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"Effect of Virtual Reality Therapy as a therapeutic adjunct in rehabilitation program among traumatic lower-limb amputees": A Parallel Open-label RCT

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1 INTRODUCTION

Amputation of the lower limb is a surgical procedure that is permanent and can be due to trauma or dysvascular causes. Loss of balance, reduced quality of life and phantom limb pain are the fundamental problems that an amputee of lower limb extremity deals with. (1)

From 2007-2013, there were 310 lower limb amputation in JPN Apex Trauma Centre. Surprisingly, the numbers rose to 92 in 2017. In the year 2017&2018, the total no. of amputation cases increased to 412. Among them, there were 272 cases of lower limb amputations. (2)

Loss of balance is due to the altered centre of gravity upon loss of a limb. (3) Limitations posed by body function and structure, thereby hindering participation in daily work activities affect the quality of life. Environmental and personal factors further influence these factors. (4)

The standard rehabilitation is training through conventional exercises, which include weight-shifting exercises, dynamic balance exercises, stool stepping, braiding and gait exercises (5). These exercise programs are used to prevent vascular disease in people with amputation and their adaptation to amputation. Whatever the time of initiation of exercise is, it contributes to the physical as well as psychosocial wellbeing in general. It improves walking balance, circulation problems, control of prosthesis and energy consumption. (6)

Regaining functional mobility, developing independence, and improving the quality of life is of utmost importance. For this, physiotherapy, the use of a prosthesis, and rehabilitation become necessary. (7)

The fundamental requirement of gait is postural stability (PS). PS is achieved by gaining control over the centre of gravity, which is achieved by weight-bearing exercises while wearing the prosthesis which focuses on hip abductor strengthening. (2)

Although many advances have been made in the designing of the prostheses, the conventional therapy remains to be the primary training regime of the rehabilitation after lower limb amputation. Although effective, they lack variability in movements and obliqueness to perform at home, thus calling for the need for a rehabilitation centre right from the beginning to the very end. Moreover, these exercises are monotonous and tiresome. So, we decided to use virtual reality in training the amputees. Also, it is difficult for amputees to visit the rehabilitation centre for the complete treatment regime due to the limitations of institutional and financial constraints.

The potential advantages of VR in rehabilitation have been among the top stories for some time now. They serve as a means to provide stimulation and enjoyment to the patient in the process of rehabilitation. (8, 9, 10)

Virtual reality is an interactive system in which the user is provided with a virtual world, and the user gets an illusion of entering into it. Gaming systems that are commercially available like Xbox Kinetic have the capability of providing virtual reality to the user. The gameplay offers various circumstances during which the activity of the player during is quite similar to the conventional exercises of standard rehabilitation regime, thus strengthening the hip abductors to control the centre of gravity, a key component of achieving postural stability and balance. These activities provide an entertaining and distracting environment to the user, thus changing the focus of the patient. These gaming sessions result in an enjoyable experience for the user, and the patient forgets about his/her injury. (11)

Biodex Balance System is a balance measuring system that is reliable and frequently tested to assess the standing balance, which is an assessment of the ability to maintain the centre of gravity and the ability of the person to move freely by deviating from the centre of gravity within a zone. (13)

This study aimed to assess the effectiveness of Virtual Reality Therapy in combination with Conventional Therapy for improving balance in Traumatic Lower Limb Amputees. We hypothesized that virtual reality could be used as a therapeutic adjunct in improving the balance of amputees. Also, it would lead to an improvement in the quality of life and reduction in phantom limb pain. Hence, the specific objectives of the study were 1) to compare the effectiveness of Virtual Reality Therapy against the Conventional therapy on limits of stability and postural stability among lower limb amputees, 2) to compare the effectiveness of Virtual Reality Therapy against the conventional therapy on pain and quality of life among lower limb amputees, 3) to compare the effectiveness of Virtual Reality Therapy against the conventional therapy on phantom limb among lower-limb amputees 4) to study the correlation of limits of stability, postural stability, phantom limb, pain and quality of life.

2 MATERIALS AND METHODS

Study Design & Setting

This protocol describes a Parallel open-label randomized control trial. The participants were randomized to either receive the Virtual Reality Therapy in addition to the conventional therapy (VRT-CT) or to receive the conventional therapy (CT). Ethical approval was obtained from the AIIMS Ethical Committee, New Delhi (Ref. no. IECPG/110/30.12.2015, RT-39/27.01.2016). One of the data collection tools of the study is WHOQOL-BREF and to use this, permission was obtained from WHO on 1^{st} November 2015. The intervention was conducted from 15.02.2016 to 18.12.2018 in the physiotherapy unit of the JPN Apex Trauma Centre by an experienced physiotherapist.

Eligibility Criteria

Inclusion criteria

- Community-dwelling adults between 18-60 years of age.
- Both male and female patients
- Unilateral Lower-limb amputees
- Patients with traumatic lower limb amputation
- Patients who can follow verbal commands
- Medically stable patients
- Patients who can wear the prosthesis for 45-60 min

Exclusion criteria

- Patients with known neurological disorders
- Patients with circulatory disorders
- Patients with a spinal deformity
- Patients who have uncontrolled diabetes
- Patients under Psychiatric Medication

The protocol used is described elsewhere (reference). A Parallel open-label randomized control trial among traumatic lower-limb amputees to either receive the Virtual Reality Therapy in addition to the conventional therapy (VRT-CT) or to receive conventional therapy (CT). The intervention was conducted in the physiotherapy unit of the JPN Apex Trauma Centre by an experienced physiotherapist. There were 50 participants in each group. Block randomization method was used. The information about the intervention which the enrolled participant will receive was in the concealed envelope.

Outcomes were assessed at baseline (time of joining) and at the end of three weeks, six weeks and nine weeks of enrolment. There were twelve sessions in three weeks' duration. Each session was of 30 minutes each. The intervention was of three weeks, and follow-ups were till nine weeks.

The primary outcome was stability, both in terms of limits of stability, i.e., to move and control their centre of gravity within their base of support, and the overall stability (Postural stability test), which is the ability to maintain the centre of balance. These outcomes were assessed by the Biodex Stability System (BSS) scoring. Its assessment is reliable, as many studies have been done to test its reliability. The Limit of Stability test challenge patients to move and control their centre of gravity within their base of support. The platform is static in this test. During each test trial, patients must shift their weight to move the cursor from the centre target to a blinking target and back to the centre as quickly as i.e. include forward, backward, left, right, forward-left, forward-right, backward-left and backward- right. The test is a good indicator of dynamic control within a normalized sway envelope. Poor control, inconsistencies or increased times suggests further assessment for lower extremity strength, proprioception, vestibular or visual deficiencies. (12)

The postural stability test will measure the ability to maintain the center of balance. The patient's score on this test assesses deviations from the centre; thus, a lower score is more desirable than a higher score. To test this, the "Dynamic Balance test" of the Biodex Balance System was used. In this test, the platform was unstable surface (level 8, 1 being the most stable and 12 being the least stable). The protocol is as follows: Test Duration: 20 seconds; Stability Level: 8 (extent of instability of the platform, range is from static (0 to 12); Stance: Two Legs. The score ranges from 0-20. (12)

There were two secondary outcomes measures in the study- pain and quality of life.

Phantom limb Pain

Phantom limb pain assessment was done by the Numeric Pain Rating Scale (NPRS).

Quality of life (QoL)

The quality of life was assessed by WHO-BREF scale.

	Experimental group (VRT+CT)	Control group (conventional therapy)
Intervention	(VRT) Seven games 1. 1. 2. 2. 3. 3. 4. 4. 5. 5. 6. 6. 7. 7. + conventional therapy	1. 1. 2. 2. 3. 3. 4. 4. 5. 5.
Intervention duration	3-4 min session for each game in 30 min session	30 minute each.
Frequency	3 weeks consisting of 12 sessions (weekly 4 times)	3 weeks consisting of 12 sessions (weekly 4 times)

Intervention Group

The VR therapy was provided by the use of Microsoft X-Box 360 Kinetic^{TM} using seven games viz. River rush 20,000 leaks, Target kick, Super saver, One bowl roll, Rally Tally (Table tennis), Boxing. The intervention protocol was as follows- The participants were familiarized with the games by a trial session of 1-2 min per game on the first day before the beginning of the actual intervention. At the starting of each game, the participant, i.e., the player, followed the instruction of the X-Box 360 for calibration of its motion sensor. The participants were then asked to play the seven games in 30 min session (total duration of VR therapy). There was a 3-4 min session for each game. The VRT intervention was given for 3 weeks in 12 sessions, 4 sessions per week on weekdays as per the participants’ convenience.

Control Group

Patients in the control group were treated with conventional therapy only. The therapy comprised of traditional prosthetic training consisting of weight-shifting, dynamic balancing activities, stool stepping, braiding, gait exercises, and climbing/descending the stairs. The participants were asked to perform Forward-backward and side to side weight shifting exercises to experience the orientation of the centre of mass over the base of support. Single limb balance exercises (stool-stepping) was recommended to increase weight bearing on the prosthesis, while advancing the sound limb. Forward and backward stepping with the sound and prosthetic limb, sidestepping and braiding was taught to patients. To improve prosthetic leg control, balance, and coordination, braiding was recommended. Participants were trained for three weeks consisting of 12 sessions of 30 minute each, 4 times in weekdays as per the participant’s convenience.

Statistical analysis

Statistical Analysis was carried out using STATA 12.0 (state corp LLC, Texas,USA). Data was presented as number (%) or mean SD/median (min-max) as appropriate. The baseline categorical and continuous variables were compared between the groups using chi-square. Fisher’s exact test and student’s ‘t’ test were used for independent groups respectively.

Intention -to- analysis was carried out for both primary and secondary outcomes. The difference in means (of LOS and PS) between the groups were compared using t-test for independent samples and reported as difference in difference (95% CI). The change in primary outcome (LOS & PS) at 3 weeks from baseline was tested using paired t – test in each group repeatedly.

For the outcomes which weren’t in normal distribution, wilcoxon rank sum test was used to compare between the groups and signed rank test was used for within group comparison. Generalized estimating equation was used to assess the change in LOS and PS over a period of time (0, 3, 6, and 9 weeks).

The p- value less than 0.05 were considered statistically significant.

3 RESULTS

Participants

The demographic details are mentioned in table 1. There were 50 patients recruited in each of the VRT-CT and CT group. The mean age in VRT-CT group was 33.4±12.8 and in CT group was 34.8±10.5. In both the groups, there were 90% males (n=45) and 10% females (n=5). 88% of the participants had either above knee or below knee amputation in both the groups. The rest comprised of the knee and hip disarticulation. 58% of the amputations were of right leg and 42% were of left leg in VRT-CT group and the CT group comprised 50 % each of the right and left amputees.

Primary outcomes of Postural Control: Limits of Stability

In both the groups, there was significant improvement after the 3 weeks regime. In each movement case, there was significant improvement after three weeks when compared with baseline. Moreover, comparison between VRT-CT and CT group showed that the VRT-CT group has significant higher scores in each of the eight movements as well as overall score.

The overall stability in the VRT-CT group at baseline was 21.3±5.1 and 62.5±3.3 after three weeks intervention. In the CT group, the overall stability was 21.6±4.6 at baseline and 32.2±4.7 at the end of three weeks. Upon comparison among the VRT-CT and CT group, there was a significant improvement in VRT-CT group. (Table 2) (Graph. 1)

There were eight individual components of the Limits of Stability namely Forward Stability, Backward Stability,

Table 1. Baseline Characteristics Between the two Groups (n=50)

Baseline Characteristics	VRT+CT (n=50)	CT (n=50)	P-value
Age	33.4 ± 12.8 (18-60)	34.8 ± 10.5 (20-59)	0.544
Gender Male Female	45(90%) 05(10%)	45(90%) 05(10%)	1.00
Amputation Level Below Knee Knee Disarticulation Above Knee Hip Disarticulation	22 (44%) 1 (2%) 22 (44%) 5 (10%)	22 (44%) 3 (6%) 22 (44%) 3 (6%)	0.732
Limb Right Left	29 (58%) 21 (42%)	25 (50%) 25 (50%)	0.422

Data Presented as number(%)

Leftward Stability, Rightward Stability, Forward-Left Stability, Forward-Right Stability, Backward-Left Stability and Backward-Right Stability. There was no difference between the baseline values of any of the individual component in both the groups. Upon reassessment after three weeks training in both the groups there was significant improvement in VRT-CT group in all of the components and also in CT group. Moreover, upon comparison between the VRT-CT and CT group, the VRT-CT group showed significant improvement in every individual component. (Table 2) (Graph 2-9)

We also tested if the improvement in balance sustained after the training. So, we checked if the improved balance was sustained after the completion of training. So, the assessment of Limits of Stability was also done at two different time points, at the end of 6^{th} and 9^{th} weeks, from the day of start of the training.

The increased stability was maintained till the end of 9 weeks in both the groups. The maintenance of improved stability was observed in all the components of Limits of Stability including overall stability. (Table 3)

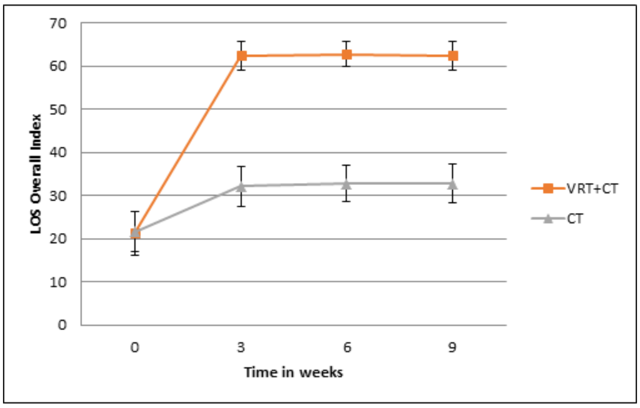

Figure 1. Limits of Stability (Overall Index)

Primary Outcomes of Postural Control: Postural Stability

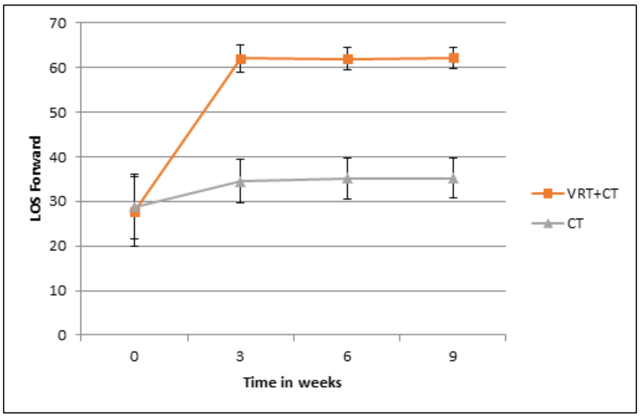

Figure 2. Limits of Stability (Forward)

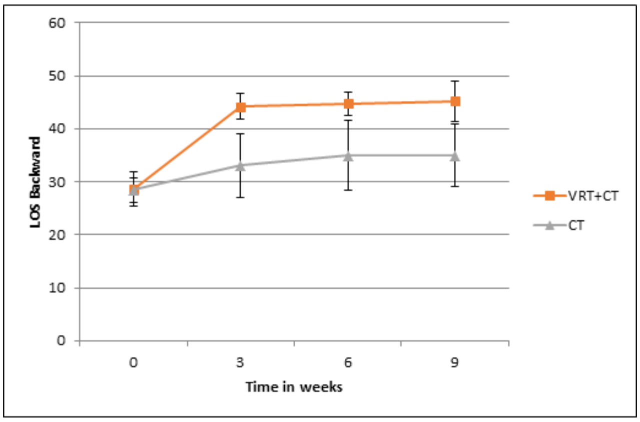

Figure 3. Limits of Stability(Backward)

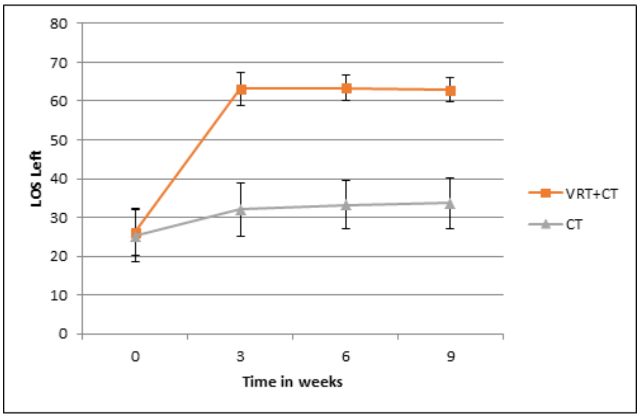

Figure 4. Limits of Stability (Left)

Table 2. Improvement in limits of stability after the intervention in both the groups

Limits of Stability	VRT+CT (n=50)	CT (n=50)	Difference in Difference between two groups (95%Confidence Interval)	P-Value a
Overall	21.3 ± 5.1	21.6 ± 4.6	-0.36 (-2.3, 1.6)	0.712
Baseline	62.5 ± 3.3	32.1 ± 4.7	30.5 (28.9, 32.1)	< 0.001
3 Weeks	< 0.001	< 0.001	30.9 (29.7, 32.0)	< 0.001
P-Value b	41.2 ± 3.5	10.2 ± 2.3		
Difference (95%CI)				
Forward	27.7 ±7.9	28.8 ± 7.2	-1.12 (-4.1, 1.9)	0.460
Baseline	62.1 ± 3.1	34.5 ±4.8	27.4 (25.9, 29.0)	< 0.001
3 Weeks	< 0.001	< 0.001	28.5 (26.6, 30.6)	< 0.001
P-Value b	34.3 ± 5.7	5.7 ± 4.2		
Difference (95%CI)				
Backward	28.6 ± 3.2	28.4 ± 2.4	0.14 (-0.9, 1.3)	0.806
Baseline	44.2 ± 2.5	33.1 ± 6.0	11.2 (9.4, 13.1)	< 0.001
3 Weeks	< 0.001	< 0.001	11.1 (9.6, 12.6)	< 0.001
P-Value b	15.6 ± 2.5	4.5 ± 4.8		
Difference (95%CI)				
Right	26 ± 8.2	25.7 ± 6.6	0.3 (-2.7, 3.2)	0.8513
Baseline	62.0 ± 3.4	34.0 ± 6.0	28.1 (26.1, 30.0)	< 0.001
3 Weeks	< 0.001	< 0.001	27.8 (25.7, 29.8)	< 0.001
P-Value b	36.0 ± 6.0	8.2 ± 4.0		
Difference (95%CI)				
Left	26.2 ± 6.1	25.2 ± 6.7	1.0 (-1.5, 3.6)	0.419
Baseline	63.1 ± 4.3	32.0 ± 7.0	31.6 (28.5, 33.5)	< 0.001
3 Weeks	< 0.001	< 0.001	30.1 (28.2, 32.0)	< 0.001
P-Value b	36.9 ± 5.9	6.8 ± 3.1		
Difference (95%CI)				
Forward- Right	27.5 ± 7.1	28.2 ± 5.5	-0.8 (-3.3, 1.7)	0.526
Baseline	62.0 ± 3.3	34.7 ± 4.4	27.2 (25.7, 28.8)	< 0.001
3 Weeks	< 0.001	< 0.001	28.0 (26.4, 29.7)	< 0.001
P-Value b	34.5 ± 4.9	6.4 ± 3.2		
Difference (95%CI)				
Forward - Left	27.8 ± 5.6	28.5 ± 5.9	-0.8 (-3.1, 1.5)	0.499
Baseline	62.7 ± 4.4	33.9 ± 6.5	28.8 (26.5, 31.0)	< 0.001
3 Weeks	< 0.001	< 0.001	29.6 (27.7, 31.4)	< 0.001
P-Value b	35.0 ± 5.7	5.4 ± 2.9		
Difference (95%CI)				
Backward-Right	27.1 ± 7.1	27.9 ± 5.8	-0.8 (-3.4, 1.8)	0.529
Baseline	61.8 ± 3.6	34.9 ±5.8	26.9 (24.9, 28.7)	< 0.001
3 Weeks	< 0.001	< 0.001	27.7 (26.1, 29.3)	< 0.001
P-Value b	34.7 ± 4.8	7.0 ± 2.9		
Difference (95%CI)				
Backward - Left	27.4 ± 5.8	27.7 ± 6.5	-0.3 (-2.7, 2.1)	0.808
Baseline	62.7 ± 3.4	33.9 ± 7.3	28.8 (26.5, 31.0)	< 0.001
3 Weeks	< 0.001	< 0.001	29.1 (27.6, 30.6)	< 0.001
P-Value b	35.3 ± 4.7	6.2 ± 2.6		
Difference (95%CI)				

P<0.05, statistically significant, Data presented as mean ± SD, ^{a}P-value for between the groups and ^{b} within the group.

There was a significant improvement in terms of Postural Stability both the groups. The overall Postural Stability showed a significant decrease in score (a lower score means increase in Postural Stability) 13.7 (9.5-15.5) vs. 4.3 (2.2-7.5) (p< 0.001) in VRT-CT group and 13.7(8.7- 15.3) vs. 9(6.3- 11.5) in CT group (p< 0.001) after the 3 weeks intervention. When compared between the VRT-CT group and CT group, (Table 4) (Graph 10)

However, upon comparison between the two groups, VRT-CT group had significant improvement in overall Postural stability (4.3 (2.2-7.5) vs. 9 (6.3- 11.5); p<0.001). Also, there was significant improvement in the VRT-CT group in case of Anterior/Posterior Index score (4.2 (2.1-7.4) vs. 8.6 (3.7-11.4); p<0.001) and Medial/Lateral Index score (0.4 (0.2-3.2) vs. 1.6 (0.3-5.1)); p<0.001) (Table 4). (Graph 10-12)

Upon assessment of the individual components of the Postural Stability, there was significant decrease (means improvement in balance) in Anterior/ Posterior Index and Medial/Lateral Index after 3 weeks training. Moreover, like LOS, the postural stability (PS) results were maintained at the end of three weeks (Table 5).

Quality of Life

The quality of life measured by the WHOQOL-BREF scale showed that there was a significant difference in the quality of life in the VRT-CT group as compared to the CT group after the three weeks intervention (Graph 13-16). At the baseline, the WHOQOL-BREF score for VRT-CT

Table 3. Maintenance of the improved stability

Limits of Stability	VRT+CT	CT	Difference (95% Confidence Interval)	P- Value*
Overall	21.3 ± 5.1	21.6 ± 4.6	-0.36 (-2.3,1.6)	0.711
Baseline	62.5 ± 3.3	32.1 ± 4.7	30.5 (29.0, 32.1)	<0.001
3 Weeks	62.8 ± 3.0	32.8 ± 4.2	29.8 (28.4, 31.3)	<0.001
6 Weeks	62.4 ± 3.2	32.7 ± 4.5	29.7 (28.1, 31.2)	<0.001
9 Weeks				
Forward	27.7 ± 7.9	28.8 ± 7.2	-1.12 (-4.1,1.8)	0.457
Baseline	62.1 ± 3.1	34.5 ± 4.8	27.5 (25.9, 29.0)	<0.001
3 Weeks	62.0 ± 2.4	35.2 ± 4.6	26.9 (25.5, 28.3)	<0.001
6 Weeks	62.2 ± 2.4	35.2 ± 4.4	27.0 (25.6, 28.4)	<0.001
9 Weeks				
Backward	28.6 ± 3.2	28.4 ± 2.4	0.14 (-0.9,1.3)	0.805
Baseline	44.2 ± 2.5	33.1 ± 6.0	11.3 (9.4, 13.0)	<0.001
3 Weeks	44.8 ± 2.2	34.9 ± 6.6	9.8 (7.8, 11.8)	<0.001
6 Weeks	45.2 ± 3.8	34.9 ± 5.9	9.9 (7.8, 11.9)	<0.001
9 Weeks				
Right	26 ± 8.2	25.7 ± 6.6	0.28(-2.6, 3.2)	0.850
Baseline	62.0 ± 3.4	34.0 ± 6.0	28.1 (26.2, 29.9)	<0.001
3 Weeks	62.1 ± 3.5	35.0 ± 6.0	27.2 (25.3, 29.1)	<0.001
6 Weeks	62.0 ± 3.3	35.2 ± 6.2	26.9 (24.9, 28.9)	<0.001
9 Weeks				
Left	26.2 ± 6.1	25.2 ± 6.7	1.04 (-1.5, 3.5)	0.415
Baseline	63.1 ± 4.3	32.0 ± 7.0	31.2 (28.9, 33.4)	<0.001
3 Weeks	63.3 ± 3.3	33.2 ± 6.2	29.9 (27.9, 31.8)	<0.001
6 Weeks	62.9 ± 3.0	33.7 ± 6.6	28.8 (26.8, 30.9)	<0.001
9 Weeks				
Forward- Right	27.5 ± 7.1	28.2 ± 5.5	-0.8 (-3.3, 1.7)	0.523
Baseline	62.0 ± 3.3	34.7 ± 4.4	27.2 (25.7, 28.8)	<0.001
3 Weeks	62.3 ± 3.1	35.5 ± 4.5	26.9 (25.4, 28.5)	<0.001
6 Weeks	62.3 ± 3.0	36.7 ± 4.7	25.8 (24.3, 27.5)	<0.001
9 Weeks				
Forward - Left	27.8 ± 5.6	28.5 ± 5.9	-0.78(-3.1, 1.5)	0.496
Baseline	62.7 ± 4.4	33.9 ± 6.5	28.8 (26.6, 31.0)	<0.001
3 Weeks	63.3 ± 3.3	34.2 ± 6.5	28.9 (26.9, 30.9)	<0.001
6 Weeks	63.2 ± 3.8	35.0 ± 6.8	27.8 (25.6, 29.9)	<0.001
9 Weeks				
Backward-Right	27.1 7.1	27.9 ± 5.8	-0.8 (-3.4, 1.8)	0.526
Baseline	61.8 ± 3.6	34.9 ± 5.8	26.9 (25.0, 28.7)	<0.001
3 Weeks	61.9 ± 3.6	35.8 ± 5.9	26.3 (24.3, 28.2)	<0.001
6 Weeks	61.9 ± 3.5	36.6 ± 6.1	25.6 (23.6, 27.6)	<0.001
9 Weeks				
Backward - Left	27.4 ± 5.8	27.7 ± 6.5	-0.3 (-2.7, 2.1)	0.807
Baseline	62.7 ± 3.4	33.9 ± 7.3	28.8 (26.6, 31.0)	<0.001
3 Weeks	62.7 ± 3.1	35.1 ± 6.5	27.4 (25.3, 29.4)	<0.001
6 Weeks	62.6 ± 3.0	35.2 ± 6.5	26.9 (24.9, 28.9)	<0.001
9 Weeks				

Datapresented as mean ± SD

VRT+CT:(Baseline, n= 50; 3 weeks, n=50; 6 weeks, n=49 and 9 weeks, n=46)

CT:(Baseline, n= 50; 3 weeks, n=50; 6 weeks, n=45and 9 weeks, n=42)

*P< 0.05, statistically significant

group was 9.4 ± 2.2 and for CT group was 8.6 ± 1.8 (p = not significant). Upon three weeks intervention, the scores increased to 20.9 ± 3.2 in VRT-CT group and 14.6 ± 2.3 in CT group (p = <0.001). Upon follow-up of the patients at six- and nine-weeks interval, this difference was maintained. The scores at the end of six and nine weeks for VRT-CT and CT group were 27.4 ± 3.2 vs, 18.2 ± 2.0 and 31.9 ± 2.0 vs, 19. 8 ± 3.0 respectively. (Table 6) (Graph 13-16)

Phantom pain scale

The phantom pain scale was measured with Numeric Pain Rating Scale. The scores ranged from 1-10, 1 being no pain at all and 10 for the worst pain sensation. The assessment of phantom pain at baseline and at the end of intervention/training regime showed that the VRT-CT group has significant reduction in phantom pain as compared to CT group as shown in Table 7 (reduction from 8 to 3 in VRT-CT group vs. 8 to 6 in CT group) (Graph 17). The was a loss of follow-up of 1 patient at the end of six weeks assessment and three more patients at the end of nine weeks assessment. The phantom pain didn't increase at both these time points after the three weeks intervention/training regime in both the groups and VRT-CT group had significantly

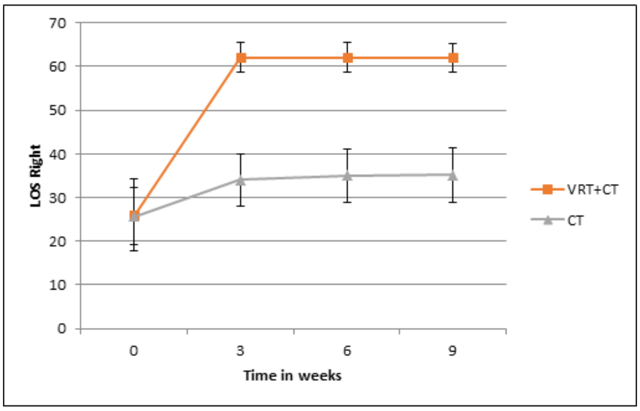

Figure 5. Limits of Stability (Right)

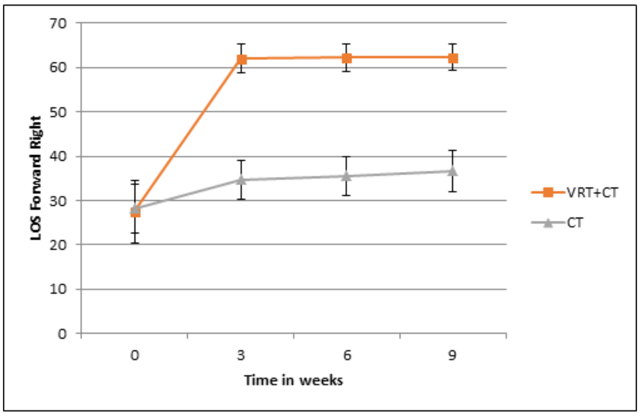

Figure 6. Limits of Stability (Forward- Right)

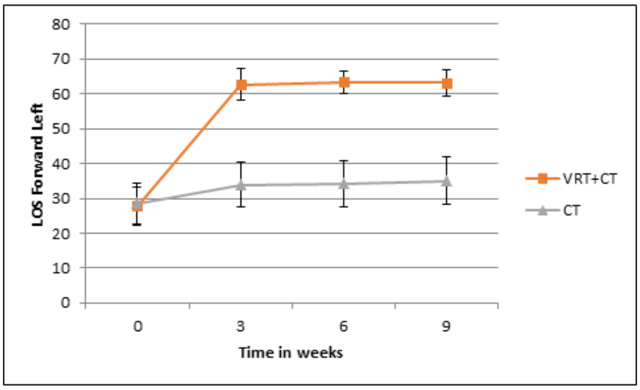

Figure 7. Limits of Stability(Forward- Left)

lesser phantom pain at the end of six weeks and nine weeks as compared to the CT group (3 vs. 6 and 2 vs. 5) (Graph 17).

4 DISCUSSION

Amputation is a permanent surgical interventions which is done to save the life of a person either to prevent necrosis from spreading, as in the case of gangrene, or if the tissue

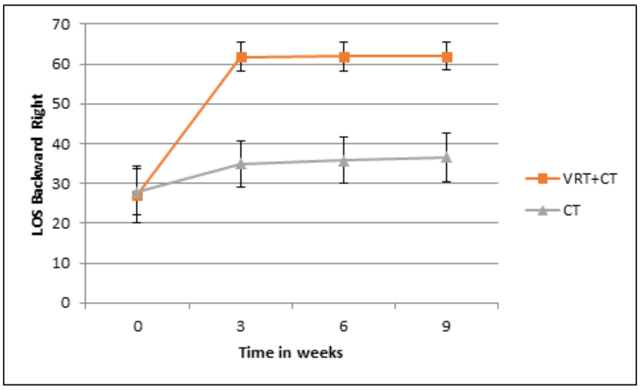

Figure 8. Limits of Stability (Backward- Right)

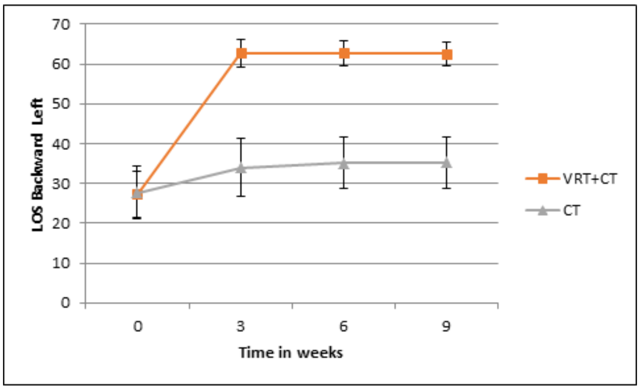

Figure 9. Limits of Stability (Backward- Left)

Table 4. Improvement in Postural stability after thein-tervention in both the groups

Postural Stability	VRT+CT (n=50)	CT (n=50)	P-Value a
Overall	13.7(9.5-	13.7(8.7-	0.795
Baseline	15.5)	15.3)	
3 Weeks	4.3(2.2-7.5)	9(6.3- 11.5)	<
P-Value b	< 0.001	< 0.001	0.001
Anterior/Posterior	11.5(7.6-	11.8	0.790
Index	21.1)	(7.0-13.9)	
Baseline	4.2(2.1-7.4)	8.6(3.7-11.4)	<
3 Weeks	< 0.001	< 0.001	0.001
P-Value b			
Medial/Lateral	6.3(2-10.8)	6.2(1.1-9.0)	0.895
Index	0.4(0.2-3.2)	1.6(0.3-5.1)	
Baseline	< 0.001	< 0.001	<
3 Weeks			0.001
P-Value b			

Data presented as median (min-max); VRT+CT:(Baseline, n= 50; 3 weeks, n=50; 6 weeks, n=49 and 9 weeks, n=46) and CT:(Baseline, n= 50; 3 weeks, n=50; 6 weeks, n=45 and 9 weeks, n=42) and *P<0.05, statistically significant

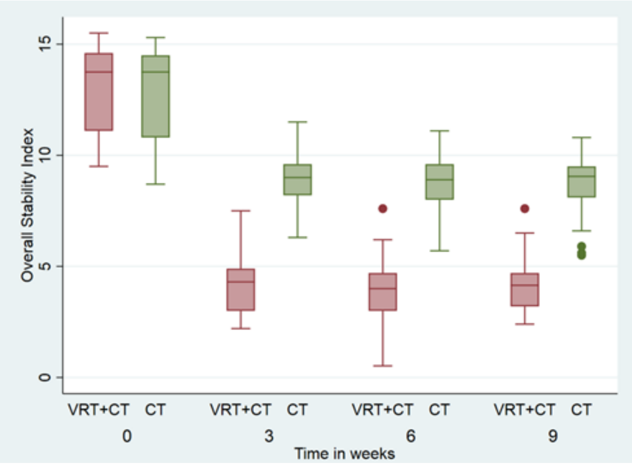

Figure 10. Postural stability(Overall Index)

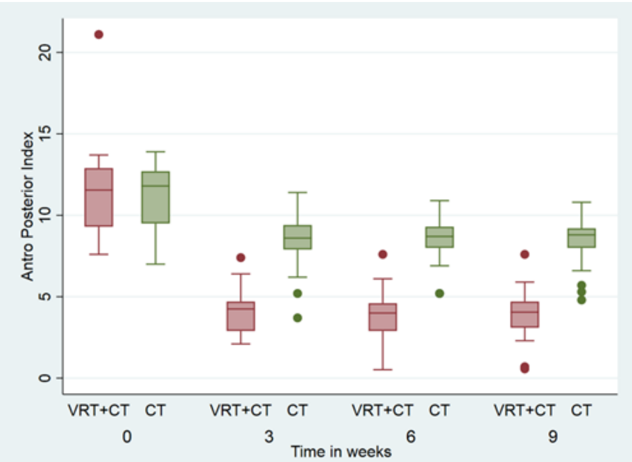

Figure 11. Posturalst ability (Anterior -Posterior Index)

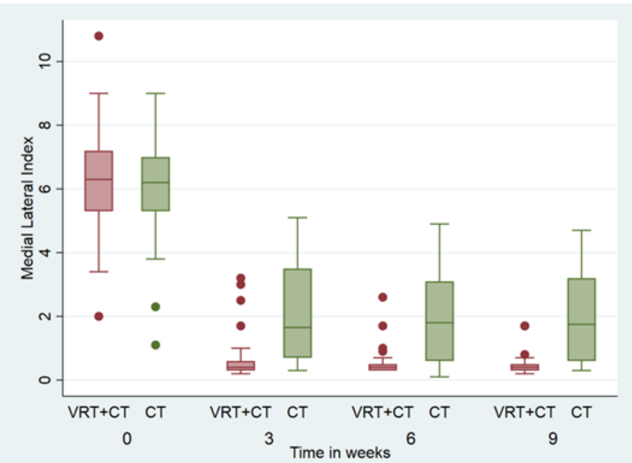

Figure 12. Posturalst ability (Medial- Lateral Index)

Table 5. Quality of Life (WHOQOL-BREF)

WHOQOL-BREF	VRT+CT	CT	Difference (95% Confidence Interval)	P-Value*
Physical Health				
Baseline	9.4 ± 2.2	8.6 ± 1.8	0.8 (.0, 1.6)	0.035
3 Weeks	20.9 ± 3.2	14.6 ± 2.3	6.3 (5.2, 7.4)	< 0.001
6 Weeks	27.4 ± 3.2	18.2 ± 2.0	9.2 (8.2, 10.3)	< 0.001
9 Weeks	31.9 ± 2.0	19. 8 ± 3.0	12.2 (11.1, 13.2)	< 0.001
Psychological Health				
Baseline	6.7 ± 2.5	6.8 ± 0.9	-0.1 (-0.6, 0.3)	0.508
3 Weeks	13.9 ± 1.7	9.4 ± 1.9	4.5 (3.8, 5.2)	< 0.001
6 Weeks	19.1 ± 2.8	12.1 ± 2.3	7.0 (6.0, 8.1)	< 0.001
9 Weeks	22.6 ± 2.9	13.4 ± 2.6	9.2 (8.1, 10.3)	< 0.001
Social Relationship				
Baseline	9.6 ± 2.5	9.3 ± 2.3	0.3 (-0.7, 1.2)	0.563
3 Weeks	9.9 ± 2.3	9.6 ± 2.4	0.4 (-0.6, 1.3)	0.077
6 Weeks	10.4 ± 2.4	9.7 ± 2.6	0.6 (-0.3, 1.6)	0.044
9 Weeks	11.3 ± 2.9	9.8 ± 2.6	1.5 (0.5, 2.4)	0.092
Environmental Health				
Baseline	11.8 ± 1.9	11.6 ± 2.3	0.2 (-0.7, 1.0)	0.710
3 Weeks	22.8 ± 2.9	16.6 ± 2.7	6.2 (5.1, 7.3)	< 0.001
6 Weeks	30.7 ± 3.7	19.9 ± 3.3	10.7 (9.3, 12.1)	< 0.001
9 Weeks	35.7 ± 3.8	22.7 ± 3.4	13.5 (12.0, 14.9)	< 0.001

Data Presented as mean ± SD; Baseline vs 3 weeks: VRT+CT,p<0.001 and CT, p<0.001, statistically significant; VRT+CT : (Baseline,n= 50; 3 weeks, n=50; 6 weeks, n=49 and 9 weeks, n=46) and CT: (Baseline, n=50; 3 weeks, n=50; 6 weeks, n=45 and 9 weeks, n=42) and *P< 0.05,statistically significant

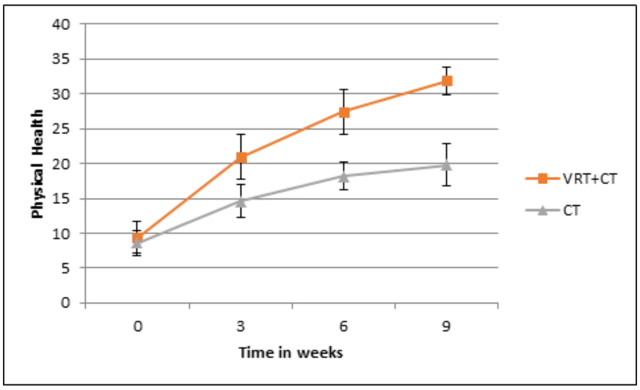

Figure 13. Quality of Life (Physical Health)

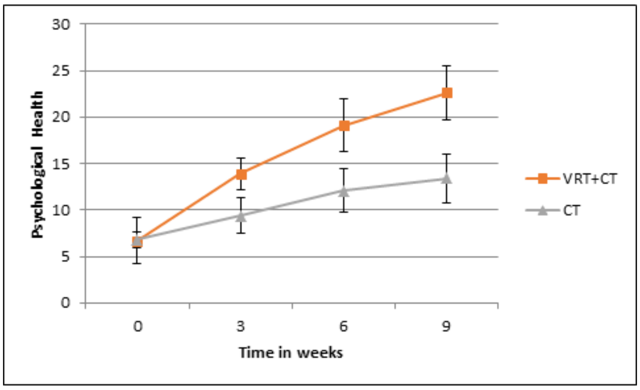

Figure 14. Quality of Life (Psychological Health)

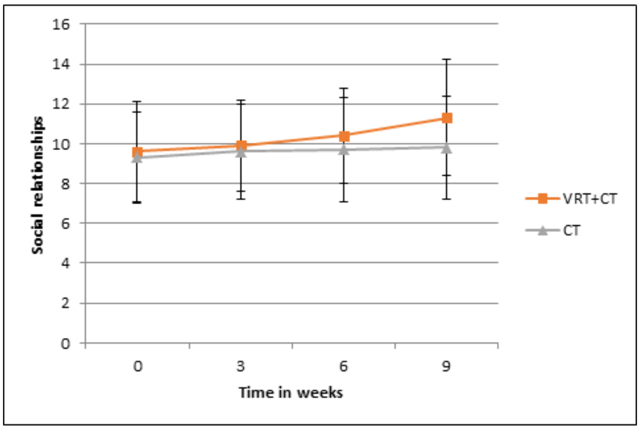

Figure 15. Quality of Life (Social Relationships)

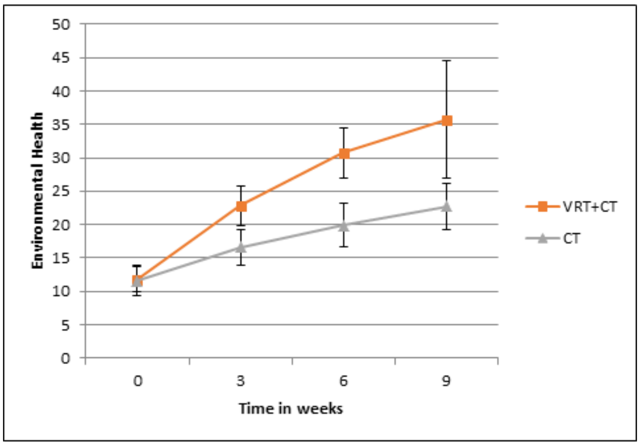

Figure 16. Quality of Life (Environment Health)

Table 6. Numerical Rating Scale for Phantom pain

Numerical Rating Scale		VRT+CT		CT	P Value
Baseline	50	8 (5-10)	50	8 (6-10)	0.784
3 weeks	50	3 (1-7)	50	6 (3-8)	< 0.001
6 weeks	49	3 (1-7)	45	5 (3-8)	< 0.001
9 weeks	46	2 (1-6)	42	5 (2-7)	< 0.001

Data presented as Median (Min – Max); Baseline vs 3 weeks: VRT+CT, p<0.001 and CT, p<0.001, statistically significant.

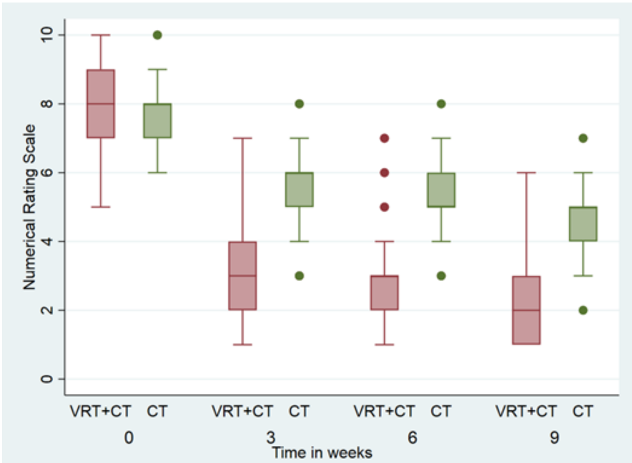

Figure 17. Phantom Pain scale (NPRS)

is severely damaged from dysvascular disease and amputation of the lower limb leads to worse alteration in centre of balance, thus making the amputee vulnerable to fall.

Physiotherapy and rehabilitation play a major role in getting the amputee back to doing activities of daily basis. However, the monotonous nature of exercises and the limited availability of the rehabilitation centres makes the standard rehabilitation process difficult.

Amputation may lead to cortex remapping, a phenomenon which is proposed to explain phantom limb pain. This alteration occurs at the cortex level, both at somatosensory and motor level. (10)

The goal of rehabilitation is to improve the quality of life of amputee. Apparently, the quality of life is used as a measurement of outcome of rehabilitation. (9)

In the last few years, the advent of technology has led our steps into a new era of Virtual Reality which seems promising not only in field of entertainment, but also in healthcare system by bringing in new advances in the field.

Virtual reality has opened doors for a new world in the field of healthcare. Although mostly used in entertainment business with the majority being the games, its full integration with the medical field is still in the process. Rehabilitation is one branch of medical field that had the benefit of integrating virtual reality technology in healthcare in the initial phase. Although not thoroughly studied, its results in the rehabilitation process are surprisingly good.

The use of virtual reality in rehabilitation as a therapeutic module gave birth to the Virtual Reality Therapy (VRT).

In this study, we observed the effects of VRT in improving balance, quality of life and reduction in phantom pain when used as an adjunct in addition to the conventional rehabilitation alone.

Microsoft X-Box 360 is a commercially available gaming console with a body sensor that allows the player to play games in a virtual reality. These games urges the player to use various movements, many of which uses similar muscle and movements like in the exercises of the training regime in conventional therapy. This gave us an idea to use the X-Box 360 VR experience as an adjunct to see if helps in attenuating the major problems faced by a lower-limb amputee.

The Objective of the study was to find out the effect of Virtual Reality Therapy in improving balance and Quality of life, and reducing phantom limb pain among the lower limb amputees. Hundred patients who have undergone lower limb amputation and coming for follow-up participated in the study. 50 subjects (90% Male) with mean age difference of 33.4 ± 12.8 received the Virtual Reality Therapy in addition to the conventional therapy (VRT-CT) and 50 subjects (90% Male) with mean age difference of 34.8 ± 10.5 received the conventional therapy (CT). Out of 50 subjects who received Virtual Reality Therapy in addition to the conventional therapy (VRT-CT), 22 were of below knee amputation, 1 was of Knee Disarticulation, 22 were above knee amputation and 5 subjects were of Hip Disarticulation. The level of amputation in conventional therapy group was below knee amputation (22), Knee Disarticulation (3), above knee amputation (22), Hip Disarticulation (3).

The participants in the VRT group were asked to play the seven games viz. River rush 20,000 leaks, Target kick, Super saver, One bowl roll, Rally Tally (Table tennis) and Boxing (3-4 min session for each game) in for a duration of 30 minutes per session. Apart from the VRT, every participant was treated with conventional therapy which comprised of traditional prosthetic training consisting of weight-shifting, dynamic balancing activities, stool stepping, braiding, gait exercises, and climbing/descending the stairs for three weeks consisting of 12 sessions of 30 minutes each. The control group received conventional therapy alone.

Training of both groups with prosthetics was initiated in parallel bars with double arm support and progressed to single arm support. When the amputee succeeds in performing the activities without support, training was continued in an open area.

In both groups, there were twelve sessions in three weeks duration. In the VRT group, the VRT treatment was given for 30 minutes in each of the 12 sessions, in addition to the conventional therapy of 30 minutes. Then the follow-up were taken at the end of 6th week and till 9th week from the start of therapy to assess the retention of balance stability after the VRT treatment.

Statistical analysis showed there was a significant difference in postural stability, limits of stability as assessed by the Biodex Stability System (BSS) scoring, QOL assessed by WHO-BREF scoring and in Phantom limb pain assessed by the Numeric Pain Rating Scale (NPRS).

When compared, the VRT group showed significantly better results compared to CT group ($P < 0.001$). The changes in this highly significant result might because VRT had a positive visual and auditory feedback with various challenging modules providing the patient high physical and cognitive demands in doing a task.

The effect of VRT was also studied in other studies and positive results were observed.

In 2018, Thunyanoot P et al. studied the effect of VRT on postural control and motor learning in ten subjects. The training was for four weeks and intervention in the control group was physical balance training whereas the virtual reality group used game. They found that in the motor training, VR proved better than conventional exercises whereas in postural analysis, both the training were equally good. (14)

One of the first studies done to study the effect of VRT on improving gait was described by Darter BJ and Wilken JM in which a 24 year old patient having transfemoral amputation underwent a 3 week gait training intervention consisting of 12 sessions. The session consisted of treadmill walking with visual feedback in real-time. Improvements in pelvis and hip motion and thus improvement in trunk was observed after 3 weeks intervention. This case study showed the potential of virtual reality in rehabilitation of amputees. (15)

Since the amputee patients are dependent on cognitive for their balance to some extent and further if any above-mentioned balance challenges during an activity happens, the demand on cognitive system increases. In such situations amputee faces high interference between cognitive and motor system coordination which ends in loosing balance. Hence such cognitive based motor-based interaction will help them to improve in their balance behaviour. (16)

Alexander C. H. Geurt et al, explained attention mechanism are highly important and impacts the balance automaticity post amputation, attentional mechanism is involved in safely maintaining in early phase of skill acquisition to compensate the distorted sensory input and loss of output structure at the side of amputee. Until a sensory motor strategy is formed the balance in amputee remains slow and jerky and dependent on cognitive and visual feedback which is immediate. (17)

The effect of virtual reality on improving balance in children between 8-18 years having unilateral transfemoral or van ness amputations was studied. Two games of Nintendo Wii FIT balance was used. The therapy was of 20 mins/day, 4 days per week and of 20 days. The outcome was measured in terms of Centre of pressure displacement and Community balance and mobility scale. After the training, the Centre of pressure displacements of amputees were closer to children of same group without amputations and there was an average increase in Community balance and mobility scale. (13)

In a real-world gait, a host of other cognitively demanding tasks may be concurrently performed, such as obstacle avoidance, route planning, uneven terrain negotiation, holding a conversation, may have impact on balance.

Although the studies mentioned above studied the effect of VRT on amputations, the uniqueness of our study is that we studied the Effect of VRT on balance, phantom limb pain and quality of life together among lower limb amputees. We had a distinct control group which had the intervention of the standard rehabilitation program.

Our study has few limitations. To begin with, the balance was measured using a single platform, i.e. Biodex SD balance system whereas balancing in day to day life situations is much more different and challenging for a lower limb amputee. Also, there were no controls for the type of amputation and prosthesis used. So, we couldn't measure the improvement within a subset of a particular type of amputation. Moreover, the weight of prosthesis was not taken into consideration. Although we included those patients who were comfortable in wearing prosthesis for 45-60 mins, the duration of usage of prosthesis by the amputee apart from the period of therapy was not considered in this study. These factors could have hard impact on our results as the higher duration of usage of prosthesis by the participant will provide higher control over managing centre of gravity and balance.

To conclude, Virtual Reality therapy is an effective tool in training the integrated cognitive- motor domain to improve balance QOL and Phantom limb Pain in lower limb amputees. VR therapy can be extended as an adjunct therapeutic tool along with conventional therapeutic regime in lower limb amputees. Moreover, the overall improvement is sustained for long period as evident by the assessment at the end of 9^{th} weeks (6 weeks after the end of training). [1–17]

Conflict of Interest: Nil

REFERENCES

[1] Engstrom B, Ven CVD, Therapy, Amputees C, Livingstone. London; 1999. Available from: https://www.icrc.org/en/doc/assets/files/other/icrc_002_0936.pdf.

[2] Darter BJ, Wilken JM. Gait Training With Virtual Reality–Based Real-Time Feedback: Improving Gait Performance Following Transfemoral Amputation. Physical Therapy. 2011;91(9):1385–1394. Available from: https://dx.doi.org/10.2522/ptj.20100360.

[3] Taylor MJD, McCormick D, Shawis T, Impson R, Griffin M. Activity-promoting gaming systems in exercise and rehabilitation. The Journal of Rehabilitation Research and Development. 2011;48(10):1171–1171. Available from: https://dx.doi.org/10.1682/jrrd.2010.09.0171.

[4] Feng H, Li C, Liu J. Virtual Reality Rehabilitation Versus Conventional Physical Therapy for Improving Balance and Gait in Parkinson's Disease Patients: A Randomized Controlled Trial. Med Sci Monit. 2019;25:4186–4192.

[5] Randy Schmitz and Brent Arnold lntertester and lntratester Reliability of a Dynamic Balance Protocol Using the Biodex Stability System. Journal of Sport Rehabilitation. 1998;7:95–101.

[6] Ülger Ö, Şahan TY, Çelik SE. A systematic literature review of physiotherapy and rehabilitation approaches to lower-limb amputation. Physiotherapy Theory and Practice. 2018;34(11):821–834. Available from: https://dx.doi.org/10.1080/09593985.2018.1425938.

[7] Heller BW, Datta D, Howitt JJ, Ipsen T, Doherty P, Langberg H, et al.; 2000.

[8] Sinha R, Heuvel WJAVD. A systematic literature review of quality of life in lower limb amputees. Disability and Rehabilitation. 2011;33(11):883–899. Available from: https://dx.doi.org/10.3109/09638288.2010.514646.

[9] Keshner EA. Virtual reality and physical rehabilitation: a new toy or a new research and rehabilitation tool. J NeuroEngineering Rehabil. 2004;1.

[10] Geurts ACH, Mulder TW. Attention Demands in Balance Recovery following Lower Limb Amputation. Journal of Motor Behavior. 1994;26(2):162–170. Available from: https://dx.doi.org/10.1080/00222895.1994.9941670.

[11] Prasertsakul T, Kaimuk P, Chinjenpradit W, Limroongreungrat W, Charoensuk W. The effect of virtual reality-based balance training on motor learning and postural control in healthy adults: a randomized preliminary study. BioMedical Engineering OnLine. 2018;17(1):1–17. Available from: https://dx.doi.org/10.1186/s12938-018-0550-0.

[12] Kim J, Son J, Ko N, Yoon B. Unsupervised Virtual Reality-Based Exercise Program Improves Hip Muscle Strength and Balance Control in Older Adults: A Pilot Study. Archives of Physical Medicine and Rehabilitation. 2013;94(5):937–943. Available from: https://dx.doi.org/10.1016/j.apmr.2012.12.010.

[13] Weiss PL, Katz N. The potential of virtual reality for rehabilitation. J Rehabil Res Dev. 2004;41(5):7–10.

[14] Andrysek J, Klejman S, Steinnagel B, Torres-Moreno R, Zabjek KF, Salbach NM, et al. Preliminary Evaluation of a Commercially Available Videogame System as an Adjunct Therapeutic Intervention for Improving Balance Among Children and Adolescents With Lower Limb Amputations. Archives of Physical Medicine and Rehabilitation. 2012;93(2):358–366. Available from: https://dx.doi.org/10.1016/j.apmr.2011.08.031.

[15] Zidarov D, Swaine B, Gauthier-Gagnon C. Quality of Life of Persons With Lower-Limb Amputation During Rehabilitation and at 3-Month Follow-Up. Archives of Physical Medicine and Rehabilitation. 2009;90(4):634–645. Available from: https://dx.doi.org/10.1016/j.apmr.2008.11.003.

[16] Andrysek J, Klejman S, Steinnagel B, Torres-Moreno R, Zabjek KF, Salbach NM, et al. Preliminary Evaluation of a Commercially Available Videogame System as an Adjunct Therapeutic Intervention for Improving Balance Among Children and Adolescents With Lower Limb Amputations. Archives of Physical Medicine and Rehabilitation. 2012;93(2):358–366. Available from: https://dx.doi.org/10.1016/j.apmr.2011.08.031.

[17] Moorthy S, Sagar S, Trikha V, Sagar R, Sawhne C, Kalaivani K, et al. Study protocol to report the effectiveness of virtual reality therapy in combination with physical therapy protocol for improving balance in traumatic lower limb amputees: A parallel, open-label, randomized controlled trial. Revista Pesquisa em Fisioterapia. 2019;9(4):524–531. Available from: https://dx.doi.org/10.17267/2238-2704rpf.v9i4.2477.

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