Retrieval Analysis Protocol
Pediatric Growing Rod Constructs

Last Date of Revision: May 2015

IMPORTANT NOTES:

- ***CARE SHOULD BE TAKEN WITH ALL EXPLANTS (E.G., NO BANGING)***
- ***PROPER TRACKING AND STORAGE SHOULD BE USED AT ALL TIMES***
- ***NEVER SCRATCH DEVICE SURFACES WITH A BRUSH***
- ***NEVER STICK FRACTURE SURFACES INTO PUTTY***
- ***DO NOT MATE FRACTURES SURFACES TOGETHER UNLESS OTHERWISE INSTRUCTED***

Explant Receipt

1. Within 48 hours of receipt, find the retrieval form and determine what information is present. The form may not be completely filled out. At a minimum, we should know the patient ID # and site name (even in cases when the form is missing since the package will list the site and the ziplock bags should list the patient ID #).
2. Make a copy of the form (put copy in binder), scan the form (email it) and keep the original form in the ziplock bag with the explant.

Photographic Assessment

Important Notes: All explanted devices should be handled with gloves.

1. Remove the explanted device components from ziplock bags and gauze.
2. Neatly arrange all components onto a white lab bench coversheet.
3. Photograph all components "as is" to capture how they were sent using the Nikon AF-S NIKKOP 18-105mm lens. Please ensure the first photograph of each device is a snapshot of the patient ID number. The photographs should capture all components together and individually. If possible, reconfigure the components to resemble a construct as if they were implanted and take photos of the construct.
4. Using ruler and calipers, measure the amount of exposed rod for any fractured rods that are still connected to the axial connectors. Record measurements in lab notebook.

5. All explanted devices should be stored in the device analysis lab in the locked cabinet in the far left hand corner of the lab.

Cleaning

Important Notes: All explanted devices should be handled with gloves.

1. After initial photographs, disassemble the constructs as needed.
2. Mark new ziplock bags with the patient ID and component name so that all disassembled components have their own bag. For example, label each rod with a number (e.g., Rod #1) and label each subassembly component accordingly (Tandem Connector #1 (assuming it was linked to Rod#1)). For any fractured rods, find the corresponding rod pieces and label each accordingly (Rod#2a, Rod #2b).
3. From the retrieval form, determine if the site soaked the devices in Sporicidin disinfectant. If not, soak all components in Sporicidin for 20 minutes. Only one set of devices should be in each tray to avoid intermingling devices from multiple patients.
4. Soak the disassembled device components in Terg-a-zyme (diluted to 10g/liter) for 30 minutes. Only one set of devices should be in each tray to avoid intermingling devices from multiple patients. Please also smartly place the newly labeled ziplock bags for each disassembled components next to the area of the soaking tray where that component is being soaked so that all components are tracked.

Macroscopic Assessment

Important Notes: All explanted devices should be handled with gloves.

1. Arrange all components on a white lab bench coversheet.
2. Use the high resolution lens (Nikon AF Micro NIKKOR 105mm) on the Nikon camera when taking photographs. If needed, use the step stool to get a good shot.
3. Please ensure the first photograph of each component is a snapshot of the patient ID number and component name, i.e., take photo of labeled ziplock bag before taking a photo of the component.
4. Take photographs of each disassembled device component zoomed in as much as possible. The photographs should capture multiple viewpoints of the components as needed (e.g., top view, side view, bottom view).

5. For each component, identify areas of interest as outlined in the table below as well as any general observations (e.g., Rod #2 fractured into 3 pieces). Photograph all areas of interest and take note of each incidence in a lab notebook. Ensure that the lab notebook clearly identifies that patient ID# and the same naming convention of each component as labeled on the ziplock bags.

Areas of Interest
mechanical damage (e.g., set screw gauging)
scratching
pitting or crevice corrosion
discoloration or staining
stress cracking or crazing (network of fine cracks)
mechanical failure
wear or burnishing
deformation and/or change of shape
galling (wear caused by adhesion between sliding surfaces)
macro porosity
fretting
embedded particles
degradation
other (list)

6. Using calipers and rulers, record the dimensions of each component in a lab notebook. Dimensions should include, but not limited to, diameters, lengths, widths, and heights.
7. Weigh each component and record in a lab notebook.
8. Record any etched or laser markings found on the components. It is very common that components are marked with a serial number, material name, manufacturer's logo, etc.
9. For any components that experienced failure, document the failure mode (e.g., rod fracture, screw/hook dissociation). For any components with set screw damage, please document the damage accordingly.
10. Make notes of any other findings or observations about the components.

Microscopic Assessment

Important Notes: Proper training on all equipment should be performed prior to using. All explanted devices should be handled with gloves.

1. Use the Hirox digital optical microscope and install the MXG-2016Z lens with the low adapter. Use the Lens/Adapter Setting to select the correct adapter so that the scale adjusts accordingly.
2. Make new folder for each patient ID #.

3. Take images of each area of interest, set screw damage, markings, and any other findings on each component. ***ALL IMAGES MUST HAVE A SCALE!***
4. In the appropriate patient's folder, save the image where the title of the image includes the component name, area of interest, and resolution. For example, the file name may be: "Rod #2b corrosion near tandem connector 40x."
5. Switch to the normal adapter with the diffuser and change the Lens/Adapter Settings accordingly.
6. For the fractured rods, take images of the 1) side views of the fracture end at 40x, 2) cross section of the fracture surface at 40x or 60x, and 3) 45 degree angle at the crack initiation site at 40x/60x, 80x, and 100/120x. For the 45 degree images, use the 3D, multi-focus synthesis, semi-automated process to get high quality images. All crack initiation sites should be facing 12 o'clock.

ALL IMAGES MUST HAVE A SCALE!

Rod Bending Photos

Important Notes: All explanted devices should be handled with gloves.

1. Find the setup in the device analysis lab and mount the Nikon camera using the Nikon AF-S NIKKOP 18-105mm lens. Manually zoom all the way out.
2. Take photo of ziploc bag with patient ID# and component name.
3. Take photo of each rod as shown in figure 1 below.

Assessment of Damage from Set Screws

1. Find mechanical damage on the surface of each rod.
2. Using diffuser lens on Hirox microscope, take image of damage area under at least 60x zoom.
3. Save each image. Record all measurements in lab notebook.

Additional Assessments: SEM and EDS protocols are not covered in this document. Proper training is necessary.

1. Use SEM to see high resolution areas of cracking.
2. Use SEM and EDS to evaluate areas of corrosion.

X-ray Evaluation

1. Contact GSF to determine if X-rays are in clinical registry database for these patients. If not, they will need to retrieve any missing X-rays which may take a while.
2. Follow the radiographic protocol and analyze each X-ray at each time point for each patient with an explanted device.

Analyses

1. Using IMAGEJ, calculate rod bending angle. See figure 1 below.
2. For devices with failure, perform a failure analysis using Hirox image to determine the mechanism of failure:
    - static-overstress, causing plastic deformation
    - shear
    - fatigue
    - torsion
    - impact
    - stress corrosion or environmental cracking
    - fatigue, or corrosion-fatigue
    - combination of above (identify)
    - other (specify)
    - unable to identify
3. On fractured surfaces, using IMAGEJ, calculate areas of slow crack growth, rapid crack growth, crack width, and crack length. See figure 2 below.

*Figure **1**: Rod Bending Analysis*

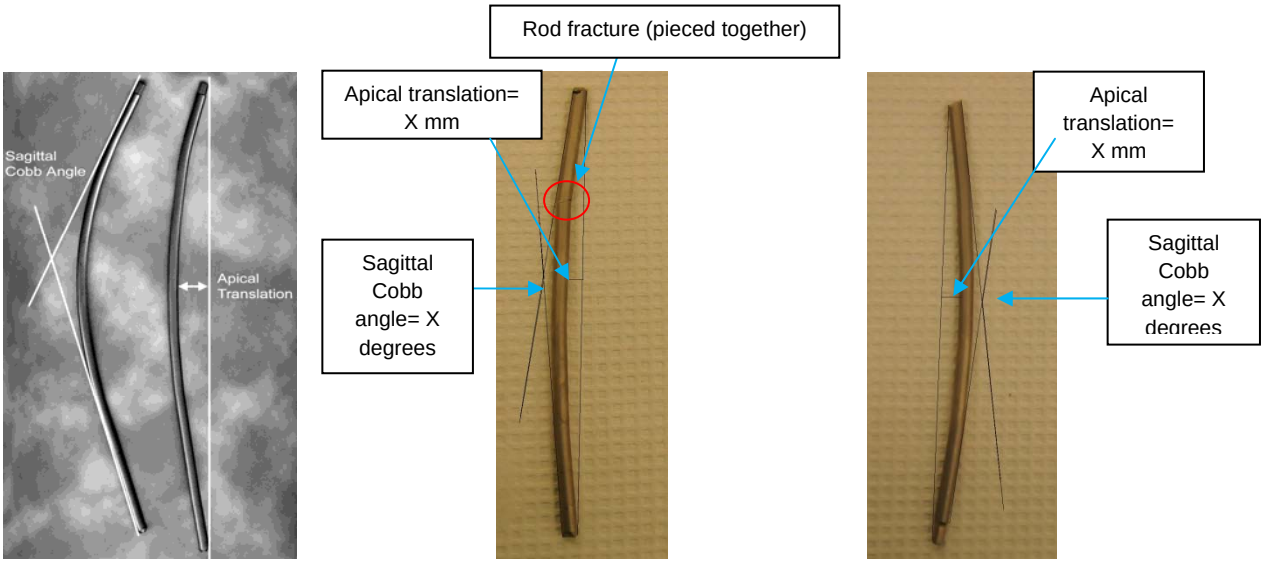

Figure 2: Failure Analysis of a Fractured Rod