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Prosthetic Reasonable Use Life Replacement Cycle for Lower Limb Prosthetic Life Care Plans



By Dale Berry, CP, FAAOP

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NURSING DIAGNOSES TO CONSIDER NANDA-I 2021-2023

Risk for Disuse Syndrome. Susceptible to deterioration of body systems as the result of prescribed or unavoidable musculoskeletal inactivity, which may compromise health.

Risk for Infection. Susceptible to invasion and multiplication of pathogenic organisms, which may compromise health.

Impaired Physical Mobility: Limitation in independent, purposeful movement of the body or of one or more extremities.

A key factor for accurately calculating a Life Care Plan for an individual who has undergone amputation is the frequency of receiving a prosthesis; as the replacement cycle of lower limb prosthetics is an essential aspect for calculating an accurate Life Care Plan (Pomeranz et al, 2010). The challenge in identifying an accurate replacement cycle for lower limb prosthetics is a lack of current empirical and reliable evidence to validate and verify the reasonable useful life (RUL) of lower limb prosthetics.

An internet search provides wide-ranging anecdotal suggestions that a lower limb prosthesis can last anywhere from a few months to a few years (georgiaprosthetics.com),

between 3-5 years (Hopkinsmedicine.org), or several months to several years (amputee-coalition.org). It is imperative to establish whether online sources are void of identifying supporting evidence, references, or details to verify or validate these projected hypotheses for the life expectancy of a prosthesis.

Of greater significance, online references commonly provide a range of replacement, most commonly identified as 3-5 years, resulting in Life Care Planners then presuming a replacement cycle of 4 years. While there is no evidence provided or referenced to substantiate the projected range of 3-5 years, if it was assumed to be true, it is unknown what percentage are replaced in what year. For example, if 1% of prostheses were replaced at 3 years and 99% were replaced at 5 years, the average replacement cycle for a prosthesis would not be 4 years, it would be 4.98 years. This complete lack of transparency and detailed reference data, therefore, makes these online average replacement ranges unreliable and ineffective sources.

There are a limited number of peer-reviewed published studies addressing the topic of prosthetic replacement. The available studies are, however, outdated, do not relate to current prosthetic technology and techniques, and have contradictory conclusions. The largest study from 1982 followed 14,400 patients in India over 25 years (1954 to 1978) and concluded that "the average life of a prosthesis is about 5 years". (Narang). A 1999 study (Datta) followed 104 transtibial amputees in the United Kingdom between

the ages of 16-60 over a 10-year period and concluded that “results cannot be accurately applied universally.” A third study published in 2008 (Nair) analyzed 173 patients from the United Kingdom over a 10-year period and concluded that, on average, trans-femoral prosthetic wearers need one new prosthesis every 10 years and the trans-tibial prosthetic wearer needed one every 7 years, while acknowledging the study measured “provision” rather than “need”. A 2019 publication opined “A prosthesis may last for 5 to 7 years” without providing any data or reference as to how this projection was established. (O’Keefe)

For prosthetic care in the United States, a prosthesis is classified by Centers of Medicare and Medicare Services (CMS) as Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS). Regulatory standards for the replacement of a prosthetic device stipulate that a prosthesis that has been in continuous use has a Reasonable Useful Lifetime (RUL) of no less than 5 years.(CFR 414.210)

There are two exceptions to the CFR 414.210 RUL guidance. Benefits Improvement and Protection Act of 2000 amended §1834(h)(1) of the Social Security Act added provision (1834 (h)(1)(G)(i)) that requires benefit coverage for the replacement of prosthetic devices or any part of such devices, without regard to continuous use or useful lifetime restrictions, if an ordering physician determines that the replacement device, or replacement part of such a device, is necessary because of any of the following:

- (I) A change in the physiological condition of the patient.
- (II) An irreparable change in the condition of the device, or in a part of the device.
- (III) The condition of the device, or the part of the device, requires repairs and the cost of such repairs would be more than 60 percent of the cost of a replacement device.

Although these regulatory guidelines provide insight as to the criteria to justify and validate the replacement of a prosthesis, they do not provide any guidance as to a defined timeline when a replacement can, should, or might be expected.

Replacement Data Collection

To obtain an accurate and detailed insight into the RUL and/or replacement cycle for current technology lower limb prostheses, non-HIPPA protected data was collected during the prior authorization process for individuals seeking prosthetic replacement services through Worker’s Compensation from 2021 to 2022.

Data collection criteria were restricted to individuals with a Trans-tibial or Trans-femoral amputation with a prior authorization request to receive medically necessary services to replace an existing definitive prosthesis or socket. Data collected was limited to:

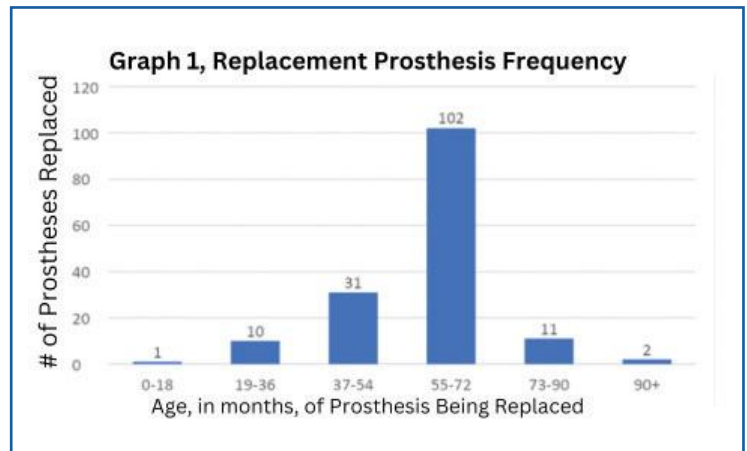
Table 1			
	Male	Female	Total
Prosthetic Wears	216	15	231
Age 18-40 in Years	32	0	32
Age 41-65	133	14	147
Age 66+	49	3	52
Trans Tibial Amputation	130	2	132
Trans Femoral Amputation	86	13	99
Replace Prosthesis	148	9	157
Replace Socket	68	6	74

- Patient Age at time of service (Range 23-87)
- Age of Current Prosthesis (Range 6-144 months)
- Service Provided:
 - Replacement Prosthesis
 - Socket Replacement

Replacement Prosthesis

Complete prosthetic replacement is deemed medically necessary when the prosthetic socket no longer accommodates the wearers’ residual limb and the prosthetic components are deemed irreparable, or the repairs would exceed 60 percent of the cost of a replacement device. A total of 157 of the prostheses in the study required a medically necessary replacement of the entire lower limb prosthesis.

Age of the prostheses being replaced ranged from 18 to 144 months with an overall average of 55.8 months. The majority (65%) of lower limb prostheses were replaced when they were between 55-72 months of age. (Graph 1).



For the transfemoral prostheses, 72% were replaced after an average of 62 months (Table 2) and for the transtibial prosthesis 61% were replaced on average at 63 months. (Table 3).

Table 2: Trans Femoral Replacement Prosthesis

Device Age in Weeks	# of Replacements	Average Months to Replace	%
0-18	0	0	0%
19-36	0	0	0%
37-54	14	48	23%
55-72	43	62	72%
73-90	2	74	3%
90+	1	144	2%
	60	61	

A total of 74 individuals were wearing sockets that required replacement ranging in age of socket from 6 to 121 months for an overall average replacement cycle of 32.3 months. For the transfemoral prosthesis, 39% of individuals required a socket replacement after 31 months on average (Table 4), and for the transtibial prosthesis, 61% required a replacement at 29.4 months on average. (Table 5).

Table 4: Trans Femoral Socket Replacement

Device Age in Weeks	# of Replacements	Average Months to Replace	%
0-12	1	6	4%
13-24	4	21	14%
25-36	11	31	39%
37-48	5	42	18%
49-60	1	59	4%
61+	6	79	21%
	28	42	

Table 3: Trans Tibial Replacement Prosthesis

Device Age in Weeks	# of Replacements	Average Months to Replace	%
0-18	1	18	1%
19-36	10	30	10%
37-54	17	47	18%
55-72	59	63	61%
73-90	9	79	9%
90+	1	98	1%
	97	58	

Table 5: Trans Tibial Socket Replacement

Device Age in Weeks	# of Replacements	Average Months to Replace	%
0-12	1	10	2%
13-24	10	19	22%
25-36	28	29	61%
37-48	6	39	13%
49-60	1	53	2%
61+	0	0	0%
	46	28	

Replacement Socket

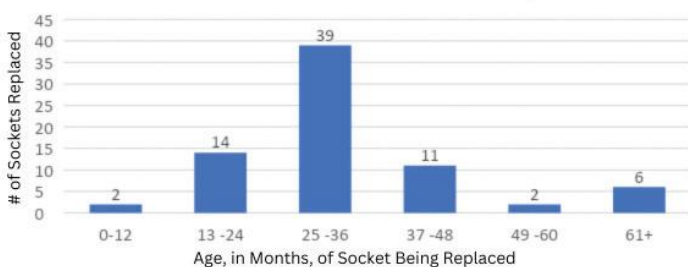
Due to normal and expected changes in the residual limb, the prosthetic socket may lose appropriate fit and function while the prosthetic components (knee, foot, ankle) are still functional and appropriate. In this event that the prosthetic socket is replaced and secured to the existing prosthetic components. (Graph 2)

Patient Age Influence on RUL

The age of the patient was determined to have a nominal influence on the replacement cycle for both the entire prosthesis and the socket. Prosthetic data was correlated in three age categories, ages 18 to 40, 41 to 65 and 66 years and above.

Prosthetic replacement of the 18-40 category was at a rate of 8 months sooner as compared to replacement prosthesis for prosthesis for wearers ages 66 years and over. The prosthetic replacement rate for the prosthesis was every 56 months from ages 18 to 40 as compared to a slower replacement rate of every 64 months after the age of 66. (Table 6).

Graph 2, Replacement Socket Frequency



The same relative calculations hold true for a replacement socket. The younger and assumed to be more active 18–40-year-olds required a socket replacement at 26 months on average while individuals the ages of 66 and older required a socket replacement on average every 30 months.

Considering that the average life expectancy for an 18-year-old male is 63.4 years (CDC Report), the accelerated replacement rates for both prostheses and sockets for the 22 years from age 18 to 40 are offset by the slower replacement rate of the 41 years from age 41 to 81.4 years. This establishes a lifetime average replacement rate of 59 months for the prosthesis and 29 months for the replacement socket.

Discussion

Although it can be accurately stated that a prosthesis can last anywhere from a few months to many years, this generic and generalized statement does not express nor represent an accurate or realistic insight for the reasonable useful life of a prosthesis. In addition, this indiscriminate range does not provide a foundation to establish or predict an accurate replacement cycle for a prosthesis.

Data collection identified that the younger age group (18-40) had a replacement rate faster than that of the old age group (66 years and older). However, over the prosthetic wearers’ predicted life span, the higher rate during the younger years would be offset by the slower replacement rate in the later years as the prosthetic wearers age. The net result is that the calculated lifespan average would be 59 months for a replacement prosthesis and 29 months for a replacement socket as shown on Table 6.

It is important to note that a new prosthesis includes a new socket, thus the replacement cycle for a replacement socket is, on average, 29 months after the individual receives a new prosthesis.

Conclusion

1. Majority of transfemoral (72%) and transtibial (61%) prosthesis are replaced between 55-72 months after the individual receives delivery of the device with an overall average of replacement of the prosthesis at 61 months and an patient-age influence prosthesis replacement average of 59 months.
2. Majority of transfemoral (39%) and transtibial (61%) sockets are replaced between 35-36 months after receiving the prosthesis with an overall average of 34 months with a patient-age influence socket replacement average of 29 months.
3. For a lower limb prosthesis, application of a lifetime replacement cycle of once every 60 months (5-years) is applicable.
4. For a lower limb replacement socket, application of a lifetime replacement cycle of one replacement socket at the half-life of the prosthesis is applicable.
5. For purpose of life care planning, a 5-year prosthetic life cycle for prostheses would include one (1) Prosthesis, one (1) Replacement Socket and three (3) incidents for Supplies and Maintenance. (Table 7)

Table 6

	Replacement Prosthesis	Replacement Socket
Patient Age in Years	Average Age in Months	Average Age in Months
18-40	56	26
41-65	58	31
66+	64	30
Patient-Age Influence	59	29

Table 7

Year 1: Months 0-12	Year 2: Months 13-24	Year 3: Months 25-36	Year 4: Months 37-48	Year 5: Months 49-60
				
New Prosthesis	Supplies & Maintenance	Replacement Socket	Supplies & Maintenance	Supplies & Maintenance

REFERENCES

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

Datta D, Vaidya SP, Alsindi Z. Analyses of prosthetic episodes in trans-tibial amputees. *Prosthet Orthot Int.* 1999 Apr;23(1):9-12

Nair, A. Hanspal. R. Zahedi, M. Saif, M. Fisher, K. (2008) Analysis of prosthetic episodes in lower limb amputees, *Prosthetics and Orthotics International*, March 2008; 32(1): 42-49

Narang I C, Jape V S. Retrospective study of 14,400 civilian disabled (new) treated over 25 years at an Artificial Limb Centre. *Prosthet Orthot Int* 1982; 6: 10–16

O’Keeffe, B, Rout, S. (2019) Prosthetic rehabilitation in the lower limb, *Indian Journal of Plastic Surgery*, 2019 Jan; 52(1): 134–143.

Pmeranz, J. Yu, N. Reid (2010) C. Role and Function Study of Life Care Planners. *Journal of Life Care Planning*, Special Edition 2010, Volume 9, Number 3 (57-106)

RUL Clarification, Revision Effective Date: 11/01/2013: <https://med.noridianmedicare.com/web/jadme/article-detail/-/view/2230703/reasonable-useful-lifetime-clarification>

U.S. Health & Human Services, Centers for Disease Control & Prevention, National Vital Statistics Reports, Vol. 71, No. 1, August 2, 2022