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Comparison of Surgeon and Physiotherapist-Directed Ponseti Treatment of Idiopathic Clubfoot

By Joseph A. Janicki, MD, Unni G. Narayanan, MBBS, MSc, FRCSC, Barbara J. Harvey, BHScPT, Anvesh Roy, MBBS, Shannon Weir, BSc, and James G. Wright, MD, MPH, FRCSC

Investigation performed at The Hospital for Sick Children, Toronto, Ontario, Canada

Background: Increasingly, the Ponseti method has been adopted worldwide as the preferred method of managing idiopathic clubfoot deformity. Following the successful implementation of the Ponseti method by orthopaedic surgeons in our institution, a clubfoot clinic was established in 2003. This clinic is directed by a physiotherapist who, using the Ponseti protocol, performs the serial cast treatment and supervises the brace management of all children with idiopathic clubfoot deformity. The purpose of this study was to compare the outcomes of physiotherapist-directed with surgeon-directed Ponseti cast treatment of idiopathic clubfeet.

Methods: We performed a retrospective cohort study of all patients with idiopathic clubfoot deformity treated from 2002 to 2006 and followed for a minimum of two years. Twenty-five children (thirty-four clubfeet) treated by surgeons were compared with ninety-five children (137 clubfeet) treated by a physiotherapist. The outcomes that were evaluated included the number of casts required, the rate of percutaneous Achilles tenotomy, the rate of recurrence, the failure rate, and the need for additional surgical procedures.

Results: At the time of presentation, the patients in the two groups were similar in terms of age, sex distribution, laterality of the clubfoot, and history of treatment. The mean duration of follow-up was thirty-four months in the physiotherapist-directed group and forty-eight months in the surgeon-directed group. No significant difference was found between the two groups with regard to the mean number of initial casts, the Achilles tenotomy rate, or the failure rate. Recurrence requiring additional treatment occurred in 14% of the feet in the physiotherapist-directed group and in 26% of the feet in the surgeon-directed group ($p = 0.075$). Additional procedures, including repeat Achilles tenotomy or a limited posterior or posteromedial release, were required in 6% of the feet in the physiotherapist-directed group and in 18% of those in the surgeon-directed group ($p = 0.025$).

Conclusions: In our institution, the Ponseti method of cast treatment of idiopathic clubfoot was as effective when it was directed by a physiotherapist as it was when it was directed by a surgeon, with fewer recurrences and a less frequent need for additional procedures in the physiotherapist-directed group. The introduction of the physiotherapist-supervised clubfoot clinic at our institution has been effective without compromising the quality of care of children with clubfoot deformity.

Level of Evidence: Therapeutic Level III. See Instructions to Authors for a complete description of levels of evidence.

The Ponseti method\(^1\) has changed the management of idiopathic clubfoot deformity from a typically surgical approach\(^2,3\) to a primarily nonoperative approach. High success rates have been reported at the University of Iowa\(^1,4\) and other centers\(^5-9\). Appropriate application of the Ponseti cast technique requires an understanding of the pathoanatomy of the clubfoot. Moreover, maintenance of correction and avoidance of recurrence depend on adherence to a strict orthotic protocol.

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following the cast treatment\(^*\), and this protocol requires the education of parents, close supervision, and often encouragement from the health-care provider.

In most centers, orthopaedic surgeons are responsible for the diagnosis, cast treatment, surgical treatment, and brace management of children with clubfeet. In countries with few specialists, the Ponseti method has been taught to, and effectively applied by, trained nonsurgical health-care providers\(^{10,11}\).

A program in which Ponseti clubfoot care is delivered by physiotherapists at a major urban children's hospital has been shown to produce good early results in a small series of children\(^{12}\).

The Ponseti method was adopted at The Hospital for Sick Children, Toronto, Ontario, Canada in late 2001. In 2003, a physiotherapist-run clubfoot clinic was established to manage all idiopathic clubfeet with the Ponseti method. This model was adopted to cope with the large number of children treated in this institution (approximately fifty-five new patients each year) and the substantial time and effort dedicated to their care that did not require surgical skills. It was thought that physiotherapists possess the knowledge and skill set necessary to learn and implement the Ponseti method successfully. A physiotherapist (B.J.H.) was taught the Ponseti method and was supervised by two orthopaedic surgeons over a two-month period before she assumed responsibility for the clubfoot clinic. In this study, we evaluated the effectiveness of the physiotherapist's nonoperative management of clubfeet by comparing the outcomes with those of the surgeon-directed Ponseti treatment of idiopathic clubfeet.

**Materials and Methods**

This was a retrospective cohort study conducted at The Hospital for Sick Children, Toronto, Ontario, Canada. The study was approved by the Research Ethics Board.

**Subjects**

All patients with idiopathic clubfoot deformities presenting from 2002 to May 2006 were identified. Clinical data were extracted from the clubfoot clinic database and from health records. Patients were included only if the clubfoot was idiopathic, had been treated by the Ponseti method, and had been followed for a minimum of two years. During this period, 260 patients (399 clubfeet) were treated. Of 140 patients who did not meet the inclusion criteria for the present study, thirty had an associated neuromuscular condition or syndrome, thirty-two were treated by surgeons who were not using the Ponseti method at the time, sixty-seven were followed for less than two years, and eight presented after the age of one year; the parents of three patients chose surgical management as the primary intervention. Patients were included in the surgeon-directed group only if they were treated by surgeons who adhered to the Ponseti protocol. Twenty-five children with thirty-four clubfeet were treated by surgeons using the Ponseti method, and ninety-five patients with 137 clubfeet were treated by the physiotherapist. All patients in the cohort were accounted for,
and none had been lost to follow-up at the time of writing (Fig. 1).

Interventions
In the surgeon-directed group, the initial evaluation, serial manipulation, and application of casts at weekly intervals were conducted by a staff orthopaedic surgeon (J.G.W. or U.G.N.) who strictly followed the Ponseti method. The only deviation from the protocol was the use of semirigid fiberglass casting treatment tape (3M Scotchcast Soft Cast, St. Paul, Minnesota) instead of plaster of Paris. Families were directed to remove the casts on the morning of the appointment to allow them to bathe the child. The same cast material was used in both treatment groups. When the forefoot correction (70° of abduction) was achieved and the hindfoot was in valgus, a percutaneous Achilles tenotomy was performed to address any residual equinus (if there was <20° of dorsiflexion). Parental preference determined whether the tenotomy was performed with the use of local anesthesia in the outpatient clinic or with the use of general anesthesia in the operating room. The majority of the tenotomies (twenty-nine of thirty-four; 85%) were done in the outpatient clinic. After the tenotomy, a cast was applied with the foot in the fully corrected position and worn for three weeks. Following the removal of the post-tenotomy cast, or directly after full correction was achieved without the tenotomy, the patient was fitted with a foot abduction orthosis (a Denis-Browne bar with open-toed high-top straight-last shoes) with the affected side(s) set at 70° of external rotation and the unaffected side at 45°. The brace was supposed to be worn full-time for three months and at night and nap times thereafter until the age of four years. Patients were followed by the surgeon at six weeks and three months after initiation of the treatment with the foot abduction orthosis, at three months after they switched to night and nap time use, and then at six-month intervals.

In the physiotherapist-directed group, the initial evaluation of all patients was completed by a staff orthopaedic surgeon. The child was referred to the physiotherapist-directed clubfoot clinic, located in the same area as the outpatient clinic, on the day of the initial assessment by the surgeon. The physiotherapist applied the serial casts according to the Ponseti protocol. The responsible surgeon performed an Achilles tenotomy when one was indicated on the basis of the criteria described above. Patients with small feet (<1% of the cohort) were treated with serial casts after the tenotomy until the feet were large enough to fit into the smallest available boots. The patients were followed by the physiotherapist at one, three, and six months after initiation of the treatment with the foot abduction orthosis. In addition, the physiotherapist was accessible by telephone to provide advice about brace wear. The physiotherapist arranged additional appointments as needed to promote tolerance of the orthotic regimen. Clinic visits were coordinated with orthotists to assess, adjust, or resize the foot abduction orthosis as needed. The responsible surgeons were available for consultation and review at any time at the discretion of the physiotherapist. Six months after the initiation of the use of the orthotics, the patients were followed at six-month intervals in the respective surgeons’ main outpatient clinic and referred back to the physiotherapist-directed clubfoot clinic if additional casts were needed to address recurrent deformity.

Outcome Measures
Baseline information included age at presentation, sex, laterality of the clubfoot, and previous treatment if any. The number of casts required for correction, the need for an Achilles tenotomy, recurrence, and other procedures, if any, were recorded. A successful outcome at two years was defined as a plantigrade foot with a straight lateral border and normal hindfoot valgus during weight-bearing, a heel-toe gait, the ability to fit comfortably in a regular shoe, and at least 10° of ankle dorsiflexion with the knee extended. Recurrence was defined as any deformity that required additional cast treatment and/or surgical procedures to restore a satisfactory position in a child for whom cast treatment had been previously completed successfully with or without an Achilles tenotomy. Failure of the Ponseti treatment was defined as a failure to achieve full correction of the clubfoot with the initial serial casts, with or without a tenotomy.

Analysis
The surgeon-directed and physiotherapist-directed treatment groups were compared to identify any differences in the baseline characteristics or outcomes, including the number of casts required for correction, the proportion of patients requiring an Achilles tenotomy, and the rates of recurrences, failures, and secondary procedures. The Student t test was used to compare means, the chi-square or Fisher exact test was used to compare proportions, and Kaplan-Meier survival analysis was conducted to compare the timing of recurrences between the two groups. Significance was considered to be a p value of <0.05 at a two-tailed level.

Source of Funding
There was no external funding for this study.

Results
One hundred and twenty patients with 171 idiopathic clubfeet treated from 2002 until 2006 met all of the inclusion criteria. The baseline characteristics of the ninety-five patients (137 feet) in the physiotherapist-directed group and the twenty-five patients (thirty-four feet) in the surgeon-directed group are summarized in Table I. The two groups of patients were similar in terms of age at presentation, sex distribution, and frequency of bilaterality. There was no significant difference between the proportions of patients with a history of cast treatment or management at other facilities. Patients who had undergone prior cast treatment were, as one would expect, older at the time of presentation than those who had not undergone any prior treatment (mean age, 4.5 and 19.5 weeks, respectively) (p < 0.001). The proportions of patients who presented late (when they were more than twelve weeks old) were similar in the physiotherapist-directed and surgeon-directed groups. The mean duration of follow-up in
the surgeon-directed group (forty-eight months) was significantly longer than that in the physiotherapist-directed group (thirty-four months); this was expected because most of those in the surgeon-directed group had begun treatment prior to the initiation of the physiotherapist-directed clubfoot clinic.

**Number of Casts and Tenotomy Rates (Table I)**

In the entire cohort of 171 clubfeet, an average of 4.8 casts was required before full correction was achieved or until an Achilles tenotomy was necessary. There was no significant difference in the number of initial casts between the physiotherapist-directed group (4.8; range, three to eleven) and the surgeon-directed group (4.6; range, two to seven) \( (p = 0.37) \). A percutaneous Achilles tenotomy was performed in 104 (76%) of the 137 feet in the physiotherapist-directed group and in twenty-six (76%) of the thirty-four in the surgeon-directed group \( (p = 0.95) \). An Achilles tenotomy was done in 130 (76%) of the 171 feet in the entire cohort (Table I).

**Recurrence Rates and Management of Recurrences (Table II)**

A recurrence of the clubfoot deformity requiring additional treatment occurred in nineteen (14%) of the 137 feet in the physiotherapist-directed group over thirty-four months and in nine (26%) of the thirty-four feet in the surgeon-directed group over forty-eight months \( (p = 0.075) \). The rate of recurrence in the entire cohort was twenty-eight (16%) of 171 over the duration of the follow-up period. Recurrence was identified at an average of 30.7 weeks (range, two to 101 weeks) in the physiotherapist-directed group and 51.7 weeks (range, two to 171 weeks) in the surgeon-directed group.

Use of survival analysis to compare the recurrence rates takes into account the differential duration of follow-up in the two groups. At the two-year follow-up point, the probability of survival (free from recurrence) was 0.86 (95% confidence interval, 0.80 to 0.91) for the physiotherapist-directed group and 0.74 (95% confidence interval, 0.59 to 0.88) for the surgeon-directed group. The log-rank (Mantel-Cox) test of equality of survival analysis took the differential duration of follow-up into account.
survival distribution between the two groups demonstrated a p value of 0.08 (Fig. 2).

Eleven patients (thirteen feet) in the physiotherapist-directed group and four patients (six feet) in the surgeon-directed group (a total of fifteen patients [nineteen feet] in the entire cohort) required additional cast treatment alone before maintenance with the foot abduction orthosis was resumed. Three patients (five feet) in the physiotherapist-directed group and two patients (three feet) in the surgeon-directed group (a total of five patients [eight feet] in the entire cohort) required both cast treatment and repeat percutaneous Achilles tenotomy before the maintenance protocol was resumed. The average number of additional casts was 3.1 (range, two to seven) in the physiotherapist-directed group and 2.4 (two, three, or four) in the surgeon-directed group. One patient (one foot) in the physiotherapist-directed group had a recurrence that necessitated an open posterior release. This patient had a four-ray foot, which made maintenance with standard orthotics difficult. Since the patient had an intact fibula and because mild longitudinal deficiencies are not considered to be a risk factor for resistant or syndromic clubfoot, he was not excluded from the study. After the posterior release, a good foot position was maintained in an ankle-foot orthosis in conjunction with boots and a Denis-Browne bar worn at night.

Failure of Ponseti Management (Table II)
The treatment failed for two of the 137 feet (one of the ninety-five patients) in the physiotherapist-directed group and three of the thirty-four feet (two of the twenty-five patients) in the surgeon-directed group (p = 0.054); thus, the treatment failed for a total of five (3%) of the 171 feet in the entire cohort. One patient had stiffness of both feet and needed bilateral plantar release followed later by posterior release in order to achieve plantigrade feet. One patient with bilateral clubfoot had no substantial response to treatment with four serial casts and underwent a posteromedial release bilaterally. One patient with unilateral clubfoot who had presented at the age of fifty weeks did not respond to initial cast treatment and underwent a posteromedial release.

Additional Procedures for Treatment of Recurrent Deformity or Failure
Additional procedures either to address recurrent deformity that had not responded to repeat cast treatment alone or to address a failure included eight repeat percutaneous Achilles tenotomies (five in the physiotherapist-directed group and three in the surgeon-directed group), posterior release with or without a plantar release (three in the physiotherapist-directed group), and posteromedial release (three in the surgeon-directed group). Eight (6%) of the 137 feet in the physiotherapist-directed group and six (18%) of the thirty-four feet in the surgeon-directed group had an additional procedure (p = 0.025); the rate of additional procedures in the entire cohort was fourteen (8%) of 171. The overall rate of open surgical treatment was 4% (six of 171 feet; four of 120 patients). No patient had required an anterior tibial tendon transfer by the time of the latest follow-up.

Discussion
The treatment of congenital clubfoot deformity has undergone substantial change in recent years. Prior to the reintroduction of the Ponseti method, treatment usually con-
sisted of a trial of cast immobilization or splinting followed by an extensive surgical clubfoot release in 50% to 90% of patients. These operatively treated clubfeet were often stiff, and 15% required additional surgery. In contrast, the Ponseti method of manipulation, cast treatment, and percutaneous Achilles tenotomy, followed by the use of a foot abduction orthosis, obviates the need for extensive operative release in 83% to 98% of clubfeet. At our institution, an average of fifty-five new patients with eighty clubfeet were seen per year from 2002 to 2006. In addition to tenotomies and follow-up visits, these children require approximately 400 casts per year. The shift away from surgical management and the sheer volume of patients seen in our institution provided the impetus to establish the physiotherapist-run clubfoot clinic in 2003. The outcomes in this series, the largest reported outside of Iowa to our knowledge, compare favorably with those in other reports. The percutaneous tenotomy rate of 76% at our institution is lower than the 87% tenotomy rate reported from Iowa. The total recurrence rate was only 16%, and the majority of the recurrences were successfully treated with repeat cast treatment alone. Only six (4%) of the 171 feet (four of the 120 children) required an open surgical release.

The only deviation from the Ponseti method in our center is the use of semirigid fiberglass casting tape. Plaster of Paris was used for short, stubby, or puffy feet and was needed for two patients in this series. Our personal experience, like that of others, has been that semirigid fiberglass is easier to use. Plaster of Paris was used for short, stubby, or puffy feet and was needed for two patients in this series. Our personal experience, like that of others, has been that semirigid fiberglass is easier to use.

The physiotherapist-run clubfoot clinic has been successful. Pirani reported success in the teaching and implementation of the Ponseti method by clinical officers and other non-physicians in Africa. Physiotherapists possess the knowledge and skill set necessary to learn and successfully implement the Ponseti method. Shack and Eastwood reported success with a program in which Ponseti clubfoot care was delivered by physiotherapists in an urban children's hospital in the United Kingdom; they found good early results in a small case series of twenty-four children. We appointed a physiotherapist who had worked for eighteen years with children with neurologic and musculoskeletal conditions, had experience with cast treatment, and therefore was ideally suited to run the physiotherapist-directed clubfoot clinic after a two-month period of hands-on training and direct supervision. The optimal or minimal training period for a physiotherapist to acquire proficiency is unknown, and it is likely to vary with the individual experience and expertise of different types of health-care providers, including surgeons. Our clubfoot clinic is in operation twice a week for approximately five to six hours each day. During this time, the physiotherapist applies the casts and provides the nonoperative care of all children with idiopathic clubfoot deformity. As a single practitioner responsible for the serial-cast-treatment program, the physiotherapist is able to accumulate greater experience than a surgeon can from his or her individual practice. The physiotherapist also shares responsibility for the training of orthopaedic residents and pediatric orthopaedic fellows in the use of the Ponseti method of cast treatment.

The physiotherapist can spend more time with individual patients (can see approximately two patients per hour as compared with four patients per hour seen by surgeons), and he or she can thus devote additional time to parental education, emphasizing the importance of the orthotic regimen. Continuity of medical care and patient education have both been found to improve compliance with treatment in many areas of medicine. Noncompliance with the use of the foot abduction orthosis has been associated with higher rates of clubfoot recurrence. Our experience with our clubfoot clinic has taught us that some children simply do not tolerate the foot abduction orthosis at night, despite the diligent and conscientious efforts of their parents and multiple modifications of the brace. Whether an early recurrence or the developmental stage of the child (toddler) predisposes him or her to this intolerance is not known. In such instances, the term “noncompliance” inappropriately ascribes the burden of responsibility on the parents and child. “Tolerance” is a more appropriate term to describe the use of the brace because this term encompasses both these children as well as those whose parents are truly “noncompliant” because of failure to follow instructions for whatever reason. The clubfoot clinic provides parents with direct access to the physiotherapist by telephone or e-mail, allowing patients to receive prompt attention if problems associated with use of the abduction orthosis arise. Such communication is likely to promote tolerance of the treatment. In addition, the physiotherapist teaches the parents to perform a stretching exercise routine for the child’s feet when they are out of the orthosis.

This study has some limitations. First, the two groups of patients being compared may have differed. Although the two groups were not significantly different in terms of age at presentation, bilateralism, sex distribution, and previous treatment, we did not use a measure of the severity of the clubfoot deformity such as the Pirani or Diméglio scoring system. It is conceivable that the magnitude of severity differed between the two groups, but this limitation is mitigated by the comparability of other known prognostic factors in the two groups. Furthermore, we did not “select” patients for either of our comparison groups. Rather, our surgeon-directed group included all patients who had been treated for idiopathic clubfoot deformity with the Ponseti method by two surgeons prior to our clubfoot clinic.
to the establishment of the clubfoot clinic, and the physiotherapist-directed group included all patients with idiopathic clubfoot deformity who presented after the establishment of the clubfoot clinic. Thus, it is less likely that there were systematic differences between the patients in the two groups.

Second, the differences in the recurrence rates between the two groups could be explained partially by the differences in the follow-up periods. The mean duration of follow-up in the surgeon-directed group (forty-eight months) was significantly longer than that in the physiotherapist-directed group (thirty-four months) because most of the patients in the surgeon-directed group began treatment prior to the initiation of the physiotherapist-directed clubfoot clinic. Additional follow-up in the physiotherapist-directed group might detect additional recurrences. However, with only one recurrence in the entire cohort occurring after the first two years, and with an average of almost three years of follow-up in the physiotherapist-directed group and no loss of patients to follow-up, longer follow-up is unlikely to substantially alter the results of this comparison. It is conceivable that with longer follow-up (more than forty-eight months), additional recurrences might be detected and additional procedures would be necessary for the cohort as a whole, but once again these events are unlikely to be distributed differently between the two groups.

Third, the patients treated by the surgeons represent those surgeons’ early experience with the Ponseti technique. Typically, as a result of a learning curve, the outcomes for patients treated later are better than those for patients treated earlier. The surgeons would have transferred their gained knowledge to the physiotherapist, thereby shortening her learning curve. However, the failure rate of the Ponseti cast treatment in the entire series was quite low (3%) and was comparable with, or better than, the rates in most other published series.\(^4,5,7,9,20\) The results of the patients treated by surgeons in the present study match the results at other centers. This suggests that the Ponseti method was applied appropriately in both groups.

Finally, we were unable to assess whether the rates of tolerance of the brace differed between the two groups, as data on compliance were not consistently acquired or recorded early in the study. We are currently collecting these data prospectively to test the hypothesis that brace tolerance and/or compliance rates are superior for children in the physiotherapist-directed group.

This study demonstrates that the Ponseti method of serial cast treatment can be employed successfully by appropriately trained health-care professionals such as physiotherapists. The size of the sample treated by the physiotherapist is large, which increases confidence in the validity of the findings for that group.

We believe that our physiotherapist-run clubfoot clinic has been a successful model of effective delivery of quality care, without compromising outcomes, at our institution. Nurse practitioners, physiotherapists, and physician assistants are playing an increasing role in the direct delivery of clinical care, including clinical, nonoperative orthopaedic care, to patients at many institutions in North America. Such a model might allow the optimal and efficient use of surgeons’ time while potentially improving the quality of care delivered and increasing patient satisfaction. The financial and medicolegal implications of such a model may well differ in various healthcare settings in other locales or countries.

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