

Evidence-Based Practice for the Individual With Amputation

by Jason T. Kahle, CPO, and M. Jason Highsmith, DPT, CP, FAAOP

How many times have you gone to your prosthetist and asked questions about certain aspects of your prosthesis, such as, “What is the best knee for me? What knee will help give me stability, so I fall less? What is the lightest foot? What foot will help me run? Why should I try a different socket? What is the advantage of pin suspension or vacuum?”

Chances are, your prosthetist had a good answer for you. The answer was probably based on previous clinical experience (also known as “anecdotal” or “subjective” information or knowledge) or maybe because your prosthetist liked the marketed features of a particular knee, foot, socket, etc. Perhaps he or she has had good service from the company that provides the component. When it comes to socket design (the most important part of any prosthesis), the prosthetist’s reasoning for fitting you into a particular liner or suspension system is even more nebulous. So what determines whether your prosthetist is choosing the best reason for fitting you into an appropriate socket, or suspension, or foot, or knee?

Questions about the effectiveness of your prosthesis are very important. Therefore, the answers need to be grounded in a solid foundation. Unfortunately, many aspects of prosthetic care, as well as other medical care, are not always based in science (also known as “empirical” information or knowledge). However, the need to scientifically quantify the effectiveness of any medical care is important and we should always try to provide appropriate evidence for the use or selection of a particular treatment or intervention. This is referred to as “evidence-based” practice and prosthetic care is not exempt from such an objective, evidentiary basis.



Knowing the Terms

Patients need to familiarize themselves with three terms: Outcome Measures, Clinical Trial, and Evidence-Based Practice.

Outcome measures are the means a scientist or a clinician (prosthetist, PT, physician, etc.) may use to quantify a certain aspect of the performance of an intervention (in this case, prosthetic care). For example, if you try a new blood pressure medication (a new intervention), when you follow up with your physician, he or she will take a reading of your blood pressure (outcome measure) to determine the effectiveness of that medication. To use a prosthetic example, if you try a new knee to see if it makes you walk faster and safer, when you follow up with your prosthetist, he or she may ask how many times you fell and time you walking and then compare it to the previous knee. The knee would be the intervention and the number of falls and time test results would be the outcome measures of that intervention.

Clinical trial refers to a research study performed to prove if one intervention or treatment is superior to another. These types of studies are commonly the most rigorous and controlled means of collecting information (or data) from which to determine how one intervention/treatment fares in comparison to others. For example, if you

observe a subject’s (patient’s) ability to use two different knees in specific environments (like an obstacle course), and then compare them. This is a design we used in our 2008 study that observed the effectiveness of the C-Leg (a computer-controlled knee) when compared to non-computer-controlled knees.

Evidence-based practice is the art of providing prosthetic care (in this case) using current research evidence based on the outcome measures conducted in clinical trial research to guide the decisions that are made between a patient with an amputation and a prosthetist about their particular case. A prosthetist will use the information reported from a study to determine if a particular prosthetic component (such as a C-leg knee prosthesis) is safer (for instance) than another knee that might be considered as an option. This has traditionally been a pharmaceutical (drug company) model, but is being applied to prosthetic, physical therapy and other healthcare interventions as well. Evidence-based practice is widely recognized and sought after by many professional organizations, including the American Psychological Association, American Occupational Therapy Association, American Medical Association and the American Physical Therapy Association, to name a few. Recently, the National Institutes of Health, a federal organization that funds healthcare research, has gotten involved at a high level with requests to fund “comparative efficacy” (another name for clinical trials) research. Basically, the interest is to determine if X intervention is superior to Y intervention.

It is important to understand these terms because this is the basis from which decisions about all healthcare practice will be made, as mandated by Medicare (and other insurance companies). Therefore, whether or not you receive a certain knee or foot may one day have less to do with the decisions that you and your prosthetists agree on and more to do with available evidence to evaluate an aspect of prosthetic care. If an insurance company cannot find sufficient evidence that a particular prosthesis will improve your care, they may not approve it.

So Is Evidence-Based Practice Good or Bad?

The goal of evidence-based prosthetic practice is to deliver prosthetic care that is based in science rather than unsound, unfounded or anecdotal methods of choosing a particular aspect of the prosthesis. The problem is that there is most likely *not* evidence to support the effectiveness of a

prosthetic component or technique. There are many reasons for this. For example, the prosthetic profession is a very small industry and is disproportionately funded for research compared to the pharmaceutical research industry funding medical science. There are only a limited amount of prosthetic manufacturing companies compared to countless other medical industry-related companies.

Additionally, far more American citizens will face pathologically high blood pressure, cholesterol and glucose problems that require intervention from the pharmaceutical world than will those who suffer from loss of a limb. From a larger public health perspective, it makes more sense to fund research that will affect virtually everyone's health. Unfortunately, such a global public

Evidence-Based Technique	Outcome Measure	Method	Advantage	Disadvantage
Electronic Medical Records	Computerized electronic record-keeping.	This, in and of itself, is not an outcome measure. However, the information in your records can be used as outcome measures (e.g., measurements, sock ply, areas of breakdown, use of assistive devices, or subjective statements).	Organized, concise dictation and measurements on patient history that can be easily interpreted, referenced and shared among your MD, PT, case manager, etc.	Conversion to an electronic-based system from a paper-based system can be expensive and time-consuming for your prosthetist.
Hill/Stair Index	Ability to ascend/descend stairs & hills/ramps.	Videotape patients' ability to ascend/descend ramps/stairs and grading that ability.	Grades patients' ability to perform an activity of daily living that they would encounter in the community.	Some facilities may not have access to stairs and hills.
Stumbles/Falls	How many times a person has fallen in a given time.	Requires that the patient keep clear records of stumbles/falls and report to their prosthetist.	Reports a very important aspect of safety while using a prosthesis.	A patient should use a journal to record these events in detail (e.g., when it happened, what you were doing when it happened and frequency).
Heart Rate	Heart rate in a given task, like walking for 2 minutes.	Use of a heart rate monitor.	Delivers quantifiable data that is related to cardiovascular.	Is not always the most reliable method of qualifying cardiovascular health.
Rate of Perceived Exertion	Difficulty of a given task as defined by the patient.	The prosthetist asks a simple question as to how difficult a task is for the patient. The patient then gives a grade on a preset scale.	Delivers quantifiable data that is related to exertion.	Is not always the most reliable method of qualifying exertion.
2,4,6 Minute Walk Test	How far someone can walk within a given time period (e.g., 2, 4 or 6 minutes).	Timed test with a stopwatch.	Easily quantifiable, simple test.	Some patients can't walk for the required time. Some facilities have limited space.
Patient Evaluation Questionnaire	A patient's subjective opinion about the prosthesis and how it affects certain aspects of daily activities.	30-minute questionnaire related to daily living activities and your prosthesis.	Delivers a score for patients' subjective opinion regarding their prosthesis.	Information is subjective and interpretation can be ambiguous.
Step Counter	Device that attaches to a prosthesis that can count the number of steps taken.	Determines how much a patient is using one device over another.	Delivers an actual number for use of the prosthesis.	Not always an accurate depiction of how important a prosthesis is to a patient.
AMP Pro(sthesis)/AMP no Pro(sthesis)	Grades functional mobility with or without a prosthesis (e.g., walk, stand or transfer).	Physical mobility assessment by prosthetist, PT, MD.	Objective classification of mobility skills during certain tasks.	Time, understanding and application of the instrument can be subjective and ambiguous.



This patient is wearing a heart rate monitor (an outcome measure) while being evaluated.

health perspective relating to the directing of research funds in places other than amputee rehabilitation is not what a person with an amputation wants to hear. At the end of the day, there are only so many sources of funding available for researchers to pursue regarding prosthetic research compared to other fields of healthcare.

Interpretation of data can also be difficult to understand and apply to a specific case.

Understanding research can be confusing and require time, effort and knowledge to fully comprehend the implications of the available research. We recently had a certain insurance company “misinterpret” our data in a major published journal article because it benefitted them to not pay for this superior, much more expensive knee. We since have had that decision reversed, but the point is, it was open for interpretation (or in this case, misinterpretation). Furthermore, an article published in 2007 by Rubin & Parrish found that 70 percent of outcome studies had problematic conclusions not justified by the research design!

Because of these reasons, a certain component or technique may not have research support. In addition, bridging the gap between scientists and clinicians can sometimes be difficult. A certain component may not perform well under some conditions, but a patient may like it better, which is difficult for a scientist to understand and quantify. How a patient feels about a prosthesis or component can be the most important aspect of the prosthesis and should not be scientifically dismissed. Evidence-based practice should not be the only determining factor in choosing a prosthesis, and in many circumstances is not at all practical.

How Does This Affect Me?

If your prosthetist participates in evidence-based practice, he or she will use valid and reliable outcome measures. In other words, they will use already researched and proven methods to determine if a prosthesis is more effective in performing its intended function. The table on p. 27 outlines common outcome measures that you may encounter.

What Can I Do, and What Should I Know?

Your prosthetist is your best resource for applicable research. He or she can do the research for you and usually has the means to obtain journal articles about prosthetics or apply the above outcome measures to your case. It certainly helps if they are members of the American Academy of Orthotists and Prosthetists and the American Orthotic and Prosthetic Association because these memberships make resources more available to their members and they exist to support prosthetists (and orthotists) in many aspects of patient care.



We commonly order several feet when we fit our patients and test them using outcome measures to determine the best performance.

There are several resources for amputees to research the effectiveness of their prosthesis, or certain aspects of their prosthesis. The ACA Web site (amputee-coalition.org) and *inMotion* are great resources. Medline, or the National Library of Medicine, is a popular research site, but requires some knowledge of the topic and the site itself. It is mostly used by researchers and clinicians. Other Web sites such as oandp.com and 360oandp.com are great resources for prosthetists and patients alike. Remember, though, that there is a big difference between an advertisement and an independent research article. Be objective about the source of information.

Conclusion

Understanding that there is evidence-based research available, and that testing your prosthesis under clinical conditions is based on that research, is an important step to understanding evidence-based practice and outcome measures. The guidelines and protocols of using outcome measures are still in the beginning stages of evolution. However, it is the direction of practice that medical professionals will most likely soon be required to follow. Knowing the terms and implications of evidence-based practice to you as an individual is crucial to understanding how evidence-based practices will affect your prosthetic care.

References

Kahle JT, Highsmith MJ, Hubbard SL. Comparison of non-microprocessor knee mechanism versus C-Leg on Prosthesis Evaluation Questionnaire, stumbles, falls, walking tests, stair descent, and knee preference. *J Rehabil Res Dev.* 2008;45(1):1-14.

Rubin A., & Parrish D. Problematic phrases in the conclusions of published outcome studies. *Research on Social Work Practice,* 2007;17 (3):334-347.