

## Peer Review File

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**Reviewer A:** Thank you for the time to publish this information. Unfortunately, the items listed below are missing and making the information not acceptable for publication:

**Comment 1:** No indication that ethical approval was obtained to use this data for research purposes

**Reply 1:** Ethics approval with institutional review board reference number are now stated in the “Method” section of the revised manuscript.

**Comment 2:** Grammatical errors, most notably: 'data was' should be 'data were'

**Reply 2:** The revised manuscript has been revised by a native English speaker.

**Comment 3:** Missing conclusions

**Reply 3:** Conclusions have been added to the revised manuscript.

**Reviewer B:** Thank you for requesting me to review this scientific article. I would like to congratulate the Authors and Institutions for developing a study on this theme, and for the time and efforts invested to elaborate this manuscript. I have enjoyed reviewing this paper and my comments are as follow.

**Comment 1:** The manuscript discussed and showed results of the French functional method of treatment of clubfoot. The authors suggested good outcomes in 86% of feet with a mean of 12 years of follow-up. A relatively high rate of surgery was observed (~40%).

**Reply 1:** We thank the reviewer for this comment. Indeed, the rate of surgery was relatively high, but the authors specifically intended to include non-idiopathic clubfeet in order to be as comprehensive as possible. The total rate of surgery for idiopathic clubfoot was 35% over the study period (1993-2010). This rate significantly decreased after 2000 (29%). However, the total rate of surgery in the present study was lower than reported by Jeans et al. (Ref 17, J Bone Joint Surg Am 2018), who had a total rate of 44% including 33% of intra-articular surgeries (posterior and posteromedial releases) for idiopathic clubfoot only. The same team also showed that both conservative methods were equally effective in terms of gait analysis results (37% of relapses with the PM vs. 29% with the FFM).

However, we have added lines in the discussion of the revised version to point out the high rate of STR in the present study (Lines 218-222).

**Comment 2:** The study seems to be a cases series with no comparative group. This study design has intrinsic methodological flaws, characterized by the lack of comparison group, potential selection, follow-up, methodologic and observer bias.

Furthermore, the methodology lacks in evidence, with several assumptions without definition or references to confirm the assumptions.

**Reply 2:** The study was commissioned by *Annals of Translational Medicine* and aimed to report a single institution experience on clubfoot functional treatment using the French Functional Method (FFM). All the clubfeet primarily treated in our institution with the FFM were included without exclusion.

The biases mentioned by the reviewer are now discussed in the “limitations” section (Lines 262-265) as well as the definitions of the assumptions to help the reader to understand the accurate concept of the FFM.

**Comment 3:** The method needs manipulation by the professional almost every day until 3 months, 3x/week until one year and 1x/week until 2-year-old. Subcutaneous section of the Achilles tendon is performed at walking age. Long-leg immobilization is applied until 3 years old, but it is not clear if they are regular braces with neutral position, or with dorsiflexion/abduction. The authors should distinguish what is lateral rotation and what is abduction in the method. There is evidence in the literature that this kind of bracing is less effective than abduction orthosis similar to Denis Browne splints.

**Reply 3:** Long-leg braces were not routinely used until 3 years old and were applied only for cases with reduced adduction ( $>0^\circ$ ) and or insufficient talo-calcaneal angle ( $<20^\circ$ ). The long-leg cast immobilization was custom made by the surgeon or the physiotherapist only for these cases (31%). The aim of these braces was never to force any dorsiflexion to avoid resultant rocker bottom deformities. In contrary, maximal abduction and external rotation were performed during the long-leg brace molding.

Lateral rotation defines the position of the CFU under the talus and therefore, refers to the hindfoot deformity, in contrast to abduction which is a forefoot deformity between the midfoot and the forefoot. Both deformities are in the axial plane.

Even though, these braces are supposed to be less effective than Denis Browne splints (Ref 19: George et al. *J Pediatr Orthop B* 2011;20(1):22-5), tolerance and compliance can be poor (34% to 61%) with Denis-Browne splints (Ref 20: Alves. *J Child Orthop* 2019;13(3):258-64), which was not the case with our long-leg immobilization.

Additional changes have been included in the Discussion Section Lines 209-213.

**Comment 4:** While the Ponseti method recommend to avoid articular releases, the French method recommends “à la carte” releases. This particular option is highly surgeon dependent and may be associated with under - overcorrection according to classic literature.

**Reply 4:** We agree with the reviewer’s comment about the surgeon dependent comment. The STR is not really a recommendation of the FFM. It is only performed in cases of under-correction or recurrences to avoid poor morphological results (clinical and radiological). In our series, there were no cases of over-correction. Prior studies were published in our institution to accurately described our surgical technique for the “à la carte” surgery and have been referenced in the manuscript. The 2 main key features of our “à la carte” technique is to never release the sub-talar joint or the talo-

calcaneal ligament to avoid over-correction into valgus. Furthermore, flexor hallucis longus and flexor digitorum longus are never lengthened to avoid calcaneus foot deformity.

## SPECIFIC COMMENTS

### ABSTRACT

**Comment 5:** Please consider revision of the abstract according to comments below.

**Reply 5:** The abstract has been revised according to the reviewer's further comments.

### INTRODUCTION.

**Comment 6:** Lines 38-39 - I suppose the Achilles tenotomy would be helpful do INCREASE tibiotalar range of motion

**Reply 6:** We thank the reviewer for this comment. We agree that PAT increases tibio-talar range of motion and this procedure was therefore performed at the walking-age in cases of insufficient tibio-talar range of motion ( $< 10^\circ$ ). This is now stated in the revised manuscript as follows: *"This procedure is carried out at walking age to increase tibio-talar range of motion if the Achilles tendon is very tight, defined by tibio-talar dorsiflexion being less than  $10^\circ$ ."*

### METHODS

**Comment 7:** Lines 69-71: What is the definition of "correct or efficient talo-navicular joint decoaptation"?

**Reply 7:** Accurate definition of correct or efficient talo-navicular joint reduction is when the navicular bone is in its anatomical position, meaning its articular surface lined up congruently with the talar head articular surface.

This state now as follows: *"The objective of the 1<sup>st</sup> phase of manipulations is to obtain a correct talo-navicular joint reduction (anatomical position of the navicular bone without talar head overcoverage) by stretching the antero-medial side of the foot (abductor hallucis) and the plantar aponeurosis (Figure 1a)"*.

**Comment 8:** Lines 70-71: It is not clear how the therapist stretches the plantar aponeurosis.

**Reply 8:** The physiotherapist holds the hindfoot with one hand and stretches the plantar aponeurosis with his contralateral thumb. The thumb follows the direction of the first metatarsal bone and applies a smooth stretch from its base to its head, with the forefoot held in supination. The exact same technique is used at least for the 1<sup>st</sup> and 2<sup>nd</sup> casts in the PM.

Detailed description is now provided as follows: *"Plantar aponeurosis is stretched by using direct massage manipulation of the sole beneath the 1<sup>st</sup> metatarsal with the thumb while maintaining forefoot supination."*

**Comment 9:** Line 76 - What plane are the authors referring? sagittal plane?

**Reply 9:** Indeed, it is the sagittal plane, similarly to the PM. This is only possible when full axial correction is performed (talo-calcaneal angle  $>20^\circ$ ).

Additional comment state now Lines 85-87 as follows: “*At this step, ankle dorsiflexion is still not possible as the CFU and talus axial correction is not complete (talo-calcaneal angle  $<20^\circ$ ).*”

**Comment 10:** Line 78 - please define / explain "smooth forward and backward movements while maintaining the medial column"

**Reply 10:** For the correction of the tibio-talar joint equinus, dorsiflexion must be avoided. The naviculo-cuneiform-1<sup>st</sup> metatarsal column has to be pushed posteriorly into the talus so that it will be progressively reintegrated into the tibio-fibular unit. As long as the talus is not in the same sagittal plane as the tibio-fibular unit, dorsiflexion cannot be performed. Otherwise, rocker-bottom deformity occurs (Figure 2a).

Detailed description is now provided Lines 90-92.

**Comment 11:** Lines 79-81: What is the definition of midtarsal breaking or concave deformity of the growth plate? Please help the reader understand the recognition and criteria of these unwanted outcomes.

**Reply 11:** The definition of midtarsal breaking corresponds to the rocker-bottom deformity as described by Koureas et al (Ref 11: J Bone Joint Surg Br 2008).

The anterior concave deformity of the growth plate is illustrated in Figure 2 (a and b). It corresponds to an anterior compression of the distal tibia physis in patients with insufficient dorsal flexion ( $<10^\circ$ ) and/or forefoot cavus. This deformity might be induced by forced cast immobilization or by walking.

**Comment 12:** Lines 83-84: Please clarify and provide evidence that the talus is outside the tibiofibular unit.

**Reply 12:** We thank the reviewer for this comment. Indeed, the term “outside” is incorrect. At this step, the talar dome is located anterior to the tibio-fibular unit but is not dislocated. A more accurate description state now Lines 92-94.

**Comment 13:** Lines 126-128: How the authors measured these angles? What were the parameters in poorly ossified bones with almost spherical ossification nucleus? Please, provide information about the experience of the observers, and also intra-inter-observer agreements.

**Reply 13:** The scoring system used in the study (ICFSG) is only performed after 6 years-old as previously described (Ref 9 and Ref 16). At this age, the tarsal bones are sufficiently ossified for measurements. This scoring system has been used in our institution for several decades but still needs validation for intra- and inter-observer agreement. However, to the best of our knowledge, no specific clubfoot validated scoring system exists in the literature after birth. The Laaveg-Ponseti score (Ref 3) has not been validated and the AOFAS and the Oxford Ankle Foot Questionnaire for children are not clubfoot-specific. This discussion has been added to the limitations section.

## RESULTS

**Comment 14:** Line 141 - a rate of 41% of surgery can be considered high, especially considering articular releases in growing foot with potential of relapses.

**Reply 14:** The rate of surgery was high, but the authors specifically intended to include non-idiopathic clubfeet in order to be as comprehensive as possible. Total rate of surgery for idiopathic clubfoot was 35% over the study period (1993-2010). This rate significantly decreased after 2000 (29%). However, total rate of surgery in the present study was lower than reported by Jeans et al. (Ref 17: J Bone Joint Surg Am 2018), who had a total rate of 44% including 33% of intra-articular surgeries (posterior and posteromedial releases) for idiopathic clubfoot only. The same team also showed (Ref 24) that both conservative methods were equally effective in terms of gait analysis results (37% of relapses with the PM vs. 29% with the FFM).

We have added an additional comment in the revised manuscript that points out the high rate of STR in the present study.

**Comment 15:** Lines 165-166 and 168 - "PAT was performed 112 times (19.6%) in the group of 166 patients without surgery (n=459)" - it is confusing, as a tenotomy is a surgical procedure. Should be without articular release?

**Reply 15:** Indeed, PAT is a surgical procedure as well as in the PM. We have intentionally separated the group of patients with single-PAT without STR, since this group had less severe initial deformities. In the non-STR group, PAT was sufficient to correct the only residual deformity (equinus) in all cases.

Changes have been made in the revised manuscript for better readability Lines 178-185

**Comment 16:** Lines 171-178 - Please clarify this sentence to help the reader understand its meaning.

**Reply 16:** Since 1993, the FFM has been performed by well-trained physiotherapists in our institution. All these physiotherapists have learned the method with the team of physiotherapists that initially developed the technique (Ref 1 and Ref 2). However, some patients of the current study (34,8%) have been managed by physiotherapists that were not trained by our team and considered less trained to the FFM.

Additional comment has been provided in the Methods section to explain the difference between FFM-trained and not FFM-trained physiotherapists (Lines 70-72).

## DISCUSSION

**Comment 17:** Please, discuss the need for intensive care during the growing period, with almost daily/weekly visits to the therapist, high rate of release, and please define the criteria and definition of "mild residual deformities" or "lack of radiological correction"

**Reply 17:** The FFM is based on very progressive manipulations that must stay pain free. Therefore, initially 5 days a week manipulations are required during the first 3 months after birth. Afterwards, physical therapy sessions are scheduled less frequently. This technique also allows surveillance of treatment observance.

The definition of “mild residual deformities” is: foot with dorsiflexion between 0-10° and calcaneal-thigh angle between 10-20°.

The “lack of radiological correction” is defined by a talo-calcaneal angle between 10-20°.

This has been added in the revised manuscript Lines 114-116 and 119-121.

**Comment 18:** The authors state that percutaneous Achilles tenotomy decreased the rate of surgery, but also state that several improvements were added to the initial method. Considering the study model, is it possible to establish cause-effect relationship between tenotomy and decreased release rate? Please clarify (Lines 193-194)

**Reply 18:** Indeed, introduction of PAT has significantly decreased the rate of STR after 2000 (Figure 9), 63,4% vs. 29.2%,  $p < 0.0001$ .

A cause-effect relationship was not established from this study and needs further investigation.

This result has been added in the Results section and clarified in the Discussion section (Lines 179-180 and 204-205).

**Comment 19:** Lines 215-217: "The “à la carte STR” is based on the same concept of correction of both conservative treatments by targeting only the pathological tissues with cautious respect for the foot muscles and tendons." Please help the reader to understand how to identify the target pathological tissue with caution during surgical release, and avoid under or hypercorrection that are widely reported in this surgical approach.

**Reply 19:** Prior studies were published and described our “à la carte” STR technique (Ref 8, Bensahel et al. J Pediatr Orthop 1987; 7(2):145-8 and Ref 9: Bocahut et al. J Child Orthop 2016; 10(2):109-17). Pathological tissues are located antero-medially (next to the talo-navicular joint) and postero-laterally (next to the tibio-talar joint). These tissues are fibrotic and the release is stopped when the tissues become soft.

The 2 main keys of “à la carte” STR technique, are to never open the sub-talar joint and to never cut the talo-calcaneal ligament to avoid over-correction. Furthermore, flexor hallucis longus and flexor digitorum longus are never lengthened to avoid calcaneus foot deformity.

Additional comment and references have been provided in the revised manuscript (Ref 8 and 9) Lines 127-130.

**Comment 20:** In general, Discussion is repetitive and could be shortened.

**Reply 20:** As recommended by the reviewer, discussion has been shortened to avoid repetition.

**Comment 21:** Lines 230 - 232: "Dynamic cavus was the most frequent (22%) mild residual deformity found (Table 4). This deformity was attributed to an imbalanced dysfunction between foot extensors and flexors muscles." --- please provide references

and evidence to assure that clubfeet are caused by muscle imbalance rather than genetic abnormal tissular properties.

**Reply 21:** We agree with the reviewer's comment. The authors tried to highlight the fact that because of clubfoot tissular proprieties, muscles hypoextensibility is associated creating some kind of "muscular imbalance" by modification of the muscles lever-arms.

The sentence has been deleted in the revised manuscript for better readability.

**Comment 22:** Lines 233 - 236: please clarify the meaning of this sentence: "The current institution considered that a night immobilization should be maintained until the patient recovered complete dynamic foot function meaning that there is no deformity when walking on heels, which is a quite a different treatment concept compared to the PM [19]." What is the definition of complete dynamic foot function?

**Reply 22:** Definition of complete dynamic foot function is the ability to walk on heels (active ankle dorsiflexion  $>10^\circ$ ) without dynamic supination, or dynamic cavus. This line has been added to the manuscript (Lines 247-252).

**Comment 23:** Lines 236 - 238: adduction is a different deformity from cavus. Please clarify. How the authors could determine "abductor hallucis muscle hypoextensibility"?

**Reply 23:** We agree with the reviewer's comment. Forefoot adduction is an axial plane deformity between the midfoot and the forefoot conversely to the cavus deformity which is a sagittal plane deformity corresponding to 1<sup>st</sup> metatarsal pronation (1<sup>st</sup> -5<sup>th</sup> metatarsal angle  $> 10^\circ$ , Davids et al. J Pediatr Orthop 2005; 25(6): 769-76). This is a clinical finding of the feeling tension of the abductor hallucis muscle in feet with persistent minimal deformity (abduction and/or cavus) compared with corrected feet. The sentence has been simplified Lines 251-252.

**Comment 24:** Figure 2 - These radiographs, beyond impaction of tibial metaphyseal bone, show evident rocker bottom deformity.

**Reply 24:** Figure 2 a) illustrates a rocker bottom deformity (midfoot breaking) associated with a distal tibia concave deformity (tibio-fibular unit) in a patient treated by the Ponseti Method, secondarily addressed in our institution for management. Figure 2b, only illustrates the distal tibia concave deformity without rocker bottom deformity (no midfoot breaking).

Figure 2 has been modified in the revised manuscript.

**Comment 25:** Figure 7 - What is the potential for this device to avoid foot adduction during its use?

**Reply 25:** This custom-made device is molded on the forefoot to avoid adduction between the midfoot and the forefoot. The forefoot is maintained aligned with the hindfoot. An additional comment now states this in the Figure 7 legend.