

Step-by-step: How D-Rev Calculates the Impact of the ReMotion Knee (v1)

The Need

The vast majority of the 1 million above-knee amputees living in low- and middle-income countries who need prosthetics each year do not have access to the devices they need to live more healthy, productive lives.¹

D-Rev's Intervention

By designing a low-cost, high-quality prosthetic knee that can be delivered through an economically self-sustaining distribution model, D-Rev aims to increase the availability and accessibility of quality prosthetics in underserved regions, and improve the health of amputees as a result.

Measuring Impact

To measure our progress in reaching amputees who need access to quality prosthetics, we track three main indicators:

1. Number of amputees fit
2. Number of amputees fit who otherwise would not have been fit with a comparable knee
3. Countries where ReMotion Knees have been sold

¹ Figure based on the following data:

- The vast majority of persons with physical disabilities in developing countries cannot access even basic rehabilitation services. [Source](#): "Guidelines for training personnel in developing countries for prosthetics and orthotics services." Geneva, WHO, 2005.
- The population of those living in low- and middle-income countries (LMIC) was 6.252 billion in 2016. [Source](#): World Bank.
- The incidence of amputation has an accepted base figure in the modern world of one to two amputees per 1,000 people in the population for all causes combined. D-Rev therefore assume an average of incidence rate of 0.15%. [Source](#): Staats, T. B. "The rehabilitation of the amputee in the developing world: a review of the literature." *Prosthetics and orthotics international* 20.1 (1996): 45-50.
- Of those living with limb loss globally, an estimated 31% are transfemoral amputees. [Source](#): World Health Organization, United States Department of Defense, and MossRehab Amputee Rehabilitation Program, "The rehabilitation of people with amputations." World Health Organization (2004).
- Average lifespan of a lower-limb prosthetic device is three years. [Source](#): Pearlman, Jon, et al. "Lower-limb prostheses and wheelchairs in low-income countries [an overview]." *IEEE Engineering in Medicine and Biology Magazine* 27.2 (2008).

*Calculation: [6,252,000,000 persons living in LMIC] * [Incidence of amputation of 0.15%] * [31% of those living with limb loss are above-knee amputees] / [3-year average lifespan for devices] = 969,060 above-knee amputees in LMIC in need of prosthetics each year*

During our clinical field trials, we also track the following:

4. Percentage of amputees fit who continue to wear their knee for a significant period of time after fitting (“Compliance Rate”)
5. Percentage of amputees who report experiencing no mechanical failures of their knee (“Non-failure Rate”)
6. Percentage of amputees fit who report being satisfied with their knee (“Satisfaction Rate”)

In the next sections are the steps that we take to calculate these impact values.

Indicator 1: Amputees fit

Overview

Where possible, we use actual clinic fitting data to calculate the number of amputees fit with our ReMotion Knee. In many cases, however, especially as the number of customer clinics grows, it is difficult for D-Rev to monitor fittings at every clinic, so the method below allows us to estimate the number of amputees fit with ReMotion Knees at those clinics from which we do not have actual data.

Survey data

To count amputees fit, we must first consider the varying lengths of time that it takes customer clinics to fit patient with the knees they have purchased. After a survey that D-Rev did of all ReMotion customers in December 2017, we found that 29% of the knees ordered by respondent customers had been fit to patients as of the date of the survey, within a median 32 days (average of 33 days) from the date of sale. Accordingly, unless we hear otherwise from customers, we assume that after 32 days, 29% of knees sold and shipped to customers will have been fit to patients. Furthermore, we assume that when a customer places a repeat order, all previously ordered knees have been fit to patients (again, unless we hear otherwise).

Key assumptions

#	Assumption	Current Value	Source of Current Value
(a)	Percentage of knees fit	29%	Survey of ReMotion Knee customers in December 2017
(b)	Number of days between sale and fitting	32 days	Survey of ReMotion Knee customers in December 2017
(c)	Percentage of knees from previous order fit once re-order has been placed	100%	Survey of ReMotion Knee customers in December 2017

(d)	Number of days between sale and fitting (distributors and other non-clinic customers only)	64 days	Assumption (b) multiplied by two. ²
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Example

A clinic places an order for 20 knees on June 1st. It takes 10 days for D-Rev to receive payment and ship the order, so the recorded sale date is June 11th. We assume no amputees will be fit with these knees until 32 days later, on July 13th, by which time we estimate six amputees (i.e., 29% of 20) will be fit with knees. Unless we gather actual fitting data from the clinic or the clinic places a reorder, we don't assume that any more amputees are fit with the remaining knees.³ If there is a reorder, however, we assume that amputees have been fit with the remaining knees as of the date of the repeat order.

Indicator 2: Amputees fit who otherwise would not have been fit (“Amputees Otherwise”)

Overview

With this indicator, we are measuring the incremental benefit that D-Rev has had on our target population, and trying to answer the question: how many of the amputees fit with ReMotion would not have had access to a knee of comparable quality if not for D-Rev’s design, marketing, and delivery of ReMotion?

There are two main considerations for when we classify an amputee as one who otherwise would not have been fit with a comparable device: (1) patient location; and (2) the alternative prosthetic knees otherwise available to the clinician/patient.

Patient location

Although there are amputees in need in High SDI countries (that is, countries in the highest category of the [socio-demographic index](#) created by the Institute for Health Metrics and Evaluation’s Global Burden of Disease Study), the systemic gaps in access are not as great as they are in lower SDI countries. For this reason, D-Rev does not currently classify any amputees fit in High SDI countries as “Amputees Otherwise”. We may re-evaluate this assumption in the future, however, if we see

² While no distributors responded to our December 2017 survey, we would expect fittings to be delayed when knees are purchased by a distributor rather than purchased directly by clinicians. Until distributor data are available, we will therefore assume that it takes twice as long for the same number of knees to be fit to patients when the knees are sold through a distributor.

³ We acknowledge that this method will likely “undercount” the number of amputees fit, and hope to capture more comprehensive fitting rate -- and timing -- data in the subsequent customer surveys.

compelling evidence that patients being fit with ReMotion Knee in High SDI countries lacked alternatives comparable in quality and price.

Quality of Existing or Available Prosthetic Knee

When amputees report previous use of a prosthetic knee, and indicate that the knee that they have used most recently is an exoskeletal knee (or a single-axis endoskeletal knee without a stability mechanism like a friction brake, e.g. the ICRC knee) then we consider them “Amputees Otherwise”, because these types of knees offer less functionality than the polycentric, endoskeletal ReMotion Knee.

Patients are also considered “Amputees Otherwise” if they had not previously worn a prosthetic knee, and the clinician indicates that they would have been fit with a knee of lower quality (i.e., an exoskeletal knee or single-axis knee endoskeletal knee without a stability mechanism), were it not for the ReMotion Knee.

Survey data

In a pilot study survey conducted by Bhagwan Mahaveer Viklang Sahayata Samiti (BMVSS, aka the Jaipur Foot Organization), in India in 2015-16, the prosthetist in charge, Dr. Pooja Mukul, found that 82 (57%) of the 143 amputees who were fit with a pre-release version of the ReMotion Knee met the criteria for “Amputees Otherwise”. That is, the patients fit into one of the following categories:

- Had used a prosthetic before, but the prosthetic used most recently was inferior (e.g., exoskeletal knee, or single-axis endoskeletal knee without a stability mechanism)
- Had never used a prosthetic knee before and, in the absence of the ReMotion Knee, would have been fit with an inferior knee (e.g., exoskeletal knee, or single-axis endoskeletal knee without a stability mechanism)

Amputees were not classified as “Amputees Otherwise” if they had previously been fit with a polycentric endoskeletal knee (e.g., Jaipur Knee or ReMotion Knee prototype).

We plan to survey additional clinics in the future for the data above; until then, we will use this 57% rate from the BMVSS pilot across all amputees fit with ReMotion Knees in non-High SDI countries to estimate the total number of amputees fit who otherwise would not have been fit with a knee of comparable quality.

Key assumptions

#	Assumption	Current Value	Source of Current Value
(e)	Percentage of amputees fit who would not otherwise	57%	Findings from pilot study survey of amputees fit in

	have been fit with comparable knee		India by BMVSS with a pre-release version of the ReMotion Knee in 2015-16.
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Example

A clinic that treats amputees in Guatemala (a Low-middle SDI country) places an order for 25 knees on August 15th. It takes 5 days for D-Rev to receive payment and ship the order, so the recorded sale date is August 20th. We assume no amputees will be fit with these knees until 32 days later, on September 21st, by which time we estimate that seven amputees will have been fit with knees. Four of these amputees (i.e., 57% of 7 amputees fit) will be assumed to be amputees who otherwise would not have been fit with a comparable knee (“Amputees Otherwise”).

Indicator 3: Countries where ReMotion Knees have been sold

Overview

We track the countries where purchasers intend to fit ReMotion Knees to understand breadth of availability and accessibility to our product. Orders (and their related countries) are not counted until the order has been paid for by the customer and shipped by D-Rev.

Example

A U.S.-based customer purchases 10 knees that they plan to take to a clinic in Ecuador to fit to amputees who live there. Upon payment and shipment of the order, we would count Ecuador -- not the United States -- as a country where ReMotion Knees have been sold.

Indicator 4: Percentage of amputees fit who are still wearing their knee for a significant period of time after fitting (“Compliance Rate”)

Overview

In medicine, compliance (also, “adherence”) describes the degree to which a patient correctly follows medical advice. Most commonly, it refers to medication or drug compliance, but it can also apply to other situations such as medical device use. When prosthetists, or those who measure, design, fabricate, fit, and service a prosthesis, study compliance, they are investigating whether or not amputees are wearing their prescribed prostheses, for how long, and perhaps if not, why not.

In a follow-up of the amputees fit by BMVSS with a pre-release version of the ReMotion Knee in 2015-16 (see survey mentioned above), we found that 89%, or 78 of 88 amputees who were contacted six months after their fittings, reported that

they were still wearing their (pre-release version) ReMotion Knees. We expect to see higher rates of compliance once we survey patients using the current version of the ReMotion Knee, which went on the market in August 2017.

For comparison, in a study by researchers Jensen and Raab of 62 above-knee amputees fit with ICRC and Otto Bock single-axis knees in Tanzania, clinicians measured a 98% compliance rate after 15 to 20 months.⁴ It should be noted that the amputees in this study consisted of younger amputees, and that the authors themselves acknowledge that the compliance rates they measured are among the highest achievable.

Key assumptions

#	Assumption	Current Value	Source of Current Value
(f)	Compliance Rate	89%	Findings from pilot study survey of amputees fit in India by BMVSS with a pre-release version of the ReMotion Knee in 2015-16

Indicator 5: Percentage of amputees who report experiencing no mechanical failures of their knee (“Non-failure Rate”)

Overview

Non-failure rate refers to the percentage of amputees whose knees gave no evidence of mechanical failures.

D-Rev has not field-tested failure rates of the version of the ReMotion Knee currently on the market, but preliminary data from customers indicate low failure rates. The clinic that has fit the most patients to date with the current version of the ReMotion Knee is The Range of Motion Project (ROMP), and of the seventy-three knees they ordered between August and December 2017, they have reported one failure to date. This translates into a failure rate of 1.4%. Because of limited data, this estimated failure rate should be seen as the lower bound of the actual failure rate; we will update our figures once more data are available.⁵

⁴ Jensen, J.S., and W. Raab. "Clinical field testing of trans-femoral prosthetic technologies: resin-wood and ICRC-polypropylene." *Prosthetics and Orthotics International* 28 (2004): 141-51.

⁵ D-Rev also tracks and responds to all reported complaints and failures on an ongoing basis, as required by the FDA.

For comparison, in the Jensen and Raab study mentioned above, 19% of patients experienced failures of function and stability related to the knee joint. [In other words, 81% of amputees did *not* experience failures in their knees.] ⁶

Key assumptions

#	Assumption	Current Value	Source of Current Value
(g)	Non-failure Rate	99%	Based on rate of failure (1.4%) reported the clinic who had fit the most amputees with ReMotion Knees as of March 2017.

Indicator 6: Percentage of amputees fit who report being satisfied with their knee (“Satisfaction Rate”)

Overview

The satisfaction rate refers to the percentage of amputees fit who self-report being satisfied with their knee in a verbal questionnaire where they had three options presented as a Likert-type scale: Dissatisfied, Neutral, or Satisfied.

In the pilot study of amputees fit with a pre-release version of the ReMotion Knee in 2015-16 by BMVSS, 83% (73 of 88), of amputees contacted six months after their fittings reported that they were satisfied with their ReMotion Knee. The other 17% (15 of 88) of amputees (a) reported being dissatisfied with the knee (3% or 3/88); (b) didn’t provide an answer (3% or 3/88) even though they reported using the knee; or (c) didn’t report satisfaction because they were not using the knee (10% or 9/88). We expect to see higher rates of satisfaction once we survey patients using the current version of the ReMotion Knee, which went on the market in August 2017.

For comparison, in the Jensen and Raab study mentioned above, 92% of patients reported being satisfied with their knees. It should be noted that the authors of this study acknowledge that the satisfaction rates they measured are among the highest achievable.

Key assumptions

#	Assumption	Current Value	Source of Current Value
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⁶ Notably, patients were studied over a longer time in this study: median periods of 15 and 20 months after fitting for the two groups studied. Because of time constraints in pilot study, follow-up in BMVSS study took place approximately six months after fitting.

(h)	Satisfaction Rate	83%	Findings from pilot study survey of amputees fit in India by BMVSS with a pre-release version of the ReMotion Knee in 2015-16
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Looking ahead

Our efforts to measure and understand the impact of our work and products are ongoing, and we are always looking to improve and refine our methods. We plan to undertake additional measurement and evaluation of the impact of the ReMotion Knee in 2018 and issue an updated Step-by-Step guide by December 31, 2018.

We make our impact measurement methods publicly available in the interest of transparency, but also so that we may learn from others. If you have any questions or comments, please email us at impact@d-rev.org.

More Resources

[Appropriate Prosthetic and Orthotic Technologies in Low Income Countries \(2000-2010\)](#). A report of the activities under the Agreement provided by the United States Agency for International Development (USAID) to the International Society for Prosthetics and Orthotics (ISPO). Authored by Dr J Steen Jensen MD DMSc and Sandra Sexton. Published by ISPO in December 2010.

[Guidelines for training personnel in developing countries for prosthetics and orthotics services](#). Authored by ISPO and World Health Organization (WHO). Published by WHO, 2005.