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Foot and ankle deformities in children with Down syndrome

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Keywords: ankle; foot; deformity; Down syndrome; treatment

Abstract

Purpose Foot and ankle deformities are common orthopaedic disorders in children with Down syndrome. However, radiographic measurements of the foot and ankle have not been previously reported. The aim of this study is to describe the foot and ankle deformity in children with Down syndrome.

Methods Children who had foot and ankle radiographs in the standing weight-bearing position were selected. Three groups of patients were identified. The relationship of radiographic measurements with age, body mass index and pain is discussed. In all, 41 children (79 feet) had foot radiographs and 60 children (117 ankles) had ankle radiographs, with 15 children overlapping between Groups I and II.

Results In Group I, hallux valgus deformity was seen before ten years of age and hallux valgus angle increased afterwards. Metatarsus adductus angle showed a significant increase ($p = 0.006$) with obesity and was higher in patients who had foot pain ($p = 0.05$). In Group II, none of the ankle measurements showed a significant difference with age or body mass index percentiles. Tibiotalar angle (TTA) and medial distal tibial angle (MDTA) were higher in patients who had ankle pain. In Group III, correlation analysis was performed between the different measurements with the strongest correlations found between TTA and MDTA.

Conclusion In children with Down syndrome, radiographic evaluation of the foot and ankle reveals higher prevalence of deformities than clinical examination. However, foot and ankle radiographs are needed only for symptomatic children with pain and gait changes.

Level of Evidence Level IV - Prognostic Study

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Introduction

Musculoskeletal disorders occur in 20% to 27% of patients with Down syndrome,[1,2] and foot deformities comprise 30% of all reported orthopaedic issues.[3] Hallux valgus and pes planus (flatfoot) are frequently reported.[1,3,4] These findings are described secondary to increased body mass index (BMI),[5] muscular hypotonia,[6] ligamentous laxity[7] and ankle instability.[8] While progressive ankle valgus is common in a variety of conditions,[9-12] there have been no reports about ankle deformities in children with Down syndrome.

Although foot and ankle disorders are frequent complaints for children with Down syndrome visiting orthopaedic clinics, and although these disorders have an impact on these children's gait,[8,13] the priority is usually to address other major and more severe disorders such as upper cervical spine instability, scoliosis, hip instability and knee malalignment.[14] However, it is reported that most foot deformities in Down syndrome, if not managed or treated in childhood, can become major problems in adulthood.[15]

Radiographic measurements of the foot and ankle have not been previously reported for children with Down syndrome. The aim of this study is to describe the foot and ankle deformities in children with Down syndrome. The relationship of these deformities with age, body mass index (BMI) and pain is discussed. Radiographic measurements of the foot and ankle, as well as the correlation between the different measurements, are reported.

Patients and methods

After obtaining the approval of our Institutional Review Board, records of all children with Down syndrome, who were seen at AI duPont Hospital for Children, Wilmington, Delaware between 2004 and 2015, were reviewed. Demographic and clinical data included age, gender, weight (kg), height (cm), BMI (kg/m^2), foot and ankle pain, reason for consultation and prior surgeries on the foot and ankle. The clinical findings that necessitated a radiographic evaluation were recorded based on the patient's chart review.

Children who had foot and ankle radiographs as part of their orthopaedic evaluation were identified. Only radiographs that were taken in the standing, weight-bearing position were reviewed. If a patient had multiple radiographs, the first radiograph was selected. Radiographic measurements on the anteroposterior view of the foot included hallux interphalangeal angle,[16] hallux valgus angle,[17] distal metatarsal articular angle,[18] first and second intermetatarsal angle,[17] first and second intermetatarsal relative length[19,20] and metatarsus adductus angle (MAA).[21] Radiographic measurements on the lateral view of the foot included talo-first metatarsal angle,[22] talo-horizontal angle,[23] talocalcaneal axial angle,[24] talocalcaneal pitch angle[25] and calcaneal pitch.[22,26] Radiographic measurements on the anteroposterior view of the ankle included tibiotalar angle (TTA)[10] and medial distal tibial angle (MDTA).[27] All radiographs were reviewed and measured by one paediatric orthopaedic surgeon (LRP).

Three groups of patients were identified: children who had foot radiographs (Group I), children who had ankle radiographs (Group II) and the third group (Group III) included children who had both foot and ankle radiographs at the same visit (the overlap between Groups I and II).

Group I

Radiographic measurements of this group were first compared between children younger than ten years old, children between ten and 13.9 years old and children 14 years old or older. Then, the measurements were compared between children with a BMI in the 95th percentile or greater and children with a BMI less than the 95th percentile. The third comparison was performed between children who had pain and children who did not.

Group II

Radiographic measurements in this group were first compared between children younger than ten years old and children ten years old or older. Then, and similar to Group I, the measurements were compared between children with a BMI in the 95th percentile or greater and children with a BMI less than the 95th percentile. The third comparison was also performed between children who had pain and children who did not.

The age limits in Group I and II were selected so that a similar number of patients could be compared. The BMI percentiles were recorded using the Center for Disease Control growth reference charts.[28] The obesity limit (95th percentile) was suggested in a previous study[29] as a better cut off than the overweight limit (85th percentile), and therefore, it was used in our study. The BMI and pain data were obtained at the same visit when the radiographic evaluation was performed.

Group III

In this group, correlation analysis was performed to detect any association between the different deformities. Statistically, independent *t*-test was used to compare the radiographic measurements. Pearson correlation was used for the correlation analysis performed in Group III. SPSS software (SPSS version 22, Chicago, Illinois) was used. Level of significance was set at 0.05.

Results

Records of 581 children with Down syndrome were reviewed (Fig. 1). Of these children, 101 children (58 boys and 43 girls) had foot and/or ankle radiographs and were included in the analysis. Group I included 41 children (27 boys and 14 girls) with anteroposterior and lateral radiographs of 79 feet in the standing weight-bearing position. Group II included 60 children (31 boys and 29 girls) with anteroposterior radiographs of 117 ankles in the standing weight-bearing position. Group III included 15 children (11 boys and four girls) with bilateral foot and ankle radiographs.

In Group I, indications for the foot radiographic evaluation were flat feet (pes planus valgus) in 36 feet (46%), foot pain in 16 (20%), hallux valgus in 12 (15%), gait abnormalities in 12 (15%), cavus foot in two (3%) and difficulty in using shoes in one foot (1%). Clinical observation reported flat feet in 46% and hallux valgus in 15% of patients. However, radiographic evaluations showed flat feet in 58% and hallux valgus in 45% of patients (Fig. 2). Flatfoot prevalence was consistent across age groups (58% in children less than ten years of age, 59% in children between ten and 13.9 years of age and 57% in children $\geq$ 14 years of age). However, hallux valgus was more common in older age groups (32% in children less than ten years of age, 52% in children between ten and 13.9 years of age and 55% in children $\geq$ 14 years of age). Changes in the measurements between the different ages are shown in Table 1. The MAA was the only measurement that showed a significant increase ($p = 0.006$) with obesity (Table 2, Fig. 3). The MAA was also higher in patients who had foot pain ($p = 0.05$) (Table 3).

In Group II, the indications for the ankle radiographic evaluation were lower limb malalignment evaluation in 73 (62%), pain in 20 (17%), in toeing in 16 (14%), valgus in six (5%) and out toeing in two (2%) children. None of the ankle measurements showed a significant difference with different ages or different BMI percentiles (Tables 4 and 5).

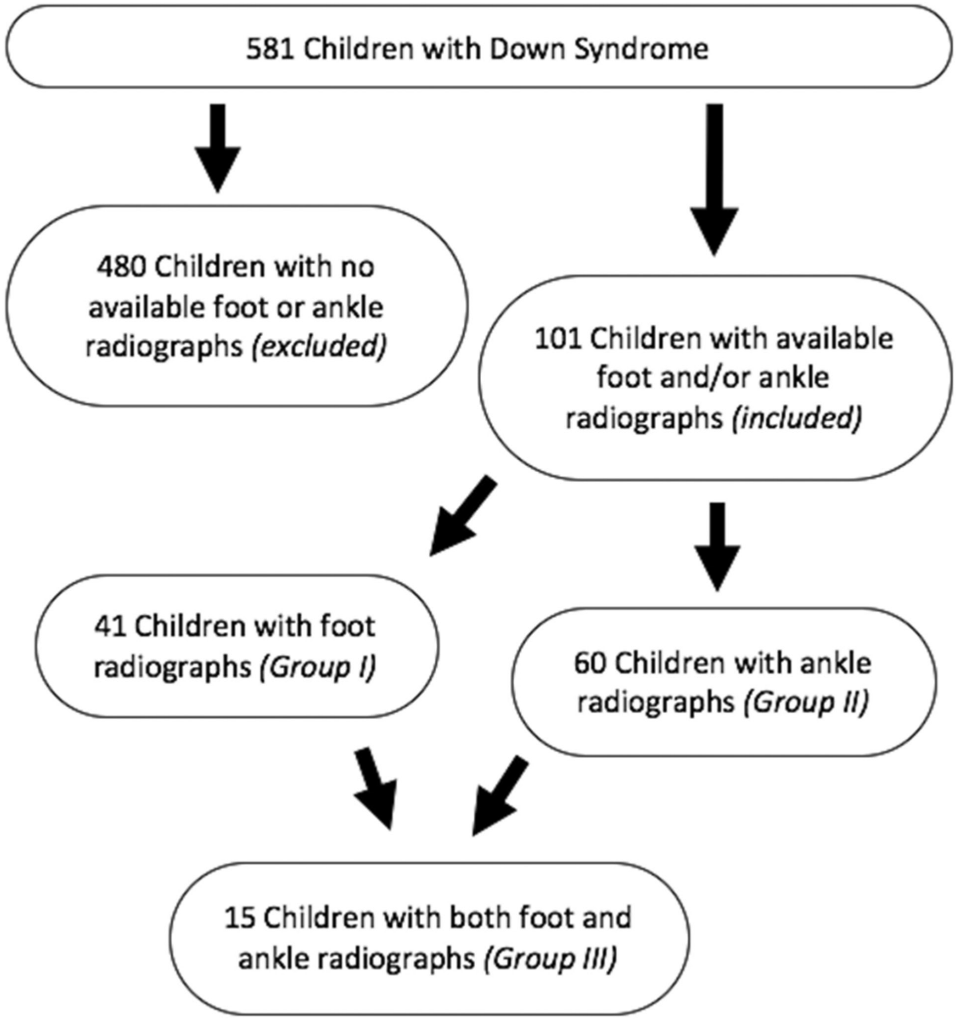

Fig. 1 Study population and the different groupings of children with Down syndrome included in the study.

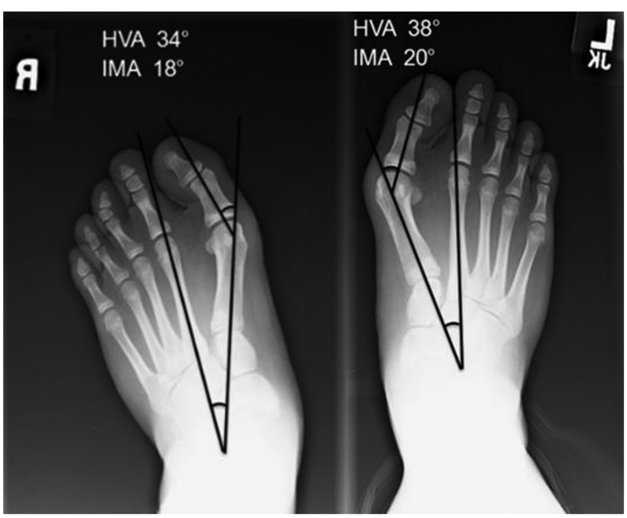

Fig. 2 A 10.3-year-old male with body mass index over 95th percentile presenting with no pain and high metatarsus adductus angle (HVA, hallux valgus angle; IMA, first and second intermetatarsal angle).

However, both TTA and MDTA were higher in patients who had ankle pain ($p < 0.01$) (Table 6).

In Group III, correlation analysis was performed between the different measurements, with the strongest correlations found between Meary angle and talo-horizontal angle and between TTA and MDTA (Tables 7 to 9).

In Group I, only one child with a painful flatfoot and interphalangeus hallux valgus had surgical correction (lateral calcaneal lengthening and Akin osteotomy). In Group II, two children with painful ankle valgus had bilateral distal medial tibial epiphysiodesis with screws. In these three cases, pain was not relieved with conservative management. Otherwise, all patients who had pain were managed conservatively.

Discussion

In Down syndrome, the prevalence of pes planovalgus (flatfoot) is reportedly 2% to 6%, and this deformity cor-

Table 1 Comparisons of radiographic measurements between different ages

Radiographic measurements	< 10 yrs (28 feet)		10 to 13.9 yrs (29 feet)		≥ 14 yrs (22 feet)		p-values		
	Mean	SD	Mean	SD	Mean	SD	< 10 yrs and 10 to 13.9 yrs	< 10 yrs and ≥ 14 yrs	10 to 13.9 yrs and ≥ 14 yrs
Anteroposterior view radiographs									
HIA (°)	15.7	5.6	17.9	7.2	15.3	5.2	0.207	0.186	0.150
HVA (°)	12.3	6.9	19.3	14.2	24.9	17.3	0.022	0.003	0.226
DMAA (°)	10.3	5.4	16.7	9.6	20.4	10.7	0.003	0.0003	0.211
IMA (°)	14.1	4.6	15.5	7.1	15.7	4.9	0.388	0.238	0.885
RL (mm)	2.4	2.3	4.2	2.4	5.2	2.5	0.005	0.0002	0.162
MAA (°)	15.9	4.8	15.7	6.8	13.0	5.2	0.891	0.037	0.117
Lateral view radiographs									
TMA (°)	8.7	8.1	14.1	12.7	13.7	14.7	0.069	0.163	0.922
THA (°)	28.1	6.5	32.4	8.6	32.0	11.1	0.047	0.152	0.911
TCAA (°)	43.0	5.0	48.8	7.8	49.4	10.8	0.002	0.017	0.830.
TCPA (°)	52.6	5.0	56.3	8.9	54.3	9.3	0.066	0.439	0.455
CP (°)	14.9	7.1	16.4	8.3	17.4	7.3	0.476	0.249	0.681
BMI percentile	73.3	26.3	72.5	24.6	80.8	18.0	0.998	0.187	0.681

BMI, body mass index; CP, calcaneal pitch angle; DMAA, distal metatarsal articular angle; HIA, hallux interphalangeal angle; HVA, hallux valgus angle; IMA, first and second intermetatarsal angle; MAA, metatarsus adductus angle; RL, first and second intermetatarsal relative length; TCAA, talocalcaneal axial angle; TCPA, talocalcaneal (pitch) angle; THA, talo-horizontal angle; TMA, talo-first metatarsal angle

Table 2 Comparisons of radiographic measurements angles between different body mass index

Radiographic measurements	≥ 95th (25 feet)		< 95th (54 feet)		p-values
	Mean	SD	Mean	SD	≥ 95th and < 95th
Anteroposterior view radiographs					
HIA (°)	15.1	6.7	17.0	5.9	0.246
HVA (°)	16.2	14.6	19.4	13.7	0.356
DMAA (°)	13.3	10.7	16.4	8.9	0.208
IMA (°)	15.0	7.1	15.1	5.0	0.924
RL (mm) (°)	3.6	3.1	4.0	2.4	0.646
MAA (°)	17.3	4.5	13.9	5.7	0.006
Lateral view radiographs					
TMA (°)	8.5	9.6	13.5	12.7	0.072
THA (°)	28.0	7.4	31.9	9.2	0.060
TCAA (°)	45.4	6.1	47.6	9.1	0.228
TCPA (°)	52.2	6.8	55.3	8.3	0.109
CP (°)	17.4	8.7	15.7	7.1	0.424

CP, calcaneal pitch angle; DMAA, distal metatarsal articular angle; HIA, hallux interphalangeal angle; HVA, hallux valgus angle; IMA, first and second intermetatarsal angle; MAA, metatarsus adductus angle; RL, first and second intermetatarsal relative length; TCAA, talocalcaneal axial angle; TCPA, talocalcaneal (pitch) angle; THA, talo-horizontal angle; TMA, talo-first metatarsal angle

relates with ligamentous laxity.[2,3] Severe flatfoot is uncommon and is found more frequently in institutionalized patients.[2,3] Flat feet and lesser toe deformities have not been associated with specific activity limitation in children and adolescents with Down syndrome; however, hallux valgus has been associated with disability during school and play activities.[30] In a podiatric study with 50 children, Concolino et al[14] reported pes planovalgus in 60% and hallux valgus in 60% of children with Down syndrome

Fig. 3 Bilateral anteroposterior foot radiographs in the standing weight-bearing position of a 12.9-year-old female (body mass index = 30 kg/m²; over 95th percentile), with bilateral hallux valgus, presenting with pain in both feet (MAA, metatarsus adductus angle).

Table 3 Comparisons of radiographic measurements angles between painful and non-painful

	Pain (26 feet)		No pain (43 feet)		p-values
Radiographic measurements	Mean	SD	Mean	SD	Pain and no pain
Anteroposterior view radiographs					
HIA (°)	17.0	7.8	16.1	5.3	0.580
HVA (°)	22.2	18.7	16.5	10.7	0.162
DMAA (°)	17.3	11.4	14.5	8.5	0.263
IMA (°)	15.8	7.6	14.7	4.5	0.473
RL (mm)	4.1	3.1	3.7	2.4	0.589
MAA (°)	16.8	5.4	14.2	5.5	0.050
Lateral view radiographs					
TMA (°)	10.7	11.4	12.7	12.5	0.491
THA (°)	29.8	8.2	31.3	9.2	0.469
TCAA (°)	45.4	7.6	47.7	8.8	0.248
TCPA (°)	54.9	4.7	54.2	9.1	0.652
CP (°)	15.7	6.0	16.4	8.2	0.651
BMI percentile	76.3	21.5	73.5	24.6	0.599

BMI, body mass index; CP, calcaneal pitch angle; DMAA, distal metatarsal articular angle; HIA, hallux interphalangeal angle; HVA, hallux valgus angle; IMA, first and second intermetatarsal angle; MAA, metatarsus adductus angle; RL, first and second intermetatarsal relative length; TCAA, talocalcaneal axial angle; TCPA, talocalcaneal (pitch) angle; THA, talo-horizontal angle; TMA, talo-first metatarsal angle

Table 4 Comparisons of radiographic ankle measurements between different ages

	< 10 yrs (60 feet)		≥ 10 yrs (57 feet)		p-values
	Mean	SD	Mean	SD	< 10 yrs and ≥ 10 yrs
TTA	5.0	4.5	4.6	6.4	0.745
MDTA	94.3	4.1	93.3	5.8	0.260
BMI percentile	81.9	20.4	86.2	14.0	0.186

BMI, body mass index; MDTA, medial distal tibial angle; TTA, tibiotalar angle

Table 5 Comparisons of radiographic ankle measurements between different body mass index

	≥ 95th (61 feet)		< 95th (56 feet)		p-values
	Mean	SD	Mean	SD	≥ 95th and < 95th
TTA	4.6	6.0	5.0	5.0	0.690
MDTA	93.6	5.5	94.0	4.5	0.688

MDTA, medial distal tibial angle; TTA, tibiotalar angle

Table 6 Comparisons of radiographic ankle measurements between painful and non-painful ankles

	Pain (19 feet)		No pain (98 feet)		p-values
	Mean	SD	Mean	SD	Pain and no pain
TTA	8.1	4.2	4.2	5.5	0.001
MDTA	97.3	4.0	93.1	4.9	0.0004
BMI percentile	88.2	14.3	83.2	18.1	0.199

BMI, body mass index; MDTA, medial distal tibial angle; TTA, tibiotalar angle

Table 7 Shows Pearson correlation analysis between the measurements

Correlations		HIA	HVA	DMAA	IMA	RL	MAA	TTA	MDTA
HIA	r	1	-0.254	-0.144	-0.387*	0.078	-0.011	-0.451*	-0.369*
	p		0.183	0.456	0.038	0.689	0.955	0.014	0.049
HVA	r	-0.254	1	0.608**	0.635**	0.132	-0.158	-0.017	-0.188
	p	0.183		0.000	0.000	0.494	0.413	0.932	0.329
DMAA	r	-0.144	0.608**	1	0.345	0.061	-0.353	-0.213	-0.418*
	p	0.456	0.000		0.067	0.752	0.060	-0.266	0.024
IMA	r	-0.387*	0.635**	0.345	1	-0.122	-0.242	0.112	0.016
	p	0.038	0.000	0.067		0.527	0.205	0.565	0.935
RL	r	0.078	0.132	0.061	-0.122	1	0.525**	0.383*	0.248
	p	0.689	0.494	0.752	0.527		0.003	0.040	0.195
MAA	r	-0.011	-0.158	-0.353	-0.242	0.525**	1	0.446*	0.490**
	p	0.955	0.413	0.060	0.205	0.003		0.015	0.007
TTA	r	-0.451*	-0.017	-0.213	0.112	0.383*	0.446*	1	0.920**
	p	0.014	0.932	-0.266	0.565	0.040	0.015		0.000
MDTA	r	-0.369*	-0.188	-0.418*	0.016	0.248	0.490**	0.920**	1
	p	0.049	0.329	0.024	0.935	0.195	0.007	0.000	

*correlation is significant at the 0.05 level (2-tailed)

**correlation is significant at the 0.01 level (2-tailed)

DMAA, distal metatarsal articular angle; HIA, hallux interphalangeal angle; HVA, hallux valgus angle; IMA, first and second intermetatarsal angle; MAA, metatarsus adductus angle; MDTA, medial distal tibial angle; p, significance; r, correlation coefficient; RL, first and second intermetatarsal relative length; TTA, tibiotalar angle

(26% isolated hallux valgus and 34% associated with metatarsus primus varus) and most of these deformities were secondary to hypotonia and ligamentous laxity.[14] A true prevalence of foot deformities in children with Down syndrome could not be reported in this study since only children who had radiographic evaluation were assessed.

Although no previous studies in Down syndrome have reported the changes of foot measurements with age, in the general population (children without Down syndrome), improvement of flexible flatfoot with age has been reported,[31] and age is considered the most important factor related to improvement of the arch height.[32]

Table 8 Shows Pearson correlation analysis between the measurements

Correlations		TMA	THA	TCAA	TCPA	CP	TTA	MDTA
TMA	r	1	0.876**	0.156	0.078	-0.693**	-0.438*	-0.561**
	p		0.000	0.456	0.711	0.000	0.028	0.004
THA	r	0.876**	1	0.437*	0.390	-0.551**	-0.393	-0.563**
	p	0.000		0.029	0.054	0.004	0.052	0.003
TCAA	r	0.156	0.437*	1	0.876**	0.510*	0.073	-0.136
	p	0.456	0.029		0.000	0.009	0.730	0.517
TCPA	r	0.078	0.390	0.876**	1	0.440*	-0.060	-0.186
	p	0.711	0.054	0.000		0.028	0.777	0.374
CP	r	-0.693**	-0.551**	0.510*	0.440*	1	0.443*	0.413*
	p	0.000	0.004	0.009	0.028		0.026	0.040
TTA	r	-0.438*	-0.393	0.073	-0.060	0.443*	1	0.920**
	p	0.028	0.052	0.730	0.777	0.026		0.000
MDTA	r	-0.561**	-0.563**	-0.136	-0.186	0.413*	0.920**	1
	p	0.004	0.003	0.517	0.374	0.040	0.000	

*correlation is significant at the 0.05 level (2-tailed)

**correlation is significant at the 0.01 level (2-tailed)

CP, calcaneal pitch angle; MDTA, medial distal tibial angle; p, significance; r, correlation coefficient; TCAA, talocalcaneal axis angle; TCPA, talo calcaneal pitch angle; THA, talo-horizontal angle; TMA, talo-first metatarsal angle; TTA: tibiotalar angle.

Table 9 Shows Pearson correlation analysis between the measurements

Correlations		HIA	HVA	DMAA	IMA	RL	MAA
TMA	r	0.438*	0.248	0.617**	0.008	0.168	0.398*
	p	0.029	0.232	0.001	0.968	0.422	0.049
THA	r	0.206	0.209	0.583**	0.009	0.189	-0.332
	p	0.323	0.317	0.002	0.964	0.365	0.105
TCAA	r	-0.296	0.073	0.355	-0.256	0.289	0.169
	p	0.151	0.730	0.081	0.217	0.161	0.418
TCPA	r	-0.290	-0.090	0.281	-0.252	0.099	0.133
	p	0.159	0.670	0.174	0.225	0.639	0.528
CP	r	-0.472*	-0.132	-0.228	-0.247	0.087	0.475*
	p	0.017	0.529	0.272	0.235	0.678	0.017

*correlation is significant at the 0.05 level (2-tailed)

**correlation is significant at the 0.01 level (2-tailed)

CP, calcaneal pitch angle; DMAA, distal metatarsal articular angle; HIA, hallux interphalangeal angle; HVA, hallux valgus angle; IMA, first and second intermetatarsal angle; MAA, metatarsus adductus angle; p, significance; r, correlation coefficient; RL, first and second intermetatarsal relative length; THA, talo-horizontal angle; TMA, talo-first metatarsal angle; TCAA, talocalcaneal axis angle; TCPA, talocalcaneal pitch angle

This improvement with age was not shown by our results in children with Down syndrome (Fig. 4). However, hallux valgus, seen after ten years of age in our group, followed a similar occurrence to that shown in the general population.[33] This finding suggests that the prevalence of hallux valgus reported for young children with Down syndrome (four to eight years) in a previous study[14] might increase with older age.

Reduced plantar arch height is reported in overweight and obese children without Down syndrome.[19] Structural changes in the foot anatomy are suggested with possible

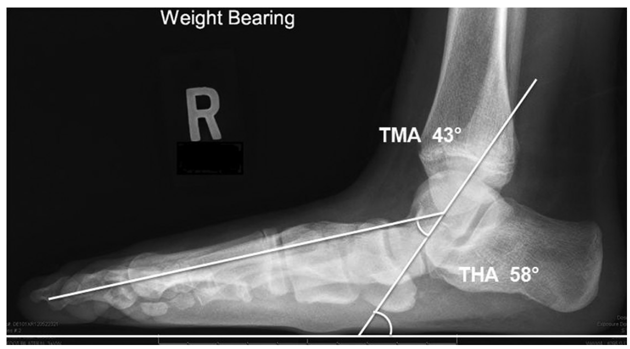

Fig 4 Lateral foot radiograph in the standing weight-bearing position of a 10.8-year-old male with flatfoot and no pain. Body mass index = 8.4 kg/m^2 (near to 50th percentile). The radiograph shows the correlation between two measurements in the lateral radiograph (TMA, talo first-metatarsal angle; THA, talo-horizontal angle).

exacerbation as excess weight-bearing continues throughout childhood and into adulthood.[19] Foot deformities in Down syndrome have been reported with increased BMI.[3] In our group of patients, radiographic evaluation did not show a difference in the arch height measurements, nor in the hallux valgus measurements, with different BMIs (Figs 2 and 4).

No difference in foot radiographic measurements was found between children with or without pain in our study; however, the pain reported by our patients and their families was mainly associated with abnormal walking, and localization of pain was difficult to assess.

Multiple studies have discussed ankle deformities in children;[10,27,34-36] however, to our knowledge, ankle measurements and deformities in children with Down syndrome have not been previously reported. While no association was found in our study between ankle valgus

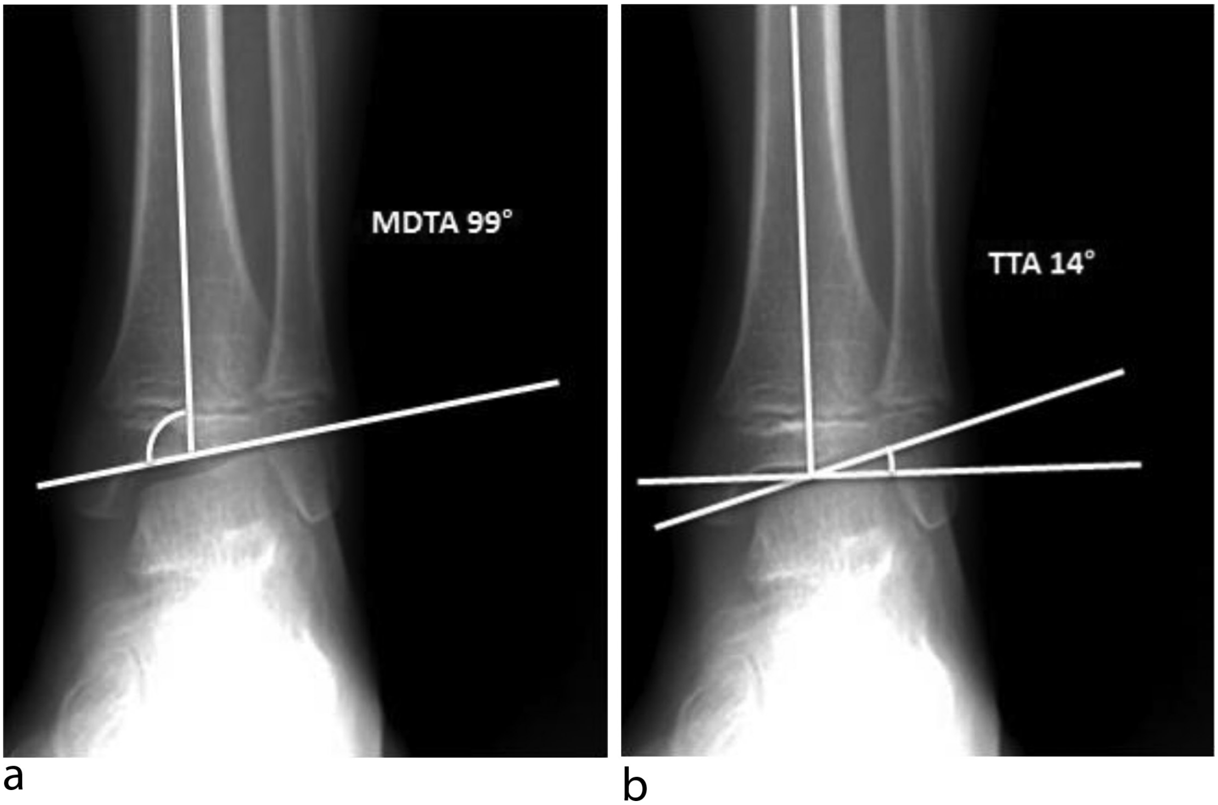

Fig 5 Anteroposterior ankle radiographs in standing weight-bearing position of a nine-year-old male with ankle valgus and pain. The radiographs show the difference between two different measurements: (**a**) medial distal tibial angle (MDTA); (**b**) tibiotalar angle (TTA), in the same ankle.

and age or increased BMI, the association between ankle pain and valgus (Fig. 5) supports previous studies showing that, although ankle valgus might remain asymptomatic for many years, it can result in walking instability, mechanical pain and difficulty wearing shoes.[10,34]

The difference in the management of foot and ankle deformities between children with and without Down syndrome was not addressed in our study. Although follow-up data were not available to evaluate the results of conservative treatment, most children with painful feet or ankles had other major musculoskeletal disorders (cervical instability, scoliosis, hip disorders or patellar instability) that might be more of a priority for the families. However, since our data did not show improvement with age, further investigation is necessary to establish the proper management options. The role of surgery is not clear, and the conservative approach is still the mainstay of treatment until further research is available.

The limitations of our study included its retrospective nature and the small number of patients. In addition, our group consisted only of children who had radiographic evaluation. The functional profile was not evaluated in our group due to the absence of an objective functional assessment tool. However, the condition is rare, and foot and ankle radiographic measurements in Down syndrome have not been previously reported. We plan to investigate the relationship between foot and ankle deformities and other lower limb malalignment deformities to detect any effect of the foot and ankle deformities on the alignment of the extremity.

In children with Down syndrome, radiographic evaluation of the foot and ankle reveals higher prevalence of deformities than clinical examination. However, foot and ankle radiographs are needed only for symptomatic children with pain and gait changes. Although our study showed that no change of flatfoot is expected with growth, and that increased BMI is not associated with specific deformities, the effect of ankle alignment on knee and lower extremity alignment is still not clear and needs to be investigated further. The radiographic findings reported in this study can serve as a useful baseline for future clinical investigations of foot deformities in Down syndrome. Moreover, the late effects on the patient's level of activity as an adult also need to be addressed, especially with elevated BMI, taking into consideration the recent improvements in life expectancy and the active participation in sports for many individuals with Down syndrome.

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COMPLIANCE WITH ETHICAL STANDARDS

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Ethical approval: All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

IRB approval was obtained prior to the study.

Informed Consent: Informed consent was not required for this work.

ICMJE CONFLICT OF INTEREST STATEMENT

None declared.

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