

Annual report 2021



AMPUTATION AND PROSTHETIC REGISTER

FOR LOWER EXTREMITIES

A Swedish national Quality Register

FOREWORD

This is a translation of the Swedish version of the SwedeAmp Annual report 2021. The format has been slightly revised.

Please visit www.swedeamp.com under “Årsrapporter” to find the full Swedish version.

QUALITY REGISTRIES IN SWEDEN

A system of around one hundred National Quality Registries provides the Swedish health care system with a unique opportunity to monitor quality and results. The registries contain individualized data about medical interventions, procedures, and outcomes. They are integrated into clinical workflows. Each registry is supported by an organization of health care professionals and patient representatives. They are jointly responsible for developing the registry.

A National Quality Registry contains individualized data concerning patient problems, medical interventions, and outcomes after treatment. It is annually monitored and approved for financial support by an Executive Committee at the Swedish Association of Local Authorities and Regions.

National Quality Registries are used in an integrated and active way for continuous learning, improvement, research, and management to create the best possible health and care together with the individual.

There is six Swedish competence centers helping to run the National Quality Registries. In a competence center, several registries share the costs for staff and systems that a single registry could not bear, e.g., in technical operations, analytical work, and use of registry data to support clinical quality improvement and helping to make registry data beneficial for different users.

Hence, a continued development of the registries can be assured although the system follows a decentralized model, i.e., each registry is governed by a professional collaboration.

For more information: [Quality registries](#) | [Kvalitetsregister](#) | [SKR](#)

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IMPORTANT MESSAGES 2021

POSITIVE DEVELOPMENT

In Sweden, the incidence of lower extremity amputation per 100,000 inhabitants has decreased continuously since the 1980s and is now around 20 / 100,000 inhabitants over 18 years of age.

The number of days from amputation to fitting of the first prosthesis has also decreased continuously and is now at a median of 58 days for transtibial amputation (TTA) and 84 days for transfemoral amputation (TFA). In TTA, time to prosthesis is 19 days shorter if the surgical technique has been performed with sagittal/skew flap compared to posterior-anterior/long posterior flap.

A NEGATIVE NOTE

Although the incidence of amputation has fallen overall in Sweden, we still observe large regional differences, with a spread of the incidence as large as 6 - 35 / 100,000 inhabitants. In addition, there are still regional differences in the choice of amputation level.

One of SwedeAmp's long-term, and perhaps the most pressing goal, has been to contribute to more equal care for patients. As long as there are obvious regional differences in amputation level, incidence, surgical technique and time to prosthesis, amputation care remains unequal. It also indicates that old treatment traditions remain in many units despite new knowledge, e.g. sagittal incisions in TTA lead to faster prosthesis supply or the importance of preserved knee joint, with the goal that the ratio TTA / (KD+TFA) should not be less than 1 within the unit.

SwedeAmp should be even better heard and spread in the country. National guidelines are required, and we hope to be able to help ensure that these can be drawn up in the future.

THE COVID PANDEMIC AND CONSEQUENCES FOR OUR PATIENT GROUP

A full evaluation of the consequences of the pandemic for our patients is not yet possible and we will continue to emphasize the pandemic effect in the following reports. The most obvious negative effect so far relates to a lesser possibility for rehabilitation and prosthetic supply.

Covid-19 has hit the whole country equally. However, we see some regional differences. Regarding our surgical data, no definite changed patterns are seen, but individual departments have reported both fewer or more amputation procedures and some have reported a larger proportion of higher amputation levels (TFA) than before. The National Board of Health and Welfare's inpatient care statistics for 2021 are expected to provide an opportunity to further shed light on the potential impact of the pandemic on the number of amputation procedures and choice of primary amputation level.

More Prosthetic and Orthotic clinics (P&O clinics) are now registering in SwedeAmp, yet fewer prostheses were registered during the pandemic years 2020-2021. In addition, fewer TFA patients who have been provided with a prosthesis have been registered during the same period. Whether this is a result of fewer registrations performed or a poorer state of health in the patients is uncertain.

The time from amputation to the start of training with a prosthesis has become shorter since the registry started 10 years ago, but for patients with TTA it has remained at the same level during the period 2019–2021 as in the previous years.

Summary 2021

Patients undergoing lower limb amputations (LLA) in Sweden are largely dominated by older people with amputation as a result of diabetes and/or vascular disease (83%), and most (93%) have other concurrent diseases or disabilities that make the rehabilitation more difficult. Within 12 months of amputation, 26% of patients undergoing TTA and 42% undergoing TFA had died.

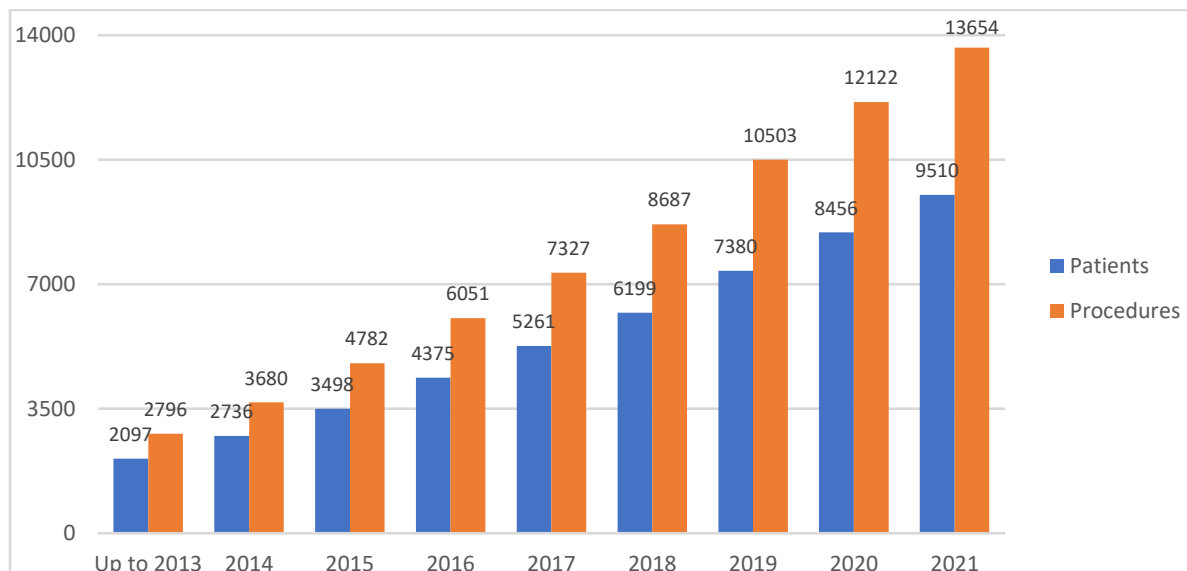


Figure 1. Development of the register. Number of registered patients and procedures performed up to 31 Dec 2021. The columns for the year 2013 also include registration of procedures performed before 2013.

This year's report includes data for approximately 9,500 patients with roughly 13,600 amputation procedures (figure 1). It is gratifying that registration of amputation procedures during the Covid pandemic has not slowed down extremely much. Statistically confirmed differences between the sexes are again confirmed, where the women have a higher proportion of amputation diagnosis "vascular disease without diabetes", a higher proportion of amputations through or above the knee joint and older age at the time of the procedure compared to the men. Many patients have reduced functional capacity and use both walking aids and wheelchairs even before the amputation.

Patients who undergo a lower limb amputation (LLA) are not a homogeneous group. There are clear differences based on amputation level and amputation diagnosis. All data demonstrate the importance of a preserved knee joint. In terms of functional ability with a prosthesis, women report poorer ability than men in both TTA and TFA. Patients with amputation due to other causes use the prosthesis more and have better mobility as compared to the group with vascular diseases. In general, many patients report both stump pain and phantom limb pain.

We hope that you will find the information in the annual report interesting and recommend it be used when planning rehabilitation efforts, when informing patients and relatives and for training various healthcare providers. With this year's report, we hope to be able to contribute valuable information for continued improvement of the care of patients undergoing LLA in Sweden and elsewhere. Everyone who contributes data to SwedeAmp is therefore doing important work!

Many Thanks to you who register in SwedeAmp!

The Steering Group for SwedeAmp, 2022-08-18

INTRODUCTION

THE CARE CHAIN

The multidisciplinary care of patients with undergoing LLA remains a challenge for many clinical units. For the majority of patients, the amputation takes place late in life as a result of vascular disease and/or diabetes and has usually been preceded by a longer period of illness, not infrequently with difficult-to-heal wounds. For a smaller group of patients, the amputation is performed earlier in life, for example due to an accident, tumor or sepsis. Regardless of the underlying cause, an amputation means an irrevocably changed situation, and multi-professional assessment and coordination is required to enable the patient to return to as normal a life as possible.

SwedeAmp aims to make visible and improve the complex care chain after lower limb amputation. On the website there are examples of regional and local care programs under the GUIDELINES tab. There are few registries that so comprehensively try to include all links in the care chain. Collected data from many healthcare providers, makes SwedeAmp unique in its kind, also internationally.

INCIDENCE AND COVERAGE

INCIDENCE

A recently published study has shown that the incidence of lower extremity amputations in Sweden has decreased from 2008 to 2017 (22.1/100,000 inhabitants in 2017), but that there are large regional differences and that the decrease only occurred in about half of the regions. The study does not provide a clear answer as to the reason for the differences but discusses reasons such as different distribution of patient- and age-groups and differences in diabetes care. You can find the study here: <https://doi.org/10.1016/j.ejvs.2022.05.033>

SwedeAmp will continue to delve into the issue.

COVERAGE AND REGISTRATION RATE

The coverage of registering units is the proportion of units that regularly register data in SwedeAmp in relation to the total number of units in Sweden. As SwedeAmp is a multi-disciplinary register, the registration rate is more than a single value. For surgical data, the registration rate is 76% (16 of 21 regions) regarding patients with amputation at levels above the ankle.

The number of P&O clinics in Sweden is variable due to changed procurement conditions in agreements with regions, offshoots, and newly added actors. SwedeAmp estimates that in 2021 there were 37 P&O clinics providing prosthetic services to varying extents. The number of registering units in 2021 was 24, which gives a registration rate of 65% for the number of P&O clinics that regularly registered in 2021.

Registration rate is reported for TTA, which is the most common amputation level in the register. The coverage ratio is calculated by comparing the register's data with the National Board of Health and Welfare's database for surgical procedures in inpatient care based on the number of people and diagnosis code "NGQ19 Transtibial amputation". The regions that register surgical data in SwedeAmp have a coverage rate of 54% for the year 2021. Comparative national statistics for prostheses and sockets are missing. The fairly low number of 54% can reflect that many patients never proceed in the care chain

and therefore are never included in SwedeAmp. The slightly reduced number of registrations in 2021 may also be a negative effect of the pandemic.

The number of surgical units registering in SwedeAmp has risen. There are now several units with close to 100% completeness of amputation procedures, which means safer analyzes and a better opportunity to compare hospitals or regions with each other. The regions with the highest completeness ratio form the basis for analysis and comparison in this annual report.

VALUE THAT SWEDEAMP ADDS TO HEALTH CARE

Care in connection with an amputation in Sweden is provided by both private and public care providers. Surgical care is usually provided by public hospitals whereas P&O services are, to a large extent, provided by private service providers. Regardless of this, close cooperation around the patient and knowledge of each other's care efforts is required. SwedeAmp enables access to a larger amount of collected data from the entire care chain, i.e. from the surgical care, prosthetic supply and rehabilitation, than each of these clinics themselves has access to. In addition, the register enables the collection and reporting of patient-reported data.

SwedeAmp demonstrates the importance of multi-professional teamwork, stimulates collaboration between healthcare providers and increases general knowledge around the patient group. All with the aim of improving the care of patients undergoing lower limb amputations.

PATIENT PERSPECTIVE

In SwedeAmp, patient-reported data (PROM) is recorded 6, 12 and 24 months after the amputation. These include amputation-specific PROMs such as how much the prosthesis is used, mobility, need for walking aids and presence of phantom limb pain, but also questions concerning general health-related quality of life. With support from SwedeAmp data, healthcare providers can get information that helps to answer questions from patients and relatives.

In this report, for the first time, data is presented for the question that was added in 2020 to shed light on whether the patient had had the opportunity to meet another person with their own experience of an amputation and the use of a prosthesis.

The steering group has two patient representatives.

GUIDELINES

National guidelines regarding lower limb amputations are missing in Sweden. However, regional differences regarding amputation level, surgical technique, rehabilitation, and prosthetic supply suggest that there is a need for such national guidelines. Local guidelines introduced by the Stockholm region are available on SwedeAmp's website. We invite everyone who has local guidelines to have these published on our website and thereby contribute to a common source of knowledge while waiting for national guidelines to be composed. International guidelines are also available on SwedeAmp's website.

QUALITY INDICATORS AND “CARE IN NUMBERS”

SwedeAmp presents three quality indicators on the national website "Care in numbers", www.vardenisiffror.se :

- Percentage of TTA relative to TFA/KD
- Percentage of re-amputations after primary TTA
- Time from TTA to first prosthesis

A high proportion of primary TTA in relation to KD/TFA is desirable, but only if these do not also result in a high proportion of re-amputations, as this means unnecessary suffering for patients and increased costs for the society. This example highlights the importance of reporting both indicators together. The percentage of re-amputations after primary TTTA varies greatly between the Swedish regions. The national average is approx. 13%.

The indicator that shows the number of days from primary amputation to testing of the first prosthesis is intended to compare the care process in the country and can demonstrate regional differences in lead times. The indicator can also be used as a measurement in local improvement work. Here, Region Blekinge can be mentioned, having decreased number of days until “first prosthetic fitting” from a median of 87 days in 2018 to 49 days in 2021.

SPREADING KNOWLEDGE AND STIMULATING COLLABORATION

During the last two years, SwedeAmp has arranged webinars in various contexts, e.g. for new register users, for users at local clinics and for all users as a group. Only a few physical meetings have been arranged due to the Covid pandemic.

Data from SwedeAmp's annual reports are used in various types of teaching around the patient group. This applies to information and teaching aimed at healthcare staff at the clinic level, but also to teaching at university level, such as for orthopedic and geriatric residents and in the physiotherapy and prosthetic & orthotic programs, respectively.

SCIENCE

During 2021, SwedeAmp has presented data at several conferences such as the 1st International Conference on Phantom Limb Pain, the ISPO UK/Norway conference, and the Nordic P&O Conference. Scientific publications that SwedeAmp participated in during the year:

- Ernstsson, O. et al 2021 Health-related quality of life in patients with lower limb amputation - an assessment of the measurement properties of EQ-5D-3L and EQ-5D-5L using data from the Swedish Amputation and Prosthetics Registry, *Disabil Rehabil* 2021, DOI 10.1080/09638288.2021.2015628
- Kuhlmann, A. et al 2022 “The Kenevo microprocessor-controlled prosthetic knee compared with non-microprocessor-controlled knees in individuals older than 65 years in Sweden: A cost-effectiveness and budget-impact analysis, *Prosthet Orthot Int* 2022, DOI: 10.1097/PXR.000000000000138

INTERNATIONAL COOPERATION

The International Society for Prosthetics and Orthotics (ISPO) has, with the support of major international organizations (USAID, ATScale-Global Partnership for Assistive Technology and UN-based UNOPS), implemented a process to introduce an international registry regarding prosthetic supply and function after amputation. In this work, SwedeAmp has been highlighted as an example and two representatives from the steering group have been part of the process. Read the published report here: <https://www.ispoint.org/page/theleadandcompass>.

Information about the SwedeAmp Register

SwedeAmp started in year 2011 and is a national quality register for lower extremity amputations, including the subsequent care chain. The registry includes the amputation procedure and its causes, prosthetic provision and rehabilitation, as well as patient-reported outcome measures. In addition, the possibility is provided for registration of objective walking ability. The register has a clear multidisciplinary focus.

OVERALL PURPOSE

- To provide a basis for work that can improve and raise the quality of the care chain in LLA
- To demonstrate differences occurring in the care (including surgical procedure, prosthetic supply and rehabilitation)
- To provide a basis for evaluation of prosthetic supply, components and rehabilitation
- To provide a basis for cost analyses
- To increase knowledge with regard to mobility and quality of life in people with LLA
- To be able to provide guidance in planning treatment for an individual patient at risk of LLA
- To stimulate and provide a basis for conducting research

STRUCTURE OF THE REGISTER

The register describes the care chain in various steps and includes patient and amputation data, prosthesis data, the patient's situation before and after the amputation and mobility data. In practice, data is entered in 6 different forms (F1 – F6). The register enables lifelong follow-up.

Briefly, each form includes the following information:

F1. Personal data and basic amputation data. Basic amputation data includes amputation level, side and date. With each new intervention, a new registration is made in F1. Registered by the user who first enters data for an amputation event.

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

F3. The prosthesis. Description of the prosthesis provision, both for the first prosthesis for the current amputation level and for subsequent prostheses.

F4. Baseline (PROM). Includes questions regarding the patient's situation before the acute deterioration that led to the amputation. The questions are answered in connection with or as soon as possible after the amputation and includes accommodation, use of walking aids and self-reported mobility.

F5. Follow-up (PROM). Follow-up is registered for patients with amputation above the ankle and is performed at three points in time: 6, 12 and 24 months after the current amputation. Information included e.g. how much the prosthesis is used, ability to independently don the prosthesis, use of walking aids, mobility with prosthesis, presence of pain, and general health.

F6. Movement data. Objective measures of walking ability are recorded here. So far, this form is rarely used and data are not presented in yearly reports as yet

For each new surgical procedure, the patient's individual social security number, the side of amputation, level of amputation and date of amputation must be registered in F1. With these four details filled in, the various parts are linked so that other data can be entered and followed.

Data is entered with personal login, Smart Card or Mobile BankID on a web-based register platform at Register Center Syd (RC Syd) in Lund ([Link](#)). Each user can register in all forms, but it is desirable that the operating unit records details of the amputation, the CPO the prosthetic supply, and the nurse, occupational therapist or physiotherapist records patient-reported data before and after the amputation. Each user can retrieve data from their own organization.

On the website ([Link](#)) there is information about the data included, a manual ([Link](#)) and an instructional video ([link](#))

The principal for SwedeAmp is Region Skåne, Sweden.

STEERING GROUP MEMBERS 2021



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Physiotherapist, Hässleholm Rehabilitation Unit, Skåne



Linda Sjöberg

Patient representative



Fredrik Martinsson

Patient representative

Basic data

REGISTRATIONS UP TO 2021-12-31

All registrations

- 9510 patients
- 13 654 interventions
- 5589 prosthesis registrations
- 2729 records regarding the patient's situation (PROM) before the amputation
- 3145 registrations regarding the patient's situation (PROM) after the amputation

Gender distribution of all patients: 39% women, 61% men

Mortality

- 58% of all registered patients were no longer alive at the turn of the year 2021/2022, where the proportion of deceased women was higher (64%) than men (55%)
- 24% mortality within 6 months after last recorded primary amputation or re-amputation
- Mortality within 12 months after the last recorded primary amputation or re-amputation was 31% and distributed by amputation level: 26% TTA, 40% KD, 42% TFA

Comment: In case of amputation above the ankle, a generally high mortality is observed, with increasing mortality at a higher level of amputation. Even after forefoot amputation, mortality is high. Previously presented data from Skåne University Hospital (SUS) (close to 100% registrations of all amputation levels) showed 20% mortality within 12 months after forefoot amputation.

Previous analysis of patients who received a prosthesis showed 9% mortality within 12 months of first prosthesis registration, which may indicate reasonable assessments of which patients receive a prosthesis.

Patient and amputation data

BASIC DATA

HOME REGION OF LIVING

| HOME REGION AT FIRST REGISTERED PROCEDURE PER PATIENT | NUMBER OF PATIENTS IN THE REGISTER | SHARE |
|---|------------------------------------|-------|
| Blekinge region | 297 | 3% |
| Dalarnas region | 403 | 4% |
| Gotlands region | 119 | 1% |
| Gävleborgs Region | 145 | 2% |
| Hallands region | 401 | 4% |
| Jönköpings region | 420 | 4% |
| Kalmar region | 131 | 1% |
| Kronobergs region | 111 | 1% |
| Skåne region | 2985 | 31% |
| Stockholms region | 1543 | 16% |
| Södermanlands region | 45 | <1% |
| Uppsala region | 140 | 2% |
| Värmlands region | 32 | <1% |
| Västmanlands region | 146 | 2% |
| Västra Götalands region | 1498 | 16% |
| Örebro region | 379 | 4% |
| Östergötlands region | 702 | 7% |
| regions with <5 registrations | 6 | <1% |
| Unknown region | 27 | <1% |
| Total | 9530 | |

Table 1. Patients home regions.

Comment: Most patients registered in SwedeAmp live in the regions of Skåne (31%), Västra Götaland (16%) or Stockholm (16%). Some regions may have a high degree of coverage despite a low number of registrations, such as e.g. Gotland. There is still a lack of registrations for patients living in the northern regions of Sweden.

AGE AND SEX

AGE AT FIRST REGISTERED PROCEDURE

| GENDER | MEAN (SD) | MEDIAN (MIN–MAX) |
|-----------------|-----------|------------------|
| Female (n=3543) | 78 (15) | 81 (0-103) |
| Male (n=5582) | 72 (15) | 74 (0-102) |
| Total (n=9125) | 74 (15) | 76 (0-103) |

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

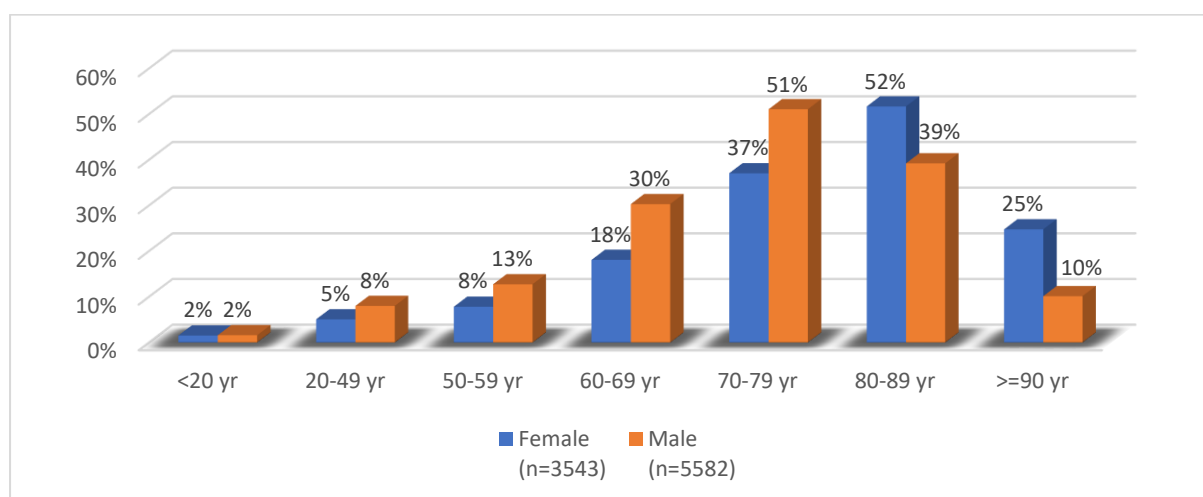


Figure 2: Age group distribution in primary amputation for women and men respectively in percentage (n=9125)

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

DIAGNOSIS AND DIAGNOSTIC GROUPS

THE PATIENT'S UNDERLYING DIAGNOSIS AT THE TIME OF THE FIRST REGISTERED SURGICAL PROCEDURE (N=8372)

- Diabetes with or without vascular disease (n=3942) 47%
- Arteriosclerosis without diabetes (n=2706) 32%
- Other vascular disease without diabetes (n=340) 4%
- Infection not related to diabetes or vascular disease (n=391) 5%
- Trauma (n=321) 4%
- Tumor (n=187) 2%
- Amputation due to congenital or acquired deformity (n=129) 2%
- Other cause (n=290) 4%
- Unknown diagnosis / not registered diagnosis (n=66) <1%

DIAGNOSTIC GROUP BY GENDER

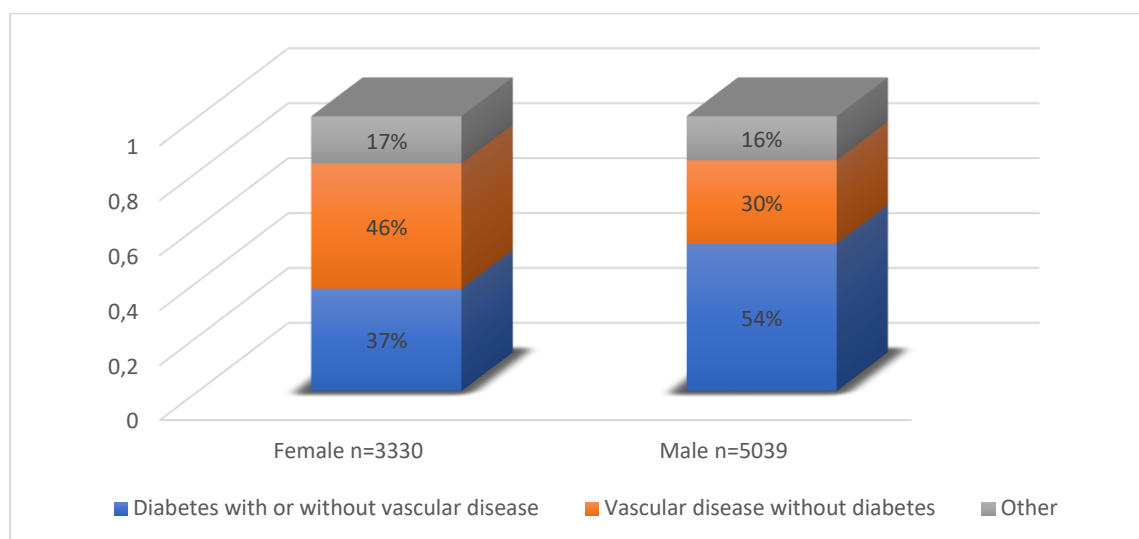


Figure 3. Distribution regarding diagnostic group at the amputation for women and men, %.

Comment: Diabetes and/or vascular disease together make up 83% of all registered diagnoses at the time of the procedure. In women, vascular disease without diabetes is the most common diagnosis at amputation. In men, diabetes with/without vascular disease is the most common diagnosis. When the diagnosis of diabetes is present, the cause of amputation is classified as diabetes unless there is an independent cause, such as e.g. trauma or tumor. The difference between the sexes regarding diagnosis group is statistically significant ($p < 0.0001$)

MEAN AGE FOR SELECTED DIAGNOSTIC GROUPS

| DIAGNOSTIC GROUP | WOMEN MEAN AGE (SD) | MEN MEAN AGE (SD) |
|--|------------------------|----------------------|
| Diabetes with/without vascular disease | 76 (12) | 73 (11) |
| | (n=1230) | (n=2660) |
| Vascular disease without diabetes | 82 (10) | 78 (11) |
| | (n=1531) | (n=1542) |
| Other diagnoses | 68 (23) | 60 (23) |
| | (n=601) | (n=839) |

Table 3. Average age at the time of the procedure for selected diagnostic groups. The difference between the diagnostic groups and sex is statistically significant ($p < 0.0001$).

SMOKING HABITS

Smoking habits at first registered procedure per patient (n=3453) for major amputations:

- 38% Never smoked
- 34% Former smokers (defined as having stopped smoking >12 months before the procedure)
- 26% Active smoker
- 2% Other nicotine product

Comment: It is sometimes difficult to group the patients correctly into the category "never smoked" and "former smoker". The steering group has decided to merge these 2 categories going forward.

CO-MORBIDITY

Presence of other illness or disability that can be expected to affect wound healing and/or rehabilitation. Number of conditions registered per patient (n=6376 patients):

- 34% (n=2184) One condition
- 33% (n=2085) Two conditions
- 26% (n=1668) Three or more conditions
- 7% (n=439) No condition

| MOST COMMON CO-MORBIDITIES (MORE THAN ONE CO-MORBIDITY CAN BE PRESENT IN THE SAME PATIENT) | NUMBER OF PATIENTS WITH CO-MORBIDITY PRESENT |
|---|--|
| Heart disease | 3946 (33%) |
| Kidney disease | 1262 (10%) |
| Chronic pulmonary disease | 892 (7%) |
| Stroke | 819 (7%) |
| Dementia | 596 (5%) |
| Reumatoid arthritis | 383 (3%) |
| Neurological disease | 265 (2%) |
| Diabetes (if not primary reason for amputation) | 873 (7%) |
| Reduced vision or hearing | 289 (2%) |
| Vascular disease (if not primary reason for amputation) | 1297 (11%) |
| Other (includes conditions present in less than 100 patienter e.g.: malign tumor, psychiatric condition, substance abuse, , reduced hand function och fracture) | 1087 (9%) |

Table 4. Most common co-morbidity. Conditions registered per patient during at least one intervention, %.

Comment: Co-morbidity within the patient group is common. For most patients, the amputation is one of several other medical conditions and the most common is heart disease. Only 7% has been reported without any co-morbidity. It is likely that co-morbidity is underreported.

SURGICAL DATA

AMPUTATION DATA

AMPUTATION PROCEDURE

In 11,739 of the amputation procedures, the type (primary amputation, re-amputation or revision) has been entered as follows:

- 80% (n=9334) primary amputation
- 13% (n=1511) re-amputation to a higher level
- 7% (n=886) revision

Comment: At Skåne University Hospital, which has an almost complete registration of all performed amputations, the proportion of primary amputations is 73%, the proportion of re-amputations 16% and revisions 11%. This shows that, only 3 out of 4 amputations are a primary procedure.

AMPUTATION LEVEL

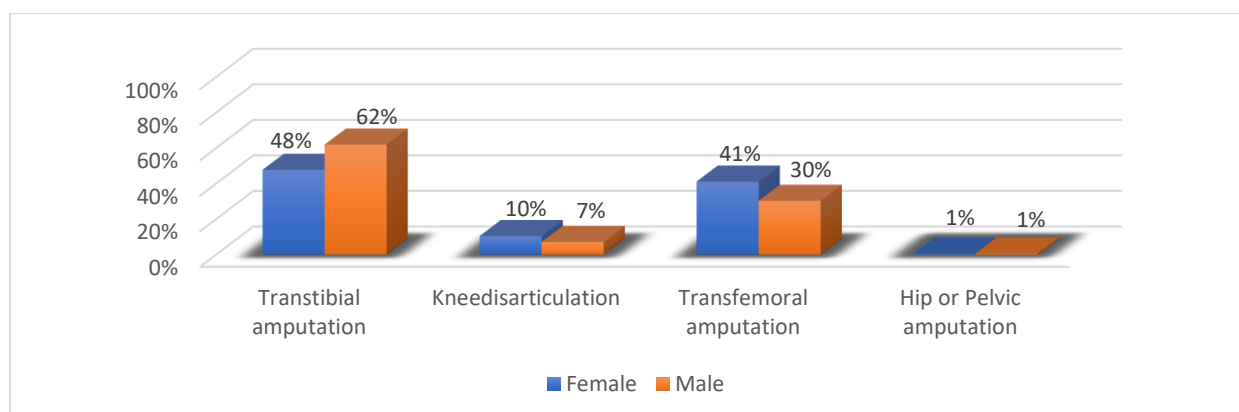


Figure 4: Distribution of amputation level above the ankle for women and men, %.

Comment: The register has so far, a low degree of coverage regarding amputation registrations below the ankle. Previous separate analyzes for Skåne University Hospital, where all lower extremity amputations are registered, have shown that amputations below the ankle account for almost 50% of all procedures.

Broad consensus prevails regarding the importance of preserving the anatomical knee joint to provide best possible conditions for good prosthetic function.

The percentage of women with a TFA level is higher than that of men (41% and 30% respectively). This may be due to that amputation due to vascular disease without diabetes is more common in women (figure 3) and that the women are older than men at the time of amputation (table 3). More detailed statistical analyzes are required to assess whether women more undergo amputation at a higher level than men, regardless of age or diagnosis.

OTHER UNDERLYING HEALTH DATA

| NUMBER OF INDICATIONS N=8714 | SHARE OF REGISTERED PROCEDURES (N=6443) |
|----------------------------------|---|
| Progressive Gangrene (n=3504) | 54% |
| Infection (n=2660) | 41% |
| Pain (n=1776) | 28% |
| Acute vascular occlusion (n=884) | 14% |
| Toxic/Septic condition (n=407) | 6% |
| Trauma (n=195) | 3% |
| Tumor (n=135) | 2% |
| Deformity (n=117) | 2% |
| Other (n=342) | 5% |

Table 5: Indication/s of amputation based on primary amputations. Several interacting causes can be registered. In 64443 interventions, a total of 10020 precipitating causes are registered, %.

Comment: The immediate indication for amputation is usually an infectious condition, which makes the surgical intervention a risky operation. Considering other co-morbidities, it is of great importance to optimize the patient as good as possible before the procedure. This means, for example, nutritional supplements, antibiotics, thromboprophylaxis and as short and fast procedure as possible

RE-AMPUTATION AFTER PRIMARY AMPUTATION LEVEL

| PRIMARY LEVEL | FINAL LEVEL TTA (%) | FINAL LEVEL KD (%) | FINAL LEVEL TFA (%) | FINAL LEVEL TPHD (%) |
|--------------------------------------|------------------------|-----------------------|------------------------|-------------------------|
| Transtibial amputation (TTA) n=4384 | 88% | 1% | 10% | <1% |
| Knee disarticulation (KD) n=659 | - | 88% | 12% | <1% |
| Transfemoral amputation (TFA) n=2115 | - | - | 99% | <1% |

Table 6a: Relationship between primary level and final level for the entire register, %

| PRIMARY LEVEL SUS | SUS FINAL LEVEL FOREFOOT (%) | SUS FINAL LEVEL TTA (%) | SUS FINAL LEVEL KD (%) | SUS FINAL LEVEL TFA (%) | SUS FINAL LEVEL TPHD (%) |
|-------------------------------------|------------------------------------|-------------------------------|------------------------------|-------------------------------|--------------------------------|
| Amputation below ankle n=1181 | 83% | 13% | <1% | 3% | <1% |
| Transtibial amputation (TTA) n=750 | | 81% | 1% | 17% | <1% |
| Knee disarticulation (KD) n=52 | | - | 83% | 15% | 2% |
| Transfemoral amputation (TFA) n=444 | | - | - | 99% | 1% |

Table 6b: Relationship between primary level and final level at Skåne University Hospital (SUS), %.

Comment: The figures describe primary amputation and the cases where re-amputation to a higher level for the same individual and the same side has subsequently been registered. The coverage rate for interventions below the ankle is close to 100% at Skåne University Hospital (SUS). Data from SUS show that 83% of amputations below the ankle stop at this level. The data from SUS also show a higher proportion of re-amputations from primary TTA and KD respectively to final level TFA as compared to SwedeAmp's total data set.

SURGICAL TECHNIQUE

| SKIN FLAP TTA | TOTAL | BLEKINGE | HALLAND | JÖNKÖ-PING | SKÅNE | VÄSTRA GÖTALAND | STOCK- HOLM |
|---|--------|----------|---------|------------|--------|--------------------|----------------|
| Sagittal/Skew | 79% | 86% | 83% | 77% | 84% | 70% | 67% |
| Anterior-Posterior/Long posterior flap | 21% | 14% | 17% | 23% | 16% | 30% | 33% |
| Number of procedures | n=2614 | n=127 | n=248 | n=215 | n=1246 | n=445 | n=333 |

Table 7: Incision technique in primary amputation or re-amputation in case of TTA, %.

Comment: The most common surgical technique for TTA is a sagittal or skew flap. To illustrate differences within the country, the six regions with most registered data are also reported. The difference between regions is noticeable. However, definitive conclusions regarding differences in surgical technique between regions still demand higher completeness of data. Fewer days to prosthetic fitting in cases where a sagittal/skew flap was used compared to other the other techniques is reported in Table 12c page 31.

ASSESSMENTS AND MEASURES IN CONNECTION WITH THE AMPUTATION PROCEDURE

Skin closure (n=4822), recorded only for major (above-ankle) amputations:

- 68% Sutures
- 20% Graphs
- 10% Vacuum treatment and 2% Open treatment

Comment: Clinical experience shows that staples should be avoided after amputation as they may lead to more wound healing problems. SwedeAmp's surgical data does not contain information on postoperative wound healing. Open- or vacuum- treatment can be an alternative for very fragile skin and risk of wound healing problems.

WALKING ABILITY BEFORE AMPUTATION

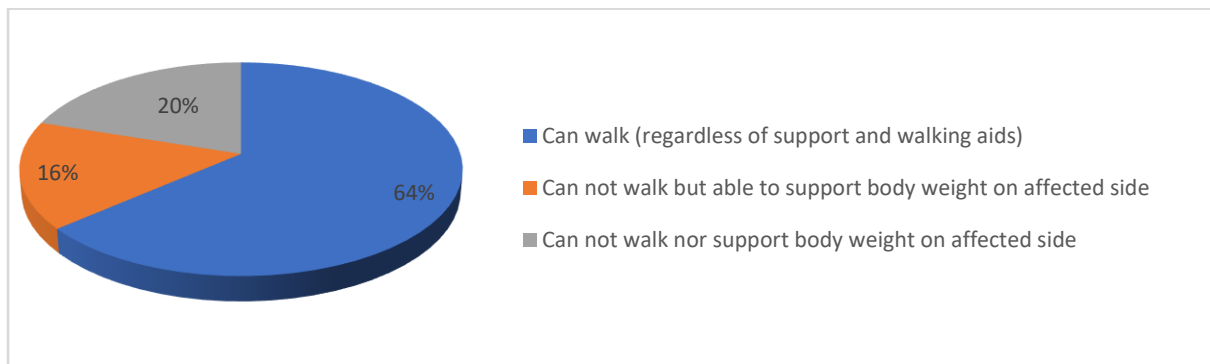


Figure 5: Walking ability before amputation (n=7590), recorded only for amputations above the ankle.

PRELIMINARY ASSESSMENT REGARDING PROSTHETIC SUPPLY

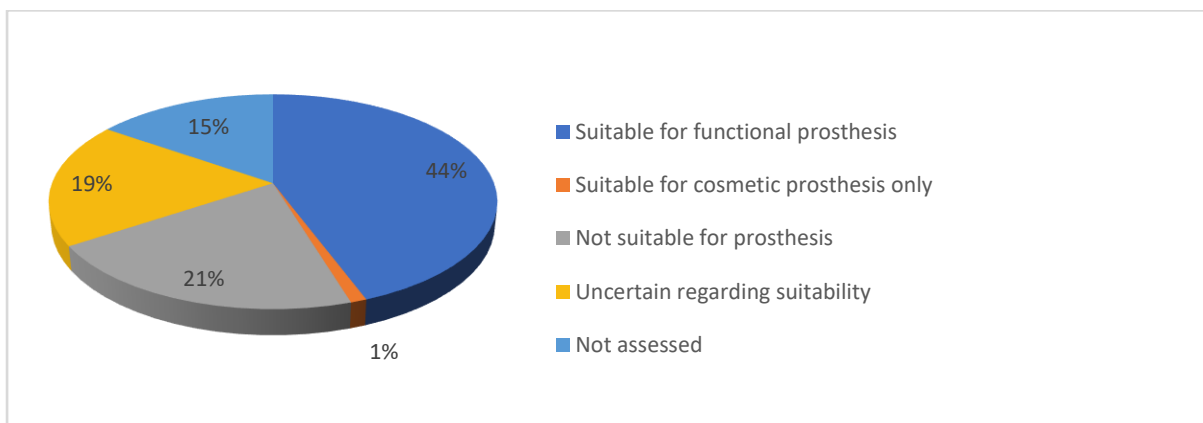


Figure 6. Preliminary assessment of suitability for prosthetic supply at the time of amputation at final level above the ankle (n=7961), (%).

Percent of patients suitable for functional prosthesis in relation to amputation level:

- TTA - 67%, KD - 28%, TFA - 24%

Comment: The difference is noticeable based on the level of amputation, where the probability of being able to walk with a prosthesis is lower the higher the level of amputation. This year, data from patients with bilateral amputations have been excluded, see also table 10.

BILATERAL AMPUTATIONS

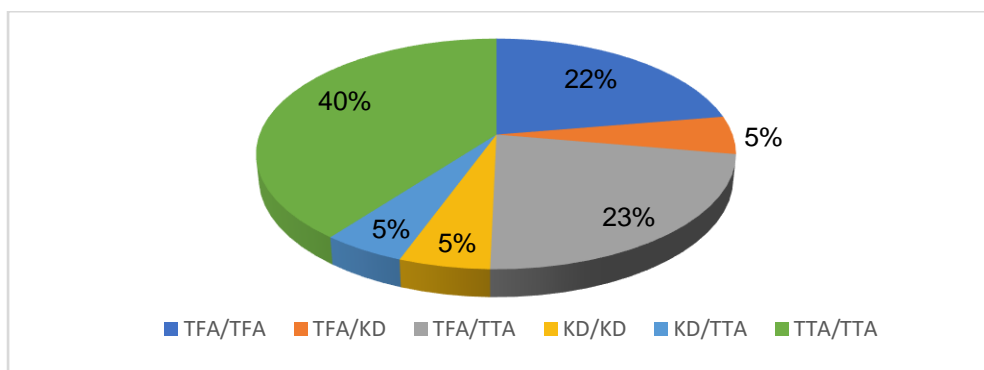


Figure 7. Combinations of amputation levels in % in case of bilateral amputation above the ankle, n=1129

DISTRIBUTION OF DIAGNOSTIC GROUPS IN BILATERAL AMPUTATIONS:

- 56% Diabetes with/without vascular disease
- 35% Vascular disease without diabetes
- 3% Infection not related to diabetes or vascular disease
- 2% Trauma
- 4% Other diagnoses

Comment: The proportion of patients with diabetes is almost 10% higher than those with bilateral amputations compared to all patients in the register. The most common combination in bilateral amputations is bilateral TTAs. From a functional point of view, it is of great importance for patients to retain at least one anatomical knee joint for better sitting balance and to be able to transfer oneself from e.g. bed to chair regardless of any prosthetic supply.

DATA PER HOSPITAL AND REGION

In year 2021 several hospitals increased the number of registrations, which means better and more complete surgical data. However, there are variations. Some hospitals have registered fewer amputations compared to the years before, other hospitals have registered significantly more. Comparisons made to the Swedish National Board of Health and Welfare's inpatient care register confirms that some regions have reduced their registrations in relation to the number of procedures carried out in the region. However, the inpatient care register also shows unusually large variations in the total number of TTA during the last years. We suspect that this might be consequences related to the Covid pandemic that should be studied more closely in the future.

REGISTRATIONS PER HOSPITAL

| HOSPITAL | 2019 | 2020 | 2021 | 2011-2021 | 2019-2021 |
|--|------|------|------|-----------|-----------|
| Blekingesjukhuset | 42 | 42 | 34 | 342 | 118 |
| Capio St Görans sjukhus | 38 | 35 | 38 | 261 | 111 |
| Centrallasarettet Växjö | 13 | 8 | 14 | 99 | 35 |
| Centralsjukhuset Kristianstad | 64 | 60 | 58 | 663 | 182 |
| Danderyds sjukhus | 96 | 74 | 4 | 270 | 174 |
| Falu lasarett | 37 | 36 | 38 | 468 | 111 |
| Hallands sjukhus Halmstad | 40 | 33 | 13 | 264 | 86 |
| Hallands sjukhus Varberg | 25 | 31 | 31 | 157 | 87 |
| Helsingborgs lasarett | 45 | 38 | 11 | 272 | 94 |
| Höglandsjukhuset Eksjö | 29 | 16 | 3 | 170 | 48 |
| Karolinska Univ.sjukhuset (Huddinge + Solna) | 37 | 40 | 10 | 352 | 87 |
| Kungälv sjukhus | 4 | 3 | 0 | 67 | 7 |
| Lasarettet i Motala | 1 | 4 | 7 | 81 | 12 |
| Länssjukhuset i Kalmar | 1 | 20 | 0 | 50 | 21 |
| Länssjukhuset Ryhov Jönköping | 40 | 30 | 26 | 337 | 96 |
| Norrköping Vrinnevisjukhuset | 74 | 62 | 72 | 453 | 210 |
| Sahlgrenska Univ.sjukhuset (Gbg + Mölndal) | 219 | 146 | 176 | 969 | 541 |
| Sjukhuset i Gävle | 25 | 90 | 75 | 203 | 190 |
| Skånes Univ.sjukhuset (Malmö + Lund) | 337 | 300 | 349 | 3483 | 986 |
| Södersjukhuset | 10 | 6 | 1 | 219 | 17 |
| Södertälje Sjukhus | 13 | 3 | 3 | 34 | 19 |
| Södra Älvsborgs sjukhus Borås | 103 | 83 | 72 | 276 | 258 |
| Uddevalla NÄL | 55 | 38 | 51 | 636 | 144 |
| Universitetssjukhuset i Linköping | 82 | 68 | 39 | 511 | 189 |
| Universitetssjukhuset Örebro | 46 | 58 | 31 | 489 | 135 |
| Visby lasarett | 29 | 21 | 15 | 178 | 65 |
| Västerås Västmanlands sjukhus | 15 | 26 | 20 | 126 | 61 |

Table 8: Number of interventions registered per hospital in total since the start of the register and separately for the years 2019-2021.

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

| REGION | PROPORTION PRIMARY LEVEL TTA / KD+TFA % | PROPORTION PRIMARY LEVEL 2017-2020 % | PROPORTION FINAL LEVEL TTA / KD+TFA % | PROPORTION FINAL LEVEL 2017-2020 % | COVERAGE RATE RATIO 2017-2020 |
|----------------------|---|--------------------------------------|---------------------------------------|------------------------------------|-------------------------------|
| Skåne | 62/38 | 62/38 | 56/44 | 57/43 | 1,0 |
| Blekinge | 50/50 | 41/59 | 42/58 | 32/68 | 1,0 |
| Örebro | 71/29 | 70/30 | 61/39 | 60/40 | 1,0 |
| Östergötland | 37/63 | 31/69 | 32/68 | 29/71 | 0,9 |
| Dalarna | 63/37 | 65/35 | 54/46 | 57/43 | 1,1 |
| Halland | 70/30 | 67/33 | 63/37 | 61/39 | 1,1 |
| Västra Götaland | 58/42 | 51/49 | 51/49 | 44/56 | 1,3 |
| Gävleborg | 64/36 | 66/34 | 60/40 | 61/39 | 1,3 |
| Gotland | 44/56 | 39/61 | 34/66 | 28/72 | 1,3 |
| Jönköping | 55/45 | 59/41 | 52/48 | 55/45 | 1,5 |
| Västmanland | 32/68 | 38/62 | 29/71 | 37/63 | 1,5 |
| Kalmar | 61/39 | 56/44 | 54/46 | 47/53 | 1,5 |
| Stockholm | 77/23 | 75/25 | 73/27 | 71/29 | 1,6 |
| Kronoberg | 86/14 | 79/21 | 79/21 | 70/30 | 2,0 |
| Värmland | 67/33 | 58/42 | 59/41 | 57/43 | 3,0 |
| Total average | 62/38 | | 56/44 | | |

Table 9: The proportion of TTA compared to KD + TFA, regarding primary amputation level as well as final level, for regions with a total of at least 10 registered amputations above the ankle, in %. The coverage rate ratio column indicates the degree of reporting for TTA in relation to the degree of reporting for KD+TFA, based on coverage rate compared to the National Board of Health and Welfare's register 2017-2020. Value close to 1 indicates that the distribution in the other columns can be considered to have realistic values.

Comment: Our data indicate significant differences within the country. Despite some skewed distribution due to factors such as incomplete reporting, an up to 2.5-fold difference is eye-catching. The proportion of primary TTA in relation to the sum of all major amputations (TTA + TFA + KD) is influenced by which care unit reports to SwedeAmp. Patients with better rehabilitation potential come to the workshop or prosthetic rehabilitation unit, and more have a lower amputation level. If amputation data have only been reported from these units, the proportion of TTA is therefore likely to be unrealistically high. If the surgical unit records amputation data, patients who do not progress to prosthetic rehabilitation are also included, and thus the percentage of TTA is lower and more representative of the population. The coverage ratio therefore helps to interpret the reasonableness of the current data. In the share of final level TTA in relation KD/TFA, the patients who have been re-amputated from a level below the ankle to final TTA level are also included. An ever-difficult clinical question is which level to choose from the start. This table can help highlight if a region tends to amputate either primary too low (if the final level differs significantly from its own primary level) or too high (if the primary level differs significantly from the national average).

POOLED ANALYSIS OF PATIENT AND AMPUTATION DATA

The basis for the 2021 year's report is roughly 9,500 patients. Among these, almost 14,000 interventions are registered.

The generally high mortality after lower limb amputation is well known. Patients who received a prosthesis had a lower mortality which assume that the clinical assessment of which patients can benefit from a prosthesis has been made with a certain plausibility.

Regarding amputation causes, gender distribution, average age and amputation levels, the picture is unchanged as compared to earlier reports. In women data show higher average age, a greater proportion with higher amputation levels, and a higher proportion of amputation due to vascular disease without concomitant diabetes and fewer amputations due to trauma as compared to men. The differences between the sexes in terms of age and amputation diagnosis are statistically assured.

Minor amputations, i.e. amputations below the ankle, are still underreported in SwedeAmp. However, the percentage of complete registrations including amputations below the ankle from individual operating units is rising. Data from the Skåne University Hospital (SUS), which has almost 100% registration of amputations on the lower extremity, shows that minor amputations make up just under half of all amputation procedures. When analyzing the final amputation level from SUS, it appears that 83% of amputations below the ankle stay at the level below the ankle. From the patient's perspective, this can mean preserved walking ability.

There is reason to assume that amputations below and above the ankle are closely related. An amputation below the ankle is often part of an effort to prevent a higher-level amputation, but may become a trigger factor for a higher amputation. Registrations of these "minor" amputations are expected to contribute to increased understanding of these correlations. This in turn requires orthopedic expertise to be early involved, and not to wait until the need for a major amputation has been established. With more complete surgical data, causal correlations can be analyzed and knowledge increase regarding who requires re-amputation at a higher level and who does not.

13% of the patients in the register are bilateral amputees. In these patients, a higher proportion with a diagnosis of diabetes is noted than for those with a unilateral amputation.

In 2021, a new variable regarding wound healing was introduced at the first prosthesis registration. Over time we hope relationships between, for example, surgical technique or antibiotic use and wound healing concerns can be established for the cases provided with prostheses.

For several of the parameters registered in SwedeAmp, it is difficult to define a clear target value for potential improvements. Examples of this are amputation level and re-amputation frequency. In general terms, it is easy to formulate: We want as low amputation level as possible and at the same time as low re-amputation frequency as possible. This is easy to say but hard to get. A lower amputation level provides generally a better condition for optimal prosthetic rehabilitation. A higher level of amputation usually means better circulation conditions and thus less risk for a re-amputation, but also leads to significantly worse conditions for the prosthetic mobility, which is clearly evident in the follow-up and PROM data later in this report.

Prosthetic data

BASIC DATA

In total, the registry contains 5589 records of prosthetic data including 3075 patients (33% women, 67% men).

Prosthetic data collection has increased significantly with more users and units entering data each year. As a result, it is estimated that a significant proportion of the Swedish prosthetic supplies are now registered. To show current conditions, based on a higher degree of coverage, this report for prosthetic data is limited to prostheses and prosthetic sockets fitted in the last 6 years, 2016-2021. For these years, 3792 registrations are presented, including 2150 patients (30% women, 70% men).

DEVELOPMENT OF REGISTERED CASES PROVIDED WITH A PROSTHESIS AND P&O UNITS/INDIVIDUAL USERS ACTIVE IN REGISTERING DATA

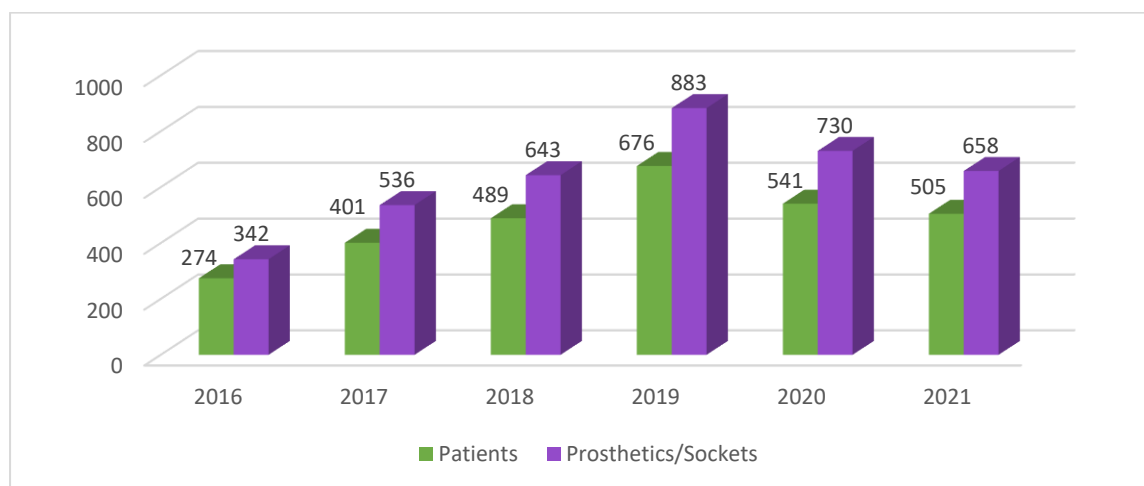


Figure 8. Development of the number of patients and the number of provided prosthetics entered into the register since 2016 (n).

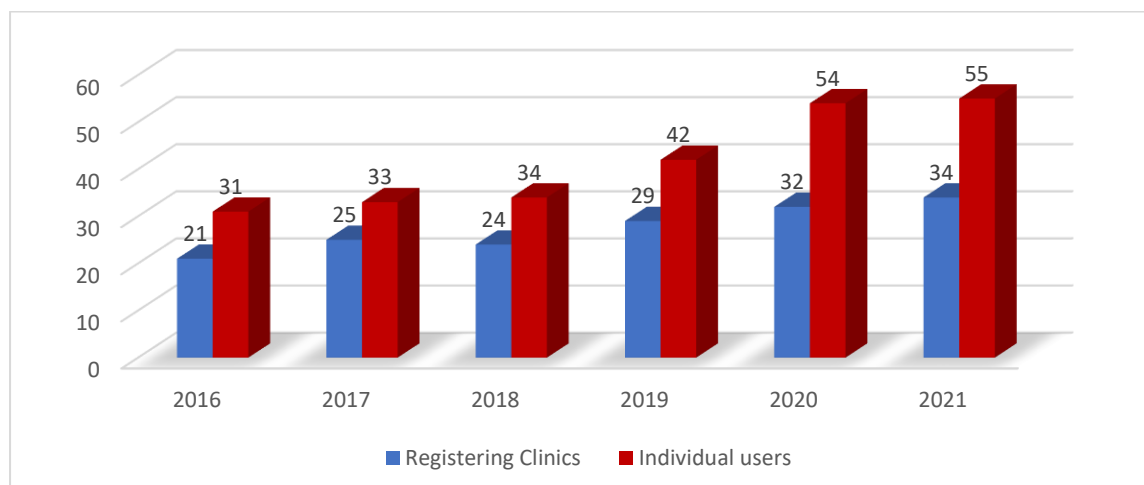


Figure 9. Development of the number of P&O clinics and individual users entering data into the register since 2016 (n).

REGISTERED PROSTHESES PROVIDED YEAR 2016-2021

First prosthesis or renewal of prosthesis/socket include 3582 registrations for 2117 patients:

- 48% (n=1704) refer to the first prosthesis for the current amputation level
- 38% (n=1356) refer to renewal of the prosthetic socket
- 15% (n=522) refer to renewal of the entire prosthesis

Reason for renewal of prosthesis or socket (n=1801) regarding functional prosthesis

- 78% (n=1395) changed residual limb volume
- 10% (n=184) improve socket fit
- 9% (n=162) worn out prosthesis
- 2% (n=38) the condition has changed (change of goals/purposes of the prosthetic supply)
- 1% (n=22) broken socket

Type of prosthesis has been specified in 3790 registrations:

- 95% (n=3582) refer to a functional prosthesis
- 5% (n=187) refer to an additional prosthesis (e.g. exercise prosthesis or hygiene prosthesis)
- <1% (n=20) refers to a cosmetic prosthesis (not possible to load when moving)
- <1% (n=1) refers to cases where prosthetic provision was not deemed appropriate.

Comment: Just under half of the data is the first prosthesis for the current amputation, and an overwhelming majority concerns a functional prosthesis (95%). Renewal of the socket alone is more common than renewing the entire prosthesis and is generally caused (77%) by altered residual limb volume. Clinical experience shows that the residual limb volume often changes before the prosthesis itself is worn out, i.e. replacement of the socket takes place before replacement of the entire prosthesis is required.

AMPUTATION LEVELS

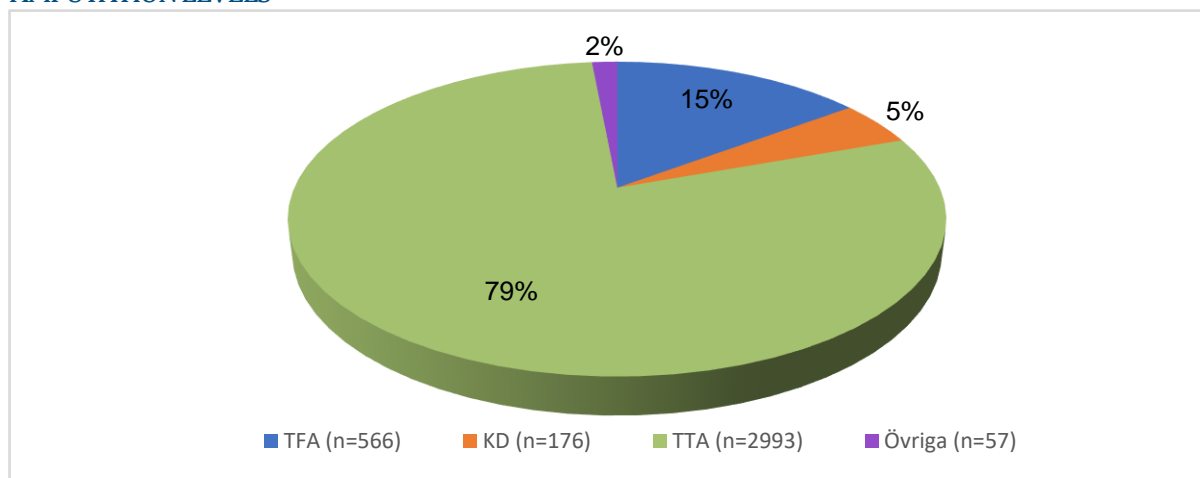


Figure 10: Proportion of prosthesis registrations, years 2016-2021, per level (total n=3792), (%).

Others consist of: Amputation through the pelvis or hip joint (n=24), amputation through the metatarsal or heel (n=23) and forefoot amputation (n=10).

| LEVEL | AMPUTATION | SHARE | AMPUTATION | SHARE | AMPUTATION | SHARE |
|--------|------------------|-----------------------------|------------------|-----------------------------|------------------|-----------------------------|
| | 2015-2016 (N) | PROVIDED WITH PROSTHESIS | 2017-2018 (N) | PROVIDED WITH PROSTHESIS | 2019-2020 (N) | PROVIDED WITH PROSTHESIS |
| TTA | 720 | 42%(n=304) | 756 | 43%(n=323) | 812 | 43%(n=348) |
| KD+TFA | 378 | 21%(n=79) | 390 | 21%(n=82) | 428 | 16%(n=68) |

Table 10. Share of patients provided with a prosthesis per level TTA and KD+TFA, respectively, and with the surgical procedure performed during three time periods between year 2015–2020. Only patients reported to be able to walk or stand/load on the involved limb at the time of the amputation are included.

Comment: The registry is dominated by TTA prostheses for both men (80%) and women (75%).

The proportion of patients who receive a prosthesis per level is in the current report based on those who were able to walk or put weight on the involved side at the time of the amputation. In the case of TFA and KD, there are, as expected, significantly fewer people who are provided with a prosthesis compared to TTA (16% and 43%, respectively, regarding patients with an amputation performed years 2019-2020). There is a lower proportion of patients at the TFA+KD level who have been provided with a prosthesis during the pandemic years 2019-2020 compared to previous years. At the same time, the proportion of KD+TFA amputations in relation to TTA has slightly increased.

AGE DISTRIBUTION AT FIRST PROSTHESIS PER PATIENT

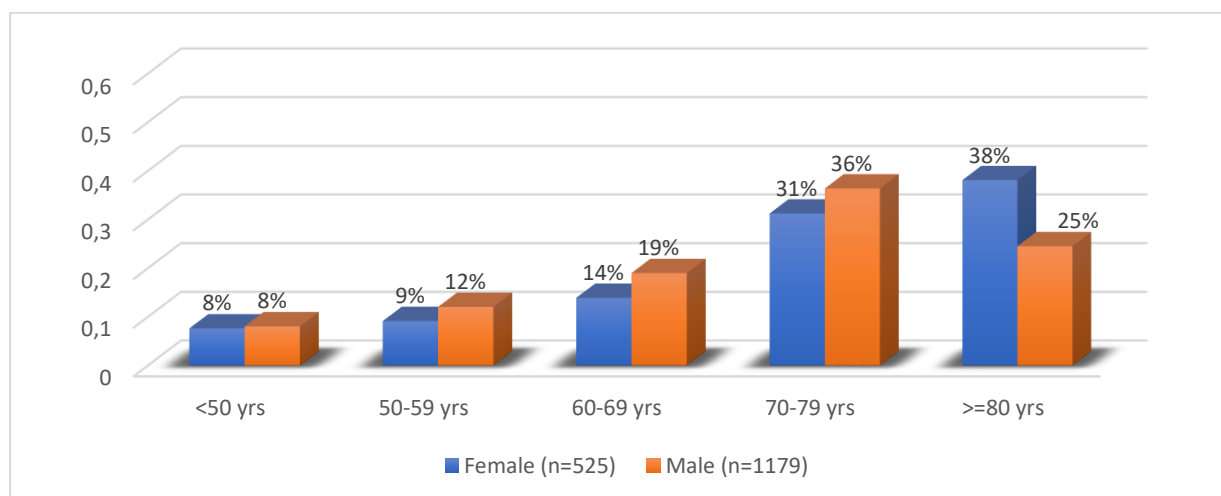


Figure 11. Age distribution at the time of fitting first prosthesis 2016-2021 (n=1704) for women and men, (%).

Comment: At the time of fitting first prosthesis, the age varied between 1-101 years. The average age for the women (73 years) was higher than for the men (70 years). The largest group of women were >80 years old at the time of the first prosthetic fitting, men between 70-79 years old.

PREREQUISITES FOR PROSTHETIC SUPPLY

COMPRESSION TREATMENT OF THE RESIDUAL LIMB (STUMP) AFTER TRANSTIBIAL AMPUTATION

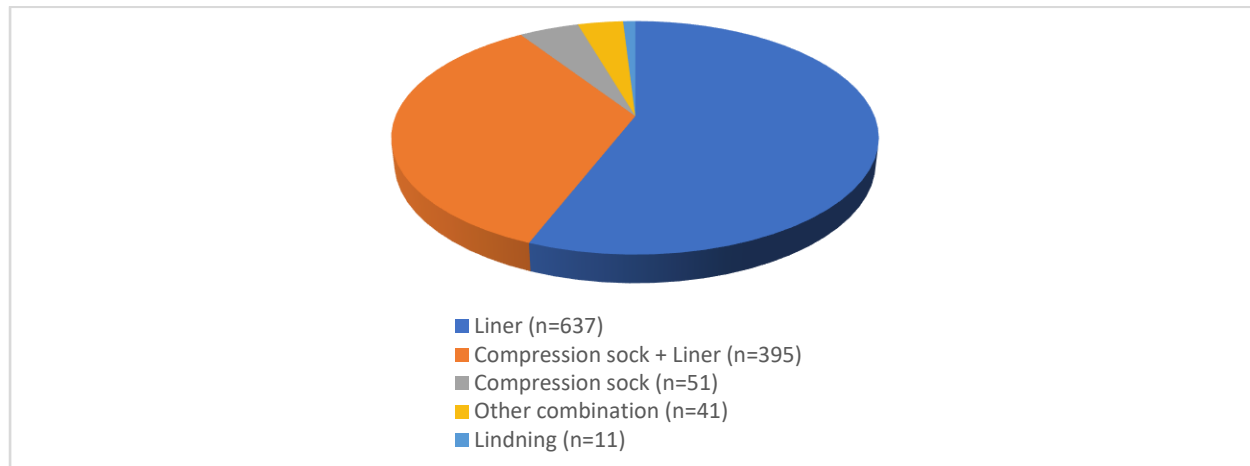


Figure 12: Type of stump compression after TTA 2016-2021, (n= 1138), (%).

Comment: Compression with liner dominates, often supplemented with compression sock when a liner is not used. Compression therapy was usually started within 1 week (51%) or within 1–3 weeks (37%) of the procedure. Bandaging (lindning n=11) is rarely used for compression.

LOAD-BEARING CAPACITY OF CONTRALATERAL LEG AT FIRST PROSTHESIS FITTING, YEARS 2016-2021

The patient's ability to support on the contralateral leg at time for the prosthesis fitting (n=1474):

- 83% Full load
- 14% Limited load
- 3% No load or very limited load

Comment: During prosthesis fitting, approx. 80% of patients can fully load their other leg. Ability to load the contralateral leg is often included in the assessment before decision on prosthetic provision and is a prerequisite for good rehabilitation results.

RESIDUAL LIMB (STUMP) PROBLEMS IN 2016-2021, ALL AMPUTATION LEVELS

| STUMP COMPLICATION AT PROTHETIC FITTING | % YES OF (N) | N | NUMBER AS ONLY COMPLICATION |
|---|--------------|-----|-----------------------------|
| Wound | 21%(2492) | 516 | 213 |
| Thin soft tissue covering | 17%(2319) | 402 | 124 |
| Pain | 14%(2922) | 414 | 118 |
| Swelling | 14%(2341) | 336 | 99 |
| Contracture in adjacent joint | 13%(2312) | 297 | 118 |
| Wide end of stump (pear shaped) | 10%(2305) | 221 | 65 |
| Adhesions skin-skeleton | 5%(2277) | 111 | 11 |
| Eksema | 3%(2284) | 71 | 20 |
| Deep skin folds | 4%(2276) | 84 | 22 |
| Other | 9%(2230) | 201 | 113 |
| Good status of remaining leg / stump | 60%(722) | 434 | |

Table 11a. Problems with the residual limb (stump) causing difficulties with prosthetic fitting. Several problems can be specified. The last column indicates the number reported as a single complication and not in combination with others. The reported numbers refer to both the first prosthesis and later prosthetic registrations.

RESIDUAL LIMB (STUMP) PROBLEMS AT PROTHETIC FITTING <6 MONTHS AND >2 YEARS AFTER TTA

| COMPLICATING PROBLEM AT PROTHETIC FITTING, TTA | <6 MONTHS POSTOP, SHARE YES OF (N) | CHANGE | >2 YRS POSTOP SHARE YES OF (N) |
|--|------------------------------------|--------|--------------------------------|
| Wound | 37%(938) | ↘ | 16%(625) |
| Swelling | 23%(796) | ↘ | 4%(591) |
| Wide end of stump (pear shaped) | 18%(780) | ↘ | 2%(590) |
| Contracture in adjacent joint | 14%(788) | → | 6%(587) |
| Pain | 12%(1377) | → | 15%(747) |
| Thin soft tissue covering | 11%(773) | → | 20%(606) |
| Eksema | 6%(767) | → | 2%(585) |
| Adhesions skin-skeleton | 5%(770) | → | 5%(588) |
| Deep skin folds | 2%(763) | → | 5%(588) |

Table 11b. Proportion YES of all registrations per problem that complicates prosthetic fitting at TTA reported in two groups. Selection for the first column (<6 months): "First prosthesis for current amputation" and fitting during the first 6 months after the amputation. Selection for the second column (>2 years): Replacement of prosthesis/socket ≥2 years after the amputation. Several contemporary problems can be listed for stump complications. Arrow illustrates change over time. Difference ≥ 10% units is illustrated as a change.

RESIDUAL LIMB (STUMP) PROBLEMS AT PROSTHETIC FITTING AFTER TTA BASED ON SURGICAL TECHNIQUES, <6 MONTHS AND >2 YEARS POSTOPERATIVELY

| COMPLICATING PROBLEM AT PROSTHETIC FITTING TTA | <6 MONTH POSTOP | | | >2 YR POSTOP | | |
|--|------------------------|---|--------------------------------|--------------------------|---|--------------------------------|
| | SAGITAL+SKEW SKIN FLAP | | LONG POSTERIOR + A-P SKIN FLAP | SAGITAL + SKEW SKIN FLAP | | LONG POSTERIOR + A-P SKIN FLAP |
| Wide end of stump (pear shaped) | 19% (355) | ↗ | 31% (78) | 4% (110) | | 0% (30) |
| Pain | 15% (690) | | 16% (167) | 17% (125) | | 10% (39) |
| Adherent skin – skeleton | 3% (406) | | 11% (87) | 6% (109) | | 0% (30) |
| Deep skin folds | 2% (347) | | 6% (78) | 6% (108) | | 0% (30) |
| Swelling | 28% (433) | | 19% (84) | 10% (111) | | 3% (31) |
| Contracture in adjacent joint | 13% (419) | ↗ | 24% (88) | 13% (110) | | 17% (29) |
| Thin soft tissue covering | 17% (410) | | 16% (89) | 24% (108) | ↘ | 10% (30) |
| Wound | 40% (519) | | 36% (110) | 22% (116) | | 21% (33) |

Table 11c. Share YES of all registrations per stump problem that complicates prosthetic fitting at TTA reported in two groups. Sagittal and Skew flaps form one group and Long posterior flaps and Anterior/Posterior flaps form the second group. Data provided for:

1. <6 MONTHS POSTOP: "First prosthesis for current amputation" and fitting < 6 months after amputation.
2. >2 YEARS POSTOP: Replacement of prosthesis/socket that has been fitted ≥ 2 years after the amputation.

Comment: In 40% of the prosthetic fittings, the stump/remaining leg did not have a good status and in 17% the contralateral limb could not be fully loaded. The large number of patients who suffer from multiple problems complicates prosthetic fitting and combinations of problems are seen (Table 11a last column). At prosthetic fitting, ulcers and thin soft tissue coverage were most commonly reported. Each stump shape is individual and will cope differently with loads during various activities. The shape and characteristics of the stump changes over time, especially during the first months after amputation. Therefore, the variables have been divided into early problems (<6 months) and later problems (>2 years). As expected, ulcers, swelling and wide stump end (pear shape) decreased over time. For other problems, the data does not show changes > 10%.

Choice of surgical flap technique in TTA also leads to different shape and characteristics of the stump. Sagittal and skewed flaps give similar properties. Long posterior flap and anterior/posterior flap give different and similar characteristics. Table 11c indicates how stump problems are affected by surgical technique in the short (first 6 months) and longer term (>2 years). It indicates that problems such as pear-shaped stump and contractures are less common with sagittal/skew flap and that thin soft tissue coverage is less common with long posterior, anterior/posterior flap in the longer term. The number of observations >2 years are few, which gives uncertain data.

The patient's activity level is also individual and can cause stresses on the stump to vary. Fluid-reducing medication is another example that can influence the stump volume.

TIME TO PROSTHETIC SUPPLY

NUMBER OF DAYS FROM FINAL AMPUTATION LEVEL TO FITTING OF THE FIRST TTA PROSTHESIS AND CHANGE OVER PERIOD OF YEARS

| TIME PERIOD (YR) | DAYS MEAN (SD) | DAYS MEDIAN (MIN-MAX) |
|-------------------|----------------|-----------------------|
| 2013-2015 (n=320) | 95 (78) | 73 (13-492) |
| 2016-2018 (n=524) | 88 (76) | 64 (11-449) |
| 2019-2021 (n=674) | 79 (63) | 58 (14-494) |

Table 12a: Time to prosthetic fitting (first prosthesis for current amputation) at final level TTA distributed per 3-year period (n=1463). Year is based on date of first fitting. In the calculation, single extreme values have been removed (<5 days and >500 days).

NUMBER OF DAYS FROM FINAL AMPUTATION LEVEL TO FITTING OF THE FIRST TFA PROSTHESIS AND CHANGE OVER PERIOD OF YEARS

| TIME PERIOD (YR) | DAYS MEAN (SD) | DAYS MEDIAN (MIN-MAX) |
|-------------------|----------------|-----------------------|
| 2013-2015 (n=62) | 123 (86) | 104 (29-484) |
| 2016-2018 (n=104) | 118 (83) | 94 (19-381) |
| 2019-2021 (n=141) | 104 (72) | 84 (21-406) |

Table 12b: Time to prosthesis testing (first prosthesis for current amputation) at final level TFA distributed per 3-year period (n=300). Year is based on date of first fitting. In the calculation, single extreme values have been removed (<5 days and >500 days).

NUMBER OF DAYS FROM FINAL AMPUTATION LEVEL TO FIRST TTA PROSTHESIS BASED ON SURGICAL TECHNIQUES

| SURGICAL TECHNIQUE TTA | DAYS MEAN (SD) | DAYS MEDIAN (MIN-MAX) |
|---|----------------|-----------------------|
| Skew + Sagittal (n=757) | 80 (76) | 50 (11-494) |
| Long posterior + Anterior/Posterior (n=205) | 87 (67) | 69 (16-376) |

Table 12c: Time to prosthetic fitting (first prosthesis for current amputation) at final level TTA distributed by surgical technique. The surgical technique options have been grouped. In the calculation, single extreme values have been removed (<5 days and >500 days). The difference is statistically significant (p=0.003).

Comment: Time from amputation to first prosthetic fitting for TTA has decreased from Md 73 days in 2013-2015 to 58 days in 2019-2021 and for TFA from Md 104 days in 2013-2015 to Md 84 days in 2019-2021. The variation is large for all levels. For TTA, the number of days to the first prosthesis is statistically

significantly less for the group where the surgical technique is either sagittal or skew flaps compared to the group where the surgical technique was performed with a long posterior or anterior/posterior flap.

SwedeAmp recommends that "Days to prosthesis" and "Time to start training with prosthesis" (in follow-up data) to be analyzed in local improvement works. Our data show that choice of surgical technique is important in TTA. Other factors of importance may be that some clinics allow prosthetic use before the amputation wound is healed while others await healing. There is no consensus on that matter. In the scientific literature, there is also no consensus on how time to prosthesis should be defined. An example is a recent American study where the number of days from amputation date to billing for the prosthesis has been calculated for over 400 patients (18-65 years) and which showed that the median time was 5 months (Mean 130 days) (Miller et al, PM&R Feb 2022, Open access). Like our data, the study demonstrated fewer days for TTA than TFA/KD, but also fewer days for men than women. Difference between gender is something SwedeAmp has not yet analyzed and must take amputation level into account.

PROSTHETIC DESIGN

Comment: A revision of the SwedeAmp prosthesis data at the turn of the year 2019/2020 means variables describing prosthesis design have changed a bit. Therefore, in some sections in this report new data has been translated and reported together with historical data. In other sections the reporting is divided into periods before and after the revision.

PROSTHETIC FOOT

Comment: In connection with the revision for prosthesis data, many variables describing prostheses have been given new response options. In the section PROSTHETIC FOOT, data entered after the revision has been translated and reported together with historical data.

TYPE OF PROSTHETIC FOOT AT TTA

| LEVEL | SACH | SINGLE -AXIS | MULTI-AXIAL | ENERGY STORING | INTELLIGENT |
|--|------|--------------|-------------|----------------|-------------|
| Transfemoral amputation (TFA) (n=503) | 19 | 34 | 17 | 429 | 4 |
| Knee disarticulation (KD) (n=167) | 11 | 5 | 8 | 141 | 2 |
| Transfemoral amputation (TTA) (n=2728) | 148 | 32 | 44 | 2491 | 13 |
| Total | 178 | 71 | 69 | 3061 | 19 |

Table 13a. Type of prosthetic foot for prostheses fitted in 2016-2021 at TTA, KD and TFA (n=3398), number.

SPECIFICATION OF PROSTHETIC FEET

ALL AMPUTATION LEVELS, PROSTHESES /PROSTHETIC SOCKETS FITTED 2016-2021

| FUNCTIONAL CLASSIFICATION* (N) | MOST COMMONLY USED FOOT | | | | | 2:ND MOST COMMONLY USED FOOT | | | | |
|--------------------------------|----------------------------------|-------------|---------------|-----|------|------------------------------|-------------|-----------------------|----|------|
| | NAME | DISTRIBUTOR | ART.NR | N | TYPE | NAME | DISTRIBUTOR | ART. NR | N | TYPE |
| 1 (n=128,17%) | Balance S | Össur | BSP | 87 | ● | SACH | Otto Bock | 1D10, 1D11, 1G6 | 20 | ● |
| 2 (n=327,44%) | Assure (incl Sure-flex) | Össur | FAPE, FAXE | 200 | ● | Trias | Otto Bock | 1C30 | 94 | ● |
| 3 (n=200,27%) | Vari-Flex | Össur | VFP, VFX | 44 | ● | Triton | Otto Bock | 1C60 | 37 | ● |
| 4 (n=91,12%) | Pro-FlexXC Och Vari-flexXC | Össur | PXC | 73 | ● | - | - | - | | |

Table 13b. Type of prosthetic foot entered in free text field for specification of prosthetic foot (n=746) split by function category (see definition below). Type of foot: ● = SACH foot, ● = Energy storing foot.

*Definition Functional category: The individual is capable of or has the potential for:

1. Walking indoors or on flat surfaces at a low walking speed, with/without walking aids.
2. Walking in indoor and outdoor environments, with/without walking aids. Clear low obstacles such as curbs, stairs or uneven surfaces (moving in society with walking aids)
3. Walking with varied walking speed. Able to walk in most environments with various challenging surfaces such as slippery, inclined or uneven. Engage in activities that require the use of a prosthesis in addition to normal walking
4. To use a prosthesis in addition to basic walking skills. Engage in very demanding activities that put the stump and the prosthesis under high stress, such as different sports activities and children's play

Comment: It is not easy to replace the anatomical foot with a prosthetic foot. Depending on how active the patient is and in which environments the prosthetic foot is used, different prosthetic foot properties are required. An energy-storing prosthetic foot is the most common for all amputation levels and was indicated in >90%. Grouping by prosthetic foot type does not currently give a good picture of how the prostheses have enabled the patient to perform different functions, as many kinds of feet are classified as energy-storing. All energy-storing feet are made of materials that are resilient, e.g., composite material with carbon fiber and fiberglass, and without great energy loss. The data show, almost all feet used today are made of these materials, but the properties differ within the "Energy-storing feet" group. Table 13b shows that prosthetic feet that meet requirements for functional category 2 are in majority (44%). The choice of a prosthetic foot could also be influenced by service providers being component manufacturers.

LINER AND SUSPENSION

Comment: For sections LINER AND SUSPENSION, it has not been possible to reliably translate the new answer options into the old answer options. Therefore, the data has been divided into the period before and after the revision. Results for each period are presented in the same way (apart from SUSPENSION AT TRANSFEMORAL PROSTHESIS).

LINER FOR SUSPENSION IN TRANSTIBIAL PROSTHESIS

| TYPE OF LINER | SUSPENSION SLEEVE WITHOUT VACCUUM | DISTAL PIN LOCK | DISTAL VACUUM | VACUUM WITH SLEEVE | VACUUM WITH VALVE | ELEVATED VACUUM | OTHER* | TOTAL |
|---------------|-----------------------------------|-----------------|---------------|--------------------|-------------------|-----------------|-----------|-------------|
| Silicone | 28 | 296 | 28 | 663 | 99 | 26 | 22 | 1162 |
| Copolymer | 18 | 7 | 2 | 364 | 71 | 11 | 4 | 477 |
| Polyurethan | 2 | 5 | 0 | 47 | 5 | 20 | 8 | 87 |
| Foam | 3 | 27 | 0 | 31 | 0 | 0 | 7 | 68 |
| Other | 0 | 1 | 1 | 5 | 1 | 0 | 2 | 10 |
| Total | 51 | 336 | 31 | 1110 | 176 | 57 | 43 | 1804 |
| Share | 3% | 19% | 2% | 62% | 10% | 3% | 2% | |

Table 14a. Type of liner and suspension respectively when fitting prosthesis/prosthetic socket 2016-2019 and TTA (n=1804), number. *Under the heading Other = PTB-strap and KBM.

| TYPE OF LINER | WITH LINER AND... | | | | | | OTHER* | TOTAL |
|---------------|-----------------------------------|--|--------------------|------------------|------------------------------|---|-----------|-------------|
| | ...VACUUM (SEALING SLEEVE+ VALVE) | ...VACUUM (SEALING SLEEVE WITHOUT VALVE) | ...DISTAL COUPLING | ...DISTAL VACUUM | ...ACTIVE VACUUM (WITH PUMP) | ANATOMICAL-MECHANICAL SUSPENSION (EX. KBM, PTB STRAP, PTSMFL) | | |
| Silicone | 352 | 176 | 89 | 41 | 6 | 39 | 45 | 703 |
| Copolymer | 95 | 74 | 1 | 2 | 4 | 68 | 5 | 244 |
| Polyurethan | 12 | 11 | 1 | 0 | 5 | 7 | 3 | 36 |
| Foam | 1 | 5 | 2 | 0 | 0 | 8 | 0 | 16 |
| Other | 1 | 0 | 0 | 0 | 0 | 3 | 1 | 5 |
| Total | 461 | 266 | 93 | 43 | 15 | 125 | 54 | 1057 |
| Share | 44% | 25% | 9% | 4% | 1% | 12% | 5% | |

Table 14b. Type of liner and suspension respectively at fitting av prostheses/socket at TTA year 2020-2021 (n=1057), n.

SUSPENSION IN TRANSTIBIAL PROSTHESIS, PROPORTION OF REGISTERED CASES PER YEAR 2016-2021

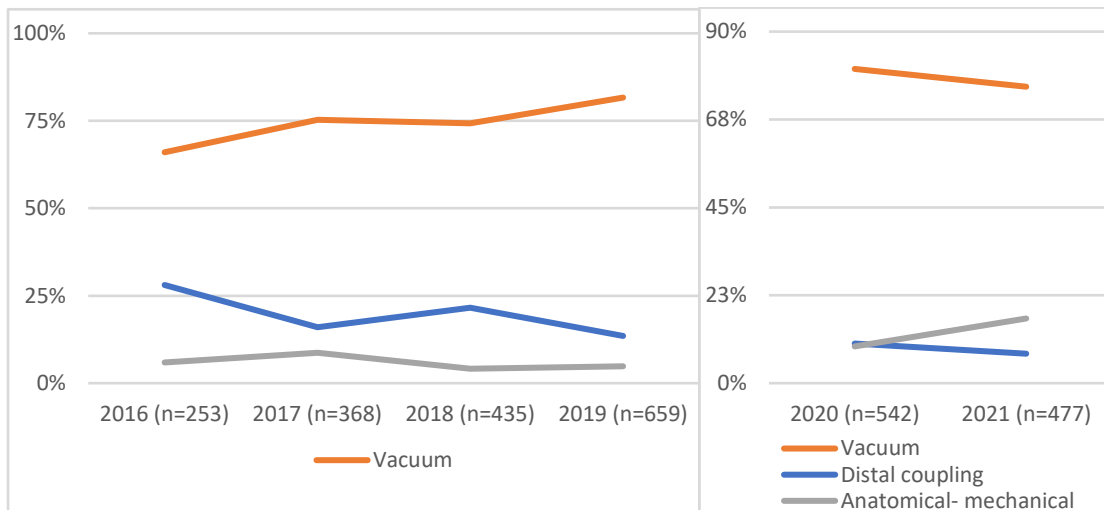


Figure 14a+b. Suspension for transtibial prosthesis. Distribution of type of suspension per year is based on "date of first fitting", during the period before revision 2016-2019 (n=1715), respectively after revision 2020-2021 (n=1019).

Comment: Tables 14a+b include those prostheses where both type of liner and type of suspension have been inserted to be able to analyze the combination of the two. The most common combinations are liner in silicone material together with suspension using liner and vacuum via sealing sleeve and valve (33%) and silicone liner with suspension using liner and vacuum via sealing sleeve without valve (17%).

Analysis of development over time for different types of suspension shows that prostheses with suspension via some kind of vacuum have been the by far the most common during the last 6 years. It is notable that the proportion of anatomical suspension has increased in the last 2 years. The trend for distal coupling is steadily decreasing.

SUSPENSION IN TRANSFEMORAL PROSTHESIS, PROPORTION OF REGISTERED CASES PER YEAR 2016-2021

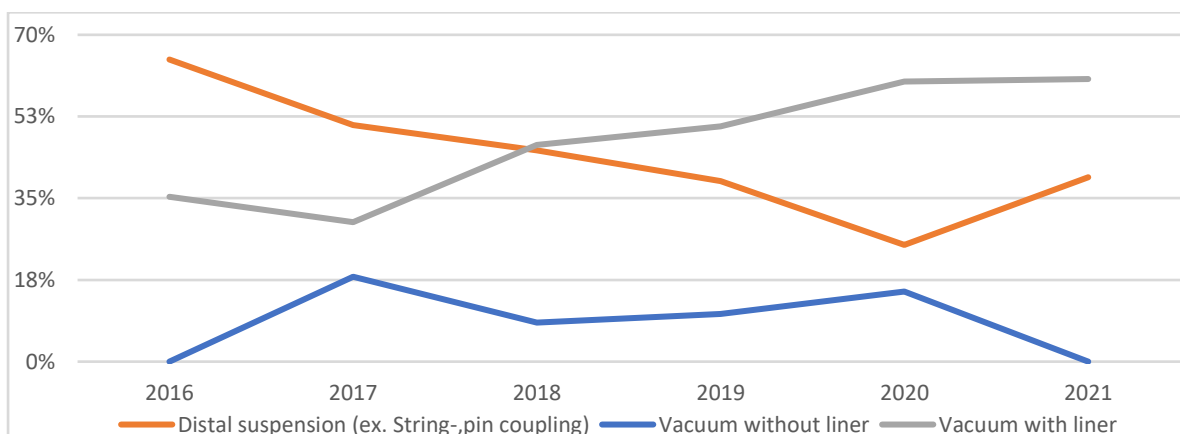


Figure 15. Suspension for transfemoral prosthesis. Distribution of registered types of suspension for each year based on "date of first fitting" (n=477).

Comment: Since 2018, "Vacuum with liner" is the most common type of suspension for TFA prostheses. However, a surprisingly large proportion of patients received a prosthesis with suspension via distal

connection in 2021 (39%). This may have its explanation in the fact that this suspension is better suited if the patient is unable to stand up for donning the prosthesis, and may be an indication that more patients with TFA prosthesis were in a worse physical condition during the pandemic year 2021 as compared to previous years.

SOCKET DESIGN AND METHOD FOR MANUFACTURING PROSTHETIC SOCKET

Comment: In connection with the revision of forms for prosthesis data, many variables describing prostheses have been given other response options. In the section "Socket design and method for the production of prosthetic sockets" results from data for prostheses and sockets fitted during the years 2016-2021 are reported and divided into a period before and after the register's revision. The method for producing the prosthetic socket is a new variable and therefore results are only available for the last few years

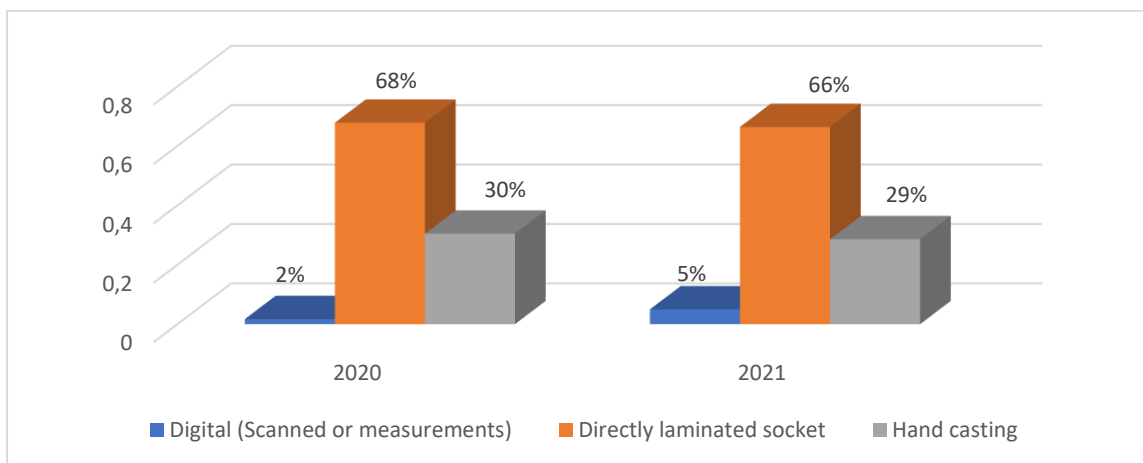


Figure 16a Distribution of different methods for producing prosthetic sockets for TTA during the years 2020 and 2021 (n=733).

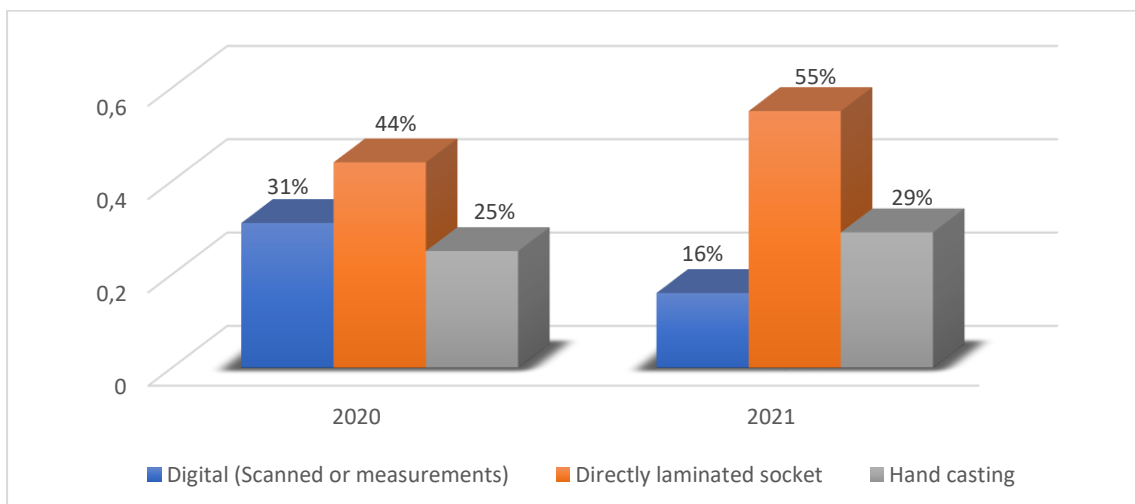


Figure 16b Distribution of different methods for producing prosthetic sockets for TFA in the years 2020 and 2021 (n=122).

SOCKET DESIGN FOR TRANSFEMORAL PROSTHESIS

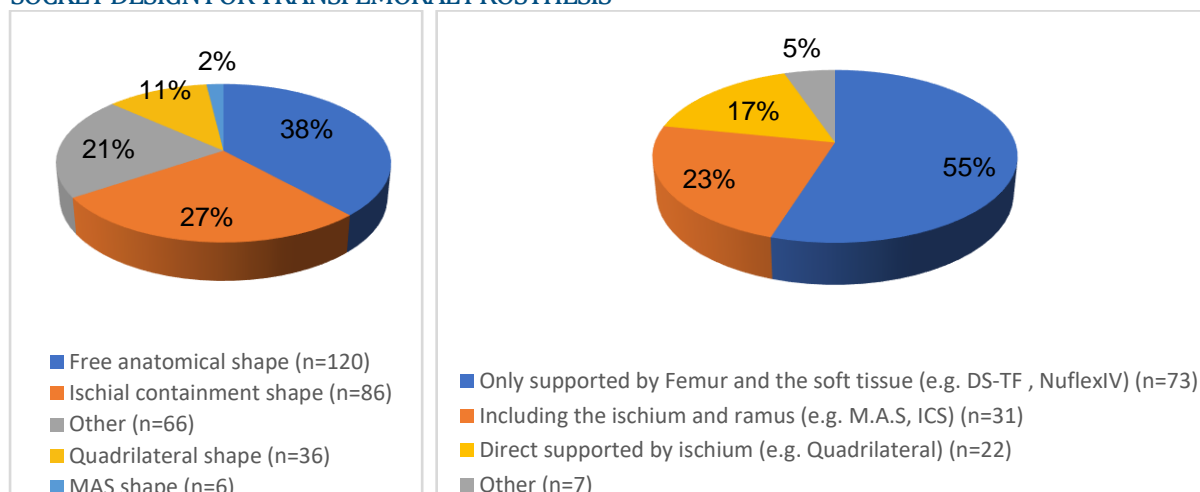


Figure 17a.+ 17b. Socket design for TFA 2016-19 (17a) and 2020-21 (17b).

Comment: Major changes in socket design and the way prosthetic sockets are produced have taken place in recent years, which has also led to changes in how forces are stabilized and affect the stump during the stance phase. During 2020-2021, it was most common for TFA sockets to apply the load/forces on the soft parts of the thigh (55%). In 40% of the cases, however, it was chosen to apply the load/forces to the pelvis. The most common method for producing a prosthetic socket in 2020-2021 was "Direct laminated socket" for both TTA (67%) and TFA sockets (52%).

TYPE OF PROSTHETIC KNEE JOINT

Comment: In connection with the improvement of the register, many variables describing prostheses have been given new answer options. In the section "TYPE OF PROSTHETIC KNEE", data entered after revision has been translated and is reported together with historical data. In the 2020 report, it was reported which type of prosthetic knee joint was most common over time. This is not presented in this year in view of the risk of incorrect conclusions, as reporting of prosthetic knee joints is likely to take place with some delay as they occur less often than replacing a prosthesis or socket.

| | MANUAL LOCK | MECHANICAL | HYDRAULIC | INTELLI-GENT | PNEU-MATIC |
|----------------------------|-------------|------------|------------|--------------|------------|
| SWINGPHASE CONTROL | | | | | |
| KD (n=153) | 51 | 18 | 39 | 32 | 13 |
| TFA (n=475) | 198 | 92 | 84 | 67 | 34 |
| Total (n=628) | 249 | 110 | 123 | 99 | 47 |
| STANCEPHASE CONTROL | | | | | |
| KD (n=123) | 35 | 31 | 36 | 17 | 4 |
| TFA (n=379) | 159 | 121 | 56 | 43 | 0 |
| Total (n=502) | 194 | 152 | 92 | 60 | 4 |

Table 15. Type of prosthetic knee joint in KD and TFA, prostheses and sockets fitted 2016-2021, n.

Definition of Control Types for Prosthetic Knee Joints:

- Manual lock: mechanically locked when standing and walking, manual unlocking when sitting
- Mechanical: the knee joint is controlled by the position of the joint(s), friction brake, springs or elastics
- Pneumatic: the knee joint is controlled using air passing through valves
- Hydraulic: the knee joint is controlled by means of oil passing through valves
- Intelligent: microprocessor-controlled knee joint, various sensors are monitored, and readings are interpreted by computer programs and adapt joint movement to the situation the prosthesis is in.

Comment: The type of prosthetic knee joint varies greatly. Knee joints with manual locks are the most common (40%) type in TFA and KD. The proportion of microprocessor-controlled knee joints (Intelligent) has significantly increased in recent years. There is an increasing amount of evidence highlighting benefits of the Intelligent Knee Joints both in terms of function and reduced fall risk (e.g. Lansade et al 2018, Kaufman et al 2018, Carse et al 2021 and Davie-Smith et al 2021), as well as health economic studies (e.g. Chen et al 2018, Kuhlmann et al 2020 and 2022).

NUMBER OF SWEDEAMP PROSTHESIS REGISTRATIONS AT INDIVIDUAL PROSTHETIC AND ORTHOTIC CLINICS

| PROSTHETIC & ORTHOTIC CLINIC | 2019 | 2020 | 2021 | TOTAL 2011-2021 |
|----------------------------------|------|------|------|-----------------|
| Falun OTA | 78 | 52 | 33 | 398 |
| Malmö OTA | 134 | 55 | 70 | 378 |
| Ortopedteknik/ Sahlgrenska | 45 | 28 | 9 | 355 |
| Solna Sundbybergsvägen OTA | 83 | 70 | 0 | 347 |
| Lund OTA | 66 | 64 | 45 | 335 |
| Södersjukhuset OTA | 52 | 66 | 101 | 299 |
| Motala OTA | 35 | 21 | 29 | 237 |
| Eksjö OTA | 32 | 22 | 25 | 200 |
| Jönköping OTA | 40 | 28 | 40 | 166 |
| Karlskrona OTA | 25 | 15 | 10 | 152 |
| Stockholm Bergshamra OTA | 31 | 24 | 46 | 148 |
| Norrköping OTA | 23 | 31 | 20 | 142 |
| Halmstad OTA | 18 | 14 | 23 | 133 |
| Kristianstad OTA | 5 | 15 | 0 | 130 |
| Torsplan OTA | 20 | 18 | 24 | 114 |
| Växjö OTA | 11 | 7 | 19 | 102 |
| Huddinge OTA | 25 | 19 | 18 | 95 |
| Varberg OTA | 15 | 18 | 18 | 94 |
| Akademiska sjukhuset Uppsala OTA | 0 | 0 | 0 | 93 |
| Ängelholm OTA | 22 | 20 | 10 | 93 |
| Västervik OTA | 3 | 4 | 2 | 80 |

| PROSTHETIC & ORTHOTIC CLINIC | 2019 | 2020 | 2021 | TOTAL 2011-2021 |
|-----------------------------------|------------|------------|------------|-----------------|
| Västerås OTA | 13 | 11 | 5 | 77 |
| Norrtälje OTA | 15 | 23 | 22 | 76 |
| Linköping OTA | 10 | 12 | 9 | 73 |
| Borås OTA | 23 | 21 | 24 | 68 |
| Trollhättan OTA | 10 | 5 | 11 | 58 |
| Uppsala Dag Hammarskjölds väg OTA | 15 | 26 | 12 | 56 |
| Helsingborg OTA | 11 | 17 | 8 | 51 |
| Ljungby OTA | 11 | 6 | 3 | 38 |
| Uddevalla OTA | 0 | 0 | 0 | 26 |
| Kalmar OTA | 3 | 3 | 0 | 16 |
| Uppsala Bergsbrunnagatan OTA | 1 | 0 | 0 | 16 |
| Karlstad OTA | 0 | 4 | 10 | 14 |
| Södertälje, Wedavägen OTA | 0 | 0 | 0 | 13 |
| Other (<10 registrations) | 8 | 11 | 12 | 44 |
| Total | 883 | 730 | 658 | 4717 |

16. Number of registrations, based on date of first fitting per Prosthetic & Orthotic Clinic and year. Clinics with <10 total entered registrations are not reported separately.

Comment: Prosthetic data registration numbers have had a strong positive trend with more registrations each year during 2016-2019. In 2020, the number of registered cases has decreased slightly. In 2020 and 2021, the number of registered data has decreased while the number of devices and registry users for prosthetic data has increased. As can be seen from the table, data is unfortunately completely missing from parts of Sweden (e.g. Örebro, Östersund, Umeå and Luleå).

POOLED ANALYSIS OF PROSTHETIC DATA

The amount of prosthetic data per year has had a stable positive trend 2016–2019. Likely as an effect of the Covid19 pandemic, the amount of data decreased in 2020-2021 as compared to 2019. At the same time, more Prosthetic&Orthotic clinics and users have registered data. There is no figure to what degree all prostheses and/or sockets have been registered. Despite the reduction data the last two years, a positive development is seen for the coverage as there are more units and users involved. The proportion of data for renewal of socket/prosthesis in relation to "First prosthesis for current level" has increased.

This year, the results highlight prostheses fitted in the years 2016-2021 to better reflect the current situation and to be based on data with a higher degree of coverage.

In 2020, a major revision of the prosthesis data form was carried out. Variables and response options to record prosthetic design and component composition were modified to be categorized in accordance with the international ISO standard. Variables to analyze goals and goal achievement, complications in the rehabilitation process, load on unhealed surgical wound and method of socket design were

introduced. In this report, registration of data according to old and new answer options has been reported separately or translated and reported together with historical data.

Prosthetic data are dominated by cases provided with a prosthesis after transtibial amputation. The majority of women were >80 years old at the time of the first prosthetic fitting, men in the age group 70-79 years.

The degree of prosthetic provision is reported as a proportion of patients with a prosthesis in relation to patients who, before amputation, could stand or walk on the affected leg. Prosthetic supply rate for TTA for patients with amputation performed in 2015-2020 has been steadily at just over 40%. For patients with a higher amputation (TFA+KD), a lower proportion of patients supplied with a prosthesis is seen (roughly 20%) and this level was further lowered (to 16%) for those with an amputation performed in 2019-2020. The lower proportion of patients with higher amputation levels provided with a prosthesis might be an effect of the pandemic.

In TTA, postoperative compression treatment of the stump is usually started within 3 weeks from the amputation (>80%) by using a liner or a liner in combination with a compression stocking.

The median time from amputation to fitting of the first prosthesis for TTA and TFA shows that the number of days has decreased compared to previous years which indicates more efficient care processes. The time decreased from 73 to 58 days for TTA and from 104 to 84 for TFA. Different surgical techniques in TTA affect the time to the first prosthesis fitting.

There are statistically fewer days to fitting of first prosthesis for patients operated with skew or sagittal flaps (median 50 days) compared to long posterior or anterior/posterior flaps (median 69 days), ($p=0.003$). Similarly, data indicating how surgical technique affects stump problems in the short (<6 months after surgery) and long term (>2 years after surgery) show a difference. Problems such as pear-shaped stump and knee contracture are less common in skew/sagittal flaps. In the long term data indicate that thin soft tissue coverage is less common with long posterior or anterior/posterior flaps. However, the number of observations >2 years is low.

Stump problems when fitting prostheses are common. Data show 40% have problems with stump/remaining leg and in 17% the contralateral leg could not be loaded adequately. Stump problems such as swelling, ulcers and a wide stump end are more common initially.

The most common reason for replacing a socket or prosthesis is a change in stump volume or shape. In this report, for the first time, the variable "Method for manufacturing prosthesis socket" is presented, which also deals with stump problems in different ways. During 2020-2021, the most common method for producing a prosthetic socket was a "Direct laminated socket" at both TTA (67%) and TFA (52%).

Most TTA prostheses have some type of vacuum suspension (76%), and TFA prostheses usually have suspension via vacuum with a liner (61%). When choosing a prosthetic foot, energy-storing feet intended for function category 2 dominate (patients who can walk in indoor and outdoor environments with/without walking aids). For patients with higher amputation levels, locking prosthetic knee joints are most common. Registered data shows that the proportion of prostheses with an intelligent prosthetic knee joint is increasing, but unfortunately, development per year cannot be followed as there is no dating of component replacements.

Follow-up and Patient-reported data (PROM)

BASELINE AND PROM – THE SITUATION BEFORE AMPUTATION

Baseline data reflect the patient's situation before the deterioration that led to amputation and is collected as soon as possible after the procedure. This report is based on:

- 2729 patients: 37% women with a mean age of 77 years (17 - 101) and 63% men with a mean age of 72 years (17 - 99).
- 72% refers to the situation before transtibial amputation, 21% transfemoral amputation, 6% knee joint amputation and 1% before other levels
- In total, 83% involve amputation as a result of diabetes and/or vascular disease (of which 48% diabetes with or without vascular disease, 31% vascular disease without diabetes, 4% other vascular disease without diabetes), 5% trauma, 8% other diagnoses, in 4% of in the cases the diagnosis is unknown or not registered
- 63% of patients with data registered in Baseline also have prosthesis data and/or follow-up data in the registry

Comment: The proportion of patients with amputation due to diabetes and/or vascular disease has not changed since last year. Baseline data is highly representative of patients receiving prosthetic rehabilitation.

ACCOMMODATION BEFORE THE FIRST AMPUTATION

- 91% Own/ordinary accommodation, including any help
- 8% Special accommodation
- 1% Other accommodation or information missing

WALKING AIDS AND WHEELCHAIR USE BEFORE THE FIRST AMPUTATION

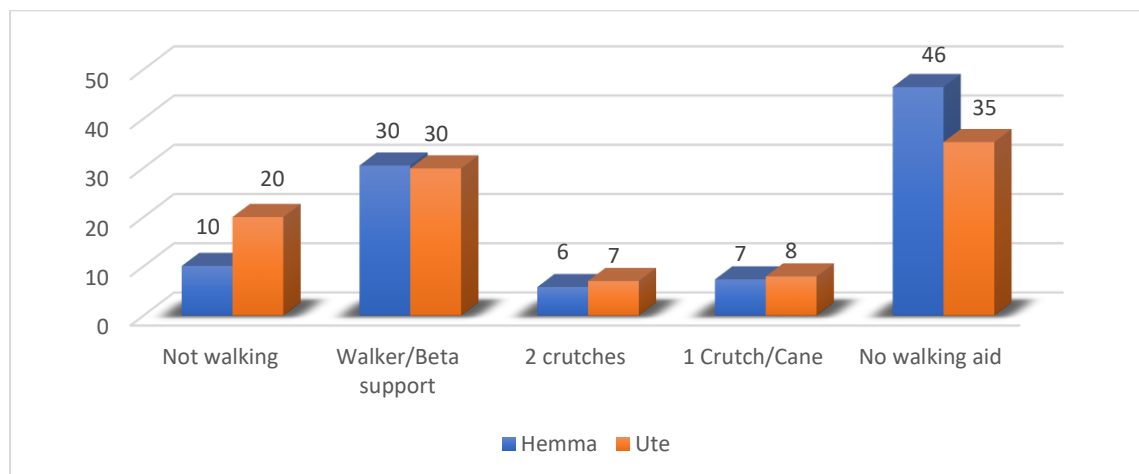


Figure 18. Use of walking aids before the amputation, %.

Walking aids AT HOME, BEFORE the first amputation per amputation level:

- Transtibial amputation (n=1904): 49% none, 45% some walking aid, 6% not walking
- Knee disarticulation (n=150): 35% none, 42% some walking aid, 23% not walking
- Transfemoral amputation (n=563): 40% none, 40% some walking aid, 20% not walking

Wheelchair use (regardless of extent) BEFORE first amputation (n=2635):

- 67% did not use a wheelchair
- 31% used a wheelchair
- 2% lacked the ability to answer the question about wheelchair use

Comment: More than half of the patients indicated that they used walking aids and about 30% indicated wheelchair use before the amputation. At higher amputation levels (KD or TFA), about 20% stated that they were not walking at all before the amputation compared to 6% at TTA, which is assumed to reflect general increased morbidity in the patients who are amputated at a higher level.

MOBILITY BEFORE THE AMPUTATION

Self-assessed mobility before the amputation is measured with the LCI-5-pre which consists of 14 questions answered on a five-point scale (0=cannot, 1= yes, if someone helps me, 2= yes, if someone is near me, 3= yes, alone, with ambulation aids, 4= yes, alone, without ambulation aids). The result is presented as two subscales (0–28) and summed to a total score (0–56). The subscales highlight basic and more demanding activities. Examples of basic activities are getting up from a chair, walking in the house, walking outside on even ground, and stepping up a sidewalk curb. Examples of demanding activities are walking outside on uneven ground, walking while carrying an object, getting up from the floor and going up a few steps without the support of a handrail.

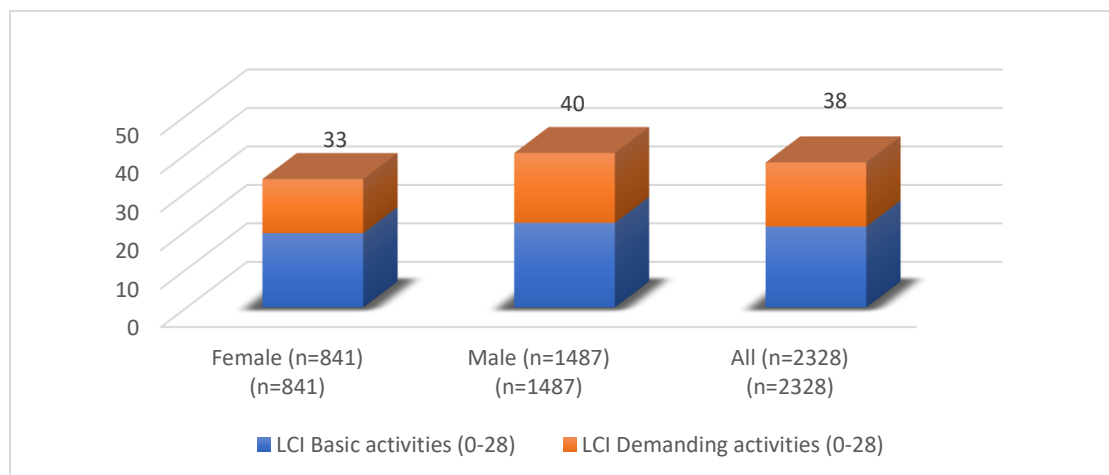


Figure 19. LCI-5 pre (median) before amputation distributed by gender and for all. The difference between the sexes is statistically significant ($p < 0.000$).

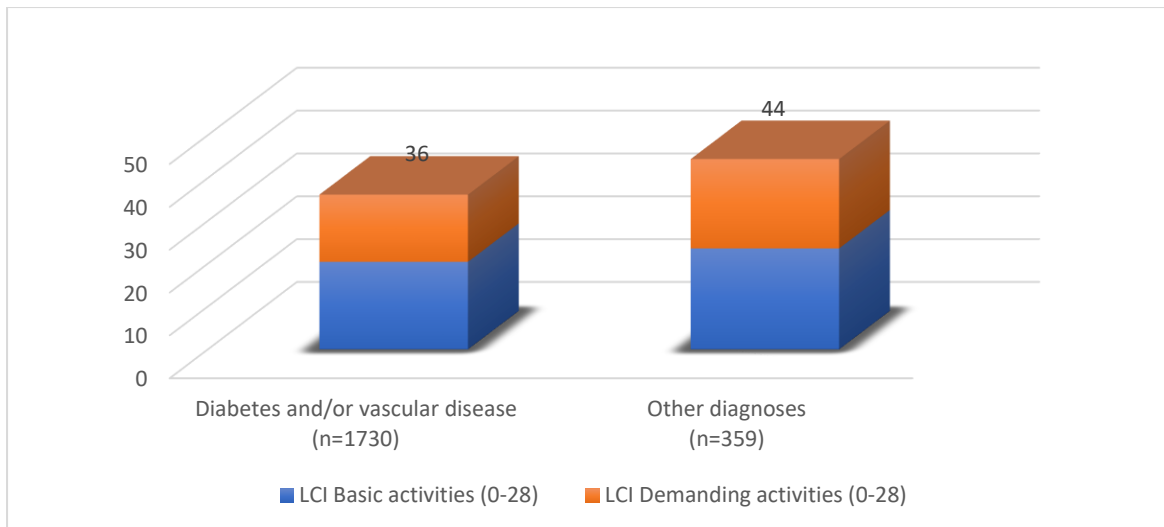


Figure 20. LCI-5 pre (median) before amputation per cause of amputation, vascular disease with/without diabetes and all other diagnoses. The difference between the diagnosis groups is statistically significant ($p < 0.000$).

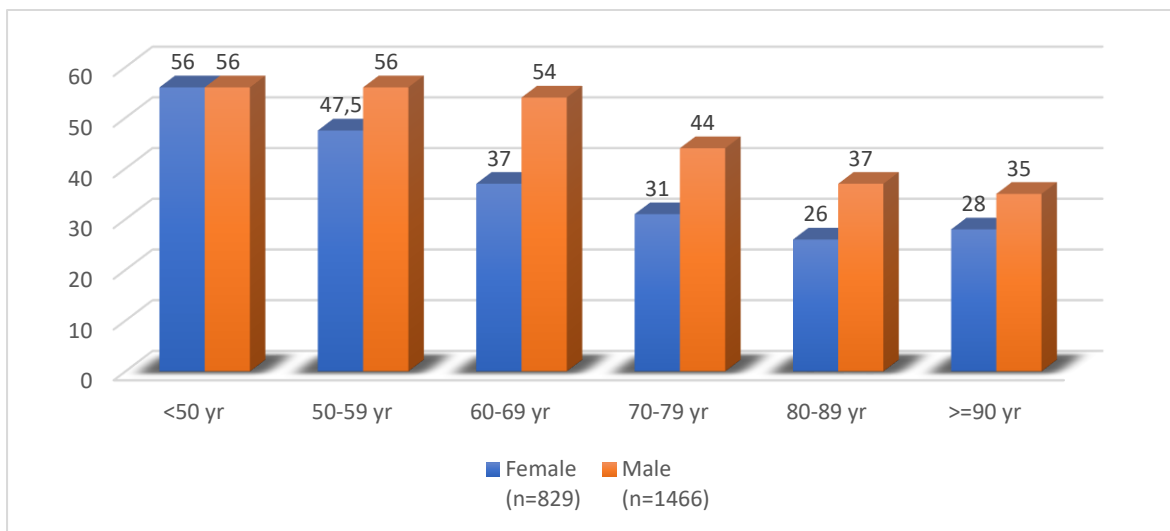


Figure 21. LCI-5-pre Total (0 - 56) (median) distributed by sex and age group.

| AMPUTATION DIAGNOS | TTA LCI-5 PRE TOTAL MEDIAN (MIN-MAX) | TFA/KD LCI-5 PRE TOTAL MEDIAN (MIN-MAX) |
|----------------------------------|--|---|
| DIABETES AND/OR VASCULAR DISEASE | | |
| Women >60yr | 35 (0-56) n=376 | 28 (0-56) n=168 |
| Men >60yr | 43 (0-56) n=761 | 40 (0-56) n=190 |

Table 17. Mobility before the amputation (LCI-pre Total, Md) in patients over 60 with an amputation diagnosis of diabetes and/or vascular disease by gender and level (TTA or TFA/KD). The difference between the sexes is statistically significant ($p < 0.000$).

Comment: Lower mobility before amputation is reported with increasing age, in vascular disease with or without diabetes as compared to other diagnoses, for those who have undergone amputation at a higher level as compared to transtibial amputation, and for women as compared to men. These factors are assumed to co-vary.

FOLLOW-UP AND PROM – AFTER AMPUTATION

Follow-ups (FU) describe the situation 6, 12 and 24 months after the amputation and refer to patients with a transtibial or higher amputation level. In the event of a new amputation (re-amputation to a higher level or amputation on the other side leading to bilateral amputation), a new follow-up period begins, i.e. 6, 12 and 24 months respectively after the patient's new situation with a higher amputation level or amputation both sides. This report is based on:

- 1976 patients (32% women, 68% men) and 3145 follow-ups:
 - 45% refer to follow-up 6 months after the amputation
 - 35% refer to follow-up 12 months after the amputation
 - 18% refers to follow-up 24 months after the amputation
- The majority concern TTA (75%), followed by TFA (19%), KD (5%) and TPHD (1%)
- The women were in mean 76 years old (18–101) and the men 72 years old (21–99) at the first FU
- At each FU, the proportion of patients with bilateral amputations is around 11%.
- 82% (n=1629) had returned to the same accommodation as before the amputation at the first FU. The mean age of those who returned to their accommodation was 72 years. The mean age for those that had not returned to their previous accommodation was 77 years.
- 82% had an amputation diagnosis of diabetes and/or vascular disease. Accounting of all diagnoses in the figure below.

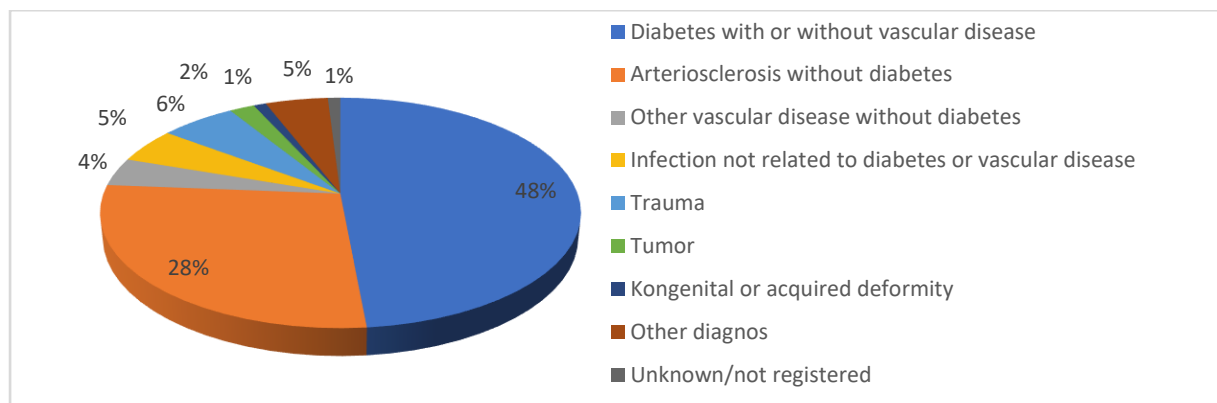


Figure 22. Distribution of amputation diagnoses at first follow-up, total n=1869.

Comment: Follow-up data is dominated by patients with TTA due to diabetes and/or vascular disease and 2/3 are men.

MENTORSHIP

The patient association "Personskadeförbundet RTP" has recently asked SwedeAmp to add a question regarding "Mentorship". The question reads "Have you, so far, been able to meet anyone else who also has a lower limb amputation (for example to ask questions)?" If No, would you like it?"

At 6 months (n=149): 39% Yes and 61% No. 73% answering NO would like to meet a fellow patient.

Comment: The question was introduced shortly before the Covid-19 Pandemic during which the possibility of meeting fellow patients has been affected. It will be particularly interesting to compare results in the coming years when rehabilitation activities can hopefully return to more normal conditions.

PROSTHETIC USE

TIME TO PROSTHETIC TRAINING

| NUMBER OF DAYS UNTIL START OF PROSTHETIC TRAINING FOR THREE TIME PERIODS | TTA MEDIAN (MIN-MAX) | TFA MEDIAN (MIN-MAX) |
|--|-------------------------|-------------------------|
| 2013-2015 | 93 (8-466) n=332 | 113 (29-490) (n=58) |
| 2016-2018 | 67 (5-500) (n=357) | 111 (19-414) (n=93) |
| 2019-2021 | 67 (17-469) (n=373) | 96 (28-444) (n=77) |

Table 18: Number of days (Median) from date of amputation to start of prosthetic training at TTA and TFA distributed by period of years based on amputation date. In the calculation, single extreme values have been removed (<5 days and >500 days).

Comment: The number of days from amputation to the start of training with a prosthesis is a way of highlighting the care chain. At both TTA and TFA, the time has been shortened since the start of the register. During the last 3-year period, prosthetic training was started at a median of about 2 months after TTA and about 3 months after TFA.

PROPORTION OF PROSTHETIC USERS PER LEVEL AT EACH FOLLOW-UP

- TTA: 94%, 94% and 93% are stated to be prosthetic users at resp. follow-up (6, 12 and 24 months)
- KD: 86%, 85% and 86% are stated to be prosthetic users at resp. follow-up (6, 12 and 24 months)
- TFA: 84%, 84% and 76% are stated to be prosthetic users at resp. follow-up (6, 12 and 24 months)

When dividing data into two diagnostic groups, a slightly lower proportion of prosthetic users with amputation due to Diabetes/Vascular disease and a slightly higher proportion of prosthetic users in those with Other diagnoses is apparent.

Comment: Asking whether the patient at the current follow-up is a prosthetic user or not (Yes/No) was introduced in 2017 and gives an answer if the patient uses a prosthesis at all, regardless of the extent or if the prosthesis is temporarily not used.

ABILITY TO INDEPENDENTLY DONN THE PROSTHESIS

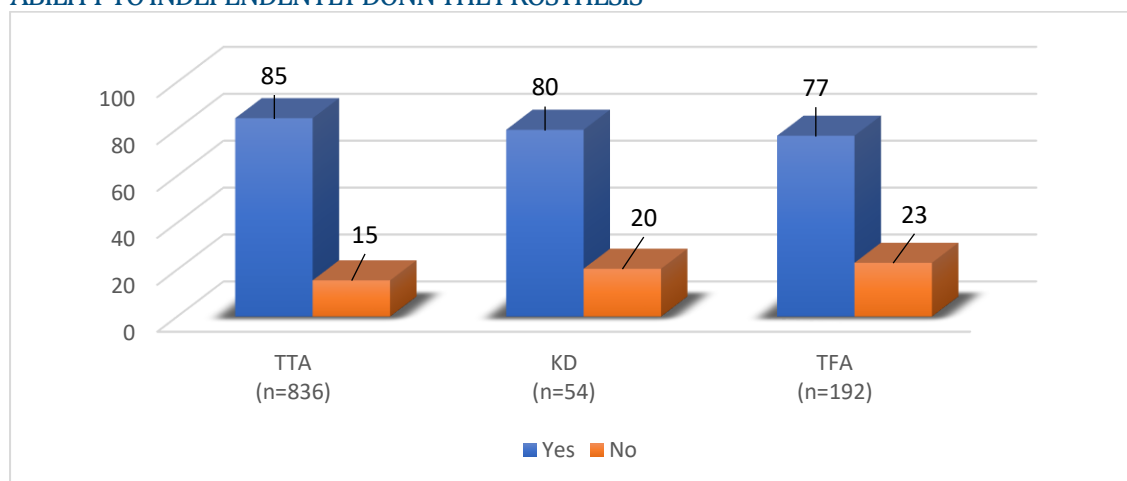


Figure 23. Ability to independently put on and take off (donna/doff) the prosthesis in unilateral TTA, KD and TFA 12 months after amputation, %.

Comment: Most patients can put on and take off the prosthesis by themselves. The need for help with donning/doffing limits the possibility of good prosthetic function. At 12 months, a slightly higher proportion with TTA (85%) can donna/doff their prosthesis compared to those with KD or TFA.

PROSTHETIC USE SCORE

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. how much one states that one wears the prosthesis in a normal week) and is reported as a number between 0–100. A score of 100 corresponds to the prosthesis being used every day >15 hours/day = basically all waking time. 0 means that the prosthesis is not used at all and 50 corresponds to being used about half of the time during a normal week, e.g. every day for 7–9 hours, or fewer days for more hours.

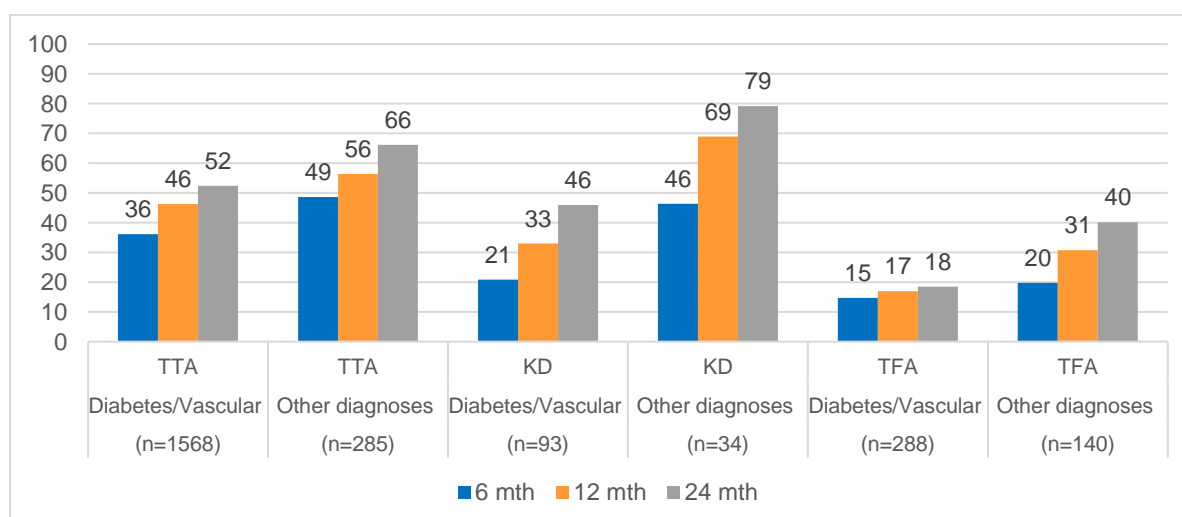


Figure 24. Average value for the Prosthetic Use score (0–100) per follow-up occasion for unilateral TTA, KD and TFA divided into two diagnostic groups. The number n indicates the total number of patients per amputation level and diagnosis group.

| SEX | TTA MEAN (SD) MEDIAN (MIN-MAX) | KD MEAN (SD) MEDIAN (MIN-MAX) | TFA MEAN (SD) MEDIAN (MIN-MAX) |
|-------|--------------------------------------|-------------------------------------|--------------------------------------|
| Women | 46 (31) 51 (0–100) n=184 | 29 (30) 17 (0–100) n=14 | 10 (12) 6 (0–52) n=44 |
| Men | 46 (31) 51 (0–100) n=377 | 36 (35) 23 (0–100) n=18 | 21 (24) 10 (0–90) n=70 |

Table 19. Prosthetic Use Score (0–100) at 12-month follow-up for unilateral TTA, KD and TFA with amputation diagnosis of diabetes and/or vascular disease reported for women and men. The differences between the sexes are not statistically significant.

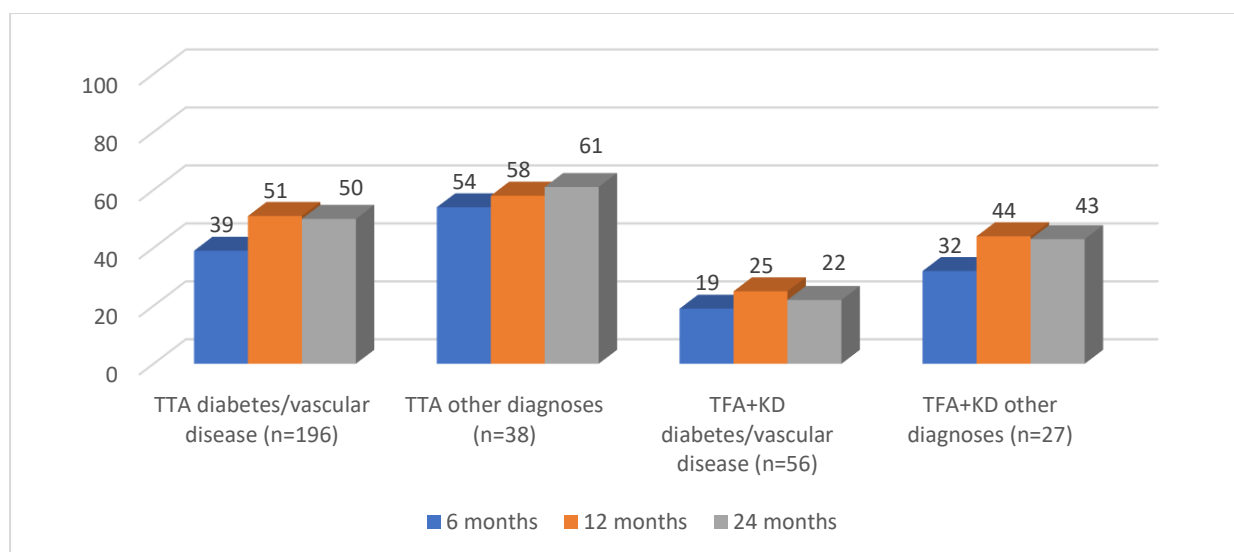


Figure 25. Longitudinal follow-up. Mean value for Prosthetic Use score in the smaller group of patients with unilateral TTA or KD/TFA who were followed on all three occasions and divided by amputation diagnosis diabetes and/or vascular disease and Other diagnoses.

PROSTHETIC USE SCORE IN BILATERAL TTA

- 6 months (n=112): Mean 40 (SD 33), Md 32 (0–100)
- 12 months (94): Mean 44 (SD 32), Md 32 (0–100)
- 24 months (n=54): Mean 57 (SD 32), Md 71 (0–100)

Comment: The prosthetic use score reflects how much the patient is wearing the prosthesis during a normal week. The use of the prosthesis slightly increased with each follow-up. Generally, the prosthesis is used less time in patients with amputation due to diabetes/vascular disease as compared to those with amputation due to other diagnoses. By far the least, the prosthesis is used by patients with TFA /KD due to diabetes and/or vascular disease and in this group lower use is reported by the women as compared to the men. In bilateral TTA, higher prosthesis use is reported than in unilateral TFA.

MOBILITY

WALKING-AID AT UNILATERAL AMPUTATION PER LEVEL AT 12-MONTHS FOLLOW-UP

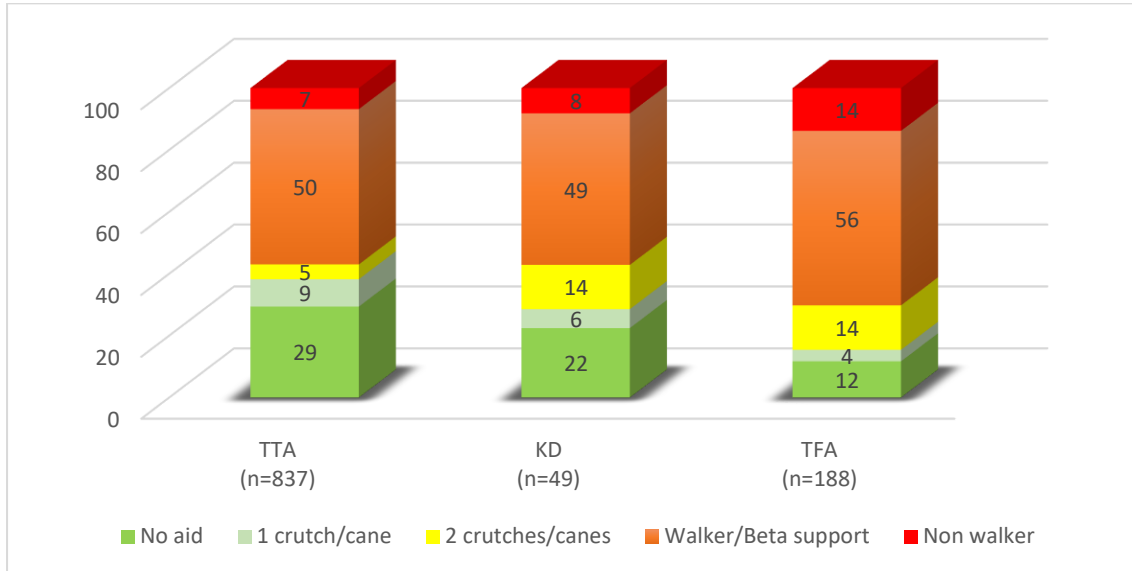


Figure 26. Walking aid when using prostheses at home 12 months after amputation for unilateral TTA, KD and TFA, (%). Non Walker = not using the prosthesis for walking

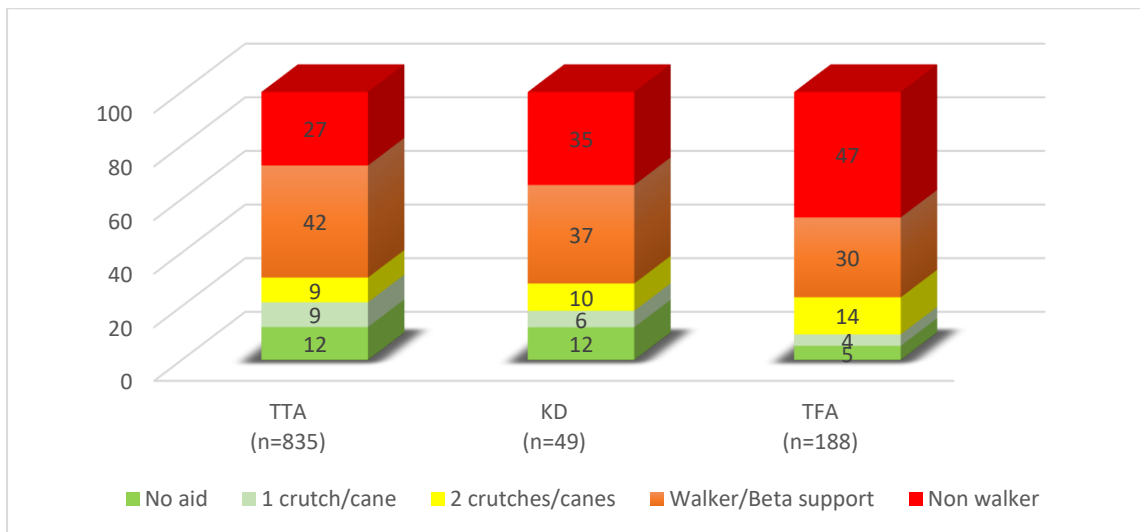


Figure 27. Walking aid when using the prosthesis outdoors 12 months after the amputation for unilateral TTA, KD and TFA (%). Non Walker = not using the prosthesis for walking

Wheelchair use (regardless of extent) in unilateral amputation 12 months after amputation:

- Transtibial amputation: 85%
- Knee disarticulation 79%
- Transfemoral amputation 94%

WALKING-AID AT HOME AND OUTDOORS IN UNILATERAL TTA

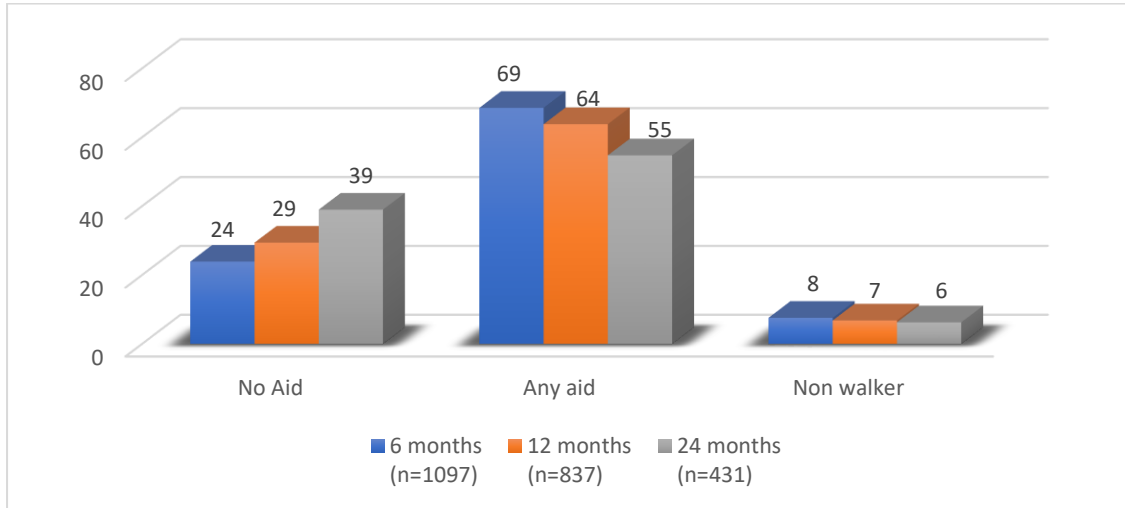


Figure 28. Summary of walking aids when using prosthesis at home 6, 12 and 24 months at unilateral TTA (%). Any walking aid includes all options according to figures 26 and 27. Non Walker = not using the prosthesis for walking

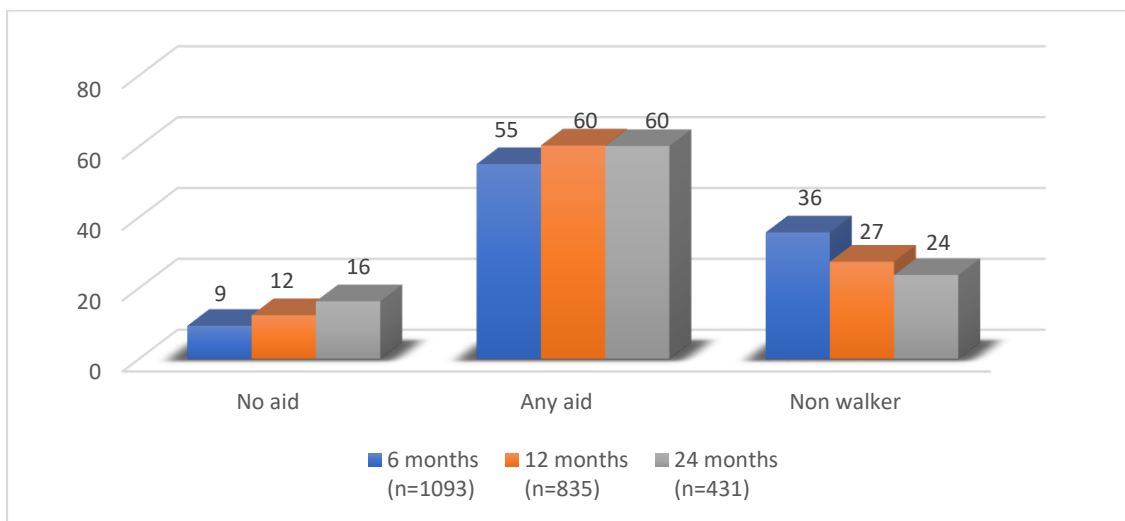


Figure 29. Summary of walking aids when using prosthesis outdoors 6, 12 and 24 months at unilateral TTA (%). Any walking aid includes all options according to figures 26 and 27. Non Walker = not using the prosthesis for walking

WALKING AIDS AT HOME AND OUTDOORS IN BILATERAL TRANSTIBIAL AMPUTATIONS

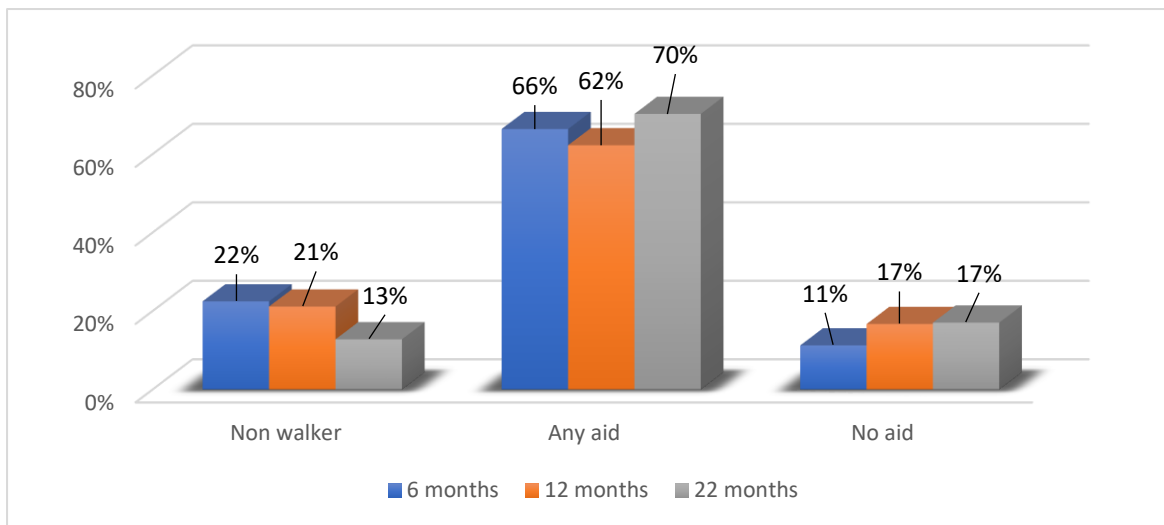


Figure 30. Summary of walking aids when using bilateral TTA prostheses at home 6, 12 and 24 months in bilateral TTA (%). Any walking aid includes all options. Non Walker = not using the prostheses for walking

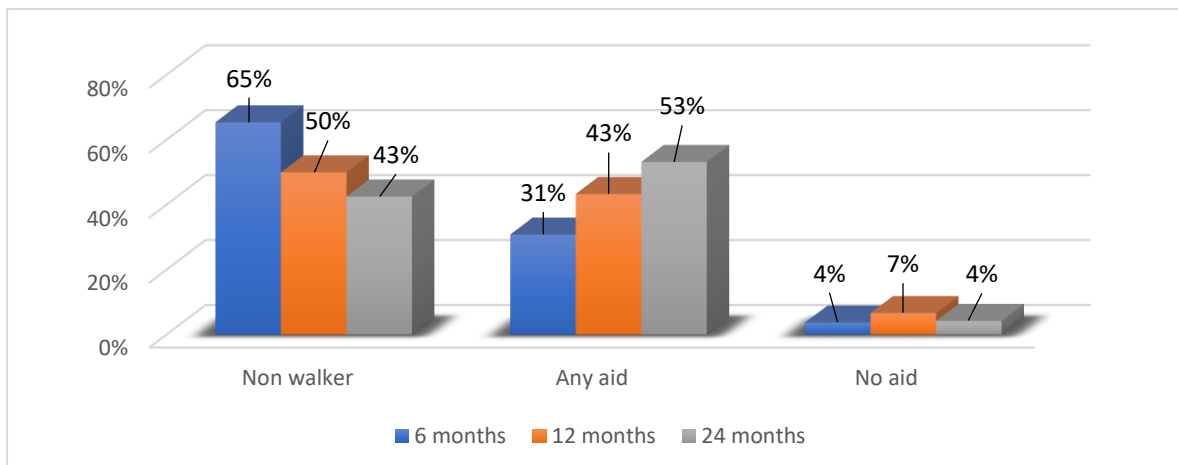


Figure 31. Summary of walking aids when using bilateral TTA prostheses outside 6, 12 and 24 months in bilateral TTA (%). Any walking aid includes all options. Non Walker = not using the prosthesis for walking

Comment: Generally, the need for walking aids is greater at TFA and KD compared to TTA, as well as for walking outdoors as compared to walking at home. Many state that they do not walk at all outdoors. In patients with unilateral TTA, there is a reduced need for walking aids over time and after 2 years, >1/3 walk at home and barely 1/6 outdoors without the support of any walking aid. However, most patients are highly dependent on both walking aids and wheelchairs.

MOBILITY AND FUNCTION WITH PROSTHESIS

Locomotor capability with prosthesis is evaluated with the Locomotor Capability Index (LCI-5) which consists of 14 questions (Franchignoni et al 2004). The patient indicates his perception of ability to perform various tasks on a five-point scale. The result is presented as two subscales (0–28) which are summed to a total score (0–56). The subscales highlight basic and more demanding activities with prosthesis. Examples of basic activities are getting up from a chair, walking indoors, walking outdoors on level ground, and walking over a curb. Examples of demanding activities are walking on uneven ground, walking while carrying an object, getting up from the floor and walking a few steps without the support of a handrail.

MOBILITY IN UNILATERAL TTA, KD AND TFA 12 MONTHS AFTER AMPUTATION

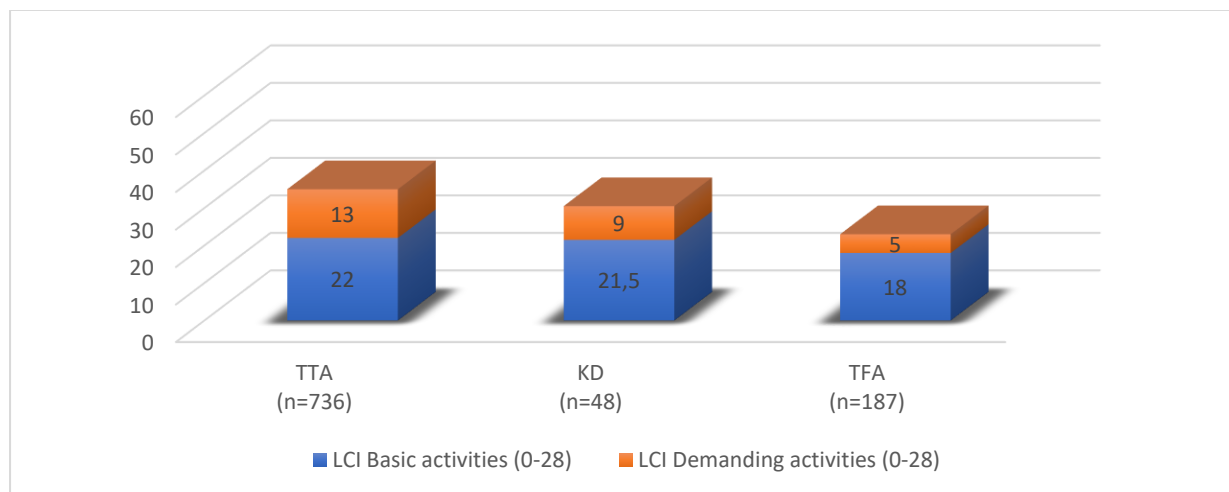


Figure 32. LCI-5 (Md) in unilateral amputation TTA, KD and TFA at 12 months follow-up after the amputation.

MOBILITY IN UNILATERAL TTA AND TFA PER DIAGNOSTIC GROUP AND FOLLOW-UP AT 6, 12 AND 24 MONTHS

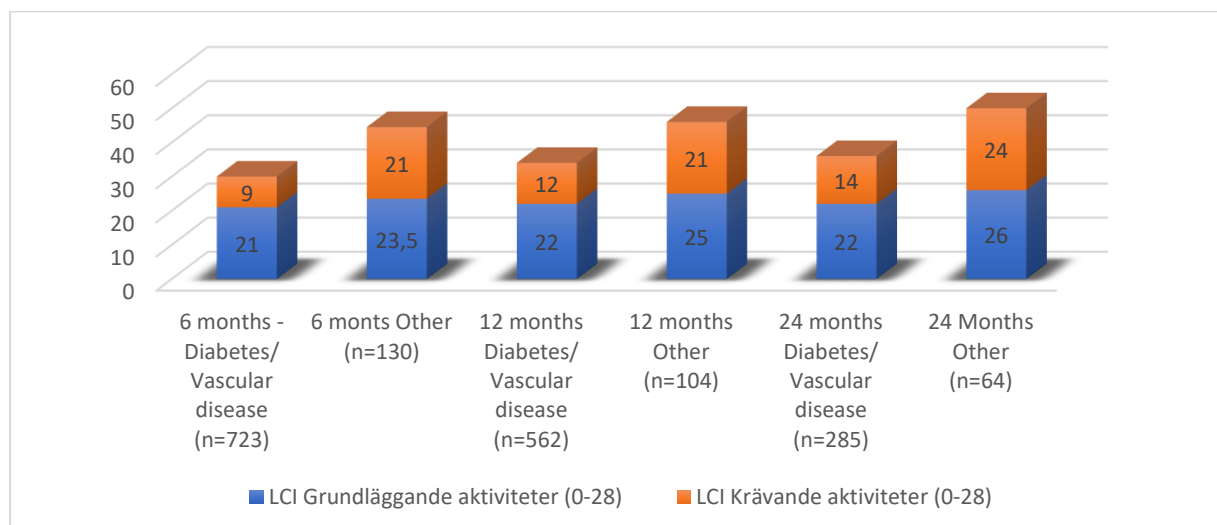


Figure 33. LCI-5 (Md) in unilateral TTA divided into diagnostic group Diabetes and/or vascular disease and Other diagnoses respectively 6, 12 and 24 months after the amputation.

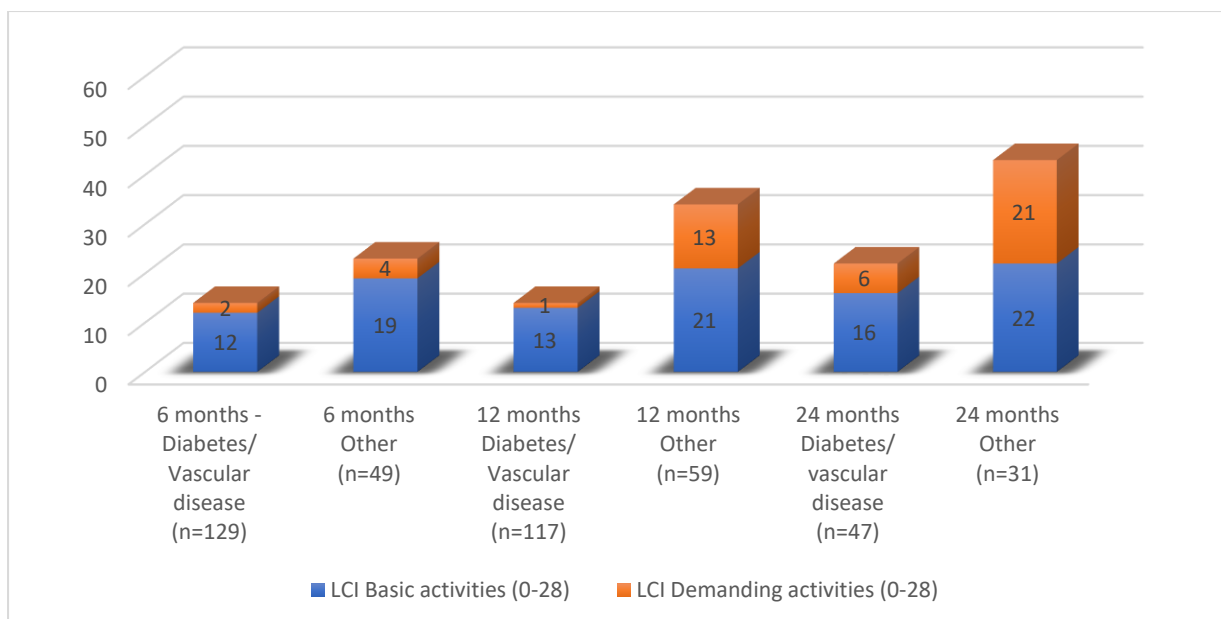


Figure 34. LCI-5 (Md) in unilateral TFA divided into diagnosis group diabetes and/or vascular disease and Other diagnoses respectively 6, 12 and 24 months after the amputation.

MOBILITY IN UNILATERAL TTA AND TFA DUE TO DIABETES AND/OR VASCULAR DISEASE, BY SEX

| | TTA | | | TFA | | |
|-------|------------------------------|-------------------|-------------------|------------------------------|------------------|------------------|
| | LCI-5 TOTAL MEDIAN (MIN-MAX) | | | LCI-5 TOTAL MEDIAN (MIN-MAX) | | |
| | 6 MONTHS | 12 MONTHS | 24 MONTHS | 6 MONTHS | 12 MONTHS | 24 MONTHS |
| Women | 20(0-56) n=232 | 28(0-54) n=184 | 24(0-53) n=90 | 8(0-44) n=44 | 9(1-56) n=49 | 11(0-41) n=18 |
| Men | 34(0-56) n=490 | 36(0-56) n=377 | 40(0-56) n=195 | 18(2-51) n=83 | 20(0-54) n=68 | 28(0-52) n=29 |

Table 20. LCI-5 Total (Md) for women and men respectively in unilateral TTA and TFA due to diabetes and/or vascular disease 6, 12 and 24 months after the amputation. The differences between the sexes are statistically significant ($p < 0.05$ in all groups). The women are older than the men in each group ($p < 0.05$).

- In TTA for other diagnoses, the women had increased their LCI-5 Total from MD 39 to 43 and the men from 46 to 52 between 6 and 24 months of follow-up
- In TFA for other diagnoses, the women had increased their LCI-5 Total from MD 25 to 41 and the men from 28 to 43 between 6 and 24 months of follow-up.

LONGITUDINAL FOLLOW-UP OF MOBILITY IN UNILATERAL AMPUTATION

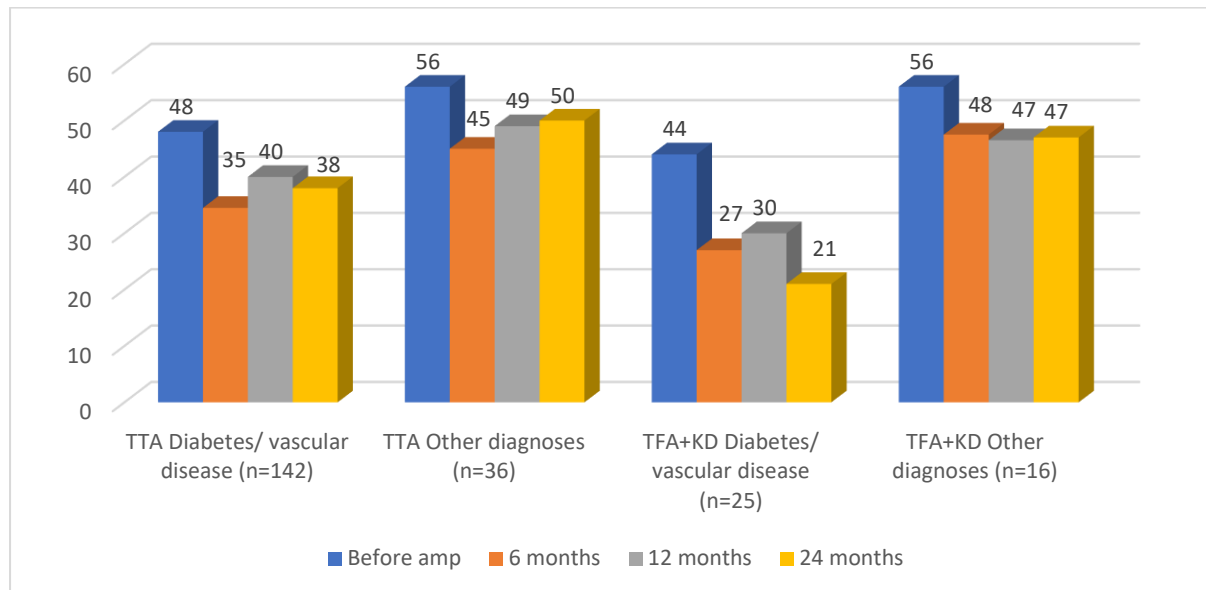


Figure 35. LCI-5 Total (Md) reported as longitudinal follow-up of the smaller group of patients where the same individual has answered the LCI before amputation and at 6, 12 and 24 months after amputation in patients with unilateral amputation distributed by level (TTA or TFA + KD) and per diagnosis (diabetes and/or vascular disease and Other amputation diagnoses).

MOBILITY (LCI-5) IN BILATERAL TTA

- 6 months (n=108): Md 11 (0–56)
- 12 months (n=89): Md 16 (0–56)
- 24 months (n=52): Md 20 (0–56)

Comment: Lower mobility with prosthesis is indicated at higher levels of amputation, in special among those with amputation due to diabetes and/or vascular disease. Women with amputation due to diabetes and/or vascular disease indicate lower mobility with a prosthesis than the men in the same group. Lower mobility is consistently indicated for the demanding activities as compared to the basic activities. Patients with bilateral TTAs report mobility comparable to patients with unilateral TFA due to diabetes and/or vascular disease, i.e. those with an above the knee amputation.

Results from the LCI-5 can be used when meeting with the individual patient. Franchignoni et al (2019) reported that the minimum detectable clinical difference for the LCI-5 is 5.66 (MDC (95)). For the individual patient, a difference of 6 points can therefore be considered to reflect improved or impaired mobility with prosthesis. Another study has reported increased fall risk at LCI <15 for the demanding activities in patients with a unilateral TTA (Dite et al 2007).

TIMED - UP AND GO TEST (TUG TEST)

The TUG is a standardized functional test that measures the time it takes to stand up from a chair with armrests, walk 3 meters, turn, walk back and sit down. In SwedeAmp, TUG is performed with the walking aid that is normally used and the time is recorded in whole seconds. Values of TUG <10 sec are considered normal and >30 sec are considered increased fall risk. In a meta-analysis, TUG for healthy elderly >60 years has been reported to be 9.4 sec (Bohannon et al 2001).

| DIAGNOS AND TIME FOR FOLLOW-UP | UNILATERAL TTA SECONDS MEAN (SD), N | UNILATERAL TFA SECONDS MEAN (SD), N |
|----------------------------------|--|--|
| DIABETES AND/OR VASCULAR DISEASE | | |
| 6 months | 23 (17) n=450 | 49 (31) n=64 |
| 12 months | 20 (18) n=303 | 39 (56) n=43 |
| 24 months | 18 (17) n=114 | 39 (32) n=11 |
| OTHER DIAGNOSIS | | |
| 6 months | 13 (14) n=86 | 30 (28) n=27 |
| 12 months | 13 (22) n=59 | 25 (37) n=33 |
| 24 months | 12 (12) n=30 | 18 (18) n=17 |

Table 21. Timed up and Go test (mean) for unilateral TTA and TFA and divided by diagnosis group and follow-up occasion.

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

- 5%, 9% and 12% of patients performed TUG <10 sec 6, 12 resp. 24 months after the amputation
- 36%, 25% and 25% of the patients performed TUG >30 sec 6, 12 respectively. 24 months after the amputation

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

- No one performed TUG <10 sec
- The majority performed TUG >30 sec (86% at 6 months, 72% at 12 months, 55% at 24 months)

Comment: The table shows better mobility in TTA compared to TFA and better mobility in those with amputations for other reasons than diabetes/vascular disease.

Dite et al (2007) reported increased fall risk at TUG->19 sec for patients with unilateral TTA 6 months after prosthetic rehabilitation. More studies regarding the relationship between TUG and fall risk in people who use prosthetic legs are requested.

PAIN

PAIN IN THE RESIDUAL LIMB (STUMP PAIN) AT UNILATERAL AMPUTATION

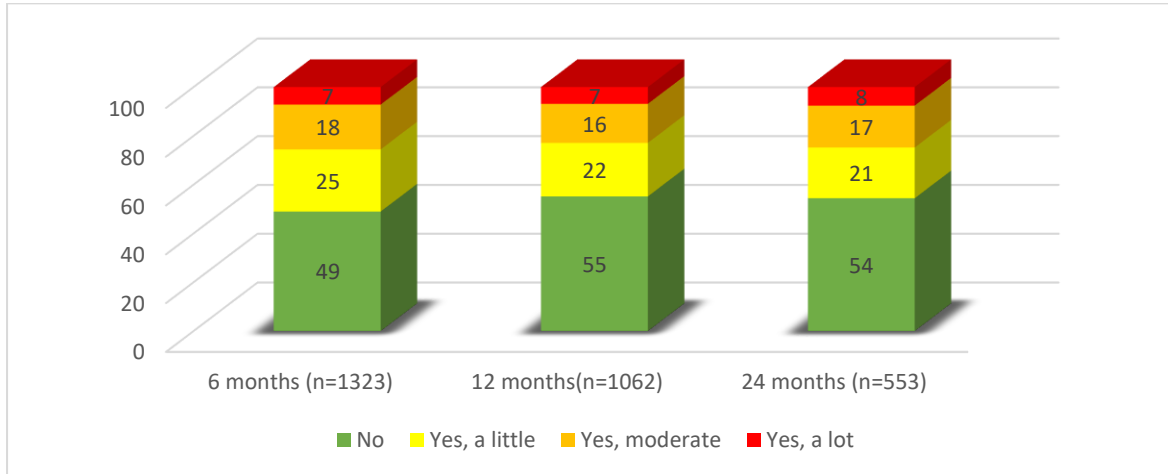


Figure 38. Occurrence of stump pain in unilateral amputation, regardless of the level above the ankle joint, at 6, 12 and 24 months (%).

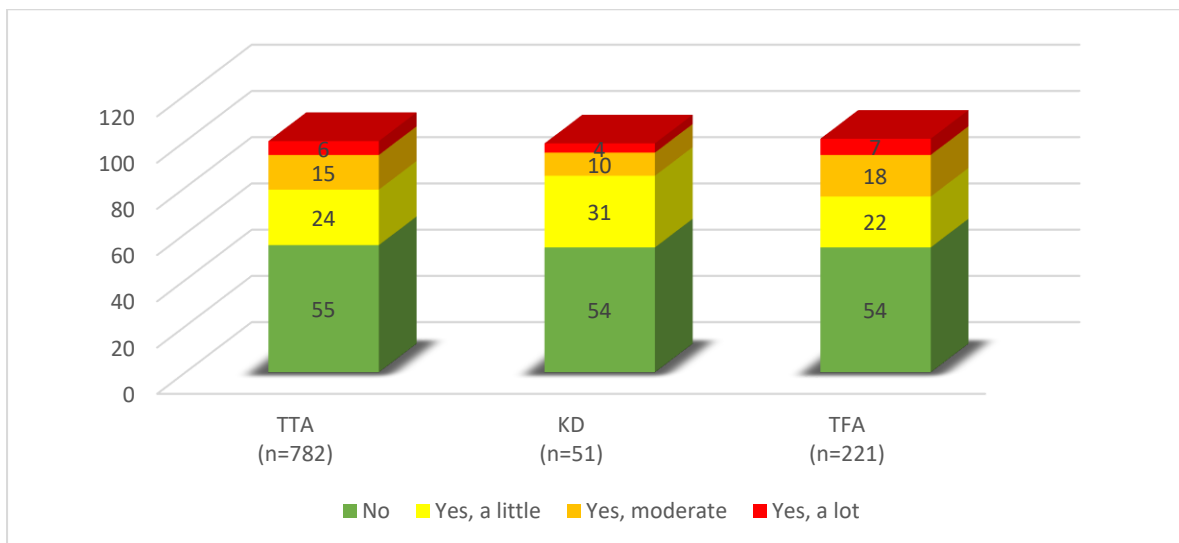


Figure 39: Occurrence of stump pain in unilateral TTA, KD and TFA 12 months after amputation, %.

TREATMENT FOR STUMP PAIN (IF ANSWER YES A LITTLE - YES A LOT, REGARDLESS OF WHICH FOLLOW-UP) (N=2081):

- 40% indicated that they had painkillers or other treatment
- 56% indicated that they had not needed any treatment
- 4% indicated that they did not have any medication or other treatment but that they would need it or that they had refrained from treatment because side effects or other discomfort

Frequency of treatment for stump pain (n=831):

59% daily, 24% one or more times/week, 17% occasional

LONGITUDINAL FOLLOW-UP – STUMP PAIN AT TTA AND TFA/KD

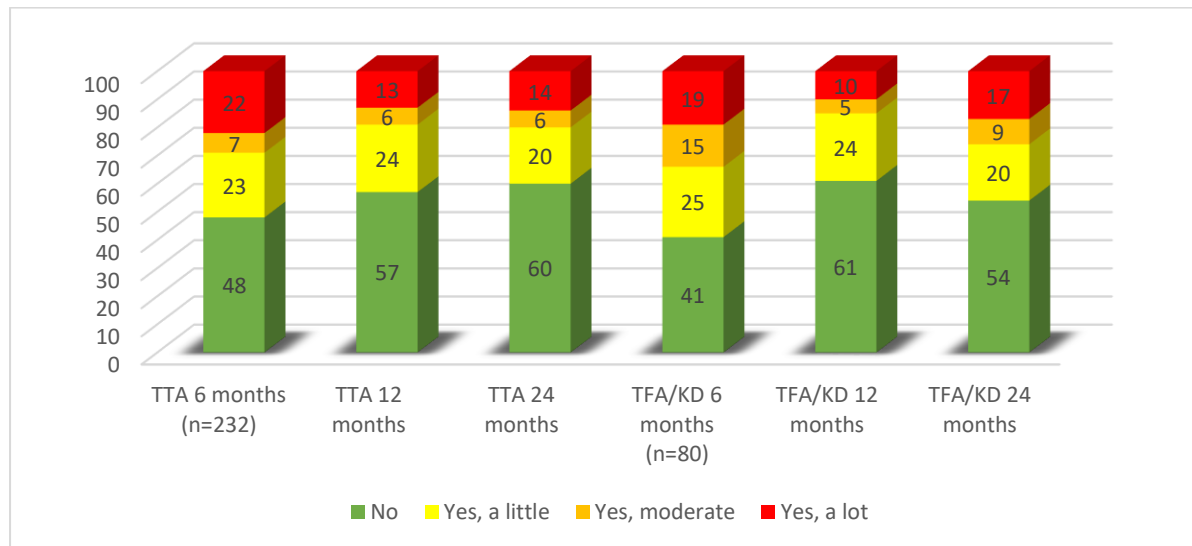


Figure 40 Longitudinal follow-up. Occurrence of stump pain in the smaller group of patients who answered the same question at all three follow-ups for unilateral TTA (n=232) and unilateral TFA+KD (n=80) regardless of amputation cause (%).

PHANTOM LIMB PAIN AT UNILATERAL AMPUTATION

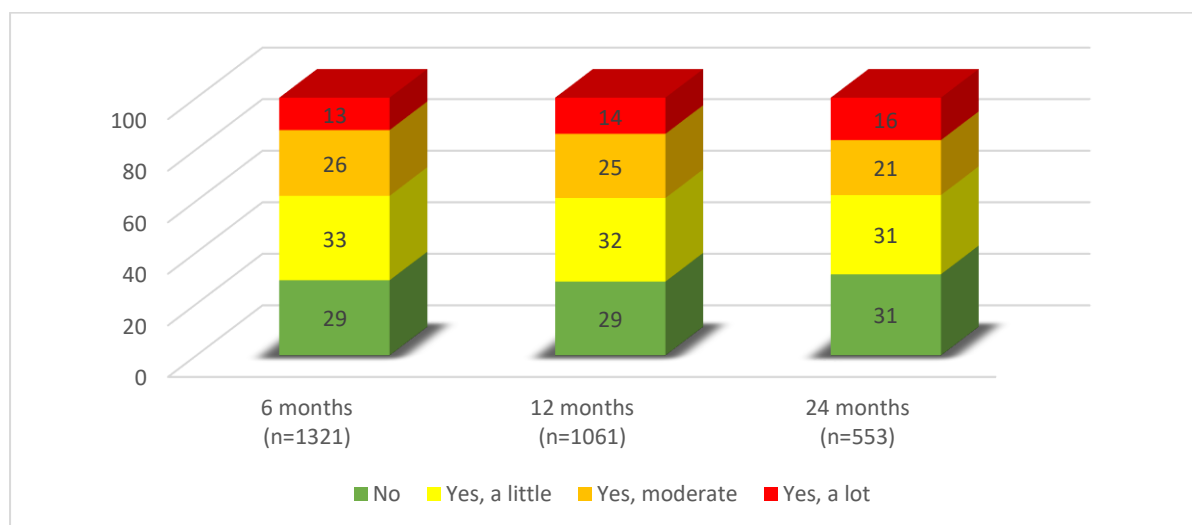


Figure 41. Occurrence of phantom limb pain in unilateral amputation, regardless of the level above the ankle joint, at 6, 12 and 24 months (%).

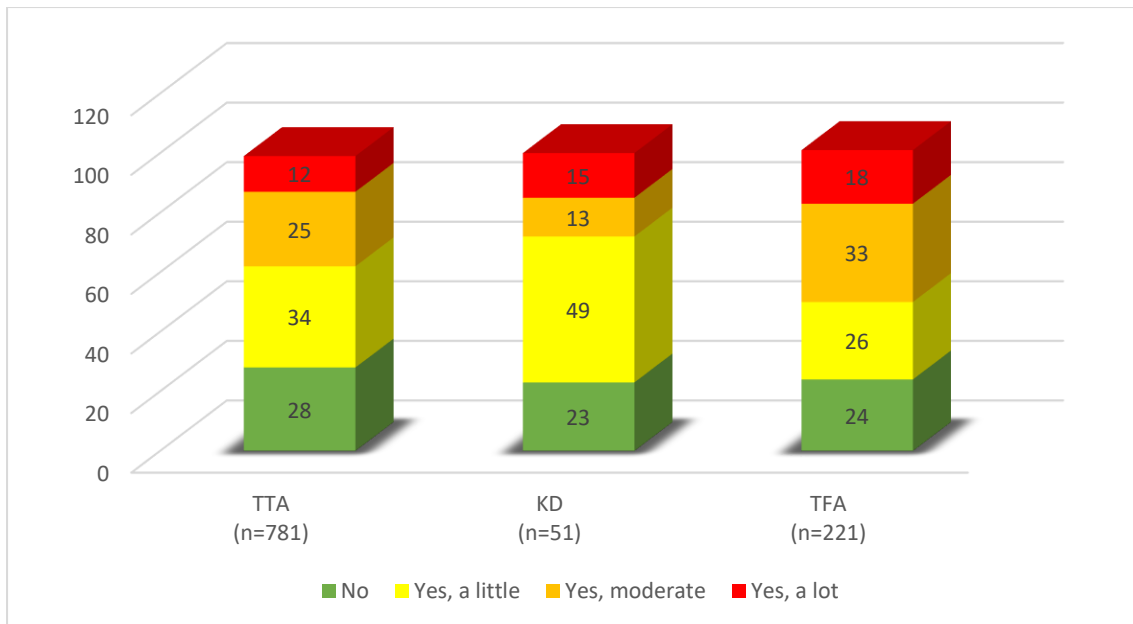


Figure 42. Occurrence of phantom limb pain in unilateral TTA, KD and TFA 12 months after amputation (%).

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

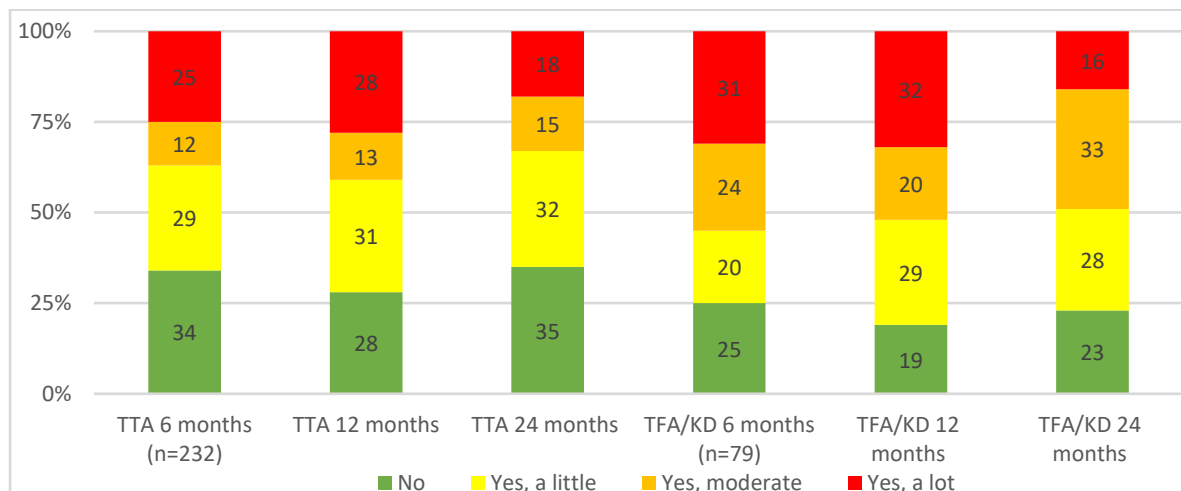


Figure 43. Longitudinal follow-up. Occurrence of phantom limb pain in the smaller group that answered the question at all three follow-ups with unilateral TTA (n=232) and unilateral TFA or KD (n=79) (%).

TREATMENT FOR PHANTOM LIMB PAIN (IF ANSWER YES A LITTLE - YES A LOT, REGARDLESS OF WHICH FOLLOW-UP) (N=2609):

- 37% stated that they had painkillers or other treatment
- 58% indicated that they had not needed any treatment
- 5% indicated that they did not have any medication or other treatment but that they would need it or that they had refrained from treatment because side effects or other discomfort

Frequency of treatment for phantom pain (n=979):
65% daily 20% one or more times/week, 15% occasional

Comment: In general, a higher proportion report having problems with phantom limb pain than stump pain. Fewer than half indicate some degree of stump pain, but approximately 70% indicate some degree of phantom limb pain. For both types of pain, approximately 40% of state to have some type of pain treatment. Longitudinal data for the smaller group of patients included in all three follow-ups indicate reduced complaints of stump pain over time. In the case of phantom limb pain improvement over time is not clear.

GENERAL HEALTH-RELATED QUALITY OF LIFE

General health-related quality of life is measured with EQ-5D consisting of 5 questions concerning: Mobility, Hygiene, Usual activities, Pains/Discomfort and Anxiety/Depression. Before the year 2017, EQ-5D-3L (3 answer options per question) was used. Since 2017 the EQ-5D-5L (with 5 answer options per question) which provides more adequate information is used. The combination of answers for each question can be calculated as an index. The index is presented as a figure between -0.594 and 1 and a higher figure indicates higher self-estimated health-related quality of life.

The table below shows the data for the EQ-5D index for the entire material, i.e. for both the 3L and 5L versions. Then results for EQ-5D-5L are reported in more detail.

| LEVEL | 6 MONTHS MEAN (SD) N | 12 MONTH MEAN (SD) N | 24 MONTH MEAN (SD) N |
|----------------------|-------------------------|-------------------------|-------------------------|
| Unilateral TTA | 0,56 (0,29) n=616 | 0,58 (0,29) n=485 | 0,57 (0,31) n=270 |
| Unilateral KD or TFA | 0,49 (0,32) n=181 | 0,47 (0,32) n=160 | 0,48 (0,34) n=94 |
| Bilateral TTA | 0,47 (0,31) n=66 | 0,40 (0,35) n=61 | 0,43 (0,35) n=41 |

Table 22. Mean value for EQ-5D Index in unilateral TTA, KD or TFA and in bilateral TTA, regardless of amputation cause.

RESULTS FROM EQ-5D-5L

EQ-5D-5L Index (Mean) at 12 months per amputation level and diagnosis:

- TTA (Diabetes/Vascular Disease (n=356): 0.59 (SD 0.28); TTA Other Causes (n=54): 0.55 (SD 0.31)
- KD (Diabetes/Vascular Disease (n=13): 0.58 (SD 0.30); KD Other Causes (n=9): 0.66 (SD 0.19)
- TFA (Diabetes/Vascular Disease (n=83): 0.43 (SD 0.33); TFA Other Causes (n=39): 0.41 (SD 0.33)

DISTRIBUTION OF ANSWERS PER QUESTION FOR UNILATERAL TTA, KD AND TFA DUE TO DIABETES/VASCULAR DISEASE AT 12 MONTHS FOLLOW-UP

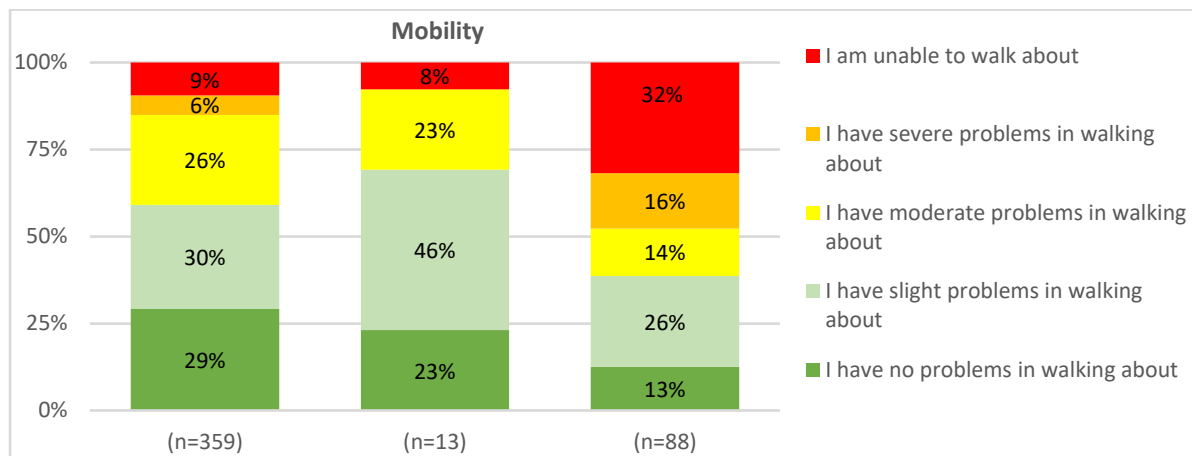


Figure 44. EQ-5D-5L Mobility in unilateral TTA (left), KD (middle) and TFA (right) due to Diabetes/Vascular disease at 12 months follow-up

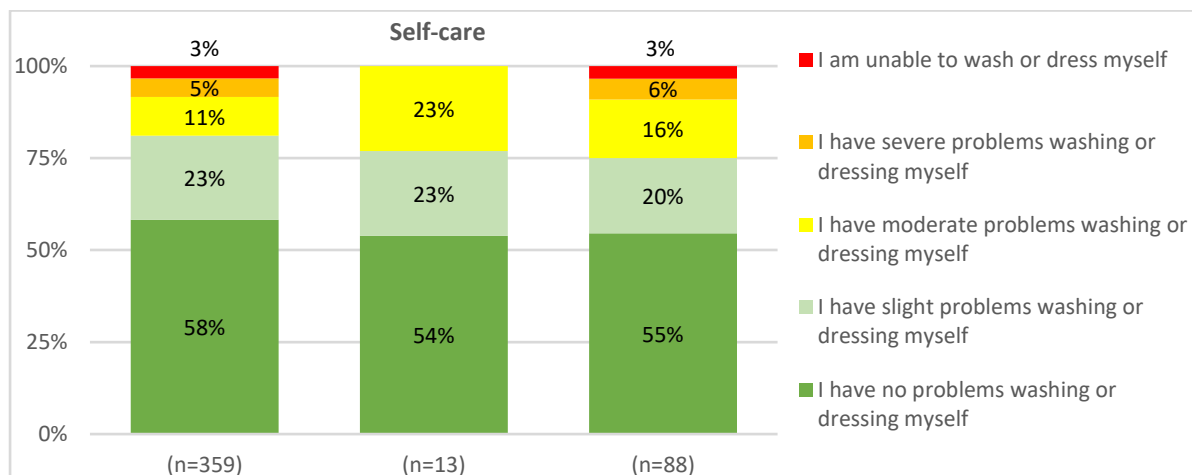


Figure 45. EQ-5D-5L Self-Care in unilateral TTA (left), KD (middle) and TFA (right) due to Diabetes/Vascular disease at 12 months follow-up

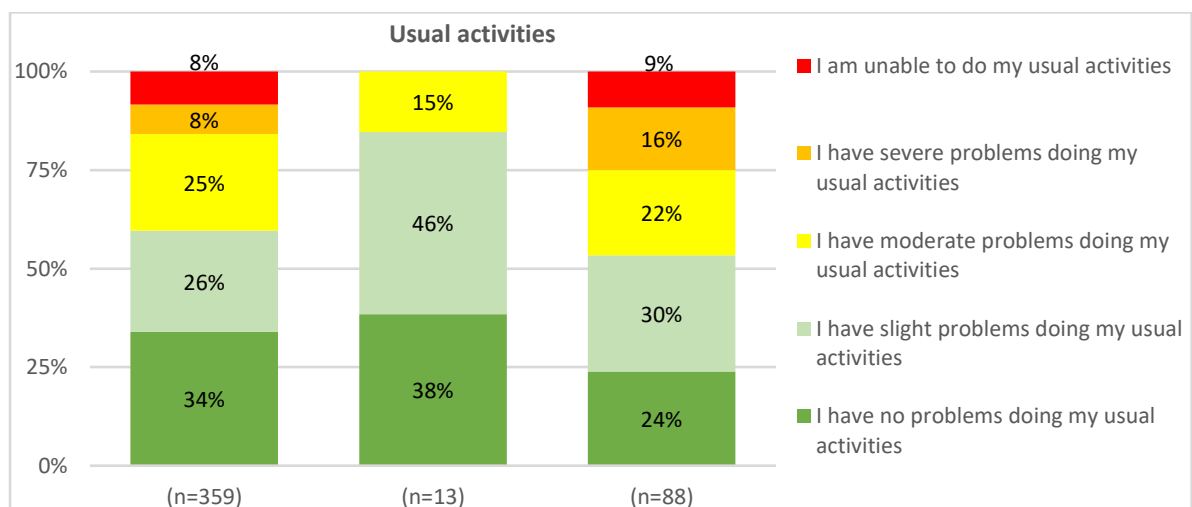


Figure 46. EQ-5D-5L Usual activities in unilateral TTA (left), KD (middle) and TFA (right) due to Diabetes/Vascular disease at 12 months follow-up

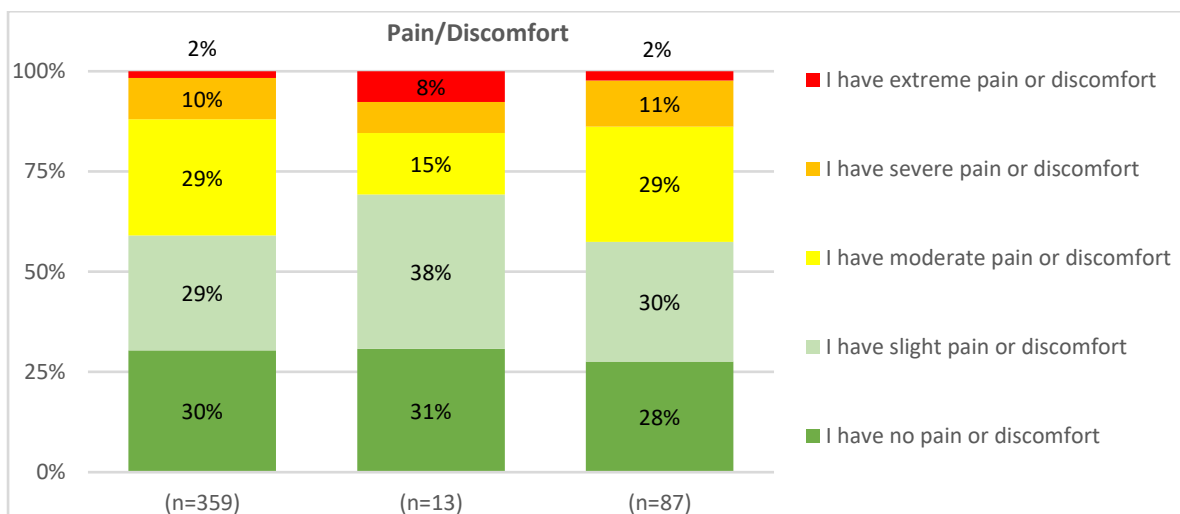


Figure 47. EQ-5D-5L Pain / Discomfort in unilateral TTA (left), KD (middle) and TFA (right) due to Diabetes/Vascular disease at 12 months follow-up

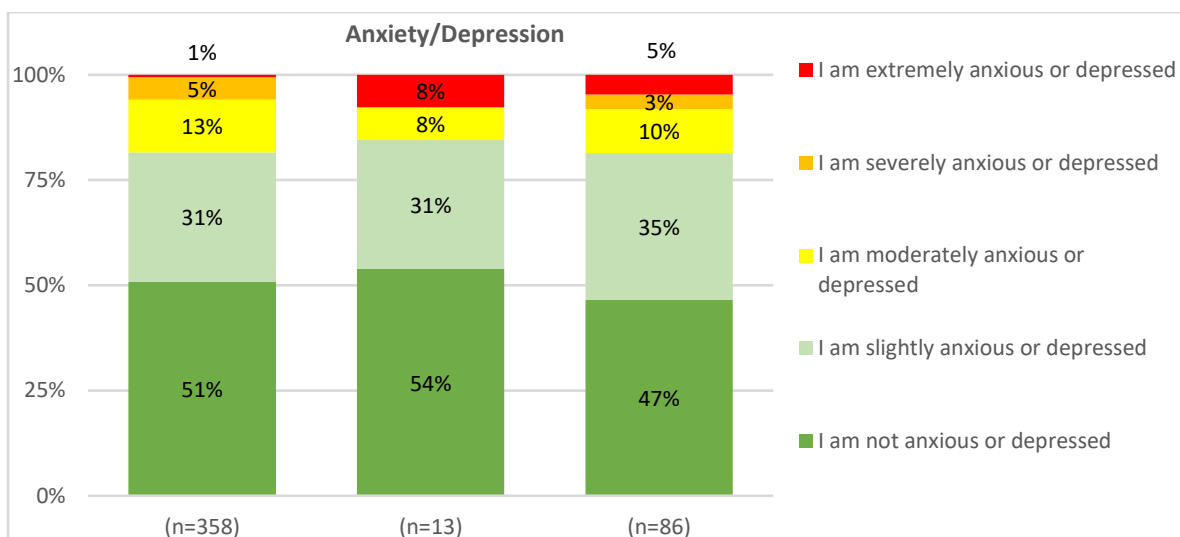


Figure 48. EQ-5D-5L. Anxiety and depression in unilateral TTA (left), KD (middle) and TFA (right) due to Diabetes/Vascular disease at 12 months follow-up

Comment: Patients with unilateral TTA report better health as measured by the EQ-5D index compared to patients with amputation at higher levels or with bilateral TTAs. The figures showing the distribution of the answer options per question visualize that the difference mainly applies to the dimension "Mobility". At 12 months follow-up, patients with unilateral TFA due to diabetes and/or vascular disease report more difficulty in walking as compared to both unilateral KD and TTA. Results for patients with KD must be considered with caution due to the low number.

Many Swedish quality registers use EQ-5D as a measure of general health and the index value can be used to calculate quality-adjusted life years in health economic research. By including EQ-5D in SwedeAmp, it is possible to compare patients with LLA to other groups of patients. In 2021, a study based on SwedeAmp data showed that the EQ-5D-5L version (with five answer options) provides more information than the version with three options (Ernstsson et al, Disabil Rehabil 2021). We recommend the use of EQ-5D-5L in future research involving patients with lower limb amputations.

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

In Sweden, it is largely elderly frail people with diabetes and/or vascular disease who undergo LLA, which is reflected in our data. In the patient-reported data, most men are >70 years old and women >75 years old, and for the majority the procedure is caused by diabetes and/or vascular disease. Many have reduced mobility even before the amputation and need to use both walking aids and a wheelchair. In general, women report poorer mobility than men before the amputation.

People with LLA are not a homogeneous group. By highlighting the situation of different subgroups, SwedeAmp can help ensure that relevant information is conveyed to patients, relatives, and care providers. The data reflecting the ability to use a prosthesis are of particular importance since the literature demonstrates clear connections between better quality of life and better ability to use a prosthesis (e.g. Davie-Smith et al. POI 2017; Wurdeman et al. POI 2018).

In recent years (2019-2021), prosthetic training has started approx. 2 months after TTA and approx. 3 months after TFA. One year after the amputation, patients with both unilateral and bilateral TTA indicate that they wear the prosthesis about half the time during a typical week (Prosthetic Use score approx. 45), while patients with unilateral TFA indicate a low degree of prosthetic use (Prosthetic Use score <20). Regarding mobility with a prosthesis (measured with the LCI-5), women indicate statistically significantly lower mobility than men in both TTA and TFA. The importance of a preserved knee joint is clearly seen in the TUG test, where those with unilateral TTA can perform the test significantly faster than those with TFA. In case of amputation due to causes other than diabetes and/or vascular disease, the prosthesis is generally used more and with better mobility. The differences between different groups of patients are confirmed in the results from the EQ-5D, where patients with TTA report a higher general quality of life than others. Within the group with amputation due to diabetes and/or vascular disease, clearly more people with TTA indicate a better ability to "walk around" (dimension mobility) than the corresponding group with TFA.

Many patients also report problems with stump pain (about 45%) and phantom limb pain (about 70%). The longitudinal follow-up indicates reduced stump pain over time, but this is not seen for phantom limb pain. Patients with higher amputation levels report more discomfort with phantom limb pain as compared to those with TTA.

In longitudinal analysis, i.e. where the same patient has been followed at all follow-ups, it must be taken into account that this group probably consists of patients with slightly better health conditions since they have neither died nor suffered a subsequent new amputation during two years. Many rehabilitation units connected to SwedeAmp have testified that the participation has led to a better clinical follow-up routine being established.

In 2020, a question regarding mentoring was introduced. This report presents the data that has been received so far, which shows that only 39% had the opportunity to meet fellow patient with LLA to, for example, ask questions. The results reflect the Covid-19 restrictions that may have prevented such meetings.

PROM and follow-up data in SwedeAmp do not represent as large number of patients as the other parts of the registry. This is partly due to follow-up data is only collected for patients with amputation above the ankle, and partly due to high mortality and co-morbidity. In Sweden, there is currently no available list of prosthetic rehabilitation units, and the clinics are organized in different ways.

Explanations and abbreviations

| | |
|-------------------------------------|---|
| EQ5D-5L | A general health index, where 5 questions with 5 options each result in a scale between minus 0, 594 and 1 (1 represents the best possible health) www.euroqol.org/ |
| KD | Knee disarticulation (amputation through the knee joint) |
| LC-5* | Locomotor Capability Index. The patient's perception of his ability to move, 0-56 and which consists of the sum of two subscales each 0-28 |
| MHFA | Mid/Hind foot amputation (amputation through mid foot or heel) |
| Primary amputation | First intervention for a condition requiring amputation per side |
| Primary amputation level | The level chosen at the time of the primary amputation |
| PROM* | Patient-reported outcome measure |
| Prosthetic Use Score* | Self-estimated report of time the prosthesis is used during a typical week, 0-100 |
| Re-amputation | Renewed amputation procedure to a higher level (through or proximal to the next joint) on a limb where a previous amputation has not yet healed |
| Revision | Surgical intervention of such an extent as to require an operating room, with debridement of amputation wound/removal of soft tissue and/or bone, but at unchanged classification of amputation level |
| Slutlig amputationsnivå | The level that was present at healing or death without healing |
| TFA | Transfemoral amputation (amputation through the thigh bone) |
| Timed - Up and Go Test (TUG) | A standardized functional test measured in seconds |
| TPHD | Transpelvic amputation/Hip disarticulation (amputation through pelvis or hip joint) |
| TTA | Transtibial amputation (amputation through tibia/fibula) |

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

See website www.swedeamp.com for references