



Review article

The SFA datalake platform and anterior cruciate ligament tear registry of the French Society of Arthroscopy (SFA): Rationale, statutes and plans



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ABSTRACT

SFA Datalake is the registry platform of the French Society of Arthroscopy (SFA). It was designed to collect and store data on arthroscopic orthopedic surgery and joint-sparing surgery in French-speaking countries. The anterior cruciate ligament (ACL) tear registry is the first registry to be set up based on SFA Datalake. Registries are intended to enable systematic standardized data collection, and provide information for surgeons to improve clinical practice and results. The ACL tear registry was designed in the light of guidelines, the literature and existing registries. Data are collected prospectively on a secure on-line application accessible via a computer or smartphone. Data collection is organized according to clinical examination results, preoperative findings, and follow-up data based on patient-administered subjective quality of life questionnaires. The pilot committee consists of 5 SFA board members, appointed for 2 years.

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1. Introduction

Under French law (Decree of November 6, 1995 concerning the National Registries Committee) [1], a registry is “a continuous exhaustive collection of nominative data concerning one or more health-related events in a predefined population, usually based on a geographic criterion, for the purposes of research and public health,

by an appropriately qualified team”. Otherwise, data collections are referred to as surveys or multicenter studies. Registries provide a means of prospective monitoring of a clearly defined patient population, with long-term follow-up, and continuous feedback to physicians and health centers to improve patient safety and health-care quality, and to enable identification of early failures to improve clinical practice. Compared to clinical studies reporting a sample of the population, registries offer more complete analysis of a pathology in a large representative population, to obtain more reliable results and conclusions [2–4].

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At present in France and in French-speaking countries, there is a dearth of information for many procedures, functional results and complications rates in sports medicine and orthopedic surgery: e.g., after operative or non-operative treatment of anterior cruciate ligament (ACL) tear [5–10]. An ACL registry seeks to fill this gap, creating standardized approaches and improved practices.

SFA Datalake is a platform belonging to the French Arthroscopy Society (SFA), designed to collect and store data on arthroscopic orthopedic surgery and joint-sparing surgery in French-speaking countries. Initiated by a symposium in 2017, it was officially launched with the first registry, for ACL tear, at the 2021 SFA Congress in Geneva. The present article presents the rationale underlying the Registry, and its functioning and governance.

2. What is the SFA membership expecting of the Registry?

In September 2018, a survey was sent out to Society members, with 10 questions intended to determine their expectations for an ACL tear registry (Fig. 1). There were 342 responses, 46% of whom claimed to perform more than 100 ACL reconstructions per year; 87% also followed up ACL tears with functional treatment, and 60% reckoned that such non-operative treatment accounted for fewer than 20 patients per year in their center.

In this survey, the main reasons why respondents might wish to register their data was to be able to dispose of a tool:

- for single- or multi-center studies (60%);
- for automatic personalized follow-up (17%);
- for comparison with other centers.

The main obstacles concerned time (55%) and data complexity (29%). For 82% of respondents, maximum data entry time should be 5 minutes per patient. Few saw difficulties with conditions of use (9%), lack of staff (8%) or data protection (<1%). The relevant data comprised complications (82%), knee function tests (60%), subjective quality-of-life questionnaires (60%) and data concerning the injury, and associated lesions and their treatment.

Most (78%) were motivated by providing registry access to as many centers as possible. Other suggestions included: that the registry be free of charge, with data entry on paper and QR code, a smartphone app to facilitate data entry at any time, automated long-term follow-up, and evaluation of practices with, for example, assessment of functional treatment in partial tear.

3. What are the aims of SFA Datalake and the ACL Registry?

Objectives were defined to meet membership expectations on the 2018 survey, as follows.

SFA Datalake is the platform of all SFA registries, dedicated to clinical follow-up and scientific research. It is free of charge for Society members, and collects medical data on patients with pathologies managed in sports medicine and orthopedic surgery. The aim is to provide independent data to improve practices in the interest of patients, medical physicians and surgeons. In contrast to certain Scandinavian registries, contributions to SFA Datalake are voluntary, and those principally involved will be clinicians and patients.

SFA Datalake aims to improve the description of the current status of pathologies and treatments, enabling analysis of short-, medium- and long-term results and rapid identification of factors for good recovery. The emphasis is on quality of life and satisfaction; taken together, the data should allow measurement and improvement of patient management quality over the long term. More generally, the aim is to inform and guide surgeons and

public bodies on optimal treatment according to the category of the patient and the injury.

More precisely, the ACL Tear Registry includes all patients with ACL injury, whether treated surgically or not. The cohort will be followed up over the long term, for at least 10 years. The main objective of the Registry and of SFA Datalake is to provide updated information on pathology, treatment and long-term results.

4. SFA Datalake statutes and regulatory aspects

The founding body, controller and owner of SFA Datalake is the French Society of Arthroscopy. The Registry is run by a pilot or scientific committee that presently comprises 5 Society members appointed for 2 years by the SFA Board. Its most important task is to ensure data transparency and scientific quality. It sets the priorities and objectives of SFA Datalake in coordination with the SFA. On a day-to-day basis, the SFA Datalake platform is run by the Registry manager.

The SFA is in charge of managing data processing and administers the funds available for the development and maintenance of SFA Datalake. The SFA registries have thus been built without initial involvement of government agencies. This voluntary approach, not relying on outside support or corporate sponsorship, was adopted to ensure complete independence and freedom in data management, notably as regards the performance of such and such an implant.

The organization and statutes of SFA Datalake adhere to the principles and good practice guidelines set out in the reference publications [11]. Governance is codified in writing and will be reviewed, shared and refined over time. To ensure effective governance and avoid any real or perceived conflicts of interest, transparency will be ensured via the SFA website and various publications, in peer-reviewed journals, congresses, SFA press releases, etc.

The SFA Datalake data are collected in line with the “Informatics and Liberties” data protection Act concerning information technology, data files and liberties (Act n° 78-17 of January 6, 1978, modified by Act n° 2004-801 of August 6, 2004, and the General Data Protection Regulation that came into force on May 25, 2018 [12]). SFA Datalake conforms to the MR003 procedure of the CNIL data protection commission. Physicians contributing to the platform must obtain the patient’s non-opposition. The patient is free to decline the use of his or her data, at any time, without having to give a reason.

Each center will have access to its own data, but otherwise the registry data can only be used under the responsibility and with the permission of the SFA, and only for research purposes. The main responsibility of the pilot committee is to ensure that data use, sharing and publication conforms to the SFA Datalake mission: i.e., high-quality research.

In case of official collaborations, the data property and access rights and the modalities of outside access will be laid out in partnership agreements and legal contracts [13,14].

5. The SFA Datalake platform

SFA Datalake is an open-source platform, accessible online via a computer or smartphone. Data are collected by surgeons and patients, who receive a secure link but cannot connect directly onto the platform. Numerous functionalities have been designed to save time and labor, greatly enhancing availability, easy archiving and data security and quality: access management, user profile, management of patients’ non-opposition or opposition, automatic mailing of questionnaires to patients, management of missing data, real-time automatic reports and standardized exports.

Survey – Questionnaire

1 – Do you perform ACL reconstruction? 2 – How many patients per year need ACL reconstruction in your center?	3 – Do you treat ACL lesions non-operatively? 4 – How many patients are followed for non-operative ACL tear?
5 – What would be your main reason for entering ACL tear data in a registry?	6 – What would be the main obstacle to your entering ACL tear data in a registry?
7 – Which 3 data do you think essential to enter in a registry?	8 – What would be the maximum reasonable data entry time per patient for complete follow-up?
9 – Would you be interested in sharing your experience and getting involved in designing a registry for the SFA to make it available to the largest possible number of centers?	10 – Free field / ideas about the registry (difficulties, challenges, what’s lacking at present...)

Fig. 1. SFA survey to draw up the ACL tear charge-book.

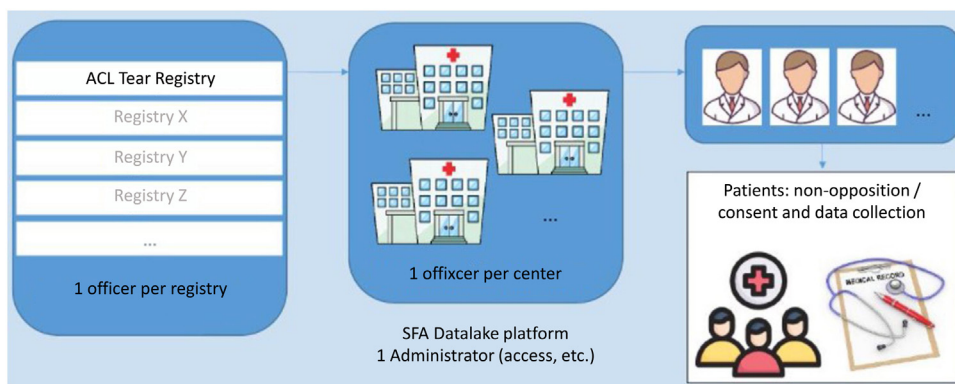


Fig. 2. The structure of SFA Datalake allows for several registries for several joints.

The platform software conforms to the General Data Protection regulation and CNIL data protection standards. Data are saved to an HDS-approved health data hosting server; extraction is pseudonymized, and the software is accessible via a personal password-protected link. The digital protection officer (DPO) provides an access code to a practitioner wishing to participate in the Registry, on request via a form available on the SFA website, requiring prior signature of an information questionnaire and SFA membership. The code allows the practitioner to access his or her patients’ data and extract them by exportation.

6. How are the registries structured?

A group of 12 surgeons recognized as experts in knee ligament pathology was formed to design and implement SFA Datalake and the SFA ACL Tear Registry. SFA Datalake was structured so as to enable design of future SFA registries. It is thus general, adaptable to different pathologies and joints (Figs. 2 and 3).

In each center, one practitioner is appointed as Datalake Administrator, but one or several practitioners in the center may participate in the platform. Each is individually responsible for securing their patients’ non-opposition ahead of data entry. Data concerning the patients, treatment and results are collected for each treatment; one lesion may entail several treatments: e.g., first-line functional treatment and second-line surgery. The possibility of a second joint lesion (e.g., contralateral, or following failure) has been taken into account.

7. Discussion

There are 2 main types of registry: health registries and quality registries. Health registries are set up and managed by national public bodies and are regulated by law to ensure good cover. According to a report by the French HCSP public health council, in Norway, there are 18 health registries, 16 of which are mandatory; the 2014 Act concerning health registries and health data processing obliges all health professionals to participate. The registries collect only a few data but have almost exhaustive population cover, at 98%, for a population of 5 million. They can thus estimate the incidence of certain pathologies and serve as a basis for follow-up [15] (Table 1).

Registries such as SFA Datalake are quality registries, with a voluntary basis, which is one of their weaknesses; incentives should be developed to encourage use. There are several options under study; notably, registry involvement could be counted for Orthoriscq accreditation, or provide a discount on SFA membership or annual congress registration fees.

Even so, the voluntary SFA ACL Tear Registry, meeting the membership’s demand for a clinical follow-up and research tool, corresponds better to the definition of a registry given by Metka Zaletel and Marcel Kralj in the PARENT study, that can apply to all European countries: “an organized system that collects, analyses, and disseminates the data and information on a group of people defined by a particular disease, condition, exposure, or health-related service, and that serves a predetermined scientific, clinical or/and public health (policy) purposes” [19]. New registry strate-

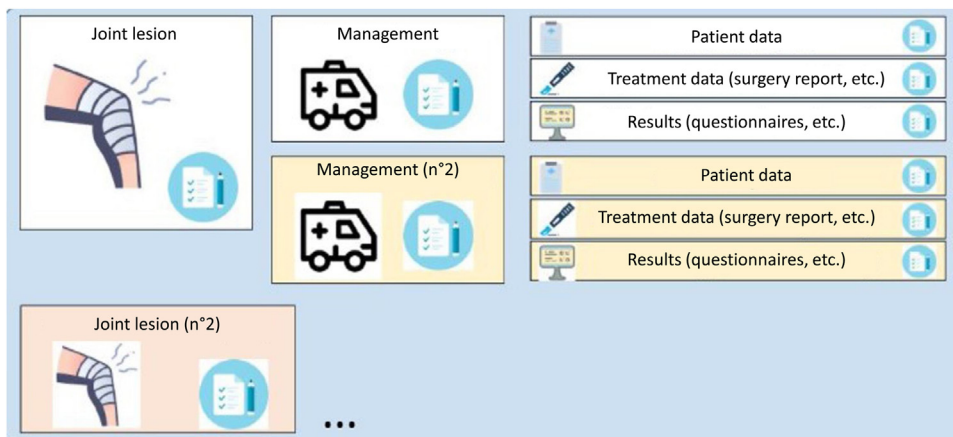


Fig. 3. Structure of a registry in SFA Datalake. One joint lesion may undergo several treatments, and 1 patient may have several lesions.

Table 1

Main anterior cruciate ligament tear registries operating in the world, with characteristics (KOOS: Knee Injury And Osteoarthritis Outcome; IKDC score: International Knee Documentation Committee subjective score; Eq5d: euroqol).

	Launch date	Patients included	Data collection	Pre-operative data	Functional scores	Post-operative follow-up
Danish [16]	2005	23,000 (2014)	Voluntary	-Epidemiology -Operative ACL injuries -PCL reconstruction -Injury mechanism	KOOS Tegner functional score	1 year
Norwegian [17]	2004	20,000 (2014)	Mandatory for all public and private hospitals	-Epidemiology -Operative or non-operative ACL injuries -Injury mechanism -PCL reconstruction	KOOS	2, 5 and 10 years
Swedish [14]	2005	52,734 (2020)	Voluntary	-Epidemiology -Operative or non-operative ACL injuries -Injury mechanism	KOOS	1, 2 and 5 years
UK national [18]	2013	15,304 (2019)	Voluntary	-Epidemiology -Injury mechanism -Operative ACL injuries	KOOS IKDC EQ5D Tegner activity score	1, 2 and 5 years
Kaiser permanent (US) [19]	2005	57,282 (2021)	Voluntary	-Demographic data -Injury mechanism -Operative ACL injuries	KOOS	1, 2 and 5 years
Luxembourg [20]	2011	2,224 (2021)	Hospital-based registry (Centre Hospitalier de Luxembourg)	-Demographic data -Injury mechanism -Operative or non-operative ACL injuries	KOOS IKDC	6-8 weeks 3-4 months 6 months, 1, 2 years
New Zealand [21]	2014	14,740 (August 2021)	Voluntary	-Demographic data -Injury mechanism -Operative or non-operative ACL injuries	Marx KOOS	6 months, 1, 2 and 5 years

gies and policies in Sweden, Norway, Australia, the UK and now France focus on this kind of “quality” registry, aiming to improve the quality of care in certain pathologies or procedures. In Norway, the quality registry development policy began in 2009, with 19 registries, rapidly growing to 51 by 2019. In Sweden, there are more than 100 [15]. Unlike health registries, quality registry management is not centralized and governed by the state; they are not regulated by specific laws, and health professionals, patient

associations or any other body wishing to set up a registry can act as manager [15].

Comparison of demographic data between registries highlights cultural differences between countries in the management of a given pathology [22]: in ACL tear, in Luxembourg and the USA the injury-to-reconstruction interval tends to be short, whereas in Denmark, Norway, Sweden, and the UK it is at least 12 months. Analysis finds that soccer is the most frequent context of injury.

Prospective follow-up rapidly revealed higher retear rates with allograft, leading to changes in practice in the USA [23].

The large quantities of data extracted from registries allow new statistical methods, such as machine learning, to be implemented to identify new risk factors and try to predict progression [24,25].

One serious limitation is the lack of radiologic assessment and systematic measurement of laxity [26], only the Danish registry includes this in follow-up. Radiologic assessment can provide a lot of information, including tunnel positioning (a major cause of failure) or onset of osteoarthritis after ACL tear [16,17]. Laximetry provides objective measurement of residual laxity and of surgical success or failure [18].

The SFA ACL registry will provide data specific to French practices, to compare and check results of studies based on other registries.

8. Conclusion

SFA Datalake is the platform for all SFA registries, dedicated to clinical follow-up and research. It is an independent, open tool, free of charge for SFA members. It collects medical data for patients with pathologies managed in sports medicine and orthopedic surgery. Data are collected prospectively on a secure digital support accessible via a computer or smartphone. Data focus on basic clinical examination measurements, preoperative data and follow-up, based on automated mailing of quality-of-life questionnaires to be filled out by patients. The registry for surgical or non-surgical treatment of ACL tear is already available.

Disclosure of interest

Dr Mouton is a member of the steering committee and a consultant for SFA Datalake, and a member of the Paediatric ACL Monitoring Initiative (PAMI) and the ESSKA steering committee. Outside the present study, Dr Cavaignac receives fees from Arthrex and Amplitude. Outside the present study, Dr Gunepin receives fees from Stryker, Fidia, SFA Score Knee, and the West Orthopedic Society (SOO) Board. Dr Thauinat is a member of the SFA Datalake steering committee and the SFA Board; outside the present study, he receives fees from Arthrex. Outside the present study, Dr Bouguennec is a consultant for Stryker, SBM and FH. Outside the present study, Dr Letartre receives fees from Arthrex and Amplitude. Outside the present study, Dr Barth receives fees from Arthrex, SBM and Move Up; he contributed to the development of SFA Datalake when he was SFA President.

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Author contributions

All authors contributed to article writing.

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