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Extra-Osseous Talotarsal Stabilization (EOTTS) in Patients with Cerebral Palsy (CP) Results in Excellent Patient Reported Outcomes and Radiographic Realignment of Subtalar Joint Instability

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Abstract

Background: The aim of this prospective nonrandomized case series study was to assess the intermediate-term outcomes of extraosseous talotarsal stabilization (EOTTS) combined with Achilles tendon lengthening for correction of flexible planovalgus foot deformity in children with cerebral palsy.

Methods: A total of 20 skeletally immature feet of 9 boys and 5 girls aged 7 to 15 years old (average 10.8 years), with Level I and II CP (according to the Gross Motor Function Classification System) and, were treated via EOTTS and Gastrocnemius recession or Achilles tendon lengthening. Six of them had diparetic and eight hemiparetic. The average follow-up time was 27.3 months (12 to 42 months). Preoperative and postoperative American Orthopedic Foot and Ankle Society-Ankle and Hindfoot (AOFAS-AH) scores, dorsoplantar talar second metatarsal angles (T2M), and lateral talar declination angles (TD) of the affected foot were recorded.

Results: Correction of the preoperative talar alignment deformity was normalized in all patients. The average TDA improved from 30.06° ± 2.74° preoperatively to 20.76° ± 2.3° postoperatively. The mean T2MA improved from 39.06° ± 2.05° preoperatively to 15.92° ± 3.12° postoperatively. The AOFAS-AH score also improved from 62.8 ± 1.74 preoperatively to 87.8 ± 2.13 at the final follow-up.

Conclusion: EOTTS and associated soft tissue procedures reliably corrected the hindfoot deformity and have shown to be a good treatment option in the treatment of flexible planovalgus feet in children with Level I and II CP.

Keywords: Spastic flatfoot; Subtalar joint instability; Talotarsal joint instability; Pes planovalgus; Cerebral palsy; Extraosseous talotarsal stabilization

Introduction

Planovalgus (PV) is the most common foot deformity in all ages of CP children [1]. The etiology of PV is multifactorial and includes bony malalignment, muscle imbalance, abnormal forces, genetic predisposition, and ligamentous structure response. One feature that is consistently found in all patients with PV is the abnormal alignment of the talus with the calcaneus and navicular. Precisely, the talus shifts medially, anteriorly, and plantarly on the calcaneus. The subtalar joint facets are no longer in constant congruity. This subtalar joint deformity can be flexible or rigid. Flexible instability has been referred to as subtalar joint instability [2,3]. The talar deviation can force the navicular to sag, leading to the collapse of the medial arch, a "flat" foot [4].

Many forms of non-surgical and surgical options have been advocated. Patient compliance, under-correction, and little to no evidence present challenges to non-surgical options [5]. Extraosseous talotarsal stabilization (EOTTS) is a minimally invasive procedure that is proven to realign and stabilize the subtalar joint (Figure 1) [6,7]. This procedure involves the placement of an implant into the sinus tarsi chamber. The implant maintains the alignment and stability of the subtalar joint while allowing a natural range of supination and pronation. The EOTTS procedure can be combined with tenotomy (ies), tendon lengthening, and other osseous procedures. The recovery process is significantly reduced over traditional reconstructive procedures (osteotomies and arthrodesis).

The purpose of this study was to investigate the use of EOTTS in pediatric CP patients with subtalar joint instability. The primary focus was on patient report outcomes, radiographic changes of talar alignment in both transverse and sagittal planes, and to report on the number of revisions, permanent removals, or complications of the EOTTS procedure.

Materials and Methods

Consecutive patients with spastic CP who underwent EOTTS procedure between June 2014 to December 2017, were prospectively evaluated. A total of 14 individuals (20 feet) were treated with EOTTS using Hypro Cure (GraMedica®, Macomb, Michigan USA), including nine boys and five girls aged 7 to 15 years old (average 10.8 years old). None of the patients had undergone previous foot surgery. Before surgery, the American Orthopedic Foot and Ankle Society–Hindfoot Score (AOFAS-AH) questionnaire was filled out. Six cases underwent bilateral surgery, and the remaining 8 had unilateral. All patients followed standardized postoperative rehabilitation. The average follow-up time was 27.3 months (12–42 months). This research was approved by the Medical ethics committee of the hospital.

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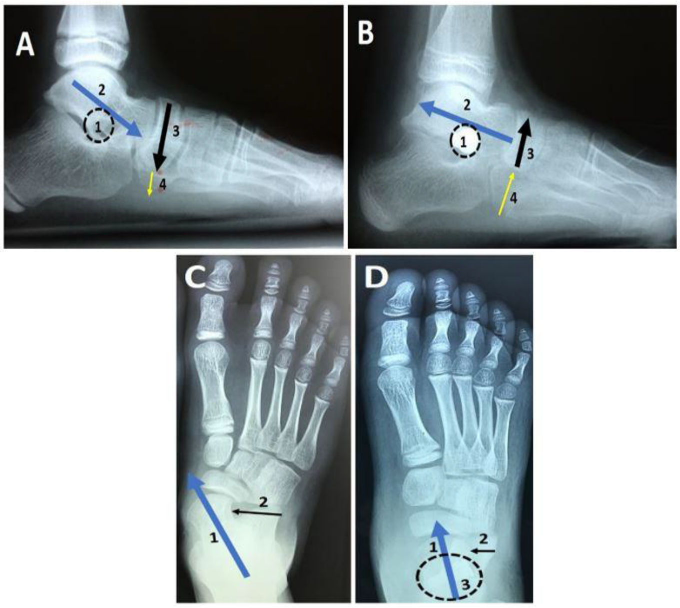

Figure 1: Pre and postoperative weightbearing images. A. Preoperative weightbearing radiograph. A1: Shows the obliteration of the sinus tarsi. A2: Sagittal talar declination and anterior displacement of the talus on the calcaneus. A3: Shows navicular drop. A4: Comparison of the plantar aspect of the navicular compared to the plantar aspect of the cuboid. Postoperative weightbearing radiograph. B1: Is the sinus tarsi implant. B2: Shows realignment of the talus on the calcaneus. B3: Shows elevation of the navicular. B4: Shows an increase elevation of the navicular compared to the cuboid. Preoperative weightbearing radiograph. C1: Shows the bisection of the talus is medial to the navicular. C2: Shows the divergence between the talus and calcaneus. D: Postoperative weightbearing radiograph. D1: Shows reduction of the transverse plane deformity and realignment of the talonavicular joint. D2: Shows reduction of the talocalcaneal divergence. D3: Shows the position of the sinus tarsi implant.

The indications for surgery were an ambulant child with level I or II CP (according to the Gross Motor Function Classification System) diagnosed with spastic flatfoot; according to the anatomical classification. Six of the patients had diparetic and eight hemiparetic. All the children had foot pain that could not be relieved by 3-6 months of conservative treatment, such as shoes or orthosis. Exclusion criteria for the EOTTS procedure were severe deformity, tarsal coalitions, vertical talus, and a rigid talotarsal joint alignment.

Surgical approach

General anesthesia was administered to all patients. The patients remained in a supine position during surgery. The EOTTS procedure was performed by making a 2 cm incision laterally over the tarsal sinus, approximately one index finger distal to the fibula. Sharp and blunt dissection of the superficial tissue was performed with curved Stevens tenotomy scissors. The ligamentous soft tissues within the superficial and deep chambers of the sinus were decompressed with the same scissors. A guidewire was inserted into the sinus tarsi until the tip was palpated medially, but without making a medial skin incision.

Subtalar joint pronation was tested by loading the 4th and the 5th metatarsal head-neck area. All the patients had excessive pronation >6°, and the goal was to normalize subtalar joint pronation to approximately 3°- 5°. Various trial sizers were inserted from the smallest size to a larger size that provided for the desired amount of subtalar joint pronation. Once the size of the sinus tarsi stent was determined, the Hypro Cure stent was placed on the guidewire and advanced to the desired position. The precise placement of Hypro Cure was confirmed by fluoroscopy. The lateral end of the device should be medial to the lateral neck of the talus.

Percutaneous Achilles tendon lengthening (Hooke Tenotomy) was performed in children with Achilles tendon contracture. In patients with hemiplegia a gastrocnemius tendon lengthening (Strayer technique) was performed in the remaining children. Peroneus lengthening was jointly performed in only six patients.

All children were stabilized with the long leg plaster cast for four weeks after surgery. The plaster cast was removed and replaced by hinged AFO in all patients for two months.

The patients were reviewed in the outpatient department every three months after discharge for a year. Then a 6-monthly outpatient visit was requested. The clinical effects of the affected foot were assessed according to the American Orthopedic Foot and Ankle Society-Ankle and Hindfoot score (AOFAS-AH) at every review in the outpatient department (Table 1).

X-ray examinations were performed every 3 months to compare the changes of the anteroposterior–talo-second metatarsal angle (T2MA) and in the lateral view talar-first metatarsal angle or talar declination angle (TDA) and navicular drop. The position of the Hypro Cure stent was also inspected for any deviation from the previous images.

All radiographic measurements were performed by the authors on the preoperative and latest follow-up radiograph.

Statistical analysis

All statistical analyses were completed using the R statistical programming language (R Core Team, 2018) [8]. Linear mixed-effects models were fitted to AOFAS-AH, T2MA, and TDA scores using restricted maximum likelihood estimation (REML) in the "nlme package" in R [9]. Linear mixed-effects models account for within-patient variance in the analysis of pooled bilateral observations and therefore use the full data set without violating the assumption of statistical independence of observations [10,11]. This results in improved efficiency and power compared to methods that reduce the number of observations to one per patient (by random selection, averaging, selection of right or left side only) to adhere to the assumption of statistical independence of observations [12].

For each score, two linear mixed-effects models were fitted to the data. The first model included only a random intercept for each patient, whereas the second included a random intercept and slope for each patient. The models were compared, along with the linear model (no random effects) as a reference, using the Akaike Information Criterion (AIC), and the best model was selected based on the AIC score. Models were validated by checking the residuals for normality using the Shapiro-Wilk test and examining standardized residuals vs. fitted values plots for heterogeneity.

Results

Correction of the preoperative talar alignment deformity was normalized in all patients. The average TDA improved from 30.06° ± 2.74° preoperatively to 20.76° ± 2.3° postoperatively, a decrease by 9.3°. The difference between the mean preoperative and postoperative TDA values was statistically significant (p=<0.05). The mean T2MA improved from 39.06° ± 2.05° preoperatively to 15.92° ± 3.12° postoperatively, a decrease by 23.14°. The difference between the mean preoperative and postoperative TDA values was statistically significant (p=<0.05). The AOFAS-AH score also improved from 62.8 ± 1.74 preoperatively to 87.8 ± 2.13 postoperatively at final follow-up, an average of 25-point increase.

No.	Gender	Age-Year	Unilateral-Bilateral	Follow Up-Months	Left-right	Pre AOFAS-AH score	POP AOFAS-AH score	Preop T2MA	Postop T2MA	Preop TDA	Poatop TDA
1	Boy	15	Unilateral	30	Left	68	86	39	13	29	18
2	Boy	7	Bilateral	36	Left	61	85	42	14	36	22
	Boy				Right	60	88	40	14	35	23
3	Girl	9	Bilateral	42	Left	65	89	37	18	29	30
	Girl				Right	67	87	41	17	35	24
4	Boy	7	Bilateral	18	Left	64	83	36	17	29	21
	Boy				Right	64	88	37	18	28	21
5	Boy	12	Unilateral	12	Left	63	92	44	13	34	20
6	Girl	14	Bilateral	26	Left	64	88	38	16	29	19
	Girl				Right	64	87	38	17	29	18
7	Boy	9	Bilateral	28	Left	63	92	42	18	28	18
	Boy				Right	63	91	39	18	27	17
8	Girl	10	Bilateral	40	Left	61	90	39	17	26	23
	Girl				Right	64	90	38	17	27	23
9	Boy	14	Unilateral	38	Left	64	92	42	16	32	24
10	Boy	8	Unilateral	36	Right	58	83	39	15	31	21
11	Boy	9	Unilateral	16	Right	59	83	38	17	28	20
12	Girl	13	Unilateral	19	Left	62	87	40	16	34	22
13	Girl	12	Unilateral	22	Left	61	88	35	18	28	21
14	Boy	15	Unilateral	20	Right	63	89	36	13	26	20

Table 1: Patient data.

Category		n	Mean	Median	St Dev.
Side	Left	11	-25.09	-25	3.86
	Right	9	-24.89	-25	2.52
Unilateral/Bilateral	Bilateral	12	-24.83	-24	3.3
	Unilateral	8	-25.25	-25.5	3.37
Gender	Boy	12	-25.17	-25.5	3.66
	Girl	8	-24.75	-24.5	2.71
Overall	-	20	-25	-25	3.24

Table 2: Summary statistics for changes in American Orthopedic Foot and Ankle Society-Ankle and Hindfoot (AOFAS-AH) score from 20 observations on 14 patients.

Category		n	Mean	Median	St Dev.
Unilateral/Bilateral	Bilateral	12	9.08	10	3.18
	Unilateral	8	9.5	9	2.73
Gender	Boy	12	9.83	10	2.59
	Girl	8	8.38	9.5	3.38
Overall	-	20	9.25	10	2.94

Table 3: Summary statistics for change in talar declination angle (TDA) from 20 observations on 14 patients.

Category		n	Mean	Median	St Dev.
Unilateral/Bilateral	Bilateral	12	22.17	21.5	2.86
	Unilateral	8	24	24	4.07
Gender	Boy	12	24	24	3.64
	Girl	8	21.25	21.5	2.38
Overall	-	20	22.9	22.5	3.42

Table 4: Summary statistics for change talar second metatarsal angle from 20 observations on 14 patients.

Score	Model	d.f.	AIC
AOFAS-AH	M0	3	194.57
	M1	4	192.77
	M2	6	193.44
T2MA	M0	3	175.81
	M1	4	177.81
	M2	6	174.4
TDA	M0	3	195.14
	M1	4	190.67
	M2	6	188.27

Table 5: Results of the model-fitting procedure based on AIC. M0 models are linear models (equivalent of paired t-test) comparing pre/post scores of feet, ignoring within-patient variability (and violating the assumption of independence of observations). M1 models are linear mixed-effects models with a random intercept for each patient. M2 models are linear mixed-effects models with a random intercept and slope for each patient.

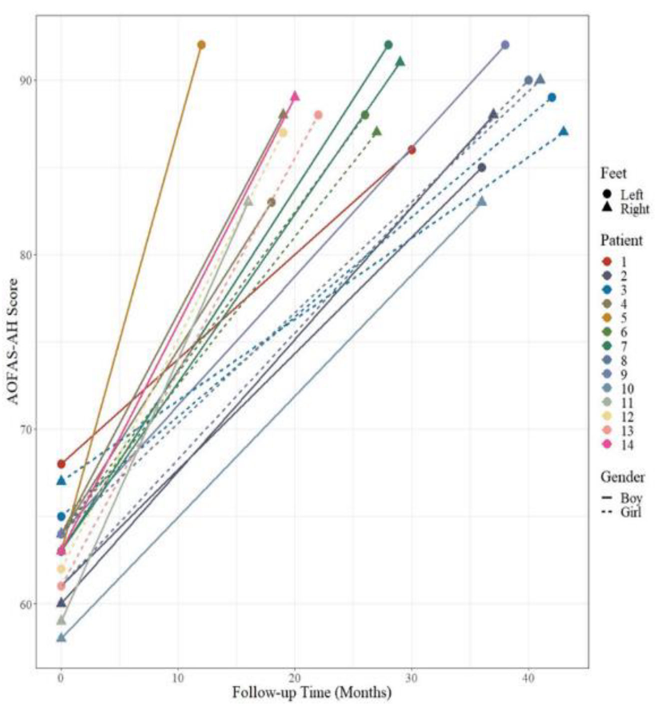

Figure 2: The changes in AOFAS-AH score from Pre (Follow-up Time=0) to Post (Follow-up Time in Months). Each observation is represented by a line segment whose first point is the Pre AOFAS-AH Score and second point is the Post AOFAS-AH Score. Points are coded by different symbols for left/right. Dashed lines represent observations taken from girls while solid lines represent observations taken from boys. Each individual patient is represented with a different color.

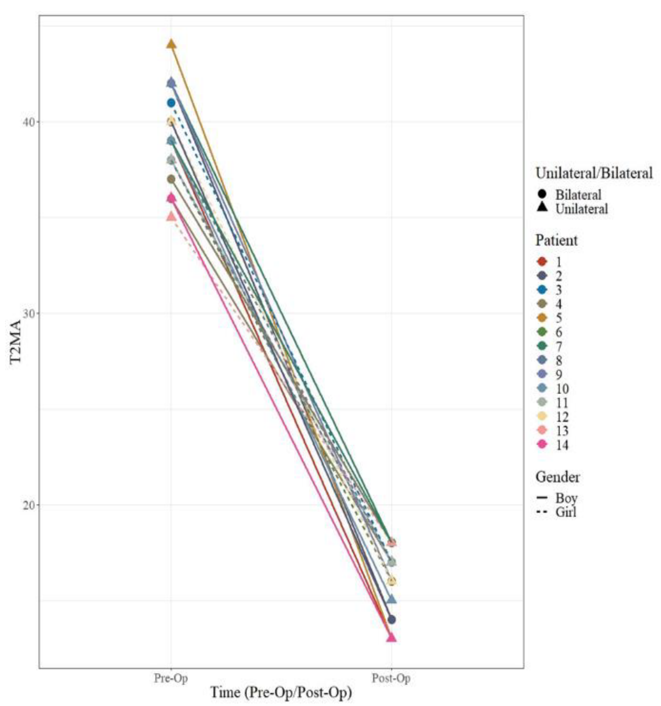

Figure 3: The changes in T2MA from Pre-op to Post-op. Each observation is represented by a line segment whose first point is the Pre-op T2MA and second point is the Post-op T2MA. Points are coded by different symbols for Lateral/Bilateral. Dashed lines represent observations taken from girls while solid lines represent observations taken from boys. Each individual patient is represented with a different colour.

Summary statistics for the AOFAS-AH, TDA, and T2MA pooled (right and left foot) data are provided in Tables 2–4. Visual representations of the Pre- vs. Post-Op changes in scores by a patient, foot (right/left), and condition (unilateral/bilateral) are provided in Figures 2–4. Boxplots of the pooled right and left foot AOFAS-AH, TDA, and T2MA score data is presented in Figure 5.

Complications

One of the patients was taken back to the operating room to reposition the implant. Another patient developed superficial incision infection that was treated with topical wound care. None of the patients required a change in implant size or permanent removal.

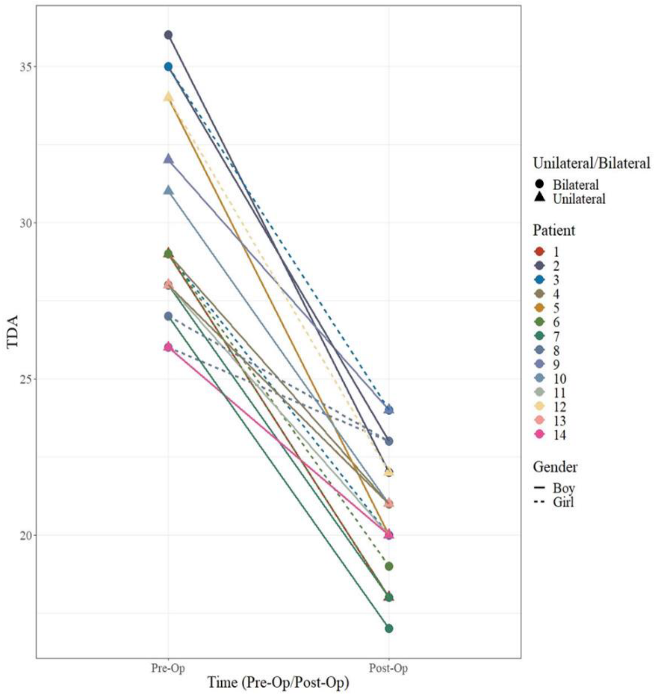

Figure 4: The changes in TDA from Pre-op to Post-op. Each observation is represented by a line segment whose first point is the Pre-op TDA and second point is the Post-op TDA. Points are coded by different symbols for Lateral/Bilateral. Dashed lines represent observations taken from girls while solid lines represent observations taken from boys. Each individual patient is represented with a different colour.

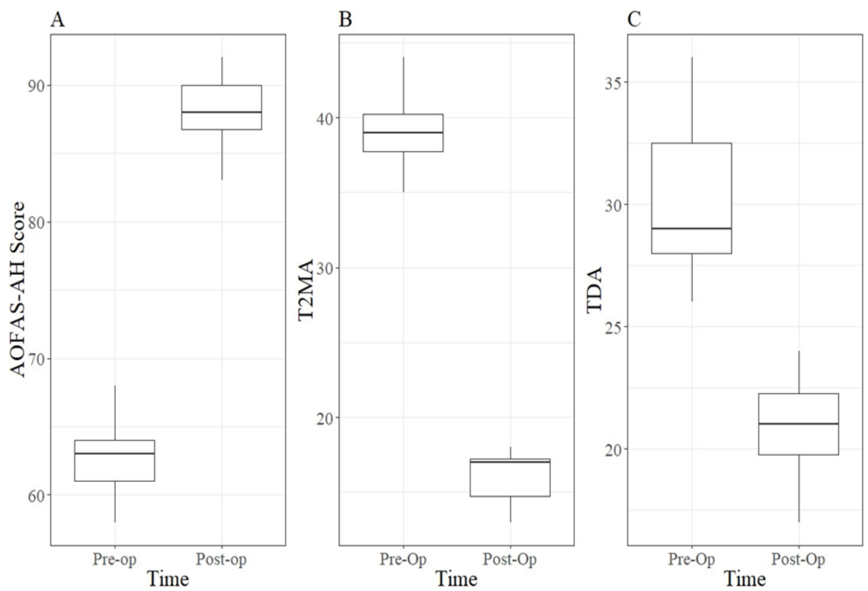

Figure 5: Boxplots of the pooled right and left foot data, 20 observations from 14 patients, based on the time the data was taken (pre-vs. post-op) for (A) American Orthopedic Foot and Ankle Society-Ankle and Hindfoot (AOFAS-AH), (B) Talar second metatarsal angle (T2MA), and (C) Talar declination angle (TDA).

Discussion

The partial or incomplete dislocation of the talus on/and the calcaneus (subtalar joint) is the primary deforming force that contributes to the development of a planovalgus foot. The talus displaces anteromedially and plantarly, forcing the foot laterally into valgus (Figure 1C). The realignment of the talus on the calcaneus realigns the navicular and reduces the valgus deformity of the foot (Figure 1D). This unnatural structural deformity leads to excessive foot pronation or hyper pronation during the stance phase of the gait cycle. An imbalance of biomechanical forces is created that must be compensated for on the distal and proximal joints, ligaments, muscles, and tendons.

Subtalar joint instability can begin in early childhood when the bones of the foot are primarily cartilaginous. The excessive continued weightbearing forces acting on the growing bones will lead to further osseous malalignment and progression of the disease process. External tibial torsion also presents, and the combination of these malformation leads to the crouch gait [13]. Excessive strain on a ligament triggers a reflex protective neurologic trigger that stimulates muscle contraction to provide increased support and stability to the affected joint. Spasticity associated with CP changes the biomechanical properties of muscles and soft tissues around joints. It may result in joint contractures, muscle shortening, pain, and functional limitations that negatively affect motor development [14].

Hyperpronation creates excessive forces specifically on the inner arch of the foot and leads to increased forces pushing against the first metatarsal dorsomedially. The peroneus longus tendon inserts into the base of the first metatarsal and is responsible for providing stability to the arch and to stabilize the first metatarsocuneiform joint. The excitement of the neurosensors of the ligaments around the base of the first metatarsal bone will trigger the peroneus longus to contract to counter the instability. This reaction occurs with every step taken; thousands of steps are made every day.

Another side-effect associated with the loss of stability between the talus and calcaneus is a valgus deformity of the hindfoot. This is a common finding in CP patients with pes planovalgus. The realignment of the talocalcaneal joint reduces the calcaneal valgus deformity. Excessive pronation of hindfoot leads to an overstretching of the Achilles tendon [15]. The neuro sensors within the Achilles tendon detect excessive strain that forces the tendon to "stiffen" to counter the excessive strain [16]. Eventually, due to the chronicity of this disease process the tendon and muscle remain in a contacted state to counter the faulty-foot biomechanical imbalance.

A recent study found a positive correlation between Achilles tendon strain and age [17]. Another study found that children with mild spastic CP had altered mechanical properties of the Achilles tendon; there was no alteration to typical material properties [18]. This was confirmed by Horsch et. al who found 83.3% children with bilateral spastic CP had equinus that was correlated with increasing age [19]. The results of posterior calf muscle-tendon weakening/lengthening procedures have been warned against as a stand-alone procedure due to re-contracture/recurrence of the equinus deformity. Recurrence of equinus when combined with other hindfoot stabilizing procedures has shown a reduced rate of recurrence.

The combination of hindfoot osseous malalignment, spasticity of the peroneus longus, and a tight Achilles tendon provides the framework for a progressive disease process within the foot and ankle. Because the foot is the foundation to the body, this will have a negative effect to proximal musculoskeletal structures. Therefore so much medical attention has been focused on hindfoot realignment. The use of external braces or ankle-foot-orthosis has shown positive effects on weightbearing function however, a primary concern is their effectiveness only occurs when the patient wears the support [20]. There also is a psychological stigma associated with wearing these devices and for that reason having an internal option to realign and improve foot function without the need, or in combination with external braces provides a better result. Surgical procedures, such as subtalar or triple arthrodesis are also advocated. The issue with a joint-destructive procedure is that the normal amount of motion that was supposed to be occurring within the fused joint now must be compensated for in the neighboring joints. Ultimate, this excessive joint motion in adjacent joints is known to cause arthritic changes.

The use of a non-arthrodesis procedure that allows a reasonable amount of joint motion is preferred over a joint-destructive procedure. This is what has led to the development of titanium implants placed into the naturally occurring space between the talus and calcaneus, the sinus tarsi. The present study showed that there was a statistically significant improvement in hindfoot alignment, reduction in pain, and superior foot function. All the patients in our cohort showed significant normalization of both the T2M and TD angles.

The outcomes on the use of extra-articular talocalcaneal stabilization has been published [21]. Vedantam et al. studied the results of 140 arthroereisis in 78 ambulatory children with neuromuscular disease using an ultrahigh-molecular-weight polyethylene STA-peg [22]. This device is intra-osseous, meaning it is partially inserted into the calcaneus. These devices are no longer in common usage because of possibility of fragmentation and bone reaction, but they still reported satisfactory results. Others used both intra- and extraosseous sinus tarsi implant that resulted in excellent results in 70% and poor in 30%. They concluded, "Even though arthroereisis presents some complications, it can be considered a useful treatment to delay or avoid a Grice subtalar arthrodesis in flexible pes valgus due to cerebral palsy." These studies help to show the type of implant, intra- or extra-osseous could be an essential consideration.

Wen et al. compared EOTTS, with the same sinus tarsi implant design used to treat the patients in the present study, to a subtalar arthrodesis procedure in a similar subset of patients [23]. They found that patients had the same overall clinical outcomes. They noted patients who were treated with subtalar fusion were at a greater risk of developing ankle, calcaneal cuboid, and/or talonavicular arthritis due to limited motion at the talocalcaneal joint. Furthermore, patients who had the subtalar fusion required more extensive surgery plus the harvesting of iliac bone crest, were at higher risk of complications.

EOTTS may decrease the need for more advanced, osseous procedures. There are limitations with EOTTS that are based on the severity of the displacement of the talus via angular measurements and the reducibility of the displacement deformity. Patient selection should be based on the severity of the deformity. A tarsal coalition must be ruled out. While the sinus tarsi implant can have a positive effect on hindfoot alignment, there could be other co-deformities within the foot structure that must also be identified and treated with non-surgical or surgical options. Failure to do so could compromise the results of the sinus tarsi implant leading to prolonged pain and removal of the implant.

There are some limitations with this study. First, the clinical outcome was evaluated only by radiographic parameters, although improvements in clinical outcomes such as foot pressure distribution are also significant after surgery. Radiographic results show the internal realignment, whereas foot pressures cannot provide the same confirmation. A second limitation was the comparison of only two radiographic angles. There are multiple potential angles that could have been selected, but the TDA and T2MA were chosen because they provide a clear indication of the alignment between the talus and forefoot (T2MA) and sagittal plane (T2MA). A third limitation is that the follow-up period is not a long-term and continued follow-up is needed.

Conclusion

The present study shows the effectiveness of EOTTS in the treatment of subtalar joint partial dislocation in pediatric patients also diagnosed with GMFCS level I and II. The data demonstrates that this approach helps to internally realign and stabilize the TTJ while still allowing a natural range of motion. Also, it affords the possibility of delaying or avoiding more aggressive surgical procedures for children whose parents do not want that kind of involved surgery for their kids. The described surgical technique is safe and efficient and could represent a useful option of treatment of reducible planovalgus deformity in cerebral palsy patients 7 years of age and older.

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