86 years mean age (5-10)	Ilizarov	-	Treatment success, complications
Ferreira 2006	Case-series	Brazil	30 (38)	19 years mean age (5-39)	Ilizarov external fixator	-	Treatment success, recurrence, complication
Akinci 2015	Case-series	Turkey	11 (15)	26 years mean age (15-50)	Posteromedial release and triple arthrodesis	-	Treatment success, complications

Quality Assessment of Included Studies

Annex Table Q8.4. Risk of Bias Assessment

Author Year	Study design	Domain 1	Domain 2	Domain 3	Domain 4	Domain 5	Domain 6	Domain 7	Domain 8	Domain 9	Domain 10
Mehtani 2018	Case series	Y	Y	Y	U	Y	Y	Y	Y	Y	Y
Sinha 2016	Case series	Y	Y	Y	U	Y	Y	Y	Y	Y	Y
Faizan 2014	Case series	Y	Y	Y	U	Y	Y	Y	Y	Y	Y
Ayana 2014	Case series	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Qureshi 2013	Case series	Y	Y	Y	U	Y	Y	Y	Y	Y	Y
Hassan 2013	Case series	Y	Y	Y	U	U	Y	Y	Y	Y	Y
Banskota 2013	Case series	Y	Y	Y	U	Y	Y	Y	Y	Y	Y
Verna 2012	Case series	Y	Y	Y	U	U	Y	Y	Y	Y	Y
Yagmurlu 2011	Case series	Y	Y	Y	U	Y	Y	Y	Y	Y	Y
Khan 2010	Case series	Y	Y	Y	U	Y	Y	Y	Y	Y	Y
Spiegel 2009	Case series	Y	Y	Y	U	Y	Y	Y	Y	Y	Y
Lourrenco 2007	Case series	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Fadel 2021	Case series	Y	Y	Y	U	Y	Y	Y	Y	Y	Y
Aslani 2023	Cross-sectional	Y	Y	Y	U	Y	Y	Y	Y	Y	Y
Ferreira 2006	Case series	Y	Y	Y	U	Y	Y	Y	Y	Y	Y
Akinci 2015	Case series	Y	Y	Y	U	U	Y	Y	Y	Y	Y

Domain 1- clear criteria for inclusion
Domain 2 – condition measured in a standard, reliable way
Domain 3 – valid methods used for identification of the condition
Domain 4 – consecutive inclusion of participants
Domain 5 – complete inclusion of participants
Domain 6 – clear reporting of demographics of the participants
Domain 7 – clear reporting of clinical information of the participants
Domain 8 – clear reporting of outcomes or follow-up results of cases
Domain 9 – clear reporting of the presenting sites/clinics demographic information
Domain 10 – appropriate statistical analysis

Y – yes; N – no; U – unclear

GRADE Profile Evidence table

Annex Table Q8.5. GRADE Evidence Profile (Casting).

Author(s): Jayson M. Villavicencio, MD

Question: Casting (e.g., Ponseti method or other casting techniques) compared to surgical management (i.e., outright surgery) for children with clubfoot who are older than 4 years

Bibliography: Ferreira GF, Stéfani KC, Haje D de P, Nogueira MP. The Ponseti method in children with clubfoot after walking age – Systematic review and meta-analysis of observational studies. PLOS ONE. 2018 Nov 20;13(11):e0207153.

Certainty assessment							Impact	Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations			
Treatment Success									
11	non-randomised studies	not serious	serious[a]	very serious[b]	not serious	none	Success rate 0.89 (95% CI: 0.82-0.94)	⊕◯◯◯ Very low[a,b]	CRITICAL
Recurrence									
9	non-randomised studies	not serious	not serious	very serious[b]	not serious	none	Recurrence rate 0.18 (95% CI: 0.14-0.24)	⊕◯◯◯ Very low[b]	CRITICAL
Casting complications									
5	non-randomised studies	not serious	not serious	very serious[b]	not serious	none	Complication rate: 0.07 (95% CI: 0.03-0.15)	⊕◯◯◯ Very low[b]	CRITICAL

CI: confidence interval

Explanations

a. high heterogeneity
b. no intended comparator (surgery)

Annex Table Q8.6. GRADE Evidence Profile (Surgery).

Author(s): Jayson M. Villavicencio, MD

Question: Surgery (e.g. Kite's surgery, Turco surgery, Ilizarov, Posteromedial release) compared to none for children with neglected clubfoot

Bibliography: Ferreira RC, Costo MT, Frizzo GG, da Fonseca Filho FF. Correction of Neglected Clubfoot Using the Ilizarov External Fixator. Foot Ankle Int. 2006 Apr 1;27(4):266–73. Aslani HS, Athari MB, Tavakoli-Darestani R, Pourmojarab A, Baroutkoub M, Zamani M. Clubfoot Deformity Treatment with Ilizarov Apparatus in the Paediatric Population without Corrective Osteotomies and Soft Tissue Release: A Cross-Sectional Study. Malays Orthop J. 2023 Nov;17(3):42–7. Fadel M, Kandil MF. Management of neglected clubfoot in children using Ilizarov external fixator and minimal invasive surgery, Sub-Saharan Africa experience. Int Orthop. 2022 Jan;46(1):125–32. Akıncı O, Akalın Y. Medium-term results of single-stage posteromedial release and triple arthrodesis in treatment of neglected clubfoot deformity in adults. Acta Orthop Traumatol Turc. 2015;49(2):175–83.

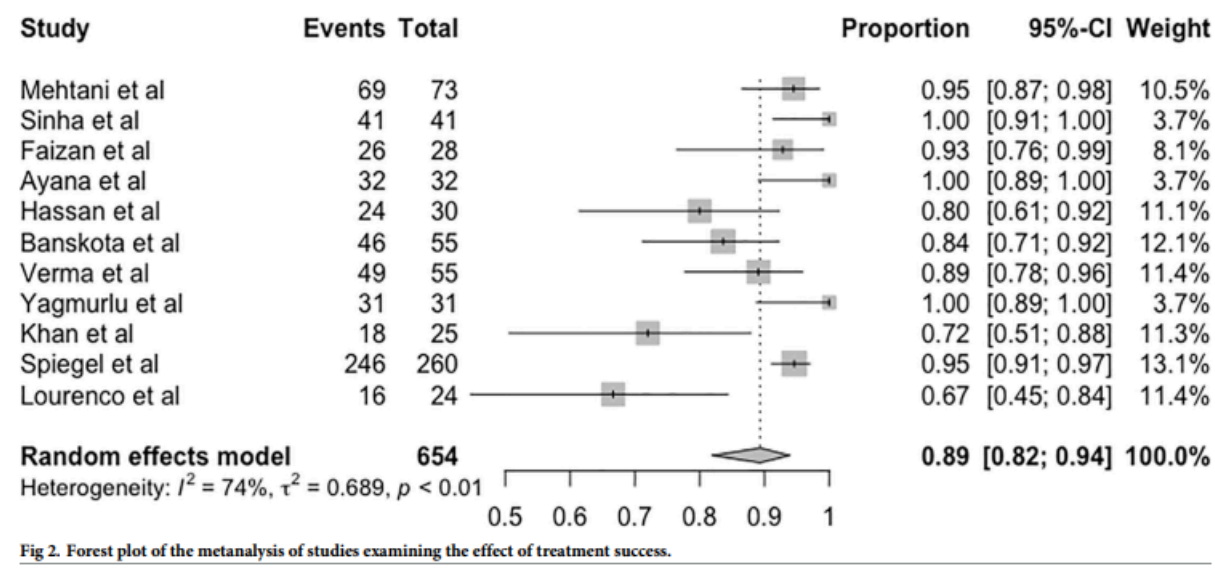
Certainty assessment							Impact	Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations			
Treatment Success									
4	non-randomised studies	not serious	serious[a]	serious[b]	not serious	none	Success rate ranges: 60% to 78.9%	⊕◯◯◯ Very low[a,b]	CRITICAL
Complications									
4	non-randomised studies	not serious	serious[a]	serious[b]	not serious	none	Complication rate: 5% to 73.7%	⊕◯◯◯ Very low[a,b]	CRITICAL
Recurrence									
1	non-randomised studies	not serious	serious[a]	serious[b]	not serious	none	Recurrence rate: 50%	⊕◯◯◯ Very low[a,b]	

CI: confidence interval

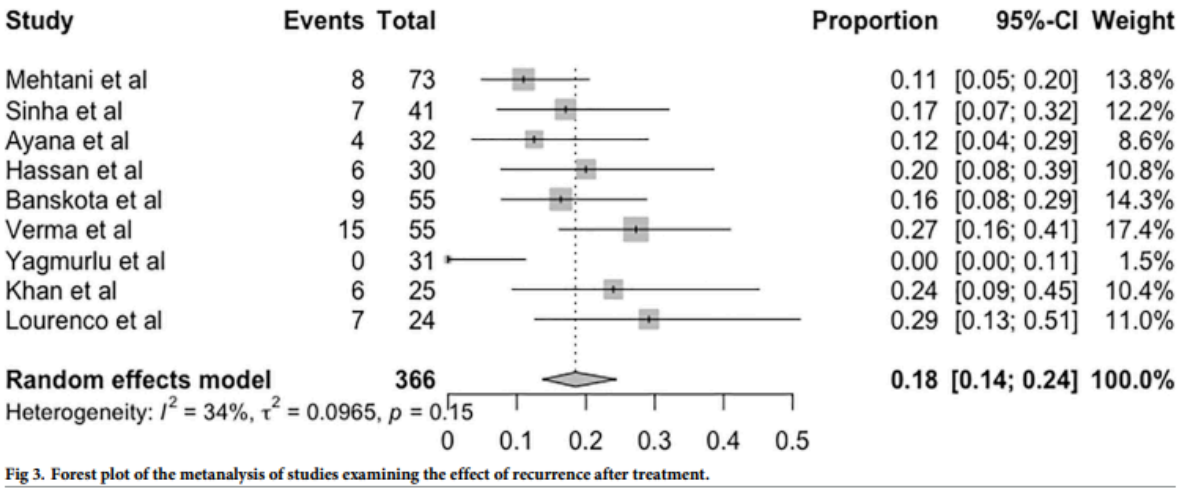
Explanations

a. inability to pool the available studies
b. no intended comparator

Forest Plots



Annex Figure Q8.2. Treatment success of Ponseti method among patients with neglected clubfoot.



Annex Figure Q8.3. Recurrence among patients with neglected clubfoot treated with Ponseti method.

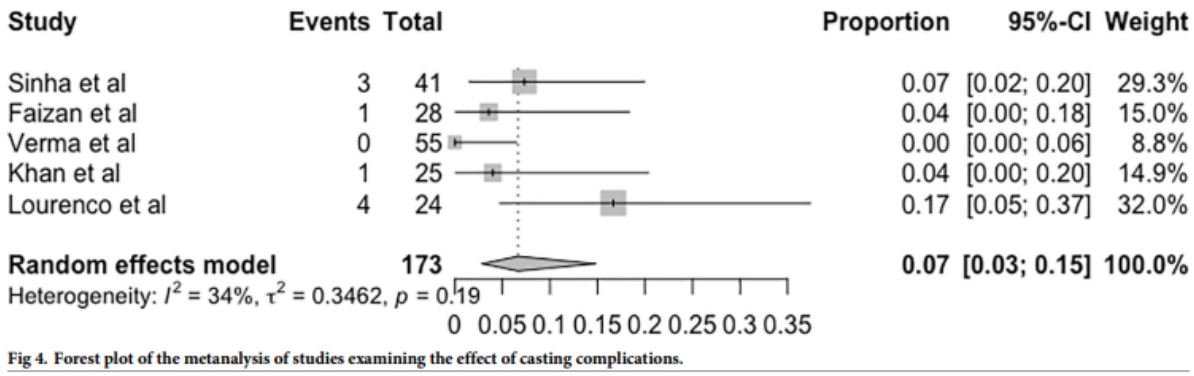


Fig 4. Forest plot of the metanalysis of studies examining the effect of casting complications.

Annex Figure Q8.4. Complication rate among patients with neglected clubfoot treated with Ponseti method.

GUIDELINE QUESTION 9: Should patients with idiopathic clubfoot be routinely monitored using clinical scoring systems such as Pirani score during and after treatment?

Research Question: Among patients with idiopathic clubfoot, how effective is routine monitoring using clinical scoring systems (e.g. Pirani scores) compared with no structural monitoring in improving treatment assessment, and predicting outcomes during and after treatment?	
Population	Patients with idiopathic clubfoot
Intervention/ Treatment	Routine monitoring using clinical scoring systems (e.g. Pirani)
Comparison	No structured monitoring (standard clinical observation without scoring tools; "eyeballing) or other clinical scoring system (e.g. Dimeglio)
Outcomes	Improved treatment assessment, better management decisions, improved prediction of outcomes
Subgroups (if any)	None
Methods	RCTs; systematic reviews of RCTs; non-randomized studies of interventions (NRSIs)

Evidence Reviewers: Karl Jeffrey E. Murillo, MD, DPCP; Aldrich Ivan Lois D. Burog, MD, MSc (cand.)
Date of Last Search: May 16, 2025

Statement of the Evidence

For infants with idiopathic clubfoot, routine use of Pirani or Diméglio scores improves assessment reliability and offers moderate prognostic utility for casting burden, tenotomy planning, and relapse risk stratification. In the absence of direct comparative trials, the combined weight of reliability evidence and prognostic associations favors structured scoring over unstructured observation, particularly when paired with systematic brace-adherence counselling and serial score tracking.

The overall certainty of the evidence is very low.

Review Methods

A systematic and comprehensive search was conducted from database inception to May 16, 2025 in MEDLINE (PubMed), Cochrane CENTRAL, HERDIN, and ClinicalTrials.gov, using both MeSH terms and free-text keywords related to idiopathic clubfoot and clinical scoring (e.g., "clubfoot" OR "congenital talipes equinovarus" OR "CTEV") AND ("Pirani" OR "Diméglio") AND ("Ponseti" OR "casts" OR "tenotomy" OR "relapse" OR "recurrence" OR "reliability" OR "inter-observer"). Reference lists of included studies and relevant reviews were hand-searched, citation tracking was performed, and no language restrictions were applied. We also sought grey literature and, where necessary, contacted authors for clarifications. Eligible studies were randomized or non-randomized comparative studies, prospective or retrospective cohorts, registries, and reliability studies that evaluated routine monitoring using clinical scoring systems (Pirani or Diméglio) during Ponseti management of idiopathic clubfoot and reported outcomes such as number of casts, need for percutaneous Achilles tenotomy, relapse/recurrence or

surgery beyond tenotomy, and/or measurement properties. Studies confined to syndromic/neuromuscular clubfoot (unless separable), radiographic-only tools without clinical scores, and case reports were excluded.

Titles/abstracts and full texts were screened against the PICO; data were extracted on setting, population, scoring method/timing, outcomes, and effect estimates. Risk of bias was assessed using QUIPS for prognostic/association studies and COSMIN principles for reliability studies; if present, randomized trials would be appraised with Cochrane RoB 2, and non-randomized comparative intervention studies with ROBINS-I. Certainty of evidence was determined using the GRADE framework. The full search strategy is presented in Annex Table 9.2.

Recommendations from Other Groups

Annex Table Q9.1. Summary of recommendations from other groups.

Group or Agency	Recommendation	Strength of Recommendation/ Certainty/Quality of Evidence
Pediatric Orthopedic Society of North America	Severity is commonly documented with Pirani or Diméglio; both have acceptable reliability after a learning curve	Narrative recommendation, no SOR
British Society for Children's Orthopedic Surgery 2022	The Pirani scoring system should be used at initial assessment, and at each visit/stage of treatment	No formal SOR reported

Ongoing Studies and Research Gaps

No registered trials directly compare structured scoring with unstructured observation. Priority research needs include prospective, multicenter prognostic models that combine score trajectories with dorsiflexion measures and objective brace-adherence monitoring; standardized and validated definitions and cut-points for relapse; and implementation studies evaluating rater training, task-sharing, and feasibility in low-resource settings.

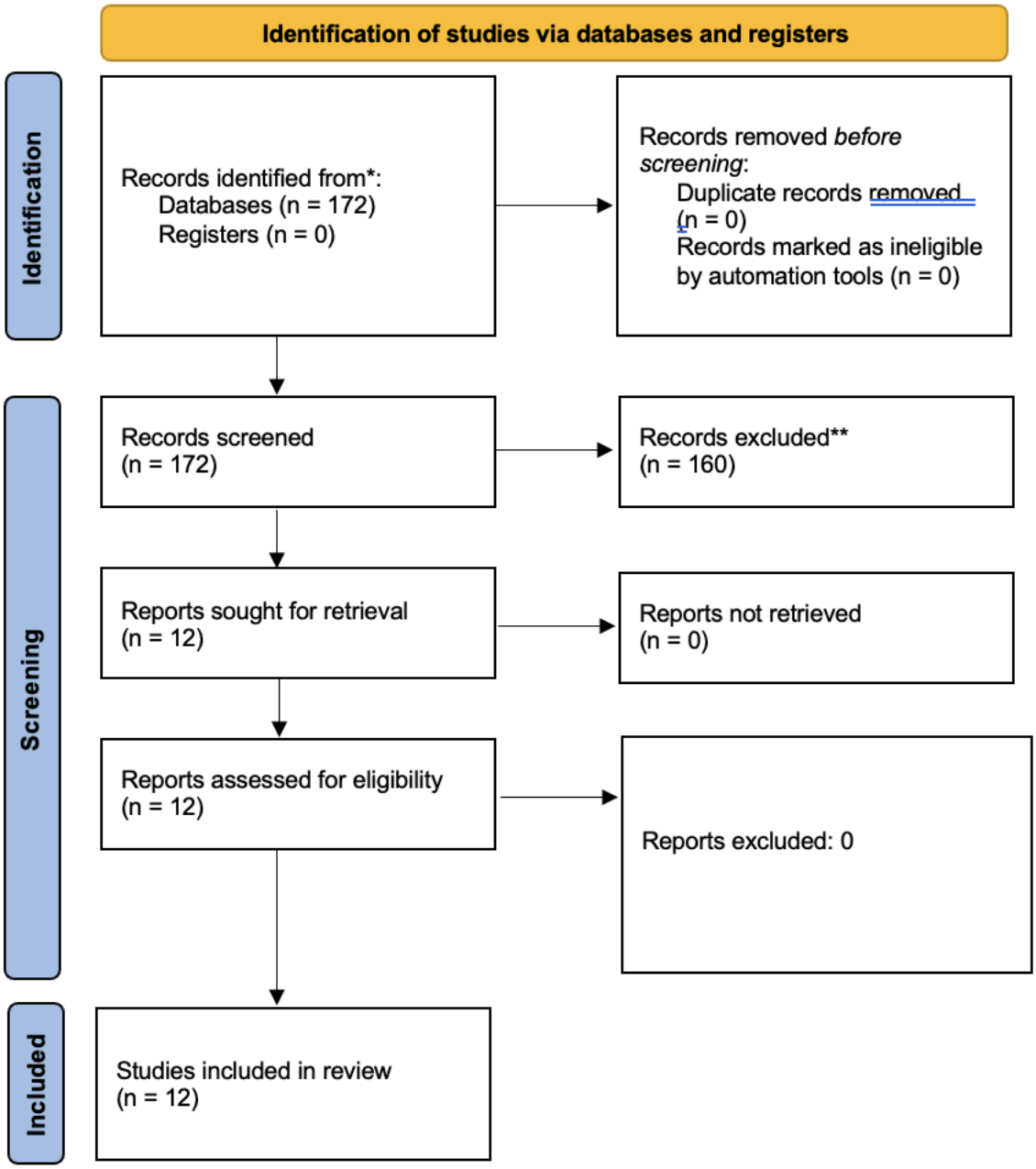
Search Strategy

Annex Table Q9.2. Search strategy (date of last search: January 27, 2025).

Datebase	Search strategy / Search terms	Date and time of search	Results	
			Yield	Eligible
Medline	("pirani"[All Fields] OR "pirani s"[All Fields]) AND ("score"[All Fields] OR "score s"[All Fields] OR "scored"[All Fields] OR "scores"[All Fields] OR "scoring"[All Fields] OR "scorings"[All Fields]) AND (("idiopathic"[All Fields] OR "idiopathically"[All Fields] OR "idiopathics"[All Fields]) AND ("clubfoot"[MeSH Terms] OR "clubfoot"[All Fields] OR "clubfeet"[All Fields])) Translations pirani: "pirani"[All Fields] OR "pirani's"[All Fields] score: "score"[All Fields] OR "score's"[All Fields] OR "scored"[All Fields] OR "scores"[All Fields] OR "scoring"[All Fields] OR "scorings"[All Fields] idiopathic: "idiopathic"[All Fields] OR "idiopathically"[All Fields] OR "idiopathics"[All Fields] clubfoot: "clubfoot"[MeSH Terms] OR "clubfoot"[All Fields] OR "clubfeet"[All Fields]	May 31, 2025 10:13AM	143	12

Datebase	Search strategy / Search terms	Date and time of search	Results	
			Yield	Eligible
	Filters: May 4, 2025 to May 31, 2025			
CENTRAL	#1 idiopathic clubfoot #2 pirani score Filters: May 4, 2025 to May 31, 2025	May 31, 2025 1:34PM	27	0
HERDIN	#1 idiopathic clubfoot #2 pirani score Filters: May 4, 2025 to May 31, 2025	May 16, 2025 11:30AM	0	0
ClinicalTrials.gov	#1 idiopathic clubfoot #2 pirani score Filters: May 4, 2025 to May 31, 2025	May 16, 2025 1PM	2	0

PRISMA Flow Diagram



Annex Figure Q9.1. PRISM flow diagram.

Included and Excluded Studies

Characteristics of Included Studies

Annex Table Q9.3. Study characteristics.

Author Year	Study design	Country	Number of patients	Population	Intervention Group(s)	Control	Outcomes
Chu 2010	Retrospective cohort	USA	123 (per-foot n=185)	Infants with idiopathic clubfoot (<60 days)	Baseline Pirani & Dimeglio scoring	-	Number of casts to correction
Gao 2014	Retrospective cohort	Canada	88 (per-foot n=119)	Infants with idiopathic clubfoot	Baseline Pirani & Dimeglio scoring	-	Casts required; tenotomy; relapse
Fan 2017	Retrospective cohort	China	— (173 cases reported)	Idiopathic clubfoot (infants)	Baseline Pirani & Dimeglio scoring	-	Number of casts; non-linear relationships by severity
Lampasi 2018	Prospective cohort	Italy	— (per-foot n=91)	Infants with idiopathic clubfoot	Baseline + serial Pirani & Dimeglio scoring	-	Casts required; need for Achilles tenotomy
Rastogi 2020	Retrospective cohort	India	— (per-foot n=90)	Infants with idiopathic clubfoot	Baseline Pirani & Dimeglio scoring	-	Casts required (correlation with scores)
Tahririan 2021	Retrospective cohort (≥12 mo FU)	Iran	100 (per-foot n=143)	Idiopathic clubfoot (infants/children)	Baseline Pirani & Dimeglio scoring	-	Casts required; relapse (thresholds and prediction)
Goriainov 2010	Retrospective cohort	UK	61 (per-foot n=83)	Infants with idiopathic clubfoot	Pirani at baseline and ~3 months	-	Late relapse risk vs initial & early Pirani
Hu 2022	Retrospective cohort	China	148	Idiopathic clubfoot (infants)	Baseline Pirani scoring + clinical variables	-	Relapse risk (adjusted OR per 1-point Pirani)
Zhao 2018	Prospective cohort	China	— (per-foot n=172)	Infants with idiopathic clubfoot	Baseline Pirani; brace adherence tracked	-	Casts required; relapse; effect of non-compliance
Goldstein 2015	Retrospective cohort	USA	86 (per-foot n=134)	Infants with idiopathic clubfoot	Dimeglio at baseline & at FAO start	-	Risk of later surgery; impact of FAO non-compliance

Author Year	Study design	Country	Number of patients	Population	Intervention Group(s)	Control	Outcomes
Pavone 2021	Reliability study (multi-rater)	Italy	— (per-foot n=54)	Idiopathic clubfoot <6 months	Pirani & Dimeglio scored by consultants vs residents	-	Inter-observer reliability (ICC)
Bettuzzi 2019	Prospective reliability study	Italy	— (per-foot n=56)	Infants with idiopathic clubfoot	Pirani & Dimeglio scored by two surgeons	-	Total-score agreement; item-level kappa; link to PAT decisions

Quality Assessment of Included Studies

Annex Table Q9.4. For Prognostic/Association studies.

Study	Domain 1	Domain 2	Domain 3	Domain 4	Domain 5	Domain 6	Overall RoB
Chu 2010 (USA)	Low	Low	Low	Low	Moderate	Moderate	Moderate
Gao 2014 (Canada)	Low	Low	Low	Low	Moderate	Moderate	Moderate
Fan 2017 (China)	Low	Unclear	Low	Low	Moderate	Moderate	Moderate
Lampasi 2018 (Italy)	Low	Low	Low	Low	Moderate	Low	Low
Rastogi 2020 (India)	Low	Low	Low	Low	Moderate	Moderate	Moderate
Tahririan 2021 (Iran)	Low	Low	Low	Low	Moderate	Low	Low
Goriainov 2010 (UK)	Moderate	Unclear–Moderate	Low	Low	High	Moderate	Moderate
Hu 2022 (China)	Low	Low	Low	Low	Low	Low	Low
Zhao 2018 (China)	Low	Low	Low	Low	Moderate	Low	Low
Goldstein 2015 (USA)	Low	Low	Low	Low	Moderate	Low	Low

Domain 1: Participation Bias
Domain 2: Attrition Bias
Domain 3: Prognostic factor measurement
Domain 4: Outcome measurement bias
Domain 5: Confounding bias
Domain 6: Analysis and reporting bias

Annex Table Q9.5. For reliability studies.

Study	Domain 1	Domain 2	Domain 3	Domain 4	Domain 5	Overall RoB
Pavone 2021 (Italy)	Low	Low	Low	Moderate	Low	Low
Bettuzzi 2019 (Italy)	Low	Low	Low	Moderate	Low	Low

Domain 1: Study design
Domain 2: Blinding
Domain 3: Stability
Domain 4: Sampling Bias
Domain 5: Analysis

GRADE Evidence Profile table

Author(s): Karl Jeffrey E. Murillo, MD

Question: Routine monitoring using clinical scoring systems (e.g Pirani) compared to no routine monitoring for infants with idiopathic clubfoot

Setting: OPD

Bibliography: 1. Chu A, et al. Clubfoot classification: Correlation with Ponseti cast treatment. J Pediatr Orthop. 2010;30:695-699. 2. Gao R, Tomlinson M, Walker C. Correlation of Pirani and Diméglio scores with number of Ponseti casts. J Pediatr Orthop. 2014;34:639-642. 3. Fan H, et al. The correlation of Pirani and Diméglio scoring systems… Sci Rep. 2017;7:14578. 4. Lampasi M, Abati CN, Trisolino G. Comparison of Diméglio and Pirani score… Int Orthop. 2018;42:2429-2436. 5. Rastogi A, et al. Correlation of Pirani and Diméglio scores with number of casts… J Clin Orthop Trauma. 2020;11:S826-S831. 6. Tahririan MA, et al. Can clubfoot scoring systems predict casts and recurrences? J Orthop Surg Res. 2021;16:216. 7. Goriainov V, Judd J, Uglow M. Does the Pirani score predict relapse? J Child Orthop. 2010;4:439-444. 8. Hu J, et al. Risk factors for relapse after Ponseti treatment. BMC Musculoskelet Disord. 2022;23:xxx. 9. Zhao D, et al. Noncompliance and relapse after Ponseti treatment. J Pediatr Orthop B. 2018;27:xxx. 10. Goldstein RY, et al. Predicting surgery beyond PAT in idiopathic clubfoot. J Pediatr Orthop. 2015;35:395-402. 11. Pavone V, et al. Interobserver reliability of Pirani and Diméglio scores. Children. 2021;8:618. 12. Bettuzzi C, et al. Interobserver reliability of Diméglio and Pirani score… J Child Orthop. 2019;13:161-167.

Annex Table Q9.6. GRADE evidence Profile.

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	routine monitoring using clinical scoring systems (e.g Pirani)	no routine monitoring	Relative (95% CI)	Absolute (95% CI)		
Predicting number of casts with Pirani												
5	non-randomised studies	not serious	serious[a]	serious[b]	not serious	none			**correlationr r 0.529** (0.364 to 0.662)	**-- per 1,000** (from -- to --)	⊕◯◯◯ Very low[a,b]	
Predicting number of casts with Dimeglio												
4	non-randomised studies	not serious	serious[a]	serious[b]	not serious	none			**correlation of r 0.616** (0.384 to 0.775)	**-- per 1,000** (from -- to --)	⊕◯◯◯ Very low[a,b]	
Predicting relapse Pirani cut-point ≥5.75												
1	non-randomised studies	not serious	not serious	serious[b]	serious[c]	none			**OR 23.31** (2.91 to 184.54)	**23 fewer per 1,000** (from 185 fewer to 3 fewer)	⊕◯◯◯ Very low[b,c]	

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	routine monitoring using clinical scoring systems (e.g Pirani)	no routine monitoring	Relative (95% CI)	Absolute (95% CI)		
Predicting relapse Dimeglio cut-point ≥17.5												
1	non-randomised studies	not serious	not serious	serious[b]	serious[c]	none			**OR 3.14** (0.90 to 10.96)	**3 fewer per 1,000** (from 11 fewer to 1 fewer)	⨁◯◯◯ Very low[b,c]	
Inter-observer reliability — Pirani total score												
1	non-randomised studies	not serious	not serious	serious[b]	not serious	none	ICC of 0.76 - 0.95				⨁◯◯◯ Very low[b]	
Inter-observer reliability — Dimeglio total score												
1	non-randomised studies	not serious	not serious	serious[b]	not serious	none	ICC of 0.80 - 0.91				⨁◯◯◯ Very low[b]	

CI: confidence interval; **OR:** odds ratio

Explanations

a. heterogeneity (center techniques, rater mix, timing and definitions)
b. indirectness to answer clinical question
c. wide confidence intervals

GUIDELINE QUESTION 10:

Should we repeat Ponseti treatment or surgical management among children with idiopathic clubfoot who had recurrence of deformity after completion of Ponseti treatment?

Research Question: Among children with idiopathic clubfoot who fail to achieve correction after initial Ponseti casting, does repeat Ponseti casting, compared with surgical management (e.g., open lengthening, posteromedial release, tendon transfers, Ilizarov method, or osteotomies), result in better functional outcomes, lower recurrence rates, and fewer complications?	
Population	Children with idiopathic clubfoot who failed to achieve correction after initial Ponseti casting (i.e., persistent deformity despite completion of standard protocol)
Intervention/ Treatment	Repeat Ponseti casting
Comparison	Surgical management (open lengthening, Posteromedial Release) add to comparator- tendon transfers, Ilizarov method of gradual correction, osteotomies
Outcomes	Functional outcomes (e.g., mobility, gait), degree of correction achieved, recurrence rate, complications, need for further procedures
Subgroups (if any)	None
Methods	RCTs; observational studies

Evidence Reviewers: Dan Louie Renz P. Tating, RN, MSc (cand.); Aldrich Ivan Lois D. Burog, MD, MSc (cand.)
Date of Last Search: June 21, 2025

Statement of the Evidence

Among children with idiopathic clubfoot who failed to achieve correction after initial Ponseti casting, repeat Ponseti casting:

- May increase success rate, number of feet in plantigrade position, and degree of dorsiflexion/ equinus of the foot.
- May decrease Pirani and Dimeglio scores
- May impact on quality of life rating as “good”

The overall certainty of the evidence is VERY LOW.

There are no studies that compared repeat Ponseti casting versus surgical interventions for relapsed or recurrent clubfoot in children.

Review Methods

A systematic search was done from the database inception June 21, 2025 using PubMed, CENTRAL, and HERDIN databases with a free text search using the terms Child, Clubfoot, Ponseti, Surgery, and synonyms for the term relapse (repeat, fail, recur, persist). See Annex Table 10.2 for the search strategy. Ongoing studies and preprints were also searched for in the Clinicaltrials.gov and WHO ICTRP registries, as well as in MedRxiv and BioRxiv preprint servers.

Inclusion criteria were observational studies or randomized controlled trials that directly compared repeat Ponseti casting versus surgical management among children with idiopathic clubfoot who failed to achieve correction after initial Ponseti casting. Outcomes of interest included successful correction, long-term foot function (strength, flexibility, endurance), health-related quality of life for the child and family, recurrence/ relapse requiring further intervention, gait function and mobility at follow-up, fegree of correction achieved (e.g., change in Pirani score, angle measurements), harms from delayed definitive management (e.g., stiffness, early arthritis), need for additional surgery, and need for additional casting episodes.

Observational studies were appraised using the Newcastle Ottawa Scale, while randomized controlled trials were appraised using the Cochrane Risk of Bias v 2.0. If sufficient data were available, a quantitative synthesis was done using RevMan 5.4. Otherwise, a narrative synthesis was done. The overall certainty of evidence was determined following the GRADE approach.

Recommendations from Other Groups

Annex Table Q10.1. Summary of recommendations from other groups.

Group or Agency	Recommendation	Strength of Recommendation/ Certainty of Evidence
British Society for Children's Orthopaedic Surgery, UK, 2021	55) Early relapse should be treated with recasting in an above-knee cast, following careful assessment of which components have relapsed. 56) If revision tenotomy is required, strong consideration should be given to performing it under GA. 57) FAB should be reintroduced when the foot is corrected (sometimes an alternative boots and bar system may help regain trust and compliance and enable reintroduction of the standard brace as soon as possible)	Not presented

Ongoing Studies and Research Gaps

From the WHO International Clinical Trials Registry Platform, an ongoing study from India titled “Equinus Recurrence And Its Treatment In Children With Idiopathic Clubfoot Following Initial Deformity Correction by Ponseti Method - A Prospective Study” was found. However, the indicated contact persons in the registry did not respond to repeated inquiries via email.

The main research gap identified in this guideline question and evidence review is the lack of studies that directly compare repeat Ponseti method versus surgical techniques in the management of relapsed clubfoot in children.

Furthermore, there is a need to identify a universal definition of relapsed clubfoot to ensure fair comparisons within and between studies.

Search Strategy

Annex Table Q10.2. Search strategy (as of June 21, 2025).

Database searched	Search strategy	Yield and Date of Search	Eligible
MEDLINE	Child* AND Clubfoot AND (repeat OR fail* OR recur* OR persist*) AND ponseti AND surg*	285 (June 21, 2025)	5
CENTRAL	Child* AND Clubfoot AND (repeat OR fail* OR recur* OR persist*) AND ponseti AND surg*	1 Review 13 Trials (June 21, 2025)	0
HERDIN	clubfoot	10 (June 21, 2025)	0
Clinicaltrials.gov	Child* AND Clubfoot AND (repeat OR fail* OR recur* OR persist*) AND ponseti AND surg*	3 (June 21, 2025)	0
WHO ICTRP	Child* AND Clubfoot AND (ponseti OR surg*)	19 (June 21, 2025)	0
Medrxiv and Biorxiv	Clubfoot Ponseti	3 (June 21, 2025)	0
Total (After removing 22 duplicate records and 2 earlier versions of a review)		310	5

Included Studies

Characteristics of Included Studies

Annex Table Q10.3. Study characteristics.

Study	Study Design	Country	Population	Intervention	Comparison	Outcomes
Ahmed 2025	Prospective, single-arm study	Egypt	33 children (50 clubfeet) with relapsed idiopathic clubfoot	Repeat Ponsetti	None	Pirani score at one to two years
Butt 2023	Retrospective study	Pakistan	40 children with recurrent clubfoot	Repeat Ponsetti	None (vs untreated and syndromic clubfoot)	Pirani score at one year
Chand 2018	Prospective, single-arm study	India	115 idiopathic clubfeet (79 children) presenting with relapse	Repeat Ponsetti	None	Pirani and Dimeglio scores, Equinus, Number of casts applied (Mean follow-up: 23.8 months)
van Praag 2018	Prospective study	Canada	35 patients (49 feet) with recurrent clubfoot	Repeat Ponsetti	None (vs children w/o recurrence)	Treatment success; Physical examination of the foot: plantigrade, straight lateral border, hindfoot alignment, dorsiflexion; DSI (Function and Satisfaction scales) (Mean follow-up: 89.6 months)
Marquez 2017	Retrospective, single-arm study	Australia	53 children (79 feet) with relapse after initial clubfoot management	Modified Ponsetti	None	Degree of passive dorsiflexion and abduction at 6 months Change in passive dorsiflexion Minor adverse events

Quality Assessment of Included Studies

Annex Table Q10.4.

Author Year	Domain 1: Selection	Domain 2: Comparability	Domain 3: Outcomes	Overall assessment
Ahmed 2025	☆	0	☆☆☆	Moderate quality
Butt 2023	☆	0	☆☆☆	Moderate quality
Chand 2018	☆	0	☆☆☆	Moderate quality
van Praag 2018	☆☆	0	☆☆	Moderate quality
Marquez 2017	☆☆	0	☆☆	Moderate quality

GRADE Evidence Profile table

Annex Table Q10.5.

Author(s): Dan Louie Renz Tating

Question: Repeat Ponsetti vs Surgery for Relapsed Clubfoot

Setting: Hospital

Bibliography:

1. Ahmed KFE, Marzouk AR, Eldin MS. Repeating Ponseti method for treating relapsed idiopathic congenital talipes equinovarus in children less than two years of age: a prospective study. BMC Musculoskelet Disord. 2025 Mar 15;26(1):263. doi: 10.1186/s12891-025-08464-8. PMID: 40087635; PMCID: PMC11909929.
2. Butt MN, Perveen W, Ciongradi CI, Alexe DI, Marryam M, Khalid L, Dobreci DL, Sârbu I. Outcomes of the Ponseti Technique in Different Types of Clubfoot-A Single Center Retrospective Analysis. Children (Basel). 2023 Aug 3;10(8):1340. doi: 10.3390/children10081340. PMID: 37628341; PMCID: PMC10453163.
3. Chand, S., Mehtani, A., Sud, A., Prakash, J., Sinha, A., & Agnihotri, A. (2018). Relapse following use of Ponseti method in idiopathic clubfoot. Journal of children's orthopaedics, 12(6), 566–574. https://doi.org/10.1302/1863-2548.12.180117
4. Marquez E, Pacey V, Chivers A, Gibbons P, Gray K. The Ponseti technique and improved ankle dorsiflexion in children with relapsed clubfoot: a retrospective data analysis. J Pediatr Orthop B. 2017 Mar;26(2):116-121. doi: 10.1097/BPB.0000000000000390. PMID: 27649368.
5. van Praag VM, Lysenko M, Harvey B, Yankanah R, Wright JG. Casting Is Effective for Recurrence Following Ponseti Treatment of Clubfoot. J Bone Joint Surg Am. 2018 Jun 20;100(12):1001-1008. doi: 10.2106/JBJS.17.01049. PMID: 29916926; PMCID: PMC6075876.

Certainty assessment							№ of patients	Summary of findings		Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Repeat Ponsetti	Impact	Certainty	
Success Rate										
1	Observational study	not serious	not serious	serious [a]	not serious	none	35	Among 35 patients, 26 (74%) did not receive surgery for recurrence and had all of the following: hindfoot in valgus, dorsiflexion of 10 degrees, and a straight lateral border.	⊕◯◯◯ Very low	CRITICAL
Plantigrade Position										
1	Observational study	not serious	not serious	serious [a]	not serious	none	35/ 49 feet	Among the 49 feet in 35 patients, 46 (94%) were in plantigrade position at follow-up.	⊕◯◯◯ Very low	CRITICAL

Certainty assessment							№ of patients	Summary of findings		Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Repeat Ponsetti	Impact	Certainty	
Pirani Score										
4	Observational studies	not serious	serious [b]	serious [a]	not serious	none	222	On a 0-6 scale, the baseline Pirani scores ranged from 2.4 to 5.5. The decrease in Pirani scores at follow-up ranges from -2.4 to -4.5.	⊕◯◯◯ Very low	CRITICAL
Degree of Dorsiflexion/ Equinus										
2	Observational studies	not serious	serious [c]	serious [a]	not serious	none	132	In terms of degrees of range of motion, the baseline dorsiflexion/ equinus ranged from 3.3 to 7.9 degrees. The improvement at follow-up ranges from +10 to +15 degrees.	⊕◯◯◯ Very low	CRITICAL
Dimeglio Score										
1	Observational study	not serious	not serious	serious [a]	not serious	none	79	On a 0-20 scale, the baseline Dimeglio score was 7.9. The decrease at follow-up was -6.0 .	⊕◯◯◯ Very low	CRITICAL
Health Related Quality of Life										
1	Observational study	not serious	not serious	serious [a]	not serious	none	35	Using the 100-point Disease Specific Instrument (DSI), the overall mean score was 83.35. In its two subscales, the mean function score was 85.52, and the mean satisfaction score was 81.17.	⊕◯◯◯ Very low	CRITICAL
Number of Casts Applied										
3	Observational studies	not serious	not serious	serious [a]	not serious	none	167	The total number of casts applied ranged from 4.3 to 5.6.	⊕◯◯◯ Very low	CRITICAL

Explanations

a. Studies found did not directly compare repeat Ponsetti casting to surgery.
b. There is a wide range of values on the change in Pirani score from baseline to follow-up.
c. There is a wide range of values on the change in dorsiflexion/ equinus from baseline to follow-up.