Clinical Trials of Newly Designed AORI Foot Abduction Brace and its Comparison with Dennis Brown Splint

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Abstract

Background:
Clubfoot is the most common congenital deformity in babies. More than 100,000 babies are born worldwide each year with congenital clubfoot. The main goal of treatment is to achieve a functional, pain-free, plantigrade foot with good mobility and without surgery. The Ponseti is a common practiced manipulative technique that which is followed by orthotic intervention. This has been shown to be a safe and effective treatment for congenital idiopathic clubfoot, and radically decreases the need for extensive corrective surgery.

Methods:
A non-randomized study recruited 110 patients who were divided into an intervention and a usual care control group by convenience sampling method performed in Rawalpindi division at Benazir Bhutto Hospital Rawalpindi over 4 years. The intervention group consisted of 30 patients using AORI Foot Abduction Brace and the control group consisted of 80 patients using Dennis Brown (DB) Splint. Outcome measures included; deformity relapse, skin damage and residual adduction. Differences between groups were explored using Chi-Square tests with 95% confidence intervals.

Results:
Chi square test was applied. Result showed that deformity was relapsed in 15% of patients in control group but there was no relapse in study group (P Value <.05). Skin damage occurred in almost 50% of patients in control group but it was about 20% in study group with P-value = <.05. Residual adduction reported in >50% of patients of patients in control group and it was 0% in study group with P-value = <.001 which is highly significant.

Conclusion:
AORI foot abduction brace is light weight, provides dynamic effects for Dorsi-flexion while D.B splint is relatively heavy and was poor to maintain Dorsi-flexion which ultimately leads to the relapse of the abduction and then equinus. In addition the fabrication cost of AORI Foot Abduction Brace was 50% of DB Splint. Our clinical trials of the AORI FAB showed very good results in maintenance of corrected clubfoot with good compliance.

Keywords: Foot Abduction Brace, Dennis Brown, Clubfoot, Deformity
Background:

Birth defects, medically known as congenital anomalies are one the major causes of physical disability in children (1) and clubfoot, medically known as congenital talipes equinovarus (CTEV) is among the most common congenital deformities that affects the mobility of a child. This does not only affect the structure of foot but also affects the activities of daily living (ADLs) with reduced mobility and inability to participate in different social, academic and sport activities.(2) Males are more frequently affected by idiopathic clubfoot than females and about half of these cases are bilateral. (3)

Differences in the incidence of clubfoot deformity have been reported across different geographical regions; for example in Africa the incidence was 0.96-1.26 per 1000, compared to 1.69-1.80 in America, 0.96-1.42 in India, 1.54-2.35 in Turkey, 0.98-1.40 in the eastern Mediterranean region, 0.50-0.53 in China and 0.64-1.24 in the West Pacific (other than China).(2) An estimate shows that 80% of the children born each year with clubfoot belong to low and low middle-income countries.(4) However in Pakistan, where this current study was based, no specific & reliable data on the incidence of clubfoot was found.

Clubfoot is a combination of deformities that includes cavus foot, foot adduction, heel varus and equines at ankle joint.(5) If untreated or not treated correctly, the sole of the foot will be unable to weight bear correctly which makes it impossible to wear normal footwear and leads to the development of thick callous and large bursa on bony prominences mainly on the talus head.(6) In addition, patients may develop osteomyelitis followed by a deep fissure on callous and therefore leading to amputation in the worst cases.

There are many different treatment methods available for the correction of clubfoot deformity ranging from conservative manipulations to corrective surgeries. (7) In past few decades the Ponseti technique is becoming widely used and has been shown to produce positive results in the treatment of clubfoot. The Ponseti method is non-invasive and cost effective method that involves serial casting followed by gentle manipulation of foot bones. Some patients also require Achilles tendon release after the correction of cavus and adduction deformities to allow foot dorsiflexion. (8) The Pirani score is frequently used to determine the severity of deformity and also to observe the progress of treatment where “6 “for most sever and “0” for normal foot.(9) After successful correction of deformity by serial casting and tendon release (if needed) the child is required to wear a foot abduction brace (FAB) to maintain the correction.(10)

The use of bracing is important to maintain the foot posture during the growth of the child to achieved correct muscle lengths and bone positions. (11) The FAB consists of bilateral shoes connected by a bar with an external rotation of 60-70 degree on affected side and 30-40 degrees of sound side. The length of bar is set to be 1 inch (2.5 cm) more than the shoulder width of child for perineal hygiene. The brace should also provide 10-15 degrees of dorsiflexion on both sides which can be worn with comfortable shoes (preferably with laces or straps).(12)

Recommended bracing schedule by Ponseti (13) is 23 hours a day for first 3 months and after 3 months, 12 hours during night time and for 2-3 hours during the day for up to 3 years of age.
The bracing is sometimes stopped earlier by some physicians depending on progress and self-adjustments of the amount of external rotation angle and wearing schedule are strongly discouraged as this has been shown to lead to relapse or recurrence of the deformity and makes further conservative management difficult. (14) The bracing period is considered as important especially first 3 months after the final cast removal, therefore proper counselling of parents/family is highly encouraged to ensure parent/family compliance which has been highlighted as most common reason of relapse or recurrence of the clubfoot deformity. (13)(15) This was further highlighted by Abdelgawad et al (10) who showed that the main reason of recurrence after correction was non-compliance with bracing program and two third of non-compliant with brace had recurrence of deformity. A further five year follow up study concluded that poor compliance with the DB Splint was thought to be the main cause of recurrence. (11) A comparative study done in 2006-2007 came up with few more reasons of recurrence of deformity and those includes 1) very rigid feet; 2) delay in availability of DB splint after final cast removal; 3) ill-fitting shoes; 4) inappropriate correction; 5) poor family compliance with bracing protocol.(16)

This study aimed to compare the clinical outcomes including deformity relapse, skin damage and residual adduction in an intervention group using AORI Foot Abduction Brace with a control group of patients using Dennis Brown (DB) Splint.

We have generated 3 hypothesis one for each variable which are 1) AORI FAB is better than DB Splint to stop the relapse of clubfoot deformity; 2) AORI FAB has less skin damaging properties then DB Splint and 3) AORI FAB has good control the forefoot adduction. Null hypothesis were generated to justify the claim of research against the above mentioned variables. Differences between groups were explored using Chi-Square tests with 95% confidence intervals.
Methods:

This was a non-randomized interventional study with convenience sampling. The study was an interventional study without any strict protocol with a total sample size of 110 children with corrected clubfoot. Participants had both unilateral and bilateral deformities treated using the Ponseti method of serial casting followed by percutaneous Achilles tendon release. The children were divided two groups called “study” and “control group”. Study group included 30 patients using the APPNA Orthopaedic Rehabilitation Foot Abduction Brace “AORI FAB” and the control group included 80 patients using DB Splint. Patients were seen before the final cast for the measurement of foot size and shoulder width which was used to adjust the bar length in both abduction braces.

The families were informed about the new brace and those who agreed were included in the study after informed parental consent had been taken. On applying brace (AORI or DB splint) for the first time (after 3 weeks of final cast) parents were asked to revisit after 15 days and again after one month which confirmed with the Ponseti guideline for the bracing program. After 2nd visit patients were asked to visit after every 3 month for re-evaluation for 3 years duration. Families were advised to use given brace (AORI or DB) for 23 hours a day for first 3 months and after that 12 hours at night and 2-4 hours during day time for three years. The Pirani score was taken to record relapse of deformity on each visit, table 1.

<table>
<thead>
<tr>
<th>Point</th>
<th>Min</th>
<th>Max</th>
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<tbody>
<tr>
<td>Lateral curve</td>
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<td>0.5</td>
</tr>
<tr>
<td>Medial crease</td>
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<td>0.5</td>
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<tr>
<td>Talus head</td>
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<tr>
<td>Posterior crease</td>
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<tr>
<td>Equinus</td>
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<tr>
<td>Palpable calcaneus</td>
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<td>0.5</td>
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</tbody>
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Table 1: The Pirani score

Patients were reminded by SMS or phone call for their upcoming appointment for follow up. All the information were recorded on designed Performa on each visit and parents were advised to visit on next due date to avoid any complication in their child treatment. Study was performed in Rawalpindi division at Benazir Bhutto Hospital Rawalpindi. In total the study ran for 4 years from 1st April 2011 to 30 March 2015. Those who missed three continuous visits were excluded from the study.

The study variables included; skin damage, forefoot abduction, rate of relapse and cost of fabrication. The first two variables were qualitative variables and the other were quantitative variables. Children who had any other deformities e.g. CP or those who took any other treatment previously for clubfoot correction were excluded. Inclusion criteria included less than 3 years of age, corrected by Ponseti technique and were willing to participate in the study.

Both AORI FAB and DB Splint braces were designed according to the guideline of Dr. Ponseti and his team. The bar was 1 inch longer then the shoulder width and the affected side foot was
given 70 degrees of external rotation while on sound side we gave 40 degrees of external rotation. The foot was kept in 10-15 degrees of dorsiflexion. The foot part was custom made for each children and also fixed with the bar to stop the parents to change angle of rotation. We preferred a leaf spring type of low profile Polypropylene AFO with 10-15 degrees of dorsiflexion incorporated with polypropylene abduction bar. Other padding materials e.g. plastazote and simple padding foam were used to pad the AFO and Velcro straps were used for fitting purpose. Differences between groups were explored using Chi-Square tests with 95% confidence intervals.

Results

2x2 contingency table was used to calculate the Chi Square test with degree of freedom “1”. Results showed that study group (AORI FAB) was having 61% male and 39% female participants and control group (DB Splint) was having 58% male and 35% were female participants. In study group (AORI FAB) 49% participants were having bilateral flatfeet and 23% with right foot and 28% were having left foot involved while in control group (DB Splint) 53% participants were having bilateral flatfeet and 21% with right foot and 26% were having left foot involved.

The result showed that deformity was relapsed in 12 patients (15%) out of 80 in control group (DB Splint) but the deformity was not relapsed in study group (AORI FAB) and P-Value was <.05 which indicates that the results are significant, therefore we can reject the null hypothesis (AORI FAB is not good to stop the relapse of deformity). For the variable skin damage, result showed that skin damage occurred in almost 40 patients (50%) in control group (DB Splint) but it was reported in 6 patients (20%) in study group (AORI FAB) and the findings were significant with P-value = <.05 therefore we rejected the null hypothesis (AORI FAB has less skin damaging properties then DB Splint).

Residual adduction was reported in 41 patients (>50%) of patients in control group (DB Splint) and it was about 0% in study group (AORI FAB) with P-value = <.001 which was highly significant so null hypothesis was rejected (AORI FAB has good control the forefoot adduction). The cost analysis of AORI FAB and DB Splint showed that average cost of AORI was 1000 PKR and average cost was DB Splint was 2000 PKR.

Discussion

The Ponseti method for clubfoot treatment is a safe, effective and economical method which can help to reduce the number of surgeries.(17) Although the Ponseti method is now becoming a gold standard correction method for clubfoot non-compliance during the bracing phase has been identified as a major factor causing failure of the Ponseti Clubfoot technique. (18) To date only one research study was found that clearly describe the issues related to non-compliance to foot abduction brace in 2012.(15) No other relevant literature that explains the issues related
to non-compliance with braces was found despite non-compliance being identified in several studies (8, 19, 20). Therefore this study explored potential clinical factors related to non-compliance and compared the BD splint with a new brace design. Statistically significant and clinically important differences between the use of the DB Splint and AORI FAB brace were found in rate of recurrence of relapses in deformity, skin damage and residual.

Previous work on the rate of recurrence of club foot deformity in patients using Dennis Brown splint has showed that the skin damage was among the one of main causes of non-compliance which was confirmed by this study with almost in 50% of patients using the DB splint in comparison to 20% of patients using the AORI FAB. This may help to reduce the number of non-compliant families previously reported using the DB Splint. (15) The selection of appropriate material for padding in AORI FAB is also very important especially at heel level because which may account for the differences in skin damage reported in AORI FAB compared to the DB Splint this may be particularly important at the heel and medial part of forefoot.

Skin damage was mainly in the form of blisters which were observed in both interventions but in some cases where the baby was healthy superficial skin damage was also observed at follow-up appointments. Proper sizing of foot part must also be considered as an important factor as braces which were found to be too loose or tight on foot are likely to be responsible for skin damage and blisters. Skin damage may also be reduced by using leather (in case of DB Splint) or AORI FAB which are considered as being more skin friendly material which could in turn improve compliance of parents who have concerns with DB Splint. (8, 15, 20). This study showed that in the study group who used the AORI FAB, no relapse of deformity was reported as there wasn’t any possibility to reduce the angle of external rotation. The same fixed external rotation is available in Steenbeek foot abduction brace (recommended by Ponseti) but in DP Splint parents were reducing the external rotation angle (>50% families) that may also lead to the recurrence of adductus and later the equinus deformity. (14, 15, 19, 20)

In the early few weeks parents showed concerns about the external rotation angle as in the initial few days they reported that child was crying and was not tolerating the brace. When this occurred some counselling of parents was carried out. This response has been previously reported in the literature also suggest that this was a factor in the lack of adherence to the bracing program and was one of the major cause of recurrence (17, 21, 22) therefore parents of all participants both in study and control group were informed by the researcher that if they were not able to follow the guidelines and recommendations then their baby may get the relapse of the deformity and for the purpose they should have to maintain strict follow-up.

The users of DB Splint were also concerned about the cost and the weight of brace because due to metal bar and leather shoes which is very heavy for babies and they were unable to lift their feet or extended one leg while the other was flexed because to the stiffness of abduction bar, while in the new brace a light weight 5mm thick bended polypropylene abduction bar was used with a low profile leaf spring AFO which was almost half of the DB Splint. Parents did not report the same movement challenges to the babies and reported that they were able to lift their feet and were able to extend their leg on one side due to the flexibility of abduction bar.

The cost was also an issue of concern (20) because most of the patients were from low income areas therefore not able to bear the cost of DB Splint which was 2000/-PKR (app 20 USD) but AORI FAB was only 1000/PKR (app 10 USD) as the Steenbeek foot abduction brace was also
costing 10 USD per unit (23) and easy for people to purchase because they have to purchase 2-3 braces at least and that’s totally depend on the growth rate of the baby. Since the Steen beek also composed of metal bar and leather shoes part and only metal part is recyclable but AORI FAB composed of almost 90% recyclable material.

Conclusion

This study concluded that there was no recurrence of clubfoot observed in study group using AORI FAB and showed good family compliance with AORI FAB and reported minimal issues in skin damage and repeated residual abduction of forefoot which was in contrast to the DB splint. Therefore we can recommend AORI FAB should be considered as a better alternative of DB Splint for the maintenance of corrected clubfeet.

Limitation

- Low sample size
- No funding was available
- Randomized sampling was not possible
- Low cooperation rate by the parents in follow-ups

Recommendation

- This study should be done with big sample size to find out more about the brace.
- Studies to differentiate the issues of non-compliance should be done
References

