Clinical Safety & Effectiveness

Autologous Bone Flap Cranioplasty Handling Process

CENTER FOR PATIENT SAFETY & HEALTH POLICY

UT Health Science Center

SAN ANTONIO
The Team

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• Mentor
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• Sponsor
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AIM Statement

The aim of this project is to reduce surgical site infections for autologous cranioplasties (tumor, stroke, trauma) by 50% by May 30, 2016.
Background- Decompressive Craniotomies

- Medical conditions creating a state of increased intracranial pressure such as:
  - Stroke
  - Trauma
  - Tumors
  - Hemorrhages

- Require sometimes an emergency intervention to remove skull/bone flap

- Decompressive craniotomy is performed to allow the brain to expand beyond the original skull contour and with time get back to its normal size.
Background- Cranioplasty

- Repair of skull defect created by the first life saving procedure
- Needed to protect brain and as matter of cosmesis
- Auto vs allograft (titanium, PMMA, hydroxyapatite, etc)
- Infections higher with autografts (especially versus titanium)
- Infection rate reported as low as 7.86% (varies 7-20%)
Basic Process

- Crani removed
- Crani bone flap cleaned and Stored
- Cranioplasty
Flow Chart

- Different teams have different protocols
- Timing of antibiotic

Patient in OR

Tray needed?

Crani- Removed

- Staff panic
- Emergent case

Bone Thawed

- Bucket is not ready until surgeon asks for it
- Cleaning method is Rn dependent
- No wash protocol
- Instruments not clean

Flap transported back

Schedule OR

Bone Processed (OR table)

- How empty containers are stored / sterilized
- Blood bank storage process unknown

Circulating RN charts/ W. Order for container

Store flap in container

- Monitoring fridge temp/ culture

Bone Flap transported to bank

- Get info on solution and protocol variation

Patien t ready?

Time to put back bone?

Bone process ed on OR table (ready)

Crani put back on head

Patient transported to recovery

- Timing of Antibiotics

- Antibiotic protocol variation for post-op
- Process for tracking infection rates
- Post Op follow up variation

Patient ready?

Patient ready?

Patient in OR

- Different teams have different protocols
- Timing of antibiotic

Patient ready?

Patient ready?

Patient ready?
Fishbone

- Management
  - Surveys protocol varies
- Man
  - Time of Year
- Mother Nature
  - Time of Year
  - Cause
- Scrub Tech(s) handling of crani varies
  - Time of Year
  - Cause
- Nurse handling method varies/ no guidelines
  - Time of Year
  - Cause
- Infection Rate
  - Storage of Supplies
  - Fridge/Storage
  - Sterilization Equipment
  - Crani Trays
- Database
  - Material
  - Machine
- Measurement
  - Effective Measures
  - Cost

Infection Management
Man Mother Nature
Nature Measurement Machine Material Cost Effective Measures
Scrub Techs crani varies
Nurse handling method varies/ no guidelines
Surgeons protocol varies
Infection Rate Database
Sterilization Equipment Crani Trays
Fridge/Storage Storage of Supplies Material
Machine
Pre-Intervention Data

- All surgeries with CPT codes 62141, 62143, 62145 or 62147 between January 1, 2012 and December 31, 2015 at all facilities for all surgeons within the Department
- By hand chart review limited to autologous cranioplasty and both surgically and non-surgically treated post operative infections identified
Pre-Intervention Data

- Pre-intervention infection rate 24/99 (24.2%)
- All but two infections treated with repeat craniectomy
- Issue: Data lapse. Won’t know how well we are doing until patient comes back (Duration from flap removal to Cranioplasty is at least 3 months and up to a year.)
Pre-Intervention Data

Number of Infections / Total Cranioplasties $u$ Chart

- CL: 21.21%
- UCL: 100.98%
Variables

• Patient population
• Bone Handling
• Storage (regulated)
• Instruments (regulated)

The most variable process is Bone Handling.
The only variable we have true control over is Bone Handling.
Pre-Intervention Observations

- **Washing**
  - No washing

- **Soaking**
  - Not completely submerged
  - Not sterile solutions

- **Storing**
  - Unclear how storage units audited

- **Thawing**
  - Not handled steriley on opening
Interventions

Protocol for bone handling
- Washing
- Sterilization
- Double Soaking
- Rinsing
- Bagging (purchase crani storage kit - pending)

Staff Education
- Surgeons
- OR Staff

Early Cranioplasty
- Agreed no early cranioplasties before 6 weeks

Tracking
- CPT CODES
- OR Database of cranioplasties
- Audits of stored bone flaps
- Check-list in EMR
Interventions

• Standardized protocol for handling of bone flap following removal and before implantation:
  – Completely submerged in Bacitracin infused normal saline x 15 minutes
  – Completely submerged in Betadine x 15 minutes
  – Irrigation with 3 liters normal saline with powered irrigation debridement system (i.e. Pulsavac)
  – Bone flap stored in sterile bag and then sterile sealed container
  – Repeat prior to implantation
Interventions-cont.

• Track all future cranioplasties
  – Established required EMR documentation checklist for OR nursing to document protocol was followed during all craniectomies and autologous cranioplasties
  – Will audit all stored bone flaps every 6 months

• Agreed with no early cranioplasties before 6 weeks
Implementation

• Researched best practices and devised a standardized protocol for the handling of the bone flap after removal and prior to replacement
• Got buy in from all surgeons regarding implementation of the protocol
• Met with OR staff and got approval from OR committee for protocol
• Filmed instructional in service video for all OR staff regarding protocol
• Created Check-list in EMR
Educational Video

Cranioplasty Protocol Training Video
CRANIAL BONE FLAP
SOAKING PROTOCOL

FOR ALL EMERGENCY CRANIOTOMIES, CRANIOTOMY
FOR ANEURYSM, AND CRANIOLASTIES

Bone flap is soaked before leaving the field, and upon return from Blood Bank for Cranioplasty.

First Soak: 50,000 Units Bacitracin/1 liter Normal Saline x 15 minutes. Make sure flap is completely submerged the entire 15 minutes.

Second Soak: Betadine Paint/Solution (6-8 bottles or 24-32 oz) x 15 minutes. Make sure flap is completely submerged the entire 15 minutes.

Step 3: Pulse Evac with 3 liters Normal Saline (without antibiotics.)
EMR Checklist

Specimen fields updated May 2016
Project Cycle

Plan
- Process Mapping
- Fishbone
- Observations
- Infection Data

Do
- Literature review
- Draft Protocol
- Draft Approval
- Video

Act
- Compliance check-list
- Educate Surgeons
- Educate OR Staff

Study
- Infection data
- Compliance
- Regular meetings with OR
Results

• Short term data consists of compliance data via face to face surveys with OR team members following all craniectomies and cranioplasties

• Long term data will consist of compliance data in EMR and prospective cranioplasty infection tracking
Results

• From April 1 to April 30, 2016
  – First full month following implementation
  – 6 autologous cranioplasties
    • 100% compliance with new cranioplasty soaking protocol
  – 5 emergency craniectomies
    • 100% compliance with new cranioplasty soaking protocol
  – No early infections
  – No early cranioplasties
### Results

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Row 1 of 6 Case Records found
Results - Infections Rate

# of Infections / # of Procedures (Plasties) u Chart

- UCL
- CL
- 50.53%
- 1.21%
Results - Protocol Compliance
Sustaining the Results

• Previously it was difficult to track cranioplasties and subsequent infections in real time. We have implemented tracking within nursing EMR
• We’ll meet regularly with OR nursing leadership to review the data
• We will use random surgeon and OR staff audit surveys to document compliance with the protocol
Return on Investment

• Cost of Implementation of Soaking Protocol
  – Minimal additional operating room time
  – Bacitracin $25
  – Betadine $95
  – Pulsavac $40
  – Normal Saline Solution $30
  – Approximately $190/case for implementation of soaking protocol
Return on Investment

• Cost of Cranioplasty ranges from $14,500-75,000

• Cost of autologous cranioplasty infection
  – Average inpatient hospital bill for 6 surgically treated autologous cranioplasty infections from January 2015 to December 2015: $82,654
  – Does not include the eventual implantation of a synthetic cranioplasty
  – Atbx 2 weeks and hospital stay 30,000-60,000$( ssi surgical site infection vs MRSA)
Return on Investment

- A 50% reduction in autologous cranioplasty infections would likely result in yearly savings to all payers in the high seven figures
Conclusion

• Pre-intervention data confirms our anecdotal suspicion of an abnormally high rate of infection associated with autologous cranioplasty

• Following extensive participant buy in and education we have had good compliance with a new cranioplasty soaking protocol which we are hopeful will reduce our rates of infection

• A successful 50% reduction in our rate of infection has the potential to save hundreds of thousands of dollars per year