Integrated Sensor Systems for Assessment of Rehabilitation in Lower Extremity Amputees

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Abstract: The emergence of internal sensor systems for prosthetic gait assessment brings new perspective in the field of amputee rehabilitation outcomes measurement. Existing methods for determining the quality of prosthetic fit are limited. New technology using integrated sensor systems, such as the “iPecs”, may provide useful quantitative metrics for clinical and rehabilitation assessment of lower extremity amputees. These systems may prove essential for mobile monitoring and biomechanical evaluation.

Background: Amputations of the lower extremity are comparably widespread. Trans-tibial amputation alone has an annual incidence rate of roughly 13 in 100,000 Americans [1]. The main causes for such amputations are vascular conditions, such as those resulting from diabetes. With the expected higher prevalence rate of diabetes in the future, it is projected that the number of persons living with an amputation will double by the year 2050 [2]. Artificial limbs that replace the lost structure below the knee are necessary to enable standing and ambulation without crutches, and to facilitate the prevention of secondary ailments. Since socket fit and static alignment of prostheses are customized to the individual user, standardized quality measures are difficult to define and often result in high variability within the end products of prosthetist’s efforts.

The tools that have been used to assess the quality of prosthetic fit and performance capabilities include questionnaires, pedometers, accelerometers, and motion analysis. While each of these methods has a unique scope, all have some shortcomings with respect to subjectivity and reliability of long-term evaluation of outcomes. A new generation of integrated sensor units promises to provide precise and extensive mobile data that may be very useful in quantifying the relevant factors for amputees.

State of the Art: Prosthetics and Orthotics (P&O) is traditionally a trade that depends widely on the practitioner’s personal professional experience. While much of the manual labor that goes into building and fitting a prosthesis has been replaced by standardized solutions over the last decades, the crucial task of optimizing socket shape and static alignment of the prosthesis remains a domain of the prosthetist’s expertise and keen eye.

Accordingly, the consistent quality of prosthetic fittings can be questioned [3], especially in regions where skilled labor is scarce. In low income countries, for instance, as estimated by the World Health Organization (WHO), approximately 20,000 orthopedic technicians was needed in 2010, whereas only 300 technicians graduate annually from training centers [4]. Efficient methods to consistently achieve a proper alignment of the prosthesis are required to increase the quantity and quality of prosthetic provisions.

The consequent application of evidence based practice principles in the field has been hampered by the inevitably narrow bandwidth of research, leading to a lack of basic science. According to Geil et al. (2009), research in P&O relies on basic research from other disciplines if it relies on basic research at all. While this phenomenon is partly due to the relative youth of sophisticated P&O research, the applied nature of the field also lends itself to applied research [5].
One aspect is also the availability of dedicated tools for static alignment. Replacing some traditional analogous measuring devices with modern computer aided scanners and laser plumb lines has contributed to a reduction of the error variance [6], without however addressing the basic problem of obtaining objective information on the quality of fit during the rectification and optimization process. Promising methods to standardize prosthetic alignment algorithms based on accurate data collection have been proposed [7], but have not gained widespread popularity.

Similarly, the usefulness of motion analysis for the optimization of prosthetic gait pattern is evident, yet in everyday practice almost irrelevant due to the extensive equipment and time demands that cannot usually be accommodated (figure 1). Recently, the adaptation of miniaturized sensors for P&O purposes has changed this situation. Ayyappa et al. [8] states that current technology provides onboard gait laboratories as components of the prosthesis, which may allow practitioners to more intimately meet the needs of their patients.

The Future of integrated Gait Analysis: The option of integrating a sensor unit directly into the weight bearing structure is unique to the field of prosthetics, as any sensor that a non-amputated subject would be equipped with can merely be attached to the surface of the body, and is thus susceptible to various measurement errors. The onset of commercially available computer controlled prosthesis knee joints in the 1990s brought about the first miniaturized sensors that were required in order to deliver the input for the respective swing phase control or stance phase safety. The Otto Bock C-Leg features a set of strain gages inside the modular shin tube adapter and uses the obtained moment information during the ground contact phase to determine the actual segment of the gait cycle.

Based on essentially the same technology, various modular components have been introduced by different manufacturers. Initially, these devices were intended to be temporarily mounted into the prosthesis, and deliver gait data to help optimize the alignment. Considerations on weight and cost of these early generation sensor units did not suggest their permanence in the prosthesis.

The prospect of measuring online gait data independent of a gait laboratory is not without inherent difficulties. Apart from the question on validity of the data collection [9], it is most of all important to decide what exactly should be measured, and how this information can be useful for clinical purposes. The iPecs (Intelligent Prosthetic Endoskeletal Component System) by College Park Industries [10], for instance, is capable of measuring forces and moments in six degrees of freedom (figures 2, 3), most of which the practitioner may be challenged to use.

First studies that utilized this tool [11] restrained themselves to longitudinal comparisons of selected output values measured in different situations of prosthesis use. Arguably, these findings require additional information on how the parameters in question relate to practically relevant factors. Values which are correlated to desirable outcomes should be identified, as else the data remains useless in practice.

There exists a need for a reliable, objective assessment method to serve as the gold standard to compare outcomes from the iPecs or other integrated sensor systems. Conventional gait analysis may be suggested as the standard for comparison of data with these systems. This approach offers the possibility to identify significant parameters characteristic of amputee gait. Once these factors are
known, integrated sensor systems may be used to assess prosthetic gait in various environments which utilizes its mobile capabilities.

Discussion: Current force and moment sensor technology and their application in prosthetics offers unique insight to prosthetic gait by allowing the collection of objective data over extended periods of time, independent of the laboratory environment. Caution is recommended when interpreting the raw data without a well defined reference, in order to avoid merely having shifted the guessing to a more technical and costly level.

Provided that the available technology is capable of identifying clinical deviations in gait patterns, it can be projected that the hardware will be subsequently optimized to become lighter, less bulky, and more affordable. It is conceivable in the future that every prosthesis will be equipped with such a mobile gait lab, improving prosthetic fit and rehabilitation assessment of lower extremity amputees.

References


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