

It is important to differentiate that the number of prostheses, socket replacements and supplies immediately following amputation is not consistent with the life cycle of a prosthesis once the patient and the prosthetic limb have become stabilized.^v

Therefore, if the question is; “how long will the prosthesis last right after amputation”, then in this case the accurate and correct answer would be between 6-months and 2-3 years.

However, once the residual limb has healed, atrophied and matured and the patient’s weight and physiological status has stabilized, from this point forward the reasonable useful life of a prosthesis is well established and consistent at 5-years.

Warranty versus Reasonable Useful Life

Another mitigating factor that can cause confusion to the Reasonable Useful Lifetime of a prosthesis is related to the warranty. A 3-year warranty is very common for major prosthetic functional components which directly relates to the International Organization for Standardization.

ISO 10328:2006 structural testing for the safety of a prosthesis requires 3 million cyclical applications of load to satisfy the required fatigue strength. German standards equate 3 million cycles with 3 years of prosthetic use and the UK system equates it to 5 years. However, *warranty does not equate to Reasonable Useful Lifetime*, simply because the warranty on a specific component has expired does not in any way set a standard of medical necessity to replace said component.

Replacement Socket

A third contributing factor to a misunderstanding related to a prosthetic life expectancy is a replacement socket. Although the prosthetic components have a reasonable useful lifetime of 5-years, due to normal and expected changes in the residual limb, the prosthetic socket may lose appropriate fit and function while the prosthetic components (foot, ankle, knee, hand, wrist, elbow etc.) are still functional and appropriate.

If there is a significant change in the patient’s residual limb, body weight or socket fit, the prosthetic socket may require replacement, which in turn is secured to the existing prosthetic components. Although the socket is considered a major component of the prosthesis, this can be confused and by some considered and counted as a new prosthesis, which it is not. A replacement socket is a custom component which is secured to the existing components of a prosthesis, so in these instances it is not a new prosthesis, but rather a replacement socket.

Studies and Peer Reviewed Published Evidence

Studies and science clearly establish overwhelmingly that 5 years is not only the reasonable useful life of a prosthesis, it is also what historical evidence validates.

A retrospective study of 14,400 prosthetic wearers over a 25-year time period established “*the average life of a prosthesis is about 5 years*”.^{vi} It is important to note that this benchmark study was done in 1982, and since that time the ISO standards for prosthetic components have increased and materials and technology for prosthetic devices have significantly improved, making prosthesis stronger, more durable and longer lasting.

A 2008 clinical study following 173 lower limb prosthetic wearers over a 10-year period and determined that trans-femoral amputees in this study on an average needed one new prosthesis every 10 years while trans-tibial amputees needed a new prosthesis every 7 years.^{vii}

Regulatory Standards

A prosthesis is classified by Medicare as Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS)^{viii, ix}.

Published regulatory standards for the replacement of a prosthetic device stipulate that a prosthesis that has been in continuous use has a reasonable useful lifetime of no less than 5 years.^{x, xi}

It is noteworthy that regulator standards provide exceptions to the 5-year RUL and provide guidance that the life expectancy of the prosthesis can be negatively affected by, but not limited to:^{xii}

- A change in the physiological condition of the patient; or
- Irreparable wear of the device or a part of the device; or
- The condition of the device, or part of the device requiring repairs and the cost of such repairs would be more than 60% of the cost of a replacement device, or of the part being replaced.

Conclusion, A Prosthesis Reasonable Life is 5-Years

The life cycle of a prosthesis over a patient's lifetime is well documented in regulatory standards as supported by historical, clinical and peer reviewed published evidence to be 5-years.

Although it is important to recognize that during this 5-year cycle that the patient will require supplies and replacement of consumable items as well as consideration for a replacement socket.

About the Author

Dale Berry, CP, FAAOP, LP is a licensed and certified prosthetist with over 40-years of clinical experience. Dale has authored 28 articles including peer reviewed studies, technical/clinical reviews and editorials and has been an invited guest lecturer at over 100 national and international scientific symposiums. Dale recently retired after 20-years as VP Clinical Operations for the largest provider of prosthesis in the USA and is now director of PXConsultation, a company dedicated to supporting and assisting Life Care Planners.

If you have questions about prosthetics, you can contact Dale directly at Dale.Berry@PXConsultation.com

i <https://www.georgiaprosthetics.com/how-long-will-a-prosthesis-last/>, <https://www.amputee-coalition.org/resources/prosthetic-faqs-for-the-new-amputee/>, <https://prostheticsolutions.com/patient-resources/faqs/how-long-does-a-prosthesis-last/>, <http://cpo.biz/patients/faq/prosthetics/>, <http://www.premierprosthetics.com/Frequently-Asked-Questions>, <http://unitedpando.com/faq-s.html>.

ii Esquenazi, Alberto, Rehabilitation After Amputation, Journal of the American Podiatric Medical Association, Volume 91, Number 1, January 2001

iii Va/Dod Clinical Practice Guideline for Rehabilitation of Lower Limb Amputation, January 2008

iv Va/Dod Clinical Practice Guideline for The Management of Upper Extremity Amputation Rehabilitation, Version 1.0, 2014

v Smith, D, et al, Prosthetic History, Prosthetic Charges, Functional Outcome of the Isolated, Traumatic Below-Knee Amputee, Journal of Trauma: Injury, Infection, and Critical Care: January 1995, Volume 38, Issue 1, P 44-47

vi Narang, C, Retrop; Retrospective study of 14,400 civilian disabled (new) treated over 25 years at an Artificial Limb Centre. P&O International, 1982, 6, 10-16

vii Nair, A. Analysis of prosthetic episodes in lower limb amputees, Prosthetics and Orthotics International, March 2008; 32(1): 42-49

viii Code of Federal Regulations, Title 42. Public Health, Chapter IV Section § 414.202

ix Code of Federal Regulations, Title 42. Public Health, Chapter IV, Section § 424.57

x Code of Federal Regulations, Title 42. Public Health, Chapter IV, Section § 414.230

xi Code of Federal Regulations, Title 42. Public Health, Chapter IV, Section § 414.210 (e), (5), (f)

xii Local Coverage Article: Lower Limb Prostheses - Policy Article (A52496)

Dale Allen Berry, CP, CP(c), LP, RTP, FAAOP

4204 Canoas Drive
Austin TX, 78730
612-810-1100

Dale.Berry@PXConsultation.com
www.PXConsultation.com

Experienced

- ✓ Certified by the American Board for Certification in Orthotics & Prosthetics as Prosthetist (CP002254)
- ✓ Certified by the Canadian Board for Certification of Prosthetists and Orthotists as a Prosthetist (CP 308) and as a Registered Technician (RTP2243).
- ✓ Fellow of the American Academy of Orthotists & Prosthetists (FAAOP)
- ✓ Licensed Prosthetist (LP) in Texas (#1830), Illinois (#211-000092) and Minnesota (#1027)
- ✓ Over 39 years of clinical care experience, 20 of those years as VP Clinical Operations for the largest provider of prosthesis in the nation with 800 clinics and 2,000 clinicians treating 1 Million patients per year.
- ✓ Invented advanced prosthetic assessment validation evaluation test, process & protocol, currently identified as industry standard and utilized by major insurance companies nationwide.
- ✓ Developed clinical operational procedure resulting in the approval of advanced computerized prosthesis for over 25,000 individuals with above knee amputation.



Expert

- ✓ Testified in over 3,500 ALJ cases related to prosthetic benefits and medical necessity verification.
- ✓ Prepared over 5,000 prosthetic life cost plans.
- ✓ Successfully appealed and overturned over 4,000 insurance denials for prosthetic devices and services.
- ✓ Extensive experience as defense & plaintiff prosthetic expert witness for deposition and in-court testimony.
- ✓ Authored 28 articles including peer reviewed studies, technical/clinical reviews and editorials.
- ✓ Invited Guest Lecturer at over 100 national and international scientific symposiums

Excellence

- ✓ Selected to serve as Chair for National Symposium at Walter Reed Army Medical Hospital to set procedure and policy to treat soldiers injured with above knee amputation
- ✓ Established Prosthetic Clinic at Albert Schweitzer Hospital in Haiti and served as Clinical Coordinator to treat over 4,000 amputees that lost limbs in the 2010 earthquake.
- ✓ Served as Team Leader in 2002 for Operation First Step, a humanitarian relief effort to establish a clinic in Kabul Afghanistan to treat victims that lost limbs from land mines.

