JOINTS 2026; 4: e2042
DOI: 10.26355/joints_202606_2042
e-ISSN: 2512-9090
Category: Technical Note

SETTING AND DEVELOPMENT OF A DATABASE FOR CLINICAL PRACTICE AND RESEARCH FOR PATIENTS UNDERGOING ANTERIOR CRUCIATE LIGAMENT RECONSTRUCTION

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ABSTRACT – The set-up of a clinical and research database should be of paramount importance for any medical context, for the development of practice and the sharing of acquired knowledge within the scientific landscape. The purpose of the manuscript is to describe the setting and development of a clinical and research database for knee arthroscopy and anterior cruciate ligament reconstruction.

The database was designed and developed using Microsoft Access (Microsoft 365 Package, Microsoft Corp., USA). Multiple boards for each individual patient’s data have been created within the database: Master Data, Preoperative Physical Examination, Preoperative scores, Preoperative magnetic resonance imaging (MRI), Preoperative Exams, Intervention, 7-day follow-up, 15-day follow-up, 30-day follow-up, 60-day follow-up, 90-day follow-up, 180-day follow-up, 365-day follow-up. In all the records, each patient was pseudonymized using an ID code. All data entered within the database are checked to meet quality standards and to ensure reliability of the information.

To ensure scientific reliability, data is validated using a color-coded system – Certain (green), Probable (yellow), and Uncertain (red) – based on the source’s proximity to original records. Adhering to ALCOA+ principles, the database prioritizes data integrity to prevent the 10% error threshold that renders analysis unreliable. An entry-point rigorous source verification is emphasized to minimize transcription errors.

This paper aims at fostering the development of guidelines on the reporting and archiving of prospective data concerning arthroscopic knee surgery, for the deployment of multi-centric collaborations and improvement of scientific evidence, in the light of sustainable and digitalized research.

KEYWORDS: Database, Clinical research, Knee, ACL reconstruction, Arthroscopic surgery.

INTRODUCTION

In the rapidly evolving scientific landscape, especially in medical research, databases represent an enormous value. Medical practitioners must offer the best treatment to the patient by staying abreast of new scientific research and contributing to clinical research, sharing results of their investigations with the scientific readership and the community. Furthermore, the development of new surgical techniques and the improvement of established skills require periodically reviewing postoperative outcomes of one's own procedures, relying on objective and accurate data collected over time[1,2]. The process became even more diffused, though expedited, during the digital era, where the collection of data in large databases was introduced to track follow-up of patients, review surgical performance, and factors influencing surgical outcomes. Furthermore, the permanent and ongoing collection of data allows the development of observational research, differing from protocol-based data collection that is generally advocated for hypothesis-oriented, interventional, or sponsored research.

In orthopedic practice, the ongoing evolution of techniques for anterior cruciate ligament reconstruction (ACLR) underscores the importance of assessing factors that contribute to procedural success or failure. However, despite several available studies published on the topic, important knowledge is still lacking concerning the surgical technique, timing of surgery, treatment of associated lesions, graft choice and combined peripheral procedures. This makes it mandatory to collect information on patient outcomes throughout the entire follow-up period, especially at the individual-surgeon and national levels. To date, there are several national or regional ACL registries that not only collect information limited to surgical procedure, but also provide outcomes related to short, medium and long-term patient follow-up[3,4]. Results of clinical studies conducted on the registry data actively contribute to the development of knowledge based on a large number of patients, also accounting for variability of techniques due to multiple-surgeon data collection, thus improving the generalizability of the research results.

Currently, there are only six national ACL registries: the Norwegian Knee Ligament Register (NKLR), the Swedish National Knee Ligament Registry (SNKLR), the Danish Knee Ligament Reconstruction Registry (DKRR), the UK National Ligament Register (NLR), the Luxembourg Ligament Register (LLR) and the New Zealand ACL Registry (NZACL). A regional registry, however, the Kaiser Permanente ACLR Registry, is present in the United States (USA)[5].

The NKLR was established in 2004, the SNKLR and DKRR in 2005, with the aim of collecting data of patients subjected to primary or revision ACLR. These registries include data relating to patient characteristics (gender, age, body mass index), to activities performed at the time of injury (sports), to surgical factors (graft size, graft type, timing of surgery) and to outcome measures (PROMS)[6-8]. The LLR was established later, in 2011, with the aim of collecting data on patients with anterior cruciate ligament injuries who were treated both surgically and conservatively, and whose clinical documentation was verified by magnetic resonance imaging (MRI)[9].

The UK NLR and the NZACL were established in 2013 and 2014, respectively, with the aim of prospectively collecting patient, surgical and follow-up data[10,11]. The Kaiser Permanente ACLR Registry is the regional registry of the United States, established in 2005. Although it is not a national registry, it collects numerous data and information from patients, surgeons and healthcare centers, in addition to those on surgical factors[12].

Although the existence of registries is of enormous importance to broaden our knowledge on ACLR and to monitor the development of this surgical technique and clinical outcomes, to date, there is no guidance on the practice of data collection at institutional or national levels for many countries and regions. It is necessary, therefore, to have a relational data management system ("RDMS" or simply "database") that can be filled out with all the details concerning surgical procedure and follow-up outcomes, which is quickly accessible and easily consultable[13].

The purpose of this paper is to share our experience and provide guidance on database development for clinical practice and research in the orthopedic field, with a specific focus on data collection for ACLR procedures.

DATABASE DEVELOPMENT

Database Architecture and Software

The database was originally designed and developed using Microsoft Access (Microsoft 365 Package, Microsoft Corp., USA), a relational database management software interface (RDBMS) that leverages the Microsoft Jet Database Engine and natively integrates within itself a module for rapid application development (RAD) management. Unlike other development environments, Access stores all the elements needed to develop complete applications in a single file: tables, queries, masks, reports, macros, pages, and forms.

Data Pseudonymization

In all the records listed above, each patient is pseudonymized and associated with a unique and unrepeatable ID code. Pseudonymization is a necessary security measure by which personal data can no longer be attributed to a specific individual without the use of additional information, in accordance with the European General Data Protection Regulation (EU-GDPR) and the Health Insurance Portability and Accountability Act (HIPAA). Therefore, it is necessary to assign a unique and identifying code to personal data and keep a separate decoding list with identifying data. This process of pseudonymization should not be confused with anonymization: with pseudonymization, the patient is always indirectly identifiable; with anonymization, the patient is no longer identifiable. It is necessary to create adequate security measures for access to Protected Health Information (PHI), especially when patient identifiers are collected. The 18 HIPAA identifiers are a good starting point for identifying confidential fields in the dataset[14].

Database Structure and Tables

Many boards relating to individual patient data have been created within the database: Master Data; Preoperative Physical Examination; Preoperative scores; Preoperative MRI; Preoperative Exams; Intervention; 7-day follow-up; 15-day follow-up; 30-day follow-up; 60-day follow-up; 90-day follow-up; 180-day follow-up; 365-day follow-up (Table 1).

The Master Data table shows patients' personal data such as date of birth, age, sex, weight, height, and BMI. Each dichotomous variable is converted into a binary numerical identifier. For example, to indicate sex, we used the following values: 0 = female; 1 = male. It is always convenient to report individual raw data rather than calculated data. A classic example is that relating to BMI data, which can be calculated from weight and height, and age data, which can be calculated from the date of birth and from the date of surgery: it is always possible to calculate BMI from height and weight later, but it is not possible to calculate height/weight from BMI, just as it is always possible to calculate age from date of birth and date of surgery later, but it is not possible to calculate the latter from age. Therefore, it is essential not to code the continuous variables but to store them as they are. Moreover, this overall table included information on the patient's primary sport activity, collected from patient admission forms.

The Preoperative Anamnestic and Clinical Assessment table shows the patients' preoperative data, including time to surgery (early 0-15 days, intermediate 15-90 days, or late over 90 days); injury environment [road, sport, activities of daily living (ADL), work]; mechanism of injury (contact or non-contact); symptoms (swelling, instability, failure, joint blockage, effusion, pain block with flexion deformity); coronal alignment (normal axis, varus, valgus); recurvatum (yes, no); medial and lateral joint line pain. Moreover, the following clinical tests are scored from 0 to 3: medial and lateral Mc Murray; medial and lateral Apley; Lachman; Lachman reverse (prone position); anterior drawer in neutral position, internal and external rotation; Pivot Shift; posterior drawer; dial at 30° and 90°; valgus and varus stress at 0° and 30°.

The Preoperative Scores table reports the patients' Tegner Activity Scale and Lysholm Knee Scoring Scale scores[15], as well as the International Knee Documentation Committee (IKDC) questionnaire final score[16], completed before surgery. The Tegner Activity Scale (TAS) is a score that ranks sports activity on a scale of 0 to 10, where zero represents disability due to knee problems and 10 represents soccer at the national or international level. The Lysholm Knee Scoring Scale is a patient-reported outcome measure (PROM) questionnaire that assesses outcomes after knee ligament surgery, specifically symptoms related to instability. The IKDC questionnaire is a subjective scale that provides patients with an overall functional score by examining three categories: symptoms, sports activity, and knee function[17].

The Preoperative MRI table includes all the data related to the MRI performed before surgery: the date it was performed, the presence/absence of a report, and the parameters related to meniscal and ligamentous injuries.

The Preoperative Examinations table includes information on the date of any injury and the number of preoperative days (elapsed time from injury to surgery), as well as all patient measurements obtained during the preoperative functional assessment test. Specifically, this test is performed in a functional assessment laboratory equipped with machines to assess the function of a specific body district, such as the ankle, knee, spine, shoulder, or hand, following trauma or surgery. Within a Knee Arthroscopy Surgical Database, the following parameters can be reported: anthropometric data (circumferences), joint flexion and extension range of motion (ROM), posterior chain flexibility, single-leg stability, functional ability (e.g., sit-to-stand with dynamometric plates for limb load asymmetry), proprioception and balance, isometric strength, agility, isokinetic strength, and ligament laxity. By carrying out multiple

Table 1. Data elements of the database for knee arthroscopy and ACLR.

Table	Variable	Unit	Data source
Master Data	Date of birth	dd/mm/yyyy	Patient management software
	Age	Years	Patient management software
	Sex	Binary (M/F)	Patient management software
	Weight	Kg	Patient management software
	Height	cm	Patient management software
	BMI	Kg/m^2	Patient management software
	Type of sport	txt	Patient management software
Preoperative Anamnestic and Clinical Assessment	Time to surgery	Coded*	Signed clinical assessment at patient admission
	Trauma environment	Coded*	Signed clinical assessment at patient admission
	Mechanism of injury	Binary	Signed clinical assessment at patient admission
	Symptoms	Coded*	Signed clinical assessment at patient admission
	Coronal alignment	Binary	Signed clinical assessment at patient admission
	Recurvatum	Binary	Signed clinical assessment at patient admission
	Medial and lateral joint line pain	Coded*	Signed clinical assessment at patient admission
	Clinical tests (for each test)	Coded*	Signed clinical assessment at patient admission
Preoperative Scores	Tegner Activity Scale	Discrete (0 to 10)	Signed medical report at patient admission
	Lysholm Knee Scoring Scale	Continuous (0 to 100)	Patient-reported questionnaire at admission
	IKDC questionnaire	Continuous (0 to 100)	Patient-reported questionnaire at admission
Preoperative MRI	Date of MRI	dd/mm/yyyy	Validated and signed radiological report
	Presence/absence of the report	Binary	Validated and signed radiological report
	Pathologic report (for each structure)	Coded*	Validated and signed radiological report
Preoperative Examinations	Preoperative arthrometric testing (GNRB® device)	mm	Laboratory report (GNRB® device output)
	Preoperative functional assessment tests	Continuous	Laboratory report (Examiner reported values)
Intervention	Date of surgery	dd/mm/yyyy	Validated and signed surgical report
	Type of surgery	txt	Validated and signed surgical report
	Surgical time	Number	Validated and signed surgical report
	Operated limb	Binary (R/L)	Validated and signed surgical report
	Arthroscopic findings (for each structure)	Coded*	Validated and signed surgical report
7-, 15-, 30-, and 60-day Follow-up	Functional assessment test	Continuous	Laboratory report (examiner reported values)
90-, 180-, and 365-day Follow-up	IKDC questionnaire	Continuous (0 to 100)	Patient-reported questionnaire at follow-up visit
	Tegner Activity Scale§	Discrete (0 to 10)	Laboratory report
	Postoperative GNRB®	mm	Laboratory report (GNRB® machine output)
	Functional assessment test	Continuous	Laboratory report (examiner reported values)

*Coded: the variable assumes discrete values basing on possible characteristics (e.g., for time to surgery, the value is 0 for early surgery within 15 days, is 1 if the surgery is between 15 and 90 days and is 2 if surgery is performed after 90 days from injury; for all individual clinical tests, the value is 0 if negative, 1 if slightly positive, 2 if moderately positive and is 3 if markedly positive).
§Registered only at 180- and 360-day follow-up, if the patient returned to sport.
International Knee Documentation Committee (IKDC), magnetic resonance imaging (MRI).

evaluations over time, it is possible to provide the patient and physicians with important information regarding the progress of the rehabilitation process, assessing the achievement of set goals, and establishing progression parameters in the motor rehabilitation pathway.

In the Intervention table, all information about the surgery undergone is reported, such as date of surgery, type of surgery, surgical time, operated limb, and arthroscopic observations. In the case of a Knee Arthroscopy Surgical Database, the following information may be reported: meniscal injuries, ligamentous injuries, femoral condyle and tibial plateau injuries, patellar injuries, fascicle injuries, and, specific to ACL reconstruction, type of graft, size and mode of fixation of the femoral tunnel. Each variable is associated with a numerical identifier. For example, to indicate the presence or absence of the lesion, we used the following association: 0 = absence of lesion; 1 = presence of lesion.

In the 7-, 15-, 30-, 60-, 90-, 180-, and 365-day Follow-up tables, all patients' measurements obtained both through the score of the IKDC questionnaire and during the follow-up functional assessment test performed at the different timings are reported. The parameters analyzed are the same as those assessed during the preoperative test, but depending on timing, some are performed rather than others.

The repetition of such tests makes it possible to compare post-treatment data with pre-treatment data and thus verify the progress of the rehabilitation process.

Data Quality

All data entered within the database are checked to meet quality standards and to ensure reliability of the information. The term “data quality” is used generically to describe the process by which data are analyzed, with the aim of assessing and validating their quality. From a scientific research perspective, the problem of data quality has been addressed in a variety of contexts, including statistics, economics and computer science. Depending on the nature of the data and the purpose for which it is being analyzed, the term “quality” is often declined into a number of concepts that define its general properties, such as: completeness, conformity, consistency, meaningfulness, scope, precision, conciseness, clarity, relevance, accuracy, correctness, duplication, integrity, concordance, importance, plausibility, objectivity, transparency, content, ease-of-use.

Each piece of data within a database may have different sources. In our surgical database, some data are collected directly or indirectly from patients and physicians, while others are retrieved from validated and signed medical records.

For what concern our database, data are classified on the basis of their reliability into: Certain data, Probable data, and Uncertain data, and each category is assigned a colorimetric score to identify its quality: green for certain data, yellow for probable data, and red for uncertain data.

This classification is based on the number of “data steps” that the information has passed through before being entered into the database. The data piece was “certain” if the information was directly and immediately (with no intermediate passages of reporting) collected by the medical records of the patient present in the official paper archive of our facility, or a copy of these records (photocopy or scan). The data piece was considered “probable” if data extracted by an instrument or tool or assessment was recently manipulated, including the calculation of derived measures. The information was considered “uncertain” if it was obtained from external sources, including clinical documents not generated by our physicians or tools, or was manually copied from internal sources into unofficial reports and then entered into the database, where the original source was not available for verification.

Example of Certain data include those directly provided by the patient about his or her biographical information, with regard to date of birth, sex, weight and height, and those reported on a report validated by the surgeon about the specifics related to the surgery; Probable data include those from the functional assessment tests that the patient performs at our functional evaluation laboratory preoperatively and at each step of follow-up, that are calculated from measurements obtained from machines by trained physical therapists that carry out the functional evaluation; Uncertain data include those related to MRI reports not signed from a trained musculoskeletal radiologist, especially if carried out outside of our radiologic department.

Validating the data according to these criteria, by the data manager, allows for more accurate classification and better structuring of the database. The classification of source certainty cannot be modified over time, unless new sources become available. Furthermore, during the study design phase, the reliability of retrospective data is taken into account to select the more reliable measures, while for prospective investigations, Probable and Uncertain variables can be improved during validation before study initiation.

Source Data Verification

All data included in the database must be validated at the time of their entry, to be checked for their correctness and completeness. Indeed, it is essential that clinical research studies produce accurate, complete and relevant outcome data (ALCOA+ criteria)[18,19]. There are eight characteristics that a datum should possess: Attributable – the data source is known and recorded – Legible – the data is human readable – Contemporaneous – source data is logged as it is generated – Original – all data come from the original source – Accurate – the data is correct – Enduring – the data is available for as long as their retention is required – Complete – all available data are included – Consistent – all data use consistent terms and are not contradictory[20].

Data quality and integrity are critical since competent authorities, Ethical Committees, and Institutional Review Boards evaluate research value and the consequent influence of outcome data on the clinical decision-making process.

Good data quality also appears to be related to the knowledge and experience of the personnel involved in data management and data entry. Indeed, data extraction and transcription are identified as those steps most likely to introduce errors[21]: if more than 10% of the data is missing or incorrect, the data analysis is considered unreliable[22]. It is, therefore, preferable to have data acquisition systems directly interfaced with data collection, archiving, and management software rather than a person responsible for manual data entry.

DISCUSSION

Using a database in health care helps in improving the diagnosis and treatment of diseases, identifying health trends in a population, and refining the management of hospitals and health care services.

A single patient generates thousands of data related to diagnosis, prognosis, treatment pathways, digital images, and laboratory test results. All this information, resulting from the intersection of data from even heterogeneous sources, could be used to predict clinical outcomes and identify patterns that could lead to new scientific breakthroughs, maximizing health care resources.

A well-structured and well-organized database that enables quick and easy access to epidemiological, clinical, technical, and quality-of-life information is essential for research, especially in surgery. Indeed, these databases can help surgeons identify treatment outcome trends, reason over quantifiable outputs, and contribute to the generation of appropriate evidence, thereby providing patients with better care. However, having a single database that can be adapted to any need is impossible; each database must be designed to meet the parameters and variables required by a specific research project. A good database should, therefore, allow for quick and simple data entry, including personal and medical information; be easily accessible by medical personnel; be password protected; and have codified electronic data to facilitate the development of multi-centric studies[23].

While the choice of Microsoft Access offers a pragmatic, cost-effective, and rapidly deployable solution for single-surgeon or single-institution settings, its limitations regarding transferability and scalability must be critically acknowledged. Microsoft Access is reliable software for creating a local relational database prototype, in contrast to a simple spreadsheet dataset, and it also allows professional data control. However, it is not designed for big data, high-volume data, or concurrent multi-user environments, as is typical of multi-centric registries. Limitations in simultaneous data entry, restricted remote web-based accessibility, and lower security thresholds compared to enterprise-level structured query language (SQL) servers or cloud-based Electronic Data Capture systems (e.g., REDCap) suggest that the current framework should be considered as a foundational step, affordable and deployable by most of the knee surgeons in small to medium settings. However, for broader implementation or inter-institutional interoperability, this local database architecture is designed to allow seamless data export and migration to more robust, scalable platforms once the dataset volume or collaborative scope exceeds local capacities.

Thanks to the existing registries, several research studies have been conducted with the aim of identifying the differences between treatment variables on the functional outcomes of patients with ACL injuries and the variables of interest, such as the choice of the graft, the surgical technique, the intervention time, and the type of treatment (conservative or surgical). To date, indeed, these registries include a large amount of data, including detailed information related to both the patient and the treatment, as well as the outcomes, thus allowing for a broad overview of the epidemiology of ACL injuries[6,23]. However, these registries also have some important limitations: poor compliance related to PROM reporting; use of the Knee Injury and Osteoarthritis Outcome Score (KOOS) as the primary outcome, although it was judged inappropriate for ACL tears; prevalent collection of data from surgically treated patients, yielding to difficult comparisons between surgical and non-surgical populations; diversity in the amount and in method of data collection as well as follow-up times for each individual registry making it difficult to compare data from different registries[24]. Furthermore, a few registries to date also include objective data on functional assessments performed on the patient before surgery and at follow-up. Data from these measurements should always be reported and linked to the patient's surgical data. In fact, just like the surgeon, the physiotherapist can also receive significant feedback on the patient's physical improvement and suggest a specific rehabilitation protocol tailored to their needs. This also makes it possible to compare results between different hospitals and healthcare providers in different parts of the country. These results, which are also important for the surgeon to obtain a complete overview of the patient's function, can subsequently be used in improvement programs and for research purposes.

Data entry into a database would be greatly facilitated with the informatization of medical records. The National Recovery and Resilience Plan (PNRR in Italy), part of the European Union program known as Next Generation EU to relaunch its economy after the COVID-19 pandemic, sets a major objective of promoting greater digitalization, inclusion, and equitable access to treatment and prevention. Thus, the informatization of medical records would represent a turning point for the creation of any clinical database, making it accessible to all health services at any time and from any place, to allow access to the patient's medical history.

CONCLUSIONS

This paper represents a call to action to foster the development of shared guidelines for the reporting and archiving of prospective data on arthroscopic knee surgery, to promote multi-centric collaborations and improve scientific evidence, in the light of sustainable and digitized research for a near tomorrow.

Conflict of Interest:

None of the authors has a potential conflict of interest to disclose in relation to this manuscript.

Funding:

No external funding or reimbursement was received for the drafting of the present manuscript.

Ethical Approval and Informed Consent:

Not applicable.

Authors' Contributions:

M.C., G.T. and M.T. drafted and edited the manuscript. R.C. edited the manuscript. P.P.M. supervised the work and approved the final draft.

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