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Do Cultural Factors Affect Outcome in Ponseti Treatment for Clubfeet in Rural America?

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Introduction

Since its inception, the Ponseti method has proven to be effective in the treatment of idiopathic clubfoot in greater than 95% of cases[1,2]. In those instances where the Ponseti method is unsuccessful, this failure is frequently due to noncompliance with the use of the post-casting abduction orthosis[3-5]. Dobbs et al suggested that noncompliance and the educational level of parents are significant risk factors for the recurrence of clubfoot deformity, and that treating physicians should consider these factors when employing the Ponseti method[2]. More recently, Haft et al reiterated that compliance with the post-correction abduction bracing protocol is crucial to avoid clubfoot recurrence[5]. No study has examined an ethnically diverse North American population to assess whether distance from the site of care affects the clinical outcome of the Ponseti method.

According to the 2005 United States Census Bureau, New Mexico is composed of approximately 1.8 million people, 50% of whom live in rural, medically underserved areas[6]. The state population is composed of approximately 44% Hispanics and 10% Native Americans. Twenty–two percent of the population has less than a high school education and 22% is uninsured. The orthopaedic needs of the rural population is underserved, with many patients traveling a significant distance to receive care in Albuquerque, the only site in the state providing pediatric orthopaedic services and the only site with physicians trained in the Ponseti method. A rural family must commute weekly to Albuquerque for about 2 months for cast applications, and intermittently thereafter for follow up and orthotic management. This travel may be difficult or impossible for families living a far distance from the treatment site. While prior studies have demonstrated effective Ponseti treatment in certain rural populations, no distinction has been made between patients living close and those living a significant distance from the site of

treatment[7-8]. Since compliance with the abduction orthosis is essential to maintain correction, orthotic follow-up, fitting, and compliance is at increasing risk the more difficult the travel to the site of care.

New Mexico, with its large rural areas and economic and ethnic diversity, offers an opportunity to examine how these factors affect both initial deformity correction and maintenance of correction using the abduction orthosis. Our hypothesis was that the success of the Ponseti treatment was related to economic factors coupled with distance to the care center.

Materials and Methods

Patients

In a prospective study, a total of 210 idiopathic clubfoot patients (102 urban patients, 125 feet; 108 rural patients, 151 clubfeet) were treated at Carrie Tingley Hospital from 2003 to 2006. Infants who had not received treatment prior to referral were invited to enroll in an IRB-approved database to track patient data and clinical photographs. Of the 210 patients, 102 infants (50 urban patients with 68 clubfeet and 52 rural patients with 72 clubfeet) enrolled in this study. Two rural patients were lost to follow-up, leaving 50 urban patients with 68 clubfeet and 50 rural patients with 70 clubfeet.

Demographic Data

Patients were divided into two groups: urban or rural, using distance traveled to the site of care. "Urban" was defined as living less than 75 miles from the study hospital: this specific radius was chosen since it includes the peripheral Albuquerque metropolitan area, encompasses surrounding communities that are within a short driving distance to the hospital, and is an area with public transportation. While there are other areas in the state that can be considered

"urban" by other definitions, the remainder of the state was defined as "rural" because of the distance from the only site of pediatric orthopaedic specialty care. The gender and ethnicity of the infant were obtained from the hospital electronic database. The electronic database did not include marital status, educational level and income of the parents, and type of insurance (private, public, or none), so a questionnaire was created to elicit this information and was mailed to each family. If the questionnaire was not returned, a telephone interview was conducted to complete this form.

Additional Data

Additional data noted in the study database included the number of casts required to obtain correction, whether Achilles tenotomy had been performed, and the number of recurrences, either early or late. Severity of clubfoot deformity was defined as mild (Pirani score of 0.5 to < 2), moderate (Pirani score of 2 to ≤ 4), or severe (Pirani score > 4). Frequency of orthotic use was quantified by family report. Compliance was measured in terms of when the orthotic was discontinued and whether discontinuation was recommended by the treating physician or done without physician consent.

Pirani Grading

The degree of deformity of each child's clubfoot was graded on every visit using the Pirani scoring system[13,14]. The Pirani system of grading clubfoot scores three clinical signs related to midfoot contracture and three clinical signs related to the hindfoot contracture. Each component of the deformity is scored either as 0 (no abnormality), 0.5 (moderate abnormality), or 1 (severe abnormality) for a total score between 0 and 6. Three cast technicians were trained in this scoring technique and consistency of scoring between observers was verified: after employing the technique for approximately one month, each technician independently graded the

same twenty clubfeet; the difference in scores were statistically assessed and found to have no significant difference. Sequential Pirani scoring was not blinded: subsequent scores for each child were recorded on the same clinic form. Scoring was done at presentation, prior to each cast application, and at the beginning and end of orthotic treatment.

Questionnaires

The Pediatric Outcomes Data Collection Instrument (PODCI) questionnaire[15,16], a validated instrument which reflects the parent's *impression* of his/her child's function after treatment, was administered. In addition, we created our own, unvalidated questionnaire which inquired of demographic variables as mentioned, assessed brace compliance, satisfaction with the final result, and difficulty commuting to the site of care. Both questionnaires were administered by mail to the patient's family at an average of 3.2 years (range 2.3 – 4 years) following completion of cast treatment. If questionnaires were not returned then a telephone interview was conducted pertaining to both questionnaires.

Ponseti Method for Manipulative Treatment

All children were treated by one of three fellowship-trained pediatric orthopaedic surgeons. Children with clubfeet were routinely treated according to the protocol as outlined by Dr. I.V. Ponseti[11,12]. During weekly clinic visits, the physician gently manipulated and stretched the foot, and applied a molded plaster cast from toes to upper thigh. Cavus was corrected first, subsequently addressing varus and adductus, emphasizing abduction and external rotation of the foot distal to the talus. Most children required a tendoachilles tenotomy to correct the equinus deformity, which was generally performed in the clinic. When the final cast was removed, usually 3 weeks following the tenotomy, the infant received an abduction orthoses which was to be worn full time for 3 months. The orthotic maintained affected feet at 70° external rotation

while normal feet were held at 40° external rotation. After the initial 3 months of fulltime orthotic use, the orthotic prescription was modified to naptime and nighttime. The parents were advised of the importance of the bracewear to prevent recurrence of deformity, and it was reinforced that this regimen must be continued until age 3 or 4.

Recurrence was defined as any relapse of deformity requiring repeat manipulation and cast application, or relapse requiring surgical intervention. Such recurrence was manifested by difficulty in applying or discomfort in wearing the abduction orthosis and was reflected in an increase in the Pirani score. One or more casts were reapplied to regain correction and a repeat tendoachilles tenotomy was performed if dorsiflexion of the foot was less than 15°. In the case of further recurrence, the choice of surgical intervention was surgeon-directed and usually predicated by stiffness of deformity and resistance to manipulative treatment. Surgical treatment involved posterior or comprehensive release and/or transfer of the tibialis anterior tendon to the middle cuneiform.

Educational Materials

At the onset of treatment, each patient's family received a written handout, in English, describing the casting and orthotic phases of treatment, along with a copy of an article about long term success of the treatment. The handouts emphasized the importance of brace compliance to maintain successful deformity correction. Several Internet website addresses were recommended on the handout, including the website of Dr. Ponseti entitled, "To Parents of Children born with Clubfoot,"[9] and "global-help.org"[10]. It was assumed that many families would use the Internet to gain a better understanding of the deformity and its treatment, and that this would reinforce brace compliance. In addition to this written material, the treating physician outlined for the caregiver

the brace protocol and emphasized the importance of brace compliance. This message was verbally reinforced at every follow up visit.

Statistical Analysis

Univariate Analysis

To compare the two groups, rural versus urban, Pirani score improvement was calculated by subtracting the initial score from the final score. The relationship of all other variables compared to Pirani score was evaluated using the student-paired t-test or analysis of variance as appropriate. Recurrence was scored based upon whether re-manipulation or surgical intervention occurred. The proportion of recurrences in the rural and urban groups and other two by two tables was compared using univariate odds ratios with 95% confidence intervals. P-values for two-by-two tables were calculated using Chi-square distribution or Fischer's exact test as appropriate.

Multivariate Analysis

Variables that significantly related to Pirani improvement were evaluated using a general linear model. Variables were fitted using a forward procedure and only kept in the model if $p < 0.05$. Statistical calculations were made with Statgraphics Plus for Windows Version 4.1, Manugistics, Inc., Rockville, MD. Data management was carried out using Microsoft Excel 2002 (Microsoft Corporation, Redmond, WA). Two-tailed tests and a Type I error rate of 0.05 were employed throughout.

Results

Baseline Patient Characteristics

Urban and rural patients were comparable with respect to demographic variables relating to family and with respect to infant characteristics and initial Pirani score (Table I). Commute time and distance to the site of care were the only significant differences between the two groups. The average duration of follow-up of the 100 patients (138 clubfeet) was 28.3 months (range 25 to 34 months).

Pirani Score as a Measure of Treatment Success

There was no statistical difference in treatment outcome amongst the three surgeons.

There was an overall initial correction in 131 (94%) of the 138 clubfeet (Table II). Seven feet were incompletely corrected after initial casting and because they were very stiff they received either a surgical release of a greater or lesser degree. These seven feet are considered to be "failures" of initial manipulative treatment and are not further discussed with respect to recurrence.

Correction from initial manipulation and cast application was similar between the remaining patients in the two groups (Table II). Of the patients included in the final analysis, one technician graded the same 82 patients from the inception to the end of the study.

With respect to the ultimate outcome, the mean improvement in Pirani score for the urban patients was 3.94 (95% CI 3.72 to 4.15), while the mean improvement in Pirani score for the rural patients was 2.51 (95% CI 2.08 to 2.93, $p < 0.001$). The strong association of urban residence with mean Pirani improvement score after total treatment persisted in a multivariate model which simultaneously adjusted for the effect of ethnicity and family income ($p < 0.001$). However, as shown in Table II, correction of deformity was not significantly different between urban and rural non-Hispanic Caucasian and Hispanic patients. Compared to urban counterparts,

rural Native Americans had a significantly greater Pirani score after what should have been the orthotic wear component of treatment ($p < 0.001$).

Recurrence of Deformity

There was an early recurrence of 34 (24.6%) clubfeet. The rural group had a total of 18 patients with early recurrences. Two non-Hispanic Caucasian patients with recurrence presented with a severe unilateral deformity and relapsed to a moderate (1) or severe deformity (1). Two Hispanic patients with recurrence presented with severe bilateral deformity and relapsed to a severe (1) or moderate (1) bilateral deformity. Fourteen Native American patients demonstrated early recurrence: all presented with severe deformity and relapsed to severe deformity.

The 18 rural patients with early clubfoot recurrence were treated with repeat manipulation and cast application, and 7 of 18 (39%) patients required a second tendoachilles tenotomy. Following this second corrective treatment, all patients were again fitted with abduction orthoses. Six patients subsequently had a second recurrence: all were Native American. Five of these six patients received a third cast treatment followed by anterior tibial tendon transfer and one had a posterior medial release.

Eight children in the urban group exhibited early recurrence: three non-Hispanic Caucasian patients with recurrence presented with either severe bilateral (1) or unilateral (2) deformity and relapsed to the previous deformity. Three Hispanic and 2 Native American patients with recurrence presented with severe unilateral (3 Hispanic infants) or bilateral (2 Native American infants) deformity and relapsed to the previous deformity. These patients, too, were treated with repeat manipulation and cast applications. Four of the 8 patients (50%) received a second tendoachilles tenotomy. One patient, after a second relapse, had a tibialis

anterior tendon transfer. There was a statistically significant difference in recurrence rate between the Native American children who were rural and those who lived in an urban setting (Table II, $p = 0.002$).

Compliance with Bracing

In all children who experienced a relapse, abduction bracing had been prematurely abandoned, but not all children in whom bracing was abandoned experienced relapse. Seven patients in whom bracing was not followed as outlined did not experience recurrence of the deformity: 4 urban patients (1 Native American, 2 Hispanic, and 2 non-Hispanic Caucasian infants) and 3 rural (1 Native American, 1 Hispanic, and 1 non-Hispanic Caucasian infant).

The remaining twenty five patients in whom bracewear was discontinued experienced recurrence: 7 urban infants (3 Native American, 2 Hispanic, and 2 non-Hispanic Caucasian infants) and 18 rural (14 Native American, 2 Hispanic, and 2 non-Hispanic Caucasian infants). Brace usage is outlined in Table II: difference in brace usage was found to be significant between urban and rural Native American patients.

PODCI as a Measure of Parent Satisfaction with Outcome

The PODCI results suggested similar levels of parental satisfaction between rural and urban non-Hispanic Caucasian and Hispanic patients (Table III) with respect to global functioning, happiness, pain and comfort, sports and physical functioning, and transfer/mobility. The rural and urban Native American parents differed significantly in their assessment of outcomes as related to the sports and physical functioning as well as global functioning categories of their child ($p < 0.001$). There were no other detectable differences from the PODCI instrument.

Odds ratios as a Measure of Early Recurrence with Respect to Various Demographic Variables

Of the variables tested, abandonment of the brace protocol was associated with a 33.3-fold increased likelihood of early recurrence in urban patients (odds ratio = 33.3, CI = 5.2 to 212.2, $p < 0.001$).

In the rural population (Table IV), a patient whose family abandoned brace usage prematurely was 120 times more likely to have a relapse (odds ratio = 120 and 95%, CI = 18.2 to 765.1, $p < 0.0001$). A family with an annual income < $20,000 had a 12.5-fold increased likelihood of recurrence (odds ratio = 12.5, 95% CI = 2.38 to 65.5, $p = 0.007$). Unmarried parents increased the chance of recurrence 4.5-fold (odds ratio = 4.5, odds ratio = 1.2 to 15.8, $p = 0.04$), public or no insurance was associated with an 8-fold increased likelihood (odds ratio = 8.0, CI = 1.8 to 35.6, $p = 0.01$), and parental education of high school or less was associated with a 5.6-fold increased likelihood of recurrence (odds ratio = 5.6, CI = 1.47 to 21.7, $p = 0.02$). Native American ethnicity increased the likelihood of recurrence 9.3 times (odds ratio = 9.3, CI = 1.7 to 50.4, $p = 0.02$). Gender, age at onset of treatment, and commute time to the facility for rural patients, were not found to have a significant effect on the risk of recurrence.

Odds ratios as a Measure of Brace Compliance

In the urban group, there was no significant association found between brace compliance and any of the listed characteristics. In the rural group (Table V), Native American ethnicity was associated with a 7-fold increased likelihood of discontinuing brace wear (odds ratio = 7.0, CI = 1.4 to 34.6, $p = 0.04$), and parental income < $20,000 was associated with a 7.1-fold increased likelihood of brace discontinuance (odds ratio = 7.1, CI = 1.6 to 31.2, $p = 0.02$).

Parent Report Describing Reasons for Discontinuation of Orthosis

The parents of 18 rural infants (2 non-Hispanic Caucasian, 2 Hispanic, and 14 Native Americans) did not adhere to the brace protocol as outlined by the physician. Reasons for discontinuing the brace were elicited by telephone interview. Parents of all ethnic groups reported that the orthotic was discontinued or worn intermittently because the infant became agitated wearing the brace, because it seemed that the deformity was much improved or completely corrected, and/or because they were unaware that the brace was a critical component in the clubfoot treatment.

Every Native American family of an infant with early recurrence participated in the telephone interview. Five different families noted that they did not fully understand the treatment regimen and that it was difficult to understand the written material. In two households, a grandparent was the infant's primary caregiver and she did not receive the instructions pertaining to the brace regimen. In these two households, English was not the primary language spoken at home. It was again verbalized that since the foot appeared corrected after Ponseti casting, the brace was not continued if the child became fussy.

Seven of the 8 urban families (2 non-Hispanic Caucasian, 2 Hispanic, and 3 Native Americans) in whose children the deformity recurred were also interviewed by telephone. They, too, reported that to them the deformity appeared corrected, and/or the infant became agitated with the brace, particularly with activity. Three of these urban families were Native American: the parents reported themselves as primary caregivers and that English was primarily spoken at home.

Discussion

The Ponseti method is an effective and appropriate initial intervention in the treatment of idiopathic clubfoot[17-19]. The Ponseti technique, as described, does, however, require aggressive, dedicated, and meticulous care on the part of both the treating physician and the parents. Several previous studies have shown that compliance with the abduction orthosis is essential to the method's success[1,2,5,20]. The Ponseti technique does not uniformly prevent the need for surgery.

Since Ponseti and colleagues demonstrated a 98% initial correction in patients with only 11% relapse[1], studies have assessed the reproducibility of the method at numerous centers throughout the world. Studies in the United States demonstrated initial correction rates ranging from 92% to 100%[1,17,22,23,24] with early relapse rates of 10% to 31% [1,2,22]. "Noncompliance" with bracing was identified as a significant cause for recurrence[1,2,17,22,23], a phenomenon confirmed by the works of Thacker et al[20] and Dobbs et al[2].

The effectiveness of the technique has also been examined in culturally diverse populations. Haft et al showed in a New Zealand population an early recurrence of 41%, with a noncompliance rate that was statistically unrelated to the intrinsic clubfoot deformity or ethnicity[5]. Because of its simplicity, low cost of application, and effectiveness in methodology, the efficacy of the Ponseti method has also been assessed in developing countries. Tindall et al[8] reported an initial correction of 98% in a South African population, and Gupta et al[7] demonstrated 100% initial correction in Ahmadabad, India. However, the follow-up period was short and the authors were unable to thoroughly assess for early recurrence. Pirani et al initiated a national program in Uganda for the treatment of clubfoot. Although specific details pertaining to his study are unclear, 80% of children had their deformity completely corrected within 2 years[25,26].

Dr. Ponseti and his colleagues have been able to achieve such a high correction rate due, partly, to the population of patients whom their institution in Iowa City attracts[1]. The Internet has provided families direct access to information about clubfoot and the Iowa clubfoot center, increasing the number of patients, many through self-referral, treated in their clinic[27, 28]. These families are self-educated on the treatment for clubfoot and motivated for the method to succeed – they therefore may be more willing to comply with the orthotic phase, the most difficult and demanding segment of treatment.

The challenge of the Ponseti treatment regimen lies not in the initial cast correction, but in the success of educating the parents and family regarding their role in the maintenance of correction by long-term abduction bracing and in providing a brace that is acceptable to child and family alike. "Noncompliance" with bracewear is difficult to define: in many infants, as the deformity recurs, the brace no longer fits and becomes uncomfortable. When the infant cries, the compassionate parent or caregiver removes the brace to alleviate the discomfort. Without the brace, the foot becomes tighter, thus perpetuating the spiral. The distinction between when the infant is being stubborn versus expressing pain is difficult to ascertain. Intervention early in this process, by timely cast stretching of the slowly tightening foot or modification of the brace, is key to success, but requires excellent communication between physician and family.

Our study demonstrates that certain patient characteristics and several parental demographic variables imply a greater risk for clubfoot recurrence. The overall early recurrence rate seen in our study was 24.6%, higher than in previous studies[1, 2, 22]. We believe that cultural factors, coupled with distance to the site of care, created a difference in clinical outcome. As in other studies[1, 2, 5, 17, 29], post-casting abduction bracing is a key factor to success or failure. We confirm that yearly family income $\leq$\$20,000, unmarried parents, public or no insurance, and a

parental education of high school or less correlated with recurrence: these problems were exacerbated by the need to take off work for an all-day expedition to clinic with increasingly expensive gas prices. Such demographic variables were correlated and would be expected to parallel one another. The initial severity of deformity and the age of presentation did not influence recurrence.

As in other studies[1,2,5,20], recurrence of deformity could be statistically correlated to premature abandonment of the post-casting orthotic program. An infant in a cast is a compelling reason to drive long distance for care. Difficulty with a brace is more easily overlooked and can be mitigated by abandoning the brace regimen in lieu of driving many hours for an orthotic visit. This would suggest that all rural subjects might demonstrate decreased brace compliance. The fact that this phenomenon was not observed in rural patients of Hispanic or non Hispanic Caucasian ethnicity suggests forces beyond mere distance and inconvenience.

The urban Native American child had recurrence rates no different than children of other ethnicities, either urban or rural. In contrast, the rural Native American child with a clubfoot deformity demonstrated a higher incidence of early recurrence than the urban Native American infant. This striking difference in outcome predicated by where the family lives suggests that there is no intrinsic difference in clubfoot pathology in the Native American child. That the only difference seemed to be a combination of ethnicity combined with locale challenged us to provide an explanation for these data.

In New Mexico, the Native American families who live a distance from Albuquerque are more likely to follow native traditions, speak their native language in the home, and utilize native healers in addition to modern medicine[30]. While families of all ethnicities frequently reported,

when their child had a recurrence of deformity, that they did not perceive the abduction orthosis as an important component for ongoing success in the treatment of their child, interviews with some of the rural Native American families in this study parents revealed that English was not the primary language spoken at home, which would further complicate this communication. In these and many Native American homes, grandparents play an important role, particularly as valued teachers and resource in child rearing. Further, there often exists a notion of shared responsibility within an interdependent family system which can result in many family members sharing childcare. In a traditional Native American home, a strong connection may exist with traditional spiritual and natural healing practices, and the family may have consulted with a medicine man or native healer.

In retrospect, the educational materials regarding Ponseti method supplied for families were not well geared to a traditional Native American family. Many Native Americans prefer visual examples or illustrations over voluminous written instructions. The readability of the handouts was greater than 12th grade level[31] making them unsuitable for many of our families of all ethnicities.

With respect to our teaching methods, the Native American culture considers that what one says and does influences outcome and, as such, many Native Americans respond to positive directions ("if the brace is used the foot will remain straight") while avoiding negative admonitions as harbingers of bad luck ("if you don't use the brace the foot will be deformed again and surgery will be needed")[32]. The nature of our orthotic admonitions tended more towards the negative than the positive (i.e. it was suggested that the deformity would recur rather than that the good results would continue.)

A 2005 survey of 300 consecutive patients at an Indian Health Service Hospital in Crownpoint, NM, demonstrated that 17% of patients required a translator to be able to accomplish the survey interview[30]. While Native translators are available at our institution, they are seldom utilized because the patients rarely volunteer the request for an interpreter. Native American patients are naturally reticent and polite: if they do not understand instructions they may prefer not to question or confront the physician because they consider it rude to do so. Upon arriving home, other family members may consider it impolite to ask about the visit to the doctor, so verbal instructions might not be passed on to family members involved in the care of the child. Our questionnaire did not ask and it was not our habit to inquire if a native healer was involved in the care of a child with clubfoot, and this would be useful information in fostering communication about the child's care. While native healers seldom conflict with modern treatment, an appreciation of their involvement can enlist them as an ally and a source of family support. Finally, in Native American families in more remote and traditional regions of New Mexico, the use and availability of technology, specifically the Internet, is limited. This minimizes the degree to which a family may educate themselves on the treatment of clubfoot.

Our study shows that there are cultural factors that impact patient education and understanding which are pivotal to parental motivation for a positive outcome. A physician can emphasize orthotic wear at every patient encounter, but if caregivers have not engaged with the importance of their own role in the treatment, the outcome will suffer. Similarly, if the physician does not understand the milieu in which the child is living and the cultural perspective from which the parents are operating, the mutual trust upon which communication fosters education will not be possible.

This study has several limitations. The series of patients in this study were evaluated and treated by three surgeons, each of whom had her/his own communication style. As each surgeon maintained continuity with each patient, the potential existed for a provider to have been more or less aggressive with education and treatment. That there is no difference in outcome amongst the three surgeons argues against significant practice variations. The potential for differences in scoring or the reliability of the scoring may explain the lack of correlation between severity of clubfoot deformity and recurrence rate. However, the magnitude of change from one end of the Pirani scale to the other is clinically relevant as it reflects the difference between a functional foot and one that is disabled[10, 14]. This is a small population: which makes assessment of multiple variables problematic. Also difficult is the lack of objective measures to assess behavior, attitude, and comprehension, such as brace usage. Although every parent was queried regarding the details of their brace usage, not every parent answered questions pertaining to their comprehension of the treatment regimen.

Finally, the cultural implications of the outcome were a surprise to us and, in this otherwise prospective study, we had to go back to retrieve data that only became important in retrospect. The identity of the primary caregiver (i.e. grandparent vs. parent), how often the primary caregiver was present during clinic appointments, and the primary language spoken at home were not uniformly established in our database.

In conclusion, the very different outcome observed between urban and rural Native American children likely relates to our inability to adequately communicate the importance of post-cast orthotic wear to the rural Native American families. The challenge will be to design an educational program geared to these families, with community outreach support, so that these children also will experience the excellent long-term results that the Ponseti method can provide.

In the Ponseti technique as in many other areas, the physician's skill as an educator is pivotal to a positive outcome. His/her ability to communicate across cultural divides, despite unfamiliar health values and behaviors, are essential to providing quality health care for diverse populations within the United States and globally.

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Table I: Base-line characteristics of the 50 urban and 50 rural patients

Characteristic	Variable	Urban N (%) or mean ± SD	Rural N (%) or mean ± SD
Gender	Male	33 (66)	26 (52)
	Female	17 (34)	24 (48)
Ethnicity of Patient	Non-Hispanic Caucasian	19 (38)	10 (20)
	Hispanic	18 (36)	20 (40)
	Native American	13 (26)	20 (40)
Parent's marital status	Married	29 (58)	22 (44)
	Unmarried	21 (42)	28 (56)
Insurance	Private	27 (54)	14 (28)
	Public or none	23 (46)	36 (72)
Highest education level of parents	High school or less	22 (44)	30 (60)
	More than High school	28 (56)	20 (40)
Family yearly income	< $20,000	10 (20)	16 (32)
	$20,000 – $39,999	14 (28)	17 (34)
	≥ $40,000	26 (52)	17 (34)
Commute time to site of care	< 1 hour	50 (100)	0
	1-5 hours	0	37 (74)
	>5 hours	0	13 (26)
Mean distance to site of care (miles)	All groups	20.5 ± 20.7	206.5 ±70.9
Mean age of patient presentation (days)	All groups	37 ± 72.7	31 ± 50.6
	Non-Hispanic Caucasian	24 ± 28.5	37 ± 87.2
	Hispanic	38 ± 60.4	25 ± 31.3
	Native American	54 ± 120.9	34 ± 44.3
Unilateral or bilateral deformity	Unilateral	32 (64)	30 (60)
	Bilateral	18 (36)	20 (40)
Pirani score	All groups	4.8 ± 0.8	4.7 ± 0.7
	Non-Hispanic Caucasian	4.9 ± 0.5	4.6 ± 0.7
	Hispanic	4.9 ± 0.7	4.7 ± 0.7
	Native American	4.5 ± 1.1	4.8 ± 0.7

Table II: Overall results of the 50 urban and 50 rural patients

Characteristic	Variable	Urban N (%) or mean ± SD	Rural N (%) or mean ± SD	p-Value
Initial Correction (# feet)	All groups	64 (94)	67 (95)	0.7
	Non-Hispanic Caucasian	24 (100)	14 (100)	0.06
	Hispanic	21 (84)	27 (93)	0.4
	Native American	19 (100)	26 (96)	0.3
Tendoachilles Tenotomy	Number of feet	63 (93)	66 (94)	0.7
Number of Casts for Initial Correction	All groups	9.3 ± 2.9	9.3 ± 4.1	1.0
	Non-Hispanic Caucasian	9.4 ± 3.1	8.9 ± 5.3	0.7
	Hispanic	8.8 ± 2.1	9.7 ± 4.4	0.4
	Native American	10.1 ± 3.7	9.1 ± 3.3	0.4
Pirani Score after Ponseti Casting	All groups	0.8 ± 0.6	1.0 ± 0.7	0.2
	Non-Hispanic Caucasian	0.7 ± 0.5	0.8 ± 0.4	0.6
	Hispanic	1.1 ± 0.7	1.1 ± 0.8	0.8
	Native American	0.7 ± 0.6	0.9 ± 0.7	0.3
Early Recurrences (# patients)	All groups	8 (16)	18 (36)	0.04
	Non-Hispanic Caucasian	3 (16)	2 (20)	0.7
	Hispanic	3 (17)	2 (10)	0.7
	Native American	2 (15)	14 (70)	0.002
Non-Compliance with Bracing Resulting in Recurrence(# patients)	All groups	7 (14)	18 (36)	0.01
	Non-Hispanic Caucasian	2 (11)	2 (20)	1.0
	Hispanic	2 (11)	2 (10)	1.0
	Native American	3 (23)	14 (70)	0.006
Recurrence after Second Cast Application (# feet)	All groups	1 (13)	6 (33)	0.1
	Non-Hispanic Caucasian	0	0	1.0
	Hispanic	1 (33)	0	0.5
	Native American	0	6 (43)	0.02
Pirani Score after Bracing	All groups	0.9 ± 0.5	2.1 ± 1.7	<0.0001
	Non-Hispanic Caucasian	0.7 ± 0.5	1.1 ± 1.1	0.1
	Hispanic	1.1 ± 0.7	1.5 ± 1.3	0.2
	Native American	0.7 ± 0.5	3.4 ± 1.7	<0.0001
Length of follow-up (months)	All groups	28.6 ± 2.7	28.0 ± 2.6	0.2
	Non-Hispanic Caucasian	28.4 ± 2.8	27.4 ± 1.5	0.3
	Hispanic	28.3 ± 2.4	27.6 ± 2.4	0.3
	Native American	29.4 ± 2.8	28.7 ± 3.0	0.5

Table III-A: PODCI scores of functional outcome based on parental report

	Transfer and Mobility (Mean ± SD)			Sports and physical functioning (Mean ± SD)			Pain and comfort (Mean ± SD)			Global functioning (Mean ± SD)		
	Urban	Rural	p-Value	Urban	Rural	p-Value	Urban	Rural	p-Value	Urban	Rural	p-Value
All groups	97.3 ± 3.8	95.1 ± 6.6	0.04	96.1 ± 4.8	87.7 ± 8.9	< 0.0001	94.8 ± 5.5	95.0 ± 8.8	0.94	96.4 ± 2.4	92.1 ± 6.6	< 0.0001
Non-Hispanic Caucasian	98.1 ± 2.1	95.8 ± 4.8	0.09	97.0 ± 3.3	95.3 ± 2.8	0.19	95.0 ± 5.5	97.8 ± 5.0	0.18	96.8 ± 1.9	96.4 ± 2.1	0.59
Hispanic	96.8 ± 4.8	95.6 ± 5.5	0.49	95.2 ± 5.4	92.6 ± 4.6	0.12	95.3 ± 5.5	97.3 ± 5.2	0.27	96.2 ± 3.1	95.7 ± 2.9	0.60
Native American	96.9 ± 4.2	94.2 ± 8.4	0.29	96.0 ± 5.7	78.9 ± 6.5	< 0.0001	94.0 ± 5.8	91.2 ± 11	0.43	96.1 ± 2.0	86.3 ± 6.7	< 0.0001

Table III-B: Number of Clubfeet in PODCI analysis

	Urban	Rural
All groups	64	67
Non-Hispanic Caucasian	24	14
Hispanic	21	27
Native American	19	26

Table IV: Odds ratios for early recurrence in a rural family

Characteristic	Variable	Early recurrence of Deformity: Yes N=18 patients	Early recurrence of Deformity: No N=32 patients	Odds Ratio* †	p value ‡
Gender	Male	10	16	1.3 (0.4 – 4.0)	0.93
	Female	8	16	1.0	
Race of Patient	non-Hispanic Caucasian	2	8	1.0	
	Hispanic	2	18	0.4 (0.1 – 3.1)	0.85
	Native American	14	6	9.3 (1.7 – 50.4)	0.02
Marital Status	Married	4	18	1.0	
	Not Married	14	14	4.5 (1.3 – 15.8)	0.04
Insurance	Private	2	16	1.0	
	Public or none	16	16	8.0 (1.8 – 35.6)	0.01
Highest Educational Level of Parents	High school or less	15	15	5.6 (1.45 – 21.7)	0.02
	More than high school	3	17	1.0	
Family Income	≤ $20,000	10	6	12.5 (2.4 – 65.5)	0.007
	$20,000 – $39,999	6	11	4.1 (0.8 – 21.2)	0.22
	≥ $40,000	2	15	1.0	
Commute Time to Site of Care	1-5 hours	13	24	1.0	
	>5 hours	5	8	1.2 (0.3 – 4.1)	0.90
Patient Noncompliant with Orthosis	Yes	16	2	120 (18.8 – 765.1)	< 0.0001
	No	2	30	1.0	
Age at Presentation	< 90 days	16	29	0.8 (0.1 – 4.7)	0.76
	> 90 days	2	3	1.0	
Pirani Score	Mild	0	0	1.0	
	Moderate	2	9	4.5 (0.2 – 100.1)	0.59
	Severe	16	23	1.4 (0.1 – 24.6)	0.39

* The values are given as the univariate (unadjusted) odds ratios, with the associated 95% confidence intervals in parenthesis. † A correction of 0.5 was used in the cell that contains a zero. ‡ P values are reported for univariate logistic regression analysis modeling recurrence.

Table V: Odds ratios for brace compliance in a rural family

Characteristic	Variable	Brace compliance: Yes N = 28	Brace compliance: No N = 22 patients	Odds Ratio* †	p value ‡
Gender	Male	14	12	1.2 (0.4 – 3.5)	0.97
	Female	14	10	1.0	
Race of Patient	non-Hispanic Caucasian	7	3	1.0	
	Hispanic	16	4	0.5 (0.1 – 3.0)	0.87
	Native American	5	15	7.0 (1.4 – 34.6)	0.04
Marital Status	Married	15	7	1.0	
	Not Married	13	15	2.4 (0.7 – 7.7)	0.21
Insurance	Private	9	5	1.0	
	Public or none	19	17	1.6 (0.4 – 5.5)	0.67
Highest Educational Level of Parents	High school or less	14	16	3.0 (0.9 – 9.6)	0.18
	More than high school	14	6	1.0	
Family Income	≤ $20,000	5	11	7.1(1.6 – 31.2)	0.02
	$20,000 – $39,999	10	7	2.2 (0.5 – 9.4)	0.46
	≥ $40,000	13	4	1.0	
Age at Presentation	< 90 days	24	21	3.5 (0.5 – 24.2)	0.51
	>90 days	4	1	1.0	
Cast Applications	1-6	9	7	0.9 (0.3 – 3.1)	0.77
	> 6	19	15	1.0	
Pirani Score	Mild	0	0	1.0	
	Moderate	7	4	0.5 (0.02 – 11.5)	0.41
	Severe	21	18	0.8 (0.05 – 14.6)	0.34

* The values are given as the univariate (unadjusted) odds ratios, with the associated 95% confidence intervals in parenthesis. † A correction of 0.5 was used in the cell that contains a zero. ‡ P values are reported for univariate logistic regression analysis modeling recurrence.