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 Original Research Article

 2
 ASSESSING CLUBFOOT SEVERITY AND MONITORING TREATMENT PROGRESS USING THE

 4
 PIRANI SCORING SYSTEM

 5
 ABSTRACT (ARIAL, BOLD, 11 FONT, LEFT ALIGNED, CAPS)

 6
 Background: Pirani scoring system is one of the classification systems and is simple, easy to use

in management of clubfoot; however, there is paucity of study using Pirani system to determine the severity and progress in the treatment of clubfoot. We therefore set out with the aim of assessing severity and monitoring the progress of treatment using the Pirani scoring system. The study was conducted at the Department of Orthopaedics and Traumatology of Obafemi Awolowo University Teaching Hospitals Complex, Ile Ife between January 2011 and June 2015. Methodology: It was a prospective study of 102 clubfeet in 61 patients who are less than 3 years of age, and born with idiopathic congenital talipes equinovarus,. Thereafter, corrective serial casts were applied after initial manipulations using Ponseti method. Variables of interest such as the biodata, midfoot score, hindfoot score, Pirani score, need for tenotomy and the number of casts to achieve correction were measured. The data obtained were subjected to statistical analysis using SPSS version 22. Significant statistical inferences were drawn at p<0.05. Results: The correlation between the midfoot score, hindfoot score, Pirani score and the number of cast to achieve correction was significant (p<0.001). Also, there was correlation between the Pirani score and the need for tenotomy (p<0.001) and between the number of cast to achieve correction and the need for tenotomy (p<0.001). Moreover, the progress of treatment can be monitored with the Pirani score (p<0.001)

Conclusion: Pirani scoring system is a simple and reliable system to determine severity and

monitor progress in treatment of clubfoot.

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Keywords: clubfoot, Pirani score, Ponseti method,

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## 11 **1. INTRODUCTION**

12 Congenital Idiopathic Talipes Equinovarus (CTEV) is a common congenital orthopaedic

- 13 condition. According to Gray K et al., it is characterised by an excessively turned in foot and
- 14 high medial longitudinal arch[1].
- 15 This entity is not just an isolated foot deformity but a complex, three-dimensional deformity of
- 16 the foot with four components which are equinus, varus, adductus and cavus deformities. The
- 17 calcaneus, navicular and cuboid bones are rotated medially in relation to talus, and they are
- 18 held in adduction and inversion by the surrounding ligaments and tendons. "Although the foot is
- 19 supinated, the front of the foot is pronated in relation to back of the foot, causing cavus. In
- addition, the first metatarsal is more plantar flexed" [2].

21 The right foot being affected slightly more often than the left. It is 2-2.5 times more common in

- males than females, regardless of the population studied [2].
- 23 There may also be development of secondary Genu recurvatum if not corrected early [3].
- 24 Clubfoot presents in two forms: "syndromic", in which other malformations exist, and the more

common "idiopathic" form, where there are no other associated malformations[4].

- Globally, approximately one in one thousand people are born with at least one clubfoot; this
- 27 incidence rate is fairly constant, with higher and lower incidences in specific ethnic groups.
- Between 150,000 and 200,000 babies are born with a clubfoot each year giving a rate of one
- 29 infant born with clubfoot every 3 minutes. Eighty percent of infants with clubfoot live in
- developing countries[5] and 3.4/1000 live births incidence was reported in Nigeria[6].

31 The Ponseti method involves stretching of the deformity in synchronized technique followed by 32 application of a long-leg cast. The standard Ponseti protocol uses weekly above knee plaster cast combined with specific manipulation techniques to correct the deformities. All components 33 of the deformity usually correct within 4 to 5 weeks with the exception of the equinus which is 34 35 corrected completely with percutaneous tendo-achilles tenotomy followed by a final plaster cast for three weeks[7]. Once plastering is finished, children are placed in a foot-abduction brace. 36 The Ponseti technique is well established and has been shown to be highly effective[8]. 37 Initial correction of the clubfoot deformity has been achieved in 95% of patients with use of 38 Ponseti method[9]. 39 "The goal of clubfoot management is to provide long term correction of the deformity resulting in 40 a foot that is fully functional, pain-free"[10] and without calluses and the patient is able to put on 41 normal shoes[11]. 42 Clubfoot has been classified into mild, moderate and severe but is too subjective. 43 There are different classification systems used to determine the severity and outcome of 44 treatment for clubfoot among which are Dimeglio/Bensahel classification system[12,13], 45 Catteral/Pirani classification system[14], Ponseti and Smoley classification system[14,15], 46 47 Harrold and Walker classification system [16] and the International Clubfoot Study Group [13]. Of these systems, the commonly used ones are the Dimeglio/Bensahel and the Catteral/Pirani 48 systems[14]. 49 50 The Pirani system, devised by Shafiq Pirani, MD, of Vancouver, has six categories; three in the 51 mid-foot and three in the hind-foot. The mid-foot categories are curvature of the lateral border of the foot (CLB), medial crease 52 (MC), uncovering of the lateral head of talus (LHT). The hind-foot categories are posterior 53 54 crease (PC), emptiness of the heel (EH), and degree of dorsi-flexion (DF)[17,18]. Each category 55 can have three scores depending on the severity which are 0, 0.5 and 1. The best possible

56 score for a normal foot is 0 and the worse is 6. Pirani et al. system had been validated and proven reliable to accurately quantify the severity of a clubfoot deformity. This system is now 57 routinely used in describing the outcomes of treatment[19]. This study is aimed at assessing the 58 severity and progress of clubfoot treatment using Pirani score. Outcome of this study will help in 59 predicting the probable patients that will benefit from tenotomy, and also assist in estimating 60 number of casting session that may be required. This in turn will assist the parent /caregiver to 61 prepare both psychologically and financially for the treatment which may help in reducing the 62 rate of dropout during treatment. 63

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#### 65 2. METHODOLOGY

It was a hospital based prospective study designed to predict the severity and monitor progress 67 of treatment of clubfoot using the Pirani classification system. Consecutive patients presenting 68 69 at the outpatient clubfoot clinic of Obafemi Awolowo University Teaching Hospitals Complex. Ile 70 If e with idiopathic clubfoot, in patients who are less than 3 years old, were recruited into the 71 study. Ethical approval was obtained from the institution ethics and research committee. An 72 informed consent was obtained from the parent/guardian. Patient's bio-data, clinical 73 examination and Pirani score at presentation was entered into a structured information sheet. 74 Corrective serial casts were applied after carrying out manipulations for three minutes according to the Ponseti method. 75

76 The ligaments, joint capsules and tendons were stretched with gentle manipulations. A plaster

cast (above knee cast) with knee in 90 degree flexion was applied after each session to retain

the degree of correction obtained and to soften the ligaments.

79 Thereby, the displaced bones were gradually brought into the correct alignment.

80 Treatment was started as soon as referral was received. After achieving correction of the

81 deformity, foot abduction brace was instituted to retain the correction. Patients were made to

wear the brace for about 23 hours a day for the first 3 months after achieving correction and

thereafter the braces are worn at nights. The Pirani scores of the patients were monitored

84 throughout the treatment period.

Severity in this study was determined based on the number of casting sessions and need for tenotomy as shown below [20]. Mild cases according to this table had less than or equal to 5 casting sessions without tenotomy; moderate cases had more than 5 casting sessions without tenotomy or less than or equal to 5 casting sessions with tenotomy while severe cases had more than 5 casting sessions with tenotomy.

#### 90 **Table 1: Severity of Categories**

Severity of Clubfoot	No of casting sessions	Need for Tenotomy
Mild	< 5	No tenotomy
Moderate	>5	No tenotomy
	≤ 5	Had tenotomy
Severe	>5	Had tenotomy

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All analyses were performed on the basis of the intention-to-treat cohort, defined as all clubfoot
patients who received at least one form of clubfoot treatment.

95 The Data that were collected included the name, age, sex, initial Pirani scores, number of

casting sessions, the need for tenotomy and Pirani score at full correction. Data collected from

97 the study groups was entered into a worksheet and analysis was performed using the statistical

98 package for social sciences (SPSS; IBM; Chicago, Illinois) software for windows version 22.

99 Frequency distribution for the variables were presented in tables and charts and significant

100 statistical deductions were made at p<0.05. Analysis of Variance (ANOVA) was also used to

101 compare mean in various severity groups in order to know which component of the score best

102 predicts severity.

### 103 3. RESULTS AND DISCUSSION

103	Sixty one patients comprising of thirty eight males (62.3%) and twenty three females (37.7%)
105	with sex ratio of 1.7:1 were recruited. Twelve weeks was the median age (range: 0.6 -134
106	weeks), twenty two patients (36.1 %) were neonates, thirty one (50.8%) were infants while the
107	remaining eight patients (13.1%) were above one year at presentation. Forty one patients
108	(67.2%) had bilateral clubfoot (82 feet) while twenty (32.8%) had unilateral clubfoot (20 feet).
109	Among the twenty unilateral clubfoot, ten patients (16.4%) were left sided while the remaining
110	ten (16.4%) were right sided. The numbers of clubfeet managed in these sixty one patients were
111	102. Sixty seven feet (65.7%) had tenotomy while thirty five (34.3%) feet did not have tenotomy.
112	The mean number of casting sessions was 5.1+/- 2.2. Nineteen feet (18.6%) had more than 6
113	casting sessions. The mean of the midfoot score, hindfoot score and the Pirani score at
114	presentation are as shown in table 2 below.

- 115
- 116 Table 2: Number of casts to achieve correction, the midfoot scores, the hindfoot scores

### 117 and the Pirani scores of the 102 feet examined.

Variables	Mean	Standard deviation
Number of cast to achieve	5.07	2.23
correction		
Midfoot score at presentation	2.36	.60
Hindfoot score at	2.39	.62
presentation		
Pirani score at presentation	4.75	.11

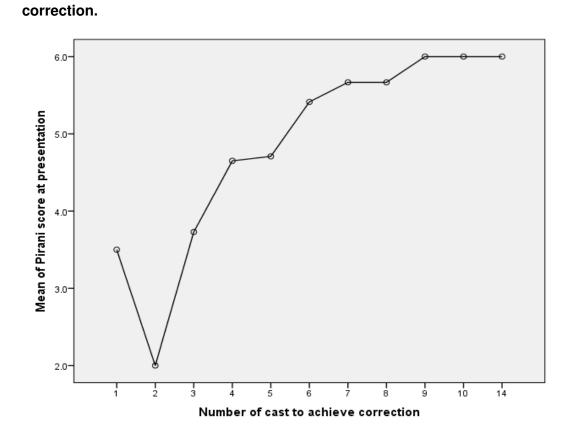
- 119 The mean Pirani score at presentation for feet that eventually had tenotomy done was 5.1 +/-
- 120 1.0 while that for the feet that did not have tenotomy done was 4.2 +/-1.1 There was a

121 statistically significant difference in the mean Pirani scores at presentation of those who had

122 tenotomy and those who did not have. (t-test= 9.24; df=1; p=<0.001; 95% C.I.=1.112-1.722).

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Figure 1: Graph depicting the Pirani score at presentation and number of cast to achievecorrection.



There was a significant statistical association using ANOVA between the Pirani, midfoot and hindfoot scores at presentation and the eventual number of casting sessions patients had p<0.001. The table below further explain the results.

Table 3: Number of casts to achieve correction versus the midfoot, hindfoot and thePirani scores

Categor	Variables	Ν	Mean	SD	TEST OF	P value
ies			no of		STAT	<
			cast		SIGNIFICANC	
					E(DF)	
Midfoot	Mild	27	3.48	0.80	F=18.62	.001
		21	0.40	0.00	1 = 10.02	
score	clubfoot					
	Moderate	42	4.29	1.40		
	clubfoot					
	Severe	33	7.36	2.07		
Hindfoo	Mild	27	3.48	0.80	F=18.62	.001
t score	Moderate	42	4.29	1.40		
	Severe	33	7.36	2.07		
Pirani	Mild	27	3.48	0.80	F=18.62	.001
score	Moderate	42	4.29	1.40	-1	
	Severe	33	7.36	2.07	_	

In order to assess for the statistical significance of whether the Pirani score can be used to monitor the progress of treatment of clubfoot using Ponseti protocol, paired T test was used to compare the Pirani score at presentation and Pirani score at full correction on one hand and the Pirani score at presentation and the score whether or not the patient had tenotomy was found to be statistically significant which means that the progress of treatment of clubfoot and whether or not the patient will need tenotomy can be assessed using the Pirani scoring system (P<0.001).

## 127 Table 4: Correlation between the Pirani scores at presentation versus at correction in one

Categories	Variables	Ν	Mean	SD	P value
					<
Pirani	At	102	4.750	1.105	.001
score	Presentati				
	on				
	At full	102	0.177	0.315	
	correction				
Pirani	Had	67	5.060	0.177	.001
score	tenoomy				
	Did not	35	4.157	1.149	
	have				
	tenoomy				

## 128 hand and versus the need for tenotomy.

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133	Tables 5: Severity of clubfoot versus mean Pirani score.
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Categories	Variable	Ν	Mean	SD	TEST OF	P value
	s		of		STAT	<
			initial		SIGNIFICANC	
			Pirani		E(DF)	
			score			
Pirani score	Mild	27	3.80	1.02	F=9.10	.001
	Moderat	42	4.67	0.98	-	
	е					
	Severe	33	5.64	0.44	-	
Number of	Mild	27	3.48	0.80	F= 18.62	.001
cast	Moderat	42	4.29	1.40		
	е					
	Severe	33	7.36	2.07		

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### 135 Discussion.

This study revealed that the age range of the patients studied was 0.6 to 134 weeks with 136 median age of 12weeks. This is rather late when compared with figures obtained by workers 137 138 in developed world such as Zimmerman et al. in 2015 who recorded median age of 52 days at tenotomy among 36 subjects[21]; Brewster et al. in 2012 recorded mean age of 4.5 weeks 139 among 51 clubfooted patients[22]. This age disparity at tenotomy was also noted by 140 141 Adegbehingbe et al. in 2015 with median age of 5.2 months among 79 patients [23] and Goksan et al. in 2015 with mean age of 44.62 months among 153 patients [24]. Late presentation as 142 seen in our study may be because most of our patients pay out of pocket to access treatment 143

144 hence, it may take a while for the parents to raise sufficient fund for the treatment. Also, there 145 are not enough trained personnel to manage clubfoot deformity in the developing countries hence, patients might have to travel several hundred kilometres to access treatment, hence the 146 147 late presentation. There was male preponderance with male to female ratio of 1.7:1, this is 148 similar to the one recorded by Lavy et al. in Malawi in 2007[25]; Pavone et al. in 2012 recorded ratio of 2:1<sup>4</sup> and Ford-Powell et al. in 2013 had a ratio of 2.7:1[26]. 149 Among the 61 patients studied, 67.2% of the patients have bilateral clubfoot, while the 150 remaining 32.8% are unilateral with equal distribution between the left and the right. This is 151 similar to the result gotten by Awang et al. in Malaysia in 2014[27]. However, this was in 152 contrast to the preponderance of unilateral clubfoot as documented by Ponseti, Matuszewski 153 and Adewole et al. in their studies at different point in time [15,28,29]. 154 155 Out of the 102 feet that had Ponseti treatment, 65.7% of them had tenotomy while 34.3% did 156 not have tenotomy. Lebel et al. in their study on 56 babies in 2012; 73% of them had percutaneous tenotomy [30]; of the two groups studied by Xu in Beijing, China in 2011, 87.5% of 157 each of them had tenotomy [31]. In contrast to this, Tindall et al. in their study done in Blantyre, 158 159 Malawi in 2005, 57 of the 98 feet corrected using the Ponseti treatment protocol did not require 160 tenotomy.

161 The mean number of casting sessions for the affected feet was  $5.1 \pm 2.2$ . Pulak et al. in Ethiopia 2012 found average number of casting sessions of 4.9[32]. Awang et al. had an average of 5.2 162 163 casting sessions[27] and Laaveg et al. in 1980 in USA had mean number of casts of 7[33]. This is an interesting finding because despite the late presentation in our setting, we still have a 164 comparable casting session with workers in other parts of the world where patients presents 165 earlier. The implication of this may be the fact that outcome of clubfoot treatment may not be 166 significantly affected by age of presentation as long as the patient is infant. This may need 167 168 further research. The average Pirani score for the feet that had tenotomy was 5.1±1.0 which

was higher than 4.2±1.1 for the feet that did not have tenotomy. This was similar to the average Pirani score gotten by Dyer et al. in their study on the role of the Pirani scoring system in the management of club foot by the Ponseti method done in 2006. In the study, the average Pirani score for tenotomy group was 4.96 and for the group without tenotomy was 4[18]. This proves that severe clubfoot( as predicted by higher Pirani score) may need tenotomy hence both the managing team and the parents of the patient may be better prepared.

Comparing the initial midfoot scores, hindfoot scores, Pirani scores and the number of casts 175 176 needed to achieve correction, the correlation between the parameters was significant, this implies that the higher the midfoot, hindfoot and Pirani scores, the more the number of casting 177 178 sessions needed by the patient to achieve correction. Since the Pirani score is made up of the 179 summation of mid and hind foot scores, this observed positive correlation which is a direct 180 proportional relationship is not unexpected. Agarwal et. al in 2014 showed positive correlation 181 between the initial Pirani scores and the number of casts to achieve full correction in 297 patients with 442 clubfeet. [34] Awang et. al in 2014 studied the effect of age, weight and initial 182 183 Pirani score on the number of casts needed for full correction and came out with the conclusion 184 that Pirani score was the only significant predictor among the parameters studied[27]. Some other authors showed the effect of midfoot, hindfoot and initial Pirani score on the rate at which 185 186 full correction was achieved and also the effect on relapse [35-37]. However, Gao et. al and Chu et. al showed no correlation between the Pirani score and the number of casts to achieve 187 188 correction in the clubfoot patients treated[14,38].

Moreover, monitoring the progress of treatment of clubfoot using the Ponseti protocol employed the paired T-test to compare the initial Pirani scores and the Pirani scores at full correction on one hand and the initial Pirani scores and whether or not the patient had tenotomy, the two showed statistical significance which implies that Pirani score can be used to monitor the progress of treatment of clubfoot using the Ponseti protocol. Pulak et.al in 2012 found out that

there was a significant difference between the pre-treatment Pirani scores and the post-

treatment Pirani scores in the 40 patients they treated in Ethiopia with the Ponseti method [32].

196 Moreover, study done by Faizan et. al in 2015 showed statistical significance between the pre

- and post treatment Pirani scores among 19 patients with 28 clubfeet[39]. Some authors also
- 198 showed statistically significant effect of the severity of clubfoot on the need for
- 199 tenotomy[18,19,32].
- In addition to this, the severity of the clubfoot determines the number of casts the patient will
- need before full correction: mild clubfoot had fewer numbers of casts than moderate which also
- has fewer numbers of casts compared with the severe clubfoot. Statistical test also showed that
- this is significant. Wang et. al in 2009 showed significant difference in the number of casts to
- achieve correction in the three groups of mild, moderate and severe clubfoot deformities they
- 205 studied[40].
- 206 4. CONCLUSION
- 207 The severity of clubfoot can be assessed using pirani scoring system and likewise the progress
- 208 of treatment in management of idiopathic clubfoot with ponseti protocol. this is simple and easy
- 209 to use.
- 210

### 211 CONSENT

Informed consent was obtained from the parents/caregivers of the patients that were recruited
for this study. This was a prerequisite to obtaining the ethical approval. A copy of the consent
will be made available to the editors on request.

215 216

## 217 ETHICAL APPROVAL

- 218 Ethical approval was obtained from the institution ethics and research committee. Registration
- 219 number: International IRB/IEC/0004553.

- National:
- 220 NHREC/27/02/2009a. Protocol number: ERC/2012/10/08.

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