

## Review

## Total ankle arthroplasty and national registers: What is the impact on scientific production?

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## ABSTRACT

**Purpose:** The purpose of this systematic review was to analyze clinical studies on total ankle replacement (TAR) whose data were extracted from national registers.

**Methods:** A systematic review of the literature, to identify all studies reporting outcomes after TAR, was performed. Two independent investigators performed the research using MEDLINE, CINAHL (Cumulative Index to Nursing and Allied Health Literature), Embase and Cochrane Databases (1950 to December 2017). The search terms used were “total ankle replacement” or “total ankle arthroplasty” AND “register” or “registers” or “registry” or “registries” or “national registry” or “national register”.

**Results:** Analysis of the literature included 18 articles from 2007 to 2017. Of these 5 articles performed a comprehensive analysis of the national registers, 5 articles evaluated complications and reasons of failure after TAR, 6 articles made a specific outcome register analysis, one article compared TAR and ankle arthrodesis while the last one analyzed the role of TAR in patients with rheumatoid arthritis.

**Conclusions:** Scientific publications extracted from national joint registers for total ankle replacement provide useful but heterogeneous information on implants survivorship, implant models and risk factors. There is still a discrepancy between the data reported by designers in clinical studies and the data reported by the registries. The centralization of registers in specialized hospitals with dedicated surgeons, the use of patient reported outcomes (PROMs) in association with surgeon assessments and periodical publications can improve the development of registries and consequently of the literature in this regard.

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## 1. Introduction

In recent years the number of countries that have adopted national joint registries throughout the world has greatly increased in order to evaluate and assess clinical and radiographic outcomes, safety and survivorship of the implants [1–3]. Most arthroplasty registers mainly concern hip and knee replacements, while only six (Australia, England/Wales/Northern Ireland, Finland, New Zealand, Norway, and Sweden) countries recruit and report the results of ankle prostheses [4–9]. The purpose of large-scale registers is to highlight results as accurately as possible annually; the quality of the data reported is heavily dependent on the participation of both the patients and surgeons [10]. In particular, these annual communications are extremely important in evaluating ankle replacement, which despite the advances in design and materials compared to the first generation of prostheses, still have many doubts over long-term durability. The data in the registers does not always correspond to that reported in the literature, in fact several studies have shown that there is a discrepancy in the survival of prosthetic implants between scientific literature and data in the registers [11–14]. Moreover a large percentage of the available scientific literature regarding total ankle replacement (TAR) is riddled with bias, secondary to industry sponsorship and inventor involvement [13,14]. The aim of this study was to review clinical studies on total ankle replacement whose data was extracted from national registers.

## 2. Material & methods

### 2.1. Search strategy

A systematic review of the literature, to identify all studies reporting outcomes after total ankle replacement, was performed. The Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) guidelines were followed for the identification of the articles [15]. Two independent investigators performed the research using MEDLINE, CINAHL (Cumulative Index to Nursing and Allied Health Literature), Embase, and Cochrane Databases (1950 to December 2017). The search terms used were “total ankle replacement” or “total ankle arthroplasty” AND “register” or “registers” or “national register” or “registry” or “registries”. Articles derived from different registers such as Rheuma Surgery or Nationwide Inpatient Sample or non-specific joint register were excluded. Also the references of relevant systematic review and meta-analysis were searched. Initially we found 1646 articles for consideration. After a first screening, 1618 records were excluded; of the remaining 32, 14 were excluded based on inclusion and exclusion criteria. Eighteen articles satisfied the criteria and were included in the systematic review (Fig. 1) [16–33].

### 2.2. Eligibility and exclusion criteria

#### 2.2.1. Types of studies

We included in this systematic review studies of level I, II, III and IV and systematic review. We excluded animal studies, biomechanical studies, in vitro studies and response to other articles.

#### 2.2.2. Data collection

Three independent reviewers analyzed all the information available from the articles (data and journal of publication, type of

study, demographics data, diagnosis, surgical procedure, follow-up duration, outcomes and complications) and entered into a spreadsheet for analysis. There were no disagreements among the reviewers at the end of the research.

#### 2.2.3. Type of articles

Considering the heterogeneity of the data present in the literature extracted from the registers we decided to divide the articles based on the primary outcomes into 5 categories:

- *Comprehensive analysis of the register.*
- *Failure Mode and complications.*
- *Specific outcome register analysis.*
- *Comparison between total ankle replacement and ankle arthrodesis.*
- *Total ankle replacement and rheumatoid arthritis.*

## 3. Results

Analysis of the literature included 18 articles from 2007 to 2016 [16–33]. Of these, 5 articles performed a comprehensive analysis of the national registers [16–20], 5 articles evaluated complications and reasons of failure after TAR [21–25], 6 articles made a specific outcome register analysis [26–31] one article compared outcomes and revision rate between TAR and ankle arthrodesis [32] and one article analyzed the role of TAR in patients with rheumatoid arthritis [33].

### 3.1. Comprehensive analysis of the register

Five articles analyzed in detail data extracted from Swedish, Norwegian, Finnish and New Zealand registers. A total of 2285 prosthesis were implanted and evaluated. In detail were 1118 (48.9%) STAR (Waldemar Link, Hamburg, Germany), 201 (8.8%) Buechel–Pappas (BP) prostheses (Wright Cremasoli, Toulon, France and Endotec, South Orange, NJ), 485 (21.2%) AES prostheses (Biomet, Nimes, France), 71 (3.1%) HINTEGRA prostheses (Newdeal, Lyon, France), 184 (8.1%) Mobility prostheses (DePuy International, Leeds, UK), 117 (5.1%) Agility Total Ankle System (DePuy International, Leeds, UK), 32 (1.4%) Thompson ParkridgeRichards (TPR) ankle prosthesis (Richards International, Memphis, TN), 66 (2.9%) Ceramic Coated Implant (CCI) mobile-bearing prosthesis (Wright Medical Technology, Arlington, TN) and the Ramses Total Ankle Arthroplasty (Laboratoire Fournitures Hospitalieres, Heimsbrunn, France) in 11 (0.5%) ankles.

The diagnoses were: rheumatoid arthritis in 903 (39.5%) patients, post-traumatic osteoarthritis in 643 (28.1%) patients, primary or idiopathic osteoarthritis in 600 (26.3%) patients and other forms of arthritis (psoriatic arthritis or ankylosing spondylitis, arthritis urica) or other diseases (hemophilia, hemochromatosis, sequelae of ligament damage, systemic lupus erythematosus) in 151 (6.6%). For percentage of diagnosis, more than one was allowed, as reported in the articles. A total of 369 (16.1%) ankles were revised and reasons were: aseptic loosening in 137 (37.1%) cases, instability in 62 (16.8%), malalignment/technical error in 47 (12.8%), infection in 40 (10.9%), fracture in 9 (2.4%), pain in 28 (7.6%), defect/wear/fracture of the polyethylene insert in 30 (8.1%), varus malalignment in 14 (3.8%) and other reasons in 2 (0.5%). The 5-year survival ranged from 0.78 to 0.90, and the 10-year survival rate ranged from 0.62 to 0.69 [15–19].

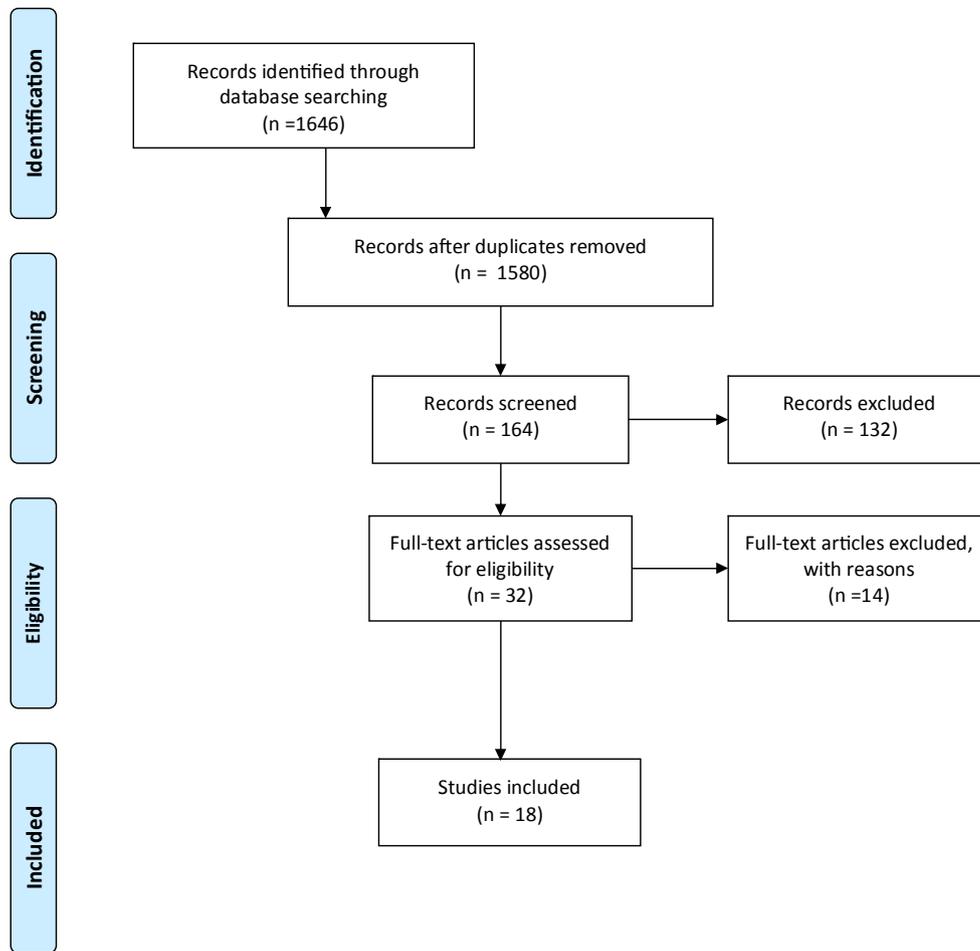


Fig. 1. A flowchart of the literature screening performed in this study.

### 3.2. Failure mode and complications

Five published articles presented in literature the complications related to TAR and failure mode, but due to the different outcomes it has been impossible to perform a quantitative analysis of all the articles, so each article has been discussed alone. In 2013, Sadoghi performed a complication based analysis in case of revision surgery of total ankle arthroplasty using worldwide arthroplasty registers summarizing relative likelihood of different causes for revision surgery [24]. One thousand one hundred and thirteen primary total ankle arthroplasty and 189 revisions were extracted from Norway and New Zealand registers and the author highlighted that the most common causes for revision surgery were aseptic loosening (38%), instability (8.5%), septic loosening (9.8%), periprosthetic fracture (2%), wear (8%), pain (12%), implant breakage (5.3%) and technical error (15%).

The same author investigated in 2014 the primary mode of failure of TAR implants using the Norwegian Register showing that there is no significant difference between any of the failure modes that are pertinent to the ankle [25].

In 2011, Labek compared data extracted from national registers with clinical studies, dividing for prosthesis model [23]. For STAR Ankle the revision rates showed statistically significant differences with the 0.68 revisions per 100 observed component years from the developers, while independent clinical studies found 2.7 revisions per 100 observed component years, and register data reported 4.09. For Buchel–Pappas clinical studies described 5.6 times more patients than registers. Of the registry patients, 16 (17.4%) had to be re-operated within the short follow-up time of 1.5 years on

average. Direct comparison revealed 14.3 times more revisions in the registry dataset than in inventor's studies and 7.5 times more in independent studies. For Agility Implant published data was not supported by the reference dataset from registries. As opposed to the registry dataset, independent studies showed a difference factor of 0.60, inventors' studies of 2.43. For Hintegra Implant no statistical difference has been reported for the revision rate between national registers and clinical studies, while for Mobility and Ramses clinical studies were not available and the only data was extracted from the New Zealand National Register.

Recently Zaidi published two clinical studies regarding complications and re-operation within 1 year after total ankle replacement and the risk of pulmonary embolism and mortality, with data extracted from the UK national joint register [21,22]. In 1185 procedures (1110 primary and 75 revisions) the 90-day mortality was 0.13% and 1-year mortality was 0.72%; no deaths were as a result of pulmonary embolism. The incidence of pulmonary embolism within 90 days following primary ankle replacement was 0.51%. There was only one pulmonary embolism following revision surgery. Patients with a Royal College of Surgeons Charlson score greater than zero were at 13 times greater risk [21].

In the other study Zaidi found that the rate of 30-day readmission following primary and revision ankle replacement was 2.2% and 1.3%, respectively [22]. In the 12 months following primary and revision ankle replacements, the revision rate (where implants needed to be removed) was 1.2% with increased odds in those orthopaedic units performing <20 ankle replacements per year and patients with a preoperative fixed equinus deformity. The

re-operation (other than revision, where implants were not removed) in the 12 months following primary and revision TARs was 6.6% and 9.3%, respectively. Rheumatoid arthritis, cemented prosthesis and high ASA grade significantly increased the odds of reoperation.

### 3.3. Specific outcome register analysis

Bartel in 2015 analyzed Kaplan–Meier survival curves after TAR among Australia, England, Wales, and Northern Ireland, Finland, New Zealand, Norway and Sweden national joint registry data sets to determine the survival rates between registries at 1-year intervals [26]. Five thousand one hundred and fifty two primary and 591 TAR revisions were evaluated over a 2 to 13-year period. Mean survival rates for primary TAR resulted 0.94 at 2 years, 0.87 at 5 years, and 0.81 at 10 years. The authors recreated Kaplan–Meier estimator curves to analyze the reproducibility of survivorship of each register at any time points. From this evaluation Bartel concluded that there were no difference in the Finnish Arthroplasty Register, The New Zealand Joint Registry and The Norwegian Arthroplasty Register between the reported values and the recreated values. A slight difference was found in The Swedish Ankle Registry while The Australian Orthopaedic Association (AOA) National Joint Replacement Registry and National Joint Registry for England, Wales and Northern Ireland provided reported data without supporting survival curves. The New Zealand Joint Registry reported a 13-year analysis on 944 primary TAR performed; 53 revisions and 6 re-revisions were performed out of the primary TAR group. The most common prosthesis implanted was the Mobility Total Ankle System ( $n = 443$ , 47%) followed by the Salto Mobile version ankle prosthesis ( $n = 316$ , 33%). Kaplan–Meier estimator was 0.98 at 2 years, 0.93 at 5 years, and 0.86 at 10 years. The Norwegian Arthroplasty Register reported a 13-year analysis on 720 primary TARs performed: 216 revisions were reported. The most common prosthesis implanted was the STAR ( $n = 537$ , 75%). The calculated Kaplan–Meier estimator was 0.91 at 2 years, 0.89 at 5 years, and 0.76 at 10 years. The Swedish Ankle Registry reported a 12-year analysis on 871 primary TARs performed: 208 revisions were reported. Several prosthesis were implanted, including the Mobility (27%), STAR (22%), BP (18%), CCI (15%) and AES (13%). The calculated Kaplan–Meier estimator was 0.87 at 2 years, 0.78 at 5 years, and 0.66 at 9 years. The AOA National Joint Replacement Registry reported a 6-year analysis on 1127 primary TARs performed: 72 revisions were reported. The 2 most common prosthesis implanted were the Mobility (44%), Hintegra total ankle prosthesis (23%), and Salto Mobile (18%) with a survivorship of 0.94 at 2 years and 0.90 at 5 years. The National Joint Registry for England, Wales and Northern Ireland reported a 5-year analysis on 999 primary TARs performed: 9 revisions were reported. The 2 most common prosthesis implanted were the Mobility (54%) and Zenith total ankle replacement (21%) with a Kaplan–Meier estimator of 0.99 at 2 years. The Finnish Arthroplasty Register reported a 7-year analysis on 491 primary TAR performed: 27 revisions were reported. The 2 most common prostheses implanted were the AES (61%) and STAR (37%). The calculated Kaplan–Meier estimator was 0.87 at 2 years, 0.78 at 5 years, and 0.66 at 9 years.

In 2013 Labek reviewed the most relevant results of worldwide register data to perform a comparison concluding that marked differences exist between Europe and Oceania with respect to indications [27]. All registers showed revision rates of approximately 10% at five years, of which about 40% of cases are for aseptic loosening. Inlay fractures are relatively common, which indicates potential for the improvement of implants. The documentation of intraoperative surgical errors leading to revision surgery varies significantly among registers. A relevant number of complications

are treated without an implant component being exchanged and therefore not covered by a register.

Recently Kamrad et al. [28], using data from the Swedish Ankle Registry, evaluated changes in PROMs after primary TAR and reported subjective satisfaction rates. PROMs included in the registry were the EQ-5D, the generic SF-36 and the region-specific SEFAS. Two hundred and forty one patients were included in the study (57% women) at a mean age of 62 years. TAR surgery was undertaken in 9 centers; 217 of the procedures (90%) were performed in 4 of these centers. PROM evaluations were completed by 133 patients after 6 months, 183 after 12 months and 167 after 24 months. TAR was performed for post-traumatic osteoarthritis in 90 patients (37%), in 67 (28%) RA in 59 (25%) idiopathic osteoarthritis (OA), and in 25 (10%) other reasons. The Rebalance prosthesis was used in 90 patients (37%), Mobility in 82 (34%), CCI in 61 (25%), and other prosthetic designs in 8 (4%). All absolute scores improved from preoperative to 24 months after surgery. Seventy one percent of the patients were satisfied or very satisfied at the latest follow-up and 12% dissatisfied or very dissatisfied.

In 2017, Muir [29] performed a review of the national registers highlighting the strengths and weaknesses. Among these the author stressed how about 50% of cases in outcome reports come from designer groups, with an average 9 to 10-year survival of 84% to 95%. Equivalent data from registries are more sobering. The annual failure rate of surgeon designers is 1.1% compared with non-designer series 1.7% and finally national joint registries of 3.2%. Moreover, the author highlights two major problems, still existing in the registers: the lack of guidelines to standardize type of complications, revision/re-operation and the use of PROMs, actually present only in Swedish and New Zealand National registers.

In 2013, Roukis and Prissel [30] performed a detailed observational analysis of the available worldwide registry data involving specific total ankle replacement use in an effort to determine any trends in usage of newly released designs and those that have fallen into disuse. The AOA “National Joint Replacement Registry” reported a total of 895 prostheses involving 10 different total ankle replacement systems. The most frequently implanted prosthesis was the Mobility (47%) followed by the Hintegra (22%). The National Joint Registry for England and Wales involved 464 prostheses of 7 different systems. The most frequently implanted prosthesis was the Mobility (57%) followed by the Zenith (22%). In Finland a total of 531 prostheses involving 5 different total ankle replacement systems were implanted. The most frequently implanted prosthesis was the LINK STAR (60%). The New Zealand National Joint Registry reported a total of 836 prostheses involving 6 different total ankle replacements. The most frequently implanted prosthesis was the Mobility (50%) followed by the Salto Mobile Prosthesis (29%). The use of the Agility and LINK STAR were abandoned in 2007. In Norway a total of 476 prostheses have been implanted, involving 5 different systems. The most frequently implanted prosthesis was the LINK STAR (87%) followed by the Mobility (7%). Finally The Swedish Joint Registry Register, including a total of 789 prostheses involving 6 different total ankle replacement systems were implanted. The most frequently implanted prosthesis was the Mobility (28%) followed by the LINK STAR (26%). However, the LINK STAR was abandoned in 2007. The Ankle Evolutive System and Buechel–Pappas were abandoned in 2008.

In 2015, Henricson and Carlsson [31] reported the long-term prosthetic survival and the number and type of complications following implantation of single and double-coated STAR prostheses reported to the Swedish Ankle Registry. All STARs ( $n = 324$ ) used in Sweden were included. The 14-year survival of the single-coated STAR was 0.47, and the 12-year survival of the double-coated STAR was 0.64. The revision rate was 40% for the high-volume surgeons and 46% for the low-volume surgeons.

### 3.4. Comparison between total ankle replacement and ankle arthrodesis

Only one recent study reported a comparison between TAR and ankle arthrodesis with data extracted from the Swedish Ankle Registry [32]. The article identified 20 patients with a TAR and a contralateral ankle arthrodesis but only sixteen were included in the study. Four patients had primary osteoarthritis, 3 post-traumatic osteoarthritis, 7 rheumatoid arthritis, one hemochromatosis and one psoriatic arthritis. Prosthesis models were respectively 4 STAR, 4 Mobility, 6 CCI and 2 AES. Previous or simultaneous subtalar fusion were performed in 4 patients with ankle replacement and in two other patients with ankle arthrodesis. Two patients underwent re-arthrodesis 28 and 58 months after the primary procedure because of non-union. Three patients had secondary surgery of their TARs. One patient was dissatisfied with the replaced ankle and 4 patients with their fused ankle. Thirteen patients with replaced ankles and 10 with arthrodesis were satisfied or very satisfied. Four patients reported a higher score for the fused ankle. Nine patients reported about the same scores for both ankles and were equally satisfied. All four patients with replaced ankle and subtalar fusion were satisfied with their ankles. No difference between TAR and ankle arthrodesis was detected in SEFAS score.

### 3.5. Total ankle replacement and rheumatoid arthritis

In 2013, Kokkonen determined the rates of primary ankle joint arthrodesis and TAR in patients with rheumatoid arthritis (RA) in Finland [33]. The author found that one third of all TARs in Finland are due to RA. Surgical procedures were performed in 14 different hospitals using 5 different implants: the LINK STAR, the AES, the Mobility, the Hintegra, and the CCI. It is interesting to note the shift from STAR to AES model in 2003. Trend of TAR in patients with RA showed an interesting increase from 1997 to 2003–2004 and then gradually decreased. Regression analysis confirmed the statistical significance of the declining trend in the incidence of primary ankle arthrodesis in patients with RA from 1997 to 2010, whereas no change was observed in the total incidence of ankle surgery in patients with RA (primary arthrodesis and TAR, pooled).

## 4. Discussion

The aim of this review was to identify the most relevant studies on TAR whose data was extracted from national registers. A total of 18 articles met our inclusion criteria, presenting different clinical outcomes [16–33]; in fact to perform a review a division of the articles in five different categories was necessary: Comprehensive analysis of the register; Failure Mode and complications; Specific outcome register analysis; Comparison between total ankle replacement and ankle arthrodesis; Total ankle replacement and rheumatoid arthritis.

The choice of dividing the articles shows how in scientific literature there is not yet a standard concerning main topics in publications deriving from the registers and the data are extrapolated as desired by the authors. Furthermore, while on one hand the number of TAR is constantly increasing [34–37], on the other the number of scientific publication deriving from national registers is decreasing, in fact only two articles were published in the current year (2017) [28,29].

In recent years the number of national registers is growing more and more, expanding also in the field of reconstructive and regenerative medicine [38–40] with the aim of recording every single procedure, but what impact does it have on scientific publications? First of all there is a risk of having conflicting data between literature and registers, especially when the articles are

published by the designers as reported in the article of Labek [23]; in fact, the author compared the outcome of specific TAR in clinical studies and in national registries. Clinical published articles reported a high degree of variation with a statistically significant difference compared to registry data. In detail the designers of STAR Ankle and BP total ankle implants published data which was statistically significantly superior to the outcome achieved in registries. Irrespective of the implant, the average revision rate to be expected according to the registry data available is 21.8% after 5 years, and 43.5% after 10 years. This can be explained by the long learning curve of the implants and the lack of individual outcomes in national registers, unlike knee and hip arthroplasty. In fact the outcomes of these two implants showed a difference of almost 300% between individual departments [23]. Moreover revision rates reported by designers show a statistical difference if compared with national registers, confirming another possible weak point of the scientific publications using the data of the registers. Also Muir [29], in his recent publication, highlighted the bias linked with designers reporting, an average 9 to 10-year survival of 84% to 95% in contrast with data reported in the national registers. Regarding annual failure in designers the rate is 1.1%, compared with 1.7% in non-designers and 3.2% in national registers.

Additionally a risk of reporting duplicate data exists when surgeons submitting results to the respective national joint register are additionally publishing manuscripts involving the same patient cohorts in peer-reviewed journals. Moreover those who analyze national registers must be aware that designers may be included and associated bias likely exists. Registration of the data is highly operator dependent and a lack of uniformity may exist among various submission to an individual register by different surgeons [41].

Another fact that emerges from the evaluation of the registers is the importance of centers and surgeons specialized in TAR surgery and with an adequate learning curve. The lack of learning curve can lead to a high percentage of failures creating a bias within the registries and the publications. It was reported by Henricson, who highlighted that the survival rate of 5-year implants was statistically superior if the first 30 cases were excluded, considered as learning curves [18]; this data is confirmed by a recent publication that identifies the learning curve in mobile-bearing ankle prostheses in 28 cases [42]. In recent years, as reported by registers, there has been a reduction in the number of hospitals and surgeons performing TAR, this can be in part due to national registry, because no one wants to be an outlier at the wrong end of the bell curve [29].

The registers are also used for the evaluation of new devices and surgical implants, with the expectation to be superior to existing products, this is not always true as reported by a study conducted by the Australian National Registry that showed a significantly worse outcome in 30% of new devices [9,43].

Moreover, in order to improve the data present in the registers, in recent years the Patient reported outcomes (PROMs) have been developed with the aim to enhance completeness and significance of data, thereby helping providers to improve quality of life of patients after joint replacement surgery, including both disease-specific and generic questions [44]. Monitoring PROMs at a national level for a certain intervention permits both local improvements in the delivery of care and national analyses such as health-economic evaluations [45]. Nationwide implementation of a PROMs programme requires a structured organisation and effective and reliable methods for data capture. Patients' response rates to the Swedish Hip Arthroplasty Registry are good, with a mean increase in EQ-5D index of 0.36 at the one-year follow-up [45]. Actually only the New Zealand and Swedish registries use patient-reported outcome measures and recently Kamrad et al.

[28] published the first article regarding the use of PROMs in TAR from the Swedish Ankle Registry, reporting statistically and clinically significant improvements in patient-reported outcomes.

But does there exist a correlation between PROMs and patient satisfaction after joint replacement?

In The New Zealand National Register a correlation has been found between 6-month PROMs with early requirement for revision [20]. A recent article analyzed the correlation of PROMs after reverse total shoulder replacement on a sample of 38 patients [46]. At a minimum follow-up of 1 year the author showed no strongly significant relationship between PROMs and patient satisfaction following elective joint replacement. These findings emphasise the need to question the appropriateness of standard PROM scores for the assessment of outcome and success following elective reverse total shoulder replacement.

Future perspectives are directed towards standardized registers, using both subjective scales managed by the patient (PROMs) and assessments performed directly by the surgeons who do not have to be designers. Furthermore, assessment scales and complications should be unique and the same in all national registers and annual publications are needed for proper development. To improve the success of national registers all prosthetic implants should be marked with an individual code, and in case of prosthetic revision the unique code would identify the case worldwide [47].

## 5. Conclusions

Scientific publications extracted from national joint registers for total ankle replacement provide useful but heterogeneous information on implants survivorship, implant models and risk factors. There is still a discrepancy between the data reported by designers in clinical studies and the data reported by the registries. The centralization of registers in specialized hospitals with dedicated surgeons, the use of PROMs in association with surgeon assessments and annual publications can improve the development of registries and consequently of the literature in this regard.

## Conflict of interest

The authors declare that there are no conflicts of interest.

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