Evaluation of a Disease-specific Instrument for Idiopathic Clubfoot Outcome

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Abstract In 2001, Roye et al. developed a disease-specific instrument (DSI) to measure outcomes of treatment for clubfoot. We assessed this instrument using a cohort of 62 patients, ages 5 through 12 years (mean, 8.6 years), with idiopathic clubfoot who were treated as infants by various methods. Treatment groups were defined by whether the patient received joint-invasive surgery (posterior or posteromedial release surgery) or joint-sparing treatment only (manipulation and casting with or without tendo-Achilles lengthening or anterior tibial tendon transfer). The DSI scales demonstrated internal consistency reliability of 0.74 to 0.85 using Cronbach's alpha. Higher (better) DSI scores were associated with "excellent" general health ratings and better health-related quality of life; lower DSI score were related to special healthcare needs.

Patients treated using joint-sparing techniques only (eg, Ponseti technique) had higher DSI scores than those who had received joint-invasive surgery. DSI scores for patients who had received posterior or posterior medial release surgery were very similar to those reported by Roye et al. in New York for a comparable group of patients. Our findings suggest the DSI is sensitive to differences in treatment technique or underlying severity of disease. These data support the use of the Roye DSI as an outcome measure for idiopathic clubfoot in children.

Level of Evidence: Level III, diagnostic study. See the Guidelines for Authors for a complete description of levels of evidence.

Introduction

Appropriate outcome measures are required to determine the outcomes of clubfoot treatment and compare different treatment techniques. The vast majority of the clubfoot treatment "outcome" literature consists of short-term followup studies that use measures that are, at best, surrogates for lifelong good foot function. These include rating schemes that combine various physical findings/radiographs/symptoms such as pain, walking distance, degrees of dorsiflexion, anteroposterior and later talocalcaneal angles, satisfaction with outcome, and so on [5–9, 13, 19].

However, these schemes are not validated and categorical determinations of good versus poor scores are arbitrarily set. The most commonly used rating scheme [7] combines points for "satisfaction," "function," "pain," "position of heel when standing," "passive motion," and "gait." The points are added together and 90 to 100 points is arbitrarily assigned "excellent," 80–89 is "good," 70–79 is fair, and below 70 is poor. Validated general quality-of-life outcome

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Each author certifies that his or her institution has approved the human protocol for this investigation, that all investigations were conducted in conformity with ethical principles of research, and that informed consent for participation in the study was obtained.

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Table 1. Disease-specific instrument for patients with clubfoot developed by Roye et al. [11] (2001)

Item	Response codes
(1) How satisfied are you with the status of your child's foot?	1 = very satisfied, 2 = somewhat satisfied, 3 = somewhat dissatisfied, 4 = very dissatisfied
(2) How satisfied are you with the appearance of your child's foot?	1 = very satisfied, 2 = somewhat satisfied, 3 = somewhat dissatisfied, 4 = very dissatisfied
(3) How often is your child teased because of his or her clubfoot?	1 = never, 2 = sometimes, 3 = usually, 4 = always
(4) How often does your child have problems finding shoes that fit?	1 = never, 2 = sometimes, 3 = usually, 4 = always
(5) How often does your child have problems finding shoes that he or she likes?	1 = never, 2 = sometimes, 3 = usually, 4 = always
(6) Does your child ever complain of pain in his or her [affected] foot?	1 = yes, 2 = no; recoded 1 = no, 4 = yes
(7) How limited is your child in his or her ability to walk?	1 = not at all limited, 2 = somewhat limited, 3 = moderately limited, 4 = very limited
(8) How limited is your child in his or her ability to run?	1 = not at all limited, 2 = somewhat limited, 3 = moderately limited, 4 = very limited
(9) How often does your child complain of pain during heavy exercise?	1 = never, 2 = sometimes, 3 = usually, 4 = always
(10) How often does your child complain of pain during moderate exercise?	1 = never, 2 = sometimes, 3 = usually, 4 = always

instruments may not be able to discriminate differences in mildly impaired individuals (eg, ceiling effects observed for FSII-R in patients with clubfoot) [11] and may not ask the most important questions concerning outcomes of a specific disorder.

In 2001, Roye et al. [11] developed, validated, and tested a simple disease-specific instrument (DSI) for outcomes of clubfoot treatment (Table 1). The resulting clubfoot DSI consists of 10 items designed to measure treatment outcomes regarding overall satisfaction, appearance, pain, and physical limitations. They demonstrated the scale could be used as an overall measure of clubfoot treatment outcomes with two distinct subscales: function and satisfaction. The published results established preliminary expected scores for patients who had received posterior-medial release (PMR) surgery. However, all had been treated by the same surgeon, and none had been treated solely by joint-sparing methods, leaving the question of whether the DSI would be sensitive to differences in treatment approach, surgeon, or other patient or clinical characteristics.

We therefore asked: (1) Are DSI scores associated with general indicators of children's overall health and well-being? We employed the mother's assessment of the child's overall health and functioning; meeting special healthcare needs criteria; and health-related quality of life as measured by the PedsQL 4.0TM [11] to assess health and well-being. (2) Can DSI scores differentiate between patients whose treatment included joint-invasive surgery and those who received joint-sparing treatment only? (3) Do children treated by posterior or posterior-medial release surgery by different surgeons at different hospitals receive similar DSI scores?

Materials and Methods

We used the DSI with a clinic-based sample of 66 children ages 5 to 12 who had undergone either surgical (posterior release [PR], PMR) or noninvasive (manipulation and casting, with or without tendo-Achilles lengthening [TAL] or anterior tibial tendon transfer [ATT]) treatment for clubfoot during infancy or early childhood. Potential subjects were identified through patient records and were deemed eligible based on diagnosis of idiopathic clubfoot, current age (5–12 years), and current residence in Iowa with biologic mother. Patients ranged in age from 5 to 12 years at the time of the interview with a mean age of 8.6 years. Four patients who were eligible did not participate and had the following characteristics: the mean age was 10.1 years; two were male; three had bilateral clubfoot; two had joint-sparing treatment; and one was seen before 3 months of age. This left 62 patients (92 clubfeet) for study. Data for this study were obtained through retrospective telephone interviews conducted between July and October 2003 with mothers of the 62. Patients were treated as infants with various methods (Table 2) and ranged from newborn to 7.3 years of age at the time they were evaluated. Twenty-seven of the patients (43.5%) were treated by 3 months of age. Because the University of Iowa Hospitals and Clinics (UIHC) is a referral center for clubfoot treatment, 45 of the 62 patients in this cohort were not primarily treated at our hospital.

Treatment groups were defined by whether the child's clubfoot was treated with joint-invasive surgery or joint-sparing techniques only. The joint-sparing group comprised 41 patients whose clubfoot condition was treated by manipulation and casting either with or without TAL or

Table 2. Referral characteristics of the Iowa patients with clubfoot by treatment method (N = 62)

Reason seen at University of Iowa Hospitals and Clinics	Joint-sparing (n = 41)	Joint-invasive (n = 21)	Total (N = 62)	Age (range) in months at presentation to Iowa
Seen at Iowa at before 3 months of age	24 (58.5)	3 (14.3)	27 (43.5)	≤ 3
Referred for recurrent deformity after manipulation and casting	7 (17.1)	5 (23.8)	12 (19.4)	20 (5–69)
Referred for failure to correct with manipulation and casting	3 (7.3)	4 (19.1)	7 (11.3)	6 (4–14)
Referred for recurrent deformity after posterior-medial release	0	4 (19.1)	4 (6.5)	33 (28–36)
Referral for second opinion in well-corrected feet	3 (7.3)	0 (0)	3 (4.8)	23 (3–54)
Referral to establish care as a result of relocation	4 (9.8)	5 (23.8)	9 (14.5)	52 (17–95)

Table 3. Characteristics of University of Iowa patients with clubfoot by treatment method

Characteristic	Joint-sparing (n = 41)	Joint-invasive (n = 21)	Total (N = 62)	Significance
Percent female	24.4%	27.3%	24.7%	0.722
Mean child age (standard deviation)	7.8 (2.3)	8.5 (2.2)	8.0 (2.2)	0.2291
Percent mother currently married or in marriage-like relationship	92.5%	95.2%	93.4%	0.171
Family income*				0.8550
\$0–20,000	2.8%	10.5%	4.2%	
\$20,000–\$39,999	25.0%	10.5%	22.2%	
\$40,000–\$59,999	27.8%	42.1%	29.2%	
\$60,000–\$79,999	22.2%	15.8%	19.4%	
\$80,000 or higher	22.2%	21.1%	25.0%	
Mother rates child's overall health "excellent"	70.7%	71.4%	71.0%	0.954
Special Health Care Need (CYSHCN)	14.6%	33.3%	21.0%	0.087

* Reduced sample size as a result of item nonresponse: joint-sparing group n = 36, posterior release/posterior-medial release group n = 19.

ATT. In this group, 24 were treated using the Ponseti method [10], whereas the other 17 were treated by other local orthopaedic surgeons who may or may not have trained in the Ponseti method. The joint-invasive treatment group consisted of 21 children who had undergone clubfoot surgery involving joint capsulotomy. Of these, nine were treated by PR surgery and 12 by PMR. Nine had undergone surgery at UIHC, whereas 12 had undergone surgery elsewhere. Two patients with bilateral clubfoot who received PR or PMR surgery on only one foot are included in this group.

All patients in the study were white, $\frac{3}{4}$ were male, and most were currently living in two-parent households (Table 3). The mothers' ratings of the child's health ranged from "good" to "excellent" with 70% excellent. These ratings were nearly identical for the two groups. Twenty-one percent of the sample met the screening definition for special healthcare needs. More ($p = 0.08$) of the patients in the invasive group were classified as having special healthcare needs compared to those in the joint-sparing group (33% versus 15%, respectively).

The primary dependent variables were the child's scores on the total, function, and satisfaction DSI scales. The 10-

item clubfoot DSI is an overall measure of clubfoot treatment outcomes with two distinct five-item subscales: satisfaction and function. The satisfaction subscale items are (1) satisfaction with status of foot; (2) satisfaction with appearance of foot; (3) teasing; (4) problems with shoes fitting; and (5) problems finding shoes the child likes. The function subscale consists of (1) whether the child ever complains of foot pain; (2) limitations in walking; (3) limitations in running; (4) pain during heavy exercise; and (5) pain during moderate exercise. The total score includes all 10 items. Scores are computed by reverse-coding, summing the responses, and then dividing the result by the number of items completed, ie, scores are a mean of the responses (Table 1). For ease of interpretation, the scores are linearly transformed to a 0 to 100 scale with 100 being best, so that 1 = 0, 2 = 33.3, 3 = 66.7, and 4 = 100 for questions with four possible answers. The one yes-or-no item (ever complains of pain in affected foot) was coded yes = 0 or no = 100. Cronbach's alpha for internal consistency reliability was 0.85 for the total DSI scale, 0.78 for the function subscale, and 0.74 for the satisfaction subscale.

The DSI's validity was assessed by examining its relationships with scores on the Pediatric Quality of Life

Inventory™ (PedsQL™ 4.0) [15–18, 20] and with two global measures of health status. The Global Health Rating [15] is the mother's response to a single item: "Overall, how would you rate your child's health now? Would you say it is excellent, very good, good, fair or poor?" Because 71% of the children in our sample were rated in "excellent" health with 24% "very good" and 5% "good" (none were rated fair or poor), we dichotomized this variable to excellent = 1 versus good or very good = 0. The 13-item screener for Children or Youth with Special Health Care Needs (CYSHCN) [2] identifies children "who have or are at increased risk for a chronic physical, development, behavioral, or emotional condition and who also require health and related services of a type or amount beyond that required by children generally" [1]. The child is defined as having special healthcare needs if responses to the screening items reveal he or she has a medical, behavioral, or other health condition that has lasted or is expected to last at least 12 months and has resulted in any of the following: (1) need for prescription medication; (2) need for more educational, medical, or mental health services than expected for his or her age; (3) need for specialized therapy; (4) functional limitations; or (5) needing treatment or counseling for a behavioral, emotional, or developmental problem [1, 4]. Twenty-one percent of the children in the UIHC cohort met this definition.

In addition to the telephone interview, 37 of the 62 mothers (60%) completed and returned the written generic PedsQL™ 4.0 [4], a brief questionnaire measuring health-related quality of life with subscales addressing physical, emotional, social, and school functioning. A total psychosocial scale score integrates the emotional, social, and school domains. The reliability and validity of the PedsQL™ have been established through an extensive research program, including a number of comparison studies of children with acute and chronic illnesses (eg, Type I diabetes mellitus, cancer, asthma, arthritis) and groups of healthy children [14, 16–18, 20].

The secondary group variable is clinic population. As a referent for our DSI results, the authors of the DSI provided us with summary DSI statistics (means and standard deviations) from their sample of 46 patients treated by PMR [11]. At the time of their evaluation, these 46 patients were of the same age as those in our sample, ranging from 5 to 12 years with an average of 8.6 years. We compared these DSI scores with those of our treatment group of 21 patients whose clubfoot had been treated using PR or PMR.

Differences between the UIHC joint-sparing and joint-invasive treatment groups with regard to child's gender, mother's marital status, child's global health rating (per mother), and child's special healthcare needs status were tested using Pearson's chi square. Differences between these two groups in family income level were determined

using the Wilcoxon rank sum test for ordinal variables. Spearman's rank order correlation coefficients were calculated to assess relationships between DSI and PedsQL™4.0 scores in the 37 cases for which both measures were available. This statistic was used to minimize possible effects of outliers. Differences in mean DSI scores between the UIHC joint-sparing and joint-invasive treatment groups were determined using t-tests for two independent samples using pooled variance estimates and two-tailed significance levels. Differences in DSI scores between the joint-invasive treatment group seen at UIHC and patients treated with PMR and described by Roye et al. [11] were determined using the same method. We assume DSI scores are normally distributed in the population of patients with clubfoot. The assumption of homogeneity of variance was met for each test. Although the distributions of DSI scores were nonnormal in this sample, the t-test is robust to departures from normality.

Power analyses (significance = $p < 0.05$, beta error < 20%) were conducted post hoc for each test of treatment group differences in mean DSI scores and are reported with results along with estimates of effect size using Cohen's *d*. All data were compiled and all analyses conducted with Stata Version 10.

Results

DSI scores were associated with the three health-related measures used in this study. Children rated by their mothers as in "excellent" health had higher scores on the total, function, and satisfaction DSI scales than those in "good or very good" health (Table 4). Those meeting population criteria as a child with special healthcare needs had lower scores on the total ($p = 0.0063$) and function ($p = 0.0008$) than those who did not (Table 5). Pearson's correlation coefficients indicated each of the three DSI scores had a positive linear relationship with the total, physical health, and psychosocial health scales of the PedsQL 4.0 (Table 6). Higher DSI scores (indicating better function and satisfaction) were associated with higher levels of physical, psychosocial, and general health-related quality of life.

DSI scores differentiated between patients whose treatment included joint-invasive surgery and patients who received joint-sparing treatment only for the total and function scores, but not the satisfaction score. Within the UIHC clinical sample, patients treated using joint-sparing techniques only had higher scores than patients who received joint-invasive surgery on the total (85.2 versus 75.1, $p = 0.040$) and function (87.2 versus 75.6, $p = 0.040$) DSI scales, but not on the satisfaction scale (Table 7).

Table 4. Disease-specific instrument (DSI) scores by global health rating, good or very good versus excellent, means and (standard deviations)*

DSI score	Good or very good (n = 18)	Excellent (n = 44)	Significance	Power
Total DSI score	72.7 (21.8)	85.5 (15.7)	0.0118	0.6201
Function subscale	73.0 (27.7)	87.5 (16.6)	0.0139	0.5426
Satisfaction subscale	72.3 (20.5)	83.5 (17.8)	0.0356	0.5257

* T-test for two independent samples, pooled variance, two-tailed significance.

Table 5. Disease-specific instrument (DSI) scores by special healthcare need status, non-CYSHCN versus CYSHCN, means and (standard deviations)*

DSI score	Non-CYSHCN (n = 49)	CYSHCN (n = 13)	Significance	Power
Total DSI score	85.0 (17.2)	69.6 (18.3)	0.0063	0.7790
Function subscale	87.8 (18.0)	66.2 (24.4)	0.0008	0.8440
Satisfaction subscale	82.2 (19.1)	72.9 (18.1)	0.1215	0.3667

* T-test for two independent samples, pooled variance, two-tailed significance; CYSHCN = Children or Youth with Special Health Care Needs.

Table 6. PedsQL[®] 4.0 descriptive statistics and Spearman rank order correlations with disease-specific instrument (DSI; N = 37)*

Statistical characteristics	PedsQL total	PedsQL physical health	PedsQL psychosocial
Mean	80.4	83.1	78.9
Standard deviation	(18.2)	(20.3)	(18.4)
Skewness	-1.22	-1.40	-0.96
Minimum, maximum	18.5, 100	12.5, 100	21.7, 100
Correlation with [†]			
DSI total score	0.63 (0.0004)	0.71 (0.0000)	0.55 (0.0063)
Function subscale	0.68 (0.0000)	0.75 (0.0000)	0.61 (0.0011)
Satisfaction subscale	0.55 (0.0068)	0.62 (0.0008)	0.48 (0.0425)

* Reduced sample size as a result of lower response rate for the written portion of the survey; [†]p value in parentheses.

Table 7. Disease-specific instrument (DSI) scores by treatment group, joint-sparing versus joint-invasive, University of Iowa sample, means and standard deviations*

DSI score	Joint-sparing (n = 41)	Joint-invasive (n = 21)	Significance	Power	Effect size (Cohen's d)
Total DSI score	85.1 (17.5)	75.0 (18.7)	0.040	0.5385	0.56
Function subscale	87.2 (18.6)	75.6 (24.3)	0.040	0.4835	0.56
Satisfaction subscale	83.1 (19.6)	74.5 (17.4)	0.100	0.4221	0.45

* T-test for two independent samples, pooled variance, two-tailed significance.

Children treated by PR or PMR surgery by different surgeons at different hospitals received similar DSI scores. Total and function DSI scores for the 21 children in the UIHC sample who had undergone PR or PMR surgery were similar to those reported by Roye et al. [11] for their cohort of 46 PMR patients (Table 8) with the exception of the DSI satisfaction score, which was higher ($p = 0.012$) in the UIHC group (74.6 versus 63.8, respectively).

Discussion

We evaluated the DSI developed by Roye et al. [11] to measure outcomes of treatment for idiopathic clubfoot in a cohort of 62 clinic patients with this diagnosis. Our research questions were: (1) Are DSI scores related to measures of general health status and quality of life? (2) Do children who have undergone PR or PMR clubfoot surgery

Table 8. Disease-specific instrument (DSI) scores for patients treated by PR or PMR, by clinic population, UIHC versus New York samples, means and (standard deviations)*

DSI scores	Iowa joint-invasive (PR or PMR) (n = 21)	New York Roye et al. [11] PMR (n = 46)	Significance	Power	Effect size (Cohen's d)
Total score	75.1 (18.7)	68.6 (14.9)	0.131	0.2890	0.384
Function subscale	75.6 (24.3)	76.3 (12.3)	0.856	0.0518	-0.036
Satisfaction subscale	74.6 (17.4)	63.8 (15.2)	0.012	0.6878	0.661

* T-test for two independent samples, pooled variance, two-tailed significance; PR = posterior release; PMR = posterior-medial release.

performed by different surgeons in different facilities have similar outcomes on the DSI scales? (3) Do DSI scores differentiate patients who received only joint-sparing treatment from those whose treatment included joint-invasive surgery?

This study has several limitations. Although we were able to establish that the joint-invasive and joint-sparing treatment groups within the UIHC cohort were comparable with regard to some key demographic variables and health status measures, data necessary to control for such clinical factors as initial severity of the child's condition were not available for analysis. No generally accepted or validated rating scheme for initial clubfoot severity exists. Since the Ponseti technique results in nearly universal initial correction of all clubfeet we have considered severity rating a moot point and have not performed any initial rating. The most commonly used rating scheme (the score of Pirani et al.) correlates with the number of casts required for correction and the need for tenotomy when the Ponseti technique is used [3, 12]. No rating scheme has been used to distinguish between feet requiring joint invasive surgery and those not requiring such surgery. Nonetheless, we are unable to determine to what degree the differences in DSI scores between patients undergoing joint-invasive versus joint-sparing treatments are attributable to treatment technique or to underlying patient differences. We also cannot be certain all patients who did not have joint-invasive treatment were treated strictly by the Ponseti method, hence our use of the more general term "joint-sparing" instead of "Ponseti" method of treatment. Therefore, no conclusion concerning Ponseti versus PMR-type treatment for clubfoot can be drawn from this study. We do not know if the differences in scores found are clinically important. Estimates of effect size (Cohen's d) suggest some of them may be, but further evaluation is needed. The young age of this patient population may be another limitation, because identifying the optimal treatment for congenital deformities is difficult as a result of the long time between treatment and the potential onset of subsequent symptoms. Long-term followup case series studies have been the gold standard in assessing natural history of orthopaedic disorders. Despite the immense literature on clubfoot treatment, there are few

long-term followup studies and fewer still that compare different treatment techniques. Although there is no substitute for long-term followup studies, appropriate assessment of short-term and intermediate results may help determine best treatment in a timely fashion. Furthermore, it is also important to identify techniques that tend to produce better or worse short-term results. A better functioning foot throughout childhood is certainly of value, even if the long-term results are not documented. Although item non-response was minimal, only 60% of those who completed the phone interview returned the written PedsQLTM4.0. Correlations between PedsQLTM4.0 and DSI scales represent only these 37 cases. However, chi square tests indicated no differences between those who did and did not complete the PedsQLTM4.0 with regard to treatment group, gender of the child, age of the child, family income, or mother's marital status. We were not able to control for several important variables, including an accurate measure of initial severity of the clubfoot condition, which may differ by treatment group. We did compare the UIHC joint-sparing and joint-invasive treatment groups on general demographics and current health status, however, and found no differences with regard to child's gender or age, mother's marital status, family income, or health status rating. The joint-invasive treatment group did have a higher proportion of children meeting special healthcare needs criteria (33% versus 15%, $p = 0.087$).

We found the Roye DSI performed well in assessing clubfoot treatment outcomes in midchildhood in our clinic-based sample. Cronbach's alpha coefficients published by Roye et al. [13] and those in our study indicate the DSI is internally consistent in two very different populations of patients with clubfoot. Our data provide evidence of the DSI's construct validity in its associations with scores on the PedsQLTM 4.0TM, mother's rating of the child's current health status, and whether the child meets population screening criteria as a Child with Special Health Care Needs. Furthermore, DSI scores discriminated, even at a very early age, between feet undergoing different treatment regimens. The similarity between the DSI scores for patients undergoing PMR or PR at UIHC and those reported by Roye et al. [11] is reassuring in that the DSI

shows nearly identical outcomes of one treatment technique provided by several different surgeons.

Our study supports the use of the Royce DSI as an outcome measure for idiopathic clubfoot in young children by providing evidence of its reliability, validity, and discriminatory power. That the total and function DSI results for the PMR/PR patients at the University of Iowa were so similar to the results reported by Royce et al. [11] provides evidence that the DSI is able to distinguish between the two treatment approaches themselves rather than the clinical setting or specific surgeons. The study also supports the use of the Ponseti technique for the treatment of clubfoot. Nonetheless, further study of the DSI, including test-retest reliability, comparisons with other validated scales, and tests with patients of different ages, must be performed before the true value of this DSI as a measure of clubfoot outcome is ascertained.

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