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# A Randomized Controlled Trial to Compare Outcomes of Super - Accelerated and Accelerated Ponseti Casting Technique in the treatment of Idiopathic Clubfoot

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A B S T R A C T

Objective: This study aims to compare the results of super accelerated (1 week) and the accelerated Ponseti techniques (2 weeks) in correcting idiopathic club feet in terms of Pirani scoring at 3 months follow up in foot abduction brace and also to investigate the influence of cast change interval on treatment outcomes as well as to study the demographics of these children.

Methodology: A Prospective Randomized Controlled Trial study was conducted in Department of Pediatric Orthopedics Children Hospital and Institute of Child Health Faisalabad from July 2021 to December 2021. Patients recruited were 3 months or younger with follow up in FAO for 3 months. a protocol was designed to compare 'Super Accelerated Ponseti' method (Group A) with the 'Accelerated Ponseti' method (group B). Group A was treated using 'Super Accelerated Technique' in which after 3rd day of first casting sequential three daily castings were performed followed by Tenotomy (total 8 days of casting). In Group B the accelerated technique was used in which four castings were done alternatively followed by tenotomy (total 10 days of casting)

Results: There was no significant difference in Median number of casts to achieve the correction between both groups (p = 0.000435). Group A needed 3 to 20 casts to attain full correction and the median number of casts was 6. Group B needed 2 to 24 casts to attain full correction and median number of casts was 5. In Super Accelerated Group there were no relapses whereas in Accelerated Group there were two cases of residual equinus in which three repeated casts were applied to achieve correction.

Conclusions: Fast casting is safe and equally efficacious in treating idiopathic clubfeet.

Keywords: Ponseti technique, idiopathic clubfeet, CTEV, accelerated Ponseti method

## Introduction

Congenital Talipes Equino Varus (CTEV), or club foot, is the most common musculoskeletal congenital deformity with a prevalence of 1 per 1000 live birth in developed world and 2 to 4 per 1000 in developing world.[1] The gold standard classic treatment of club foot is weekly serial casting described by Ignacio Ponseti in the 1940s.[2] The weekly plaster from thigh to foot gradually corrects the deformity in usually 4 to 5 casts. In the last cast equinus is corrected in over 95% patients with percutaneous tenotomy. Later, feet are placed in foot abduction brace and followed up at regular intervals up to age of 3 years or more. The aim is to achieve painless, plantigrade, cosmetically and functionally normal feet.[3]

Recent literature has shown that different accelerated casting regimes have the same safety and efficacy as the standard Ponseti protocol. The accelerated ponseti method reduces the time of treatment with equivalent results of standard Ponseti, which oils the wheel of treatment for more benefits and better compliances.[4]

Morcuende was the first to publish results on accelerated ponseti technique in 2005. He studied 230 patients (319 clubfeet) from Clubfoot clinic at IOWA. Based on geography 108 patients were assigned to 5 days and 111 patients to 7 days of casting interval. He concluded 5 days casting was as safe and effective in children less than 1 year even after previous unsuccessful nonsurgical treatment.[5] Xu in 2011 presented a preliminary report from General hospital Beijing on twice a week casting for 26 patients (40 feet) in accelerated group. He studied it to be safe and

effective and considerably shortened the treatment.[6] Harnet (2011) from CURE International Hospital Malawi

further accelerated to thrice a week cast and published comparable outcomes.[7] Recently (2020) Alaeddin Azmi from An- Najah National University, Ramallah accelerated the Ponseti method to manipulation, casting and tenotomy in one week's span, showing successful results in 11 severe idiopathic clubfeet in less than 3 months.[8]

Given the advantages of newly described accelerated technique and suggested safety it is worth to prospectively study results in a comparative manner in a large sample. We studied two groups of idiopathic clubfeet in accelerated model of casting phase but different pattern. One group was casted consecutively (Super accelerated) and other was on alternate days (Accelerated casting).

The primary objective of this study is to compare the results of super accelerated (1 week) and the accelerated Ponseti techniques (2 weeks) in correcting idiopathic club feet presenting to Children's Hospital Faisalabad in terms of Pirani scoring at 3 months follow up in foot abduction brace. The secondary aim is to investigate the influence of cast change interval on treatment outcomes as well as to study the demographics of these children.

## Methodology

The study was conducted in Department of Pediatric Orthopedics Children Hospital and Institute of Child Health Faisalabad from July 2021 to December 2021. Patients recruited were 3 months or younger with follow up in FAO for 3 months. After approval from Institutional Review Board (IRB), a protocol for a prospective randomized controlled trial was designed to compare 'Super Accelerated Ponseti' method (Group A) with the 'Accelerated Ponseti' method (group B). Group A was treated using 'Super Accelerated Technique' in which after 3rd day of first casting sequential three daily castings were performed followed by Tenotomy (total 8 days of casting). In Group B the accelerated technique was used in which four castings were done alternatively followed by tenotomy (total 10 days of casting) (Table I). The scheduling was done according to the personal availability at our center. In both groups when 5 castings were done on defined patterns (A or B) to achieve correction, it was called 'Ideal Casting'. When more than 5 casts were required to achieve correction in either group it was defined as 'Non ideal casting'. Correction was defined when modified Pirani score was zero.

Patients were randomized using the manual lottery method in the two groups after initial evaluation. Blinding was not possible. Written informed consent was signed by the parent or guardian. All the patients were treated in club foot clinic by a standard team. The recordings and photographic records were made by independent assessor on a prescribed proforma.

Idiopathic unilateral or bilateral Congenital Talipes Equino Varus (CTEV) < 90 days old (3 months) were included. Positional, relapsed, recurrent or previously treated CTEV, CTEV secondary to neuromuscular conditions, arthrogryposis, trauma, Syndromic CTEV or associated limb deficiencies etc. were excluded.

Serial plaster treatment using Ponseti method was continued until clinical correction was achieved. A percutaneous tendo-Achilles tenotomy was performed when dorsiflexion was < 10° followed by 3 weeks cast. The defined endpoint of treatment for both groups, labelled 'treatment time in plaster' refers to the number of days in plaster prior to a tenotomy.

Both groups were given foot abduction braces to wear for three years following their plaster treatment, 23 hours per day for the first three months, followed by night-time bracing until the child's third birthday, in accordance with the standard local Ponseti program.

All patients were treated as outpatients, thereby reducing any bias from altered compliance and enabling us to directly compare the efficacy of the two methods in terms of correction of the deformity. All feet were scored using the Pirani scoring recorded by an independent assessor at the time of first evaluation, after last cast and monthly for three months at each follow up while wearing the foot abduction orthosis (FAO). Complications were recorded.

## Results

A total of 58 patients with 87 clubfeet were included. 41 (70%) were males, 29 (50%) were bilateral and 7 patients had positive family history. 28 patients with 43 clubfeet were randomized in Group A whereas 30 patients with 44 clubfeet were randomized in Group B as shown in figure 1. Mean age in both groups was 5 days with a range of 2 to 60 days in group A and 1 to

Table 1. Group A and Group B Duration of casting.

| Group | Monday | Tuesday | Wednesday | Thursday | Friday | Saturday | Sunday |
|---|---|---|---|---|---|---|---|
| Super Accelerated (A) | | | | | 1st cast | | |
| | | 2nd cast | 3rd cast | 4th cast | Final Tenotomy | | |
| Accelerated (B) | 1st cast | | 2nd cast | | 3rd cast | | |
| | 4th cast | | Final Tenotomy | | | | |

30 days in Group B ( p = 0.0825) . In group A 22 (78%) patients were male while in group B 19 (63%) were males. 53% were bilateral feet in group A and 50% bilateral feet in group B. 24 out of 58 patients came from outside Faisalabad city. In group A 53% whereas in group B 33% patients were out of station. As shown in consort diagram (Figure 2).

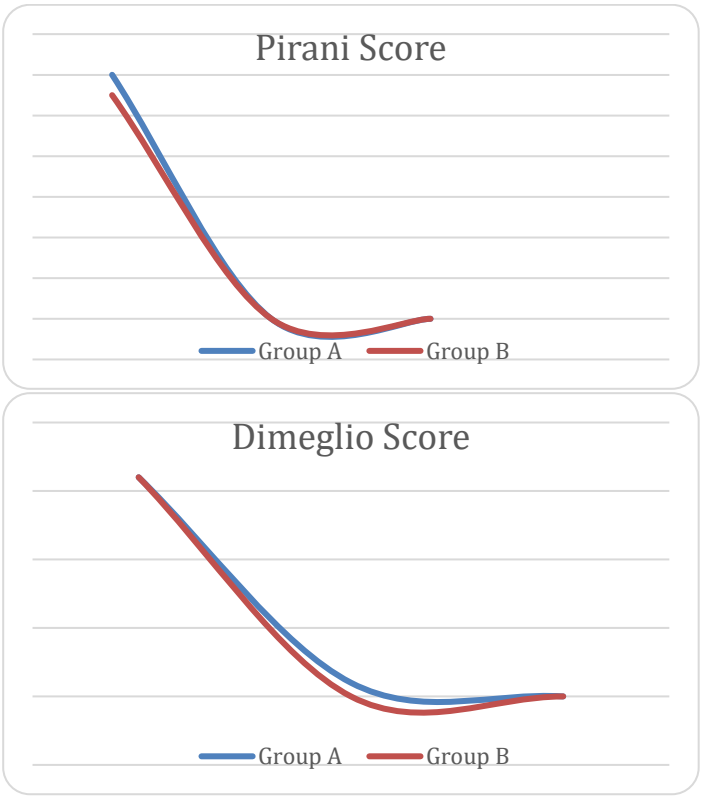


Figure 1. The mean Pirani and Dimeglio score at the pretreatment, immediate post treatment and final follow-up

There was no significant difference in Median number of casts to achieve the correction between both groups (p = 0.000435). Group A needed 3 to 20 casts to attain full correction and the median number of casts was 6(only one patient attained full correction in 20 cast). Group B needed 2 to 24 casts to attain full correction (only one patient attained full correction in 24 cast) and median number of casts was 5. Required tenotomies were 41 feet out of 43 feet and ideal number of casts were applied in 17 feet out of 43 feet in Group A. Required tenotomies were 37 out of 45 feet and ideal number of casts were applied in 13 out of 44 feet in Group B. 4 Patients dropped out. The mean pre-treatment, immediate post treatment and final follow-up Pirani and dimeglio are given in (Table I).

In Super Accelerated Group there were no relapses, one patient dropped out after 1st cast and one patient had muscle deep wound in popliteal region after tenotomy in cast. After healing of wound, casting was started again until correction was achieved. In Accelerated Group there were two cases of residual equinus in which three repeated casts were applied to achieve correction. Three patients dropped out, one died due to complications of diarrhea and two were absent after 2nd and 3rd casts. (Table II).

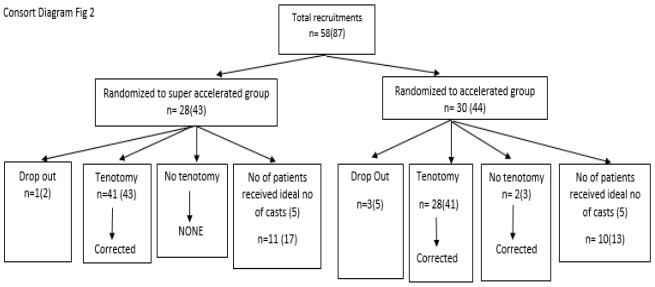


Figure 2. Consort Diagram

Table II: Comparison of baseline characteristics, functional scoring and number of casts between randomized groups.

| Variables* | SUPER ACCELERATED (Group A) N = 28(43) | ACCELERATED (Group B) N = 30(45) | P value from inferential test^ |
|---|---|---|---|
| Median age in days (IQR) at onset | 5 (2 days-60 days) | 5 (1 day-30 days) | 0.0825 |
| Males | 22/28 (78%) | 19/30 (63%) | |
| Bilaterally | 15/28 (53%) | 15/30 (50%) | |
| Positive family history | 01/28 | 06/30 | |
| Number of pt. from out of city | 14/28 (53%) | 10/30 (33%) | |
| Tenotomy Required | 41/43 (95%) | 37/45(82%) | |
| Median baseline Pirani score | 6 | 5.5 | 0.04 |
| Median pre-Dimeglio scoring | 16 | 16 | 0.316 |
| Drop outs | 01(02) | 03(05) | |
| Median Pirani score after tenotomy | 0 | 0 | 0.0391 |
| Median Pirani scoring at 3 months | 0 | 0 | |
| Median casts (IQR) before PAT | 6(3-20) | 5(2-24) | 0.000435 |
| Median DAYS IN CAST before PAT | 9 (6 – 26) | 10(3-40) | 0.18 |
| No of feet treated by ideal cast number | 17/43(39.53%) | 13/45(28.88%) | |

**Continuous variables presented as median (IQR, interquartile range) as data were tilted.* *^T.TEST for significant difference between the means of two groups, which may be related in certain features.*

## Discussion

The Ponseti method is an established "Gold Standard" technique for the treatment of idiopathic clubfeet involving 4 to 5 weekly castings for most patients to correct all components of clubfoot deformity. A major constrain to compliance in these families is multiple visits that require transportation, lodging, costs, time away from work and family.[9] Further researchers have observed that prolonged casting is associated with risk of osteopenia, pressure sores, skin rashes, and disuse atrophy. This inspired orthopedic surgeons to try a shorter time line to achieve similar results.[10] Morcueda et al (2005) were first to publish accelerated results of 5 day casting, however discouraged the practice of 3 or 4 day interval since that caused edema and swelling.[5] Later Islam et al (2011)[11], Harnet et al (2010)[7] and multiple authors showed comparable outcomes with the ability to complete successful treatment in twice or thrice a week casting.[4, 12-16]

In a recent systematic review of 13 studies between 2015 to 2022 comparing conventional with accelerated model, accelerated Ponseti showed superior impact over standard Ponseti considering the duration of treatment excluding three weeks cast after tenotomy (22.53 days vs. 40.61 days, p<0.001). The accelerated method had a mean of 19.2 days lower than the standard Ponseti method of treatment (95%: 17.6-20.6). No significant difference was reported between the two methods considering final Pirani score (0.64 vs. 0.56, p=0.194), number of casts (5.23 vs. 5.25, p=0.425), rate of tenotomy (66.2% vs. 63.1%, OR=1.246, 95% CI: 0.86-1.80, p=0.245), relapse rate (9.51% vs. 8.54%, OR=1.126, 95% CI: 0.68-1.86, p=0.642) and complication rate (14.4% vs. 13.1%, OR=1.130, 95% CI: 0.58-2.19, p=0.717).[4]

In 2020 Alaaeldin A, Ahmed further reduced the cast timing and published results of 11 patients with 16 severe congenital idiopathic clubfeet treated by 5 castings within a week, with all of them having percutaneous Achilles tenotomy. The deformity was found to be corrected in 29 days, whereas it is expected to take at least 56 days if classic Pirani method was performed, assuming 5 weekly castings in addition to the tenotomy procedure (PAT) and subsequent three-week casting (PAT cast). All treated clubfeet had no difficulty to be put in Dennis brown splint. The average follow-up time was 24.2 months (range 20–34 months) with a mean Pirani score after last follow up session of 0.56. None of the patients needed any surgeries.[8]

Enough evidence exists in literature regarding regimes involving 5 days, twice or thrice a week casting in achieving comparable results to classic Ponseti method, however the newly described accelerated model of alternate or daily casting needs further research for its efficacy and safety in significantly reducing treatment time.

In our study we have prospectively compared daily casting (super accelerated – Group A) with alternate day casting (accelerated – Group B) to achieve corrected feet in idiopathic CTEV under 3 months of age. Mean pre and post correction Pirani score and median casts (6) applied to achieve correction in both groups were comparable. Median days in cast before PAT was 9 (6 – 26) in Group A and 10(3-40) in Group B. PAT was required in 95% in the super accelerated group Ponseti group and in 82% in the accelerated Ponseti group consistent with the literature. A total of 9/58 (15.55%) patients experienced rashes, minor sores in the heel, loosening of cast and one patient had a deep sore in popliteal region. None of the patients relapsed at 3 months follow up and tolerated bracing well.

Accelerated model reduced total duration in cast from classical 56 days to 43 days which was subsequently reduced to 29 days in fast casting regimens (our study) cutting down significantly by 27 days. However number of feet receiving ideal number of casts (described as 5 cast prior to PAT) were 17/43 (39.53%) in Group A and 13/45 (28.88%) in Group B indicating one third of these feet required more than usual number of casts.

Interestingly, there was no evidence of excessive edema on the 2nd cast of the alternate day regime as expected previously by Morcquende, suggesting an alternate way of doing the one week fast casting which can also facilitate scheduling in different clinic setups.

The parents reportedly liked visualizing and washing their child's foot and leg at shortened intervals. Whilst the number of casts and associated clinic visits for the corrective casting still averaged five, the shortened treatment phase reduced the likelihood of treatment being interrupted, which has previously been a factor reducing parental satisfaction ([17])

The strength of our study is being a prospective randomized comparison where both groups were casted in a weeks' time but alternate pattern with similar baseline demographics. A single team performed the casting whereas the scoring was performed by an independent assessor.

Limitations of our study was short duration of follow-up.

## Conclusion

Fast casting is safe and equally efficacious in treating idiopathic clubfeet. It cuts cost and saves time. The pattern of alternate or daily casting are both tolerated well by patients. Parents can expect more than usual number of casts to achieve correction. However fast

casting is tolerated well and brace compliance is similar. Study with larger sample size and longer follow up will further strengthen the outcomes of our study.

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