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LOW TEMPERATURE THERMOPLASTIC SPLINTING IN THE MANAGEMENT OF CONGENITAL TALIPES EQUINOVARUS

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ABSTRACT Congenital talipes equinovarus (CTEV) is one of the most common congenital deformities. Treatment of clubfoot should begin at the earliest to have the best outcome. The goal of treatment is to eliminate all deformities of CTEV so that patient has a functional, pain free, plantigrade foot with good mobility within minimum time duration. Treatment includes non-surgical and surgical methods. Conventionally Plaster of Paris (POP) is used for splinting though leather, polypropylene and rubber are also used.

Objective of this study is to evaluate the effectiveness of low temperature thermoplastic (LTTP) splinting in CTEV management. This is an on observational study over a period of one year in Thirty-two CTEV patients with Pirani score of less than three. Effectiveness of LTTP splinting was evaluated in detail. It was found that LTTP splinting was cost effective, cosmetically better, reusable, demoldable, and easier to apply. It was of light weight, and required lesser time. It avoids the need for repetitive casting and same splint can be used as maintenance splint also. Pirani score lowered from 3 to 0 after 6 months of splinting. **Conclusion** –The compliance in donning the splint was high and acceptable among the children studied. Parental satisfaction regarding the splint wearing time and correction of deformity factor was high. Skin complications associated with POP casting were absent in the study population. Hence correction of CTEV with LTTP splinting was more effective than conventional POP casting.

KEYWORDS : Congenital Talipes Equinovarus, Pirani Score, Low Temperature Thermoplastics.

INTRODUCTION

Congenital talipes equinovarus (CTEV), is one of the most common congenital deformities. The incidence of CTEV is 1 in 1000 live births with a male to female ratio of $2:1^1$. 50% cases are bilateral. In unilateral cases, right side affection dominates². The exact etiology of CTEV remains unknown³. The deformities are: **C**avus, forefoot **A**dduction, inversion or **V**arus and ankle dorsiflexion or **E**quinus (CAVE). This may often be associated with tibial torsion of varying degrees.

CTEV Management should be started immediately or very soon after birth to guarantee high success rates ⁴. Neglected clubfoot causes crushing physical, social, psychological, and financial burdens on the patients, their families, and the society. The goal of treatment is to eliminate all the deformities of CTEV so that patient has a functional, pain free, plantigrade foot with good mobility within minimum time duration. Historically, the treatment of clubfoot had been challenging. Treatment includes non-surgical and surgical methods^{5,6}. Over the years, many different forms of treatment ranging from gentle manipulation and strapping, serial plaster corrections, forcible manipulation including the use of mechanical devices for surgical correction have been tried. Sir Ignacio Ponseti, at the university of Iowa, developed a method of treating clubfoot by manipulation and serial casting in the year 1950 (Fig.1). He observed success rate of 85-90% without requiring surgery⁷. Ponseti casting is the most popular non surgical method⁸. An above knee POP cast with knee in 90° is put in the corrected position obtained after gentle manipulation. The cast is removed after lweek and manipulation repeated in more corrected position. Once full correction is achieved, the final cast in this position, with foot in 60-70 degrees abduction is left in place for 3 weeks. Ponseti's protocol then calls for a brace to maintain the foot in abduction and dorsiflexion to prevent relapse. Clubfoot in an otherwise normal child can be corrected in 2 months or less with Ponseti's method, with or without tendoachilles tenotomy. The corrected position has to be maintained in an abduction splint for 3-4 years. Without a diligent follow- up bracing program, relapse occurs in more than 80% of cases.

The commonly used materials for splints after correction of deformity include Plaster Of Paris (POP), leather, polypropylene (High Temperature Thermoplastic, or HTTP), rubber etc. The fabrication procedures using these materials are complicated, and demand more time and manpower (Table 1). Of these POP has been the most frequently used. With POP, however, it is more time consuming, required more than one method and removal was more difficult. It was also with complications such as skin ulceration, eczema and dry skin.

Low Temperature thermoplastics or LTTP (Fig 2) is a good alternative to the conventional materials for casting or splintage[®]. It is Polycaprolactam and polyurethane based material covered with a layer of 0.6mm foam. It is ideal for spinal, upper limb and lower limb orthosis. As the name indicates this material is thermo-labile and is moudable at low temperature of 65-70°C which is tolerable to human skin. The material can be heated in water at 70° and can be dabbed with a towel to remove moisture. In the meantime, the temperature will fall to about 40°C, which is experienced as agreeable. Then, the material can be directly placed on the bare skin which after complete cooling will be strong enough for normal daily use¹⁰. This results in more perfect alignment to the body and more cosmetically superior to POP. It is fingerprint resistant, got excellent elasticity, shape and craft memory, non irritating, non allergic; hence better for serial casting in children who require prolonged application^{9,10,11}.

Thermoplastic material doesn't shrink and is remouldable (Fig 4) and reusable¹⁰. This in turn reduces duration of fabrication and thereby manpower requirements to a substantial extent. As the deformity of the patient improves, modification can be attained in the same appliance by simply heating and remoulding¹². The added advantage is that the same splint used in the final bracing can be converted into the maintenance brace for longer period which is impractical with a POP cast. With other materials like HTTP, maintenance splint will have to be made afresh, thereby escalating the cost of continued rehabilitation ^{9,12a}. Cost required for 5 or 6 POP castings will be Rs. 3,000 to 4,000. Cast required for LTTP

(thickness 2 mm to 4 mm- Fig- 2) splinting is only one, which can be moulded and applied in the more corrected position in the weekly visits. The cost of this single splint will be Rs.9,000 to 10,000, which includes the cost of maintenance splint. Setting up of water bath (Fig 3) is of course the additional expenditure, but this can be used for other patients too. Although the cost during the initial steps of LTTP splinting is 3 or 4 times higher than that of POP, the total cost after 4 to 6 repeated corrections would be the same or even less with LTTP. This method is particularly suited for developing countries where there are fewer doctors. The technique is easy to learn by allied professionals, such as therapists and orthopedic assistants. As the child grows, if further splinting is required, additional amount of LTTP material can be added in layers on to the currently used material. This will reduce total cost of fresh splint.

Not many studies are done regarding the use of LTTP in management of CTEV. In this study conducted in our institution, an attempt has been made to explore the effectiveness of LTTP splinting in the management of CTEV.

METHODOLOGY

This is an observational study done in a period of one year (April 2014 – March 2015). The study was conducted on Patients with unilateral and bilateral CTEV attending Department of Physical Medicine & Rehabilitation, Government Medical College, Kozhikode, a tertiary care centre in Kerala. After complete clinical examination, children having unilateral and/or bilateral feet with Pirani score¹³ of <3 were studied. Patients were below 6 months, were from both sexes. Post operative patients and children having other associated anomalies were excluded from the study.

Before making splint, measurements of foot are taken. LTTP material is then cut according to the measurement. The material is then heated in water at 70°C in hot water oven. Once it became flexible it is removed from water and is dabbed with a towel to remove excess moisture. Then, the material is directly placed on bare skin. After moulding, cutting and smoothening of corners and contours was easily done with simple tools like sharp scissors or knife. Additional piping / padding if necessary can be given with matching colors. A knee ankle foot orthosis (KAFO- Fig 5) is thus made and adequate strapping (velcro strapping) is given at thigh, leg, ankle and foot and is the splint is now ready for use. Additional reinforcement can be done using extra material if required, in multiple layers. The child was reviewed on 8^{th} day thereafter. During each visit, after further corrective manipulation in the order of cavus \rightarrow adduction \rightarrow varus \rightarrow equinus¹⁴, the same splint was applied in the corrected position, after immersing in warm water. Once full correction has been satisfactorily attained after repeated splinting, it is maintained with an ankle foot orthosis (FIG 6) which is fabricated by converting the same KAFO. Each patient is followed up for six months. At the end of six months of splinting, the child is evaluated using the Pirani scoring system.

During a period of 1 year, a total of 35 patients with unilateral/bilateral CTEV with Pirani score less than 3 were studied. 3 patients lost follow up and were excluded from the study. So, a total of 32 patients were studied in detail. Thirtytwo CTEV patients (42 feet) with Pirani score of less than 3 were studied. Male to female ratio was 1.9:1.Unilateral to bilateral ratio was 2.2:1. Age of patient ranged from 1 day of life to 3 months of age. Out of 32 patients, 22 patients (68.8%) had unilateral and 10 patients(31.2%) had bilateral CTEV. Unilateral to bilateral ratio is 2.2:1. Out of 22 unilateral cases, 15 patients (68%) had right side CTEV and 7 patients (32%) had left side CTEV, with right to left ratio of 2.2:1. So in this study a total of 42 feet were given splinting using LTTP material.

RESULTS

Minimum number of mouldings done in LTTP splint was 4 and maximum of 7. 14 patients underwent 6 mouldings (43.8% - highest percentage); 10 patients (31.3%) had 4 mouldings; 6 patients (18.3%) had 5 mouldings and 2 patients (6.3%) had maximum of 7 mouldings.). In the right side, minimum Pirani score was 0 and maximum was 3 (8 patients each (50%) had Pirani of 2.5 and 3; 5 patients (15.6%) had Pirani of 1.5 and 4 (12.5%) had Pirani of 2). In the left side, 5 patients (15.1%) had Pirani of 1.5 and 6 patients with 3; 3 (9.4%) each had Pirani of 1 and 2.5. At the end of 6 months, only 1 patient (3.1%) had Pirani of 0 (Chart 1). Paired t test was done and found that it is statistically significant (p value < 0.001 (Table 2). At the end of 6 months, 1 and 30 patients (93.8%) had Pirani of 0.

There were no complications observed in the present study. None of the parents complained about the complications on using the splint.

DISCUSSION

It is estimated that more than 100,000 babies are born worldwide each year with clubfoot. The incidence of CTEV in males are more compared to females, with a male to female ratio of 2:1 15,16,17 . Male:female ratio in the present study is 1.9:1, which is consistent with the Bor et al study¹⁸. According to Pavone et al this is almost similar¹⁹. The number of moulding per feet in our study was four to seven. In a series by Ponseti et al^{6} , the number of cast per feet was five to ten (average 7.6). According to studies by Porecha et al²⁰ and Bor et al¹⁸, average number of cats is 6.8 and 6.3 respectively. Morcuende et al reported that 90.0% of the patients required five or fewer casts²¹. Ponseti et al⁶ reported five to twelve weeks duration of casts (average 9.5 weeks). In another study by Laaveg et al²², the average duration was 8.6 weeks. In our study duration of application of splinting varied from 4 weeks to 7 weeks (average 5.5 weeks).

Pirani score is the commonly used tool²³. The use of the Pirani score for correlating the severity of clubfoot and the number of castings is supported by Dyer et al²⁴ who found a good correlation (r = 0.72) between initial modified Pirani six-point scoring and the number of casts. In the present study, the change in Pirani after six months was assessed and found that there is significant decrease in score. Paired t test was done and was statistically significant (p value <0.001).

The success rate of Kite is maximum 58% while that of Ponseti is 78 – 98%²⁵. In the present study, CTEV with Pirani score of less than three showed 95% success rate. Hui C et al²⁶ enrolled 30 patients: 12 randomized to plaster of paris and 18 to semirigid fibreglass. There was no difference in the number of casts required for clubfoot correction between the groups (p = 0.13). It is easy to apply and remove. In world literature the complication rate is 8%. In the present study none of the patient developed any complications.

CONCLUSIONS

- 1. LTTP splinting by Ponseti method is an excellent method in the treatment of clubfoot.
- It avoids the complications of casting as well as surgery and gives a painless, mobile, normal-looking, functional foot which requires no special shoes and allows fairly good mobility.
- 3. Proper motivation and persuading the parents to accept long-term brace treatment helps maintain the correction over a longer period of time and prevents relapse.
- 4. LTTP splinting was cost effective, cosmetically better, light weight, durable, reusable, remouldable, easy to apply and with lesser time requirement,
- 5. Since LTTP use avoids the need for repetitive casting, it is

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more acceptable to the parents than conventional POP casting.

- 6. Same LTTP splint can be used as maintenance splint.
- 7. There was no skin complications in any of the patients studied.
- 8. Compliance was high in both patients and content factor among parents of children were satisfactory.
- 9. In the present study, CTEV with Pirani score of less than three showed 95% success rate
- 10. Further research is required to substantiate the long-term impact.





Table 1: High Temperature Thermoplastics Vs LTTP

	HTTP				LTTP	
Activation	130-160 degrees				60-70	
Means of	Infrared or convection oven			Water bath or dry		
activation					heater	
Fabrication	On a mould			Directly onto the		
			patient			
Wear	Prolonged or permanent				Short term	
						1000
10.00						
						100
				•		•
					•	
				•		•
	1000					

Fig 2: LTTP Sheet



Fig 3: LTTP Sheet In Hot Water Oven



Fig 4: Flexible Heated LTTP Material



Fig 5: LTTP Knee Ankle Foot Orthosis (KAFO)



Fig 6: LTTP Ankle Foot Orthosis (AFO)- Maintenance splint

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Table 2: Initial And Final Pirani Score Pirani score-initial and final at Mean Standard p value 6th month Deviation Right side 1.85 1.10 0.000 1.20 0.000 Left side 1.11 35 30 25 20 15 initial Pirani score 10 Final score 5 0 0.5 1.5 2.5 3 Pirani 1 2 0

Chart 1: Pirani Scoring-Initial And Final

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