

Congenital isolated clubfoot: Correlation between prenatal assessment and postnatal degree of severity

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ABSTRACT

Objective

Since prenatal diagnosis of isolated clubfoot has a false positive rate (FP) of 10%-40%, fetal parameters that might correlate with post-natal confirmation and grade of severity were investigated.

Method

Retrospective analysis (2013-2019) of cases analysed with three-dimensional multiplanar view. The following data were recorded: the angle between the long axis of foot and lower leg; width, length and width-to-length ratio (W/L) of the foot; tibia length and calf width (T/C) ratio. Severity after birth was assessed using the Pirani classification.

Results

Diagnosis was confirmed in 45/53 neonates (84.9%, FP 15%). Values were higher for both angle and W/L in true vs false positive cases (median angle 100.4° versus 69.55°, $p < .000$; median W/L 0.53 vs 0.45, $p = .001$), no difference for T/C (3.77 vs 3.48, $p = .8$). The area under the curve for angle was 0.98 (CI 0.94-1.00), with a diagnostic cut-off of 84.7° (PPV of 100%, NPV of 66.7%). Median Pirani score, available for 33 neonates (73.3%) was 3 (IQR 3-4): only angle correlated with Pirani score (Spearman coefficient 0.36, $p = .04$)

Conclusion

Measuring the angle between the foot and lower leg can reduce the FP rate of prenatal congenital clubfoot diagnosis and better predict the need for postnatal treatment.

1 INTRODUCTION

Clubfoot, or congenital talipes equinovarus, is a deformity of the foot composed of four elements: cavus foot, metatarsus adductus, heel varus, and equinus, which affects approximately 1-3/1000 live births.¹ It can be unilateral (30%-40%) or bilateral (60%-70%), isolated (50%-70%) or associated with other structural or genetic anomalies.^{2, 3}

International guidelines for performance of the routine mid-trimester fetal ultrasound scan recommend identifying and describing the presence of both legs and feet, but do not specify anything about their position and relationship.⁴ As a consequence, detection of isolated clubfoot in prenatal life is not considered in the standard screening evaluation of fetal anatomy.⁴ Prenatal ultrasound screening has a poor detection rate: false positive rates of 10%-40% have been reported, due to cases of malposition of the fetal feet.^{3, 5}

The diagnosis of clubfoot requires visualization of the tibia and fibula in the same plane as the sole of the foot, in one or both legs. Waiting for fetal movements is essential in order to identify the true positioning of the feet, since clubfoot is fixed throughout the examination time. Exclusion of associated anomalies such as neurological or skeletal malformations is of paramount importance, since the finding of a physical deformity is a source of anxiety for parents and an accurate diagnosis makes it possible to assess the best treatment option. Evaluation of the placenta and amniotic fluid is necessary to exclude the possibility of oligohydramnios being the cause of fetal malposition.⁶ There have been reports in the literature of prenatal parameters that may help to identify severe cases of clubfoot,⁷⁻⁹ but none of these have been incorporated into a routine evaluation of the fetal legs and feet. The purpose of this study is to identify a possible correlation between the prenatal description of isolated clubfoot and its degree of severity after birth.

2 METHODS

A retrospective analysis was made of all pregnancies referred to the Fetal Therapy Unit "Umberto Nicolini" of our third-level referral hospital, from 1 January 2013 to 31 December 2019.

Clubfoot was defined by the ultrasonographic (US) evidence of deformity of the foot in which one or both feet are excessively plantar flexed, with the forefoot swung medially and the sole facing inward. All the examinations were almost 30 minutes long per fetus, in order to observe at least one movement of the feet. Whenever the diagnosis was made in the second trimester, a second evaluation was offered in the third trimester to confirm the presence of clubfoot, and in none of the included cases was the diagnosis changed.

All cases underwent detailed evaluation in order to exclude association with other malformations, and in selected cases chorionic villous sampling or amniocentesis was offered to exclude associated aneuploidy or genetic anomalies. Cases where oligohydramnios was responsible for fetal foot malposition were excluded.

In cases of isolated prenatal clubfoot, either monolateral or bilateral, orthopedic counseling of the parents was performed by a pediatric orthopedic surgeon, in the course of which parents were offered postnatal evaluation and follow-up in our center for confirmation of diagnosis in order to plan a therapeutic strategy.

The retrospective evaluation was performed on all cases where a multiplanar view of the fetal leg had been obtained at a second trimester scan using a volumetric US probe (GE E8, GE Voluson 730, Medical Systems, Zipf, Austria), and postnatal outcome and follow-up were both available. Two obstetricians one junior and one senior, blinded to the outcome examined the stored images and calculated the following parameters (in accordance with those previously reported), as shown in Figure 1:

1. the angle between the long axis of the foot and of the lower leg (Angle), with no angle considered normal, $<80^\circ$ mildly abnormal, 80° - 100° moderate, and $>100^\circ$ severe⁷;
2. the width, length and width-to-length ratio (W/L) of the foot, correlated with gestational age through linear equations⁸;
3. the ratio between tibia length and calf width (T/C), measured at the upper third of the tibial bone from the posterior boundary of the tibia toward the posterior peripheral skin.⁹

There were concordant measurement results for both operators, so the widest angle or the higher ratio was chosen. Whenever the clubfoot was bilateral, the side with the worst parameter was chosen for analysis. Data on maternal characteristics, modality of conception and obstetrical outcome were also collected. The clubfoot severity after birth was assessed for all cases and was ranked according to the Pirani score,¹⁰ the most valuable clinic evaluation scale for clubfoot. This method combines reproducibility and easiness in classifying clubfoot severity: six separate elements are considered: cavus, empty heel, posterior crease, curved lateral border, medial crease, and lateral talus head prominence. Each deformity is subdivided into three classes (0 normal, 0.5 mild, 1 severe with a total maximum grade of severity of 6).

In all confirmed cases, the elective treatment was the Ponseti technique, which is presently the gold standard of care for the management of congenital clubfoot,^{11, 12} since it not only decreases the number of total procedures, but also the use of extensive surgical procedures, which are indicative of less severity in relapsed deformities.¹³ The Ponseti method is a conservative treatment method

for clubfoot. The manipulation approach and casting make it possible allow to reduce the number of “traditional” extensive surgical intervention performed in the past and, even in case of relapse, there is less need to adopt a more aggressive approach because the stretched structures of the affected foot respond better to recasting and re-manipulation, which are the first approaches in case of relapse. This minimally invasive approach involves a weekly serial long leg casting which is repeated until correction is achieved. After the first phase of correction with serial manipulation and casting (on average 4-5 casts gradually correct the main deformities of the clubfoot) in over 80% of patients percutaneous Achilles tenotomy is performed to correct the equinus deformity. A final cast is kept on after the tenotomy for 2-3 weeks post operation. When the cast is removed in the clinic, a brace (Mitchell-Ponseti brace, C-prodirect,UK) is worn. The brace is of paramount importance to prevent the relapse.

All women provided a written consent for any further scientific evaluation: given the retrospective nature of the analysis, ethical committee approval was not required.

2.1 Statistical analysis

The Mann-Whitney *U* test and Pearson χ^2 test were performed to make univariate comparisons of quantitative and qualitative variables, respectively, between groups. Spearman correlation coefficient was adopted to estimate correlation between the variables. Performance in predicting postnatal clubfoot by prenatal US parameters was determined by receiver operating characteristics (ROC) curve analysis. Stepwise logistic regression analysis was performed to determine which parameters contributed significantly to the prediction of postnatal clubfoot. SPSS Statistics v. 26.0 (IBM Corp., Armonk, NY, USA) was employed for statistical analyses and graph constructions.

3 RESULTS

During the study period, isolated clubfoot was suspected in 73 fetuses: in two cases (2.7%) a pathogenic copy number variant was found at prenatal CGH-array and they were excluded from the study; seven cases (9.6%) were lost to follow-up, while stored images with multiplanar view were available in 53 of the remaining 64 cases (82,8%). Maternal age, conception with assisted reproductive technology, gestational age at ultrasound diagnosis and obstetrical outcome are the main characteristics of the population summarized in Table [1](#). None of the cases ended with miscarriage or termination of pregnancy.

In none of the examinations was there discordance in diagnosis of clubfoot between the second and third trimester ultrasound scans.

Of the 53 fetuses included in the analysis, a diagnosis of clubfoot was confirmed in 45 neonates (84.9%), with a false positive rate of 15%. None of these 45 cases had a postnatal diagnosis of genetic or neurological problems. Maternal characteristics and obstetrical outcome showed no differences between true and false positive cases. There was reproducibility of the measurements between the two operators, so there were no inconsistent cases. The correlation with postnatal confirmation of clubfoot diagnosis was explored for each of the prenatal parameters analysed - unilateral or bilateral CF, the angle between the long axis of the foot and of the lower leg (Angle), width-to-length ratio (W/L) of the foot, and ratio between tibia length and calf width (T/C) - (see Table 1). When bilateral, clubfoot was more likely to be confirmed after birth ($P .06$).

Both for Angle and for W/L, higher values were found if the suspected diagnosis was confirmed after birth, compared to the lower values reported in the false positive cases (median Angle value 100.4° vs 69.55° , respectively, $P < .000$; Spearman correlation coefficient 0.60; median W/L value 0.53 vs 0.45, $P .001$; Spearman correlation coefficient 0.45). No difference was found in the T/C ratio between cases with or without postnatal confirmation of clubfoot (3.77 vs 3.48 , $P .8$, Spearman correlation coefficient 0.03). The Area under curve (AUC) calculated for Angle was 0.98 (CI 0.94-1.00), so the 80° cut-off value gave a sensitivity of 97.8% and a specificity of 87.5% with a positive predictive value (PPV) of 97.8% and a negative predictive value (NPV) of 87.5% (Figure 2).

According to our data, the best diagnostic cut-off value is an angle of 84.7° , which would give a sensitivity of 91.1% and a specificity of 100% with a PPV of 100% and a NPV of 66.7%. Given the slight difference between the two cut-offs and the higher sensitivity of the 80° cut-off already established in the literature, it seems advisable to keep the latter as the standard. The AUC for W/L was 0.87 (CI 0.74-0.99), with the best cut-off value of ≥ 0.48 (sensitivity 90.9%, specificity 71.4%), that gives a positive predictive value of 95.2% and an NPV of 55.5% (Figure 3). The W/L MoM performed the same, with an AUC of 0.86 (CI 0.73-0.99).

Most of the affected newborns (25/45, 57.1%) had an Angle exceeding 100° , defined as severe, while in 19/45 (42.2%) the Angle was moderate (80° - 100°), and in one case the Angle was only mildly abnormal (68.4°). In the false positive group, seven cases (87.5%) had a mildly abnormal Angle and one a moderately abnormal Angle (of 83.7°). All cases were considered as a malposition of the foot during pregnancy with no evidence of deformity after birth.

Hence, the highest rate of erroneous diagnosis of clubfoot was observed in those cases with prenatal evaluation of mild angle degree (87.5%) while such rates were 5.5% and 0% for moderate and severe angle degrees, respectively ($P < .0001$). By applying logistic regression models, the only variable that independently and significantly correlated with the primary outcome (detection of clubfoot) was the Angle, so it was impossible to build a predictive model based on the two variables which emerged as being significantly different at univariate analysis.

The Pirani score at neonatal orthopedic evaluation was available for 33 out of 45 (73.3%) neonates with a median value of 3 (range 0-6, IQR 3-4). There was a significant correlation between prenatal Angle and postnatal Pirani score (Spearman correlation coefficient 0.36, $P .04$, Figure 3) while no correlation was found between W/L or T/C and the Pirani score (Spearman correlation coefficients -0.08 and -0.14 , $P .68$ and $.47$, respectively).

4 DISCUSSION

We have found that measurement of the angle between the foot and lower leg allows optimal prenatal diagnosis of club foot and better predicts the need for postnatal treatment. This is a retrospective analysis of a large consecutive series of isolated clubfoot, performed at a single center that is a referral hospital for the prenatal diagnosis and treatment of fetal anomalies and for pediatric surgery and orthopedics. In particular, as regards the treatment of clubfoot after birth, our hospital is the national referral center in Italy for the Ponseti method.

Clubfoot is a skeletal anomaly that may indicate the presence of more severe conditions, so its finding in prenatal life requires detailed ultrasound evaluation. The criteria for the diagnosis of clubfoot were established at the very beginning of the fetal ultrasound era, when Benacerraf and Frigoletto described five cases of prenatal ultrasound diagnosis of clubfoot in 1985.¹⁴ Since then, numerous studies have clarified the significance of this anomaly as a possible tip of the iceberg for other more severe conditions: a recent statement from the Society for Maternal and Fetal Medicine has clearly summarized the state of the art.¹⁵

Apart from cases where clubfoot is related to genetic syndromes or neurological issues, analysis of isolated cases with regard to postnatal evaluation is reported in only a few series. The largest series from Sharon-Weiner et al⁶ reported an accurate work-up for the evaluation of fetal clubfoot in order

to exclude associated anomalies and postnatal follow-up in 65 cases where the diagnosis was confirmed as isolated clubfoot. To our knowledge, this series is the largest one reported so far from an unselected low-risk population: its findings are therefore of primary importance for defining the detection rate of prenatal clubfoot, which has a high false positive rate (23.8%) and in 11% is defined as complex after birth.^{3, 5} Compared to this study, our series has a lower false positive rate (15%), although ours was a selected population of fetuses referred to expert operators for a detailed evaluation.

Three series have analysed the prenatal parameters that could predict postnatal severity of isolated clubfoot.⁷⁻⁹ Glotzbecker et al⁷ evaluated 42 cases of clubfoot, translating a radiographic score (Di Meglio score) in the ultrasonographic evaluation of the clubfoot severity, so as to identify an angle between the long axis of the foot and of the lower leg, with no angle considered normal, $<80^\circ$ mildly abnormal, $80^\circ-100^\circ$ moderate, and $>100^\circ$ severe. The importance of this study lies in the standardization of the evaluation of clubfoot in order to better define prognosis, and give orthopedic pediatricians who provide prenatal counseling a more reliable way of predicting the postnatal severity of the anomaly.

The other two series attempted to achieve the same goal: Liao et al⁸ compared a group of 27 fetuses with a diagnosis of clubfoot with a control group of 129 normal fetuses. They analysed the plantar shape and deformity, translating what is done postnatally to the ultrasonographic evaluation of the fetus: more specifically, they measured the width, length and width-to-length ratio of the foot, correlated with gestational age through linear equations, and they found that the affected feet were wider and shorter than the normal feet, and had a greater width-to-length ratio and a smaller bi-malleolar angle. Hershkovitz and Tepper,⁹ on the other hand, worked on the three-dimensional evaluation of the fetal leg with the multiplanar view, and analysed the ratio between the tibia length and calf width in order to define a nomogram for this value.

Ours is the first series in which all these three parameters were analysed together so as to assess their correlation with the postnatal severity of clubfoot. Its main limitation is the retrospective nature of the study and the small number of cases, although 33 cases in 7 years are considerable for a relative uncommon anomaly. The need to analyze stored images reduced the number of cases available, as did the loss of cases to postnatal follow-up, since some of the pregnant women were referred from faraway hospitals. Many women come to our center during pregnancy from other

parts of the country, but then deliver elsewhere: that explains the loss of neonates follow-up, since parents decided not to come back after the birth for practical reasons.

Our study had several strengths, which included: the retrospective analysis of the stored volumes was performed by two operators blinded to the results to assess the reproducibility of the measures; the comprehensive evaluation at our center allowed accurate diagnosis of true isolated congenital clubfoot; no additional genetic anomalies or neurological problems were observed at postnatal evaluation. Moreover a single pediatric orthopedic surgeon skilled in the treatment of clubfoot assessed all clubfeet and ranked the feet according to the Pirani score. Finally correlation of prenatal evaluation with postnatal outcome was possible in 33 cases, for which complete postnatal follow-up information was available, together with quantitation of the Pirani score. The Di Meglio and Pirani scores remain the most widely accepted clubfoot severity grading systems. However, their prognostic value remains questionable, at least in the early treatment stages.^{16, 17} Since the two grading systems have been reported to have a similar correlation with prognosis,^{16, 17} we adopted Pirani score as our elective grading score system. It should be noted that in actuality it is not the scoring system which is important, but the final clinical results, also because the steps involved in the Ponseti method do not change whether the clubfoot is mild or severe. The only real discrepancy could be whether the Achilles tenotomy is performed.

Mild cases of clubfoot (with a Pirani score under 3) are more likely to avoid this procedure than the more severe cases (Pirani score over 3.5), as also stated by Dyer and Davies.¹⁸

The only parameter that correlated significantly with the Pirani score was the degree of the angle between the long axis of the foot and of the lower leg. This finding is particularly important for effective prenatal orthopedic counseling which enables pediatricians to centralize severe cases to a referral center. Moreover, prompt definition of the strategy for the correction of the clubfoot reduces parents' anxiety.

As reported by Radler et al,¹⁹ when comparing maternal attitude toward postnatal confirmation or not of suspected clubfoot, those mothers who thought that their child had a malformation were negatively affected in the postnatal period even though the child was not affected. On the other hand, mothers who were expecting clubfoot in their children were focused on the general well-being of the newborn with a higher level of satisfaction with the accuracy of prenatal evaluation.

In our study, it was not possible to calculate the rate of false negative diagnosis for clubfoot, but a starting point has been established for reducing the rate of false positive cases. No differences were found in maternal characteristics between the true and false positive cases, but it should be stressed that the suspicion of clubfoot in the second trimester should be followed by further evaluation during the third trimester in order to confirm a true deformity of the foot unrelated to a malpositioning of the legs: waiting for fetal leg movements is mandatory during ultrasound examination to demonstrate the fixity of the foot.

In all of our cases, there was a strong correlation between the degree of the angle between the long axis of the foot and of the lower leg and postnatal confirmation of the anomaly: all of the cases with a value above 80° were more likely to be real clubfoot, with a positive predictive value of 97.8%. Incidentally, this is a parameter which can be measured using the classic bidimensional ultrasonographic view, also when a 3D scan (mostly used in third level centers) is not available.

The reproducibility is quite low for the width-to-length ratio of the foot, where the multiplanar mode view makes it possible to obtain a better definition of the foot.

5 CONCLUSIONS

Although accurate prenatal diagnosis of clubfoot undoubtedly helps parents to understand the prognosis, a high false positive rate unnecessarily increases parents' anxiety. This false positive rate can be significantly reduced by measuring the angle between the foot and the lower leg, reserving prenatal orthopedic counseling for those cases which really will need postnatal treatment. This observation, based on a small number of cases, needs further prospective studies to be included in a fetal ultrasound examination of cases with suspected clubfoot.

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Each of the authors participated actively in the study, making a substantial contribution to the concept, design, analysis and interpretation of data, and helping to draft the manuscript critically for its intellectual content. Each of the authors approved the version of the manuscript submitted.

CONFLICT OF INTEREST

None of the authors report a conflict of interest in the past 3 years with any commercial entities which are marketing or developing products related to the subject matter of the manuscript.

TABLE 1. Clinical characteristics and outcome of the study population

Variable	Confirmed clubfoot (45)	No clubfoot (8)	P
Maternal age, y	33 (29-35)	30 (27-34)	.23
GA at US evaluation	21.2 (20.1-23.4)	21.5 (21.0-24.2)	.56
Unilateral	13/45 (28.8%)	5/8 (62.5%)	.06
Bilateral	32/45 (71.2%)	3/8 (37.5%)	
ART (yes)	4/45 (9.5%)	0/8	.65
GA at delivery, wk. d	40 (38.6-40.5)	39.3 (37.6-40.1)	.55
Birth weight, g	3650 (3275-3915)	3260 (3065-3550)	.69
Angle	100.4 (97.7-107.7)	69.55 (0.00-75.27)	<.000
T/C	3.77 (3.33-4.25)	3.48 (2.80-4.65)	.82
W/L	0.53 (0.50-0.58)	0.45 (0.41-0.51)	.001
W/L MoM	1.23 (1.18-1.37)	1.06 (0.97-1.20)	.001
Pirani Score	3 (3-4)	<i>n.a.</i>	

- *Note:* Data are expressed as median value and range or percentage.
- Abbreviations: ART, assisted reproductive technology; GA, gestational age; MoM, multiple of median; T/C, ratio between tibia length and calf width; US, ultrasound; W/L, foot width-to-length ratio.

FIGURES

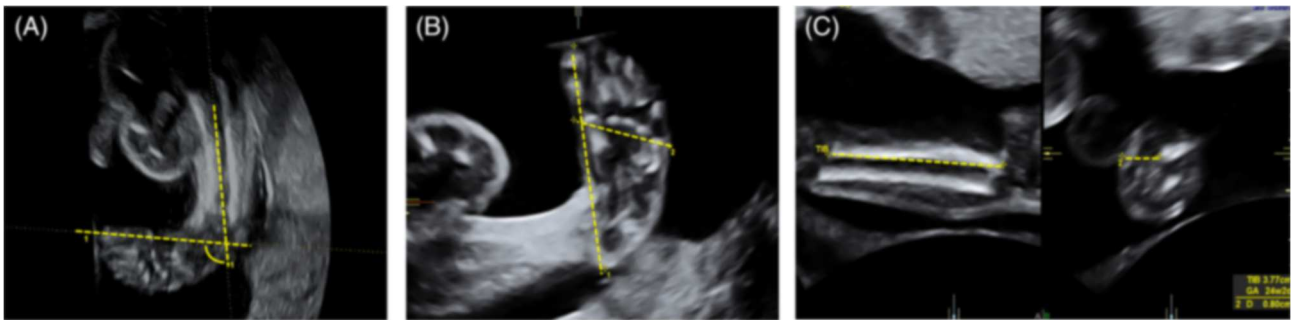


FIGURE 1

Measurement of fetal parameters in congenital clubfoot. A, Angle between the long axis of the foot and the lower leg, B, width, length and width-to-length ratio (W/L) of the foot, C, ratio between tibia length and calf width (T/C), measured at the upper third of the tibial bone from the posterior boundary of the tibia toward the posterior peripheral skin

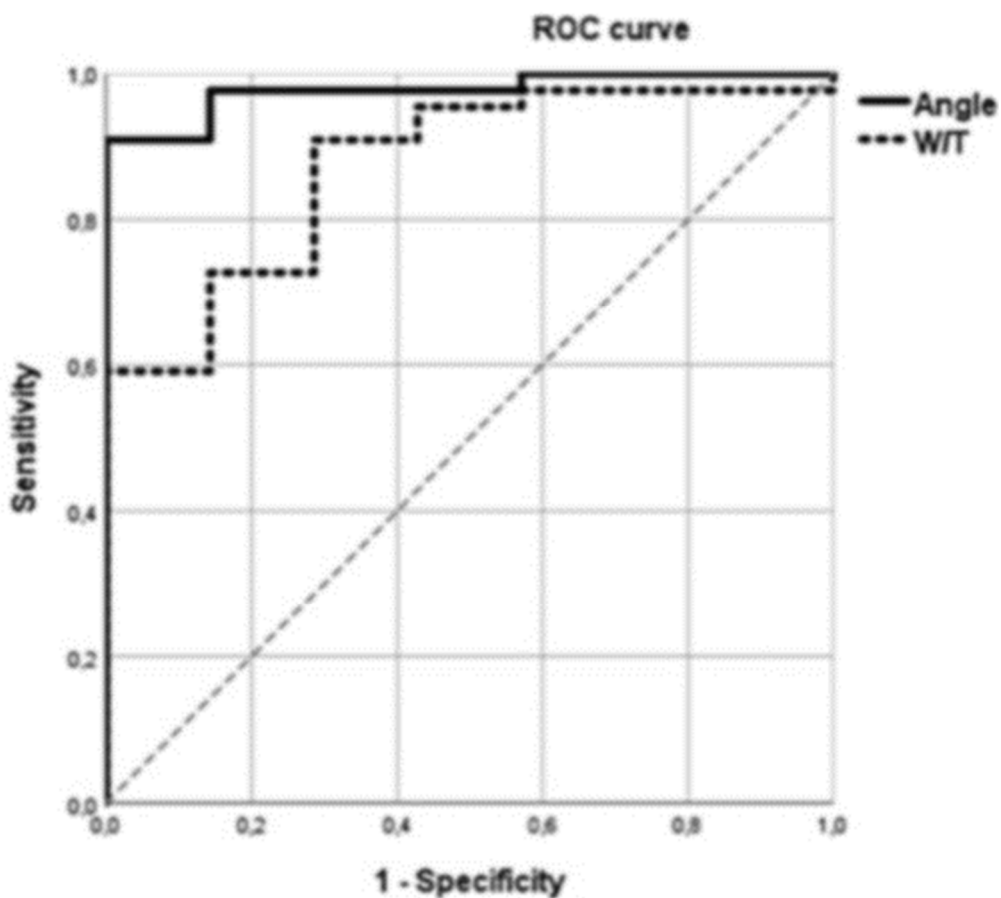


FIGURE 2

Receiver operating characteristics (ROC) curve analysis for angle and width-to-length ratio (W/L) of the foot

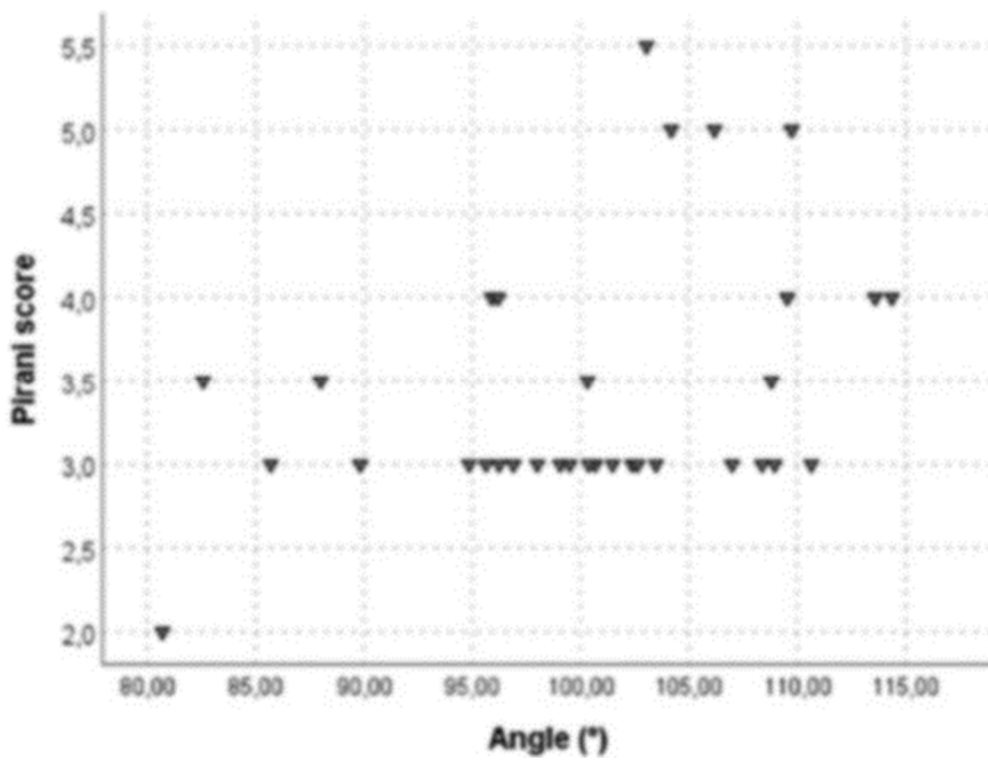


FIGURE 3

Spearman correlation coefficient between Angle and Pirani score

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