Developing a method to quantitatively assess residual patient material in reusable medical devices

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The comments and opinions expressed in this presentation are those of the speaker, and do not necessarily reflect the formal position of the FDA.

Outline

- Overview
  - Goals of project
- Background
  - Reprocessing reusable medical devices
  - Established methods of test soil detection
- Experimental approach
  - Preliminary data
- Future directions

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Overview of Project

FDA has received reports of reusable medical devices that contain residual patient material even after being cleaned, which poses a risk for infection.

Goals:

1. To develop an assay for assessing residual debris in reusable medical devices

2. To quantitatively determine the impact of different device designs on the ability to remove organic material from reusable medical devices

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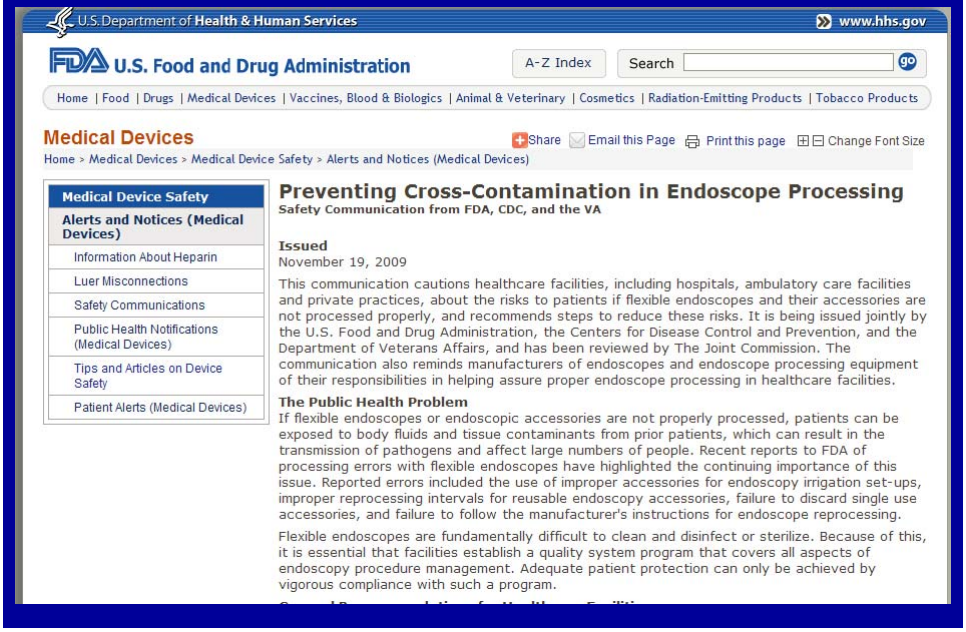
Background

- Cleaning is an important first step in reprocessing for effective disinfection and/or sterilization of reusable devices.
- Organic material has been found to compromise the effectiveness of certain sterilization processes
- Improper cleaning of reusable devices (e.g. endoscopes) increases the possibility of infection for patients
  - Patient to patient transmission (Hepatitis)
  - Environmental transmission (*Pseudomonas*)

Endoscopes



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Medical Devices

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Preventing Cross-Contamination in Endoscope Processing
Safety Communication from FDA, CDC, and the VA

Issued
November 19, 2009

This communication cautions healthcare facilities, including hospitals, ambulatory care facilities and private practices, about the risks to patients if flexible endoscopes and their accessories are not processed properly, and recommends steps to reduce these risks. It is being issued jointly by the U.S. Food and Drug Administration, the Centers for Disease Control and Prevention, and the Department of Veterans Affairs, and has been reviewed by The Joint Commission. The communication also reminds manufacturers of endoscopes and endoscope processing equipment of their responsibilities in helping assure proper endoscope processing in healthcare facilities.

The Public Health Problem
If flexible endoscopes or endoscopic accessories are not properly processed, patients can be exposed to body fluids and tissue contaminants from prior patients, which can result in the transmission of pathogens and affect large numbers of people. Recent reports to FDA of processing errors with flexible endoscopes have highlighted the continuing importance of this issue. Reported errors included the use of improper accessories for endoscopy irrigation set-ups, improper reprocessing intervals for reusable endoscopy accessories, failure to discard single use accessories, and failure to follow the manufacturer's instructions for endoscope reprocessing.

Flexible endoscopes are fundamentally difficult to clean and disinfect or sterilize. Because of this, it is essential that facilities establish a quality system program that covers all aspects of endoscopy procedure management. Adequate patient protection can only be achieved by vigorous compliance with such a program.

Arthroscopic Shaver Handles

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Medical Device Safety

Alerts and Notices (Medical Devices)

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Ongoing Safety Review of Arthroscopic Shavers

FDA has become aware of instances in which pieces of tissue have remained within certain arthroscopic shavers, a device used in some orthopedic surgical procedures, even after the cleaning process was believed to have been completed according to the manufacturer's instructions. Reports submitted to FDA suggested that the tissue retained was not evident to the naked eye. Multiple manufacturers of these devices recently informed their customers of this situation and reiterated the importance of proper cleaning procedures.

We are concerned about this because retained tissue in these devices can compromise the entire sterilization process. We are actively working with the manufacturers of these devices to gather more data about this situation and to understand its potential public health impact. As the FDA obtains more information that better defines the situation and determines whether there are specific risks, we will provide that information to facilities, health care providers and the public.

The FDA encourages facilities that use any of these types of devices to evaluate the adequacy of their cleaning procedures. Hospitals should consider taking the following steps to minimize any potential risk to patients:

- Be sure that all personnel responsible for device cleaning and sterilization at your facility are aware of and comply with all steps in the manufacturer's instructions for thoroughly cleaning these devices prior to sterilization. Please refer to the specific instructions provided in the labeling or user manual for each brand and/or model of shaver your facility uses.
- Consider inspecting the inside of the devices following cleaning to ensure that they have been cleared of any tissue or fluids. There may be multiple ways to accomplish this. As one example, the facility that brought this situation to our attention uses a 3mm video scope to inspect the channels of the shaver handpiece.

Background

April 2009

- During an investigation of an outbreak of Pseudomonas infections, a hospital found that some of their orthopedic surgical devices contained residual bits of patient material even after being cleaned

- residual organic material has been found to compromise the effectiveness of certain sterilization processes

Regulatory Relevance

- FDA has become aware of other types of reusable devices that retained patient debris after cleaning, indicating that this issue is not limited to a particular device or facility
- Manufacturers of reusable medical devices must provide users with reprocessing instructions, including cleaning instructions
  - cleaning instructions must be validated by the manufacturer as being effective to remove soil
  - manufacturers validate cleaning by performing simulated soiling and cleaning of the device, followed by some measurement of residual debris
- Any device that is found to have residual debris after performing the manufacturer-recommended cleaning steps should be reassessed to determine which aspect of the cleaning validation failed

Factors that must be considered for validation of cleaning

- type of test soil used (clinically relevant)
- location of the soil in device (inside device; under sheaths, etc.)
- method of inoculation of test soil
- length of time for the soil to dry on the device (to simulate worse case conditions)
- assessment of soil removal
- quantitative endpoints of “cleaned” device

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The ideal assessments for residue will be:

Accurate

Sensitive

Quantitative

Fast

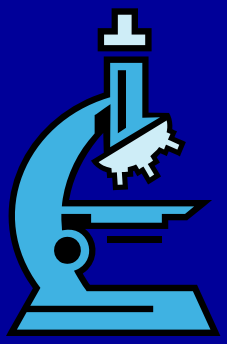
Easy

Inexpensive

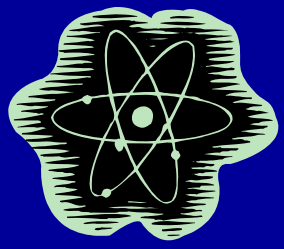
Can be used by manufacturers and users (using a test soil or clinical soil)

Methods that have been used to assay for residues

Direct



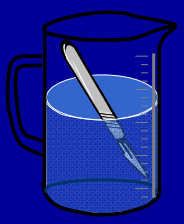
Scanning electron microscopy,
surface chemistry analysis,
photoelectron analysis
staining



Radionuclide tracers

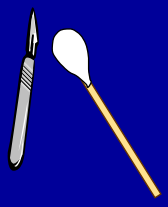
Methods that have been used to assay for residues

Indirect



Liquid Extraction

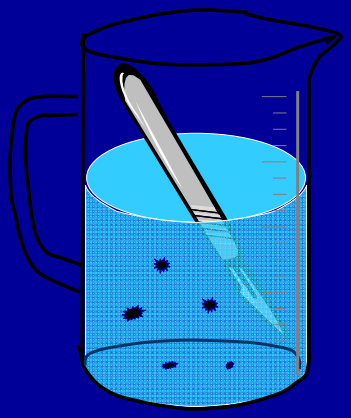
- Protein (Bradford, ninhydrin, autoanalyzer, etc.)
- Lipids and oils (Nile Red Dye)
- Carbohydrates (phenol-sulfuric acid protocol)
- Endotoxin (limulus amoebocyte lysate assay)
- Hemoglobin
- Total organic carbon
- Viable microorganisms



Swab

- Protein
- ATP fluorescence assay
- Viable microorganisms

The problems with solid debris in liquid eluate:



Sampling error

Inaccuracy

General Protocol

1. Apply test soil to device
2. Allow test soil to dry for defined time periods
3. Clean devices
4. Assess residual debris

Test soil and inoculation

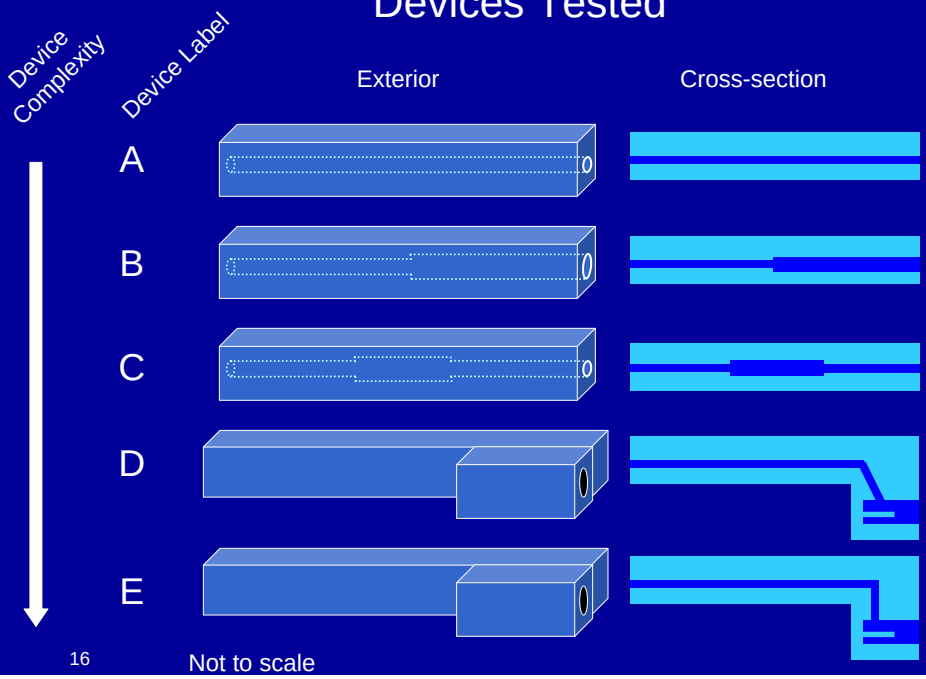
Test soil adapted from
Standardised Test Soil Blood 1: Composition, Preparation, Application
M.Pfeifer, Zentr Steril 1998;6 (6);304-310

Coagulated blood test soil

- Purified blood proteins (hemoglobin, albumin, fibrinogen, thrombin)
- Forms a jello-like substance

- Dispense test soil directly into lumen of device
- Invert to mix, ensuring that all interior surfaces are coated with test soil
- Set down horizontally
- Allow to dry

Devices Tested



General Protocol

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Assessments for debris

Swab – followed by Bradford assay for protein

Liquid extraction – followed by Bradford assay

HPLC analysis

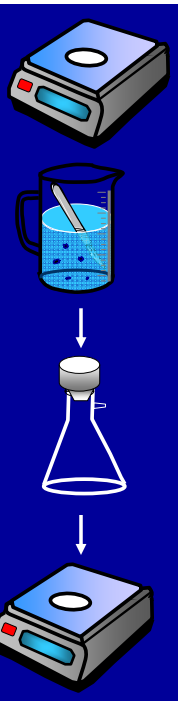
Mass spectrometry

Quantitative imaging analysis (FTIR/Raman spectroscopy)

Filter-weighing approach to assess residual debris in medical devices

Equipment:

- Nylon filters (0.2 micron pore size)
- Microbalance (or analytical balance)
- Filtered water
- Container for device
- Filtering equipment



Pre-weigh filter

Extract debris

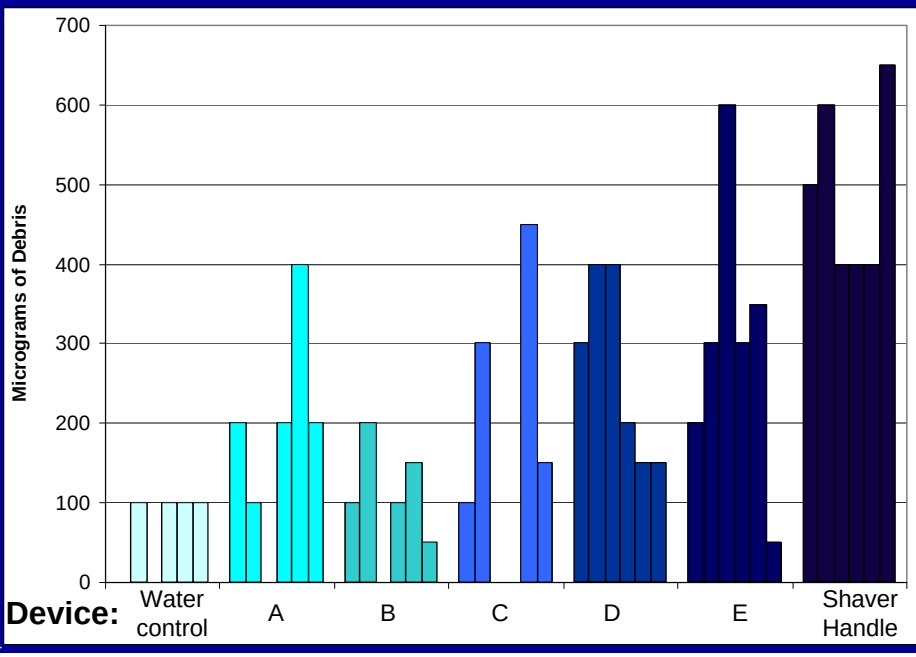
Filter extraction liquid (can save filtered liquid for further analysis)

Dry filter and weigh

Filter-weighing method to assess residual debris

- Sensitive
- Quantitative
- Requires few pieces of specialized equipment
- Relatively straightforward to perform
- Saved filtrate can be used in downstream applications
- Entire sample is filtered – no sampling error
- Accurately quantifies insoluble material

Summary of filter-weighing approach to assess residual debris



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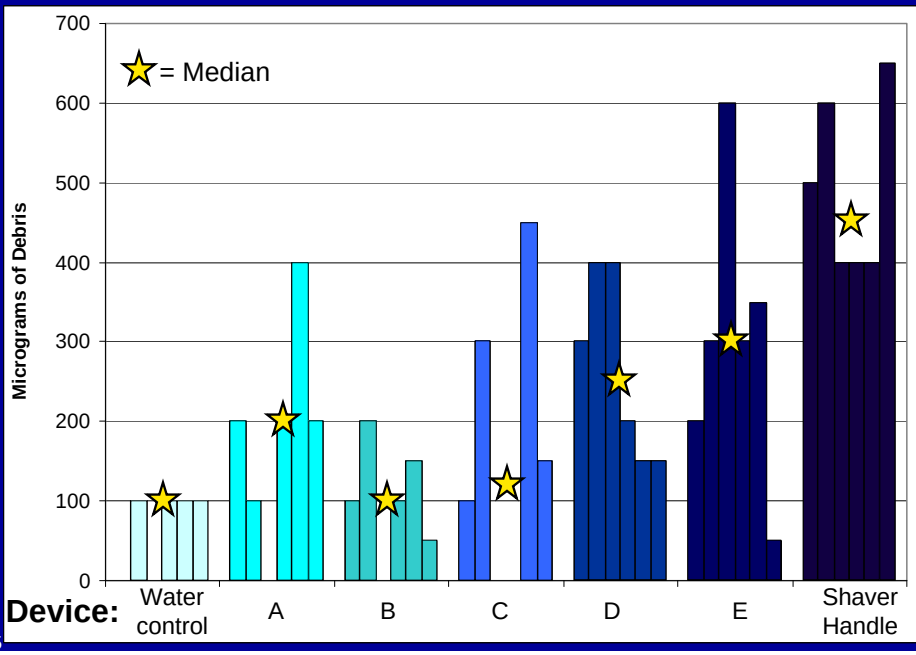
Summary of filter-weighing approach to assess residual debris



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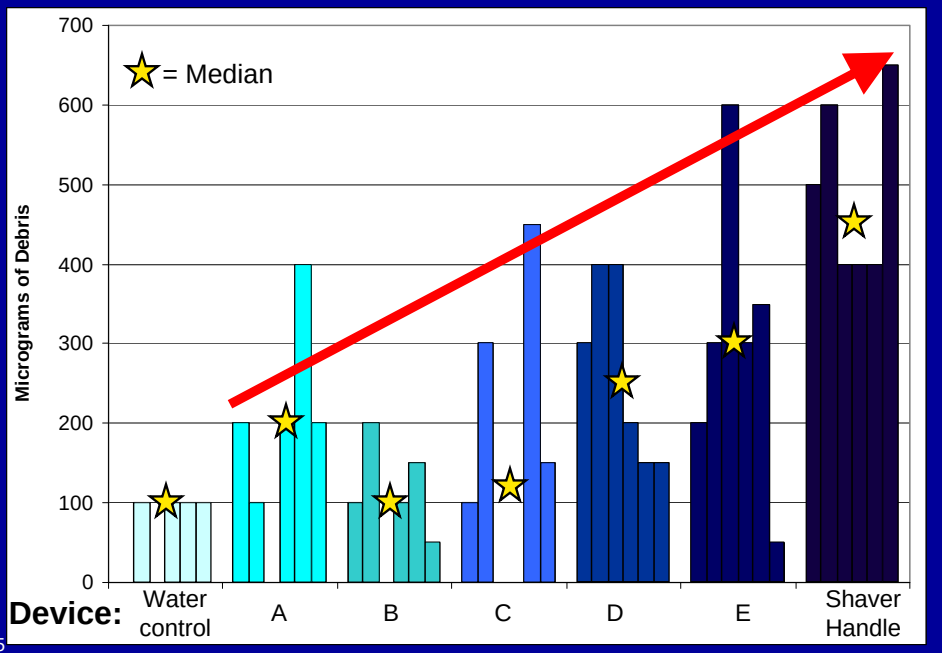
Summary of filter-weighing approach to assess residual debris



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Conclusions

The filter-weighing approach to assess residual debris in devices reveals a trend of increasing debris with increasing device complexity

These preliminary data support the continued development of the filter-weighing method to assess residual debris in reusable medical devices

Future Experimental Directions

- Repeat experiments with microbalance
  - Greater sensitivity – may more precisely define contributions from designs
- Use imaging technology (with Division of Physics)
  - Characterize debris on filters using Fourier Transfer Infrared technology
  - Characterize debris inside devices using Raman spectroscopy with a microprobe
- Purchasing additional medical devices
  - More data possibly relating debris retention to device design
  - Ability to see the range of debris found in these devices

Acknowledgements

Division of Biology
Vicki Hitchins
Rebecca Bour

Division of Solid Fluid Mechanics
Nandini Duraiswamy

Division of Physics
Sophia Tan
Ilko Ilev

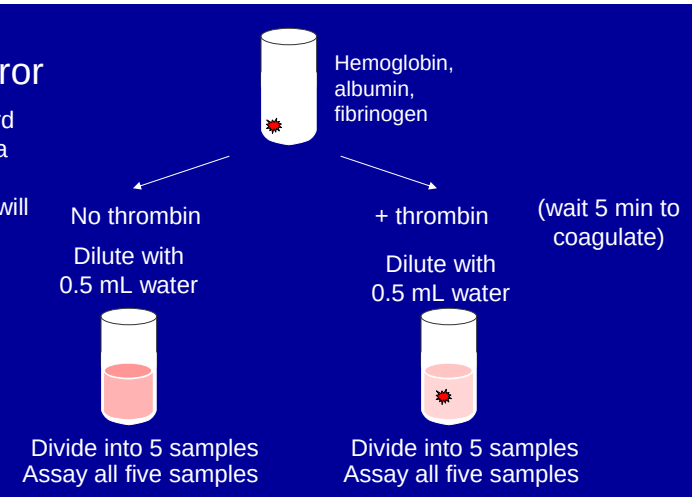
University of MI Hospitals
Jahan Azizi

Special Thanks to
CDRH Machine Shop

FDA Commissioner's Fellowship

Sampling error

Using the Bradford assay to sample a solution with insoluble protein will yield inaccurate results



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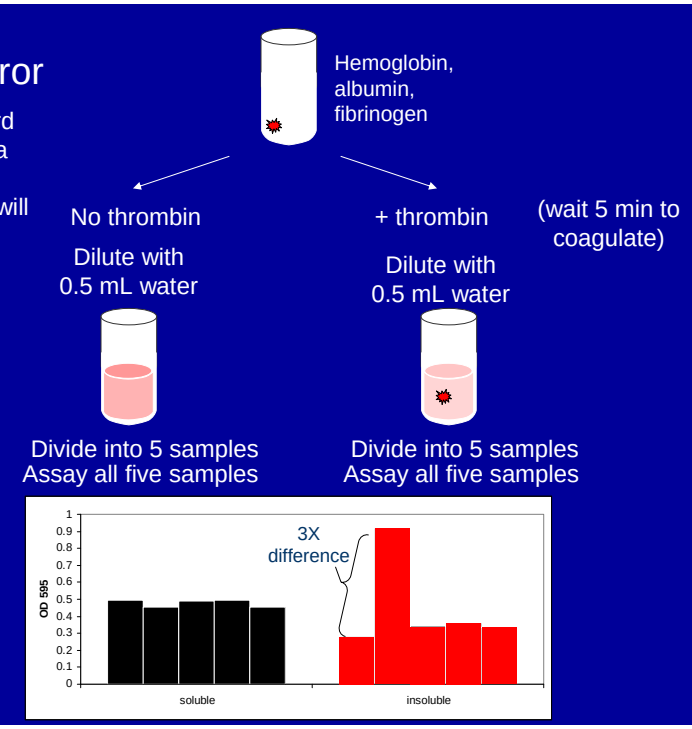
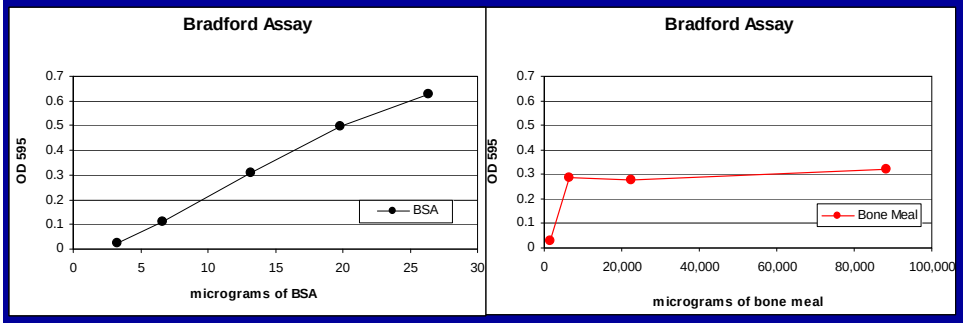


Bone cannot be accurately measured using a Bradford assay

Bone is ~30% protein [1]

Mineralization of tissue can be detected with dyes (Alizarin red S for Calcium, Von Kossa for Phosphate), semi-quantitatively [2]

Bone is often quantified by mass or density



[1] Heaney RP. Burckhardt P, Heaney RP, Dawson-Hughes B, eds. *Nutritional Aspects of Osteoporosis 2006*. Amsterdam: Elsevier Inc; 2007:191–197.

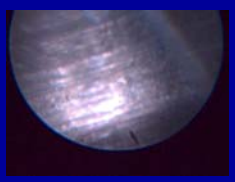
[2] Gregory CA, et al., Anal Biochem. 2004 Jun 1;329(1):77-84.

Debris found in arthroscopic shaver handles

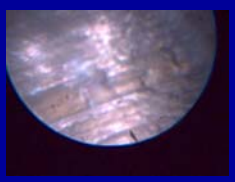
Blade Port

Blade Port - Closeup

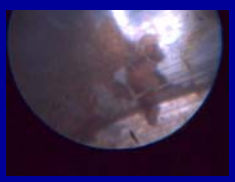
Suction Lumen - Clean



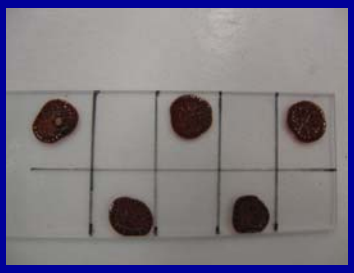
Suction Lumen - Debris



Suction Lumen - Debris



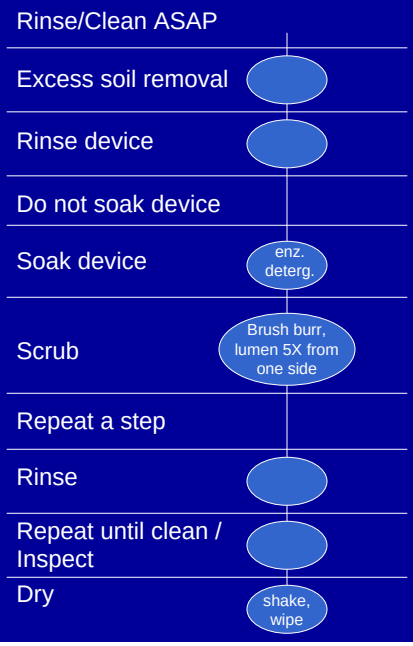
Efficacy of debris extraction method



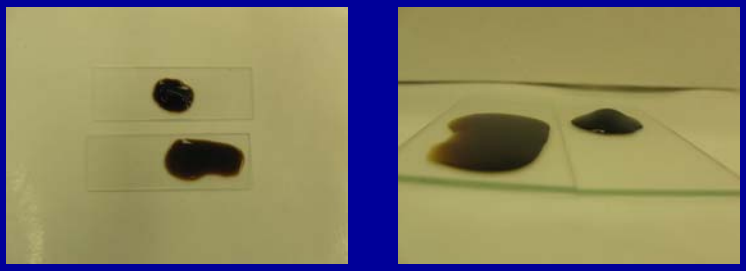
16 milligrams → 200 micrograms

Appearance of filters

Cleaning Protocol



Appearance of coagulated blood test soil



Variables in cleaning procedure

Device

Test soil

Application

Dry time

Cleaning

Assessment