Orthopaedics & Traumatology: Surgery & Research xxx (xxxx) xxx

Contents lists available at ScienceDirect

Orthopaedics & Traumatology: Surgery & Research

journal homepage: www.elsevier.com

Original article

Consensus statement on data to be entered in the ACL tear registry: SFA-DataLake

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ARTICLE INFO

Article history:
Received 26 May 2022
Accepted 15 July 2022
Available online xxx

Keywords:
Anterior cruciate ligament
Registry
Methodology
Follow-up

ABSTRACT

Introduction: Anterior cruciate ligament (ACL) reconstruction is a frequent procedure, with room for improvement by rehabilitation measures and associated peripheral and meniscal surgeries that are currently under assessment, requiring follow-up. Outside France, there have been ACL registries for 20 years now. The French Arthroscopy Society (SFA) decided to set up an ACL tear registry within its SFA DataLake registry platform.
Material and method: This article presents the methodology underlying the ACL Tear Registry: i.e., identification, definition and coding of essential and relevant data. A test phase comprised an initial assessment to improve data quality and overall coherence, to optimize data-entry time for patients and practitioners, who are the guarantors of the registry's use and efficacy.
Results: The SFA DataLake ACL Tear Registry was made available to SFA members in December 2021. It aims to enable a review of practices for surgeons, early detection of failure of procedures and implants, with rates of failure and abnormal complications, and identification of prognostic factors for outcome, especially regarding original items that do not figure in previous registries.
Conclusion: SFA DataLake strikes a balance between "indispensable" and "original" items. The choice of contents and data quality is founded on a robust methodology with overall coherence, enabling analysis of large cohorts and comparisons with the literature and other registries. However, it remains to assess rates of data entry and item relevance as the Registry progresses.
Level of evidence: IV.

Abbreviations

ICRS	International Cartilage Repair Society
BMI	body-mass index
KOOS	Knee injury and Osteoarthritis Outcome Score
ACL	anterior cruciate ligament

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https://doi.org/10.1016/j.otsr.2022.103392
1877-0568/

Please cite this article as: N. Bouguennec, M. Thaunat, J. Barth et al., Consensus statement on data to be entered in the ACL tear registry: SFA-DataLake, Orthop Traumatol Surg Res, https://doi.org/10.1016/j.otsr.2022.103392

PRO patient-reported outcome
PROMs patient-reported outcome measures
SFA French Arthroscopy Society (Société Francophone d'Arthroscopie)
SKV Self Knee Value

1. Introduction

Registries enable long-term prospective monitoring of a given pathology, with large patient numbers thanks to their multicenter structure. They have 3 aims: 1) to improve postoperative course by feedback to surgeons and centers; 2) to detect procedure and implant failure as early as possible, with rates of failure and abnormal complications; and 3) to identify prognostic factors for good or poor clinical and functional outcome [1–4]. Thus, they can allow cost savings in public health [5]. A hip replacement registry was set up by the French Society of Orthopedic Surgery and Traumatology (SoFCOT) in 2006 [6]. In other countries, national anterior cruciate ligament (ACL) registries were set up in Norway in 2004, Sweden and Demark in 2005, Luxembourg in 2011, the UK in 2013 and New Zealand in 2014 [2,3,5,7]. There are also regional registries in the USA (Kaiser Permanent Registry, MOON Registry). ACL registries are important because of the large annual number of reconstructions and outstanding issues of technique (e.g., choice of graft, associated peripheral and meniscal procedures) and of rehabilitation and return to sport [1]. The French Arthroscopy Society (SFA) therefore undertook to set up an ACL tear registry [8]. This involved determining the items to be included or not, striking a balance between including a large number of assessment criteria, with a risk of discouraging input by patients and surgeons, or including only a few, which would reduce data-entry time but make the registry less useful. There is at present no consensus as to which criteria are necessary for an ACL registry.

This article presents the methodology underlying the SFA DataLake ACL Tear Registry and the choice of data for inclusion so as to meet the SFA charge-book as defined at project initiation.

2. Materials and method

A working group was set up by 12 centers involved in ACL pathology: 10 in France, 1 in Belgium and 1 in Luxembourg. It met regularly to define data for inclusion and then test the coherence of the initial version of the registry.

2.1. Requirements and charge-book

The main aim was to meet SFA members' expectations as reported in a survey conducted in September 2018:

- to enable scientific studies in the home center or multicenter studies;
- to enable automatic personalized follow-up;
- to enable comparison with other centers;
- with maximum 5-minutes data-entry time for surgeons;
- and requiring non-complex data relating to the specificities of French-speaking surgeons.

The limitation on data-entry time required the platform to be ergonomic and utilizable in everyday practice.

The registry was constructed in the light of guidelines [9,10], the literature [11–16] and comparison with other registries [3,17,18].

2.2. Registry structure

Initially, 3 categories of data were considered, based on the Outcome Measures Framework: characteristics, treatment and results. Subcategories were reviewed, and consensus was reached on those deemed essential to the registry [16,19].

2.3. Definition of essential data

In a second stage, the working group split into 3 subgroups to define essential data in each of the 3 categories and subcategories: characteristics (pre-treatment, demographics, lesions, diagnoses), treatment (surgery report, non-operative treatment data), and results (quality-of-life questionnaires, resumption of activity, new injuries).

Data were defined as "essential" following the levels advocated by Rolfson et al. [20]:

- level 1: basic patient and procedure data: e.g., gender, and date of surgery;
- level 2: more detailed patient and procedure data: e.g., weight and age, and surgical technique;
- level 3: quality-of-life data;
- level 4: radiographic and more complex results.

Registries should focus on the first 3 levels.

On analysis of guidelines [9,10], the literature [11–16] and other registries [3,17,18], the subgroups drew up lists if items for inclusion, which were then reduced to "core data elements" or a "minimum set of necessary data items" [13], according to 3 questions:

- is the item used in everyday practice by the working group members? (i.e., clinical relevance);
- is the item found in other ACL registries?;
- is the item found in the literature or is it one of the validated items in treatment or follow-up? (i.e., scientific relevance).

Thus, items were either included or excluded.

2.4. Coding essential data and data quality

As poor definitions are one cause of poor data entry [13], great care was taken in defining each item. To ensure data quality in terms of coherence and exactitude, the type of response for each item was predefined: running list or not, single or multiple choice, range of values. To ensure exhaustiveness, all fields were made mandatory, while leaving the user free to respond "no data or not applicable". To avoid intrusion in the data-entry protocols [13] and enhance data security, users were accorded limited access, with no possibility of altering the form.

2.5. Test phase

Once essential data had been defined and the platform set up, a test phase in real-use conditions was conducted by the working group members to check adherence to the charge-book and identify any data-quality problems such as possibilities of missing responses, incoherence, etc. This enabled final decisions to be made. Some initially overlooked items were added at this point, where user experience had detected a gap.

3. Results

To be included in the registry, patients were required to have an operated or non-operated ACL pathology, and provide consent (or parents' consent for minors) [1,21]. Bone avulsion or ligament agenesis were excluded. Surgeons were required to be SFA members, in which case they were given an ID and password.

Table 1
Registry subcategories.

Areas	Sub-category of data
Characteristics	Demographic data
	Disease history
	Family history
	Medical history
	Description of trauma
	Social status
	Joint lesion
Treatment	Type of treatment
	Surgery report
Results	Clinical examination
	PRO (Patient-reported outcome)

The registry enabled patients to be included by practitioners in the centers, with preoperative data on patients and lesions, intraoperative data, and follow-up data. Table 1 shows the various subcategories.

The various phases determined the item categories: indispensable items (identity, demographics), surgery report items, pre- and postoperative clinical and functional scores, and follow-up items (Table 2). Some items not featuring in other registries were included, especially regarding the surgery report and functional scores. These represent the specificity of the SFA DataLake ACL Tear Registry:

- a composite knee evaluation score to improve analysis of factors for return to activity:
  - subjective IKDC score,
  - Tegner score,
  - Self Knee Value (SKV) [22],
  - ACL-RSI return to sport after injury scale [23,24];
- a French exception: lateral tenodesis/anterolateral ligament reconstruction [25];
- a focus on current research in ACL tear treatment:
  - knee movement at injury,
  - growth-plate status at reconstruction,
  - ACL remnant before any surgery,
  - type of surgery: reconstruction or repair,
  - vancomycin-soaking of prepared graft,
  - description of meniscal lesions and type of treatment, especially for ramp lesions and root lesions,
  - notchplasty.

Follow-up for non-surgical functional treatment is also an original area: only the Swedish registry includes these data [26,27].

Conversely, some criteria used in other registries were excluded: surgeon experience; type of anesthesia, type of hospital admission, direct anterior drawer on clinical examination, laximetry, KOOS (Knee injury and Osteoarthritis Outcome Score) functional score, operating timer, tourniquet time, and type of antibiotic prophylaxis [18,28].

4. Discussion

Registries were first developed in Scandinavia for arthroplasties in the 1970s [21,29]. ACL registries were set up in the same countries almost 20 years ago, including large cohorts with preoperative assessments, intraoperative data, and prospective follow-up on clinical examination and/or functional scores, depending on the registry. Registries are often national in scope. As well as long-term follow-up, they enable assessment of practices and feedback to surgeons, and improve health safety by identifying early failures of techniques or implants and highlighting factors affecting outcome [1–3,5,7,8,21,30,31].

Unlike registries that include posterior cruciate ligament lesions [21], the present SFA DataLake registry is restricted to primary ACL reconstruction, repair or revision. Bone avulsion and ligament agenesis were excluded, due to differences in nosology and treatment. Like in the Swedish registry, non-surgical cases were included [26,27]. And like in the Danish registry, collateral ligament lesions were included [18,32].

5. Charge-book and requirements for an ACL registry

Choice of data is fundamental, as the problem with registries is analyzing the results, and it can be difficult to extract those results and conclusions that are clinically relevant [29]. This choice has direct implications for rates of input by both surgeons and patients, which is a priority as it enhances statistical power and maintains a positive cost/benefit ratio [33]. The Norwegian and Swedish registries have inclusion rates of respectively 86% and 90% of all annual

Table 2
Item data.

Items	Item data
Indispensable items = identity, demographic data	Full name/gender/date of birth/contact details (e-mail – telephone – postal address)
	Involved side/date of injury/injury-to-surgery time
	Activity at time of injury, and mechanism
	Body-mass index (BMI)
	History of injury to: the same knee/contralateral knee/family history of ACL lesion
	Sports
	Occupation/smoking status
Surgery report items	Preoperative testing under anesthesia (Lachman/Jerk)
	ICRS cartilage involvement and defect size/meniscal involvement
	Type of graft
	Tunnel diameters
	Types of femoral/tibial screwing, types of femoral/tibial fixation
	Collateral ligament involvement and associated treatments
Pre- and postoperative clinical and functional scores (Fig. 1)	Subjective IKDC
	Tegner
	Self Knee Value (SKV) [22]
	ACL-RSI [23,24]
Follow-up items	Satisfaction with state of knee
	Any revision or contralateral surgery
	Type of sport resumed
	Occupation resumed

Data category	Variable	Preop	6 months	12 months	24 months	5 years	10 years
Satisfaction and progression	Satisfaction		X	X	X	X	X
	Progression		X	X	X	X	X
Secondary surgery	Reopération of same knee		X	X	X	X	X
	Date of reopération						
	Reason						
	Operation on contralateral knee		X	X	X	X	X
	Date of operation						
	Reason						
Return to sport	Present sport		X	X	X	X	X
	Level		X	X	X	X	X
	Compared to pre-injury		X	X	X	X	X
	Reason for difference						
PROFESSION	Present occupation		X	X	X	X	X
	Compared to pre-injury		X	X	X	X	X
	Reason for difference						
PROM	Tegner	X		X			
	ACL-RSI		X	X	X		
	Subjective IKDC	X	X	X	X	X	X
	SKV	X	X	X	X	X	X

Fig. 1. Frequency of follow-up according to type of data.

ACL reconstructions [3,34]. A very short data-entry time of less than a minute and continuous feedback to centers are indispensable for a high input rate [1,35]. The Norwegian registry, for example, aims to have a data-entry time of less than 10 minutes, which seemed too long according to users of the SFA DataLake ACL Tear Registry.

To limit the rate of missing data at entry [36], items are made mandatory. The indispensable items are especially demographic data and the description of the population.

The number of items for clinical analysis was limited due to the subjective nature of clinical tests. The Lachman test, with 87% sensitivity and 93% specificity, and the pivot-shift test, with 61% sensitivity and 97% specificity, are deemed indispensable, while, as in other registries, direct anterior drawer, with 48% sensitivity and 93% specificity, was not included as it provides no extra information [2,3,7,28,37].

Including PROMs (Patient-Reported Outcome Measures) increases the efficacy of a registry and of comparative studies [21,38]. The Scandinavian registries use the KOOS score, enabling comparisons between the national registries, and because it seems easier for patients to fill out than the 2000 IKDC scale [21]. The SFA DataLake ACL Tear Registry does not use the KOOS score, being too long to fill out and liable to reduce the data-entry rate. The subjective IKDC is quicker and the SKV shows proven reproducibility and correlation to other functional scores, and were preferred [22]. The Tegner score and ACL-RSI were also included, due to the growing importance of global and psychological assessment of return to sport in ACL lesions [23,24,36,39,40].

6. Particularities of the SFA DataLake ACL tear registry

The particularity of the Registry is that it includes “original” items not seen in other registries but which can shed better light on ACL pathology and assessment of techniques or lesions for which there is no current consensus [41].

Adding items on lateral tenodesis or anterolateral ligament reconstruction could shed light on any difference in results or follow-up [25,42,43]. There are many techniques, and a description of the technique has been included [44]. The item on growth-plate status at surgery aims to identify pediatric ACL reconstructions, which are the focus of a European registry that is presently being set up and for which there is no therapeutic consensus [45].

Other non-consensual elements were also included: conserving an ACL remnant [46,47], reconstruction or repair [48], vancomycin-soaking of the prepared graft [49,50], type of treatment of meniscal lesions, notably ramp lesions and meniscal root lesions [51–54], and notchplasty [55,56].

In the Norwegian registry, follow-up is based on KOOS score at 2, 5 and 10 years [1]. Clinical and functional progression after ACL surgery stretches over the first 2 years [57], but the ACL Tear Registry includes 6-month and 1-year follow-up to assess correlations between early factors and late results (Fig. 1).

7. Limits and perspectives

Registries have drawbacks. They are heterogeneous databases with non-randomized cohorts, given the large numbers of surgeons, centers, techniques and indications that are inherent to the very concept of a registry. On the other hand, the large number of patients can reveal significant differences for low-incidence demographic and surgical parameters.

Setting up this registry was the first step, and had to conform to the charge-book. But the registry will evolve as it is implemented on a large scale. It is therefore essential to assess the long-term relevance of the data and items included in the registry, especially in terms of the items' positive predictive value. [36]. These registries could also make use of artificial intelligence to assess correlations [58,59].

8. Conclusion

The choice of data content and quality for the SFA DataLake ACL Tear Registry was guided by a robust methodology based on guidelines, the literature, other registries and clinical practice. Items were selected from an exhaustive list, to minimize data-entry time and thus ensure widespread use while enabling comparative studies. The Registry thus strikes a balance between "indispensable" items and "original" items that will help improve practices and assess techniques and recently reported associated lesions. Regular monitoring of data-entry rates and item relevance according to users' experience will, however, be indispensable.

Disclosure of interest

Dr Bouguennec: outside the present study, fees from Stryker, SBM, FH. Dr Thaunat: outside the present study, fees from Arthrex. Dr Cavaignac: outside the present study, fees from Arthrex and Amplitude. Dr Letartre, outside the present study, fees from Arthrex and Amplitude. Dr Mouton is a steering committee member and consultant for SFA Datalake, member of the Paediatric ACL Monitoring Initiative (PAMI) and ESSKA steering committee.

The other authors declare that they have no competing interest.

Funding

The study was funded by the French Arthroscopy Society (SFA).

Contributions

Bouguennec: data collection, article writing and re-editing; Mouton and Thaunat: data collection, re-editing; other authors: data collection.

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