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TITLE: Clinical Utility and Pitfalls of Ultrasound Guided
Foreign Body Removal in War Fighters

PRINCIPAL INVESTIGATOR: James W. Murakami, MD, (Original Award to PI,
William E. Shiels II, D.O., deceased 5/5/15)

CONTRACTING ORGANIZATION: Research Institute at Nationwide Children's Hospital Columbus
Columbus, Ohio

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<p>Purpose: To demonstrate that 1) ultrasound guided foreign body removal (USFBR) is superior to conventional surgery in the cadaver model, 2) USFBR can be taught to radiologists and generate competency, and 3) radiologists can apply the technique in the patient setting to remove foreign bodies.</p> <p>Materials and Methods: Radiologist and surgeon removed nine 1-cm foreign bodies using the USFBR method (P) and traditional surgery (S) with and without wire guidance (W) on the cadaver model. Technique was evaluated by removal success, time, incision size, and wound closure. Analysis of variance was applied to the data.</p> <p>USFBR was taught to 48 radiologists at 4 hospitals. Instruction and evaluation covered instrument alignment, hand/transducer position, forceps use, foreign body definition, forceps grasp, recognition of volume averaging, and oblique cross cut artifact. Pre-training testing included single toothpick removal over 15 minutes. Training included didactic and hands-on instruction. Post-training evaluation consisted of 5 toothpick removals of 15 minutes each. Data were evaluated using chi squared and Fisher's exact tests.</p> <p>Clinical implementation of USFBR included foreign body removal under ultrasound guidance by a trained radiologist. Parameters including age of patient, radiologist, removal success, type and size of foreign body(ies), incision size, foreign body retention time, reason for removal, symptoms, modalities used in detection, wound closure, and sedation are recorded in an online database.</p> <p>Results: USFBR technique shows a higher success rate and smaller incision size in comparison to surgical technique alone in the cadaver. Removal success: P 100%, S 78%, and W 89% (p=0.320).</p> <p>With training, radiologist scores improved from 21-52% pre-training to 90-100% post-training (p<0.001). After instruction, the removal success rate was 90% (judged on quantity, time, and technique).</p> <p>In the clinical setting site 1 was 63% successful (5/8) at the first attempt and 100% successful after two attempts, site 4 was 100% successful (11/11) at the first attempt, and site 5 was 0% successful (0/1) at the first attempt. The overall success rate was 80% at the first attempt (16/20).</p> <p>Conclusion: USFBR is superior to non-guided surgical technique. The USFBR approach taught in a simulation environment improves radiologist technique and removal outcomes. A radiologist who completes simulation training can remove a variety of imbedded foreign bodies.</p>		

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Introduction:

A three Part study with minimally invasive ultrasound guided foreign body removal was designed to demonstrate that 1) ultrasound guided foreign body removal (USFBR) is superior to conventional surgery in the cadaver model, 2) USFBR can be taught to radiologists and generate competency, and 3) radiologists can apply the technique in the patient setting to remove foreign bodies. Part 1 was a cadaver cohort study with video comparison between radiologists with percutaneous ultrasound guided foreign body removal (USFBR), conventional surgical foreign body removal, and wire localization followed by surgical foreign body removal, comparing incision size, time of procedure, wound closure (number of sutures), overall removal success and procedural differences. Part 2 was an educational efficacy research project. The physicians were trained with a turkey breast simulator. They were evaluated and measured on their performance and competency development with USFBR. Part 3 involved clinical implementation of USFBR in military health care setting as part of patient care of DoD health care beneficiaries with symptomatic soft tissue foreign bodies.

Body:

PART 1: A cadaver cohort study with video comparison between radiologists with percutaneous USFBR, conventional surgical foreign body removal, and surgical foreign body removal with wire localization comparing incision size, time of procedure, wound closure (number of sutures), overall removal success and procedural differences. In this component, comparison data was collected using human cadaver thighs for testing differences between the surgical and percutaneous techniques. Procedures were videotaped for a detailed analysis and accurate documentation of major and minor procedural differences. Statistical analysis projected 9 removals per procedure type would provide complete data sets for demonstration of statistical significance.

A total of 27 foreign bodies were implanted into human cadaver tissue. The anatomical materials used were human cadaver thighs. To remain consistent, all foreign bodies were the same. A 1 cm piece of a wooden toothpick was used to represent a traditional foreign body implanted in the cadaver tissue. Each cadaver thigh had 3 foreign bodies positioned into the tissue by the PI. The study coordinator, timed, observed and documented the foreign body removals. A graphic animation artist recorded the procedures to substantiate the findings. This same footage was used to develop future training materials in Part 2 of the 3 Part study. A surgeon and a radiologist performed the foreign body removals and reported the start and end time, the incision size, number of sutures as well as the success or failure of the foreign body removal. This was in conjunction with the written and video documentation for accuracy of findings.

Using a traditional surgical method following the skin marking of the foreign body location, the surgeon completed 9 foreign body removals (3 in each thigh). The incision size for each removal ranged from 30mm – 58mm with a mean of 45.78 mm. The number of sutures ranged from 4 to 9 in order to effectively close the wound. The time to complete the procedure (skin to skin time) ranged from 4-15 minutes with a mean of 8.33 min.; 7 of the 9 removal attempts were successful. One foreign body was unable to be located by the surgeon. In a clinical setting with an actual patient, the surgeon would typically send the 5 patients to Radiology for wire localization and then the surgeon would re-operate with the

wire localization method or percutaneous ultrasound guided foreign body removal would be completed by a radiologist.

The PI used ultrasound guidance for placement of localization wires at the site of each of 9 foreign bodies (3 in each thigh). The surgeon then used an operative method following the wire localization to remove the foreign bodies. The incision size for each removal ranged from 24mm – 39mm with a mean of 32.1 mm. The number of sutures ranged from 3 to 6 in order to effectively close the wound. The time to complete the procedure (skin to skin time) ranged from 4-12 minutes with a mean of 7.1 min.; 8 of the 9 removals were successful. One foreign body was unable to be located by the surgeon.

The third removal type was percutaneous interventional radiological ultrasound guided foreign body removal. The technique was performed by a radiologist who completed 9 foreign body removals (3 in each thigh). The incision size for each removal ranged from 5mm – 9mm with a mean of 6.4 mm. Sutures are not needed for this removal technique due to the minimal incision size. An adhesive bandage placed over the wound is standard of care. The time to complete the procedure (skin to skin time) ranged from 3-26 minutes with a mean of 12.2 min.; all 9 percutaneous removals were successful.

Unforeseen technical issues with cadaver materials occurred with both the surgical and the radiological procedures. The surgeon, commented that operative removal was a much easier in a cadaver compared to a live human because operative sites were not complicated by bleeding. During a procedure with a live patient the surgeon would need to stop every few minutes to manage bleeding which would lengthen the procedure time. During his first removal he commented that “this is necessitating significant tissue destruction to find the foreign body”. Additionally, the surgeon felt that blunt dissection facilitated movement of the foreign bodies in the surgical field; the surgeon switched from a blunt dissection to a sharp dissection to alleviate the movement issue. Both the surgeon and the radiologist reported the remarkable amount of movement with the foreign body removal. The surgeon noted that the 3 foreign bodies implanted in the third thigh with the traditional surgical removal were placed in the subcutaneous fat and not the muscle which made locating the foreign body easier. The wooden toothpicks were colored which the surgeon commented helped when searching for the foreign bodies. This was an advantage to the surgical method in the cadaver because the radiological method does not use an open operative field in which to see the color of the toothpick to help with localization. The surgeon also verbalized the learning process of following the fascial penetration site for his operative approach; he said that once he adapted to that technique then the process was simplified. Live human tissue with a foreign body and the time it takes to seek treatment would not leave such an easy hole to follow in order to locate the foreign body. This is seen as an advantage to the operative procedure in a cadaver. With respect to wire localization procedure, the surgeon noted that wire localization made the removal process much easier. The key to success with this method was having an experienced interventional radiologist provide 6 proper placement of the localization wire. If someone other than an experienced radiologist placed the wire, the failure rate would most likely increase. The radiologist in this study had performed over 100 foreign body removal procedures on living patients and noted that it is was very difficult working with cadaveric material. The mechanical (elastic) properties of the cadaver tissue effect the percutaneous ultrasound guided foreign body removal, seeming to add a degree of difficulty to cadaveric removal not experienced in live humans.

The hypothesis for Part 1 was proven partially correct in that ultrasound guided foreign body removal (USFBR) is faster and more effective than open surgical removal, with smaller incisions. The results found that USFBR is more effective than open surgical removal, with smaller incisions. However, the results also showed that the surgical method was faster. The results could have been affected by taking into account the differences in live tissue versus the dead tissue used with the cadaver thigh in this study. During future work or another comparison between radiologists with percutaneous USFBR, conventional surgical foreign body removal, and surgical foreign body removal with wire localization some changes would be recommended. Natural colored wooden 11 toothpicks would be a better choice than colored toothpicks that are easy to see in the cadaver tissue. Live tissue would alleviate the movement of the foreign body; but there would be no way to conduct a study on live patients with standardized implanting foreign bodies. A study could be done with live patients with existing foreign bodies but then there would not be any controls. Live patients would also have blood to make the operative portions of the study more life-like; however a researcher would not ever subject a patient to undue trauma from a surgical method if the percutaneous ultrasound guided foreign body removal technique were available. The findings showed the percutaneous ultrasound guided foreign body removal technique to have much less tissue destruction than operative techniques; the incision size is also much smaller in this technique. This would result in a faster healing time if the foreign body removal was performed in a live patient. Sutures are not needed in the radiological method. The success rate was 100% for the percutaneous ultrasound guided foreign body removal technique; whereas, the success rate for traditional surgical method and surgical with wire localization were only 78% and 89% respectively. Graphs of the cadaver cohort study data spreadsheet, incision size, removal time, wound closure (number of sutures) and overall success are in Appendices 3-7.

PART 2:

Conventional radiography is very efficient in identifying and aiding in the removal of radiopaque foreign bodies; however, radiolucent foreign bodies may be more difficult to detect. Undetected foreign bodies can cause significant morbidity, repeated visits, high cost, and extensive surgery. Percutaneous ultrasound guided soft tissue foreign body removal (USFBR) has been used with greater than 95% efficacy in civilian wound care (series with over 400 patients; Shiels 2007), but has not been used extensively in the military. The purpose was to train DoD healthcare beneficiary physicians in USFBR to facilitate removal of both radioopaque and radiolucent foreign bodies. Competency in USFBR will add to the armamentarium available to military physicians to treat soldiers affected by an IED. The ultimate goal of this body of work was to train physicians in a clinical setting to improve the quality of care of the war fighter wounded from an IED and removal of retained foreign bodies using ultrasound guidance.

The competency training, testing, and documentation of military physicians in USFBR techniques included formalized and standardized procedural training, with development of clinical guidelines. Competency testing and training involved one day of didactic and hand-on training, with pre-test and post-test components. A full day training session was conducted 2 times at 4 different military treatment facilities (MTFs). Each session recruited 6 military physicians that participated in the training.

Physicians watched a brief video demonstration of USFBR procedure as an example before starting the pre-test. Each physician completed a 15 minute pre-test with the removal of one wooden foreign body from a turkey breast that simulated the tissue of a human.

Documentation of omissions and errors for removal success, time to removal, demonstration of technical component proficiency, and successful recognition/management of technical pitfalls were recorded to compare to the post-test after training.

Didactic training included a slide presentation, and video animations. Trainers discussed sonographic characterization with wood, metal, glass, plastic, stone and ceramic foreign bodies. Standardized stepwise instruction in USFBR was taught to the physicians which included options for forceps position-vertical versus horizontal, open forceps versus closed forceps, foreign body definition prior to removal, blunt dissection versus sharp dissection and hydrodissection. Options for instrumentation and clinical management following USFBR was reviewed. The following examples of pitfalls were included in the presentation with explanations of how to address each situation in the clinical setting: volume averaging artifact, oblique crosscut artifact, transducer angulation, central foreign body grasp, forceful foreign body grasp, and tissue grasp versus clean foreign body grasp.

Hands-on tissue model mentored training incorporated the subjects practicing removal of both wooden and metal foreign bodies from a turkey breast. Trainers were at each station and the physicians being trained rotated stations to gain experience from different trainers. They were taught techniques to improve their method and fine-tune their ultrasound skills. Content from the didactic lecture and video animations were included in the standardized stepwise instruction and physicians were trained to proficiency.

Post-test data was collected to document competency in a turkey breast tissue model with the incorporation of standardized procedural steps in USFBR procedures including proper procedural steps and recognition/management of procedural pitfalls with the same grading as in the pre-test. This grading included: time to removal, success/failure of removal, proper/errant alignment of insonation and instruments, proper/errant hand position and transducer position, proper/errant use of forceps in field of operation, proper/errant stepwise foreign body definition, proper/errant forceps grasp of foreign body, recognition or lack thereof-volume averaging artifact, and recognition or lack thereof-oblique crosscut artifact. Each physician was required to successfully remove 5 wooden foreign bodies. To demonstrate procedural proficiency each foreign body needed to be removed within the same 15 minute time frame as the pre-test. The training and testing was videotaped for review and confirmation of accuracy and proper documentation success.

The objective for this phase of the project was to standardize training in ultrasound foreign body removal which was accomplished through the following specific aims. To develop standardized pretesting format, document physician pretraining competence, develop standardized training procedures, document physician post training competence, compare pre/post physician competence across MTFs and develop a training manual.

The hypothesis was proven to be correct documenting that programmatic USFBR simulator training significantly improves competency and foreign body removal performance success. With training, radiologist scores improved from 21-52% pre-training to 90-100% post-training ($p < 0.001$). After instruction, the removal success rate was 90% (judged on

quantity, time, and technique). Appendix 8: USFBR Competency Training & Testing Summary

Recommended changes for future work might be to better document the training level of the recruited subject. We had documentation of comparison of the physicians as trainers with the results of the subjects performance, but the data might not reflect the trainer's skill but rather the level of the research subjects ultrasound experience. Some physicians as subjects were first year residents while others were experienced radiologists with years of experience. Some radiologists had more hands on experience with ultrasound, while physicians from other departments did not have as much experience using an ultrasound transducer. There was discussion about pursuing a comparison study between radiologists with another physician specialties, but our goal is to improve communication between departments so they can feel comfortable referring patients to radiology or an area where a physician has USFBR trained experience. Therefore, to reduce the competitive nature, this might not be the best method for a future study. However, there are many ways that the focus of a future USFBR study can be adapted to gain knowledge on how best to improve USFBR training.

PART 3:

Physicians trained in Part 2 who successfully completed post-test competency training were recruited to participate in the Part 3 clinical implementation portion of the study. Trained physicians removed foreign bodies from DoD healthcare beneficiaries in a clinical setting. Documentation of USFBR included procedural parameters such as embedded foreign body source, symptoms, diagnostic modality, foreign body type, measurements, location, success or failure of removal attempt.

The Part 3 results proved the hypotheses to be correct in that following programmed simulator training, ultrasound guided foreign body removal (USFBR) can be implemented in the military medical care system and can be more effective than traditional surgical removal using several objective parameters for comparison. The specific aim was to implement USFBR in the Department of Defense (DoD). Procedural training was successful with the standardized training used in Part 2 and guidelines for physicians to use in the clinical setting for successful percutaneous ultrasound guided foreign body removal in patients.

Data from Parts 1-3 were submitted to the Radiological Society of North America (RSNA) as an abstract and presented at the annual meeting in Chicago Illinois on December 3, 2015. In the clinical setting at the time the abstract (Appendix 9) was submitted, USFBR was 100% successful in 7 (of 25 expected) patients, ages 9-73 years, by four trained radiologists. Objects removed included rock, metal, bone, and plastic, length 4 to 30 mm, retention from 2 to 864 days, incision size from 2 to 8 mm with one suture closure and one child sedated. The final results as presented at RSNA (Appendix 10) reported that site 1 was 63% successful (5/8) at the first attempt and 100% successful after two attempts, site 4 was 100% successful (11/11) at the first attempt, and site 5 was 0% successful (0/1) at the first attempt. The overall success rate was 80% at the first attempt (16/20).

Some recommendations for future USFBR clinical implantation studies would be to focus on the research subjects' term at the post/location, PI, support and location. Many of the

physicians as subjects recruited were deployed or moved locations before they could perform USFBR to help with data collection. If the PIs at each MTF had an increased level of research experience or support via a research coordinator, then they would not be as overloaded with the IRB and funding requirements need to complete the research in an effective manner. The location of the participating MTF might also be a factor for the success of future studies. Some locations see more injured war fighters and other might treat more civilian employees or family members as DoD healthcare beneficiaries. If a future research project focuses on treating warfighters, then the MTF would need to be located where there are increased numbers of injured soldiers. Focus on recruitment efforts would also be important. Due to the sensitive nature of injured warriors, there was some concern about “recruitment” so the focus of our study was on physician or self-referral. The recruitment numbers might increase if there is a way to revise the recruitment process. Increase recruitment would translate to less pain, return to combat and better quality of life for the patients as subjects with successful USFBR.

Key Research Accomplishments

- Successful cadaveric study demonstrated that the radiological method is better than the surgical method in the removal of foreign bodies
- 48 physicians were successfully trained in USFBR
- Increase knowledge of USFBR in the military setting
- Patients with successful USFBR have a better quality of life with less pain

Reportable Outcomes

An abstract was submitted and accepted by the Radiological Society of North America (RSNA) (Appendix 9). The results for Parts 1-3 were presented at the annual meeting in Chicago IL on December 3, 2015 (Appendix 10). No other publications or presentations have been submitted, to date, for this research.

The PI at Tripler Army Medical Center applied for funding based on work supported by this award. The new research project is essentially the same training of USFBR with an additional component of a train the trainer concept included. The grant proposal is not technically a continuation of this project but rather a new project with a different focus. However, the research opportunity applied for and received was based on experience and training supported by this award. The research project “Clinical Utilities and Pitfalls of Ultrasound Guided Foreign Body Removal-Train the Trainer Program (Pilot Study)” was funded by an Intra-Agency Agreement FY15 AMEDD Advanced Medical Technology Initiative (AAMTI) for an 18 month period from 2015-2016.

Conclusion

USFBR is superior to non-guided surgical technique. The USFBR approach taught in a simulation environment improves radiologist technique and removal outcomes. A radiologist who completes simulation training can remove a variety of imbedded foreign bodies.

Clinical Relevance: USFBR can be used to remove foreign bodies while minimizing patient discomfort and potential tissue damage.

The knowledge gained from this research demonstrates that USFBR is a more effective and less traumatic method of removing foreign bodies and should be readily implemented into the military system by training military physicians. Clinical outcomes research, training, and implementation studies in military USFBR are timely and have significant potential to rapidly improve care of war fighters wounded in current and future conflicts. The general public will benefit from this successful clinical implementation and dissemination of USFBR technology and care first in the setting of VA patients that have transitioned from active duty with blast injuries, either with successful treatment at MTFs (with improved function and ability to contribute to society at-large), or dissemination of USFBR care into the Veterans Affairs (VA) health system for care of the respective VA beneficiaries. Additionally, success with military related USFBR care should aid rapid dissemination of USFBR care into the civilian adult and pediatric care systems, providing enhanced care of penetrating wounds with retained foreign bodies, of ballistic, blast, or non-ballistic origin.

References

Shiels WE II, Babcock DS, Wilson JL, Burch RA. Localization and Guided Removal of Soft-tissue Foreign Bodies with Sonography. *AJR* 1990; 155(6):1277-128.

Shiels II WE: Soft Tissue Foreign Bodies: Sonographic Diagnosis and Therapeutic Management. *Ultrasound Clinics*. October 2007. Vol. 2, Issue 2, 669-81.

Close JK, Shiels WE II, Foster JA, Powell DA: Percutaneous Ultrasound-guided Intraorbital Foreign Body Removal. *Ophthal Plast Reconstr Surg*. 2009 Jul-Aug; 25(4):335-7.

Appendices

Appendix 1: James W. Murakami, MD Curriculum Vitae

Appendix 2: Foreign Body Removal Record Form

Appendix 3: Cadaver Cohort Study Data Spreadsheet

Appendix 4: Cadaver Cohort Comparison Study-Incision size

Appendix 5: Cadaver Cohort Comparison Study-Removal Time

Appendix 6: Cadaver Cohort Study – Wound Closure (Number of Sutures)

Appendix 7: Cadaver Cohort Study - Overall Success

Appendix 8: USFBR Competency Training & Testing Summary

Appendix 9: Rooks VJ, Meadows JM, Carlson CL, Krasnokutsky MV, Mullens FE, Haeuptle BM, Lustik M, Murakami JW, Shiels WE 2015. Ultrasound Guided Foreign Body Removal: Cadaver, Simulation, and Clinical Implementation Outcomes. *Radiological Society of North America*. Abstract

Appendix 10: Rooks VJ, Meadows JM, Carlson CL, Krasnokutsky MV, Mullens FE, Haeuptle BM, Lustik M, Murakami JW, Shiels WE 2015. Ultrasound Guided Foreign Body Removal: Cadaver, Simulation, and Clinical Implementation Outcomes. *Radiological Society of North America*. Presentation

APPENDIX 1

CURRICULUM VITAE

James W. Murakami, M.D., M.S.

PRESENT TITLE AND AFFILIATION

*Clinical Assistant Professor
The Ohio State University College of Medicine
Columbus, Ohio*

*Pediatric Radiologist
Nationwide Children's Hospital
Columbus, Ohio*

CITIZENSHIP AND VISA STATUS

U.S. Citizen

OFFICE ADDRESS

*Children's Radiological Institute
Nationwide Children's Hospital
700 Children's Drive
Columbus, OH 43205
P: (614)722-2289
F: (614)722-2332
James.Murakami@nationwidechildrens.org*

EDUCATION

UNDERGRADUATE EDUCATION

1985	University of California Berkeley Berkeley, CA	B.S. Chemistry
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GRADUATE EDUCATION

1995	University of Washington Seattle, WA	M.S. Bioengineering
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1990

**University of California San
Diego**
San Diego, CA

M.D.

POST-GRADUATE EDUCATION & TRAINING

7/97-10/97

**Children's Hospital of
Pittsburgh and the University
of Pittsburgh School of
Medicine**
Pittsburgh, Pennsylvania

Fellowship-Pediatric
Interventional Radiology

7/96-6/97

**Children's Hospital and
Medical Center and the
University of Washington
School of Medicine**
Seattle, Washington

Fellowship-Pediatric
Radiology

7/95-6/96

**University of Washington
School of Medicine**
Seattle, Washington

Residency-Radiology

7/93-6/95

**University of Washington
School of Medicine**
Seattle, Washington

Fellowship-NCI Radiology
Research

7/91-6/93

**University of Washington
School of Medicine**
Seattle, Washington

Residency-Radiology

7/90-6/91

**Swedish Hospital
Transitional Internship**
Seattle, Washington

Internship

ACADEMIC APPOINTMENTS

- 2000- Current Clinical Assistant Professor - Radiology
Ohio State University
Columbus, OH
- 2000-Current Adjunct Assistant Professor- Radiology
Medical College of Ohio
Toledo, OH
- 1999-Current Pediatric Radiologist
Nationwide Children's Hospital
Columbus, OH
- 1997-1999 Staff Radiologist
Children's Hospital and Regional Medical Center
Seattle, WA
- 1997-1999 Assistant Professor- Radiology
University of Washington School of Medicine
Seattle, WA
- 1996-1997 Acting Instructor-Radiology
University of Washington School of Medicine
Seattle, WA

STATE LICENSURE AND CERTIFICATIONS

LICENSURE

1999 Ohio (active)

1990 Washington (inactive)

CERTIFICATIONS

1990 National Board of Medical Examiners

1996 American Board of Radiology

1999 & 2009 Certification of Advanced Qualification in Pediatric Radiology

HONORS AND AWARDS

1985 Phi Beta Kappa
University of California Berkeley
Berkeley, CA

1985 Phi Lambda Upsilon National Chemistry Honor Society
University of California Berkeley
Berkeley, CA

1985 Merck Index Award
University of California Berkeley
Berkeley, CA

1985 American Institute of Chemists Award
University of California Berkeley
Berkeley, CA

1990 Baird Hastings Honor Society
University of California San Diego
San Diego, CA

RESEARCH SUPPORT

ONGOING RESEARCH

Peer Reviewed

Award #W81XWH-08-2-0162 Murakami (Co-I) 09/29/2008-Present
Telemedicine & Advanced Technology Research
Center (TATRC)
Clinical Utility and Pitfalls of Ultrasound Guided Foreign Body Removal in War Fighters
(USFBR)
3 Part Multi-Center Study:
Part 1- USFBR is faster and more effective than traditional open surgical removal, with smaller
incisions. IRB08-00017
Part 2- Programmatic USFBR simulator training significantly improves competency and foreign
body removal performance success. IRB12-00224
Part 3- USFBR can be readily implemented in the military medical care system with excellent
clinical results for the wounded war fighters. IRB13-00895
\$849,452.00

Peer Reviewed

Grant #26002213, IRB13-00409 Murakami (Co-I) 10/15/2013-Present
Nationwide Children's Hospital Foundation
Safety of Allergen-Specific Intralymphatic Immunotherapy in the United States
Randomized, placebo-controlled, double-blind clinical trial of three-injection protocol for
intralymphatic allergen immunotherapy given over the course of 8 weeks, compared to subjects
receiving traditional subcutaneous immunotherapy (SCIT).

Peer Reviewed

Grant #N/A, IRB13-00519 Murakami (PI) 08/16/2013-Present
Resting State Network (RSN) analysis of previously acquired functional Magnetic Resonance (fmr) data acquired from children with seizures during pre-operative work-up.
The study aims to use RSN analysis to better understand brain connectivity in patients with seizures in order to help plan surgical intervention. One paper is currently in press and another in progress.

Peer Reviewed

Grant #N/A, IRB14-00631 Murakami (Co-I) 08/29/2014-Present
Percutaneous Image-guided Gastrojejunostomy Tube Placement: Large Tertiary Care Children's Hospital Experience
Retrospective chart review of all image-guided percutaneous gastrojejunostomy tube placement procedures performed in Nationwide Children's Hospital Department of Radiology from 2009-2014 for the purposes of assessing details of our unique procedural technique, tips for placement, complications, and patient outcomes.

COMPLETED RESEARCH

Peer Reviewed

Grant N/A, IRB06-00458 Murakami (PI) 08/04/2006 - 4/2/2008
Cervical Spine Osteoid Osteoma: CT-guided Percutaneous Radiofrequency Ablation via Thyroid Gland
Retrospective case study of a child with an osteoid osteoma of the cervical spine successfully treated using a trans-thyroid needle approach, with CT-guided percutaneous radiofrequency ablation.

PATENTS AND TECHNOLOGY LICENSES

ISSUED PATENTS

1. US Patent Application 5,943,433 “Method of Correcting Inhomogeneity of Spatial Intensity in an Acquired MR Image,” Avinash Gopal B, (Based on original patent application number 60/002,517 “Intensity Correction of Phased-Array Surface Coil Images” filed 8/18/1995 by **Murakami JW**), licensed to General Electric Company, December 30,1996

PUBLICATIONS

1. **Murakami JW**, Courchesne E, Press GA, Yeung-Courchesne R, Hesselink JR., Reduced Cerebellar Hemisphere Size and its Relationship to Vermal Hypoplasia in Autism. **Archives of Neurology** 1989; 46:689-694.
2. Courchesne E, Press GA, **Murakami JW**, Berthoty D, Grafe M, Wiley C, Hesselink JR., The Cerebellum in Sagittal Plane--Anatomic-MR Correlation: 1. The Vermis. **AJNR** 1989; 10:659-665 & **AJR** 1989; 153:829-835.
3. Press GA, **Murakami JW**, Courchesne E, Berthoty D, Grafe M, Wiley C, Hesselink JR., The Cerebellum in Sagittal Plane--Anatomic-MR Correlation: 2. The Cerebellar Hemispheres. **AJNR** 1989; 10:667-676 & **AJR** 1989; 153:837-846.
4. Press GA, **Murakami JW**, Courchesne E, Grafe M, Hesselink JR., The Cerebellum: 3. Anatomic-MR Correlation in the Coronal Plane. **AJNR** 1990; 11:41-50 & **AJR** 1990; 154:593-602.
5. **Murakami JW**, Courchesne E, Haas RH, Press GA, Yeung-Courchesne R., Cerebellar and Cerebral Abnormalities in Rett Syndrome: A Quantitative MR Analysis. **AJR** 1992; 159:177-183.
6. **Murakami JW**, Weinberger E, Tsuruda JS, Mitchell JD, Yuan C, Multislab Three-dimensional T2-weighted Fast Spin-Echo Imaging of the Hippocampus: Sequence Optimization. **JMRI** 1995; 5:309-315.
7. Weinberger E, **Murakami JW**, Shaw DWW, White KS, Radvilas MK, Yuan C, Three-Dimensional Fast Spin Echo: T1-Weighted Imaging of the Pediatric Spine. **JCAT** 1995; 19(5):721-725.
8. Yuan C, **Murakami JW**, Hayes CE, Tsuruda JS, Hatsukami TS, Wildy KS, Ferguson MS, Strandness DE, Phased-Array Magnetic Resonance Imaging of the Carotid Artery Bifurcation: Preliminary Results in Healthy Volunteers and a Patient with Atherosclerotic Disease. **JMRI** 1995; 5:561-565.
9. **Murakami JW**, Hayes CE, Weinberger E, Intensity Correction of Phased Array Surface Coil Images. **MRM** 1996; 35:585-590.
10. **Murakami JW**, Winters WD, Weinberger E, Rosenbaum DM, Extensive Reflux of Air During Enema for Intussusception Without Reduction: case report. **Can Assoc Radiol J** 1998; 49:334-335.

11. **Murakami JW**, Weinberger E, Shaw DWW, Normal Myelination of the Pediatric Brain Imaged with Fluid Attenuated Inversion Recovery (FLAIR) MR Imaging. **AJNR** 1999; 20:1406-1411.
12. **Murakami JW**, Rosenbaum DM, Right to Left Pulmonary Shunting in Pediatric Hepatopulmonary Syndrome. **Clin Nuc Med** 1999; 24:897.
13. Coley BD, **Murakami JW**, Koch BL, Shiels WE, Bates G, Hogan M, Diagnostic and interventional ultrasound of the pediatric spine. **Pediatr Radiol** 2001; 31:775-785.
14. Coley BD, Shiels WE, Elton S, **Murakami JW**, Hogan MJ, Sonographically guided aspiration of cerebrospinal fluid pseudocysts in children and adolescents. **AJR** 2004; 183:15-7-1510.
15. Sutphen SA, **Murakami JW**, Radiofrequency ablation of a cervical osteoid osteoma: A trans-thyroid approach. **Pediatr Radiol** 2007; 37:83-85.
16. Shiels WE, Kang R, **Murakami JW**, Hogan MJ, Wiet GJ, Percutaneous Treatment of Lymphatic Malformations. **Otolaryngology-Head and Neck Surgery** 2009; 141:219-224.
17. Young AS, Shiels WE, **Murakami JW**, Coley BD, Hogan MJ, Self-embedding Behavior: Radiologic Management of Self-inserted Soft-Tissue Foreign Bodies. **Radiology** 2010; 257:233-239.
18. Young CM, Shiels WE, Coley BD, Hogan MJ, **Murakami JW**, Jones K, Higgins GC, Rennenbohm RM. Ultrasound-guided corticosteroid injection therapy for juvenile idiopathic arthritis: 12-year care experience. **Pediatr Radiol** 2012; 42(12):1481-9.
19. Young CM, Horst DM, **Murakami JW**, Shiels We, Ultrasound guided corticosteroid injection of the subtalar joint for treatment of juvenile idiopathic arthritis. **Pediatr Radiol** 2015; Epub February 12
20. Bush MA, **Murakami JW**, Default Mode Network in a small cohort of children with abnormal brain MRIs. **Pediatr Epilepsy** 2016; in press.

ABSTRACTS

1. **Murakami JW**, Courchesne E, Haas RH, Press GA, Yeung-Courchesne R, Quantitative Magnetic Resonance Analysis in Rett Syndrome: Cerebral and Cerebellar Abnormalities. Presented at the 20th Annual Meeting of the Child Neurology Society, 1991.

2. Weinberger E, Yuan C, Shaw DW, White KS, Maravilla KR, **Murakami JW**, Evaluation of the parasellar region with a 3D T1-weighted fast spin-echo technique. Presented at the 1st Annual Meeting of the Society of Magnetic Resonance, 1994.
3. Chooljian D, Tsuruda JS, **Murakami JW**, Mitchell J, Comparison Between 3D Fast Spin-Echo (FSE) with 3DFT Gradient Recalled Echo (GRE) Imaging in the Evaluation of Cervical Neural Foramina. Presented at the 32nd Annual Meeting of the American Society of Neuroradiology, 1994.
4. **Murakami JW**, Mitchell J, Weinberger E, Tsuruda J, Yuan C, Multi-slab Three-Dimensional Fast Spin-Echo Sequence Optimization for T2-weighted Hippocampal Imaging. Presented at the 2nd Annual Meeting of the Society of Magnetic Resonance, 1994.
5. Weinberger E, **Murakami JW**, Shaw DW, Radvilas MK, Fast Spin Echo with Reduced Flip Angle Refocusing RF Pulses: Proton Density and T2-Weighted Pediatric Brain Imaging. Presented at the 3rd Annual Meeting of the Society of Magnetic Resonance, 1995.
6. **Murakami JW**, Hayes CE, Weinberger E, Intensity Correction of Phased Array Surface Coil Images. Presented at the 3rd Annual Meeting of the Society of Magnetic Resonance, 1995.
7. Shaw DWW, Weinberger E, **Murakami JW**, Geyer JR, Born DB, Evidence of Wallerian Degeneration across the Corpus Callosum following Ventricular Catheter Placement. Presented at the 36th Annual Meeting of the American Society of Neuroradiology, 1998.
8. Coley BD, Shiels WE, Koch BL, Hogan MJ, **Murakami JW**, Diagnostic and Interventional US of the Pediatric Spine. Presented at the 43rd Annual Meeting of the Society for Pediatric Radiology, 2000.
9. Shiels WE, Coley BD, Hogan MJ, **Murakami JW**, Soft-tissue and intraosseous foreign bodies in children: Outcomes with sonographically guided intervention. Presented at the 43rd Annual Meeting of the Society for Pediatric Radiology, 2000.
10. Stredney D, Wiet GJ, Bryan J, Sessanna D, **Murakami JW**, et. al., Temporal Bone Dissection Simulation-An Update. Presented at the Medicine Meets Virtual Reality Conference, 2001.
11. Shiels WE, **Murakami JW**, Coley BD, Hogan MJ, Focused Sclerotherapy of Macrocystic Lymphatic Malformations. Presented at the 46th Annual Meeting of the Society for Pediatric Radiology, 2003.

12. Coley BD, Shiels WE, Elton S, **Murakami JW**, Hogan MJ, Ultrasound guided aspiration in the management of patients with cerebrospinal fluid pseudocysts. Presented at the 46th Annual Meeting of the Society for Pediatric Radiology, 2003.
13. Lewis JR, Algaze A, Leguire LE, Rogers GL, **Murakami JW**, Roberts C, Age Effect on FMRI Using Grating Visual Stimuli. Presented at the Association for Research in Vision and Ophthalmology (ARVO) Meeting, 2003.
14. Long FR, **Murakami JW**, Wheller J, Chest CT Angiography (CTA) in Infants with Congenital Heart Disease Using Respiratory Motion-Free Full Inflation Controlled Ventilation (CV) Multidetector CT. Presented at the 47th Annual Meeting of the Society for Pediatric Radiology, 2004.
15. Shiels WE, **Murakami JW**, Coaxial Catheter System for Contained Sclerotherapy of Small Cystic Masses in Children. Presented at the 47th Annual Meeting of the Society for Pediatric Radiology, 2004.
16. Coley BD, Shiels WE, **Murakami JW**, Hogan MJ, Semi-Upright Ultrasound Guided Lumbar Puncture in Infants. Presented at the 47th Annual Meeting of the Society for Pediatric Radiology, 2004.
17. Young AS, Shiels WE, **Murakami JW**, Coley BD, Hogan MJ, Self-Mutilation in Adolescents: Radiological Management of Self-inflicted Soft Tissue Foreign Bodies. Presented at the 94th Annual Meeting of the RSNA, 2009.
18. Shiels WE, Young CM, Coley BD, Hogan MJ, **Murakami JW**, Higgins G, Ultrasound-Guided Percutaneous Therapy for Juvenile Idiopathic Arthritis: 12 Year Care Experience. Presented at the 53rd Annual Meeting of the Society for Pediatric Radiology,.
19. Shiels WE, **Murakami JW**, Bleomycin Protein Microfoam: Stability Testing and Clinical Applications. Presented at the 36th Annual Meeting of the Society of Interventional Radiology, 2011.
20. Shiels WE, **Murakami JW**, Directed Tumoral Therapy of Aneurysmal Bone Cysts in Children. Presented at the 54th Annual Meeting of the Society for Pediatric Radiology, 2012.
21. Young C, Shiels WE, Coley B, Hogan M, **Murakami JW**. Technique, Safety, and Efficacy of Ultrasound-guided Corticosteroid Injection of the Subtalar Joint for Treatment of Juvenile Idiopathic Arthritis. Presented at the 96th Annual meeting of the RSNA, 2011

BOOK CHAPTERS

1. Courchesne E, Townsend JP, Akshoomoff NA, Yeung-Courchesne R, Press GA **Murakami JW**, Lincoln AJ, James HE, Saitoh O, Egaas B, Haas RH, Schreibman L, A New Finding: Impairment in Shifting Attention in Autistic and Cerebellar Patients, in Atypical Cognitive Deficits in Developmental Disorders: Implications for Brain Function, eds. Sarah H. Broman and Jordan Grafman, Lawrence Erlbaum Associates (Publishers), Hillsdale New Jersey, 1994

LECTURES/PRESENTATIONS

- | | |
|-----------|---|
| 1999-2013 | Techniques of Freehand Invasive Sonography
85 th -99 th Annual Meetings of the RSNA |
| 2000 | Tricks for Percutaneous Nephrostomy in Infants and Small Children.
Workshop
25 th Annual Meeting of the Society of Uroradiology |
| 2001 | Sedation Techniques in Pediatric Diagnostic and Interventional
Radiology. Workshop
26 th Annual Meeting of the Society of Uroradiology |
| 2001-2013 | Musculoskeletal Interventional Sonographic Procedures (“Hands-on”
Workshop) Refresher Course
87 th -99 th Annual Meetings of the RSNA |
| 2001 | Common Pediatric Emergency Procedures (Technical “How-to” Workshop)
Refresher Course
87 th Annual Meeting of the RSNA |
| 2012 | Current Topics in Pediatric Interventional Radiology
12 th Annual Meeting of the Asian Oceanic Society of Pediatric Radiology |
| 2013 | Successful Pediatric MR and Case Review
9 th Annual Magnetic Resonance Imaging Seminar |

PROFESSIONAL MEMBERSHIPS AND ACTIVITIES

- Member, American Roentgen Ray Society (*ARRS*)
- Member, Radiological Society of North American (*RSNA*)
- Member, American College of Radiology (*ACR*)
- Member, Society of Pediatric Radiology (*SPR*)
- Member, American Society of Pediatric Neuroradiology (*ASPN*)
- Member, Society of Interventional Radiology (*SIR*)
- Member, Society of Pediatric Interventional Radiology (*SPIR*)
- Member, Central Ohio Pediatric Society (*COPS*)

I have reviewed the curriculum vitae for completeness and accuracy and agree with its content.

Signature _____

Date _____

APPENDIX 2
Foreign Body Removal Record Form

Date: _____

Surgical procedure

Removal technique: () **Surgical** - traditional surgical removal following skin marking of foreign body location

Cadaver thigh: () #1
FB location () #1 () #2 () #3

Cadaver thigh: () #2
FB location: () #1 () #2 () #3

Cadaver thigh: () #3
FB location: () #1 () #2 () #3

Surgical procedure

Removal technique: () **Wire localization** – surgical removal of the foreign bodies following ultrasound guided placement of localization wires at the site of each foreign body.

Cadaver thigh: () #4
FB location: () #1 () #2 () #3

Cadaver thigh: () #5
FB location: () #1 () #2 () #3

Cadaver thigh: () #6
FB location: () #1 () #2 () #3

Radiological procedure

Removal technique: () **Percutaneous** - interventional radiological ultrasound guided foreign body removal

Cadaver thigh: () #7
FB location: () #1 () #2 () #3

Cadaver thigh: () #8
FB location: () #1 () #2 () #3

Cadaver thigh: () #9
FB location: () #1 () #2 () #3

FB type: wood

Incision size (self report): _____

Incision size (video confirmation): _____

Time of procedure (self report): _____

Time of procedure (video confirmation): _____

Wound closure/number of sutures (self report): _____

Wound closure/number of sutures (video confirmation): _____

Overall removal success: (self report): _____

Overall removal success: (video confirmation): _____

Procedural differences as noted by study coordinator from documentation during procedure and review of video documentation: Notes: (see back of page)

APPENDIX 3

	Thigh #	Cadaver Specimen Information	Size of wooden FB (part of a toothpick) to be removed in cm	Incision size in mm	Overall removal success	Time determined that FB could not be located	(Self report & study coordinator observe) Time of procedure to remove FB w/o closure or stopped looking for FB	(Self report & study coordinator observe) Time of procedure to remove FB (w/ sutures) skin to skin time	# of sutures	Suture style
Surgical Procedure - traditional surgical removal following skin marking of foreign body location	S1	#5862 Female, 87 years old Cause of death: Alzheimer's	1	44	No	11	11	15	8	continuous
Surgical Procedure - traditional surgical removal following skin marking of foreign body location	S2	#5862 Female, 87 years old Cause of death: Alzheimer's	1	41	No	10	10	11	8	continuous
Surgical Procedure - traditional surgical removal following skin marking of foreign body location	S3	#5862 Female, 87 years old Cause of death: Alzheimer's	1	58	Yes	1	4	9	9	continuous

	Thigh #	Cadaver Specimen Information	Size of wooden FB (part of a toothpick) to be removed in cm	Incision size in mm	Overall removal success	Time determined that FB could not be located	(Self report & study coordinator observe) Time of procedure to remove FB w/o closure or stopped looking for FB	(Self report & study coordinator observe) Time of procedure to remove FB (w/ sutures) skin to skin time	# of sutures	Suture style
Surgical Procedure - traditional surgical removal following skin marking of foreign body location	S4		1	54	Yes		5	10	6	interrupted
Surgical Procedure - traditional surgical removal following skin marking of foreign body location	S5		1	43	Yes		2	4	5	interrupted
Surgical Procedure - traditional surgical removal following skin marking of foreign body location	S6		1	30	Yes		2	5	4	interrupted

	Thigh #	Cadaver Specimen Information	Size of wooden FB (part of a toothpick) to be removed in cm	Incision size in mm	Overall removal success	Time determined that FB could not be located	(Self report & study coordinator observe) Time of procedure to remove FB w/o closure or stopped looking for FB	(Self report & study coordinator observe) Time of procedure to remove FB (w/ sutures) skin to skin time	# of sutures	Suture style
Surgical Procedure - traditional surgical removal following skin marking of foreign body location	S7		1	39	Yes		2	7	5	interrupted
Surgical Procedure - traditional surgical removal following skin marking of foreign body location	S8		1	58	Yes		5	11	6	interrupted
Surgical Procedure - traditional surgical removal following skin marking of foreign body location	S9		1	45	Yes		4	8	5	interrupted

	Thigh #	Cadaver Specimen Information	Size of wooden FB (part of a toothpick) to be removed in cm	Incision size in mm	Overall removal success	Time determined that FB could not be located	(Self report & study coordinator observe) Time of procedure to remove FB w/o closure or stopped looking for FB	(Self report & study coordinator observe) Time of procedure to remove FB (w/ sutures) skin to skin time	# of sutures	Suture style
Surgical Procedure - Wire localization - surgical removal of the foreign bodies following ultrasound guided placement of localization wires at the site of each foreign body	W1	#5849 right leg Male 91 years old Cause of death: Dementia & Heart Disease	1	30	Yes	3	8	4	interrupted	
Surgical Procedure - Wire localization - surgical removal of the foreign bodies following ultrasound guided placement of localization wires at the site of each foreign body	W2	#5849 right leg Male 91 years old Cause of death: Dementia & Heart Disease	1	25	Yes	1	4	3	interrupted	
Surgical Procedure - Wire localization - surgical removal of the foreign bodies following ultrasound guided placement of localization wires at the site of each foreign body	W3	#5849 right leg Male 91 years old Cause of death: Dementia & Heart Disease	1	24	Yes	3	6	3	interrupted	

	Thigh #	Cadaver Specimen Information	Size of wooden FB (part of a toothpick) to be removed in cm	Incision size in mm	Overall removal success	Time determined that FB could not be located	(Self report & study coordinator observe) Time of procedure to remove FB w/o closure or stopped looking for FB	(Self report & study coordinator observe) Time of procedure to remove FB (w/ sutures) skin to skin time	# of sutures	Suture style
Surgical Procedure - Wire localization - surgical removal of the foreign bodies following ultrasound guided placement of localization wires at the site of each foreign body	W4	#5849 left leg Male 91 years old Cause of death: Dementia & Heart Disease	1	30	Yes	4	7	5	interrupted	
Surgical Procedure - Wire localization - surgical removal of the foreign bodies following ultrasound guided placement of localization wires at the site of each foreign body	W5	#5849 left leg Male 91 years old Cause of death: Dementia & Heart Disease	1	39	No	8	8	12	6	interrupted
Surgical Procedure - Wire localization - surgical removal of the foreign bodies following ultrasound guided placement of localization wires at the site of each foreign body	W6	#5849 left leg Male 91 years old Cause of death: Dementia & Heart Disease	1	30	Yes	6	10	4	interrupted	

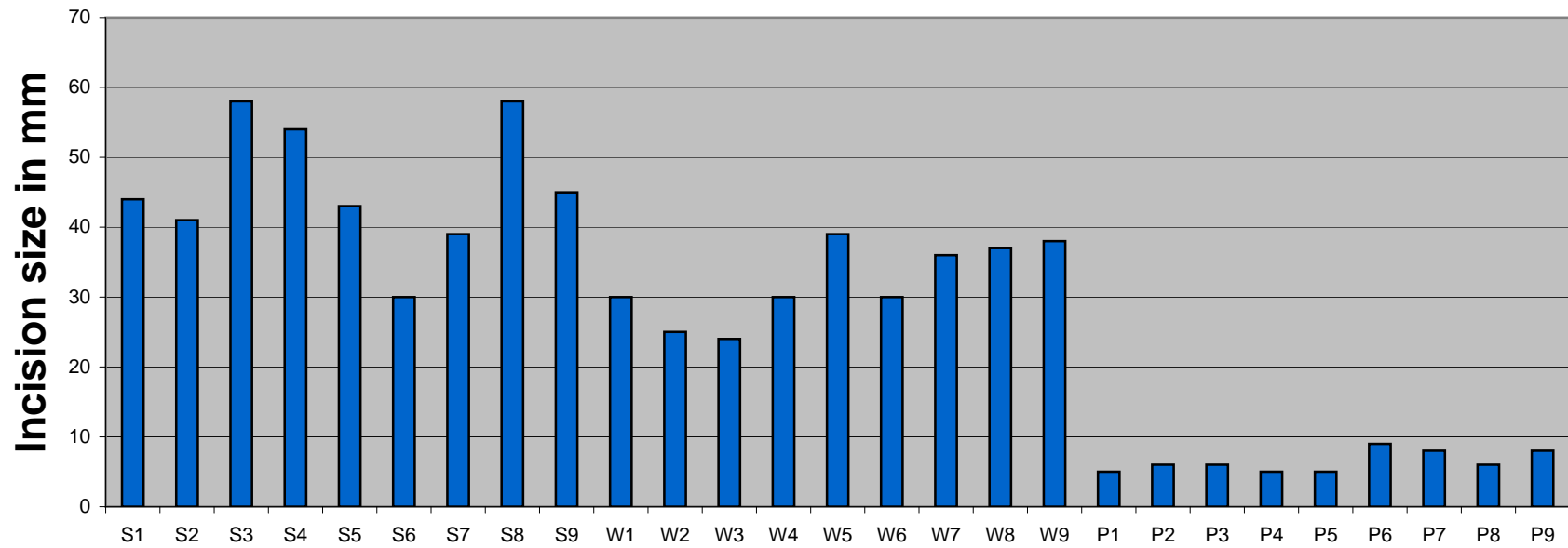
	Thigh #	Cadaver Specimen Information	Size of wooden FB (part of a toothpick) to be removed in cm	Incision size in mm	Overall removal success	Time determined that FB could not be located	(Self report & study coordinator observe) Time of procedure to remove FB w/o closure or stopped looking for FB	(Self report & study coordinator observe) Time of procedure to remove FB (w/ sutures) skin to skin time	# of sutures	Suture style
Surgical Procedure - Wire localization - surgical removal of the foreign bodies following ultrasound guided placement of localization wires at the site of each foreign body	W7	#5348 Male 81 years old Cause of death: Liver Disease	1	36	Yes	2	5	5	interrupted	
Surgical Procedure - Wire localization - surgical removal of the foreign bodies following ultrasound guided placement of localization wires at the site of each foreign body	W8	#5348 Male 81 years old Cause of death: Liver Disease	1	37	Yes	1	6	6	interrupted	
Surgical Procedure - Wire localization - surgical removal of the foreign bodies following ultrasound guided placement of localization wires at the site of each foreign body	W9	#5348 Male 81 years old Cause of death: Liver Disease	1	38	Yes	2	6	6	interrupted	

	Thigh #	Cadaver Specimen Information	Size of wooden FB (part of a toothpick) to be removed in cm	Incision size in mm	Overall removal success	Time determined that FB could not be located	(Self report & study coordinator observe) Time of procedure to remove FB w/o closure or stopped looking for FB	(Self report & study coordinator observe) Time of procedure to remove FB (w/ sutures) skin to skin time	# of sutures	Suture style
Radiological Procedure Removal Technique - Percutaneous - interventional radiological ultrasound guided foreign body removal	P1	#5862 Female Right leg 87 years old Cause of death: Alzheimer's	1	5	Yes		10	10	0	N/A
Radiological Procedure Removal Technique - Percutaneous - interventional radiological ultrasound guided foreign body removal	P2	#5862 Female Right leg 87 years old Cause of death: Alzheimer's	1	6	Yes		10	10	0	N/A
Radiological Procedure Removal Technique - Percutaneous - interventional radiological ultrasound guided foreign body removal	P3	#5862 Female Right leg 87 years old Cause of death: Alzheimer's	1	6	Yes		4	4	0	N/A

	Thigh #	Cadaver Specimen Information	Size of wooden FB (part of a toothpick) to be removed in cm	Incision size in mm	Overall removal success	Time determined that FB could not be located	(Self report & study coordinator observe) Time of procedure to remove FB w/o closure or stopped looking for FB	(Self report & study coordinator observe) Time of procedure to remove FB (w/ sutures) skin to skin time	# of sutures	Suture style
Radiological Procedure Removal Technique - Percutaneous - interventional radiological ultrasound guided foreign body removal	P4	#5861 Female Right leg 68 years old Cause of death: Huntington's Chorea	1	5	Yes		23	23	0	N/A
Radiological Procedure Removal Technique - Percutaneous - interventional radiological ultrasound guided foreign body removal	P5	#5861 Female Right leg 68 years old Cause of death: Huntington's Chorea	1	5	Yes		26	26	0	N/A
Radiological Procedure Removal Technique - Percutaneous - interventional radiological ultrasound guided foreign body removal	P6	#5861 Female Right leg 68 years old Cause of death: Huntington's Chorea	1	9	Yes		17	17	0	N/A

	Thigh #	Cadaver Specimen Information	Size of wooden FB (part of a toothpick) to be removed in cm	Incision size in mm	Overall removal success	Time determined that FB could not be located	(Self report & study coordinator observe) Time of procedure to remove FB w/o closure or stopped looking for FB	(Self report & study coordinator observe) Time of procedure to remove FB (w/ sutures) skin to skin time	# of sutures	Suture style
Radiological Procedure Removal Technique - Percutaneous - interventional radiological ultrasound guided foreign body removal	P7	#5861 Female Left leg 68 years old Cause of death: Huntington's Chorea	1	8	Yes		4	4	0	N/A
Radiological Procedure Removal Technique - Percutaneous - interventional radiological ultrasound guided foreign body removal	P8	#5861 Female Left leg 68 years old Cause of death: Huntington's Chorea	1	6	Yes		13	13	0	N/A
Radiological Procedure Removal Technique - Percutaneous - interventional radiological ultrasound guided foreign body removal	P9	#5861 Female Left leg 68 years old Cause of death: Huntington's Chorea	1	8	Yes		3	3	0	N/A

Cadaver Cohort Comparison Study



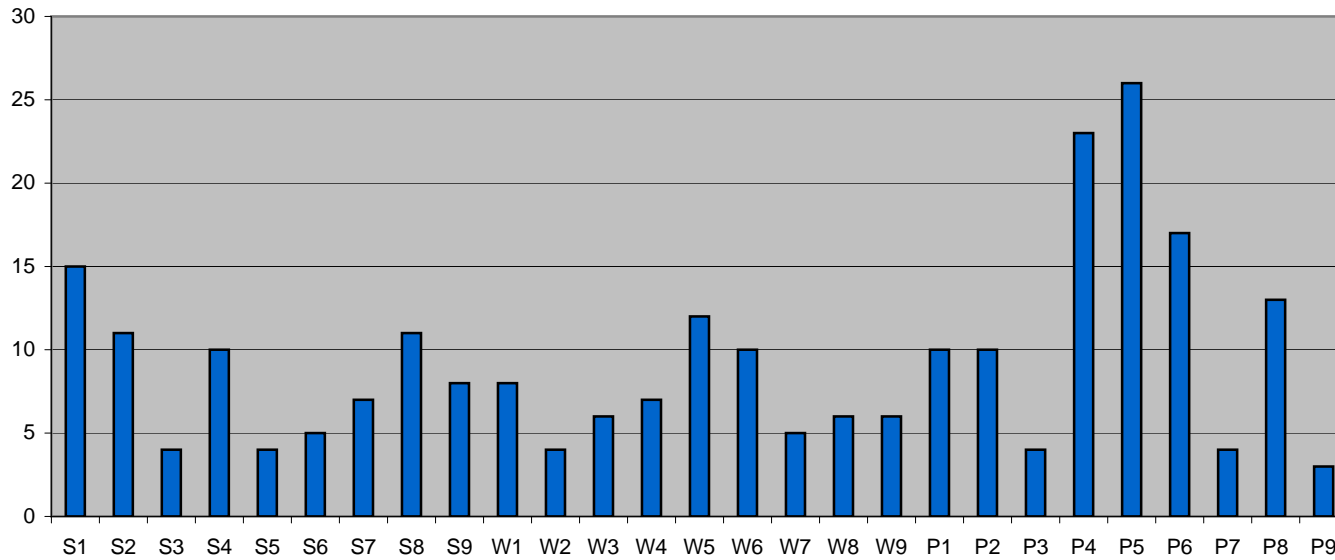
S=Traditional Surgical

W=Surgical with Wire Localization

P=Radiological/Percutaneous US

Cadaver Cohort Comparison Study

Time in Minutes to Remove Foreign Body

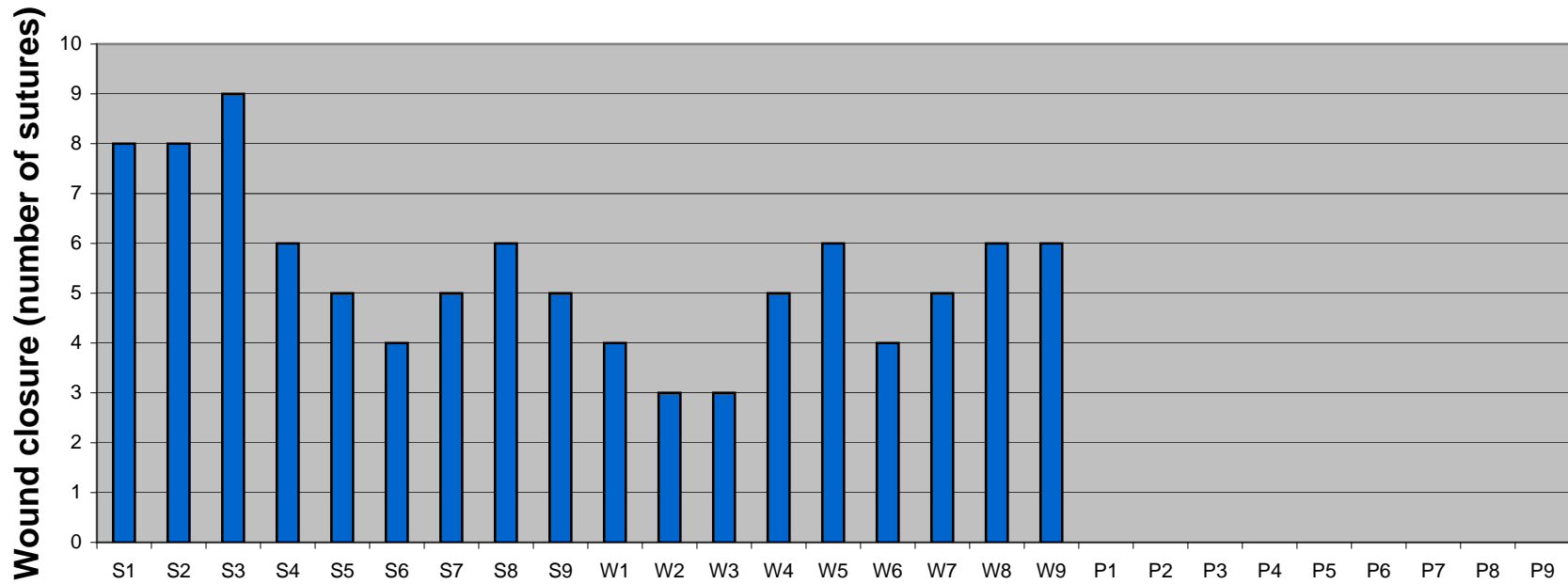


S = Traditional Surgical Procedure

S=Surgical Procedure with Wire Localization

P = Radiological Procedure - Percutaneous US

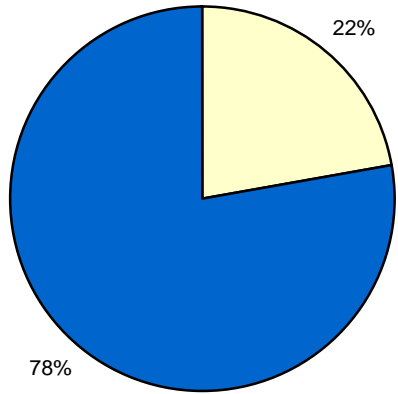
Cadaver Cohort Comparison Study



S=Traditional Surgical
W=Surgical with wire localization
P=Radiological/Percutaneous US

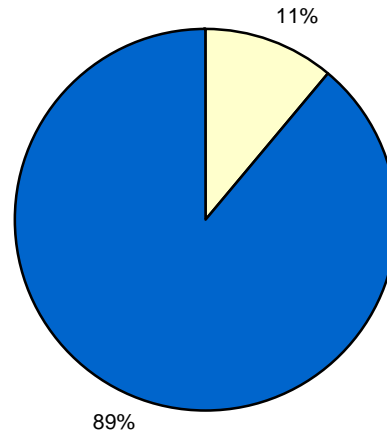
Cadaver Cohort Comparison Study

Traditional Surgical



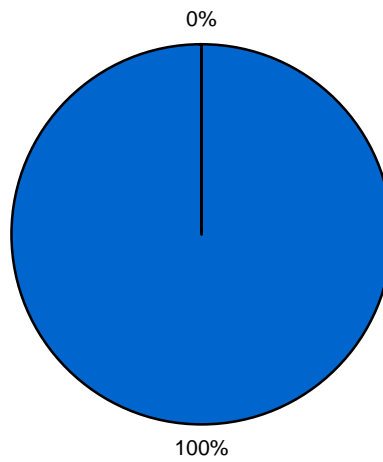
□ Failure Rate ■ Success Rate

Surgical with Wire Localization



□ Failure Rate ■ Success Rate

Radiological/Percutaneous US

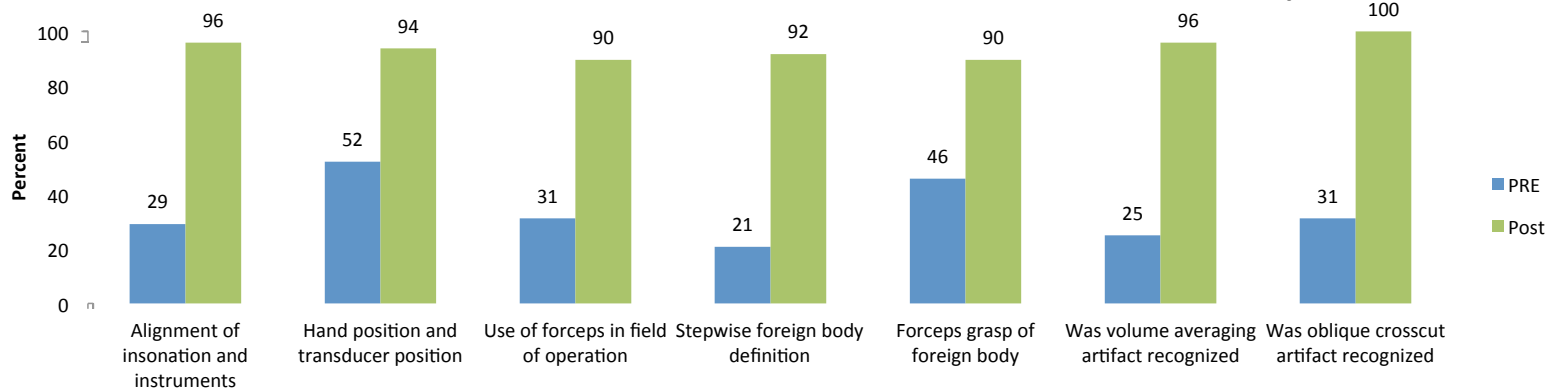


□ Failure Rate ■ Success Rate

APPENDIX 8: 1 of 7 - By Medical Center and Overall

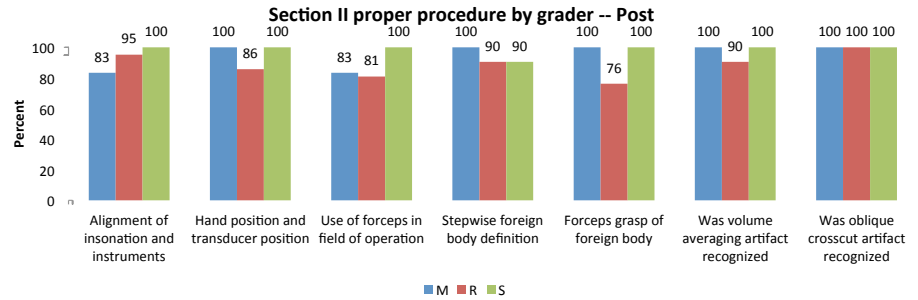
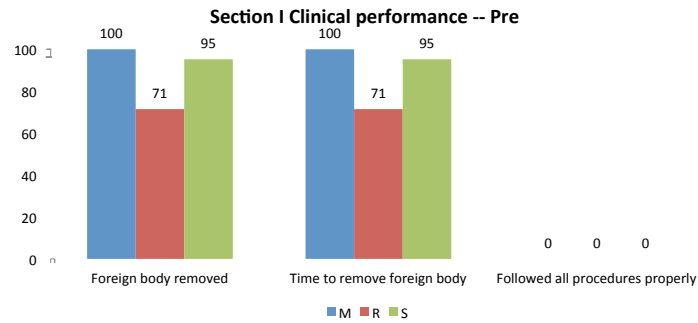
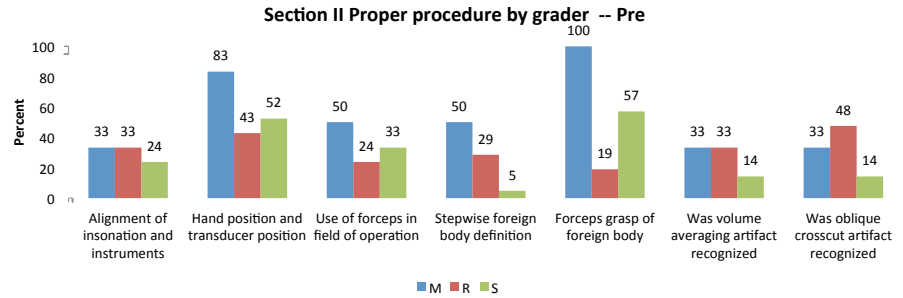
	All (n=48)		BAMC (n=12)		MAMC (n=12)		TAMC (n=12)		WRNMMC (n=12)		p-value
	n	%	n	%	n	%	n	%	n	%	
PRE											
Section I											
Foreign body removed	41	85	11	92	10	83	11	92	9	75	0.606
Time to remove foreign body	41	85	11	92	10	83	11	92	9	75	0.606
Followed all procedures properly	0	0	0	0	0	0	0	0	0	0	
Section II											
Alignment of insonation and instruments	14	29	2	17	3	25	5	42	4	33	0.569
Hand position and transducer position	25	52	6	50	4	33	9	75	6	50	0.235
Use of forceps in field of operation	15	31	6	50	2	17	5	42	2	17	0.206
Stepwise foreign body definition	10	21	2	17	3	25	2	17	3	25	0.918
Forceps grasp of foreign body	22	46	5	42	7	58	5	42	5	42	0.800
Was volume averaging artifact recognized	12	25	1	8	3	25	5	42	3	25	0.314
Was oblique crosscut artifact recognized	15	31	4	33	1	8	6	50	4	33	0.176
POST											
Section II											
Alignment of insonation and instruments	46	96	12	100	11	92	11	92	12	100	0.555
Hand position and transducer position	45	94	12	100	11	92	11	92	11	92	0.785
Use of forceps in field of operation	43	90	12	100	11	92	10	83	10	83	0.483
Stepwise foreign body definition	44	92	12	100	11	92	11	92	10	83	0.536
Forceps grasp of foreign body	43	90	12	100	11	92	10	83	10	83	0.483
Was volume averaging artifact recognized	46	96	12	100	12	100	12	100	10	83	0.100
Was oblique crosscut artifact recognized	48	100	12	100	12	100	12	100	12	100	

Pre Post comparison for Proper procedure (% of participants who performed properly)



APPENDIX 8: 2 of 7 - By Grader

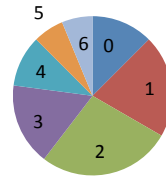
	Graded by								p-value
	All (n=48)		M (n=6)		R (n=21)		S (n=21)		
PRE	n	%	n	%	n	%	n	%	
Section I: Clinical Performance									
Foreign body removed	41	85	6	100	15	71	20	95	0.051
Time to remove foreign body	41	85	6	100	15	71	20	95	0.051
Followed all procedures properly	0	0	0	0	0	0	0	0	
Section II: Proper procedure									
Alignment of insonation and instruments	14	29	2	33	7	33	5	24	0.772
Hand position and transducer position	25	52	5	83	9	43	11	52	0.216
Use of forceps in field of operation	15	31	3	50	5	24	7	33	0.506
Stepwise foreign body definition	10	21	3	50	6	29	1	5	0.028
Forceps grasp of foreign body	22	46	6	100	4	19	12	57	<0.001
Was volume averaging artifact recognized	12	25	2	33	7	33	3	14	0.319
Was oblique crosscut artifact recognized	15	31	2	33	10	48	3	14	0.066
POST									
Section II Proper procedure									
Alignment of insonation and instruments	46	96	5	83	20	95	21	100	0.194
Hand position and transducer position	45	94	6	100	18	86	21	100	0.128
Use of forceps in field of operation	43	90	5	83	17	81	21	100	0.113
Stepwise foreign body definition	44	92	6	100	19	90	19	90	0.732
Forceps grasp of foreign body	43	90	6	100	16	76	21	100	0.028
Was volume averaging artifact recognized	46	96	6	100	19	90	21	100	0.261
Was oblique crosscut artifact recognized	48	100	6	100	21	100	21	100	



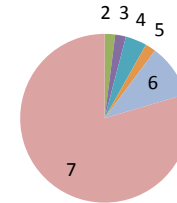
APPENDIX 8: 3 of 7 - Proper procedure

Section II Total	Pre		Post	
	n	%	n	%
0	6	12.5	0	0.0
1	10	20.8	0	0.0
2	13	27.1	1	2.1
3	8	16.7	1	2.1
4	5	10.4	2	4.2
5	3	6.3	1	2.1
6	3	6.3	5	10.4
7	0	0.0	39	81.3

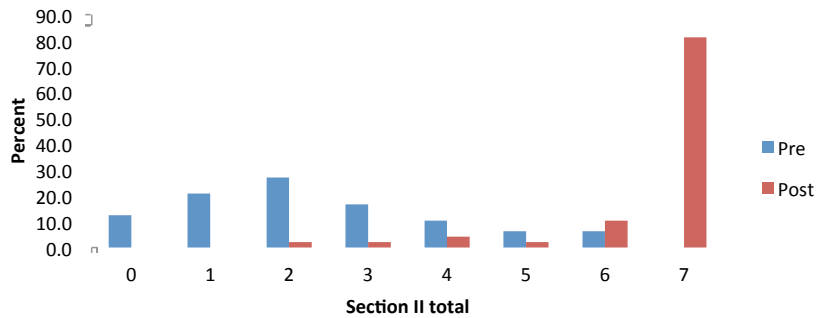
Proper Procedure -- Pre



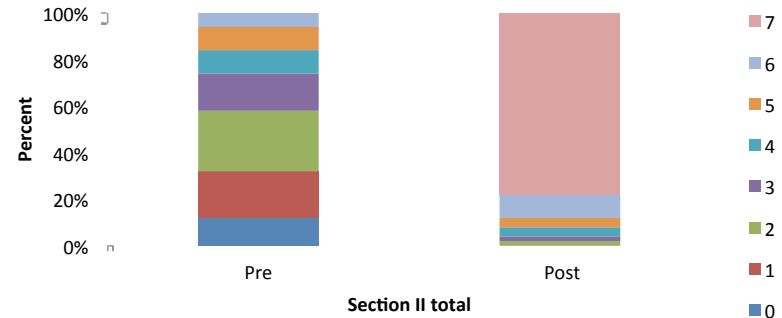
Proper procedure -- Post



Proper Procedure score

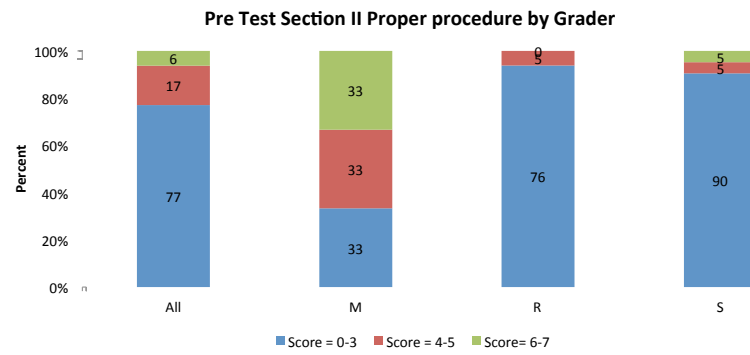
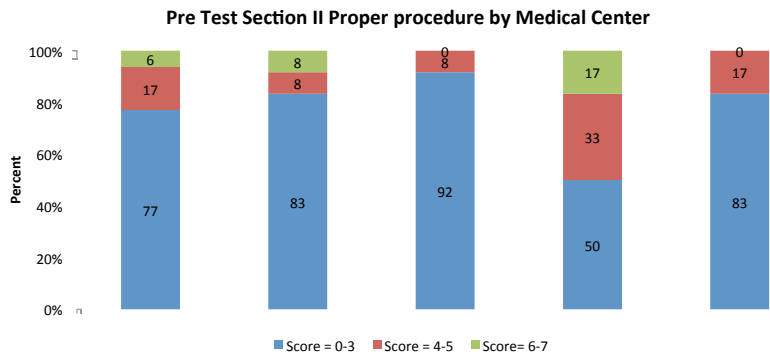


Proper procedure score



APPENDIX 8: 4 of 7 - PRE-TEST Section II: Proper procedure

	Total score (0-7)								p-value
	0-3		4-5		6		7		
	n	%	n	%	n	%	n	%	
All	37	77	8	17	3	6	0	0	0.220
Medical center									
BAMC	10	83	1	8	1	8	0	0	
MAMC	11	92	1	8	0	0	0	0	
TAMC	6	50	4	33	2	17	0	0	
WRNMMC	10	83	2	17	0	0	0	0	
Grader									0.008
M	2	33	2	33	2	33	0	0	
R	16	76	2	5	2	0	0	0	
S	19	90	1	5	1	5	0	0	

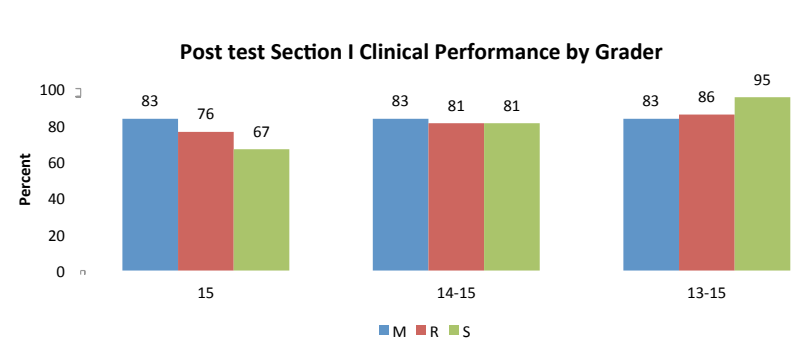
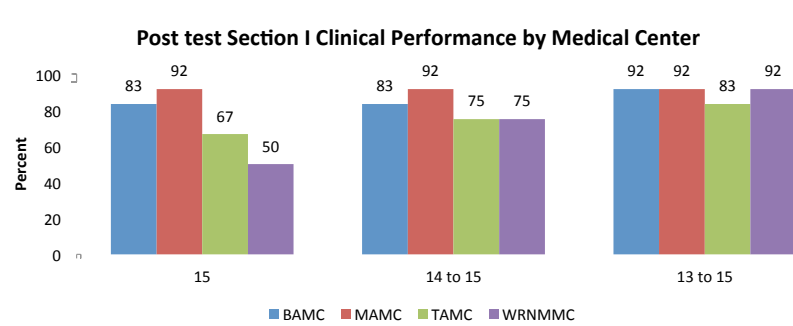
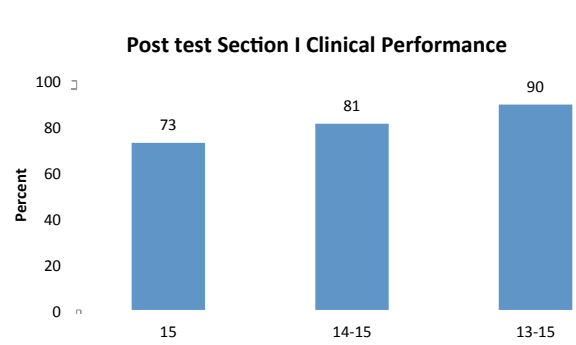


APPENDIX 8: 5 of 7 - POST-TEST Section I: Clinical Performance

	Total score (0-15)							
	0-9		10-12		13-14		15	
	n	%	n	%	n	%	n	%
All	2	4	3	6	8	17	35	73
Medical center								
BAMC	0	0	1	8	1	8	10	83
MAMC	1	8	0	0	0	0	11	92
TAMC	1	8	1	8	2	17	8	67
WRNMMC	0	0	1	8	5	42	6	50
Grader								
M	1	17	0	0	0	0	5	83
R	1	5	2	10	2	10	16	76
S	0	0	1	5	6	29	14	67

	0-10		11-13		14-15	
	n	%	n	%	n	%
All	3	6	6	13	39	81
Medical center						
BAMC	0	0	2	17	10	83
MAMC	1	8	0	0	11	92
TAMC	2	17	1	8	9	75
WRNMMC	0	0	3	25	9	75
Grader						
M	1	17	0	0	5	83
R	2	10	2	10	17	81
S	0	0	4	19	17	81

	0-9		10-12		13-15	
	n	%	n	%	n	%
All	2	4	3	6	43	90
Medical center						
BAMC	0	0	1	8	11	92
MAMC	1	8	0	0	11	92
TAMC	1	8	1	8	10	83
WRNMMC	0	0	1	8	11	92
Grader						
M	1	17	0	0	5	83
R	1	5	2	10	18	86
S	0	0	1	5	20	95

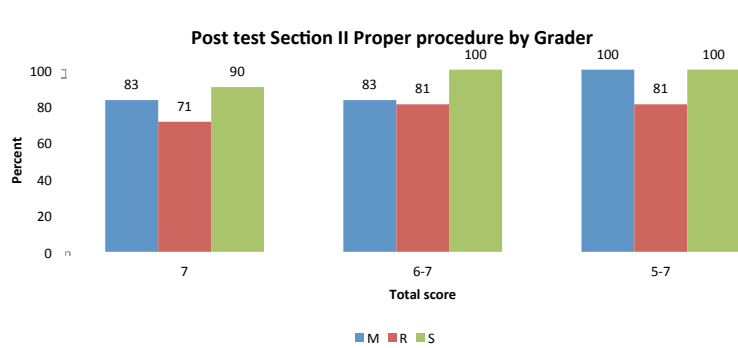
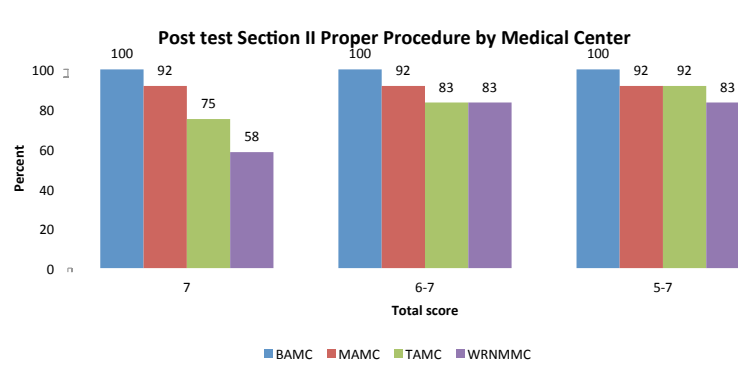
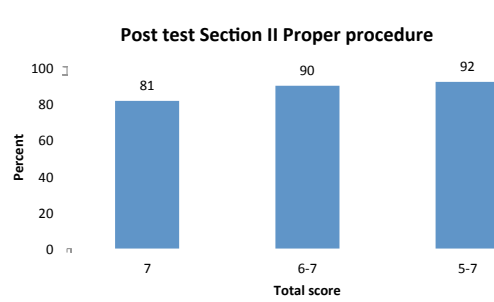


APPENDIX 8: 6 of 7 - POST-TEST Section II Proper procedure

	Total score (0-15)							
	0-3		4-5		6		7	
	n	%	n	%	n	%	n	%
All	2	4	3	6	4	8	39	81
Medical center								
BAMC	0	0	0	0	0	0	12	100
MAMC	1	8	0	0	0	0	11	92
TAMC	1	8	1	8	1	8	9	75
WRNMMC	0	0	2	17	3	25	7	58
Grader								
M	0	0	1	17	0	0	5	83
R	2	10	2	10	2	10	15	71
S	0	0	0	0	2	10	19	90

	0-3		4-5		6-7	
	n	%	n	%	n	%
All	2	4	3	6	43	90
Medical center						
BAMC	0	0	0	0	12	100
MAMC	1	8	0	0	11	92
TAMC	1	8	1	8	10	83
WRNMMC	0	0	2	17	10	83
Grader						
M	0	0	1	17	5	83
R	2	10	2	10	17	81
S	0	0	0	0	21	100

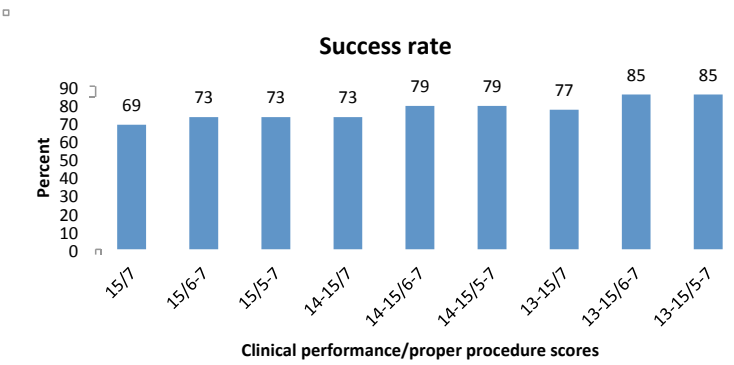
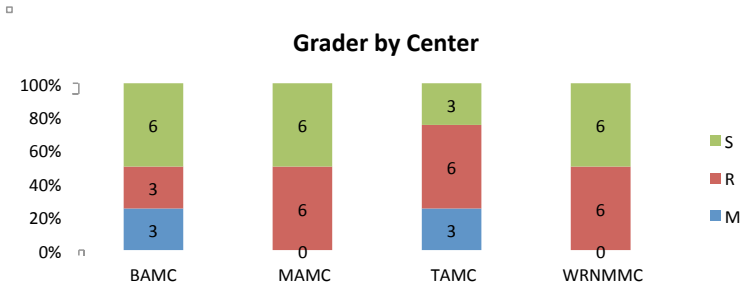
	0-3		4		5-7	
	n	%	n	%	n	%
All	2	4	2	4	44	92
Medical center						
BAMC	0	0	0	0	12	100
MAMC	1	8	0	0	11	92
TAMC	1	8	0	0	11	92
WRNMMC	0	0	2	17	10	83
Grader						
M	0	0	0	0	6	100
R	2	10	2	10	17	81
S	0	0	0	0	21	100



APPENDIX 8: 7 of 7 - Grader by center and Success rate

Graded by	BAMC (n=12)		MAMC (n=12)		TAMC (n=12)		WRNMMC (n=12)	
	n	%	n	%	n	%	n	%
M	3	25.0	0	0.0	3	25.0	0	0.0
R	3	25.0	6	50.0	6	50.0	6	50.0
S	6	50.0	6	50.0	3	25.0	6	50.0

Clinical performance score	Proper procedure score	Label	Post Success	
			n	%
15	7	15/7	33	69
15	6-7	15/6-7	35	73
15	5-7	15/5-7	35	73
14-15	7	14-15/7	35	73
14-15	6-7	14-15/6-7	38	79
14-15	5-7	14-15/5-7	38	79
13-15	7	13-15/7	37	77
13-15	6-7	13-15/6-7	41	85
13-15	5-7	13-15/5-7	41	85



Submission Type: Scientific Papers

Submission Status: Accepted

Contact: Veronica Josephine Rooks MD
INSTITUTION: Tripler Army Medical Center
Dept of Radiology

E-
Mail: veronica.j.rooks.mil@mail.mil

Primary Category: Vascular/Interventional
Secondary Category: Other

Thu Dec 03 2015 10:40AM - 10:50AM ROOM E352

02) Ultrasound Guided Foreign Body Removal (USFBR): Simulation Training and Clinical implementation Outcomes

V J Rooks, MD; J M Meadows, Tripler AMC, HI; C L Carlson, MD, MS; M V Krasnokutsky, MD; F E Mullens, MD, MPH; B M Haeuptle, BS,MA; et al. (veronica.j.rooks.mil@mail.mil)

PURPOSE

USFBR can be taught to radiologists in a stepwise approach to generate competency, and radiologists can apply the technique in the patient setting to remove foreign bodies.

METHOD AND MATERIALS

USFBR was taught to 48 radiologists at 4 hospitals. Training included didactic and hands-on instruction covering 7 components: instrument alignment, hand/transducer position, forceps use, foreign body definition, forceps grasp, recognition of volume averaging, and oblique cross cut artifact. Pre-training testing assessed removal of a single toothpick imbedded in a turkey breast in 15 minutes. Post-training evaluation consisted of 5 toothpick removals.

Ongoing clinical implementation of USFBR includes foreign body removal under ultrasound guidance by a trained radiologist. Parameters including age of patient, which radiologist, removal success, type and size of foreign body, incision size, foreign body retention time, reason for removal, symptoms, modalities used in detection, wound closure, and sedation are recorded. Data were analyzed using chi-squared and Fisher's exact tests for categorical outcomes and analysis of variance for continuous outcomes.

RESULTS

After training, radiologists' scores improved from 21-52% pre-training to 90-100% post-training ($p < 0.001$ for each component).

Clinical to date, USFBR has been 100% successful in 7 (25 expected) patients, ages 9-73 years, by 4 trained radiologists. Objects removal length 4 to 30 mm, retention time 2 to 864 days, incision 2 to 8 mm. 1 closure. 1 sedated.

CONCLUSION

Ultrasound guided foreign body removal approach taught in simulation improves radiologist technique and removal outcomes. A radiologist who completes simulation training can remove a variety of imbedded foreign bodies.

CLINICAL RELEVANCE/APPLICATION

USFBR can be used to remove foreign bodies while minimizing patient discomfort and potential tissue damage.

FIGURE (OPTIONAL)

**** no data entered ****

Disclosures:

Nothing to disclose:	Veronica Rooks
Nothing to disclose:	Jefferey Meadows
Nothing to disclose:	Christian Carlson
Nothing to disclose:	Michael Krasnokutsky
Nothing to disclose:	Frank Mullens
Nothing to disclose:	Beth Haeuptle
Nothing to disclose:	Michael Lustik
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Questions:

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Ultrasound Guided Foreign Body Removal: Simulation Training and Clinical Implementation Outcomes

JM Meadows MD

VJ Rooks MD

CL Carlson MD

MV Krasnokutsky MD

FE Mullens MD

MB Lustik

BM Haeuptle MA

CB Hoehne

J Murakami MD

WE Shiels DO



Disclosures

- Telemedicine and Advanced technology Research Center (TATRC). Grant Award No. W81XWH-08-2-0162SOW.
- The views expressed in this abstract/manuscript are those of the author(s) and do not reflect the official policy or position of the Department of the Army, Department of Defense, or the US Government.

Background

- During military operations in Iraq and Afghanistan, many military members sustained soft tissue injuries with various forms of embedded foreign bodies.
- Teach USFBR techniques to military radiologists in a standardized setting which can be used to remove symptomatic foreign bodies in military personnel as a less invasive alternative to traditional surgical removal.

Hypothesis

- USFBR can be readily implemented in the military medical care system with excellent clinical results (greater than 90% successful removal without retained fragments from USFBR sites) for the wounded war fighters and can be more effective than traditional surgical removal based on several objective parameters of comparison.

Materials and Methods

- IRB approved, multicenter prospective study.
- Part 1: Simulation Training
 - Teach USFBR techniques to radiologists in a stepwise approach to establish competency.
- Part 2: Clinical Implementation
 - Apply USFBR techniques effectively in a clinical setting to remove foreign bodies in patients.

Cadaver Cohort

	Surgical Excision	Wire- Localization	US-guided
Incision Size (mean)	4.5 cm	3.2 cm	0.6 cm
# of Sutures	4-9	3-6	None
Time (mean)	8.3 min	7.1 min	12 min
Removals	7 / 9	8 / 9	9 / 9

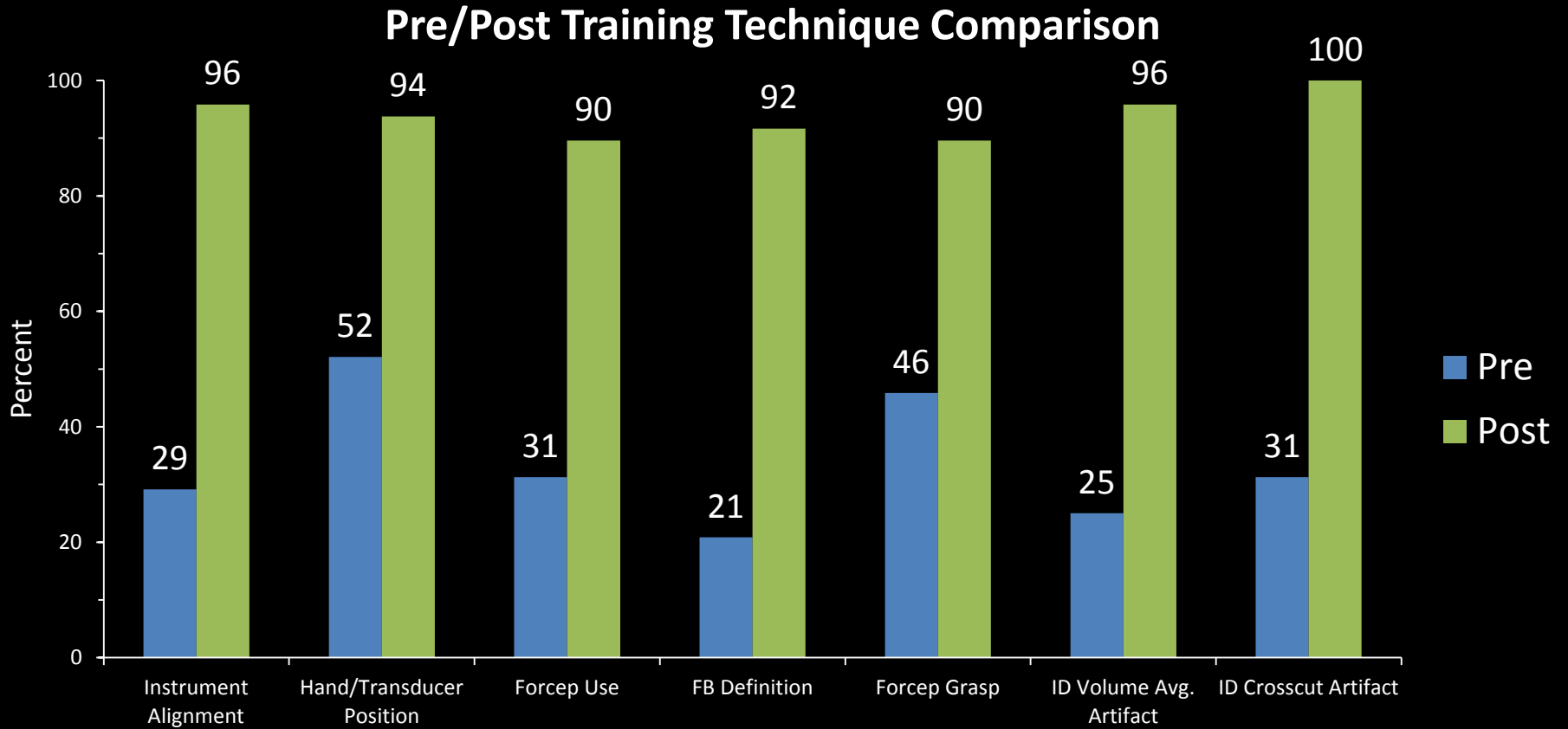
Materials and Methods

- Part 1: Simulation Training
 - USFBR was taught to 48 radiologists at 4 hospitals over a two year period.
 - Radiologists were shown an introductory video on foreign body removal.
 - Radiologists were assessed in removal of a single foreign body in 15 minutes.
 - Radiologists were then given approximately 45 hours of hands-on training.
 - Radiologists were reassessed in removing 5 foreign bodies (15 minutes allotted per attempt).

video

video

Part 1 Results



Part 1 Results

- Scores improved from 21-52% pre-training to 90-100% post-training for each component ($p < 0.001$)

Materials and Methods

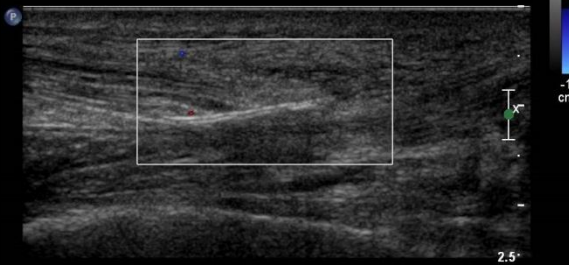
- Part 2: Clinical Implementation
 - Foreign body removal in patients over 10 months.
 - Data was collected in an online database:
 - Physician
 - Age of patient
 - Type of FB
 - Size of FB
 - Retention time
 - Reason for removal
 - Symptoms
 - Wound closure
 - Antibiotics
 - Sedation

Ono fish spine in thigh



RIGHT THIGH Long

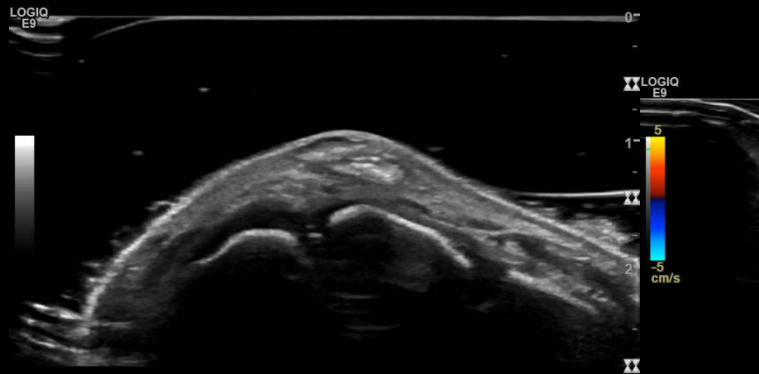
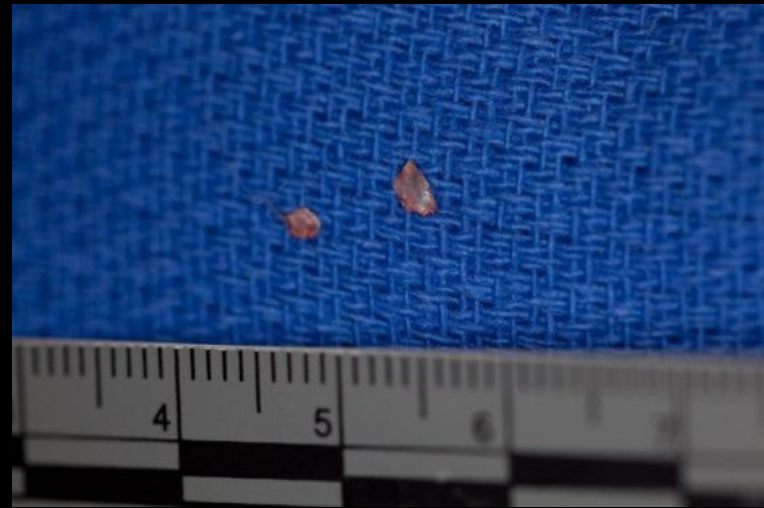
1 cm



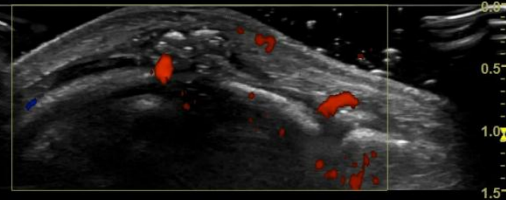
RIGHT THIGH Long



Coral in dorsal foot



LEFT FOOT DORSAL TRANS

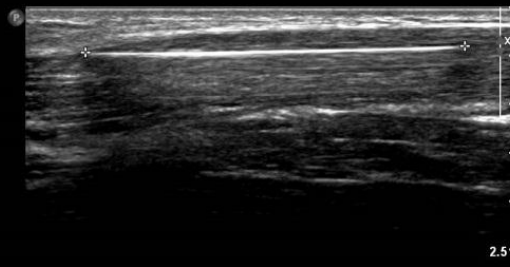


LEFT FOOT DORSAL TRANS

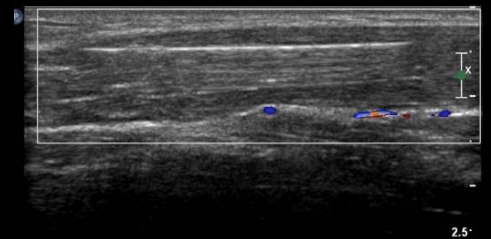
Contraceptive implant in muscle



2D
64%
C 57
P Low
Res

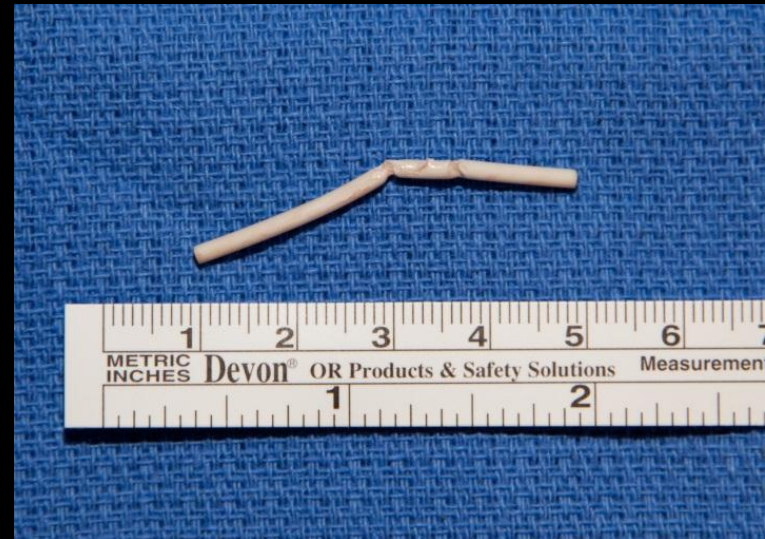


Right ARM IMPLANON Long

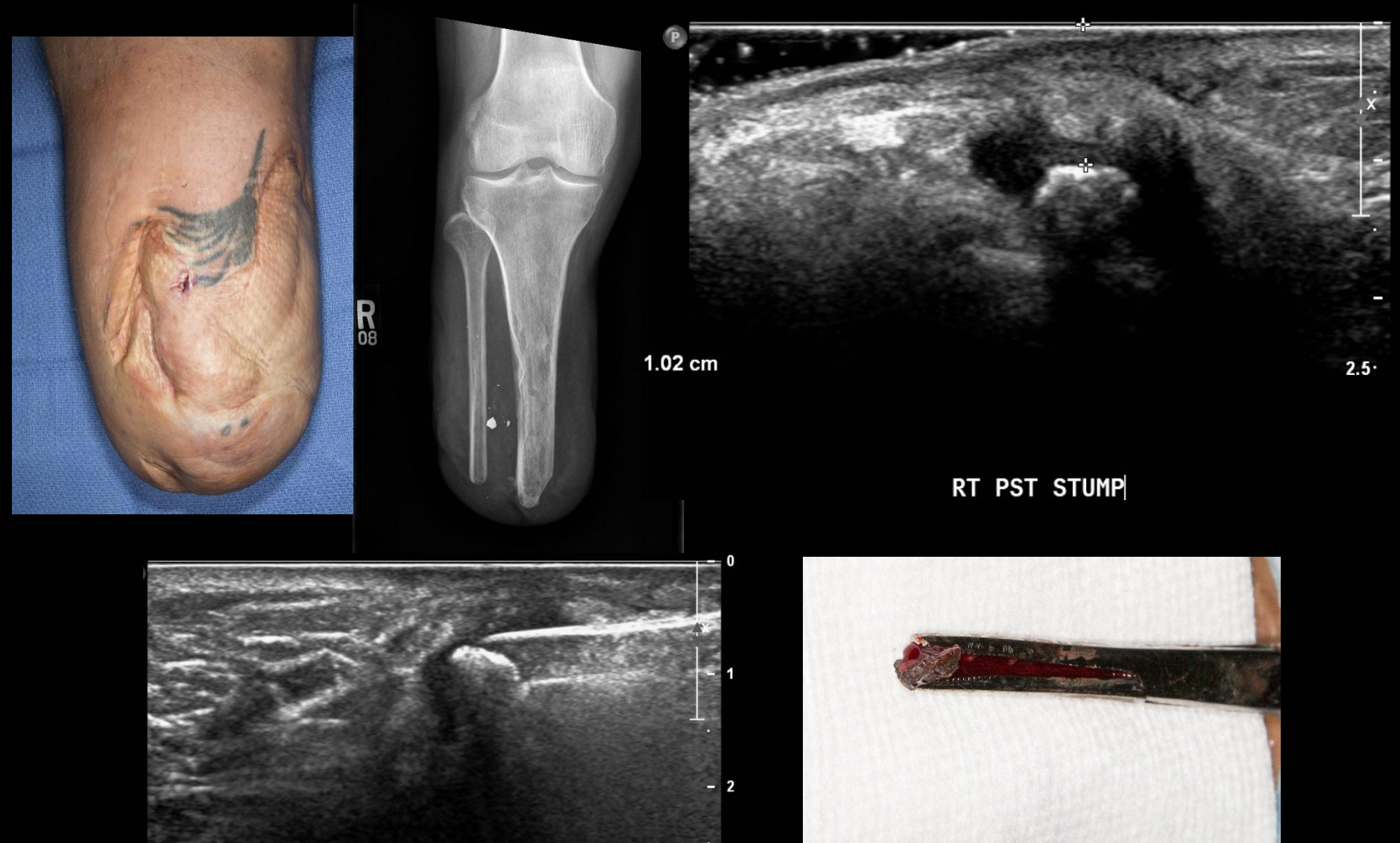


Right ARM IMPLANON Long

Dist: 0.31 cm



Shrapnel in lower leg

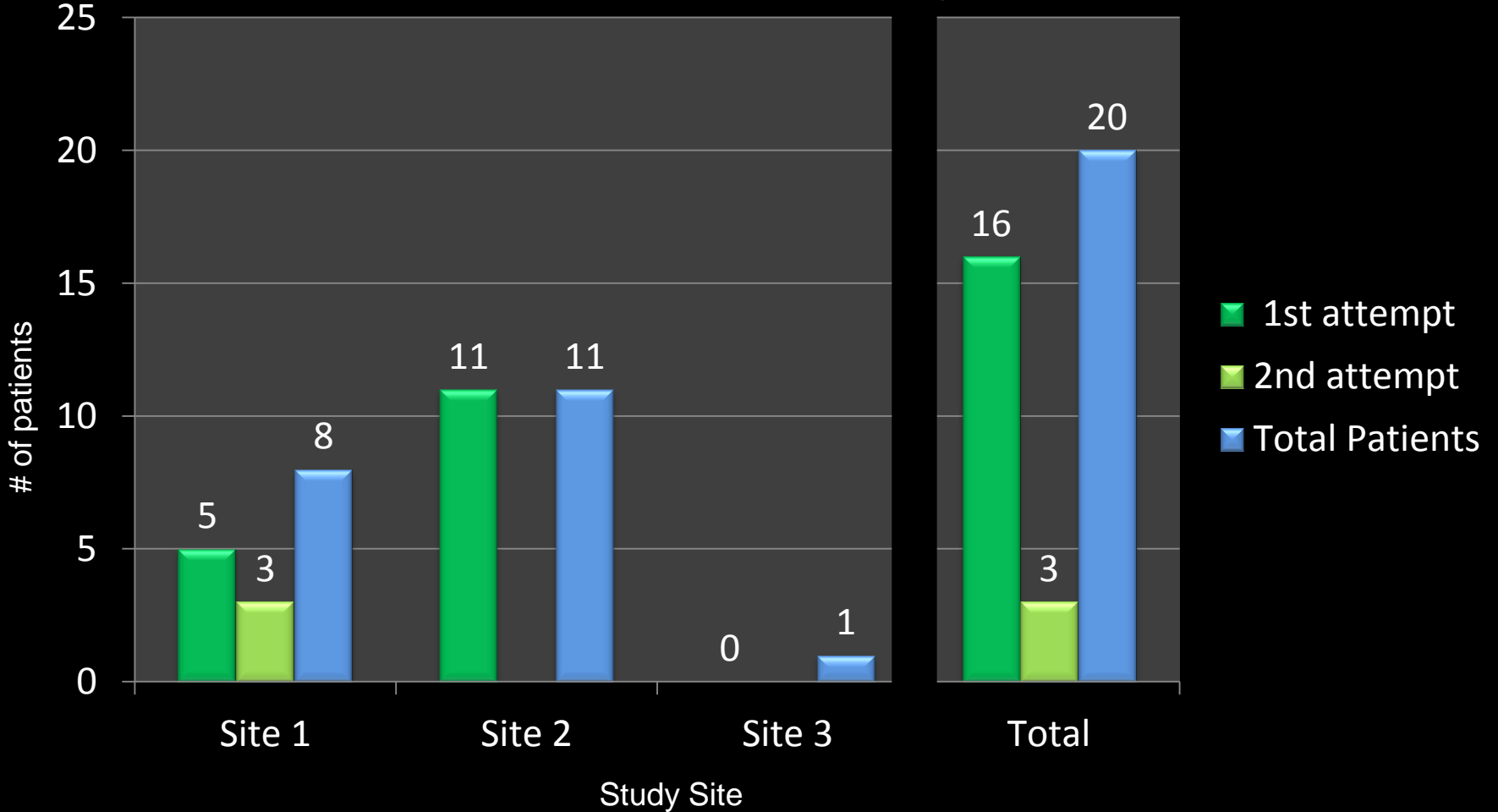


Part 2 Results

- 19 of 20 (95%) of foreign bodies were successfully removed in a clinical setting.

Part 2 Results

Successful Removals According to Site



Part 2 Results

- Patient ages: 8-66 yr
- FB type: metal (7), plastic (8), coral (2), glass (1), fish spine (1) fiber (2)
- FB size: 1-40 mm
- Retention time: 2-3572 d
- Incision: 2-8 mm
 - 1 suture closure
- Sedation: 18 local, 2 IV + local

Conclusion

- USFBR taught in a simulation setting improves technique and removal outcomes.
- Radiologists that complete simulation training are able to apply techniques successfully in a clinical setting.

References

1. Holmes PJ. Miller JR. Gutta R. Louis PJ. Intraoperative imaging techniques: a guide to retrieval of foreign bodies. Oral Surgery Oral Medicine Oral Pathology Oral Radiology & Endodontics. 100(5):614-8, 2005 Nov.
2. Woo VL. Gerber AM. Scheible W. Seo KW. Bookstein JJ. Leopold GR. Real-time ultrasound guidance for percutaneous transluminal retrieval of nonopaque intravascular catheter fragment. American Journal of Roentgenology. 133(4):760-1, 1979 Oct.
3. Porter MD. Schriver JP. Ultrasound-guided Kopans' needle location and removal of a retained foreign body. Surgical Endoscopy. 14(5):500, 2000 May.
4. Nelson AL. Sinow RM. Real-time ultrasonographically guided removal of nonpalpable and intramuscular Norplant capsules. American Journal of Obstetrics & Gynecology. 178(6):1185-93, 1998 Jun.
5. Leung A. Patton A. Navoy J. Cummings RJ. Intraoperative sonography-guided removal of radiolucent foreign bodies. Journal of Pediatric Orthopedics. 18(2):259-61, 1998 Mar-Apr. Ultrasound used to guide intraoperative removal.
6. Shiels II WE, Soft Tissue Foreign Bodies: Sonographic Diagnosis and Therapeutic Management - Ultrasound Clinics. October 2007. Vol. 2, Issue 2, 669-81.
7. Shiels II WE, Babcock DS. Wilson JL. Burch RA. Localization and guided removal of soft-tissue foreign bodies with sonography. AJR. American Journal of Roentgenology. December 1990. 155(6):1277-81.



THANK YOU

