

Repair of Chronic Tendoachilles Rupture – Bosworth Technique versus Peroneus Brevis Transfer Technique - A Retrospective and Prospective Study

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What to Learn from this Article?

Surgical repair of the chronic Tendo-Achilles rupture provides significantly better outcomes both clinically and functionally although there is not much data to prove the superiority of one technique of repair from the other technique. Hence, surgeon should choose the technique of repair based on his expertise and experience.

Abstract

Introduction: Chronic rupture of Achilles tendon causes marked functional impairment. The recommended treatment for this is surgery and various techniques have been reported in the literature.

Materials and Methods: From 2008 to 2016, 30 patients (20 men and 10 women) operated with Bosworth Technique (23 patients) or peroneus brevis (PB) tendon transfer (7 patients) were included for the study. At 12-month follow-up, all patients were assessed with regard to post-operative complications, the American Orthopaedic Foot and Ankle Society (AOFAS) Ankle-Hindfoot score, and ankle range of motion.

Result: AOFAS scores increased from an average 61.57/100 (range, 58-80) pre-operatively to 95.91 (range, 90-98) post-operatively for Bosworth technique. AOFAS scores increased from an average 61.14/100 (range, 58-64) pre-operatively to 96.71 (range, 94-98) post-operatively for PB tendon transfer technique. All patients were able to perform their daily activity unrestrictedly at last follow-up. Two patient experienced wound dehiscence and 1 patient had hypertrophic scar in Bosworth technique while 1 patient experienced wound dehiscence in PB Tendon transfer technique.

Conclusion: Both the techniques have near similar functional outcome and complication rate. However, Bosworth technique has limitations in the form of requirement of the distal stump and imparting of bulky consistency to the tendoachilles which are not present with PB tendon transfer technique. Either of the technique can be used as per the surgeon's preference and expertise as well as patients profile and choice.

Keywords: Bosworth technique, chronic Achilles tendon rupture, peroneus brevis tendon transfer.

Introduction

The Achilles tendon is the strongest, largest, and thickest tendon in the body [1], yet it is the most frequently ruptured tendon [2], with most ruptures occurring at the watershed area approximately 2-6 cm proximal to insertion of the tendon [1].

Achilles tendon ruptures and incidences, in general, have increased substantially during the past few decades and are most commonly seen in middle-aged males, 30-50 years old, who participate intermittently in recreational athletic with 75% of all ruptures occurring during sporting activities [1, 2]. Ruptures



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additionally can occur in the older patient, usually in those with underlying tendinosis, and may be asymptomatic or subclinical. They usually do not feel the classical sensation of being kicked or hit in the calf nor hear an audible snap, and ruptures tend to occur during low-energy activities. As such, these ruptures may be more difficult to recognize and may be more frequently missed on initial evaluation.

Although there is debate of what may be considered a chronic injury, 4-10 weeks have been used by various authors [1, 2] since 4 weeks is the earliest time point that has demonstrated histological evidence of chronic healing [3].

Patients initially present with swelling, complaints of weakness, difficulty in climbing up and down stairs, loss of balance, and a tendency to fall forward. Loss of Achilles function leads to loss of plantar flexion strength, weakness, fatigue, limp, inability to run, heel rise, and play sports [1, 2]. There is wasting in the calf muscle and often a palpable gap between the ends of the Achilles tendon. In chronic tendoachilles rupture, there is 20% less endurance of the muscle, and the treatment becomes more difficult [2]. If the tendon is not repaired or immobilized, retraction of the muscle fibers leads to decreased muscle tension until it becomes zero at about 60% of the fibers' resting length [4].

The delay in treatment results from decreased pain after the initial injury, as well as misdiagnosis by the first evaluator, in up to 20-36% of patients [4]. These delays in treatment, whether operative or non-operative, can have detrimental effects on the final outcomes.

In the management for chronic tendoachilles rupture, conservative treatment has now been entirely abandoned because of better results and less functional morbidity by operative methods. Moreover, clinical evaluations of non-operative treatment have demonstrated a rerupture rate of 10-30%. Other drawbacks of non-operative treatment include decreased plantar flexion and decreased endurance when compared to surgically repaired tendons.

Moreover, several current studies favor operative repair through open or percutaneous techniques in younger, active patients who wish to return to pre-injury activities. Definitive advantage of surgical repair includes lower rerupture rate in surgically repaired Achilles tendon, however, the complications of operative repair include infection and poor wound healing at the surgical site which is more deliberated.

The primary goal of any surgical treatment is to restore the function and strength of the gastrocnemius-soleus complex by recreating the optimal length-tension relationship by many surgical techniques described for the management of neglected Achilles ruptures which include end-to-end repair of the tendon as in V-Y plasty; gastrocnemius soleus complex "turn-down" of proximal Achilles tendon tissue described by Bosworth [5] and others like Coughlin; local tendon transfer techniques like that of peroneus brevis (PB) [6] or flexor hallucis longus (FHL) tendon or by use of synthetic grafts including carbon fiber composites, polyglycol threads, and polyester mesh. Any of these techniques each with

their own pros and cons can be used by the surgeon depending in the patients demand and surgeon's expertise.

Aims and objectives

The purpose of this article is to evaluate and compare the clinical and functional outcomes of 30 patients presenting with chronic tendoachilles rupture who were treated either by Bosworth Technique or PB tendon transfer technique and to determine the advantage disadvantage of each technique over the other. The patients functional outcome were assessed in post-operative period by active plantar flexion at the ankle and by ankle-hindfoot scale developed by the American Orthopaedic Foot and Ankle Society (AOFAS score) [7] and were compared statistically from the active plantar flexion at the ankle and AOFAS score taken pre-operatively. Boyden clinical score was taken only in post-operative period after patient resume their normal unrestricted activity.

Materials and Methods

Patients

This study was conducted at the Department of Orthopedics in L.L.R.M. Medical College and Associated Hospital, Meerut, during the period of 2015-2016. A series of 30 patients (20 men and 10 women) were included for the study. All patients were admitted through OPD and operated with either Bosworth Technique or PB tendon transfer from 2008 to 2015 were included and reviewed retrospectively, and case operated from 2015 to 2016 were included and followed up prospectively. Patient with associated severe comorbidities such as uncontrolled diabetes, poor skin condition, and compound tendoachilles rupture were excluded from the study. Magnetic resonance imaging of the affected leg was done on each patient to assess the severity of rupture, partial rupture, or complete tear.

Surgical procedure

Bosworth technique [5]

Anesthesia was given in the form of spinal anesthesia/general anesthesia. The patient was placed prone on the operating table with body supported on bolster one each at just below the level of shoulder supporting the body at the anterior wall of the chest and other bolster at the level of level of pubic symphysis. Pneumatic tourniquet was applied to the lower extremity at the thigh. The whole extremity was then painted and draped under aseptic precautions.



A posterior longitudinal midline incision, extending from the calcaneus to the proximal one-third of the calf was given and the ruptured tendon was exposed. The scar tissue formed between the ends of the ruptured tendon was then excised with sharp dissection.



From the median raphe of the gastrocnemius muscle, a strip of tendon approximately 1.5 cm wide and 17.5-22.5 cm long was freed and left attached just proximal to the site of rupture. Strip was then turned distally and passed transversely through the proximal tendon and anchored there with absorbable suture.



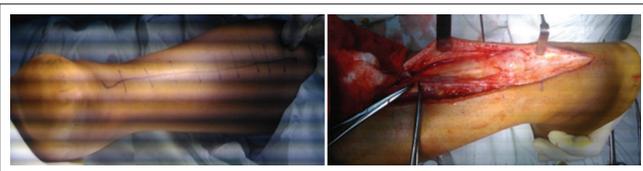
The strip was then passed distally and then transversely through the distal end of the tendon and passed again through this end from anterior to posterior. While holding the knee at 90° and the ankle in plantar flexion, the fascia strip was drawn tight and anchored with absorbable suture. The strip was then brought proximally and passed transversely through the proximal end of the tendon, and then was carried distally and sutured on itself.



Wound was closed and above knee cast was applied with ankle in maximum equinus.

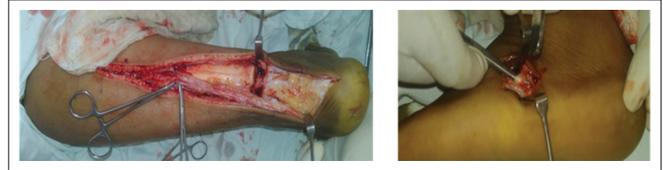
PB tendon transfer technique

Anesthesia was given in the form of spinal anesthesia/general anesthesia. The patient was placed prone on the operating table with body supported on bolster one each at just below the level of shoulder supporting the body at the anterior wall of the chest and other bolster at the level of level of the pubic symphysis. Pneumatic tourniquet was applied to the lower extremity at the thigh. The whole extremity was then painted and draped under aseptic precautions.

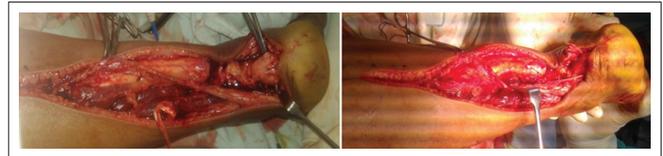


A posterior longitudinal midline incision, extending from the calcaneus to the proximal one-third of the calf was given and the ruptured tendon was exposed. A 2 cm longitudinal incision was then made at the base of 5th metatarsal. Both distal and proximal stump of the ruptured tendon were mobilized by removing peritendinous adhesions and resecting the ruptured tendon back to the healthy tendon. Soft tissue anterior to the soleus and

gastrocnemius were released to allow maximum excrucion and minimizing gap between the tendon stumps.



The PB tendon was then identified and exposed through the incision at the foot and was released from its base after placing a locking suture with absorbable suture. Through the posterior longitudinal midline incision over the Achilles tendon, the deep fascia overlying the peronei muscles was incised identifying the PB tendon and withdrawing through the midline incision.



The PB muscle was then mobilized, and a longitudinal tenotomy parallel to the tendon fibers was done in both the tendon stumps. A plane was developed in the distal stump of Achilles tendon and PB graft was passed through the tenotomy. It will then be sutured to both sides after putting the ankle in full plantar flexion.



PB tendon was then passed beneath into the proximal incision and then from medial to the lateral through transverse tenotomy in proximal stump, and then it was secured with absorbable sutures. The PB was then sutured back on itself on the lateral side of proximal incision. Wound was closed and above knee cast was applied with ankle in maximum equinus.

Post-operative care

Sutures were removed at 2 weeks and above knee cast with ankle at maximum equines continued till 4 weeks. After 4 weeks, cast was changed again and below knee cast with foot gradually brought in plantigrade position was applied for next 2 weeks. At 6-8 weeks, full weight bearing was allowed with the application of removable brace with foot in plantigrade position, and gentle range of motion exercises for 20 min twice a day was begun along with isometric ankle exercises supplemented with knee strengthening exercise. After 3 months, toe raising exercise with progressive resistance exercises and proprioceptive exercises were started. After 6 months, full unrestricted activity was allowed.

Follow-up protocols

The patients were called for 1st follow-up at 15 days for stitch removal.

2nd follow-up was at 1 month after surgery when below knee cast was applied bringing the foot in plantigrade position from equines.

3rd follow-up was at 2 months after surgery when the cast was removed and physiotherapy started.

4th follow-up was at 3 months after surgery at which first AOFAS score and active plantar flexion is measured for the outcome.

Subsequent follow-ups were then at every 3 months interval till 1 year from surgery at which final AOFAS score and active plantar flexion were measured followed by yearly follow-up.

Results

A series of 30 patients (20 males and 10 females) were included for the study out of which 23 patients (16 males and 7 females) were operated by Bosworth technique for tendon repair while 7 patients (4 males and 3 females) were operated by PB tendon transfer technique.

Out of 30 patients included in the study 20 patients (66.67%) were male and 10 patients (33.33%) were female thus giving a male-to-female ratio of 2:1. Age of the patients was between 21 and 48 years with mean age of 41 years with standard deviation of 6.34. Out of 30 patients included in the study, 17 patients (56.67%) had tendoachilles rupture at the right side and 13 patients (43.33%) had rupture at the left side. It was found that minimum follow-up duration of the patients was 12 months while the maximum was up to 84 months with the median value of 24 months and interquartile range of 6. Out of the 30 patients in our sample size, 14 (46.67%) had a history of injection at the tendoachilles and 16 (53.33%) did not have a history of injection at tendoachilles.

In patients operated with Bosworth Technique, pre-operative active plantar flexion of the patients ranged from 10° to 40° with median value of 25° and mean active plantar flexion of 22.61. The improvement in active plantar flexion was seen at post-operative period of 12 months with range of 40-50 with median value of 50 and mean active plantar flexion of 49.13°. On comparison, it is found to highly statistically significant with $p < 0.001$. Pre-operative AOFAS score of the patients was from 58 to 80 with median value of 60 and mean value of 61.57. The improvement in AOFAS score was seen during post-operative period of 12 months which was found to be from 90 to 98 with median value of 97 and mean value of 95.91. On comparison with pre-operative AOFAS score, a significant improvement was seen which was found to be highly statistically significant with $p < 0.001$.

In patients operated with PB tendon transfer technique, pre-operative range of motion of the patients was from 20° to 40° with median value of 30° and mean active plantar flexion of 28.57. The improvement in active plantar flexion was seen during post-operative period of 12 months with range of 40-50 with median value of 50 and mean active plantar flexion of 50°. On comparison, it is found to highly statistically significant with $p < 0.001$. Pre-operative AOFAS score of the patients was from 58 to 64 with median value of 62 and mean value of 61.14. The improvement in AOFAS score was seen during post-operative period of 12 months

which was found to be from 94 to 98 with median value of 97 and mean value of 96.71. On comparison with pre-operative AOFAS score a significant improvement was seen which was found to be highly statistically significant with $p < 0.001$.

AOFAS score of the patients at 12-month post-operative operated by Bosworth technique ranged from 90 to 98 with median value of 97 and mean value of 95.91. AOFAS score of the patients at 12-month post-operative operated by PB tendon transfer technique ranged from 94-98 with median value of 97 and mean value of 96.71. On comparison between AOFAS scores of the patients at 12-month post-operative by Bosworth technique and AOFAS scores of patients at 12-months post-operative by PB tendon transfer technique, it was found to be not statistically significant with p -value more than 0.05.

In post-operative functional status of the 30 patients included in our study, as measured by Boyden score, 29 (96.67%) cases were excellent and 1 (3.33%) cases were good at 12 months after the repair of chronic tendoachilles rupture. In our study, out 30 patients operated for chronic tendoachilles rupture, it was found that in 3 patients (10%) problem in wound healing occurred in the form of wound dehiscence out of which 2 required reverse sural flap for closure. Only 1 patient (3.33%) had the complication of hypertrophic scar over the incision site. No post-operative surgical site infection was found out in any of the 30 cases. None of the 30 cases suffered from rerupture of the tendoachilles.

Discussion

This study was conducted during 2015-16 on 30 patients who presented with chronic tendoachilles rupture and were treated with either Bosworth Technique of tendoachilles repair or by PB tendon transfer technique in the Department of Orthopedic Surgery of L.L.R.M Medical College and associated S.V.B.P Hospital, Meerut, from 2008-2016.

In this study, the age of the patients was between 21 and 48 years with mean age of 41 years. Male patients (66.67%) were affected more than female patients (33.33%) with ratio M:F = 2:1. This can probably be attributed to sports participation which has undergone an increase in recent decades, and therefore there has been subsequent rise in injuries due to sporting activity. The Achilles tendon has been one of the most common sports-related injuries. Schepesis *et al.* [8] observed in 2002 that tendoachilles rupture is observed in men in the fourth to fifth decades of life with male-to-female injury ratios range from 2:1 to 12:1. Running, sprinting, jumping, and agility activities involving explosive plyometric contractions are usual mechanisms.

In this study, all of our patients suffered trauma at their ankle which lead to rupture of tendoachilles which has been consistent with the study conducted by Suchak *et al.* [9] in 2005. In our study, 14 patients (46.67%) had a history of corticosteroid injection at their Achilles Tendon while 16 patients (53.33%) had no history of steroid injection. Studies conducted by Maffulli and Ajis [10] in 1998 and White *et al.* [11] in 2007 implicated two drugs that have been associated with delayed healing and tendon necrosis which were fluoroquinolone antibiotics and corticosteroids.

Fluoroquinolone antibiotics have been observed to weaken the Achilles tendon extracellular matrix, resulting in less tensile tendon strength. Corticosteroids used to decrease tissue inflammation, also cause collagen to weaken and decrease blood supply to an already avascular structure.

The duration of presentation of patient to us with the chronic tendoachilles rupture ranged from 3 to 36 months. In many patients, the initial symptoms after an Achilles tendon rupture diminish quickly. In a study conducted by Christensen [12] in 1953, out of 57 patients with acute Achilles rupture, 19 of them reported to be painless. Patients with Achilles tendon ruptures frequently are unable to stand on the toes of the involved side, however, active plantar flexion may be intact due to partial ruptures, recruitment of plantar flexors, and an intact plantaris muscle. The lack of pain and no obvious loss of plantar flexion can be misleading and up to 20-25% of cases, the diagnosis is missed initially [13, 14]. The failure to establish the diagnosis at the initial presentation is the most common reason for delayed treatment. Hence, the patient is unable to get the required treatment in time and thus showing a wide range of presentation. The follow-up duration of our study ranged from minimum 12 months to maximum of 84 months with average duration of follow-up being 23.6 months which is consistent with the literature.

In our study, out of 30 patients who underwent operative intervention for chronic tendoachilles rupture, 23 of them underwent repair by Bosworth Technique while PB tendon transfer was done on the 7 patients.

For patients who underwent repair by Bosworth Technique, we observed that pre-operative functional score AOFAS score of the patients ranged from 58 to 80 with mean AOFAS score of 61.57. Active plantar flexion of these patients averaged at 22.61° ranging from 10° to 40°. For patients who underwent repair by PB tendon transfer, we observed that pre-operative functional score AOFAS score of the patients ranged from 58 to 64 with mean AOFAS score of 61.14, and they had range of active plantar flexion from 20° to 40° with average flexion of 28.57° in pre-operative period.

The average AOFAS score of the patients who underwent repair by Bosworth Technique significantly increased to 95.91 with a range from minimum 90 to a maximum of 98. Active plantar flexion of these patients averaged at 49.13° ranging from 40° to 50°. The average AOFAS score of patients whose tendoachilles was repaired by PB tendon significantly increased to 96.71 with a range from minimum 94 to a maximum of 98. Active plantar flexion of these patients averaged at 48.57° ranging from 40° to 50°.

Out of 30 patients, 5 (16.67%) patients gave a poor score on Boyden scale in pre-operative period to their condition while rest 25 (83.33%) patients had a fair score in Boyden scale. However, in post-operative period, only 1 (3.33%) patient had a good score on Boyden scale while rest (96.67%) had excellent score on Boyden scale which a significant improvement as compared to previous non-operative state.

No intraoperative complication were encountered in any of our cases. Among the post-operative complications, wound

dehiscence was found in 3 (10%) of our patients and in 1 (3.33%) patient hypertrophic scar over the incision site was found. Scar hypertrophy was later managed by triamcinolone acetate injection locally with compression bandage. Out of the 3 patients with wound dehiscence in post-operative period, 1 was managed conservatively and healing occurred with daily cleaning and dressing of wound with normal saline and placental extract while other 2 patients were managed by reverse sural flap surgery for their wound. There was no post-operative instability in any of our patients. No post-operative infection was reported in our group. There was no incidence of rerupture following the procedure in our group.

Although wound healing is usually a general complication for most procedures, it is particularly concerning for an Achilles tendon repair. This is because the tendon itself has relatively little soft-tissue coverage, and this area of skin has a notoriously poor blood supply. Therefore, any type of wound healing problem can easily end up involving the tendon itself. For most patients, there is approximately a 2-5% chance of a significant wound healing problem. The risk of a wound healing problem increases significantly in smokers and diabetics. In our study, 2 patients showed post-operative wound dehiscence, for which sural flap was done while 1 was healed conservatively with daily dressing by the placental extract.

Wound detachment and rerupture are well-known complications after open surgical treatment of Achilles tendon ruptures. However, open rerupture after surgical treatment of the Achilles tendon occurs much less frequently as compared to conservative treatment. According to a meta-analysis by Bhandari *et al.*, [15] the rerupture rate with surgical treatment (3.1%) was significantly lower than with non-surgical treatment (13%). However, there were wide confidence intervals in his included studies. In a meta-analysis by Khan *et al.*, [16] the rerupture rates were estimated at 3.5% and 12.6% in surgically and non-surgically treated patients, respectively. García Germán *et al.* [17] reported on 2 cases in which they hypothesized that open rerupture may have been related to incomplete closure of the paratenon. Mellor and Patterson [18] reported that the rates of wound break down, infection and rerupture after surgical repair were lower when special care was taken to perform a correct separate repair of the paratenon. Graf *et al.* [19] found that the role of a well-vascularized paratenon was of paramount importance in the surgical treatment of a rupture and correct closure could help vascularization and avoid adhesion to superficial layers. We performed a complete suture of the paratenon in all of our cases and we found no rerupture of the tendon although we believe that more cases are needed to comment with certainty about the rerupture rate.

Animal studies have shown the importance of mechanical loading in tendon healing. Langberg *et al.* [20] in 1999 and Olesen *et al.* [21] in 2007 have stated in their study that tendon strengthening occurs because exercise leads to anabolic responses of tendons such as increase in the formation of type I collagen in peritendinous tissue, as shown by microdialysis measurements. In 2009, Kjaer *et al.* [22] showed in human models that mechanical load leads to an increase in collagen synthesis and tendon size.

The current AAOS guidelines [23] recommend early, protected, post-operative weight-bearing. In our study, all our patients were placed on protected weight bearing as early as within 4 weeks of post-operative period.

On comparing the clinical and functional outcome between the Bosworth technique of tendon repair and PB tendon transfer technique, it was not found to be of statistical significance as each of the technique independently provided the near to normal result at 12 months after the surgery. The AOFAS score of 95.91 for the Bosworth technique is only marginally lower than the AOFAS score of 96.71 by the PB tendon transfer technique of tendon repair.

As far as active plantar flexion at the ankle is concerned in the post-operative patients, Bosworth technique (49.13°) fared well although marginally when compared to PB tendon transfer (48.57°). As we all know that plantar flexors are the muscles that push off the ground during walking. Harvesting the plantar flexors results in weakening the push-off phase of walking and is distressing, particularly in young patients [24]. In cadavers, the failure load was significantly higher in Achilles tendons reconstructed with the PB tendon [25]. After PB tendon augmentation, the strength of eversion may be mildly weakened but that of plantar flexion can be maintained [26].

According to a study conducted by Clarke *et al.* [27] in 1998, the 2 peroneal muscles contribute only 4% of the work capacity for plantar flexion, but for eversion the PB tendon contributes about 28% of the total work strength. Thus, the use of the PB tendon may cause a strength deficit in eversion of the ankle but a negligible deficit in plantar flexion. Nonetheless, the peroneus longus, which is the major evorter of the hind foot, may take over some of the functions of the PB [28]. Thus, subjective weakness in ankle function after PB tendon augmentation is minimal [29]. This can be cause of slightly less active plantar flexion although insignificant in patient with PB tendon transfer. Moreover, it can also be hypothesized that Bosworth technique does not disturb other compartment of the leg. This, in theory, can cause decrease in movement at the ankle joint due to more dissection around the ankle as well as more involvement of normal functioning tendon for reparative function, which is not done in case of Bosworth technique. Nonetheless, in our patients, ankle movement exercise was performed during rehabilitation as early as 2-month post-operative period and ankle strengthening exercises were started within 3-month post-operative period to reduce the post-operative stiffness of the joint and to achieve near normal range of motion at the ankle.

Conclusion

Chronic Achilles tendon ruptures are not uncommon and potentially debilitating. Many surgical treatments are available

for the reconstruction of a neglected tendoachilles rupture. The choice of management is partly guided by the type of tendon lesion, with most injuries requiring operative management. Many techniques can be used to repair or reconstruct a tendon with a chronic rupture. Most studies have been retrospective and small and have focused on the results of a single technique. There is no concrete data to support one technique over another; hence, there is no "gold standard". Most agree, however, to achieve the optimal functional outcome surgical reconstruction is required. Regardless of the chosen technique, the ultimate goal of surgical treatment is to restore the length tension relationship such that sufficient plantar flexion power is attained.

Bosworth technique is a simple, safe, and predictable repair with the limitation of requirement of distal stump of at least minimum 2 cm. This technique combines the benefit of operative procedure with reduced rate of rerupture and non-operative procedure by being technically simple, and therefore restoring the tendon length and producing excellent functional improvement as shown by marked improvement in post-operative AOFAS score. Moreover, no separate incision is required apart from exposing the Achilles tendon and it does not disturb the anatomy of the adjacent compartments of the leg gives it the edge over other procedures.

PB tendon transfer technique is one of the fewest tendon transfer technique with no limitations as of Bosworth Technique and is not associated with any residual morbidity in the foot when compared with FHL or FDL tendon transfer. Theoretical partial loss of eversion of the foot is negligible and well compensated by the peroneus longus. Although this technique does involve violation of two compartments of the leg instead of one as in Bosworth technique, final clinical and functional outcome is marginally higher for PB technique and is not statistically significant.

Both the techniques are simple, safe, and none of them have a higher complication rate or residual deformity when compared to each other. However, Bosworth technique has some limitations in the form of requirement of the distal stump for the repair of tendoachilles and imparting of bulky consistency to the tendoachilles post-repair which seldomly gives discomfort to the patient in post-operative rehabilitation period. These limitations are not present with PB tendon transfer technique.

Both the techniques have near similar functional and clinical outcome, and hence either of the technique can be used as per the surgeon's preference and expertise as well as patients profile and choice after due consideration of procedure of the technique and possible complications and risks associated with either of them.

Further study and critical analysis are needed with a larger sample size and a longer follow-up.

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