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Quality Initiatives in Foot and Ankle Surgery

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Abstract

Quality initiatives in orthopedics and traumatology are becoming more and more popular worldwide. They can include both mandatory and voluntary methods, such as standardized mandatory surveys, compulsory quality reports, registries, personal certificates, or launching centers of excellence, which means a certification of a whole department. Even in foot and ankle surgery registries, certifications and centers of excellence have been established. This chapter provides an overview of different approaches used to improve quality of care in patients with foot and ankle disorders. We present different methods in use today and discuss their key characteristics.

Keywords: quality initiatives, registries, certifications, PROMS

1. Introduction

Since the arthroplasty registries were established in the 1970s and 1980s [1, 2], it became apparent that even total ankle replacements would be reported in these registers. Today, registries for total ankle replacement exist in Finland, Germany, New Zealand, Norway, Sweden and the United Kingdom.

Studies comparing registry data on patient outcomes after total joint replacement report significant and clinically relevant differences, especially with regard to revisions and survival curves [3]. This underlines the value of registries in outcome research. In addition, registry data can be useful in postoperative surveillance of medical device implants for establishing regulations.

Stemming from registry data on silicon breast implant problems, and metal related problems in total hip replacements, in 2017, the European Union adopted the medical device regulation (MRD). The MDR will have a great impact on industry and their implants, since manufacturers will not only have to comply with more extensive regulations in order to introduce new

or modified implants, in addition, it will have to provide clinical data about their existing implants. In this context, implant registries will play an important role; thus, total hip, knee, shoulder and total ankle replacement registries will have to be taken into consideration.

Another initiative aimed at improving quality in foot and ankle surgery is specialist certification. There are different methods of obtaining certification; it can be based on participation in a number of different cadaver courses, or scientific activity, or even verification of having done surgical interventions. In addition to national certification in individual countries, the European Foot and Ankle Society (EFAS) also offers specialist certification as well.

Mandatory public external quality assurance programs—like those in Germany [4] that cover total hip and knee replacement, as well as osteosynthesis in proximal femur fractures—to our knowledge have not yet been established for foot and ankle surgery procedures.

Finally, a third type of initiative in foot and ankle surgery is to establish competence centers/centers of excellence. This would entail certifying an entire department or institution as a means of improving quality in patients care. One such system is based on the ISO 9001 quality standards and focuses on optimizing structural and process quality. Thus, by having a way of checking, recording, and analyzing quality indicators and surrogate parameters, this leads to improved clinical outcomes.

Quality can be defined by surrogate parameters for clinical results such as X-ray parameters, number of revisions, survival rates, as well as by patients' perspective and satisfaction.

Today, the patients' perspective and the use of the so-called patient-related outcome measures (PROMs) play an important role in registries [5] and in centers of competence.

This chapter provides a review of such quality initiatives, presenting characteristics of individual systems. In addition, reasons why individual, national or, regional registries are not interchangeable and why they have to be seen in the context of their national health care systems are discussed.

2. Registries

There are many types of medical registries, some that focus on diagnosis, like cancer registries, others like trauma registries containing data on hip dysplasia, or medical treatment registries with data on pharmaceuticals or medical devices

Total ankle replacement registries have been established in New Zealand as well as in some European countries (**Table 1**).

All of these registries focus on hard endpoint/outcome measures as a surrogate parameter representing quality of treatment. Those quality indicators are mainly peri- and postoperative complications, reoperations without exchange of components, revisions with exchange of components, complete total joint replacement, as well as implant and patient survival rates. These endpoints are related to indications/diagnoses such as idiopathic osteoarthritis, posttraumatic conditions or inflammatory diseases, or providers/hospitals, or implants [6, 7]. Despite being similar, minimal datasets also exist making it such that results from the different comparable benchmarks

Finland
France
Germany
Lithuania
Norway
Spain
Sweden
United Kingdom

Table 1. European countries with total ankle replacement registries.

must be entered carefully due to national particularities. Implants are not necessarily the same in different countries; therefore, differences in reporting and structural differences may occur. For example, in Sweden, all total ankle replacements are done in 12 centers [8]; in contrast, in Germany, 1 to more than 100 total ankle replacements are performed in 205 different centers [9]

Foot and ankle surgery registries can be managed by the national foot and ankle societies, like in Sweden or Germany [10, 11], or they can be part of the national joint replacement registries like in Norway [7] or in the United Kingdom [6].

Registries can contain hard endpoints like revisions, survival rates, patient satisfaction, pain relief, and improvement of function by using patient reported outcome measures called PROMs [10, 11].

Figure 1 gives an example of data on pain and function from the German registry for total ankle replacement showing the American Foot and Ankle Societies' ankle and hindfoot scale (AOFAS-AHS) computed from 144 patients preoperatively, as well as 3–6 months, 1 year and 2 years after total ankle replacement, respectively. **Figure 2** shows data on patient satisfaction, recorded at different follow-up times.

Ideally, not only one surgical procedure, for example, ankle prosthesis implantation but also alternative therapy options are included in a registry. A good example is the Swedish ankle registry that uses PROMs and covers total ankle replacement as well as ankle fusions and supramalleolar osteotomies [10]. Adding to this, Sweden is working on a national foot registry that includes other surgical procedures.

Other examples of foot and ankle registries, besides those focused on total ankle replacements, are hallux valgus and amputation registries in patients with diabetic foot syndrome, or one from Norway that focuses on total replacement of the first metatarsophalangeal joint [7]. These registries are mentioned as examples of other registers, in Europe and worldwide, focused on treatment of foot and ankle disorders.

Studies using registry data linked to data from health insurance companies/systems can be used to analyze and report quality in healthcare [12]. However, this has not yet been widely established in foot and ankle surgery because the range of procedure codes used in complex

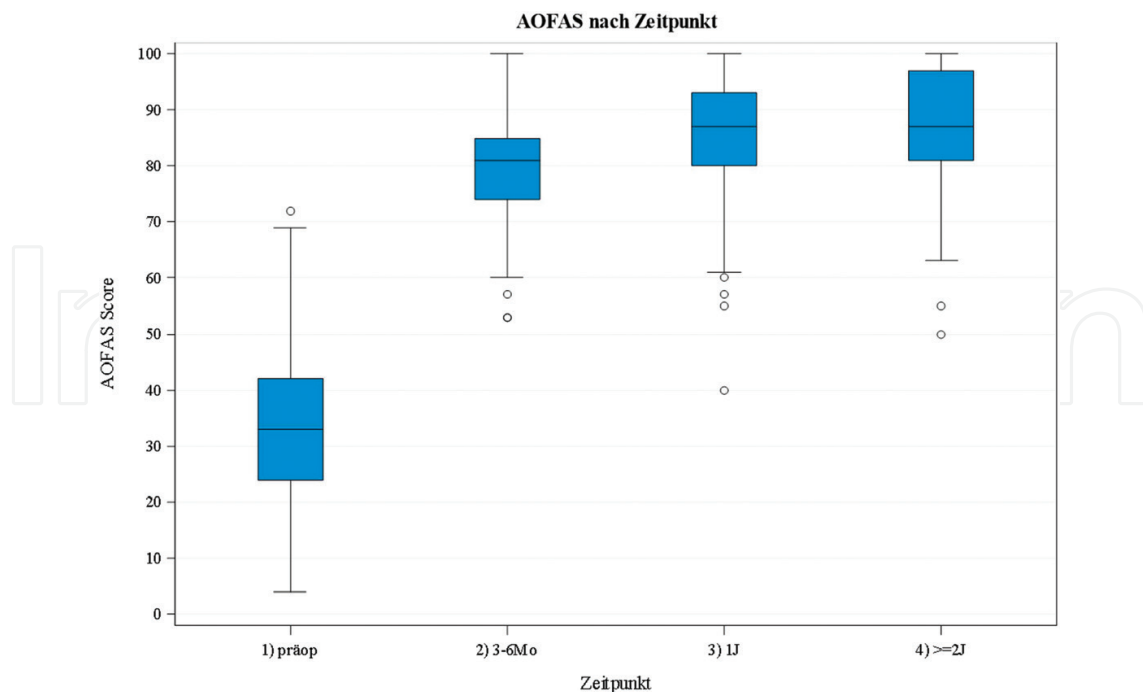


Figure 1. Outcome data from German foot and ankle societies’ total ankle replacement register: AOFAS-score—follow-up of 2 years completed (n = 144 patients, medians and interquartile ranges (IQR) are given; circles = outlier >1.5 IQR).

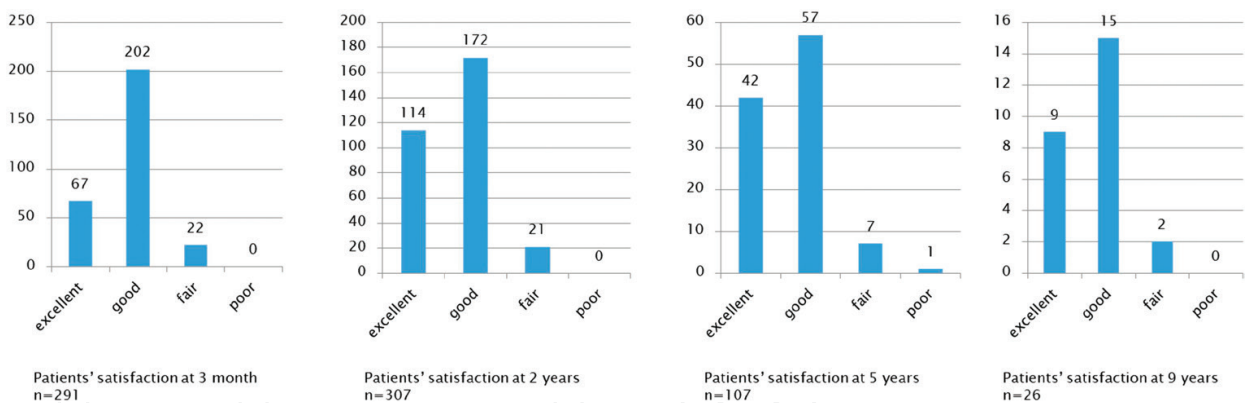


Figure 2. Data from the German Total ankle replacement registry showing patient satisfaction from 3 months to 9 years.

foot surgery makes it problematic to assign a single foot operation, especially in countries where different insurance providers pay for the treatments.

3. Personal certification of surgeons

Parallel to the establishment of registries, in the last 5–10 years, personal certification of surgeons has become more prevalent. These personal certifications require that surgeons participate in a number of standardized courses with lectures, as well as hands-on workshops, either on sawbones or on cadaver specimens. Some of these certifications also require that one provides verification of having performed a number of predetermined surgical procedures. For example, the German foot and ankle Society’s (deutsche Assoziation für Fuß und Sprunggelenk e.V.)

certification is based on having attended eight courses with lectures and hands-on workshops on cadaver specimens. These cover all the main topics in foot and ankle surgery, such as anatomy, surgery on tendons, osteotomies of fore- and hindfoot, foot disorders in children, arthrodesis, arthroscopy, rheumatic diseases, and diabetic foot syndrome. To receive certification, candidates are not required to perform a predetermined number of surgical procedures; however, they must take part in all eight of these courses [13]. In contrast, the master certificate from the society for foot surgery in Germany (Gesellschaft für Fußchirurgie) is based on a credit point system, requiring that one participate in lectures and hands-on workshops using cadaver specimens, seminars on different foot and ankle surgery related topics, and the option to get credit points for participating in a choice of other topics. In addition, a predetermined number of surgical procedures are required [14]. There is no oral exam necessary in either of these two certification systems.

Beyond these national personal certificates, the European foot and ankle society (EFAS) has established the European certification in trauma and orthopedic foot and ankle surgery with the stated goal “to promote the highest standard of practice in our field of expertise to benefit patients” [15]. To receive the EFAS certificate, candidates must provide evidence of 5 years of practice in the specialty, with a certified logbook. Additional criteria include meeting attendance, publications, and fellowships. Candidates must sit for an examination, consisting of a multiple choice questionnaire (MCQ) and viva [15].

4. Centers of excellence

Establishing centers of excellence requires focusing on the fact that it is not solely the surgeon who is involved in patient care. In order to provide a good quality of total inpatient treatment, processes and structures must be optimally coordinated. This can be achieved, for instance, by means of ISO 9001—a worldwide accepted standard defining requirements for effective quality management used widely in the industry. Using this methodology, structure quality and process quality are measured directly, while quality in results and outcomes must be recorded and analyzed using the so-called “quality indicators” as surrogate parameters. One example for such a quality initiative in foot and ankle surgery is the German FussCert© initiative [5, 6].

In this system, besides following legal verification, standard operation procedures for treatment and after treatment, as well as the management of complications, have to be recorded. Qualification of the lead surgeon, as well as all the associated surgeons, is required and the so-called “main surgeons” (“Hauptoperateur”) are defined. All elective surgery has to be done or assisted by one main surgeon. Management of institutionalized meetings must be established, and education and training must be standardized. Throughout the year, further educational activities for the entire team as well as for the individual surgeon must be planned prospectively and carried out. All elective surgery has to be done by or assisted by a so-called “main surgeon,” who has to verify s/he has performed a minimum volume of foot procedures in the past 2 years. In addition, verification must be provided indicating that a minimum volume of procedures are performed in the entire center each year. Cooperation with professions involved in inpatient treatment must be regulated and confirmed in a written agreement. The so-called quality circles, meetings with participating surgeons, and cooperating partners are obligatory, where results, problems, and other important topics are discussed. Satisfaction surveys of referring physicians and patients have to be done and analyzed regularly. Clinical results, such as

frequency of complications, correction angles, and so on, must be recorded and analyzed. An annual management review has to be provided to make the results transparent.

These centers are established in three different ways: centers for maximum providers, standard centers, and centers performing foot surgery in an outpatient setting. Each of these centers has different demands as it relates to volume, both of the centers and the individual main surgeon.

After passing the certification process, consisting of a formal control and control of the content of all application forms, an onsite visit (certification audit) by two experts is conducted. To date, hospitals do not have official quality management certification. An expert in quality management as well as a yearly monitoring audit will take place over the next 2 years. A new cycle with a complete certification process follows every 3 years to ensure that all these demands continue to be met.

The demands upon these centers will be regularly updated in the context of revisions of ISO 9001 quality standards and FussCert® system certification [16].

5. Conclusion

Standardized mandatory surveys and compulsory quality reports are well known in different procedures in health care, but are uncommon in foot and ankle surgery. This may be due to the variety of different foot and ankle disorders, as well as the great variety of the treatment options available in individual disorders.

Registries are a common and trusted system used in outcome research in foot and ankle surgery, where a high level of representation and coverage can be assumed. The latter can become problematic in countries with a voluntary registry without linkage to public health data. Nevertheless, despite providing a broad overview of patients' outcomes and having proven to improve clinical results, registries cannot account for causal relationships in most of the cases [17].

For those countries with difficulties establishing registry with a high level of representation and coverage (due to a voluntary system, a decentralized health care system and/or missing linkage to public health data), certification of individual surgeons as well as entire centers can be a viable and transparent system to analyze and improve quality in patient care.

Nevertheless, data from all of these initiatives have to be validated in order to provide reliable results from which to draw conclusions.

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