IMPROVEMENT IN UNILATERAL ABOVE KNEE AMPUTEE'S LIMIT OF STABILITY BY USING VIBROTACTILE FEEDBACK

ABSTRACT

Background: Human balance is directly associated with stability and postural control, which in turn is essential to perform daily life activities effectively. Amputation in the above-knee (transfemoral) amputee results in loss of sensory feedback of the amputated limb, and therefore it leads to poor postural stability. To assess postural stability, the Limit Of Stability (LOS) is a reliable parameter. The LOS and falling are negatively correlated to each other; a faller has a low LOS. Hence, it is found that the amputee's LOS without an assistive device is lower as compared to the healthy individual. According to recent studies, Weight Shifting Exercise (WSE) has been reported useful in boosting the sound limb's LOS of the amputee. It is also found that the prosthetic socket interface's feedback is not sufficient to maintain balance, although an amputee's gait is satisfied with the prosthetic limb. In addition to this, it is also found that artificial feedback improves postural control. In this thesis, an insole-based vibrotactile feedback system is developed to provide vibrotactile feedback to the stump of above-knee amputees during WSE. Amputees have a greater problem for controlling dynamic balance in the anteroposterior direction than the mediolateral direction; the aim of this thesis is to examine the effect of VF on the prosthetic and sound limbs' LOS of the unilateral above-knee amputee only in the sagittal plane (anterior and posterior direction).

Three studies have been performed in this thesis; i) Validation of developed insoles with the gold standard Zebris Force Plate (ZFP) system for identifying the COP_{sag} during WSE in eyes-opened and eyes-closed conditions, ii) The effect of Vibrotactile Feedback (VF) on the LOS of the above-knee amputee during the forward and backward WSE is investigated and further, iii)

The effect of VF on the LOS of the above-knee amputee with the fixed prosthetic ankle (SACH foot) and movable prosthetic ankle (single-axis prosthetic foot (SA-foot)).

Method: Two types of printed insoles [Printed Dielectric Sensors Insole (PDSI) and Printed FSR Insole (PFSRI)] are developed by using the screen-printed machine for making vibrotactile feedback system for the above-knee amputee. The VF is provided through miniature vibratory motors. Once the displacement of the developed printed insole's COP_{sag} exceeds the threshold value, these motors are driven. VF was provided on the anterior and posterior side of the above-knee amputee's stump during the forward and backward WSE, respectively. The case-control study was designed to validate developed insoles with ZFP. The cross-sectional study was designed to study VF's effect on the above-knee amputee's LOS without the assistive device in the last two clinical studies.

Five amputees and five healthy subjects were recruited for studies, amputees were selected with inclusion criteria of i) K2 or above K2 level activity of amputee with the ability to maintain their balance during the forward and backward WSEs, ii) Prosthetic foot size equal to or less than the length of the developed insole, iii) Percentage of stump length equal to or greater than 66.6% (2/3)rd length of the femur to ensure the consistency of vibrotactile placement and (iv) ability to maintain their balance during the forward and backward WSEs. The exclusion criteria were: i) Deformity or any injury involved in the contralateral limb, ii) Use of an assistive device for support during walking, iii) Flat foot deformity in the sound limb, and iv) Presence of any cardiovascular or musculoskeletal deformity.

Each participant performed the forward and backward WSEs on the gait lab's ZFP. The COP_{sag} data was recorded for the displacement of COP_{sag} from normal standing to the maximum leaning position in the respective WSE direction. Further, data was processed by using the novel

developed algorithm for detecting the phases of WSE to evaluate the LOS. Welch's method was used to analyse the change in frequency of COP at the specific Power Spectral Density (PSD).

In the first study, the interclass correlation coefficient (Pearson's Coefficient of Correlation; 'r') and Coefficient of Determination (R^2) by using simple linear regression between the developed insoles and ZFP (PDSI and ZFP, and PFSRI and ZFP) were calculated. For validity, an agreement between the printed insoles and ZFP was examined by using Bland-Altman Plot for peak detection and LOS's measurement. In the second study, the paired t-test was performed to analyse VF's effect on the LOS. The univariate analysis of COP (UNIANOVA) was performed for main effect and interactions of divisions (B_1 to S_3), WSE (NS, FS and BS), VF (with and without VF) and limbs (prosthetic and sound limbs of amputee and right and left limbs of healthy subjects). In the final clinical study, the paired t-test was performed for analyzing the VF's effect on the unilateral above-knee amputee's LOS with fixed and movable prosthetic ankle joint. The repeated-measures ANOVA was also used to assess VF's main and interaction effect with types of ankle joint and limbs (prosthetic and sound limbs) during the forward and backward WSE.

Results: The average interclass correlation coefficient (r) and Coefficient of Determination (R^2) were found to be higher for PFSRI (0.84±0.13 and 0.64±0.31, respectively) than PDSI (0.70±0.90 and 0.550±0.386, respectively). The Bland-Altman Plot for LOS amplitude showed that the limit of agreement of PDSI with ZFP around the mean difference is far more deviated (average in PDSI 11.02±4.21 mm) than the PFSRI (average in PFSRI 1.32±2.39 mm). Bland-Altman Plot for the peak detection in WSE data showed that the limit of agreement of PDSI with ZFP around the mean difference is far more deviated (average in PDSI 1.26±0.78 sec) than the PFSRI (average in PFSRI 0.19±0.12 sec). A significant difference was observed in the sound limb's LOS with eyes-opened and eyes-closed conditions by using data of ZFP (LOS found from

PDSI data: EO=23.73±5.45 mm EC=19.42±4.98 mm, $p<0.05$). However, the significant difference was not observed by using data of both insoles (LOS found from PDSI data: EO=9.90±3.02 mm EC=8.50±2.39 mm and LOS found from PFSRI data: EO=18.00±10.79 mm EC=13.92±10.35 mm, $p>0.05$). Therefore, both insoles' data was not acceptable for comparing the LOS between two conditions, but the error in peak detection by using both insoles was around less than one sec (≈ 0.72) which was used for providing the threshold value to the vibrotactile feedback system.

The results of the second study showed that the sound and prosthetic limbs' LOS of the above-knee amputees significantly ($p<0.05$) improved with VF during the forward (19.80±5.7 to 23.21±5.9) and backward (-12.63±8.2 to -15.08±8.2) WSEs, respectively. The result of frequency analysis of COP_{sag} showed that in eyes-closed condition, the cerebellum and proprioception sensory systems (correspond to 1 -5 Hz frequency) highly contributed to control the balance in the transition phase (Phase 2) (range found from 0.78 to 2.88 Hz), and the visual and vestibular sensory systems (correspond to 0 -1 Hz frequency) highly contribute to control the balance in the sustenance phase (Phase 3) (range found from 0.01 to 0.85 Hz) during WSE. This is in line with the previous study reported that the vestibular system is the primary sensory system that provides graviceptive body-orientation information. The frequency of Phase 3 significantly decreased with VF (average 0.17±0.03 Hz to 0.15±0.01 Hz, $p<0.05$) during the forward WSE only in the amputee. The prosthetic limb's frequency >1 Hz, which is corresponding to proprioception, is significantly decreased with VF (1.65±0.711 Hz to 0.78±0.49 Hz, $p<0.05$) in the transition phase (Phase 2) during backward WSE. It could be assumed that the alertness for vibration at the LOS level may reduce the weightage on proprioception during the backward WSE.

The results of the third study showed that during forward WSE, the prosthetic limb's LOS with SACH foot is significantly higher than the prosthetic limb's LOS with SA-foot in both VF conditions (with and without VF) (with VF: 27.95±11.0 mm to18.38±5.56 mm, p=0.02 and without VF: 31.85±7.8 mm to 25.48±5.51 mm, p=0.01). Significant improvement of sound limb's LOS with VF during the forward WSE was observed with both types of prosthetic foot [SACH: 24.13±5.3 mm (without VF) to 28.68±4.4 mm (with VF), p=0.001 and SA-foot: 27.03±4.63 mm (without VF) to 31.05±6.32 mm (with VF), p=0.01]. Significant improvement of prosthetic limb's LOS with VF during the forward WSE was observed only with SA-foot [18.38±5.56 mm (without VF) to 25.48±5.51 mm (with VF), p=0.002]. In general, the net amputee's LOS while using SACH foot improved with VF during the forward WSE (25.4±5.04 to 29.85±4.2, p=0.003) and, the net amputee's LOS while using SA-foot improved with VF during both forward and backward WSEs [23.06±4.49 to 28.30±5.16, p=0.003 (forward WSE) and -9.30±5.50 to -13.5±3.33, p=0.012 (backward WSE)].

Conclusion: Above-knee amputee's LOS improves with VF. The prosthetic limb's LOS with a fixed ankle does not improve with VF due to the prosthetic ankle's constraining motion. This thesis found that if motion is available at the prosthetic ankle (e.g. single-axis prosthetic foot), the VF improves the prosthetic limb's LOS. Although the moveable ankle has a lower LOS in both VF conditions (with and without feedback) compared to the fixed ankle, nevertheless movable ankle joint is prescribed for improvement in the gait cycle. It is well known that as the mobility of the prosthetic component improves, the stability decreases. Therefore, clinically, the moveable ankle joint is not prescribed where stability is the prime concern compared to the functionality during the gait cycle. This thesis's findings show that it can be possible to improve the movable

ankle joint's stability by providing VF. The present study suggests that the advanced prosthetic foot with ankle motion may also provide a larger LOS with VF.