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Dr. Saral Patel
Assistant Professor, Department of Orthopaedics, BJ medical college, Ahmedabad, Gujarat, India

Dr. Mohnish Gadhavi
Assistant Professor, Department of Orthopaedics, BJ medical college, Ahmedabad, Gujarat, India

Dr. Ashwini Patel
Resident doctor, Department of Orthopaedics, BJ medical college, Ahmedabad, Gujarat, India

Dr. Jayesh Taral
Resident doctor, Department of Orthopaedics, BJ medical college, Ahmedabad, Gujarat, India

Dr. Harshil Poriya
Resident doctor, Department of Orthopaedics, BJ medical college, Ahmedabad, Gujarat, India

Correspondence
Dr. Mohnish Gadhavi
Assistant Professor, Department of Orthopaedics, BJ medical college, Ahmedabad, Gujarat, India

Results of ponseti method in congenital talipes equino varus children of more than 1.5 years of age

Dr. Saral Patel, Dr. Mohnish Gadhavi, Dr. Ashwini Patel, Dr. Jayesh Taral and Dr. Harshil Poriya

Abstract
Introduction: It is estimated that more than 100,000 babies are born worldwide each year with congenital clubfoot. Eighty percent of the cases occur in developing nations. Most are untreated or poorly treated. Neglected (older aged) clubfoot causes crushing physical, social, psychological and financial burdens on the patients, their families, and the society. Globally, neglected clubfoot is the most serious cause of physical disability among congenital musculoskeletal defects. A dramatic reduction in radical clubfoot operation has been reported in parts of the world where Ponseti treatment has been introduced. There have been some reports of Ponseti treatment being given successfully to children with neglected clubfoot, but there has been no general acceptance of treating children older than 2 years with this method. Today, these children are probably treated with radical operations or left untreated. The purpose of this study is to examine the results of Ponseti method in old age clubfoot children.
Aim: To evaluate the outcome of Ponseti method of clubfoot patients of more than 1.5 years of age.
Materials and Methods: The study was conducted in Patients outdoor department of orthopedic department of CHA where the service is offered for all outpatients who come from all over the country. Patients were selected on the basis of inclusion and exclusion criteria as:
Inclusion criteria: Patients with club foot with more than 1.5 years of age, Assessment is executed by qualified Orthopedics, both male and female were included. Exclusion criteria: Patients with age less than 1.5 years, Patients who are medically unstable, Patients who have isolated clubfoot, like metatarsus adductus, heel varus.
Results and Discussion: We have found a statistical significant improvement in ability for the children with congenital clubfoot of more than 1.5 years' age. Between pre-and post-correction phase Z value is 152.2 ($p<0.05$) and between post correction and post brace phase Z value is 4.61($p<0.05$) which is statistically significant, which is comparable to Abhinav Sinha, Anil Mehtani *et al*. (2016) study, who studied 41 clubfeet in 30 patients, presenting after the walking age, were evaluated to determine whether the Ponseti method is effective in treating neglected clubfoot. The mean Pirani score was 5.41 before treatment and 0.12 after treatment. All feet (100%) achieved painless plantigrade feet without any extensive soft tissue surgery. Comparison with it in my study mean Pirani score is 5.79 precorrection and 0.04 post correction. 100% correction rate achieved.
Conclusion: The results of treatment of CTEV by PONSETI method is much more efficient and compliant. As PONSETI method has very less dropout, very less recurrence, very good compliance, Less time period of treatment, Less complication. As a whole the clubfoot patients of more than 1.5 years of age getting functional improvement after Ponseti method and the result were significant.

Keywords: ponseti, congenital, talipes equino, varus children, 1.5 years

Introduction
It is estimated that more than 100,000 babies are born worldwide each year with congenital clubfoot. Eighty percent of the cases occur in developing nations. Most are untreated or poorly treated. Neglected (older aged) clubfoot causes crushing physical, social, psychological and financial burdens on the patients, their families, and the society. Globally, neglected clubfoot is the most serious cause of physical disability among congenital musculoskeletal defects.
Most of the literature on treatment of neglected clubfoot focuses on soft tissue release surgery, osteotomy or fixators. The problem in developing country is the large number of patients and scarcity of skilled surgeons and OT time. Further, the good short-term results have shown to deteriorate over longer follow up resulting in rigid painful feet. The scars are cosmetically unacceptable. Lastly, any relapse after surgical treatment was very difficult to manage.

This calls for a simpler method that can be easily applied to larger population with better results.

A dramatic reduction in radical clubfoot operation has been reported in parts of the world where Ponseti treatment has been introduced [1].

There have been some reports of Ponseti treatment being given successfully to children with neglected clubfoot [2, 3, 4], but there has been no general acceptance of treating children older than 2 years with this method. Today, these children are probably treated with radical operations or left untreated [5]. The purpose of this study is to examine the results of Ponseti method in old age clubfoot children.

Aim

To evaluate the outcome of Ponseti method of clubfoot patients of more than 1.5 years of age.

Materials and Methods

Study design: The aim of the study is to explore the results of Ponseti method in congenital talipes equino varus children of more than 1.5 years of age, a retrospective survey over last from 1st June 2015 to 28th Feb 2017, at CHA patient's outdoor department.

Sample selection: For the accomplishment of the study, the documents (Assessment form, SOAP notes, and Discharge summary) of those patients was selected, who had already been treated and discharged from patients outdoor department of CHA from 1st June 2015 to 28th Feb 2017.

Study site: The study was conducted in Patients outdoor department of orthopedic department of CHA where the service is offered for all outpatients who come from all over the country.

Data collection procedure: Researcher started the study and collected the relevant information from previous assessment, SOAP notes and discharge summary of each participant.

Inclusion criteria

- Patients with club foot with more than 1.5 years of age.
- Assessment is executed by qualified Orthopedics.
- Both male and female were included

Exclusion criteria

- Patients with age less than 1.5 years.
- Patients who are medically unstable.
- Patients who have isolated clubfoot, like metatarsus adductus, heel varus.
- Relapse after surgery.

Limitation of the study

There were some limitations or barrier to consider the result of the study as below:

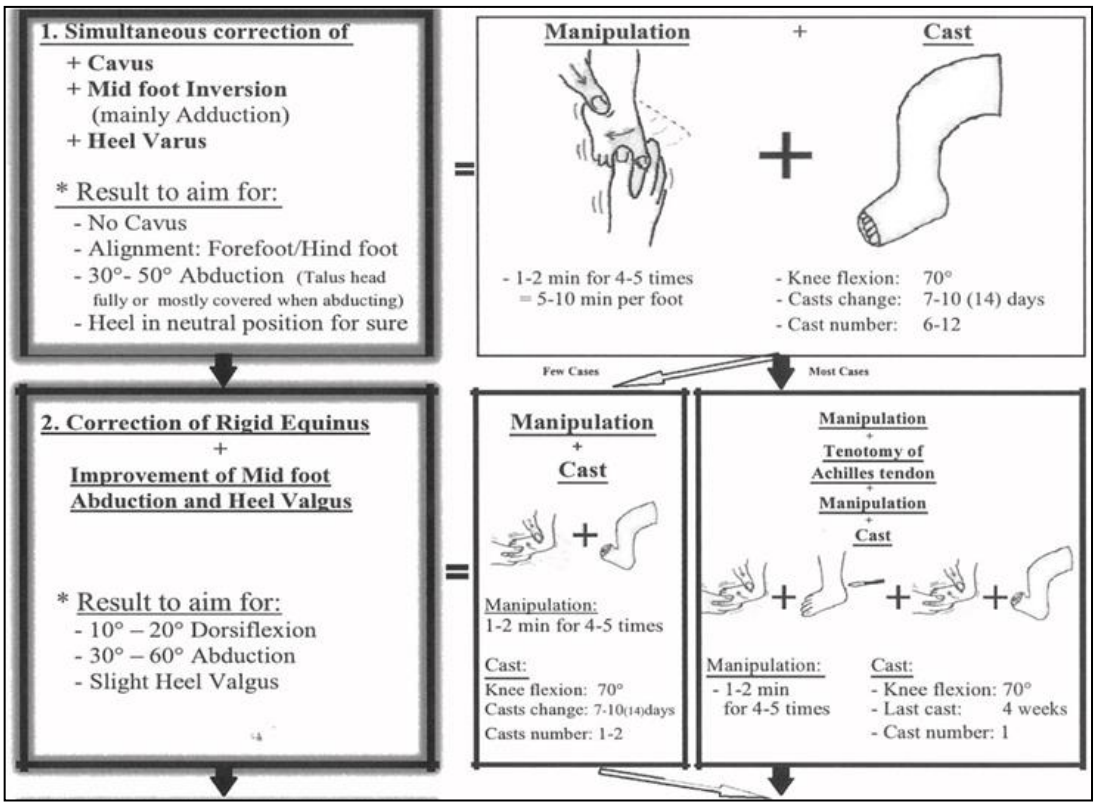
- The first limitation of this study is sample size, which is 70 comparable to other study.
- Another relative limitation is time. As in my study average 2 year follow up has been done and average duration of treatment was 2.3 years.
- As the study was conducted at Civil hospital Asarwa Ahmedabad (CHA) which may not represent the whole country.

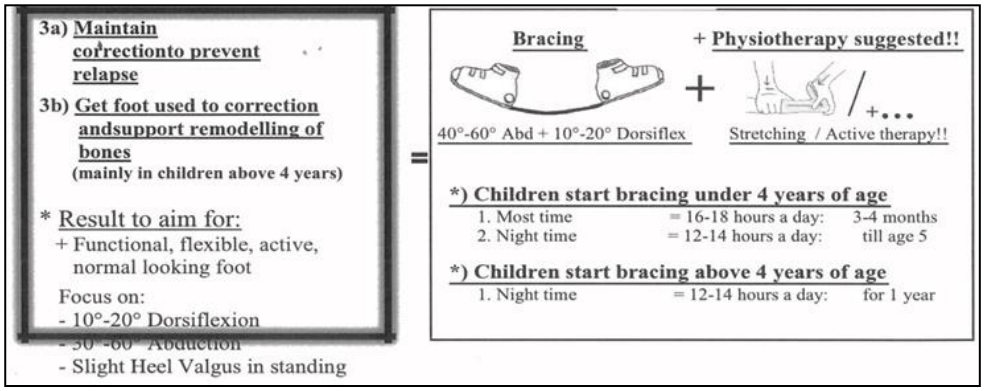
Pirani severity scoring

This scoring system was used to evaluate the results of Ponseti method in congenital talipes equino varus children of more than 1.5 years of age. The scoring was done every time the feet were examined: before the treatment, during the correction phase, during the bracing phase and at later check-ups.

Overview of clubfoot treatment

Using the ponseti method (basic guideline) older children clubfoot treatment using the ponseti method (guideline)





The treatment starts with gradual correction of the deformity: Cavus, Mid foot Inversion, Heel Varus and the Rigid Equinus need to be corrected. The tenotomy of the Achilles tendon is strongly suggested in most cases to correct the Equinus. After full correction a relapse needs to be prevented. This is done by bracing.

Observations and Results

1. Sex Distribution

Table 1

Sex	No. Of ctev children
Male	53
Female	17
Total	70

2. Foot Affected

Table 2

Affected foot	Total no.
Unilateral	33
Bilateral	37
Affected foot	Unilateral
Right	17
Left	16

3. Dropout

Table 3

DROPOUT	NO.OF CHILDREN
CASTING	07
BRACING	03
TENOTOMY	00

4. Age Distribution

Table 4

AGE WHEN 1ST CAST GIVEN	NO. CHIDREN
1.5 YEARS TO 2 YEARS	28
2-5 YEARS	21
5-10 YEARS	19
>10 YEARS	2

5. Brace compliance

Table 5

Brace compliance	Children
Good	49
Fair	20
Bad (poor)	1
Total	70

6. No of Tenotomies

Table 6

BRACING WITH TENOTOMIES	55
BRACING WITHOUT TENOTOMIES	15

7. Casting after which Pilani score is Zero

Table 7

Total no. Casting after Which pirani score is zero	No. Of child
5	27
6	15
7	8
8	4
>8	16
Total	70

8. Types of recurrence

Table 8

TYPES OF RECURRANCE	
VARUS	14
EQUINUS	12
DYNAMIC SUPINATION	2
TOTAL	28

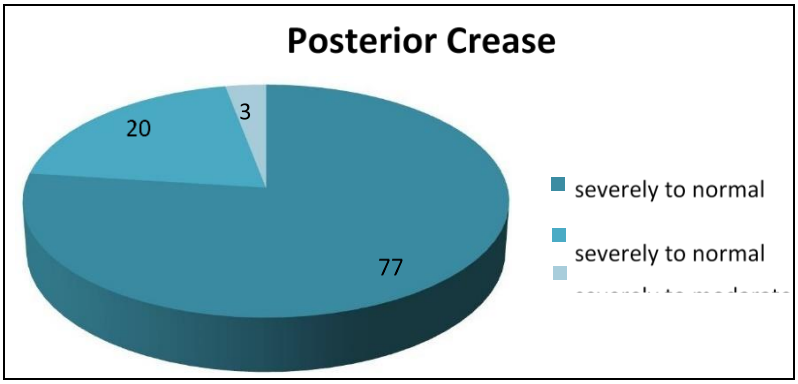
9. Outcome of Ponseti measurement by Pirani severity score

Table 9

Pirani severity scale	Scale Ranking			Total Number of participants
	Level-1 Severely abnormal	Level-2 Moderately abnormal	Level-3 Normal	
Posterior Crease				70
Pre- correction score	60 (86%)	10 (14%)	0 (%)	
Post- correction score	0 person	2 person (3%)	68 person (97%)	

Interpreting the result

According to pirani severity scale (Posterior Crease) function improves in 83% from severely to normal, in 14% from moderately to normal and in 3% from severely to moderate.



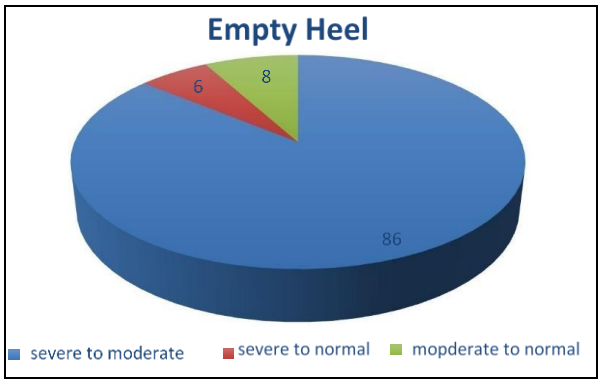
Empty Heel

Table 10

	Scale Ranking			Total Number of participants
Pirani severity scale	**Level-1 Severely abnormal**	**Level-2 Moderately abnormal**	**Level-3 Normal**	70
Empty Heel				
Pre- correction score	64 (91%)	6 (9%)	0 (%)	
Post- correction score	0 (%)	60 (86%)	10 (14%)	

Interpreting the Result

According to pirani severity scale (Empty heel) function improves in 86% from severely to moderate, in 6% from severity to normal and in 8% from moderately to normal



Rigid Equinus

Table 11

	Scale Ranking			Total Number of participants
Pirani severity scale	**Level-1 Severely abnormal**	**Level-2 Moderately abnormal**	**Level-3 Normal**	70
Rigid Equinus				
Pre- Correction score	64 (91%)	6 (9%)	0 (%)	
Post- correction score	0 (%)	60 (86%)	10 (14%)	

Interpreting the result

According to pirani severity scale (Rigid Equinus) function improves in 77% from severely to normal, in 20% from moderately to normal and in 3% from severely to moderate.

Interpreting the result

According to pirani severity scale (Rigid Equinus) function improves in 77% from severely to normal, in 20% from moderately to normal and in 3% from severely to moderate.

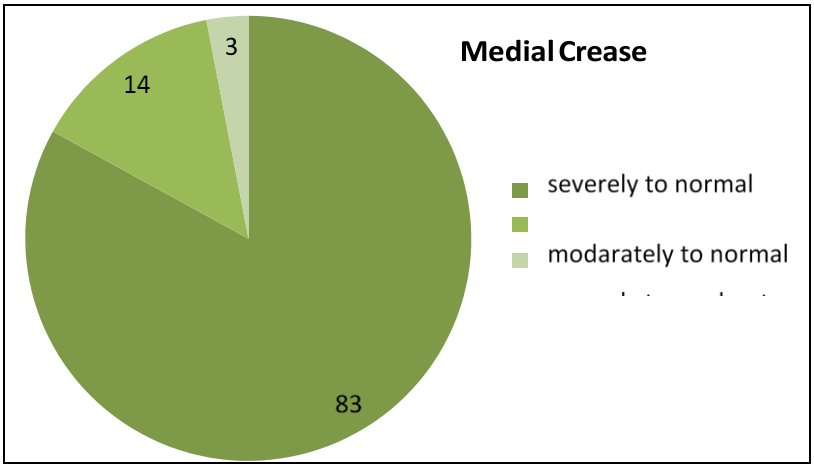
Medial Crease

Table 12

	Scale Ranking			Total Number of participants
Pirani severity scale	**Level-1** Severely abnormal	**Level-2** Moderately abnormal	**Level-3** Normal	70
Medial Crease				
Pre- correction score	60 (86%)	10 (14%)	0 (%)	
Post- correction score	0 (%)	2 (3%)	68 (97%)	

Interpreting the result

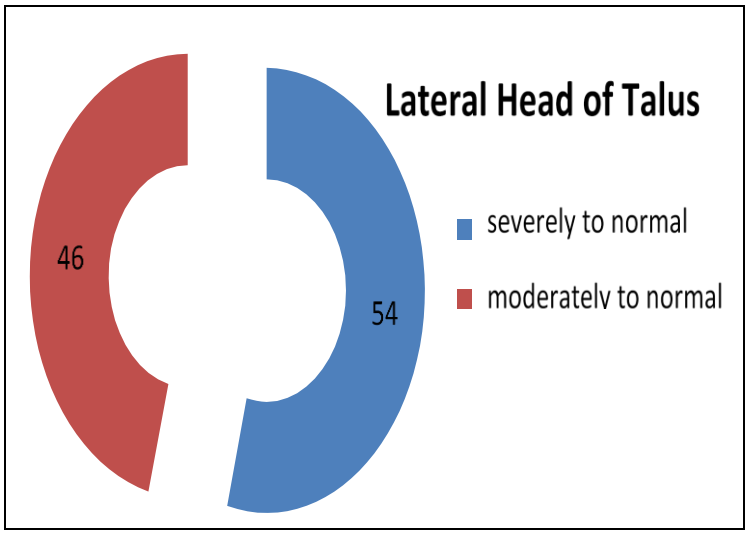
According to pirani severity scale (Medial Crease) function improves in 69% from severely to normal, in 20% from moderately to normal and in 11% from severely to moderate.



Lateral head of talus

	Scale Ranking			Total Number of participants
Pirani severity scale	**Level-1** Severely abnormal	**Level-2** Moderately abnormal	**Level-3** Normal	
Lateral Head of talus				70
Pre- correction score	38 (54%)	32 (16%)	0 (%)	
Post correction score	0 (%)	0 (%)	70 (100%)	

According to pirani severity scale (Lateral Head of Talus) function improves in 54% from severity to normal and in 46% from moderately to normal

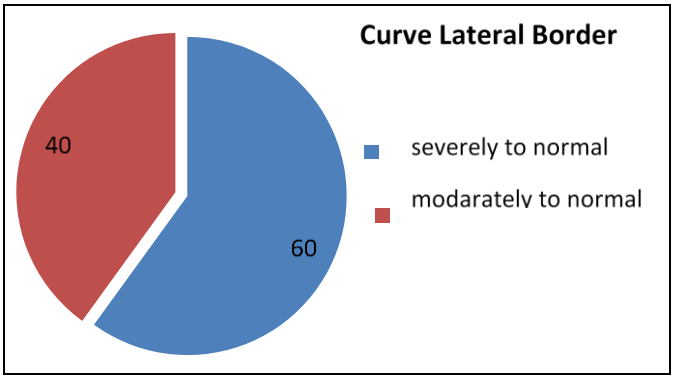


Curve lateral border

	Scale Ranking			Total Number of participants
Pirani severity scale	**Level-1 Severely abnormal**	**Level-2 Moderately abnormal**	**Level-3 Normal**	
Curve Lateral Border				70
Pre correction score	42 (60%)	28 (40%)	0 (%)	
Post correction score	0 (%)	0 (%)	70 (100%)	

Interpreting the result

According to pirani severity scale (Curve Lateral Border) function improves in 60% from severity to normal and in 40% from moderately to normal.



We have observed 70 children's functional ability level by following Pirani severity scale before and after given plaster cast. Their age is above 1.5 years. According to Pirani severity scale 56 children or 80% children out of 70 children are observed in level-1or severely abnormal in pre-test score, but during post-test score those who have level-1, functional ability have been improved to 60% children to level-2, 91% to level-3.

Mean value of total pirani score of precreation is 5.79(±0.30) and mean value of total pirani score of post correction is 0.04(±0.14). So observed difference was found to be statistically significant as per Z test. (Z value=152.2, p value <0.05).

Mean value of total pirani score of post correction is 0.04(±0.14) and mean value of total pirani score of post brace is 0.29(±0.39). So observed difference was found to be statistically significant as per Z test. (Z value=4.61, p value <0.05).

Discussion

The older age children with clubfoot deformity are unable to mix with their peers because of stigmatization, and as a result very few go to school. Most of the literature on treatment of older age clubfoot has focused on extensive soft tissue release surgery, osteotomies, and various types of fixators or arthrodesis. Long term studies of surgical procedures have shown poor results with complications like painful feet, arthritis, and stiffness of ankle and subtalar joint, and residual deformity. The few studies, evaluating the use of Ponseti method in older age children with clubfeet have shown promising results.

The purpose of this study is to evaluate the effect of Ponseti method to improve functional ability among clubfoot children of more than 1.5 years of age. To determine this, the we have observed pre-test & post-test score in Pirani severity Scale among those children who had taken Ponseti method.

In study, out of 70, 75% male and 25% female chidren, which shows male are more affected, which is comparable to Lourenço and Morcuende study [1, 3] who treated 17 patients (24 feet) with neglected clubfeet, with mean age of 3.9 years and 78% male and 22% female chidren. In my study, mean age is 3.5 years. The reason is genetic etiology and lack awareness about ctev, poverty and limited treatment resources in our country.

Khan and Kumar [7] and Mehtani [6] had treated patients in average and 10 casts, respectively, which was comparable to my study with average total cast are 7.6 and mean period of casting 3.6. More casts needed for correction as compare to infants due to soft tissue contracture and more rigidity of foot in older children

In my study, all the 70 children treated by the Ponseti method of cast application achieved painless, supple, plantigrade, and cosmetically acceptable feet in all children (100%), which is comparable to Khan and Kumar study [7], who treated neglected clubfoot in 21 children (25 feet) over 7 years and found good results in 18 feet (85.7%).

In my study, 79% children required tenotomy during treatment which is comparable to Verma *et al*. [2] who evaluated Ponseti method in toddlers and found 86% required tenotomies during treatmemt. Tenotomy is required in most of patients because of more equinus rigidity for which cast alone is not sufficient.

We have found a statistical significant improvement in ability for the children with congenital clubfoot of more than 1.5 years' age. Between pre-and post-correction phase Z value is 152.2 ($p<0.05$) and between post correction and post brace phase Z value is 4.61($p<0.05$) which is statistically significant, which is comparable to Abhinav Sinha, Anil Mehtani *et al*. (2016) study [6], who studied 41 clubfeet in 30 patients, presenting after the walking age, were evaluated to determine whether the Ponseti method is effective in treating neglected clubfoot. The mean Pirani score was 5.41 before treatment and 0.12 after treatment. All feet (100%) achieved painless plantigrade feet without any extensive soft tissue surgery. Comparison with it in my study mean Pirani score is 5.79 precorrection and 0.04 post correction. 100% correction rate achieved.

The recurrence rate 40% of in our series is also is comparable to that of most of the studies done in infants.

Despite the encouraging results seen in our study, there are certain limitations. Application of above knee casts is troublesome for older children. It makes an independent child totally dependent on their parents. Second, we found that older children had difficulty accepting the foot abduction brace and no definite protocol is available regarding bracing in older children. We advocated at least 1 year of night time bracing even in older children but 5 patients who didn't tolerate the foot abduction brace had to be given a custom-made ankle foot orthosis (AFO). The usefulness of the AFO, however, remains doubtful. Recurrence was seen in 28 cases, but feet were still supple and responded to repeat Ponseti casting unlike surgical recurrence. Further all relapses were due to non-adherence to bracing protocol.

The larger patient samples and followup period would be required to establish fully the efficacy of Ponseti method for treating neglected clubfoot but our results our encouraging.

We feel that Ponseti method either fully takes care of this stubborn deformity or reduces the extent of residual surgical release and it should be a good alternative for

treatment of older age children with clubfoot.

Conclusion

The results of treatment of CTEV by PONSETI method is much more efficient and compliant. As PONSETI method has very less dropout, very less recurrence, very good compliance, Less time period of treatment, Less complication. As a whole the clubfoot patients of more than 1.5 years of age getting functional improvement after Ponseti method and the result were significant.

This study will try to represent the strong evidence of the "Excellent Outcome of Ponseti method for the management of children with clubfoot patients of more than 1.5 year of age group.

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