DEVELOPMENT OF PROSTHETIC KNEE TECHNOLOGY FOR TRANS-FEMORAL AMPUTEES IN DEVELOPING NATIONS

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INTRODUCTION

A survey of prosthetic solutions for trans-femoral amputees in developing countries indicates that most current options are poorly engineered with inadequate incorporation of basic biomechanical principles for the attainment of high quality gait outcomes. High patient acceptance levels of current technology (Jensen et al., 2004; Jensen, 2004) must not be taken as a license to deploy poorly engineered and constructed prostheses in these regions. Researchers at LeTourneau University have developed a prototype prosthetic knee unit aimed at providing users in the developing world with an affordable solution without sacrificing functionality. Through a program of structured product development with feedback from key stakeholders, this knee will provide a sustainable component which is low cost, locally manufactured and should significantly improve the gait of users.

METHOD

A four step process of product development with integrated feedback was adopted (Figure 1). Firstly, a prototype knee unit was designed and fabricated. This involved consideration of materials and mechanical function, as well as design for manufacturability. Much consideration was given to well-regarded US knees and the embodiment of their operational principals in a lower cost, locally manufacturable design.

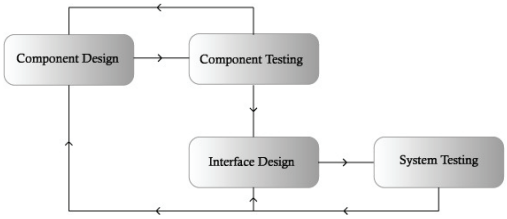

Figure 1: Development Method Flowchart

Having established a prototype knee design, consideration then turned to validation of the design through physical testing under laboratory conditions. The first stage of this work was assessment of the unit for mechanical strength, wear and fatigue. The testing program was developed from the guidelines of ISO 10328. After validating the knee as an isolated component, focus was shifted to evaluation of the knee as part of a full transfemoral prosthesis. A comparative laboratory-based study is being conducted with the assistance of US subjects comparing their current US prosthesis with a new limb incorporating the prototype knee unit. Comparative evaluations are conducted using the university's gait lab with a Motion Analysis Falcon camera system and a multi-axial Bertec forceplate. Markers are placed on subjects using a modified Helen Hayes marker set. EMG data is also collected during the gait trials to assess muscular adaptations with the new prosthesis.

Finally, the field performance of the knee is being assessed through a limited deployment program in Kenya, Sierra Leone and Bangladesh. Limbs incorporating the knee will be worn by the participants for a period of up to five years. Durability of the knee design is assessed through annual inspections by project personnel. Patient functionality outcomes are also assessed annually through a simplified field gait analysis system. Local manufacturability is assessed by training local clinic staff to fabricate the knee and then periodically reviewing production outcomes.

RESULTS AND DISCUSSION

Initial static testing of the knee was positive, with the knee successfully passing both loading conditions for static compression loading under ISO10328. Compliant fatigue testing of the knee is ongoing. An initial gait comparison assessment was conducted with a 16 year old female subject who is currently using a modified ischial containment socket, an Ossur 4-bar knee with extension bias, and an Ossur single axis foot. Preliminary data for the two prostheses indicates close correlation of both kinetic and kinematic gait parameters. Further work is scheduled to confirm these observed similarities. 26 amputees are currently participating in the field assessment program. In May 2006, 15 knees which had been in service in Kenya for twelve months were surveyed for wear and durability, and an additional six were assessed in Bangladesh in March 2007. All knees displayed minimal wear and retained proper motion without restriction. The 15 Kenyan knees had been manufactured by local clinic personnel, confirming the feasibility of producing the knees onsite. Preliminary results from the field gait system in Bangladesh have shown it to provide reliable data on patient gait outcomes. Development of protocols for the clinical application of this data is continuing.

Outcomes to date indicate that the LEGS knee offers a combination of high end-user functionality, rugged durability, low cost and an ability to be manufactured within developing countries. Further testing of knee influences on patient biomechanics are ongoing, as well as field evaluation of patient outcomes.

REFERENCES

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