

COVER PAGE

SCIENTIFIC PROTOCOL (SINGLE-CENTER)

Study document for ClinicalTrials.gov submission

Official Title	Single-center retrospective descriptive case series study of clavicle nonunion: epidemiology, surgical management, and functional outcomes
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Document type	Scientific protocol (retrospective observational study)

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# Single-center retrospective descriptive case series study of clavicle nonunion: epidemiology, surgical management, and functional outcomes

## Scientific Protocol Summary

### Study identifiers

Study reference	To be completed by the DRCI
Acronym	To be completed
Protocol version	1

### Project team

Data Controller	CHU de Brest, 2 avenue Foch, 29609 Brest Cedex, France
Principal Investigator / Study Coordinator	Dr Agathe YVINOUE, CCA-AHU; agathe.yvinou@gmail.com / agathe.yvinou@chu-brest.fr; Department of Orthopaedic and Trauma Surgery, CHU de Brest (Cavale Blanche site), Boulevard Tanguy Prigent, 29200 Brest, France
Resident (if applicable)	Anaëlle KOPP
Department	Department of Orthopaedic and Trauma Surgery
Scientific Committee (if applicable)	To be completed by the DRCI
Ethics Committee (if applicable)	To be completed by the DRCI
Biostatistician	Dr Hoel LETISSIER; hoel.letissier@chu-brest.fr; Department of Orthopaedic and Trauma Surgery, CHU de Brest (Cavale Blanche site), Boulevard Tanguy Prigent, 29200 Brest, France
Methodologist	Title / Surname / First name / email / professional address (to be completed)
Funding	No funding
DPO contact	protection.donnees@chu-brest.fr
Legal framework	Project compliant with Reference Methodology MR-004. Declaration date: 20 August 2018. Declaration No.: 2205306 v0.

Objectives and purpose

Background, objectives, and rationale

This single-center retrospective observational study describes a case series of clavicle nonunions treated surgically at CHU de Brest. Clavicle nonunion is a rare complication associated with pain, functional limitation, and reduced quality of life. Surgical management most often involves plate fixation, with generally favorable union rates; however, no clear superiority has been shown for a specific plate type or graft strategy in the literature (Wiss 2021; Hollo 2020; Song 2021; Muhlenfeld 2024).

The project relies exclusively on data generated during routine care (medical records and imaging), without additional visits or interventions. Given the low local incidence, an exhaustive description of operated cases is required to characterize patient profiles, management, and outcomes.

Remaining uncertainties include (i) whether bone grafting is systematically necessary, (ii) the impact of clavicular length restoration, (iii) predictors of nonunion repair failure, and (iv) the magnitude and variability of functional improvement. Recent studies suggest that 3.5 mm locking plates may be sufficient in most nonunions, and that functional outcomes improve significantly, albeit with inter-patient variability. Recent cohorts have also identified risk factors for failure (age, BMI, smoking, chronicity of nonunion).

Vascularized bone reconstruction may be considered salvage therapy for recalcitrant nonunions or segmental defects, with high union rates but increased donor-site morbidity depending on the flap. Other salvage options have also been described (e.g., the Masquelet technique).

Study purposes:

- Improve patient management: refine indications (plate alone vs plate + graft), follow-up scheduling, and prevention of reoperations.
- Evaluate local practice: document complications, reinterventions, and real-world functional outcomes at the center.
- Surveillance: monitor infections, implant failures, and persistent nonunions.

Primary objective	Primary endpoint
Describe clinical, radiological, and therapeutic characteristics of clavicle nonunions treated surgically in our center, and estimate the union rate after surgery.	Union rate at 6 months (assessment window 4-8 months), defined clinically and radiographically; complementary analysis: time to union (weeks).
Secondary objectives	Secondary endpoints
Functional outcomes at last follow-up.	Constant and/or DASH scores; pre/post change if available; proportion of clinical

	success.
Complications and reinterventions.	Infection, implant failure, persistent pain, revision; time to reintervention.
Factors associated with failure of union.	Age, sex, smoking, time from fracture to surgery, plate type, graft (yes/no), graft type, comorbidities, radiographic morphology.
Factors associated with poor functional outcome.	Same variables as above (exploratory).
Comparison of technical strategies.	Plate alone vs plate + graft; graft type; non-vascularized vs vascularized graft in recalcitrant cases - compare union, time to union, functional scores, complications, reinterventions.
Recovery trajectories.	Pain (VAS), range of motion (elevation/abduction), return to activities/work (weeks).

### Ethical considerations

The project raises no specific ethical concerns. It does not undermine participants' dignity, does not stigmatize any specific group, and follows applicable professional and ethical rules. Participation is based on the absence of objection (opt-out) after clear and complete information has been provided. Confidentiality and anonymity are ensured throughout the study.

### Public interest justification

The project pursues a public interest by clearly stating its purposes and expected benefits for patients, the healthcare system, and the scientific community.

#### Purposes:

- Improve quality of care: standardize description of surgically treated clavicle nonunion patients, techniques used (type of fixation, bone grafting), and outcomes (union, complications, functional scores) to optimize indications and post-operative follow-up.
- Evaluate professional practices: measure real-world performance (union rate/time to union, reinterventions, morbidity) and identify opportunities for improvement (protocols, implant choices, rehabilitation schedule).
- Generate useful and reproducible knowledge: produce real-world data on a rare and heterogeneous condition with limited robust evidence to inform local recommendations and future literature syntheses.
- Contribute to care planning and appropriateness: estimate organizational impact (pathway, consultations, imaging, reoperations) to guide resources toward the most effective and efficient strategies.

#### Benefits:

- Benefits for patients (direct / short-term)
  - Better selection of indications (plate alone vs graft), limiting reoperations and complications.
  - Standardized follow-up (assessment windows, union criteria), promoting faster return to activities and work.
  - Reduced unnecessary exposure (non-relevant visits/exams) through harmonization of practices.
- Benefits for society and the healthcare system (indirect / medium-term)
  - Reduced avoidable costs related to revision surgery, prolonged sick leave, and complications.
  - Improved equity of access to evidence-informed management, including for complex or delayed cases.
  - Strengthened quality and safety of care via outcome indicators monitored over time (union, complications, satisfaction).
- Benefits for the scientific community (indirect / short- and long-term)
  - Exhaustive single-center data useful for meta-analyses and inter-center comparisons on homogeneous criteria (Constant, DASH, union rate/time to union).
  - Hypothesis generation for future trials (role of grafting, implant type, predictors of failure) and translational research (biology of nonunion).

## Results dissemination and valorization

Any results disseminated outside the project team will be anonymized and will not allow direct or indirect identification of patients or healthcare professionals. CHU de Brest owns the data; no use or transfer to a third party may occur without prior agreement. The authors' affiliation must include 'CHU de Brest'.

Work derived from this protocol will be communicated and/or published under the responsibility of the study lead and/or supervisor. Co-authors will include investigators involved in the study in proportion to their contribution, together with the biostatistician. A copy of publications will be sent to the Delegation for Clinical Research and Innovation (DRCI).

Publication rules will follow international recommendations (N Engl J Med. 1997;336:309-315).

The study may be registered by the project investigator on an open-access registry before the first patient is included, if required by journals.

Planned publication: Orthopaedics & Traumatology: Surgery & Research (OTSR, category C).

Planned oral communications: SOO 2026; SOFCOT 2026.

## Methodology

### Study design

Single-center cohort study reusing data generated during routine care.

Participant inclusion is retrospective.

### Study population: description and justification

#### Period of interest

Patients managed between 1 January 2000 and 31 December 2024.

#### Inclusion criteria

Eligible cases (per clavicle) must meet all of the following:

- Period and center: patients managed at CHU de Brest (Orthopaedics-Traumatology Department) and operated for clavicle nonunion between 01/01/2000 and 31/12/2024 (to ensure at least 1 year of follow-up at the time of analysis).
- Age: 18 years or older at the time of the index surgery.
- Diagnosis: clavicle nonunion defined as absence of clinical and radiographic union at least 6 months after the initial fracture, or radiographic signs of nonunion (gap, absence of bridging callus, sclerotic bone ends) with compatible symptoms, documented in the record.
- Index treatment: surgical management of the nonunion (plate fixation with/without graft, vascularized graft, or another reconstructive technique).
- Minimal available data: pre-operative and/or intra-operative imaging confirming nonunion, and at least one post-operative clinical and/or radiographic assessment (regardless of exact timing).
- Scope: aseptic and/or septic nonunions.

#### Non-inclusion criteria

Cases will not be included if any of the following apply:

- Age under 18 years.
- Non-surgical management only (conservative treatment).
- Acute clavicle fractures (time since fracture under 6 months without nonunion criteria) or delayed union without nonunion criteria.
- Pathological fractures due to tumor or metastasis; congenital clavicle nonunion.
- Management outside the study period or outside CHU de Brest.
- Objection to data processing / lack of legal basis (if applicable under local GDPR framework).
- Adults under legal protection (guardianship/curatorship) if applicable.

Exclusion criteria (after initial screening):

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- Insufficient documentation to assess exposure and/or primary outcome: no usable pre- or post-operative imaging and no post-operative follow-up available (immediate loss to follow-up).
- Early death unrelated to the condition or surgery before any post-operative assessment.
- Active infection not documented: suspected sepsis at the site without microbiological confirmation and without a clear therapeutic strategy preventing septic/aseptic classification.
- Major concomitant ipsilateral trauma (e.g., severe brachial plexus injury, major scapulothoracic stiffness, recent glenohumeral arthroplasty) making functional scores uninterpretable.
- Unresolved inconsistent identifiers/duplicates (same patient - same clavicle).

### Sample size

As this is a single-center retrospective descriptive case series over 24 years, the expected number of patients is estimated to be at most 30 at CHU de Brest. The condition is rare.

### Data sources

Data originate exclusively from routine care and are available in medical records and imaging archives.

### Variables

Only data strictly necessary to conduct the research will be collected.

Identifying data: Yes - age and sex.

Health data: Yes - weight, height, treatments related to the study and concomitant treatments, examination results, results from biological samples (if any), medical imaging (MRI, CT, ultrasound, X-ray), adverse effects and adverse events, personal/family history, comorbidities or associated events, and data related to a health status likely to influence results.

Patient data:

- Major comorbidities: diabetes, vascular disease, renal failure, osteoporosis, inflammatory diseases, immunosuppression.
- Treatments influencing union: chronic corticosteroids, bisphosphonates, anti-TNF, etc.
- Pre-operative ASA score (I-IV).

Initial fracture data:

- Mechanism (fall from standing height / sport / road traffic accident / high-energy / iatrogenic).
- Side (if not already recorded) and dominant hand.
- Initial fracture management (non-operative / operative; if operative: type of fixation).

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- Complications of initial management (infection, implant breakage, secondary displacement).
- Number of previous interventions on the same clavicle (0, 1, >=2).
- Date of initial fracture.
- Date of first surgery.
- Date of nonunion diagnosis.
- Date of index nonunion surgery.

Nonunion characteristics (pre-operative):

- Time from fracture to nonunion surgery (weeks).
- Nonunion type (hypertrophic / atrophic / oligotrophic).
- Bone loss / diastasis (mm).
- Bone-end quality (sclerosis, osteolysis).
- Pain (VAS 0-10 at rest and during activity).
- Pre-operative function (Constant, DASH if available).
- Glenohumeral range of motion (forward elevation degrees, abduction degrees, external rotation, internal rotation).

Infection status (if suspected/history):

- Clinical signs (sinus tract, discharge, erythema, inflammatory pain).
- Pre-operative CRP (mg/L) and ESR (mm/h).
- MSIS pre-operative criteria.
- Aspiration/samples (date, number of specimens).
- Microbiology (organisms, susceptibility, colonization vs infection).
- Classification (aseptic vs septic nonunion).

Pre-operative imaging:

- Standard radiographs (yes/no; date; views).
- CT scan (yes/no; date; measured defect).
- Other (MRI / bone scan).
- Radiographic criteria of nonunion (absence of bridging, radiolucent line, diastasis).

Operative details (index surgery):

- Surgery date.
- Type of anesthesia (general / regional / combined).
- Approach (superior, anterior).
- Debridement / freshening (yes/no; description).
- Reduction / length restoration (yes/no; target mm).
- Fixation type (3.5 mm locking plate / non-locking plate / other; manufacturer/implant).
- Additional fixation (cortical/locking screws, cerclage/tension band, structural graft).

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- Bone graft (none / non-vascularized autograft / allograft / vascularized graft).
- Harvest site (iliac cancellous/corticocancellous, fibula, other).
- Graft volume/length (mL / mm).
- Antibiotic prophylaxis (drug, dose, duration).
- Intra-operative samples (number, sites).
- Intra-operative complications (neurovascular injury, iatrogenic fracture, bleeding).
- Operative time (minutes) / blood loss (mL).
- Drain (yes/no; removal post-op day).

Immediate post-operative course and rehabilitation protocol:

- Immobilization (type, duration).
- Load/constraint release schedule (week X).
- Physiotherapy (start, goals, frequency).
- Analgesics/antibiotics (drugs, durations).
- Length of stay (days); discharge home/rehab facility.

Clinical and radiological follow-up:

- For each visit (e.g., 6 weeks, 3-4 months, 6 months, and last follow-up):
  - Pain (VAS/NRS).
  - Function (Constant and/or DASH; record score version).
  - Range of motion (elevation, abduction, external rotation, internal rotation).
  - Patient satisfaction (yes/no or 0-10 scale).
  - Return to activity/work (yes/no; time in weeks).
  - Imaging (radiographs yes/no; union criteria).
  - Clinical union (yes/no).
  - Radiographic union (yes/no).
  - Date of first documented union (YYYY-MM-DD).

Endpoints:

- Primary endpoint: union rate at 6 months (yes/no at month 6; window 4-8 months).
- Time to union (days/weeks from index surgery to first evidence of union).
- Secondary endpoints: Constant/DASH at last follow-up; complications; reinterventions; return to activities.

Complications and adverse events:

- Early complications ( $\leq 30$  days): hematoma, superficial/deep infection, wound dehiscence, complex regional pain syndrome.

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- Late complications: implant failure, persistent nonunion, secondary septic nonunion, stiffness.
- Reinterventions (date, indication, procedures performed).
- Hardware removal (yes/no; indication; time from surgery).

Resources consumed (organizational impact):

- Number of consultations (pre-/post-operative).
- Number of imaging exams (radiographs, CT).
- Cumulative sick leave (days).
- Total hospitalization duration (days).

Photos/videos/audio recordings: No.

### Data preparation

The coordinator will identify eligible subjects from CHU de Brest medical records, maintain a correspondence table for included subjects, and enter the pseudonymized data to be analyzed into the study database.

No transfer of data outside CHU de Brest will be performed.

### Methods, processing, and data analysis

Software/tools:

Analyses will be conducted in R ( $\geq 4.3$ ) and cross-checked in Python. R is chosen for reproducibility (version-controlled scripts) and suitability for small samples and censored data.

Methods:

- Descriptive statistics: mean  $\pm$  SD or median [IQR]; counts and percentages. Proportions (e.g., union at 6 months) will be reported with 95% confidence intervals.
- Time to union: Kaplan-Meier curves; Cox regression modeling.
- Exploratory comparisons: Fisher's exact test for categorical variables; Mann-Whitney U test (or Student's t-test) for continuous variables.
- Multivariable analyses: Cox regression for time to union; linear regression for Constant/DASH scores.

### Study limitations

Potential limitations include the retrospective single-center design and small sample size ( $\sim 30$ ).

Design-related limitations and mitigation:

- Selection bias (only operated cases; loss to follow-up): define inclusion/exclusion criteria a priori; provide a flowchart of exclusions/losses; compare included vs non-included when possible.

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- Indication bias (technique chosen based on patient profile): stratified analyses (plate alone vs graft; septic vs aseptic).
- Temporal heterogeneity (changes in implants/techniques over 2000-2025).
- Single-center (limited external validity): provide detailed description of local context and discuss generalizability versus literature.

Data-source limitations and mitigation:

- Information/classification bias (incomplete/heterogeneous records): standard operational definitions (union; septic vs aseptic nonunion); data dictionary; double review of a random sample ( $\geq 10\%$ ) with discrepancy resolution.
- Outcome measurement (clinico-radiographic union; functional scores not always available): specify assessment windows (4-8 months); document information source (clinical vs imaging); define a functional sub-cohort a priori.
- Radiographic assessment variability: standardized reading grids; blinded review by two trained readers.

Analytical limitations:

- Small sample / low number of events (risk of overfitting).
- Missing data (particularly functional scores).
- Potential informative censoring / variable follow-up.
- Limited causal inference (non-randomized; residual confounding).
- Reproducibility: analyses will be scripted and version-controlled.

## Planned timeline and feasibility

Key project milestones and estimated timeline:

Step	Description	Dates	Duration
Authorization	Receipt of authorization (CPP/DPO/Management)	31/01/2026	-
Participant information	D0 = 05/02/2026 (letters + transparency portal) - statutory period	05/02/2026 to 04/04/2026	2 months
Data extraction and entry	Extract records and imaging (PACS), operative reports; enter CRF/REDCap; quality control	05/04/2026 to 31/07/2026	4 months
Data analysis	Database lock; R/Python analyses; figures and tables	01/08/2026 to 30/09/2026	2 months
Writing and reporting	Internal report and manuscript/presentation	10/2026 to 12/2026	3 months
Results presentation	Thesis presentation /	15/01/2027	-

	main oral communication		
Planned end of study	Official date (after database lock and analyses)	30/09/2026	-
Database destruction	5 years after end of study	30/09/2031	-

#### Feasibility:

- Team: 2 orthopaedic surgeons (shoulder/trauma), 1 resident plus 1 senior surgeon (Dr Yvinou) for data collection, and a biostatistician (Dr Letissier).
- Resources: access to PACS and medical records; R >= 4.3 and Python 3.11 environments; restricted hospital storage; pseudonymization.
- Volume: about 30 cases - exhaustive data extraction in 4 months; analyses in 2 months.
- Risk control: random double review of at least 10% of cases.

## Privacy, security, and confidentiality of data

### Respect for data subject rights

Patients will be informed in a complete and fair manner, using understandable terms, about the objectives of the research and their rights through at least one of the following methods.

- Information via the hospital website (transparency portal)
  - Eligible patients may be informed through an information notice published on the hospital transparency portal. In case of objection, it will be forwarded to the hospital Data Protection Officer (DPO) without delay. The coordinator will also ensure that patients who have previously objected to systematic reuse of their data for research are excluded (via the local 'non-objection verification' process). If no objection is received from patients or their legal representatives within one month, data collection will be implemented.
  - Eligible patients for this website-based information are those who consulted or were hospitalized at CHU de Brest at least once since September 2025, having received generic information about the transparency portal and possible data reuse for research.
- Information via postal letter
  - Patients may be informed by postal letter. In case of objection, it will be forwarded to the DPO without delay. Patients who have previously objected to systematic reuse of their data for research will be excluded and not contacted. If no objection is received within one month, data collection will be implemented.
- Information handed directly to the patient

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- The information notice may be handed directly to patients by qualified hospital staff. If a patient objects after inclusion, the objection will be transmitted to the DPO without delay. If no objection is received, data collection will be implemented.

Additional remarks:

- For minors, an age-appropriate version of the information notice will be provided; each legal representative will be informed.
- For deceased persons, data may be reused for this research without prior information, except for persons who died before 2019 (date of the generic information campaign on data reuse at CHU de Brest) or if the person (or representatives) expressed written refusal during life.
- Undelivered postal letters (e.g., unknown address): persons will not be considered informed and will not be included.
- Non-responsive patients (coma, etc.) at the time of data collection: persons will not be considered informed and will not be included.
- DPO contact: protection.donnees@chu-brest.fr

Selected information method(s):

- Website transparency portal notice (eligible patients only): Not selected
- Postal letter: Selected
- Hand-delivered notice: Not selected

## Confidentiality and data security

### Management of re-identification risk

The correspondence table contains identity, inclusion number, and postal address (if postal notification is used). It is an Excel file protected by a password and stored in a study-specific folder on a secure CHU de Brest server. Entry and access are restricted to members of the care team for included subjects, using named user sessions. No transfer of this file is permitted.

Study database:

- Content: study data and subject inclusion number only (pseudonymized data; no names or contact details).
- Format, protection, and hosting: password-protected Excel file (with a password different from the correspondence table), stored in a study-specific folder on a secure CHU de Brest server.
- Data entry: performed only by members of the care team because entry requires consultation of nominal medical records.
- Access: restricted to CHU de Brest staff involved in the study, through named user sessions.

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- Data analysis: conducted only by CHU de Brest staff using local software. If online tools are used, no variable names will be entered online.
- Transfer: no transfer outside CHU de Brest. If needed, internal transfer will be done via the secure BlueFiles platform.

Persons with access to the correspondence table:

- Dr Agathe Yvinou
- Dr Hoel Letissier
- Resident Anaëlle Kopp

### Data media

Data will be hosted on the hospital's secure server with protected access.

### Archiving

The study data file may be retained on the institution's shared network by the data controller/investigator until two years after the last publication of study results, or, if no publication occurs, until the date results are presented.

In addition, the data file and all study documents will be archived by the investigator for five years after the end of the study.

Archiving consists of retaining a copy of the data on secure IT media controlled by the data controller, with access restricted to necessary personnel.

### Appendices

Appendices include:

- Information notice provided to data subjects, where applicable.
- Study case report form (CRF).
- Bibliography.

Bibliography:

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## Patient Information Notice / Right to Object (Retrospective Study)

<b>Official Title of Study:</b>	Single-center retrospective descriptive study of a case series of clavicle nonunion: epidemiology, surgical management, and functional outcomes
<b>Study Acronym:</b>	PSEUDO-CLAV
<b>NCT Number (if available):</b>	Not yet assigned
<b>Sponsor / Data Controller:</b>	Brest University Hospital (CHU Brest)
<b>Principal Investigator / Scientific Lead:</b>	Dr Agathe Yvinou, Orthopaedic and Trauma Surgery, Brest University Hospital (CHU Brest)
<b>Document Type:</b>	Patient information notice (right to object / opt-out information sheet)
<b>Document Date:</b>	14 August 2025
<b>Version:</b>	ENR-XXX_V1

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This document provides information about the use of previously collected health data for research. You may object to the use of your data at any time, as described in the document.

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## **INFORMATION NOTICE**

### **PSEUDO-CLAV Study**

Single-center retrospective descriptive study of a case series of clavicle nonunion: epidemiology, surgical management, and functional outcomes

**Data Controller:** Brest University Hospital (CHU Brest)

### **Scientific Lead**

Dr Agathe Yvinou  
Orthopaedic and Trauma Surgery  
Brest University Hospital (CHU Brest)

### **CHU Brest Data Protection Officer (DPO) Contact**

DPO email address: [protection.donnees@chu-brest.fr](mailto:protection.donnees@chu-brest.fr)

Dear Sir or Madam,

CHU Brest is the sponsor of a research study entitled “PSEUDO-CLAV” under the scientific responsibility of Dr Agathe Yvinou.

This study will be conducted using your health data that were already collected during your care at CHU Brest. It does not involve any direct contact with you, nor any modification of your care. However, you have the option to object to the use of your data for this study.

If you do not wish your data to be included in the study, simply inform the CHU Brest Data Protection Officer or the study’s scientific lead. This decision will have no consequences for your relationship with the medical and nursing teams, nor for the quality of your current or future care. You do not need to provide a reason.

### **What is the purpose of the research?**

The aim of this study is to describe the clinical, radiological, and therapeutic characteristics of clavicle nonunions treated surgically in our center, and to estimate the bone union rate after surgery, in order to improve knowledge and medical practice in this field.

### **What data will be used?**

The data used in this study come from your medical record. They include medical information (history of the trauma, medical and surgical history, steps of medical and surgical management, laboratory data such as blood test and bacteriology results, antibiotics received, multidisciplinary meeting reports), surgical information (types of surgery and dates, types of implants and grafts), and radiological information (imaging examinations performed and their interpretation).

These data will be pseudonymized, meaning they will be coded and will not include your first or last name. They will be processed confidentially, only by authorized members of the research team, for scientific purposes only.

### **Who will have access to the data?**

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Authorized members of the research team who perform the analyses will have access to the study data in coordination with the scientific lead. All these individuals are bound by professional secrecy and confidentiality.

The results will be published in scientific journals and/or presented at conferences. They will always be presented in an aggregated manner so that it will be impossible to identify an individual participant in the study.

### **How will the study be conducted and how will your data be protected?**

A computerized file containing only the data strictly necessary for the study will be created within CHU Brest. Your first and last names will not appear in this file.

Only authorized members of the research team will be able to access the data. Access to the database will be secured by an individual password. Analyses will always be carried out confidentially. No individual data will be extracted from the database.

The results of the study will improve current knowledge and optimize the management of patients who may experience the same medical situation as you did.

Your health data collected for this research will be kept and archived for a maximum of 5 years after the end of the study.

### **What are your rights?**

In accordance with the French Data Protection Act of January 6, 1978 (as amended) and the General Data Protection Regulation (GDPR) of April 27, 2016, you have the right to access, rectify, and restrict the processing of your data.

These rights may be exercised through the Data Protection Officer.

You may object at any time to the processing of your data for this study, provided that analyses are not already underway or completed.

A minimum period of 30 days between dissemination of this information notice and the start of analyses will be respected to allow you to exercise your right to object.

If you have any questions about your rights, you may contact our Data Protection Officer. You also have the right to lodge a complaint with the French Data Protection Authority (CNIL) if you consider that your rights are not being respected.

### **What is the regulatory framework for this study?**

This study received a favorable opinion from the CRET (Comité de Réflexion Ethique de Territoire). It is conducted as part of a public-interest mission entrusted to CHU Brest.

The processing implemented in the context of this research complies with the regulatory provisions allowing a healthcare institution to process data for scientific research purposes (Article 9(2) of the GDPR).

### **Future collaborations and other possible uses**

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As part of future scientific collaborations, CHU Brest may share coded data with institutional or industrial teams in France or abroad, or make them available on a secure research-dedicated website, in accordance with points (i) and (j) of Article 9(2) of the GDPR.

If your data are transferred to a country outside the EU, CHU Brest undertakes to ensure an adequate level of protection of personal data in accordance with applicable regulations.

You may also object at any time to the use of your health data for other research, activity analyses, or future studies conducted by the care team or other authorized professionals, under the responsibility of a physician.

Finally, you may request access to your medical record in accordance with Article L1111-7 of the French Public Health Code and the GDPR.

### **How to object to the use of your data for the PSEUDO-CLAV study**

- By email: [protection.donnees@chu-brest.fr](mailto:protection.donnees@chu-brest.fr)
- Via the transparency portal: Transparency portal ([chu-brest.fr](http://chu-brest.fr)) - <https://transparence.chu-brest.fr/>
- By contacting the scientific lead: Dr Agathe Yvinou
- By post: CHU Brest, Hôpital Morvan, Direction Générale / DPO, 2 avenue Foch, 29609 Brest, France

### **Template letter to send by email or post**

First name / Last name:

Date of birth:

Place of birth:

I object to the use of my health data collected during my care for this research.

Date: \_\_\_\_\_ Signature: \_\_\_\_\_