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# Evaluation of long-term outcomes of congenital clubfoot treatment with the Ponseti method: association of radiological parameters and quality of life – preliminary results

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## Abstract

**Introduction and Objective.** The clinical relevance of residual radiographic abnormalities following Ponseti treatment of idiopathic congenital clubfoot remains incompletely understood. The aim of the study is to investigate the association between specific radiographic findings of the International Clubfoot Study Group outcome evaluation system and patient-reported outcome measurement at long-term follow-up.

**Materials and Method.** This single-centre, cross-sectional follow-up study included 25 patients treated for idiopathic congenital clubfoot using the Ponseti method between 2006–2016. The patients were reassessed between 2023–2026. Weight-bearing radiographs were evaluated using the 12 parameters included in the International Clubfoot Study Group outcome evaluation system. Each patient contributed one radiographic score, corresponding to the foot with the worse score in bilateral cases. The primary outcome was the patient-reported OxAFQ-C Physical domain. Associations were assessed using Spearman's rank correlation coefficient.

**Results.** Twenty-five patients, including 9 with bilateral involvement, were evaluated. Mean age was 13.6 ± 2.3 years. The mean radiographic and OxAFQ-C Physical scores were 5.7 ± 2.0 and 87.7 ± 9.8, respectively. Radiographic scores were not significantly associated with OxAFQ-C Physical ($\rho = -0.29$; $p = 0.158$; bootstrap 95% CI = 0.65 to 0.16).

**Conclusions.** In this preliminary cohort, no statistically significant correlation was observed between radiographic findings and patient-reported physical functioning. Small sample size and non-validated Polish questionnaire translations limited interpretation. These preliminary findings should be interpreted cautiously due to the small sample size and require confirmation in larger studies.

## Key words

clubfoot, Ponseti method, long-term outcomes, radiography, patient-reported outcome measures

## INTRODUCTION

Idiopathic congenital clubfoot is among the most common congenital musculoskeletal deformities. A European population-based study reported a prevalence of 1.13 per 1,000 births, including 0.92 per 1,000 for isolated clubfoot in the Wielkopolska region, one of the biggest regions in Poland, where the prevalence of non-chromosomal clubfoot was 0.88 per 1,000 births. Currently, the treatment starts in the first weeks of life to achieve the best correction possible. The Ponseti method, based on serial manipulation and casting, Achilles tenotomy when indicated, and subsequent foot-abduction bracing, is the standard approach to treatment. The primary goal is to achieve a flexible, painless, plantigrade foot that permits everyday activities and the use of conventional footwear. Nevertheless, relapse and residual deformity remain important concerns, underscoring the need for long-term assessment of outcome [1, 2].

Clinical correction, however, does not necessarily implicate complete restoration of normal skeletal anatomy. Ponseti and colleagues described persistent radiographic abnormalities in patients with generally satisfactory long-term functional outcomes [3]. More recently, Agarwal et al. reported residual hindfoot abnormalities on weight-bearing radiographs despite clinically corrected, painless feet, while Svehlik et al. documented persistent morphological deviations at an 18-year follow-up [4, 5]. On the other hand, selected early radiographic measurements have been associated with later relapse requiring surgery [6]. These findings suggest that radiographic abnormalities should be interpreted in the context of specific clinical outcome assessment rather than considered in isolaton.

The description and rating of treated clubfoot remains heterogeneous. The core outcome set (COS) developed by Gelfer et al. recommends standardized clinical and patient-reported outcomes, including the complete Oxford Ankle Foot Questionnaire for Children (OxAFQ-C), after a minimum follow-up of five years. Radiographic assessment was not incorporated into the final COS, and the full International Clubfoot Study Group (ICFSG) score did not reach inclusion in final consensus during voting

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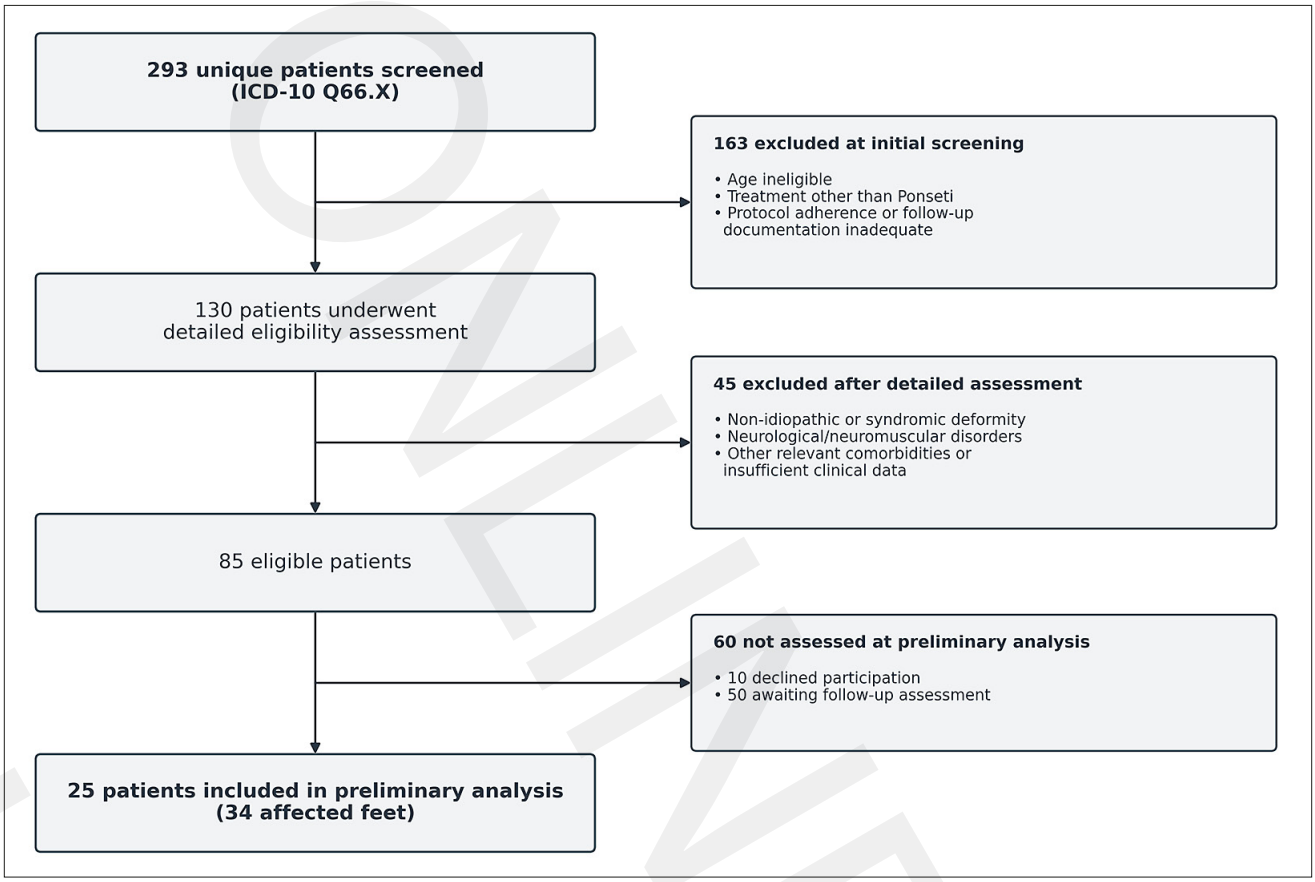



**Figure 1.** Flow diagram of patients screening, detailed eligibility assessment, and inclusion in the preliminary analisis

[7]. Nevertheless, a Core Outcome Set for clubfoot defines minimum reporting requirements and does not preclude complementary assessments. The radiographic component of the ICFSG evaluation system described by Bensahel et al. incorporates 12 parameters covering different aspects of foot and ankle anatomy, providing a structured approach beyond individual angular measurements [8]. This tool was not used in the presented study since it provides wide, comprehensive assessment of radiological parameters.

Patient-reported measures can capture difficulties that are not necessarily obvious from anatomical assessment alone. The OxAFQ-C evaluates the impact of foot and ankle problems in three separate domains: Physical, School and Play, and Emotional [9]. The relationship between the cumulative burden of residual radiographic abnormalities and these patient-reported outcomes following Ponseti treatment remains insufficiently characterized. Clarifying this relationship may also help identify questions for future studies of individual radiographic parameters.

The aim of the presented study is to assess the association between the radiographic component of the ICFSG outcome evaluation system and patient-reported outcomes at long-term follow-up after Ponseti treatment of idiopathic clubfoot. The OxAFQ-C Physical domain was designated as the primary outcome, with its School and Play and Emotional domains considered secondary outcomes.

## MATERIALS AND METHOD

**Study design and participants.** This single-centre observational study combined a retrospective review of patients treated using the Ponseti method between 2006–2016 with a cross-sectional long-term follow-up assessment conducted from December 2023 – May 2026. A total of 293 unique patients identified by ICD-10 Q66.X codes were screened. At the initial screening, 163 patients were excluded because they did not meet the age criterion, had received other treatment, lacked documented adherence to the Ponseti protocol, or had insufficient follow-up documentation. Of the remaining 130 patients, 45 were excluded after detailed assessment because of non-idiopathic or syndromic deformity, neurological or neuromuscular conditions, arthrogryposis, other conditions potentially affecting foot and ankle function, or insufficient data records.

Eligible patients aged 7–16 years and 11 months had previously undergone Ponseti treatment at our centre between 2006–2016. Previous relapse requiring repeat casting, repeat Achilles tenotomy, or tibialis anterior tendon transfer was not an exclusion criterion. Of the 85 eligible patients, 10 declined participation at some stage, and 50 were awaiting examination. This preliminary analysis comprised 25 examined patients (34 affected feet), including nine with bilateral clubfoot. The recruitment process is presented in Figure 1.

**Follow-up and radiographic assessment.** Clinical examination, radiographs and questionnaires were obtained

during a single follow-up visit. Weight-bearing dorsoplantar and lateral foot radiographs and an anteroposterior weight-bearing ankle radiograph were obtained using a standard projection protocol. Only the 12-item radiographic component of the International Clubfoot Study Group (ICFSG) system was used: five anteroposterior foot, six lateral foot, and one anteroposterior ankle parameter [8]. Each parameter was classified binary – as normal (0) or abnormal (1), producing a total score of 0–12 per affected foot; higher scores indicated more abnormalities. Two investigators assessed the radiographs together and reached a consensus on each result. Uncertain findings were additionally reviewed with an experienced paediatric orthopedic surgeon.

**Questionnaire outcomes.** Children independently completed the Oxford Ankle Foot Questionnaire for Children (OxAFQ-C), covering the Physical, School and Play, and Emotional domains. The original instrument was validated in a cohort of children aged 5–16 years, including patients with congenital deformities, commonly clubfoot. Each domain was scored separately and transformed to a 0–100 scale, with higher scores indicating better outcomes. The Physical domain was the primary outcome; the remaining domains were secondary outcomes [9]. Caregivers independently completed the 10-item Roye Disease-Specific Instrument (DSI); its Satisfaction, Function, and total scores were analyzed as exploratory caregiver-proxy outcomes [10]. Investigators could clarify the questions upon request. Research-team Polish translations of both questionnaires were used as they had not yet undergone formal psychometric validation.

**Statistical analysis.** The patient was the primary unit of analysis. In bilateral cases, the foot with the higher total radiographic score represented that patient; equal scores contributed as a single patient value. Associations between radiographic score and questionnaire outcomes were examined using two-sided Spearman rank correlations. A 95% percentile bootstrap confidence interval for the primary correlation was calculated from 20,000 patient-level resamples. Continuous variables were summarized using means and sample standard deviations, with medians and interquartile ranges reported where informative. Categorical variables were presented as counts and percentages. Spearman's rank correlation with average ranks for tied observations was used to examine associations between the patient-level radiographic score and each questionnaire outcome. Two-sided asymptotic p-values were calculated. The primary correlation was accompanied by a 95% percentile bootstrap confidence interval derived from 20,000 patient-level resamples. A sensitivity analysis replaced the worse-foot radiographic score with the mean score of both affected feet in bilateral cases. Statistical significance for the primary analysis was defined as $p<0.05$. Secondary and exploratory analyses were interpreted without adjustment for multiple comparisons. Calculations were performed using Python 3.13.5, NumPy 2.3.5, and SciPy 1.17.0.

## RESULTS

**Study population.** Of 293 unique patients screened, 163 were excluded at initial screening and 45 after detailed eligibility assessment. Of the 85 eligible patients, 10 declined participation and 50 were awaiting examination. The remaining 25 constituted all participants who had completed a study visit by the preliminary analysis cutoff (Fig. 1).

**Table 1.** Patient characteristics and follow-up outcomes. Idiopathic clubfoot after Ponseti treatment, preliminary analysis (n=25)

| Characteristics | Result |
|---|---|
| Patients, N | 25 |
| Affected feet, N | 34 |
| Age at follow-up (years) | 13.55–2.27 |
| Age at follow-up, range (years) | 8.58–16.04 |
| Gender, N(%) | |
| Male | 14 (56%) |
| Female | 11 (44%) |
| Clubfoot laterality, N(%) | |
| Unilateral | 16 (64%) |
| Bilateral | 9 (36%) |
| Radiographic assessment | |
| ICFSG radiographic score (worse foot, 0–12) | 5.72 ± 2.01 |
| ICFSG score, range | 2–10 |
| Child-reported outcomes (OxAFQ-C, 0–100) | |
| OxAFQ-C Physical (primary outcome) | 87.66 ± 9.81 |
| OxAFQ-C School and Play | 90.77 ± 11.14 |
| OxAFQ-C Emotional | 85.77 ± 9.64 |
| Caregiver-proxy outcomes (Roye DSI, 0–100) | |
| Roye DSI Satisfaction | 84.26 ± 12.75 |
| Roye DSI Function | 87.99 ± 16.67 |
| Roye DSI Total | 86.14 ± 12.42 |

The cohort comprised 25 patients (34 affected feet), including 14 males (56%) and 11 females (44%). Sixteen patients (64%) had unilateral and nine (36%) had bilateral clubfoot. Mean age at assessment was 13.55 ± 2.27 years (range: 8.58–16.04). Complete radiographic and questionnaire data required for the planned analyses were available for all 25 patients (Tab. 1). Seven patients (28%) had previously received treatment for relapse. All seven underwent repeat casting; four subsequently underwent repeat Achilles tenotomy, two underwent tibialis anterior tendon transfer, and one required casting alone. These were seven distinct patients. All achieved renewed clinical correction and had completed relapse treatment before the long-term study visit.

**Radiographic and questionnaire outcomes.** The mean worse-foot ICFSG radiographic score was 5.72 ± 2.01 (range, 2–10; median, 6; interquartile range, 4–7). The mean OxAFQ-C Physical score was 87.66 ± 9.81 (median, 87.5; interquartile range, 83.3–91.7). Seven patients (28%) attained the maximum School and Play score. Results for the remaining OxAFQ-C domains and caregiver-reported Roye DSI are presented in Table 1.

**Correlation and sensitivity analysis.** The association between the ICFSG radiographic score and the primary outcome, OxAFQ-C Physical, was not statistically significant (Spearman's $\rho = -0.291$; $p=0.158$; 95% bootstrap CI= −0.652 to 0.160) (Fig. 2).

Neither the School and Play ($\rho = -0.351$; $p = 0.086$) nor the Emotional domain ($\rho = -0.226$; $p = 0.277$) showed a

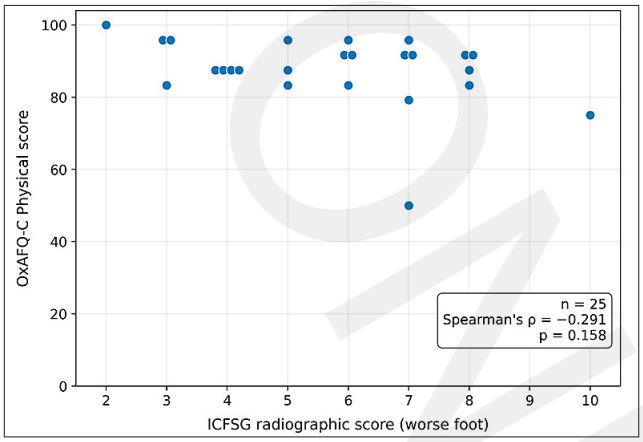



**Figure 2.** Relationship between the worse-foot ICFSG radiographic score and the child-reported OxAFQ-Physical domain score (n=25)

**Table 2.** Correlations between ICFSG radiographic scores and questionnaire outcomes. Patient-level analysis, n = 25; worse foot used for bilateral clubfoot

| Outcome | Spearman's rho | Two-sided p |
|---|---|---|
| Child-reported outcomes (OxAFQ-C) | | |
| Physical – primary outcome | -0.291 | 0.158 |
| School and Play | -0.351 | 0.086 |
| Emotional | -0.226 | 0.277 |
| Caregiver-proxy outcomes (Roye DSI) | | |
| Satisfaction | -0.522 | 0.007 |
| Function | -0.213 | 0.306 |
| Total | -0.400 | 0.047 |

Primary outcome: 95% percentile bootstrap CI, −0.652–0.160 (20 000 resamples)

Spearman rank correlation, two-sided asymptotic p-values; ties retained (n = 25)

For bilateral clubfoot, the higher ICFSG score represented the patient

Secondary and caregiver-proxy analyses were exploratory; p-values were unadjusted

statistically significant correlation with the radiographic score (Tab. 2).

In exploratory caregiver-proxy analyses, negative correlations were observed for Roye DSI Satisfaction (ρ = −0.522; p = 0.007) and total score (ρ = −0.400; p = 0.047), but not Function (ρ = −0.213; p = 0.306). Exploratory p-values were not adjusted for multiple comparisons (Tab. 2). Using the mean radiographic score of both affected feet in bilateral cases, rather than the worse-foot score, produced a similar primary result (ρ= −0.298; p=0.148).

## DISCUSSION

The primary finding of this preliminary study was that the summed ICFSG radiographic score was not significantly associated with child-reported physical functioning after Ponseti treatment. However, the estimated correlation was negative (ρ = −0.291), and its wide 95% confidence interval (−0.652–0.160) did not exclude a clinically relevant association. Thus, the present findings should not be interpreted as evidence that residual radiographic abnormalities are unrelated to patients' physical functioning.

These observations are consistent with the broader distinction between anatomical correction and functional outcome reported in recent literature. Vahidi et al. assessed radiological, clinical, paedobarographic, and quality-of-life outcomes after Ponseti treatment, illustrating the complementary information provided by different outcome domains [11]. In a systematic review of 14 studies, Rastogi and Agarwal reported persistent radiographic abnormalities despite generally favourable clinical outcomes after long-term follow-up [12]

Agarwal et al. identified residual hindfoot radiographic abnormalities in clinically corrected feet [4], while Svehlik et al. reported persistent radiographic deviations alongside functional and quality-of-life outcomes at adult follow-up [5]. These findings provide context, but are not direct validations of our patient-level correlation, given differences in population, imaging methods, and outcome measures.

Radiographic measurements may also help predict treatment outcomes. Li et al. demonstrated that radiographs obtained early during treatment may help identify patients at risk of relapse requiring surgery [6]. In contrast, current study examined the relationship between radiographic findings at long-term follow-up and patient-reported outcomes. A composite ICFSG score based on 12 parameters was used, each one classified as normal or abnormal, not as an exact degree of deformity [8]. This approach does not account for the severity of individual abnormalities and may therefore overlook associations between specific radiographic findings and patient-reported outcomes. The findings do not argue against clinically indicated radiographic assessment.

Exploratory analyses showed negative correlations between the radiographic score and caregiver-reported Roye DSI Satisfaction (ρ = −0.522; p = 0.007) and total scores (ρ = −0.400; p = 0.047). In contrast, the association with child-reported OxAFQ-C Physical was not statistically significant. The two questionnaires assess different aspects of treatment outcomes, and these correlations were did not formally compared. Bouchard et al. reported that differences between child- and parent-reported OxAFQ scores varied between Canadian and Indian cohorts and that relapse was associated with poorer scores in the Canadian cohort [13]. Sharma et al. also reported poorer parent-reported outcomes in children with persistent clinical deformity [14]. Neither study directly examined the association between the radiographic score in the current study and Roye DSI. As the caregiver analyses in the current study were exploratory and not adjusted for multiple comparisons, these results require confirmation. Previous relapse may be another relevant clinical factor. Seven of the 25 patients in the current study had required additional treatment, including repeat casting, repeat Achilles tenotomy or tibialis anterior tendon transfer. All achieved renewed clinical correction and completed relapse treatment before the study visit.

In the multicentre CoCo study, relapse was associated with poorer clinical and quality-of-life outcomes [15]. Moerman et al. found that early radiographic abnormalities were associated with subsequent additional surgery and that caregiver-reported Roye DSI satisfaction was lower among children who required surgery [16]. Unlike the presented study, they assessed early radiographs as predictors of later treatment rather than relating long-term radiographic scores directly to questionnaire results. The current study was not designed to assess the separate effects of relapse history

or subsequent treatment. This clinical heterogeneity was regarded as a limitation and a direction for future research, rather than an explanation of the observed correlations.

Patient-reported outcomes capture aspects of daily life that anatomical measurements cannot directly describe, including school activities, play, and emotional well-being. Consistent with this broader approach, the international clubfoot core outcome set includes patient-centred outcomes and recommends an appropriate questionnaire, such as OxAFQ-C [7]. Collecting both child and caregiver perspectives may provide complementary information, although their scores are not interchangeable. The present study did not measure environmental exposures or access to care, and cannot draw conclusions about rural–urban or other environmental differences.

**Limitations of the study.** The principal limitations are the small preliminary sample and incomplete recruitment: only 25 of 85 eligible patients had completed follow-up at the analysis cutoff. Selection bias and imprecision are possible, as reflected by the wide confidence interval for the primary correlation. The single-centre setting limited generalisability. The seven patients with treated relapse added clinical heterogeneity, but the study was neither designed nor powered to estimate its effect. Joint radiographic assessment by two investigators allowed consensus scoring but did not permit assessment of independent interobserver agreement. Research-team Polish translations of both questionnaires lacked formal psychometric validation, and high questionnaire scores may have restricted discrimination in some domains. Finally, the cross-sectional analysis could not establish causality or determine whether objective clinical function mediated associations between radiographic findings and perceived outcomes.

Completion of recruitment should improve precision and may permit analyses of selected clinical factors. Future work could examine individual radiographic components alongside objective functional measures and patient- and caregiver-reported outcomes, including the possible contribution of relapse history. Such analyses require adequate sample size and pre-specification rather than additional subgroup tests in the present preliminary cohort.

## CONCLUSIONS

In this preliminary cohort, the composite ICFSG radiographic score was not significantly associated with child-reported physical functioning at long-term follow-up after Ponseti treatment. Exploratory associations with caregiver-reported satisfaction require confirmation in a larger cohort. Radiographic findings should be interpreted alongside the child's and caregiver's perspectives on daily functioning. The limited sample and ongoing recruitment preclude definitive conclusions about the relationship between anatomical and patient-reported outcomes.

**Ethics.** The study protocol was approved by the institutional Bioethics Committee (Approval No. KE-0254/254/12/2023). The research was conducted in full compliance with the ethical standards outlined in the Declaration of Helsinki and adhered to all relevant national and institutional regulations regarding the ethical conduct of research involving human participants. All participants were thoroughly informed about the purpose of the study and provided their written informed consent prior to participation.

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