

**DEVELOPMENT OF CENTER OF PRESSURE-BASED
VISUAL FEEDBACK SYSTEM FOR IMPROVED
MINIMUM TOE CLEARANCE (MTC): VALIDATION IN
TRANSFEMORAL AMPUTEES**

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TRANSFEMORAL AMPUTEES**

by

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CERTIFICATE

This is to certify that the thesis entitled **“Development of Center of Pressure-Based Visual Feedback System for Improved Minimum Toe Clearance (mTC): Validation in Transfemoral Amputees”** which is being submitted by **Mr. Ashutosh Tiwari** to the Indian Institute of Technology Delhi, India, for the award of the **“Doctor of Philosophy in Biomedical Engineering”** is a bonafide research work carried out by him under my supervision and guidance.

The thesis work, in my opinion, has reached the requisite standard. The results presented in this thesis have not been submitted in part or in full to any other University or Institute for the award of degree or diploma.

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ABSTRACT

Individuals with lower limb amputation are at higher risk of falls given their compromised balance, loss of lower limb muscle strength, and altered gait pattern. It has been estimated that there are roughly 0.62 amputees in India per thousand population. This translates to close to one million individuals with amputations in the country. With the prevalence of infectious diseases, diabetic mellitus, and traumas, lower-limb amputation is expected to increase in the future. In the past, the investigation of falls and rehabilitation strategies to prevent falls in amputees have received considerable attention. In general, transfemoral amputees (also known as above-knee amputees) are at a higher risk of falling than transtibial amputees (below-knee amputees). Moreover, transfemoral amputees often encounter reduced toe clearance, resulting in trip-related falls and increasing the risk of falling. To compensate for anticipated reduced toe clearance, transfemoral amputees adopt various locomotion strategies such as vaulting, circumduction, and hip-hiking. But, all these techniques for enhancing the toe clearance impose undesirable gait deviation and deteriorate the overall walking efficiency.

Toe clearance, particularly the minimum toe clearance (mTC), was most sensitive to the angular rotation of the ankle joint followed by the hip joint and, lastly, the knee joint. Therefore, researchers have been focusing on designing advanced actively actuated ankle joints to improve mTC. However, due to the high cost of these advanced techniques, they are rare among the poor or lower-middle-class community-dwelling people in developing countries with lower-limb loss. Therefore, developing biomechanically appropriate rehabilitation techniques, which promise to enhance the toe clearance in low-cost passive transfemoral prostheses, is of utmost importance. Thus, the present thesis aims to contribute to the research area of gait rehabilitation with the

objective to enhance toe clearance using biomechanically appropriate rehabilitation techniques in low-cost passive transfemoral prostheses.

To this end, I investigated the effect of the CoP displacement on the mTC and associated toe clearance outcome parameters. A comprehensive analysis of swing phase joint angle modulation responsible for the altered mTC and associated toe clearance outcome parameters was also carried out. A novel CoP-based feedback system was developed that consists of the instrumented shoe and pressure insole for real-time toe clearance and CoP measurement, respectively. The data were collected from six able-bodied participants and three unilateral transfemoral amputees. The experiment was conducted during three different walking sessions- baseline, feedback, and retention while participants walked on the treadmill. During the baseline session, data were acquired during unconstrained walking without feedback. Subsequently, during the feedback session, participants were asked to shift the CoP anteriorly/posteriorly at heel strike to match the target CoP location using visual feedback provided through a monitor screen placed in front of the participant's line of sight. Finally, to assess the lasting effect of training on toe clearance, a retention session was conducted.

During feedback, a posterior shift in the CoP improved the mTC significantly from $4.68 \pm 0.40\text{cm}$ to $6.12 \pm 0.68\text{cm}$ ($p < 0.025$) in able-bodied participants. A similar significant improvement in mTC from $4.60 \pm 0.55\text{cm}$ to $5.62 \pm 0.57\text{cm}$ was observed in amputees during a posterior shift of CoP. Besides mTC, maximal toe clearances, i.e., maxTC_1 and maxTC_2 , also showed a significant increase ($p < 0.025$) during the posterior shift of CoP in able-bodied participants and amputees. Moreover, during retention, mTC did not differ significantly ($p > 0.05$) from feedback conditions in amputees, suggesting active learning of feedback training. During the mid-swing phase, posterior CoP shift feedback significantly increases ($p < 0.05$) the hip and knee

flexion angle by 11.55 ± 0.52 degrees and 11.86 ± 0.36 degrees respectively in amputees, whereas a significant increase ($p < 0.05$) in ankle dorsiflexion, hip, and knee flexion angle by 3.60 ± 0.25 degrees, 3.22 ± 0.23 degrees, and 1.27 ± 0.12 degrees respectively compared to baseline was observed in able-bodied participants. Moreover, an opposite kinematic adaptation was seen during anterior CoP shift feedback. There were evidence earlier about the protocols on heel strike modulation associated with gait improvement; however, this is the first study that developed and validated the posterior shift in CoP protocol with improved minimum toe clearance in lower limb amputees. In addition, the present work demonstrated kinematic modulations in lower limb joints which may be responsible for improved minimum toe clearance.

The proposed research work demonstrated a significant potential of real-time visual feedback of CoP in improving mTC, maximal toe clearances in able-bodied and amputee participants. A longer training time can further enhance the mTC with walking speed. Also, a careful replacement of visual feedback to vibrotactile feedback may promise home-based gait training for mTC in transfemoral and transtibial amputees.

सार

निचले अंगों के विच्छेदन वाले व्यक्तियों को गिरने का अधिक जोखिम होता है जिसके कारण उनका असंतुलन, निचले अंगों की मांसपेशियों की ताकत की कमी, और परिवर्तित चाल का होना पाया जाता है। यह अनुमान लगाया गया है कि भारत में प्रति हजार जनसंख्या पर लगभग ०. ६२ विकलांग हैं। संक्रामक रोगों, मधुमेह और आघात के प्रसार के साथ, भविष्य में निचले अंगों के विच्छेदन में वृद्धि होने की उम्मीद है। अतीत में, अपंगों में गिरने को रोकने के लिए गिरने और पुनर्वास रणनीतियों की जांच पर काफी ध्यान दिया गया है। सामान्य तौर पर, ट्रांसफेमोरल एम्प्यूटीज़ (ऊपर-घुटने के एम्प्यूटीज़ के रूप में भी जाना जाता है) से ट्रांसस्टिबियल एम्प्यूटीज़ (नीचे-घुटने के एम्प्यूटीज़) की तुलना में गिरने का अधिक जोखिम होता है। इसके अलावा, ट्रांसफेमोरल एम्प्यूटीज़ में अक्सर पैर के अंगूठे की सतह से दूरी कम हो जाती है, जिसके परिणामस्वरूप ट्रिपिंग से संबंधित गिरावट होती है और गिरने का खतरा बढ़ जाता है। प्रत्याशित कम पैर के अंगूठे की सतह से दूरी की क्षतिपूर्ति करने के लिए, ट्रांसफेमोरल एम्प्यूटीज़ विभिन्न रणनीतियों को अपनाते हैं जैसे कि वॉल्टिंग, पर्यावर्तन और हिप-हाइकिंग। लेकिन, पैर के अंगूठे की सतह से दूरी को बढ़ाने के लिए ये सभी तकनीकें अवांछनीय चाल विचलन को लागू करती हैं और समग्र चलने की क्षमता को खराब करती हैं।

पैर के अंगूठे की सतह से दूरी, विशेष रूप से न्यूनतम अंगूठे की सतह से दूरी (एमटीसी), टखने के जोड़ के कोणीय रोटेशन के लिए सबसे अधिक संवेदनशील होती है, इसके बाद कूल्हे के जोड़ और अंत में, घुटने के जोड़। इसलिए, शोधकर्ता एमटीसी में सुधार के लिए उन्नत सक्रिय रूप से टखने के जोड़ों को डिजाइन करने पर ध्यान केंद्रित कर रहे हैं। हालांकि, इन उन्नत तकनीकों की उच्च लागत के कारण, वे विकासशील देशों में गरीब या निम्न-मध्यम-वर्गीय समुदाय-निवासी लोगों के बीच दुर्लभ हैं। इसलिए, बायोमेकेनिकल रूप से उपयुक्त पुनर्वास तकनीक विकसित करना

अत्यंत महत्वपूर्ण है, जो कम लागत वाले निष्क्रिय ट्रांसफेमोरल कृत्रिम अंग में पैर के अंगूठे की सतह से दूरी को बढ़ाने का दावा करता है। इसलिए, वर्तमान थीसिस का उद्देश्य चाल पुनर्वास के अनुसंधान क्षेत्र में योगदान करने के साथ कम लागत वाले निष्क्रिय ट्रांसफेमोरल कृत्रिम अंग में बायोमैकेनिकल रूप से उपयुक्त पुनर्वास तकनीकों का उपयोग करके पैर के अंगूठे की सतह से दूरी बढ़ाने का था।

इस थीसिस में, मैंने एमटीसी और संबंधित अंगूठे की सतह से दूरी मापदंडों पर सीओपी विस्थापन के प्रभाव की जांच की थी। परिवर्तित एमटीसी और संबंधित पैर के अंगूठे की सतह से दूरी मापदंडों के लिए जिम्मेदार स्विंग चरण संयुक्त कोण मॉड्यूलन का व्यापक विश्लेषण भी किया था। एक नया सीओपी-आधारित फीडबैक सिस्टम विकसित किया गया था जिसमें क्रमशः वास्तविक समय में अंगूठे की सतह से दूरी और सीओपी माप के लिए उपकरण वाले जूते और दबाव इन्सोल शामिल था। डेटा को छह सक्षम प्रतिभागियों और तीन एकतरफा ट्रांसफेमोरल एम्प्यूटियों से एकत्र किया गया था। प्रयोग तीन अलग-अलग वॉकिंग सेशन- बेसलाइन, फीडबैक और रिटेंशन के दौरान आयोजित किया गया था, जबकि प्रतिभागी ट्रेडमिल पर चलते थे। बेसलाइन सत्र के दौरान, बिना किसी प्रतिक्रिया के अप्रतिबंधित चलने के दौरान डेटा प्राप्त किया गया था। इसके बाद, फीडबैक सत्र के दौरान, प्रतिभागियों से कहा गया था कि वे सीओपी को आगे/पीछे एडी का सतह से स्पर्श पर स्थानांतरित करें ताकि प्रतिभागी की दृष्टि के सामने रखी गई मॉनिटर स्क्रीन के माध्यम से प्रदान की गई दृश्य प्रतिक्रिया का उपयोग करके सीओपी के लक्ष्य स्थान से मिलान किया जा सके। अंत में, अंगूठे की सतह से दूरी पर प्रशिक्षण के स्थायी प्रभाव का आकलन करने के लिए, एक प्रतिधारण सत्र आयोजित किया गया था।

फीडबैक के दौरान, सीओपी में पीछे की ओर बदलाव ने सक्षम प्रतिभागियों में एमटीसी को 8.6 ± 0.8 सेमी से 6.12 ± 0.6 सेमी ($p < 0.029$) में काफी सुधार किया। एमटीसी में इसी

तरह का महत्वपूर्ण सुधार 8.60 ± 0.99 सेमी से 9.62 ± 0.96 सेमी तक सीओपी के पीछे की शिफ्ट के दौरान एम्प्यूटीज़ में देखा गया था। एमटीसी के अलावा, मैक्सटीसी १ और मैक्सटीसी २ ने भी सक्षम प्रतिभागियों और एम्प्यूटीज़ में सीओपी की पिछली पारी के दौरान एक महत्वपूर्ण वृद्धि ($p < 0.029$) दिखाई। इसके अलावा, प्रतिधारण के दौरान, एमटीसी एम्प्यूटीज़ में फीडबैक स्थितियों से भिन्न नहीं था ($p > 0.09$), फीडबैक प्रशिक्षण के सक्रिय सीखने का सुझाव देता है। मध्य-स्विंग चरण के दौरान पीछे सीओपी विस्थापन फीडबैक से बेसलाइन की तुलना में, एम्प्यूटीज़ में कूल्हे और घुटने के लचीलेपन के कोण में क्रमशः 11.99 ± 0.92 डिग्री और 11.86 ± 0.36 डिग्री, जबकि सक्षम प्रतिभागियों में टखने का पृष्ठीय मोड़, कूल्हे और घुटने के लचीलेपन के कोण में क्रमशः 3.60 ± 0.29 डिग्री, 3.22 ± 0.23 डिग्री, और 1.26 ± 0.12 डिग्री कोण देखा गया था। इसके अलावा, पूर्वकाल सीओपी विस्थापन फीडबैक के दौरान एक विपरीत गतिज अनुकूलन देखा गया था। चाल सुधार के साथ जुड़े एड़ी प्रहार मॉड्यूलन पर प्रोटोकॉल के बारे में पहले सबूत थे; हालांकि, यह पहला अध्ययन है जिसने सीओपी प्रोटोकॉल में पीछे विस्थापन को विकसित और मान्य किया है जिसमें निचले अंगों के एम्प्यूटीज़ में पैर के अंगूठे की सतह से न्यूनतम दूरी में सुधार हुआ है। इसके अलावा, वर्तमान कार्य ने निचले अंगों के जोड़ों में किनेमेटिक मॉड्यूलन का प्रदर्शन किया जो न्यूनतम अंगूठे की सतह से दूरी को बेहतर बनाने के लिए जिम्मेदार हो सकता है।

प्रस्तावित शोध कार्य ने एमटीसी में सुधार, सक्षम और विकलांग प्रतिभागियों में अधिकतम अंगूठे की सतह से दूरी में सीओपी की वास्तविक समय की दृश्य प्रतिक्रिया की एक महत्वपूर्ण क्षमता का प्रदर्शन किया। भविष्य में एक लंबा प्रशिक्षण के साथ एमटीसी को और भी बढ़ाया जा सकता है। इसके अलावा, दृश्य प्रतिक्रिया का एक सावधानीपूर्वक प्रतिस्थापन विब्रोटेक्टिल प्रतिक्रिया के लिए ट्रांसफ़ेमोरल और ट्रांसस्टिबियल एम्प्यूटीज़ में एमटीसी के लिए घर-आधारित चाल प्रशिक्षण का दावा कर सकता है।

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LIST OF ABBREVIATIONS

LLA	Lower limb amputation
CoP	Center of pressure
CoM	Center of mass
RoM	Range of motion
vGRF	Vertical ground reaction force
SACH	Solid ankle cushion heel
mTC	Minimum toe clearance
maxTC ₁	First maximum toe clearance
maxTC ₂	Second maximum toe clearance
GC	Gait cycle
TLA	Trailing limb angle
IMU	Inertial measurement unit
IR	Infra-red
FGA	Foot-to-ground angle
LED	Light emitting diode
PSD	Position sensitive device
CCD	Charge-coupled device
LoS	Line of sight
FSR	Force sensitive resistor
UTM	Universal testing machine
RMSE	Root mean square error
PVC	Poly vinyl chloride
AP	Anteroposterior
ML	Mediolateral
DAQ	Data acquisition unit
TTL	Transistor-transistor level

FedAntCoP	Anterior CoP shift feedback
FedPostCoP	Posterior CoP shift feedback
RetAntCoP	Anterior CoP shift retention
RetPostCoP	Posterior CoP shift retention
PFedAntCoP	Anterior CoP shift post feedback
PFedPostCoP	Posterior CoP shift post feedback
HS	Heel strike
TO	Toe-off
IS	Initial swing
TS	Terminal swing
FF	Flat foot
SD	Standard deviation