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Quantitative and Qualitative Comparison of a New Prosthetic Suspension System with Two Existing Suspension Systems for Lower Limb Amputees

Transtibial prosthetic designs incorporate suspension systems consisting of liners and coupling components. Manufacturers continuously seek improvement in prosthetic components.[1,2] The contours and buildups on the polyethylene foam liner (Pelite) worn inside the prosthetic hard socket help retain the prosthesis. A belt or strap also sometimes provides an extra means of security. Suspension sleeves, pulled over the prosthesis to give extra suspension, were introduced as an added feature, and later, silicone liners were invented to improve suspension by establishing a firm bond between the residual limb and the liner.[3,4] Internal pin lock systems and, recently, single or multiple hypobaric seals around the liners were developed as alternatives to external accessories. Improved suspension has been reported in objective and subjective studies as an advantage of silicone liners.[4] Silicone liners are less bulky than other types of suspension. Enhanced suspension and cosmesis have produced higher satisfaction rates among transtibial amputees.[5,6]

Satisfaction is said to be correlated with low piston motion, decreased unwanted sounds during functional tasks, and ease of don and doff.[7Y9] A suspension system should not only retain the prosthesis to the residual limb but also provide comfort, enhanced function, and ease of don and doff. The ease and simplicity of donning and doffing are of critical importance among prosthetic users.[10,11] The users have reported difficulty in the proper alignment of pins in the pin lock systems. These systems may also cause a phenomenon called Bmilking[caused by tissue stretch at the pin site, particularly during the swing phase of gait.[12,13] This milking might be the cause of pain and discomfort at the distal end of the residual limb, particularly during swing.

Researchers have investigated the pros and cons of different transtibial suspension systems both objectively and subjectively. The studies have targeted different determinants of successful prosthetic provision; lack of pistoning has been one of the main variables that indicate proper socket fit.[14] Some research studies have shown preferences for the pin lock and suction systems with total-surfaceY bearing sockets over the polyethylene foam liners used with patellar tendonYbearing sockets,[4,7,15,16] which exert high pressures on the residual limb.

Pistoning is defined as the vertical displacement mainly occurring within the prosthetic socket either between the residual limb and the liner or between the liner and socket wall.[17] Improper suspension might result in residual limb skin problems, gait deviations, and discomfort.[8,18] Several methods have been used for measuring the pistoning inside the prosthetic socket.[16] This has been mostly conducted by radiography,[8,18] ultrasound,[19] and computerized tomography.[20] A recent method used a photographic technique for evaluation of piston motion between the liner and the socket.[21,22] Finally, the use of motion analysis systems by reflective markers was recently introduced to measure pistoning.[7] The very same method was adopted in this study to evaluate the effect of the newly designed suspension system on pistoning.[7] Pistoning measurement has been mostly performed through gait simulation because either evaluation during the real gait had been detrimental to the amputee or some technical limitations hindered the measurement during the real gait.[1]

Qualitative surveys in the field of prosthetics have frequently used the Prosthesis Evaluation Questionnaire (PEQ) to investigate the effects of prostheses on the quality-of-life among individuals with amputation. Good reliability and validity have

been reported for the PEQ.[23] The PEQ research on prosthesis satisfaction has revealed that donning and doffing might play important roles in amputees' satisfaction.[24]

Although silicone suspension systems such as the pin lock and the hypobaric seal-in liners are said to provide enhanced suspension for lower limb prostheses,[4] some disadvantages such as increased pain at the residual limb and difficulty of donning and doffing are also attributed to them.[7] To overcome some of the disadvantages of the pin lock and suction suspension systems, the authors of the current study invented, produced, and evaluated a new prosthetic suspension system compared with the pin lock and suction systems. The purposes of this study were to compare the new suspension system with the two existing methods of suspension in the pistoning motion between the prosthetic liner and the socket and to compare satisfaction and perceived problems of transtibial amputees. The authors hypothesized that the new suspension system will cause less pistoning compared with the pin lock system, whereas the resultant pistoning will be higher than that of the suction suspension system. The authors' other hypothesis was that there will be a significant increase in satisfaction rates with the new suspension system than with the other two systems.

METHODS

Participants

Ten individuals with transtibial amputation were selected as a convenience sample to participate in this prospective study. The inclusion criteria were unilateral transtibial amputation, activity levels of K2YK3 according to the American Academy of Orthotists & Prosthetists,[25] residual limbs free of wound and pain, no upper limb disability, experience with silicone liners, no volume fluctuation

in the residual limb, and the ability to ambulate independently. The stump length, measured from the inferior edge of the patella to the distal end of the stump, had to be no less than 13 cm. All participants used transtibial prostheses with the pin lock suspension system before the initiation of this study. Table 1 lists the individual characteristics of all subjects. The University of Malaya Ethics Committee approved this research study. The subjects were required to sign a consent form to enter this study, and the researchers considered each subject as his own control.

Three prostheses were fabricated for each subject by a single registered prosthetist to ensure uniform design, alignment, and fit. Three suspension systems were selected, including the new lower limb suspension design (Fig. 1). The other two systems were (1) the shuttle lock and pin (Dermo Liner with Icelock-clutch 4 H214 L 214000) and (2) the suction suspension (Seal-In X5 Liner with Icelock Expulsion Valve 551). Other prosthetic components were common among the three prostheses (Flex-Foot Talux and Tube adaptor).

Transparent thermoplastic material ensured that the sockets were total-surface bearing[7] and had visible walls, through which the researchers could detect the internal features. The processes of checkout, gait evaluation, and gait training were performed in the Brace & Limb Laboratory, University of Malaya. Furthermore, the PEQ required at least 1 mo of prosthetic use for each prosthetic type to allow for adaptation to the new prostheses.