AUTOMATED MEASUREMENT AND DOCUMENTATION OF PROSTHETIC FUNCTION: SATISFYING INSURERS

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This presentation describes a device (iPecs™ - Intelligent Prosthetic Endoskeletal Component System from College Park Industries, Inc. – Fraser, MI) that allows continuous, unattended measurement of forces and moments transmitted to the prosthetic socket, as well as movement-related aspects of gait during real-world functional tasks. The device is intended to be compatible with existing endo component systems, and provide clinicians with objective measures relative to prosthetic functioning.

The field of prosthetics is advancing rapidly in terms of the application of materials, technology, and processes to prosthetic devices. Materials that are used in the production of prosthetic components have changed dramatically over the past decade, providing higher energy return or more energy dissipation\(^1\), as desired. Carbon-fiber and other composite prosthetic components are no longer considered exotic, and newer materials are always on the horizon. Active systems or those that ostensibly sense the wearer’s intentions with respect to movement – whether by surface myography or direct neural input – can provide output to terminal prosthetic devices. Hence, even the terms robotics, bionics, and biomimetics are becoming more commonly used by prosthetists.

One goal of the integration of newer materials and technologies into prosthetic devices is the return of the user to normal function. Although the apparent race to create the ideal prosthesis in terms of its potential to assist in returning patients to normal function continues, one interesting aspect of this push is the fact that there are limited available options for prosthetists with respect to objectively measuring prosthetic function. Currently, options such as gait laboratories and bulky load cells are impractical in terms of availability and cost.

One method often used by prosthetists to make decisions regarding the effects of component selection and alignment is Observational Gait Analysis (OGA), in which a prosthetist visually observes a patient’s gait after implementing a change. OGA is used clinically to assist in dynamic alignment and sometimes to evaluate prosthetic outcomes, but it is subjective and has been reported to have only moderate inter-observer reliability\(^2\). In effect, due to the subjective nature of OGA the results aren’t suitable for direct comparison between caregivers, as is the case with standardized measurements. Requesting input or feedback from patients regarding how they feel when wearing prosthesis – perhaps in an attempt to identify some of the perceived forces acting on the patient – is an additional source of information for the prosthetist. Yet it, too, is subjective.

As we move toward a more evidence-based model of practice, objective documentation of gait parameters conventionally analyzed using OGA could enhance the reliability of those measures.

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Miniaturization of electromechanical sensors, telemetry, and enhancements in software, have made it possible to build upon the pioneering research conducted by notable research groups to date \(^3\text{4,5,6,7}\) that have demonstrated an ability to measure pylon forces and moments. The uniqueness of the iPecs™ is that it is a state-of-the-art battery operated telemetric device capable of real-time measurement of forces and moments. Prosthetists can use it in their daily practice to supplement OGA, document mechanical outcomes, follow patient activity patterns (fig. 1), assist in the optimization of prosthetic alignment, and obtain adequate reimbursement by providing evidence of a variety of outcome measures.

![Figure 1. Serial patient activity monitoring capability of iPecs™ system](image)

Over the last 50 years, a number of dedicated and hard-working individuals have attempted to measure the forces and moments transmitted through the prosthetic pylon to the end-user, and have demonstrated that they can be resolved \(^3\text{4,5,6,7}\). The inclusion of this level of objective information, in conjunction with the subjective input of patients, could provide clinicians with insight into relationships between device selection, alignment and patient use. In addition, prosthetists could use the real-time feedback capability of the device to immediately view the effects of component selection, alignment changes or other factors, and make adjustments as necessary (fig. 2).

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As a further benefit, taking serial measurements of previously subjectively-rated aspects of gait could provide the prosthetist with a “functional blueprint” of their patients while using selected configurations of components and alignments. This would provide the prosthetist with a better understanding of their patients’ individual responses to various components; discriminating, objective outcomes metrics; and a way to document and substantiate the benefits received by patients. Ultimately, it could also help demonstrate the efficacy of the prosthetist’s clinical judgment. As a result of testing completed with this unobtrusive on-board device to date employing transtibial amputees, we agree with the statement made by Frossard (5), namely that “This outcome tends to highlight the need for individual-based rather than population-based biomechanical analyses of transfemoral amputees,” which is the intent of the device and the desire of prosthetists.