ANNUAL REPORT 2019

A shortened English version of the original Swedish annual report which can be found in original format at www.swedeamp.com

INDEX

SWEDISH NATIONAL QUALITY REGISTRIES

There are today more than 100 Swedish National Quality registries providing the Swedish health care system with a unique opportunity to monitor quality and results from real-life clinical data. Learn more about the organization here: https://kvalitetsregister.se/englishpages.2040.html

SwedeAmp, founded in 2011, is a national quality register for lower extremity amputations, including the subsequent care. The register covers the amputation procedure and its causes, prosthesis supply and rehabilitation, as well as patient-reported outcome measures. The register has a clear multidisciplinary focus.

THE OVERALL PURPOSE OF SWEDEAMP:

- To provide a foundation for improvements of the quality for the care regarding patients undergoing lower limb amputations
- To highlight the differences that occur in the process of care during amputation, prosthesis supply and rehabilitation
- To provide a foundation for the evaluation of amputation, prosthesis adaptation, prosthetic components and rehabilitation
- To provide a basis for cost analyses
- To provide a basis for communication within the multidisciplinary team
- To increase knowledge about the function and quality of life for individuals with lower limb amputations and to provide guidance when planning treatment for an individual patient.

SUMMARY 2019

This year's report includes data from just over 7,200 patients with just over 10,000 amputation procedures (Figure 1). The patient group is dominated by an elderly group of people with lower limb amputations due to diabetes and/or vascular diseases (84%), where most (93%) had other concomitant diseases or disabilities that were considered a complication to rehabilitation. Within 12 months of the amputation, 26% of patients with transtibial amputations and 41% of patients with transfemoral amputations had passed away.

This year's report confirms that a preserved knee joint provides the best conditions for prosthetic mobility. All outcomes reflecting aspects of function in use of a prosthesis point toward the same result. Patients with a transtibial amputation state to use the prosthesis more, have less need for walking aids and have better mobility, compared to patients with higher amputation levels. Patients with amputation due to diabetes and/or vascular disease generally state a poorer functional ability and use their prosthesis less than those with amputations due to other diagnoses. Compared to men, women have to a higher degree the amputation

diagnosis "vascular disease without diabetes", a larger proportion of amputations through or above the knee joint, and a higher average age at the procedure.

The most common level of amputation registered is a transtibial amputation, with sagittal flaps being the most common surgical technique. Postoperative compression treatment of the residual limb, using a liner, is usually started within 1-3 weeks after the amputation. Just over 1/3 of patients receive prostheses, with fitting taking place about 8 weeks after amputation (Md 58 days in year 2017-2019), which is two weeks faster than during the first period (Md 70 days in 2011-2013). At higher amputation levels, fewer patients receive prostheses and the time from amputation to fitting of the prosthesis is longer than for transtibial amputations.

The data represent patients residing in different parts of Sweden. However, the northern regions are not represented. The regions of Skåne, Stockholm, Västra Götaland and Östergötland together conduct 72% of the registrations. Skåne University Hospital (SUS) nearly has 100% coverage for amputation procedures on the lower extremity (including foot amputations) and several comparisons are therefore made between the register's total data and data from SUS. These analyses show great similarities but a larger proportion of forefoot amputations have been registered at SUS. This highlights that minor amputations, i.e. amputations of the toe and foot, are most probably underrepresented in the register. In the case of minor amputations, prosthesis supply and rehabilitation rarely occur and therefore those are currently not included in the PROM and follow-up data.

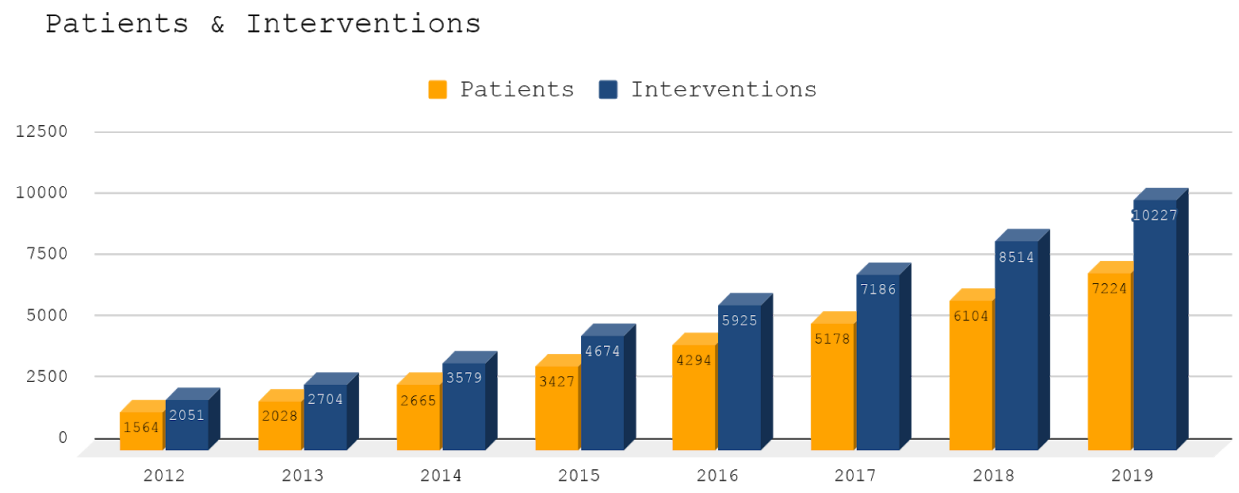


Figure 1. Development of the register. The number of registered patients and procedures performed up to and including 31 Dec 2019. The columns for 2012 also include registered surgical procedures performed before 2012.

In conclusion, fragile elderly people with amputations above the ankle dominate the register. For these, a large amount of robust data is available. Data for the much smaller group of patients with amputations for reasons other than dysvascular diseases (e.g trauma, tumor or sepsis), who are often significantly younger at the time of amputation, should be considered with caution until more data is available.

With this year's report, we hope to be able to contribute with valuable information for the continued improvement of the care of patients undergoing lower limb amputations in Sweden. Everyone who contributes with data to SwedeAmp is an important part of the puzzle.

Many thanks to you who register in SwedeAmp!

SwedeAmp Lund steering group, 2020-06-25

PREAMBLE

HEALTH CARE PATHWAY

Amputation of the lower extremity is often part of a long health care pathway which requires multidisciplinary engagement. For the majority of patients, the amputation occurs late in life due to vascular disease and/or diabetes and has usually been preceded by a longer period of illness, often with difficult-to-heal wounds. For a small group of patients, the amputation is performed earlier in life, e.g. due to trauma, tumour or sepsis. For everyone, however, the amputation means an irreversibly changed situation where multi-professional assessment and coordination is required to enable the patient to return to as normal a life as possible.

SwedeAmp intends to make visible and improve the complex Health care pathway after amputation of the lower extremity. On the website www.swedeamp.se there are examples of regional and local care guidelines under the tab RIKTLINJER (currently only available in Swedish).

At present, we are not aware of any other national register that so comprehensively includes all links in the Health care pathway in the event of a lower limb amputation. This makes SwedeAmp unique in its kind - also internationally.

(Link) to a short movie presentation for the Swedish quality register for amputations and prothesis.

Click image to watch video.

INCIDENCE AND COVERAGE

INCIDENCE

According to the National Board of Health and Welfare's database for inpatient surgeries, the total number of amputation procedures on the lower extremity (primary amputation and re-amputation, regardless of cause and amputation level) was between 33 and 39 per 100,000 inhabitants, during the period 1998-2016. The incidence varies a lot, both geographically and over time, as does the level of amputation. At present, it is not possible to comment on the reason for these differences. One of the overall purposes of the register is to try to find explanations for these.

DEGREE OF COLLABORATION TO THE REGISTER

By degree of collaboration, we are referring to the proportion of clinics that actively register data in SwedeAmp, in relation to existing clinics in Sweden. As SwedeAmp is a multidisciplinary register, the degree of collaboration is more than a single value. For surgical data, the degree of collaboration is 62% (13 of 21 regions) for patients with amputation at levels higher than the ankle. For surgical data, a region is considered active if it has 10 or more registered patient cases in 2019.

In Sweden, there are currently 30 P&O (Prosthetics & Orthotics) clinics who fit prosthetics. For these, the collaboration rate is 70%, i.e. 21 units have registered prosthesis data in SwedeAmp during the year 2019.

COVERAGE OF REGISTERING UNITS

Registration coverage is reported for transtibial amputations, which is the most common level of amputation. The coverage rate is calculated by comparing the register's data with the National Board of Health and Welfare's database for inpatient surgeries. This is based on the number of people and the diagnostic code "NGQ19 Transtibial Amputation". The regions that actively register surgical data in SwedeAmp had a coverage rate of 72% in 2019.

Comparative national statistics for prostheses and prosthetic sockets are lacking.

SwedeAmp has not yet reached full coverage. The clinics involved in prosthesis supply and prosthetic rehabilitation have adopted registration in SwedeAmp to a relatively high degree. This means that these specific patients are registered in good numbers. However, a large proportion of patients pass away within a short time after the amputation and many are not eligible for prosthesis supply and rehabilitation. It is important to note that amputation is often an acute or subacute life-saving procedure for a patient who is typically ageing and has multiple illnesses.

We call for a further increase in the coverage of surgical data, in particular, to gain more knowledge about the fragile group of patients who do not reach prosthetic rehabilitation. At Skåne University Hospital (SUS) there is close to 100% coverage for surgical data. This year's report, therefore, highlights data for several variables specific to SUS and compares it with all the data in SwedeAmp.

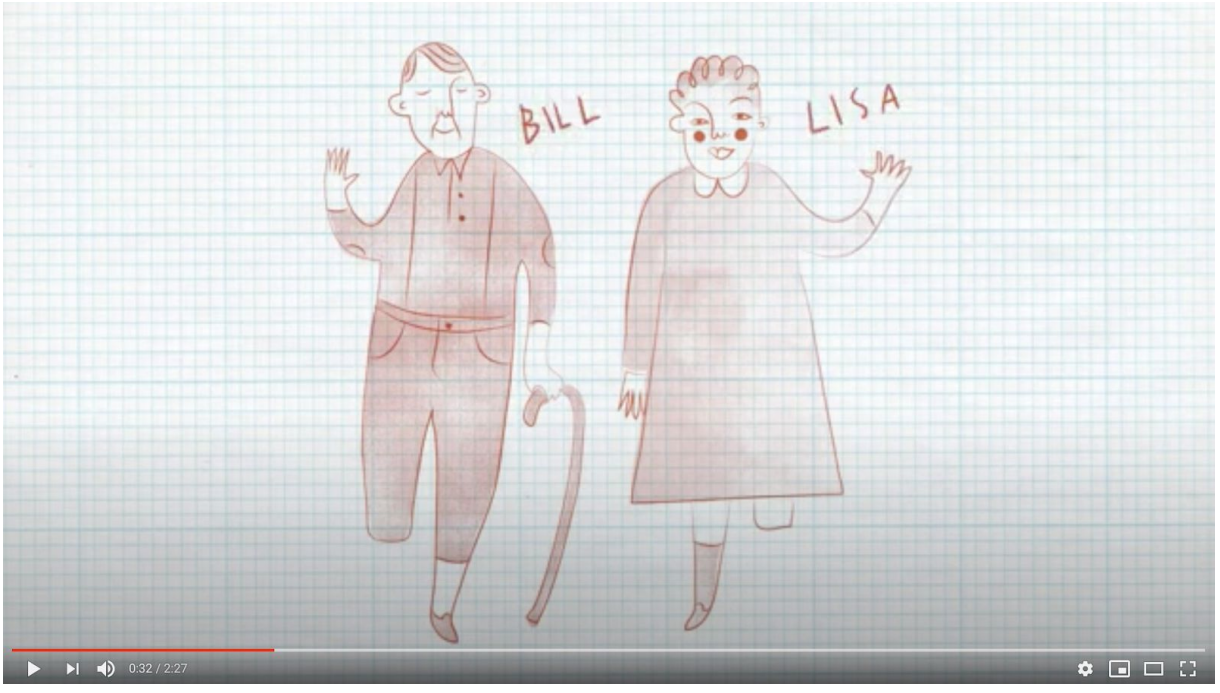
SWEDEAMP'S CONTRIBUTION VALUE

Today, different care providers, both private and public, document the care given with regard to an amputation and the subsequent rehabilitation. There is a complex interplay between several professional categories, where an evaluation of the end-result and its quality requires a massive basis of data and careful commentary. SwedeAmp provides access to a larger amount of aggregated data from the amputation, the prosthesis supply and the rehabilitation, than what each of these clinics themselves have access to. SwedeAmp points out the importance of interdisciplinary teamwork, which has led to local guidelines aimed to improve the care of individuals undergoing lower limb amputations.

PATIENT PERSPECTIVE

In SwedeAmp, patient-reported data (PROM – patient-reported outcome measures) is registered at follow-up 6, 12 and 24 months after the current amputation. These include outcomes, such as how much the prosthesis is used, mobility and the use of walking aids, but also issues of pain and health-related quality of life. This information is an important knowledge base of how the patient's situation is affected. With support from SwedeAmp data, caregivers can get a good basis for answering patients' questions. An easy-to-read short version of the 2018 annual report has been produced and can be given directly to patients and relatives. In 2019, the steering group was expanded with two new patient representatives.

An example of SwedeAmp's contribution value from a patient's perspective was made into a short video (link), created and published in 2015.



Click image to watch video.

CARE GUIDELINES

National guidelines regarding lower limb amputation care are lacking in Sweden. SwedeAmp has participated in initiatives to develop regional guidelines in Stockholm and Gothenburg. Both guidelines were published 2019 and are available on our website.

We also recommend various international guidelines, including:

- WHO Standards for Prosthetics and Orthotics Service Provision" (Link)
- Report on Major Lower Limb Amputations Due to Vascular Disease: A Multidisciplinary Approach to Surgery and Rehabilitation (link) from the International Society Prosthetics and Orthotics
- British Association of Chartered Physiotherapists in Amputee Rehabilitation (BACPAR)

QUALITY INDICATORS AND CARE IN NUMBERS

SwedeAmp is now presented at "*Vården i siffror*" (link). The quality indicators presented include:

- The proportions of transtibial amputations relative to transfemoral amputations
- The proportion of re-amputation after a primary transtibial amputation.
- The time from a transtibial amputation to receiving the first prosthesis.

A high proportion of primary transtibial amputations is desirable - but only if these do not also lead to a high proportion of re-amputations, as this means unnecessary suffering for patients, in addition to unnecessary costs to society. This example highlights the importance of reporting both indicators together. The indicator showing the number of days from primary amputation to the first prosthesis, aims to compare the healthcare process and efficiency and the patients' access to prosthesis supply in the country. This indicator can show regional differences in lead times and be remedied if resources are available.

DISSEMINATE KNOWLEDGE AND STIMULATE INTERDISCIPLINARY PROFESSIONAL COLLABORATION

Data from SwedeAmp's annual reports are used in various types of education. This applies to the training of care staff, but also to university-level educations (e.g. physiotherapists, surgeons and prosthetists)

SwedeAmp regularly arranges meetings where different professionals have the opportunity to meet and share each other's experiences. In 2019, two such meetings were arranged - one in Gothenburg and one in Malmö.

SCIENCE

The 2018 annual report is the basis for SwedeAmp's first scientific publication published in 2020. (Link)

Further scientific studies are currently ongoing and will be announced on the website as soon as accepted for publication.

STRUCTURE OF REGISTER

The register describes the Health care pathway in different steps and includes patient and amputation data, prosthesis data, the patient's situation before and after the amputation and mobility data. In practice, data is entered in 6 different forms (F1 - F6). The register enables lifelong follow-up. In short, each form includes the following information:

F1. Personal Data and Basic Amputation Data. Basic amputation data includes the Swedish social security number (also identifying sex), the level of amputation, side and date. With each new surgical procedure, a new registration is made in F1.

F2. The amputation procedure. Information about the procedure such as the type of procedure (primary amputation, re-amputation or surgical revision), cause of amputation, surgical method and complication prevention measures.

F3. The prosthesis. Description of the prosthesis supply, both for the first prosthesis for the current amputation level and any following prostheses.

F4. Baseline (PROM). Includes questions regarding the patient's situation before the acute deterioration, which lead to amputation. The questions are answered in connection with, or as soon as possible after the amputation, and concern housing, the use of walking aids and self-assessed mobility.

F5. Follow-up (PROM). Follow-up is registered for patients with an amputation above the ankle and is performed three times: 6, 12 and 24 months after the current amputation. Information include e.g. how much the prosthesis is used, the ability to independently put on and take off the prosthesis, use of walking aids, mobility with a prosthesis, presence of pain and general health.

F6. Mobility data. Objective measures of walking ability are registered here.

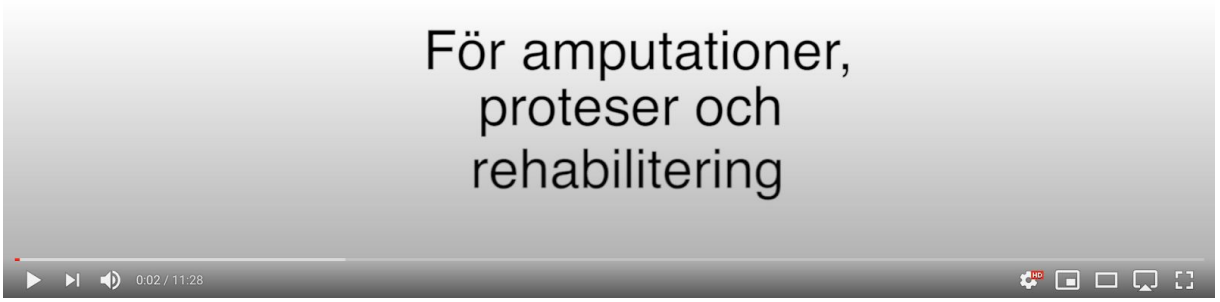
All data to be entered in the different forms 2-6 can be found in paper form on www.swedeamp.com under "vårdgivare"

For each new procedure on the same patient, the social security number, side, amputation level and amputation date must be registered in F1. With these four tasks completed, the various parts are linked so that other data can be entered and followed.

Data is registered with a personal login on a web-based national register platform at *Registercentrum Syd (RC Syd)* in Lund (link). Each user can register in all forms, but it is desirable that a surgical unit supply data regarding the amputation, the prosthesis supply is registered at a P&O unit, and a nurse, occupational therapist or physiotherapist register patient-reported data before and after the amputation. Each user can retrieve data from their own organization/clinic. On the website you will find more detailed information, a detailed manual (link) and an instructional video (link).

AMPUTATIONS- & PROTESREGISTER
för nedre extremiteten

Instructions for use



Click image to watch instruction video.

The Principle for SwedeAmp and patient data is Region Skåne.

STEERING GROUP MEMBERS 2019-2020

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Patient Representative

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BASIC DATA REGISTRATION

REGISTRATIONS UP TO AND INCLUDING 2019-12-31

All registrations

- 7224 patients
- 10227 interventions
- 3921 prosthetic registrations
- 2108 PROM registrations prior to amputation
- 2430 PROM registrations after amputation

Total patient and amputation data

- 7224 patients: 39% female (n=2840), 61% men (n=4384)
- 14% (n=1035) of the patients had bilateral amputations (defined as amputation through the metatarsals or higher on both sides).

Mortality

- 53% of all patients in the register since the start 2012 were no longer alive at the end of the year (n=3801)
- The proportion of deaths were higher for females (58%), than men (49%)
- Mortality within 6 months of the last registered primary amputation or re-amputation was 23%
- Mortality within 12 months of the last registered primary amputation or re-amputation was 30%
- Distribution of mortality per amputation level at 12 months:
  Transtibial amputation 26%, Knee disarticulation 40%, Transfemoral amputation 41%

Comment: This year's report generally shows a slightly higher mortality than in previous years. This can be explained by the fact that the number of registrations at surgical units has increased and thus the register now contains a higher proportion of patients who do not reach prosthesis rehabilitation and follow-up. Nearly a quarter of patients died within 6 months of the procedure. Mortality is higher at higher amputation levels.

PATIENT- AND AMPUTATION DATA

BASIC DATA

DOMICILE REGION

DOMICILE REGION AT FIRST REGISTERED PROCEDURE PER PATIENT	NUMBERS OF PATIENTS IN REGISTER	PROPORTION
Blekinge region	224	3%
Dalarnas region	333	5%
Gotlands region	94	1%
Gävleborgs Region	22	<1%
Hallands region	270	4%
Jönköpings region	344	5%
Kalmar region	100	1%
Kronobergs region	89	1%
Skåne region	2506	35%
Stockholms region	1081	15%
Södermanlands region	6	<1%
Uppsala region	108	2%
Värmlands region	8	<1%
Västmanlands region	93	1%
Västra Götalands region	1102	15%
Örebro region	302	4%
Östergötlands region	519	7%
Regions with < 5 registrations	6	<1%
Unknown region	17	<1%
Total	**7224**	

Table 1. The patients' domicile regions.

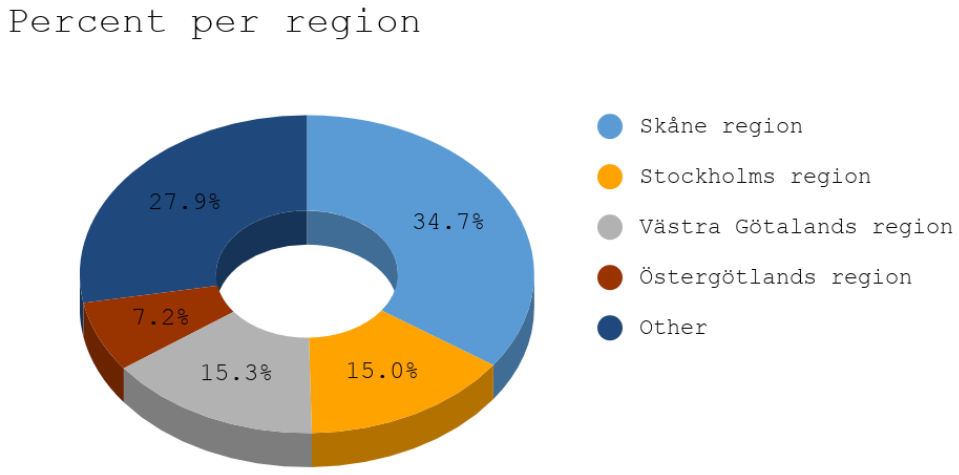


Figure 2. The patients' domicile regions at first registered procedure (%)

Comment: Most patients registered in SwedeAmp live in Region Skåne (35%), Västra Götaland region (15%) or Stockholm region (15%). Registration is still largely lacking for patients from northern Sweden.

AGE AND SEX

AGE AT FIRST REGISTERED PROCEDURE

SEX	AVERAGE (SD)	MEDIAN (min–max)	P-VALUE DIFFERENCE BETWEEN THE SEXES
Woman (n=2426)	78 (14.1)	81 (0 - 103)	p< 0.0001
Man (n=3646)	72 (14.4)	74 (0 - 102)	
Total (n=6072)	74 (14.5)	76 (0 - 103)	

Table 2: Age at the first registered procedure for men and women.

AGE GROUP BY SEX

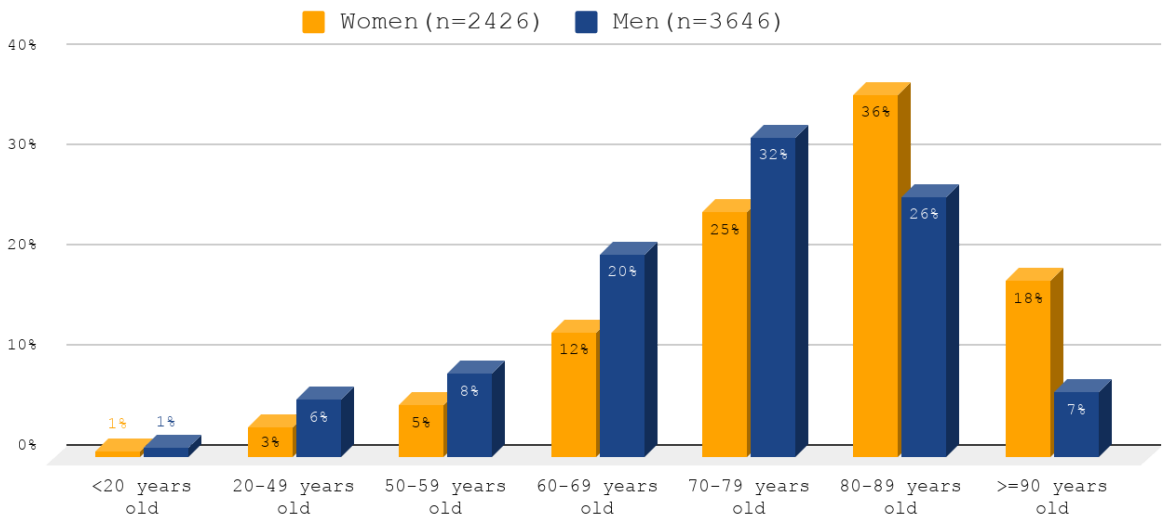


Figure 3: Age group distribution at primary amputation for women and men as a percentage (n = 6072)

Comment: Most amputations occur at an advanced age. Women are older than men at the time of amputation and dominate the two oldest age groups. The age difference between the sexes is statistically significant (p <0.0001).

DIAGNOSIS AND DIAGNOSTIC GROUPS (PER PATIENT)

The patient's underlying diagnosis at the time for amputation procedure (n = 6537)

- Diabetes with or without vascular disease (n=3118) 48%
- Arteriosclerosis without diabetes (n=2116) 32%
- Other vascular disease without diabetes (n=254) 4%
- Infection not related to diabetes or vascular disease (n=296) 5%
- Trauma (n=247) 4%
- Tumour (n=145) 2%
- Amputation due to congenital or acquired deformity (n=86) 1%
- Other reason (n=237) 4%
- Unknown diagnosis/not registered (n=38) <1%

DIAGNOSTIC GROUP BY SEX

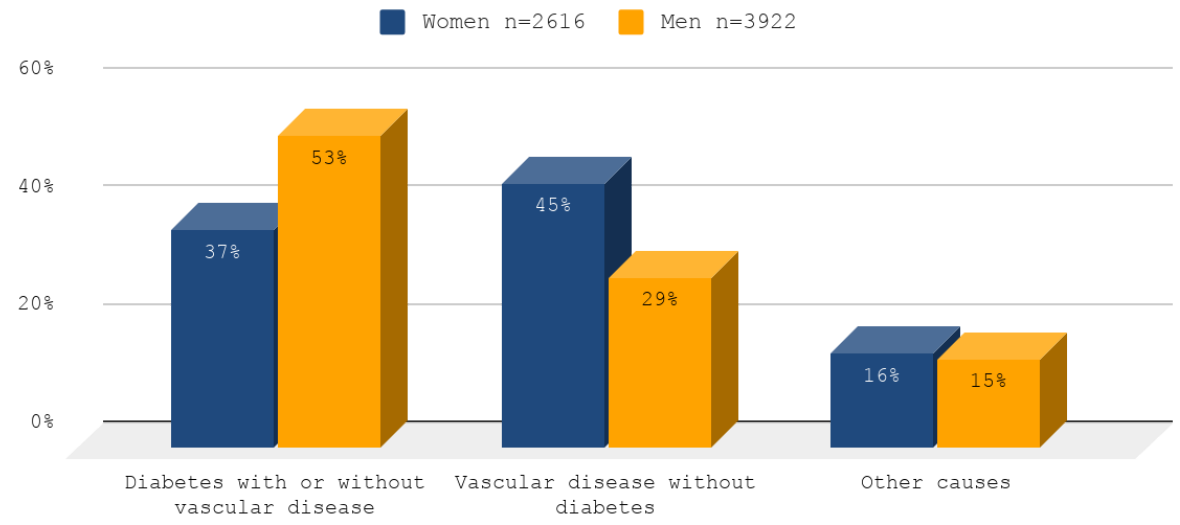


Figure 4: Diagnostic group distribution at amputation for women and men, % (P <0.0001).

Comment: Diabetes and/or vascular disease together make up 84% of all registered diagnoses at the amputation. In women, a vascular disease without diabetes is the most common diagnosis at amputation. In men, diabetes with/without vascular disease is the most common diagnosis. When the diagnosis of diabetes is present, the cause of amputation is classified as diabetes unless there is an independent cause, such as trauma or tumour.

The difference between the sexes regarding the diagnostic group is statistically significant (p <0.0001). To analyse whether the difference may be affected by a low degree of coverage, the distribution of diagnoses by sex is also reported separately for Skåne University Hospital (Figure 5), where the coverage rate for amputation procedures is close to 100%. This is compared with other registering hospitals (Figure 6). The figures strengthen the conclusion regarding the difference in amputation diagnosis based on sex.

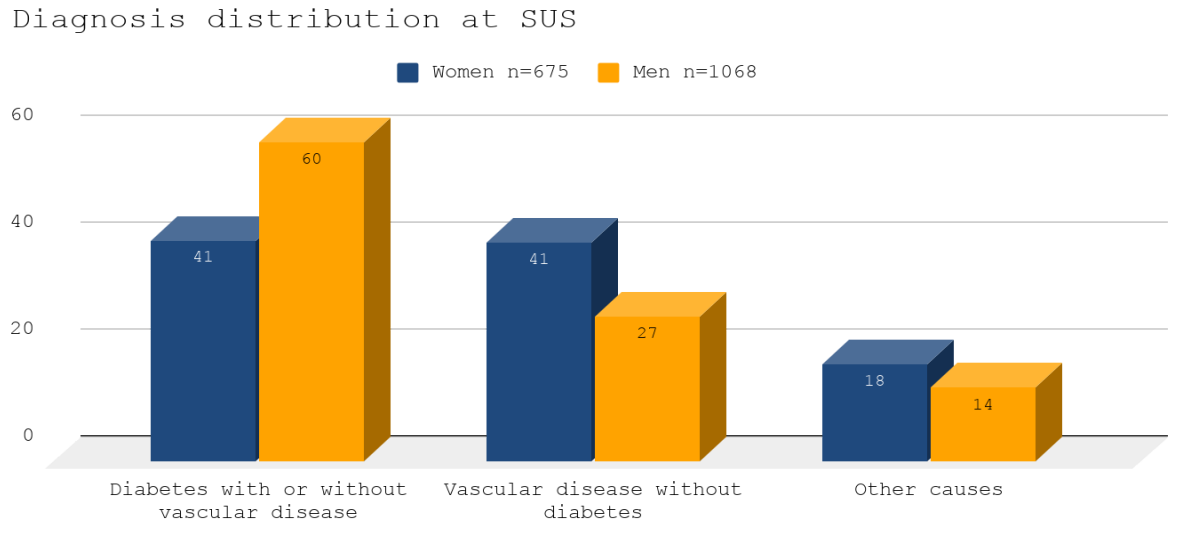


Figure 5. Diagnostic group distribution for amputation procedures at Skåne University Hospital, %.

AVERAGE AGE AT AMPUTATION FOR SELECTED DIAGNOSTIC GROUPS

DIAGNOSTIC GROUP	WOMAN Average age (SD)	MAN Average age (SD)
Diabetes with/without vascular disease	76 (12) (n=1112)	72 (11) (n=2449)
Vascular disease without diabetes	82 (10) (n=1331)	78 (11) (n=1273)
Other diagnoses	68 (21) (n=451)	58 (22) (n=641)

Table 4. The average age at the procedure for selected diagnostic groups. The differences between the groups are statistically significant (p <0.0001).

SMOKING HABITS

Smoking habits at first registered procedure per patient (n=2763), in amputation above the ankle:

- 38% Never smoked
- 26% Current smoker
- 35% Former smoker (defined as stopped smoking> 12 months before the amputation)
- 2% Other nicotine products

Comment: For many patients, information regarding smoking habits has not been registered.

COMORBIDITY

Presence of other illness or disability expected to affect wound healing and/or rehabilitation.

Number of conditions registered per patient (n = 4234 patients):

- 34% (n=1440) One condition
- 31% (n=1333) Two conditions
- 27% (n=1156) Three or more conditions
- 7% (n=305) No conditions

MOST COMMON CAUSES OF COMORBIDITY *(multiple conditions can be indicated for the same patient)*	NUMBER OF PATIENTS WITH CURRENT COMORBIDITY
Heart disease	2663 (34%)
Kidney disease	824 (11%)
Chronic lung disease	581 (7%)
Stroke	577 (7%)
Dementia	415 (5%)
Rheumatoid arthritis	266 (3%)
Neurological disease	191 (2%)
Diabetes (If not primary diagnosis for amputation)	536 (7%)
Impaired vision or hearing	208 (3%)
Vascular disease (If not primary diagnosis for amputation)	499 (6%)
Other (This includes conditions which less than 100 patients suffered from, for example, general medical problems, malignant disease, mental illness, substance abuse, problems with the musculoskeletal system, impaired hand function and fracture)	751 (10%)

Table 5. Most common comorbidities. The data are conditions that have been registered per patient in at least one procedure, %.

Comment: For the majority of patients, one or several other conditions are stated, with the most common being heart disease. In only 7%, comorbidity has been reported as "not present". Comorbidities are likely underreported.

SURGICAL DATA

AMPUTATION DATA / AMPUTATION PROCEDURE

Of the registered 8993 procedures, the type (primary amputation, re-amputation or surgical revision) has been specified as follows:

- 80% (n=7187) primary amputation
- 13% (n=1173) re-amputation at higher amputation level
- 7% (n=625) revision
- <1% (n=8) uncertain

Type of amputation, separately for Skåne University Hospital (n = 2826):

- 73% (n=2076) primary amputation
- 17% (n=478) re-amputation at higher level
- 10% (n=272) revision

Comment: The proportion of re-amputations and surgical revisions are probably underreported in cases where the registration of procedures has not been done at the surgical unit, but at a clinic for prosthesis

supply/rehabilitation. As Skåne University Hospital has a near 100% registration rate of amputation procedures, the figures for primary amputations, re-amputations and revisions are probably more in line with reality. This is also confirmed by figures from the National Board of Health and Welfare's database for inpatient surgeries, reporting the proportion of revisions to be around 10%.

LEVEL OF AMPUTATION

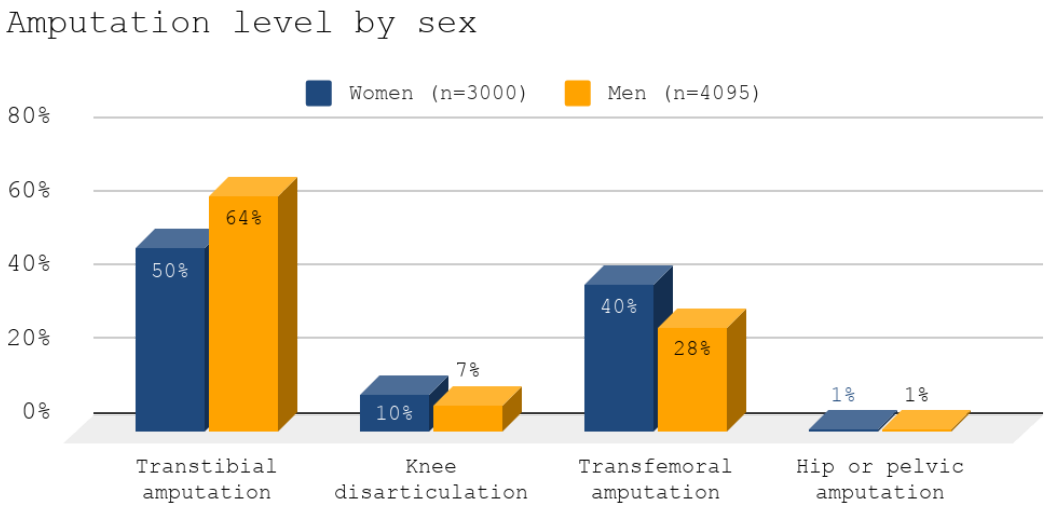


Figure 7: Distribution of amputation level above the ankle for women and men (n = number of procedures per sex). The figure does not show amputations below ankle level (n = 1898).

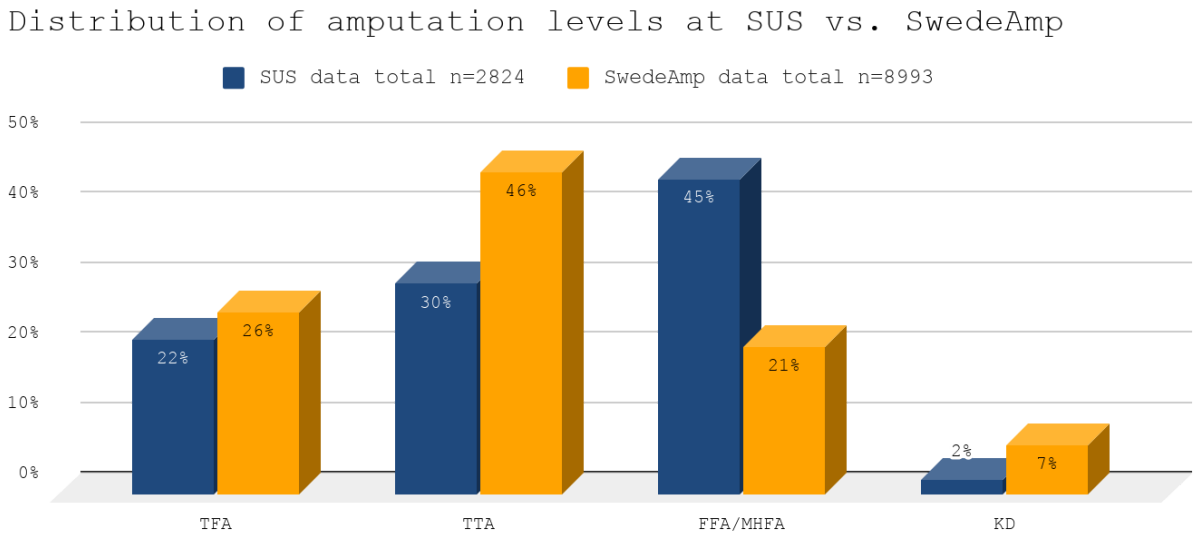


Figure 8: Distribution of amputation levels at Skåne University Hospital (SUS) and in SwedeAmp in total. TFA = transfemoral amputation; KD = knee disarticulation; TTA = transtibial amputation; FFA / MHFA = forefoot and mid/hind foot amputation

Comment: There is a broad consensus regarding the importance of maintaining an anatomical knee joint, to give the patient the best possible conditions for good prosthetic function. The proportion of women with a TFA level is higher than in men (40% and 28%, respectively). This can be explained by the fact that amputation due to vascular disease without diabetes is more common for women (figure 4) and that women are older than men at the procedure (Table 3). Amputations below the ankle are probably underreported in the register. This is evident when data from Skåne University Hospital (SUS), which has close to 100% registration of all performed amputations on the lower extremity, is compared with SwedeAmp's total data. Amputations below the ankle constitute the largest proportion of amputation procedures at SUS.

OTHER UNDERLYING HEALTH DATA

PRECIPITATING CAUSES AT PRIMARY AMPUTATION

CAUSE (SEVERAL COOPERATIVE CAUSES CAN BE REGISTERED) NUMBER OF PRECIPITATIONS n=7541	PROPORTION OF INTERVENTION % WITH REGISTERED CAUSE (n = 4954)
Progressive gangrene (n=2652)	54%
Infection (n=1894)	38%
Pain (n=1344)	27%
Acute vascular occlusion (n=696)	14%
Toxic/Septic condition (n=351)	7%
Trauma (n=151)	3%
Tumour (n=103)	2%
Deformity (n=87)	2%
Other (n=263)	5%

Table 6: Precipitating cause(s) for amputation based on primary amputations. In 4954 procedures, a total of 7541 precipitations are registered, %.

Comment: The precipitating cause for amputation is dominated primarily by progressive gangrene, but also by infection and pain.

RE-AMPUTATION AFTER PRIMARY LEVEL OF AMPUTATION

PRIMARY LEVEL	FINAL LEVEL TTA (%)	FINAL LEVEL KD (%)	FINAL LEVEL TFA (%)	FINAL LEVEL TPHD (%)
Transtibial amputation (TTA) n=2757	90%	1%	9%	<1%
Knee disarticulation (KD) n=429	-	88%	12%	<1%
Transfemoral amputation (TFA) n=1556	-	-	99, 6%	<1%

Table 7a: Relation between primary amputation level and final level, %.

PRIMARY LEVEL SUS	SUS FINAL LEVEL FOREFOOT (%)	SUS FINAL LEVEL TTA (%)	SUS FINAL LEVEL KD (%)	SUS FINAL LEVEL TFA (%)	SUS FINAL LEVEL TPHD (%)
Amputation below the ankle (n=954)	83%	13%	<1%	3%	<1%
Transtibial amputation (TTA) n=627		81%	1%	17%	<1%
Knee disarticulation (KD) n=50		-	82%	16%	2%
Transfemoral amputation (TFA) n=360		-	-	99%	1%

Table 7b: Relation between primary amputation level and final level at Skåne University Hospital (SUS), %.

Comment: The report describes the primary amputation and the cases where re-amputation to a higher level for the same individual and the same side has been registered. The highest proportion of re-amputations is seen after a primary knee disarticulation (KD), followed by TTA and, as expected, the lowest at TFA.

SURGICAL TECHNIQUE

SKIN FLAP TTA	ALL % (n)	REGION BLEKINGE %	REGION HALLAND %	JÖNKÖPINGS REGION %	REGION SKÅNE %	VÄSTRA GÖTALAND REGION %	STOCKHOLM REGION %
Sagittal	72% (1665)	86%	77%	72%	82%	45%	67%
Anterior/Posterior	14% (305)	7%	4%	19%	16%	12%	7%
Long posterior	9% (230)	7%	19%	6%	<1%	24%	24%
Skew	4% (106)	0	<1%	2%	1%	20%	1%
Number of procedures	**n=2306**	**n=106**	**n=161**	**n=188**	**n=104**	**n=292**	**n=218**

Table 8: Type of skin flap technique in primary amputation or re-amputation in transtibial amputations, %.

Comment: The most common surgical technique at TTA is the sagittal flaps. To illustrate differences within the country, the six regions with data for > 100 registered cases are reported. The difference between Blekinge, Skåne and Västra Götaland is noticeable. However, the proportion of procedures with sagittal flaps has increased in Västra Götaland compared with the previous annual report (33% sagittal up to and including 2018).

ASSESSMENTS AND PROCEDURES IN CONNECTION WITH THE AMPUTATION

Priority of the surgical procedure (n=2313):

- 9% (n=199) Emergency procedure (within 12 hours)
- 74% (n=1703) Subacute procedure (13 hours - 1 week)
- 18% (n=411) planned procedure (>1 week)

Antibiotics at the time of procedure (n = 2340), (registered only for amputations above the ankle):

- 3% (n=67) No antibiotics
- 25% (n=583) Preoperative only
- 5% (n=109) Postoperatively only
- 68% (n=1581) Pre and postoperatively

Skin closure (n = 2802), (registered only for amputations above the ankle):

- 68% (n=1918) Sutures
- 19% (n=527) Surgical clips
- 10% (n=290) Vacuum treatment
- 2% (n=67) Open treatment

Pre Anticoagulants (n = 2135) in 89% of procedures (registered only for amputations above the ankle)

Pre Nutritional supplements (n=2018) in 56% of the procedures (registered only for amputations above the ankle)

Comment: All the variables above were introduced in 2017, which explains the lower number of registrations. With an increased amount of data, we intend to be able to analyse whether, for example, antibiotics or skin closure techniques play a role in the risk of surgical revision or re-amputation.

WALKING ABILITY BEFORE AMPUTATION

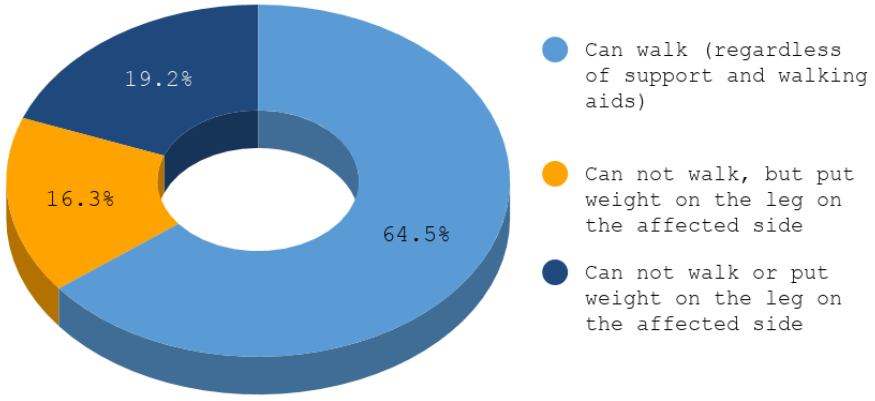


Figure 9a: Walking ability before amputation, SwedeAmp's total data (n = 5921), (registered only for amputations above the ankle amputation.

Comment: In SwedeAmp's total data set, it appears that about 1/3 of the patients cannot walk before the amputation.

PRELIMINARY ASSESSMENT REGARDING PROSTHESIS SUPPLY

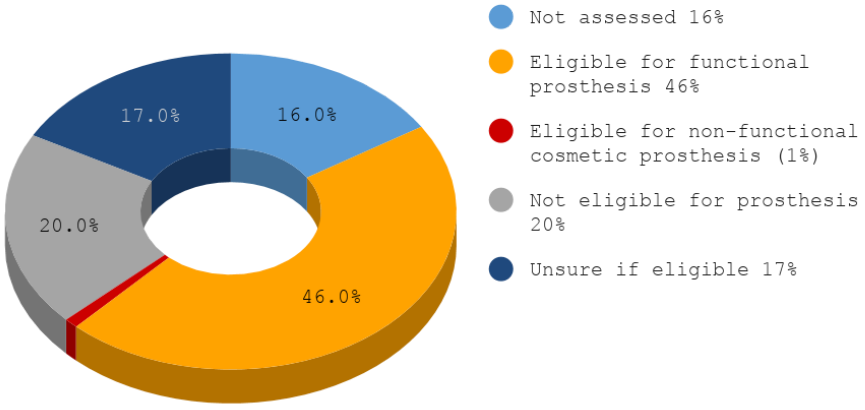


Figure 10. Preliminary assessment of prosthesis supply in connection with the procedure to the final amputation level above the ankle (n = 6171), (%).

Proportion of patients assessed as eligible for a functional prosthesis in relation to amputation level:

- Transtibial amputation (TTA) 54% (n=2223/4096)
- Knee disarticulation (KD) 22% (n=131/605)
- Transfemoral amputation (TFA) 19% (n=437/2348)

Comment: There is a significant difference between the amputation levels and only 22% and 19%, respectively, of the patients with KD and TFA were assessed as eligible for a functional prosthesis.

BILATERAL AMPUTATIONS

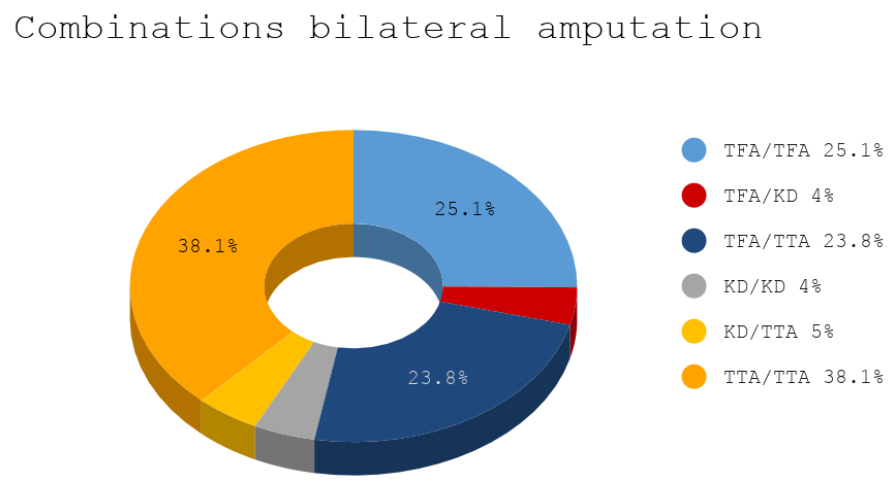


Figure 11a. Combinations of amputation levels in patients with bilateral amputation, in %, n = 1035.

Bilateral amputation (defined as amputation through the metatarsal bones or higher on both sides) occurred in n=1035 of the registered patients.

Distribution of diagnostic groups in patients with bilateral amputations:

- 52% Diabetes with/without vascular disease
- 35% Vascular disease without diabetes
- 5% Infection not related to diabetes or vascular disease
- 2% Trauma
- 6% Other diagnosis

Comment: The most common combination in patients with bilateral amputations is bilateral TTA, with the most common diagnosis being diabetes with or without vascular disease. From a functional point of view, it is of high importance for patients with bilateral amputations to have at least one anatomical knee joint left.

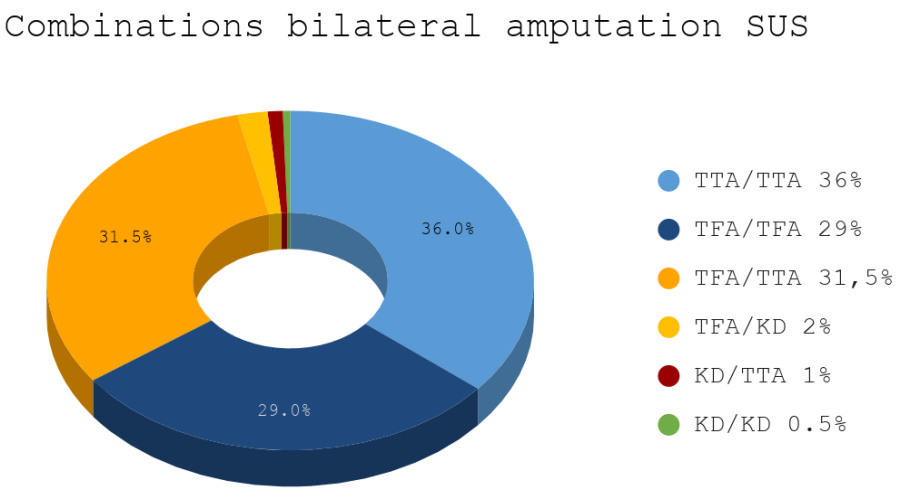


Figure 11b. Combinations of amputation levels in bilateral amputations above the ankle Skåne University Hospital, % (n = 655)

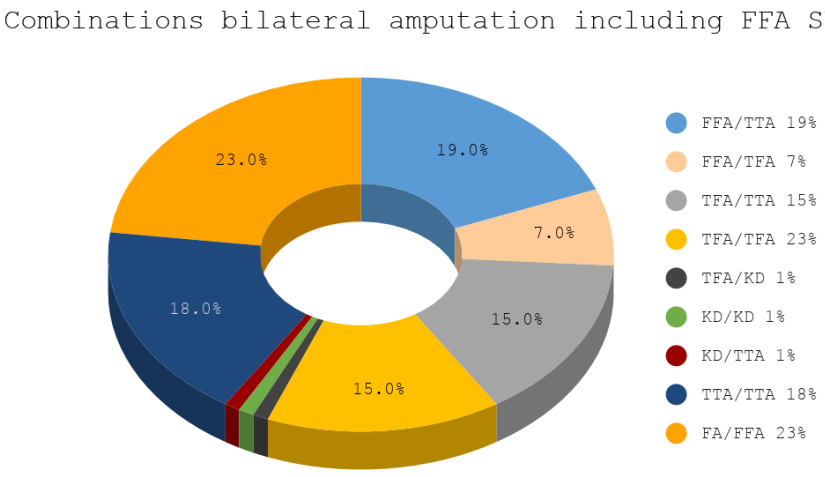


Figure 11c. Combinations of levels in bilateral amputations including forefoot amputations (FFA) at Skåne University Hospital, % (n = 848)

Comment: To verify the total amount of data with data from Skåne University Hospital (SUS), data regarding bilateral amputations are presented both without (Figure 11b) and with (Figure 11c) the inclusion of forefoot amputations. The data also represent patients who never reach rehabilitation with prostheses. The figures show that the combinations in bilateral amputation above the ankle do not differ significantly between SwedeAmp and SUS.

Data per hospital and region

Registrations per hospital

HOSPITAL	2017	2018	2019	Total - 2011-2019
Skånes University Hospital (Malmö/Lund)	326	294	335	2825
Central Hospital Kristianstad	49	68	64	545
Uddevalla NÄL	58	90	55	545
Sahlgrenska University Hospital (Göteborg/Mölndal)	44	58	200	623
University Hospital Linköping	54	54	82	403
University Hospital Örebro	66	52	46	398
Falu Hospital	34	39	37	390
Vrinnevi Hospital Norrköping	75	72	66	307
County Hospital Ryhov Jönköping	34	65	40	278
Blekinge Hospital	61	34	25	249
Helsingborgs Hospital	44	59	45	223
Karolinska University Hospital (Solna/Huddinge)	34	50	36	300
Södersjukhuset	29	31	10	208
Hallands Hospital Halmstad	30	35	17	195
Danderyds Hospital	6	19	96	192
Capio S:t Görans Hospital	43	29	36	185
Höglands Hospital Eksjö	26	27	29	147
Visby Hospital	39	28	25	137
Södra Älvsborgs Hospital Borås	2	13	101	119
Hallands Hospital Varberg	35	18	25	94
Västmanlands Hospital Västerås	18	14	15	80
Central Hospital Växjö	12	11	11	75
Hospital Motala	11	5	1	68
Kungälvs Hospital	9	3	4	64
Ystad Hospital	5	8	22	41
County Hospital Kalmar	1	8	1	29
Södertälje Hospital	1	8	12	27
County Hospital Gävle	1	6	16	23
Other hospitals (<10 registrations)	14	16	11	217
Total	**1174**	**1221**	**1464**	**8987**

Table 9: Number of procedures registered per hospital in total since the start of the register and separately for the year 2017-2019

DISTRIBUTION OF AMPUTATION LEVEL TTA IN RELATION TO KD/TFA PER REGION

REGION	TTA+KD+TFA (N)	DISTRIBUTION PRIMARY LEVEL TTA / KD+TFA %	DISTRIBUTION FINAL LEVEL TTA / KD+TFA %
Blekinge	212	52/48	45/55
Dalarna	315	63/37	54/46
Gotland	81	46/54	36/74
Gävleborg	15	67/33	63/37
Halland	244	70/30	63/37
Jönköping	374	55/45	53/47
Kalmar	77	60/40	58/42
Kronoberg	77	88/12	83/17
Skåne	1570	60/40	55/45
Stockholm	840	78/22	74/26
Uppsala	81	81/19	81/19
Västmanland	72	32/68	30/70
Västra Götaland	1069	63/37	56/44
Örebro	364	71/29	61/39
Östergötland	383	37/63	35/65

Table 10: Proportion of TTA compared to KD + TFA, in percent, for both current primary amputation level and final level, for regions with at least 10 registered amputations above the ankle, %.

Comment: The proportion of primary TTA for all registrations is 66% in relation to the proportion of KD + TFA (34%). The results indicate significant differences within the country. The proportion of primary TTA in relation to the sum of all major amputations (TTA + TFA + KD) is affected by which kind of clinical unit reports to SwedeAmp.

Patients with better potential for rehabilitation come to the P&O clinic or prosthesis rehabilitation clinic, many having a lower amputation level. If amputation data has only been reported from these clinics, the proportion of TTA is therefore likely to be unrealistically high. If the surgical unit registers amputation data, patients who do not move on to prosthetic rehabilitation are also included. Thus, the proportion of TTA becomes lower. Regarding the proportion of final level TTA in relation to KD/TFA, the patients who have gone from an amputation below the ankle to a final TTA level are also included.

COMPILED ANALYSIS OF PATIENT AND AMPUTATION DATA

The foundation for this year's report is just over 7,000 patients who have undergone amputation procedures up to and including 2019-12-31. Together, they add up to over 10,000 registered procedures.

Regarding the cause for amputation, gender distribution, average age and amputation levels, the scope is unchanged. In women, a higher average age, a higher amputation level, and a higher proportion with amputation due to vascular disease without concomitant diabetes are demonstrated. Women also have fewer amputations due to trauma compared to men, which are all in line with the scientific literature. Some general underreporting of diabetes may be suspected, as the manifestations of concomitant vascular

disease often dominate the clinical picture. The difference between the sexes in terms of age and amputation diagnosis is statistically significant.

It is well known that amputation patients with lower limb amputations, as a group, have a high degree of comorbidities. SwedeAmp provides the opportunity to register a dozen specific conditions of special importance for wound healing and rehabilitation. In the current report, these questions have been answered by 59% of the patients, and in more than half, there are two or more conditions registered. In only 7% of the cases it was actively stated that no other comorbidity was present. There is a large dominance of concomitant cardiovascular disease, but also kidney disease and chronic lung disease occur.

Amputations below the ankle are probably underreported in SwedeAmp. Data from Skåne University Hospital (SUS), which has almost 100% registration of amputations on the lower extremity, shows that amputations below the ankle make up almost half of all amputation procedures. Analysing data from the final amputation level at SUS, shows that 83% of amputations below the ankle stay at a level below the ankle. From the patient's perspective, this may mean preserved walking ability. There is reason to assume that amputations below and above the ankle are closely related to each other.

Amputation below the ankle is often performed as an attempt to prevent an amputation at a higher level, but can also be a trigger for a higher amputation. Well-functioning registration of these "minor" amputations is expected to provide an increased understanding of these connections, and thereby contribute to the optimisation of existing possibilities to make a limited intervention below the ankle, at an earlier stage of the disease progression. This in turn presupposes that orthopaedic surgical expertise is involved early, and not only when the need for a transtibial amputation has been manifested. SwedeAmp's steering group recommends that as many surgical clinics as possible also start to register amputations below the ankle. This will make it possible to follow the patient throughout the entire care process.

Bilateral amputations (i.e. midfoot or higher level) have been recorded in 11% of patients. Among these, a higher proportion is diagnosed with diabetes than in those with unilateral amputations.

Since 2017, some new parameters have been included. These are indications (triggering causes of the primary amputation) and measures in connection with the surgical procedure (antibiotics, anticoagulants, nutritional supplements and registration of time priority). These variables do not yet allow further analysis, due to the short time they have been in use. One variable, not yet in the register, is time to wound healing after surgery. Today, surgical follow-up at the surgical unit is often lacking. SwedeAmp welcomes local initiatives regarding follow-up routines and hopes to be able to enter time to wound healing in the register in the future.

For several variables, it is difficult to define a clear target value for potential improvements. Examples of these are amputation level and re-amputation frequency. In general, we want as low amputation level as possible and at the same time as low re-amputation frequency as possible. However, this is easier said than done. A lower amputation level provides better conditions for optimal prosthetic rehabilitation, but larger risk for non-healing. A higher level usually means better circulation and less risk for re-amputation, but worse conditions for prosthetic rehabilitation. This is visible in the patient-reported data later in this report.

PROSTHESIS DATA

BASIC DATA

A total of 3921 registrations of prosthesis data has been entered for 2215 patients (31% women, n=735, 69% men, n=1480).

The first prosthesis and the renewal of the prosthesis or socket have been stated in 3238 registrations:

- 52% (n=1671) refer to the first prosthesis for the current level
- 16% (n=517) refer to the renewal of the entire prosthesis
- 32% (n=1050) refer to the renewal of the prosthetic socket

The prosthesis type has been specified for 3467 registrations:

- 92% (n=3239) refer to a functional prosthesis
- 4% (n=143) refer to supply with an extra prosthesis (e.g exercise prosthesis or hygiene prosthesis)
- <1% (n=15) refer to a non-functional aesthetic prosthesis (not intended as gait support)
- 2% (n=70) refers to cases where it has been assessed that prosthesis supply and prosthetic rehabilitation is not appropriate.

Comment: Just over half of the registered prosthesis data constitutes the first prosthesis for the current amputation. Renewal of the socket alone is more common than a renewal of the entire prosthesis. The variable "type of prosthesis registration" is now mandatory as it is necessary to be able to calculate the quality indicator "Time to first prosthesis", reported in Table 13.

REGISTERED PROSTHESES

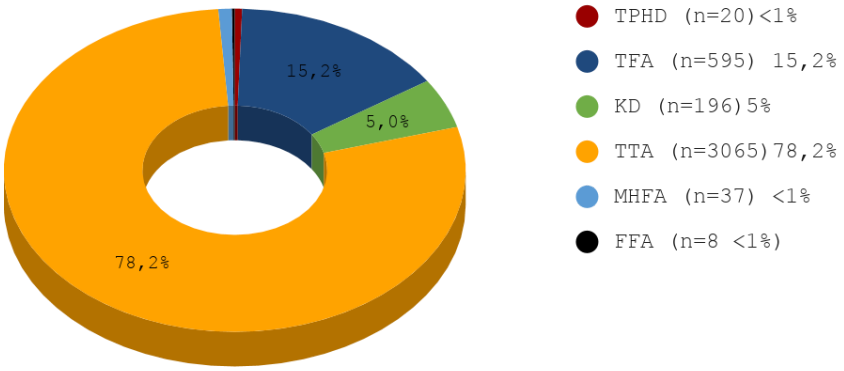


Figure 12: All prosthesis registrations, per level (n = 3921), (%). TPHD = Amputation through the pelvis or hip joint, TFA = Transfemoral amputation, KD = Knee disarticulation, TT = Transstibial amputation, MHFA = Amputation through the metatarsal or hindfoot, FFA = Forefoot amputation.

LEVEL	PATIENTS WITH AMPUTATION 2011-2018 (n)	PROPORTION PROVIDED WITH PROSTHESIS % (n)
Transtibial amputation	3011	34% (n=1035)
Knee disarticulation and Transfemoral amputation	1978	15% (n=292)
All	**5425**	**24% (n=1317)**

Table 11. The proportion of patients in SwedeAmp with surgical procedures performed during the years 2011-2018 who have been supplied with prostheses, per level TTA or KD/TFA.

Comment: The register is dominated by prostheses for TTA. In relation to the number of procedures per level, the proportion of prosthesis supply for TFA and KD is, as expected, considerably lower. The number of registered prostheses and sockets has almost doubled in 2019 compared to 2018. Patients with procedures performed in 2019 have been excluded from the analysis since many of the prosthesis supplies are expected to take place in 2020. Although the number of prosthesis data increases for each year, underreporting is still likely.

AGE DISTRIBUTION AT FIRST PROSTHESIS SUPPLY PER PATIENT

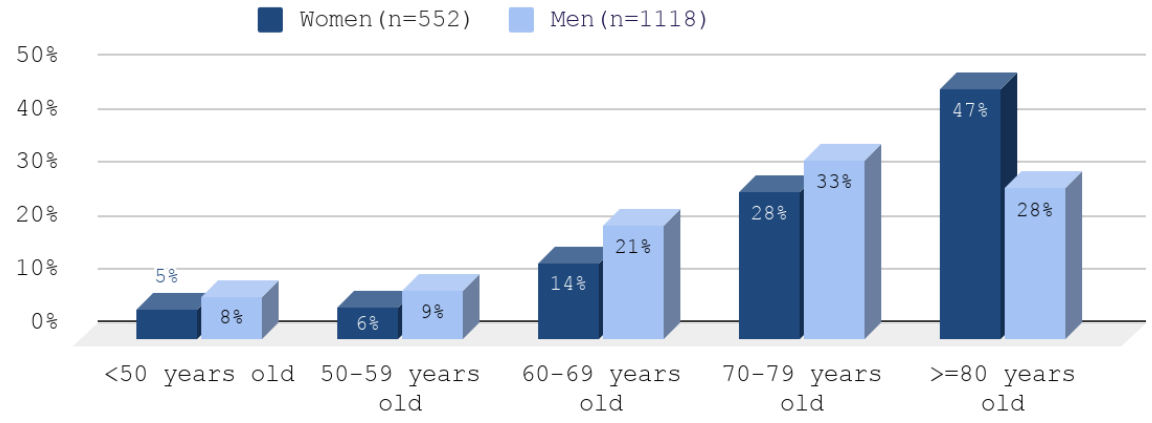


Figure 13. Age distribution at the first prosthesis supply (n = 1670) within each sex, (%).

Comment: The patient's age at the first prosthesis supply varied between 5 - 101 years old. Women were generally older than men at the first prosthesis supply (average age women 75 years, men 70 years). Nearly half of the women were > 80 years old at the time of the first prosthesis supply. For men, the first prosthesis supply was more evenly distributed from the age of 60.

Prerequisites for prosthesis supply

Compression after transtibial amputation

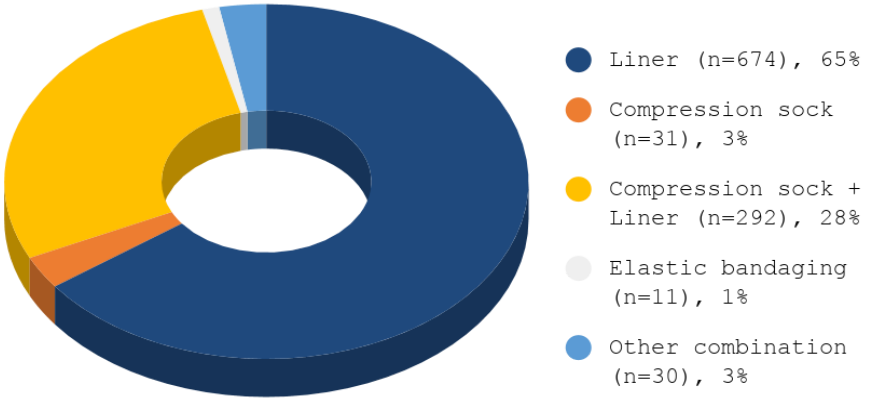


Figure 14a: Type of residual limb compression after TTA, (n=1038), (%) (% shown in the list to the right)

The start of compression treatment of the amputation residual limb occurred within 1 week in 50% of cases, in 33% within 1-3 weeks, in 11% within 4-6 weeks and in 6% of cases> 6 weeks after amputation. The amount of data for compression treatment start (n=859) is significantly higher compared to previous years (n=558).

Comment: The large addition of data in 2019 confirmed the data from the 2018 annual report. Compression with a silicone liner dominates greatly. The compression treatment was usually started within 1 week (50%) and for a further 33% within 1-3 weeks after the procedure.

Weight-bearing capacity on the contralateral limb

The patient's ability to put weight on the contralateral limb at the time of the first prosthesis fitting (n= 1501):

- 80% Full weight-bearing capacity
- 16% Limited weight-bearing capacity
- 4% No or very limited weight-bearing capacity

Comment: Although the amount of data for this variable has increased by 38%, the results are in line with 2018. At the time of the first prosthesis fitting, about 80% of patients can put full weight on their other limb. The ability to put weight on the contralateral leg is often included in the assessment before a decision on prosthesis supply is made, and is a prerequisite for a good rehabilitation result.

RESIDUAL LIMB PROBLEMS COMPLICATING PROSTHESIS FITTING

RESIDUAL LIMB PROBLEMS COMPLICATING PROSTHESIS ADJUSTMENT	QUANTITY	QUANTITY AS A SINGLE COMPLICATION
Pain	407	156
Wound	419	186
Thin tissue coverage	264	73
Contracture in nearby joints	227	88
Swelling	234	64
Adherent skin to bone	94	13
Eczema	58	26
Deep skin folds	68	15
Bulbous distal end	133	40
Other	202	92

Table 12a. Problems with the residual limb that complicate prosthesis fitting (n = 1285). Several problems can be specified. The last column indicates the number reported as a single complication and not in combination with others. The report refers to both the first prosthesis and registrations when changing the socket and/or prosthesis.

RESIDUAL LIMB PROBLEMS DIVIDED INTO TIME PERIOD AFTER AMPUTATION

RESIDUAL LIMB COMPLICATIONS AT PROSTHETIC FITTING TTA	<6 MONTH POSTOP. PROPORTION "YES" OF (n)	>2 YEAR POSTOP. PROPORTION "YES" OF (n)
Pain	13% (872)	18% (254)
Wound	48% (408)	26% (179)
Thin tissue coverage	18% (286)	28% (164)
Contracture in nearby joints	27% (294)	11% (152)
Swelling	36% (299)	5% (153)
Adherent skin to bone	8% (284)	8% (153)
Eczema	7% (285)	3% (152)
Deep skin folds	4% (277)	5% (153)
Bulbous distal end	23% (287)	5% (154)
Other	22% (292)	12% (158)

Table 12b. Problems with the residual limb that complicate the prosthesis fitting at TTA (Selection for groups "First prosthesis for current amputation" and <6 months postoperatively and replacement of prosthesis/socket 2 years and later after the amputation). Several problems can be identified.

Comment: Combinations of several aggravating problems often occur, the most common being pain and wounds. The extent and type of problems change over time and with regular prosthesis use. As expected, problems with swelling and bulbous distal ends decrease. In the same way, the problems with thin tissue coverage increase with time. It is gratifying that "Eczema or similar skin problems" do not seem to increase- but even decrease over time, and also that contractures in the nearby joints are decreasing.

It is surprising that as many as 26% have wounds on the residual limb 2 years or more after the amputation, and that the proportion of pain is larger than at the earlier follow-up. For a clearer analysis, longitudinal data on a group of patients who have been followed over a long period with repeated prosthetic supplies should be studied.

Time to prosthesis supply

Number of days from final amputation level to fitting of first prosthesis

Level	Days Average (SD)	Days Median (min-max)
Transtibial amputation (TTA) (n=1284)	85 (68)	65 (6 - 500)
Knee disarticulation (KD) (n=67)	112 (75)	96 (26 - 341)
Transfemoral amputation (TFA) (n=265)	112 (78)	92 (19 - 484)

Table 13a. Time to prosthesis fitting by amputation level; TTA, KD and TFA (n=1616). In the calculation, individual extreme values have been removed (<5 days and> 500 days).

Number of days from final amputation level to fitting of first prosthesis at TTA reported in time periods

Time period (years)	Days Average (SD)	Days Median (min-max)
2011-2013 (n=186)	83 (54)	70 (15 - 406)
2014-2016 (n=387)	86 (74)	66 (11 - 492)
2017-2019 (n=458)	82 (70)	58 (18 - 441)

Table 13b: Time to prosthesis fitting (first prosthesis for current amputation) at final TTA level distributed per period of 3 years (n = 1031). Year is based on the date of the first fitting. In the calculation, individual extreme values have been removed (<5 days and> 500 days).

Number of days from final amputation level to fitting of first prosthesis at TTA and various surgical techniques

Surgical technique skin flap TTA	Days Average (SD)	Days Median (min-max)
Skew (n=29)	77 (79)	47 (20 - 386)
Sagittal (n=449)	79 (76)	50 (11 - 492)
Long posterior (n=78)	80 (57)	60 (16 - 268)
Anterior/Posterior (n=64)	88 (69)	71 (16 - 376)

Table 13c: Time to prosthesis fitting (first prosthesis for current amputation) at final TTA level, distributed by surgical skin flap techniques. In the calculation, individual extreme values have been removed (<5 days and> 500 days).

Comment: Time from amputation to the first prosthesis fitting for TTA has decreased from an average of 70 days in 2011-2013 to 58 days in 2017-2019. Longer time to prosthesis fitting at higher amputation levels is evident and at all levels, there is great variation. Median time at TTA indicates fewer days to a prosthetic fitting with a sagittal surgical technique and skew skin flaps compared to techniques. SwedeAmp recommends that “Number of days to prosthesis” and “Time from amputation to start of training with prosthesis” (in follow-up data) should be analysed for local improvement work. New variables for prosthesis data will enable an analysis of the large spread of number of days. Some clinics allow prosthesis use before the amputation wound is healed while others strictly await healing. There is no consensus on the issue yet.

PROSTHESIS DESIGN

PROSTHETIC FOOT

TYPE OF PROSTHETIC FOOT AT TRANSTIBIAL AMPUTATION

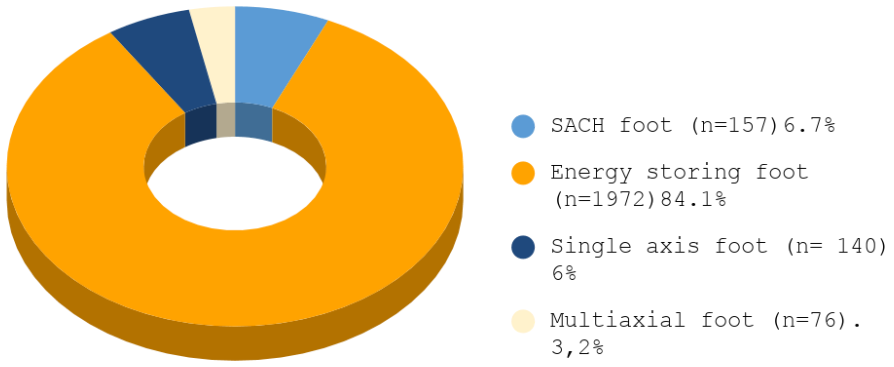


Figure 14. Type of prosthetic foot at TTA, (n=2354), (%).

TYPE OF PROSTHETIC FOOT IN TOTAL AND PER AMPUTATION LEVEL

LEVEL	Sach	Single axis	Multiaxis	Energy storing	Intellegent
Transtibial amputation (TTA) (n=2354)	157	140	76	1972	9
Knee disarticulation (KD) (n=161)	12	12	10	125	2
Transfemoral amputation (TFA) (n=466)	27	53	24	358	4
Total	**196**	**205**	**110**	**2455**	**15**

Table 14a. Type of prosthetic foot at TTA, KD and TFA (n = 2981), number

SPECIFICATION OF PROSTHETIC FOOT – ALL AMPUTATION LEVELS

FUNCTION CATEGORY 1-4* (Quantity)	MOST COMMON FOOT					SECOND MOST COMMON FOOT				
	Type of foot	Distributor	Art. nr	Qty	Type	Type of foot	Distributor	Art. nr	Qty	Type
1 (n=96)	SACH	Otto Bock	1D10, 1D11, 1G6	26		Balance	Össur	FBP	18	
2 (n=353)	Assure (inkl Sure-flex)	Össur	FAPE, FAXE	196		Trias	Otto Bock	1C30	109	
3 (n=172)	Triton	Otto Bock	1C60	47		Vari-Flex	Össur	VFP, VFX	32	
4 (n=62)	Pro-Flex XC och Vari-flex XC	Össur	PXC	50		-	-	-		

Table 14b. Type of prosthetic foot specified in a free text field at "specification of prosthetic foot (n = 683) distributed by function category (see definition below). Type of foot: blue round symbol = SACH foot, green round symbol = Energy-storing foot.

*** Definition Function category:**

The individual has the ability or potential to:

1. Walk indoors or on flat surfaces at low gait speed, with/without walking aids. Walk in indoor and outdoor environments, with/without walking aids.
2. Clear low obstacles such as curbs, stairs or uneven surfaces (i.e. move around in society with walking aids)
3. Walk with varied gait speed. Ability to walk in most environments with different challenging surfaces, e.g when slippery, sloping or uneven. Perform activities that require the use of prostheses in addition to regular walking
4. Use a prosthesis for a purpose exceeding basic walking ability. Perform very demanding activities that expose the residual limb and prosthesis to high strain, such as many different sports activities and children's play

Comment: It is not easy to replace the anatomical foot with a prosthetic foot. Depending on how active the amputee is and in which environments the prosthetic foot is used, different properties of the prosthetic foot are required. An energy-storing prosthetic foot is most common at all three levels and was reported in about 80% of the cases. For TTA prosthesis registrations in 2019, the proportion of energy-storing feet was higher (92%). Grouping of prosthetic foot types does not currently provide a good picture of how the prosthesis has given the patient the conditions for different functions, as many different feet are classified as energy-storing. Common to these is that they are made of resilient materials, e.g. composite material with carbon and/or fibreglass, without great energy loss. As the data shows, almost all feet used today are made up of these materials to varying degrees, but the properties differ within the group. Table 14b shows that prosthetic feet that can meet the requirements for F2 (registration for amputation procedures), are used in 52% of cases.

LINER AND SUSPENSION METHOD – TRANSTIBIAL PROSTHESIS

TYPE OF LINER	SUSPENSION SLEEVE WITHOUT VACUUM	DISTAL PIN LOCK	DISTAL VACUUM	VACUUM WITH SLEEVE	VACUUM WITH EXPULSION VALVE	ACTIVE VACUUM PUMP	OTHER*	TOTAL
Silicone	40	506	40	793	204	29	32	**1644**
Copolym-er	23	14	3	446	88	15	5	**594**
Polyureth-ane	5	16	1	70	22	24	10	**148**
Foam	4	20	0	31	2	0	4	**61**
Other	0	3	1	15	1	0	1	**21**
Total	**72**	**559**	**45**	**1355**	**317**	**68**	**52**	**2468**

Table 15 Type of liner and suspension method at TTA (n = 2468), number. *The heading "Other" for suspension method includes PTB strap and KBM/supracondylar.

Comment: The table includes only those prostheses where both the type of liner and the type of suspension methods are registered, in order to be able to analyse the combination of the two. The most common suspension method is some variant of vacuum (71%) followed by distal pin lock (23%). The most common type of liner is silicone liner (67%) followed by copolymer liner (gel liner) (24%). The most common combinations are silicone liners with a vacuum without expulsion valve (32%) and silicone liners with a distal pin lock (21%).

SOCKET DESIGN FOR TRANSFEMORAL PROSTHESIS

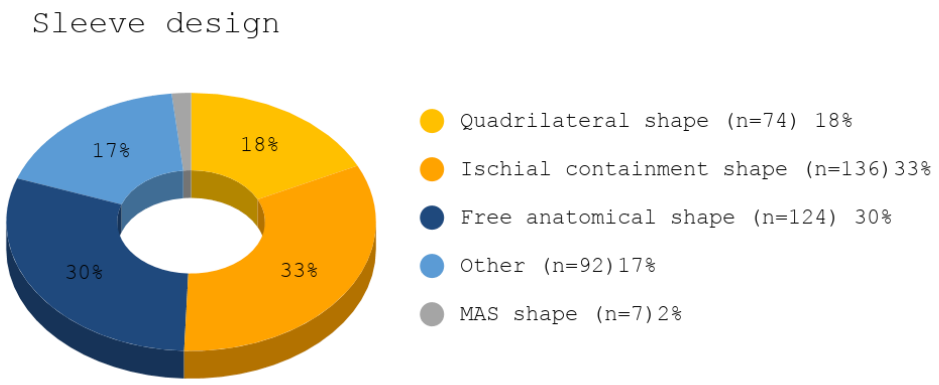


Figure 15. Socket design at TFA (n=433), (%)

Comment: No model dominates. "Ischial containment shape" (33%) and "Free anatomical shape" (30%) are most common. MAS is rare (2%). The choice of socket design probably differs depending on the residual limb length. (Subischial shape will be recorded from 2020).There are still too few registrations regarding residual limb length to compare against socket design.

Type of prosthetic knee joint

	MANUAL LOCK	MECHANICAL	PNEUMATIC	HYDRAULIC	INTELLIGENT
SWING PHASE CONTROL					
Knee disarticulation (n=160)	49	24	21	38	28
Transfemoral amputation (n=450)	178	96	34	94	48
Total (n=610)	**227**	**120**	**55**	**132**	**76**
STANCE PHASE CONTROL					
Knee disarticulation (n=123)	36	38	6	18	25
Transfemoral amputation (n=386)	144	149	0	54	39
Total (n=509)	**180**	**187**	**6**	**72**	**64**

Table 16. Type of prosthetic knee in knee joint amputation and transfemoral amputation, quantity.

Definition of control mechanism for prosthetic knee joint:

- Manual lock: mechanically locks when standing and walking, manual unlocking when sitting
- Mechanical: the knee joint e.g. controlled by the joint(s) position, friction brakes etc.
- Pneumatic: the knee joint is controlled by means of air passing through valves
- Hydraulic: the knee joint is controlled using oil that passes through valves
- Intelligent: microprocessor-controlled knee joint, often with hydraulics

Comment: In 2019, a large new amount of data was also registered for this variable (+55%). The type of prosthetic knee joint varies greatly. Knee joints with a manual lock or mechanical control are more common (60%), compared to the more advanced knee joints that are controlled with pneumatics, hydraulics and/or microprocessors. The proportion of more advanced knee joints has increased compared to previous years. It is the use of microprocessor-controlled knee joints that have increased the most from a low figure in previous years.

RENEWAL OF PROSTHESIS OR SOCKET

Reasons for renewal of prosthesis or socket only (n = 1566)

- 77% change in stump volume
- 13% improve socket fit and <1% broken socket
- 7% prosthesis >2 years worn
- 2% prosthesis <2 years worn

Comment: Next to a doubling (+79%) of the number of registrations, but largely unchanged statistics for the variable compared to previous years. Change in stump volume continues to be the most common cause of renewal.

NUMBER OF PROSTHESES REGISTRATIONS AT P&O CLINICS

P&O CLINIC	2017	2018	2019	TOTAL 2011-2019
Ortopedteknik/ Sahlgrenska	31	24	43	316
Falun OTA	47	92	77	314
Solna Sundbybergsvägen OTA	136	55	85	280
Malmö OTA	2	93	134	253
Lund OTA	25	49	69	228
Motala OTA	20	34	24	153
Eksjö OTA	31	22	32	152
Södersjukhuset OTA	7	25	51	127
Karlskrona OTA	22	20	24	126
Kristianstad OTA	13	19	0	110
Jönköping OTA	14	27	40	98
Halmstad OTA	13	1	18	96
Akademiska sjukhuset Uppsala OTA	6	4	0	96
Växjö OTA	11	11	10	76
Västervik OTA	14	23	3	74
Torsplan OTA	20	1	20	72
Norrköping OTA	19	17	10	69
Varberg OTA	14	13	15	58
Stockholm Bergshamra OTA	2	8	29	57
Västerås OTA	26	12	9	57
Huddinge OTA	9	14	21	55
Linköping OTA	1	15	4	42
Ängelholm OTA	3	8	6	38
Trollhättan OTA	15	10	0	30
Ljungby OTA	15	10	0	30
Uddevalla OTA	4	6	11	29
Norrtälje OTA	0	0	0	26
Helsingborg OTA	0	12	12	25
Borås OTA	0	0	11	25
Uppsala Dag Hammarskjölds väg OTA	0	3	15	18
Kalmar OTA	0	0	3	13
Uppsala Bergsbrunnagatan OTA	4	0	1	13
Södertälje Wedavägen OTA	11	2	0	13
Övriga (<10 registreringar)	0	3	8	22
Totalt	**520**	**623**	**808**	**3184**

Table 17. Number of registrations, based on date of first fitting per P&O unit and year. Units with <10 total entries entered are not reported separately.

Comment: The number of registrations of prosthesis data has a strong positive trend with more registrations for each year. At some units, the number of registrations has decreased and as can be seen from the table, data from parts of Sweden are completely missing (eg Örebro, Karlstad, Östersund, Umeå and Luleå).

OVERALL ANALYSIS OF PROSTHESIS DATA

SwedeAmp's prosthesis data is dominated by transtibial prostheses (78%). In TTA, postoperative compression treatment of the residual limb is usually started within 3 weeks of the amputation (> 80%) by using a liner or liner in combination with a compression sock. The median time from amputation to the fitting of the first prosthesis at TTA shows a positive trend with fewer days (now 58 days) compared to previous years. Most TTA prostheses have some type of vacuum suspension, the second most common being pin locks. When choosing a prosthetic foot, energy-storing feet dominate. For patients with higher amputation levels, simpler mechanical prosthetic joints combined with some type of energy-storing prosthetic foot are most common. The proportion of more advanced knee joints has increased in 2019.

The most frequently registered residual limb problems are pain and wounds. . For the first time, problems in connection with prosthesis adaptation are also reported and divided into two different time periods: <6 months versus >2 years after amputation. As expected, changes in stump volume dominate reasons why a socket or prosthesis needs to be renewed.

In summary, the prosthesis data illustrate large variations. We expect the register to be able to detect differences in the prescription of prostheses and their components in the future, as well as demonstrate the consequences this has for the patient, and contribute to improvements.

In future reports, we hope to be able to link residual limb problems and prosthesis-related issues to rehabilitation outcomes. To be able to link information about the correct prosthesis to rehabilitation outcomes with certainty, it must be possible to register the identity number of the prosthesis/socket during follow-up in SwedeAmp (PROM). There is currently no established national standard for marking that makes it easy to find the identity of the prosthesis/socket. SwedeAmp's proposal is as follows:

- The marking must be readable without additional equipment such as scanners or equivalent. The marking must be placed so that it can be read without having to remove the prosthesis/socket. The patient must be informed about the prosthesis' marking to be able to report the prosthesis' identity themselves in the event of a telephone follow-up.
- Labelling must contain a number that is unique to each socket/prosthesis, information about at which clinic/center it was manufactured and the date it was fitted.

To what extent all prostheses and sockets have been registered, there is no figure. Recent years show that there is an increasing number of prosthesis data registrations: In 2018, it was 20% more than in 2017, and in 2019, 30% more than in 2018. Thus, this large increase of prosthesis data should mean that the coverage rate also increases significantly. More and more P&O clinics register in SwedeAmp, which is positive, but not everyone contributes to data. The collaboration/registration rate for P&O units in 2019 was 70% (21 of 30). It is unfortunate that the degree of collaboration is not greater, given the large variation in SwedeAmp data and the fact that very few other statistics are available within prosthetic care.

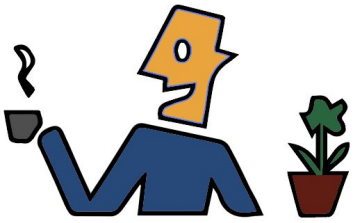
Follow-up and patient reported data (PROM)

PROM – the situation before amputation (baseline)

The patient's condition before the deterioration which led to amputation is collected as soon as possible after the procedure.

This year's report is based on:

- 2108 patients of which 37% were women with an average age 77 years (17 - 101) and 63% men with average age 71 years (9 - 98).
- 72% refers to the situation before transtibial amputation, 21% transfemoral amputation, 6% knee disarticulation, 1% other levels.
- 84% refers to the situation before amputation due to diabetes and/or vascular disease, 11% other diagnoses, and in 5% of cases the diagnosis is unknown/not registered



Comment: Compared to 2018, the proportion of patients with amputation due to diabetes and/or vascular disease is slightly higher (2018: 77%). The Baseline data probably largely reflect patients being assessed for prosthetic rehabilitation, as registration has often been entered in connection with this.

Housing situation before the first amputation

- 90% Own/ordinary housing, including any assistance
- 8% Special housing
- 2% Other accommodation or information is missing

WALKING AIDS AND WHEELCHAIR USE BEFORE THE FIRST AMPUTATION

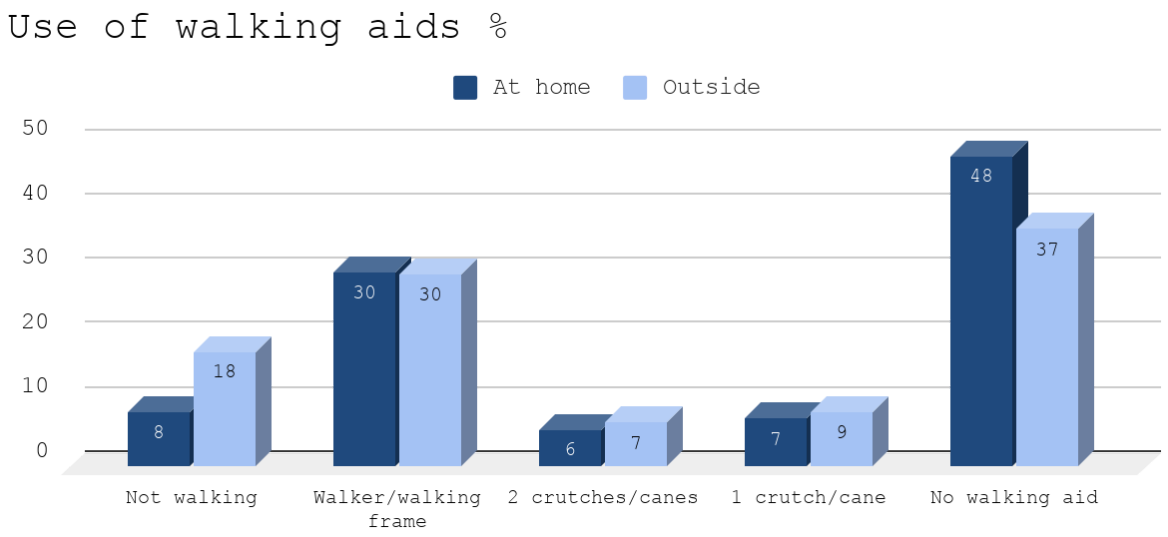


Figure 16. Use of walking aids before amputation, %

Walking aids at home before the amputation, per amputation level:

- Transfemoral amputation (n=400): 42% none, 40% some walking aid, 17% not walking
- Knee disarticulation (n=114): 35% none, 47% some walking aid, 18% not walking
- Transtibial amputation (n=1882): 50% none, 46% some walking aid, 5% not walking

Wheelchair use (regardless of extent) before the first amputation (n=1897):

- 70% did not use a wheelchair
- 29% used a wheelchair
- 1% could not answer the question regarding wheelchair use

Comment: Almost half of the patients used walking aids, even before the amputation. Patients whose amputation level became TTA used a slightly lower degree of walking aids and fewer stated that they were not walking, compared with those undergoing TFA or KD, which probably reflects a higher degree of morbidity at the higher amputation levels.

MOBILITY BEFORE AMPUTATION

Self-reported level of mobility before amputation is measured with LCI-5-pre, which consists of 14 questions answered on a five-point scale (0 = can not, 1 = yes, with the help of another person, 2 = yes, with supervision, 3 = yes, independently with walking aids, 4 = yes, independently without walking aids).

The result is presented as two subscales (0-28) and summed up to a total score (0-56). The subscales illustrate basic and more demanding activities with prostheses. Examples of basic activities are getting up from a chair, walking indoors, walking outdoors on a flat surface and walking over a curb. Examples of demanding activities are walking on uneven ground, walking and at the same time carrying an object, getting up from the floor and walking a few steps without the support of a railing.

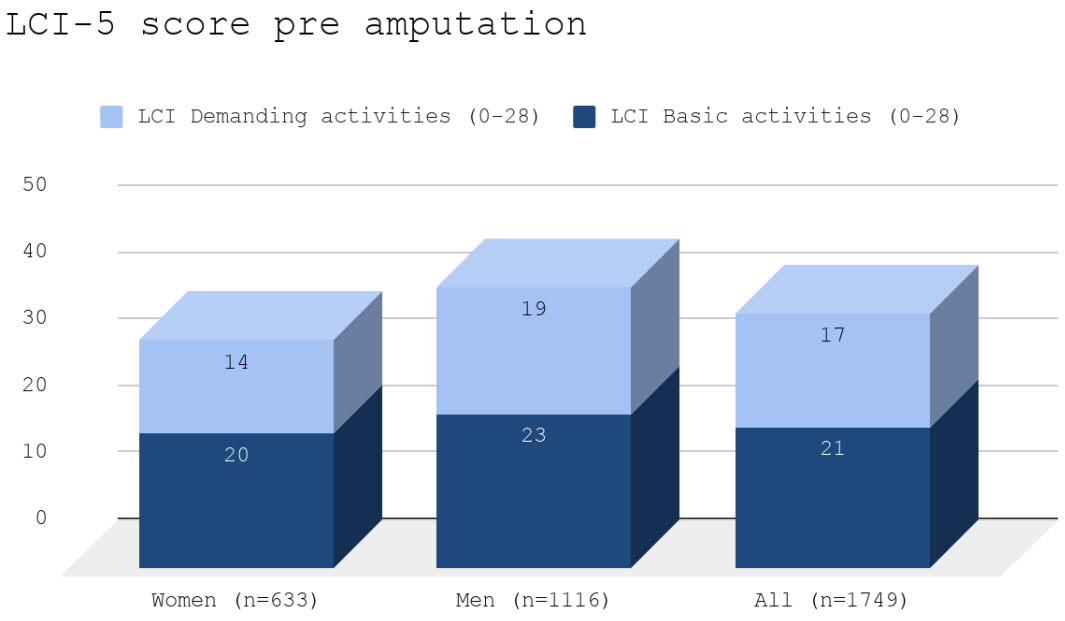


Figure 17. LCI-5 pre (median) before amputation, by sex and for all. The difference between the sexes is statistically *significant* (p <0.000)

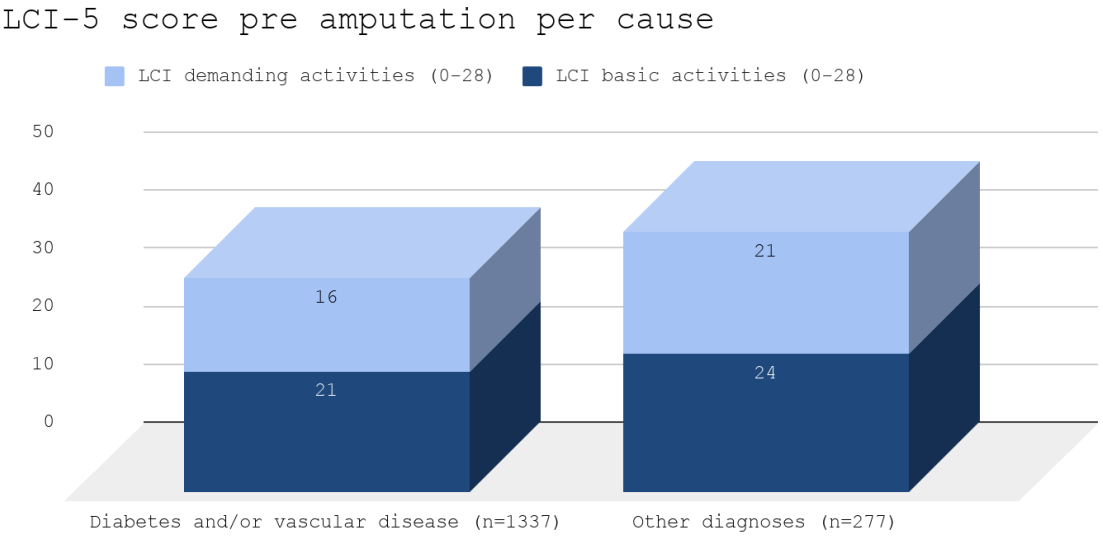


Figure 18. LCI-5 pre (median) before amputation per amputation causes vascular disease with/without diabetes and all other diagnoses. The difference between the diagnostic groups is statistically significant (p <0.000)

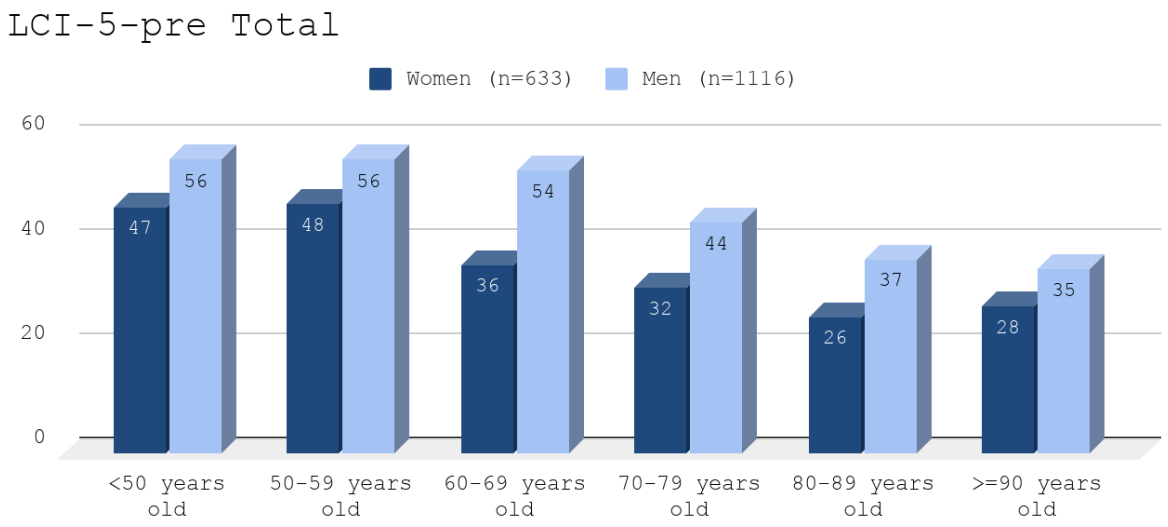


Figure 19. LCI-5-pre Total (0 - 56) (median) by sex and age group.

Amputation diagnosis diabetes and/or vascular disease	TTA LCI-Pre Total Median (min-max)	TFA/KD LCI-Pre Total Median (min-max)
Woman > 60 years	35 (0-56) n=325	28 (0-56) n=146
Man > 60 years	44 (0-56) n=584	42 (0-56) n=157

Table 18. Pre-amputation mobility (LCI-pre Total, Md) in patients over the age of 60, with amputation diagnosis diabetes and/or vascular disease per sex and level: The differences between the sexes are statistically significant (TTA p <0.000, TFA / KD p = 0.001)

Comment: Women report lower mobility before amputation compared to men. In the same way, lower mobility before an amputation procedure due to diabetes and/or vascular disease is reported, compared with other causes of amputation. With increasing age, the mobility is reported to be lower in the age groups over 60 years. When analysing patients > 60 years with amputation due to diabetes and/or vascular disease to sex and amputation level, lower mobility is evident in women and in patients with a higher amputation level.

PROM - FOLLOW-UP AFTER AMPUTATION

Follow-ups describe the situation 6, 12 and 24 months after the amputation and refers to patients with a transtibial or higher amputation level. In the event of a new amputation (re-amputation to a higher level or bilateral amputation), a new follow-up period begins, i.e. 6, 12 and 24 months, respectively, after the last amputation or re-amputation to a higher level.

This year's report is based on:

- 1395 patients (33% women, 67% men) and 2430 follow-ups:
  - 47% (n=1142) 6 months after amputation
  - 34% (n=842) 12 months after amputation
  - 17% (n=424) 24 months after amputation
  - 1% of registrations refer to follow-ups performed> 2 years
- The majority of follow-ups concern TTA (74%), followed by TFA (19%) and KD (6%)
- Women were in mean 77 years old (18-101) and men 71 years old (21-98) at the first registered follow-up
- 90% of follow-ups involve unilateral amputations and 10% concern bilateral amputations
- 80% had amputation diagnosis diabetes and/or vascular disease

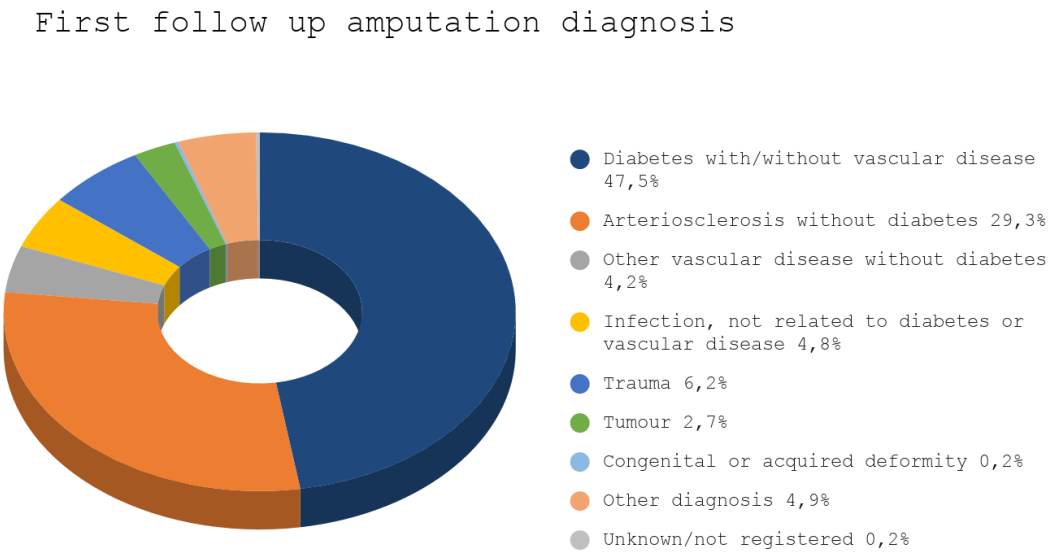
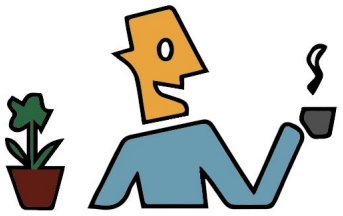


Figure 20. Distribution of amputation diagnoses at the first follow-up (%).

Comment: Patients with a unilateral TTA due to diabetes and/or vascular disease dominates the follow-up data. Two-thirds are men. The average age at follow-up was 77 years for women and 71 years for men. Registration has mainly taken place at units for prosthetic rehabilitation. This means that the information presented to a large extent represents patients attending prosthetic rehabilitation. The following report only includes the defined follow-ups at 6, 12 and 24 months after the amputation.

HOUSING SITUATION AFTER AMPUTATION



- 81% (n = 1133) had at the first follow-up returned to the same accommodation as before the acute deterioration which led to the amputation.
- 19% (n=260) had not returned to the same accommodation.
- The average age of those who returned to their homes was 72 years. For the group who did not return to their homes, the average age was 77 years.

TIME TO PROSTHETIC TRAINING

TIME TO START OF PROSTHESIS TRAINING DIVIDED BY LEVEL	DAYS AVERAGE (SD)	DAYS MEDIAN (min-max)
Transtibial amputation (n=1086)	101 (72)	83,5 (5 - 500)
Knee disarticulation (n=78)	146 (79)	125,5 (17 - 360)
Transfemoral amputation (n=244)	130 (81)	112 (19 - 490)

Table 19: Number of days from amputation (final level) to start of training with an individual prosthesis at the rehabilitation unit, divided by level. In the calculation, individual extreme values have been removed (<5 days and> 500 days).

TIME TO START OF PROSTHESIS TRAINING IN TTA, COMPARISON BETWEEN TIME PERIODS	DAYS AVERAGE (SD)	DAYS MEDIAN (min-max)
2011-2013 (n=184)	102 (51)	91 (27 - 440)
2014-2016 (n=338)	107 (74)	86 (5 - 466)
2017-2019 (n=314)	79 (60)	62 (10 - 500)

Table 20: Number of days from amputation to start of prosthesis training for patients with transtibial amputations, by year, based on date of training start. In the calculation, individual extreme values have been removed (<5 days and> 500 days).

Comment: Shorter time from amputation to prosthesis training start highlights a more effective Health care pathway. Given the large variation in the number of days, the median value should primarily be considered. Analysis for patients with TTA divided into time periods shows that time to start of prosthesis training has decreased since the register started to publish these figures. .

PROSTHESIS USE

ABILITY TO INDEPENDENTLY DONN AND DOFF THE PROSTHESIS

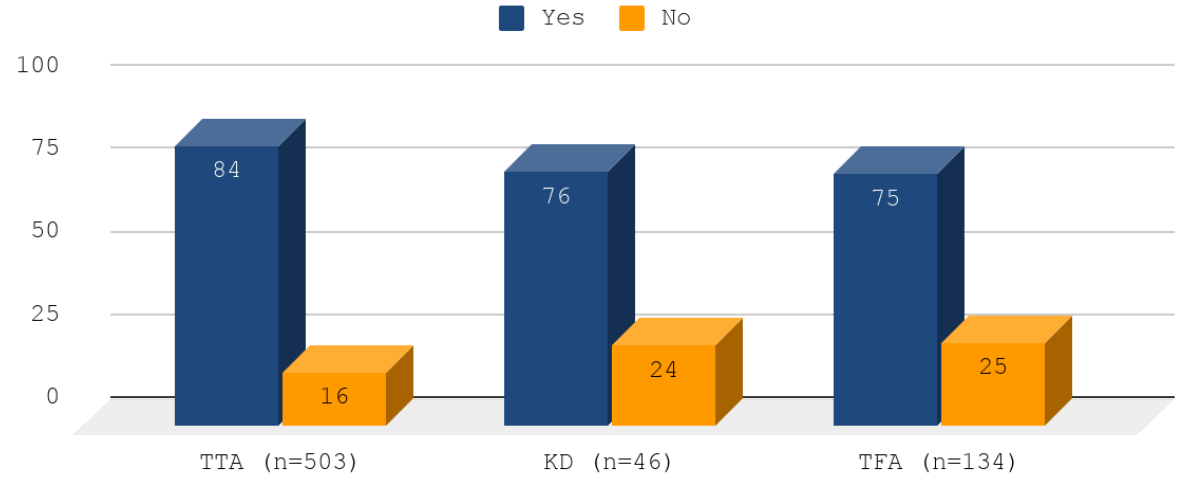


Figure 21. Ability to independently put on and take off the prosthesis in unilateral TTA, KD and TFA 12 months after amputation,%.

Comment: Not being able to put on and take off the prosthesis without help limits the possibility of a good prosthetic function. A slightly higher proportion of people with TTA (84%) can independently put on and take off the prosthesis 12 months after the amputation compared to those with KD and TFA (approx. 75%).

PROSTHETIC USE SCORE

Prosthetic Use score (0-100) combines the number of days/week and the number of hours/day the prosthesis is normally used (i.e. how much the patient states to normally wear the prosthesis).

100 corresponds to the prosthesis being used every day> 15 hours/day. 50 corresponds to the prosthesis e.g. being used every day for 7-9 hours, or fewer days, but for more hours/day. 0 means that the prosthesis is not used at all during a normal week.

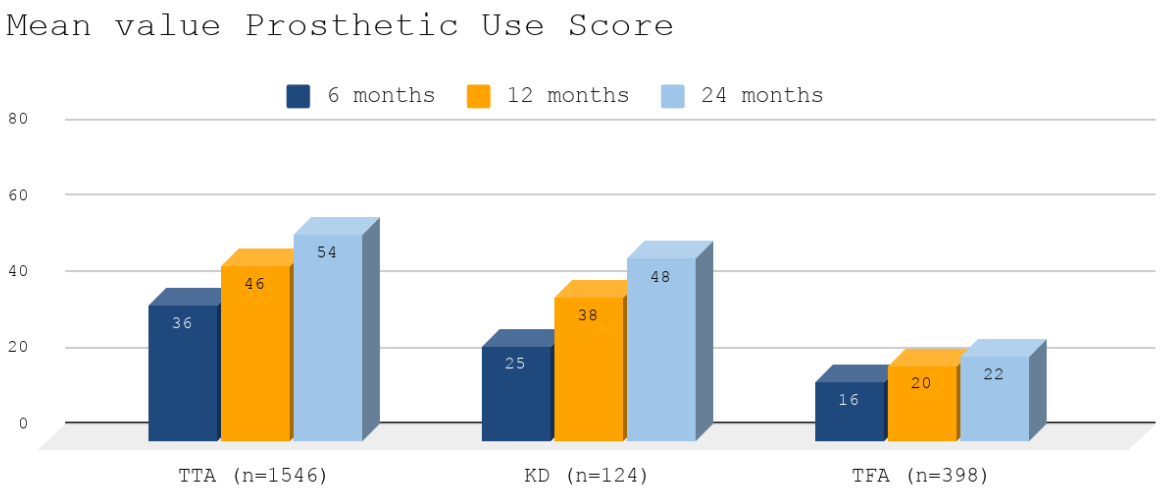


Figure 22. Mean value for Prosthetic Use score per follow-up occasion in unilateral TTA, KD and TFA. The number (n) indicates the total number of patients per amputation level.

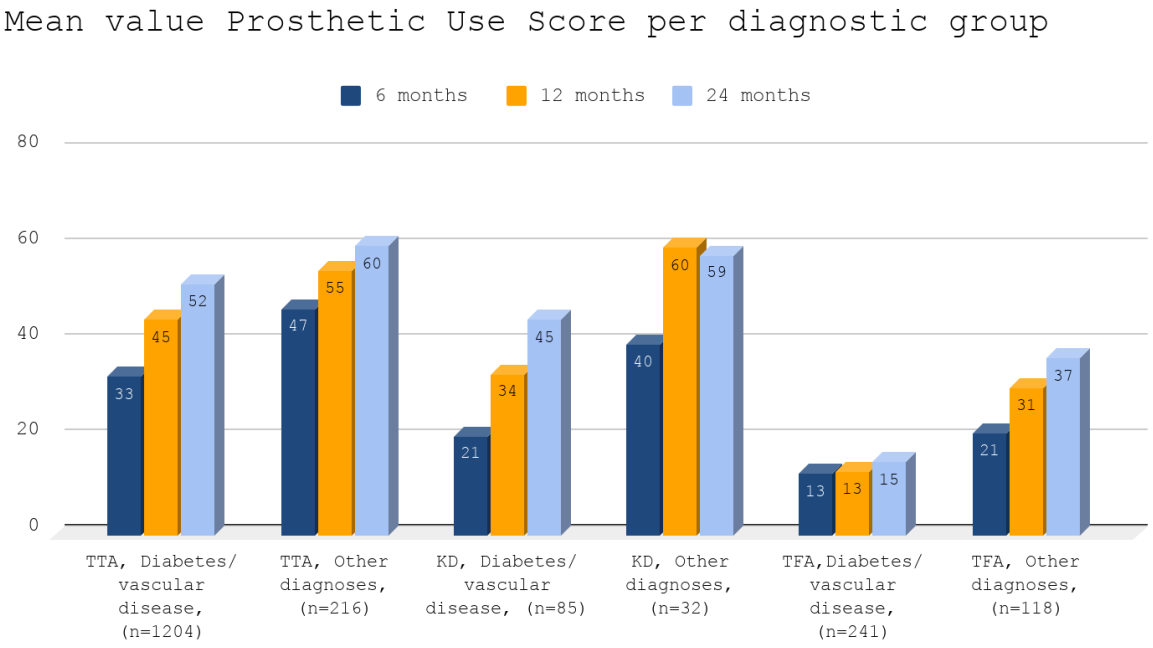


Figure 23. Mean value for Prosthetic Use score per follow-up occasion in unilateral TTA, KD and TFA, divided into two diagnostic groups. The number n indicates the total number of patients per amputation level and diagnosis group.

SEX	TTA Mean (SD) Median (min-max)	TFA Mean (SD) Median (min-max)
Woman	45 (2,5) 51 (0-100) n=159	13 (2,7) 4 (0-71) n=55
Man	46 (1,7) 51 (0-100) n=372	24 (3,0) 9 (0-100) n=94

Table 21. Prosthetic Use score at the 12-month follow-up for women and men, per amputation level unilateral TTA and TFA. The difference between the sexes is statistically significant at TFA (p = 0.036) but not at TTA.

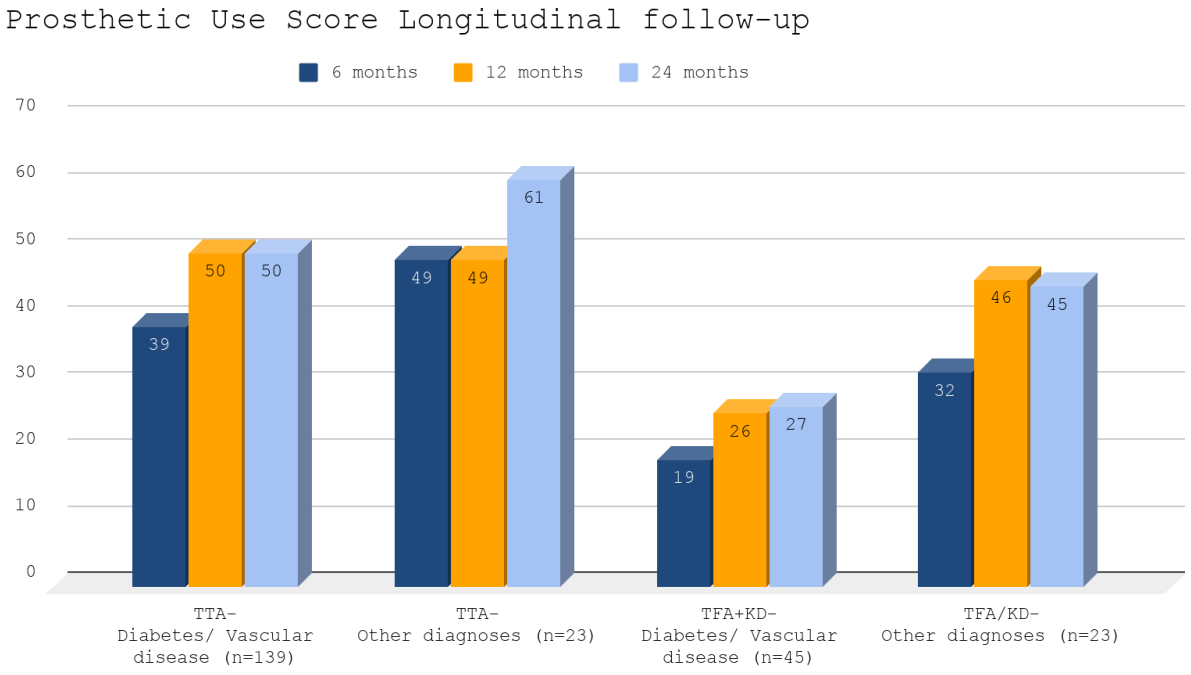


Figure 24. Longitudinal follow-up. Mean Prosthetic Use score in the smaller group of patients with unilateral TTA and KD/TFA, followed on all three occasions (6, 12 and 24 months), divided by amputation diagnosis Diabetes and/or Vascular Disease and Other diagnoses.

Comment: In general, prosthesis use increases slightly over time and the prosthesis is used more in TTA compared to those with amputations at higher levels. Reporting by sex (12-month follow-up) indicates that a TTA prosthesis is used to the same extent by both sexes, but men use a TFA prosthesis slightly more than women. A low degree of prosthesis use is reported in patients with TFA due to diabetes and/or vascular disease. The longitudinal follow-up of the small group of patients with unilateral TTA and KD/TFA followed on all three occasions (Figure 24) confirms the same result.

MOBILITY

MOBILITY AIDS

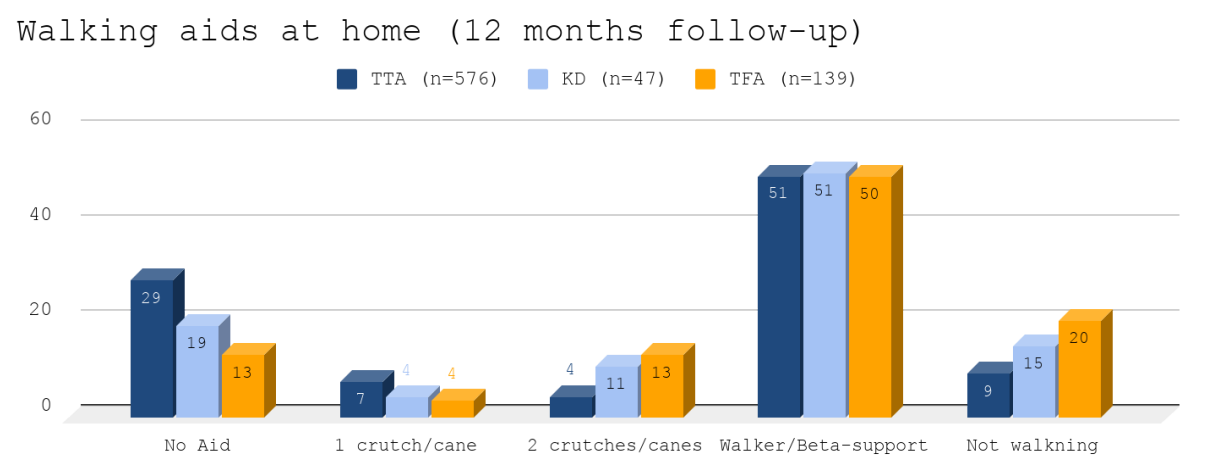


Figure 25. Walking aids for prosthesis use at home 12 months after amputation in unilateral TTA, KD and TFA, (%).

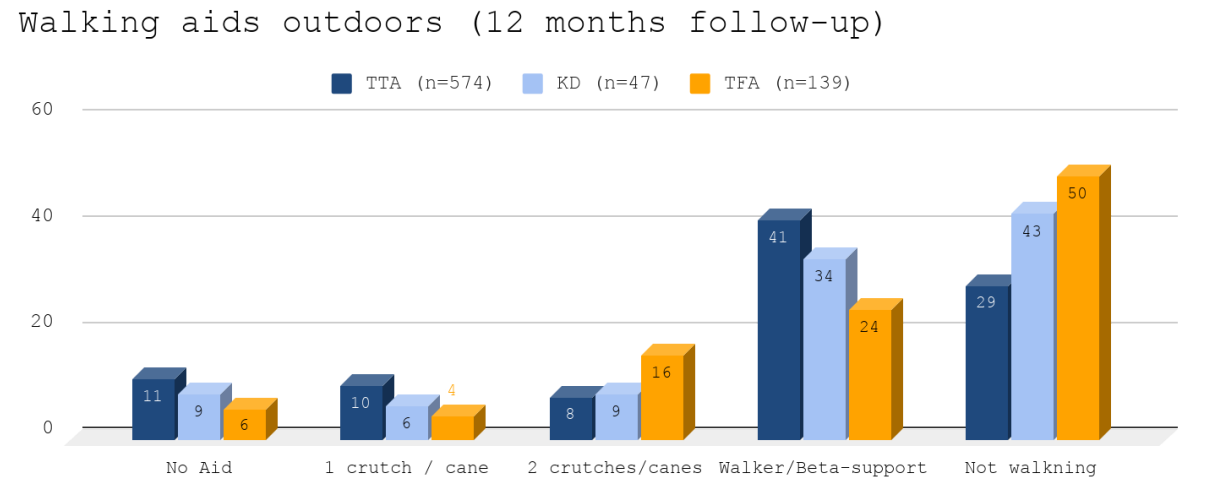


Figure 26. Walking aids at outdoor prosthesis use 12 months after amputation in unilateral TTA, KD and TFA (%).

Wheelchair use (regardless of extent) in unilateral amputations after 12 months from procedure:

- Transtibial amputation: 84%
- Knee disarticulation 80%
- Transfemoral amputation 93%

WALKING AIDS AT HOME AND OUTDOORS IN UNILATERAL TTA

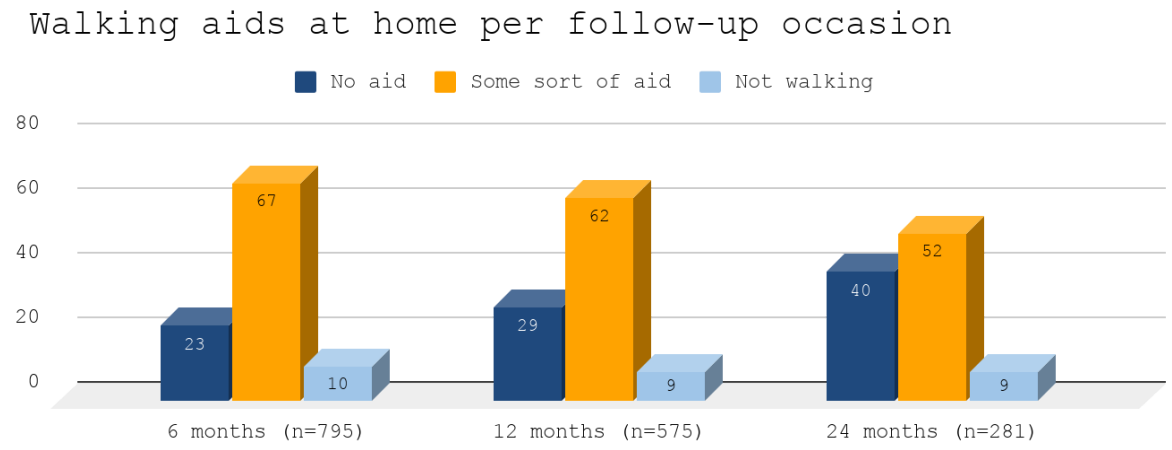


Figure 27. Summary of walking aids at prosthesis use at home 6, 12 and 24 months after unilateral TTA (%). A walking aid includes all the alternatives according to figure 26.

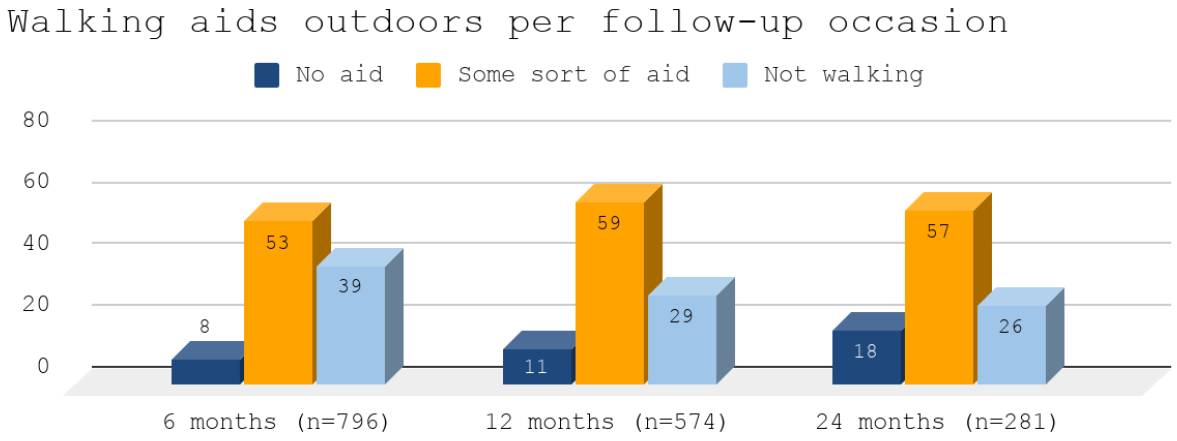
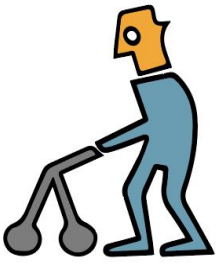


Figure 28. Summary of walking aids at outdoor prosthesis use 6, 12 and 24 months after unilateral TTA (%). A walking aid includes all the alternatives according to figure 26.



WALKING AIDS AT HOME AND OUTDOORS IN BILATERAL AMPUTATIONS

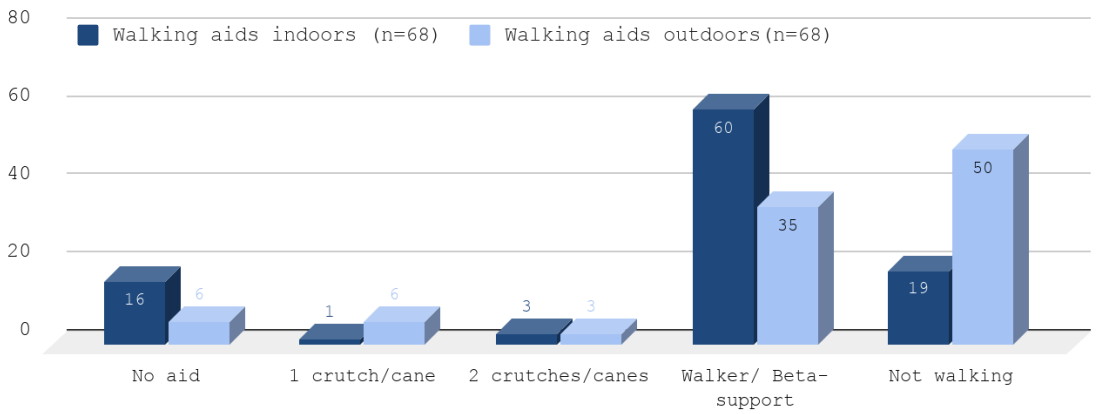


Figure 29. Walking aids for prosthesis use at home and outdoors, respectively, at 12-month follow-up for patients with bilateral amputations, regardless of the combination of amputation levels (%).

Wheelchair use (regardless of extent) in bilateral amputations at 12 months: 94%

Comment: Patients with a lower limb amputation are to very high degree dependent on both walking aids and wheelchairs. Many also state that they do not wear the prosthesis outdoors at all. In general, the need for walking aids is greater at TFA and KD compared with TTA and when walking outdoors compared with walking at home. In patients with unilateral TTA, there is a reduced need for walking aids over time, and no walking aid is stated in 40% at home and 18% outdoors.

COMFORT OF PROSTHETIC SOCKET

The perception of how comfortable the prosthetic socket is, is indicated by a number between 0-10 (0 = worst possible comfort, 10 = best possible comfort) in accordance with the Socket comfort score.

LEVEL	6 Months MD (min-max)	12 months MD (min-max)	24 months MD (min-max)
Transtibial amputation, TTA	8 (1 - 10) n=323	7 (0 - 10) n=226	7 (0 - 10) n=137
Knee disarticulation, KD	6 (0-10) n=15	7,5 (3-10) n=16	-
Transfemoral amputation, TFA	7 (0 - 10) n=81	7 (0 - 10) n=56	8 (1 - 10) n=29

Table 22. Median value of the socket comfort score (0 - 10) in unilateral TTA, KD and TFA at 6, 12 and 24 months.

Comment: The "socket comfort score" was introduced as a new variable in 2017. At KD, the number at 24 months is <10 and not reported.

MOBILITY WITH A PROSTHESIS

The ability to move with a prosthesis is estimated with the Locomotor Capability Index (LCI-5) which consists of 14 questions. The patient indicates their ability to perform various tasks on a four-point scale. The result is

presented as two subscales (0 - 28) which are summed to a total score (0 - 56). The subscales illustrate basic and more demanding movements with prostheses. Examples of basic activities are getting up from a chair, walking indoors, walking outdoors on a flat surface and walking over a curb. Examples of demanding activities are walking on uneven ground, walking and at the same time carrying an object, getting up from the floor and walking a few steps without the support of a railing.

MOBILITY IN PATIENTS WITH A UNILATERAL AMPUTATION AT 12 MONTHS FOLLOW-UP

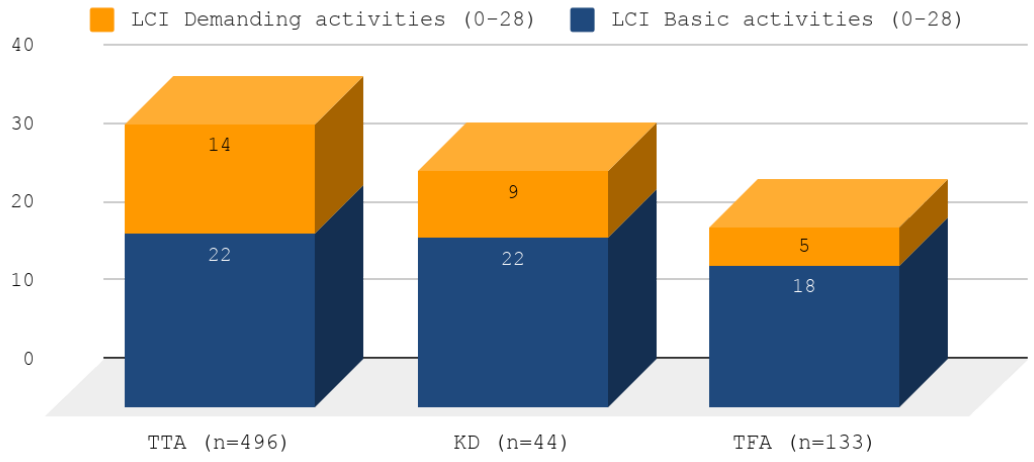


Figure 30. LCI-5 (Md) at unilateral TTA, KD and TFA at 12 months follow-up after amputation. The differences between the levels are statistically significant (p <0.000)

MOBILITY IN UNILATERAL TTA PER DIAGNOSTIC GROUP AND FOLLOW-UP

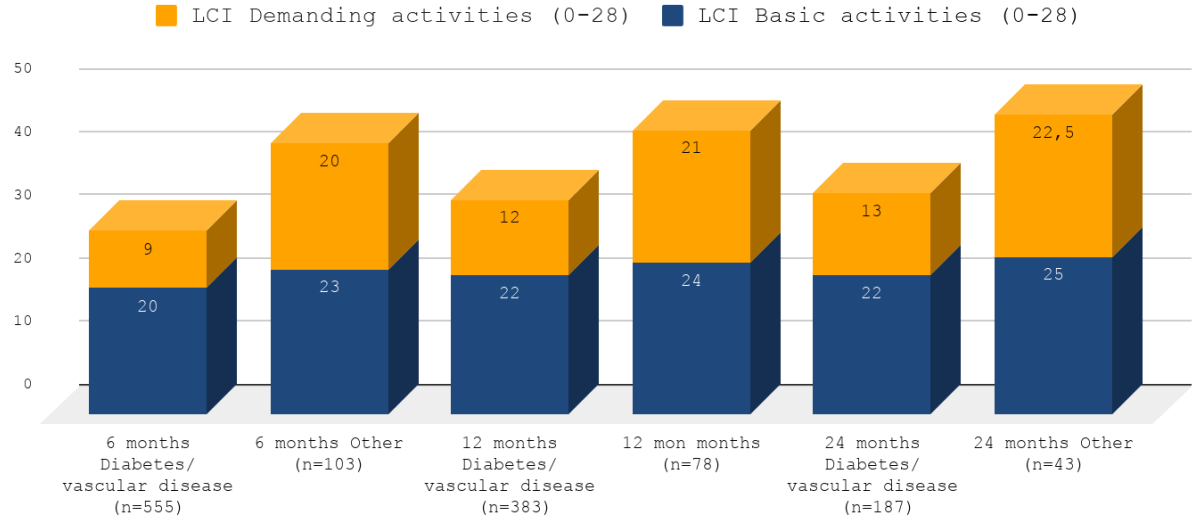


Figure 31. LCI-5 (Md) in unilateral TTA, divided into the diagnosis group diabetes and/or vascular disease and other diagnoses 6, 12 and 24 months after amputation.

MOBILITY IN UNILATERAL TFA PER DIAGNOSTIC GROUP AND FOLLOW-UP

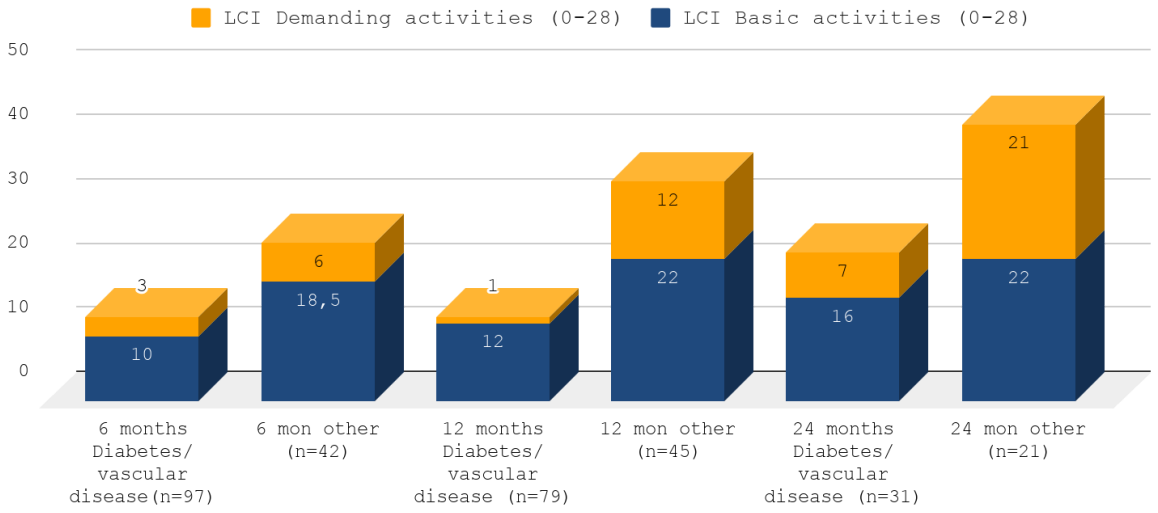


Figure 32. LCI-5 (Md) in unilateral TFA divided into diagnosis group diabetes and/or vascular disease and other diagnoses 6, 12 and 24 months after amputation.

MOBILITY FOR WOMEN AND MEN WITH UNILATERAL TTA OR TFA DUE TO DIABETES AND/OR VASCULAR DISEASE

	TTA LCI-5 Total median (min-max)			TFA LCI-5 Total median (min-max)		
	6 months	*12 months*	*24 months*	*6 months*	*12 months*	*24 months*
Woman	17 (0-56) n=174	28 (0-54) n=122	24 (0-53) n=60	7 (2-44) n=35	9 (0-56) n=33	-
Man	34 (0-56) n=390	37 (0-56) n=260	40 (0-56) n=129	18 (2-51) n=61	20,5 (0-54) n=44	32,5 (0-52) n=22

Table 23. LCI-5 Total (Md) for women and men with unilateral TTA and TFA due to diabetes and/or vascular disease 6, 12 and 24 months after amputation. The number of women with TFA at 24 months was <10 and is not reported. The differences between the sexes are statistically significant (TTA p <0.000 at all three follow-ups; TFA p <0.000 at 6 months and p = 0.004 at 12 months).

LONGITUDINAL FOLLOW-UP ON MOBILITY

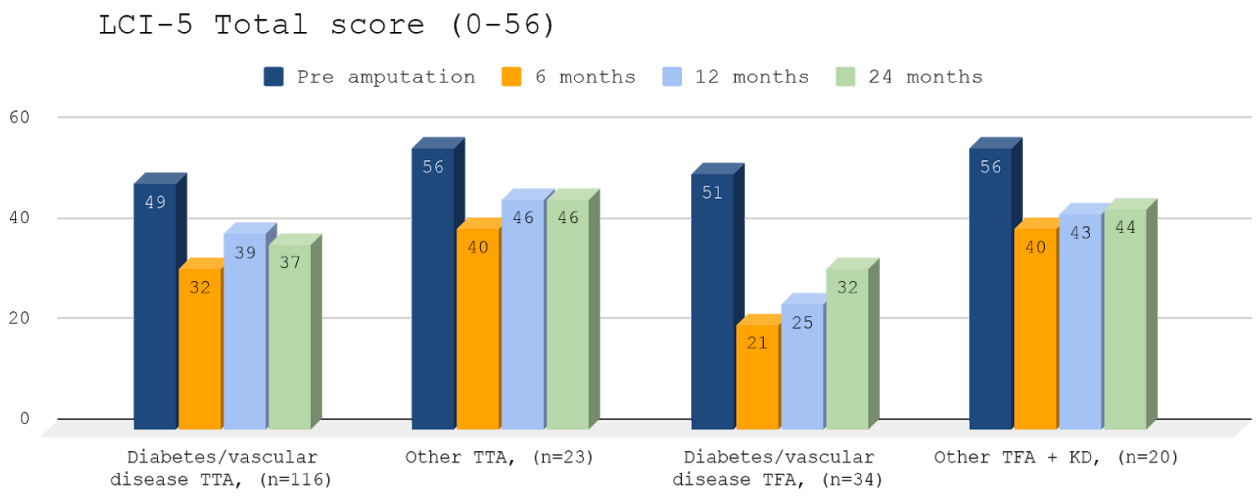


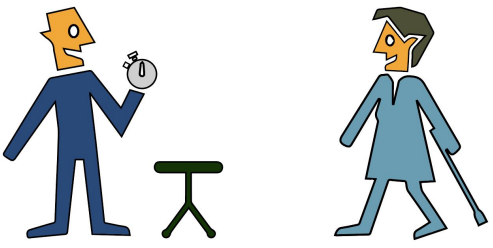
Figure 33. Longitudinal follow-up of the smaller group of patients with unilateral amputations where the same individual has answered the LCI-5 before amputation and at 6, 12 and 24 months after amputation, distributed by level (TTA or TFA + KD) and by diagnosis (diabetes and/or vascular disease and other amputation diagnosis).

Comment: Lower self-reported mobility is indicated at higher amputation levels. Women, with TTA or TFA, due to diabetes and/or vascular disease report lower prosthetic mobility than men with the same level of amputation, respectively. At KD/TFA due to diabetes and/or vascular disease, markedly low mobility is indicated and consistently lower mobility, measured by LCI-5, is stated for the demanding activities compared to the basic activities.

An increased risk of falling in patients with LCI-5 score <15 for the demanding activities has been reported in patients with unilateral TTA 6 months after prosthetic rehabilitation (Dite et al 2007). In the report above, only patients with amputations due to other causes than diabetes and/or vascular disease have >15 for the advanced activities at 12 months. This highlights an increased risk of falling for a very large group of patients with lower limb amputations.

TIMED - UP AND GO TEST (TUG)

TUG is a standardized mobility test that includes the time it takes to get up from a chair, walk 3 meters, turn, go back and sit back down again. In SwedeAmp, TUG is performed using the patient's usual walking aid, and the time is measured in full seconds. Values of TUG <10 sec are considered normal and> 30 sec are considered as increased fall risk.



DIAGNOSIS AND TIME INTERVAL	UNILATERAL TTA, Seconds AVERAGE (SD), amount	UNILATERAL TFA, Seconds AVERAGE (SD), amount
DIABETES AND/OR VASCULAR DISEASE		
6 months	27 (17), n=347	61 (35), n=45
12 months	25 (18), n=211	64 (47), n=28
24 months	24 (16), n=100	-
OTHER DIAGNOSES		
6 months	18 (13), n=71	41 (29), n=24
12 months	16 (10), n=46	30 (18), n=26
24 months	18 (14), n=19	29 (19), n=12

Table 24. Timed - up and Go test in full seconds (average) for one-sided TTA and TFA, divided by diagnostic group and follow-up occasion. Only 5 patients had performed the TUG test with TFA due to diabetes and/or vascular disease at 24 months follow-up and is therefore not included.

Unilateral transtibial amputation due to diabetes and/or vascular disease:

- TUG <10 sec was performed by 6%, 9% and 13% of patients at follow-up 6, 12 and 24 months
- TUG> 30 sec was performed by 35%, 24% and 25% of patients at follow-up 6, 12 and 24 months

Unilateral transfemoral amputation due to diabetes and/or vascular disease:

- TUG <10 sec was not performed by any individual at any follow-up
- TUG> 30 sec was performed by 87% and 75% of the patients at follow-up 6 and 12 months

Comment: The TUG test generally shows reduced mobility and increased risk of falling, especially at TFA. There is extensive scientific literature available, both for patients with lower limb amputations and other groups. In a meta-analysis, Bohannon et al (2001) reported TUG values of 9.4 seconds in healthy elderly> 60 years old. In another study, Dite et al (2007) reported an increased risk of falling at TUG value> 19 sec in patients with unilateral TTA 6 months after prosthetic rehabilitation.

PAIN

RESIDUAL LIMB PAIN AT UNILATERAL AMPUTATION

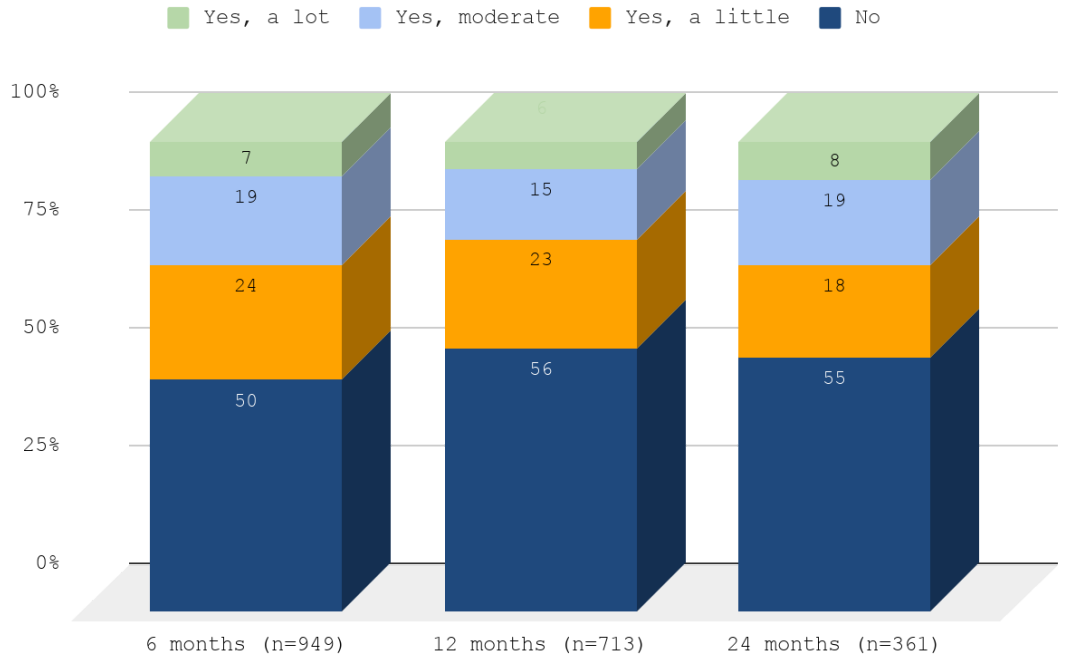


Figure 35. Incidence of residual limb pain in unilateral amputation, regardless of level above the ankle, at the 6, 12 and 24 month follow-up, (%).

LONGITUDINAL FOLLOW-UP - PAIN IN THE RESIDUAL LIMB IN TTA AND TFA/KD:

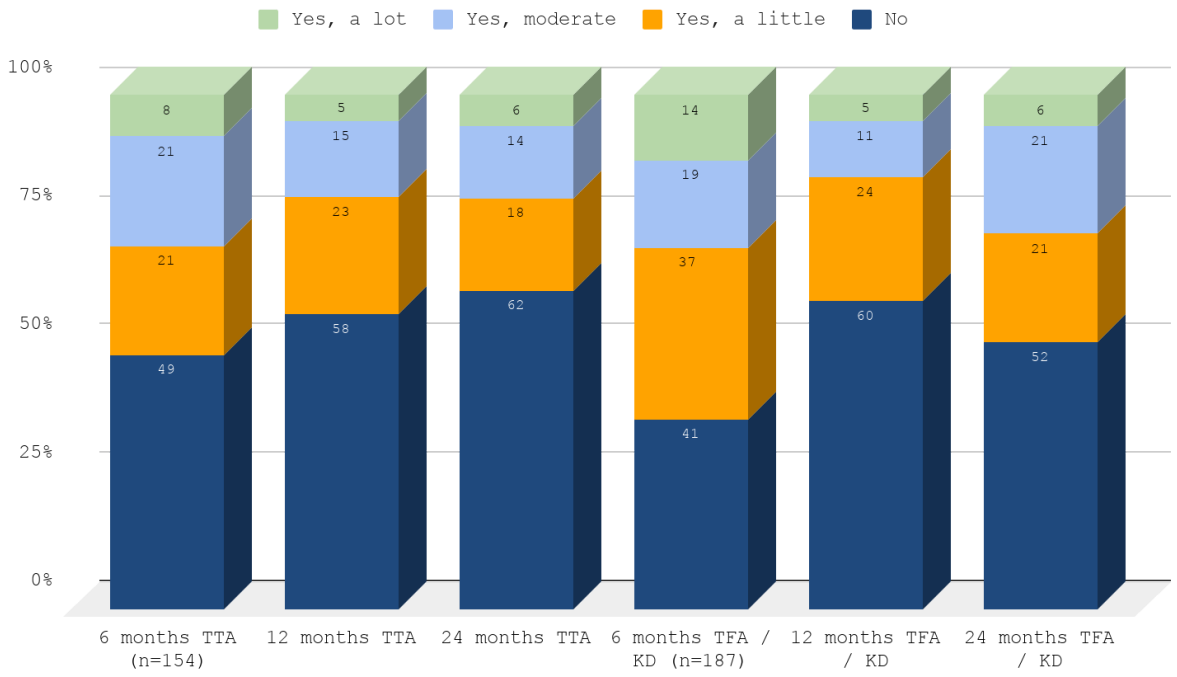


Figure 36. Longitudinal follow-up. Prevalence of residual limb pain in the smaller group of patients who answered the same question at all three follow-ups in unilateral TTA (n = 154) and unilateral TFA + KD (n = 63) (%).

TREATMENT OF RESIDUAL LIMB PAIN (FOR ANSWER "YES A LITTLE" - "YES A LOT", REGARDLESS OF WHICH FOLLOW-UP) (N = 1600)

- 37% indicated that they received pain medication or other treatments
- 59% indicated that they did not need any treatment
- 4% stated that they did not receive any medication or other treatment, but that they would have needed it, or that they had given up treatment due to side effects or other discomforts

Frequency of treatment for residual limb pain (n = 569): 58% daily, 24% a few times/week, 18% occasionally.

PHANTOM LIMB PAIN

PHANTOM LIMB PAIN - UNILATERAL AMPUTATION

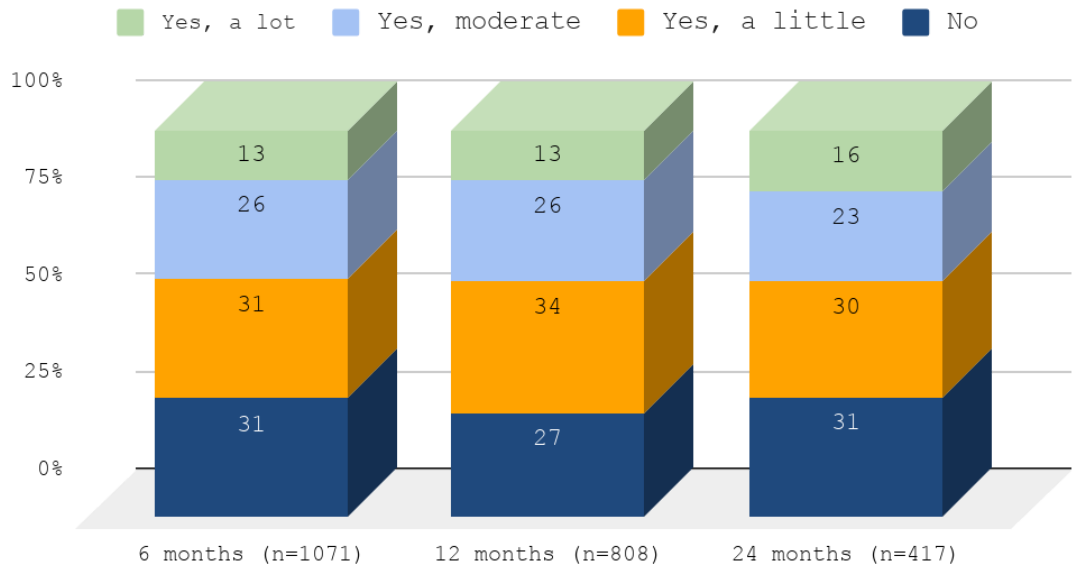


Figure 37. Prevalence of phantom pain limb in unilateral amputation, regardless of level above the ankle, at the 6, 12 and 24 month follow-up, (%).

LONGITUDINAL FOLLOW-UP PHANTOM LIMB PAIN - UNILATERAL TTA AND TFA/KD:

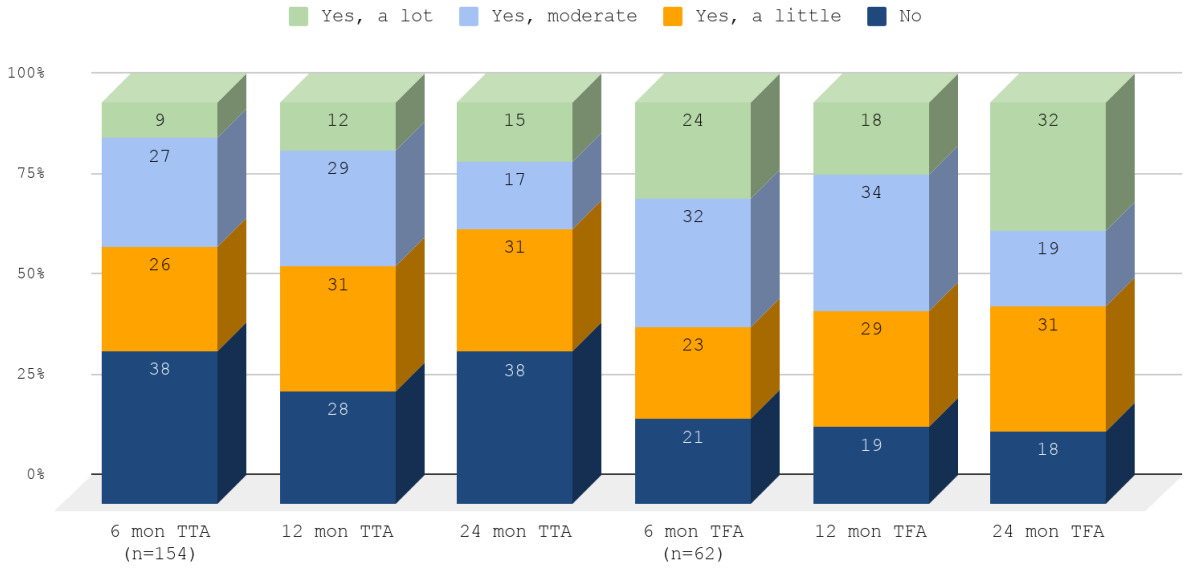


Figure 38. Longitudinal follow-up. Prevalence of phantom limb pain in the smaller group of patients who answered the question at all three follow-ups in unilateral TTA (n = 154) and unilateral TFA + KD (n = 62) (%)

Treatment of phantom limb pain (for answer "yes a little" - "yes a lot", regardless of the follow-up) (n = 1914):

- 37% indicated that they received pain medication or other treatments
- 57% indicated that they did not need any treatment
- 6% stated that they did not receive any medication or other treatment, but that they would have needed it, or that they had given up treatment due to side effects or other discomforts

Treatment frequency for phantom limb pain (n = 686): 64% daily 21% a few times/week 15% occasionally

Comment: About half of the patients indicate some degree of residual limb pain, and more (just over ⅔) indicate some degree of phantom pain. For both types of pain, 37% of them received treatment. For residual limb pain, 57% indicate daily treatment and for phantom pain, 67% state daily treatment. Based on longitudinal data of the smaller group of patients followed at all three follow-ups, it can be said that residual limb pain, especially in TTA, indicates some improvement over time. However, the same pattern is not seen for phantom pain. More problems with phantom pain are also reported in TFA/KD compared with TTA.

Overall situation

The question refers to the patient's perception of their current overall situation as an amputee. In the figures, the five answer alternatives have been merged into three levels (very good/good, neither good nor bad, very bad/bad).

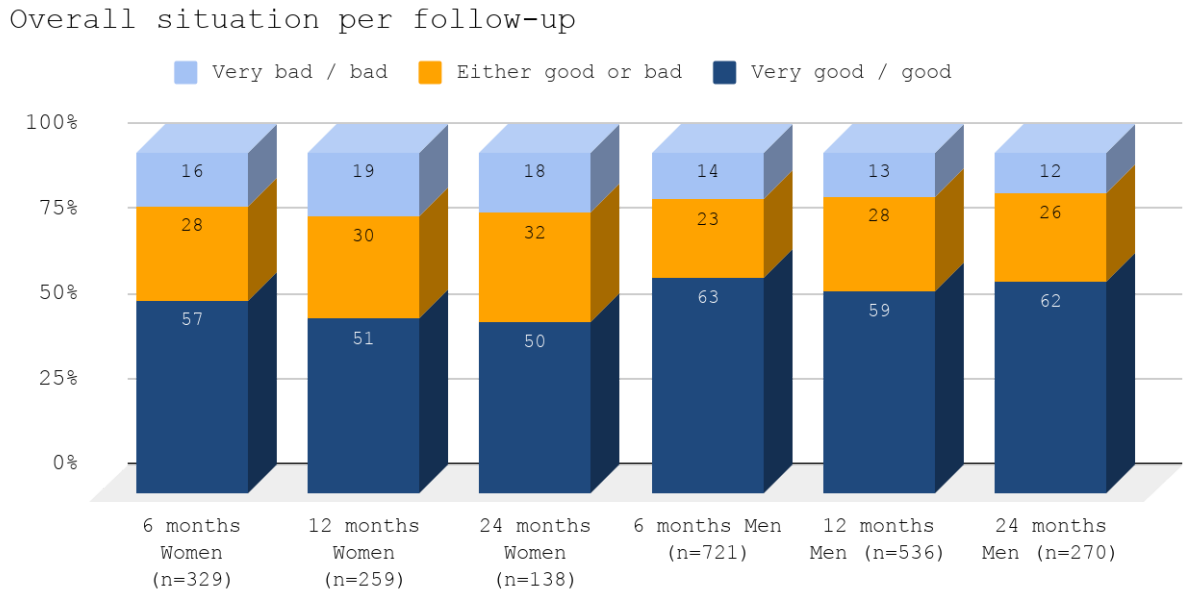


Figure 39. The patient's overall situation as an amputee 6, 12 and 24 months after the amputation, distributed by sex. The summary applies to all patients regardless of amputation level and amputation diagnosis (%)

OVERALL SITUATION AT UNILATERAL AMPUTATION - LONGITUDINAL FOLLOW-UP BASED ON LEVEL

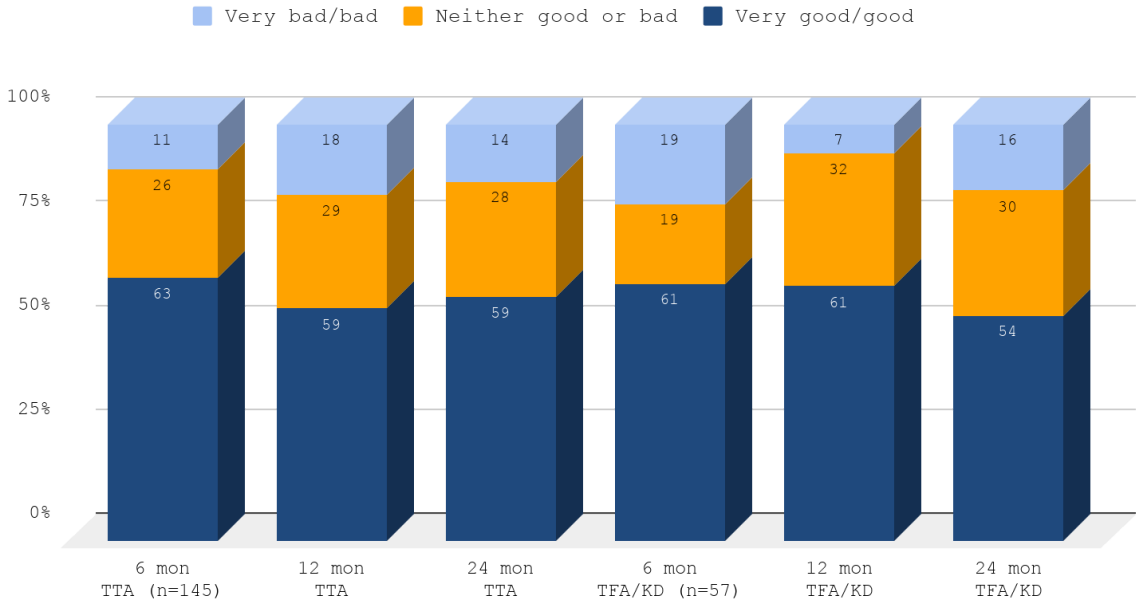


Figure 40. Longitudinal follow-up. The overall situation as an amputee in the small group of patients who answered the same question at all three follow-ups, divided into unilateral TTA (n = 145) and unilateral TFA + KD (n = 57).

Comment: In general, just over half of the patients rate their overall situation as an amputee as good or very good, without any significant changes over time. This is confirmed in the longitudinal data where patients with unilateral TTA answered the same question at all three follow-ups. In the longitudinal follow-up of the smaller group of patients with KD and TFA, there is a tendency for a slightly worse situation at 24 months.

HEALTH INDEX EQ - 5D - 5L

The EQ-5D index consists of 5 questions that shed light on mobility, hygiene, main activities, pain/discomfort and anxiety/depression. The answers can be calculated as an index value ranging from minus 0.594 and 1. A higher value indicates a higher self-rated health/health-related quality of life. SwedeAmp uses the EQ-5D-5L, with five response options since 2017. Previously, EQ-5D-3L was used and those results are not currently reported.

LEVEL	6 MONTHS AVERAGE (SD) amount	12 MONTHS AVERAGE (SD) amount	24 MONTHS AVERAGE (SD) amount
Unilateral Transtibial amputation	0,558 (0,295) n=349	0,594 (0,284) n=242	0,597 (0,301) n=140
Unilateral Knee or Transfemoral amputation	0,459 (0,316) n=116	0,468 (0,326) n=90	0,505 (0,339) n=55
Bilateral amputation (all combinations)	0,365 (0,319) n=50	0,412 (0,357) n=41	0,380 (0,377) n=33

Table 25. Mean value for EQ-5D-5-level Index in unilateral TTA, unilateral KD or TFA and in bilateral amputations, regardless of the amputation cause.

Comment: The EQ-5D index shows that individuals with unilateral TTA rate their general health higher than those with a higher amputation level. It also shows that both groups have slightly better health over time, i.e. a slightly higher index value. In recent years, a few studies using EQ-5D have been added to investigate general health after a leg amputation. EQ-5D is used as a patient-reported measure in many other Swedish quality registers and is used to calculate quality-adjusted life years in health economics studies for different patient groups. By including EQ-5D in SwedeAmp, it is possible to compare patients with lower limb amputation to completely different groups of patients.

OVERALL ANALYSIS OF THE PATIENT'S SITUATION BEFORE AND AFTER AMPUTATION

Studies have shown that there is a clear link between a better quality of life and a better ability to use a leg prosthesis (Davie-Smith et al. POI 2017; Wurdeman et al. POI 2018). However, people who have undergone lower limb amputation have different conditions for function with a prosthesis. For this reason, the patient's situation before and after the amputation is, in many cases, presented separately based on amputation diagnosis and amputation level. Data on patients with bilateral amputations is also often presented separately. The absolute largest amount of data in SwedeAmp is available for people with unilateral TTA due to diabetes and/or vascular disease. Analysis of results from the smaller group of patients with amputation due to other causes should be considered with caution, as this group is smaller and less homogeneous.

This year's report confirms that the group of patients often has reduced physical function already before the amputation. Pre-amputation mobility was stated to be lower for patients with diabetes and/or vascular disease than for others, and also lower at higher amputation levels and lower for women than for men. Many used both walking aids and wheelchairs. Most (90%) lived in their own homes before the amputation. At the first registered follow-up after the amputation, 81% had returned to the same accommodation as before the procedure.

Start of prosthetic rehabilitation takes place earlier in patients with TTA than among those with at higher amputation levels. In patients with TTA, the median time from amputation to the start of prosthesis training has decreased by almost 4 weeks since 2011-2013, now stated at 62 days. This can probably be explained by faster prosthetic production and a more efficient health care pathway

This year's report confirms that a preserved knee joint provides the best conditions for being able to use a prosthesis. All measurements in SwedeAmp that reflect different aspects of functioning with a prosthesis (prosthetic use score, use of walking aids, LCI-5, TUG and EQ-5D-5L) give the same picture. Patients with TTA state that they use the prosthesis more, have less need for walking aids and have better mobility compared to patients with higher amputation levels (KD and TFA). Patients with amputation due to diabetes and/or vascular disease generally have a poorer function and use their prosthesis less than those amputated due to other diagnoses.

The differences based on amputation diagnosis and amputation level are confirmed in the longitudinal analyses where only the small group that has registered data at all follow-ups is reported. The significantly lower number of patients in these follow-ups is partly due to high mortality and partly due to new amputation procedures being carried out within two years, and thus a new follow-up chain with new conditions has begun. When analysing the data, one must consider that the group of patients being followed for two years probably represents patients who have better general health than those who have not been able to be followed for two years.

In this year's report, more data has been analysed based on sex. In patients with the amputation diagnosis of diabetes and/or vascular disease, women report poorer mobility than men, even within the same level of

amputation. Regarding prosthesis use after 12 months, no difference is seen between the sexes at TTA, but at TFA women report less prosthesis use than men. For both sexes, however, a low use of TFA prosthesis is stated.

Many patients report problems with residual limb pain (about 50%) and phantom pain (about 67%). For the first time this year, longitudinal data is also reported for pain. These indicate some reduced residual limb pain over time, especially in TTA. Concerning phantom pain, no clear change is visible over time. Patients with TFA/KD report more problems with phantom pain compared to those with TTA.

In summary, just over half of the patients rate their overall situation as an amputee as good or very good and no significant changes are seen over time or between the sexes. Here, too, for the first time, longitudinal data are reported which confirm the result at TTA. However, patients with KD/TFA seem to rate their overall situation as somewhat worse over time. In TTA, the health index EQ-5D-5L indicates both a certain improved general health over time and better health than in KD/TFA, but longitudinal data for a defined group are not yet reported here.

In 2019, SwedeAmp has just over 7,000 patients registered, among these, follow-up data is available from a much smaller proportion; about 1400 patients. This is due to several factors: 1) follow-up data only concerns procedures above the ankle. 2) High mortality and co-morbidity rates mean that many patients never reach prosthetic rehabilitation. 3) All prosthetic rehabilitation units probably do not participate in SwedeAmp. In Sweden, prosthetic rehabilitation is organized under different principals and there is no current list of active units. This complicates the calculation of the register's degree of collaboration and degree of coverage for follow-up data, making it difficult to reach out with information to units where prosthetic rehabilitation takes place.

AFTERWORD

Since 2012 when we became a Swedish National Quality Register, we see a growing interest in the care of patients with lower limb amputations. This report includes some of the parameters we can analyze on a national level. Each clinic can also analyze their own data from their own perspectives as well..

Making it possible for each clinic to compare their own data with national data is a good way of improving quality. The amount of data in SwedeAmp is now beginning to be big enough to compare different treatment regimens and different geographical areas with each other. Over time, this will hopefully improve the quality of care for all patients with lower limb amputations in Sweden.

By time we hope and believe more clinics will engage in SwedeAmp.

“Prosthetic rehabilitation is not a cost, it is an investment” - Nils-Odd Tönnevold (Chairman of IC2A global patient organisation)

Bengt Söderberg & Kerstin Hagberg

Founder, Registry Director & Deputy Registry Director for SwedeAmp

CLARIFICATIONS AND ABBREVIATIONS

Bilateral amputation	Double-sided amputation - simultaneously or on different occasions
CPO	Certified prosthetists/orthotists
Diabetes	All types of diabetes, including diet-treated
EQ 5D-5l*	A general health index, where 5 questions with 5 alternatives each result in a scale between minus 0, 594 and 1 (1 represents the best possible health) www.euroqol.org/
KD	Knee disarticulation, knee amputation (amputation through the knee joint)
LCI-5*	Locomotor Capability Index. The patient's perception of their ability to move, 0 - 56, which consists of the sum of two subscales each 0 - 28
MHFA	Mid/Hind foot amputation (amputation through mid or hind foot)
P&O	Prosthetics & Orthotics
Primary amputation	The first intervention for a condition requiring an amputation, per side
Primary amputation level	The level selected at the primary amputation
PROM	Patient-reported outcome measures
Prosthetic Use Score*	Self-estimated report for time the prosthesis is used during a normal week, 0–100
Re-amputation	Revised amputation procedure to a higher level (through or proximal to the next joint) on an extremity where a previous amputation has not yet healed
Revision	Surgical intervention of such a scope that an operating room is required, with cleaning of amputation wounds/removal of soft tissue and/or bones, but with unchanged classification of amputation level
Final amputation level	The level that existed during healing or at death without healing
Socket Comfort Score*	The patient's self-assessment of how comfortable the current prosthesis socket is, 0-10
TFA	Transfemoral amputation (amputation through the femur)
Timed - Up and Go Test (TUG)	A standardized function test measured in seconds
TPHD	Transpelvic amputation/Hip disarticulation (amputation through the pelvis or hip joint)
TTA	Transtibial amputation (amputation through the lower leg)

Unilateral amputation	One-sided amputation

** for all PROM measures, a higher figure is a better outcome <*

See the website www.swedeamp.com for references