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Human Tissue Procurement from Atlanto-Axial Fusion Surgery

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Christoph P Hofstetter[1], Nguyen Tran[1], Cathryn Payne[1]

[1]Department of Neurological Surgery, University of Washington

PRECISION Human Pain ...

Cathryn Payne
University of Washington

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We use this protocol and it's working

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Abstract

Purpose

Describe the human tissue removal, preservation, storage, and transportation procedures during tissue procurement from patients undergoing C1-2 arthrodesis (surgical immobilization of a joint by fusion of the adjacent bones).

Responsibility

The Human Tissue Procurement and Processing Core at the University of Washington and the University of Texas at Dallas are responsible for maintaining this protocol, ensuring it is updated and controlled, and ensuring that users receive proper training prior to its implementation.

Definitions and Abbreviations

DRG = dorsal root ganglia
OR = operating room
PPE = personal protective equipment
UTD = The University of Texas at Dallas
UW = University of Washington

Tissue Recovery Sites

Local hospitals

Tissue Recovery Team

UW Surgical Staff
UW Research Coordinator
UW Scrub Nurse

Materials

Materials provided by the hospital:

1. PPE including surgical scrubs gloves, hair nets, led vests and shoe covers
2. Waste disposal bins

Materials provided by UW Research Team

1. Powdered dry ice (see below)
2. Containers for dry ice (cooler, with biohazard label on the lid)
3. Sterile dissection tools (small forceps)
4. Ruler
5. Sterile storage tubes (1/5mL epitubes, 5mL epitubes)
6. Labels
7. Stickers
8. Shipping boxes
9. Sharpies

Powdered Dry Ice

- Dry ice (pellets or blocks) must be pulverized to a fine powder to ensure proper freezing of human tissues. Using a hammer, crush the dry ice in an ice bucket (Globe Scientific 2.5L Rectangular Ice buckets with Lid) or styrofoam container.
- To ensure that the dry ice particulates are small enough, run the pulverized dry ice through a mesh grate/netting.

C1-2 DRG Recovery Notification

1 The identification of subjects will be done one of two ways:

Outpatients

- For established patients scheduled for C1-2 arthrodesis, identified either through an EPIC electronic screening report or during a clinic visit, the study coordinator may directly initiate contact using a pre-approved script.
- After reviewing the patient's electronic medical record (EMR) against the study criteria, the study coordinator will call to inquire about their interest and arrange a time to obtain consent. If the patient expresses interest, consent will be obtained during their hospital stay.

Inpatient admitted and scheduled for surgery

- For patients admitted to the hospital for an acute injury and identified during the surgeon's call schedule, the research coordinator will be notified of the potentially eligible subject.
- After reviewing the patient's electronic medical record (EMR) against the study criteria, the coordinator will approach the patient in their hospital room to discuss potential participation. If the patient expresses interest, consent will be obtained during their hospital stay.

2 The research coordinator will approach potential participants to provide a detailed explanation of the study, including its purpose, procedures, risks, and potential benefits. Consent will be obtained in strict adherence to ethical guidelines and institutional review board (IRB) standards. Whether the patient is identified in an outpatient or inpatient setting, the coordinator will ensure the patient is fully informed, given the opportunity to ask questions, and feels comfortable before obtaining consent.

2.1 Exclusion criteria include:

- Patient being <18 years of age
- Unable to consent due to language comprehension or non-English speaking

OR

- Being unable to consent due to cognitive deficit.

3 Obtain baseline information regarding participant in accordance with study guidelines.

Tissue Procurement

4 The research coordinators prepare the materials/equipment and wait for the allotted time to join the surgeon in the OR.

5 The research coordinator dons PPE, enters the OR, and sets up their materials/equipment on a table within the OR.

6 The following surgical approach for C1-2 arthrodesis is performed irrespective of the patient's pain classification (acute or chronic):

C1 lateral mass screws are placed bilaterally. The entry point for each screw is located at the midpoint of the junction between the C1 posterior arch and the lateral mass. Screws of appropriate length and diameter are then inserted to achieve secure fixation.

Next, C2 pars screws are placed bilaterally. The entry point for these screws is positioned 3 mm lateral and 3 mm rostral to the inferomedial aspect of the inferior C2 articular surface. The screws are inserted along a trajectory parallel to the C2 pars.

7 The operating surgeon performs a bilateral C2 dorsal root ganglion (DRG) neurectomy (using a bone scalpel or surgical tool) to facilitate adequate hemostasis and access to the facet joints the dorsal root ganglion from C1-C2 (ref Fig 1).

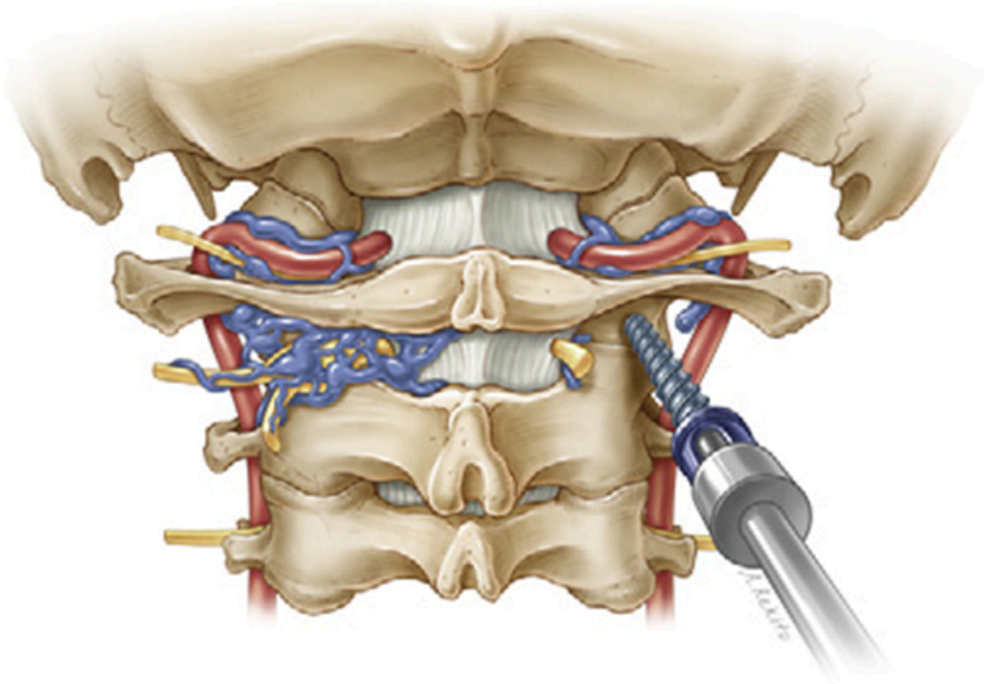

Figure 1. Illustration showing the placement of a C1 lateral mass screw on the right side after sectioning the C2 nerve root

8 Once removed, the surgeon transfers the tissue to the scrub nurse. During this transfer, the surgeon notifies the research coordinator of the tissue specimen type (e.g., DRG,

capsule, cartilage), laterality, and any irregularities.

The level and extent of tissue we receive can vary from patient-to-patient. As a result, DRG size and tissue quality may vary.

9 The scrub nurse removes the tissue from the surgical instrument and places this on TELFA or a sample petri dish, which is then passed to the research coordinator.

10 The research coordinator then buries the tissue directly in powdered dry ice (fresh-frozen preparation).

11 Meanwhile, the operating surgeon will proceed with surgery by entering the C1-2 facet joints, the cartilage is removed with a curette, and the cortical bone surface decorticated with the high-speed bur.

12 The resected facet joint cartilage and facet joint capsule is transferred to the scrub nurse, who places this on TELFA or a sample petri dish which is then passed to the research coordinator. The surgeon notifies the research coordinator of the specimen type being transferred.

13 The research coordinator then buries the tissue directly in powdered dry ice (fresh-frozen preparation).

14 The storage containers, 1.5 mL epitube for small DRGs or baggies for larger DRGs are labeled with the research ID and biospecimen information (i.e., 34, C1-2, left DRG).

15 After 2-3 minutes, the tissues specimens are uncovered. The size (cm) of the length and diameter of the DRGs are recorded, along with an image of the tissue sample.

16 Once the length and diameter of the DRG is recorded, the DRGs are placed into their designated labeled tubes over dry ice. Capsule and cartilage are transferred directly from dry ice to their respective epitubes.

Packing, Clean-up, and Transport

17 Excess biofluids, TELFA, and petri dishes are disposed of in OR waste bins.

18 Used tools and sharpies are placed into a large Ziploc bag and sealed, to be sterilized by research coordinators.

19 The dry ice cooler containing the biospecimen tubes, and Ziplock bag are taken with the research coordinator.

20 Upon exiting the OR, PPE research coordinator removes all PPE and takes biospecimens to the freezer.

Biospecimen Logging, Storage, and Shipment

21 All frozen biospecimen tubes collected from a research subject are placed into a cardboard cryo freezer box that is labeled on all sides with the study and PIs name. These boxes are stored in a secure -80°C freezer.

22 All biospecimen tubes are logged on a tissue storage log that resides within a protected data server. The following information is kept in the tissue log that resides within a protected data server. The following information is kept in the tissue log:

1. Research ID
2. Age
3. Sex
4. Race
5. Ethnicity
6. Medical History (both EMR retrieval and patient self-report during interview)

23 Images of the tissue within the OR (after flash freezing) are placed into designated folders on the protected data server for each subject.

24 Once 3 patient samples are stored, tissues to be shipped to UTD on dry ice, maintaining the standards outlined by the US Department of Transportation and Hazardous Material Regulations 49 CFR § 100-185. UTD team is notified of shipment and sent tracking information via email.

25 Tissue is logged and stored at -80°C upon arrival.