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Effect of Pre-Prosthetic Training in Balance and Prosthetic Performance in Traumatic Unilateral Trans-Femoral Prosthesis Users in the Age Group of 20-40 Years

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ABSTRACT

Background: Amputation at the trans-femoral level can be very challenging for the amputee as well for the surgeon, the prosthetist, the physical therapist. Learning to walk after a trans-femoral amputation is many times harder than learning to walk after a trans-tibial amputation. The trans-femoral amputee not only has to learn to use a prosthetic knee but also must learn to coordinate the interaction of the foot components with the prosthetic knee, which requires more mental energy. The trans-femoral amputee has more difficulty with balance and decreased proprioception and therefore a greater risk and greater fear of falling. For these reasons, the rehabilitation process is much more difficult for the trans-femoral amputee. The physical therapist must also know how to train the patient to function in all mobility situations, and must also be familiar with issues that are relevant to amputees need.
Objective: The purpose of the study is to assess of effectiveness of pre-prosthetic training methods in balance and functional outcomes in new trans-femoral prosthetic users.
Method: A randomized controlled study with 27 subjects had been recruited on the basis of inclusion criteria and divided into two groups. Group A (N=15, old trans-femoral prosthetic user) using their prosthesis for at least one year regularly for their daily routine as an active community walker and Group B (N=12, first time trans-femoral prosthetic user) and the amputation was a result of trauma with their first trial prosthesis for conventional gait training after the departmental protocol of pre-prosthetic stump conditioning were assessed on the four Performance Oriented Balance and Prosthetic Mobility scales, i.e. TUG, FSST, Cadence and AMP Tool and the pre and post GT and comparison of performance between old and new AK prosthesis users were analysed using paired t test for significance.
Results: The pre and post GT has a statistically significant difference in TUG, FSST, cadence and AMP score at $p<0.000$. When compared between groups; Group A (old) and Group B (new AK) there is a statistically significant difference in the mean performance of TUG and AMP scores at $p<.05$, however no difference was found between FSST and Cadence.

Conclusion: Pre-prosthetic stump conditioning and conventional gait training has an important role in improving the overall balance and functional outcome of the amputee after the prosthetic fitting. Need specific pre-prosthetic training and conventional gait training shall be a part of the comprehensive trans-femoral amputation rehabilitation.

Key Words: Amputation, gait, exercise, artificial limb, prosthesis, lower limb amputation, physical balance.

INTRODUCTION

Ambulation and standing in an upright position is a feature unique to humans. These are the basic activities required for all activities of daily living [1]. Both these postures are unstable positions, which require constant muscular activities and complex neuro-muscular controls. These functions are significantly expected to be compromised after amputation because of loss of distal body mass, making the amputees prone for balance impairment and thus for falls. Here balance is defined as the ability to maintain the centre of gravity over the base of support, where as fall can be defined as inability of a person to meet the intrinsic and extrinsic demands of mobility within a specific environment [2]. The combination of anatomical, physiological and biomechanical alterations is responsible for balance impairment and falls in amputee population, which can have following hazards: falls, fear of falling, fall related mortality and morbidity, gait deviations, increased energy expenditure.

As mentioned earlier, the basic aim of amputee rehabilitation is to achieve the highest level of functional independence, here the balance performance of an amputee seems to be an important predictor of rehabilitation outcome and thus, should be included in the Prosthetic training program for amputees. To monitor programme success it is therefore necessary to evaluate the skills required for mobility using prosthetic devices. Learning to walk after a trans-femoral amputation is many times harder than learning to walk after a trans-tibial amputation. The trans-femoral amputee not only has to learn to use a prosthetic knee but also must learn to coordinate the interaction of the foot components with the prosthetic knee, which requires more mental energy. Skills such as coming to a stand, standing balance, ambulation, and negotiating hills, stairs, and uneven terrain are more difficult. The transfemoral amputee has more difficulty with balance and decreased proprioception and therefore has both a greater risk and greater fear of falling. For these reasons, the rehabilitation process is much more difficult for the transfemoral amputee than for the trans-tibial amputee [3].

The conventional therapeutic approach is to exercise a set of balance training activities during standing in the parallel bars [4]. The trainee is using the upper limbs to assist the development of postural control through balance and step position exercises, which include antero-posterior weight shifting with knees and hips extended, lateral weight shifting, circular pelvic rotations over both legs with shoulders remaining over the stance position, raising both arms above the head, alternate knee flexion and extension. The role of a therapist is to guide the trainee and monitor proper execution of activities. Another important role of the therapist is physically to prevent the patient from falling during exercise. Physical therapy is more prolonged (usually at least twice as long as for the trans-tibial amputee), and a better understanding of prosthetic components is required on the part of the physical therapist. From the above scenario, it is evident that the main challenge for people in the field of rehabilitation of amputee is to equip them with better mobility and safe functional skills. There is a need to look at the amputees holistically, to keep them mobile and help them to lead a more active and fulfilling life [5].

Also the Outcome measures are becoming increasingly important in all health care professions. Functional outcome measures are of particular importance in lower limb amputee rehabilitation, since much of the rehabilitation process is concerned with increasing the mobility and personal independence of the amputees. Clinicians involved in rehabilitation of lower limb amputation increasingly need to use the outcome measures to demonstrate that they are providing a clinically effective service [6]. The purpose of the study is to assess of effectiveness of conventional gait training methods in balance and functional outcomes in new trans-femoral prosthetic users.

Experimental hypothesis

There is a significant difference between conventional gait training methods and balance and functional outcomes in new trans-femoral prosthetic users.

Null hypothesis

There is no significant difference between conventional gait training methods and balance and functional outcomes in new trans-femoral prosthetic users.

Study design and participants

A randomized controlled trial was conducted at Pt. Deendayal Upadhyaya National Institute for Persons with Physical Disabilities (Divyangjan), New Delhi, India. Single blinded random participants fulfilling the inclusion criteria were assigned into groups: Group A (N=15, old trans-femoral prosthetic user) using their prosthesis for at least one year regularly for their daily routine as an active community walker and have come for renewal of their trans-femoral prosthesis or repair of current prosthesis. Group B (N=12, first time trans-femoral prosthetic user) and the amputation was a result of trauma and coming to the department with their first trial prosthesis for conventional gait training, after the departmental protocol of pre-prosthetic stump conditioning program. The Inclusion Criteria were: Post-traumatic unilateral Above-Knee Amputees between 20 and 40 years and the Exclusion Criteria were amputees with a complicated stump, presence of neuroma, extensive skin graft, sensory loss over the stump, presence of other co-morbidities likely to affect balance and stability and unsatisfactory prosthetic alignment/fitting.

Procedure

The study groups (both Group A and B) were assessed on the four Performance Oriented Balance and Prosthetic Mobility scales, i.e. TUG, FSST and Cadence (For Balance) and AMP Tool (for prosthetic performance). The best score out of three trials was taken as the final score.

For the new prosthetic users, pre on and post-gait training effect on the four Performance Oriented Balance and Prosthetic Mobility scales, i.e. TUG, FSST and Cadence (For Balance) and AMP Tool (for prosthetic performance) after conventional gait training protocol of the department, was taken additionally by the best score out of three trials as the final score.

The pre-prosthetic training includes ROM, strengthening, balance and skin care education, and conventional gait training protocol of the department includes weight shifting, shifting onto the Prosthetic Side, Pelvic rotation, Stepping on multiple heights and positions, Tandem walk, within parallel bar and a controlled environment with a full length Mirror on one side. The total duration of gait training was for 2-3 weeks.

Pre-prosthetic training

Trans-femoral amputees seen for the first time before their initial/trial prosthesis, pre-prosthetic treatments would include ROM, strengthening, balance, skin care education and simulated pre-prosthetic gait training. The pre-prosthetic stump conditioning is shown in the pictures below.

Stump De-sensitisation

Hip abductors strengthening

Hip adductors Strengthening

Hip extensors Strengthening

Conventional gait training

Weight Shifting

Training should start with anterior/posterior and lateral weight shifting. First, have the amputee perform these activities using both upper limbs. Then, advance the patient to single upper limb support, and finally to no upper limb support. During the weight-shifting activity, encourage the amputee to note how the pressure on the residual limb changes with movement from one side to the other.

Shifting Onto the Prosthetic Side

Shifting onto the prosthetic side is a combination of the anterior and lateral weight shift. Initially, the amputee stands in the parallel bars with the prosthetic foot approximately one step length in front of the opposite foot and shifts his or her weight first onto the prosthetic side foot and then back onto the sound side foot. Use manual cues to help the amputee achieve proper weight shift onto the prosthesis. A side mirror helps the physical therapist check to be sure that the shift is not too far anterior, and a mirror at the end of the bars helps the amputee see if sufficient lateral weight shift is achieved and ensure a lateral trunk lean does not occur

Pelvic Rotation

For the trans-femoral amputee to acquire an acceptable gait pattern, pelvic (and trunk) rotation should be restored. In able-bodied gait, the pelvis begins in 5 degrees of forward rotation at initial contact. Through stance, the pelvis rotates backwards 10 degrees to reach 5 degrees of backward rotation at pre-swing. Forward rotation is again started at pre-swing, reaching 5 degrees of forward rotation by the end of the gait cycle.

Stepping of multiple heights and positions

Stepping of multiple heights and positions. This encourages the amputee to move in the transverse plane within the prosthesis using the hip musculature. Additionally, performing this drill at different speeds will develop the balance and stability required for ambulation on various terrains.

Tandem walk

Start by placing a straight, taped line on the floor. Instruct the amputee to walk with a heel-to-toe pattern with emphasis on maintaining stability and balance while they are ambulating on the prosthetic side.

Weight shifting

Loading on the prosthetic limb

Stepping on variable heights

Tandem walking

Parameters Studied

Test 1 - TUG Test

Subject sits on a standard arm chair with that against the chair, arm rested over the arm rest and walking aid at hand if required. Subject used their regular prostheses and foot wear. After the subject states that he is ready, the test starts. On the word " GO" the subject stands, walks to a line on the floor, 3m away, turns and walks back to the chair and sits down again. The end of the test is defined as the subject's buttocks first touché the chair seat surface. Subject chooses his own comfortable and safe walking speed. A stop watch is used to time the performance in seconds. A trial test may be given to the subject. The chair should be stable to prevent from falling. Here the old prosthetic users used their regular prostheses, where as the new users used their first trial prostheses and walking aid if required [7].

Test 2 - FSST

The square is formed by using four walking canes, resting flat on the floor. Canes were 90 cm long. The direction and type of handle used is not important. Subject stands in square no 1, facing square no 2. The aim is to step as fast as possible in to each square in following sequence 'square no 2,3,4,1,4,3,2 and 1'. The sequence requires the subject to step forward, backward, sideward (right and left). The score is recorded as time taken to complete the sequence. The stop watch stops when the first foot contacts the floor in square no 2 and finishes when the last foot comes back to touch the floor in square no 1. Following instructions are given to the subjects:

- Try to complete the sequence as fast as possible without touching the sticks.
- Both feet should make contact with the floor in each square.
- Face forward during the entire sequence as far as possible.

The sequence is then shown to the subject. One practice trial is given to ensure that the subject knows the sequence. The test is repeated if the subject fails to complete the sequence successfully, looses balance, or makes contact with the cane during the sequence. Subjects who were unable to face forward during the entire sequence and needed to turn before stepping in to the next square, were still given a score. The examiner stood in a position to see all the steps taken by the subject and to assist the subject if required, in a close supervision [8].

Test 3- AMP Tool:

The test starts with the subject seated in a hard chair with arm rest. The test here is performed only with the prostheses. Avoid unnecessary chatter throughout the test. Safety first, no task should be performed if either the subject or examiner is uncertain of a safe outcome. Subjects were asked to perform each of the 21 items in AMP for the maximum score of 47. The subject has the option to refuse any task at any time. The examiner has the option by professional judgment to exclude any test item that they perceived to be contraindicated or if the examiner felt the task unsafe or impossible to attempt because of subject's physical disability. A score of zero was assigned to any refusal or contraindicated test item. The subject performs the test at a self selected pace to avoid the effect of fatigue [9].

Data analysis

Statistical Methods:

Descriptive statistical analysis has been carried out in the present study. Outcome measurements are measured for TUG, FSST and Cadence (For Balance) and AMP Tool (for prosthetic performance) and presented as mean±SD. Significance is assessed at 5 % level of significance with $p<0.05$ less than this is considered as statistically significant difference.

Statistical tests:

Paired 't' test as a parametric test had been used to analysis the variables pre to post with calculation of percentage of change.

Statistical software:

The Statistical software used is SPSS 20.0

Interpretation of Significance p value:

What do we mean by a 'small' p-value (one small enough to cause us to reject the idea that there was really no difference)? By convention, p-values of less than 0.05 are considered 'small'. That is, if p is less than 0.05 there is a less than one in 20 chance that a difference as big as that seen in the study could have arisen by chance if there was really no true difference. With p-values this small (or smaller) we say that the results from the trial are statistically significant (unlikely to have arisen by chance). Smaller p-values (say $p<0.01$) are sometimes called 'highly significant' because they indicate that the observed difference would happen less than once in a hundred times if there was really no true difference.

Non-significance does not mean 'no effect'. Small studies will often report non-significance even when there are important, real effects which a large study would have detected.

Statistical significance does not necessarily mean that the effect is real: by chance alone about one in 20 significant findings will be spurious.

Statistically significant does not necessarily mean clinically important. It is the size of the effect that determines the importance, not the presence of statistical significance.

RESULTS

Table 1: Descriptive Statistics: Trans-femoral Amputees (Old and New)

SN	Characteristics	Group A (Old)	Group B (New)
1.	N	15	12
2.	Mean Age in Years	34.60±4.86	33.75±7.14
3.	Side of Amputation Right Left	 9 6	 5 7
4.	Type of Prosthesis	AK Conventional	AK conventional
5.	Mean Stump Length (in cm)	17.41±4.79	23.52±6.5
6.	Mean Duration of Prosthetic Use (in Years)	7.47±4.91	Not Applicable
7	Mean Duration of Gait Training (in Days)	Not Applicable	16.33±2.9

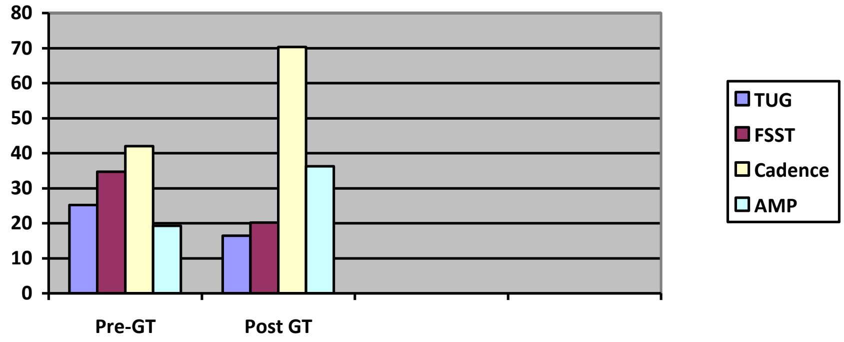
The above table shows that in Group A (Old trans-femoral prosthesis user) there were 15 subjects with mean age 34.60±4.86years with 9 right LE and 6 left LE amputations and mean stump length of 17.41±4.79 cm and the mean duration of prosthetic use 7.47±4.91years, whereas in Group B (New trans-femoral prosthesis user) there were 12 subjects with mean age 33.75±7.14years with 5 right LE and 7 left LE amputations and mean stump length of 23.52±6.5 cm and the mean duration of prosthetic training is 16.33±2.9 days were included in the study.

Table 2: Paired t test: Pre and post conventional gait training in new prosthesis users.

SN	Performance	AK mean score (Pre GT-New)	AK mean score (Post GT-New)	t-test for equality of mean		
				T	df	Sig 2tailed
1.	TUG	25.25±6.45	16.42±2.19	5.659	11	.000**
2.	FSST	34.67±6.661	20.17±4.44	8.081	11	.000**
3.	Cadence	42±7.67	70.33±9.16	-9.242	11	.000**
4.	AMP	19.25±4.33	36.25±2.83	-26.57	11	.000**

*** Statistically Significant difference p<0.05; Paired t test*

The above table shows that in pre and post GT there is a statistically significant change in means of TUG, FSST, cadence and AMP score when means were analyzed from pre intervention to post intervention between the groups with p<0.000.



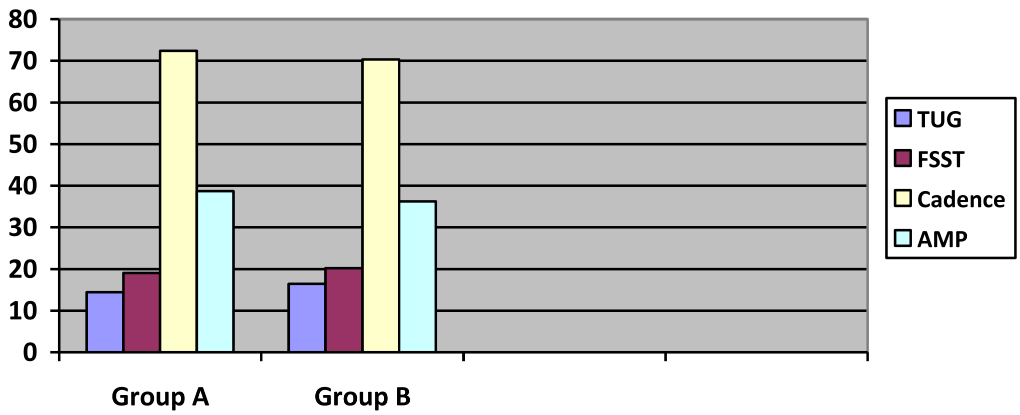
Graph 1: Comparison of Pre and Post GT mean.

Table 3: Comparison between Group A (Old AK)and Group B (New AK).

SN	Performance	Group A (Old AK)	Group B New AK (Post GT)	t-test for equality of mean		
				T	df	Sig 2tailed
1.	TUG	14.40±2.1	16.42±2.1	-2.37	25	.026**
2.	FSST	19.07±3.8	20.17±4.4	-.691	25	.496
3.	Cadence	72.40±1.4	70.33±9.1	.621	25	.540
4.	AMP	38.73±1.4	36.25±2.8	2.766	25	.014**

***Significant Difference*

The above table shows that, there is a statistically significant difference in the mean performance of TUG and AMP scores between Group A (old) and Group B (new AK) trans-femoral prosthesis users at p<.05, where the Old trans-femoral prosthesis users performed better than the New trans-femoral prosthesis users. But there was no statistically significant difference in Cadence and FSST scores of old and new trans-femoral prosthesis users at p>.05.



Graph 2: Comparison between Group A (Old prosthesis user) and Group B (New prosthesis user)

DISCUSSION

Massion J described three stereotypical motor responses that are used to ensure that COM stays within BOS for maintaining Balance. It includes the following: Ankle strategy, Hip strategy and the stepping strategy. These strategies are also evident during the functional activities like walking. Loss of distal body part, sensory inputs, along with loss of strategy makes the prosthetic limb user amputee patient prone for falls in the challenging situations of daily routine in the community and he has to respond to environmental, demands during ambulation and other tasks in anticipatory (feed forward) and reactive (feedback) modes [2, 10].

There are several important connections between Aging and prosthetic uses. Aging can have a dramatic effect on skeletal and Cardio-vascular system, the two body systems, that are most vital for the prosthetic users. Any one over the age of 30 years needs to recognize that Aging will have an effect on his mobility. Also the psychological aspect of individual plays an important role in Rehabilitation outcome. Physiological functions and performance measures generally improve rapidly during childhood and reaches to their maximum between the late teens and 30years of age. Functional capacity then declines with age, deterioration often varies widely at a particular age, but not all declines are at the same rate, furthermore typical aging effects are greatly influenced by regular exercise [11]. According to Woolacott, from about 30 years of age, a functional decline in performance can be detected in most of the organs and body system, especially when faced with challenges [2].

Effect of the prosthetic Alignment on standing Balance is also an important issue. Alignment of prosthesis is established by relative geometric position and orientation of the various prosthetic components such as socket, shank, foot piece etc. Optimal alignment is a crucial factor for the successful rehabilitation of amputees and no less important is the quality of fit of socket, suspension, and cosmoses. According to Persson BM., a standing BK amputee adapts to the prosthetic alignment through accommodation by the contra lateral limb. It has been concluded that a well trained BK amputee is able to adapt to the drastic changes in alignment while preserving a well balanced position [12].

Early in the Gait Training an amputee may make an exaggerated effort to dig the heel in the floor at initial contact and early loading response to use the resultant pressure at the stump, as an indicator of contact with the floor. The Amputee may learn to interpret this sensory experience as secure position for loading response and progressing in to mid-stance. The duration of Gait training for an amputee with the prosthesis varies from amputee to amputee & it depends upon several factors, such as Age of amputee, cause of amputation, presence of other co-morbidities etc. (6 weeks to 6 months). Study of static and dynamic prosthetic weight bearing in elderly trans-tibial amputees by M E Jones, concluded that static weight bearing while clinical gait training should be, utilized as a guide to an amputee's prosthetic weight bearing tolerance, required during walking. There is extensive literature available, which says that, static weight bearing is important for gait training. Still it has been observed that even after the regular gait training of amputees, these patients continued to have poor balance than normal individuals [13].

Symmetry between the limbs during gait promotes a smooth and efficient gait pattern. As noted earlier, individuals with lower-limb amputation demonstrate decreased symmetry between the prosthetic and sound limbs. Both groups in this study also demonstrated decreased symmetry in step length and single limb support time. Variability in performance is expected in early learning (Shum way Cook, 2001) [2]. When mastery of a task is achieved, variances between trials decrease. Subjects in this study continued to demonstrate large variability between trials, signifying that 2-3 weeks of prosthetic training is not enough time for one to master a new motor task of prosthetic gait. Symmetry is also influenced by velocity (Donker & Beck, 2002; Nolanet al., 2003; Zucker-Levin, 2003) [14]. Greater inter-limb symmetry is noted at higher externally paced velocities (Nolan et al., 2003; Zucker-Levin, 2003) [14]. Participants in this study all ended with low walking velocities (self-selected), limiting the ability to achieve inter-limb symmetry. The lower velocities maybe attributed to the use of an assistive device or overall decreased functional ability at the end of training with a prosthesis. Asymmetry in gait following an amputation is also hypothesized to be caused by: loss of muscle groups and sensation; pain, fear or habit; decreased weight bearing through the prosthesis; and the rigid ankle foot complex of the prosthesis (Donker & Beck, 2002; M. E. Jones et al., 2001) [14]. In the present study all of these factors except pain may have limited the subjects' ability to improve symmetry since all subjects had a pain rating between 0 - 1 out of 10 when walking with the prosthesis. In relation to fear, all subjects self-assessed abilities at a higher level corresponding with increased self-confidence. An actual fear of falling measure was not taken; however, it is reasonable to conclude that individuals with increased self-confidence may be less fearful. In terms of habit, all subjects trained with their prostheses for the first time. It should be noted that participants' gait patterns prior to the amputation were not assessed. If an individual had pain or weakness in the affected lower extremity, an asymmetrical gait pattern may have been developed prior to prosthetic training. Low velocities and the factors noted above may have limited the participants' ability to improve symmetry, and the large variances and low power due to the small sample size further limit the ability to find statistical changes in symmetry.

Studies utilising the functional outcome scale: the Amputee Mobility Predictor (AMP); a balance test, the Berg Balance Scale (BBS); and gait velocity indicated that the three measures were correlated. The correlation between the AMP and BBS is not surprising, since these tests have nine items in common. Velocity is often considered an overall measure of function. It demonstrated by the moderate correlation between the functional measure and balance scale, even though neither directly measures velocity. Therapists must choose their tests carefully in order to best represent what they are seeking. If they want to determine risk of falls, the BBS would be the most appropriate choice. If they are looking more for functional mobility as needed for re-integration into the community, velocity may be the best overall measure. With the moderate to strong correlation noted among the three measures, therapists would not need to measure all three. They could individualize their examinations by selecting the most appropriate measure for each patient [1,9].

CONCLUSION

From the observations and data analysis of the study results, it can be concluded that Pre-prosthetic stump conditioning and conventional gait training has an important role in improving the overall functional outcome of the amputee after the prosthetic fitting. Length of the residual stump has an important role in achieving higher rehabilitation outcome in trans-femoral prosthetic users. A new prosthetic user may be benefited with the Balance specific training program along with conventional gait training. Further study is required on effect of balance specific training in new prosthetic user for higher functional outcomes. Need of walking aid in early period of prosthetic use in new as well as old AK prosthetic user (20% of old and 58% of new AK prosthesis user were using walking aids) and poor performance of the AK prosthetic user on balance as well as prosthetic performance indicates that AK amputees were more prone to falls. Here the importance of preservation of anatomical knee joint may be emphasized wherever possible, in achieving higher functional outcome is self explanatory.

Limitations of the study

1. The study was conducted on small samples.
2. It's difficult to determine the long-term effect on outcome measures as intervention was done only for 2-3 weeks.
3. Balance and prosthetic performance were measured but affect on muscle strength, co-ordination, previous activity level were not measured.
4. Study lacks analysis of the effects of complications/unknown co-morbidities on outcomes and the wide age range.
5. Measurements were taken directly after the conventional gait training, with no follow-up. Without such follow-up, retention of learning cannot be assessed.

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