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Universal Neonatal Foot Orthotics for Metatarsus Adductus

Clinical studies results publications

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6 Months Boy

Results after 14 days

worldwide patent CE FDA

UNFO
med ltd
Universal Neonatal Foot Orthotics

UNFO - Revolutionary Therapy of Metatarsus Adductus (MTA) Why is it Better from Any Other Treatment exists?

Why is it better for the Patients? (The Babies and their Parents)

- No need for Casting or Hospitalization
- Much more user friendly than any other treatment
- Almost no restriction for the Baby during the treatment (washing, crawling, dressing, Hygienic issues and so on)
- Much Shorter treatment (6 weeks full days + 6 weeks nights only for most cases)
- Best scientifically proven treatment results with less regression rates
- Possibility to treat mild cases that are not treated today due to the casting treatment inconvenience and complications, hence reducing from 15-20% to zero the mild cases that are NOT cured spontaneously!

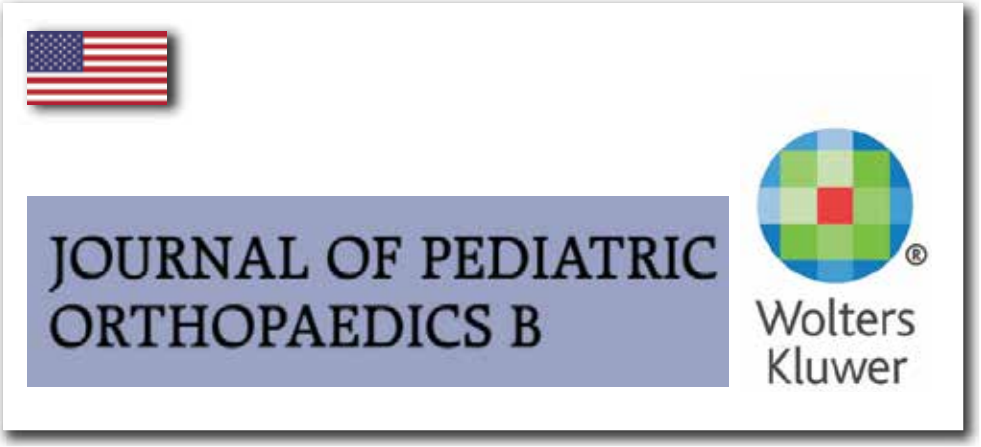
Why is it better for the Doctors? (The Pediatric Orthopedics)

- Giving the best solution to their patients
- Possibility to treat mild cases that are not treated today due to the casting treatment inconvenience and complications, hence reducing from 15-20% to zero the mild cases that are NOT cured spontaneously!
- The only product with 6-points dynamic circular fixation, Anti Cavus +Anti Adductus

Why is it better for the Therapists? (The Pediatric Orthotists)

- Giving the best solution to their patients
- Clean, easy and Patient friendly treatment
- Possibility to solve problems immediately (in contrary to problems under cast that are not possible to solve)

	UNFO 2018	BeBax 1990	Serial Cast 1836	Strapping Very Old
Patients (Babies and Parents) Satisfaction, Restrictions and Complications	▪ Almost No restrictions ▪ Very minor complications that can be solved immediately ▪ Dynamic ,Easy to use and change by parents according to treatment progress	▪ Should remove several times a day ▪ Pressure sores ▪ Not Dynamic, no influence by parents during treatment	▪ Baby bathe limitations ▪ Delay in Baby Crawling and development ▪ Skin Breakdowns ▪ Hygienic discomfort ▪ Impossible to treat injuries under cast ▪ Static treatment ▪ Needs to be replaced 3 times	▪ Baby bathe limitations ▪ Delay in Baby Crawling and development ▪ Skin Breakdowns ▪ Hygienic discomfort ▪ Impossible to treat injuries under strap ▪ Static treatment ▪ Needs to be replaced every 2 days
Treatment Duration	6 Weeks (full day) 6 Weeks (night only)	8-14 Weeks + 3- 6 months Last reverse shoes (not always)	6 Weeks (3 serial casts) + 3- 6 months Last reverse shoes	8-12 Weeks + 3- 6 months Last reverse shoes
Long Term Results Quality	Excellent	Fair	Good	Fair
Installation	▪ 1 Orthotist after short training ▪ Free Ankle Joint ▪ Single Strap	▪ 2 Orthotists ▪ Fixed Ankle Joint ▪ 2 Straps	▪ Doctors/Cast specialist /Orthotist Only ▪ Full leg(s) fixed	New installation every 2 days (by specialist)
Doctors /Specialists Opinion and Satisfaction	▪ Excellent for all cases (The only treatment with 6-point dynamic circular fixation, Anti Cavus +Anti Adductus) ▪ Clean, easy and Patient friendly treatment	Fair for Mild cases, Poor for moderate & Severe cases	▪ Fair (used for moderate & severe cases only) ▪ "Dirty" work with cast	Poor



Novel device for nonsurgical correction of rigid forefoot adduction in children

Daniel Freedman, Pavel Kotlarsky and Mark Eidelman

OPEN

Novel device for nonsurgical correction of rigid forefoot adduction in children

Daniel Freedman, Pavel Kotlarsky and Mark Eidelman

Forefoot adduction deformity (FAD) (commonly called metatarsus adductus) is reported as the most common congenital foot deformity in newborns. Early diagnosis and treatment are important in rigid cases, as better outcomes have been reported if treatment was initiated before 9 months of age. While casting and splinting is the current standard of care for nonsurgical management of rigid FAD (RFAD), several orthoses have demonstrated equal benefit. The Universal Neonatal Foot Orthotic (UNFO) brace is below ankle orthosis that provides continuous pressure, thereby correcting the deformity without casting. To the best of our knowledge, UNFO is the first brace that operates below the ankle. The aim of this study was to compare the effectiveness of UNFO shoe to standard serial casting in the treatment of RFAD in infants. Between the years 2012 and 2019 we treated 147 feet (94 patients): 52 using the UNFO shoes and 95 by standard casting and splinting protocol. The treatment groups were compared based on treatment duration, complications, and recurrence of deformity. Mean full-time treatment duration was significantly shorter in the UNFO group, while no significant difference in the total duration of treatment was observed. Similar complication and recurrence rates were demonstrated. In conclusion, treatment with UNFO is equally effective to serial casting. The use of UNFO increases convenience and diminishes social burden, thus providing a distinct advantage over other treatment modalities. *J Pediatr Orthop B* **31: e202–e207 Copyright © 2021 The Author(s). Published by Wolters Kluwer Health, Inc.**

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Keywords: foot deformity, forefoot adduction, metatrsus adductus, metatarsus varus, rigid foot deformity

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Introduction

Forefoot adductus deformity (FAD) occurs in one to three cases per 1000 births and has been reported as the most common congenital foot deformity in newborns [1–3]. There is no consensus in the literature regarding the terminology. The most used terms are metatarsus adductus and metatarsus varus. Many use the names metatarsus adductus and metatarsus varus interchangeably to address the same pathology [4]. Some define metatarsus varus as a rigid type of metatarsus adductus [3]. Others define metatarsus varus as a slightly different deformity where there is supination of the forefoot in addition to forefoot adduction. The deformity is rigid, and a medial deep crease is seen at the transition between the midfoot and the hindfoot [5,6].

FAD is a congenital condition where the forefoot is adducted with respect to the midfoot. Several classification systems have been proposed to help categorize the disorder [2,7–11]. The most popular classification, described by Bleck, uses the heel bisector method, where the severity of the condition is defined by the amount that a line bisecting the heel to the webspace of the second and third toes deviates laterally [7] (Fig. 1). Another frequently used classification system describes the condition based on foot flexibility, classifying the foot as either flexible, semi-rigid, and rigid [8,9,11].

The need for treatment of FAD is controversial and largely depends on its severity: mild and moderate FAD has shown to correct naturally with age [11,12]. However, for rigid FADs (RFAD), prompt evaluation and treatment are essential in managing the condition, as better functional outcomes were reported when treatment was initiated before 9 months of age [6,7,13]. Additionally, remodeling of the tarsometatarsal joint becomes less likely after this time [13,14]. Foot deformities should be corrected prior to the commencement of weight bearing to prevent the negative effects of ground reaction forces on malaligned feet. Left untreated or undertreated, FAD in the older child or young adult can progress to permanent foot deformities, such as hallux valgus [15,16], as well as skewfoot [10]. Furthermore, previous studies have identified a correlation between uncorrected FAD and fifth metatarsal stress fractures [17,18], as well as Jones fractures [19].

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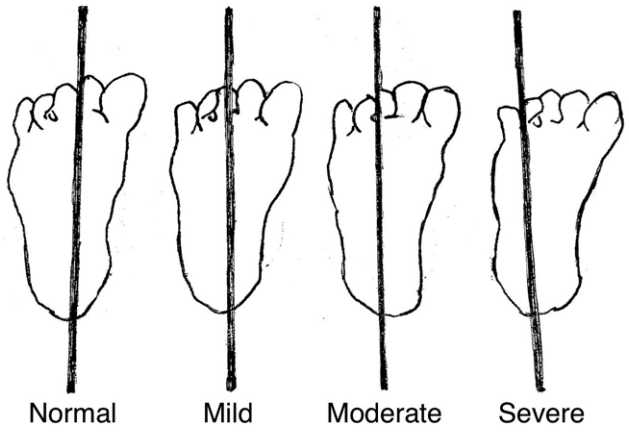
The treatment of FAD is mostly nonsurgical, with surgical treatment reserved for treatment-resistant cases in older children [20,21]. Nonsurgical treatment of FAD can be split into orthoses and casting, yet a consensus remains uncertain. Both above knee and below knee casting have demonstrated effectiveness in the treatment of moderate and severe FAD [14,22]. While serial casting has proven efficacious at restoring deformity and currently remains the standard of care, its use is not without complications, thereby highlighting the importance of alternative methods of treatment. Several studies have demonstrated similar results to serial casting using various orthoses and bandages for the treatment of severe FAD, and noted added benefits as well [23,24].

Fig. 1



Bleck classification method of metatarsus adductus (MA). The normal foot has a line that bisects the heel and the second and third toe webspace. Mild metatarsus adductus has a line that bisects the heel and the third toe, moderate metatarsus adductus has a line that bisects the heel and the third and fourth toe webspace, while severe metatarsus adductus has a line that bisects the heel and the fourth and fifth toe webspace [7].

The Universal Neonatal Foot Orthotic (UNFO) shoe (UNFO Med Ltd.; Holon, Israel) is a novel device designed for correction of FAD (Figs 2 and 3). It is composed of polypropylene on the outside and thermoplastic elastomer on the inside, providing constant molding and applying continuous pressure for gradual correction of FAD. To the best of our knowledge, this is the first device that operates below the ankle, mimicking a sandal in design, thus providing much less of a social burden associated with serial casting. To our knowledge, no controlled data exist to date comparing serial casting to below ankle orthoses for the treatment of RFAD.

The aim of our study was to compare the effectiveness of the UNFO shoe to standard serial casting in the treatment of RFAD in infants.

Materials and methods

Research population

This is a retrospective study comparing the efficacy of treatment by casting and splinting to UNFO in infants with RFAD. We extracted data from electronic medical records of all patients who presented to our hospital between 2012 and 2019 with the diagnosis of FAD. The extracted data included: age, sex, type and length of treatment, any complications, and recurrences. During the years 2012–2017, we treated all RFAD patients with casting and splinting protocol. From the beginning of 2018,

Fig. 2

The UNFO (Med Ltd.; Holon, Israel) shoes. UNFO, Universal Neonatal Foot Orthotic.

Fig. 3

A 3-month-old baby with the UNFO (Med Ltd.; Holon, Israel) shoes on. UNFO, Universal Neonatal Foot Orthotic.

we switched our treatment to UNFO. We, therefore, compared two retrospective cohorts – casting and splinting treatment (2012–2017) to UNFO treatment (2018–2019).

Inclusion criteria were patients with severe rigid FAD, as defined by the Bleck and the flexibility classification methods, who first presented to our department at less than 1 year of age. Exclusion criteria were patients who had other concurrent medical comorbidities (patients with developmental dysplasia of the hip that were treated and reached Graf type I hip before the commencement of FAD treatment were included) and patients that did not complete the full follow-up period up to walking age. The study was approved by the institutional ethics committee.

Classification:

FAD is primarily classified by two methods. The Bleck classification method describes the deformity by the degree of lateral deviation of a line that bisects the heel and the second and third toe webspace [7]. Description of deformity is outlined in Fig. 1. The other common classification method defines the deformity by the flexibility of the foot under passive manipulation. One that easily returns to midline is considered flexible, one that partially returns to midline is considered semi-rigid, and a foot unable to be returned to midline is considered rigid [8,9,11,13]. When in addition to forefoot adduction, forefoot supination is present, a deep medial crease at the transition between the mid and hindfoot is present [5,6].

Universal Neonatal Foot Orthotic treatment protocol

The UNFO shoes have two sizes and are designed to fit patients between ages 2 and 12 months (Figs 2 and 3). The smaller size intended for feet 7–9 cm in length, and the bigger size for feet 9–10 cm in length. Treatment ideally should commence between 3 and 6 months of age. During the first 6 weeks, the patients were treated full time, for 23 h daily, allowing a brief removal of the shoe twice daily for hygienic purposes. After 2 weeks of treatment, we expect to achieve near correction. Following additional 4 weeks, a slight overcorrection is expected. At this stage, the parents were instructed to start maintenance protocol for the following 6 weeks: 3 weeks of 15 h/day, and the rest 12 h/day (Fig. 4). If a patient had recurrence of deformity during the maintenance period, additional 2 weeks of full-time treatment was administered, with a subsequent similar 6-week tapering period. Routine follow-ups were scheduled 1 month following treatment cessation, and then several follow-ups until the commencement of ambulation.

Casting and Splinting treatment protocol

Patients were placed in an above-knee cast for 2 weeks. After this period, if the correction was not achieved, they were casted for two additional weeks. Subsequently, the patients were placed in a custom-made ankle-and-foot-orthosis (AFO) for maintenance of correction for 8–16 weeks: the first half in a full-time splint (23 h/day) and the second half in a part-time splint (12 h/day).

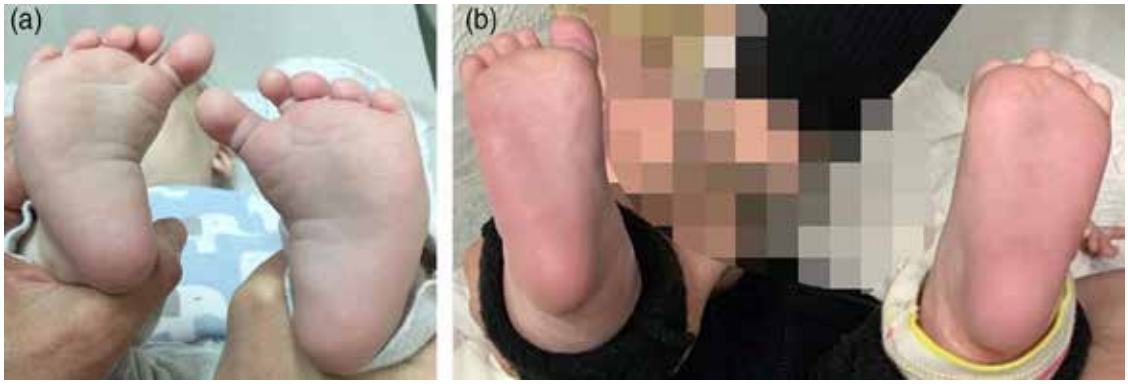
Data analysis

We compared the treatment methods based on the duration of treatment (full-time vs. part-time), associated complications, and recurrence of deformity. In the casting and splinting group, full-time treatment was length of time the patient was in a cast combined with the time in a full-time splint. In the UNFO group, full-time treatment was defined as the period in which the patient was instructed to wear the shoe for 23 h daily. Recurrence of FAD was defined as any feet that required treatment after being deemed corrected.

Statistical analysis

Descriptive statistics were used to describe and analyze the data relating to patient characteristics, recurrence, and complication rates. A two-tailed *t*-test with a P value <0.05 for significance was used to compare the two treatment populations for age at first presentation and for comparison of treatment duration.

Fig 4



Four and a half months old patient with bilateral rigid forefoot adduction deformity (RFAD); (a) initial deformity before treatment, (b) the result one month after cessation of treatment.

Table 1 Demographics of patients receiving Universal Neonatal Foot Orthotic and casting and splinting treatments

Treatment group	Average age at presentation (months ± SD[a])	Number of feet	Left feet	Right feet	Male	Female
UNFO	5.45 ± 2.09	52	27	25	32	20
Casting and splinting	4.23 ± 1.94	95	51	44	57	38

The difference in the average age at first presentation was statistically significant with $P<0.01$.
UNFO, Universal Neonatal Foot Orthotic.
[a]SD. - Standard Deviation.

Results

Between the years 2012 and 2019, 174 feet (111 patients) with RFAD presented to our department. Out of these, 27 feet in the casting and splinting group were lost to follow-up and were excluded. Included in the final analysis were 147 feet (94 patients): 52 in the UNFO group and 95 in the casting and splinting group. Patients demographics are described in Table 1.

The length of treatment is depicted in Fig. 5. Although full-time treatment was shorter in the UNFO group by approximately 1 week, there was no significant difference in the total treatment duration.

The complication rates were 0.17 and 0.13 in the UNFO and casting and splinting groups, respectively. In the UNFO group, mild skin irritation was noted in three feet, and superficial pressure sores in four feet. In the casting and splinting group, skin abrasions secondary to cast removal were seen in four feet, and superficial pressure sores in seven feet. None of the complications in either treatment group warranted treatment cessation or led to long-term disability.

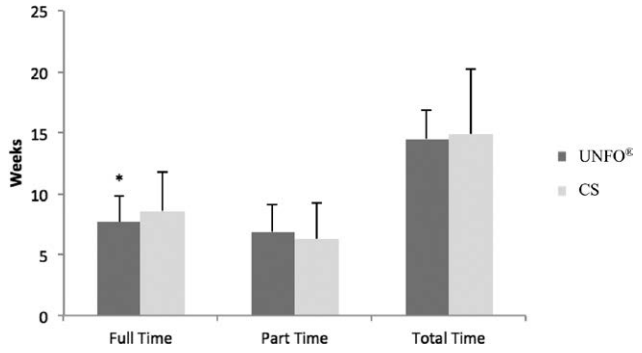
The recurrence rates were 0.05 and 0.06 in the UNFO and casting and splinting groups, respectively. In the UNFO group, a recurrence was noted in two feet of one patient at the age of 7 months. This patient's parents initially placed the UNFO on the wrong feet, thereby, exacerbating the deformity. This mistake was realized and explained to the parents on the first 2 weeks follow-up examination, whereby treatment was subsequently restarted. The patient reached correction after 6 weeks of full-time treatment, but recurrence was noted 3 weeks into part-time treatment. The protocol was restarted from the beginning, and eventually, full correction was achieved. In the casting and splinting group, five feet of three patients had recurrence of deformity at a mean age of 13.4 months, which necessitated reinitiating full-time treatment (without casting).

Discussion

Forefoot adduction deformity (FAD) is the most common congenital foot deformity [1,2]. While mild and moderate deformities can resolve spontaneously; severe deformity, especially when of the rigid type, and combined adduction and supination type deformity, requires treatment [6,13]. When indicated, treatment should commence as soon as possible, preferably before 9 months of age [7]. The current standard treatment is serial casting to achieve correction followed by a splint to maintain the achieved correction. To the best of our knowledge, the UNFO (UNFO Med Ltd.; Holon, Israel) shoe is the first device that operates below the ankle mimicking a sandal in design. To our knowledge, this is the first study directly comparing serial casting to below ankle orthoses in the treatment of RFAD.

In our study population, comparable proportions of sex and foot laterality were observed between the two patient groups, demonstrating the similarity of the two

Fig. 5



Comparison of treatment duration between UNFO and casting and splinting groups. The difference in the length of full-time treatment was statistically significant with $P=0.01$. Statistical significance is indicated by *. The error bars represent one standard deviation. UNFO, Universal Neonatal Foot Orthotic.

investigated populations. We observed that in the casting and splinting group, the treatment was initiated roughly one month earlier than in the UNFO group. This is because there is no time restriction to commencement of casting and splinting treatment whereas the UNFO is only designed for infants between 2 and 12 months. Despite the later onset of treatment in the UNFO group, we failed to observe any difference in the final result or recurrence rate. This fact is supported by the literature; as long as treatment is initiated before 9 months of age, better outcomes are expected [7,25].

No significant difference in the total duration of treatment between the groups was observed. However, the mean full-time treatment duration was significantly shorter in the UNFO group. In both groups, few patients required longer treatment. The two main reasons were the presence of deep medial crease at the transition between the mid and hindfoot as well as poor parental treatment compliance. Based on our experience, we recommend modifying the UNFO protocol in patients with deep medial crease, by continuing full-time treatment for a period of 8 weeks instead of six. The subsequent maintenance period should remain the same.

There was a very low and comparable rate of minor skin complications in both groups, though, none warranted cessation or modification of treatment, or resulted in any long-term disability. In the UNFO group, superficial pressure sores were seen over the pressure points of the shoe on the heel and the first metatarsal head. The UNFO shoes can be easily modified to relieve pressure from these areas (Video 1, Supplemental digital content 1, *http://links.lww.com/JPOB/A58* describes the technique for shoe modification). After implementing this shoe modification technique, no further complications were observed. Additionally, parents are advised to dress their infants in thicker socks and use the dedicated hygiene periods during full-time treatment to prevent and monitor for superficial skin complications. In few patients, the parents complained that the shoe occasionally came off. This was easily resolved by guiding the parents to appropriately tighten the hook and loop strap and reinforce the grip around the foot using a paper tape. The modifiability of the UNFO, as well as the assigned period for daily foot inspection, offer it a distinct advantage allowing for earlier detection and treatment of complications.

Similar recurrence rates were observed in both groups. The recurrence in the UNFO group occurred in both feet of a single patient that were related to poor parental compliance throughout all stages of treatment, as previously described. This case stresses the importance of ensuring parental understanding and commitment before the commencement of treatment, particularly, when using removable orthotics that give parents full control over the treatment.

While all patients in our study achieved full correction of the deformity, with none requiring surgery, several advantages for orthoses over casting and splinting treatment have been previously demonstrated. In a randomized controlled trial comparing the use of Bebax orthoses to serial casting, equal effectiveness was demonstrated between the two methods in the treatment of severe metatarsus adductus in patients younger than 9 months of age [23]. Other benefits for the use of orthoses have been identified, including lower cost and better hygiene [23,25]. Additional burdensome factors associated with casting include the potential for serious complications such as circulatory and nerve problems if the cast is applied too tight [11], and the associated difficulty in identifying complications, other than toe discoloration, while in full-time casting [25]. Additionally, in implementing the UNFO protocol, we reduced both the length and number of treatment visits, compared to the casting and splinting protocol. Cosmetically, UNFO looks like a sandal, which led to higher parental satisfaction with the treatment. Furthermore, only one shoe is needed throughout the whole treatment, without any adjustments or modifications (except for replacement of the hook and loop strap which got worn-off during treatment in a small number of cases). These factors help illuminate the superiority of orthoses in comparison to serial casting.

For many years, serial casting with subsequent AFO splint was the standard treatment protocol in our institution. However, following the appearance of the UNFO shoes, we found the UNFO protocol to be far more convenient and equally effective. Moreover, the patients' parents' satisfaction was also remarkably high with the UNFO treatment, as well as the cost was slightly lower, compared to casting and splinting protocol. Consequently, starting from 2018 we have treated all our FAD patients with UNFO.

Conclusion

The results of our study indicate that the treatment with UNFO is equally effective to serial casting, the current standard of care. All infants with RFAD treated with UNFO achieved timely full correction without any major complications. The use of UNFO increases treatment convenience and diminishes social burden, thus providing a distinct advantage over other treatment modalities.

Acknowledgements

Conflicts of interest

There are no conflicts of interest.

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Universal neonatal foot orthotics—a novel treatment of infantile metatarsus adductus

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ORIGINAL ARTICLE

Universal neonatal foot orthotics—a novel treatment of infantile metatarsus adductus

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Abstract

Approximately one in 100 babies has metatarsus adductus) MTA(. Although most deformities may resolve spontaneously, moderate and severe deformities might cause future discomfort and are therefore often treated. Common treatment alternatives include stretching, serial casting, and orthoses. Surgery is reserved for severe cases that are unresponsive to conservative management. The purpose of this study was to present our experience with a novel orthosis designed to correct and maintain correction of MTA in infants. Seventy-three children between the ages of 4 and 11.5 months with moderate to severe MTA were treated using the Universal Neonatal Foot Orthosis (UNFO). Treatment was started in cases of rigid deformity when the child was first seen in the clinic, or after the age of 5 months in children with moderate or severe but flexible deformity that failed to improve spontaneously. The orthosis was applied for 23 h daily. Weaning was started after a complete correction of the deformity was achieved. Follow-up was continued at least until walking age. Results were assessed utilizing the heel bisector line (HBL) as a measure of foot deformity before, during, and after treatment completion, and at the end of follow-up. Seventy-one patients (114 feet (were followed from the time of diagnosis to at least walking age. There were 102 severe (HBL at, or lateral to, the 4^{TH} toe) and 12 moderate MTA (HBL between 3^{rd} and 4^{th} toes). Average age at the beginning of treatment was 6.58 months (range 4–11.5). Of the study population, 56 patients (98 feet) improved significantly by the end of the follow-up. In 11 children (11 feet), no change was noted, and in 3 children (3 feet), worsening of the deformity was observed at the end of follow-up. In one child who discontinued treatment after 6 weeks, there was no change in one foot and worsening in the other. Minor side effects were observed in 11 patients, all resolved uneventfully.

Conclusion: UNFO is an effective treatment for moderate and severe MTA in children younger than10 months, with only infrequent minor side effects.

What is Known:

- *Debate exists as to which patient warrants treatment since spontaneous improvement is the rule. However, some deformities persist to adulthood and may be esthetically unpleasing.*
- *Treatment modalities available vary from benign neglect, special shoe ware that are either static or need special tools, and knowledge to adjust or casting by an orthopedic surgeon*

What is New:

- *This is a description of the results of treatment with a new orthotics which may be applied by pediatricians to treat this very common neonatal deformity. The orthotics provides an excellent, short duration solution, easy for the baby and caregiver with results comparable to those of more elaborate orthotics and casting*
- *The use of digital pictures to assess forefoot adduction deformity severity instead of radiographs is a reliable measurement method.*

Keywords Neonatal foot deformity · Forefoot adduction · Metatarsus adductus

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Introduction

Metatarsus adductus (MTA) is a very common foot deformity with an estimated incidence of one in 100 babies [1]. In most children, a complete spontaneous resolution is expected. However, in up to 14% of affected children, the deformity persists to adulthood [2, 3]. Many pediatricians regard MTA as a cosmetic issue of minor functional significance [4]. However, it is well documented that unresolved MTA may require further treatment [5–11].

As good outcomes are usually expected, a dilemma exists regarding the indications for treatment, patient selection, and treatment timing. This is further complicated by the notion that early intervention, before 8 to 9 months of age, when spontaneous improvement is more likely, carries a better chance for deformity improvement [11, 12]. Treatment options vary widely from watchful follow-up, passive stretching, bracing, serial casting, and, rarely, surgical correction [13]. When the deformity is mild and flexible, no treatment is usually indicated [14]. When more severe, less flexible adductus is present, bracing or serial casting is often recommended with reported long-term success rates of approximately 90% [15, 16].

Different methods have been described to grade MTA severity. The heel bisector line (HBL) is a line drawn along the longitudinal axis of the heel. The point at which this line crosses the toes represents the position of the forefoot relative to the hindfoot. Normally, the HBL passes between the second and third toe [17, 18]. Determining the HBL can be performed visually, on a standing hardcopy picture of the foot, or on plain radiographs [12]. Flexibility of the deformity is judged clinically by the ability to manually correct the deformity [4, 12, 13, 16].

In light of reports that 10–14% of MTA cases persist to adulthood and some require surgical intervention, a more proactive approach is advocated by some authors for rigid, severe deformities [1, 3, 13, 15, 19]. In the current study, we report the treatment outcomes using a novel foot orthosis, Universal Neonatal Foot Orthotics (UNFO) (UNFO MED LTD., Holon, Israel http://www.unfo-med.co.il/), designed to correct and maintain correction of forefoot adduction.

Materials and methods

This study was approved by our institutional review board.

Until June 2014, all infants diagnosed with moderate or severe MTA were treated in our institution by serial casting. Once correction of the deformity was achieved, reverse last shoes were used until walking age. Since June 2014, families whose infants were diagnosed with moderate or severe MTA were offered treatment with UNFO or serial casting.

MTA was graded according to its severity and rigidity. Severity was defined as mild when the HBL passed at the third toe, moderate when the HBL was between the third and fourth toe, or severe when the line fell at, or lateral to, the fourth toe. When the line passed through a toe, the HBL was marked as 10, 20, 30, etc. (for the first, second, or third toe respectively). When the line passed between two toes, the HBL was marked as 25 (between the second and third toes), 35 (between the third and fourth toes), etc. (Fig. 1). Rigidity was defined according to the ability to correct the adductus deformity while manipulating the forefoot. If full correction could be achieved, the deformity was defined as flexible, and if not, it was defined as rigid.

Assessment To document the severity of MTA, pictures of the infant's feet were taken at each visit. All pictures were taken while the infants were lying in the prone position on their caregivers' laps (Fig. 1). The knees were flexed to 90°; the legs were held firmly proximal to the malleoli and turned outwards. A digital camera positioned parallel to the infant's foot was used and all pictures were saved in the patient's digital file. The pictures from the beginning of treatment, end of treatment, and end of follow-up were all gathered in a random order and the HBL was evaluated by an orthopedic surgeon who was blinded to the infant's identity and stage of treatment. Furthermore, in cases of unilateral MTV, pictures of both feet were taken and sent for evaluation. Therefore, the pictures that were assessed included also normal untreated feet.

To validate the grading method utilizing digital pictures taken in a standard manner, 90 pictures of the abovementioned cohort including pictures of the normal, unaffected side were randomly chosen and reviewed by three experienced pediatric orthopedic surgeons. The pictures were taken at different stages, before, during, and at the end of treatment. The pictures were presented to the surgeons in a random order with respect to the child's identity and stage of treatment. Each surgeon marked the HBL on each picture and documented where it crossed the forefoot relative to the toes. The results of the three surgeons were compared to ensure an interobserver correlation.

Treatment UNFO is a novel orthosis designed to correct and maintain MTA correction. The major principle of this orthosis is the application of three points of pressure, with the ability to increase the pressure gradually over the apex of the deformity laterally. The heel is held firmly inside the orthosis, the medial side of the orthosis curves around the head of the first metatarsus applying a second point of pressure. An adjustable strap winds around the base of the fifth metatarsus applying a third point of pressure at the deformity's apex. This strap can be easily tightened to apply more pressure (Fig. 2). The right and left orthoses are not interchangeable. The orthosis is available in two sizes, the small size accommodates infant feet up to the age of 4 months and the larger size is for those older than 4 months. The orthosis is not intended for standing or walking.

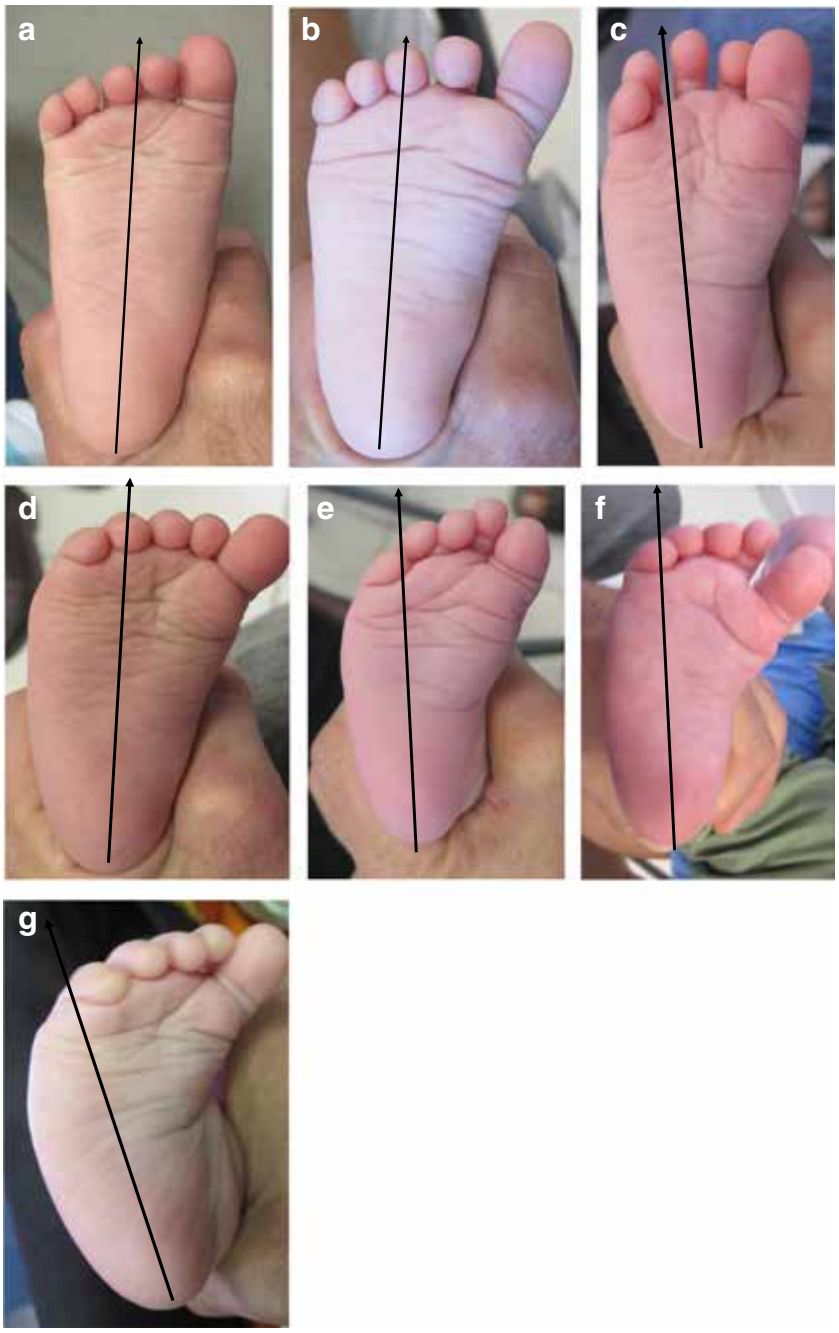

Fig. 1 Different grades of MTA determined according to heel bisector line (HBL). Pictures taken in a standard manner. **a** Normal, HBL=25, crossing between the second and third toes. **b** Mild, HBL=30, crossing the third toe. **c** Moderate, HBL=35, crossing between the third and fourth toe. **d**–**g** Severe, HBL =40, crossing the fourth toe, HBL=45 crossing between the fourth and fifth toes, HBL=50 crossing the fifth toe, and HBL=55, crossing lateral to the fifth toe, respectively

Treatment indications Treatment with UNFO was considered only for cases of moderate or severe MTA. It was started at the patient's first visit if the deformity was rigid and if the foot was large enough for the small UNFO size. If the deformity was flexible and the patient was younger than 5 months, treatment was postponed until the age of 5 months to avoid overtreatment where spontaneous improvement is generally expected.

Treatment protocol All patients were treated and followed by a single pediatric orthopedic surgeon (AP). When a decision to treat was made, caregivers were offered two options: serial casting followed by reverse last shoes after achieving full correction or UNFO treatment. All families but two refused casting, making it impossible to form a control group.

Initially, the UNFO was applied for 23 h a day. Parents were instructed to take it off a few times a day to inspect the feet for skin redness, bruises, or wounds. The adjustable strap was tightened over the dorsum and lateral side of the foot to achieve a snug fit which in turn applied a corrective force to the deformity without causing skin or vascular compromise. When full correction was achieved, gradual weaning of the

Fig. 2 The UNFO orthosis viewed from above (**a**) and from the side (**b**), showing the adjustable strap that applies pressure over the apex of the deformity laterally

orthoses began. During weaning, the UNFO was initially applied for 18 h a day for 3 weeks, and then, at night, only for at least three additional weeks. At the end of this period, the parents were encouraged to keep the orthosis on at night only, as long as the orthosis fit. All babies were scheduled for a follow-up visit on the first and third weeks after the UNFO was first applied, and then at 3–4-week intervals, individually based on compliance and deformity improvement. After treatment cessation, follow-up visits were scheduled on the third, sixth, and 12th weeks, and after the age of 18 months, every 6 months, and followed at least until walking age.

In infants where relapse occurred after the end of treatment, the UNFO was re-applied. If the foot was too big for the UNFO, treatment with serial casting and reverse last shoes was used.

At each visit, the flexibility and severity of the deformity were documented. The foot was examined for wounds, bruises, or redness of the skin. Pictures were taken using a standard protocol and a digital camera.

Statistical analyses were performed for both validating the assessment of MTA severity using digital pictures and for the success of the UNFO treatment. To test the validity of the measurement method based on clinical pictures, Krippendorf's alpha coefficient was utilized. The data and measurements of the UNFO treated patients were analyzed with two types of tests: a paired *t*-test and a Wilcoxon non-parametric signed-rank test. To further test the significance, two additional tests, a repeated measures ANOVA test and a Friedman non-parametric test, were used. The significance of the infant's age at the beginning of treatment was tested using both Pearson's and Spearman's non-parametric correlation coefficients. Utilizing a multivariate repeated measure model, the effect of the deformity's rigidity and the presence or absence of a medial crease on the change of HBL were examined. To test whether the severity of the deformity had any influence on the success of the treatment, a McNemar test was used.

Results

Of the 73 patients treated, 71 patients (114 feet) completed the follow-up period and were available for evaluation at walking age. One of the two unavailable patients failed to return due to relocation overseas and pictures of the other were not available for evaluation. Of the 71 patients, 30 were female. Forty-three patients were treated for bilateral MTA. There were 102 severe and 12 moderate MTA. Rigid deformities were observed in 23 (22.5%) infants with severe MTA and in 3 (25%) infants with moderate MTA.

The average age at the first visit was 4.63 (range 1–11.5) months with the average age at the beginning of treatment being 6.58 (range 4–11.5) months. The average duration of treatment, including the weaning period, was 3.97 (0.75–9.5) months and the average age at the last follow-up was 25.5 (range 14–49) months, with the mean follow-up duration from the beginning of treatment being 18.9 months. At the end of the follow-up period, 56 patients (98 feet) improved significantly. In 11 children (11 feet), no change was noted, and in three children (three feet), worsening was observed. In one infant who discontinued treatment after 6 weeks, there was no change in one foot and worsening in the other. In another infant who discontinued treatment for unilateral MTA after 3 weeks, there was an initial improvement of HBL from 50 to 35. However, relapse was seen at the end of the follow-up period.

Minor side effects such as skin redness and superficial bruising were observed in 11 patients, all resolved uneventfully. In two infants, excessive feet sweating was reported but did not require any treatment modification.

The use of digital pictures to document the HBL showed good interobserver correlation (alpha=0.78) confirming the validity of this method. Measurements just before the beginning of treatment, at the end of treatment, and at the latest follow-up were selected for comparison. When the pre-treatment HBL was compared to the end of treatment HBL,

a significant improvement in the magnitude of the deformity was noted ($p<0.05$). When the end of treatment HBL was compared to the results at the end of the follow-up period, a significant deterioration (loss of correction) was seen ($p<0.05$). However, this deterioration was significantly smaller than the initial improvement ($p<0.05$). When pre-treatment and end of follow-up HBL were compared, a significant improvement was seen ($p<0.05$). The data is presented in a graph showing the HBL before and after treatment and at the end of follow-up (Fig. 3).

There was no correlation between the change in HBL from the beginning to the end of treatment and the age at the beginning of treatment ($p<0.05$). When analyzing the effect of severity, more severe deformities were more likely to exhibit greater deterioration at the end of follow-up ($p<0.05$). The presence or absence of a medial crease had no correlation to the final outcome.

Discussion

There are several methods to grade MTA severity. The use of weight-bearing radiographs is well documented [20, 21]. We elected not to use radiographs to avoid unnecessary radiation exposure to both the baby and caregiver. Also, since infants do not bear weight naturally, it is impossible to determine the amount of pressure that should be applied to the infant's foot while taking radiographs. Other investigators also found that radiographs were not imperative to evaluate MTA severity [22, 23]. Rushforth [3] used photographs of the feet in the standing position, grading the severity of MTA as mild, moderate, and severe. In the current study, digital pictures using a standard non-weight-bearing protocol were utilized to evaluate the MTA severity. Our results show this grading technique to be very reproducible with good interobserver reliability. We have found that its advantages of avoiding radiation exposure and the ease of obtaining the pictures without unnecessarily forcing an infant to bear weight make it a worthy alternative.

It is well documented that not all cases of MTA resolve spontaneously. In up to 14% of the feet, the deformity persists to adulthood [2, 3, 12]. Once a baby is diagnosed as having significant MTA and a decision is made to start treatment, the literature suggests that, for best results, a treatment should begin before the age of 8–9 months [2, 11]. A major issue in the management of MTA is the inability to predict at an early age which deformity will resolve spontaneously and which will persist if not treated. In accordance with other studies (2,16-19), we elected to treat the more severe deformities, especially those that failed to improve spontaneously. Our finding that good correction was achieved despite postponing treatment to the age of 5 months enables the treating physician to wait and follow the patients thus minimizing the likelihood of overtreatment.

Several treatment methods for MTA have been described. For many years, serial casting had been the gold standard treatment for MTA. However, side effects such as severe skin bruises, deep wounds, circulatory problems, and nerve injury that may result in a foot drop have been reported [17]. Also, casting is time-consuming for the treating physician and is difficult to care for by the families. Additionally, there are inconveniences and risks involved in applying and removing the cast. With UNFO treatment, these complications are very rare since the orthosis is taken off at least once a day allowing the caregiver to inspect the infant's foot regularly. Furthermore, unlike casts, where wetting of the cast is forbidden, during UNFO treatment, bathing is encouraged. We did not specifically test patient discomfort or family satisfaction.

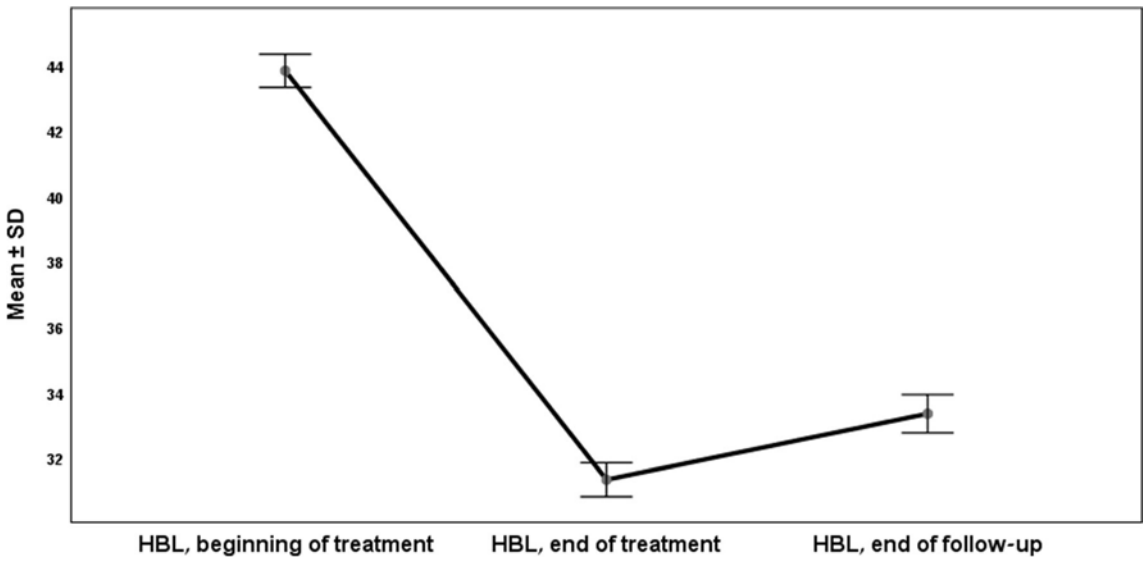

Fig. 3 A comparison between the HBL at the beginning of treatment, end of treatment, and end of follow-up

However, from our experience when examining the infants in the clinic, applying and removing the UNFO did not elicit crying (unlike what sometimes happens when a cast is applied or removed) supporting our assumption that no pain or discomfort were inflicted by the orthotics. In addition, anecdotally, two families who had an older sibling treated by casting refused casting of their baby, but were very pleased with the UNFO treatment.

Other orthoses have been used as alternatives to casting, some of which extend above the ankle and restrict its motion [17]. Bebax [19, 20], a below ankle orthosis, was shown to be as successful as casting. This orthosis, however, is adjusted only by the treating physician using an Allen wrench. A major advantage of UNFO over other available devices is the ability of the caregiver, as instructed by the treating physician, to control the amount of corrective pressure applied to the foot by tightening or loosening the strap, without the need for any special mechanical tools. We feel that the progressive but gradual and controlled increase in the corrective forces applied to the feet results in superior deformity corrections while minimizing adverse side effects. Applying the UNFO is simple and straightforward and can be performed by the parents and monitored by the primary care physician. Since a small but significant deterioration was observed in the last follow-up, almost solely in the severe deformity group, we suggest that a longer period of nighttime bracing be recommended for these children. The deterioration after treatment cessation may represent partial rebound of the soft tissues to their deformed state once the corrective forces were discontinued. Since it is well accepted that MTA tends to improve as time goes by (1-4,5), it is reasonable to assume that this small but significant deterioration was unlikely to occur if the improvement was spontaneous, implying that the effect seen was possibly related to the treatment.

One limitation of this study is the lack of a control, untreated group. However, all of our patients exhibited deformities that were at least moderate that either did not improve during follow-up or when the child was close to 8 months old. Therefore, we felt it was unethical to have a non-treatment control group. Furthermore, we were unable to recruit patients for a cast treatment control group with the UNFO treatment being available. However, comparison of our results to available data in the English language medical literature shows that our UNFO treatment results were not inferior to casting, despite our stricter selection criteria of older, more severe, and rigid MTA. A second limitation is that the study was conducted in a single center. However, in light of the simplicity of UNFO application and follow-up, we believe that these results are easily reproducible in other centers.

In conclusion, UNFO is an effective treatment for moderate and severe MTA in children younger than 10 months. It compares favorably with serial casting and other braces, can be applied by pediatricians, and has only infrequent minor adverse effects.

Abbreviations *HBL,* Heel bisector line; *MTA,* Metatarsus adductus; *UNFO,* Universal Neonatal Foot Orthosis

Authors' Contributions AP and RL—study design and preparation of manuscript
AP—patient recruitment, treatment, and follow-up
RL, NS, and VG—measurement of pictures
ML—data analysis

Data availability We will share all our data upon request.

Code availability Not relevant

Declarations

Ethics approval The study was approved by the institutional review board.

Consent to participate All families gave their consent to participation of their babies in this study.

Consent for publication All the authors gave their consent to this publication. All families were consented for publication without disclosure of any identifiable information regarding the patients.

Competing interests The authors declare no competing interests.

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Metatarsus adductovarus (MTA): efficacy of treatment with UNFO braces

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ABSTRACT

Introduction

Metatarsus adductovarus (MTA) is a congenital malformation that affects about 7% of newborns. To date, the gold standard for treatment is the application of a gypsum or another orthoses for correction. If untreated, MTA is associated with an increased risk of residual deformity in adulthood, stiffness of deformity, pain, arthritis and hallux valgus. The aim of the study was to verify the efficacy and safety of UNFO braces in the treatment of mild, moderate and severe MTA within the first year of life.

Materials and Methods

40 consecutive (80 feet) patients, with mild, moderate or severe MTA were treated with UNFO braces for 12 weeks. The mean age at first treatment was 2.8 months (min 1 - max 9.5). The severity of the disorder was classified in 11 patients as mild, in 24 as moderate, in 5 severe on the right and in 11 mild, in 26 moderate, and in 3 severe on the left, using the Bleck classification (using the calcaneum bisector).

Results

Patients were evaluated at the end of treatment with the UNFO at the 12th week. The average age at the last visit was 8.3 (min 4 - max 12.5).
Resolution of the MTA was achieved in all cases.
The correction was maintained at a follow-up of 20 weeks in all patients apart from 3 cases

Discussion

MTA is a relatively frequent and underestimated deformity (up to 7% of the population), in some cases it reaches and exceeds the incidence of valgus calcaneum.
Given the high incidence and the large percentage of underestimated cases (about 85%) the risk of progression and residual deformity and rigidity is high.
About 14% of cases do not resolve spontaneously, but most cases respond very well to conservative treatment. Complete correction of the forefoot occurred in all cases; in the face of excellent results in clinical terms, no major complication was found during treatment, only minor skin complications that were completely resolved on removing the braces.

Conclusions

UNFO braces area a valid and safe alternative to gypsum or other types of orthosis in all cases where a specialist deems a brace necessary. In the face of excellent clinical results, if used during the first 9 months of life, they are linked to a low number of complications, usually minor and of low significance. The ergonomics and easy use of UNFO braces make them suitable for even very young infants (neonates) and for a simple home management by parents.

ARTICLE

Introduction

Metatarsus adductovarus (MTA) is a congenital malformation that affects about 7% of births, even if the incidence rises to 16-17% when the first child is affected and in the case of premature or twins babies. MTA has in some cases a higher incidence of valgus calcaneus (1, 2, 3). In other cases there is the same incidence in premature and full term births, but it persists longer in premature babies (4) compared to those born at term.

The family risk is relatively high: 1 in 20.27 (5) if a family member is affected. The most plausible cause today is positional during intrauterine life. It is a pathology that occurs after the eighth week of intrauterine life and therefore falls into malposition, immediately after deformations such as the congenital clubfoot or the reflective foot; the malformations include those that occur before the eighth week of foetal life. (6)

If untreated, MTA is associated with an increased risk of residual deformity in adulthood, stiffness of deformity, pain, arthritis and hallux valgus. (7)

MTA responds very well to conservative treatment.

To date, the gold standard in treatment is the application of a gypsum or other corrective orthoses (8); the complications of the application of plaster casts are, as expected, decubitus, intolerance, difficult management with weekly changes, hygiene, technical difficulty; the other orthoses have the characteristic of being operator-dependent, they must be strictly controlled by the doctor, they are rigid.

UNFO braces are available on the market in two sizes and are adaptable to children of all ages ranging from birth to crawling. They have 3 pressure points, leaving the ankle free to move, and have the advantage of being light and easy to use in a way that can easily be managed by parents without specialist support, and are therefore removed for daily hygiene.

Material and Method

Product features**:** UNFO is a pre-moulded corrective shoe for the treatment of MTA in new born babies up to the time they begin crawling. The orthosis consists of a rigid part to support the foot and an adjustable tear-off system that acts through 6 fixing points divided into two levels (from top to bottom and from the outside to the inside) leaving free the joint of the ankle.

MTA patients, aged 1-9.5 months, were included in the study; excluded from the study were patients who had already been treated for MTA, with congenital or neuro muscular disorders, and those suitable for the study according to the researcher.
40 consecutive patients with mild or moderate MTA were treated with UNFO braces for 12 weeks - a total of 80 feet, 25 males, and 15 females were treated.
The mean age at first treatment was 2.8 months (min 1 - max 9.5).
The severity of the disease was classified as mild in 11 patients, moderate in 24, in 5 severe on the right and in 11 mild, moderate in 26, and 3 severe on the left according to the Bleck classification (using the calcaneal bisector) (9); while the flexibility of the feet at the initial visit was well correctable in 11, partially correctable in 27, hardly correctable on the right in 2 and slight in 11, and moderate on the left in 29.
All patients followed the protocol treatment scheme:
The protocol provided for 6 weeks of treatment 24 hours a day, then another 6 weeks only for the night. The visits were made every 2 weeks until the twelfth. At the twelfth week the guardians were removed and follow-up visits were performed at 16 and 20 weeks. Each patient was visited and classified at the initial visit by the principal researcher or by a doctor of the same team, assessed according to the inclusion and exclusion criteria.

Results

Every patient was evaluated clinically every 2 weeks until the twelfth week of treatment, then at the sixteenth and twentieth weeks. at each visit, the foot was evaluated from the clinical point of view using the classification of Bleck to assess the calcite bisector and residual flexibility. In the presence of the parents, the status of the skin, the parents' compliance in management (putting and removing the braces) and the compliance of the small patients were assessed.
Patients were assessed at the end of treatment with UNFO at the 12th week. The average age at the last visit was 8.3 (min 4 - max 12.5).
Resolution of the MTA was achieved in all cases.
The correction was maintained at a follow-up of 20 weeks in all patients except for 3 cases, where the MTA was still mild, and the brace was applied for a further 4 weeks with resolution of the problem. The aforementioned cases were all initially classified as severe and with low flexibility.
No major complications occurred, 2 superficial sores, 1 additional visit to 2 patients for intolerance of the brace and adjustments to it.

Discussion

MTA is a relatively frequent and underestimated deformity (up to 7% of the population), in some cases it reaches and exceeds the incidence of valgus calcaneum.
Given the high incidence and the large percentage of underestimated cases (about 85%) the risk of progression and residual deformity and rigidity is high.
About 14% of cases do not resolve spontaneously, but most cases respond very well to conservative treatment.

Currently the Gold Standard for treatment is the use of set gypsum, with many associated complications. The best age to start conservative treatment for good results is before nine months of life.

In the bibliography, the percentage of good outcomes from conservative treatment is high, but the percentage of complications related to it is equally high. (8)
UNFO braces are present on the market with excellent results linked to them and few complications.

UNFO braces have the characteristics of being easy to use, flexible, leaving the ankle free, and being available in two sizes which is good for smaller children (from birth to toddlers).

We therefore present our experiences with 40 subjects treated with UNFO for MTA. The braces are based on the application of pressure at 3-points, and the degree of correction is maintained by the Velcro strap in the central parts.

In contrast to plaster casts, UNFO braces have better home management of the deformity and the patient, are easy to use and give excellent results. Compared to Bebax braces, they have a lower need for specialist assessments, since the correction is standard and not adjustable.

All patients followed the protocol treatment scheme:
The protocol provided for 6 weeks of treatment 24 hours a day, then another 6 weeks only for the night. The visits were made every 2 weeks until the twelfth. At the twelfth week the braces were removed and follow-up visits were performed at 16 and 20 weeks. Each patient was visited and classified at the initial visit by the principal researcher or by a doctor of the same team, assessed according to the inclusion and exclusion criteria.

Complete correction of the forefoot was achieved in all cases, on considering a maximum time of 12 weeks; in cases in which there was a relapse (2 cases) this was still a residual live and well correctable deformity, which was treated and resolved by another 4 weeks of UNFO. Treatment was started as early as possible (mean age at

the start of treatment 2.8 months), in agreement with the literature that specifies a successful outcome of conservative treatment if initiated early. (9)

In the face of excellent results in clinical terms, no major complications were found during treatment, only small skin complications that were completely resolved on removal of the braces (2 cases) with a maximum percentage of 5%.

Conclusions

Metatarsus adductovarus (MTA) is a frequent and underestimated disorder in the infant population; if left untreated, it leads to rigid, painful and difficult-to-treat residual deformities during growth. In most cases, it does not resolve spontaneously, but still responds well to conservative treatment if started early.

UNFO braces are a valid and safe alternative to gypsum or other types of orthosis in all cases that a specialist deems one necessary. In the face of excellent clinical results, if used during the first 9 months of life, they are linked to a low number of complications, usually minor and insignificant. The ergonomics and easy use of UNFO braces even makes them suitable for very young infants (new borns) and for simple domiciliary management by their parents.

Further randomised trials are needed to improve the accuracy of the results.

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