Title**: Corrective bandage for conservative treatment of metatarsus adductus: A retrospective study.**

Running title**:** Corrective bandage for metatarsus adductus

AUTHORS:

Elia Utrilla Rodríguez (Utrilla-Rodríguez E)

Physiotherapist. Paediatric Rehabilitation Service, University Hospitale "Virgen de Macarena", Seville (Spain).

Address: Avd. Dr. Fedriani, 3, 41071 Sevilla.

Phone: +34 955 00 80 00

E-mail: eliautrilla@gmail.com

María Jesús Guerrero Martínez-Cañavete (Guerrero-Martínez-Cañavete MJ)

Physiotherapist. Paediatric Rehabilitation Service, University Hospitale "Virgen de Macarena", Seville (Spain).

Address: Avd. Dr. Fedriani, 3, 41071 Sevilla.

Phone: +34 955 00 80 00

E-mail: mjguerrero@us.es

Manuel Albornoz Cabello, Ph.D (Albornoz-Cabello M)

Lecturer at the Department of Physiotherapy, University of Seville.

Address: Departamento de Fisioterapia. Calle Avicena, s/n. 41009 Seville (Spain)

Phone: +34 954486528

E-mail: malbornoz@us.es

Pedro V. Munuera, Ph.D (Munuera PV) **CORRESPONDING AUTHOR**

Lecturer at the Department of Podiatry, University of Seville.

Address: Departamento de Podología. Calle Avicena, s/n. 41009 Seville (Spain)

Phone: +34 954482170

E-mail: pmunuera@us.es

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ABSTRACT

Background: Metatarsus adductus is the most common congenital foot deformity observed in children.

Objectives: To analyze the evolution of a corrective bandage of the semi-rigid metatarsus adductus (MA) foot in newborn and to recommend the age interval at which to start treatment of MA with corrective bandage alone, without the need of splints.

Study Design: An observational, clinical study was performed at the University Hospital "Virgen Macarena," in Seville, Spain. Children born with semi-rigid metatarsus adductus feet at the Virgen Macarena University Hospital in Seville during the years 2010-2011 were included. Corrective bandaging was applied to all children until clinical correction of the deformity. Sex, laterality of the deformity, weight and length of the newborn, age at the start of treatment, antecedents related to the pregnancy and birth, type of treatment (bandaging, splints) and correction or no correction with bandaging alone were recorded. Age differences at the start of the bandaging treatment between patients whose deformity was corrected with and without the need of splints were examined. The ROC curve method was applied to analyze the predictive ability of the age at the start of bandaging treatment relative to whether the deformity was corrected or not corrected with bandaging alone.

Results: The bandage achieved complete correction in 68.1% of the metatarsus adductus patients and corrected the deformity more frequently in girls compared to boys

(p=0.017). Of the 56 patients who began the treatment within the first month of life, 92.8% were corrected with the corrective bandaging alone.

Conclusion: Corrective bandages showed high effectiveness, particularly in girls, and overall when started within the first month of life.

INTRODUCTION

Metatarsus adductus is the most common congenital foot deformity observed in children, and its frequency has increased in recent years (1 to 3 per 1000 newborns)[1-3]. It is a complex deformity that requires knowledge of its causal components prior to correct treatment[4,5], as treatment and expected outcomes will differ accordingly. There is a disorder of the alignment of the forefoot, with varying degrees of adduction and supination (Figure 1). Moreover, the outer side edge of the foot is convex, with a lateral and dorsal prominence at the base of the fifth metatarsal and cuboid bone. Although the calcaneus is in a valgus position, there is no equinus deformity, in contrast to a club-foot. In some cases, the deformity improves or corrects itself spontaneously. However, if these outcomes do not occur and the deformity is also not treated, then the child will have an altered gait, i.e., he or she will walk with the toes pointed toward the midline ("in-toeing") and may experience recurrent tripping, that could moreover have a significant impact on both the child and parents[6]. This dysfunction results in an increased number of falls due to the child's consequent psychomotor retardation[7,8]. Furthermore, in the long-term, the pressure exerted by the shoe may be a predisposing factor for the development of hallux valgus[3,9].

The classification used for years at Hospital Universitario Virgen Macarena de Sevilla for this deformity, is the following[9]: Grade 1, when there is adduction of the forefoot without inversion, being able to perform abduction passively or by means of stimulation of the peroneal musculature; Grade 2, when the foot is slightly shortened, the forefoot is in adduction and inversion, the external border of the foot is convex (with prominent base of the fifth metatarsal), and the internal border concave, with normal longitudinal

arc, and that can be partially corrected; Grade 3, which corresponds to feet with more structured deformity, because we have to add kidney-shaped form to the features reported above, with transversal sulci in the medial region of the foot, increased internal longitudinal arc, marked longitudinal shortening of the foot and passive correction of the forefoot is not possible. Cases of grade 3 deformity require surgery whilst grade 1 and 2 cases can be corrected traditionally[9].

Treatment of the metatarsus adductus foot varies depending on the degree of misalignment, ranging from observation and conservative (observation and monitoring) in mild cases, to the placement of serial casts, thermoplastic splints, and even surgery in the most severe cases[10, 11]. Most authors agree that the best therapeutic option will be dependent on the initial flexibility of the foot, which ranges from a waiting attitude in mild cases to surgery for the stiffest feet[2, 4, 7, 9, 12-15]. There is a general consensus that, in the most flexible cases (grade 1 feet, according to the classification of the Virgen Macarena Hospital[9]), a vigilant attitude should be adopted or parents should be taught foot flexibility exercises to be performed regularly at home. However, to the best of our knowledge, there is little scientific literature supporting successful treatments of more severe cases of MA. Thus, determining the most appropriate treatment remains controversial. Most studies of semi-rigid or second-grade metatarsus adductus have shown that treatment with serial casts below the knee is the most common therapy[1, 4, 10, 16-18]. This treatment is followed in frequency by the placement of position-correcting splints and parental control of the child's sitting and sleeping postures[4, 12, 16, 19]. Although this is a rather aggressive treatment, in the authors' opinion, more simple and cost-effective new techniques could be developed, i.e. by means of corrective bandages. To

the best of our knowledge, only a few studies have recommended treatment with corrective bandaging as the primary conservative treatment option [9, 13, 14]. This technique has the advantage of allowing daily manipulation and correction of the foot, as well as reducing treatment time and cost.

The main aim of this study was to ascertain the effectiveness of a corrective bandaging treatment of the semi-rigid (or second-grade 2) metatarsus adductus foot in newborns at the Virgen Macarena Hospital in Seville. Another aim was to establish the most recommended age interval at which to commence start this treatment in order to achieve correction of the deformity with bandaging alone, without applying splints.

STUDY DESIGN

A retrospective study was designed with children born with semi-rigid or second-grade MA feet during the years 2010-2011 who were treated with corrective bandaging. The study was performed at the Virgen Macarena Hospital in Seville, Spain, and was approved by the Hospital's Ethics Committee.

Participants

The inclusion criteria for participants included having been diagnosed with second-grade MA foot according to the classification of the Hospital Virgen Macarena[9], and having received no prior treatment. The exclusion criteria were patients with skeletal dysplasia, neuromuscular pathology, or other abnormalities of the foot, and children whose medical records were incomplete or who had not completed treatment. The final number of patients who met the selection criteria was 94.

Tests and measures

The variables recorded were: gender (male or female), laterality of the deformity (unilateral right or left, or bilateral), weight (grams) and length (centimeters) of the newborn, age (days) at the start of the treatment, antecedents related to the pregnancy and birth (normal vaginal, Cesarean section, vacuum suction or forceps), type of treatment (bandaging, splints) and its duration (days), and whether the deformity was corrected with bandaging alone.

Two experienced physiotherapists treated all of the children in the same manner (EUR: 22 years as a physiotherapist, 18 years of experience as a pediatric physiotherapist; and MJGMC: 40 years as a physiotherapist, 37 years of experience as a pediatric physiotherapist).

Procedure

Treatment with corrective bandaging was performed by physical therapists with more than 20 years of experience in the children's physiotherapy unit at our hospital. Treatment sessions were conducted five5 days a week for approximately 15 minutes per foot and consisted of a first phase of flexing the retracted structures of the foot with corrective manipulation and stimulation of the peroneal muscles with a toothbrush. Subsequently, corrective bandaging was applied using cotton bandages and strips of adhesive dressings placed from the base of the first metatarsal to the top of the leg.

Bandaging followed a distal to proximal direction. After several layers of cotton bandage, the strip was placed over the head of the first metatarsal and then on the plantar surface of the remaining metatarsals ending on top of the leg, under the knee (Figure 2). Thereafter, several layers of bandage were applied to maintain plaster strip tension and correction achieved during manipulation. The bandage was not so tight as to

compromise circulation, and was examined before the child left the physiotherapy unit. If necessary, it was removed and replaced with another bandage.

The bandaging was renewed every other day until the deformity was clinically corrected. Correction criteria included complete correction of the external convexity of the foot, absence under palpation of the prominence of the fifth metatarsal base, and balance in the musculature of the foot[8]. Patients were followed up at two years after treatment initiation.

Data analysis

The data were analyzed using IBM SPSS statistics v. 20 (SPSS Science, Chicago, USA). The analysis included a general descriptive analysis with a determination of the means and standard deviations of the quantitative variables measured, and absolute and relative frequencies (as percentages) of the qualitative variables. Next, the potential associations of the variables laterality, sex, and type of birth with the effectiveness of the bandaging treatment were evaluated using the chi-squared or Fisher's exact tests in the case of 2×2 contingency tables. Age differences at the start of the bandaging treatment between patients whose deformity was corrected without splints and those who needed splints were examined using the Mann-Whitney U-test. A subsequent test of potential age differences was performed by binning the ages at the start of treatment into four intervals and comparing the cases that did or did not require splints using the chi-squared test. Finally, the ROC curve method was applied to analyze the predictive ability of age at the start of the bandaging treatment relative to whether the deformity was corrected with bandaging alone or whether splints would be required. Values of the area under the curve (AUC), sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) were determined. In all of the analyses, α significance

level was established at 0.05, or confidence level = 0.95. Also, β value (type II error) was *a priori* established at 0.2, or power (1 - β) = 0.8.

RESULTS

Descriptive data

The number of second-grade MA feet studied was 94 patients. Of these patients, 54.3% (51/94) were girls, 45.7% (43/94) boys, 80.9% (76/94) were affected bilaterally, and 19.1% (18/94) were affected unilaterally. In the unilaterally affected cases, 38.8% (7/18) were left feet and 61.1% (11/18) were right feet. Regarding the type of delivery, 69.1% (65/94) were normal vaginal, 18.1% (17/94) Cesarean section, 8.5% (8/94) vacuum suction, and 4.3% (4/94) forceps. The values of the remaining quantitative variables recorded are listed in Table 1.

Effectiveness of corrective bandages

Importantly, regarding the effectiveness of the treatment with bandaging, 68.1% (64/94) of the patients with MA, whether unilateral or bilateral, were corrected with bandaging alone. In addition, in the remaining 31.9% (30/94) patients, it was necessary to apply a posterior splint. The bandaging treatment was more effective in girls compared to boys: 78.4% (40/51) of the girls did not need a splint versus 55.8% (24/43) of the boys ($p=0.017$). As shown in Table 1, the mean number of bandages required for clinical correction was 7.74. The nearest round number would be eight bandages. As the bandages were changed each other day, it could be upheld that the mean time required for treatment was 16 days.

Recommended age interval at which to commence treatment with corrective bandages

Comparison of the time from birth to the start of treatment between patients for whom the correction of the deformity was obtained with bandaging alone and patients for whom it was necessary to apply splints showed that a favorable outcome would more

likely occur when the earlier the treatment was initiated (Mann-Whitney U = 151.5; $p < 0.001$). The age at which treatment was started for patients in whom the correction was achieved with bandage alone (n = 64) was 23.41 ± 21.07 days, and for whom splints were necessary (n = 30) was 107.63 ± 64.41 days.

The ages at the start of the treatment were binned into 4 intervals: up to two weeks (28 patients, two required half-cast plaster splints), between two weeks and one month (28 patients, two of them needed splints), between one month and three months (26 patients, 14 needed splints), and more than three months (12 patients, all needed splints). There was a significant difference between the children who had started treatment before one month of age and the remaining patients, independent of the need for splints (Chi-squared = 41.17; $p < 0.001$).

The ROC curve was calculated to obtain a predictive value for age in days at the start of treatment as a predictor of whether a splint would be needed. In this study, 30 patients needed splints and 64 patients did not. For the patients who needed a splint, the ROC curve values were selected to be positive, and the value of the AUC (Area: 0.921, Standard Error: 0.034, $p < 0.001$; 95% IC 0.855 – 0.987) was computed (Figure 3).

The optimal value of the age at which to start the treatment was obtained for a value of AUC equal to 0.921. This optimum value corresponded to the sensitivity. In particular, the sensitivity at this optimum was 0.933 (95% CI 0.787-0.982), and the specificity was 0.719 (95% CI 0.599-0.814). Using these data, the optimal age for starting treatment was four weeks (> 27.50 days). The results with this criterion, as well as the odds ratios derived from those data, are listed in Table 3. The corresponding PPV (true

positives/[true positives + false positives]) was 61% (95% CI 46.5-73.6%), and the NPV (true negatives/[true negatives + false negatives]) was 96% (95% CI 86.0-98.8%).

Experimental power calculation

The first group (lesser or equal to 27 days) has a proportion of patients that require a splint of $\frac{2}{46+2} = 0.04167$. The second group would obtain a proportion of $\frac{28}{18+28} = 0.6087$. Therefore, by applying these data to the power calculation formula for two proportions we obtain the following result:

$$Z1\text{-}\beta = \frac{|p_1 - p_2|\sqrt{n} - z_{1-\frac{\alpha}{2}}\sqrt{2p(1-p)}}{\sqrt{p_1(1-p_1) + p_2(1-p_2)}}$$

Where P1=0.04167, P2=0.6087, n=94

$Z_{1-\frac{\alpha}{2}} = 1.96$, because α=0.05

$$P = \frac{p_1 + p_2}{2} = \frac{0.04167 + 0.6087}{2} = 0.3252$$

$$Z1\text{-}\beta = \frac{|0.04167 - 0.6087|\sqrt{94} - 1.96\sqrt{2 \cdot 0.3252(1-0.3252)}}{\sqrt{0.04167(1-0.04167) + 0.6087(1-0.6087)}} = 7.96$$

By obtaining a Z value greater than 4 we can state that the power of the study, 1-β is greater than 0.8 and approximate to the unit, whereby the authors consider that this is an optimal result.

DISCUSSION

In the present study, a new method of treatment based on the application of corrective bandaging is described. This technique was performed on 94 MA patients of second-grade severity according to Virgen Macarena Hospital classification[9]. Only a few references using this approach have been found in the literature[9, 13, 14]. The present study found that the feet were completely corrected with this treatment in 68.1% of the patients and that the mean time required for treatment was 16 days, which clearly indicate the effectiveness of the treatment both clinically and in terms of cost-effectiveness. The clinical correction was maintained, at least, during the two years of follow-up.

Most authors agree that the best therapeutic option will be dependent on the initial flexibility of the foot, which ranges from a waiting attitude in mild cases to surgery for the stiffest feet[2, 4, 7, 9, 12-15]. There is general consensus that, in the most flexible cases (first-grade feet, according to the classification of the Virgen Macarena Hospital[9]), a vigilant attitude should be adopted or the parents should be taught foot flexibility exercises to be performed regularly at home.

Different treatment possibilities have been proposed such as in cases where the deformity is semi-rigid or of second grade. In the literature, the treatment of choice is usually serial casts, as reflected in studies from the mid twentieth century[1, 4, 8, 13, 17], in which acceptable results for the correction of the MA foot are reported after the placement of serial casts, with treatment duration from 6 to 12 weeks.

Another commonly proposed treatment method is the application of corrective splints. This treatment has been advocated by authors such as Votta and Weber[20] and Chong[21], and recently by Herzenberg and Burghardt[22] who performed a clinical trial using 43 MA

feet and compared the correction obtained with serial casts with that obtained using splints. The results of the latter study showed that the two methods provided similar corrections. Moreover, while the cost was much less with a splint, the treatment time was 6 weeks with casts compared to 12 weeks with a splint.

Surgical treatment in the most severe or most rigid cases has been advocated by several authors[23, 24], although this approach has more secondary complications and longer recovery times. The procedure may involve adductor tenotomy of the abductor hallucis, an anteromedial release of the foot, or even a percutaneous correction as described by Knorr et al.[25] in a study on 34 metatarsus adductus feet treated using this technique.

Analysis of the results in the present study showed that the MA feet that were not completely corrected with bandaging, but also required the use of splints, were those for which treatment was initiated relatively late. Of the 56 patients who began treatment within the first month of life, 92.8% were corrected with bandaging alone. Of the 25 patients whose treatment began between the first and third months of life, only 48% were corrected with bandaging alone. In addition, all of the 13 patients whose treatment began after the third month of life needed splints and corrective bandaging.

The area under the ROC curve is equivalent to the probability that if we were to choose two children at random, one who needed a splint and the other not, the test would classify them correctly. Therefore, the area under the ROC curve (AUC) estimates the capacity to distinguish or differentiate whether or not a splint is needed in the future. The diagnostic test would have more capacity for discrimination the greater the area under the curve. In our study we obtained an AUC of 0.921 (95% CI: 0.855-0.987) and because 0.500 is not included in the confidence interval we can interpret that the test provides positive information on the diagnosis. The cut-off obtained is greater or equal

to 27.50, and the prediction of whether or not a splint is required, according to the age at which the patient commenced treatment with bandages, using data from this cut-off point, is shown in Table 3.

These results confirm the importance of the early diagnosis and treatment of the MA foot. While most published studies indeed advocate early treatment of MA and recommend starting treatment within the first year of life, they do not comprehensively analyze the potential differences that may exist within this time period[5]. Some previous studies did not find any statistically significant relationship between the patient's age and the treatment outcome[9, 17]. This finding contrasts with the present results, which showed a clear relationship between the age at the start of the treatment and the type and duration of treatment required for final correction.

One limitation of the present study is that it was only feasible to analyze the corrective bandaging method over the short and medium terms, as the patient follow-up time was two years. The authors believe that it would be appropriate for future research to analyze the corrective bandaging method in the long term, particularly at the end of the child's growth period.

In summary, the corrective bandaging method studied in the present work achieved a complete correction in 68.1% (64/94) of metatarsus adductus patients. The other 31.9% (30/94) patients needed the application of a posterior splint. All corrections were maintained to at least the two-year follow-up. The bandaging treatment corrected the deformity more frequently in girls than in boys (78.4% of the girls and 55.8% of the boys did not need splints). The age at the start of the bandaging treatment influenced the likelihood of success in these second-grade metatarsus adductus cases. Of the 56

patients who began treatment within the first month of life, 92.8% were corrected with the corrective bandaging alone.

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TABLE 1

	Mean	Median	Standard deviation	Minimum	Maximum	Total
Age from birth at start of treatment (days)	50.29	24	56.148	3	300	94
Number of bandages applied	7.74	8	3.114	1	14	94
Weight at birth (g)	3373.53	3307.50	456.805	2060	4500	94
Length at birth (cm)	49.606	49.500	1.9768	43	54	94

Table 1: Descriptive statistics of the quantitative variables used in the study.

TABLE 2

Age at which treatment was started (days) (n = 94)	**Was a splint needed?**	
	No	**Yes**
Up to two weeks (n = 28)	26	2
	40.6%	6.7%
Between two weeks and one month (n = 28)	26	2
	40.6%	6.7%
Between one month and three months (n = 26)	12	14
	18.8%	46.7%
More than three months (n = 12)	0	12
	0%	40%

Table 2: Distribution of patients who needed and who did not need half-cast plaster splints, by intervals of age at the start of the bandaging treatment.

TABLE 3

Splint needed?	**Age at which treatment was started**		
	Age ≤ 27 days (N)	**Age ≥ 28 days (N)**	**Total (N)**
No	46 (true negatives)	18 (false positives)	64
Yes	2 (false negatives)	28 (true positives)	30
	N = 48	N = 46	N = 94

		95 % IC
Likelihood ratio	35.78	7.71 - 165.99
Likelihood ratio +	3.32	2.22 - 4.97
Likelihood ratio -	0.09	0.02 - 0.36

Table 3: Prediction of the need for plaster half-cast splints for the treatment of metatarsus adductus, taking as lower cut-off point 27.5 days in age at the time of starting the bandaging treatment (Sensitivity 93.3%; specificity 71.9%) and Odds Ratios derived from those data.

FIGURE LEGENDS

Figure 1. One-day-old child with metatarsus adductus.

Figure 2. Cotton bandage and end of the strip of adhesive tape, below the knee.

Figure 3. ROC graphic. 1-Specificity is represented instead of Specificity so that correct diagnosed cases can stay under the curve. In that way, false positives and false negatives would stay above the curve.