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# Poor survivorship of total ankle replacements. 1368 cases from the period 1994–2021 in the Norwegian arthroplasty register

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A R T I C L E I N F O

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A B S T R A C T

*Background and purpose:* The aim of the study was to present the performance of total ankle replacements (TAR) in a national register.
*Methods:* All surgeons in the country report to the Norwegian Arthroplasty Register. The completeness of primary TARs in NAR was 79–90% in the years 2017–2020. Cox regression analyses and the Kaplan-Meier method were used to study implant survival and revision risk.
*Results:* 1368 primary TAR´s were implanted in 1266 patients during the period 1994–2021. The last few years saw a marked decrease in the incidence of TARs. The overall survival at 5 years was 81.1% (80.9–81.3) and 69.3% (66.4–72.2) at 10 years. Higher age was strongly associated with better survival. Current prosthesis designs had a better survival than earlier designs ((HRR 0.7, 95% CI 0.6–0.9)
*Conclusion:* Revision rates were high in our registry, but current implants had better survival. Younger age increased the risk of revision.
*Level of evidence:* Level II: prospective cohort study
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## 1. Introduction

End-stage ankle arthritis is a debilitating condition, and in contrast to total hip and knee replacements the role of total ankle replacement (TAR) is still controversial. TAR has been available since the 1970 ´s and every decade since has seen new generations of ankle implants.

Currently total hip and knee replacements have a 10-year survival of around 95% [1]. The longevity of TAR is poorer; the Norwegian Arthroplasty Register (NAR) published a study in 2007 [2] with a 10-year survival of 76%, and the latest study from the Swedish Ankle Registry (SwedAnkle) in 2020 showed a 10-year survival of 74% [3].

National joint register data on TAR are available from Sweden [3–5], Finland [6], England and Wales [7], Australia [8], New Zealand [9,10] and Norway [2]. In these registers, the primary outcome is any component revision. 5 year survival of the implants ranges from 85% in Swedankle to 93.6% in the England and Wales registry [7]. The latter register acknowledges that underreporting of revisions to arthrodesis is a serious concern.

The aim of this study was to present long-term survivorship data for primary total ankle replacements, and to identify if gender, age, prosthesis brand, mobile or fixed bearing design, diagnosis or period of surgery were associated with the risk of revision. We also wanted to compare the survivorship of early and current designs of TAR, and to present the types of revisions that are done on failed TARs.

## 2. Materials and methods

### 2.1. The register and the patients

The Norwegian Arthroplasty Register (NAR) was established in 1987 as a hip arthroplasty register and was extended to include all other joint replacements including TAR in 1994. All Norwegian surgeons report primary and revision TARs to NAR. The completeness of registration in the register was evaluated in 2017–2018 and 2019–2020 by comparing it with the Norwegian Patient Register (NPR), where NCSP-codes for all Norwegian patients are recorded.

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This showed that 79–90% of primary TARs were reported to NAR, while 68–77% of TAR revisions were reported [11] [12].

### 2.2. Analyses and statistics

All prosthesis brands that had more than 50 registrations were analyzed separately. The remaining designs were analyzed together in the "other" group. Full references for prosthesis brands are found in the appendix, along with a breakdown of the "other" group. The prosthesis brands were grouped into "early designs" (STAR, Norwegian TPR, CCI and AES) and "current designs" (the remaining designs) and the survivorship of these two groups were compared. The prosthesis brands were also grouped according to whether the polyethylene component was fixed or mobile relative to the tibial component. Only brands with more than 50 registrations were included in the latter analysis.

It was possible to record more than one diagnosis, and more than one reason for revision and type of revision surgery on the same operation. Hierarchical lists were made, so that each patient had only one reason for revision in the analyses. For example, infection was always recorded as the primary reason when other causes also were recorded. Conversely pain was only recorded as a cause of revision when there were no other causes stated. Similar hierarchical lists were made for the types of reoperations, and these lists are available in the appendix.

Survival probabilities were calculated using the Kaplan-Meier method. The main end point was revision, defined as the removal or exchange of any of the three prosthetic components. When fewer than 10 patients remained at risk, the curves were terminated. Cox regression analyses were used to study the effect of age, gender, prosthesis brand, type of bearing, diagnosis and time period of surgery on the revision risk, adjusted for age, gender and diagnosis. Death dates of the patients were obtained from Statistics Norway, and the patients that had died during the study period were censored from the day of their death. No missing data were imputed. Bilateral TARs were treated as two separate registrations. P-values of less than 0.05 were considered statistically significant, and 95% confidence intervals were also used to indicate statistical significance.

### 2.3. Ethical issues and funding

The registry is approved by the Norwegian data inspectorate (reference number 03/00058–20/CGN), and the study has been conducted in accordance with Norwegian and EU data protection legislation. The patients provided a written consent to registration. The study had no external funding.

## 3. Results

### 3.1. Primary procedures

During the period 1994–2021, 1368 primary TARs were performed in 1266 patients. The incidence of primary procedures was highest between 2008 and 2016 with approximately 80–90 procedures annually. Since 2016 there has been a decrease in the number of procedures, which coincides with a large drop in the number of hospitals that offer ankle replacement surgery (Table 1). In 2015, 7 hospitals performed TARs, but between 2019 and 2021 only 2 hospitals did TARs in our country.

Table 2 shows baseline data for the different prosthesis brands.

Fig. 1 shows the primary diagnosis by year, showing that inflammatory arthritis was the dominant diagnosis until around 2003.

### 3.2. Survival analyses

The Kaplan Meier implant survival for all the TARs combined was 81.1% (80.9–81.3)) at 5 years, 69.3% (66.4–72.2) at 10 years and 59.3% (55.4–63.2) at 15 years **(**Table 3**).**

The survival curves of the different implant designs are shown in Fig. 2. The TM arthroplasty had a significantly better survival than the STAR in the adjusted Cox-regression, while the Salto Talaris implant had better survival bordering on significance ($p = 0.06$) (Table 3).

The survival of TARs stratified by diagnosis are shown in Fig. 3.

There was an increasing risk of revision with decreasing patient age at the time of surgery, visualized in Fig. 4. These differences were significant in the Cox regression analysis, see Table 3. There was a large difference in survival between the age groups, the oldest age group (age 75 +) had a 10-year survival of 87.2% while the youngest group (< 45) had a 10-year survival of 54.6% (Table 3).

Gender did not significantly affect the survivorship. Patients operated in the time period 2002–2007 had a higher risk of revision (HRR 1.5, 95% CI 1.0–2.2) compared to the first period, Kaplan Meier curves are presented in Fig. 5. When arthroplasty brands were grouped into 'early' and 'current' designs, we found a lower risk of revision for the latter (HRR 0.7, 95% CI 0.6–0.9), visualized in Fig. 6. Fixed bearing implants also had better survival than mobile bearing implants (HRR 0.7, 95% CI 0.5–0.9).

### 3.3. Revision surgery

Twenty-eight percent of the TARs were revised at least once. The indications for revisions are seen in Table 4. The most frequent indication for revision was polyethylene fracture or wear, which occurred in 6.2% of all cases, but was only seen in the mobile bearing designs (STAR, Mobility, CCI).

The STAR arthroplasty had the highest proportion of prostheses revised due to polyethylene fracture or wear, at 12.8%.

Polyethylene exchange was the most common revision procedure, followed by ankle fusion. This is presented **in** Table 5, where the procedures are tabulated with the indications for revision.

## 4. Discussion

### 4.1. Revision rates

In the present study the survival of primary total ankle replacements was lower than in many single centre studies. There may be several reasons for this. Many of the procedures recorded are from low-volume centres, and these registry data presents the "real life" results of average surgeons and average patients. Some other registry studies also report a much higher survival than ours, for example a study from the UK registry where the 5 year survival was 93.6 [7].

Surprisingly, the survival of TARs operated in the most recent period (2014–2021) is similar to those operated between 1994 and 2001. There may be several reasons for this. In the early period, inflammatory joint disease was by far the most common indication. These patients often had multiple joint disease and a very low physical function. In these patients, the threshold to revise is presumably higher as the patients often accept a higher degree of pain and dysfunction, and it is possible that many failed implants were not revised in this early period. In addition, the implants available for revision to a new replacement or a fusion were much more primitive at that time than in the later periods.

### 4.2. Early versus current designs

We found a better survival of the current prosthesis designs. This was also reported from Swedankle [3].

**Table 1**
Number of primary procedures per implant brand and number of hospitals performing TAR year by year during the inclusion period 1994–2021.

| | Mobile bearing | | | Fixed bearing | | | Other brands combined | Number of hospitals | Total |
|---|---|---|---|---|---|---|---|---|---|
| | STAR | Mobility | CCI | Salto Talaris | TM Total Ankle | INFINITY | | | |
| 1994 | 0 | 0 | 0 | 0 | 0 | 0 | 11 | 5 | 11 |
| 1995 | 0 | 0 | 0 | 0 | 0 | 0 | 8 | 6 | 8 |
| 1996 | 7 | 0 | 0 | 0 | 0 | 0 | 10 | 6 | 17 |
| 1997 | 5 | 0 | 0 | 0 | 0 | 0 | 3 | 3 | 8 |
| 1998 | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 2 |
| 1999 | 22 | 0 | 0 | 0 | 0 | 0 | 0 | 5 | 22 |
| 2000 | 19 | 0 | 0 | 0 | 0 | 0 | 0 | 5 | 19 |
| 2001 | 32 | 0 | 0 | 0 | 0 | 0 | 0 | 6 | 32 |
| 2002 | 36 | 0 | 0 | 0 | 0 | 0 | 0 | 7 | 36 |
| 2003 | 25 | 0 | 0 | 0 | 0 | 0 | 0 | 3 | 25 |
| 2004 | 34 | 0 | 0 | 0 | 0 | 0 | 5 | 4 | 39 |
| 2005 | 36 | 0 | 0 | 0 | 0 | 0 | 4 | 6 | 40 |
| 2006 | 62 | 0 | 0 | 0 | 0 | 0 | 1 | 7 | 63 |
| 2007 | 52 | 4 | 0 | 0 | 0 | 0 | 2 | 8 | 58 |
| 2008 | 59 | 2 | 4 | 0 | 0 | 0 | 1 | 9 | 66 |
| 2009 | 57 | 26 | 12 | 0 | 0 | 0 | 1 | 8 | 96 |
| 2010 | 40 | 26 | 13 | 0 | 0 | 0 | 0 | 9 | 79 |
| 2011 | 50 | 16 | 17 | 0 | 0 | 0 | 7 | 9 | 90 |
| 2012 | 39 | 12 | 12 | 0 | 0 | 0 | 19 | 10 | 82 |
| 2013 | 38 | 15 | 11 | 22 | 0 | 0 | 6 | 9 | 92 |
| 2014 | 0 | 0 | 9 | 61 | 3 | 0 | 1 | 6 | 74 |
| 2015 | 1 | 0 | 0 | 84 | 3 | 0 | 1 | 7 | 89 |
| 2016 | 0 | 0 | 0 | 80 | 16 | 0 | 1 | 6 | 97 |
| 2017 | 0 | 0 | 0 | 27 | 22 | 2 | 3 | 4 | 54 |
| 2018 | 0 | 0 | 0 | 35 | 20 | 11 | 5 | 4 | 71 |
| 2019 | 0 | 0 | 0 | 0 | 8 | 29 | 3 | 3 | 40 |
| 2020 | 0 | 0 | 0 | 0 | 1 | 25 | 3 | 2 | 29 |
| 2021 | 0 | 0 | 0 | 0 | 5 | 21 | 3 | 2 | 29 |
| Total | 616 | 101 | 78 | 309 | 78 | 88 | 98 | | 1368 |

**Table 2**
Baseline characteristics of the patients with the different prosthesis brands.

| All | All 1368 | STAR 616 | Salto Talaris 309 | CCI 78 | Mobility 101 | TM 78 | Infinity 88 | Others 98 |
|---|---|---|---|---|---|---|---|---|
| Age | | | | | | | | |
| ≤ ***60*** | 609 (44%) | 311 (50%) | 118 (38%) | 41 (53%) | 35 (35%) | 32 (41%) | 23 (26%) | 49 (50%) |
| >***60*** | 759 (56%) | 305 (50%) | 191 (62%) | 37 (47%) | 66 (65%) | 46 (59%) | 65 (74%) | 49 (50%) |
| Gender | | | | | | | | |
| Men | 634 (46%) | 263 (43%) | 155 (50%) | 45 (58%) | 43 (43%) | 51 (65%) | 39 (44%) | 38 (39%) |
| Women | 734 (54%) | 353 (57%) | 154 (50%) | 33 (42%) | 58 (57%) | 27 (35%) | 49 (56%) | 60 (61%) |
| Diagnosis: | | | | | | | | |
| Fracture sequela | 425 (31%) | 195 (32%) | 92 (30%) | 33 (42%) | 30 (30%) | 26 (33%) | 15 (17%) | 34 (35%) |
| Inflammatory | 392 (29%) | 213 (35%) | 73 (24%) | 3 (4%) | 30 (30%) | 8 (10%) | 22 (25%) | 43 (44%) |
| Ligament injury | 176 (13%) | 30 (5%) | 67 (22%) | 21 (27%) | 4 (4%) | 24 (31%) | 21 (24%) | 9 (9%) |
| Primary Osteoarthritis | 317 (23%) | 155 (25%) | 65 (21%) | 20 (26%) | 34 (34%) | 18 (25%) | 18 (21%) | 7 (7%) |
| Other | 58 (4%) | 23 (4%) | 12 (4%) | 1 (1%) | 3 (3%) | 2 (3%) | 12 (14%) | 5 (5%) |

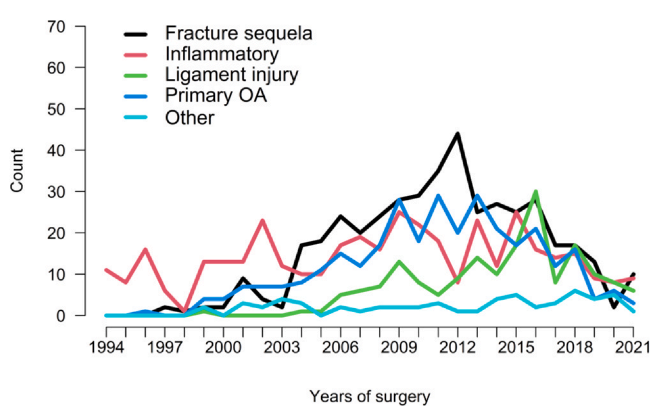


**Fig. 1.** Indications for ankle replacements by year.

There may be several reasons for a lower revision rate in the newer implants. The introduction of these implants coincides with a centralization of these procedures to fewer centers. There are many possible biases in this analysis, and one cannot conclude that the implants themselves are better, although it is one of several possible explanations.

Another concept that is largely overlapping with “current” and “early” implants is that of fixed and mobile bearing. As these groups are almost identical, it is difficult to evaluate the importance of the mobile bearing design by itself, but from our data we can see that polyethylene wear and fracture only occurred in mobile bearing implants, in line with findings in a study from the US Food and Drug Administration, where polyethylene-related revisions were almost exclusively reported in mobile bearing TARs [13]. Also the recently published TARVA study found inferior results with *current* mobile-bearing TAR´s compared to current fixed bearing implants [14].

### 4.3. Indications for revision

The most common indication for revision was polyethylene wear or breakage, which predominantly was a problem with the mobile bearing STAR and Mobility brands, and no cases of polyethylene breakage or wear were recorded in fixed bearing implants. The

**Table 3**
Cox-regression results and Kaplan-Meier survival analysis.

| | N (%) | Revisions | HRR | 95% CI | p | 5 yrs survival | 10 yrs survival | 15 yrs survival |
|---|---|---|---|---|---|---|---|---|
| All | 1368 | 386 | - | - | - | 81.1 (80.9–81.3) | 69.3 (66.4–72.2) | 59.3 (55.4–63.2) |
| *Gender* | | | | | | | | |
| Males | 634 (46%) | 184 | 1.1 | 0.9–1.4 | 0.24 | 80.8 (77.5–84.1) | 65.6 (61.1–70.1) | 54.3 (47.2–61.4) |
| Females | 734 (54%) | 202 | 1 | | | 81.7 (78.8–84.6) | 72.1 (68.4–75.8) | 62.5 (57.6–67.4) |
| *Age groups* | | | | | | | | |
| Under 45 years old | 180 (13%) | 88 | 2.5 | 1.9–3.3 | < 0.001 | 70.1 (63.2–77.0) | 54.6 (46.6–62.6) | 42.3 (33.5–51.1) |
| 45–59 | 428 (31%) | 156 | 1.7 | 1.4–2.2 | < 0.001 | 77.5 (73.4–81.6) | 61.2 (55.9–66.5) | 50.5 (43.6–57.4) |
| 60–74 | 585 (43%) | 122 | 1 | | | 85.2 (82.3–88.1) | 77.0 (72.9–81.1) | 68.6 (62.7–74.5) |
| 75 and older | 175 (13%) | 20 | 0.6 | 0.4–1.0 | 0.042 | 89.1 (84.4–93.8) | 87.2 (81.9–92.5) | - |
| *Diagnosis* | | | | | | | | |
| Fracture sequela | 425 (31%) | 131 | 1 | | | 79.8 (75.9–83.7) | 68.1 (63.0–73.2) | 55.5 (47.7–63.3) |
| Inflammatory disease | 392 (29%) | 96 | 0.8 | 0.6–1.0 | 0.056 | 85.1 (81.4–88.8) | 75.7 (70.8–80.6) | 65.8 (59.3–72.3) |
| Ligament injury/instability | 176 (13%) | 46 | 1.2 | 0.9–1.7 | 0.22 | 78.7 (72.0–85.4) | 60.6 (49.6–71.6) | - |
| Primary osteoarthritis | 317 (23%) | 95 | 1.2 | 0.9–1.6 | 0.15 | 80.6 (76.1–85.1) | 67.7 (61.8–73.6) | 57.5 (49.3–65.7) |
| Other | 58 (4%) | 18 | 1.0 | 0.6–1.7 | 0.91 | 72.9 (60.0–85.8) | 62.1 (46.2–78.0) | - |
| *Prosthesis brand* | | | | | | | | |
| STAR | 616 (45%) | 233 | 1 | | | 80.1 (77.0–83.2) | 67.3 (63.4–71.2) | 56.6 (51.9–61.3) |
| Salto Talaris | 309 (23%) | 53 | 0.7 | 0.5–1.0 | 0.06 | 93.5 (89.2–97.8) | - | - |
| CCI | 78 (6%) | 31 | 1.2 | 0.8–1.7 | 0.39 | 71.3 (61.1–81.5) | 56.9 (44.9–68.9) | - |
| Mobility | 101 (7%) | 29 | 0.9 | 0.6–1.4 | 0.74 | 76.8 (68.4–85.2) | 70.1 (60.9–79.3) | - |
| TM | 78 (6%) | 7 | 0.5 | 0.2–1.0 | 0.044 | 90.5 (83.8–97.2) | - | - |
| Infinity | 88 (6%) | 4 | 0.5 | 0.2–1.4 | 0.20 | - | - | - |
| Others | 98 (8%) | 29 | 0.8 | 0.9–1.4 | 0.80 | 84.4 (77.0–91.8) | 71.5 (61.3–81.7) | 61.9 (48.4–75.4) |
| *Design group* | | | | | | | | |
| Early | 729 (53%) | 276 | 1 | | | 79.7 (76.8–82.6) | 66.5 (63.0–70.0) | 56.1 (51.8–60.4) |
| Current | 639 (47%) | 110 | 0.7 | 0.6–0.9 | 0.014 | 83.2 (80.1–86.3) | 76.6 (71.9–81.3) | - |
| *Year of surgery* | | | | | | | | |
| 1994–2001 | 119 (9%) | 35 | 1 | | | 88.8 (83.1–94.5) | 80.5 (72.9–88.1) | 68.5 (58.7–78.3) |
| 2002–2007 | 327 (24%) | 143 | 1.5 | 1.0–2.2 | 0.049 | 78.0 (73.5–82.5) | 63.6 (58.1–69.1) | 53.6 (47.7–59.5) |
| 2008–2013 | 439 (32%) | 145 | 1.4 | 0.9–2.1 | 0.11 | 78.1 (74.2–82.0) | 66.4 (61.7–71.1) | - |
| 2014–2021 | 483 (35%) | 63 | 0.9 | 0.6–2.5 | 0.92 | 85.2 (81.7–88.7) | - | - |
| *Bearing* | | | | | | | | |
| Mobile bearing | 795 (63%) | 293 | 1 | | | 79.0 (76.1–81.9) | 66.7 (63.4–70.0) | 57.0 (52.7–61.3) |
| Fixed bearing | 475 (37%) | 64 | 0.7 | 0.5–0.9 | 0.004 | 85.2 (81.7–88.7) | - | - |

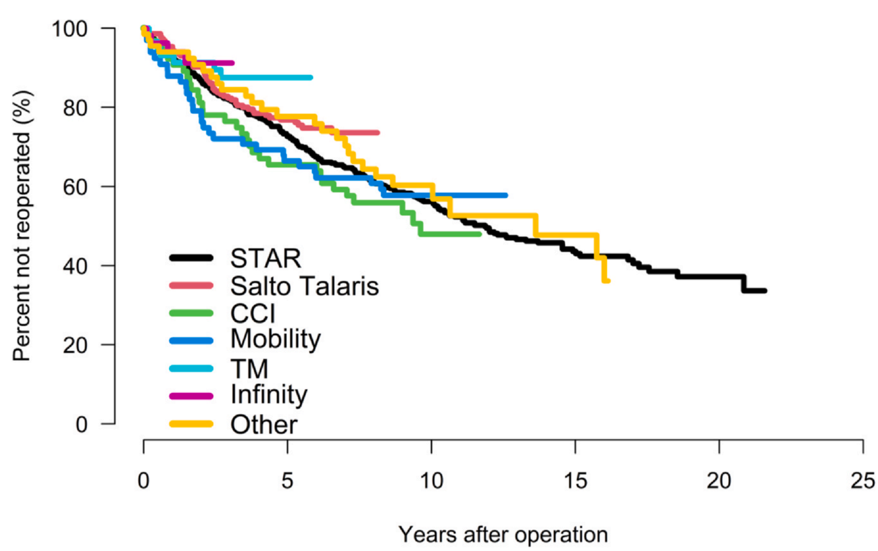


**Fig. 2.** Survival of ankle replacements by prosthesis brand.

second and third most common reason for revision was aseptic loosening of the talar and tibial components. In the two implant brands currently in use (TM and Infinity) we have recorded only one case of aseptic loosening in the 168 implants reported, and there is hope that these newer implants will perform better regarding this problem, but still the follow up time is too short to conclude.

### 4.4. Decreased incidence of TAR

The last few years have seen a decline in the number of TARs in Norway. In 2016, 97 cases were done on 4.2 million inhabitants over the age of 15, that is 2.3 alloplasties pr $10^5$ inhabitants. In 2020, this number had decreased to 0.6 per $10^5$. This is the same incidence as Sweden had in 2016 [3], and they had also experienced a decline in the incidence since 2010, although not as marked as in Norway. In the other registries the incidence has been relatively stable the last decade, with Finland and Australia having approximately the same incidence as Norway, while New Zealand has almost three times as many replacements per population [15].

One main reason for the decline in Norway is probably the decrease in the number of hospitals offering this type of surgery. Also, modern treatment of inflammatory arthritis has also decreased the

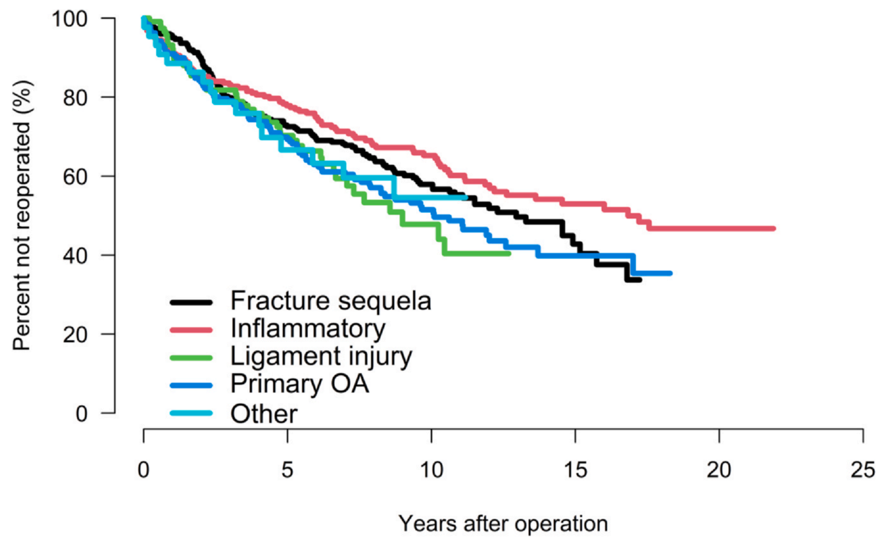


**Fig. 3.** Survival of ankle replacements by diagnosis.

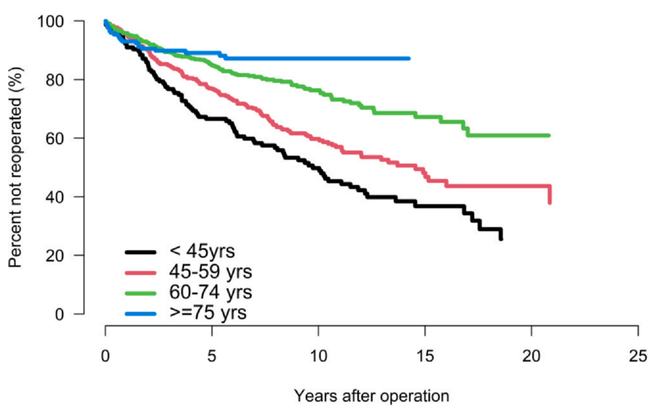


**Fig. 4.** Survival of ankle replacements by age group.

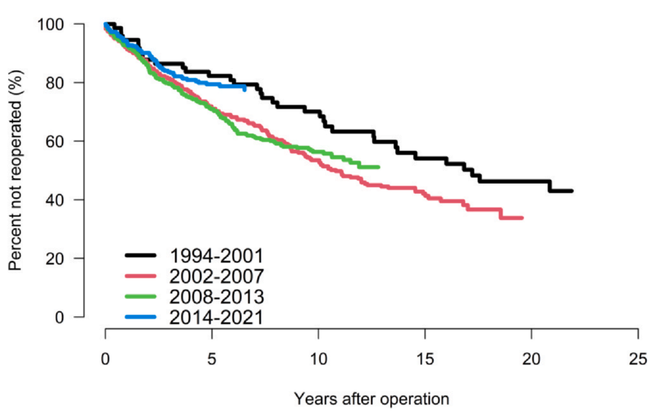


**Fig. 5.** Survival of ankle replacements by period of surgery.

demand for ortopedic surgery in this specific patient group, but this effect should be similar in other high-income countries, where a similar decrease in the frequency of TAR has not been seen. Most likely the covid-19 pandemic also has had an effect on the number of elective surgeries done in 2020 and 2021, and it is possible that the recent decrease is not as substantial as it seems from the numbers reported.

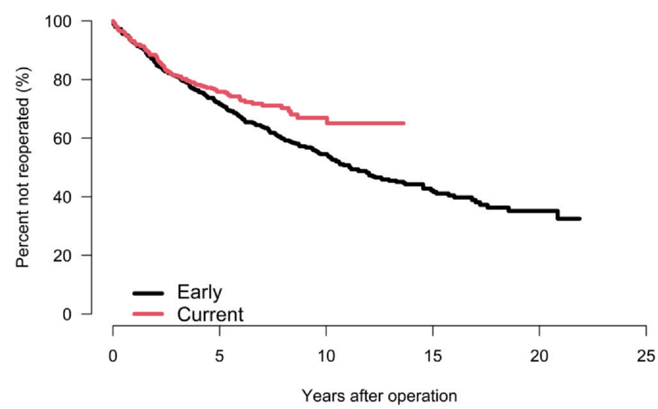


**Fig. 6.** Survival of ankle replacements by early or current designs.

### 4.5. Age

Our study showed that younger patients had a high risk of revision, and that this risk decreased with increasing age. The effect of age on the results of ankle alloplasty is controversial, and two single center studies with 811 [16] and 395 [17] patients found no effect of age on the revision risk. In the UK [7], the Swedish [4,5] the New Zealand [10] and the Australian [8] registries they also found that increasing age at the primary operation was associated with a lower risk of revision.

The effect of age that we demonstrate in this paper is quite large, and the risk of revision within 10 years is tripled for a patient under 45 compared to one over 75. This is important information when advising patients about ankle replacement, and it supports the notion that ankle replacement is most suitable for the population over the age of 60.

### 4.6. Strengths and limitations

The strength of a registry study is that it collects data from a large population without selection of patients, implants or surgeons. Thus the outcomes presented are realistic for patients and surgeons in similar settings, and the external validity will often be higher than results from highly specialized centers. This gives us a viewpoint that is invaluable when evaluating the effect of ankle replacements from a society´s perspective.

**Table 4**
Indications of revision for each prosthesis brand.

| | STAR | Salto Talaris | CCI | Mobility | TM | Infinity | Other | Total |
|---|---|---|---|---|---|---|---|---|
| No revision | 383 | 256 | 47 | 72 | 71 | 84 | 69 | 982 |
| | 62,2% | 82,8% | 60,3% | 71,3% | 91,0% | 95,5% | 70,4% | 71,8% |
| Infection | 9 | 5 | 0 | 5 | 3 | 1 | 1 | 24 |
| | 1,5% | 1,6% | 0,0% | 5,0% | 3,8% | 1,1% | 1,0% | 1,8% |
| Aseptic loosening talus | 27 | 13 | 12 | 5 | 0 | 0 | 12 | 69 |
| | 4,4% | 4,2% | 15,4% | 5,0% | 0,0% | 0,0% | 12,2% | 5,0% |
| Aseptic loosening tibia | 22 | 8 | 11 | 3 | 0 | 1 | 6 | 51 |
| | 3,6% | 2,6% | 14,1% | 3,0% | 0,0% | 1,1% | 6,1% | 3,7% |
| Polyethylene wear/fracture | 79 | 0 | 1 | 5 | 0 | 0 | 0 | 85 |
| | 12,8% | 0,0% | 1,3% | 5,0% | 0,0% | 0,0% | 0,0% | 6,2% |
| Fracture | 8 | 2 | 1 | 0 | 1 | 1 | 0 | 13 |
| | 1,3% | 0,6% | 1,3% | 0,0% | 1,3% | 1,1% | 0,0% | 1,0% |
| Instability/dislocation | 12 | 1 | 2 | 1 | 0 | 0 | 1 | 17 |
| | 1,9% | 0,3% | 2,6% | 1,0% | 0,0% | 0,0% | 1,0% | 1,2% |
| Axis deviation | 18 | 5 | 1 | 3 | 0 | 1 | 2 | 30 |
| | 2,9% | 1,6% | 1,3% | 3,0% | 0,0% | 1,1% | 2,0% | 2,2% |
| Pain alone | 38 | 13 | 3 | 7 | 3 | 0 | 4 | 68 |
| | 6,2% | 4,2% | 3,8% | 6,9% | 3,8% | 0,0% | 4,1% | 5,0% |
| Other | 20 | 6 | 0 | 0 | 0 | 0 | 3 | 29 |
| | 3,2% | 1,9% | 0,0% | 0,0% | 0,0% | 0,0% | 3,1% | 2,1% |
| Total | 616 | 309 | 78 | 101 | 78 | 88 | 98 | 1368 |

**Table 5**
Type of revision for each cause of revision.

| | Exchange of the whole TAR | Exchange proximal component | Exchange distal component | Soft tissue debridement | Polyethylene exchange | Ankle fusion | Removal of TAR component | Other | Total |
|---|---|---|---|---|---|---|---|---|---|
| Infection | 1 | 0 | 0 | 9 | 5 | 0 | 8 | 1 | 24 |
| Aseptic loosening talus | 28 | 1 | 6 | 0 | 0 | 27 | 6 | 1 | 69 |
| Aseptic loosening tibia | 10 | 30 | 0 | 0 | 1 | 4 | 6 | 0 | 51 |
| Polyethylene wear/fracture | 3 | 7 | 1 | 0 | 61 | 11 | 0 | 2 | 85 |
| Fracture | 2 | 0 | 1 | 0 | 3 | 5 | 1 | 1 | 13 |
| Instability/dislocation | 0 | 1 | 2 | 0 | 7 | 5 | 2 | 0 | 17 |
| Axis deviation | 8 | 8 | 3 | 0 | 4 | 5 | 0 | 2 | 30 |
| Pain alone | 6 | 11 | 2 | 1 | 29 | 13 | 4 | 2 | 68 |
| Other | 4 | 6 | 0 | 0 | 15 | 1 | 0 | 3 | 29 |
| Total | 62 | 64 | 15 | 10 | 125 | 71 | 27 | 12 | 386 |

There are however several biases inherent in registry studies that makes it difficult to draw firm conclusions. One major problem with registry studies in general, and in this one specifically, is under-reporting. In our registry the reporting of TAR is lower than hip and knee replacements, and only 68.2% of revisions were registered in 2019/20 [12]. This affects the accuracy of our findings. The method of validation is not 100% accurate, as data from the Norwegian Patient Registry is viewed as the "gold standard". Our experience suggests that this is often not correct, as the NPR may have double recordings. This issue has not yet been studied adequately for TARs, and should be a research priority for the registry.

Another important source of bias is the surgeon. Technical skills, indications for surgery, indications for revision and reporting practice may differ from surgeon to surgeon and may produce very different results. The last few years only 4–5 surgeons have been doing ankle replacements in our country, and therefore surgeon factors may have a large impact on the results.

## 5. Conclusion

The implant survivorship of total ankle replacement in our national register is consistently poor. Current fixed bearing prosthesis designs had better survival than earlier designs. Younger age increased the risk of revision, and patients should be advised accordingly.

## Declaration of Competing Interest

We hereby declare that none of the authors have associations or financial involvement (i.e. consultancies/advisory board, stock ownerships/options, equity interest, patents received or pending, royalties/honorary) with any organizations or commercial entities having a financial interest in or financial conflict with the subject matter or research presented in the manuscript.

## Appendix

| | |
|---|---|
| *Hierarchical list of diagnoses* | |
| 1 | Posttraumatic osteoarthritis |
| 2 | Inflammatory disease |
| 3 | Sequela to ligament injury |
| 4 | Primary osteoarthritis |
| 5 | Other |
| *Hierarchical list of revision procedures* | |
| 1 | Exchange of the whole TAR |
| 2 | Exchange of the tibia component |
| 3 | Exchange of the talar component |
| 4 | Soft tissue debridement |
| 5 | Polyethylene exchange |
| 6 | Ankle fusion |
| 7 | Only removal of component |
| 8 | Other |
| *Hierarchical list of indications for revision* | |
| 1 | Infection |
| 2 | Aseptic loosening talus |
| 3 | Aseptic loosening tibia |
| 4 | Polyethylene fracture/wear |
| 5 | Fracture |
| 6 | Instability or luxation |
| 7 | Axis deviation |
| 8 | Pain |
| 9 | Other |

| *TAR brands with less than 50 registrations* | *Number of primary operations* |
|---|---|
| Norwegian TPR (fixed bearing) | 32 |
| AES (mobile bearing) | 3 |
| Hintegra (mobile bearing) | 11 |
| Rebalance (mobile bearing) | 15 |
| Salto Mobile (mobile bearing) | 12 |
| Cadence (fixed bearing) | 8 |
| Infinity with Inbone talus (fixed bearing) | 6 |

| *Full reference to the main prosthesis brands and current ownership* | | |
|---|---|---|
| STAR | Scandinavian Total Ankle Replacement | Stryker Corporation, Kalamazoo, Michigan, USA. |
| Salto Talaris | | Smith & Nephew, Watford, England |
| CCI | Ceramic Coated Implant Evolution | Wright Medical Technology, Arlington. Discontinued. |
| Mobility | | DePuy International, Leeds, UK. Discontinued |
| TM | Trabecular Metal Total Ankle) | Zimmer inc, Warsaw, Indiana, USA |
| Infinity | | Stryker Corporation, Kalamazoo, Michigan, USA. |

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