

Results of Ponseti Brasil Program: Multicentric Study in 1621 Feet: Preliminary Results

Monica P. Nogueira, MD, PhD,* Ana C.d.B.F. Queiroz, MD,† Alessandro G. Melanda, MSc,‡
 Ana P. Tedesco, MD,§ Antonio L.G. Brandão, MD,|| Claudio Beling, MD,¶
 Francisco H. Violante, Jr, MD,# Gilberto F. Brandão, MD,¶¶ Laura F.A. Ferreira, MD,**
 Leandro S. Brambila, MD,†† Leopoldina M. Leite, MD, PhD,‡‡ Jose L. Zabeu, MD, MSc,§§
 Jung H. Kim, MD, MSc,||| Kalyana E. Fernandes, MD,¶¶¶ Marcia A.S. Arima, MD,###
 Maria D.P.Q. Aguilar, MD,*** Orlando C.d. Farias Filho, MD, MSc,†††
 Oscar B.d.A. Oliveira Filho, PhD,‡‡‡ Solange d.S. Pinho, MD,§§§ Paulo Moulin, MD,|||
 Reinaldo Volpi, MD, PhD,¶¶¶ Mark Fox, MD,#### Miles F. Greenwald, MD,####
 Brandon Lyle, MD,#### and Jose A. Morcuende, MD, PhD####

Background: The Ponseti method has been shown to be the most effective treatment for congenital clubfoot. The current challenge is to establish sustainable national clubfoot treatment programs that utilize the Ponseti method and integrate it within a nation's governmental health system. The Brazilian Ponseti Program (Programa Ponseti Brasil) has increased awareness of the utility of the Ponseti method and has trained > 500 Brazilian orthopaedic surgeons in it.

Methods: A group of 18 of those surgeons had been able to reproduce the Ponseti clubfoot treatment, and compiled their initial results through structured spreadsheet.

Results: The study compiled 1040 patients for a total of 1621 feet. The average follow-up time was 2.3 years with an average correction time of approximately 3 months. Patients required an average of 6.40 casts to achieve correction.

Conclusions: This study demonstrates that good initial correction rates are reproducible after training; from 1040 patients only 1.4% required a posteromedial release.

Level of Evidence: Level IV.

Key Words: clubfoot, Ponseti method, conservative treatment, national program, outcomes

(*J Pediatr Orthop* 2017;37:e197–e201)

Although it was historically assumed that long-term casting and surgical treatment of clubfeet was the best method of care, numerous studies over the past 2 decades have shown that invasive clubfoot surgery can result in increased disability and pain later in life.^{1–8} Clubfoot treatment has been remarkably changed after introduction of the Ponseti method, developed in the 20th century by Ignacio Ponseti at University of Iowa. In the past 15 years, the method has replaced surgery as the gold standard of treatment for clubfoot.^{9–15}

The treatment is minimally invasive and cost-effective and consists of serial casting, tenotomy of the Achilles tendon, and use of abduction brace to prevent relapses. Using this technique, physicians have demonstrated satisfactory and rapid initial correction within 4 to 5 weeks with minimal complications in the majority of cases.^{16–23} The technique has also greatly reduced the number of extensive foot surgeries, such as posteromedial releases, being performed for clubfoot treatment.⁷

In recent years, several countries, including Brazil, have initiated national programs aiming to train orthopaedic surgeons and increase awareness of this novel and effective technique. Changing clubfoot treatment from extensive surgery to the Ponseti method is a process, and can occur by National Program Initiatives on physician training, which is the case of Brazil (a bottom up approach), or start from governmental level combined with training with or without nongovernmental entities

From the *State Hospital of Sao Paulo (HSPE); #Association for Care of Disabled Children (AACD); **University Hospital of the University of Sao Paulo, São Paulo; §§Pontifical Catholic University, Parque das Universidades-Campinas; ##Vivendas Clinic, Sao Jose do Rio Preto; §§§Child Municipal Hospital, Guarulhos; ¶¶Hospital State University of Sao Paulo- UNESP, Botucatu, SP; †Association for Disabled People of Alagoas ADEFAL, Maceió, AL; ‡State University of Londrina (UEL), Paraná; ††Orthopedic Hospital of Londrina, Londrina, PR; §Neuro-orthopedic Institute, Caxias do Sul, RS; ||Orthopedics and Trauma Institute of Passo Fundo, RS; ||Santo Antonio Hospital Sister Dulce, Salvador, BA; ¶Mineiro Orthopedic Institute, Belo Horizonte, MG; ‡‡Federal University of Uberlandia, Jardim Umuarama, MG; ‡‡Mother and Child Unit of the University Hospital of Federal University of Maranhão (HUUFMA), São Luis, MA; ¶¶Clinical Fracture Center of Children's Rehabilitation (CRI), Natal, RN; ***São Zacharias Hospital, Rio de Janeiro, RJ; †††Federal University of Paraíba, João Pessoa – PB; ||||Children State Hospital Nossa Senhora da Gloria, Vitória, ES, Brazil; and ####Carver College of Medicine at the University of Iowa, Iowa City, IA.

The authors declare no conflicts of interest.

Reprints: Monica P. Nogueira, MD, PhD, State Hospital of Sao Paulo (HSPE), Ibirapuera Av., 981 Indianópolis, São Paulo 04028-000, SP, Brazil. E-mail: monipn@uol.com.br.

Copyright © 2016 Wolters Kluwer Health, Inc. All rights reserved.

DOI: 10.1097/BPO.0000000000000801

(top down approach), as in Uganda and Bangladesh.^{21–23} Both approaches have to overcome cultural and economical local barriers to be successful. Brazil, like other developing countries, is home to many children who have nontreated walking clubfoot because of social, organizational, and economic barriers to treatment. A central goal of this national program initiative was to increase the number of children with clubfeet who receive treatment in tandem with developing an extensive, country-wide data registry.²⁴ This was an initial step in developing a well-organized, high-functioning and self-sustainable program with the goal of eliminating untreated clubfoot deformities.

This study utilizes the beginnings of the national program database to assess the initial outcomes of the program and investigate barriers to care. The primary goal is to demonstrate effectiveness of the Ponseti method among different practitioners in the country, while comparing those initial results with the existing literature. This study will also attempt to demonstrate that the Ponseti method is reproducible in developing countries, making the argument that country-wide clubfoot treatment programs using the Ponseti method are a significant step toward reducing disability and improving quality of life.

METHODS

From January 2007 to December 2008 a group of 13 Brazilian orthopaedic surgeons trained by or recognized by the Ponseti method experts from the Ponseti International Association and the University of Iowa organized a total of 21 conferences throughout Brazil, reaching most states in the country. Those Brazilian orthopaedic surgeons trained in the Ponseti method had been in continuous mentorship programs (courses, hand on experience, and evaluation of clinical results). They were evaluated by Iowa experts and recommended to this program. The cities holding the conferences were strategically chosen because they were regional centers equipped to provide care for clubfoot patients from surrounding areas. The orthopaedic surgeons were contacted by local organizers to participate in the training. Training was led by 3 orthopaedic surgeons (from the group of 13 experts) in each city, was 2 days long, and available at no cost. The number of participants in each symposium is listed in Table 1. Overall, a total of 556 orthopaedists were trained, about 7% of orthopaedic surgeons practicing in Brazil.²⁴

Symposiums were open to orthopaedic surgeons from public and private sectors (Brazil has a mixed health system) and those were led by 3 expert instructors in each city, consisting of a group of 13 orthopaedic surgeons who had been trained in the technique. The course was 2 days long, with the first day consisting of lectures in the morning and casting workshops with clubfoot models in the afternoon. The second day included clinical case discussion and proper use of the abduction brace. A printed Ponseti manual was translated in Portuguese and

TABLE 1. Number of Participants of the Symposium and Number of Orthopaedic Surgeons in Each State

Symposiums, City	Participants	Total of Orthopaedic Surgeons Per State
Belo Horizonte, MG	25	809
Campina Grande, PB	24	74
Salvador, BA	39	292
Fortaleza, CE	40	160
Rio de Janeiro, RJ	14	978
Recife, PE	23	168
Manaus, AM	19	71
Belem, PA	28	81
Campo Grande, MS	25	107
Aracaju, SE	12	43
Natal, RN	14	70
Brasília, DF	50	150
Goiania, GO	45	238
São Luis, MA	43	40
Teresina, PI	39	41
Londrina, PR	27	548
Maceió, AL	11	48
Porto Alegre, RS	19	530
Florianópolis, SC	14	268
Uberlândia, MG	37	809
Vitória, ES	8	157
Total	556	5682

Participants from cities in bold are coauthors in this study. São Paulo is not listed because there was no symposium there in this project, but 7 coauthors are from São Paulo State. Minas Gerais State had 2 symposiums.

distributed to physicians attending the symposiums. The symposia in Brazil generated an initial team of 18 regional “champions”: orthopaedists practicing the Ponseti method and interested in participating in the initiation of the national program. A retrospective study was performed using patient data from the initial implementation of the program. The learning curve of the participants of this study consisted of 2 or 3 years from the symposiums that happened in 2007 and 2008 to 2010, at the time of compilation of this data. The participants were not accessed after their training. The Ponseti method application was standard in all reported centers. It was a consecutive case series. Children with idiopathic congenital clubfeet were included; children with neurological or syndromic clubfeet were excluded in the study, as well as children with prior surgery other than tenotomy. All patients with idiopathic clubfeet treated by those centers were included in the data analysis. Casting and bracing at all 18 regional treatment centers were performed in strict accordance with the technique published by Dr Ignacio Ponseti.^{7,16} Brace protocol was also used for children after walking age. Despite difficulty, continuous brace use for 3 months was recommended in almost all cases under 6 years of age. Braces were manufactured locally.

The following variables were retrospectively evaluated: age and sex of the patient at initiation of treatment, the number of casts required for correction, and whether the patient underwent an Achilles tenotomy or/and anterior tibial transfer. Success of treatment, patient compliance with the bracing phase and occurrence of deformity relapse were also evaluated. Success of treatment was measured by

TABLE 2. Classification Criteria

Classification	Variable Criteria
Great	Foot fully plantigrade with at least 10 degrees of passive ankle dorsiflexion
Good	Absence of any residual deformity or pain Foot fully plantigrade—dorsiflexion between zero and 10 degrees
Regular	No residual deformity and free from pain. Little residual deformity and free from pain
Poor	Required additional surgery other than anterior tibial tendon transfer, or posteromedial release Failure of initial correction and need for extensive soft tissue release (posteromedial release)

both a qualitative description of deformity correction (Table 2) and an average rate of improvement based on the Pirani scoring system, a scientifically validated and widely used method of quantifying progression of treatment of clubfoot deformity.²¹ Pirani scoring was used during casting and at the latest follow-up.

Age was quantified in number of days since birth on first clinical visit to participating institutions. A tendo-achilles tenotomy was indicated if dorsiflexion of the ankle was <15 degrees. When the anterior tibial muscle strongly supinated the foot during gait, it was transferred to the third cuneiform to prevent additional relapses. Anterior tibial transfer was also performed after serial casts for treatment of relapses, after 4 years of age. Relapse was defined as the reappearance of any of the components of the deformity, including cavus, adductus, varus, and/or equinus. Brace use was prescribed for a 24-hour use during the initial 3 months followed by use during naps and overnight sleep until the age of 4. Parent’s self-report on brace wear was used to assess compliance.

Final treatment outcomes were assessed using 2 separate methods so as to ensure reproducible classification by participating physicians. The primary method of categorizing treatment success was done according to the widely utilized Pirani scoring system.²¹ The scoring system assesses the degree of contracture in the midfoot and hindfoot, a reliable method to evaluate the extent of clubfoot deformity. The second method of scoring was developed to facilitate comparisons that exceeded simple anatomic changes and additionally considered the intensity and depth of treatments; for example, degrees of dorsiflexion, or if further treatment was required beyond simple manipulation and casting. Criteria were assigned to the labels, “great,” and “good,” “regular,” or “poor” to aid in classification of initial correction (Table 2). All 4 classifications were established before organization and analysis of data, being used in a previous symposium in 2005 by many of the participants (orthopaedic surgeons). Any foot receiving a score of great or good by the treating physicians was considered a successful treatment.

Patient treatment statistics and outcomes were compiled and analyzed using Statistical Analysis System. The records were analyzed in accordance with the

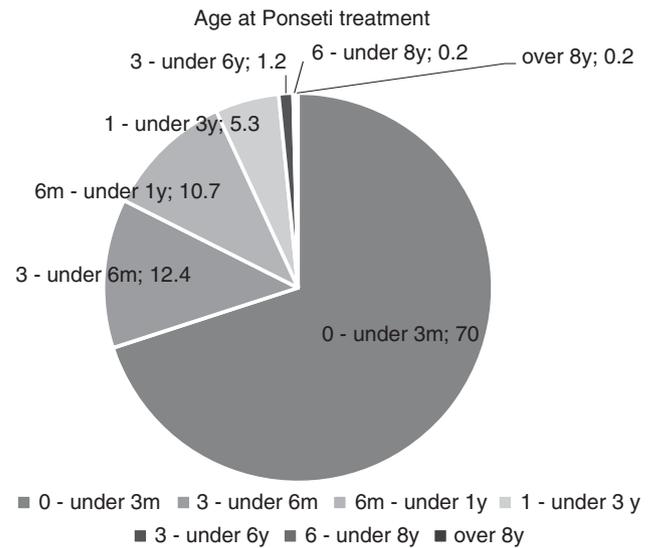


FIGURE 1. Age at Ponseti treatment.

guidelines outlined by Institutional Review Board approval.

RESULTS

A total of 707 patients (68%) were male (1108 feet) and 333 patients (32%) were female (513 feet), with a total of 1040 patients and 1621 feet. Average age was 4.5 months, babies presented before 3 months in 70% of patients (Fig. 1).

The average follow-up time was 2.3 years with an average correction time of approximately 3 months. Patients required an average of 6.40 casts (range, 1 to 40; SD, 3.80) for correction. A total of 19.4% of patients did not receive a tenotomy, whereas 77.4% received 1 tenotomy and 3.2% received multiple tenotomies. In 11 services, tenotomy was performed in cast room under local anesthesia, and in 7 other services, it was performed under general anesthesia. The overall initial correction rate for this study was 92.6% using the qualitative correction score with an overall relapse rate of 29.0% (Fig. 2). Average initial Pirani score was 5.30 (range, 1.5 to 6; SD, 0.97) and average final Pirani score was 0.75 (range, 0 to 6; SD, 1.01). There was no correlation between Pirani

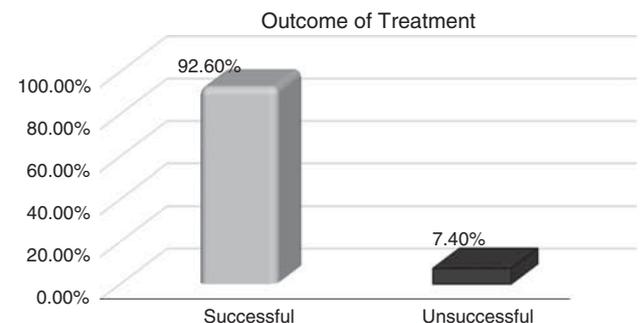


FIGURE 2. Outcome of treatment.

scores and descriptive method of classification. Only 22 of the 1621 feet needed posteromedial release surgery, comprising 1.4% of patients treated. In total, 67.2% of patients were compliant with the brace phase of treatment. Of those who were noncompliant with the bracing phase of treatment, 69.8% experienced relapse, whereas only 12.6% of those who were compliant with bracing had relapses. There was no statistical difference for achieving correction status between those who had received prior treatment to those who had not. Nine orthopaedic surgeons participating in this study were from the public sector, and 9 orthopaedic surgeons were from the private sector. There was no statistical difference between treatment outcomes in the private sector versus treatment outcomes in the public sector.

In comparing patients who were older than 14 months versus younger than 14 months, (nonwalking age × walking age) 94.6% of feet were 14 months or younger, whereas 5.4% of feet were older than 14 months. There was significant difference between the 2 age groups concerning: relapses (more frequently seen in the older children), brace compliance (better in the younger group), and final Pirani Score (also better in the younger group).

There was no significant difference between age groups relative to: number of casts, percentage of tenotomies, and initial Pirani Scores. Both age groups had a high percentage of successful clinical results with no significant differences.

DISCUSSION

This is the first study of the Ponseti method outcomes performed on such a large scale in Latin America. Including >1000 patients, this robust and diverse study provides valuable information regarding treatment outcomes following the national initiative to train Brazilian orthopaedists with the Ponseti method. Many statistical outcomes were consistent with other studies recently published in the literature, suggesting that orthopaedists successfully learned and applied the technique to their patients following the completion of the study. Brazil is the biggest country in South America, and has socio-economic challenges and contrasts; the country provides this study with a novel look at the dissemination of the Ponseti Method, which has been scarcely studied in the past. Brazil's strong educational system and developing infrastructure facilitated a very quick transition from invasive surgical intervention to the less-invasive Ponseti technique. Follow-up time was short (average, 2.3 y), specially for the study of relapses, but it was able to document success of initial Ponseti treatment, representing initial correction rate.

Considering the economical and geographic disparities among centers of treatment, it was again shown that results can be successful even after prior treatment, and majority of patients were referred before 14 months, even having the referral net not yet well developed (Table 3). This indicates that it is possible to have more younger patients arriving for treatment if a referral net is well-established

TABLE 3. Age Group Comparison Following Different Variables

Variables	0-14 mo (%)	14+ mo (%)	P
No. casts	6.4	6.93	0.19
Tenotomies (1 +)	79.80	81.40	0.78
Relapse	28.20	44.20	0.02
Brace compliance	68.20	40.00	0.0006
Initial Pirani score	5.30	5.15	0.28
Final Pirani score	0.71	1.68	0.0001
Successful treatment	92.70	89.70	0.52

in the future, and that will drive results to be better, because families of younger patients are more compliant, as shown, and relapses will have a tendency to decrease.

Pirani score was more important in the cast phase, helping the surgeon to understand the evolution of deformity correction; the descriptive classification was more focused in the final clinical result considering necessity of posteromedial release—that was considered in this study a failure of the Ponseti method.

The low number of posteromedial releases (only 1.4%) has to be emphasized, reflecting that trained orthopaedic surgeons should have a high rate of success with the Ponseti method.

It is also worthy of mention that Ponseti treatment was equally successful in both the private and the public environment; for a developing country that can mean you only have to have access to treatment, and the “neglected” (nontreated walking) children will disappear.

Barriers to service delivery are numerous: difficulties for following brace protocol, lack of transportation, difficulties to get the abduction brace, some centers with no trained personnel are treating children with clubfoot, whereas others with good capacity do not receive enough patients, and even difficulties about following the Ponseti protocol.^{11,25}

As demonstrated in this paper, the dissemination of the Ponseti technique has been largely successful in Brazil and can be used as a model for other countries working to adopt the technique. Even after training 7% of orthopaedic surgeons in Brazil, unfortunately the training program was not able to include all the orthopaedic surgeons who treat clubfoot in Brazil. There are still patients being treated by orthopaedic surgeons without Ponseti method training. The aim in the future will be to include all clubfoot patients to be treated in reference centers. This study also shed insight on the limitations of the technique after looking into older populations.²⁶⁻³² The study was also able to look at older ages with many children older than 3 years receiving treatment for the first time. The majority of children in this study were babies, reinforcing the impact of the training program for these Brazilian orthopaedic surgeons, but the number of children after walking age with nontreated clubfoot in Brazil is still not small—it will be the subject of a future study.

The large number of patients involved also added strength to the study, and the geographical diversity of

the physicians providing data reflects the reproducibility of the high rates of the Ponseti initial correction reported in the literature from different clinics around the country.

REFERENCES

- Morcuende JA. Congenital idiopathic clubfoot: prevention of late deformity and disability by conservative treatment with the Ponseti technique. *Pediatr Ann.* 2009;35:128–130. 132–136.
- Noonan KJ, Richards BS. Nonsurgical management of idiopathic clubfoot. *J Am Acad Orthop Surg.* 2003;11:392–402.
- Aronson J, Puskarich CL. Deformity and disability from treated clubfoot. *J Paediatr Orthop.* 1990;10:109–119.
- Wesley MS, Barenfeld PA, Barrett N. Complications of the treatment of clubfoot. *Clin Orthop.* 1972;84:93–96.
- Herzenberg JE, Radler C, Bor N. Ponseti versus traditional methods of casting for idiopathic clubfoot. *J Paediatr Orthop.* 2002;22:517–521.
- Aplington JP, Riddle CD Jr. Avascular necrosis of the body of the talus after combined medial and lateral release of congenital clubfoot. *South Med J.* 1976;69:1037–1038.
- Morcuende JA, Dolan LA, Dietz FR, et al. Radical reduction in the rate of extensive corrective surgery for clubfoot using the Ponseti method. *Pediatrics.* 2004;113:376–380.
- Dobbs MB, Nunley R, Schoenecker PL. Long-term follow-up of patients with clubfeet treated with extensive soft-tissue release. *J Bone Joint Surg Am.* 2006;88:986–996.
- Zionts LE, Zhao G, Hitchcock K, et al. Has the rate of extensive surgery to treat idiopathic clubfoot declined in the United States? *J Bone Joint Surg Am.* 2010;92:882–889.
- Jayawardena A, Wijayasinghe SR, Tennakoon D, et al. Early effects of a ‘train the trainer’ approach to Ponseti method dissemination: a case study of Sri Lanka. *Iowa Orthop J.* 2013;33:153–160.
- Boardman A, Jayawardena A, Opreescu F, et al. The Ponseti method in Latin America: initial impact and barriers to its diffusion and implementation. *Iowa Orthop J.* 2011;31:30–35.
- Owen RM, Penny JN, Mayo A, et al. A collaborative public health approach to clubfoot intervention in 10 low-income and middle-income countries: 2-year outcomes and lessons learnt. *J Pediatr Orthop B.* 2012;21:361–365.
- van Bosse HJ. Ponseti treatment for clubfeet: an international perspective. *Curr Opin Pediatr.* 2011;23:41–45.
- Heilig MR, Matern RV, Rosenzweig SD, et al. Current management of idiopathic clubfoot questionnaire: a multicentric study. *J Pediatr Orthop.* 2003;23:780–787.
- Zionts LE, Sangiorgio SN, Ebrahimzadeh E, et al. The current management of idiopathic clubfoot revisited: results of a survey of the POSNA membership. *J Pediatr Orthop.* 2012;32:515–520.
- Ponseti IV. *Congenital Clubfoot Fundamental of Treatment.* Oxford: Oxford University Press; 1996.
- Dobbs MB, Gurnett CA. Update on clubfoot: etiology and treatment. *Clin Orthop Relat Res.* 2009;467:1146–1153.
- Cooper DM, Dietz FR. Treatment of idiopathic clubfoot: a thirty-year follow-up note. *J Bone Joint Surg Am.* 1995;77:1477–1489.
- Segev E, Keret D, Lokiec F, et al. Early experience with the Ponseti method for the treatment of congenital idiopathic clubfoot. *Isr Med Assoc J.* 2005;7:307–310.
- Göksan SB, Bursali A, Bilgili F, et al. Ponseti technique for the correction of idiopathic clubfeet presenting up to 1 year of age. A preliminary study in children with untreated or complex deformities. *Arch Orthop Trauma Surg.* 2006;126:15–21.
- Pirani S, Naddumba E, Mathias R, et al. Towards effective Ponseti clubfoot care: the Uganda sustainable clubfoot care project. *Clin Orthop Relat Res.* 2009;467:1154–1163.
- Ford-Powell VA, Barker S, Khan MS, et al. The Bangladesh clubfoot project: the first 5000 feet. *J Pediatr Orthop.* 2013;33:e40–e44.
- Perveen R, Evans AM, Ford-Powell V, et al. The Bangladesh clubfoot project: audit of 2-year outcomes of Ponseti treatment in 400 children. *J Pediatr Orthop.* 2014;34:720–725.
- Nogueira MP, Pereira JC, Duarte PS, et al. Ponseti Brasil: a national program to eradicate neglected clubfoot—preliminary results. *Iowa Orthop J.* 2011;31:43–48.
- Nogueira MP, Fox M, Miller K, et al. The Ponseti method of treatment for clubfoot in Brazil: barriers to bracing compliance. *Iowa Orthop J.* 2013;33:161–166.
- Nogueira MP, Ey batlle AM, Alves CG. Is it possible to treat recurrent clubfoot with the Ponseti technique after posteromedial release?: a preliminary study. *Clin Orthop Relat Res.* 2009;467:1298–1305.
- Khan SA, Kumar A. Ponseti’s manipulation in neglected clubfoot in children more than 7 years of age: a prospective evaluation of 25 feet with long-term follow-up. *J Pediatr Orthop B.* 2010;19:385–389.
- Spiegel DA, Shrestha OP, Sitoula P, et al. Ponseti method for untreated idiopathic clubfeet in Nepalese patients from 1 to 6 years of age. *Clin Orthop Relat Res.* 2009;467:1164–1170.
- Banskota B, Banskota AK, Regmi R, et al. The Ponseti method in the treatment of children with idiopathic clubfoot presenting between five and ten years of age. *Bone Joint J.* 2013;95:1721–1725.
- Lourenço AF, Morcuende JA. Correction of neglected idiopathic club foot by the Ponseti method. *J Bone Joint Surg Br.* 2007;89:378–381.
- Tindall AJ, Steinlechner CW, Lavy CB, et al. Results of manipulation of idiopathic clubfoot deformity in Malawi by orthopaedic clinical officers using the Ponseti method: a realistic alternative for the developing world? *J Pediatr Orthop.* 2005;25:627–629.
- Ayana B, Klungsoyr PJ. Good results after Ponseti treatment for neglected congenital clubfoot in Ethiopia. A prospective study of 22 children (32 feet) from 2 to 10 years of age. *Acta Orthop.* 2014;85:641–645.