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Title

Obtaining Real-World Data to Generate Real-World Evidence for Prosthetic Devices

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None

Summary

One of the impediments in the provision of prosthetic devices for people with limb loss is a lack of outcomes data to inform regulatory decisions regarding the benefit of these prosthetic devices. Information about outcomes of people with lower limb absence is available in scientific publications, but numbers in these studies are generally small and there is a data bias towards high income countries. Moreover, there is no accepted standardized outcome measure that allows comparisons to be made. Hence, the synthesis of a plausible convincing argument for the provision of prosthetic services to individuals with lower limb absence is lacking. Furthermore, the quality improvement offered by the available services are not measured in a consistent manner. Assessing the success of amputee care approaches are generally done with lab-based/in-clinic methods which provides a limited perspective. Real world evidence (RWE) based approaches are needed to provide a better objective understanding of function achieved by the individuals with limb loss in their day-to-day life. Real world data and real-world evidence are becoming important aspects in medical device approval, as emphasized by the U.S. Food and Drug Administration (FDA). Transition of data acquisition into the real world offers a unique, previously inaccessible perspective of daily physical function.

Introduction/ basics

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Material method; implementation/ process

Real world data can be easily obtained from wearable mobile devices used during everyday life. Activity monitoring using triaxial accelerometers provides the opportunity to assess function in the free-living environment. Sensors are emerging that will provide measurements of wear time and activity to be recorded continuously throughout the day (Figure 1 and 2).

Results

Data from these sensors can be uploaded into the cloud daily. Individual function can be assessed and tracked over extended lengths of time up to 6 months. A dashboard is available to objectively demonstrate how function changes over time (Figure 3). This data can be monitored by a medical professional as a reimbursable service.

Discussion/ conclusion; conclusion for the practice

There is a need to measure and report objective patient outcomes. This data can support evidence-based decision making and enhance health care delivery. Development of functional outcome measures from real world data is key to quantifying the effects of rehabilitation and prosthetic treatment. Collection of real-world data places minimal burden on subjects and provides quantitative usage information previously inaccessible to clinicians. Increasing sensor affordability and data quality make clinical translation of this data possible. With objective data acquired in the free-living environment, marked improvement in outcomes can be achieved.

References

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