CURRICULUM VITAE

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University of Maryland School of Medicine

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Contact Information

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Education

2001-2003	BS	Science/MD Program with Jefferson Medical College, Pennsylvania State University, University Park, PA.
2003-2007	MD	Jefferson Medical College, Philadelphia, PA.
2016-2021	MS	Clinical/Translational Research University of Maryland, Baltimore, MD

Post Graduate Education & Training

2007-2008	Internship	University of Maryland School of Medicine, Department of Orthopaedics, Baltimore, MD
2008–2012	Residency	University of Maryland School of Medicine, Department of Orthopaedics, Baltimore, MD.
2012–2013	Chief Resident	University of Maryland School of Medicine, Department of Orthopaedics, Baltimore, MD.
2013–2014	Fellowship	Shoulder and Elbow – University of Pennsylvania, Philadelphia, PA.

Certification

2016 – 2026 American Board of Orthopaedic Surgery

Licensure

2013	Pennsylvania (inactive)
2014	Maryland (active)

Employment History

Academic Appointments

2014	Assistant Professor, (Shoulder & Elbow Surgery), Department of Orthopaedics, University of Maryland School of Medicine

Other Appointments

2018-present	Chief, Orthopaedics, VA Maryland Healthcare, Baltimore Maryland

Hospital Privileges

2014-present	University of Maryland Medical Center and Shock Trauma Center, Baltimore, MD.
2014-present	University of Maryland Mid-Town Campus, Baltimore, MD.
2014-present	Veteran's Administration Health Care Medical Center, Baltimore, MD
2016-present	University of Maryland Waterloo Surgery Center
2016-present	University of Maryland, Rehabilitation and Orthopaedic Institute
2020-present	University of Maryland Prince George's Hospital Center

Professional Society Memberships

2011	Member, AAOS/OREF/ORS Clinician Scholar Development Program
2012	Maryland Representative, AOA Resident Leadership Forum
2014	AAOS/ORS Grant Writing Workshop
2014	AAOS/OREF/ORS New Investigator Workshop
2014	Member, Maryland Orthopaedic Society
2014	Member, American Academy of Orthopaedic Surgeons
2016	Candidate Member, American Shoulder and Elbow Surgeons

Honors and Awards

2003–2007	Honors – Bachelor of Science/MD Program, Pennsylvania State University, University Park, PA.
2010	MOA – 1st place Basic Science Award
2010	EOA – Resident Award Winner

2011	MOA – 2nd place Basic Science Award
2011	IMAST Whitecloud Award nominee
2011	University of Maryland, School of Medicine Department of Orthopaedics Employee of the Month.
2012	MOA – 2nd place Basic Science Award
2013	Top Research presentation at Resident Graduation
2014	Joseph P. Iannotti Award in Shoulder Surgery at the University of Pennsylvania
2015	Junior Faculty of the Year Teaching Award
2016	Nurses Choice Award for the Surgery Attending awarded by the nursing Staff at the Baltimore VA Healthcare System
2016	Junior Faculty of Year Teaching Award
2017	Medical student teaching award: University of Maryland SOM Mentor Recognition Award for Productivity Impact. Presented at the 40th Annual Medical Student Research day Celebration.
2018	Charles S. Neer Award Principal Investigator for Benzol Peroxide Effectively Decreases Pre-Operative Propionibacterium acnes Shoulder Burden: A Randomized Trial.
2018	Inducted into Faculty AOA honor society
2019	2019 Dean's Award for Excellence in Clinical and Applied Research On behalf of Dr. Greg Carey and the Office of Student Research
2019	RSNA 2019- Education Exhibit Award – Glenoid Bony Morphology Prior to Shoulder Arthroplasty: What the Surgeon wants to know and why

Scope of Clinical Practice

Clinical Expertise

Orthopaedic Surgeon – Shoulder & Elbow Surgery

Scope of Practice (FY 2020 /July 2019-April 2020)

Site of Practice:	University of Maryland Health Center
Total Number of Encounters:	Surgical Cases: 7 in-patients 7 outpatients Clinic cases: 1 new patient
Site of Practice:	University of Maryland Mid-Town Campus
Total Number of Encounters:	Surgical Cases: 10 in-patients 14 outpatients

Site of Practice: University of Maryland Medical Center
Shock Trauma Center
Total Number of Encounters: Surgical Cases: 0
Clinic: 0

Site of Practice: University of MD Orthopaedic & Rehabilitation Institute
Total Number of Encounters: Surgical Cases: 12 in-patients 110 outpatients
Clinic Visits: 2 new patients 2 follow-up

Site of Practice: Veteran's Administration Healthcare Medical Center
Total Number of Encounters: Surgical Cases: 17 in-patients 24 outpatients

Site of Practice: University of Maryland Waterloo Surgical Center
Total Number of Encounters: Surgical Cases: 31 outpatients

Site of Practice: University of Maryland Department of Orthopaedics
Texas Station Clinic
Total Number of Encounters: Clinic Visits: 152 new patients 327 follow-up patients

Site of Practice: University of Maryland Camden Yards Clinic
Total Number of Encounters: Clinic Visits: 302 new patients 682 follow-up patients

Administrative Service

Local

2019	Member, Shoulder Panel. Annual Meeting of the Maryland Orthopaedic Association, Annapolis, MD February 9, 2019

National

2018	Reviewer, The American Journal of Sports Medicine -1 review per year
2019	ASES abstract review committee 2019 – 3 reviews per year

Institutional Service

2014	Evaluation committee
2016– present	Midtown Quality Committee
2017– present	Associate Program Director of orthopaedic residency
2017– present	Program Evaluation Committee of orthopaedic residency

2017– present	Co-Director Resident Research
2018	Clinical Competency Committee

Teaching

Teaching Service/Mentoring

2014-present Advising and mentoring past and current orthopaedic residents. particularly those with an interest in sports or upper extremity surgery. These relationships have resulted in numerous. publications. Several have matched in shoulder/elbow fellowships.

Mentor medical students throughout the application process into residency and several students through completion of residency.

10 medical students through the PRISM/FRCT program
35 residents
6 residents in Upper Extremity
500 hours a year

2015–2017 Member, Ana Valencia PhD dissertation committee. Biological and Functional changes in supraspinatus muscle after Rotator Cuff Tear.

Residents and Medical Students

2014-present Didactic Lectures. 3-4 lectures per year to University of Maryland Orthopaedics residents and rotating medical students as part of the Overall weekly education curriculum. 15-30 residents and students.
60 hours a year.

Didactic Lectures to local hospital as grand rounds and to various Departments within the University including Physical Therapy and Family Medicine. Average 2-3 grand round lectures per year.
No students. 50 hours a year.

Intern Education

2014-present Teach in the human cadaveric anatomy lab performing surgical approaches and techniques. Lead dissections for shoulder/elbow. Once per month throughout the year.

Led dissections for shoulder/elbow for orthopaedic interns at the University of Maryland Johns Hopkins, Georgetown, George Washington, Union Memorial and Howard Universities. Labs occur once per year.

From 2014 to present – approximately 120 students

Conferences

2014-present	Maintained weekly shoulder/elbow surgery indications conferences for rotating orthopaedic residents and medical students.

Outpatient Clinics

2014-present	Provide significant educational exposure in a clinical setting. Multiple residents rotate on a regular basis including residents from orthopaedics, family medicine, emergency medicine and internal medicine.

Surgical Operating Room

2014-present	All surgical cases involve at least one resident and/or medical student. Basis of these interactions in the operating room with repetition hone skills learned by the resident by the end of the shoulder/elbow rotation.
	Primary educator for elective shoulder/elbow surgery at the VA Hospital

Research Experience

2005–2007	Rothman Institute, Philadelphia, PA. Mentored by Todd Albert, M.D., and Alpesh Patel, M.D. *Transforaminal Lumber Interbody Fusion: a retrospective look at Outcomes two years after surgery. Review: Spinal cord injuries during pregnancy.*
2009–2010	Research Resident – University of Maryland School of Medicine, Department of Orthopaedics, Baltimore, MD.

Grant Support:

Completed Grants

7/1/2009 – 6/30/2010	(Co-Investigator Dr. Gilotra, 5%; PI - Steven Ludwig, MD) *Bioelectricity Effects of Capacitive Coupling in a Rabbit Spine Infection Model* Biomet Industry Grant Total Direct Costs: $50,000. Co-Investigator role, animal modeling
7/1/2015 – 6/30/2016	(PI 100%) *Etiology of Fatty Infiltration in Chronic Rotator Cuff* *Tears: Model Development and Feasibility* VISN 5 Pilot Research Award Total Direct Cost: $30,000.
7/1/2016 – 6/30/2017	(PI 100%) *Mechanism of Rotator Cuff Fatty Infiltration: Role of Suprascapular Nerve and Aging,* Orthopaedic Research and Education Foundation Total Direct Cost: S50,000

<u>Patents, Inventions and Copyrights</u>

2020	RE: U.S. Provisional Patent Application Number: 62/961,475 Title: “Compliance Monitoring Device” UMB Docket Number: MG-2020-019. January 16, 2020
2021	RE: U.S. Patent Application Number: 62/963,752 Title: “Dual-Cup, Reverse Configuration Shoulder Prosthesis” (“Invention”) UMB Docket Number: MG-2021-046 (PCT) QB Reference 171351.00014

Application Number PCT/US2021/014396 filed January 21, 2020

Filed under USA The Cooperation Treaty January 21, 2021

2021 RE: U.S. Provisional Application Number: 62/979,736

Title: “Device and Method for Deltoid Elastography Optimization” (“Invention”)

UMB Docket Number: MG-2020-092

VA Reference No.: 2020-076, March 17, 2020

Application for patent made in USA February 22, 2021

Serial Number: 63/151,879

Publications

Peer-Reviewed Journal Publications

1. Moazzaz P, Gupta MC, Maitra S, **Gilotra MN,** Martin RB, Reddi AH, Chen J. *RHBMP-7 Induced Posterior Spinal Fusion in Female Rats Is Dependent On Estrogen Status.* Journal of Investigative Medicine 52(Suppl 1):S160.3-S160 · December 2003. DOI: 10.1136/jim-52-suppl1-461.
2. Chen JL, Gupta MC, Moazzaz P, Shin EC, **Gilotra MN,** Gilotra MM, Maitra S, Curtiss S, Reddi AH. *BMP-7-augmented posterior spinal fusion in female rats: Preliminary results for estrogen replacement in an animal model of osteoporosis.* Journal of Investigative Medicine 52(Suppl 1): S112 · December 2003. DOI: 10.1097/00042871-200401001-00188.

3. Moazzaz P, Gupta MC, Gilotra MM, **Gilotra MN,** Maitra S, Theerajunyaporn T, Chen JL, Reddi AH, Martin RB. *Estrogen-dependent actions of bone morphogenetic protein-7 on spine fusion in rats.* Spine 2005 Aug 1; 3015):1706-11.
4. **Gilotra MN,** Griffith C, Schiavone J, Nimmagadda N, Noveau J, Ludwig SC. *Capacitive coupling reduces instrumentation-related infection in rabbit spines.* A pilot study. Clin Orthop Relat Res 2012 Jun; 470(6):1646-51.
5. Paryavi E, Yanko M, Jaffe D, Nimmagadda N, Noveau J, Shiavone J, **Gilotra MN,** Gelb D, Ludwig SC. *Implantable direct current spinal fusion stimulators do not decrease implant-related infections in a rabbit model.* Am J Orthop 2014;43(5):E98-104.
6. **Gilotra MN,** Nguyen T, Jaffe D, Sterling R. *Dilute Betadine wash reduces implant-related bacterial burden in a rabbit knee prosthetic infection model.* Am J Orthop. 2015 Feb;44(2):E38-41.
7. **Gilotra MN,** Nguyen T, Christian M, Davis D, Henn RF, Hasan SA. *Botulinum Toxin is Detrimental to Repair of a Chronic Rotator Cuff Tear in a Rabbit Model.* Journal of Orthopaedic Research. 2015 Aug;33(8):1152-7.
8. Paryavi E, **Gilotra MN,** Johnson AJ, Pensy RA, Eglseder WA, Abzug JM. *Upper Extremity injuries in motorcyclists: Implications for mortality and need for rehabilitation services.* J Trauma Acute Care Surg 2015;78(5):1021-1025. PMID 25909425.
9. Valencia AP, Iyer SR, Pratt SJ, **Gilotra MN,** Lovering RM. *A method to test contractility of the supraspinatus muscle in mouse, rat and rabbit.* J Appl Physiol(1985). 2016 Feb 1;120(3):310-7. Doi: 10.1152/japplphysiol.00788.2015. Epub 2015 Nov 19. PMID:26586911.
10. **Gilotra MN,** Shorofsky M, Stein J, Murthi AM. *Healing of Rotator Cuff Tendons in a Rat Model Utilizing Botulinum Toxin and Immobilization.* BMC Musculoskeletal Disord 2016;17(1):127.
11. **Gilotra MN**, Christian MW, Lovering RM. *Rotator Cuff Tear Consequent to Glenohumeral Dislocation.* J Orthop Sports Phys Ther. 2016 ;46(8):708. doi: 10.2519/jospt.2016.0413. PMID: 27477475
12. Shiu B, Song X, Iacangelo A, Kim H, Jazini E, Henn RF, **Gilotra MN**, Hasan SA. *Os acromiale fixation: a biomechanical comparison of polyethylene suture versus stainless steel wire tension band.* J Shoulder Elbow Surg. 2016; 25(12):2034-2039.
13. Valencia AP, Iyer SR, **Gilotra MN**, Lovering RM. *Effects of Rotator Cuff Tear on Supraspinatus Muscle Contractility*: 2093 Board #245 June 2, Med Sci Sports Exerc. 2016; 48(5 Suppl 1):588. doi: 10.1249/01.mss.0000486766.03871.63. No abstract available. PMID: 27360918
14. Dubina A, Shiu B, **Gilotra MN,** Hasan SA, Lerman D, Ng VY. *What is the Optimal Reconstruction Option after the Resection of Proximal Humeral Tumors?* A Systematic Review. Open Orthop J. 2017 Mar 22;11:203-211. doi: 10.2174/1874325001711010203. eCollection 2017. Review. PMID: 28458733
15. Valencia AP, Iyer SR, Spangenburg EE, **Gilotra MN,** Lovering RM. *Impaired contractile function of the supraspinatus in the acute period following rotator cuff tear.* BMC Musculoskelet Discord. 2017 Nov 9;18 (1):436. doi; 10.1186/s1289-017-1789-5. PMID: 29121906

16. Jauregui JJ, Nadarajah V, Shield WP 3rd, Henn RF 3rd, **Gilotra MN**, Hasan SA. *Reverse Shoulder Arthroplasty: Perioperative Considerations and Complications*. JBJS Rev. 2018 Aug 14. doi: 10.2106/JBJS.RVW.17.00152. [Epub ahead of print] No abstract available.
PMID: 30106764
17. Valencia AP, Lai JK, Iyer SR, Mistretta KL, Spangenburg EE, Davis DL, Lovering RM, **Gilotra MN**. *Fatty Infiltration Is a Prognostic Marker of Muscle Function After Rotator Cuff Tear.* Am J Sports Med. 2018 Jul;46(9):2161-2169. doi: 10.1177/0363546518769267. Epub 2018 May 11. PMID: 29750541
18. Davis DL, Kesler T, **Gilotra MN**, Almardawi R, Hasan SA, Gullapalli RP, Zhuo J. *Quantification of shoulder muscle intramuscular fatty infiltration on T1-weighted MRI: a viable alternative to the Goutallier classification system*. Skeletal Radiol. 2018 Sep 10.
19. Jauregui JJ, Nadarajah V, Shield WP 3rd, Henn RF 3rd, **Gilotra MN,** Hasan SA. *Reverse Shoulder Arthroplasty: Perioperative Considerations and Complications*. JBJS Rev. 2018 Aug;6(8):e3. doi: 10.2106/JBJS.RVW.17.00152.
20. Kolakowski L, Lai JK, Duvall GT, Jauregui JJ, Dubina AG, Jones DL, Williams KM, Hasan SA, Henn RF 3rd, **Gilotra MN**. Neer Award 2018: *Benzoyl peroxide effectively decreases preoperative Cutibacterium acnes shoulder burden: a prospective randomized controlled trial.* J Shoulder Elbow Surg. 2018 Sep;27(9):1539-1544.
21. Wang KC, Jones A, Kambhampati S, **Gilotra MN**, Liacouras PC, Stuelke S, Shiu B, Leong N, Hasan SA, Siegel EL. *CT-based 3D printing of the glenoid prior to shoulder arthroplasty: Bony morphology and model evaluation. J Digit Imaging*
22. Horton S, Smuda P, Jauregui JJ, Nadarajah V, **Gilotra MN,** Henn RF 3rd, Hasan AS. *Management of symptomatic os acromiale: a survey of the American shoulder and elbow surgeons.* Int Orthop. 2019 Jan 3. doi: 10.1007/s00264-018-4269-0. [Epub ahead of print]
23. **Gilotra MN,** Klein A, Elkassabany N, Kuntz AF, Huffman GR, Glaser DL. *Risk Factors for Cerebral Desaturation Events During Shoulder Surgery in the Beach Chair Position*. Arthroscopy. 2019 Mar;35(3):725-730. doi: 10.1016/j.arthro.2018.10.123. Epub 2019 Feb 4.
PMID:30733033
24. Duvall G, Kaveeshwar S, Sood A, Klein A, Williams K, Kolakowski L, Lai J, Enobun B, Hasah SA, Henn RF, **Gilotra MN**. *Benzoyl peroxide use transiently decreases Cutibacterium acnes load on the shoulder*. J Shoulder Elbow Surg 2019 [Epub ahead of print, October 29].

25. Sood A, Duvall G, Ayyaswami V, Hasan SA**, Gilotra MN**. *Evaluating the readability of online patient education materials regarding shoulder surgery: How do medical institution web sites rate?* J Surg Orthop Adv. 2019 Fall;28(3):209-214. PMID: 31675298

26. Nadarajah V, Stevens KN, Henry L, Jauregui1 JJ, Smuda MP, Ventimiglia DJ, **Gilotra MN**, Hasan SA & Henn RF 3[rd]. *Patients undergoing shoulder surgery have high preoperative expectations.* Published Journal: Knee Surgery, Sports Traumatology, Arthroscopy (2020)
27. Schumaie A, Kovacevic D, Schmidt C, Green A, Rokito A, Jobin C, Yian E, Cuomo F, Koh J, **Gilotra MN,** Ramire M, William M, Burks R, Stanley R, Hasan S, Paxton S, Hasan S, Nottage W, Levine W, Srikumaran U, Grawe B. *Defining massive rotator cuff tears: a Delphi consensus study.* J Shoulder Elbow Surg (2020) 29, 674-680
28. Klein A, Jauregui JJ, Raff E, Henn RF, Hasan SA, **Gilotra MN.** J. *Early outcomes and complications of obese patients undergoing shoulder arthroplasty:* A meta-analysis.
Clin Orthop Trauma. 2020 Mar;11(Suppl 2):S260-S264. doi: 10.1016/j.jcot.2019.09.002. Epub 2019 Sep 3. PMID: 32189951
29. Davis DL, **Gilotra MN**, Hovis JP, Almardawi R, Hasan SA. J. *Association of Rotator Cuff Tear Patterns and Intramuscular Fatty Infiltration on Magnetic Resonance Imaging*.
Clin Imaging Sci. 2019 Aug 2;9:38. doi: 10.25259/JCIS_36_2019. eCollection 2019.
30. Davis DL, Zhuo J, Almardawi R, Mulligan ME, Resnik CS, Abdullah SB, Khalifah HA, Henn RF III, **Gilotra MN**, Hasan SA, Gullapalli RP. *Association of Patient Self-Reported Shoulder Scores to Quantitative and Semiquantitative MRI Measures of Rotator Cuff Intramuscular Fatty Infiltration*: A Pilot Study. AJR Am J Roentgenol. 2019 Dec;213(6):1307-1314. doi: 10.2214/AJR.19.21218. Epub 2019 Sep 11. PMID: 31509429
31. Davis DL, Almardawi R, Henn RF, Zhuo J, Mulligan ME, Resnik CS, Abdullah SB, Al Khalifah H, **Gilotra MN**, Hasan SA, Gullapalli RP. *Correlation of Quantitative Versus Semiquantitative Measures of Supraspinatus Intramuscular Fatty Infiltration to Shoulder Range of Motion and Strength:* A Pilot Study. Curr Probl Diagn Radiol 2020 June 20 26:S0363-0188(20)30122-5. doi: 10.1067/j.cpradiol.2020.06.007. Online ahead of print. PMID:32654835
32. Weir TB, Simpson N, Aneizi A, Foster MJ, Jauregui JJ, Gilotra MN, Henn RF 3rd, Hasan SA. Single-shot liposomal bupivacaine interscalene block versus continuous interscalene catheter in total shoulder arthroplasty: Opioid administration, pain scores, and complications. J Orthop. 2020 May 11;22:261-267. doi: 10.1016/j.jor.2020.05.006. eCollection 2020 Nov-Dec. PMID: 32435107
33. Lo L, Koenig S, Leong NL, Shiu BB, Hasan SA, **Gilotra MN**, Wang KC. *"Glenoid bony morphology of osteoarthritis prior to shoulder arthroplasty: What the surgeon wants to know and why.* Skeletal Radiology (2020). https://doi.org/10.1007/s00256-020-03647-x
34. Chin KM, **Gilotra MN**, Horton S, Hasan SA. *Identifying the Safe Zone in Arthroscopic Anterior Elbow Capsulectomy*: A Cadaveric Study Orthopedics. 2020 Sep 1;43(5):e399-e403. doi: 10.3928/01477447-20200619-07. Epub 2020 July 7. PMID: 32602919
35. Kator J, Aneizi A, Nadarajah V, Sajak PMJ, Zhan M, **Gilotra MN**, Akabudike NM, Packer JD, Henn RF 3rd. *Predictors of early postoperative pain interference*

following orthopaedic surgery. J Orthop. 2020 Nov 13;22:579-583. doi: 10.1016/j.jor.2020.11.009. eCollection 2020 Nov-Dec.PMID: 33299270

36. Henry LE, Aneizi A, Nadarajah V, Sajak PM, Stevens KN, Zhan M, **Gilotra MN**, Packer JD, Henn RF 3rd. *Preoperative expectations and early postoperative met expectations of extremity orthopaedic surgery*. J Clin Orthop Trauma. 2020 Oct;11(Suppl 5):S829-S836. doi: 10.1016/j.jcot.2020.06.027. Epub 2020 Jun 16.PMID: 32999564
37. Kaveeshwar S, Duvall G, Jones DL, O'Hara NN, Klein A, Diedrich AM, Kolakowski L, Lai JK, Hasan SA, Henn RF 3rd, **Gilotra MN**. *Risk factors for increased shoulder Cutibacterium acnes burden*.JSES Int. 2020 Jun 3;4(3):464-469. doi: 10.1016/j.jseint.2020.04.020. eCollection 2020 Sep.PMID: 32939469
38. Nhan DT, Woodhead BM**, Gilotra MN**, Matsen FA 3rd, Hsu JE. *Efficacy of Home Prophylactic Benzoyl Peroxide and Chlorhexidine in Shoulder Surgery: A Systematic Review and Meta-Analysis*s.JBJS Rev. 2020 Aug;8(8):e2000023. doi: 10.2106/JBJS.RVW.20.00023.PMID: 32796196 No abstract available.
39. Nadarajah V, Sood A, Kator JL, Foster MJ, Jauregui JJ, **Gilotra MN,** Hasan SA, Henn RF 3rd. *Evaluation of preoperative pain in patients undergoing shoulder surgery using the PROMIS pain interference computer-adaptive test.* J Clin Orthop Trauma. 2020 Jul;11(Suppl 4):S539-S545. doi: 10.1016/j.jcot.2020.04.025. Epub 2020 Apr 30.PMID: 32774026
40. Kovacevic D, Suriani RJ Jr, Grawe BM, Yian EH, **Gilotra MN**, Hasan SA, Srikumaran U, Hasan SS, Cuomo F, Burks RT, Green AG, Nottage WM, Theja S, Kassam HF, Saad MA, Ramirez MA, Stanley RJ, Williams MD, Nadarajah V, Konja AC, Koh JL, Rokito AS, Jobin CM, Levine WN, Schmidt CC; *Management of irreparable massive rotator cuff tears: a systematic review and meta-analysis of patient-reported outcomes, reoperation rates, and treatment response.* American Shoulder and Elbow Surgeons Massive Cuff Evaluation and Research Initiative (ASES MERIT) Investigators.J Shoulder Elbow Surg. 2020 Dec;29(12):2459-2475. doi: 10.1016/j.jse.2020.07.030. Epub 2020 Aug 4. PMID: 32763381 Review.
41. Foster MJ, O’Hara NN, Weir TB, AA, Henn RF III, Packer JD, Hasan SA, Slobogean GP, **Gilotra MN**. *Difference in Resident Versus Attending Perspective of Competency and Autonomy During Arthroscopic Rotator Cuff Repairs* - JBJS Open Access, Section AOA Critical Issues in Education. Published January-March 2021; 6 (1): e20.00014 doi 10.2106/JBJS.OA.20. 00014.The article was first published on February 24, 2021

<u>Web Based</u>

1. Kaveeshwar S., **Gilotra MN**, Reverse shoulder arthroplasty. PTRS Research Seminar. Identifying significant risk factors for increased endogenous Cutibacterium

acnes burden, AAOS Poster, Virtual presentation, September 2020. Orlando, FL, March 2020

2. AAHS and POSNA sponsored Residents and Fellow Education – Web based educational conference for residents and fellows**. Gilotra MN**, Medial and lateral epicondylitis. June 28, 2020
3. Reverse shoulder arthroplasty. PTRS Research Seminar. Virtual presentation, September 2020.
4. Reverse shoulder arthroplasty. PIVOT physical therapy. Virtual presentation, February 2021.

Book Chapters/Reviews

1. **Gilotra MN,** Gelb D. *Indications for Fusion to Treat Adult Scoliosis.* Arthritis and Arthroplasty. Spine 2010:208-213.
2. Shiu B, **Gilotra MN,** Ludwig S. *Prevention of Postoperative Spinal Wound Infections.* Review Article. Contemporary Spine Surgery 2011, Aug 1; 128:1-8.
3. Torres S, **Gilotra MN,** Glaser DL. *Open Reduction and Internal Fixation of Proximal Humerus Fractures.* Operative Techniques in Orthopaedic Surgery, Volume 3, Hand, Shoulder and Elbow .
4. **Gilotra MN,** O'Brien MJ, Savoie FH III. *Arthroscopic rotator cuff repair: Indication and technique in.* In Throckmorton TQ (ed): Instructional Course Lectures. Vol 65. Rosemont: American Academy of Orthopaedic Surgeons 2016.
5. Lai J, **Gilotra MN.** *The Surgical Handbook*. Thieme Publishers. 2020

Other Brief Communication (Review).

1. **Gilotra MN,** Hoffman GR. *Triceps Tendon Reconstruction in the Setting of Elbow Stiffness: A Surgical Technique.* University of Pennsylvania Orthopaedic Journal, 2015. (On Google Scholar).
2. **Gilotra, MN**. "Floating Shoulder." *Medscape Drugs & Diseases* (2019).

Published Multimedia

1. ASES Podcast - Episode 7 - JSES Literature Update
   2020-02-17
   Hosts of the American Shoulder and Elbow Surgeons Podcast Dr. Peter Chalmers and Dr. Rachel Frank review the most cited papers in the Journal of Shoulder and Elbow Surgery from 2018. Guests include Dr. Greg Cvetanovich on "Quantifying success after total shoulder arthroplasty" by Simovitch et al., Dr. Eric Mahkni on "Epidemiology of ulnar collateral ligament reconstruction in Major and Minor League Baseball pitchers" by Camp et al., and **Gilotra MN,** on "Longitudinal observational study of reverse total shoulder arthroplasty for irreparable rotator cuff dysfunction" by Gerber et al.

2. ASES Podcast - Episode 20 - Journal of Shoulder and Elbow Surgery Most Downloaded of 2018 September 12, 2020 In this episode of the American Shoulder and Elbow Surgeons Podcast, Dr. Peter Chalmers and Dr. Rachel Frank conduct a review of some of the most downloaded papers in the Journal of Shoulder and Elbow Surgery from 2018. Guests include Dr. Luke Austin on pre-operative education to reduce opioid use, **Dr. Mohit Gilotra** on benzoyl peroxide to prevent C. Acnes infections, and Dr. Gregory Hoy on treatment of multi-directional instability.

Major Invited Speeches

Local

1. *How to treat complications in total shoulder arthroplasty.* Presented at the Maryland Orthopaedic Society meeting, 2015.
2. *How to examine the shoulder in 30 seconds.* Presented at Prince Georges Hospital Grand Rounds, Maryland, 2019.
3. *How to examine the shoulder in 30 seconds.* Presented at Holy Cross Grand Rounds, Maryland, 2019.
4. *What's new in shoulder surgery.* Presented Prince Georges Hospital Grand Rounds, Maryland, 2019.
5. *Q&A: Best way to do injections.* Prince Georges Hospital Grand Rounds, Maryland, 2019.
6. *History of reverse shoulder replacement, how to manage complications and optimize soft tissue balancing.* Presented Sinai Orthopedic Ground Rounds. Baltimore, Maryland, January 28, 2020.
7. *Update on arthroscopic options for instability.* MOA meeting, Annapolis, Maryland, February 2020.
8. *Reverse shoulder arthroplasty Part 1*, University of Maryland PT Camden Yards, February 2021

National

9. *An objective way to measure deltoid tension during reverse shoulder arthroplasty.* Presented at Arthrex Lab, Naples Florida, November 13, 2015.
10. *Risk factors for increase c acnes burden.* Phoenix Society Meeting, Nemacolin, PA, 2019

Proffered Communication

Podium Presentations

1. **Gilotra MN,** Shorofsky M, Stein J, Murthi AM. *Healing of Rotator Cuff Tendons in a Rat Model Utilizing Botulinum Toxin A and Immobilization.* Presented at the Maryland Orthopaedic Association, Baltimore, MD. April 24, 2010. 1st Place Basic Science Award.
2. **Gilotra MN,** Shorofsky M, Stein J, Murthi AM. *Healing of Rotator Cuff Tendons in a Rat Model Utilizing Botulinum Toxin A and Immobilization.* Presented at the International Congress of Shoulder and Elbow Surgery Meeting, Edinburg, Scotland. September 6, 2010.
3. **Gilotra MN,** Shorofsky M, Stein J, Murthi AM. *Healing of Rotator Cuff Tendons in a Rat Model Utilizing Botulinum Toxin A and Immobilization.* Presented at the Eastern Orthopaedic Association, Naples, FL. October 24, 2010. Resident Award Winner.
4. **Gilotra MN,** Griffith C, Schiavone J, Nimmagadda N, Noveau J, Kim H, Gelb D, Ludwig S. *Capacitive Coupling Reduces Instrumentation Infection in a Rabbit Spine Model.* Presented at the Lumbar Spine Research Society meeting, Chicago, IL. May 5, 2011.
5. **Gilotra MN,** Griffith C, Schiavone J, Nimmagadda N, Noveau J, Kim H, Gelb D, Ludwig S. *Capacitive Coupling Reduces Instrumentation Infection in a Rabbit Spine Model.* Presented at the Maryland Orthopaedic Association, Baltimore, MD. May 7, 2011. 2d Place Basic Science Award.
6. **Gilotra MN,** Griffith C, Schiavone J, Nimmagadda N, Noveau J, Kim H, Gelb D, Ludwig S. *Capacitive Coupling Reduces Instrumentation Infection in a Rabbit Spine Model.* Presented at the International Meeting of Advanced Spine Techniques, Copenhagen, Denmark. July 14, 2011. Whitecloud Award Nominee.
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Abstract

Dissertation Title: Analysis of Sling Wear Time after Shoulder Surgery

Mohit N. Gilotra MD

Introduction: Sling wear is a component of rehabilitation after shoulder surgery. The purposes of this study were to observe the predictors of sling wear and to determine if a threshold of sling compliance improved patient-reported outcomes.

Methods: We performed a prospective observational study of 105 postoperative patients fitted with temperature-sensing slings to monitor adherence. Demographic factors were analyzed as predictors of sling wear. The relationship of actual sling wear with patient reported and radiographic outcome was explored.

Results: There was a weak correlation between patient reported and actual sling wear time. Females and patients with lower BMI were most likely to be 80% adherent with sling wear and exhibited better patient reported outcomes but no difference in radiographic failures.

Conclusion: There is an association between high adherence and patient reported outcome. Further studies will elicit the social mediators of postoperative sling behavior and treatments to improve patient adherence and outcome.

Analysis of Sling Wear Time After Shoulder Surgery

by
Mohit N. Gilotra

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List of Abbreviations

AIC	Akaike's Information Criterion
ASES	American Shoulder and Elbow Surgeons
MAM	Medical Adherence Measure
MCID	Minimal Clinically Important Difference
VAS	Visual Analog pain Score

Chapter 1: Introduction and Background

Adherence in Medicine

Adherence to medical treatment is defined as the extent to which patients follow regimens prescribed by their treating providers. The World Health Organization cites poor adherence as one of the major causes in the failure to recover from long-term illnesses[1]. The most common medical treatment prescribed are prescription medications. Medication adherence rates are difficult to measure and are often patient reported which may or may not be inaccurate. A secondary way to measure outpatient medication adherence are either objective laboratory values expected in response to oral medication ingestion or the actual clinical success of medication treatment. Higher adherence rates usually correlate to better clinical outcomes[2]. For example, higher medication adherence in epilepsy patients leads to a decreased risk of seizures. Factors associated with decreased adherence in this population are usually social and environmental such as poverty and education[3-5]. Novel approaches to improve adherence rates are ongoing including phone-based reminders and video-based education tools[6].

In general, adherence rates are higher for acute conditions than for chronic illnesses, because of perceived patient investment in the condition. Patients with acute pain or loss of function are more likely to adhere to physician recommendations[2]. In chronic conditions where the manifestations are sometimes silent, medications are often preventing downstream sequalae such as stroke after prolonged hypertension[7]. This trend is commonly noted in medication regimens for diseases such as cancer, schizophrenia, and many others [8, 9]. Adherence to screening for breast cancer via mammograms is higher in patients who have a family history of breast cancer or a previous biopsy compared to those who have not had any previous breast cancer history [10].

Treatment regimens are not only medication based but also lifestyle recommendations like screening or diet. The treatment for congestive heart failure includes both medications and diet restrictions. Lifestyle recommendations may be more difficult to adjust as food specific habits can be entrenched for decades. Gilotra et al. showed that congestive heart failure patients confessed that dietary nonadherence is a large component of hospital re-admission. Despite multiple admissions to the hospital, these patients still had difficulty with changing such habits [11].

Adherence in Orthopaedics

Immobilization via a cast or an orthosis is the principal outpatient treatment regimen. In children, a cast is used to treat most fractures to maintain optimal patient adherence. A body spica cast immobilizes infant femur fractures and even makes perianal care very difficult[12]. Casts are not feasible for larger children/adults or for long term purposes that may cause skin breakdown[13]. A removable orthosis is the primary intervention to manage idiopathic conditions such as scoliosis and clubfoot[14, 15]. Ankle fractures and severe ankle sprains are treated with a removable boot [16]. The benefits of a removable orthosis for skin hygiene and early passive motion rehabilitation are balanced with the potential for decreased adherence.

Several orthopaedic studies have highlighted the importance of brace wear for patient outcome. These studies used a temperature sensor for accurate measurement of brace wear. Decreased time in a brace was one of the biggest independent risk factors for curve progression in adolescent idiopathic scoliosis[17]. When brace was prescribed for 16 hours a day, 12 hours of wear was associated with decreased curve progression[18]. This has been corroborated over several studies at separate instiutions[14, 17-21]. Other factors include level of skeletal maturity, patient body habitus and initial size of curve. Decreased clubfoot recurrence is associated with increased use of post-cast bracing. Sangiorgio et al. showed the average family utilized the brace 62% of what was recommended by the physician and 77% of what was reported by the family. The threshold for clubfoot correction was 5 hours/day still, less than the 8 hours/day requested by the physician[22]. Even in the highest adherence families, time in the brace waned over several months from treatment initiation[23].

Specific to shoulder surgery, a sling is prescribed to patients to protect tendon repairs for soft tissue healing. Tendons heal to bone in predictable stages: inflammatory, reparative and remodeling phases[24]. During the first week, inflammation is predominant from the surgical approach and local manipulation of the soft tissue and bone. In the next month, the repaired enthesis lays a disorganized scar. During the first six weeks, the repaired tendon is especially vulnerable to excessive strain that can result in re-tear[25-27]. After the reparative phase, the collagen fibers in the scar remodel and align in response to loading. Prolonged immobilization though can impair the remodeling phase and affect collagen orientation with decreased tendon mechanical properties [28, 29]. Re-tear rate after rotator cuff repair varies between 10 and 90% based on the patient population [30]. The complex healing process is not just subject to sling immobilization but also patient age, smoking, size of tear and chronicity of tear[31, 32].

Patient reported sling adherence and its association with outcome has been studied. Cuff et al. demonstrated that poor adherence may be related to inferior functional outcomes but did not assess for possible indicators of poor adherence beyond workers' compensation status[33]. Workers' compensation status may be a marker of a younger non adherent population. Silverio et al. evaluated the effects of social and demographic factors with patients' self-reported adherence and improvement in shoulder outcomes as measured by functional evaluations[34]. Smoking was significantly associated with increased sling adherence. Also sling adherence had no association with patient reported outcome. However, the authors indirectly measured shoulder sling wear via a patient medical adherence questionnaire which patients may not accurately respond to. In fact, Morten et al. have shown that when back brace wear is accurately monitored, wear time as reported by the patient is unreliable[14].

Temperature Based Approach to Adherence and Validation

Temperature sensor technology has been utilized to objectively measure brace adherence as stated previously in back braces for scoliosis and foot braces for clubfoot. The self-reported adherence is significantly higher than the temperature-recorded adherence rates [18, 22]. In those studies, the temperature sensors used in braces were in direct contact with patients' bodies. Shoulder slings have a looser fit, and it was unknown whether temperature sensors can accurately measure sling use. We then validated sensor location in the sling and an algorithm for measuring sling wear time.

Three Onset data logger (HOBO MX2201; Onset Computer Corporation, Bourne, MA) (Figure 1) were fitted in three locations on DonJoy UltraSling (DonJoy Performance, Dallas, TX) shoulder slings, which are routinely used postoperatively. The data loggers are small (dimensions, 3.35 x 5.64 x 1.8 cm; weight, 12.75 grams), battery-powered devices (battery life 2+ years) that feature an internal microprocessor, data storage, and sensors that can measure contact temperature readings with up to 0.5°C of accuracy. The data logger was set to record temperature readings every 15 minutes. Data is transferred from the sensors wirelessly to a mobile device via Bluetooth 4.0 technology.

Figure 1: An Onset Data logger HOBO MX2201 juxtaposed to quarter.

Data loggers were manually sutured into 3 locations on each shoulder sling: 1) inner aspect of the bolster in contact with the abdomen, 2) inner aspect of the sling at the medial elbow, and 3) inner aspect of the sling at the palmar surface of the carpometacarpal joint. These locations were chosen because they were noted to have more continuous body contact when the shoulder sling was worn. Continuous body contact with the implanted data loggers allows for accurate temperature readings and decreased fluctuations that can occur if the data logger is not flush against the body.

Four volunteers then wore the sling throughout parts of the day and night to simulate the patient experience. Healthy volunteers removed the sling at undirected timepoints, for personal hygiene and for any daily needs. All volunteers had a body temperature in the normal range and were not febrile during the study period. The participants kept a detailed log of actual sling wear time to compare as a gold standard to the wear time detected by the temperature sensors. When the sling was not in use, we asked volunteers to leave the sling in an environment at room temperature.

We evaluated the ability of the sensor to distinguish between body heat while the sling is being worn and ambient heat in warm environment. The sling was placed into the trunk of a car during a hot day with the outside temperatures ranging from 80 to 90°F (Figure 2a, 2b)

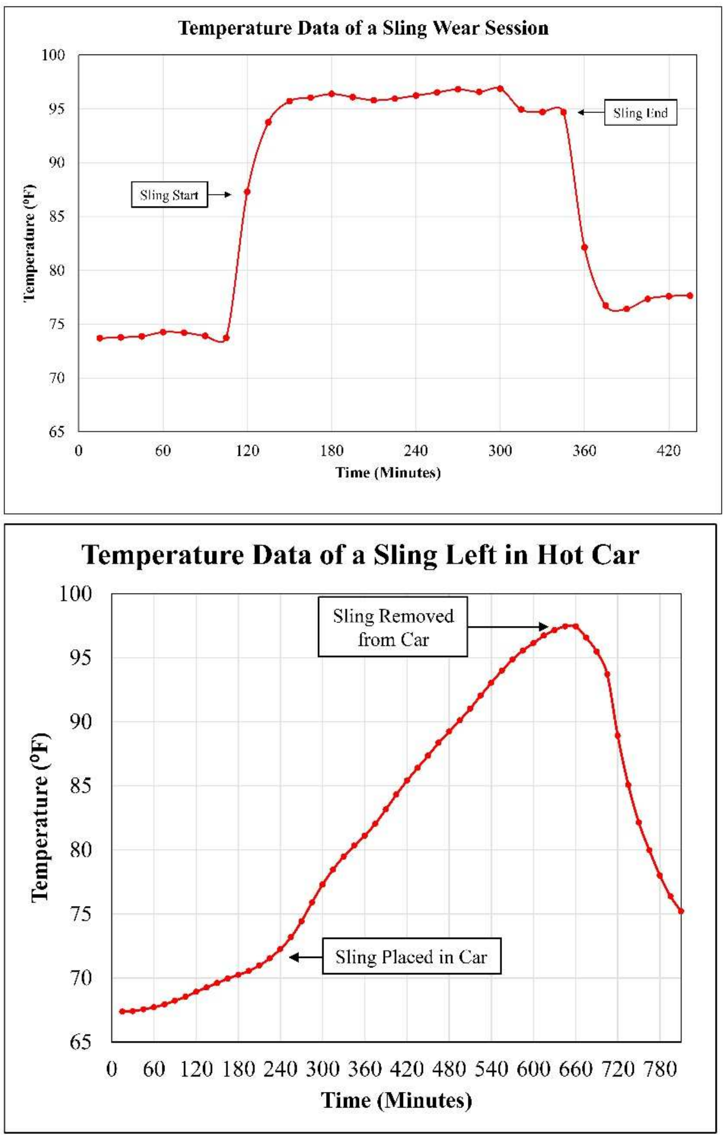

Figure 2a: Sample analysis of a sling wear session. Figure 2b: Sample analysis of a sling left in a hot trunk of car

For the validation, sensors recorded 4,405 temperature readings over a 1,101.5-hour period or a total of 13,215 temperature readings for all three temperature sensor locations. The minimum sample size for sensitivity studies ranges between 60 to 4,860 tests performed[35]. The sample size of four volunteers is similar to prior studies validating temperature sensors to monitor compliance with bracing for adolescent idiopathic scoliosis, which used three volunteers[14].

Per the sling specific temperature algorithm, the diagnostic accuracies for the bolster, elbow, and wrist areas of the data loggers were 99.5%, 99.1%, and 99.3%, respectively. There was no statistically significant difference between the three locations ($p > .05$). When the sling was left in the trunk of a car with outside temperatures ranging between 80 and 90°F, it took 4.17 hours for the data logger to equilibrate to a temperature of 85°F before eventually peaking at 97°F approximately 6.83 hours later. In comparison, when the sling was worn, the temperature reached 85°F in <45 minutes. The rate of temperature increase was 0.48□F per minute for actual sling wear, while it was 0.06□F per minute for the sling in a hot car. Although the final temperatures reached by the sensor in the hot environment versus when the sling was worn were similar, the final temperature was met at a much slower rate (eight times slower) when the sensor was in a hot environment. This highlights the efficiency of conductive (i.e., actual sling wear) versus convective (i.e., sling in a hot car) heat transfer. Our algorithm can discern the difference in rates of temperature change to determine whether the shoulder sling is being worn. Implementation of the algorithm improves the accuracy of the loggers and decreases false positive readings.

Specific Aims

The overall purposes of the present study are to a. identify indicators of poor sling adherence after shoulder surgery and b. directly measure the relationship between patient sling adherence and outcome post shoulder surgery

Aim 1: To measure predictors of sling wear time after shoulder surgery

Primary Hypothesis: Age and Female gender will predict increased patient wear time with postoperative sling.

Secondary Hypothesis: Patient reported sling wear will correlate with actual sling wear time.

Aim 2: To compare/contrast shoulder outcome in low and high sling wear adherence as measured by actual time in the sling

Primary Hypothesis: High protocol adherent patients (≥80% sling wear) will have a significantly higher patient reported outcome compared to low adherent patients (<80% sling wear).

Secondary Hypothesis: High adherent patients (≥80% sling wear) will have decreased radiographic complications compared to low adherent patients (<80% sling wear).

Chapter 2: Materials and Methods

<u>Overview</u>

Patients were prospectively enrolled from 2017 to 2020 after indicated for any shoulder surgery that requires six weeks of postoperative shoulder immobilization (i.e. rotator cuff repair, shoulder arthroplasty, or fracture fixation). Inclusion criteria entailed age over 18 years old, presentation to the outpatient practice for elective surgery and English speaking. Patients were recruited from my surgical practice and underwent the usual standard of care throughout the surgical and post-operative recovery process. Patients were consented in the office two months prior to surgery and were told that a temperature sensor is placed but not that the sling wear time is measured. Approval was obtained through the University of Maryland, Baltimore Institutional Review Board.

In a randomized clinical trial, patients improved back brace wearing adherence when they were told explicitly about the monitoring compared to a group that was unaware[36]. In our study, the goal was to reduce approval seeking behavior in two ways: 2 months' time from consent to surgery and patients unaware of the temperature monitoring reason. Other temperature based bracing studies have used a similar approach. Morton et al. told patients about temperature devices in back braces monitoring comfort[14]. Sangiorgio et al. told families that probes on clubfoot sandals were monitoring temperature for future changes in comfort and families were given a full debriefing at the end of the study[22]. Approval seeking behavior from patients, though, is distinct from the Hawthorne effect. The Hawthorne effect in the broadest of definitions is any change of behavior in response to research monitoring.

A quarter sized temperature sensor (as described in the introduction) is placed inside the sling bolster immediately after surgery. Our previous work shows have validated this sensor location with over 99% accuracy in measuring actual sling wear time. A one-inch slit is made in the center of the sling bolster's outer cloth. A padded sensor is placed in the foam of the bolster. The cloth is then closed with a running 2-0 nylon suture (Ethicon, Cincinnati, OH) and then covered with a padded Aquacel Silver dressing (Convatec, Oklahoma City, OK). The sensors are retrieved after six-week immobilization and data uploaded via Bluetooth and converted to Microsoft Excel. Temperature is recorded every 15 minutes throughout the six-week postoperative period. A validated algorithm is utilized to determine total wear time. Sensors are $50 each and can be reused for over 20 patients based on battery life.

Patients are counseled to wear the sling 20 hours per day with 4 hours of rest for hygiene and home exercises during daytime hours. Patients are requested to wear the sling throughout the night during sleep. The percent time in sling is calculated by total hours worn divided by 20 hours per day (140 hours/week) over the six-week post-operative period. Eighty percent adherence (112 hours/week) is then 16 hours per day: 16/20 = 0.8. In a clubfoot study, roughly 62% brace wear threshold was adequate for deformity correction[22]. In scoliosis studies, there was a wide range of adherence from less than 50% to over 90% with optimal adherence around 80% for improved outcome [14, 17-21, 36]. In one sling study, 80% adherence was utilized as an arbitrary cutoff differentiating a low adherent and high adherent groups[37]. We planned to use the same 80% threshold for this study. In a pilot review of our initial 10 patients, 8 participants met this 80% threshold.

Patients complete a sling adherence questionnaire (Figure 3) at the six-week postoperative visit. This survey was used in one prior study to measure patient-reported sling wear[34] and was augmented to include sling specific questions from a previous medical adherence measure (MAM)[38].

Medical Adherence Measure
(MAM)

Name______________________________ **Date:**______________

Directions: Patients who have undergone rotator cuff surgery have to follow a difficult regimen which often changes the way they function in normal life. Exercise, work, diet—these are all things that change as you recover from surgery. As you know, all these changes take quite a bit of time and can be difficult to stick with. Since not all patients use the same guidelines after a surgery, we would like to know how *you* managed the first six weeks after surgery. Your answers will help us learn which parts are easy for you and which parts are difficult. Please be honest because your answers can help us improve our program. Thank you.

The following questions refer to the six week period right after surgery.

1. How often were you supposed to wear your shoulder sling?
a) once/week b) three times/week c)once/day d) during the day e) during the night
f) all the time
2. Why did you have to wear a shoulder sling?______________________________

____

3. Did the amount of time you wore your shoulder sling change over the six week period?
a) no, I was pretty much consistent b) I wore the sling more towards the end
c) I wore the sling more towards the beginning
4. How many hours a day was your shoulder sling off? ______________________________

5. How many days a week was your shoulder sling off? ______________________________
6. What activities required that you take your shoulder sling off? *Circle all that apply*
a) cleaning/general housework b) changing clothes c) showering
d) brushing hair/putting on makeup e) sleeping f) eating
g) cooking meals/snacks h) writing i) exercising
j) dressing up for special events k) using the computer l) for work
m) reaching high shelves n) driving
o) other:______________________________
7. What kind of physical exercise did you do during the first six weeks after surgery?
a) formal physical therapy b) no exercise c) light exercise on my own
7. What is the best description of your living situation during the first six weeks after surgery?
a) I lived with a significant other b) I lived alone c) I lived with family member/s
d) I lived with roommates
8. Who helped you with basic functions during the first six weeks after surgery? *Circle all that apply*
a) significant other b) mother/father c) child d) sibling
e) roommate f) friend g)other:______________
9. On a scale of 1-10 (10 being the best) how highly would you rate how often you wore your shoulder sling?
1 2 3 4 5 6 7 8 9 10
10. What would have made it easier for you to wear your sling more often?______________________________

____

Figure 3: Sling Medical Adherence Measure (MAM) [34, 38]

<u>Aim 1: To measure predictors of sling wear time after shoulder surgery</u>

Primary Hypothesis: Age and Gender will predict increased patient wear time with postoperative sling.

- H_0: No factors will be associated with the increased adherence group

- H_1: Increasing age and female gender will be associated with the increased adherence group

Exposures

Risk Factor	Variable Range	Univariate Analysis
Age	Continuous	T-test
Gender	Nominal: Male or Female	Chi-square
Race	Nominal: Caucasian, African American, Other	Chi-square
Body Mass Index (BMI)	continuous	T-test
Smoking	Nominal: Current, Former, Never	Chi-square
Diabetes – Current diagnosis	Binary: Yes or No	Chi-square
Hand Dominance	Binary: Yes or No	Chi-square
Surgical Procedure	Nominal: Rotator cuff repair, Shoulder replacement, Other	Chi-square

Table 1: Risk Factors for total sling wear time

Outcome: Sling wear time meeting 80% threshold cutoff categorical variable

Analysis: All factors assessed via a univariate model. Factors with a $P \leq 0.1$ were included in a multivariate stepwise analysis.

Secondary Hypothesis: Patient reported sling wear will correlate with actual sling wear time.

- H_0: No correlation between patient reported sling wear and actual sling wear time
- H_1: Correlation between patient reported sling wear and actual sling wear time

Patient reported sling wear from Sling MAM survey, question #4, Figure 3. Actual sling wear time recorded from temperature sensor.

Analysis: Pearson's correlation comparing two continuous variables. Sensitivity and Specificity analysis comparing 80% thresholds in patient reported values versus actual time recorded.

Aim 2: To compare/contrast shoulder outcomes in low and high sling wear adherence as measured by actual time in the sling

Primary Hypothesis: High protocol adherent patients (≥80% sling wear) will have a significantly higher patient reported outcome compared to low adherent patients (<80% sling wear).

- H_0: $S_H = S_L$

  The mean American Shoulder and Elbow Surgeons (ASES) score will be the same in high and low adherent patients

- H_1: $S_H \neq S_L$

  The mean ASES score will be significantly different in high adherent patients compared to low adherent patient patients

Exposure: Sling wear time meeting 80% threshold cutoff

Outcomes: Patients are evaluated with the American Shoulder and Elbow Surgeons Score (Figure 4) preoperatively, six weeks, twelve weeks postoperatively. The American Shoulder and Elbow Surgeons Score (ASES)[39] is a well-established, reliable, and validated patient reported outcome score. It measures pain and patient function specific to activities of daily living ranging from 0 to 100 where 100 is a normal shoulder. The minimal clinically important difference (MCID) is 21 points[40]. The Visual Analog Pain Score (VAS) is provided at the same time points as a secondary outcome measure and is also well-established, reliable, and validated. Both scores were analyzed as a continuous variable. (Table 2)

Patient Self-Evaluation

Pain:

How bad is your pain today (mark line)?

No pain at all ______________________________ Pain as bad as it can be

Function: Circle the number in the box that indicates your ability to do the following activities:

0 = Unable to do; 1 = Very difficult to do; 2 = Somewhat difficult; 3 = Not difficult

Activity	Right arm	Left arm
1. Put on a coat	0 1 2 3	0 1 2 3
2. Sleep on your painful or affected side	0 1 2 3	0 1 2 3
3. Wash back/do up bra in back	0 1 2 3	0 1 2 3
4. Manage toiletting	0 1 2 3	0 1 2 3
5. Comb hair	0 1 2 3	0 1 2 3
6. Reach a high shelf	0 1 2 3	0 1 2 3
7. Lift 10 lbs above shoulder	0 1 2 3	0 1 2 3
8. Throw a ball overhand	0 1 2 3	0 1 2 3
9. Do usual work – List: ____________	0 1 2 3	0 1 2 3
10. Do usual sport – List: ____________	0 1 2 3	0 1 2 3

Figure 4: American Shoulder and Elbow Society Score[39]

Analysis: Two sample means t-test comparing high adherent and low adherent patients

Secondary Hypothesis: High adherent patients (≥80% sling wear) will have decreased radiographic complications compared to low adherent patients (<80% sling wear).

- H_0: $C_H = C_L$

  The frequency of radiographic complication will be the same in both adherent groups

- H_1: $C_H \neq C_L$

The frequency of radiographic complication will be significantly different in high adherent patients compared to low adherent patients.

Outcomes: Radiographic evidence of failure: Patients undergo a standard set of imaging based on the surgical procedure at six weeks when the sling is discontinued. For rotator cuff repairs, patients are evaluated with an ultrasound at six weeks to visualize tendon healing. For anatomic shoulder replacements, x-rays show subscapularis osteotomy healing and shoulder stability. For reverse shoulder replacements, x-rays show shoulder stability. For fracture patients, x-rays depict any fragment diastasis compared to immediate postoperative X-rays. Patients' radiographs binarily defined as healed or not healed. (Table 2)

Analysis: Chi-square test comparing high adherent and low adherent patients.

	Preoperative Visit	**Day of Surgery**	**2 Weeks Postop**	**6 weeks post**	**12 weeks postop**
Consent	X				
VAS	X			X	X
ASES	X			X	X
Sensor Sling Implantation		X			
Sensor Removal				X	
Radiographic Evaluation	X	X		X	

Table 2: Study Timeline

Power analysis

The main outcome is Aim 2, Hypothesis1: Do high adherent patients have a clinically significant difference in the ASES score: MCID is 21 points and SD is 23.3[40]. An acceptable threshold is considered wearing the sling at least 16 hours/day (see methods) with an assumed allocation ratio of 4 adherent patient to every one non adherent patient based on early enrollment pilot data of 10 patients. 65 patients are necessary. Assuming a 20% attrition rate, then a goal of 82 patients to be recruited. Attrition rate includes lost to follow-up or patient directed premature disposal of sling.

See below from Stata/SE 13.0 for Mac

Estimated sample sizes for a two-sample means test t test assuming sd1 = sd2 = sd Ho:

m2 = m1 versus Ha: m2 != m1

Study parameters: alpha = 0.0500 power = 0.8000 delta = 21   m1 = 64.0000 m2 =

85.0000 sd = 23.3000 N2/N1 = 4.0000

Estimated sample sizes: N = 65 N1 = 13 N2 = 52

Chapter 3: Results

<u>Overview</u>

A total of 105 patients were assessed for eligibility for the study and consented. Of the 105 patients consented, 16 elective surgical procedures were cancelled or indefinitely delayed due to COVID-19 restrictions. Four patients received a type of sling not amenable to sensor placement. Eighty-four patients underwent an elective procedure and sensor sling implantation. Nineteen patients were further excluded from the study for lost to follow-up or losing their sling in the first six weeks (Figure 5).

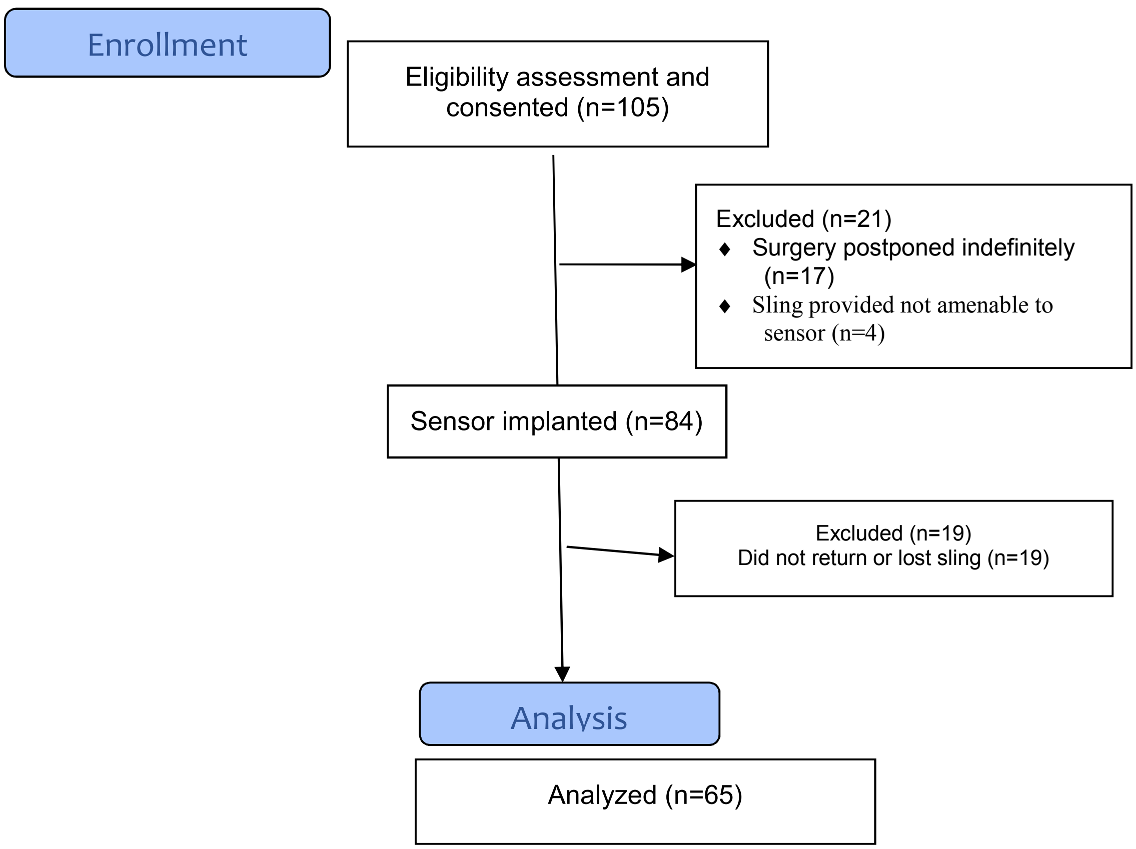

Figure 5. STROBE Flow Diagram

Aim 1: To measure predictors of sling wear time after shoulder surgery

Primary Hypothesis

Table 3 shows the patient demographics, surgical factors, and sling use per week. In the univariate analysis, female gender and BMI were predictors of sling adherence. A multivariable stepwise regression analysis revealed female gender and lower BMI were significant predictors of 80% adherence threshold ($p = 0.001$). Final model was obtained by backward stepwise elimination to achieve minimum Akaike Information Criterion.

	All (N = 65)	80% adherence and above (n = 30)	Less than 80% (n = 35)	p-value
Age (years), mean (SD)	59.0 (13.5)	60.9 (13.6)	57.3 (13.4)	0.30
Female, n (%)	33 (50.8)	21 (70.0)	12 (34.3)	0.004
Race, n (%)				0.88
Black	33 (50.8)	15 (50.0)	18 (51.4)	
White	29 (44.6)	14 (46.7)	15 (42.9)	
Other	3 (4.6)	1 (3.3)	2 (5.7)	
Smoking, n (%)				0.76
Never	32 (49.2)	15 (50.0)	17 (48.6)	
Former	22 (33.8)	11 (36.7)	11 (31.4)	
Current	11 (16.9)	4 (13.3)	7 (20.0)	
History of Diabetes, n (%)	17 (26.2)	10 (33.3)	7 (20.0)	0.22
BMI, kg/m^2, mean (SD)	32.4 (7.7)	30.4 (7.2)	34.1 (7.7)	0.05
Dominant hand, n (%)	34 (55.7)	15 (53.6)	19 (57.6)	0.75
VAS pain score, mean (SD)	5.9 (2.6)	5.6 (2.8)	6.3 (2.5)	0.38
ASES Baseline scores, mean (SD)				
Function	18.8 (10.5)	17.9 (11.3)	20.0 (9.8)	0.58
Total score	39.1 (19.3)	39.9 (18.3)	38.3 (20.5)	0.76
Surgery, n (%)				0.34
Rotator cuff repair	21 (32.3)	7 (23.3)	14 (40.0)	
Arthroplasty	39 (60.0)	20 (66.7)	19 (54.3)	
Other	5 (7.7)	3 (10.0)	2 (5.7)	
SD, standard deviation; BMI, body mass index; VAS, visual analog scale, ASES, American Shoulder and Elbow Surgeons				

Table 3: Participant and Injury Characteristics by Adherence Status

Secondary Hypothesis

Patients reported 85.2 ± 15.3% total adherence, but the actual adherence was 77.2 ± 35.0% (r = 0.32; *P* = 0.01), weak correlation. Using 80% threshold adherence, patient-reported adherence was highly sensitive (82.8%), poorly specific (28.6%) and had low accuracy (53.1%) in estimating the actual 80% adherence rate.

<u>Aim 2: To compare/contrast shoulder outcomes in low and high sling wear adherence as measured by actual time in the sling</u>

Primary Hypothesis

There were no significant differences in baseline ASES scores (39.1 ± 19.3 versus 39.9 ± 18.3) and VAS scores (5.9 ± 2.6 versus 5.6 ± 2.8) between ≥80% and <80% adherence thresholds, respectively. At six weeks, 80% adherent patients had less pain than less adherent patients (2.7 ± 2.5 versus 4.1 ± 2.5) but no difference in ASES scores (Table 4). At 3 months, patients with ≥80% adherence had significantly better VAS scores (1.6 ± 2.6 versus 3.7 ± 3.0) *P* < 0.01), and 3-month ASES scores (73.3 ± 21.5 versus 57.8 ± 24.0); *P* = 0.02).

Outcome	80% adherence or more (n = 30)	Less than 80% adherence (n = 35)	Mean difference (95% CI)	p-value
VAS Pain score, mean (SD)	2.68 (2.50)	4.14 (2.52)	-1.46 (-2.85 to -0.08)	0.04
ASES Function Score, mean (SD)	19.00 (11.99)	18.68 (12.14)	0.32 (-6.35 to 6.99)	0.92
ASES Total score, mean (SD)	55.60 (20.03)	47.96 (20.72)	7.64 (-3.63 to 18.90)	0.18

Table 4: Association between adherence status, VAS and ASES scores at 6 weeks

Secondary Hypothesis

There were five cases of radiographic failure in the lower adherence group compared to none in the higher adherence group. At 80% threshold adherence, this did not reach statistical significance.

Outcome	80% compliance or more (n = 29)	Less than 80% compliance (n = 36)	p-value
Radiographic failure	0 (0%)	5 (13.89%)	0.06

Table 5: Association between sling compliance and radiographic failure at 6 weeks

<u>Highlighted Case Example</u>

Patient RS is a 63-year-old right hand dominant African American female with a left proximal humerus malunion who presents one year after a fracture treated nonoperatively after a motor vehicle collision. She is a nonsmoker, not a diabetic and has a BMI 34.5. She has significant pain with a VAS of 7 and overall loss of function with forward elevation to 45 degrees, abduction to 45 degrees and no external rotation or internal rotation. Her preoperative ASES score is 45, preoperative x-rays show severe malunion (Figure 6). She underwent a left reverse shoulder replacement (Figure 7) and did well for two weeks.

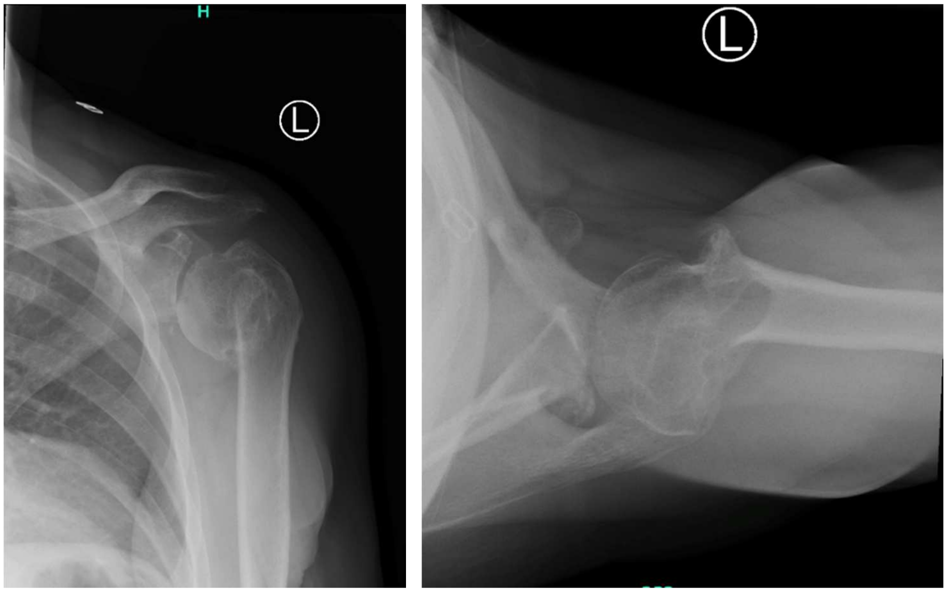

Figure 6: Preoperative X-ray. Grashey and axillary X-rays of the left shoulder show varus and apex anterior proximal humerus malunion.

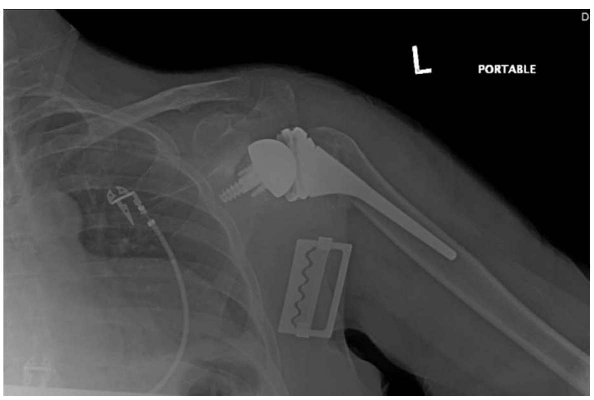

Figure 7: Immediate postoperative X-ray. Grashey X-ray of left shoulder showing reverse shoulder arthroplasty.

Patient RS was very adherent with sling wear for two weeks then began to wear her sling much less and presented to the office dislocated at three weeks (Figures 8 and 9).

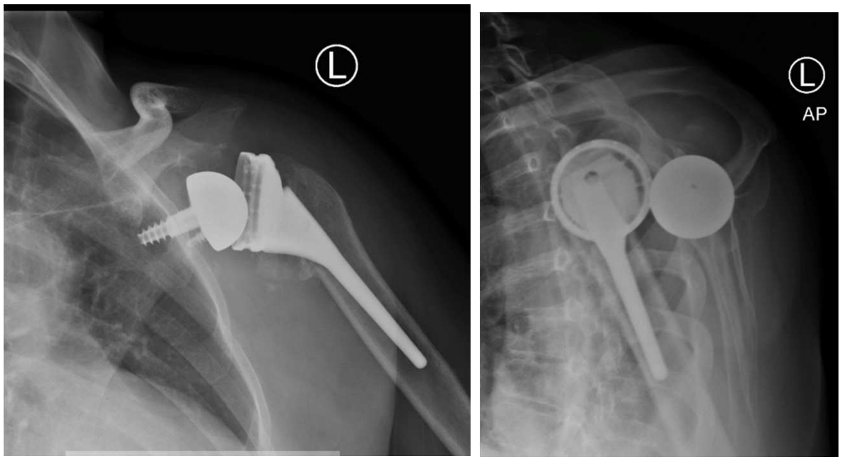

Figure 8: Three weeks postoperative X-rays. Grashey and Scapular Y X-rays of left shoulder showing a dislocated reverse shoulder replacement

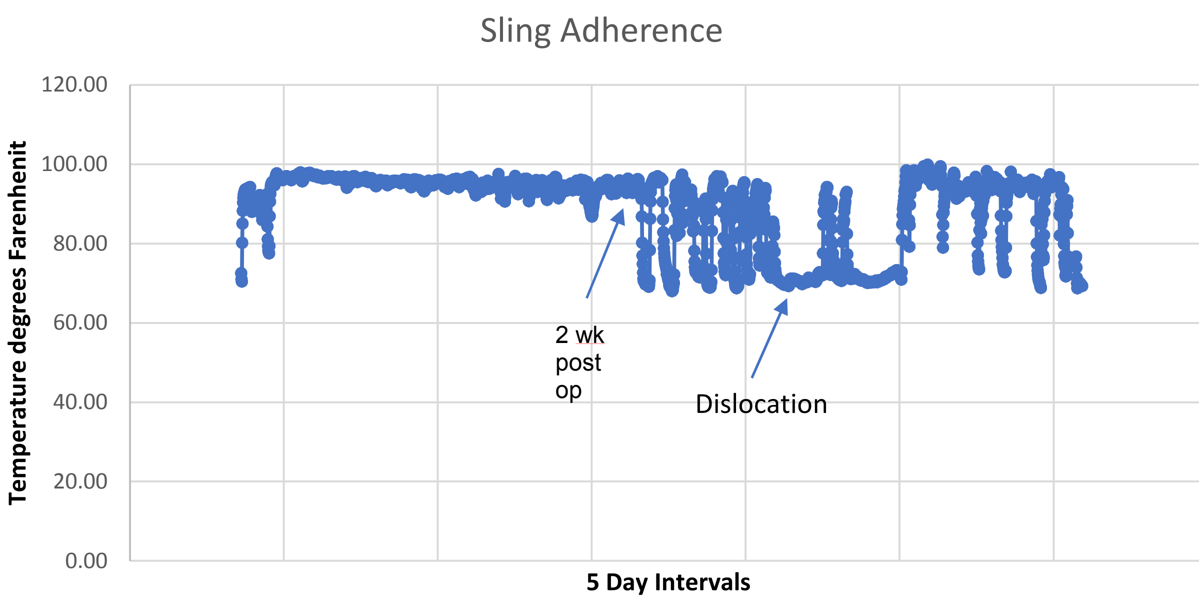

Figure 9: Sling Adherence graph for Patient RS. Dislocation occurred during the third week postop during a stretch of days when patient was not wearing sling.

She was treated with a closed reduction without a repeat operation. She wore her sling consistently at 90% adherence rate for six weeks and had no further complication. At 6 months follow-up, her VAS was 1 and ASES 85 with forward elevation to 150 degrees, abduction to 100 degrees, external rotation to 30 degrees and internal rotation to her low back (Figure 10).

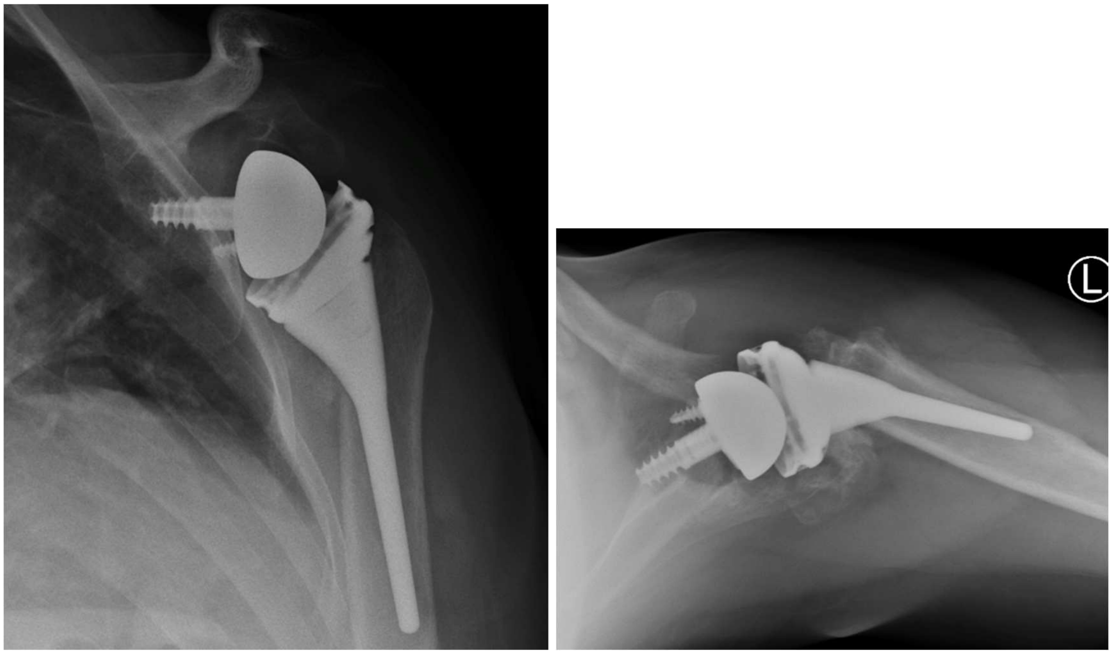

Figure 10: 6-month postoperative x-rays. Grashey and axillary X-rays of the left shoulder shows stable prosthesis.

Chapter 4: Discussion

Sling adherence is an important facet of postoperative rehabilitation after shoulder surgery. Little is known regarding actual sling wear beyond what is patient reported. Based on previous temperature monitoring of back braces for adolescent idiopathic scoliosis, there is little correlation with patient reported sling wear and actual sling wear[14]. Our study also showed a weak correlation between patient reported and actual time in sling. Female gender was the strongest predictor of actual sling wear. The higher adherent population did report better postoperative outcomes, but an 80% threshold effect was not found for radiographic outcome.

Our results may be specific to an American urban population. Grubhofer et al. prospectively monitored 50 patients in Zurich, Switzerland undergoing rotator cuff repair with a similar temperature monitor in the sling[37]. Investigators used a higher abduction orthosis than in our study and patients were also blinded to the use of a sensor. Subjects reported their sling wear at the six-week mark after removal of the sensor. A two-part consent was performed so that patients needed to consent to stay in the study at six weeks after a debriefing of the study's intentions. Patients were instructed to wear the sling 23 hours/day and a threshold compliance was also set at 80%. Forty-eight percent of patients met this threshold and overall patients in Zurich wore their sling several hours more per week than in Baltimore. No demographic factors predicted adherence. No radiographic or patient reported outcomes were provided. In Baltimore, wear rates were predicted by gender.

Prior studies in scoliosis and clubfoot research have shown patients do not accurately report their brace use[14, 18, 22]. In using 80% as a cutoff off we found in our sample that those with at least 80% compliance are more compliant than advised by the surgeon, while less compliant patients use their sling half the time. Similar to the Zurich study[37], the relatively arbitrary 80% adherence cutoff was utilized in our study as there is no clear benchmark for adherent and non-adherent behavior. Adherence-Nonadherence is more likely a spectrum dependent on many factors including the diagnosis, procedure and patient's inherent ability to heal.

Gender and age have played a role for medication adherence in multiple investigations. Lauder et al reported on drug adherence for patients presenting to the emergency room with hypertensive urgency[41]. Male sex and a higher number of medications prescribed were predictors of nonadherence. Khan et al found increased age was a positive predictor for medication adherence for corneal conditions[42]. The orthopaedic studies on adolescent idiopathic scoliosis and clubfoot have not elicited an age or gender association with orthosis wear time but these conditions are in a pediatric population and scoliosis is much more common in females[18, 22]. Gender and age may be a marker of health literacy and health education. Lower health literacy is associated with concerns and distrust of physician recommended medication regimens[43]. Further evaluation of the less-adherent cohort is ongoing to understand if education/lower health literacy is truly a causal pathway mediator. Further studies may include alternate education tools with videos and photos showing the importance of sling wear and modifying sling wear based on patient size.

The threshold of sling wear adherence to achieve a satisfactory outcome is unknown. Katz et al. showed 12 hours a day of back brace wear was associated with decreased curve progression whether it was prescribed for 16 or 23 hours/day[18].

Decreased clubfoot recurrence is associated with increased use of post-cast bracing. The threshold for clubfoot correction was 5 hours/day still less than the 8 hours/day requested by the physician[22]. Healing after a surgical intervention such as rotator cuff repair and shoulder replacement is more complex and does not rely on sling wear alone. Other factors include patient age, tear size, chronicity of tear and co-morbidities such as smoking[44, 45]. Eighty percent threshold adherence did not predict radiographic healing, but a lower threshold may be predictive.

Although an optimal threshold adherence was not found, increased sling wear was associated with improved patient reported outcomes. Prior studies have failed to show differences in functional outcomes for patient-reported compliance with sling use after rotator cuff repairs[34, 37]. This study compared actual sling compliance with postoperative patient-reported outcomes using temperature-sensing devices to monitor sling use. The results of our study demonstrate patients with higher sling compliance have better ASES and VAS scores at two postoperative time intervals. Although there is an association of increased sling wear and patient reported outcome, the causal pathway is less clear because increased sling wear did not lead to better radiographic outcomes in this study. The study was powered to assess a minimal clinically important difference in ASES score and was not powered to detect a difference in radiographic outcome. Only a few patients suffered a radiographic failure and even fewer were clearly related to sling wear such as the highlighted patient RS.

Social determinants of health may not only predict sling wear but also patient reported outcome after surgery. In ophthalmology, a participants' glaucoma medication adherence was correlated not only with level of pain but also social support role difficulties as determined in a personalized coaching program[46]. Porter et al evaluated grit and resiliency scores in patients undergoing cuff repair[47]. Higher rated optimism was associated with higher postoperative ASES scores. Preoperative ASES scores, though, were not included in this analysis. When comparing high adherence and low adherence groups in our study there was no difference in baseline ASES scores. Patient grit and optimism may be a co-variate for sling adherence and patient reported outcome.

A simplified directed acyclic graph (Figure 11) highlights potential mediators and co-variates in the complex interplay from predictors of sling wear to the patients' outcome. Gender and BMI may not directly lead to increased sling wear but there is likely a social determinant mediator. Sling wear is associated with improved patient reported outcome, but patient optimism may be an influencer for both factors. Sling wear is not associated with radiographic healing, but smoking/diabetes have shown to be, and both can lead to better patient outcome.

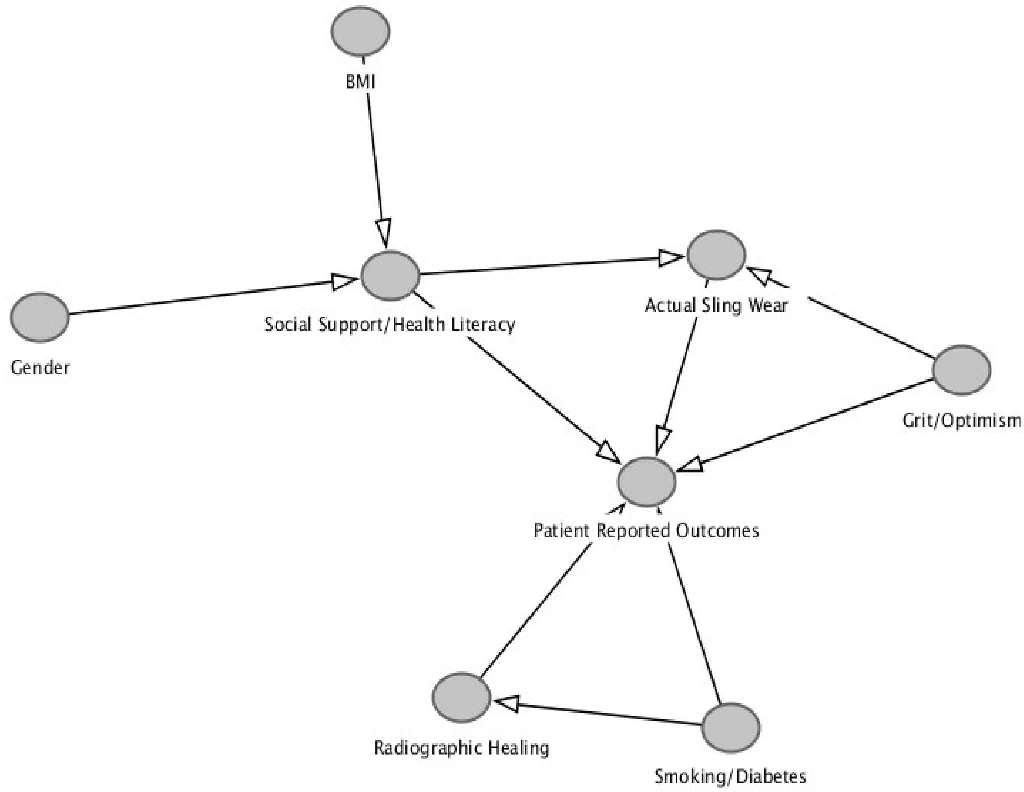

Figure 11. Directed acyclic graph

Patients are instructed to wear a sling after rotator cuff surgery to avoid excessive strain on the repair and decrease the incidence of re-tear. Prolonged shoulder sling immobilization, though, has been linked to shoulder stiffness[48]. Patients were asked to remove the sling for about 4 hours/day for hygiene and simple home exercises to prevent stiffness. A few patients were classified as over adherent or wearing the sling more than 100% of the time that was recommended. These few patients presented with stiffer shoulders at early postoperative timepoints but there were not enough patients for a complete analysis.

Sling may not be necessary for smaller tears. Tirefort et al. [49] recently randomized 80 patients after rotator cuff repair to sling immobilization and no postoperative immobilization. In an appropriately powered study, there was no difference in ultrasound-based healing at 6 months. Pain and early motion were slightly better in the non-immobilized group. All tears were considered small or medium which have a high healing rate. The study did not include larger tears where immobilization remains the recommendation in the immediate postoperative period. Adherence with sling immobilization was self-reported and may not reflect actual sling wear; that is, subjects randomized to the sling immobilization are not blinded and may not be wearing the sling an appreciable amount.

There are several limitations in this study. Three months is a relatively short postoperative timepoint. The poor ASES scores for the less adherent group may improve with longer follow-up. Our lost to follow-up is relatively high but consistent with other urban population studies. Time in sling is a general marker of postoperative behavior but actual activity out of the sling is not accounted for. Resting an arm while sitting is less risk to a repair than moving furniture for example.

Future directions include longer follow-up and an analysis of both over-adherent patients and those who dispose of the sling completely. We plan to analyze time of day adherence with patient outcome. Future studies include randomizing shorter versus longer timepoints in the sling for various procedures and with continuous temperature monitoring. Education and social determinants evaluation may play a role in not only improving sling wear but also improving patient outcome.

In conclusion, patient reported sling wear weakly correlated with actual sling wear after shoulder surgery. Females are more likely to wear the sling and reach 80% adherence. Eighty percent adherence is associated with higher ASES and better VAS scores but not radiographic outcome.

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