Annual report 2024



AMPUTATION- AND PROSTHETICS REGISTRY

FOR THE LOWER EXTREMITY

A Swedish national quality register

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Preface

This is the English version of the 2024 SwedeAmp Annual Report. It is slightly shortened and somewhat adapted to an international audience. Even though the lay-out may differ a bit, the numbering of Tables and Figures are all in line with the Swedish version for 2024, which can be downloaded at our webpage: <u>SwedeAmp</u>. We kindly ask for your understanding regarding any linguistic imperfections and wish to emphasise the report is not a peer-reviewed scientific publication.

SUMMARY

In Sweden, patients undergoing a lower limb amputation are predominantly older individuals, with amputation performed due to diabetes and/or vascular disease. This group accounts for 82% of all registered patients. SwedeAmp holds data on more than 13,000 patients (39% women, 61% men) with over 19,000 amputation procedures (Figure 1).

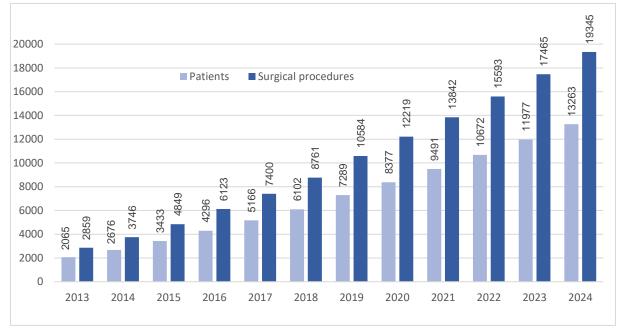


Figure 1. Number of registered patients and procedures per year until 2024. The columns for 2013 include data from years prior to 2013.

The median age at the patient's first registered amputation is 76 years (women Md 79 years, men Md 74 years). The vast majority (94%) also have other concurrent illnesses or impairments that affect survival and the possibility for prosthetic rehabilitation. Mortality is high (39% within 12 months) and highest among those with amputation due to vascular disease without diabetes (43%). In patients with amputation due to diabetes (with or without vascular disease), the 12-month mortality is 32%. Within one year, 28% of patients with transtibial amputation (TTA) and 43% of those with transfemoral amputation (TFA) had died.

All follow-up data indicate better prosthetic functioning when the anatomical knee joint is preserved, compared with the higher levels of amputation. Our data reveal regional differences in amputation level. Swedish regions with a higher proportion of amputations through or above the knee (KD/TFA) in relation to below-knee (TTA) are encouraged to review their routines and implement improvements.

We observe differences between sexes. Women are older, the amputation is more often due to "vascular disease without diabetes," and women more frequently undergo a higher amputation (KD/TFA) compared with men. Data indicate that fewer

women than men receive a prosthesis—this appears to apply regardless of amputation level, age group, or cause of amputation. Women report poorer mobility prior to amputation and poorer prosthetic mobility after amputation. In many cases, women also report lower quality of life at follow-up compared to men.

Following a primary amputation, additional procedures (revision or re-amputation to a higher level) may be necessary to achieve healing. Data from Skåne University Hospital (SUS) show that such surgical interventions usually occur within 2 months, but a prolonged process involving multiple repeated procedures over the course of a year may also occur. Minimizing the number of subsequent operations, while avoiding an unnecessarily high primary amputation level, is a difficult equation requiring surgical knowledge and experience.

The surgical technique in TTA plays a role. Today, so-called sagittal or skewed flaps dominate in all Swedish regions participating in the register. Our prosthetic data show that these flaps lead to faster prosthetic provision compared with posterior flaps. During the early phase of prosthetic rehabilitation, fewer complicating factors at the time of prosthetic provision are reported with sagittal/skewed flaps compared with posterior flaps, while no difference is seen related to later prosthetic provisions. (e.g. after two years).

More patients with TTA compared to those with higher levels (KD/TFA) receive a prosthesis (49% vs. 22%). The analysis includes patients who, prior to amputation, were reported able to walk or bear weight on the affected side. The number of days from amputation to the first prosthetic fitting in patients with TTA is currently md 73 days. The corresponding time for TFA is 93 days. This is a slight increase which might be due to procurement or re-organization processes and shortages of staff with orthopedic technical expertise. The variation in time to first prosthesis is however large. A postoperative "stump infection" or "fall injury," increases the time to first TTA prosthesis by 1.5–2 months compared to cases whit "no complications" reported. Different rehabilitation interventions result in different conditions for early mobilization with prosthesis. Delayed wound healing is the most common postoperative complication in TTA. Under the right conditions, patients with unhealed surgical wounds can still load the stump in a prosthesis and thereby start gait training earlier. One such condition is a short lead time for prosthesis fabrication. Our data show that in cases where prosthetic training started before complete healing, it has usually been with a "direct-laminated prosthetic socket." This is one reason why the time to first TTA prosthesis is shorter with a direct-laminated socket compared with digital or manual cast methods.

Having an additional prosthesis with features not included in the everyday prosthesis may be a prerequisite for participating in sports, work and family life, or for visiting a public pool. Our data show that an additional prosthesis is most often prescribed as a hygiene prosthesis, activity prosthesis, or spare prosthesis, and primarily for children and individuals under 69 years of age. People who undergo amputation at a younger or working age are fewer in number, but their need for access to additional prostheses is substantial.

Our patient-reported data show that many patients report reduced mobility already prior to surgery. Time to start of prosthetic training is currently about 3 months after TTA and nearly 4 months after TFA. Most patients with unilateral or bilateral TTA use their prostheses to a significant extent. Patients with unilateral TFA due to diabetes and/or vascular disease use their prosthesis significantly less and generally report great difficulties in all follow-up data. Many patients report problems with residual limb pain and phantom limb pain, which do not change significantly over time. Patients with TFA report more severe phantom limb pain compared with those with TTA.

We hope you read the entire report with interest! Data from SwedeAmp clearly show that the time has come to introduce national guidelines for care during and after amputation in Sweden.

Thanks to Everyone contributing to SwedeAmp!

June 2025 SwedeAmp Steering Committee, Lund, Sweden

About SwedeAmp Care Pathway

High age and multimorbidity are common among patients undergoing lower limb amputation in Sweden. Amputation often occurs late in life as due to vascular disease and/or diabetes, frequently following a prolonged period of illness, and not seldom in connection with non-healing foot ulcers. For a smaller group of patients, the amputation is performed at younger age, for example due to accident, tumor, or sepsis. Regardless of the underlying cause, the loss of a foot or limb represents an irreversible change in life, and multiprofessional care is a prerequisite to enable the patient to return to as normal a life as possible.

The multidisciplinary care of patients with lower limb amputation remains a challenge for many clinical units. SwedeAmp aims to highlight and improve this complex care pathway by including all stages of the process. Aggregated data from many care providers, concerning a small and vulnerable group of patients, make SwedeAmp unique, even from an international perspective. Examples of guidelines can be found on the website under the tab CARE GUIDELINES.

Incidence and Coverage

INCIDENS

The incidence (based on the National Board of Health and Welfare's surgical statistics database) of lower limb amputations (through and above the ankle) in Sweden has decreased in recent years to approximately 17 per 100,000 inhabitants, with varying regional differences (11- 32 per 100,000 inhabitants).

PARTICIPATION RATE

Participation rate refers to the proportion of units that regularly register data in SwedeAmp in relation to the total number of existing units in Sweden that perform procedures or provide treatment. Since SwedeAmp is a multidisciplinary register, the participation rate cannot be summarized in a single value. For surgical data concerning patients with amputation above the ankle, the participation rate is 81% (17 out of 21 regions).

The number of prosthetic clinics in Sweden is variable due to changes in e.g. procurement agreements and new units. In 2024, SwedeAmp estimated there were 35 workshops that, to varying degrees, provide patients with prostheses. During 2024, 27 of these units were connected to the register, resulting in a participation rate of 73%.

COVERAGE RATE

Coverage rate is reported for transtibial amputation, which is the most common amputation level in the register. It is calculated by comparing the register's data with the National Board of Health and Welfare's inpatient surgery database, based on the number of individuals and the diagnosis code "NGQ19 Transtibial amputation (TTA)." The regions that report surgical data to SwedeAmp have a coverage rate of 82% (Figure 2).

After a decline in coverage during the pandemic years (2020–2021), the coverage rate is now higher than ever before. Region Stockholm has significantly increased its coverage compared to previous years. There are more units with nearly 100% coverage of amputation procedures, which enables more reliable analyses and a better ability to compare hospitals or regions with one another. Regions with the highest coverage form the basis for analysis and comparison in this report. No national comparative statistics for prostheses and prosthetic sockets are currently available.

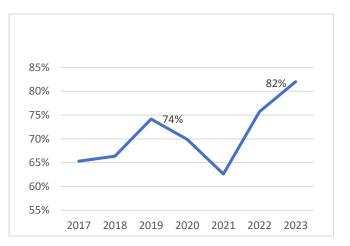


Figure 2. Coverage rate for transtibial amputation

VALUE SWEDEAMP CAN ADD TO HEALTHCARE

In Sweden, care related to amputation is provided by both private and public healthcare providers. Surgical care and rehabilitation are most often publicly managed, while prosthetic workshops are largely delivered through private contractors. Regardless of how the care is organized, close collaboration around the patient is essential.

SwedeAmp enables the collection of aggregated data from the entire care pathway, something individual care providers do not have access to. The register's systematic data collection has contributed to a more unified national approach to followup routines, something that was previously lacking. SwedeAmp demands multiprofessional collaboration and increases the knowledge for the group of patients, which aims to improve the quality of care.

PATIENT PERSPECTIVE

In SwedeAmp, patient-reported outcome measures (PROM) are collected for patients with amputations above the ankle. These data concern the patient's situation prior to the amputation as well as at follow-ups 6, 12, and 24 months after the procedure. PROM data are important sources of information on how the patient's situation is affected by healthcare interventions, and provide insight into e.g. mobility, how much the prosthesis is used, the need for walking aids, the presence of phantom limb pain, and general health-related quality of life.

In the report, PROM are presented separately for patients with different causes and levels of amputation, and to some extent also by sex. This material can be used by healthcare providers when informing patients and their relatives. An easy-to-read version of the annual report is available on the website. The steering committee includes two patient representatives.

CARE GUIDLINES

Swedish national guidelines for the care of patients undergoing lower limb amputation are currently lacking, despite that regional differences in care have been highlighted. Regional and local guidelines do exist, but national guidelines would be preferable. SwedeAmp aims to contribute to the development of national guidelines and the assessment for such a process has therefore been submitted to the NPO for Musculoskeletal Disorders.

On the SwedeAmp website, access is provided to regional, local, and international guidelines. We encourage the publication of additional guidelines related to amputation care on the website to help establish a shared knowledge base while awaiting national guidelines.

NATIONAL QUALITY REGISTRIES IN SWEDEN AND SWEDEAMP

The organization of national quality registers in Sweden is currently undergoing a comprehensive restructuring. Each registry must be connected to a data controller (a position named CPUA) and a register competence center for data storage and data handling. SwedeAmp is connected to the CPUA and competence center (RCSyd) in Region Skåne. The IT-platform is named 3C.

QUALITY INDICATORS AND "CARE IN NUMBERS"

SwedeAmp presents three quality indicators on the national platform "Vården i siffror" (www.vardenisiffror.se):

- Proportion of transtibial amputations
- Proportion of re-amputations after primary transtibial amputation
- Time from transtibial amputation to first prosthesis fitting

A high proportion of primary TTA relative to KD/TFA is to prefer, but only if this does not lead to a high proportion of reamputations, as this entails unnecessary suffering for patients and increased costs to society. The proportion of reamputations after primary TTA varies greatly between regions reporting to SwedeAmp. The national average is approximately 12%. The number of days from TTA to first prosthesis fitting is an indicator highlighting the care chain and reveal regional differences in lead times.

SPREADING KNOWLEDGE

Our annual reports serve as an important source for spreading knowledge about the patient group and are regularly used for education. This applies, for example, to healthcare staff at the clinical level as well as in higher academic education degrees such as physiotherapists, physicians, surgeons, and CPO programs.

SCIENCE AND RESEARCH

Several data extractions for research based on SwedeAmp's data have been carried out in recent years. In 2024, a study evaluating our data was published:

Johannesson et al, *Evaluation of the SwedeAmp database: Focus on coverage and amputation level rates*, CPOJ 2024 Vol. 7 Issue 2, <u>https://www.ncbi.nlm.nih.gov/pubmed/39990240</u>

Other ongoing studies will be presented at the International Society for Prosthetics and Orthotics (ISPO) World Congress in Stockholm in June 2025. We encourage health economic studies, as well as studies in which data are cross-linked with other national quality registers. Patients who undergo amputation have often received care for a long period prior to surgery and need support long after the procedure.

INTERNATIONAL COLLABORATION

When SwedeAmp was launched in 2011, it was the first comprehensive national register in the world to collect data on patients with amputations, their prostheses, and outcomes/follow-up. There is now a growing international interest in developing similar national registers. ISPO, WHO, the Clinton Foundation, and AT Scale have all shown interest in establishing a global register modelled on SwedeAmp.

During the ISPO World Congress in Stockholm 2025 (which will host several thousand participants from across the globe), the hope is to initiate this effort through two accepted symposia:

"The importance of a global longitudinal database platform for collection of big data related to amputations, prosthetics and outcome" and "Pros and Cons using National Registry Data for research – examples from SwedeAmp."

REGISTRY INFORMATION - SWEDEAMP

Since 2011, SwedeAmp has been a national quality register for lower limb amputations, including the subsequent care pathway. The register covers the amputation procedure and its causes, prosthetic provision and rehabilitation, as well as patient-reported outcomes. The register has a clear multidisciplinary focus.

AIM OF SWEDEAMP

- To provide a basis for local improvement initiatives that can enhance the quality of the care for people with a lower limb amputation in Sweden
- To highlight differences in care related to amputation, prosthetic provision, and rehabilitation
- To provide a basis for evaluating prosthetic fitting, prosthetic components, and rehabilitation
- To increase knowledge about the patient group by describing patients' mobility and quality of life
- To stimulate and support research, including cost analyses

STRUCTURE OF THE REGISTER

The register describes the care pathway in various stages and includes patient and amputation data, prosthetic data, the patient's situation before and after the amputation, as well as mobility data. Data are entered using six different forms (F1– F6). In brief, each form includes the following information:

F1. Personal Data and Basic Amputation Information Includes amputation level, side, and date. For each new procedure, a new F1 form must be completed. *Entered by the user who first records data for a specific amputation event.*

F2. The Amputation Procedure / Surgical Data Includes, i.e.type of procedure (primary amputation, re-amputation or revision), cause, surgical method and other care. *Preferably registered by the operating surgeon*.

F3. The Prosthesis Describes prosthetic provision, both for the first prosthesis and for subsequent prostheses. *Preferably* registered by the CPO.

F4. Baseline (PROM) Is registered for major amputations and describes the patient's situation prior to the acute deterioration that led to amputation, covering housing, walking aids, and mobility. *Preferably registered by ward or rehabilitation staff.*

F5. Follow-up (PROM) Is registered for major amputations at three time points (6, 12, and 24 months after amputation) and includes, for example, prosthesis use, walking aids, mobility with prosthesis, pain, and general health. Further follow-up is possible. *Preferably registered by physiotherapist or rehabilitation staff.*

F6. Mobility Data Objective measures of walking ability can be registered, but few data have been entered to date. *Preferably* registered by the CPO

For each new procedure on the same patient, the personal Swedish ID number, side, amputation level, and amputation date must be entered in F1. These four data points link the different parts, allowing additional data to be entered and followed.

Personal log-in is required to register data. Data are entered into a web-based register platform hosted by the competence center (RCSyd). Detailed information about the variables included, a manual, and a link to an instructional video are available on the website <u>SwedeAmp</u>. The authority for SwedeAmp is Region Skåne.

STEERING GROUP 2025



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General Core Data

ALL REGISTRATIONS AS OF 31 DECEMBER 2024

- 13,263 patients (39% women and 69% men)
- 19,345 procedures
- 17,314 surgical entries
- 8,206 prosthetic registrations
- 3,811 baseline patient-reported data (PROM) entries
- 5,106 registrations regarding the patient's situation (PROM) after the amputation

Comment:

The number of data points presented in the report varies depending on the variable in question. This is due to either incomplete registration, newly added variables or the fact that certain variables apply only to specific subgroups.

ALL SURGICAL PROCEDURES

- 38% of amputations were minor amputation (through the ankle, midfoot, or toes)
- 62% were major amputations (TTA or higher levels)
- Equal distribution between right- and left-side procedures

MORTALITY

- 62% of all patients in the database were no longer alive at the end of 2024, with a higher proportion of deceased women (67%) than men (59%)
- Mortality within 6 months after the most recently registered primary amputation or re-amputation was 32%
- Mortality within 12 months after the most recently registered primary amputation or re-amputation was 39%, distributed by diagnosis: Diabetes with or without vascular disease 32%, Vascular disease without diabetes 43%, and Other causes 21%
- Mortality within 12 months after the most recently registered primary amputation or re-amputation, distributed by level of amputation: 28% TTA, 40% KD, 43% TFA

Comment: Major amputations are generally associated with high mortality, which increases with higher levels of amputation. Even minor amputations are associated with significant mortality. Data from Skåne University Hospital (SUS), which reports close to 100% of all lower limb amputation procedures, shows 18% mortality within 12 months after minor amputations.

This year's report presents, for the first time, mortality by diagnosis. It shows that 12-month mortality for patients with diabetes is 32%, compared to 43% for patients with vascular disease without diabetes—highlighting the frailty of this patient population.

Mortality within 12 months among patients registered to have a prosthesis was approximately 10%.

SWEDISH REGION OF RESIDENCE

REGION OF RECIDENCE	NUMDER OF PATIENTS	%
Blekinge län	375	3%
Dalarnas län	505	4%
Gotlands län	174	1%
Gävleborgs län	303	2%
Hallands län	576	4%
Jönköpings län	573	4%
Kalmar län	167	1%
Kronobergs län	155	1%
Skåne län	3,732	28%
Stockholms län	2,301	17%
Södermanlands län	162	1%
Uppsala län	165	1%
Värmlands län	97	0.7%
Västernorrlands län	6	-
Västmanlands län	253	2%
Västra Götalands län	2,174	16%
Örebro län	475	4%
Östergötlands län	1,028	8%
Missing or unknown etc	42	0.3%
Total	13,263	

Table 1. Region of residence of registered patients.

Comment: Most patients registered in SwedeAmp reside in the counties of Skåne (28%), Stockholm (17%), or Västra Götaland (16%). Some regions, such as Gotland, may have high coverage despite a low number of cases. Registration remains incomplete for a large portion of patients living in northern Sweden (not listed in the Table)

Patient and Amputation Data

AGE AND SEX

AGE AT FIRST REGISTERED PROCEDURE

SEX	MEAN (SD)	MD (MIN-MAX)
Women (n=4537)	77 (14)	79 (31-98)
Men (n=6800)	71 (15)	74 (12-98)
Total (n=11337)	74 (15)	76 (12-98)

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Table 2. Age at first registered primary amputation for women and men. The age difference is statistically significant (p < 0.001).

AGE GROUP BY SEX

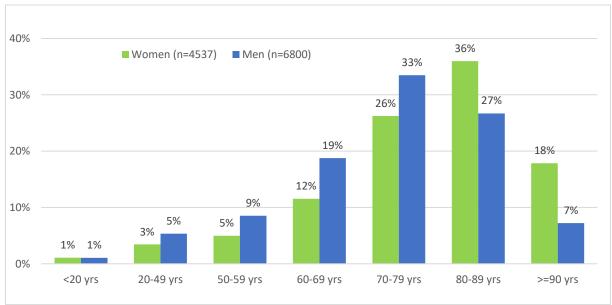


Figure 3. Distribution of age groups at the time of primary amputation for women and men, % (n = 10,225).

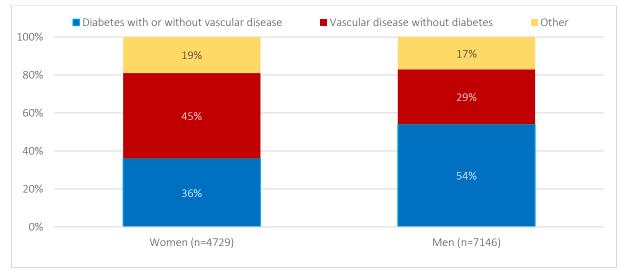
Comment: Most amputations in Sweden are performed at advanced age. Most women are over 80 years old at the time of their first amputation, while most men are younger than 80 years.

Surgical Data

DIAGNOSES AND DIAGNOSTIC GROUPS

UNDERLYING DIAGNOSIS AT FIRST REGISTERED AMPUTATION PROCEDURE PER PATIENT (N = 11,875)

- Diabetes with or without vascular disease: (n=5,568) 47%
- Arteriosclerosis without diabetes: (n=3,713) 31%
- Other vascular disease without diabetes: (n=475) 4%
- Infection not related to diabetes or vascular disease: (n=585) 5%
- Trauma: (n=432) 4%
- Tumour: (n=264) 2%
- Congenital or acquired deformity: (n=171) 1%
- Other causes: (n=433) 4%
- Unknown / not registered diagnosis: (n=234) 2%



DIAGNOSIS GROUPS BY SEX

Figure 4. Distribution of diagnostic groups at the time of amputation, by sex (%).

Comment: Diabetes and/or vascular disease account for 83% of all registered amputation diagnoses. Among women, vascular disease without diabetes is the most common diagnosis. Among men, diabetes with or without vascular disease is the most frequent cause. If diabetes is present, the cause of amputation is classified as diabetes unless a clear alternative cause exists, such as trauma or tumor. The difference in diagnosis distribution between the sexes is statistically significant (p < 0.001).

MEAN AGE BY DIAGNOSTIC GROUP

DIAGNOSTIC GROUP	WOMEN MEAN AGE (SD)	MEN MEAN AGE (SD)
Diabetes with/without vascular diseases	76 (12), n=1 656	73 (11), n=3 722
Vascular disease without diabetes	82 (10), n=2 057	78 (10), n=2 007
Other	68 (23), n=824	60 (23), n=1 071

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Table 3. Mean age at the time of amputation for selected diagnostic groups. Differences between groups and sexes are statistically significant (p < 0.001).

SMOKING HABITS

Smoking habits at the time of the first registered procedure per patient with amputation above the ankle

- 72% Never smoked or former smokers (defined as having quit >12 months before the procedure)
- 27% Active smokers
- 2% Use of other nicotine products

Comment: According to the Public Health Agency of Sweden, 8% of the Swedish population aged 65–84 smoke daily. Smoking is more prevalent within our patient group

COMORBIDITY

Presence of other medical conditions or impairments likely to affect wound healing and/or rehabilitation.

	PATIENTS WITH EACH COMORBIDITY
Heart disease	5,353 (33%)
Kidney disease	1,764 (11%)
Chronic pulmonary disease	1,255 (8%)
Stroke	1,039 (6%)
Dementia	810 (5%)
Rheumatoid arthritis	457 (3%)
Neurological disease	393 (2%)
Diabetes (if not primary cause of amputation)	1,200 (7%)
Vision or hearing impairment	359 (2%)
Vascular disease (if not primary cause of amputation)	1,723 (11%)
Other (e.g. malignancy, psychiatric/mental, abuse, fracture or other orthopaedic impairment including the hand)	1,786 (11%)

Table 4. Most common comorbidities. Based on conditions registered for at least one procedure per patient.

Number of comorbidity conditions registered per patient (n = 6,991 unique primary amputations, i.e. each patient is counted only once even if bilaterally amputated):

- 34% (n=2 371) One condition
- 34% (n=2 372) Two conditions
- 27% (n=1 852) Three of more conditions
- 6% (n=396) No condition

Comment: There is a very high degree of comorbidity within this patient group. For the majority of patients, the amputation is one of several coexisting medical conditions, with heart disease being the most common. In only 6% of cases has comorbidity been reported as not present. Comorbidity is likely underreported.

AMPUTATION DATA

AMPUTATION PROCEDURES

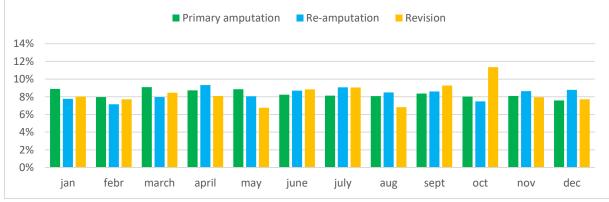
- Out of 16,815 amputation procedures, 80% (n = 13,395) are primary amputations
- 12% (n = 2,072) re-amputations to a higher level
- 8% (n = 1,348) revisions

Skåne University Hospital (near 100% coverage) show slightly higher proportions of revisions and re-amputations:

- 75% (n = 3,267) primary amputations
- 15% (n = 668) re-amputations to a higher level
- 10% (n = 434) revisions

AMPUTATION PROCEDURES BY MONTH

An analysis of monthly procedure distribution does not indicate any major seasonal pattern. A slightly higher proportion of revisions in September and October may reflect complications stemming from care limitations during the summer months.



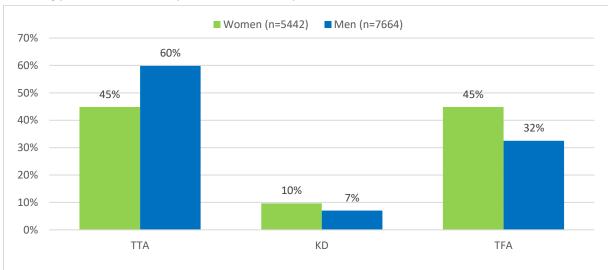


AMPUTATION LEVEL

For 16,823 amputation procedures with more detailed data registered, the distribution of levels is as follows:

- 38% (n=3 575) amputation below the ankle (minor amputation)
- 62% (n=13 248) amputation above the ankle (major amputations) (54% TTA, 8% KD, 38% TFA, 1% TPHD)

Comment: The register continues to have low coverage for minor amputations. Previous separate analyses from Skåne University Hospital, have shown that minor amputations account for nearly 50% of all amputation procedures.



Interestingly, the distribution of amputation levels differs by sex:

Figure 6. Distribution of major amputation levels by sex (%). Pelvis and hip amputations (TPHD) are less than 1% in both sexes.

Comment: There is broad consensus regarding the importance of preserving the anatomical knee joint to provide the patient with the best possible conditions for functioning with a prosthesis. The proportion of women with TFA is higher than men (45% vs. 32%), which has been assumed to amputations in women more often are due to vascular disease without diabetes (Figure 4), and women being older than men at the time of surgery (Table 3). However, a more in-depth analysis has shown that the likelihood of female patients losing an anatomical knee joint is higher compared to male patients, regardless of age and the underlying diagnosis leading to the amputation. This analysis can be found as an appendix in the 2022 annual report (in Swedish).

IMMEDIATE CAUSE OF AMPUTATION

Immediate causes (n=15 980)	Procedures with each cause (n=13 395)
Progressive Gangrene (n=5 507)	34%
Infection (n=4 486)	28%
Pain (n=2 928)	18%
Acute vascular condition (n=1 267)	8%
Toxic/sepsis condition(n=586)	4%
Trauma (n=265)	2%
Tumour (n=177)	1%
Deformity (n=174)	1%
Other (n=608)	4%

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Table 5. Immediate cause(s) of amputation based on primary amputations. Multiple contributing causes may be registered. For 13,395 procedures, a total of 15,980 immediate causes were recorded, %.

Comment: The immediate indication for amputation is most often an infectious condition, which makes the surgical procedure a high-risk operation. Given the presence of comorbidities, it is essential to optimise the patient's condition as much as possible prior to surgery. This includes, for example, nutritional supplementation, antibiotics, thrombosis prophylaxis, and minimising preoperative fasting.

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RE-AMPUTATION IN RELATION TO PRIMARY AMPUTATION LEVEL

PRIMARY LEVEL	FINAL LEVEL				
	TTA (%)	KD (%)	TFA (%)	TPHD (%)	
TTA n=6 269	86%	1%	13%	< 1%	
KD n=914	-	85%	14%	< 1%	
TFA n=3 295	-	-	98%	2%	

Table 6a. Relationship between primary and final amputation level across the register. TPHD includes hip and pelvic amputations.

	FINAL LEVEL AT SUS					
PRIMARY LEVEL AT SUS	MINOR (%)	TTA (%)	KD (%)	TFA (%)	TPHD (%)	
Minor amputation n=1 732	84%	15%	< 1%	5%	< 1%	
TTA n=981		79%	1%	19%	< 1%	
KD n=56		-	79%	20%	2%	
TFA n=613		-	-	97%	3%	

Table 6b. Relation between primary and final amputation level at Skåne University Hospital (SUS) with high coverage of procedures.

PRIMARY LEVEL with	FINAL LEVEL with DIABETES AT SUS							
DIABETES AT SUS	MINOR (%) TTA (%) KD (%) TFA (%) TPHD (%)							
Minor amputation n= 847	80%	17%	< 1%	3%	< 1%			
TTA n= 384		87%	<1%	13%	0 %			
KD n= 10		-	60%	40%	0%			
TFA n= 139		-	-	100%	0%			

Table 6c. Relationship between primary and final level in patients with diabetes diagnosis at <u>SUS</u>, %. Patients who died within 6 months of the last procedure are not included in the calculation. Patients with bilateral amputations are included.

Comment: The tables describe the primary amputation level and cases in which a re-amputation to a higher level for the same individual and the same side has subsequently been registered. Data from Skåne University Hospital (SUS) show that 84% of minor amputations (below the ankle) remain at that level. The data from SUS show a higher proportion of re-amputation from primary TTA or KD to final level TFA compared to the total dataset (Table 6a). Table 6c presents data from SUS separately for patients with a diabetes diagnosis causing amputation.

TIME FROM PRIMARY TO FINAL AMPUTATION LEVEL AT SKÅNE UNIVERSITY HOSPITAL

An in-depth analysis of the number of re-operations (revision and re-amputation) and the time between primary and final level, based on data from SUS, shows that:

- A patient with a final level below the ankle undergoes an average of 1.8 procedures.
 - If the final level is TTA, the following amputation sequence includes an average of 3 procedures over a mean of 76 days (between the first and last registered procedure).
 - If the final level is TFA, the subsequent amputation sequence includes an average of 4 procedures extended over almost one year.
- A patient who undergoes a primary TTA and ultimately heals at TTA undergoes an average of 1.6 procedures.
- A patient who is re-amputated to TFA (from TTA) undergoes an average of 3.1 procedures within one month.

Comment: With this data, we want to show it is worthwhile attempting to remain at the lowest possible level. If the final level is one level higher, revisions and re-amputations often take place within 1–2 months. Patients who progress from a minor amputation to a final TFA go through a very prolonged process, with many procedures over almost a year. It would be desirable to conduct a deeper analysis of this latter group to identify patients with poor potential to heal at the initially selected lower amputation level. If more Swedish surgical units register all their amputation procedures, including minor amputations, more robust analyses can be performed in the future.

SURGICAL TECHNIQUE

TTA FLAPS	ALL	BLEKINGE	HALLAND	JÖNKÖPING	SKÅNE	VÄSTRA GÖTALAND	STOCK- HOLM
Sagittal/ Skew	81%	87%	84%	81%	85%	74%	78%
Anterior- Posterior/ Long posterior	19%	13%	16%	19%	15%	26%	22%
Procedures	n=3779	n=167	n=314	n=297	n=1578	n=699	n=724

Table 7a. TTA flap techniques in total and separately in regions with a high number of registrations, %.

TTA FLAPS	2015 – 2017	2018 – 2020	2021 – 2023
Sagittal / Skew	77%	80%	85%
Anterior-Posterior / Long posterior			15%
Procedures (n)	n=766	n=1051	n=1141

Table 7b. TTA flap technique described for period of years, %.

Comment: The most common surgical technique for TTA is sagittal or skewed skin flaps. In the past, we have identified significant regional differences in the choice of flap technique at TTA level. Nowadays, we are pleased to observe smaller differences within the country, which is clearly reflected in Table 7b. Advantages of sagittal flaps for future prosthetic provision are provided under "Prosthetic Data" and include e.g. fewer stump-related problems and shorter time to prosthetic fitting (see Table 11c and 12b).

ASSESSMENTS IN CONNECTION WITH THE AMPUTATION

WALKING ABILITY PRIOR TO THE AMPUTATION

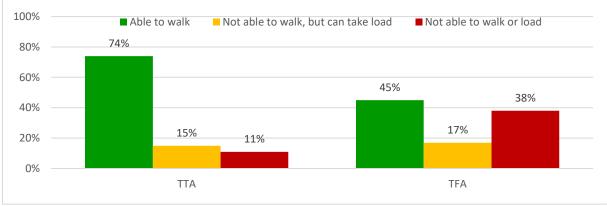


Figure 7. Walking ability before amputation (n = 8,507, divided into TTA and TFA). Walking ability is only registered for major amputation levels. "Cannot walk but can bear weight" refers to the leg on the side for amputation.

Comment: The ability to undergo prosthetic rehabilitation is influenced by the patient's functional capacity prior to the procedure. More than half of the patients undergoing TFA are reported as unable to walk or bear weight on the affected leg at the time of surgery. This is one reason why fewer TFA patients receive a prosthesis compared to those with TTA (see Table 10, Prosthetic Data). Other reasons include the significantly greater difficulty in achieving a good prosthetic solution at a higher level and the challenge for patients to use a prosthesis that includes a prosthetic knee joint.

TTA (n=4938) KD (n=639) TFA (n=3522) 100% 80% 60% 40% 20% 60% 60% 100%

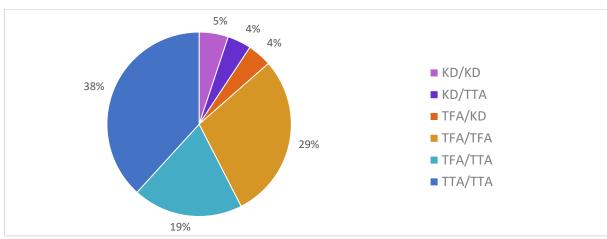
PRELIMINARY ASSESSMENT OF PROSTHETIC REHABILITATION POTENTIAL

Figure 8. Preliminary assessment of prosthetic provision in connection with the surgery reported for final major amputation levels (%).

Comment: The figures illustrate that the potential to become a prosthesis user after TFA is often limited. The preliminary assessment is most often made close to the time of the amputation, when the patient is at their most critically ill. It is important to adopt a generous attitude toward future possibilities regarding prosthetic provision.

BILATERAL AMPUTATIONS

COMBINATIONS OF MAJOR AMPUTATION LEVELS



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DISTRIBUTION OF DIAGNOSTIC GROUPS IN BILATERAL AMPUTATION:

- 57 % Diabetes with or without vascular disease
- 37 % Vascular disease without diabetes
- 7 % Other diagnosis (e.g. infection, trauma, other)

Comment: The proportion of patients with diabetes is approximately 10% higher in cases of major bilateral amputation levels compared to the register's overall patient population. The most common combination in bilateral amputation TTAs. Patients with bilateral TTAs have in many cases good potential for satisfactory function with prostheses. From a functional perspective, retaining at least one anatomical knee joint is of great importance for improved sitting balance and for facilitating transfers, regardless of prosthetic provision

AMPUTATION LEVEL DISTRIBUTION BY SWEDISH REGION

	PRIMARY LEVEL RATIO TTA / KD+TFA (%)		FINAL LEVEL RATIO TTA / KD+TFA (%)		COVERAGE RATIO (INDICATE DATA QUALITY) *
REGION	ALL YEARS	2020 - 2024	ALL YEARS	2020 - 2024	2019 - 2023
Blekinge	47/53	40/60	40/60	35/65	1.0
Dalarna	63/37	64/36	55/45	58/42	1.0
Södermanland	53/47	54/46	54/46	55/45	1.0
Västra Götaland	55/45	46/54	46/54	36/64	1.0
Örebro	69/31	63/37	57/43	54/46	1.0
Halland	64/36	60/40	57/43	54/46	1.1
Skåne	61/39	58/42	56/44	54/46	1.1
Östergötland	36/64	32/68	32/68	29/71	0,8
Gotland	48/52	52/48	36/64	39/61	1.2
Gävleborg	57/43	57/43	54/46	53/47	1.2
Västmanland	32/68	32/68	27/73	29/71	1.3
Jönköping	57/43	58/42	52/48	54/46	1.4
Stockholm	75/25	71/29	69/31	63/37	1.4
Kalmar	58/42	47/53	52/48	42/58	1.7
Värmland	67/33	68/32	63/38	64/36	2.7
Kronoberg	88/12	89/11	82/18	85/15	4
All	60/40	55/45	53/47	49/51	

Table 8. Proportion of TTA compared with KD + TFA, both regarding primary amputation level and final level, for regions with at least 10 registered major amputations, %.

* The "Coverage ratio" column indicates the degree of reporting for TTA in relation to KD + TFA, based on coverage rates compared to the Swedish National Board of Health and Welfare's amputation registry for the years 2019–2023. A value close to 1 indicates that the distributions in the other columns can be considered realistic.

Comment: A challenging question for the surgeon is which level to choose for the primary procedure. This table indicates differences in Sweden and show whether one region tends to perform primary amputations at a too low level (the final level deviates substantially from the region's own primary level) or at a too high a level (the primary level differs significantly from the national average). If the final proportion of KD/TFA is high, potential reasons should be considered. There may be shortcomings in surgical planning, technique, and/or postoperative care. SwedeAmp encourages regions with a high proportion of KD/TFA in relation to TTA to review their routines for amputation care.

If amputation data are reported solely by prosthetic workshops, the proportion of TTA is likely unrealistically high. If the surgical unit registers the amputation data, patients not considered for prosthetic rehabilitation are also included, resulting in a lower and more representative TTA proportion. The coverage ratio helps in evaluating the reliability of the data present.

Note: The number of all procedures registered per hospital is presented in the Swedish version of the Annual report 2024 (Table 9) available on the website <u>SwedeAmp</u>.

COMBINED ANALYSIS OF PATIENT AND AMPUTATION DATA

The basis for this year's report comprises just over 13,000 patients who underwent surgery until 31 December 2024. More than 19,000 procedures are registered for these patients.

The generally high mortality following lower limb amputation is well known. Patients in the register also registered in the Prosthetic data and have a major amputation show lower mortality. We conclude that the clinical judgement regarding which patients are likely to benefit from a prosthesis is being made with reasonable accuracy.

We still lack data from the northern part of Sweden, which is regrettable. We encourage more units to join SwedeAmp to enable even better evaluation of amputation data on a national level.

Regarding causes of amputation, sex distribution, mean age, and amputation levels, the picture remains unchanged. Among women, we observe a higher mean age, a larger proportion undergoing higher-level amputations, and more amputations due to vascular disease without concurrent diabetes, as well as fewer trauma-related amputations compared with men. The differences between sexes in terms of age and amputation diagnosis are statistically significant.

One of SwedeAmp's messages is to preserve the anatomical knee joint. While the goal should be to amputate as distally as possible, the risk of re-amputation to a higher level must be minimised. The analysis of the ratio between primary and final level shows that close to 80% of amputations below the knee joint remain at that level. Even foot amputations are "worthwhile," as data from Skåne University Hospital show that fewer than 20% of patients are re-amputated to a higher level. From the patient's perspective, this may mean preserved walking ability.

Whether a re-amputation rate of around 20% is "reasonable," or whether a lower frequency should be pursued, without increasing the number of primary TFAs, cannot be answered by our data. A more detailed analysis of cases with re-amputations shows that if the final level is one step proximal, the surgical process is usually completed within two months. It is assumed that patients' morbidity does not increase significantly during this relatively short period, such that the continued rehabilitation process is not severely affected.

However, for patients whose initial procedure is a minor amputation and end up with a TFA within the same amputation sequence, a prolonged process is observed, with an average of four re-operations over one year. With better understanding of the healing potential in this specific patient group, it should be possible to avoid a protracted course of revisions and re-amputations and thereby minimise the number of cases where the initial lower-level amputation "wasn't worth attempting."

International recommendations state the ratio of primary TTAs to KD/TFAs should not be less than 1. The fact that several Swedish regions still fall below this target ratio is concerning. Each region is encouraged to analyse why their figures deviate and to improve the decision-making process and amputation care.

The proportion of sagittal flaps used in TTA now stands at 82%, and we see virtually no regional differences. Since sagittal flaps may lead to faster prosthetic provision without long-term disadvantages, this positive development is beneficial to our patients.

Prosthetic Data

BASIC DATA

The register contains a total of 8,206 prosthetic registrations for 4,293 patients (33% women, 67% men).

The collection of prosthetic data increased from the register's first years (2011) up until the pandemic. During the pandemic years (2020–2022), the number of registrations declined, but again increased in 2023. In 2024, for the first time, the number of prosthetic registrations in a single year exceeded 1,000. The number of prostheses per patient increased slightly in 2024, while the proportion of socket replacements and additional prostheses also increased. As a result, the coverage rate—i.e. the number of registered prostheses in relation to those fitted—is improved during 2024.

To reflect current conditions, likely based on a higher coverage rate, this year's report has been limited to prostheses and sockets fitted during the past six years, i.e. 2019–2024. For these years, 4,887 prosthetic registrations for 2,657 patients (30% women, 70% men) are presented. The distribution of prostheses to the right and left side is even.

PROSTHESES FITTED 2019–2024

- 43% (n = 1,984) refer to the first prosthesis at the current level
- 44% (n = 2,005) refer to socket replacement
- 13% (n = 610) refer to full prosthesis replacement

Reasons for replacement of prosthesis or socket (n = 2,167) concerning functional prostheses:

- 77% (n = 1,911) change in stump volume
- 5% (n = 113) to improve socket fit
- 10% (n = 252) worn-out prosthesis
- 6% (n = 152) change in the patient's condition (change in goals/purpose of prosthetic provision)
- 2% (n = 48) damaged socket

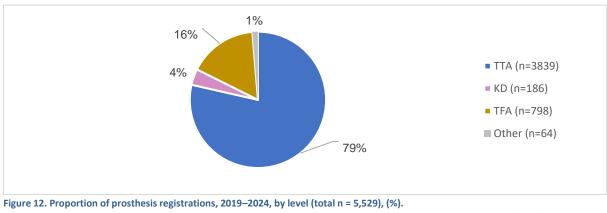
Regarding prosthesis type, it was reported that:

- 94% (n = 4,599) refer to a functional prosthesis
- 5% (n = 266) refer to an additional prosthesis (e.g. sports or hygiene prosthesis), see section "Additional Prosthesis"
- <1% (n = 22) refer to a cosmetic prosthesis (cannot be used for load bearing during transfers)

Comment: The ambition is that all prostheses that have been fitted should be registered. Clinical experience indicates that most patients by time will need to update the prosthesis with a new socket or an entirely new prosthesis due to changes in the residual limb or new needs for components. Therefore, we assume the proportion of data representing the first prosthesis for the current amputation level should be well below 50%. This year, 33% of the prosthetic data represent the first prosthesis, compared to 51% five years ago.

Replacement of the socket alone is more common than replacement of the entire prosthesis (54% versus 13%) and in most cases (79%) this is due to changes in stump volume. In other words, socket replacement typically occurs before a full prosthesis replacement is needed. An overwhelming majority of the data concern a functional prosthesis (94%).

AMPUTATION LEVELS



"Other" includes: Hip or pelvic amputation (n = 30), midfoot or heel amputation (n = 27), and forefoot amputation (n = 17).

PROPORTION OF PATIENTS BEEING PROVIDED WITH A PROSTHESIS

	PATIENTS 2018 - 2019		PATIENTS 2020 - 2021		PATIENTS 2022 - 2023	
LEVEL	(N)	% PROVIDED WITH PROSTHESIS	(N)	% PROVIDED WITH PROSTHESIS	(N)	% PROVIDED WITH PROSTHESIS
ТТА	747	51% (n=383)	686	53% (n=361)	680	49% (n=334)
KD+TFA	423	21% (n=90)	379	21% (n=78)	427	22% (n=93)

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Table 10. Proportion of patients with unilateral amputation who have been provided with a prosthesis, by level (TTA vs. KD + TFA), for procedures performed during three time periods. Note The data is based on patients able to walk or stand/bear weight on the affected limb prior to the procedure and only the highest amputation level for the first amputated limb per patient is included in the calculation.

Comment: The register is dominated by prostheses at TTA level for both sexes (80% for men and 74% for women).

The proportion of patients provided with a prosthesis per level is based on patients who, prior to amputation, were able to walk or bear weight on the affected side. As expected, significantly fewer patients receive a prosthesis following TFA or KD compared with TTA (22% and 49%, respectively, for procedures performed in 2022–2023). Patients who underwent surgery in 2024 were not included in the analysis, since prosthetic provision cannot for all cases be expected within the same year. For the same reason, amputations performed in 2018 were included in the analysis.

The proportion of women provided with a prosthesis is lower than that of men regardless of level, age group, or over time. A preliminary analysis indicates this is also the case regardless of the underlying cause of amputation.

AGE DISTRIBUTION AT FIRST PROSTHESIS PROVISION

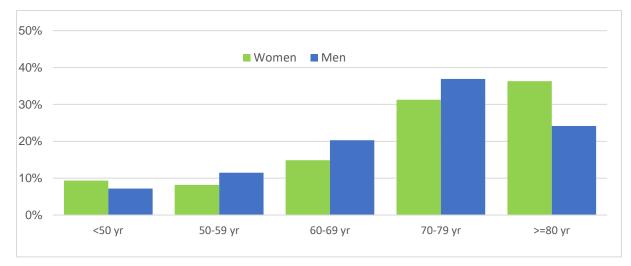


Figure 13. Age distribution at first prosthetic provision, fitted 2019–2024 (n = 1,869), for women (n = 598) and men (n = 1,271) (%).

Comment: At the time of the first prosthetic provision 2019 - 2023, the patient age ranged from 1 to 101 years. The mean age for women (74 years) was slightly higher than for men (71 years). In recent years, there has been a trend toward a higher mean age at the time of first prosthesis fitting, but no change in the gender distribution.

CONDITIONS FOR PROSTHETIC PROVISION

POSTOPERATIVE COMPRESSION TREATMENT TTA

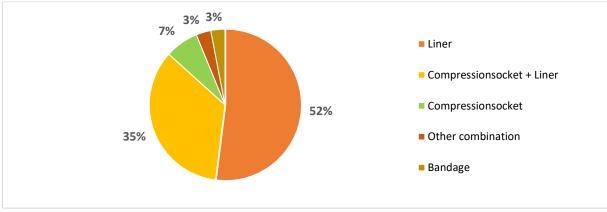


Figure 14. Type of stump compression after TTA, 2019–2024 (n = 1,329), (%).

Comment: Various types of compression for oedema prophylaxis are used postoperatively in TTA. The compression is also used to stabilise stump volume prior to prosthesis fitting. Compression with a liner is by far the most common method, often in combination with a compression sock when the liner is not used. Compression treatment after TTA was most often initiated within 1 week (53%) or within 2–3 weeks (36%) after the procedure. Note: Most patients have a rigid dressing during the first 5-7 days after the amputation.

TIME FROM AMPUTATION TO PROSTHETIC PROVISION

NUMBER OF DAYS TO FITTING OF FIRST PROSTHESIS IN **TTA** AND DEVELOPMENT OVER TIME

PERIOD (YEARS)	NUMBER OF DAYS MEAN(SD)	NUMBER OF DAYS MD (MIN-MAX)
2016 - 2018 (n=539)	85 (71)	63 (6 - 423)
2019 - 2021 (n=784)	84 (70)	59 (14 - 451)
2022 - 2024 (n=712)	97 (72)	73 (12 - 471)

Table 11a. Time to prosthesis fitting (first prosthesis for the current amputation) at final TTA level, distributed by 3-year periods (n = 2,035). Year is based on the date of first fitting. Extreme outliers (<5 days and >500 days) have been excluded from the calculation.

NUMBER OF DAYS TO FITTING OF FIRST PROSTHESIS IN TFA AND DEVELOPMENT OVER TIME

PERIOD (YEARS)	NUMBER OF DAYS MEAN(SD)	NUMBER OF DAYS MD (MIN-MAX)		
2016 - 2018 (n=102)	116 (89)	90.5 (19 - 484)		
2019 - 2021 (n=173)	110 (82)	85 (13 - 468)		
2022 - 2024 (n=190)	119 (82)	93.5 (28 - 435)		

Table 11b. Time to prosthesis fitting (first prosthesis for the current amputation) at final TTA level, distributed by 3-year periods (n=465). Year is based on the date of first fitting. Extreme outliers (<5 days and >500 days) have been excluded from the calculation.

NUMBER OF DAYS TO FITTING OF FIRST PROSTHESIS IN **TTA** BY SURGICAL FLAP TECHNIQUE

SURGICAL FLAP TECHNIQUE, TTA	NUMBER OF DAYS MEAN(SD)	NUMBER OF DAYS MD (MIN-MAX)
Sagittal + Skew (n=1153)	82 (70)	56 (11 - 492)
Long posterior + Anterior/Posterior (n=277)	88 (68)	68 (16 - 471)

Table 11c. Time to prosthesis fitting (first prosthesis for the current amputation) at final TTA, distributed by surgical flap technique. The flap technique options have been grouped. Extreme outliers (<5 days and >500 days) have been excluded from the calculation. There is a statistically significant difference (p < 0.001) in the number of days between amputation and prosthesis fitting among the different surgical techniques.

DAYS TO FIRST PROSTHESIS IN **TTA** BY <u>METHOD OF SOCKET FABRICATION AND MEASUREMENT</u>

METHOD, TTA	NUMBER OF DAYS MEAN(SD)	NUMBER OF DAYS MD (MIN-MAX)		
Direct-laminated socket (n=807)	77 (60)	56 (12 - 444)		
Digital model, scanning or measure (n=88)	115 (66)	101.5 (19 - 355)		
Manual casting (n=155)	142 (87)	121 (22 - 471)		

Table 11d. Time to prosthesis fitting (first prosthesis for the current amputation) at final TTA level, distributed by fabrication and measurement method (n = 1,050; Note: the variable was introduced December 2020). The difference in the number of days to first prosthesis between the groups is statistically significant (p < 0.001).

DAYS TO FITTING FIRST PROSTHESIS IN TTA BY POSTOPERATIVE COMPLICATION

TYPE OF COMPLICATION (N, %)	NUMBER OF DAYS MEAN(SD)	NUMBER OF DAYS MD (MIN-MAX)	DELAY NUMBER OF DAYS (MD)
No complications (n=179, 39%)	79 (58)	60 (17-339)	
Delayed wound healing (n=139, 30%)	106 (75)	87 (25-444)	27
Delay due to fall injury (n=24, 5%)	114 (72)	100 (26-272)	40
Stump infection (n=43, 10%)	134 (88)	121 (27-471)	61
Comorbidity (physical or mental (n=28, 6%)	151 (75)	137 (48-355)	77
Other complications (n=37, 8%)	102 (74)	89 (27-389)	29

Table 11e. Time to prosthesis fitting (first prosthesis for the current amputation) at final level, unilateral TTA, distributed by type of complication (n = 450).

Comment: Time from amputation to the first prosthesis is one of our quality indicators and serves as a measure of efficiency for the multiprofessional care chain, which can be influenced by many different factors — such as the patient's general condition, choice of preoperative measures (e.g. nutrition), and the unit providing the care. The underlying diagnosis and various comorbidities may mean that patients are admitted to different types of hospital wards at the time of amputation. At units more rarely managing patients with amputations, less established routines may lead to a delay in postoperative treatment and rehabilitation. Data collected so far indicate that "Delay due to fall injury" and "Stump infection" prolonged the time to first TTA prosthesis by 1.5–2 months. There is however a large variation in number of days even when "No complication" is reported.

In TTA the number of days until the first prosthesis is fitted is shorter if the surgical technique involves sagittal or skewed flaps, compared with long posterior or anterior/posterior flaps (p<0.001). It is also statistically confirmed that a pear-shaped stump and skin-to-bone adhesions are more commonly present at the time of first prosthesis fitting when surgery is performed with a long posterior or anterior/posterior flap, compared to sagittal/skewed flaps (See Table 12b). These factors generally complicate optimal prosthetic function.

Rehabilitation efforts for this group of patients varies across the country. In some cases, prosthetic training is provided as inpatient care with daily sessions over several weeks, but more commonly, rehabilitation occurs through outpatient visits once or twice per week. In some parts of the country, the training is carried out at a so-called "Gait School," a unit specialised on amputee rehabilitation, while elsewhere, it is handled by staff at units with less experience handling prosthetic rehabilitation. Some clinics in Sweden allow prosthesis use before the amputation wound has fully healed, while others wait

for complete healing. There is no consensus whether waiting for healing is the best approach or if early mobilisation with a prosthesis is preferable. When loading a not-yet-healed stump in a socket the suspension, fit, and volume adaptation must be consistently optimal not to jeopardise the ongoing healing. This requires access to an experienced team for frequent checkups, prosthetic adjustments, and with competence to monitor the wound/supply wound care. The conditions required to initiate safe prosthetic training before healing varies in the country.

The most common postoperative complication is delayed wound healing (30% in unilateral TTA – see Table 11e). If prosthetic training can begin before the surgical wound is healed, the time to prosthesis fitting may be reduced by approximately 4 weeks (Table 11e). The stump volume changes significantly in the early period after amputation, which makes a short lead time from socket measurement to prosthesis fitting important. The most common method for fabricating TTA sockets in cases where prosthetic training started before healing is the "direct-laminated socket."

Other possible reasons for longer time to first prosthesis may include increased waiting times linked to organisation matters and shortages of staff with orthopaedic technical expertise.

The median number of days from amputation to first prosthesis in TTA decreased from the start of the register (2011) up until the pandemic years but increased from 56 to 72 days in 2020 - 2022. In 2023, a slight recovery was observed but this again increased to 76 days in 2024. At the same time, fewer TTA sockets were produced using the direct-laminated method and more used digital techniques. The median number of days to the first prosthesis is lower with the direct-laminated socket method (56 days) compared with the method using digital technology (101 days).

For TFA, the number of days to prosthesis has also increased slightly in the most recent period and is now Md 93 days.

There is no consensus in the literature on how "time to prosthesis" should be defined. One example is an American study in which the number of days from date of amputation to prosthesis billing was calculated for over 400 patients (aged 18–65), showing Md 5 months (mean 130 days) (Miller et al., 2022). Like our data, the study reported fewer days for TTA than for TFA/KD, and fewer days for men than for women. Our data also indicate that time to first prosthesis is shorter for men than for women.

WEIGHT-BEARING ABILITY CONTRALATERAL LIMB AND STUMP PROBLEMS AT PROSTHETIC FITTING

The patient's ability to bear weight on the contralateral limb at the time of first prosthetic fitting years 2019–2024 (n = 1,796):

- 81% Full weight-bearing
- 16% Limited weight-bearing
- 3% No or very limited weight-bearing

FACTORS COMMONLY HINDERING APPROPRIATE FUNCTION AT THE TIME OF PROSTHESIS FITTING IN TTA, <6 MONTHS VS. >2 YEARS POSTOPERATIVELY

At the time of prosthesis fitting, different challenges arise in creating a functional connection between the residual limb and the prosthesis, depending on whether the amputation is recent or if the patient has already been a prosthesis user for a period. Several complicating factors may be present. Data from 2011–2024 have been used to obtain a sufficient volume to allow for statistical analyses of differences.

TTA RESIDUAL LIMB FACTORS	<6 MONTHS POSTOP % (N)	>2 YEARS POSTOP % (N)	* P-VALUE
Wound	33% (n=963)	11% (n=174)	Yes (<0.001)
Oedema	17% (n=927)	3% (n=173)	Yes (<0.001)
Broad end (pear-shaped)	15% (n=915)	2% (n=173)	Yes (<0.001)
Thin skin cover, prominences	13% (n=904)	31% (n=174)	Yes (<0.001)
Eczema/Dermatitis	4% (n=904)	1% (n=173)	Yes (0.025)
Contracture in knee joint	8% (n=921)	3% (n=173)	ns
Deep skin folds	1% (n=904)	1% (n=173)	ns
Pain	12% (n=902)	10% (n=149)	ns
Skin-bone adhesion	3% (n=906)	3% (n=173)	ns

Table 12a. Proportion of all TTA prosthetic registrations (2011–2024) by factors commonly hindering good prosthetic function at the time of fitting, presented in two groups. Multiple concurrent factors may be reported. Selection for the first column (<6 months): "First prosthesis for current amputation" and fitting during the first 6 months after amputation. Selection for the second column (>2 years): Replacement of prosthesis/socket \geq 2 years after amputation.

*"Yes" = a statistically significant difference of 'Yes' responses between the time periods. . ns = not statistically significant

FACTORS COMMONLY HINDERING APPROPRIATE FUNCTION AT THE TIME OF PROSTHESIS FITTING IN TTA, BASED ON SURGICAL TECHNIQUE, <6 MONTHS VS. >2 YEARS POSTOPERATIVELY

ТТА	<6 N	IONTHS POSTOP	*	>2 YEARS POSTOP *			
RESIDUAL LIMB FACTORS	SAGITTAL + SKEW % (N)	LONG POST + A-P % (N)	* P-VALUE	SAGITTAL + SKEW %(N)	LONG POST + A-P % (N)	* P-VALUE	
Broad end (pear-shaped)	14% (n=494)	25% (n=91)	Yes (0.009)	0% (n=54)	0% (n=20)	ns	
Skin-bone adhesion	1% (n=488)	9% (n=90)	Yes (<0.001)	2% (n=54)	5% (n=20)	ns	
Pain	14% (n=495)	11% (n=90)	ns	9% (n=47)	25% (n=16)	ns	
Deep skin folds	2% (n=489)	1% (n=90)	ns	0% (n=54)	0% (n=20)	-	
Oedema	20% (n=502)	16% (n=91)	ns	0% (n=54)	10% (n=20)	ns	
Contracture in knee joint	8% (n=500)	12% (n=92)	ns	7% (n=54)	5% (n=20)	ns	
Thin skin cover, prominences	15% (n=488)	10% (n=90)	ns	29% (n=55)	25% (n=20)	ns	
Wound	37% (n=520)	28% (n=94)	ns	13% (n=55)	5% (n=20)	ns	

Table 12b. Proportion of all registered stump-related problems that commonly hinder good prosthetic function in TTA, based on surgical technique, presented in two groups: Sagittal and Skew flaps versus Long Posterior and Anterior/Posterior flaps. Selection for the first column (<6 months): "First prosthesis for current amputation" and fitting within the first 6 months after amputation. Selection for the second column (>2 years): Replacement of prosthesis/socket ≥2 years after amputation.

*"Yes" = a statistically significant difference of Yes responses based on flap technique. ns = not statistically significant

Comment: The ability to bear weight on the contralateral limb is commonly important in the decision to provide a prosthesis and is a prerequisite for a good rehabilitation outcome. Nearly 1 of 5 patients had limitations or were unable to bear weight on the contralateral leg at the time of first prosthesis fitting, and in 44%, the residual limb was not in good condition.

Each residual limb is unique and has different conditions for tolerating load during various activities. At the time of prosthesis fitting, different factors that commonly hinder optimal prosthetic function can be registered. During the first period prosthetic function is often affected by changes in the shape and stump properties related to the healing process, muscle atrophy, and the initial weight-bearing in a socket. Later, the challenges are often related to greater strain on the stump as a result of increased activity and prosthetic use in more demanding situations. As the prosthesis becomes a larger part of daily life, the patient becomes more dependent on a reliable prosthetic function. Changes in medication, such as diuretics, can additionally affect stump volume.

The prosthetic data have been divided based on the period after TTA the prosthesis was fitted (<6 months vs. >2 years) to analyse how common various factors are in the early vs. late postoperative phases. The data show the proportion of cases involving wounds, oedema, broad stump end (pear-shaped), and eczema/dermatitis significantly decreased over time, while "thin skin cover" significantly increased over time. For all other factors, no significant differences were observed between the time periods.

The choice of surgical flap technique in TTA results in different stump shapes and characteristics. Sagittal and slightly skewed flaps (so-called Skew flaps) result in similar shapes and features. Long posterior flaps and anterior/posterior flaps result in a different, yet mutually similar, shape and profile. Table 12b shows how common various factors are based on the flap technique at the time of first prosthesis fitting (within 6 months) and in the long term (>2 years). At first prosthesis fitting (within 6 months), factors such as pear-shaped stump and skin-to-bone adhesions are significantly less common with sagittal/skewed flaps.

Prosthetic Design

A revision of the prosthetic data form (F3) was made at the turn of the year 2020–2021. Variables describing prosthetic design were changed or reformulated. In this annual report, prosthetic data are presented in two different ways depending on the period in which the data were collected, before or after the revision.

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PROSTHETIC FOOT

TYPE OF PROSTHETIC FOOT - TOTAL AND BY AMPUTATION LEVEL

LEVEL	SACH	SINGLE-AXIS	MULTI-AXIS	ENERGY-STORING	INTELLIGENT
TTA (n=1156)	34	15	13	1086	8
KD (n=58)	3	1	3	49	2
TFA (n=221)	4	23	2	191	1
Total (n=1435)	41 (3%)	39 (3%)	18 (1%)	1326 (92%)	11 (1%)

Table 13a. Classification of prosthetic feet according to the variables prior to registry revision. Type of prosthetic foot for prostheses fitted in 2019–2020 for TTA, KD, and TFA (n = 1,435), n (%).

LEVEL	NON ENERGY-STORING		ENERGY-STORING				
	SINGLE- AXIS (INCL. SACH)	MULTI- AXIS	FOR LESS ADVANCED GAIT	FOR GAIT IN VARIOUS CADENCE	FOR GAIT ON UNEVEN GROUND	MICRO- PROCESSOR CONTROLLED	
TTA (n=2 315)	96	8	871	907	433	0	
KD (n=102)	11	0	35	35	21	0	
TFA (n=457)	46	5	183	161	60	2	
Total (n=2 874)	153 (5%)	13 (0%)	1089 (38%)	1103 (38%)	514 (18%)	2 (0%)	

Table 13b. Classification of prosthetic feet according to the variables after registry revision. Type of prosthetic foot for prostheses fitted in 2019–2024 for TTA, KD, and TFA, n (%).

CATEGORY OF PROSTHETIC FOOT - ALL LEVELS, PROSTHESES, AND SOCKETS 2019-2024

Functional categorisation is based on the activities that the prosthesis user is capable of or has the potential to perform. The categorisation is similar to the so-called K-Levels used in US.

FU	NCTIONAL CATHEGORY PRESCRIBED PROSTHETIC FEET	(N)	%
1.	Has the ability or potential to use a prosthesis for transfers or ambulation in level surfaces at a fixed cadence. Limited and unlimited household ambulator	465	19%
2.	Has the ability or potential for ambulation with the ability to transverse low-level environmental barriers such as curbs, stairs, or uneven surfaces. Typical of the limited community ambulator.	1314	54%
3.	Has the ability or potential for ambulation with variable cadence. Typical of the community ambulator able to transverse most environmental barriers and may have exercise activity that demands prosthetic use beyond simple locomotion.	427	17%
4.	Has the ability or potential for prosthetic ambulation that exceeds basic skills, exhibiting high impact, stress, or energy levels. Typical of the prosthetic demands of the child, active adult, or athlete.	239	10%

Table 13c. Type of prosthetic foot specified in a free-text field (n = 2,639, for which the content could be interpreted in n = 2,445 cases), Distributed by functional category, n %. Note all amputation levels are included.

Comment: Replacing the anatomical foot with a prosthetic foot is not easy. Depending on how active the patient is and in which environments the prosthetic foot is used, different properties are required. An energy-storing prosthetic foot for less advanced walking (category 2) is the most common across all amputation levels. Energy-storing feet are constructed from materials that are resilient, such as composite materials with carbon and fiberglass, providing minimal energy loss. Non-energy-storing and single-axis prosthetic feet are more common in prostheses for higher amputation levels.

LINER AND SUSPENSION

The method used to connect the prosthesis to the residual limb (suspension) is crucial for good walking ability. During stance phase, the body weight must be securely supported, and forces are transferred between the stump and the prosthesis. During swing phase, the prosthesis must be lifted and precisely positioned on the ground to be ready to take the body weight as the prosthetic foot gets in contact with the ground.

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LINER FOR SUSPENSION IN TTA PROSTHESES

	VACUUM				WITHOUT		
TYPE OF LINER	WITH SLEEVE	WITH VALVE	ACTIVE WITH PUMP	DISTAL	DISTAL PINLOCK	KNEE-CUFF	OTHER*
Silicon (n=494)	423	51	0	0	0	5	15
Copolymer (n=236)	202	17	8	1	2	3	3
Polyurethan (n=37)	23	7	5	0	2	0	0
Soft foam (n=34)	17	1	0	0	11	2	3
Other (n=9)	4	1	0	1	1	0	2
Total (n=810)	669 (83%)	77 (9%)	13 (2%)	2 (<1%)	16 (2%)	10 (1%)	23 (3%)

Table 14a. Type of liner and suspension at the fitting of prostheses/prosthetic sockets in 2019–2020 for TTA, n (%).

	LINER AND						
TYPE OF LINER	VACUUM (SLEEVE + VALVE)	VACUUM (SLEEVE WITHOUT VALVE)	DISTAL COUPLING	DISTAL VACUUM	ACTIVE VACUUM (WITH PUMP)	ANATOMICAL- MECHANICAL SUSPENSION (E.G. KBM, PTB, PTS ETC)	OTHER
Silicone (n=1,530)	1116	51	166	102	22	44	29
Copolymer (n=892)	728	12	16	8	7	117	4
Polyurethan (n=104)	75	3	1	3	12	9	1
Soft foam (n=16)	1					11	4
Other (n=7)	2				1	3	2
Total (n=2,549)	1,922 (75%)	66 (3%)	183 (7%)	113 (4%)	41 (2%)	184 (7%)	40 (2%)

Table 14b. Type of liner and suspension at the fitting of prostheses/prosthetic sockets in TTA, 2019–2024, n (%).

SUSPENSION IN TTA PROSTHESIS, PROPORTION PER YEAR 2019-2024

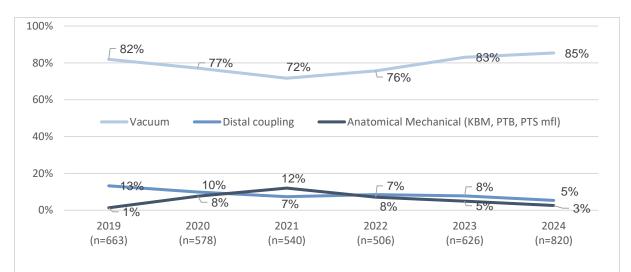
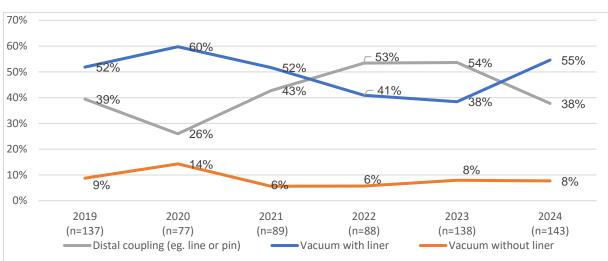


Figure 15. Distribution of 3 suspension types for TTA prostheses, 2019–2024, based on the date of first fitting (n = 3,733). Other types of suspensions are not illustrated in the figure.

Comment: Tables 14a and 14b include prostheses for which both liner type and suspension type have been registered, to analyse the combination of the two. The most common suspension for TTA prostheses is "With liner and vacuum via sealing with sleeve and valve" (75%). The most common liner type is the silicone liner (approx. 60%). This combination is also the most common representing 44% of all combinations. The trend over the past six years shows no clear change.



SUSPENSION IN **TFA** PROTES, PROPORTION PER YEAR 2019–2024

Figure 16. Distribution of 3 suspension types for TFA prostheses, 2019–2024, based on the date of first fitting (n = 749). Other types of suspensions are not illustrated in the figure.

Comment: "Vacuum with liner" was the most common suspension type for TFA prostheses in 2024. "Distal suspension (e.g. pin locking)" was more common during the pandemic years (2022 -2023). This can hypothetically be explained by patients with a general poorer health during this period and thus requiring a simpler method for suspension. "Distal suspension" is often easier to manage for a patient who is unable to stand while donning the prosthesis.

SOCKET DESIGN AND METHOD FOR FABRICATION OF PROSTHETIC SOCKET

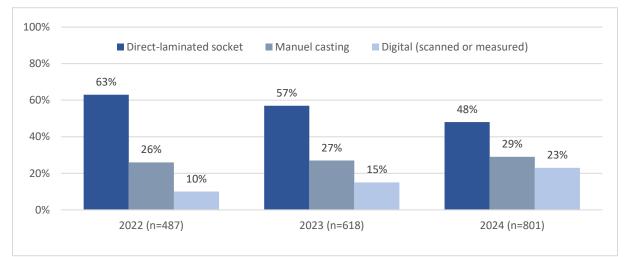


Figure 17a. Distribution of methods for fabrication of TTA sockets during the years 2022–2024 (n = 1,906).

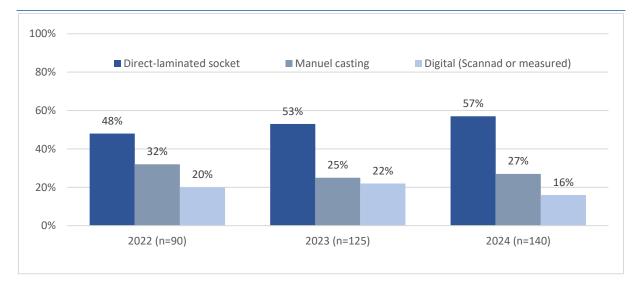
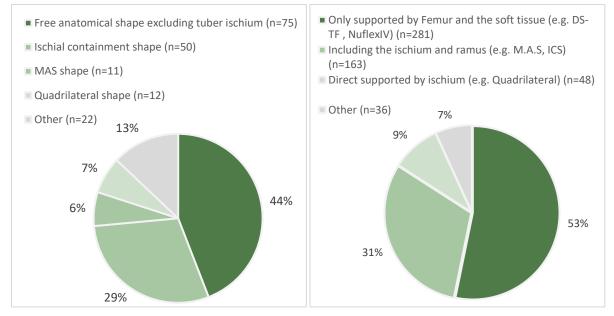


Figure 17b. Distribution of methods for fabrication of <u>TFA</u> sockets during the years 2022–2024 (n = 355)

SOCKET DESIGN IN TFA PROSTHESES



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Comment: Socket design affects how forces applied to the residual limb are distributed and stabilised during stance phase. The design also influences mobility in the adjacent proximal joint. In TFA, the most common approach is to support/capture forces solely through the soft tissues of the thigh (53%). In 40% of cases, forces were captured to parts of the pelvis. The most common method for fabricating a prosthetic socket in 2023 was a "direct-laminated socket," in both TTA (48%) and TFA (57%). In TTA sockets, the direct-laminated method is declining, while digital methods are increasing. In TFA, the direct-laminated method is on the rise.

TYPE OF PROSTHETIC KNEE JOINT

	MANUAL LOCK	MECHANICAL	HYDRAULIC	INTELLIGENT (MPK)	PNEUMATIC
SWING PHASE CON	TROL:				
KD (n=124)	13	4	11	18	5
TFA (n=408)	64	27	34	37	14
Total (n=532)	77 (34%)	31 (14%)	45 (20%)	55 (24%)	19 (8%)
STANCE PHASE CON	ITROL:				
KD (n=98)	33	31	12	16	6
TFA (n=339)	128	122	50	39	0
Total (n=437)	56 (34%)	41 (25%)	22 (13%)	44 (27%)	3 (2%)

Table 15a. Type of prosthetic knee joint in KD and TFA (older variables), prostheses and sockets fitted in 2019–2020, n (%).

	LOCKED	GEO-	CONSTANT JOINT	AUTORESPONSIVE JOINT RESISTANCE		
	LOCKED	METRIC LOCK	RESISTANCE	PNEUMATIC	HYDRAULIC	MICRO- PROCESSOR
SWING PHASE CON	TROL:					
			Spring resistance			
KD (n=105)	55	-	17	2	9	22
TFA (n=451)	224	-	65	15	41	104
Total (n=556)	279 (50%)	-	82 (15%)	17 (3%)	50 (9%)	126 (23%)
STANCE PHASE CON						
			Mechanical brake			
KD (n=60)	11	-	17	-	22	8
TFA (n=417)	218	-	66	-	29	103
Total (n=477)	229 (48%)	-	83 (18%)	-	51 (11%)	111 (23%)

Table 15b. Type of prosthetic knee joint in KD /TFA (new variables), prostheses and sockets fitted 2019–2024 for unique patients, n (%).

Definition of type of prosthetic knee joint:

- Manual lock: mechanically locked during standing and walking; manually unlocked for sitting
- Mechanical: the knee joint is controlled through joint positioning, friction brakes, springs, or elastic elements
- Pneumatic: the knee joint is controlled using air passing through valves
- **Hydraulic:** the knee joint is controlled using oil passing through valves
- Microprocessor-controlled knee joint (MPK): various sensors are monitored, and their readings interpreted by software to adapt joint movement to the situation in which the prosthesis is used

Comment: The type of prosthetic knee joint varies greatly. Manually locked knee joints are the most common type for TFA and KD prostheses as most patients in the registry are old and fragile. There is growing evidence highlighting the advantages of MPK joints in terms of improved function and reduced risk for falls (e.g. Lansade et al. 2018, Kaufman et al. 2018, Carse et al. 2021, and Davie-Smith et al. 2021), as well as in health economic studies (e.g. Chen et al. 2018, Kuhlmann et al. 2020 and 2022).

PROSTHESIS TYPE - ADDITIONAL PROSTESES

Unlike all other sections in this annual report, the topic of Prosthesis Type – Additional Prosthesis primarily concerns younger and otherwise healthy individuals. A prosthesis is by no means as adaptable in function as the amputated segment of the limb. An additional prosthesis, with features not included in the everyday prosthesis, may be essential for participating in activities such as sports or visiting public swimming facilities. The prescription of an additional prosthesis is supported by Article 7 of the UN Convention on the Rights of the Child. This article establishes that all children with disabilities have the right to fully enjoy all human rights and fundamental freedoms on an equal basis with other children—which may also include children of adults with disabilities. In our data, only 382 additional prostheses have been registered. These 382 prostheses/sockets have been prescribed to 287 individuals, and in 88 cases the type of additional prosthesis has been specified. Children (aged 0–18) are most commonly prescribed an additional prosthesis and only 3% of older individuals (>69 years) have an additional prosthesis registered. The most common type is a hygiene prosthesis (61%), followed by an activity prosthesis (19%) and a spare prosthesis (10%).

The data indicate large regional differences in the prescription of additional prostheses. However, the information is likely incomplete. This may be due to only the patient's first prosthesis have been registered in SwedeAmp, and no entry made for an additional prosthesis. It may also be due to variations in the regulations governing the prescription of additional prostheses across Swedish regions. In some parts, the prescription of an additional prosthesis is permitted, while in others, this possibility is restricted to varying degrees. In regions with limited access to additional prostheses, it is likely that old prostheses are reused to meet the patient's needs. These cases are rarely registered and may be a source of error in the reported data.

NUMBER OF PROSTHESIS REGISTRATIONS PER ORTHOPEADIC WORKSHOP/CLINIC

Note: The number of prosthesis registrations per unit is presented in the Swedish annual report (Table 16)

Comment: Registration of prostheses/sockets has developed well over several years, and in 2024 more than 1,000 prosthetic data entries were reported in a single year. Many units contribute prosthetic data. We have estimated the number of Swedish orthopaedic workshops to be 27 when satellite services are consolidated. Of these, two-thirds reported more data in 2024 than the mean number of registrations from previous years.

COMBINED ANALYSIS OF PROSTHETIC DATA

Year 2024 marks the highest number of prosthetic data entries since the register was established. Unfortunately, data from the northern healthcare regions are still missing. To reflect current conditions and likely based on a higher coverage rate this report has been limited to prostheses and prosthetic sockets fitted over the past six years, i.e. 2019–2024. For these years, 4,887 prostheses for 2,657 patients (30% women, 70% men) are presented. The distribution between prostheses for the right or left side is even.

The proportion of patients provided with a prosthesis was 49% for TTA and only 21% for TFA when calculated among those who underwent amputation during 2022–2023 and able to walk/stand on the affected side before the procedure. The proportion of women receiving a prosthesis is lower than for men, regardless of age group, underlying cause of amputation, or amputation level. At the time of first prosthesis fitting, most men are aged 70–79, and most women are over 80 years. In recent years, we can see a trend toward a higher mean age at the start of prosthetic use, now at 71 years for men and 74 years for women.

Unfortunately, the number of days from amputation to first prosthesis fitting has increased in recent years for both TTA and TFA and is now Md 73 days for TTA and Md 93 days for TFA. Individual variation is considerable, and the time to first prosthetic fitting can be influenced by many different factors (see comment page 28-29). Data collected so far indicate that "Delay due to fall injury" and "Stump infection" prolong the time to first prosthesis by 1.5–2 months. Preliminary analysis shows that if prosthetic training can begin before the surgical wound has fully healed, the time to prosthesis can be shortened by approximately 4 weeks.

In TTA, the number of days to first prosthesis is statistically significantly lower when the surgical technique involves sagittal or skewed flaps compared with long posterior or anterior/posterior flaps. It is also statistically confirmed that, at the time of

first prosthesis fitting, factors such as "broad stump end" and "skin-to-bone adhesions" are more commonly observed following surgical techniques using long posterior or anterior/posterior flaps compared with sagittal/skewed flaps. Clinical experience suggests that these factors hinder optimal prosthetic function.

There is also a large and statistically significant difference in time to prosthesis depending on the method used for fabrication and design of the prosthetic socket: Md 56 days with a "direct-laminated socket," compared with Md 101 days with digital technology and Md 121 days with "manual casting." The difference can partly be explained by varying production times but may also reflect a more efficient care process and a commitment to early prosthetic rehabilitation, versus a more cautious approach aimed at avoiding early loading of the stump. Our data show that the "direct-laminated socket" is the most common method when prosthetic training has begun before healing.

At the time of prosthesis fitting, 81% of patients were able to bear full weight on the contralateral limb. The occurrence of stump-related problems at the fitting of a TTA prosthesis changes over time. The proportion of patients with wounds, oedema, broad stump end, and eczema decreases, while the proportion of "thin skin cover/prominences" increases over time.

The most common configuration of a TTA prosthesis includes:

- 1. A direct-laminated prosthetic socket with suspension via silicone liner and vacuum using sleeve plus valve
- An energy-storing foot designed for ambulation in indoor and outdoor environments, with or without walking aids, allowing the patient to handle minor obstacles such as curbs, stairs, or uneven surfaces (move about in the community using a walking aid)

The most common configuration of a TFA prosthesis includes:

- 1. A direct-laminated socket designed for weight-bearing on the femur and its soft tissues, with suspension via vacuum and a liner
- 2. A manually locked knee joint and an energy-storing foot for less advanced gait

A prosthesis is by no means as multifunctional as the amputated segment of the limb. In certain situations, an additional prosthesis may be required, a prosthesis including functions lacking in the everyday prosthesis. These functions may be essential for e.g. participating in physical education classes or visiting public swimming facilities. Additional prostheses are most prescribed to children (aged 0–18) and rarely registered for older adults. The most common type of additional prosthesis is a hygiene prosthesis (61% of cases), followed by activity prosthesis (19%) and spare prosthesis (10%).

The patient's situation before the amputation BASELINE - PATIENT-REPORTED DATA

Information about the patient's situation before the deterioration that led to the amputation is collected as close to the procedure as possible. Baseline data reported are based on the first recorded above-ankle procedure per patient, i.e., the situation prior to any later amputation performed on the same patient is not included. In total, there are 3811 baseline registrations.

This year's report is based on registrations carried out during the last 10 years (2015 – 2024) and relates to:

- 2,902 patients: 36% women, mean age 76 years (16 100) and 64% men, mean age 72 years (16 99).
- 71% refers to the situation before TTA, 23% TFA, 5% KD and 0.5% before other levels.
- Amputation diagnosis at the first procedure per patient was 85% diabetes and/or vascular disease (of which 50% diabetes with or without vascular disease, 30% vascular disease without diabetes and 5% other vascular disease without diabetes).
- 15% consisted of other diagnoses (e.g. trauma, tumour or infection without diabetes/vascular disease).
- 70% of patients with data recorded in Baseline also have prosthetic data and/or follow-up data in the registry.
- The majority (91%) lived in their own/ordinary accommodation before the amputation (8% in special housing, 1.5% in other accommodation).

Comment: Baseline data primarily reflect patients with amputation due to diabetes and/or vascular disease and largely represent patients who are or have been in contact with some form of prosthetic rehabilitation.

USE OF WALKING AIDS BEFORE THE AMPUTATION

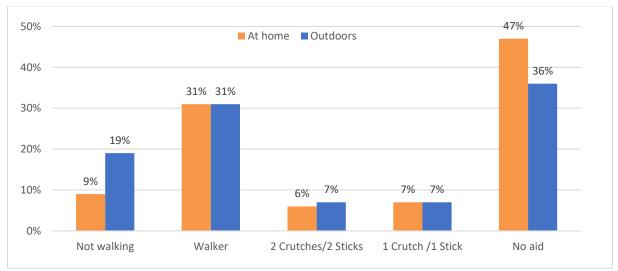


Figure 19. Use of walking aids at home (n=2,860) and outdoors (n=2,843) before the first amputation above the ankle, %

Level	No Walking Aid	Any Walking Aid	Not walking at home
TTA (n=2034)	49%	45%	6%
KD (n=149)	36%	41%	23%
TFA (n=651)	42%	41%	17%

Table 17. Use of walking aids at home, before the first amputation per level TTA, KD, TFA, %.

USE OF WEELCHAIR BEFORE THE AMPUTATION

30% of the patients used a wheelchair (regardless of extent) before the first amputation, 70% did not use a wheelchair.

Comment: Many patients used walking aids before the amputation and 30% stated that they used a wheelchair to some extent. At higher amputation levels (KD or TFA), more people (23% and 17% respectively) stated that they were not walking at all before the amputation as compared to TTA, which reflects the frailty of the patient group even in the time before the amputation.

MOBILITY BEFORE AMPUTATION

Self-rated mobility before the amputation is measured with Locomotor Capability Index pre (LCI-5-pre) which consists of 14 questions with a five-point scale (0=cannot, 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 results are presented as two subscales (0–28) and summed up to a total score (0–56). The subscales highlight basic and more advanced activities. Examples of basic activities include getting up from a chair, walking indoors, walking outdoors on flat ground, and walking across a curb. Examples of advanced activities include walking on uneven ground, walking while carrying an object, getting up from the floor and walking a few steps without the support of a railing.

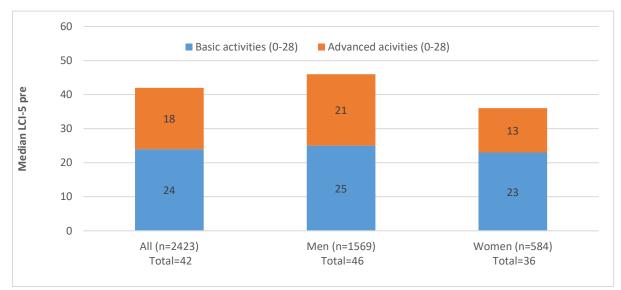
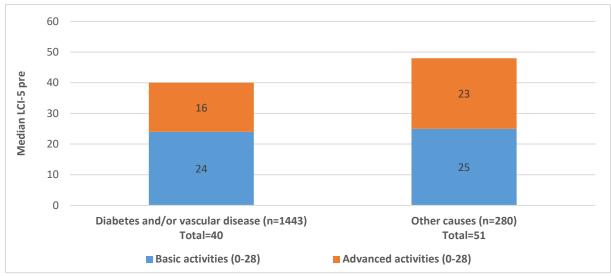
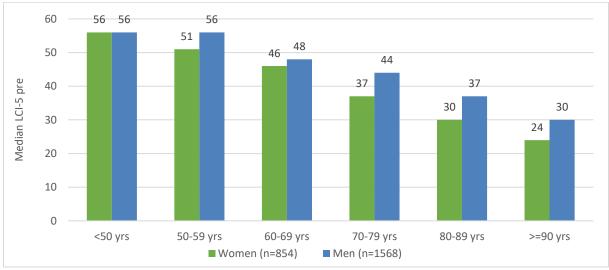
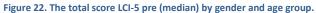


Figure 20. LCI-5 pre (median) before amputation reported by sex and for the total group. LCI-5 pre total score is listed under each bar. Men report higher mobility compared to women (p<0.001) and the difference mainly applies to the demanding activities.









SEX	TTA LCI-5 PRE TOTAL MEDIAN (MIN-MAX), n	TFA / KD LCI-5 PRE TOTAL MEDIAN (MIN-MAX), n
Women	35 (0 - 56) n=361	28 (0 - 56) n=166
Men	43 (0 - 56) n=815	37 (0 - 56) n=176

Table 18. Total score LCI-5 pre (median) by gender and amputation level (TTA and KD/TFA). The differences between women and men are statistically significant in both TTA and KD/TFA (p < 0.01).

Comment: Women report lower mobility before the amputation as compared to men, and this is especially true for the more advanced locomotor activities. Mobility is reported lower with increasing age. Patients with amputation due to other reasons than diabetes and/or vascular disease report better mobility before the amputation. The basis for the "baseline data" largely reflects patients who have received prosthetic rehabilitation.

The patient's situation after the amputation FOLLOW-UP AND PATIENT-REPORTED DATA

Follow-ups refer to patients with TTA or higher amputation levels and describe the situation 6, 12 and 24 months after the amputation. In the event of a new amputation (re-amputation to a higher level or amputation on the contralateral limb), a new follow-up period is initiated to describe the patient's new situation. A total of 5,106 follow-ups are registered.

This year's report is based on follow-ups carried out over the past 10 years, i.e. 2015 - 2024 and concerns:

- 2,468 individuals (32% women, 68% men) and 4,390 follow-ups:
- 42.5% refers to follow-up 6 months after the amputation
- 35% refers to follow-up 12 months after the amputation
- 21% refers to follow-up 24 months after the amputation
- 1.5% refers to follow-up carried out >2 years and is not reported in this year's report
- Most of the follow-ups concern TTA (75.5%), followed by TFA (19.5%), KD (4.5%) and TPHD (0.5%)
- The average age at the first registered follow-up was 72 years, (women 74 years (14–100), men 72 years (20–99))
- 82% of patients had a diagnosis of amputation, diabetes and/or vascular disease
- 83% of the patients had returned to the same accommodation as before the amputation at their first follow-up. The average age was higher for those who had not returned to the same accommodation (77 years vs 71 years)
- Patients with bilateral amputations at follow-up make up about 12%. These are presented in a separate section

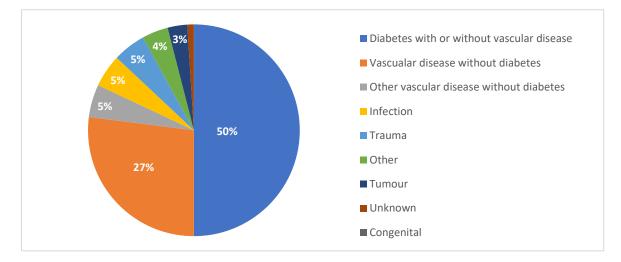


Figure 23. Distribution of amputation diagnoses (%) at the first follow-up session per patient (n=1,613). The report requires that the amputation diagnosis in surgical data (form F2) is registered.

Comment: As in previous years, follow-up data are dominated by men (2/3), by patients with a unilateral TTA and by amputation due to diabetes and/or vascular disease.

UNILATERAL AMPUTATION

This section presents data for patients with a unilateral amputation followed during the last 10 years, i.e. 2015 - 2024.

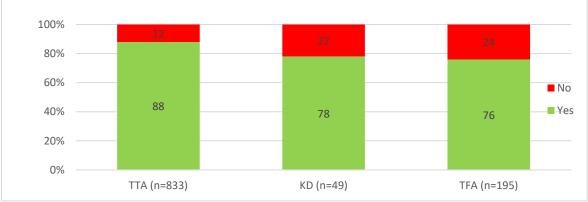
PROSTHESIS USE AFTER UNILATERAL AMPUTATION

TIME UNTIL START OF PROSTHETIC TRAINING

PERIOD OF YEARS	NUMBER OF DAYS TTA MEDIAN (MIN-MAX)	NUMBER OF DAYS KD MEDIAN (MIN-MAX)	NUMBER OF DAYS TFA MEDIAN (MIN-MAX)
2016 - 2018	67 (10 - 484) n=653	99 (26 - 264) n=39	102.5 (19 - 490) n=152
2019 - 2021	63 (15 - 471) n=980	101 (33 - 383) n=35	98 (21 - 480) n=211
2022 - 2024	82 (14 - 493) n=684	147 (54 - 412) n=32	105 (6 - 488) n=199

Table 21: Number of days (Median) from amputation to start protest training in unilateral TTA, KD and TFA distributed over three time periods (based on amputation date). Individual outliers have been removed (<5 days and >500 days).

Comment: The number of days until the start of prosthetic training is an indicator of the care chain from date of amputation to the start of prosthetic rehabilitation. Prosthetic training currently initiates barely 12 weeks after a unilateral TTA and about 3 weeks later after a unilateral TFA. The time to prosthetic rehabilitation has increased slightly in accordance with the data reporting time to the first prosthetic fitting (Prosthesis data page 27). The increase may indicate e.g. longer waiting times in healthcare, longer production times for the prosthesis or other barriers in the care chain.



DONNING THE PROSTHESIS

Figure 24. Ability to independently don the prosthesis in unilateral TTA, KD and TFA 12 months after amputation, %.

Comment: Needing help to put on the prosthesis limits the possibility of independent prosthetic function. Most patients with TTA state that they can don the prosthesis completely independently 12 months after the amputation. At a higher amputation level, there are more people who cannot don the prosthesis themselves, which is indicated by almost 1/4 in TFA.

PROSTHETIC USE SCORE (PUS)

The Prosthetic use score (Hagberg et al 2004) combines the number of days/week and the number of hours/day the prosthesis is normally used (i.e. *as much as the patient states that he or she normally wears the prosthesis during a normal week*). PUS is reported between 0–100 and where 100 corresponds to the prosthesis being used every day >15 hours/day, basically all waking hours. 0 means that the prosthesis is not used at all, and 50 corresponds to the prosthesis being used about half of the time during a week, e.g. every day for 7–9 hours, or fewer days but more hours.

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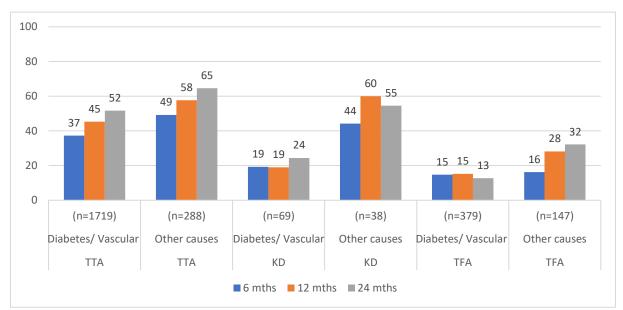


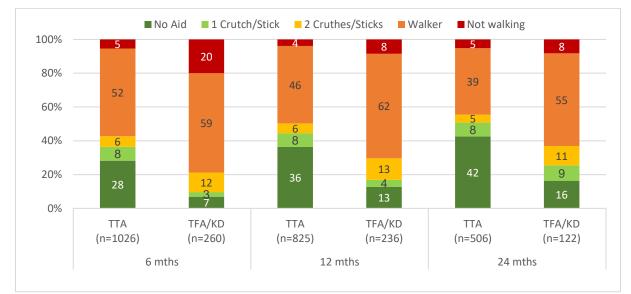
Figure 25. Mean Prosthetic Use score (0–100) per follow-up occasion in unilateral TTA, KD and TFA divided into two diagnostic groups. The number n indicates the total number of patients per amputation level and diagnosis group.

SEX	TTA	KD	TFA
	MEAN (SD)	MEAN (SD)	MEAN(SD)
	MD (MIN-MAX), n	MD (MIN-MAX), n	MD (MIN-MAX), n
Women	41 (31)	13 (14)	12 (15)
	32 (0 - 100)	8 (0 - 32)	5 (0 - 71)
	n=175	n=14	n=58
Men	47 (32)	26 (26)	18 (22)
	52 (0 - 100)	12 (1 - 71)	7 (0 - 90)
	n=439	n=12	n=81

Table 23. Prosthetic Use Score (0-100) at 12 months follow-up in unilateral TTA, KD and TFA with amputation diagnosis diabetes and/or vascular disease reported separately for women and men. In TTA, the difference between the sexes is statistically significant (p<0.05). Note low KD count.

Comment: Patients with unilateral TTA generally wear the prosthesis more during a week than patients with a higher amputation level, and the time of use increases with each follow-up. The average time the prosthesis is used during a normal week in TFA and KD due to diabetes and/or vascular disease is very low. Within each group there are however some patients who use the prosthesis more.

MOBILITY-AIDS



USE OF WALKING AIDS AT FOLLOW-UPS



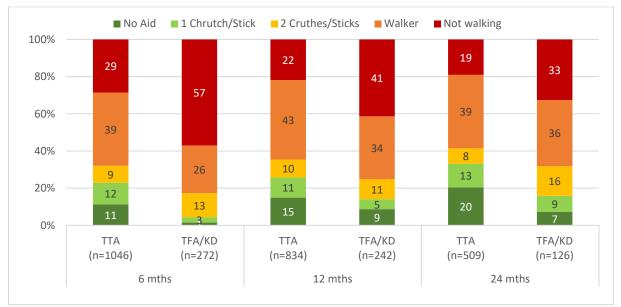


Figure 27. Walking aids in use of the prosthesis OUTDOORS at 6, 12 and 24 months in unilateral TTA, respectively KD/TFA (%).

Comment: The need for walking aids is generally greater at the higher amputation levels (KD/TFA) compared to TTA, and when walking outdoors compared to walking at home. Many people state that they do not walk outdoors at all. In unilateral TTA, many (42%) manage without assistive devices at the 24-month follow-up at HOME, the corresponding figure for TFA/KD is 16%, but the need for walking aids and a wheelchair remains for more than half of the patients regardless of amputation level.

USE OF WHEELCHAIR 12 MONTHS AFTER A UNILATERAL AMPUTATION:

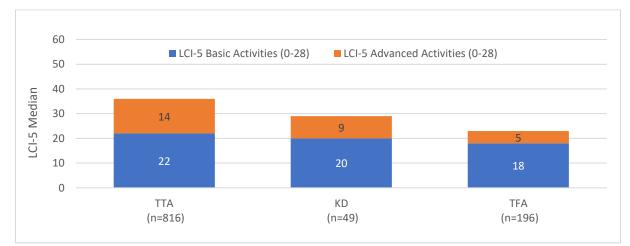
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- Transtibial amputation (TTA): 83%
- Knee disarticulation (KD): 83%
- Transfemoral amputation (TFA): 96%

Comment: A large proportion of patients use a wheelchair, even in unilateral TTA. We have chosen not to specify when and how the wheelchair is used. Experience from this patient group is that many use a wheelchair during their morning chores and later in the day after several hours of using the prosthesis. Having access to a wheelchair is also important at night for toilet visits and on occasions when the prosthesis cannot be used at all, for example in the case of wounds on the residual limb or when a prosthetic part is out of order.

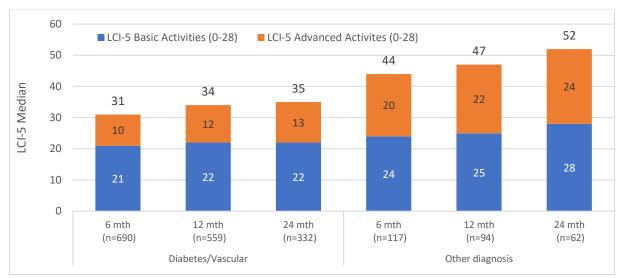
PROSTHETIC MOBILITY

Prosthetic mobility is evaluated using the Locomotor Capability Index (LCI-5) which consists of 14 questions (Franchignoni et al 2004). The patient states his or her perception of the ability to perform different tasks with the prosthesis on a five-point scale (0=cannot, 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 results are presented as two subscales (0–28) that are summed up to a Total score (0–56). The subscales highlight basic and advanced locomotor activities with prostheses. Examples of basic activities include getting up from a chair, walking indoors, walking outdoors on flat ground, and walking across a curb. Examples of advanced activities include walking on uneven ground, walking while carrying an object, getting up from the floor and walking a few steps without the support of a railing.



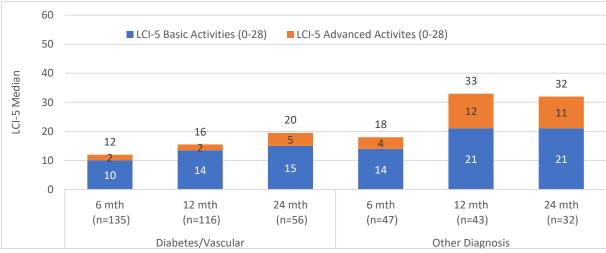
MOBILITY LCI-5) 12 MONTHS AFTER UNILATERAL AMPUTATION

Figure 28. LCI- 5 (Median) in unilateral amputation TTA, KD and TFA at 12 months follow-up after the amputation. LCI-5 Total score (0 - 56) is listed above each bar.



MOBILITY (LCI-5) IN UNILATERAL TTA AND TFA PER GROUP OF DIAGNOSIS AND FOLLOW-UP





Figur 30. LCI-5 (Median) in unilateral TFA, divided into Diabetes and/or Vascular Disease and Other Diagnoses, respectively, and reported 6, 12 and 24 months after the amputation. LCI-5 Total score (0 - 56) is listed above each bar.

	TTA LCI-5 TOTAL MEDIAN (MIN-MAX)			TFA LCI-5	TOTAL MEDIAN (M	IN-MAX)
	6 MTH	12 MTH	24 MTH	6 MTH	12 MTH	24 MTH
Women	21 (0–56)	25 (0–55)	25 (0–53)	8 (0–44)	9 (2–56)	12 (0–51)
	n=174	n=163	n=101	n=49	n=47	n= 22
Men	34 (0–56)	38 (0–56)	39 (0–56)	16 (0–51)	22 (2–54)	26 (0–52)
	n=467	n=394	n=226	n=73	n=65	n=34

MOBILITY (LCI-5) IN MEN AND WOMEN WITH TTA OR TFA DUE TO DIABETES AND/OR VASCULAR DISEASE

Tabell 24. LCI-5 Total (0-56) reported for women and men with unilateral TTA or TFA due to Diabetes and/or Vascular disease at followups 6, 12 and 24 months after amputation. In TTA, the difference is statistically significant (p<0.001) at all points in time. In TFA, the difference is statistically significant only at the 12-month follow-up (p=0.002).

MOBILITY (LCI-5) REPORTED PER QUESTION IN **TTA** DUE TO DIABETES/VASCULAR DISEASE, 12 MONTHS AFTER AMPUTATION

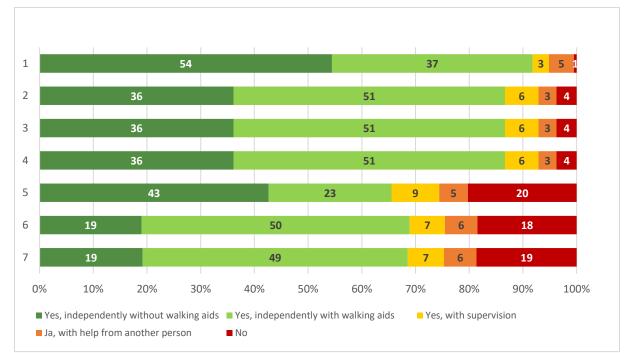


Figure 31a. Distribution of responses per LCI-5 question regarding <u>basic activities</u>, in unilateral <u>TTA</u> due to Diabetes and/or vascular disease at follow-up 12 months after amputation, n = 562, %. The questions concern: 1: Get up from a chair. 2: Walk indoors. 3: Walk outdoors on level ground. 4: Go up one stair using a handrail. 5: Go down one stair using a handrail. 6: Step up a curb. 7: Step down a curb.

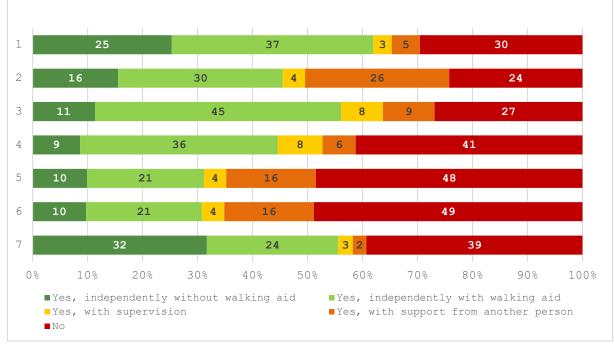


Figure 31b. Distribution of responses per LCI-5 question regarding <u>advanced activities</u>, in unilateral <u>TTA</u> due to Diabetes and/or vascular disease at follow-up 12 months after amputation, n = 565, %. The questions concern: 1: Pick up an object from the floor. 2: Get up from the floor. 3: Walk outdoors on uneven ground. 4: Walk outside in bad weather. 5: Go up a few steps without a handrail. 6: Go down a few steps without the help of a handrail. 7: Walk while carrying an object.

MOBILITY (LCI-5) REPORTED PER QUESTION IN **KD/TFA** DUE TO DIABETES/VASCULAR DISEASE, 12 MONTHS AFTER AMPUTATION

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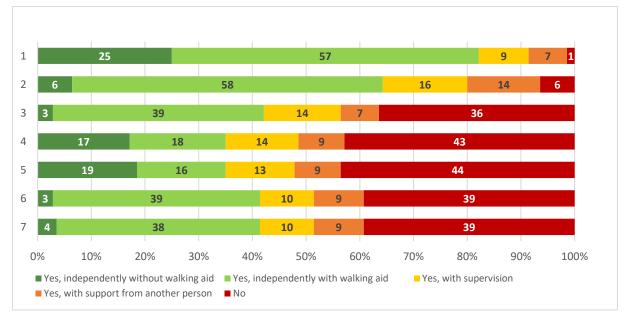


Figure 32a. Distribution of responses per LCI-5 question regarding basic activities, in unilateral KD/TFA due to Diabetes and/or vascular disease at follow-up 12 months after amputation, n = 140, %. The questions concern: 1: Get up from a chair. 2: Walk indoors. 3: Walk outdoors on level ground. 4: Go up one stair using a handrail. 5: Go down one stair using a handrail. 6: Step up a curb. 7: Step down a curb.

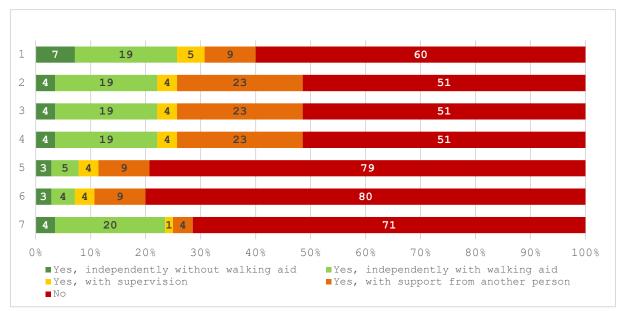


Figure 32b. Distribution of responses per LCI-5 question regarding advanced activities, in unilateral KD/TFA due to Diabetes and/or vascular disease at follow-up 12 months after amputation, n = 140, %. The questions concern: 1: Pick up an object from the floor. 2: Get up from the floor. 3: Walk outdoors on uneven ground. 4: Walk outside in bad weather. 5: Go up a few steps without a handrail. 6: Go down a few steps without the help of a handrail. 7: Walk while carrying an object.

Comment: Patients with unilateral amputation involving the knee (KD/TFA) report a significantly lower prosthetic mobility compared to TTA, especially in amputation due to diabetes and/or vascular disease. There is also a clear difference between women and men, where women generally report lower mobility capacity. Without comparable functional tests, we cannot know whether this difference is due to women having a more realistic assessment in their answers or whether their ability to move is lower than that of men. Not surprisingly, lower mobility is also consistently reported for the advanced activities

compared to the basic activities. Franchignoni et al (2019) reported that the minimal detectable difference for LCI-5 is 5.66 (MDC (95)). For the individual patient, a difference of 6 points between two measurement occasions can therefore be considered to reflect improved or impaired mobility with a prosthesis.

In this year's report, we have chosen to report LCI-5 results per question at the 12-month follow-up for patients with amputation due to diabetes and/or vascular disease. A large proportion of TFA/KD patients (>50%) state that they cannot cope with any of the demanding activities at the 12-month follow-up.

TIMED - UP AND GO TEST (TUG-TEST) UNILATERAL AMPUTATION

Timed-up and Go (TUG) is a standardized and general performance test that includes the time it takes for a person to get up from a chair with armrests, walk 3 meters, turn around, go back and sit down. In SwedeAmp, TUG is performed with the walking aid that is normally used by the patient and the time is measured in whole seconds. In a meta-analysis, the TUG for healthy elderly >60 years was reported to be 9.4 seconds (Bohannon et al 2001).

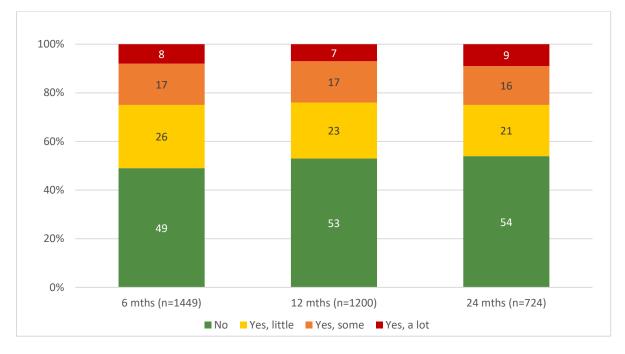
AMPUTATION CAUSE AND FOLLOW-UP OCCASION	TTA SEC, MEAN (SD), N	TFA/KD SEC, MEAN (SD), N
DIABETES /VASCULAR		
6 mths	27 (17) n=435	58 (37) n=94
12 mths	25 (21) n=340	50 (37) n=61
24 mths	22 (15) n=155	49 (36) n=23
OTHER DIAGNOSIS		
6 mths	19 (14) n=74	41 (31) n=30
12 mths	18 (23) n=56	41 (40) n=37
24 mths	15 (16) n=33	24 (22) n=23

Tabell 25. Timed-up and Go test (Mean) in unilateral TTA and TFA/KD and divided by diagnosis group and follow-up occasion.

Comment: In general, the TUG test shows impaired mobility and indicates a risk of falling, especially for people with a high amputation (TFA/KD) and amputation due to diabetes and/or vascular disease. The test is performed with support of the patient's normally used walking aid, which for many is a walker and thus will include e.g. time to handle the brake.

Dite et al (2007) have reported an increased risk of falling at TUG->19 sec in patients with unilateral TTA 6 months after prosthetic rehabilitation. Only patients with unilateral TTA not caused by diabetes/vascular disease have a mean value for TUG around or less than 19 seconds.

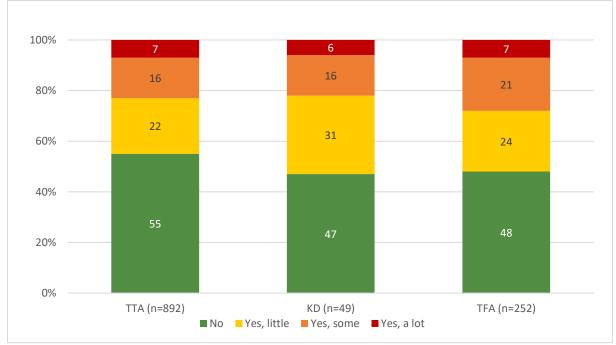
PAIN



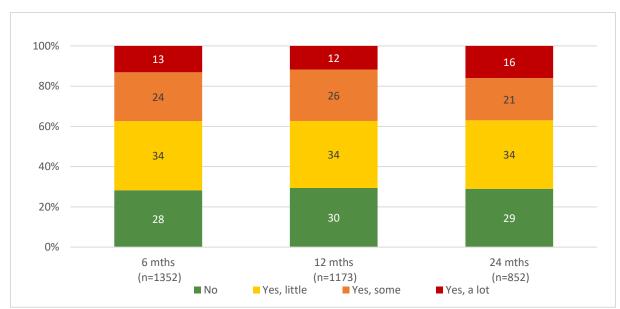
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RESIDUAL LIMB PAIN IN PATIENTS WITH UNILATERAL AMPUTATION

Figure 33. Incidence of residual limb pain in patients with unilateral amputation above the ankle, at 6.12 and 24 months follow-up, (%).

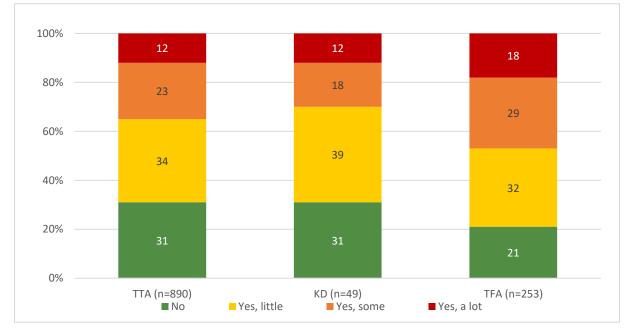






PHANTOM LIMB PAIN IN PATIENTS WITH UNILATERAL AMPUTATION







Comment: In general, more patients report problems with phantom limb pain (around 50%) than residual limb pain (around 30%). Patients with TFA report greater problems with phantom pain as compared to the other levels. More pain related data is reported in the section "Longitudinel data" and in the Swedish version of this report.

QUALITY OF LIFE AFTER UNILATERAL AMPUTATION

Quality of life is measured with the generic health status questionnaire named EQ-5D-5L, which consists of 5 questions related to the dimensions of Mobility, Hygiene, Usual Activities, Pain/Discomfort and Anxiety/Depression. Each question has 5 answer options. The combination of answers can be calculated as an index resulting in a value between -0.594 and 1. A higher index means a better self-rated health-related quality of life.

LEVEL	6 MTHS	12 MTHS	24 MTHS
	MEAN (SD)	MEAN (SD)	MEAN(SD)
ТТА	0.57 (0.28)	0.59 (0.28)	0.58 (0.29)
	n=1007	n=807	n=494
KD/TFA	0.48 (0.32)	0.48 (0.31)	0.48 (0.33)
	n=299	n=266	n=167

Table 26. Mean EQ-5D-5L Index at unilateral TTA and KD/TFA

LEVEL		6 MTHS MEAN (SD)	12 MTHS MEAN (SD)	24 MTHS MEAN (SD)
TTA	Women	0.50 (0.3) n=192	0.56 (0.27) n=161	0.47 (0.31) n=111
TTA	Men	0.59 (0.27) n=488	0.62 (0.27) n=391	0.61 (0.28) n=228
KD/TFA	Women	0.47 (0.3) n=78	0.40 (0.3) n=64	0.34 (0.31) n=45
KD/TFA	Men	0.48 (0.33) n=104	0.49 (0.3) n=94	0.45 (0.36) n=51

Table 27. Mean EQ-5D-5D Index in unilateral TTA and KD/TFA due to diabetes and/or vascular disease reported for women and men. In TTA, the difference between women and men is statistically significant (p<0.05) at all three follow-ups. In KD/TFA, the difference is only statistically significant at the 12-month follow-up.

DIABETES/VASCULAR DISEASE AND REPORTED SEPARATELY FOR TTA, KD AND TFA
EQ-5D-5L Mobility

EQ-5D-5L DISTRIBUTION OF ANSWERS PER DIMENSION, 12 MONTHS AFTER AMPUTATION DUE TO

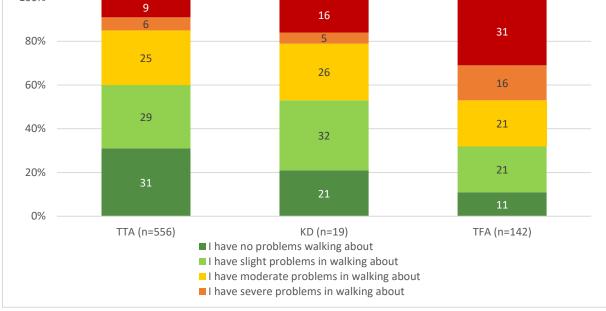


Figure 39. EQ-5D-5L Mobility

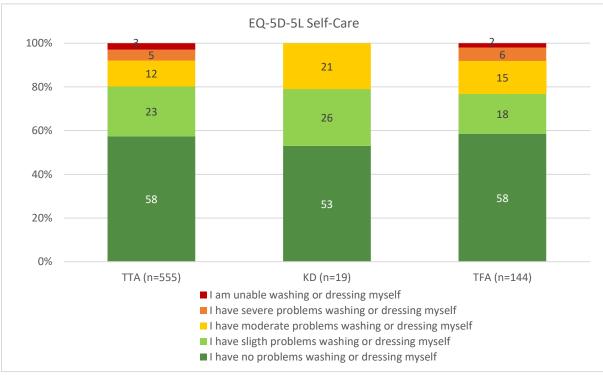


Figure 40. EQ-5D-5L Sel-Care

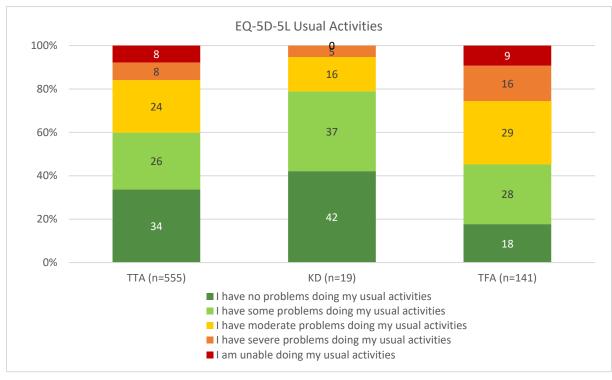


Figure 41. EQ-5D-5L Usual Activities

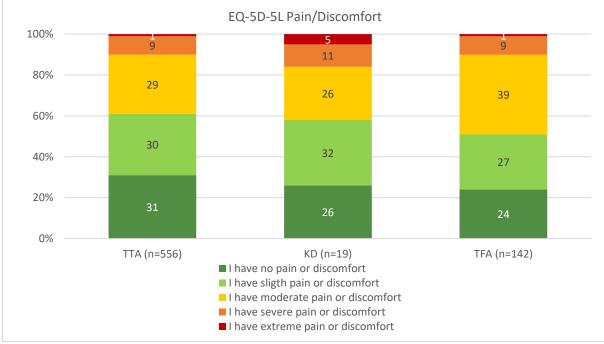


Figure 42. EQ-5D-5L Pain/Discomfort

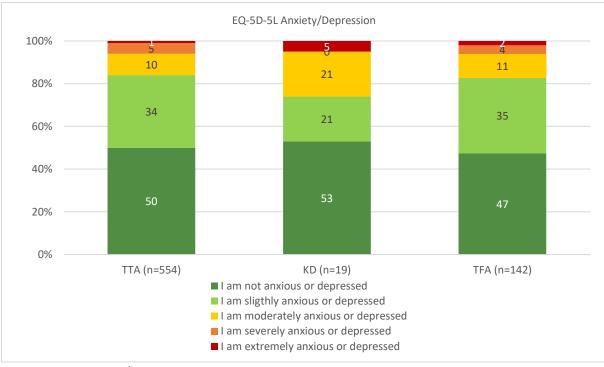
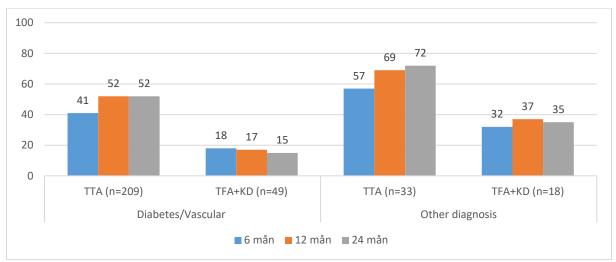


Figure 43. EQ-5D-5L. Anxiety/Depression

Comment: Patients with unilateral TTA report better overall health as measured by the EQ-5D index compared to patients with amputation at higher levels. Women with TTA report poorer overall quality of life compared to men. The distribution of responses in terms of Mobility shows large differences based on the level of amputation. Patients with unilateral TFA due to diabetes and/or vascular disease report significantly greater difficulty walking around compared to the other levels. Results reported for KD should be considered with caution due to the low number. Many Swedish quality registries report EQ-5D as a measure of general health, which makes it possible to compare patients with lower limb amputations with other patient groups. The EQ-5D index can be used to calculate quality-adjusted life years in health economic studies. Since 2023, data for the EQ-5D-3L (version with 3 response options) that the registry used until 2017 is no longer reported.

LONGITUDINAL FOLLOW-UP UNILATERAL AMPUTATION

This following section presents the smaller group of patients with unilateral amputation for which data have been collected at all time points, i.e. the same group of individuals are included at each follow-up. The report thus provides more precise prospective data over time, from amputation to follow-up after 2 years, for a smaller group of patients. The data consist of follow-ups performed over the past 10 years (2015–2024).



LONGITUDINAL FOLLOW-UP PROSTHETIC USE

Figure 44. Mean Prosthetic Use score (0-100) for the smaller group of patients with unilateral TTA or KD/TFA who have been followed on all three occasions (6, 12 and 24 months) reported per amputation diagnosis (Diabetes and/or vascular disease and Other diagnoses).

LONGITUDINAL FOLLOW-UP PROTHETIC MOBILITY

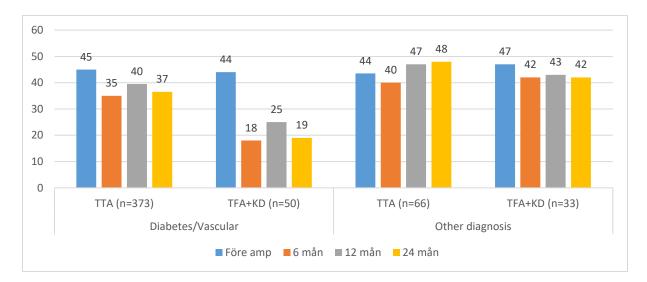


Figure 45. LCI-5 Total score (0-56) (Md) Longitudinal data for the smaller group of patients in whom the same individual has responded to LCI-5 regarding the situation before the amputation and at follow-ups (6, 12 and 24 months) after the amputation. The figure shows patients with unilateral amputation by level (TTA and TFA + KD) and by diagnosis (Diabetes and/or vascular disease and Other diagnoses).

LONGITUDINAL FOLLOW-UP PAIN

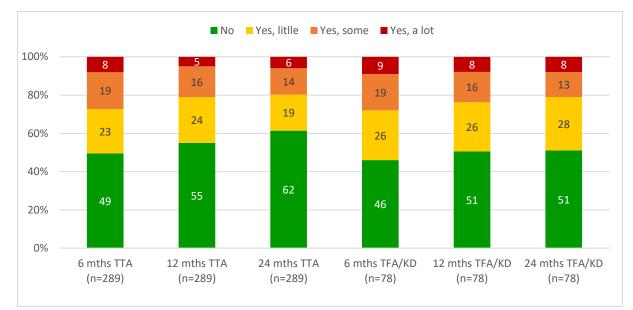


Figure 46. Prevalence residual limb pain in the smaller group that answered the question at all three follow-ups in unilateral TTA (n=289) and unilateral TFA or KD (n=78) (%).

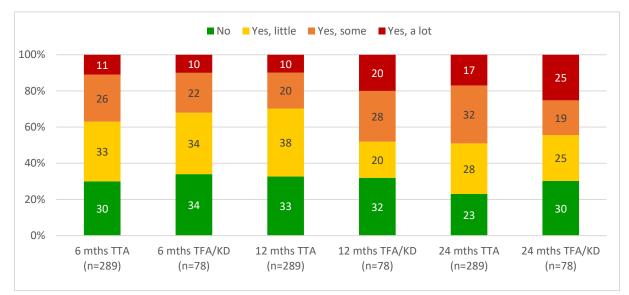


Figure 47. Prevalence of phantom limb pain in the smaller group that answered the question at all three follow-ups in unilateral TTA (n=289) and unilateral TFA or KD (n=78) (%).

Comment: This section presents the group of patients with data available at each time point. This means the data probably reflect patients with slightly better health considering that they survived the first two years after the amputation, did not undergo any re-amputation or amputation on the opposite limb during this period, and have been able to participate at follow-ups until 24 months. Patients with unilateral TTA report to use the prosthesis more over time, which is not the case for patients with TFA/KD. Regarding mobility, the largest decline after the amputation is shown in patients with TFA/KD due to diabetes/vascular disease. In TTA, slightly fewer people report problems with residual limb pain over time. However, continued severe residual limb pain is reported among 5-10% of the patients. In terms of phantom limb pain, patients with unilateral KD/TFA report more pain than patients with TTA, also over time. About 10% in unilateral TTA and 17-25% in KD/TFA report a lot of problems with phantom limb pain and there is no clear change over time.

BILATERAL AMPUTATIONS

This section presents follow-up data for patients with major bilateral amputations. The report is limited to follow-ups carried out during the last 10 years (2015 - 2024). The report for patients with bilateral amputations is based on:

- 239 patients (23% women and 77% men)
- The mean age at first follow-up as a bilateral amputee was 73 years
- The largest group consists of patients with bilateral TTAs (n=177)
- 93% have an amputation diagnosis of diabetes and/or vascular disease

Patients with bilateral TTAs are presented separately and patients with one side TTA and one side with a higher level (KD or TFA) are presented separately. Other combinations of amputation levels are not reported due to low numbers.

PROSTHETIC USE SCORE (0-100) AT 12 MONTHS

- Prosthetic Use score (0-100) Bilateral TTAs: Mean 46 (SD 32)
- Prosthetic Use score (0-100) TTA + KD/TFA: Mean 25 (SD 33)

Note that prosthetic use in patients with bilateral amputations does not reflect one prosthesis per amputation side but the use of any prosthesis, regardless of for which limb. In the combination of TTA + KD/TFA, prosthesis use therefore most likely refers to the TTA prosthesis as a TTA prosthesis is more comfortable to wear when sitting, improves balance in sitting and facilitates low transfers (i.e. transfer from e.g. wheelchair to toilet or from one chair to another chair) as compared to a TFA/KD prosthesis.



WALKING AIDS AT HOME AND OUTDOORS AT 12 MONTHS

Figure 48. Walking aids used while walking with prostheses at home and outdoors in patients with bilateral TTAs, at 12 months (%).

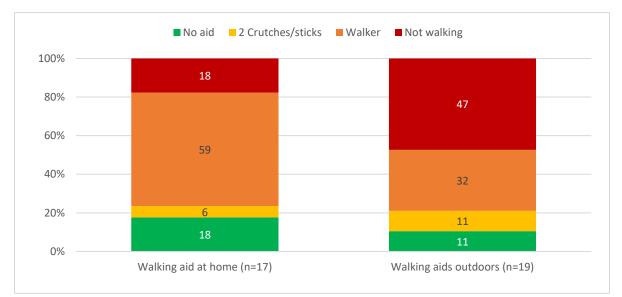
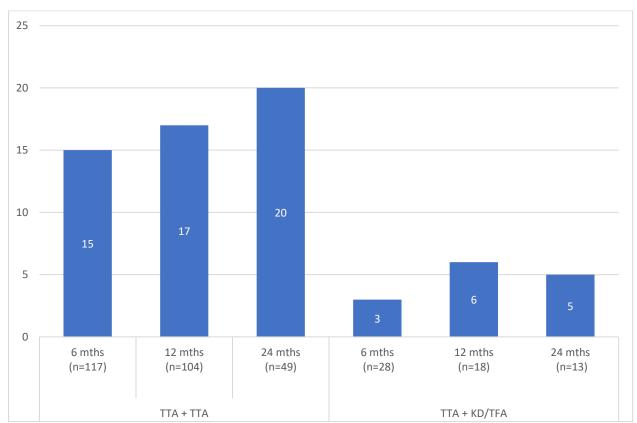


Figure 49. Walking aids used while walking with prostheses at home and outdoors in patients with bilateral amputation combining TTA + KD/TFA at 12 months, (%). Note the low number of n. Note 1 crutch/stick was not reported to be used by anyone.

USE OF WHEELCHAIR: 92% of patients with bilateral amputations state that they use a wheelchair (regardless of extent).



PROSTHETIC MOBILITY (LCI-5)

Figure 50. Prosthetic Mobility, LCI-5 Total (0-56, Md) at 6-, 12- and 24-months follow-up reported for patients with bilateral TTAs (TTA+TTA) and for patients with one side TTA and the other side KD or TFA (TTA + KD/TFA). Values represent to large degree by the Basic activities. In bilateral TTAs, 4 points represent Advanced activities at each follow-up occasion. In the combination TTA + KD/TFA, 0 points are given for the Advanced activities at all follow-ups.

QUALITY OF LIFE (EQ-5D-5L)

LEVEL	6 MTHS	12 MTHS	24 MTHS
	MEAN (SD)	MEAN (SD)	MEAN (SD)
	N	N	N
Bilateral TTAs	0.53 (0.28)	0.46 (0.32)	0.47 (0.31)
	n=87	n=62	n=38
TTA + KD/TFA	0.18 (0.29)	0.28 (0.33)	0.19 (0,32)
	n=27	n=23	n=19

Table 28. Mean EQ-5D Index (EQ-5D-5L) in bilateral amputations, separately for patients with bilateral TTAs and for patients with one side TTA and the other side with a higher level of amputation (KD/TFA).

Comment: In bilateral amputations, it is of high importance to have intact anatomical knee joints. Patients with bilateral TTAs report more prosthetic use and significantly better mobility as compared to patients with only one preserved knee joint, i.e. KD or TFA on the other side. Patients with bilateral TTAs, in many cases, show more prosthetic use and better prosthetic mobility than patients with a unilateral amputation above the knee. Walking outdoors requires the support of walking aids for almost all patients with bilateral amputations. See data reported for patients with unilateral amputation for comparison.

Summary of the patient's situation before and after the Amputation

This annual report presents PROM and follow-up data for SwedeAmp registrations performed during the last 10 years (2015–2024) with the aim to reflect the current situation for patients with amputation above the ankle in Sweden. Registration of baseline and follow-up parameters are usually conducted by physiotherapists at a prosthetic rehabilitation clinic. Many patients never reach prosthetic rehabilitation due to high morbidity and mortality, which affects data collection at baseline (the situation before the amputation) and follow-up. The baseline data largely reflects patients who also receive prosthesis. Clinics involved in SwedeAmp entails that a national common follow-up procedure is followed.

People with lower limb amputations are not a homogeneous group. Our data show important differences based on amputation level, amputation diagnosis and differences between women and men. By highlighting the situation of different groups of people with a lower limb amputation, SwedeAmp helps to spread knowledge and information to patients, relatives and caregivers. After a lower limb amputation, the ability to use a prosthesis is of major importance as a clear relation between better quality of life and better prosthetic mobility has been demonstrated (e.g. Davie-Smith et al. POI 2017; Wurdeman et al. POI 2018).

This report is dominated by the largest group of patients undergoing a lower limb amputation in Sweden, those with amputation due to diabetes and/or vascular disease. The largest amount of follow-up data concerns patients with a unilateral TTA.

In short, this year's report on baseline and follow-up data can be summarized as follows:

- Mobility is often reduced even before the amputation, and more than half use walking aids at home before the amputation. Even more people use walking aids outdoors. In addition, women report poorer mobility before the amputation compared to men.
- The number of days from the amputation to the start of training with a prosthesis has slightly increased compared to the previous annual report. The median time to prosthetic rehabilitation start is now about 3 months after TTA and almost 4 months after TFA. See also time to prosthesis under Prosthetic data.
- A unilateral TTA leads to more prosthetic use, better prosthetic mobility and less need for walking aids compared to higher amputation levels within the same diagnostic group. One year after a TTA due to diabetes and/or vascular disease 87% state that they can walk independently indoors and on flat ground outdoors, with or without the support of walking aids.
- Patients with amputation through or above the knee joint (KD/TFA) due to diabetes and/or vascular disease wear the prosthesis significantly less and indicate significantly poorer prosthetic mobility than other groups.
- Being able to independently climb stairs is a difficulty for many patients with a lower limb amputation, especially at amputation levels involving the knee joint. One year after a KD/TFA due to diabetes and/or vascular disease, about 35% state that they can climb stairs with the support of a handrail and fewer than 10% that they can climb stairs if a handrail is missing.
- Many patients report residual limb pain (about 50%) and phantom limb pain (about 70%). Patients with TFA report
 greater problems with severe phantom limb pain compared to those with TTA and no clear changes are seen over time.
- Women report in many cases a lower health-related quality of life compared to men.

Explanations and abbreviations

EQ 5D-5L*	A general health PROM, consisting of 5 questions each with 5 response alternatives) which can be presented as an index scale between minus 0, 594 and 1 (1 represents the best possible health) www.euroqol.org/
KD	Knee disarticulation (amputation through the knee joint)
LCI-5*	Locomotor Capability Index-5. A PROM (0- 56) questionnaire on prosthetic mobility which consists of the sum of two subscales (each $0 - 28$)
MHFA	Mid/Hind foot amputation (amputation through midfoot or heel)
Primary amputation	The first amputation per side
Primary amputation level	The level of amputation at the primary amputation per side
PROM	Patient-reported outcome
Prosthetic Use Score (PUS)*	A PROM (0-100) describing how much the patient is wearing the prosthesis a normal weak
Re-amputation	A second amputation procedure to a higher level (through or proximal of the next joint) on a limb where a previous amputation has not yet healed
Revision	A surgical procedure including wound cleaning/removal of soft tissues and/or shortening of bone structures, but not resulting in a higher amputation level
Final amputation level	The amputation level when healed or at death without healing
SUS	Skåne University Hospital
TFA	Transfemoral amputation (amputation through femur)
Timed- Up and Go Test (TUG)	A standardized gait test measured in seconds
ТРНО	Transpelvic amputation/Hip disarticulation (amputation through hip or pelvis)
TTA	Transtibial amputation (amputation through Tibia)

*For all PROM measures, a higher number represents a better outcome

See the website <u>Vetenskapliga publikationer | SwedeAmp</u> for references